In February 2013, GlaxoSmithKline (GSK) announced a commitment to further clinical transparency through the public disclosure of GSK Clinical Study Reports (CSRs) on the GSK Clinical Study Register.

The following guiding principles have been applied to the disclosure:

- *Information will be excluded in order to protect the privacy of patients and all named persons associated with the study*
- *Patient data listings will be completely removed* to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the* ***GSK Clinical Study Register****.*
- *Aggregate data will be included; with any direct reference to individual patients excluded*

**Complete removal of patient data listings may mean that page numbers are no longer consecutively numbered*

Division: Worldwide Development
Retention Category: GRS019
Information Type: Clinical Study Report

Title:	A 12-Week, Parallel-Group, Double-Blind, Randomised, Placebo-Controlled, Multicentre, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension - Report of data from main phase

Phase: II

Compound Number: GW823093

Effective Date: 24-Nov-2006

Description:

This study was designed to evaluate the dose-response, efficacy, safety and tolerability of a range of doses of GW823093 (denagliptin; DEN), compared to placebo, over a 12-week Main Phase in subjects with type 2 diabetes mellitus (T2DM). A 12-week Extension Phase followed the Main Phase to evaluate the safety, tolerability and time course for glycaemic effects after an additional 12 weeks of dosing. This Clinical Study Report (CSR) presents data for the Main Phase only. In total, 371 subjects were randomised to receive placebo, 2.5mg, 7.5mg, 15mg, 30mg or 45mg DEN. In the ITT with last observation carried forward (LOCF) Population, at Week 12, compared to placebo, clinically and statistically significant decreases from baseline in HbA1c were observed in the 45mg (adjusted difference: -0.84% [95% confidence interval (CI): -1.13, -0.55], p<0.001) and 30mg (-0.80% [95% CI: -1.09, -0.50], p<0.001) DEN groups, respectively). Statistically significant differences were also observed for the 15mg (adjusted difference: -0.45% [95%CI:-0.74,-0.16], p=0.002) and 7.5mg (adjusted difference: -0.53% [95%CI:-0.82,-0.24], p<0.001) DEN groups. The overall dose response profile supports achievement of glycaemic efficacy. Except for the placebo and 2.5mg DEN groups, mean fasting plasma glucose (FPG) decreased rapidly over the first 4 weeks of treatment, with no further decrease apparent over the subsequent 8 weeks. At Week 12 decreases from baseline compared to placebo in fructosamine were statistically significant for the 45mg (-38.9µmol/L [95% CI: -53.8, -23.9, p<0.001]), 30mg (-39.6µmol/L [95% CI: -54.6, -24.6, p<0.001] 15mg (-29.2µmol/L [95% CI: -43.9, -14.5, p<0.001]) and 7.5mg (-22.4µmol/L [95% CI: -37.1, -7.6, p=0.003 DEN groups. At Week 12, 2-, 3-, 4- and 3-fold decreases relative to placebo in pro-insulin:insulin ratio were observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups, respectively; the treatment difference was not statistically significant for any DEN group. Increases in Homeostasis model assessment (HOMA) beta cell function were observed with DEN; the greatest increases occurred in the 30mg and 45mg groups. No statistically significant treatment difference compared to placebo in lipid parameters was observed. DEN was generally well tolerated and had an acceptable safety profile. The overall rate of AEs across the groups was 32-42%, did not appear to be dose-related, and was similar to the placebo group (38%). In summary, denagliptin, at doses of 7.5mg, 15mg, 30mg and 45mg, was found to be effective in reducing HbA1c after 12 weeks of treatment, which was clinically relevant for the 30mg and 45mg groups. The overall dose response profile was supportive of achievement of glycaemic efficacy. All doses of denagliptin were generally well tolerated.

Subject: GW823093 (Denagliptin), Phase IIb, Dipeptidyl peptidase-IV (DPPIV) Inhibition, Type 2 Diabetes Mellitus, Dose-Ranging, Safety, Efficacy, Tolerability

Authors: [redacted]

Indication Studied: Type 2 diabetes mellitus

Initiation Date:	28 Apr 2005
Completion Date:	26 Apr 2006 (Main Phase only)
Date of Report:	24 November 2006

Sponsor Signatory: (and Medical Officer)	[redacted] MD FRCP Vice President, Clinical Development, Alternative Development Program, GlaxoSmithKline, Upper Merion, USA

This study was performed in compliance with Good Clinical Practices and GlaxoSmithKline Standard Operating Procedures for all processes involved, including the archiving of essential documents.

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Synopsis

Identifier: GM2006/00396/00 **Study Number:** DPB100925

Title: A 12-Week, Parallel-Group, Double-Blind, Randomised, Placebo-Controlled, Multicentre, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Investigators: Multicentre study.

Study centers: Ninety-four centres from nine countries.

Publications: None at the time of this report.

Study Period: 28 Apr 2005 – 26 Apr 2006 (Main Phase only).

Phase of Development: II

Objectives:

Primary

- To evaluate the dose response and efficacy of GW823093 (denagliptin; 2.5mg, 7.5mg, 15mg, 30mg and 45mg), versus placebo on the change in HbA1c after 12 weeks of dosing in subjects with T2DM.

Secondary

- To investigate the safety and tolerability of a range of doses of denagliptin versus placebo over 12 weeks of dosing in subjects with T2DM.
- To evaluate the effect of a range of doses of denagliptin, versus placebo, on glycaemic parameters (HbA1c, fasting plasma glucose [FPG], fasting fructosamine), fasting insulin and serum lipid profile during 12 weeks of dosing in subjects with T2DM.
- To characterise the pharmacokinetics (PK) of denagliptin in type 2 diabetic subjects after chronic administration using a combined sparse and serial sampling scheme, and to investigate PK/pharmacodynamic (PD) relationships (e.g. safety and efficacy endpoints).
- To evaluate the effect of a range of doses of denagliptin on DPP-IV inhibition as part of population PK assessment.

Exploratory

- To evaluate plasma denagliptin concentrations, glucose, insulin, glucagon, active (intact) glucagon like peptide-1(GLP-1), and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the Main Phase.

- To evaluate the correlation between the serial PK of denagliptin and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the Main Phase.
- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and cardiac troponin I (cTnI) at each collection time point in the Main and Extension Phases.
- To evaluate exploratory endpoints described in the Informed Consent including pharmacogenetics, lipomics and/or proteomics. Pharmacogenetics data were collected to investigate the potential influence of genetic variation on glycaemic control after denagliptin treatment. Samples were taken and frozen for future analysis as described in the Informed Consent Document.

NOTE: PK and PD data are not summarised in this Clinical Study Report (CSR), but will be presented in a separate CSR.

Methodology: A multi-centre, randomised, double-blind, placebo-controlled, parallel-group dose-ranging study with five active treatment arms conducted in two phases: the Main Phase (first 12 weeks of treatment) and an Extension Phase (second 12 weeks of treatment). Subjects with T2DM who were drug-naïve, treated with diet and exercise or on prior oral anti-diabetic monotherapy were recruited.

The study comprised six study periods: Pre-Screen, Screen, Run-In, Main Phase, Extension Phase and Post-treatment Follow-up. This CSR details the results for all phases up to and including the Main Phase of the study only.

Number of subjects:

Number of subjects	Placebo	Denagliptin					Total
		2.5mg	7.5mg	15mg	30mg	45mg	
Planned, n	61	61	61	61	61	61	366
Entered run-in, n							476
Randomised, n	64	61	62	63	59	62	371
Safety Population[1]	64	61	63	66	60	61	375
Completed Main Phase, n (%)	49 (77)	47 (77)	54 (86)	60 (91)	55 (92)	56 (92)	321 (86)
Total withdrawn, n (%)	15 (23)	14 (23)	9 (14)	6 (9)	5 (8)	5 (8)	54 (14)
Withdrawn due to adverse events n (%)	5 (8)	4 (7)	0	0	1 (2)	0	10 (3)
Withdrawn due to lack of efficacy n (%)	5 (8)	1 (2)	0	1(2)	1(2)	0	8 (2)
Withdrawn for other reasons n (%)	5 (8)	9 (15)	9 (14)	5 (8)	3 (5)	5 (8)	36 (10)

1. Includes 4 subjects who erroneously received double-blind medication during the run-in

Diagnosis and main criteria for inclusion: Men and women aged 18 to 75 years with T2DM and Body Mass Index (BMI) ≥24kg/m^2 and ≤40kg/m^2 receiving diet and exercise therapy or taking only one oral anti-diabetic agent, and willing to stop treatment at Screening (Visit 2). HbA1c level at Pre-Screen (Visit 1) ≥7.0% and ≤8.5% for subjects treated with monotherapy; ≥7.5% and ≤10.0% for subjects treated with diet and exercise only. FPG level at Screen (Visit 2) ≥140mg/dL (7.8 mmol/L) and ≤240mg/dL (13.3mmol/L) for all subjects and at baseline (Visit 5) ≤240mg/dL (13.3mmol/L).

Treatment administration: 4 week single-blind placebo run-in followed by randomisation (1:1:1:1:1:1 ratio), with stratification for gender and prior therapy (diet and exercise or monotherapy), to receive double-blinded placebo or 2.5mg, 7.5mg, 15mg, 30mg, or 45mg of denagliptin (DEN) once daily for 12 weeks. All subjects received active treatment during the Extension Phase. Subjects randomised to placebo in the Main Phase received 2.5mg of DEN from the Week 12 visit. Subjects randomised to DEN in the Main Phase remained at their randomised dose and dosing regimen in the Extension Phase in a blinded fashion.

2.5mg DEN capsule batch numbers: [redacted]

15mg DEN capsule batch numbers: [redacted]

Placebo capsule batch numbers: [redacted]

Criteria for evaluation:

Primary endpoint

- Change from baseline (Week 0) in HbA1c at Week 12.

Secondary endpoints

- Change from baseline (Week 0) in HbA1c at Weeks 4 and 8.
- Change from baseline (Week 0) in FPG at Weeks 1, 2, 3, 4, 6, 8 and 12
- Proportion of subjects who achieve various HbA1c (≤6.5%, <7% and ≤8%) and FPG (<126mg/dL [7.0mmol/L] and <140mg/dL [7.8mmol/L]) targets, and/or achieve a clinically meaningful decrease in HbA1c (≥0.7%) and FPG (≥30mg/dL [1.7mmol/L]).
- Change from baseline (week 0) in fructosamine, fasting serum insulin, pro-insulin and pro-insulin:insulin ratio at Weeks 4, 8 and 12.
- Population PK parameters of DEN including clearance (CL) and volume of distribution (V) with assessment of demographic covariates influencing DEN PK. Dependent on the final compartmental model describing DEN disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK.

Other metabolic endpoints

- Percent change from baseline (Week 0) in fasting lipids (triglycerides [TGs], free fatty acids [FFAs], total cholesterol [TC], low density lipoprotein cholesterol [LDL-c] high density lipoprotein cholesterol [HDL-c]) and HOMA measures (insulin sensitivity [IS] and beta cell function [BCF]) based on log-transformed data at Weeks 4, 8, and 12.

Safety

- Safety and tolerability, assessed by the incidence and severity of adverse events (AEs) over the course of the Main Phase.
- Haematology, urinalysis and clinical chemistry laboratory parameters at each visit.
- Incidence and severity of hypoglycaemia over the course of the Main Phase.
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic blood pressure (BP) and radial heart rate (HR) at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Weeks 4 and 12.
- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist:hip ratio at Week 12.

Exploratory endpoints

- Descriptive statistics of plasma DEN concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- Correlation between the serial PK of DEN and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.
- Descriptive statistics of population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the Main Phase.

NOTE: PK and PD data are not summarised in this CSR, but will be presented in a separate CSR.

Statistical methods:

The Intent-to-treat (ITT) Population was used to assess efficacy and consisted of all randomised subjects who received at least one dose of randomised study medication, had a baseline assessment and had at least one corresponding on-therapy (scheduled or unscheduled) efficacy assessment. The Safety Population was used to assess the safety data and consisted of all subjects who received at least one dose of study medication.

Comparison of the change in HbA1c, FPG, fructosamine, fasting insulin, pro-insulin and pro-insulin:insulin ratio from baseline at Week 12 between each of the five DEN treatment groups and placebo was assessed using an analysis of covariance model with terms for gender, prior therapy (diet and exercise/monotherapy), treatment, region and baseline measurement. Point estimates and corresponding 95% confidence intervals (CI) were calculated. To address the issue of multiplicity, inferences from the study were based on a closed testing procedure. The highest dose, DEN 45mg, was to be assessed first, in comparison to placebo (5% level, 2-sided). If this comparison was significant, then the comparison of the DEN 30mg dose to placebo was to be interpreted at the 5% level. This process continued, going down through all the doses, until the first non-

significant test was reached. With this approach, no adjustment to the significance level at each step was needed.

The primary comparison of interest was based on analysis of the ITT Population with last observation carried forward (LOCF). In addition, sensitivity analyses were carried out on the ITT without LOCF and Per-protocol (PP) Populations, along with a repeated measures analysis. An investigation into the dose-response curve was carried out using an ANCOVA model and orthogonal contrasts to test for trends. HbA1c, FPG, fructosamine, fasting insulin, pro-insulin, and pro-insulin:insulin ratio were summarised at each treatment week where data were collected.

Differences between treatment groups in the proportion of subjects who achieved HbA1c (≤6.5%, <7%) and FPG (<126mg/dL [7.0mmol/L]) targets, or achieved a decrease in HbA1c ≥0.7% and FPG ≥30mg/dL [1.7mmol/L]) at Week 12, were assessed based on a logistic regression model with terms for treatment, gender, prior therapy, and baseline measurement. Summary statistics were provided at each visit where data were collected.

For all lipid (TGs, FFAs, TC, LDL-c, HDL-c) and HOMA (IS and BCF) assessments, the percentage change from baseline (log-transformed data) were summarised at each treatment week where data were collected. Statistical analysis for lipids was performed at Week 12, using an analysis of covariance with terms for gender, prior therapy, treatment, region and log-transformed baseline. The point estimates and corresponding 95% CI for treatment ratios were calculated.

Safety endpoints included reported AEs, clinical laboratory tests, hypoglycaemic episodes, weight, waist and hip circumference, waist:hip ratio, BMI, cuff systolic and diastolic BP, radial HR and ECGs. All safety analyses were performed on the Safety Population.

Descriptive statistics were provided for population cardiac biomarkers CK-MB and cTnI at each collection time point.

Summary:

Efficacy endpoints

Primary objective: At Week 12, adjusted changes from baseline compared to placebo were clinically and statistically significant in the 45mg and 30mg DEN groups. Comparisons to placebo were also statistically significant for the 15mg and 7.5mg DEN groups. Mean HbA1c increased from baseline in the placebo group. Results are summarised in the following table for the ITT with LOCF Population.

Change from baseline at Week 12 in HbA1c (%)	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n[1]	59	56	59	62	56	58
Baseline: mean±SD	7.76±0.68	8.02±0.93	7.97±0.76	7.88±0.65	7.77±0.66	8.07±0.75
Week 12: mean±SD	8.18±1.33	8.20±1.28	7.93±1.16	7.92±0.92	7.43±0.86	7.68±0.96
Adjusted change from baseline[2]:						
mean±SE	0.46±0.105	0.18±0.873	-0.07±0.104	0.01±0.102	-0.34±0.107	-0.38±0.105
Adjusted mean difference vs PBO[2]						
Mean	-	-0.28	-0.53	-0.45	-0.80	-0.84
[95% CI]	-	[-0.58, 0.01]	[-0.82, -0.24]	[-0.74, -0.16]	[-1.09, -0.50]	[-1.13, -0.55]
P-value	-	0.061	<0.001	0.002	<0.001	<0.001

1. Number of subjects with a value at baseline and at Week 12
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

At Week 12, for subjects previously treated with monotherapy there was an increase in HbA1c in the placebo group, this resulted in a greater decrease from baseline in HbA1c relative to placebo in subjects previously treated with monotherapy compared to diet and exercise.

The overall dose response profile supports achievement of glycaemic efficacy. Generally, the reductions in HbA1c were similar for the 30mg and 45mg DEN groups, and the 7.5mg group produced a slightly larger reduction than the 15mg group.

Secondary objectives

HbA1c and FPG: Mean decreases in HbA1c from baseline were apparent by Week 4 of treatment. In the 30mg and 45mg DEN groups further decreases in HbA1c were observed at 8 weeks which were sustained to Week 12.

At Week 12, adjusted decreases from baseline compared to placebo in mean FPG were clinically and statistically significant for the 45mg and 30mg DEN groups; mean FPG increased from baseline in the placebo group. Results are summarised in the following table for the ITT with LOCF Population.

Change from baseline at Week 12 in FPG (mmol/L)	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n[1]	62	58	62	63	58	60
Baseline: mean±SD	9.64±1.97	9.64±2.41	9.89±2.02	9.93±1.59	9.94±2.24	9.98±1.74
Week 12: mean±SD	10.21±2.88	9.83±2.68	9.58±3.09	9.86±2.14	8.94±2.20	9.23±2.27
Adjusted change from baseline[2]:						
mean±SE	0.52±0.273	0.11±0.282	-0.28±0.272	0.07±0.270	-0.95±0.281	-0.71±0.276
Adjusted mean difference vs PBO[2]						
Mean	-	-0.40	-0.80	-0.58	-1.46	-1.22
[95% CI]	-	[-1.18, 0.37]	[-1.56, -0.04]	[-1.34, 0.17]	[-2.23, -0.69]	[-1.99, -0.46]
P-value	-	0.306	0.039	0.130	<0.001	0.002

1. Number of subjects with a value at baseline and at Week 12
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Except for the placebo and 2.5mg DEN groups, mean FPG decreased rapidly over the first 4 weeks of treatment, with no further decrease apparent over the subsequent 8 weeks.

At Week 12, the proportion of subjects with a HbA1c value of ≤6.5% was highest in the 45mg and 30mg DEN groups (14% and 16%, respectively) but were not statistically significant compared to placebo.

The proportion of subjects with a HbA1c value of <7% was highest in the 45mg and 30mg DEN groups (24% and 25%, respectively) and was statistically significant for the 45mg DEN group (odds ratio 3.24 [95%CI: 1.11, 9.52], p=0.032]).

The proportion of subjects with a reduction from baseline in HbA1c of ≥0.7% was highest in the 30mg DEN group (38%), followed by the 45mg group (29%) but were not statistically significant compared to placebo.

Results are summarised in the following table for the ITT with LOCF Population.

HbA1c responders at Week 12, n (%)	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n[1]	59	56	59	62	56	58
HbA1c ≤6.5%	6 (10%)	4 (7%)	4 (7%)	5 (8%)	9 (16%)	8 (14%)
Odds ratio vs PBO	-	0.92	1.15	1.20	2.68	3.24
95% CI	-	0.21, 3.95	0.27, 4.92	0.30, 4.83	0.74, 9.77	0.85, 12.37
P value	-	0.909	0.852	0.795	0.135	0.085
HbA1c <7%	11 (19%)	9 (16%)	12 (20%)	9 (15%)	14 (25%)	14 (24%)
Odds ratio vs PBO	-	1.10	1.99	1.04	2.15	3.24
95% CI	-	0.36, 3.36	0.69, 5.76	0.35, 3.13	0.76, 6.13	1.11, 9.52
P value	-	0.866	0.202	0.941	0.152	0.032
HbA1c reduction ≥0.7%	10 (17%)	6 (11%)	14 (24%)	10 (16%)	21 (38%)	17 (29%)
Odds ratio vs PBO	-	0.46	1.43	1.01	3.65	2.00
95% CI	-	0.14, 1.50	0.53, 3.85	0.36, 2.78	1.41, 9.48	0.76, 5.24
P value	-	0.198	0.481	0.991	0.008	0.161

1. Number of subjects with a value at baseline and at Week 12

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

At Week 12, the proportion of subjects with a FPG <7.0mmol/L was similar in the 45mg, 7.5mg and 2.5mg DEN groups (range 14%-15%) and lowest in the 15mg group (6%), but were not statistically significant compared to placebo.

The proportion of subjects with a reduction from baseline in FPG of ≥1.7mmol/L was highest in the 45mg and 30mg DEN groups (30% and 31%, respectively) and was statistically significant for the 45mg (odds ratio: 3.00 [95%CI: 1.08, 8.30], p=0.034) and 30mg (odds ratio 3.24 [95%CI: 1.15, 9.13], p=0.026) DEN groups.

Results are summarised in the following table for the ITT with LOCF Population.

FPG responders at Week 12, n (%)	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n[1]	62	58	62	63	58	60
FPG <7mmol/L	5 (8%)	8 (14%)	9 (15%)	4 (6%)	6 (10%)	9 (15%)
Odds ratio vs PBO	-	1.77	2.57	1.09	1.56	3.14
95% CI	-	0.50, 6.30	0.72, 9.11	0.26, 4.62	0.41, 5.91	0.89, 11.14
P value	-	0.380	0.145	0.906	0.509	0.077
Reduction ≥1.7mmol/L	8 (13%)	12 (21%)	13 (21%)	10 (16%)	18 (31%)	18 (30%)
Odds ratio vs PBO	-	1.90	1.59	1.35	3.24	3.00
95% CI	-	0.63, 5.72	0.55, 4.62	0.45, 4.00	1.15, 9.13	1.08, 8.30
P value	-	0.254	0.396	0.590	0.026	0.034

1. Number of subjects with a value at baseline and at Week 12

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Fructosamine and serum insulin: At Week 12, adjusted decreases from baseline compared to placebo in fructosamine were clinically and statistically significant for the 45mg (-38.9µmol/L [95% CI: -53.8, -23.9, p<0.001]), 30mg (-39.6µmol/L [95% CI: -

54.6, -24.6, p<0.001]), 15mg (-29.2µmol/L [95% CI: -43.9, -14.5, p<0.001]) and 7.5mg (-22.4µmol/L [95% CI: -37.1, -7.6, p=0.003]) DEN groups. An increase in fructosamine compared to baseline was observed in the placebo group (mean±SE: 19.9±5.44µmol/L).

At Week 12, treatment difference compared to placebo in change from baseline in mean fasting serum insulin and in mean fasting pro-insulin was not statistically significant for the 45mg DEN group (p=0.295 and p=0.403, respectively). No trend with respect to dose of DEN was observed.

At Week 12, 2-, 3-, 4- and 3-fold decreases relative to placebo, in change from baseline in mean pro-insulin:insulin ratio was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups, respectively. The treatment difference was not statistically significant although there was a trend towards clinical improvement in the pro-insulin:insulin ratio with DEN.

Results are summarised in the following table for the ITT with LOCF Population.

Change from baseline in pro-insulin:insulin ratio	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n[1]	56	52	58	62	52	54
Baseline: mean±SD	0.35±0.24	0.43±0.29	0.35±0.21	0.38±0.25	0.41±0.22	0.36±0.17
Week 12: mean±SD	0.34±0.19	0.42±0.26	0.32±0.20	0.32±0.23	0.31±0.15	0.31±0.14
Adjusted change from baseline: mean±SE	-0.02±0.018	0.01±0.019	-0.04±0.018	-0.06±0.017	-0.08±0.018	-0.06±0.018
Adjusted mean difference vs PBO[2]						
Mean	-	0.03	-0.02	-0.04	-0.06	-0.04
[95% CI]	-	[-0.02, 0.08]	[-0.07, 0.03]	[-0.09, 0.01]	[-0.11, -0.01]	[-0.09, 0.01]
P-value	-	0.286	0.457	0.136	0.021	0.094

1. Number of subjects with a value at baseline and at specified visit
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

HOMA Beta-cell function and Insulin Sensitivity: At Week 12, percent decreases in HOMA IS compared to baseline were observed in the 15mg, 30mg and 45mg DEN groups. A decrease in HOMA IS was also observed in the placebo group. A percent increase in HOMA BCF compared to baseline was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups; the greatest increases were observed in the 30mg and 45mg groups. A small decrease in HOMA BCF was observed in the placebo group. Results are summarised in the following table for the ITT with LOCF Population.

% Change from baseline in HOMA Parameter	Denagliptin					
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
HOMA IS (%), n[1]	53	49	55	62	52	53
Baseline: GM	58.89	56.18	51.51	53.51	61.39	53.29
(CV%)[2]	61.80	54.56	60.89	64.29	60.75	63.84
Week 12: GM	57.02	58.91	51.59	51.39	60.07	50.24
[-SE, +SE][3]	[53.05, 61.30]	[54.13, 64.12]	[47.40, 56.16]	[47.59, 55.48]	[55.79, 64.69]	[46.12, 54.72]
Ratio to baseline[4]:						
GM	-3.17	4.86	0.17	-3.96	-2.14	-5.72
[-SE, +SE][3]	[-8.93, 2.95]	[-1.79, 11.96]	[-6.20, 6.97]	[-10.27, 2.79]	[-6.90.2.86]	[-12.00, 1.00]
BCF (%), n[1]	53	49	55	62	52	52
Baseline: GM	36.96	38.35	38.47	37.32	33.97	37.74
(CV%)[2]	54.41	62.16	58.30	58.10	70.88	65.48
Week 12: GM	35.06	36.85	42.15	39.46	42.60	47.31
[-SE, +SE][3]	[32.15, 38.24]	[33.51, 40.53]	[38.69, 45.92]	[36.84, 42.26]	[38.67, 46.92]	[43.46, 51.51]
Ratio to baseline[4]:						
GM	-5.13	-3.91	9.57	5.75	25.40	25.36
[-SE, +SE][3]	[-10.61, 0.69]	[-9.34, 1.83]	[3.38, 16.14]	[0.11, 11.71]	[17.42, 33.92]	[17.63, 33.59]

1. Number of subjects with a value at baseline and at specified visit
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. SE in log scale added or subtracted, then entire quantity exponentiated
4. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)

Serum lipids: At Week 12, relative to placebo, there were small statistically non-significant, non detrimental changes in serum lipids at all doses of DEN. No trend with respect to dose of DEN was observed.

Safety endpoints

Adverse events: Overall, the incidence of on-therapy AEs in the DEN groups was low (range 32-42%) and similar to placebo (38%). No AE increased in incidence with increasing dose of DEN. Events occurring in ≥5% of subjects in any treatment group are summarised in the following table for the Safety Population.

AE by Preferred Term, n (%)	Denagliptin					
	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Subjects with at least 1 AE	24 (38%)	22 (36%)	20 (32%)	28 (42%)	19 (32%)	23 (38%)
Back pain	1 (2%)	0	0	4 (6%)	0	2 (3%)
Headache	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0	2 (3%)
Nasopharyngitis	3 (5%)	3 (5%)	7 (11%)	3 (5%)	3 (5%)	0
Nausea	1 (2%)	2 (3%)	2 (3%)	4 (6%)	1 (2%)	0
Constipation	3 (5%)	0	0	2 (3%)	1 (2%)	1 (2%)
Hyperglycaemia	0	3 (5%)	0	0	0	0

NOTE: Hypoglycaemic events that were not SAEs are reported separately

Three subjects in each of the 45mg DEN and 2.5mg DEN groups, and one subject in each of the 15mg DEN and 30mg DEN groups had severe on-therapy AEs. No severe AE was reported by more than one subject in any treatment group.

There was a low incidence of hypoglycaemia (one subject in the placebo group and two subjects in the 15mg DEN group).

Serious Adverse Events (SAEs): No subjects died during the study. Five subjects experienced six on-therapy non-fatal SAEs: one subject in each of the placebo, 2.5mg DEN and 45mg DEN groups and two in the 30mg DEN group. One on-therapy non-fatal SAE was considered to be related to study treatment. This subject experienced gastroenteritis on Day 53, 1 day after the last dose of study medication (placebo), which was moderate in intensity for which the subject was withdrawn.

Adverse Events Leading to Withdrawal: Three subjects (5%) in the placebo group, three subjects (5%) in the 2.5mg DEN group and one subject (2%) in the 30mg DEN group had AEs leading to withdrawal. The only event occurring in more than one subject in any group was hyperglycaemia in 2 subjects (3%) in the 2.5mg group.

Adverse Events of Special Interest: AEs of myalgia, hypertension, blood pressure increased, fluid retention and hypoglycaemia were infrequent for all treatment groups.

Pregnancy: No subjects became pregnant during the study.

Vital Signs: No apparent trends were visible in ECGs or vital signs. There was no visible difference from placebo in weight change; reductions in weight were observed in all treatment groups.

Laboratory Values of Potential Clinical Concern: There were no apparent trends in haematology or clinical chemistry results.

Biomarker endpoints: Small increases from baseline in CK-MB at Week 12 were observed across all DEN dose groups except the 15mg group; the greatest increase was observed in the 30mg DEN group (mean±SD; 0.32±1.47µg/L). Mean CK-MB was similar at baseline and Week 12 in the placebo group. No clinically relevant changes in CK-MB or cTnI were observed.

Conclusions:

- The overall dose response profile supports achievement of glycemic efficacy with DEN. Similar clinically and statistically significant reductions in HbA1c from baseline compared to placebo occurred at the 30mg and 45mg doses of DEN (-0.80% and -0.84% respectively at week 12 ($p<0.001$)). The results for FPG and fructosamine were similar to that seen for HbA1c. A rapid onset of action was demonstrated. There were small statistically non-significant, non detrimental changes in serum lipids, fasting insulin, pro-insulin and pro-insulin:insulin ratio. However, although not statistically significant, there was a trend for clinical improvement in the pro-insulin:insulin ratio with DEN.
- A percent increase in HOMA BCF was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups, the greatest increases occurring in the 30mg and 45mg groups; HOMA BCF decreased slightly in the placebo group.

- Denagliptin was well tolerated with an acceptable safety profile. The incidence of on-therapy AEs in the DEN groups (range 32-42%) was similar to placebo (38%) and did not appear to be dose-related. The majority of AEs were mild to moderate in intensity and there was a low rate of treatment-related AEs. The most frequently reported events in the DEN-treated groups were nasopharynigitis (16 subjects, 5%), nausea (9 subjects, 3%) and headache (8 subjects, 3%). No subjects died. Five subjects experienced six on-therapy SAEs: one subject in each of the placebo, 2.5mg DEN and 45mg DEN groups and two in the 30mg DEN group. Seven subjects had AEs that led to early withdrawal from the study (3 subjects (5%) each in the placebo and 2.5mg DEN groups, and one subject (2%) in the 30mg DEN group)
- There was a very low incidence of hypoglycaemia and no apparent trends were visible in ECGs, vital signs, haematology or clinical chemistry results. There were no detrimental effects on blood pressure. There was no visible difference from placebo in weight change; reductions were observed in all treatment groups. No clinically relevant changes in CK-MB or cTnI were observed.

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Abbreviations

ACM	Medial cerebral artery
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine transaminase
ANCOVA	Analysis of covariance
AST	Aspartate transaminase
BCF	Beta cell function
BMI	Body mass index
BUN	Blood urea nitrogen
BP	Blood pressure
bpm	Beats per minute
CABG	Coronary artery bypass graft
CHF	Congestive heart failure
CI	Confidence interval
CIB	Clinical investigator brochure
CK-MB	Creatine kinase MB
CL	Clearance
CSR	Clinical study report
cTnI	Cardiac troponin-I
DEN	Denagliptin
DPP-IV	Dipeptidyl peptidase-IV
ECG	Electrocardiogram
eCRF	Electronic case report form
FCBG	Fasting capillary blood glucose
FFA	Free fatty acids
FPG	Fasting plasma glucose
GCP	Good clinical practice
GCSP	Global clinical safety and pharmacovigilance
GIP	Glucose dependent insulinotropic polypeptide
GLP-1	Post prandial glucagon like peptide-1
GSK	GlaxoSmithKline
HbA1c	Glycosylated haemoglobin
HDL-c	High density lipoprotein cholesterol
HOMA	Homeostasis model assessment
HR	Heart rate
IDMC	Independent Data Monitoring Committee
IEC	Independent ethics committee
IND	Investigational new drug
IR	Insulin resistance
IRB	Institutional Review Board
IS	Insulin sensitivity
ISA	Insulin sensitising agents
ITT	Intent-to-treat
IUD	Intrauterine device

Continued...

Abbreviations (Cont/d.)

kg	Kilogram(s)
L	Litre
LDH	Lactate dehydrogenase
LDL-c	Low density lipoprotein cholesterol
LLRR	Lower limit of reference range
LOCF	Last observation carried forward
MedDRA	Medical dictionary for regulatory activities
MET	Metformin
µmol	Micromole
mg	Milligram
mL	Millilitre
mmHg	Millimetres of mercury
mmol	Millimole
NYHA	New York Heart Association
OAD	Oral anti-diabetic
od	Once daily
OTC	Over-the-counter
PD	Pharmacodynamics
PK	Pharmacokinetics
pmol	Picomole
PP	Per protocol
PPAR	Peroxisome proliferator activated receptor
PTCA	Percutaneous transluminal coronary angioplasty
QC	Quality control
QUEST	Quest Diagnostic Laboratory
RAP	Reporting analysis plan
RAMOS	Registration and medication ordering system
RBC	Red blood cell
RDM	Remote data management
SAS	Statistical Analysis System
SAE	Serious adverse event
SBP	Systolic blood pressure
SD	Standard deviation
SDAC	Statistical data analysis centre
SE	Standard error
SOP	Standard operating procedures
SUs	Sulphonylureas
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
TG	Triglyceride
TSH	Thyroid stimulating hormone
TZD	Thiazolidinedione
UDS	Urine drug screen
ULRR	Upper limit of reference range

Continued...

Abbreviations (Cont/d.)

US	United States
V	Volume of distribution
WBC	White blood count
WHO	World Health Organisation

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1. ETHICS

1.1. Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center ethics committee or institutional review board.

1.2. Ethical Conduct of the Study

This study was conducted in accordance with 'good clinical practice' (GCP) and all applicable regulatory requirements, and the guiding principles of the Declaration of Helsinki (1996 version).

1.3. Subject Information and Consent

Written informed consent was obtained from each subject prior to the performance of any study-specific procedures. Electronic case report forms (eCRFs) and subject diary cards were provided for each subject's data to be recorded.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study was conducted at 94 centres from nine countries (see Section 6.1). The investigators were selected because of their interest in the study, their ability to conduct the study according to ICH-GCP standards and their ability to enrol eligible subjects.

To ensure that study procedures were consistent across all investigational sites, GlaxoSmithKline (GSK) representatives reviewed the protocol, eCRF and procedures for reporting safety data with the investigators and their staff. An investigator meeting for the North American/Canadian sites was held in Florida in March 2005. In Europe, investigator meetings were conducted for individual countries, or for individual centres, depending on what was deemed the most appropriate method.

GSK was responsible for the administration of the study, including clinical trials supply management.

All data management activities were performed by GSK.

All laboratory assessments were analysed by a central laboratory. Quest Diagnostics Clinical Laboratories Inc., Middlesex, UK and Quest Diagnostics Clinical Trials Laboratory, Van Huys, CA 91405, USA were responsible for most of the laboratory assessments. Quest Diagnostics sub-contracted Linco Assay Services, Saint Charles, MO

63304, USA to analyse glucagon, Pathway Diagnostics Corporation Laboratory, Malibu, CA 90265, USA to analyse DPPIV and GLP-1 and Nichols Institute, San Juan Capistrano, CA 92690, USA to assay LDH isoenzyme.

PK analysis was performed at GSK.

eResearch Technology, Inc., NJ 08807, USA were responsible for the central analysis of ECGs.

An Independent Data Monitoring Committee (IDMC) was utilised in this study to assess safety data in order to protect the ethical and safety interests of the subjects recruited, while protecting, as far as possible, the scientific validity of the study. The IDMC reviewed unblinded study data, however, to ensure that the study team remained blinded to the treatment codes, a Statistical Data Analysis Centre (SDAC) external to the sponsor was used and was responsible for unblinding the data for the IDMC. The IDMC members, specific responsibilities of and procedures followed by the IDMC are described in full in the IDMC Charter.

The authors of the Clinical Study Report for DPB100925 were [redacted] Contract Medical Writer; [redacted] Cardiovascular and Metabolic Medicines Development Centre, GSK; [redacted] and [redacted] Drug Development Sciences, Cardiovascular and Metabolic Medicines Development Centre, GSK.

3. INTRODUCTION

3.1. Background

Type 2 diabetes mellitus (T2DM) accounts for more than 85% of the total number of diabetes cases. The primary manifestation of this disease is chronic hyperglycaemia, resulting from resistance to insulin action at a cellular and molecular level and inadequate secretion of endogenous insulin. The incidence and prevalence of T2DM is considered to be at epidemic levels in North America and Europe and is increasing worldwide, with a projected estimate that approximately 221 million people will have the condition by the year 2010 [Amos, 1997]. T2DM is a major health care issue due to increased patient morbidity and mortality resulting from complications arising from the disease, especially cardiovascular, renal, and neurological, as well as the costs associated with the management of its complications.

The medical management of patients with T2DM consists of diet, exercise, and weight reduction, together with oral anti-diabetic medications or insulin therapy, as appropriate. Current pharmacological treatments for T2DM include drugs that increase insulin secretion (sulphonylureas [SU] and meglitinides), increase glucose utilisation (glitazones), reduce hepatic glucose production (metformin), and delay glucose absorption (α-glucosidase inhibitors). Side effects of these medications include hypoglycaemia (primarily seen with SUs) and gastrointestinal disturbances (primarily seen with metformin). Side effects of the glitazones can include weight gain and fluid retention in certain patients.

T2DM treatment is evolving. In order to achieve glycaemic targets, multiple agents and complementary mechanisms are frequently required. Consequently, new agents with mechanisms that are different, yet complementary, to existing classes are required.

GW823093 (Denagliptin; DEN) is a selective inhibitor of the dipeptidyl peptidase IV enzyme (DPP-IV) and is being investigated for the treatment of T2DM. DPP-IV rapidly inactivates the incretin hormones glucagon like peptide-1 (GLP-1) and glucose dependent insulinotrophic polypeptide-1 (GIP-1) secreted by cells in the gut in response to meal ingestion. Inhibiting the natural action of DPP-IV through use of a DPP-IV inhibitor improves the stability of GLP-1 and potentiates the physiologic actions of GLP-1 such as glucose dependent insulin secretion and inhibition of glucagon production. GLP-1 is a new therapeutic target of an emerging class of compounds called gliptins.

3.2. Rationale

Dipeptidyl-peptidase (DPP-IV), also known as the T-cell antigen CD26, is a serine aminopeptidase. DPP-IV rapidly ($t1/2 < 5$ min) inactivates the incretins, GLP-1 and glucose dependent insulinotropic polypeptide (GIP), by cleaving off a dipeptide at the penultimate alanine near the amino-terminus of GLP-1 (7-36) amide. Improving the stability and action of GLP-1 and GIP, which are responsible for at least 50% of nutrient stimulated insulin secretion, has been shown to improve glycaemic control in subjects

with T2DM. DEN is a selective DPP-IV inhibitor being investigated for the treatment of T2DM. In addition to DEN, several oral DPP-IV inhibitors have progressed to clinical studies in healthy individuals and subjects with T2DM. Studies up to 52 weeks in duration with another DPP-IV inhibitor compound (LAF-237-Novartis) have demonstrated improvements in glycaemic control with an acceptable tolerability/safety profile [Ahrén, 2004a; Ahrén, 2004b; Pratley, 2004].

A single-dose study with DEN has been completed. DEN was well tolerated after single oral doses of 2.5, 5, 10, 15, 25, and 50mg in healthy male subjects. There were no severe adverse events (AEs), serious AEs (SAEs) or drug-related AEs leading to discontinuation. Headache, nausea and dizziness were the most frequently reported events with episodes occurring more frequently with DEN than placebo. There did not appear to be any investigational product- or dose-related trend in the frequency of clinical chemistry, haematology or urinalysis shifts from pre-dose. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities.

Two multiple-dose studies have been completed. DEN was administered at doses of 5, 15 and 30mg for 13 days to healthy lean and obese subjects (DPB10002) and for seven days to subjects with T2DM (DPB10003). In both studies, DEN was well tolerated and no serious or significant AEs or clinically significant findings were observed. There was no apparent dose-related trend in the frequency of clinical chemistry, haematology or urinalysis shifts from baseline. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities. Substantial DPP-IV inhibition (≥70% at 24 hours at the 15 and 30mg doses) was observed in both studies. Data from both studies indicated a dose-related reduction in fasting and post-prandial glucose. An apparent increase in post-prandial insulin was seen after a single dose and after seven days of dosing in subjects with T2DM (DPB10003).

The highest proposed dose (45mg) has recently been assessed in a 10 day repeat dose study in healthy subjects (DPB102875). This study was the first to evaluate the safety, tolerability and pharmacokinetics of multiple doses (10 days) of a 45mg dose of DEN. Twenty nine healthy volunteers were enrolled and preliminary listings of reported blinded AEs were available for analysis. AEs were reported by 18/27 (67%) subjects; headache, light headedness and diarrhoea were the most commonly reported events. One individual was discontinued from the study due to left flank pain and dysuria. The symptoms resolved in one day and the subject refused additional diagnostic tests required for analysis of nephrolithiasis. Another individual developed severe nausea and emesis, but was able to complete the study. Based upon review of blinded data, no events were expected to preclude inclusion of 45mg doses in larger Phase 2/3 trials.

This Phase IIb dose-ranging study evaluated the dose-response, efficacy, safety and tolerability of a range of doses of DEN compared to placebo over a 12 week period in subjects with T2DM. A subsequent 12 week Extension Phase will evaluate the safety and tolerability and time course for glycaemic effects after an additional 12 weeks of dosing.

The dose range for this study was determined by examining the preliminary results of multiple dose studies in healthy volunteers and in subjects with T2DM that had completed and were being analysed just prior to starting this study. The planned doses of 2.5, 7.5, 15, 30 and 45mg targeted a range of DPP-IV inhibition profiles and exposures to DEN. The dose range was designed to determine both minimally effective and maximally safe and tolerable doses. The lowest dose (2.5mg) was anticipated to be below the therapeutic threshold. Based on glucose data from DPB10003, the therapeutic dose range was expected to be between 5mg and 30mg/day. The highest dose (45mg) was at the higher end of the allowable clinical dose range based on current safety assessment data.

An IDMC was utilised during the study. The committee was composed of members external to GSK. The objective of the committee was to monitor safety data (e.g., clinical chemistry, AEs) on an on-going basis to ensure maximal safety for recruited subjects and to maintain integrity of the data.

4. STUDY OBJECTIVES

4.1. Primary

- To evaluate the dose response and efficacy of denagliptin (2.5mg, 7.5mg, 15mg, 30mg and 45mg), versus placebo on the change in HbA1c after 12 weeks of dosing in subjects with T2DM.

4.2. Secondary

- To investigate the safety and tolerability of a range of doses of denagliptin versus placebo over 12 weeks of dosing in subjects with T2DM.
- To evaluate the effect of a range of doses of denagliptin, versus placebo, on glycaemic parameters (HbA1c, fasting plasma glucose [FPG], fasting fructosamine), fasting insulin and serum lipid profile during 12 weeks of dosing in subjects with T2DM.
- To characterise the pharmacokinetics (PK) of denagliptin in type 2 diabetic subjects after chronic administration using a combined sparse and serial sampling scheme, and to investigate PK/pharmacodynamic (PD) relationships (e.g. safety and efficacy endpoints).
- To evaluate the effect of a range of doses of denagliptin on DPP-IV inhibition as part of population PK assessment

4.3. Exploratory Objectives

- To evaluate plasma denagliptin concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the Main Phase.

- To evaluate the correlation between the serial PK of denagliptin and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the Main Phase.
- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the Main and Extension Phases.
- To evaluate exploratory endpoints including pharmacogenetics, lipomics and/or proteomics. Pharmacogenetics data were collected to investigate the potential influence of genetic variation on glycaemic control after denagliptin treatment. Samples were taken and frozen for future analysis.

NOTE: PK and PD data are not summarised in this CSR, but will be presented in a separate CSR.

5. INVESTIGATIONAL PLAN

5.1. Overall Study Design

This study was a multi-centre, randomised, double-blind, placebo-controlled, parallel-group dose-ranging study with five treatment arms plus a placebo arm conducted in two phases: the Main Phase (first 12 weeks of treatment) and an Extension Phase (second 12 weeks of treatment). Only results for the Main Phase are presented in this CSR. The study design is shown in Figure 1.

Subjects with T2DM who were drug-naïve, treated with diet and exercise, or on prior oral anti-diabetic monotherapy were recruited. Initial HbA1c criteria at the pre-screening visit (Visit 1; Week -6) were as follows:

- HbA1c level ≥7.0% to ≤8.5% for subjects on oral anti-diabetic monotherapy
- HbA1c level ≥7.5% to ≤10.0% for subjects on diet and exercise alone

Study procedures were performed according to the Schedule of Assessments shown in Table 1. Approximately one week after providing informed consent and completing the pre-screen visit, eligible subjects attended a Screening visit (Visit 2; Week -5) to determine eligibility to proceed in the study. Eligible subjects were taken off their anti-diabetic medications and prohibited concomitant medications for the duration of the trial. Subjects were provided with a glucose meter and instructed on its operation and frequency of use.

Standard diabetic dietary and exercise advice was provided at the beginning of the Run-in and reinforced at every visit thereafter. Approximately one week after the Screening Visit, eligible subjects returned to the clinic to start a 4 week run-in period. Subjects were dispensed three bottles of single-blind placebo run-in medication and instructed to take 1 capsule daily in the morning at breakfast from each bottle.

FPG was tested at Weeks -4 (Visit 3) and -2 (Visit 4) by a central laboratory and at Week 0 (Visit 5) by fasting capillary blood glucose (FCBG) and a central laboratory. If FPG was >240mg/dL (13.3mmol/L) at Visit 3 or 4, the test was repeated by a central laboratory and if FPG remained >240mg/dL (13.3mmol/L) the subject was not eligible to be randomised, was withdrawn from the study and referred for follow-up. If FCBG at Week 0 (Visit 5) was > 240mg/dL (13.3mmol/L) (after repeated FCBG), a blood sample to assess FPG was drawn. If FPG was > 240mg/dL (13.3mmol/L) on confirmation of a central laboratory measure, a subject was not eligible to be randomised, was withdrawn from the study and referred for follow-up.

Upon successful completion of the run-in phase, each subject was stratified by gender and prior therapy (diet and exercise; monotherapy) and randomly assigned (1:1:1:1:1:1 ratio) to one of five doses of DEN od or placebo for 12 weeks within each stratum. All subjects received active treatment during the Extension Phase. Subjects randomised to placebo in the Main Phase received 2.5mg of DEN at the Week 12 visit. Subjects

randomised to DEN in the Main Phase remained at their randomised dose and dosing regimen in the Extension Phase in a blinded fashion.

Subjects who had a FPG >270mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, or 11 were asked to return to the clinic as soon as possible for a retest. If the FPG remained >270mg/dL (15.0mmol/L) upon retest, the subject was withdrawn from the study.

Table 1 Schedule of assessments

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Double-blind Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12
	Week -6	Week -5	Week -4	Week -2	Baseline /Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Informed Consent, Medical History, Demographics[1]	√	√										
Inclusion/Exclusion Criteria		√	√	√	√							
Concomitant Medications	√	√	√	√	√	√	√	√	√	√	√	√
Physical Examination		√			√					√		√
Blood Pressure and Heart Rate[2]		√	√	√	√	√	√	√	√	√	√	√
ECG (locally and centrally read)		√			√				√			√
Blood Samples for Safety: Haematology, Urinalysis and chemistry[3]		√			√	√	√	√	√	√	√	√
Efficacy: HbA1c	√			√	√				√		√	√
Efficacy: Fasting plasma glucose	√	√	√	√	√	√	√	√	√	√	√	√
Fasting Capillary Blood Glucose (FCBG) (fingerstick)					√							
Efficacy: Fructosamine		√		√	√				√		√	√
Lipids (TC, LDL-c, HDL-c, TG, FFA)		√			√				√		√	√
Insulin, pro-insulin					√				√		√	√
PK /PD– sparse sampling					√				√			√
PK/PD – serial sampling					√					√		√
Blood Sample for PGx[4]					√							
Blood Sample Population Cardiac Biomarkers: CK-MB, cTnI		√			√				√			√
Blood sample: exploratory endpoints					√				√			√
Weight, height[5]		√	√	√	√	√	√	√	√	√	√	√
Waist and hip measurements		√			√							√

(Continued.)

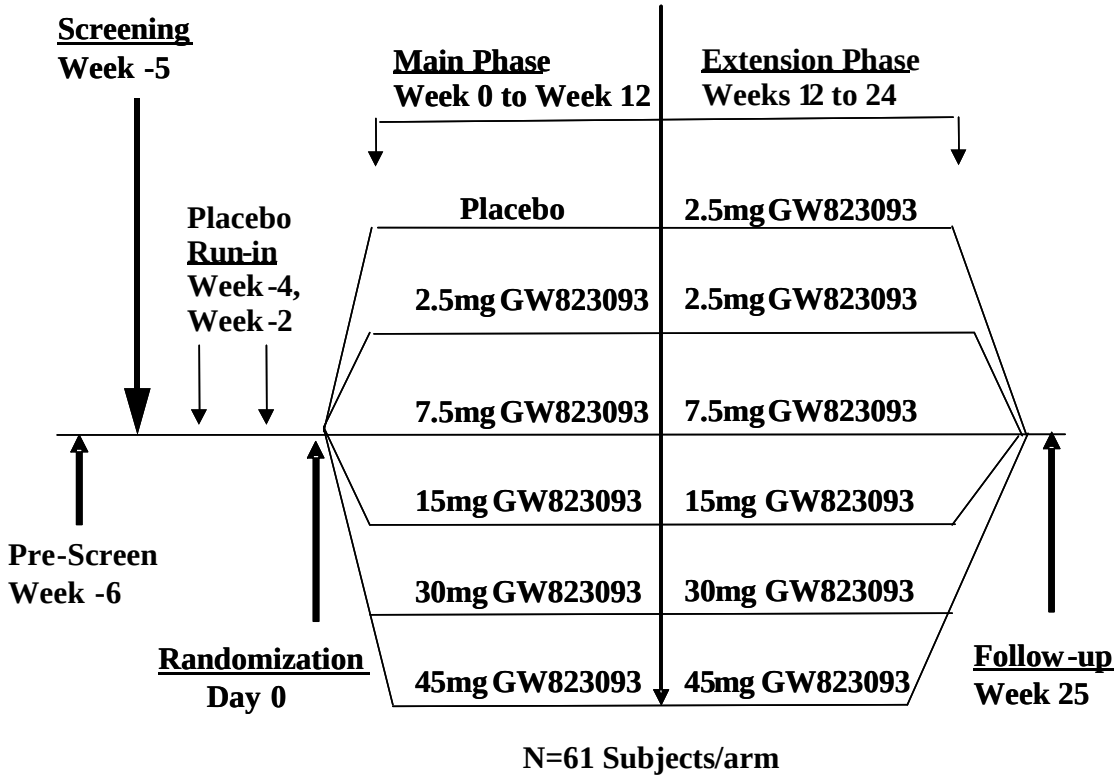
Table 1 Schedule of assessments (Cont./d)

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Double-blind Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12
	Week -6	Week -5	Week -4	Week -2	Baseline /Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Pregnancy Test[6]		√			√				√		√	√
Discontinue prior anti-diabetic medication		√										
Issue investigational product[7]			√	√	√				√		√	√
Diet and Exercise Advice		√	√	√	√	√	√	√	√	√	√	√
Adverse and Hypoglycaemic Events		√	√	√	√	√	√	√	√	√	√	√
Compliance				√	√				√		√	√

1. At the pre-screening visit, informed consent and brief medical history only
2. Blood pressure and HR (in duplicate) were taken pre-dose on Week -5 (Visit 2), Week 0 (Visit 5), Week 4 (Visit 9), Week 12 (Visit 12)
3. TSH at Screening (Visit 2 only; faecal occult blood assessment performed if reduction in haemoglobin $\geq$ 2 g/dL from baseline during the course of the study
4. PGx sample could be taken at any time during the study after the PGx Informed Consent had been obtained
5. Height at Screening (Visit 2) and confirmed at Baseline (Visit 5)
6. Serum pregnancy at Screening (Visit 2) and pre-dose on Week 0 (Visit 5), Weeks 4 (Visit 9), 8 (Visit 11), and 12 (Visit 12). Urine pregnancy pre-dose on Week 0 (Visit 5)
7. Single-blind medication issued at Week -4 (Visit 3) and Week -2 (Visit 4)

CONFIDENTIAL

Figure 1 Study Design



GW823093 = denagliptin; DEN

5.1.1. Discussion of Study Design, Including the Choice of Control Group

The dose rationale for this study is discussed in detail in Section 5.4.4.

5.2. Protocol Amendments

The study protocol was approved on 16 December 2004 and underwent two amendments.

Protocol Amendment 1 (approved 10 March 2005): applicable to all centres

The following exploratory objective was added:

- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the Main and Extension Phases.

An ECG measurement at Visit 2 and central ECG reading process for all ECGs was added. Clarification of FPG inclusion criteria and hypoglycaemia reporting procedures was provided.

Protocol Amendment 2 (approved 5 April 2006): applicable to all centres

Cardiac troponin withdrawal criteria were added to provide additional assurance of subject safety in the trial and to provide for consistency of subject evaluation in the event of a significant elevation in cTnI. The level of cTnI for withdrawal of subjects from the trial was based on consideration of levels which may be indicative of cardiac injury (levels that exceed the 99th percentile of those values collected in a normal healthy population) and the characteristics of the assay used by the designated central laboratory where values of >0.35ng/mL are associated with coefficient of variation ≤10%.

5.3. Selection of Study Population

5.3.1. Inclusion Criteria

A subject was eligible for inclusion in this study only if all of the following criteria applied:

1. Subjects with T2DM as defined by the criteria of the American Diabetes Association and recognised by WHO, Expert Committee on the Diagnosis and Classification of Diabetes Mellitus [American Diabetes Association, 2004] at least three months preceding screening. Eligible subjects must have demonstrated endogenous insulin production as manifested by a fasting C-peptide level of ≥0.8ng/mL at screening.
2. Concurrent T2DM therapy:
   - Must have been diet and exercise treated, OR
   - Not taking more than 1 oral anti-diabetic agent, and willing to stop treatment at Screening (Visit 2)

   Previous diabetes monotherapy was limited to: sulphonylureas, glitinides, biguanides, or α-glucosidase inhibitors such as acarbose. A thiazolidinedione (TZD) was only acceptable if stopped 3 or more months prior to screening. Monotherapy with a fixed-dose combination drug was not allowed. Subjects must not have been taking any oral anti-diabetic (OAD) combination therapy (including with a fixed dose combination drug) for at least 3 months prior to the screen visit.
3. Glycaemic parameters:
   - HbA1c level at Pre-screening (Visit 1)
     - For subjects treated with monotherapy: ≥7.0% and ≤8.5%;
     - For subjects treated with diet and exercise only: ≥7.5% and ≤10.0%
   - Fasting glucose level at the Screening Visit (Visit 2):
     - For subjects treated with monotherapy: FPG ≥140mg/dL (7.8 mmol/L) and ≤240mg/dL (13.3mmol/L) (Note: Subjects must have discontinued any OAD combination therapy at least 3 months prior to screening)
     - For subjects treated with diet and exercise or no therapy: FPG ≥140mg/dL (7.8mmol/L) and ≤240mg/dL (13.3mmol/L)

- Fasting Capillary Blood Glucose (FCBG) was the first assessment performed in the clinic at Week 0 (Visit 5). If FCBG in the clinic was >240mg/dL (13.3mmol/L) (after repeated), a blood sample to assess FPG was drawn (no other Visit 5 assessments conducted at that time). The subject was re-dispensed their remaining run-in medication and sent home to await the FPG results. Randomisation and completion of all Visit 5 assessments was delayed until measurement was confirmed by central laboratory measurement of FPG. If FPG >240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject was not eligible to be randomised and was withdrawn from the study and referred for follow-up.

4. Men and women who were 18 to 75 years of age inclusive at the time of Screening (Visit 2).
5. Body Mass Index (BMI) ≥24 (kg/m2) and ≤40 (kg/m2).
6. If subject was a smoker, must have been able to abstain while in clinic at each visit.
7. If female, was eligible to enter and participate in this study:
    - If of non-childbearing potential (i.e., physiologically incapable of becoming pregnant (tubal ligation), including any female who was post-menopausal [>1 year without menstrual period]); or,
    - If of child-bearing potential, had a negative pregnancy test at Screening (Visit 2) (serum) and at Week 0 (Visit 5) (urine and serum) and:
    - Had a male partner who was sterile prior to the female subject's entry into the study and was the sole sexual partner for that female subject, or
    - Used double-barrier methods of contraception; condoms (with spermicide) and intrauterine devices (IUDs) were acceptable, or
    - Used hormonal contraceptives (oral, depots, patches etc) with double-barrier methods of contraception as outlined above, or
    - Abstained from sexual intercourse, or
    - Was with a same-sex partner and did not participate in bisexual activities where there was any risk of pregnancy.
8. Informed Consent: a signed and dated written consent obtained from the subject before any study related procedures were performed.

5.3.2. Exclusion Criteria

A subject was not eligible for inclusion in this study if any of the following criteria applied:

1. Metabolic disease including but not limited to:
    - Diagnosis of Type 1 diabetes mellitus
    - Uncorrected thyroid dysfunction. (NOTE: subjects with hypothyroidism on a stable dose of thyroid replacement therapy for at least 3 months prior to

Screening (Visit 2), and who had a screening thyroid stimulating hormone (TSH) within the limits of normal could have participated).

- Significant weight gain or loss (as defined as >5% of total body weight) within the past 3 months prior to Screening (Visit 2).

2. Previous use of insulin:
   - Within 3 months of screening;
   - For >2 weeks when used for acute illness in the last 12 months prior to Screening (Visit 2);
   - Used for more than 1 year when associated with gestational diabetes mellitus.
3. History of clinically significant cardiovascular disease including:
   - Documented myocardial infarction in the past year
   - Coronary revascularisation including percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) surgery in the previous year
   - Unstable angina
   - Clinically significant arrhythmia or valvular heart disease
   - Congestive heart failure (CHF) classified as New York Heart Association (NYHA) Class II, III or IV heart failure
   - Blood pressure >150/100mmHg or HR >100 beats/minute. Subjects using antihypertensives must have been on stable doses during the 3 months prior to Screening and during the trial
   - A QTc interval ≥440msec in males and ≥450msec in females at Screening (Visit 2)
   - Other clinically significant ECG abnormalities which, in the opinion of the Investigator, may have affected the interpretation of safety and/or efficacy data, or which otherwise contraindicated participation in a clinical trial with a new chemical entity.
4. Fasting serum triglycerides ≥400mg/dL (4.5mmol/L) at Screening (Visit 2). If a subject was receiving lipid-lowering therapy, then they must have been on the same dose of therapy for the past 3 months.
5. Was currently lactating, pregnant or actively trying to become pregnant.
6. Had a significant renal impairment as defined by serum creatinine >2mg/dL (>176μmol/L).
7. History of significant co-morbid diseases active within the previous 6 months (e.g., gastrointestinal disease, etc.).
8. History of pancreatitis.

9. Had a documented history of chronic or advanced hepato-biliary disease including a history of, or positive laboratory results for hepatitis at Screening (Visit 2), and/or clinically significant hepatic enzyme elevation including:
    - Any one of the following enzymes greater than 2.5 times the upper limit of the reference range (ULRR) value at Screening (Visit 2)
        - alanine transaminase (ALT)
        - aspartate transaminase (AST)
        - alkaline phosphatase (ALP)
        - had a total bilirubin level >1.5 times the ULRR at Screening (Visit 2).
10. Had a history of alcohol or substance abuse within the previous year, as determined by the Investigator or a positive urine drug screen (UDS) at Screening (Visit 2) or during treatment:
    - Unwilling to refrain from the use of excessive alcohol or illicit drugs and adhere to other protocol-stated restrictions while participating in the study.
    - History of alcohol abuse defined as an average weekly intake of greater than 21 units or an average daily intake of greater than 3 units (males) or defined as an average weekly intake of greater than 14 units or an average daily intake of greater than 2 units (females). One unit being equivalent to a half-pint of beer or 1 measure of spirits or 1 glass of wine.
    - The Investigator exercised their medical judgment to determine if a UDS was indicated.
11. Was currently taking prohibited concomitant medications.
12. Known allergy to any of the capsule excipients, or history of drug or other allergy, which, in the opinion of the responsible study physician, contradicted participation.
13. Received treatment with an investigational drug or participated in any other clinical trial during the previous 3 months.
14. Clinically significant anaemia (i.e., haemoglobin <12.0g/dL or <120.0g/L for males and <11.0g/dL or <110.0g/L for females) or any other abnormal haematological profile that was considered by the investigator to be clinically significant.
15. In the opinion of the Investigator had a risk of non-compliance with study procedures, or could not read, understand, or complete study-related materials, particularly the informed consent.
16. Had any concurrent condition or any clinically significant abnormality identified on the screening physical examination, laboratory tests, ECG, including pulmonary, neurological or inflammatory diseases, which, in the opinion of the Investigator, may have affected the interpretation of efficacy and safety data, or which otherwise contraindicated participation in a clinical trial with a new chemical entity.

5.3.3. Other Eligibility Criteria Considerations

To assess any potential impact on subject eligibility with regard to safety, the investigator was to refer to the available documents for detailed information regarding warnings, precautions, contraindications, AEs, and other significant data pertaining to the investigational products being used in this study. Such documents included, but were not limited to, the Clinical Investigator Brochure (CIB) or equivalent as provided by GSK.

5.3.4. Predetermined Criteria for Subject Withdrawal

5.3.4.1. Subject Withdrawal from the Investigational Product

Every effort was made to keep subjects in the study. However, a subject was discontinued prior to completion of the study for the following reasons:

- Subjects who had a FPG >270mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, or 18 were asked to return to the clinic as soon as possible for a retest. If the FPG remained >270mg/dL (15.0mmol/L) upon retest, the subject was withdrawn from the study. Subjects with a FPG >270mg/dL at Visit 12 were not allowed to enter the Extension Phase.
- Subjects who had cTnI values >0.35ng/mL were contacted as soon as possible for withdrawal from study and further evaluation including a follow-up 3 months after withdrawal.
- Introduction of any oral anti-diabetic medication other than study medication.
- ALT or AST levels ≥3x upper limit of reference range (ULRR) and a concurrent total bilirubin level ≥2.0x ULRR (predominantly direct), or an isolated ALT or AST ≥5x ULRR, all being confirmed on repeated testing after Baseline (Visit 3).
- AE which in the opinion of the investigator required withdrawal.
- Severe or repeated occurrences of hypoglycaemia which in the opinion of the investigator required withdrawal.
- Consent withdrawn.
- Lost to follow-up.
- Protocol violation.
- Termination of study by sponsor.
- Other: reason documented in eCRF.

5.3.4.2. Subject Withdrawal from the Study

Any subject who entered the study (i.e., gave written informed consent), but did not, for any reason, complete the study was considered as a withdrawal, irrespective of whether they had received any study medication.

5.4. Investigational Products

5.4.1. Description of Investigational Products

DEN capsules are white, opaque capsules with no identifying markings, containing white to off-white beads. Capsules were prepared to contain each dose of study medication (i.e., 2.5mg, 15mg, or placebo). The capsules were comprised of hypromellose and contained sugar spheres and hypromellose. All study medication was manufactured by GSK. The following batch numbers were used during this study and all had a 24 month shelf life from the date of manufacture:

Product	Batch	Manufacture Date
2.5mg denagliptin capsules	[redacted]	11-Oct-04 12-Oct-04 08-Mar-05
15mg denagliptin capsules	[redacted]	09-Mar-05 20-Oct-04 19-Oct-04 21-Oct-04 18-Oct-04
Placebo capsules	[redacted]	14-Apr-05 06-Oct-04

5.4.2. Dosages and Administration

5.4.2.1. Run-In

At Visit 3 (Week -4) subjects were provided with three bottles (Bottle A, Bottle B and Bottle C) of single-blind placebo and instructed to take one capsule daily from each bottle in the morning no more than 30 minutes prior to breakfast. On mornings when the subjects came to the clinic for a fasted visit (Visit 4 Week -2), they refrained from eating or drinking anything but water, and took the daily dose of study medication at the clinic when instructed by study personnel.

5.4.3. Treatment

At the baseline Visit 5 (Week 0), subjects were dispensed three bottles (Bottle A, Bottle B and Bottle C) of double-blind study medication and instructed to take one capsule daily from each bottle in the morning no more than 30 minutes prior to breakfast. On mornings when the subjects came to the clinic for a fasted visit they refrained from eating or drinking anything but water, and took the daily dose of study medication at the clinic when instructed by study personnel.

5.4.4. Dose Rationale

The dose range for this study was determined by examining the preliminary results of multiple dose studies that had been completed and were currently being analysed from healthy volunteers and subjects with T2DM. The planned doses of 2.5, 7.5, 15, 30 and 45mg targeted a range of DPP-IV inhibition profiles and exposures to DEN. The dose

range was designed to determine both minimally effective and maximum effective safe and tolerable doses. The lowest dose was anticipated to be below the therapeutic threshold. Based on glucose and other PD data from DPB10003 the therapeutic dose range was expected to be between 5mg and 30mg/day.

The highest proposed dose (45mg) was assessed in a 10 day repeat dose study in healthy subjects (DPB102875). This study was the first to evaluate the safety, tolerability and pharmacokinetics of multiple doses (10 days) of a 45mg dose of DEN. Twenty-nine healthy volunteers were enrolled; based upon review of blinded data, no events were expected to preclude inclusion of 45mg doses in larger Phase 2/3 trials.

The PK profiles in healthy subjects and subjects with type 2 diabetes appear similar. Thus, the DEN exposures from the current study were expected to be similar to those obtained previously in multiple dose studies in healthy subjects. In Study DPB10001 subjects received single oral doses of DEN ranging from 2.5mg to 50mg. Exposures increased greater-than-dose-proportionately across this dose range. A single dose of 50mg administered to fasted healthy subjects resulted in a geometric mean AUC (0-24h) and Cmax of 7422ng.h/mL and 653ng/mL, respectively. In study DPB10002 DEN was administered to healthy volunteers as single daily doses of 5mg, 15mg, or 30mg DEN for 13 days. At steady-state, geometric mean AUC (0-24h) and Cmax following a 30mg dose were approximately 5181ng.h/mL and 406ng/mL, respectively. In healthy subjects over 13 days of dosing DEN accumulated relative to Day 1. By day 13 AUC (0-24h) and Cmax had increased by ~30 and ~19%, respectively. In T2DM subjects minimal accumulation was observed (~11%) following 7 days of dosing.

The no adverse event limit (NOAEL) exposure limit was set by non-clinical toxicology findings in a 14-day mouse study. At the NOAEL dose in this study, AUC(0-24h) and Cmax were 13,381 ng.h/mL and 11,223 ng/mL, respectively. In addition, 6-month non-clinical toxicology studies had been completed in the rat and dog. The rat was the most sensitive of these two species with AUC(0-24) and Cmax of 25,502 ng.h/mL and 6,879 ng/mL.

Preliminary PK data at steady-state from study DPB102875 (45mg QD) were used to simulate the AUC(0-24h) and Cmax distributions in a large population (4000 subjects simulated). Simulations were performed based on mean exposures and variability observed in DPB102875 (log-normal distribution assumed). For AUC(0-24h), ~0.3% of subjects are predicted to exceed NOAEL limits in the 14-day mouse study. The maximum AUC(0-24h) observed in these simulations was 14,522ng.h/mL (~9% above the NOAEL AUC(0-24h)). No subjects were predicted to exceed the NOAEL Cmax limit following a 45mg dose. The maximum Cmax observed in these simulations was 1,548 ng/mL (~7.3 –fold below the NOAEL Cmax).

Predicted Steady-State Exposures and Cover Relative to NOAEL[1]				
AUC(0-τ) (ng.h/mL)				
Dose (mg)	Predicted Median AUC(0-τ)	Fold-Cover Relative to Median Predicted AUC(0-τ)	Predicted Maximum AUC(0-τ)	Fold-Cover Relative to Maximum predicted AUC(0-τ)
2.5	244	55	431	31
5	488	27	862	16
7.5	732	18	1,293	10
15	2,187	6	5,079	3
30	5,134	3	10,609	1.3
45[2]	8,379	2	14,522	0.9
Cmax (ng/mL)				
Dose (mg)	Predicted Median Cmax	Fold-Cover Relative to Median Predicted Cmax	Predicted Maximum Cmax	Fold-Cover Relative to Maximum Predicted Cmax
2.5	39	289	126	89
5	77	146	266	42
7.5	117	96	377	30
15	261	43	937	12
30	551	20	1,579	7.1
45	841	13	1,548	7.3

1. NOAEL AUC(0-τ) = 13,381 ng.h/mL; NOAEL Cmax = 11,223 ng/mL
2. Approximately 0.3% of subjects are predicted to exceed NOAEL AUC(0-τ) at the 45mg dose level

5.4.5. Blinding

Single-blind study medication was used during the run-in phase, during which the subject was blinded to study treatment but the investigator was not. Eligible subjects were then randomised four weeks later to double-blind study medication.

During the run-in period, subjects received 3 bottles, all containing placebo (which matched DEN capsules). At the baseline visit and all subsequent dispensing visits, subjects received 3 bottles of study medication, such that taking one capsule from each bottle daily provided the appropriate dose to the subject (i.e., placebo, 2.5mg, 7.5mg, 15mg, 30mg, or 45mg).

SAEs that were reported to GSK were unblinded by Global Clinical Safety and Pharmacovigilance (GCSP) staff at GSK for the individual subject. Additionally, if there was an expedited regulatory report to one or more regulatory agencies, the report would identify the subject's treatment assignment.

In the case of an emergency, the investigators had the ability to unblind a subject's treatment assignment by way of GSK's telephone-based, interactive voice response system (Registration and Medication Ordering System; RAMOS). However, this did not happen during this study.

When the Data Look was carried out for this study, dummy treatment codes were used to ensure the study team were blinded to the treatment codes.

The IDMC had access to unblinded study data. To ensure the study team remained blinded to the treatment codes, a SDAC external to the sponsor was responsible for

unblinding the data for the IDMC as described in the IDMC Charter. All IDMC meetings consisted of open and closed sessions; no unblinded study data were discussed during the open sessions when sponsor personnel were present.

5.4.6. Treatment Assignment

Subjects were assigned to study treatment in accordance with the randomisation schedule. The randomisation code was generated using the GSK randomisation system RandAll. Subjects were allocated to the 6 treatment groups in a 1:1:1:1:1:1 ratio. The randomisation was stratified based on gender and prior therapy (diet and exercise or monotherapy). A fixed block size of 6 was used. Central randomisation was used (i.e. blocks were applied globally from one central list).

At Visit 5, each subject was randomised by a telephone based, interactive voice response system (RAMOS). The investigator or designee used RAMOS to register the subject, randomise the subject and provide medication assignment information.

5.4.7. Assessment of Compliance

Subject compliance with study medication was assessed at Visits 5, 9, 11 and 12. Compliance was calculated based on the number of capsules dispensed and the number returned and the days between the date dispensed and the date returned. Calculated percentage compliance was entered into the electronic Case Report Form (eCRF). If the subject was calculated to be less than 80% compliant with study medication the subject was counseled by appropriate study personnel. If the subject remained less than 80% compliant for two consecutive visits the subject was discontinued and the early withdrawal procedures followed.

5.4.8. Treatment of Investigational Product Overdose

There is no specific antidote for an overdosage of DEN. In the event of an actual or suspected overdose individuals were to be referred to an appropriate facility and managed with supportive therapy as determined necessary by the treating physician. The GSK Medical Monitor was to be contacted immediately. Overdosage was to be recorded as an Adverse Event and the individual followed appropriately until full resolution. Adverse Events that occurred as a result of the overdose were to be recorded.

5.5. Prior and Concomitant Medications and Non-Drug Therapies

5.5.1. Permitted Medications

All concomitant medications taken during the study were recorded in the eCRF. The minimum requirement was that drug name and the dates of administration were recorded. Oral anti-hypertensives and statins were permitted concomitant medications, provided subjects were on the same drug, on a stable dose for 3 months prior to screening and throughout their participation in the study, unless a dose adjustment was medically necessary to manage the subject during the trial.

5.5.2. Prohibited Medications

Subjects were not to use any of the following medications during the course of the study; however, if they were taking them at the time of Screening, they were to discontinue them over a washout phase during the 4 week run-in period:

- Oral anti-diabetic agents: subjects who had received a TZD within the 3 months prior to Screening (Visit 2).
- Insulin (per exclusion criteria)
- Subjects on warfarin or digoxin were not allowed to participate in this study. Subjects were not to be washed off of these medications for the purposes of meeting eligibility criteria.
- Oral anticoagulants (other than aspirin and non-steroidal anti-inflammatory drugs).
- Oral or injectable corticosteroids (other than inhaled and intranasal).
- Monoamine oxidase inhibitors and tri-cyclic amines
- Antiretroviral drugs
- Prescription and over-the-counter weight loss drugs.

5.5.3. Non-drug Therapies

The Principal Investigator was to exercise their medical judgment to decide if non-prescription (over-the-counter; OTC) medications or preparations had the potential to affect the subjects' response with respect to the endpoints of, or their participation in, the study. If OTC compounds had such potential, then they were to be discontinued and recorded in the concomitant medication section of the eCRF.

5.6. Study Assessments and Procedures

5.6.1. Demographic and Baseline Assessments

Demographic data included date of birth, race, sex, height, reproductive status (for women), body weight, waist and hip circumference, and BMI. Baseline characteristics included a comprehensive physical examination, medical conditions and medical history including concomitant medications, alcohol and tobacco use.

A routine physical examination was performed by a qualified and licensed medical professional (i.e., physician, physician's assistant or certified nurse practitioner). A complete physical examination, including a thorough review of all body systems, was done at Visits 2, 5, 10, 12, and 18 (or early withdrawal).

5.6.2. Efficacy Assessment

5.6.2.1. Primary Efficacy Endpoints

- Change from baseline (Week 0) in HbA1c at Week 12.

5.6.2.2. Secondary Efficacy Endpoints

- Change from baseline (Week 0) in HbA1c at Weeks 4 and 8.
- Change from baseline (Week 0) in FPG at Weeks 1, 2, 3, 4, 6, 8 and 12
- Proportion of subjects who achieved various HbA1c (≤6.5%, <7% and ≤8%) and FPG (<126mg/dL [7.0mmol/L] and <140mg/dL [7.8mmol/L]) targets, and/or achieved a clinically meaningful decrease in HbA1c (≥0.7%) and FPG (≥30mg/dL [1.7mmol/L]).
- Change from baseline (Week 0) in fructosamine, fasting serum insulin, pro-insulin and pro-insulin:insulin ratio at Weeks 4, 8 and 12.
- Population PK parameters of DEN including clearance (CL) and volume of distribution (V) with assessment of demographic covariates influencing DEN PK. Dependent on the final compartmental model describing DEN disposition, additional PK parameters also may have been estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK.

5.6.2.3. Other Efficacy Endpoints

- Percent change from baseline (Week 0) in fasting lipids (triglycerides [TGs], free fatty acids [FFAs], total cholesterol [TC], LDL-c, HDL-c) and HOMA measures (insulin sensitivity [IS] and beta cell function [BCF]) based on log-transformed data at Weeks 4, 8, and 12.

5.6.2.4. Exploratory Endpoints

- Descriptive statistics of plasma DEN concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling.
- Correlation between the serial PK of DEN and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition.
- Descriptive statistics of population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point.
- Plasma and serum samples were stored to evaluate exploratory endpoints. Examples may include pharmacogenetics, lipomics and/or proteomics and DPP-IV Inhibition.

NOTE: PK and PD data are not summarised in this CSR, but will be presented in a separate CSR.

5.6.3. Safety Assessments

- Pregnancy test (in all females)
- TSH
- Standard panels for safety:
  - Haematology
  - Clinical chemistry
  - Urinalysis
  - Immunochemical faecal occult blood analysis for subjects experiencing reductions in haemoglobin of ≥2g/dL over the course of the study
- Incidence and severity of hypoglycaemic events
- ECG read centrally and locally at Visits 2, 5, 9, 12, 16 and 18
- Blood pressure and heart rate measurements
- Body weight, waist and hip circumference and BMI.

5.6.3.1. Adverse Events

AEs and SAEs were collected from the time a subject consented to participate in the study until he/she completed the study (including any follow-up period).

Definition of an AE: Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product.

The investigator made an assessment of intensity for each AE and SAE reported during the study. The assessment was based on the investigator's clinical judgment. The intensity of each AE and SAE recorded in the eCRF was assigned to one of the following categories:

Mild: An event that was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: An event that was sufficiently discomforting to interfere with normal everyday activities.

Severe: An event that prevented normal everyday activities.

The investigator was obligated to assess the relationship between investigational product and the occurrence of each AE/SAE. The investigator used clinical judgment to determine the relationship. Alternative causes, such as natural history of the underlying

diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to the investigational product were considered and investigated. The investigator also consulted the clinical investigator brochure (CIB) in the determination of his/her assessment.

Events of hypoglycaemia *per se* were not reported as an AE, but were reported as Serious Adverse Events if they fulfilled the definition (see Section 5.6.3.2).

Abnormal laboratory findings (e.g., clinical chemistry, haematology, and urinalysis) or other abnormal assessments that were judged by the investigator as clinically significant, but not associated with the disease being studied, were recorded as AEs or SAEs if they met the appropriate definition.

5.6.3.2. Serious Adverse Events

A SAE was any untoward medical occurrence that, at any dose, resulted in death, was life-threatening, required hospitalisation or prolongation of existing hospitalisation, resulted in disability/incapacity, or was a congenital anomaly/birth defect.

From the time a subject consented to participate in the study until he or she completed the study (including any follow-up period), all SAEs assessed as related to study participation (e.g., protocol-mandated procedures, invasive tests, or change in existing therapy) or related to a GSK concomitant medication, were reported. SAEs were reported to GSK by way of the SAE page in the eCRF within the timeframes stated in the protocol.

There may be minor discrepancies in the details of the SAEs included in the clinical narratives compared with the safety tabulations. This is because the data come from two different databases and have been collected at different points in time. However, it is considered that these differences, if any, are minor in nature and do not change the overall clinical significance or understanding of the SAE.

5.6.3.3. Hypoglycaemia

Subjects recorded symptoms of hypoglycaemia on a Hypoglycaemic Symptoms Log at each visit and, wherever possible, produced a corresponding fingerstick glucose reading for each event. Subjects also recorded routine recording of glucometer readings on a Glucose Log as directed by the Investigator.

Using the Hypoglycaemic Symptoms Log, the investigator was responsible for assessment and documentation of events/symptoms that were diagnostic or indicative of hypoglycaemia. These data included recording whether there were symptoms, associated blood glucose values if available, interventions, whether there was external assistance and additional assessment of the events similar to those recorded for AEs. Information recorded by the subject, but judged by the Investigator not to be hypoglycaemia, were noted in the ‘site comments’ section of the log and recorded as an AE where appropriate.

5.6.3.4. Pregnancies

Serum pregnancy testing was conducted at the screening visit (Visit 2), randomisation visit (Visit 5), week 4 (Visit 9), week 8 (Visit 11) and Week 12 (Visit 12) or early withdrawal visit for women of childbearing potential.

If at anytime a subject became pregnant while enrolled in the study, she was to immediately stop taking the study medication and discontinue from the study. The subject was to be followed to determine the outcome of the pregnancy. Generally, follow-up was to be no longer than 6 to 8 weeks following the estimated delivery date. Any premature termination of the pregnancy was to be reported.

While pregnancy itself was not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons was to be recorded as an AE or SAE.

A spontaneous abortion is always considered to be a SAE and was to be reported as such. Furthermore, any SAE occurring as a result of a post-study pregnancy and was considered reasonably related to the investigational product by the investigator, was to be reported to GSK.

5.6.3.5. Clinical Laboratory Evaluations

The following laboratory tests were performed at the times specified in the Schedule of Assessments Table (Section 5.1, Table 1).

HAEMATOLOGY	SERUM CHEMISTRY	URINALYSIS
RBC count Haemoglobin Haematocrit Platelet Count Total White Cell Count At Screening only: Differential: Neutrophils Lymphocytes Monocytes Eosinophils Basophils RBC morphology	Sodium Potassium Chloride Bicarbonate LDH (>2x ULRR collect LDH isoenzymes) Total Protein Albumin Blood Urea Nitrogen Creatinine Total and direct bilirubin Alkaline Phosphatase Aspartate transaminase (AST) Alanine transaminase (ALT) Calcium Phosphorus (inorganic) Uric Acid	Glucose Bilirubin Protein Ketones RBCs/HPF and WBCs/HPF STOOL SAMPLE Fecal occult blood assessment on 3 consecutive stools only for subjects with reduction in haemoglobin ≥2g/dL over the course of the study
GLYCAEMIA FACTORS HbA_{1c} Glucose Fructosamine (total and corrected for plasma proteins) Insulin Pro-insulin C-peptide	THYROID STATUS TSH (at Screening only) POPULATION CARDIAC BIOMARKERS Creatine kinase MB (CK-MB) Troponin I (cTnI)	PREGNANCY TEST β-HCG (serum and urine)

A central laboratory (QUEST Diagnostics) was used for the analysis of all routine laboratory assessments and where appropriate, QUEST outsourced the analysis of certain parameters (see Section 2). Details concerning preparation and shipment of samples were provided by QUEST to the investigator before the beginning of the study.

The reference range and values of potential clinical concern (F1 and F3 flags) for haematology and biochemistry laboratory results are shown in Table 2.

Table 2 Laboratory Values Considered by the Sponsor to be of Potential Clinical Concern

Laboratory Parameter	SI Units	Reference Range (F1)	Values of Potential Clinical Concern (F3)
Haematology			
Haemoglobin			
male (18-64, ≥65 years)	g/L	138-172, 118-168	>20 below LLRR[1] or >10 above ULRR[1]
female (18-64, ≥65 years)	g/L	120-156, 111-155	>20 below LLRR[1] or >10 above ULRR[1]
Haematocrit			
male (18-64, ≥65 years)	ratio	0.410-0.500, 0.360-0.490	>0.05 below LLRR[1] or >0.04 above ULRR[1]
female (18-64, ≥65 years)	ratio	0.350-0.460, 0.330-0.460	>0.05 below LLRR[1] or >0.04 above ULRR[1]
White Blood Cell Count	10^9/L	3.8-10.8	>1 below LLRR[1] or >5 above ULRR[1]
Total Neutrophils	10^9/L	1.8-8.0	<0.5 x LLRR[1]
Lymphocytes	10^9/L	0.85-4.1	<0.5 x LLRR[1]
Platelets	10^9/L	130-400	<80 or >500
Biochemistry			
Total Bilirubin	µmol/L	0-22	>1.5 x ULRR[1]
Total Protein			
13-64 years, ≥65 years	g/L	60-85, 58-81	<45 or >100, <33 or >96
Albumin	g/L	32-50	<28 or >55
AST (SGOT)			
13-64 years, ≥65 years	U/L	0-42, 0-55	>3 x ULRR[1]
ALT (SGPT)	U/L	0-48	>3 x ULRR[1]
GGT			
male (13-64, ≥65 years)	U/L	0-65, 0-75	>3 x ULRR[1]
female (13-64, ≥65 years)	U/L	0-45, 0-75	>3 x ULRR[1]
Alkaline Phosphatase	U/L	20-125	>3 x ULRR[1]
male (16-19, ≥20 years)	U/L	30-225, 20-125	>3 x ULRR[1]
female (16-19, ≥20 years)	U/L	30-165, 20-125	>3 x ULRR[1]
Creatinine	µmol/L	44-124	>159
Blood Urea Nitrogen			
13-64 years, ≥65 years	mmol/L	2.5-9, 2.5-10.5	>2 x ULRR[1]
Uric Acid			
male	µmol/L	240-510	>654
female	µmol/L	150-450	>654
Sodium	mmol/L	135-146	<130 or >151
Potassium	mmol/L	3.5-5.3	<3.0 or >6.3
Bicarbonate	mmol/L	20-32	<16 or >40
Calcium	mmol/L	2.12-2.56	<1.8 or >3.0
Phosphorus			
13-64, ≥65 years	mmol/L	0.8-1.45, 0.7-1.4	>0.323 below or above RR[1]
Other Tests			
Glucose	mmol/L	3.9–6.1	<3 or >22
Triglycerides	mmol/L	0.00 – 2.24	>9.04

1. RR = reference range; LLRR = lower limit of the reference range; ULRR = upper limit of the reference range.

5.6.3.6. Physical Examination and Vital Signs

A physical examination was conducted at Visits 2, 5, 10 and 12. Vital signs, including systolic and diastolic blood pressure, heart rate and body weight were measured at each clinic visit (except Visit 1). The subject's height (without shoes) was measured at Visits 2 and 5 only. Waist and hip circumference was measured at Visits 2, 5 and 12.

The vital signs values considered by the sponsor to represent baseline shift flagging (F2 flag) or to be values of potential clinical concern (F3 flag) are shown in Table 3.

Table 3 Vital Signs Values Considered by the Sponsor to Represent Baseline Shift Flagging or to be of Potential Clinical Concern

Parameter	Units	Baseline Shift Flag (F2)	Potential Clinical Concern Value (F3)
Systolic blood pressure (SBP	mmHg	increase or decrease >30 in same posture	>170 or <100
Diastolic blood pressure (DBP)	mmHg	increase or decrease >20 in same posture	>110 or <50
Heart rate (HR)	bpm	increase or decrease >30	>120 or <50

5.6.3.7. Electrocardiograms

A standard 12-lead ECG was recorded at Visits 2, 5, 9 and 12 and was read locally and centrally. Any clinically significant ECG abnormalities were documented in the ECG sections in the eCRF.

The ECG values considered by the sponsor to represent baseline shift flagging (F2 flag) or to be values of potential clinical concern (F3 flag) are shown in Table 4.

Table 4 ECG Values Considered by the Sponsor to Represent Baseline Shift Flagging or to be of Potential Clinical Concern

Parameter	Units	Change from Baseline of Potential Clinical Concern (F2)	Potential Clinical Concern Value (F3)
PR interval	msec	Increase of > 25% when baseline PR >200 msec Increase of > 50% when baseline PR ≤200 msec	>300 msec
QRS interval	msec	Increase of > 25% when baseline QRS >100 msec Increase of > 50% when baseline QRS ≤100 msec	>200 msec
QTc interval	msec	Increase of > 10% when baseline QTc >440 msec Increase of > 20% when baseline QTc ≤440 msec	>500 msec
Ventricular rate	bpm		Supine: < 50 or > 120

5.6.3.8. Biomarker Assessments

Blood samples were taken for the exploratory population cardiac biomarkers CK-MB and cTnI at Visits 2, 5, 9 and 12. Additional samples were stored for exploratory analyses of biomarkers. Any analyses will be dependent on what biomarkers are assayed. The decision to evaluate additional biomarkers will be done after the study.

5.7. Data Quality Assurance

The study was conducted according to GCP. To ensure that study procedures across all investigator sites were consistently followed, protocol, eCRF, and safety reporting were reviewed with the investigator and his/her personnel responsible for the conduct of the study by GSK representatives at the investigator sites.

Adherence to protocol requirements, verification of data generation completeness and accuracy were achieved through monitoring visits to each investigator site. Subsequent data handling and reporting processes were subject to in-process Quality Control. All the above procedures were performed according to methodologies detailed in GSK Standard Operating Procedures (SOPs).

This study used Phase Forward's InForm system. InForm is a web-based clinical trials data management system that provides investigational sites a standardised and validated, remote, electronic data capture system for the collection of clinical trial data. Activities performed using InForm include data entry, modification, review and validation. Each activity performed carries a unique user identification code and a date-time stamp.

InForm training for this multi-centre global study was provided to site staff at the Investigator meeting by PharmaLink. Study-specific eCRF training for the monitors was provided via teleconference, and Lotus Notes Sametime Connect™ web meeting software and in some cases in person by GSK Data Management. Additionally, an InForm interactive training database was available to site staff and study monitors for independent follow-up training.

The application was fully validated using test data, prior to distributing the url for site use.

Encrypted clinical trial data were transmitted from the site via the internet to a firewall protected network server, and then via an application server into the clinical database (e.g., InForm puts data into a shared drive).

An electronic audit trail of all changes made to the eCRF was kept within the InForm system. This audit trail identified the user making the change by userID, and date and time of change.

Pre-defined data validation checks were run within the eCRF as the data were entered and submitted by authorised site staff. The resulting data queries were then resolved. Additional queries were generated within the eCRF by authorised GSK staff as a result of data review (e.g., source document review, external data reconciliation).

In addition to InForm eCRF data, electronic laboratory data and ECG data were delivered to GSK by external vendors. These data were reconciled with the eCRF data and resulting discrepancies were queried within the eCRF.

Additional quality control (QC) was carried out by extracting SAS datasets, and comparing printed copies against the eCRF for at least 1 patient per pathway on the study (e.g. 1 Completer, 1 Withdrawal and 1 Screen Fail). This reconciliation was performed

towards the end of main phase and again towards the end of extension phase. The subjects were chosen randomly on both occasions from lists of Completed, Withdrawn and Screen Failed patients.

AEs and concomitant medications were coded by the autoencoder using company standard dictionaries (GSK Drug) and industry standard dictionaries (MedDRA).

SAEs were reported for this study. SAE data were documented according to standard GSK practice in the GSK standard InForm eCRF. Upon submission of the SAE entry, a system-generated e-mail was sent to the GSK Global Clinical Safety and Pharmacovigilance (GCSP) department to facilitate rapid reporting as outlined in the study protocol.

The principal investigator electronically signed and dated each InForm casebook attesting to his/her responsibility for the quality of all data included therein, and that the data represented a complete and accurate record of each subject's participation in the study. At the end of the study once all data queries were resolved, a CD-ROM containing eCRF PDFs (the PDF contains all of the patient's eCRF data, the data queries, and a copy of the audit trail) was sent to site along with a letter explaining how to view the data on the PDF. Upon delivery of the CD-ROM, the study site notified GSK of receipt of the CD.

After data management procedures were completed the database was released on 22 Aug 2006. Following release the database was frozen on 29 Aug 2006.

The original validated data (eCRFs, etc.) will be archived according to company standard procedures.

There were no investigator site audits conducted by GSK's department of Worldwide Regulatory Compliance - GCP group.

5.8. Data Analysis Methods

5.8.1. Timings of Planned Analyses

5.8.1.1. Interim Analyses and Data Monitoring

No interim analysis was planned for this study.

An external independent Statistician produced the summaries required for the IDMC. Details of the procedures and summaries to be produced were specified in the IDMC Charter and the IDMC RAP for this protocol.

A Data Look prior to database freeze was performed using dummy treatment codes from RandAll to maintain the treatment blind.

5.8.2. Changes in the Conduct of the Study or Planned Analyses

All changes in the conduct of the study were as detailed in Protocol Amendment 1 and 2 (see Section 5.2).

Changes in the planned analyses were as follows:

- Reproductive status is no longer collected on the eCRF and therefore was not summarised as part of subject demographics.
- Indirect bilirubin was calculated in-house and summarised in the appropriate laboratory tables.
- The HOMA parameters of insulin resistance (IR), beta-cell function (BCF) and insulin sensitivity (IS) were summarised and or/listed.
- The HbA1c target of ≤8% was not formally analysed at Week 12 as this historical target is no longer deemed necessary; HbA1c targets of ≤6.5% and <7% were still analysed at Week 12.
- Fructosamine was stated in the protocol as fructosamine (total and corrected for protein). It was no longer possible to measure fructosamine corrected for protein so only one fructosamine variable was reported for this study.
- The variable blood urea nitrogen (BUN) was replaced by the variable serum urea. BUN is the American terminology for serum urea. In order to follow the GSK principle of using British English to standardise spelling and terminology, it was agreed that BUN should not be used since it is synonymous with serum urea.
- References to drug naïve have been changed to diet and exercise as it is believed this is a better reflection of the population referred to as drug naïve (a subject is considered as diet and exercise [drug naïve] if they have not taken any anti-diabetic medication within the three months prior to the pre-screen visit date).
- The central laboratory for this study, QUEST, used different assays to measure insulin in Europe (Immulite method) and in the US (Linco method). On comparison of the insulin results from the two assays by GSK, the results appeared similar with no statistically significant differences between them. However, for completeness, analyses of both insulin analyses by region (assay method) for insulin and pro-insulin:insulin ratio, and summaries by region for the HOMA variables of IS and BCF, were presented.
- The definition of the Safety Population used in the final analysis was more inclusive than that stated in the protocol to allow inclusion of subjects who received study medication during the run-in period in error:
    - **Protocol defined Safety Population:** all randomised subjects who received at least one dose of study medication.
    - **RAP defined Safety Population:** all subjects who received at least one dose of study medication. Any subjects erroneously taking double-blind study medication during the run-in period were included in this population.

The following definitions of protocol violators were removed; this decision was made and documented at the Main-Phase Populations Review Meeting.

- Subject randomised into the incorrect strata (gender and prior therapy) and subjects randomised to the diet and exercise (drug naïve) strata, who from reviewing their prior anti-diabetic medications have taken prior medications for any length of time in the three months prior to their pre-screen visit date, and are therefore more representative of a subject randomised to the monotherapy strata (these will be reviewed on a case-by-case basis).
- Subjects who violate the FPG inclusion criteria as follows will be reviewed on a case-by-case basis to determine whether the subject is a protocol violator:
- FPG at Screening (Visit 2) <7.8mmol/L.
- FPG at Baseline >13.3mmol/L.

5.8.3. Sample Size Considerations

The sample size of 58 evaluable subjects per treatment group (61 allowing for 5% unevaluable for primary endpoint assessment) was based on a last observation carried forward (LOCF) analysis of the difference between DEN and placebo with regards to change from baseline in HbA1c at Week 12. It was calculated to achieve a precision in estimating the treatment effect of 0.8% for the 95% CI, assuming a standard deviation (SD) of 1.1%. The calculated sample size provided 93% power to detect a clinically relevant treatment difference of 0.7%. All statistical tests were performed using two-sided tests of significance. The significance level for each individual hypothesis was 5% and the overall significance level was also 5%. No adjustment for the significance level was needed because the stepwise test was closed.

5.8.3.1. Sample Size Sensitivity

The effects of changes in the assumed SD on the precision in estimating the treatment effect (measured by the width of the 95% CI), the treatment difference that could be detected with 90% power and the power to detect a clinically relevant difference of 0.7%, based on a sample size of 58 per treatment arm, are all summarised in Table 5.

Table 5 The Effects of Changes in the Assumption of Standard Deviation

Standard deviation (%)	Precision in estimating treatment effect (width of 95% CI) (%)	Treatment difference that can be detected with 90% power (%)	Power to detect clinically relevant difference of 0.7% with 58 subjects per arm (%)
0.9	0.66	0.54	99
1.0	0.73	0.60	96
1.1	0.80	0.66	93
1.2	0.87	0.72	88
1.3	0.95	0.78	83
1.4	1.02	0.84	77

5.8.4. Analysis Populations

The following populations were assessed:

Safety Population. This population consisted of all subjects who received at least one dose of study medication and was used for assessing safety. Any subjects erroneously taking double-blind study medication during the run-in period were included in this population.

Intent-to-Treat Population (ITT). This population consisted of all randomised subjects who received at least one dose of randomised study medication, had a baseline assessment and had at least one corresponding on-therapy (scheduled or unscheduled) efficacy assessment. This was the primary population for assessing efficacy.

Per Protocol Population (PP). This population consisted of any ITT subjects who were compliant with protocol-specific criteria. Subjects with specified protocol deviations and non-completers of the Main Phase were excluded from the PP Population. Completers for this purpose were subjects who had a HbA1c value at the Week 12 visit. The PP Population was used for a supporting analysis of the primary endpoint comparison only.

5.8.5. Treatment Comparisons

The primary objective of the study was assessed through tests of hypotheses. The primary endpoint was the change from baseline to Week 12 in HbA1c which was compared between each DEN group and placebo.

The primary analysis was performed on the ITT Population with LOCF.

To address the issue of multiplicity, inferences from the study were based on a closed testing procedure [Marcus, 1976]. The highest dose, DEN 45mg, was assessed first, in comparison to placebo. This was tested at 5% significance level. If the comparison was significant, then the comparison of the DEN 30mg dose to placebo was also interpreted at 5% level. This process continued, going down through all the doses, until the first non-significant test was reached. With this approach, no adjustment to the significance level at each step was needed.

The primary comparison was also performed using the ITT Population where missing values were not imputed and a further comparison where repeated measures analyses were used.

5.8.6. General Considerations for Data Analyses

5.8.6.1. Multicentre Studies

This study was conducted in 94 centres across North America and Europe.

For the US, geographical region was first classified as follows (based on the US Census Bureau):

- Northeast: [redacted]
- Midwest: [redacted]
- South: [redacted]
- West: [redacted]

For the purposes of analysis, region was classified as:

- US/Canada: Northeast, Midwest, South and West US, and Canada.
- Eastern Europe: Latvia, Romania, Czech Republic and Greece.
- Western Europe: Finland, Germany and Sweden.

Geographical region was included as a factor for the primary analysis model, that is, analysis of the primary efficacy endpoint (and secondary endpoints where specified) were adjusted for region.

For the primary efficacy endpoint only, treatment-by-region interaction was assessed using a 10% significance level. In the presence of a significant treatment-by-region interaction, the method of Gail and Simon [Gail, 1985] was used to test for qualitative interaction using a 10% significance level.

5.8.6.2. Other Strata and Covariates

The effects of baseline measurement and the stratification variables, gender and prior therapy, were controlled for in all efficacy measures that were analysed using analysis of covariance [Fleiss, 1986]. Gender and prior therapy were taken as recorded in the eCRF (i.e. actual gender and prior therapy). The stratification variables as recorded in RAMOS were not used (in the event that subjects were randomised into the incorrect strata).

5.8.6.3. Examination of Subgroups

Subgroup summaries were produced for the primary endpoint by the following:

- Previous treatment (diet and exercise, monotherapy)
- Gender
- Baseline HbA1c (<7.5%, 7.5-8.5% and >8.5%)
- Baseline BMI (<27kg/m^2, 27–30kg/m^2 and >30kg/m^2)
- Region.

Subgroup summaries were only produced if there were at least 15 subjects per group.

In addition, a supplementary summary table by detailed region was also included. Detailed region was defined as follows: Sweden/Finland, Czech Republic/Latvia, Romania/Greece, Germany, Canada, US Northeast/Midwest/West Region and US South Region.

5.8.6.4. Multiple Comparison/Multiplicity

To address the issue of multiplicity, inferences from the study were based on a closed testing procedure.

5.8.7. Data Handling Conventions

5.8.7.1. Treatment Allocation

[redacted] After database freeze, the treatments within the incorrectly administered containers were supplied by Clinical Trial Supplies (see following table). Two subjects had received a total dose of 20mg DEN from the 3 containers; this dose had not been studied. [redacted] Although they were randomised to the 45mg group they took a total dose of 32.5mg. It was agreed by the study team that this subject would be allocated to the 30mg treatment group for Safety and the (randomised) 45mg treatment group for Efficacy, as per the Intent-to-Treat principle.

[redacted]

5.8.7.2. Premature Discontinuation and Missing Data

Analysis of the ITT Population was performed using the LOCF approach. For subjects who withdrew from the study, the last valid observation recorded on-treatment (scheduled or unscheduled) was carried forward to all remaining Main Phase visits. Also, for subjects who had missing observations prior to the last Main Phase treatment visit, the closest previous non-missing on-treatment observation was carried forward to missing visits. If a subject had missing observation(s) immediately after baseline, the baseline observation was not carried forward and the visit(s) was left as missing.

For the primary efficacy endpoint, two additional sensitivity analyses were performed. In the first approach, values were not imputed for post-baseline assessments which were missing. In the second approach, a repeated measures analysis was performed; this approach was a model based method over time.

5.8.7.3. Derived and Transformed Data

Baseline

Baseline was defined as the period immediately preceding treatment with double-blind study medication. Change from baseline was computed as (visit value – baseline value). All Baseline assessments that were made on treatment were re-assigned to the first on-treatment visit.

For efficacy parameters:

- The data to be used for the Baseline value was the last scheduled or unscheduled value recorded for that parameter that was taken between 7 days prior to Main Phase treatment start date and Main Phase treatment start date.

For safety parameters:

- The data to be used for the Baseline value were the last scheduled or unscheduled values recorded for that parameter that was taken between Screening (Week -5) and the Main Phase treatment start date.
- If subjects erroneously received double-blind study medication during the run-in period, their baseline assessment was taken as the last time point prior to receiving double-blind medication (expected to be the Screening visit).

Age

Age was calculated from the Baseline visit. Age in years was calculated by taking the number of years between the Baseline visit date and the subject's date of birth. An

adjustment was made if the months were the same, as age is not increased until the birthday has occurred.

BMI

The BMI for each subject was defined as weight (kg) divided by the height (m) squared (height measured at baseline).

Waist: Hip Ratio

The waist: hip ratio was defined as the waist circumference (cm) divided by the hip circumference (cm).

Duration of Diabetes

Duration of diabetes was calculated from the Baseline visit.

Indirect Bilirubin

Indirect bilirubin was calculated as total bilirubin minus direct bilirubin.

HOMA (Homeostasis Model Assessment) Measures

HOMA2 is a computer-generated model consisting of non-linear empirical equations solved numerically to predict glucose, insulin and c-peptide concentrations in the fasting state for any combination of beta-cell function (BCF) and insulin sensitivity (IS) [Matthews, 2004]. This software was employed to yield an estimate of IS and BCF from fasting plasma insulin and FPG levels using the HOMA model (C-peptide was not employed in this model as this endpoint was only collected at Screening).

Insulin resistance is the inverse of insulin sensitivity (1/IS).

As HOMA is a steady state model, only clinically realistic values that would be seen in a fasting subject should be used. These are:

- Plasma glucose 3.5 to 25.0mmol/L (63-450mg/dL; note subjects were withdrawn from this study if their FPG measurement was >270mg/dL)
- Plasma insulin 20 to 400pmol/L

Any values out of these ranges were omitted from the HOMA model.

Exposure

Each subject's exposure in days to study medication was calculated as follows:

- (double-blind study medication stop date – double blind study medication start date) + 1.

Total exposure in subject years was calculated for each treatment group by totalling all subjects' exposure within that treatment group and then dividing by 365.25.

5.8.7.4. Assessment Windows

For classifying AEs and hypoglycaemic events the following periods of the Main Phase were defined:

Pre-Therapy: The onset date was before the start date of double-blind Main Phase study medication. If the onset date was on the start date of double-blind Main Phase medication, then the event was considered as on therapy, as this is the conservative approach.

For subjects who did not withdraw during the Main Phase

On-Therapy: start date ≤ onset date.

For subjects who withdrew during the Main Phase

On-Therapy: start date ≤ onset date.

Post-Therapy: onset date ≥ Main Phase treatment stop date + 3 days.

Any event occurring on or after the start date of Extension Phase medication was reported in the Extension Phase. If for some reason a subject did not take their first dose of Extension Phase study medication in clinic at their Week 12 visit (i.e. there is a gap in treatment between the Main and the Extension Phases), then any AE or hypoglycaemic event occurring between the date of last dose of Main Phase medication and before the first dose of Extension Phase medication was reviewed on an case-by-case basis prior to unblinding the Main Phase treatment codes (to ensure these data were assigned to Main Phase).

5.8.7.5. Values of Clinical Concern

Reference (normal) ranges for laboratory parameters collected throughout the study were provided by the central laboratory. In addition to the reference ranges, threshold criteria of change from baseline or values of laboratory variables considered to be of potential clinical concern were defined by the sponsor. The laboratory measurements were summarised and flagged using the following flagging system, denoted by the terms F1, F2 and F3.

- F1 Reference range flagging: denotes all laboratory values above or below the reference range.
- F2 Change from baseline of potential clinical concern flagging: denotes laboratory values that have increased or decreased from baseline by more than a sponsor-defined level.
- F3 Potential clinical concern flagging: denotes a laboratory value considered by the sponsor to be a potential clinical concern.

The limits and ranges associated with the F1 and F3 flags for laboratory results, standardised for all studies in the clinical programme, are shown in Table 2.

The vital signs and ECG values considered by the sponsor to represent a baseline shift (F2 Flag) or to be of potential clinical concern (F3 flag), standardised for all studies in the clinical programme, are shown in Table 3 and Table 4, respectively.

5.8.8. Study Population

5.8.8.1. Disposition of Subjects

The number of subjects who entered the run-in phase, the number of subjects who were randomised into the study, the number of subjects within each population (Safety, ITT and PP), and the number of subjects who completed the Main Phase of the study were summarised for each treatment group and overall. The number of subjects in the above populations within each stratum (gender and prior therapy) were summarised by treatment group.

The number of subjects in each centre who were included in the Safety Population, the ITT Population and who completed the study were summarised for each treatment group and overall.

Reasons for discontinuation pre-therapy (during screening or run-in) were summarised. Reasons for discontinuation on-therapy were summarised for each treatment group and overall. A by-subject listing of data on subject reasons for discontinuation for both pre- and on-therapy was produced.

5.8.8.2. Protocol Deviations

Inclusion – Exclusion Criteria

The number and percentage of subjects who were randomised into the study, but deviated from the inclusion or exclusion criteria, were summarised for each treatment group and overall. A by-subject listing was also produced.

Per Protocol Population

The following criteria defined major protocol deviations, which led to the exclusion of a subject from the PP Population:

- Prohibited concomitant medications:
  - Oral anti-diabetic agents.
  - Insulin (per exclusion criteria).
  - Subjects on warfarin or digoxin.
  - Oral anticoagulants (other than aspirin and non-steroidal anti-inflammatory drugs).
  - Oral or injectable corticosteroids (other than inhaled and intranasal).
  - Monoamine oxidase inhibitors and tri-cyclic amines.

  - Antiretroviral drugs.
  - Prescription and OTC weight loss drugs.
- Non-compliance with study medication.
- Treatment was not taken according to randomisation.
- Subject took double-blind study medication during the Run-In Phase
- Subjects in the monotherapy strata who had a washout period (number of days between Screening Visit (Visit 2, Week -5) and Baseline Visit (Visit 5, Week 0) that was less than 28 days.
- Subjects treated by Investigator [redacted] (Centre [redacted] Due to a systematic violation of the planned visit schedule resulting in completion of the study in approximately 12 weeks rather than 24 weeks and potentially starting Extension Phase study medication during the Main Phase.
- Subjects who violated the HbA1c inclusion criteria as follows were reviewed on a case-by-case basis to determine whether the subject was a protocol violator:
  - HbA1c at Pre-Screen (Visit 1): Diet and Exercise Subjects <7.5% or >10%; Monotherapy subjects: <7% or >8.5%.

Any unforeseen circumstance occurring during the Main Phase study period was reviewed on an individual basis (prior to unblinding the Main Phase) to determine whether it constituted a protocol deviation.

A summary of major protocol deviations leading to exclusion from the PP Population was provided. Subjects who did not complete the Main Phase of the study were also excluded from the PP Population, but these subjects were not included in the above table as they were not protocol violators *per se*. A by-subject listing of these data was produced.

A listing of concomitant medications was produced and a clinical review highlighted all prohibited medications and the timings relative to study medication when their use was prohibited. This process was completed prior to unblinding the Main Phase treatment codes.

5.8.8.3. Demographic and Baseline Characteristics

Demography and Baseline Data

Demographic data included age, ethnicity, sex, height, body weight and waist and hip circumference. BMI and waist: hip ratio was calculated in-house (see Section 5.8.7.3). Furthermore, BMI and age were also categorised as: BMI (<27kg/m^2, 27 – 30 kg/m^2, >30kg/m^2) and age (<65, ≥65 years). These demographic data were summarised by treatment group and overall.

BMI and duration of diabetes were summarised by strata (gender and prior therapy). Summaries on race categories were also generated.

Summaries of disease history (prior therapy and duration of diabetes) and substance use (alcohol and tobacco) were generated.

Medical History

The number and percentage of subjects with each past and current condition were reported for each treatment group and overall. Past conditions are those reported as 'past' and current conditions are those reported as 'current' at screening. Past and current conditions were reported separately. A by-subject listing of data of past and current medical conditions was produced.

Concomitant Medications

The GSK drug dictionary was used to code drug names. The number and percentage of subjects receiving prior anti-diabetic medications, prior medications and concomitant medications were summarised separately by treatment group and overall. A summary of prior sulphonylurea (SU) and prior metformin medications was also produced. Prior medications are those started before randomisation, concomitant medications are those taken at any time after randomisation (i.e. on or after the first date of study medication dosing) and up to (but not including) the start date of Extension Phase study medication (including those started prior to randomisation which were continued during the Main Phase study period).

5.8.8.4. Treatment Compliance

The number and percentage of subjects in the following categories for overall compliance were presented for each treatment group and overall by visit: 0%, >0% to <80%, 80% to 120%, >120% compliant; the reason for non-compliance was also summarised. A summary of overall compliance was also generated.

Compliance (for double-blind treatment) was measured at Weeks 4, 8 and 12 (and early withdrawal visit, if applicable). Overall study (Main Phase) non-compliance was defined as not being compliant for two or more out of the three compliance visits.

5.8.9. Efficacy Analyses

Analysis of covariance (ANCOVA) was the statistical method used to assess changes from baseline for the endpoints in this study. One of the assumptions underlying this method is that the response variable is normally distributed. The distributions of the efficacy endpoints in this study were examined along with the influence of any extreme outlying observations. In the event of any extreme outliers, a sensitivity analysis was provided.

5.8.9.1. Primary Efficacy Measures

The primary objective of comparing the change in HbA1c from baseline at Week 12 between each of the five treatment groups and the placebo group was performed using a (5% two-sided) hypothesis test. This test was based on an analysis of covariance model

with terms for gender, prior therapy (diet and exercise/monotherapy), treatment, region and baseline measurement (continuous covariate). The point estimates and corresponding 95% CI for treatment differences from placebo were calculated. To address the issue of multiplicity, a closed testing procedure was used. With this approach, CIs for treatment differences below the last statistically significant treatment difference (i.e. treatment comparisons for doses below the last significant dose) were identified as 'for descriptive purposes only'.

The treatment-by-baseline, treatment-by-region, treatment-by-prior-therapy and treatment-by-gender interactions were investigated at a significance level of 10% but interactions were not included in the main model where treatment effects were tested and compared. If the treatment-by-baseline interaction was statistically significant, each active dose to placebo slope coefficient was examined to see if they were all in a common direction. If the treatment-by-region, treatment-by-prior-therapy or treatment-by-gender interactions were statistically significant, the likelihood ratio test for qualitative significance proposed by Gail and Simon [Gail, 1985] was performed. The Shapiro-Wilk test for normality of the efficacy variables performed using PROC UNIVARIATE were included in the SAS statistical output in support of the efficacy analysis.

Sensitivity Analyses

The primary efficacy analysis was based on an analysis of the ITT with LOCF Population, however a sensitivity analysis was also performed on the ITT without LOCF Population, the PP Population and the ITT Population without LOCF using repeated measures.

An additional sensitivity analysis was conducted for the primary endpoint on the ITT with LOCF Population. Subjects treated by Investigator [redacted] (Centre [redacted] were excluded due to a systematic violation of the planned visit schedule resulting in completion of the study in approximately 12 weeks rather than 24 weeks and potentially starting Extension Phase study medication during the Main Phase.

Repeated Measures

For the assessment of differences between the treatment groups with regard to repeated measures over time, a multivariate linear model analysis incorporating on-therapy values at all time points was employed (PROC MIXED in SAS). The estimated method was Restricted Maximum Likelihood and the Kenward-Rogers adjustment to the denominator degrees of freedom for the F-test was applied [Kenward, 1997]. The model used saturated means and an unstructured covariance matrix. The dependent variable was change in HbA1c from baseline; effects in the model were gender, prior therapy (diet and exercise/monotherapy), treatment, region, baseline measurement, time, and treatment-by-time interaction. Time was treated as the repeated variable within a subject. Subject, treatment, region, gender, prior therapy and time were treated as class variables.

Dose-Response

An investigation into the dose-response curve was conducted. An ANCOVA model was fitted with response of change from baseline at Week 12 with model terms for gender,

prior therapy (diet and exercise/monotherapy), treatment, region and baseline HbA1c. Firstly, orthogonal contrasts to test for linear, quadratic and cubic trends [Robson, 1959] were carried out using the CONTRAST statement within PROC MIXED in SAS. Based on the outcome from these tests, the least-square means (model-adjusted) from the ANCOVA model were used as data in a weighted regression to estimate the predicted dose response curve.

A figure showing the least-square means (model-adjusted) across each of the 6 doses (Placebo [Dose 0], 2.5, 7.5, 15, 30 and 45mg) with 95% CI and the predicted dose response curve with 95% CI were produced. This figure included the p-values for the linear, quadratic and cubic trends.

Further exploratory work was carried out examining dose on the log-scale.

5.8.9.2. Secondary Efficacy Measures

For all secondary efficacy parameters, the comparisons of interest were between treatment groups and the placebo group.

To assess the difference between treatment groups with regards to change from baseline to Week 12 in FPG, fructosamine, fasting serum insulin, pro-insulin and pro-insulin: insulin ratio, an analysis of covariance with terms for gender, prior therapy, treatment, region and baseline measurement were performed. The point estimates and corresponding 95% CI for treatment differences were calculated.

Responder Analysis

Differences between treatment groups in the proportion of subjects who achieved the HbA1c targets of ≤6.5% and <7% and the FPG target of <126mg/dL (7.0mmol/L) at Week 12 were assessed based on a logistic regression model with terms included for treatment, gender, prior therapy, and baseline measurement.

Differences between treatment groups in the proportion of subjects who achieved a clinically meaningful decrease from baseline in HbA1c (≥0.7%) and FPG (≥30mg/dL [1.7mmol/L]) were assessed in the same manner.

5.8.9.3. Other Efficacy Measures

Lipids

For all lipid parameters (TGs, FFAs, TC, LDL-c, HDL-c) the percentage change from baseline (based on log-transformed data) was summarised at each visit where data were collected. Formal statistical analysis was performed at Week 12, using an analysis of covariance with terms for gender, prior therapy, treatment, region and log-transformed baseline measurement. The point estimates and corresponding 95% CI for treatment ratios were calculated.

HOMA Measures

HOMA measures (IS and BCF) were logarithmically transformed and summarised at each visit by treatment group.

5.8.10. Safety Analyses

5.8.10.1. Extent of Exposure

The number of days of exposure to study medication were summarised for each treatment group and overall. Subject exposure was also categorised and the number and percentage of subjects in each category presented for each treatment group and overall.

5.8.10.2. Adverse Events

AEs were summarised by their occurrence in regard to therapeutic phase, i.e. pre-therapy, on-therapy and post-therapy as defined in Section 5.8.7.4.

AE summaries were performed using the preferred terms and body system assigned by the Medical Dictionary for Regulatory Activities (MedDRA).

The proportion of subjects reporting each type of AE was tabulated for each treatment group. The following summaries of AEs were provided:

- all AEs
- treatment-related AEs
- common AEs (≥5% incidence).

If a relationship to drug was missing or unknown it was assumed, for the purpose of analyses, to be drug-related. In the case of an AE occurring more than once within a time period (pre-therapy, on-therapy or post-therapy), only one event in that period was used in the summary. When summarising by Intensity, maximum intensity in that period was used if an AE occurred with different intensities within the same period.

Dotplots (with relative risks and CI) for common AEs were produced for the doses of 15, 30 and 45mg versus placebo.

5.8.10.3. Deaths and Serious Adverse Events

SAEs were summarised by their occurrence with regard to therapeutic phase, i.e. pre-therapy, on-therapy and post-therapy as defined in Section 5.8.7.4.

5.8.10.4. Adverse Events Leading to Discontinuation of Investigational Product and/or Withdrawal from the Study and Other Significant Adverse Events

A summary of the number and percentage of subjects with pre-therapy and with on-therapy AEs leading to permanent discontinuation of study drug (subjects who

discontinued and re-started study medication were not considered as withdrawals) from the Main Phase of the study were displayed separately.

5.8.10.5. Clinical Laboratory Evaluations

Laboratory data (clinical chemistry and haematology) were summarised, for each treatment group, at every assessed time point. Parameter values and change from baseline were summarised separately. An additional table of selected laboratory parameters at each time point which included study end was also produced.

Each laboratory test was summarised, for each treatment group, at every assessed time point using classification by reference ranges as "> reference range high" (i.e. >ULRR), "< reference range low" (i.e. <LLRR).

The number of subjects with abnormal values at any time on-therapy were summarised for each treatment group and overall. The display categorised the data according to whether the values met predefined criteria of potential clinical concern (see Section 5.8.7.5).

5.8.11. Other Safety Measures

Hypoglycaemic Events

Hypoglycaemic events merit special attention in the development and study of drugs for the treatment of type 2 diabetes since they are often related to the efficacy of a compound. In order to accomplish this, hypoglycaemic events were collected separately and were reported separately from AEs (see Section 5.6.3.3). However, any hypoglycaemic event which met the criteria for a SAE was included in the SAE summaries.

Vital Signs

All vital signs data (systolic BP, diastolic BP and heart rate) were summarised at every assessed time point by treatment group. Change from baseline was also derived and summarised.

A summary of vital signs of potential clinical concern (see Section 5.8.7.5) at any time on-therapy was presented.

Urinalysis

Urinalysis dipstick results (glucose, bilirubin, protein, ketones, RBCs/HPF and WBCs/HPF) were summarised at each assessed time point by treatment group.

Weight, Hip and Waist Circumference, Waist: Hip Ratio and BMI

Weight (kg), hip circumference (cm), waist circumference (cm), waist: hip ratio and BMI, were summarised at each time point by treatment group. Summary statistics for change from baseline at each visit were also produced. Percentage change from baseline

was also summarised for weight. An additional table of change from baseline in weight which includes study end was also produced.

Electrocardiograms

Ventricular Rate (bpm), RR Interval (msec), PR Interval (msec), QRS Duration (msec), QT Interval (msec), QTcB Interval (msec) and QTcF Interval (msec) were summarised by treatment group and visit. Parameter values and change from baseline were summarised separately.

A summary of the number and percentage of subjects who had abnormal and/or clinically significant ECG findings were displayed by treatment group and overall.

The number and percentage of subjects with ECGs of potential clinical concern (see Section 5.8.7.5) occurring at any time on-therapy were presented separately.

5.8.12. Biomarker Analyses

Descriptive statistics were provided for the population cardiac biomarker, CK-MB at each collection time point in the Main Phase. A summary was produced for specific ranges of the population biomarker cTnI at each visit; the ranges of interest are: <0.2, ≥0.2 to 0.35, >0.35 to 1.5 and >1.5µg/L. This summary was considered as exploratory for this study.

6. STUDY POPULATION RESULTS

6.1. Disposition of Subjects

6.1.1. Number and Distribution of Subjects

The first subject was randomised into the study on 03 June 2005 and the last visit of the last subject (for the main phase of the study) occurred on 26 April 2006.

Subject disposition is summarised in Table 6. In total, 371 subjects from 94 centres in nine countries were randomised with 321 subjects from 89 centres in nine countries completing the study. The number of subjects who completed the Main Phase across treatment groups ranged from 47 to 60.

Table 6 Summary of Subject Disposition

Subject disposition, n	Placebo	Denagliptin					Total
		2.5mg	7.5mg	15mg	30mg	45mg	
Entered run-in							476
Randomised	64	61	62	63	59	62	371
Safety [1]	64	61	63	66	60	61	375
Withdrawn	15	14	9	6	5	5	54
Completed	49	47	54	60	55	56	321

Data Source: Section 12, Table 10.1, Table 10.3

1. Safety Population includes 4 subjects who erroneously received double-blind medication during the run-in.

The number of subjects randomised and completed by region is presented in Section 12, Table 10.3. This study was conducted in the US/Canada (34%), Western Europe (Finland, Germany and Sweden; 40%) and Eastern Europe (Latvia, Romania, Czech Republic and Greece; 27%). The number of subjects randomised ranged from one to 18 per centre, with the number of subjects randomised per country ranging from seven in Latvia to 108 in Germany.

6.1.2. Reasons for Pre-randomisation Withdrawal

Of the 1687 subjects screened and/or entered the run-in phase of the study, 1312 (78%) withdrew before randomisation. The reasons for withdrawal are summarised in Table 7. The predominant reason for non-randomisation was non-compliance with eligibility criteria (71%).

Table 7 Summary of Screen and Run-in Failures

Withdrawal Reason, n (%)	Total (N = 1687)
Did not fulfil eligibility criteria	1197 (71%)
Subject decision	48 (3%)
Other	26 (2%)
Lack of glycaemic control	16 (<1%)
Prohibited medication use	10 (<1%)
Lost to follow-up	8 (<1%)
Missing	4 (<1%)
Protocol violation	2 (<1%)
Adverse event	1 (<1%)
Total	1312 (78%)

Data Source: Section 12, Table 10.4

6.1.3. Reasons for Run-in Withdrawal

Four subjects erroneously received double-blind medication during the run-in period. [redacted] The reasons for withdrawal of these subjects prior to randomisation are shown in Table 8. These 4 subjects have been included in the Safety Population as defined in Section 5.8.4.

Table 8 Summary of Reasons for Run-in Withdrawal

[redacted]

6.1.4. Reasons for Post Randomisation Withdrawal

Of the 371 randomised subjects, 50 (13%) withdrew during the double-blind Main Phase treatment period. Reasons for withdrawal are summarised in Table 9. The main withdrawal reason in the 2.5mg DEN group was due to an AE (7%). The main withdrawal reasons in the 7.5mg group were protocol violation and subject decision (both 5%). Reasons for withdrawal in all other DEN dose groups occurred with a low incidence (≤3% in any group). The primary reason for withdrawal in the placebo group was due to an AE (8%).

Table 9 Summary of Reasons for Post Randomisation Withdrawal (Randomised Population)

Withdrawal reason n (%)	Placebo	Denagliptin					Total
		2.5mg	7.5mg	15mg	30mg	45mg	
	(N=64)	(N=61)	(N=62)	(N=63)	(N=60)	(N=61)	(N=371)
Adverse event	5 (8%)	4 (7%)	0	0	1 (2%)	0	10 (3%)
Protocol violation	0	2 (3%)	3 (5%)	1 (2%)	1 (2%)	1 (2%)	8 (2%)
Other	1 (2%)	1 (2%)	0	1 (2%)	2 (3%)	1 (2%)	9 (2%)
Subject decision	2 (3%)	2 (3%)	3 (5%)	0	0	1 (2%)	8 (2%)
Lost to follow up	1 (2%)	0	2 (3%)	0	0	2 (3%)	5 (1%)
Lack of efficacy[1]	5 (8%)	1 (2%)	0	1 (2%)	1(2%)	0	8 (2%)
Did not meet eligibility criteria	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
Total withdrawn	15 (23%)	14 (23%)	8 (13%)	3 (5%)	5 (8%)	5 (8%)	50 (13%)
Completed Study	49 (77%)	47 (77%)	54 (87%)	60 (95%)	55 (92%)	56 (92%)	321 (87%)

Data Source: Section 12, Table 10.5

1. Also includes the terms 'insufficient therapeutic effect' and 'lack of glycaemic control'

Note: the data in this table is not the same as in Data Source Table 10.5 due to the removal of the 4 subjects erroneously dosed with double-blind medication in the run-in as these subjects were not randomised (see Section 6.1.3). Additionally, lack of efficacy, insufficient glycaemic control and lack of glycaemic control have been combined.

6.2. Protocol Deviations

Table 10 summarises those subjects who were excluded from the PP Population due to a protocol violation. The reason for the majority of subjects in all treatment groups not meeting the requirements for inclusion in the PP Population was due to lack of a Week 12 HbA1c value. Although subjects that did not have a Week 12 HbA1c value were not major violators as defined in Section 5.8.8.2, they were excluded from the PP Population.

Table 10 Summary of Major Deviations Leading to Exclusion from the Per Protocol Population (ITT Population)

Major deviation n (%)	Placebo	Denagliptin				
		2.5mg	7.5mg	15mg	30mg	45mg
	(N=62)	(N=59)	(N=62)	(N=63)	(N=58)	(N=60)
Total	25 (40%)	13 (22%)	13 (21%)	8 (13%)	7 (12%)	12 (20%)
No Week 12 HbA1c value[1]	13 (21%)	11 (19%)	7 (11%)	3 (5%)	3 (5%)	7 (12%)
Systematic violation of visit schedule	6 (10%)	2 (3%)	1 (2%)	5 (8%)	2 (3%)	2 (3%)
Out of range HbA1c for inclusion criteria	5 (8%)	0	4 (6%)	1 (2%)	1 (2%)	1 (2%)
Randomised to monotherapy with washout <28 days	4 (6%)	0	3 (5%)	2 (3%)	2 (3%)	1 (2%)
Non-compliance with study medication	3 (5%)	1 (2%)	1 (2%)	0	2 (3%)	2 (3%)
Took prohibited medication	2 (3%)	1 (2%)	0	0	0	2 (3%)
Rx was not taken according to protocol	0	0	0	0	1 (2%)[2]	1 (2%)[3]

Data Source: Section 12, Table 10.7

1. Although subjects that did not have a Week 12 HbA1c value were not major violators, they were excluded from the PP Population
2. [redacted]
3. [redacted]

A summary of inclusion/exclusion criteria deviations is provided in Section 12, Table 10.6.

6.3. Populations Analysed

The numbers of subjects in each study population are summarised in Table 11. The number of subjects in each study population by gender and prior therapy is provided in Section 12, Table 10.2.

Of the 375 subjects in the Safety Population, four non-randomised subjects, (1 in 7.5mg DEN group, 3 in 15mg DEN group) received double-blind study medication during run-in. Therefore, the Safety Population includes four more subjects than the Randomised Population. [redacted] This subject was assigned to the 30mg group for Safety analyses and to the 45mg group for Efficacy analyses (as per the ITT principle).

In total, 286 subjects completed the Main Phase of the study without a major protocol violation and were therefore included in the PP Population.

Table 11 Summary of Study Populations

Study Population	Placebo	Denagliptin 2.5mg	Denagliptin 7.5mg	Denagliptin 15mg	Denagliptin 30mg	Denagliptin 45mg	Total
Entered Run-in							476
Randomised	64	61	62	63	59	62	371
Safety	64	61	63	66	60	61	375
ITT	62	59	62	63	58	60	364
Completers	49	47	54	60	55	56	321
Per-Protocol	37	46	49	55	51	48	286

Data Source: Section 12, Table 10.1

1. The number of subjects in the Safety Population is greater than the number of subjects randomised due to the Safety Population including 4 subjects who took double-blind study medication during run-in (see Section 6.1.3).

6.4. Demographics and Other Baseline Characteristics

6.4.1. Demographic Characteristics

The demographic characteristics for the Safety Population are summarised in Table 12. Demographic data were similar across treatment groups with respect to age, gender, race, weight, BMI and waist circumference. The mean age of subjects was 59.6 years, mean BMI 31.0kg/m^2 and mean waist circumference 104cm. There was a similar proportion of male and female subjects (49% vs. 51%) and the majority of subjects were non-Hispanic (94%).

A summary of the distribution of subjects by race and racial combinations is provided in Section 12, Table 10.12 and Table 10.13. The majority of subjects fell into the category 'white' (91%).

Demographic characteristics by gender and prior therapy are provided in Section 12, Table 10.10.

Table 12 Summary of Demographic Characteristics (Safety Population)

Demographic Characteristic	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)	Total (N=375)
Gender [n (%)], n	64	61	63	66	60	61	375
Male	32 (50%)	30 (49%)	31 (49%)	33 (50%)	29 (48%)	29 (48%)	184 (49%)
Female	32 (50%)	31 (51%)	32 (51%)	33 (50%)	31 (52%)	32 (52%)	191 (51%)
Age (years), n	64	61	63	66	60	61	375
Mean ± SD	60.8 ± 10.9	58.6±9.5	60.4 ± 12.4	59.9 ± 8.0	58.8 ± 9.95	59.2 ± 7.85	59.6 ± 9.9
Median	63.0	59.0	64.0	59.5	60.0	60.0	61.0
Range	33 – 75	30 – 75	19 – 75	42 – 73	34 – 75	34 – 74	19 - 75
Race [n (%)], n	64	61	63	66	60	61	375
Hispanic/Latino	6 (9%)	5 (8%)	5 (8%)	1 (2%)	2 (3%)	4 (7%)	23 (6%)
Not Hispanic/Latino	58 (91%)	56 (92%)	58 (92%)	65 (98%)	58 (97%)	57 (93%)	352 (94%)
BMI (kg/m^2), n	64	61	63	66	60	61	375
Mean ± SD	30.6 ± 4.8	31.5 ± 4.7	30.8 ± 4.8	30.6 ± 4.1	31.5 ± 4.6	31.5 ± 4.2	31.0 ± 4.5
Median	29.6	30.9	30.4	30.4	31.0	31.1	30.6
Range	23.2 – 39.6	20.7 – 40.8	22.8 – 41.2	20.2 – 39.6	22.6 – 39.8	24.3 – 40.1	20.2 – 41.2
<27	15	10	17	13	14	10	79
27 - 30	20	16	12	15	7	14	84
>30	29	35	34	38	39	37	212
Weight (kg), n	64	61	63	66	60	61	375
Mean ± SD	86.9 ± 15.7	89.3 ± 16.9	87.7 ± 16.3	86.7 ± 14.3	90.4 ± 18.3	90.2 ± 14.8	88.5 ± 16.0
Median	83.1	85.0	86.2	86.9	87.5	85.8	86.1
Range	59.0 – 143.0	52.9 – 130.6	56.1 – 135.0	53.0 – 113.0	57.8 – 143.0	62.5 – 122.0	52.9 – 143.0
Waist circumference (cm), n	64	61	63	66	60	61	375
Mean ± SD	103.5 ± 12.53	104.7 ± 11.15	103.8 ± 11.55	102.2 ± 9.70	106.1 ± 12.48	104.6 ± 11.04	104.1 ± 11.42
Median	101.0	105.0	103.0	100.5	104.0	104.0	103.0
Range	82 – 139	74 – 131	82 – 132	84 – 121	82 – 147	72 – 138	72 – 147

Data Source: Section 12, Table 10.8

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Characteristics for smoking history and alcohol consumption in the Safety Population were similar in all treatment groups (Table 13).

Table 13 Summary of Smoking History and Alcohol Consumption (Safety Population)

Demographic Characteristic, n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)	Total (N=375)
Smoking History, n	64	61	63	66	60	61	375
Never	42 (66%)	39 (64%)	38 (60%)	45 (68%)	42 (70%)	40 (66%)	246 (66%)
Current	10 (16%)	12 (20%)	10 (16%)	9 (14%)	12 (20%)	10 (16%)	63 (17%)
Former	12 (19%)	10 (16%)	15 (24%)	12 (18%)	6 (10%)	11 (18%)	66 (18%)
Alcohol Consumer, n	64	61	63	66	60	60	374
Yes	26 (41%)	24 (39%)	19 (30%)	23 (35%)	21 (35%)	19 (32%)	132 (35%)
No	38 (59%)	37 (61%)	44 (70%)	43 (65%)	39 (65%)	41 (68%)	242 (65%)

Data Source: Section 12, Table 10.14

6.4.2. Baseline Characteristics

Baseline diabetes characteristics are summarised in Table 14 for the Safety Population. All treatment groups were generally similar with respect to duration of diabetes, pre-study therapy and baseline HbA1c, both overall and by diet and exercise/monotherapy strata. Across treatment groups, the mean duration of diabetes was 5.3 years and ranged from 0.0 to 35.6 years reflecting a mixed prior therapy population. Forty-one percent of subjects were managed by diet and exercise compared to 59% who received monotherapy treatment; with a slightly lower percentage of diet and exercise subjects in the 15mg group. Mean baseline HbA1c overall was 7.90%, in the diet and exercise strata 7.98% and in the monotherapy strata 7.85%.

Table 10.11 in Section 12 provides a breakdown of baseline HbA1c by HbA1c range (<7.5, ≥7.5 - <8, ≥8 - <8.5 and ≥8.5%) both overall and by diet and exercise/monotherapy strata. Overall, slightly fewer subjects had a baseline HbA1c ≥8.5%, although there was some variation across treatment groups and between diet and exercise/monotherapy strata.

Table 14 Summary of Baseline Diabetes Characteristics (Safety Population)

Demographic Characteristic	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)	Total (N=375)
Number of years with diabetes, n	64	61	63	66	60	61	375
Mean ± SD	5.4±4.6	5.3±4.6	5.7±6.0	5.1±4.8	5.3±5.1	5.1±4.2	5.3±4.9
Median	4.3	5.1	3.7	3.6	4.6	3.8	4.0
Range	0.1 – 24.2	0.0 – 22.7	0.3 – 35.5	0.2 – 23.6	0.2 – 29.7	0.1 – 18.5	0.0 – 35.5
Pre-study diabetes treatment [n (%)], n	64	61	63	66	60	61	375
Diet and Exercise	28 (44%)	24 (39%)	27 (43%)	24 (36%)	25 (42%)	25 (41%)	153 (41%)
Monotherapy	36 (56%)	37 (61%)	36 (57%)	42 (64%)	35 (58%)	36 (59%)	222 (59%)
HbA1c (%), n	64	58	60	63	58	59	362
Mean ± SD	7.74±0.67	7.99±0.93	7.96±0.76	7.88±0.65	7.75±0.67	8.09±0.71	7.90±0.74
Median	7.70	7.80	7.70	8.00	7.75	8.10	7.80
Range	6.1 – 9.3	6.4-10.1	6.6-9.9	6.5-9.6	6.4-9.6	6.7-9.5	6.1-10.1
HbA1c (%) Diet and Exercise Strata, n	28	23	25	24	24	24	148
Mean ± SD	7.70±0.64	8.08±0.88	8.15±0.84	7.87±0.47	8.00±0.69	8.12±0.71	7.98±0.72
Median	7.70	7.70	7.70	7.90	8.00	8.15	7.80
Range	6.1–9.3	7.0-9.8	7.2-9.7	6.9-8.6	6.7-9.6	6.7-9.5	6.1-9.8
HbA1c (%) Monotherapy Strata, n	36	35	35	39	34	35	214
Mean ± SD	7.77±0.70	7.94±0.98	7.83±0.69	7.89±0.74	7.58±0.60	8.07±0.73	7.85±0.76
Median	7.65	7.80	7.70	8.00	7.50	8.00	7.80
Range	6.6–9.3	6.4-10.1	6.6-9.9	6.5-9.6	6.4-8.6	6.8-9.5	6.4-10.1

Data Source: Section 12, Table 10.8, Table 10.9

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6.4.3. Other Past Medical Conditions

A summary of prior medical conditions by system organ class is provided in Section 12, Table 10.15. Forty-one percent of subjects had a past medical condition.

Table 10.17 in Section 12 summarises the most frequent past diabetes medical conditions by treatment group. The frequency of past diabetes medical conditions was low and similar across treatment groups (≤5% in any treatment group).

Table 15 summarises the most frequent past cardiovascular (CV) medical conditions. The frequency of past CV medical conditions was similar across treatment groups. The most commonly occurring past CV condition was myocardial infarction in the 2.5mg DEN group (8%) followed by hypertension in the 30mg DEN group (5%). All other past conditions occurred in ≤3% of subjects.

Table 15 Past Cardiovascular Medical Conditions Reported by More than One Subject in Any Treatment Group (Safety Population)

		Denagliptin				
Preferred Term n (%)	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Total	5 (8%)	8 (13%)	7 (11%)	9 (14%)	5 (8%)	5 (8%)
Myocardial infarction	1 (2%)	5 (8%)	2 (3%)	2 (3%)	2 (3%)	1 (2%)
Arrhythmia	1 (2%)	0	2 (3%)	0	0	1 (2%)
Angina pectoris	0	0	0	2 (3%)	0	1 (2%)
Oedema	1 (2%)	1 (2%)	0	2 (3%)	1 (2%)	1 (2%)
Hypertension	1 (2%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0
Myocardial ischaemia	1 (2%)	2 (3%)	2 (3%)	1 (2%)	1 (2%)	0

Data Source: Section 12, Table 10.19

6.4.4. Other Current Medical Conditions

A summary of current medical conditions by system organ class is provided in Section 12, Table 10.16. Eighty-eight percent of subjects had a current medical condition.

Table 16 presents current diabetes medical conditions at baseline. More subjects presented with diabetes-related conditions in the placebo group (61%) and fewer presented with diabetes conditions in the 15mg DEN group (39%). The most frequent diabetes related condition in all treatment groups was dyslipidaemia, occurring with the highest frequency in the placebo group (55%) and lowest frequency in the 15mg DEN group (33%).

Table 16 Current Diabetes Medical Conditions (Safety Population)

Preferred Term n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Total	39 (61%)	28 (46%)	32 (51%)	26 (39%)	29 (48%)	28 (46%)
Dyslipidaemia	35 (55%)	24 (39%)	30 (48%)	22 (33%)	25 (42%)	27 (44%)
Neuropathy peripheral	9 (14%)	5 (8%)	5 (8%)	4 (6%)	3 (5%)	2 (3%)
Diabetic retinopathy	0	0	1 (2%)	0	2 (3%)	0
Microalbuminuria	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0
Proteinuria	1 (2%)	1 (2%)	0	1 (2%)	0	0
Nephropathy	0	0	0	1 (2%)	0	0

Data Source: Section 12, Table 10.18

Table 17 presents current CV medical conditions at baseline. More subjects presented with CV-related conditions in the placebo group (70%) compared to the DEN treatment groups (range 49% to 60%). The most frequent CV related condition in all treatment groups was hypertension, occurring with the highest frequency in the placebo group (64%).

Table 17 Current Cardiovascular Medical Conditions Reported by More than One Subject in Any Treatment Group (Safety Population)

Preferred Term n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Total	45 (70%)	31 (51%)	31 (49%)	34 (52%)	36 (60%)	34 (56%)
Hypertension	41 (64%)	30 (49%)	29 (46%)	33 (50%)	34 (57%)	33 (54%)
Arteriosclerosis	4 (6%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	1 (2%)
Peripheral vascular disorder	3 (5%)	0	3 (5%)	0	0	1 (2%)
Coronary artery disease	5 (8%)	3 (5%)	1 (2%)	0	0	1 (2%)
Myocardial ischaemia	4 (6%)	1 (2%)	1 (2%)	1 (2%)	0	2 (3%)
Arrhythmia	4 (6%)	0	1 (2%)	1 (2%)	0	0
Cardiac valve disease	2 (3%)	0	0	0	1 (2%)	0
Ventricular dysfunction	1 (2%)	0	2 (3%)	0	0	0
Oedema	1 (2%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	1 (2%)

Data Source: Section 12, Table 10.20

6.4.5. Previous Medications

A summary of prior medications by ATC Classification in the Safety Population is provided in Section 12, Table 10.22. Seventy-five percent of subjects received prior medication. The most frequently taken prior medications were related to the CV system. Prior CV medications were taken by more subjects in the placebo group (72%) compared to the DEN treatment groups (range 54% to 63%).

A summary of prior anti-diabetic medications by ATC Classification is provided in Section 12, Table 10.21. Sixty percent of subjects received prior anti-diabetic medications, the most frequently taken being metformin/metformin hydrochloride in all treatment groups.

A summary of prior sulphonylurea (SU) and metformin medications taken by subjects receiving prior monotherapy, by ATC Classification is provided in Table 18. A higher proportion of subjects received prior biguanide therapy than prior SU therapy. A similar proportion of subjects received prior biguanide therapy across treatment groups; fewer subjects in the 30mg DEN group received prior SU therapy compared to the other treatment groups.

Table 18 Prior Sulphonylurea and Metformin Medications in Monotherapy Stratum (Safety Population)

		Denagliptin				
ATC Level 4/Ingredient n (%)	Placebo (N=36)	2.5mg (N=37)	7.5mg (N=36))	15mg (N=42)	30mg (N=35)	45mg (N=36)
Total	36 (100%)	35 (95%)	36 (100%)	42 (100%)	33 (94%)	35 (97%)
Biguanides	22 (61%)	22 (59%)	25 (69%)	29 (69%)	29 (83%)	27 (75%)
Metformin	11 (31%)	11 (30%)	15 (42%)	13 (31%)	19 (54%)	13 (36%)
Metformin hydrochloride	11 (31%)	11 (30%)	10 (28%)	15 (36%)	10 (29%)	14 (39%)
Metformin hydrochloride + RSG	0	0	0	0	1 (3%)	0
Buformin	0	0	0	1 (2%)	0	0
Sulphonamides, Urea Derivatives	14 (39%)	13 (35%)	11 (31%)	15 (36%)	4 (11%)	8 (22%)
Glibenclamide	3 (8%)	6 (16%)	3 (8%)	5 (12%)	2 (6%)	3 (8%)
Glimepiride	5 (14%)	3 (8%)	3 (8%)	5 (12%)	0	5 (14%)
Glipizide	4 (11%)	1 (3%)	1 (3%)	3 (7%)	2 (6%)	0
Gliclazide	1 (3%)	3 (8%)	4 (11%)	3 (7%)	0	0
Tolbutamide	1 (3%)	0	0	0	0	0

Data Source: Section 12, Table 10.23
RSG = rosiglitazone
Note: The percentages in this table are based on the number of monotherapy subjects.

6.5. Concomitant Medications

The most commonly received concomitant medications (i.e. those taken by >5% of subjects in any treatment group) are summarised in Table 19. The proportions of subjects who received concomitant medications during the study were similar across the treatment groups.

The most frequently taken concomitant medications across treatment groups were agents acting on the renin-angiotensin system, serum lipid reducing agents and analgesics. Although there were some differences between the groups in the proportions of subjects receiving specific medications, there were no clinically marked differences between the groups.

Table 19 Concomitant Medication Received by More Than 5% of Subjects in Any Treatment Group (Safety Population)

Ingredient n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Total	54 (84%)	49 (80%)	48 (76%)	52 (79%)	42 (70%)	48 (79%)
Ramipril	5 (8%)	3 (5%)	4 (6%)	6 (9%)	0	4 (7%)
Lisinopril	8 (13%)	2 (3%)	2 (3%)	2 (3%)	1 (2%)	4 (7%)
Enalapril	4 (6%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	3 (5%)
Perindopril	1 (2%)	3 (5%)	2 (3%)	4 (6%)	1 (2%)	1 (2%)
Enalapril maleate	1 (2%)	0	4 (6%)	0	0	0
Simvastin	10 (16%)	5 (8%)	9 (14%)	5 (8%)	3 (5%)	5 (8%)
Atorvastatin calcium	6 (9%)	6 (10%)	4 (6%)	4 (6%)	3 (5%)	2 (3%)
Fenofibrate	4 (6%)	0	3 (5%)	1 (2%)	1 (2%)	5 (8%)
Metoprolol	6 (9%)	1 (2%)	3 (5%)	1 (2%)	4 (7%)	4 (7%)
HCTZ	5 (8%)	3 (5%)	3 (5%)	0	3 (5%)	5 (8%)
Indapamide	4 (6%)	1 (2%)	3 (5%)	1 (2%)	4 (7%)	4 (7%)
Amlodipine besilate	5 (8%)	1 (2%)	4 (6%)	3 (5%)	3 (5%)	2 (3%)
Acetylsalicylic acid	17 (27%)	10 (16%)	9 (14%)	12 (18%)	5 (8%)	9 (15%)
Paracetamol	3 (5%)	3 (5%)	2 (3%)	7 (11%)	1 (2%)	11 (18%)
Ibuprofen	2 (3%)	2 (3%)	4 (6%)	7 (11%)	5 (8%)	6 (10%)
Vitamins NOS	0	4 (7%)	1 (2%)	1 (2%)	0	0
Flucticasone propionate	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)
Levothyroxine sodium	4 (6%)	1 (2%)	2 (3%)	3 (5%)	3 (5%)	4 (7%)

Data Source: Section 12, Table 10.24

6.6. Treatment Compliance

A summary of study medication compliance by week is provided in Section 12, Table 10.25. Compliance was defined as receipt of ≥80% and ≤120% of prescribed study medication. A definition of overall Main Phase study compliance is given in Section 5.8.8.4. Compliance was assessed at Weeks 4, 8 and 12 after the start of double-blind treatment. Subjects were compliant at most of the visits, on average at least 93% of the visits (Table 20).

Table 20 Summary of Overall Compliance with Study Medication (Safety Population)

% of visits at which subject Compliant	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Mean ± SD	93.0±21.2	96.5±15.2	96.0±15.4	97.5±13.5	95.3±17.4	95.9±18.9
Median	100.0	100.0	100.0	100.0	100.0	100.0
Range	0 - 100	0 – 100	0 – 100	0 – 100	0 – 100	0 - 100

Data Source: Section 12, Table 10.26

7. EFFICACY RESULTS

7.1. Primary Efficacy Results

The change from baseline to Week 12 in mean HbA1c is summarised in Table 21 for the ITT Population with LOCF. Treatment differences compared to placebo in changes in mean HbA1c from baseline are shown graphically in Section 13, Figure 11.7. Mean changes from baseline in HbA1c over time are shown graphically in Section 13, Figure 11.2.

At Week 12, following adjustments for baseline, gender, region, prior therapy and treatment, reductions compared to placebo were clinically and statistically significant in the 45mg and 30mg DEN groups (-0.84% [95% CI: -1.13, -0.55; p<0.001] and -0.80% [95% CI: -1.09, -0.50; p<0.001], respectively; adjusted change from baseline [mean±SE]: -0.38±0.11% and -0.34±0.11%, respectively). Comparisons to placebo were also statistically significant for the 15mg (-0.45% [95% CI: -0.74, -0.16; p=0.002]) and 7.5mg (-0.53% [95% CI: -0.82, -0.24]; p<0.001) DEN groups (based on the closed testing procedure as described in Section 5.8.5). Mean HbA1c increased from baseline at Week 12 in the placebo group (mean±SE: 0.46±0.11%).

Table 21 Analysis of Change from Baseline in HbA1c (%) at Week 12 (ITT Population with LOCF)

Change from baseline at Week 12 in HbA1c (%)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	59	56	59	62	56	58
Baseline: mean±SD	7.76±0.68	8.02±0.93	7.97±0.76	7.88±0.65	7.77±0.66	8.07±0.75
Week 12: mean±SD	8.18±1.33	8.20±1.28	7.93±1.16	7.92±0.92	7.43±0.86	7.68±0.96
Adjusted change from baseline[2]:						
mean±SE	0.46±0.105	0.18±0.107	-0.07±0.104	0.01±0.102	-0.34±0.107	-0.38±0.105
Adjusted mean difference vs PBO[2]						
Mean	-	-0.28	-0.53	-0.45	-0.80	-0.84
[95% CI]	-	[-0.58, 0.01]	[-0.82, -0.24]	[-0.74, -0.16]	[-1.09, -0.50]	[-1.13, -0.55]
P-value	-	0.061	<0.001	0.002	<0.001	<0.001

Data Source: Section 13, Table 11.2

1. Number of subjects with a value at baseline and at Week 12
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

The statistical output for Table 11.2 is provided in Section 13, Table 11.3.

When examining the change from baseline at Week 12 data, one outlier was observed in the 30mg group (large non-responder; 2.6%) and one outlier in the 45mg group (large responder; -2.9%) (see ICH Data Listing 14). On removal of the outliers the conclusions

remain the same, but numerically the mean change from placebo was slightly smaller for the 45mg group than the 30mg treatment group.

There was evidence of a treatment-by-region interaction for the primary analysis (p=0.0802). This was examined and was likely to be due to the large placebo worsening in the Western Europe subgroup (see Section 13, Table 11.10). This interaction became non-significant in the ITT without LOCF and PP Population analyses.

Summary statistics at Week 12 for HbA1c by region, gender, prior therapy, baseline HbA1c and BMI are provided in Section 13, Table 11.10, 11.11, 11.12, 11.13 and 11.14, respectively. Although sample sizes were relatively low, decreases at Week 12 in HbA1c were observed to vary with region; a decrease was observed at 30mg and 45mg DEN in Eastern European subjects, at all DEN dose groups in US/Canadian subjects (with less of an effect seen at 45mg compared to the other regions) and at 45mg DEN only in Western European subjects. Worthy of note was a large placebo worsening in the Western Europe group. Decreases in HbA1c at Week 12 were similar in females and males. Decreases in HbA1c increased with increasing baseline HbA1c value and in subjects with a higher baseline BMI value.

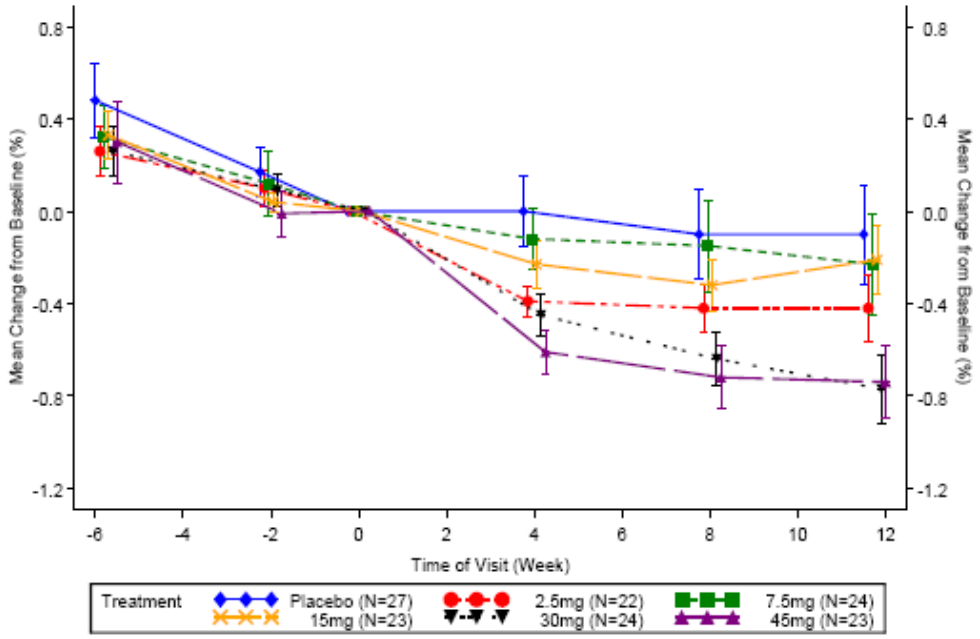
Mean changes from baseline in HbA1c over time by diet and exercise and monotherapy strata are shown in Figure 2 and Figure 3, respectively.

For subjects previously treated with Diet & Exercise, mean HbA1c decreased over time in all DEN groups with the greatest reduction in the 30mg group (mean±SE:-0.77±0.15%) and 45mg (-0.74±0.16%) treatment groups. There was a small reduction in the placebo group (-0.10±0.21%).

For subjects previously treated with Monotherapy there was a small reduction in HbA1c at Week 12 for the 30mg (-0.02±0.13%) and 45mg (-0.15±0.10%) treatment groups. However there was an increase in the placebo group (0.87±0.18%) resulting in greater decrease from baseline in HbA1c relative to placebo in subjects previously treated with monotherapy compared to diet and exercise.

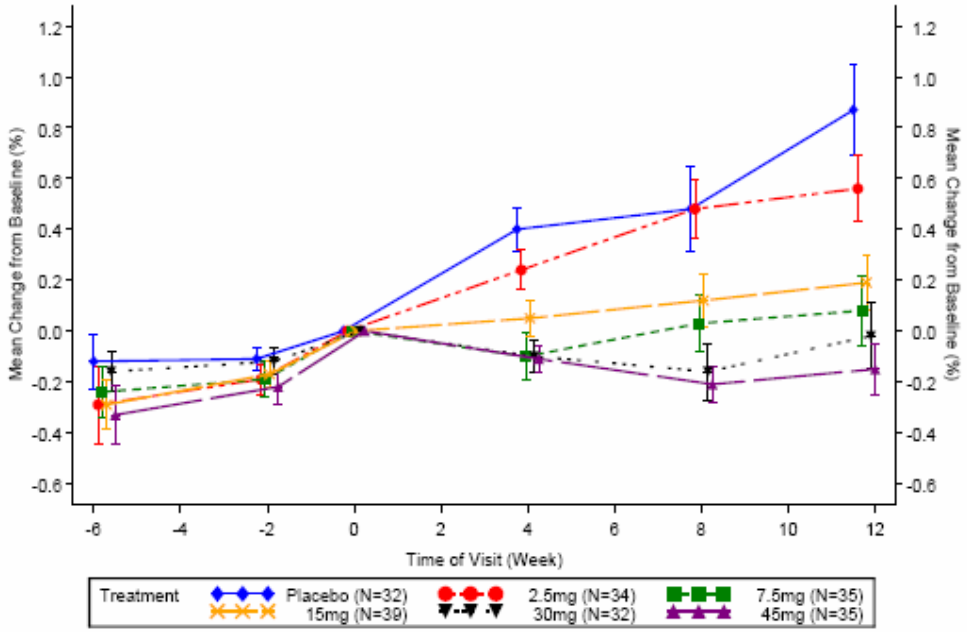
Overall the reductions in HbA1c compared to placebo seen with both the 30mg and 45mg dose of DEN in subjects on previous monotherapy and those on diet and exercise are clinically relevant.

Figure 2 **Mean Change from Baseline (Plus and Minus SE) for HbA1c (%) for Diet and Exercise Strata by Visit (ITT Population with LOCF)**



Data Source: Section 13, Figure 11.5
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

Figure 3 Mean Change from Baseline (Plus and Minus SE) for HbA1c (%) for Monotherapy Strata by Visit (ITT Population with LOCF)



Data Source: Section 13, Figure 11.6
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

7.1.1. Sensitivity Analyses

Analysis of change in HbA1c from baseline to Week 12 for the ITT Population without LOCF is provided in Section 13, Table 11.5.

The primary efficacy analysis was repeated for the PP Population (Section 13, Table 11.8). In the PP Population, the adjusted treatment difference at Week 12 was clinically and statistically significant compared to placebo for the 45mg (-0.73% [95% CI: -1.05, -0.40], p<0.001; change from baseline [mean±SE]: -0.37±0.11%) and 30mg (-0.75% [95% CI: -1.06, -0.43], p<0.001; change from baseline [mean±SE]: -0.39±0.11%). Comparisons to placebo were also statistically significant for the 15mg and 7.5mg DEN groups. Mean HbA1c increased from baseline at Week 12 in the placebo group (mean±SE: 0.35±0.12%)

Both the ITT without LOCF and PP analyses were supportive of the primary ITT with LOCF analysis.

There was no evidence of treatment-by-covariate interactions in the ITT without LOCF or PP Populations.

Sensitivity analysis of change from baseline in HbA1c to Week 12 excluding subjects from centre [redacted] (see Section 5.8.9.1) are provided in Section 13, Table 11.54. The results were consistent with the ITT with LOCF Population.

7.1.2. Repeated Measures

At Week 12, following repeated measures analysis and adjustments for baseline, gender, region, prior therapy and treatment, reductions compared to placebo were clinically and statistically significant in the 45mg and 30mg DEN groups (-0.85% [95% CI: -1.17, -0.52, p<0.001] and -0.82% [95% CI: -1.14, -0.51, p<0.001], respectively; change from baseline [mean±SE]: -0.37±0.12% and -0.35±0.11%, respectively) (Section 13, Table 11.15). Comparisons to placebo were also statistically significant for the 15mg (-0.46% [95% CI: -0.77, -0.15; p=0.004]) and 7.5mg (-0.55% [95% CI: -0.87, -0.23; p<0.001]) DEN groups (based on the closed testing procedure as described in Section 5.8.5). Mean HbA1c increased from baseline at Week 12 in the placebo group (mean±SE: 0.48±0.12%)

The repeated measures analysis was supportive of the primary ITT with LOCF analysis.

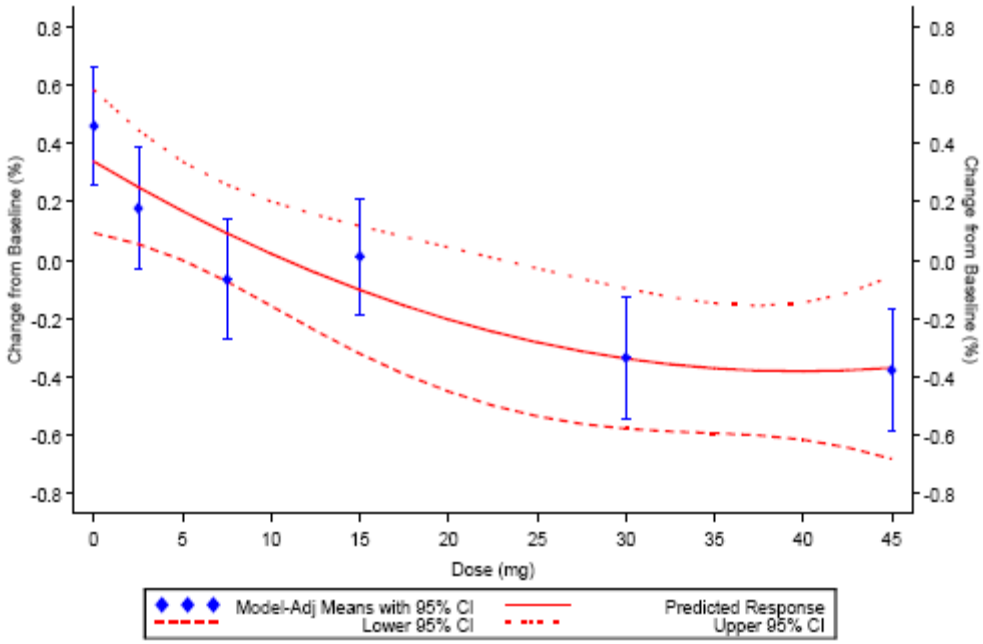
7.1.3. Dose-Response

As this study was a dose-response study, in addition to assessing pairwise comparisons an investigation into the dose-response curve was carried out.

Orthogonal contrasts were used to assess the fit of a model through the model adjusted means. The linear and quadratic terms were significant (p<0.001 and p=0.044 respectively), which meant a quadratic model was fitted to the model adjusted means (see Figure 4). The curvature was likely to be due to the 15mg group showing a smaller reduction in change from baseline than the 7.5mg group. The statistical model was as follows: change from baseline at Week 12 in HbA1c = 0.339 - 0.0363 dose + 0.000456 $dose^2$.

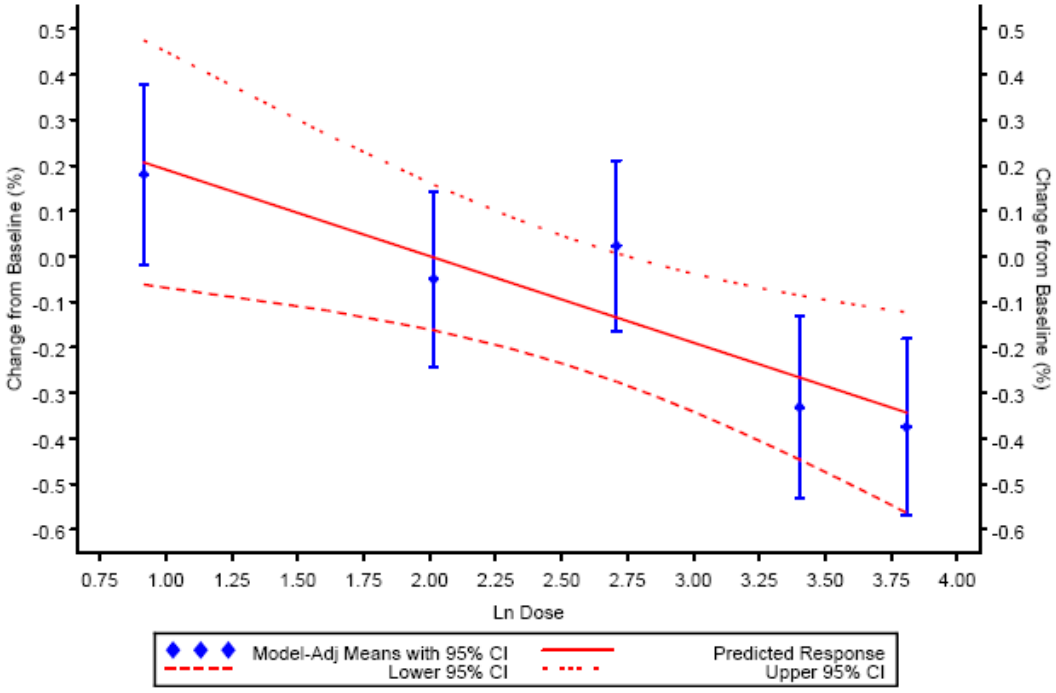
In addition, dose was examined on the log-scale (excluding placebo) (Figure 5). The dose response profile showed a greater reduction in change from baseline in HbA1c with increasing dose, with the 7.5mg group producing a slightly larger reduction that the 15mg group and the dose profile reaching a plateau for the top two doses of 30mg and 45mg. The statistical model was as follows: change from baseline at Week 12 in HbA1c = 0.381 - 0.190 log (dose). A doubling in dose was estimated to give a 0.132% improvement in change from baseline at Week 12 in HbA1c.

Figure 4 **Figure of Predicted Dose-response Curve for Change from Baseline in HbA1c (%) at Week 12 (ITT Population with LOCF)**



Data Source: Section 13, Figure 11.14
Linear: p<0.001; quadratic: p=0.044; cubic: p=0.438.

Figure 5 Figure of Predicted Ln Dose-response Curve for Change from Baseline in HbA1c (%) at Week 12 (ITT Population with LOCF)



Data Source: Section 13, Figure 11.60
Linear: p<0.001; quadratic: p=0.397; cubic: p=0.537.

7.2. Secondary Efficacy Results

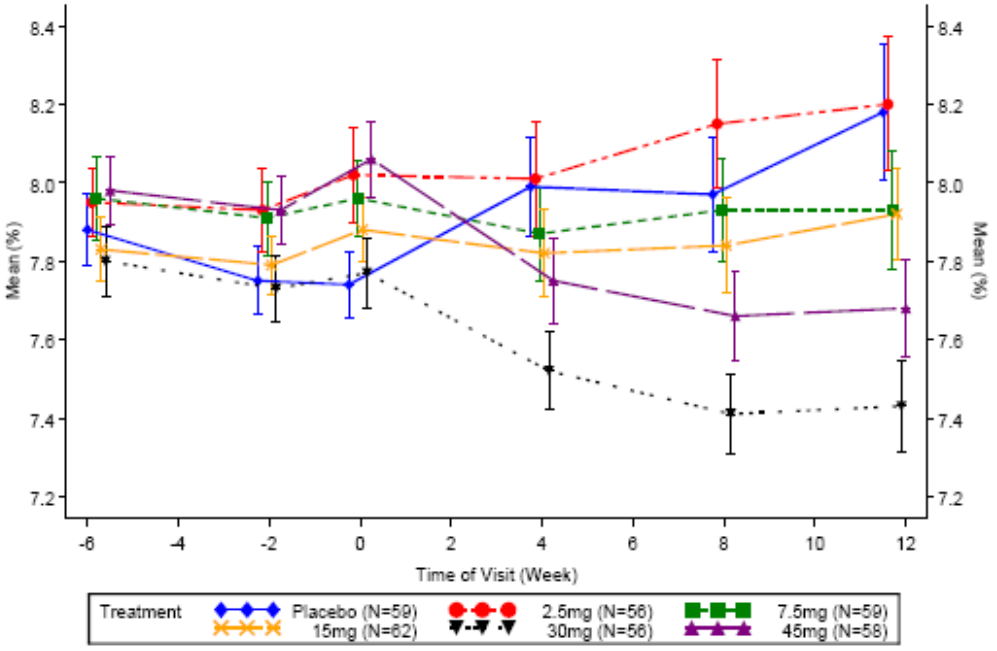
7.2.1. Glycaemic Control

7.2.1.1. Mean HbA1c Over Time

Mean HbA1c over time for the ITT Population with LOCF is shown Figure 6 and for the diet and exercise and monotherapy strata in Section 13, Figures 11.3 and 11.4, respectively. Results for HbA1c by visit for the ITT Population with LOCF are provided in Section 13, Table 11.1 and for the diet and exercise and monotherapy strata in Section 13, Table 11.12.

Mean decreases in HbA1c from baseline were apparent by Week 4 of treatment. In the 30mg and 45mg DEN groups further decreases in HbA1c were observed at 8 weeks which were sustained to Week 12. Mean values for HbA1c at each visit were similar to baseline in the 7.5mg and 15mg DEN groups; mean HbA1c increased over time in the 2.5mg DEN and placebo groups.

Figure 6 Mean HbA1c (%) (Plus and Minus SE) by Visit (ITT Population with LOCF)



Data Source: Section 13, Figure 11.1
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

A summary of HbA1c values at each visit for the ITT Population without LOCF is provided in Section 13, Table 11.4 and for the PP Population in Section 13, Table 11.7.

Changes in mean HbA1c over time in the DEN and placebo groups for the PP Population were consistent with the ITT Population with LOCF.

7.2.1.2. FPG

Analysis of change from baseline in mean FPG to Week 12 is summarised in Table 22. The adjusted treatment difference was clinically and statistically significant compared to placebo for the 45mg (-1.22mmol/L [95% CI: -1.99, -0.46, p=0.002]; adjusted change from baseline [mean±SE]: -0.71±0.28mmol/L) and 30mg (-1.46mmol/L [95% CI: -2.23, -0.69, p<0.001]; adjusted change from baseline [mean±SE]: -0.95±0.28mmol/L) DEN groups. Mean FPG increased from baseline at Week 12 in the placebo group (mean±SE: 0.52±0.27mmol/L).

Table 22 Analysis of Change from Baseline in FPG (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline at Week 12 in FPG (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	62	58	62	63	58	60
Baseline: mean±SD	9.64±1.97	9.64±2.41	9.89±2.02	9.93±1.59	9.94±2.24	9.98±1.74
Week 12: mean±SD	10.21±2.88	9.83±2.68	9.58±3.09	9.86±2.14	8.94±2.20	9.23±2.27
Adjusted change from baseline[2]:						
mean±SE	0.52±0.273	0.11±0.282	-0.28±0.272	0.07±0.270	-0.95±0.281	-0.71±0.276
Adjusted mean difference vs PBO[2]:						
Mean	-	-0.40	-0.80	-0.58	-1.46	-1.22
[95% CI]	-	[-1.18, 0.37]	[-1.56, -0.04]	[-1.34, 0.17]	[-2.23, -0.69]	[-1.99, -0.46]
P-value	-	0.306	0.039	0.130	<0.001	0.002

Data Source: Section 13, Table 11.19

1. Number of subjects with a value at baseline and at Week 12
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

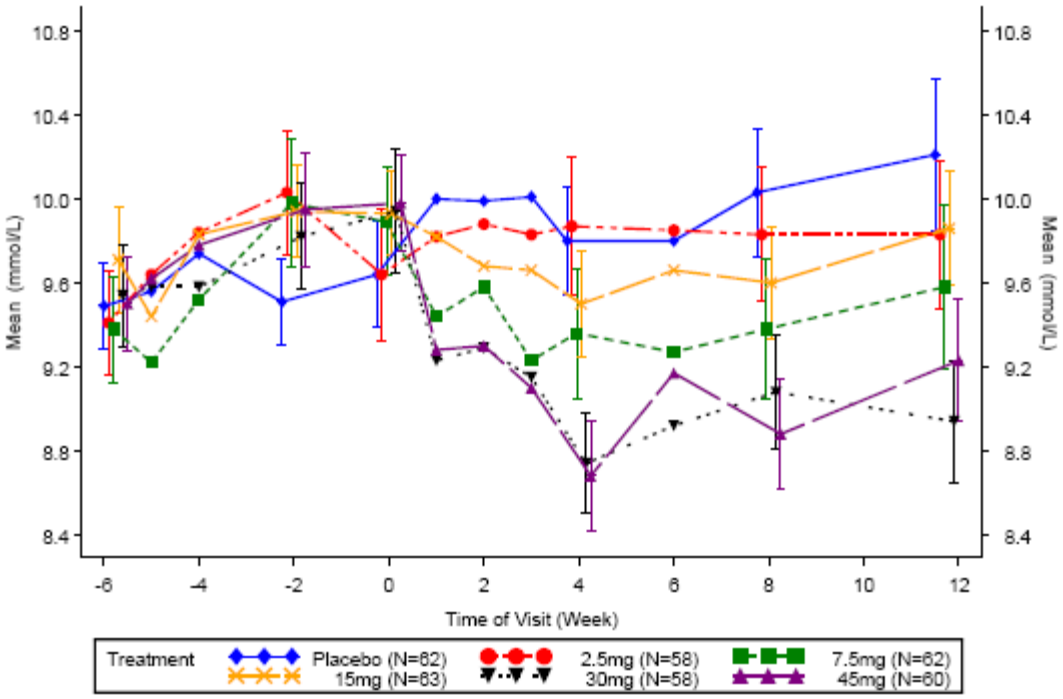
NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Summary statistics for change in FPG from baseline to Week 12 by prior therapy are provided in Section 13, Table 11.18. Decreases from baseline in FPG at Week 12 relative to placebo were generally greater in subjects previously treated with monotherapy compared to diet and exercise alone. At Week 12, the greatest decreases in FPG compared to baseline in the diet and exercise stratum were observed in the 30mg and 45mg DEN groups and in the monotherapy stratum in the 7.5mg, 30mg and 45mg DEN groups.

Results for mean FPG over time are provided in Section 13, Table 11.17 and illustrated graphically in Figure 7. The greatest decreases in mean FPG from baseline at each on-therapy visit were observed in the 30mg and 45mg DEN groups; decreases in mean FPG were generally similar at each time point in both groups. Mean FPG decreased rapidly over the first 4 weeks of treatment, with no further decrease apparent over the subsequent 8 weeks.

A rapid decrease in mean FPG over the first 4 weeks of treatment was also observed in the 7.5mg DEN group and to a lesser degree in the 15mg DEN group, with no further decrease apparent over the subsequent 8 weeks. Mean FPG was similar to baseline at all on-therapy visits in the 2.5mg DEN group and was generally above baseline at each on-therapy visit in the placebo group.

Figure 7 Mean (Plus and Minus SE) FPG (mmol/L) by Visit (ITT Population with LOCF)



Data Source: Section 13, Figure 11.16
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

7.2.1.3. HbA1c and FPG Target Achievers and Responders at Week 12

The proportions of subjects achieving target levels of HbA1c (≤6.5% and <7%) and the proportions of subjects who responded to treatment (HbA1c reduction of ≥0.7%) at Week 12 are summarised in Table 23 for the ITT Population with LOCF.

At Week 12, the proportion of subjects with a HbA1c value of ≤6.5% was highest in the 45mg and 30mg DEN groups (14% and 16%, respectively) but were not statistically significant compared with placebo.

At Week 12, the proportion of subjects with a HbA1c value of <7% was highest in the 45mg and 30mg DEN groups (24% and 25%, respectively) and although the numerical difference was small compared to the placebo proportion (19%), the 45mg DEN group was statistically significant (odds ratio: 3.24 [95% CI: 1.11, 9.52, p=0.032]).

At Week 12, the proportion of subjects with a reduction from baseline in HbA1c of ≥0.7% was highest in the 30mg DEN group (38%), followed by the 45mg group (29%) but were not statistically significant compared with placebo.

Table 23 Analysis of the Proportion of HbA1c Responders at Week 12 (ITT Population with LOCF)

HbA1c responders at Week 12, n (%)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	59	56	59	62	56	58
HbA1c ≤6.5%	6 (10%)	4 (7%)	4 (7%)	5 (8%)	9 (16%)	8 (14%)
Odds ratio vs PBO	-	0.92	1.15	1.20	2.68	3.24
95% CI	-	0.21, 3.95	0.27, 4.92	0.30, 4.83	0.74, 9.77	0.85, 12.37
P value	-	0.909	0.852	0.795	0.135	0.085
HbA1c <7%	11 (19%)	9 (16%)	12 (20%)	9 (15%)	14 (25%)	14 (24%)
Odds ratio vs PBO	-	1.10	1.99	1.04	2.15	3.24
95% CI	-	0.36, 3.36	0.69, 5.76	0.35, 3.13	0.76, 6.13	1.11, 9.52
P value	-	0.866	0.202	0.941	0.152	0.032
HbA1c reduction ≥0.7%	10 (17%)	6 (11%)	14 (24%)	10 (16%)	21 (38%)	17 (29%)
Odds ratio vs PBO	-	0.46	1.43	1.01	3.65	2.00
95% CI	-	0.14, 1.50	0.53, 3.85	0.36, 2.78	1.41, 9.48	0.76, 5.24
P value	-	0.198	0.481	0.991	0.008	0.161

Data Source: Section 13, Table 11.33

1. Number of subjects with a value at baseline and at Week 12

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

The proportions of subjects achieving target levels of FPG (<126mg/dL [7.0mmol/L] and the proportions of subjects who responded to treatment (≥30mg/dL [1.7mmol/L]) at Week 12 are summarised in Table 24 for the ITT Population with LOCF.

At Week 12, the proportion of subjects with a FPG <7.0mmol/L was similar in the 45mg, 7.5mg and 2.5mg DEN groups (range 14%-15%) and lowest in the 15mg group (6%) but were not statistically significant compared with placebo.

At Week 12, the proportion of subjects with a reduction from baseline in FPG of ≥1.7mmol/L was highest in the 45mg and 30mg DEN groups (30% and 31%, respectively) and was statistically significant for the 45mg (odds ratio: 3.00 [95% CI: 1.08, 8.30, p=0.034]) and 30mg (odds ratio: 3.24 [95% CI: 1.15, 9.13, p=0.026]) DEN groups.

Table 24 Analysis of the Proportion of FPG Responders at Week 12 (ITT Population with LOCF)

FPG responders at Week 12, n (%)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	62	58	62	63	58	60
FPG <7mmol/L	5 (8%)	8 (14%)	9 (15%)	4 (6%)	6 (10%)	9 (15%)
Odds ratio vs PBO	-	1.77	2.57	1.09	1.56	3.14
95% CI	-	0.50, 6.30	0.72, 9.11	0.26, 4.62	0.41, 5.91	0.89, 11.14
P value	-	0.380	0.145	0.906	0.509	0.077
Reduction ≥1.7mmol/L	8 (13%)	12 (21%)	13 (21%)	10 (16%)	18 (31%)	18 (30%)
Odds ratio vs PBO	-	1.90	1.59	1.35	3.24	3.00
95% CI	-	0.63, 5.72	0.55, 4.62	0.45, 4.00	1.15, 9.13	1.08, 8.30
P value	-	0.254	0.396	0.590	0.026	0.034

Data Source: Section 13, Table 11.35

1. Number of subjects with a value at baseline and at Week 12

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

7.2.1.4. Fructosamine, Fasting Serum Insulin, Pro-insulin and Pro-Insulin:insulin Ratio

Analysis of change from baseline to Week 12 in fructosamine is summarised in Table 25. The adjusted treatment difference was clinically and statistically significant for the 45mg (-38.9µmol/L [95% CI: -53.8, -23.9, p<0.001], 30mg (-39.6µmol/L [95% CI: -54.6, -24.6, p<0.001]; 15mg (-29.2µmol/L [95% CI: -43.9, -14.5, p<0.001]; and 7.5mg (-22.4µmol/L [95% CI: -37.1, -7.6, p=0.003] DEN groups, respectively. An increase in fructosamine at Week 12 compared to baseline was observed in the placebo group (mean±SE: 19.9±5.44µmol/L).

Table 25 Analysis of Change from Baseline in Fructosamine (mcmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in fructosamine (μmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	55	53	61	62	57	58
Baseline: mean±SD	306.5±39.3	312.8±53.5	311.0±53.1	308.6±48.8	312.3±55.7	316.3±55.1
Week 12: mean±SD	325.9±68.0	317.6±70.5	309.5±63.4	300.7±50.2	292.2±60.5	295.8±47.6
Adjusted change from baseline[2]: mean±SE	19.9±5.44	5.0±5.55	-2.5±5.16	-9.3±5.12	-19.7±5.34	-19.0±5.29
Adjusted mean difference vs PBO[2]:						
Mean	-	-14.9	-22.4	-29.2	-39.6	-38.9
[95% CI]	-	[-30.2, 0.5]	[-37.1, -7.6]	[-43.9, -14.5]	[-54.6, -24.6]	[-53.8, -23.9]
P-value	-	0.057	0.003	<0.001	<0.001	<0.001

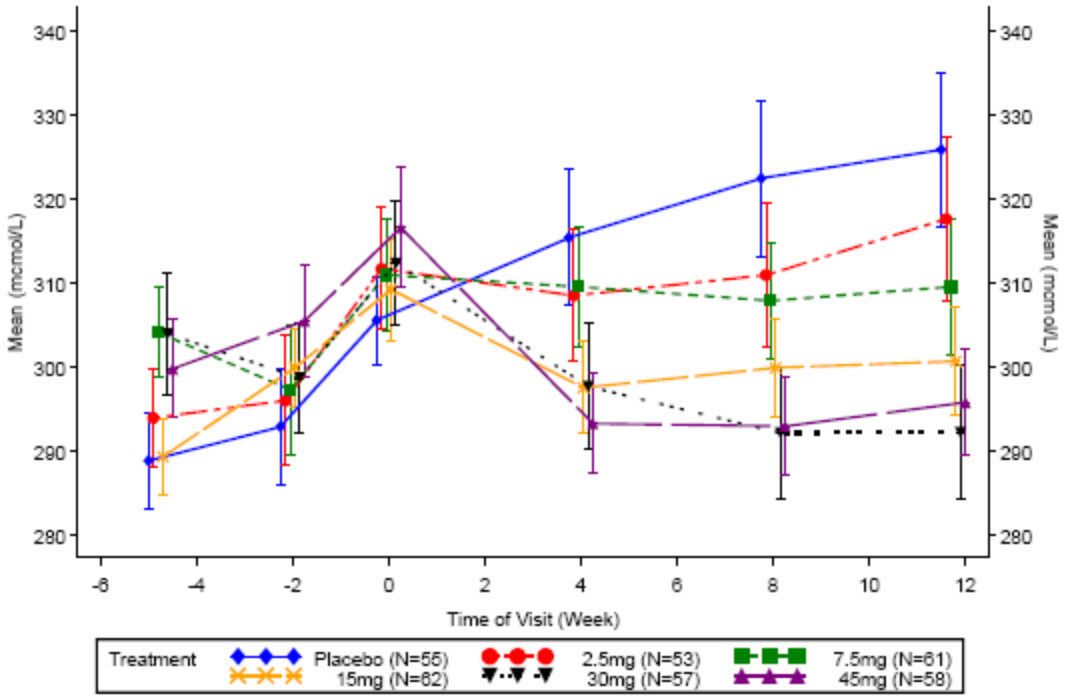
Data Source: Section 13, Table 11.22

1. Number of subjects with a value at baseline and at specified visit
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Results for mean fructosamine over time are provided in Section 13, Table 11.21 and illustrated graphically in Figure 8. Mean fructosamine decreased over the first 4 weeks of treatment, with no further decrease apparent over the subsequent 8 weeks. The greatest decreases in mean fructosamine from baseline at each on-therapy visit were observed in the 15mg, 30mg and 45mg DEN groups. Mean fructosamine was similar to baseline at each on-therapy visit in the 2.5mg and 7.5mg DEN groups and progressively increased above baseline at each on-therapy visit in the placebo group.

Figure 8 **Mean (Plus and Minus SE) Fructosamine (mcmol/L) by Visit (ITT Population with LOCF)**



Data Source: Section 13, Figure 11.23
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

Analysis of change from baseline to Week 12 in mean fasting serum insulin is summarised in Table 26. Results for mean fasting serum insulin over time are provided in Section 13, Table 11.24. Compared to placebo, there was a trend towards an increase in mean fasting serum insulin for all DEN groups although the treatment difference was not statistically significant. No trend with respect to dose of DEN was observed. 95% CIs were wide and overlapping across treatment groups reflecting the variability in the data.

There were visible outliers in the 7.5mg, 15mg and 45mg groups. These outliers were removed and the analysis re-run (Section 13, Table 11.56). The conclusions were not altered.

Table 26 Analysis of Change from Baseline in Fasting Serum Insulin (pmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in insulin (pmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	56	52	58	62	53	54
Baseline: mean±SD	87.8±52.4	104.1±82.8	113.9±109.4	104.0±65.5	87.5±47.2	109.5±73.5
Week 12: mean±SD	87.9±52.1	92.0±56.3	125.6±171.0	109.1±77.4	92.7±54.7	118.2±77.1
Adjusted change from baseline[2]: mean±SE	-2.04±8.51	-10.55±8.80	12.14±8.36	5.27±8.06	3.23±8.73	10.70±8.64
Adjusted mean difference vs PBO[2]:						
Mean	-	-8.51	14.18	7.31	5.27	12.74
[95% CI]	-	[-32.66, 15.65]	[-9.37, 37.72]	[-15.79, 30.42]	[-18.64, 29.17]	[-11.18, 36.65]
P-value	-	0.489	0.237	0.534	0.665	0.295

Data Source: Section 13, Table 11.25

1. Number of subjects with a value at baseline and at specified visit
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Analysis of change from baseline to Week 12 in mean fasting pro-insulin is summarised in Table 27. Results for mean fasting pro-insulin over time are provided in Section 13, Table 11.27. There was no consistent trend with respect to change from baseline in mean fasting pro-insulin compared to placebo for the DEN groups; the treatment difference was not statistically significant.

Table 27 Analysis of Change from Baseline in Fasting Pro-Insulin (pmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in pro-insulin (pmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	57	53	61	62	56	58
Baseline: mean±SD	30.2±30.19	36.9±22.12	36.9±22.12	35.5±32.79	32.2±20.25	37.4±31.41
Week 12: mean±SD	27.4±19.62	35.2±25.87	32.8±31.97	30.7±26.90	26.3±15.64	34.8±34.33
Adjusted change from baseline[2]: mean±SE	-4.28±2.33	-0.97±2.42	-1.21±2.25	-4.63±2.23	-6.49±2.35	-1.53±2.31
Adjusted mean difference vs PBO[2]:						
Mean	-	3.31	3.06	-0.35	-2.21	2.75
[95% CI]	-	[-3.32, 9.94]	[-3.31, 9.44]	[-6.70, 6.00]	[-8.71, 4.29]	[-3.71, 9.22]
P-value	-	0.327	0.345	0.914	0.504	0.403

Data Source: Section 13, Table 11.28

1. Number of subjects with a value at baseline and at specified visit
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Analysis of change from baseline to Week 12 in mean pro-insulin:insulin ratio is summarised in Table 28. Change from baseline by visit is shown in Figure 9. Results for mean pro-insulin:insulin ratio over time are provided in Section 13, Table 11.30.

At Week 12, 2-, 3-, 4- and 3-fold decreases relative to placebo in change from baseline in mean pro-insulin:insulin ratio was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups, respectively. The adjusted treatment difference compared to placebo was not statistically significant, although there was a trend towards clinical improvement with DEN. A mean±SE decrease of -0.02±0.018 was observed in the placebo group.

Table 28 Analysis of Change from Baseline in Pro-Insulin:Insulin Ratio at Week 12 (ITT Population with LOCF)

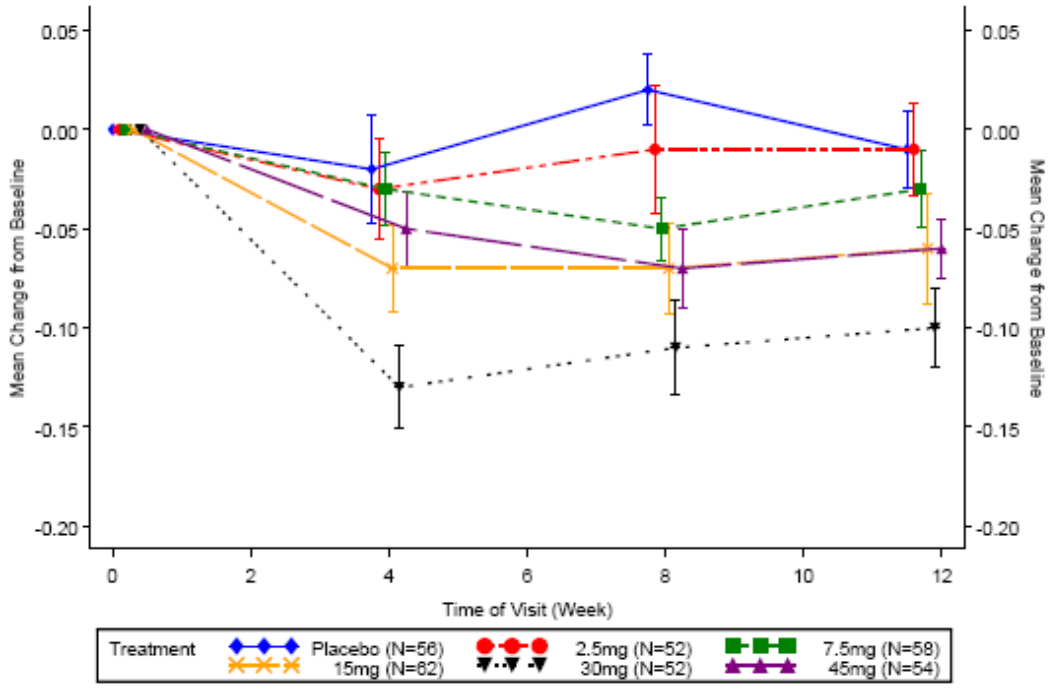
Change from baseline in pro-insulin:insulin ratio	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	56	52	58	62	52	54
Baseline: mean±SD	0.35±0.24	0.43±0.29	0.35±0.21	0.38±0.25	0.41±0.22	0.36±0.17
Week 12: mean±SD	0.34±0.19	0.42±0.26	0.32±0.20	0.32±0.23	0.31±0.15	0.31±0.14
Adjusted change from baseline[2]: mean±SE	-0.02±0.018	0.01±0.019	-0.04±0.018	-0.06±0.017	-0.08±0.018	-0.06±0.018
Adjusted mean difference vs PBO[2]:						
Mean	-	0.03	-0.02	-0.04	-0.06	-0.04
[95% CI]	-	[-0.02, 0.08]	[-0.07, 0.03]	[-0.09, 0.01]	[-0.11, -0.01]	[-0.09, 0.01]
P-value	-	0.286	0.457	0.136	0.021	0.094

Data Source: Section 13, Table 11.31

1. Number of subjects with a value at baseline and at specified visit
2. Based on ANCOVA: change = baseline + gender + region + prior therapy + treatment

NOTE: A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

Figure 9 Mean (Plus and Minus SE) Change from Baseline in Pro-Insulin:Insulin Ratio by Visit (ITT Population with LOCF)



Data Source: Section 13, Figure 11.33
NOTE: Subjects shown at each visit are those with values at baseline and that visit.
N = No. subjects at Week 12 (after LOCF)

Results for the adjusted change from baseline to Week 12 in mean fasting serum insulin and mean pro-insulin:insulin ratio by region (Europe and US/Canada) are summarised in Section 13, Tables 11.66, 11.68, 11.70 and 11.72. There was no consistent difference in results between regions; the 95% CIs were wide and overlapping across regions, reflecting the variability in the data.

7.3. Other Efficacy Results

7.3.1. HOMA

Results for HOMA IS and BCF at Weeks 4, 8 and 12 based on log-transformed data are provided in Section 13, Tables 11.52 and 11.53, respectively, and are shown in Table 29 for Week 12 only.

At Week 12, small percent decreases in HOMA IS, which were not clinically relevant, compared to baseline were observed in the 15mg, 30mg and 45mg DEN groups (-3.96% [-SE, +SE: -10.27, 2.79], -2.14% [-SE, +SE: -6.90, 2.86] and -5.72% [-SE, +SE: -12.00, 1.00], respectively). A decrease in HOMA IS was also observed in the placebo group (percent change from baseline: -3.17% [-SE,+SE: -8.93, 2.95].

At Week 12, a percent increase in HOMA BCF compared to baseline was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups. The greatest increases were observed in the 30mg and 45mg groups (percent change: 25.40 [-SE,+SE: 17.42, 33.92] and 25.36 [-SE,+SE: 17.63, 33.59], respectively) which were clinically relevant. A small decrease in HOMA BCF was observed in the placebo group (-5.13 [-SE,+SE: -10.61, 0.69]).

No apparent trend in change from baseline over time in either HOMA IS or BCF was observed in any DEN group.

Table 29 Summary Statistics of Log-Transformed HOMA IS (%) and BCF (%) at Week 12 (ITT Population with LOCF)

HOMA		Denagliptin				
	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
HOMA IS (%), n[1]	53	49	55	62	52	53
Baseline: GM	58.89	56.18	51.51	53.51	61.39	53.29
(CV%)[2]	61.80	54.56	60.89	64.29	60.75	63.84
Week 12: GM	57.02	58.91	51.59	51.39	60.07	50.24
[-SE, +SE][3]	[53.05, 61.30]	[54.13, 64.12]	[47.40, 56.16]	[47.59, 55.48]	[55.79, 64.69]	[46.12, 54.72]
Ratio to baseline[4]:						
GM	-3.17	4.86	0.17	-3.96	-2.14	-5.72
[-SE, +SE][3]	[-8.93, 2.95]	[-1.79, 11.96]	[-6.20, 6.97]	[-10.27, 2.79]	[-6.90.2.86]	[-12.00, 1.00]
BCF (%), n[1]	53	49	55	62	52	52
Baseline: GM	36.96	38.35	38.47	37.32	33.97	37.74
(CV%)[2]	54.41	62.16	58.30	58.10	70.88	65.48
Week 12: GM	35.06	36.85	42.15	39.46	42.60	47.31
[-SE, +SE][3]	[32.15, 38.24]	[33.51, 40.53]	[38.69, 45.92]	[36.84, 42.26]	[38.67, 46.92]	[43.46, 51.51]
Ratio to baseline[4]:						
GM	-5.13	-3.91	9.57	5.75	25.40	25.36
[-SE, +SE][3]	[-10.61, 0.69]	[-9.34, 1.83]	[3.38, 16.14]	[0.11, 11.71]	[17.42, 33.92]	[17.63, 33.59]

Data Source: Section 13, Tables 11.52, 11.53

1. Number of subjects with a value at baseline and at specified visit
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. SE in log scale added or subtracted, then entire quantity exponentiated
4. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)

Results for percent change from baseline to Week 12 in HOMA IS and BCF by region (Europe and US/Canada) are summarised in Section 13, Tables 11.74 and 11.75. There was no consistent difference in results between regions; the 95% CIs were wide and overlapping across regions, reflecting the variability in the data.

7.3.2. Lipids

Triglycerides

Analysis of change from baseline to Week 12 in TGs based on log-transformed data is shown in Table 30. The adjusted treatment difference compared to placebo showed

percent decreases in TGs for all DEN groups which were not statistically significant. A mean percent decrease (GM [-SE, +SE]) from baseline of -1.42% [-5.61, 2.96] was observed in the placebo group.

An outlier was observed in the 30mg group. This outlier was removed and the analysis re-run (Section 13, Table 11.58). Although, there was less of an effect observed in this treatment group, the conclusions remained the same.

Table 30 Analysis of Log-transformed Triglycerides (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in TGs (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	58	58	60	62	56	58
Baseline: GM	2.01	1.90	1.82	1.92	2.00	1.99
(CV%)[2]	(38.36)	(54.15)	(55.86)	(47.61)	(49.87)	(54.80)
Week 12: GM	1.96	1.82	1.66	1.87	1.63	1.76
[-SE, +SE]	[1.86, 2.07]	[1.71, 1.94]	[1.56, 1.77]	[1.77, 1.99]	[1.56, 1.71]	[1.66, 1.86]
Adjusted ratio to baseline[3,4]:						
GM	-1.42	-4.62	-11.02	-2.82	-17.46	-10.37
[-SE, +SE]	[-5.61, 2.96]	[-8.67, -0.39]	[-14.73, -7.14]	[-6.80, 1.33]	[-21.02, -13.74]	[-14.17, -6.40]
Adjusted percent difference vs PBO[4]						
GM	-	-3.25	-9.74	-1.42	-16.27	-9.08
[95% CI]	-	[-14.03, 9.22]	[-19.93, 1.75]	[-12.46, 11.01]	[-25.85, -5.46]	[-19.42, 2.58]
p-value[5]	-	0.592	0.094	0.813	0.004	0.122

Data Source: Section 13, Table 11.38

1. Number of subjects with a value at baseline and at Week 12
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)
4. Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy +Treatment.
5. A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference were for descriptive purposes only.

Results for mean TGs over time are provided in Section 13, Table 11.37 and Figure 11.40.

Free fatty acids

Analysis of change from baseline to Week 12 in FFAs at Week 12 based on log-transformed data is shown in Table 31. The adjusted treatment difference relative to placebo showed no consistent trend in FFAs across the DEN groups; there were no statistically significant differences. A mean (GM [-SE, +SE]) percent decrease from baseline of -4.14% [-9.09, 1.08] was observed in the placebo group.

Table 31 Analysis of Log-transformed FFAs (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in FFAs (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	57	52	61	62	56	57
Baseline: GM	0.49	0.55	0.52	0.48	0.54	0.47
(CV%)[2]	(41.72)	(44.60)	(48.02)	(49.13)	(41.29)	(42.16)
Week 12: GM	0.47	0.50	0.46	0.48	0.46	0.47
[-SE, +SE]	[0.44, 0.51]	[0.47, 0.53]	[0.44, 0.49]	[0.46, 0.51]	[0.43, 0.50]	[0.44, 0.50]
[3]						
Adjusted ratio to baseline[3,4]:						
GM	-4.14	-4.61	-10.11	-2.82	-11.35	-4.25
[-SE, +SE]	[-9.09, 1.08]	[-9.78, 0.86]	[-14.60, -5.39]	[-7.64, 2.24]	[-15.97, -6.48]	[-9.19, 0.97]
[3]						
Adjusted percent difference vs PBO[4]						
GM	-	-0.48	-6.23	1.38	-7.52	-0.11
[95% CI]	-	[-14.49, 15.82]	[-18.89, 8.42]	[-12.27, 17.15]	[-20.26, 7.24]	[-13.80, 15.77]
P-value[5]	-	0.950	0.384	0.853	0.300	0.989

Data Source: Section 13, Table 11.41

1. Number of subjects with a value at baseline and at Week 12
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)
4. Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy +Treatment
5. A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference were for descriptive purposes only.

Results for mean FFAs over time are provided in Section 13, Table 11.40 and Figure 11.43.

Total cholesterol

Analysis of change from baseline to Week 12 in TC based on log-transformed data is shown in Table 32. The adjusted treatment differences relative to placebo showed percent decrease in TC across the DEN groups although the differences were not statistically significant. A mean (GM [-SE, +SE]) percent increase from baseline of 0.17% (-1.70, 2.07) was observed in the placebo group.

Table 32 Analysis of Log-transformed Total Cholesterol (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in TC (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	58	58	60	62	56	58
Baseline: GM	5.13	5.24	5.21	5.09	5.42	5.28
(CV%)[2]	(19.69)	(23.68)	(19.75)	(21.13)	(19.98)	(17.95)
Week 12: GM	5.17	5.36	5.22	5.13	5.29	5.16
[-SE, +SE]	[5.05, 5.29]	[5.23, 5.49]	[5.09, 5.37]	[4.99, 5.28]	[5.15, 5.43]	[5.03, 5.29]
Adjusted ratio to baseline[3,4]:						
GM	0.17	2.63	-0.14	0.04	-1.42	-1.70
[-SE, +SE][3]	[-1.70, 2.07]	[0.72, 4.58]	[-1.97, 1.72]	[-1.76, 1.88]	[-3.29, 0.49]	[-3.52, 0.17]
Adjusted percent difference vs PBO[4]						
GM	-	2.46	-0.31	-0.13	-1.59	-1.86
[95% CI]	-	[-2.79, 7.99]	[-5.35, 5.00]	[-5.14, 5.15]	[-6.65, 3.75]	[-6.87, 3.41]
P-value[5]	-	0.364	0.906	0.961	0.552	0.481

Data Source: Section 13, Table 11.44

1. Number of subjects with a value at baseline and at Week 12
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)
4. Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy +Treatment
5. A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference were for descriptive purposes only.

Results for mean TC over time are provided in Section 13, Table 11.43 and Figure 11.46.

HDL-c

Analysis of change from baseline to Week 12 in HDL-c based on log-transformed data is shown in Table 33. The adjusted treatment difference relative to placebo showed no consistent trend across the DEN groups, differences were not statistically significant. A mean (GM [-SE, +SE]) percent increase from baseline of 4.36% [2.71, 6.04] was observed in the placebo group.

Table 33 Analysis of Log-transformed HDL-c (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in HDL-c (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	58	58	60	62	56	58
Baseline: GM	1.17	1.26	1.24	1.21	1.23	1.23
(CV%)[2]	(20.95)	(26.66)	(26.61)	(27.57)	(22.63)	(26.07)
Week 12: GM	1.23	1.26	1.30	1.22	1.27	1.27
[-SE, +SE]	[1.20, 1.27]	[1.23, 1.30]	[1.25, 1.34]	[1.18, 1.26]	[1.23, 1.30]	[1.22, 1.31]
Adjusted ratio to baseline[3,4]:	4.36	1.03	4.81	0.50	3.02	3.42
GM	[2.71, 6.04]	[-0.59, 2.65]	[3.18, 6.46]	[-1.04, 2.06]	[1.37, 4.71]	[1.78, 5.07]
[-SE, +SE][3]						
Adjusted percent difference vs PBO[4]						
GM	-	-3.20	0.43	-3.70	-1.28	-0.91
[95% CI]	-	[-7.42, 1.23]	[-3.89, 4.95]	[-7.81, 0.60]	[-5.60, 3.23]	[-5.21, 3.59]
P-value[5]	-	0.154	0.848	0.090	0.570	0.687

Data Source: Section 13, Table 11.47

1. Number of subjects with a value at baseline and at Week 12
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)
4. Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy +Treatment
5. A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference were for descriptive purposes only

Results for mean HDL-c over time are provided in Section 13, Table 11.46 and Figure 11.49.

LDL-c

Analysis of change from baseline to Week 12 in LDL-c based on log-transformed data is shown in Table 34. The adjusted treatment differences relative to placebo showed no consistent trends across the DEN groups; differences were not statistically significant. A mean (GM [-SE, +SE]) percent decrease from baseline of -1.25% [-4.09, 1.68] was observed in the placebo group.

Table 34 Analysis of Log-transformed LDL-c (mmol/L) at Week 12 (ITT Population with LOCF)

Change from baseline in LDL-c (mmol/L)	Placebo (N=62)	Denagliptin 2.5mg (N=59)	Denagliptin 7.5mg (N=62)	Denagliptin 15mg (N=63)	Denagliptin 30mg (N=58)	Denagliptin 45mg (N=60)
n[1]	58	55	56	59	55	55
Baseline: GM	2.92	2.95	3.03	2.85	3.18	2.97
(CV%)[2]	(31.25)	(34.71)	(31.19)	(38.82)	(28.86)	(33.17)
Week 12: GM	2.89	3.14	3.03	2.85	3.19	2.96
[-SE, +SE]	[2.79, 3.00]	[3.02, 3.25]	[2.90, 3.16]	[2.69, 3.01]	[3.07, 3.32]	[2.84, 3.08]
Adjusted ratio to baseline[3,4]:	-1.25	6.18	0.44	-1.47	1.70	-0.26
GM	[-4.09,	[3.03, 9.41]	[-2.49, 3.46]	[-4.28, 1.42]	[-1.31, 4.80]	[-3.20, 2.76]
[-SE, +SE][3]	1.68]					
Adjusted percent difference vs PBO[4]						
GM	-	7.52	1.71	-0.23	2.98	1.00
[95% CI]	-	[-1.02, 16.79]	[-6.29, 10.38]	[-7.97, 8.17]	[-5.15, 11.82]	[-6.97, 9.64]
P-value[5]	-	0.086	0.684	0.956	0.483	0.812

Data Source: Section 13, Table 11.50

1. Number of subjects with a value at baseline and at Week 12
2. CV (Coefficient of variation) = 100*sqrt (exp[(SD on log scale)^2]-1)
3. % change based on log-transformed data: 100*(exp[mean change on log scale]-1)
4. Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy +Treatment
5. A closed test procedure was used. Tests were performed in a hierarchical manner, that is, tests were applied sequentially where testing did not proceed to the next step unless the previous test was found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference were for descriptive purposes only.

Results for mean LDL-c over time are provided in Section 13, Table 11.49 and Figure 11.52.

7.4. Efficacy Conclusions

- The overall dose response profile supports achievement of glycaemic efficacy. All doses of denagliptin with the exception of the 2.5mg dose, produced clinically and statistically significant reductions in HbA1c from baseline at week 12 compared to placebo. Generally the reductions in HbA1c were dose dependent (ranging from -0.28% at the 2.5mg dose to -0.84% at the 45mg dose relative to placebo) although the 7.5mg produced a slightly larger reduction than the 15mg dose.
- At Week 12, for subjects previously treated with monotherapy there was an increase in the placebo group, this resulted in a greater decrease from baseline in HbA1c relative to placebo in subjects previously treated with monotherapy compared to diet and exercise.
- Mean decreases in HbA1c from baseline were apparent by Week 4 of treatment. In the 30mg and 45mg DEN groups further decreases in HbA1c were observed at 8 weeks which were sustained to Week 12.

- Reductions from baseline to week 12 in FPG relative to placebo, were clinically and statistically significant (accounting for the closed test procedure) at the 30 (-1.46mmol/L) and 45mg (-1.22mmol/L) doses of DEN.
- Except for the placebo and 2.5mg DEN groups, mean FPG decreased rapidly over the first 4 weeks of treatment, with no further decrease apparent over the subsequent 8 weeks.
- At Week 12, the proportion of subjects achieving a HbA1c value of ≤6.5% and <7% was slightly higher in the 45mg and 30mg DEN groups than the placebo group.
- The proportion of subjects achieving a FPG <7.0mmol/L at week 12 with DEN was not significantly different to placebo.
- At Week 12, the proportion of subjects with a reduction from baseline in HbA1c of ≥0.7% or FPG of ≥1.7mmol/L was highest in the 30mg (38% and 31%, respectively) and 45mg (29% and 30%, respectively) DEN groups. However relative to placebo (13%), the treatment difference was only statistically significant for FPG at the 45mg and 30mg DEN groups.
- All doses of denagliptin with the exception of the 2.5mg dose, produced clinically and statistically significant reductions in fructosamine from baseline at week 12 compared to placebo.
- Relative to placebo, there were statistically non-significant changes (accounting for the closed test procedure) in fasting serum insulin, pro-insulin and the proinsulin:insulin ratio from baseline to week 12 at all doses of DEN. Although, not statistically significant, there was a trend for clinical improvement in the pro-insulin:insulin ratio with DEN.
- At Week 12, small percent decreases in HOMA IS compared to baseline were observed in the 15mg, 30mg and 45mg DEN groups; a similar decrease was observed in the placebo group. Percent increases in HOMA BCF compared to baseline was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups with the greatest increases in the 30mg and 45mg groups. A small decrease in HOMA BCF was observed in the placebo group.
- Relative to placebo, there were no detrimental or clinically relevant or statistically significant changes (accounting for the closed test procedure) in fasting serum lipids from baseline to week 12 at all doses of DEN. No trend with respect to dose of DEN was observed.

8. SAFETY RESULTS

8.1. Extent of Exposure

The numbers of subjects in each treatment group exposed to study medication, and the duration of exposure are summarised in Table 35. The mean duration of exposure to study medication during the double-blind Main Phase was slightly shorter in the placebo (69.6 days) and 2.5mg DEN (72.4 days) groups compared to the higher DEN dose groups (range 76.7 to 79.5 days). However, the median duration of exposure to study medication was the same across all treatment groups. Twenty-three percent of subjects received placebo for more than 84 days (i.e. 12 weeks) compared to 33% who received 2.5mg DEN, 38% who received 7.5mg DEN, 29% who received 15mg DEN, 33% who received 30mg DEN and 36% who received 45mg DEN.

Table 35 Duration of Exposure to Double-Blind Study Medication (Safety Population

Subject exposure (days), n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
≤14	6 (9%)	2 (3%)	3 (5%)	4 (6%)	2 (3%)	0
15-28	2 (3%)	3 (5%)	1 (2%)	1 (2%)	0	3 (5%)
29-56	9 (14%)	8 (13%)	3 (5%)	4 (6%)	2 (3%)	4 (7%)
57-84	32 (50%)	28 (46%)	32 (51%)	38 (58%)	36 (60%)	32 (52%)
>84	15 (23%)	20 (33%)	24 (38%)	19 (29%)	20 (33%)	22 (36%)
Mean±SD	69.6±25.04	72.4±24.11	78.2±20.65	76.7±21.61	79.5±16.68	78.2±17.45
Median	84.0	84.0	84.0	84.0	84.0	84.0
Range	5-94	1-92	8-105	5-94	7-91	18-95

Data Source: Section 14, Table 12.1

8.2. Adverse Events

8.2.1. Frequency of Adverse Events

Run-in Phase

The most commonly occurring AEs (i.e. events reported by more than one subject) during the run-in phase are presented in Table 36. Only one AE was reported by more than two subjects in any treatment group: nasopharyngitis by 3 subjects in the 2.5mg DEN group.

Table 36 Pre-Therapy Adverse Events Reported by at Least Two Subjects in Any Treatment Group (Safety Population)

AE by Preferred Term, n (%)		Denagliptin				
	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Subjects with at least 1 AE	12 (19%)	15 (25%)	11 (17%)	17 (26%)	4 (7%)	11 (18%)
Nasopharyngitis	0	3 (5%)	1 (2%)	2 (3%)	1 (2%)	1 (2%)
Hypoaesthesia	0	2 (3%)	0	0	0	0
Nausea	2 (3%)	0	0	0	0	1 (2%)
Abdominal pain upper	0	0	0	2 (3%)	0	0
Shoulder pain	0	0	0	2 (3%)	0	0
Chest pain	0	0	1 (2%)	2 (3%)	0	0
Fatigue	1 (2%)	0	0	0	0	2 (3%)

Data Source: Section 14, Table 12.2

On-therapy Phase

On-therapy events occurring in more than one subject (in any treatment group) are summarised in Table 37. Across DEN groups, 36% of subjects reported at least one on-therapy AE. The incidence of on-therapy AEs was highest in the 15mg DEN group (42%) and lowest in the 7.5mg and 30mg groups (both 32%); 38% of subjects reported AEs in the placebo group. Hypoglycaemic events are not included in Table 37, but are discussed in Section 8.5.4.

The system organ classes most frequently involved were infections and infestations in the placebo (11%), 2.5mg DEN (11%), 7.5mg DEN (16%), 15mg DEN (14%), 30mg DEN (10%) and 45mg DEN (15%) groups, gastrointestinal disorders in the placebo (11%), 15mg DEN (11%), 30mg DEN (12%) and 45mg DEN (10%) groups and musculoskeletal and connective tissue disorders in the 15mg DEN (12%) and 45mg DEN (15%) groups (Section 14, Table 12.3).

The most frequently occurring AEs were nasopharyngitis in the 7.5mg DEN group (11%) and back pain and nausea in the 15mg DEN group (both 6%). All other AEs occurred with an incidence ≤5% in any treatment group. No AE increased in incidence with increasing dose of DEN.

Table 37 On-Therapy Adverse Events Reported by at Least Two Subjects in Any Treatment Group (Safety Population)

AE by Preferred Term, n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Subjects with at least 1 AE	24 (38%)	22 (36%)	20 (32%)	28 (42%)	19 (32%)	23 (38%)
Dizziness	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	2 (3%)
Upper respiratory tract infection	1 (2%)	2 (3%)	1 (2%)	1 (2%)	0	2 (3%)
Acute sinusitis	0	0	0	0	0	2 (3%)
Back pain	1 (2%)	0	0	4 (6%)	0	2 (3%)
Muscle spasms	0	0	0	0	0	2 (3%)
Headache	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0	2 (3%)
Constipation	3 (5%)	0	0	2 (3%)	1 (2%)	1 (2%)
Arthralgia	0	2 (3%)	0	1 (2%)	0	1 (2%)
Hypertension	1 (2%)	0	2 (3%)	0	0	1 (2%)
Nasopharyngitis	3 (5%)	3 (5%)	7 (11%)	3 (5%)	3 (5%)	0
Nausea	1 (2%)	2 (3%)	2 (3%)	4 (6%)	1 (2%)	0
Influenza	0	0	0	2 (3%)	0	0
Abdominal pain	2 (3%)	0	0	0	0	0
Cough	2 (3%)	0	0	1 (2%)	0	0
Hyperglycaemia	0	3 (5%)	0	0	0	0
Vision blurred	0	0	2 (3%)	0	0	0

Data Source: Section 14, Table 12.3
NOTE: Hypoglycaemic events that were not SAEs are reported separately
Sorted by descending order for the 45mg DEN group

Post Therapy Phase

A summary of all post therapy AEs is provided in Section 14, Table 12.4. Three post therapy AEs occurred in 2 subjects in the placebo group: influenza, pneumonia and abdominal pain upper.

8.2.1.1. Adverse Events Related to Treatment

On-therapy AEs considered to be related to study medication are summarised in Section 14, Table 12.6. Only two AEs considered to be related to study medication were reported by more than one subject in any treatment group: constipation in two subjects in the placebo group and hyperglycaemia in three subjects in the 2.5mg DEN group.

8.2.1.2. Adverse Events by Maximum Intensity

The proportions of subjects with mild, moderate or severe events are summarised by maximum intensity in Table 38. Most events were of mild or moderate intensity.

Table 38 On-Therapy Adverse Events by Maximum Intensity (Safety Population)

Maximum Intensity of AEs, n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Mild	13 (20%)	6 (10%)	17 (27%)	13 (20%)	8 (13%)	12 (20%)
Moderate	11 (17%)	13 (21%)	3 (5%)	14 (21%)	10 (17%)	8 (13%)
Severe	0	3 (5%)	0	1 (2%)	1 (2%)	3 (5%)

Data Source: Section 14, Table 12.5

All severe AEs are listed in Table 39. Three subjects in each of the 45mg DEN and 2.5mg DEN groups, and one subject in each of the 15mg DEN and 30mg DEN groups had severe on-therapy AEs. No severe AE was reported by more than one subject in any treatment group. One severe event of hyperglycaemia was reported, by one subject in the 2.5mg DEN group.

Table 39 Severe On-Therapy Adverse Events (Safety Population)

AE by Preferred Term, n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Subjects with at least 1 severe AE	0	3 (5%)	0	1 (2%)	1 (2%)	3 (5%)
Intestinal polyp[1]	0	0	0	0	0	1 (2%)
Tension headache	0	0	0	0	0	1 (2%)
Renal colic	0	0	0	0	0	1 (2%)
Cerebrovascular accident	0	0	0	0	1 (2%)	0
Nausea	0	0	0	1 (2%)	0	0
Gout	0	1 (2%)	0	0	0	0
Dyspepsia	0	1 (2%)	0	0	0	0
Hyperglycaemia	0	1 (2%)	0	0	0	0

Data Source: Section 14, Table 12.5
NOTE: Hypoglycaemic events that were not SAEs are reported separately
1. The AE term 'intestinal polyp' has been clarified and is now known to be an event of 'diverticular perforation'

8.3. Serious Adverse Events

A SAE was defined as any event which was fatal, life threatening, disabling or incapacitating or resulted in hospitalisation, prolonged a hospital stay or was associated with congenital abnormality/birth defect. In addition, any event which the investigator regarded as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may have been associated with the use of the drug was to be documented as a serious event.

8.3.1. Deaths

No subjects died.

8.3.2. Non-Fatal Events

8.3.2.1. Pre-therapy Non-fatal Serious Adverse Events

[redacted] The event was ongoing at the time of withdrawal and was considered by the investigator to be unrelated to study medication.

A full narrative for the subject with a pre-therapy SAE is provided in Section 15.

8.3.2.2. On-therapy Non-fatal Serious Adverse Events

Five subjects experienced six on-therapy non-fatal SAEs (Table 40 and Table 41): one subject in each of the placebo, 2.5mg DEN and 45mg DEN groups and two in the 30mg DEN group.

One on-therapy non-fatal SAE was reported by the investigator as being related to study treatment. [redacted] The event was moderate in intensity for which the subject was withdrawn. The event was resolving at the time of withdrawal.

Brief narratives for the two subjects in the 30mg DEN group experiencing SAEs of stroke and cerebrovascular accident follow.

[redacted]

[redacted] Concomitant medications included cilazapril (Inhibace), metoprolol tartrate (Vasocardin), rhefluin and amlodipine (Amlodipin). [redacted] The subject was withdrawn from the study. The subject was discharged from hospital after approximately 5 months; the event was considered resolved with sequelae. [redacted]

Full narratives for subjects with on-therapy SAEs are provided in Section 15.

Table 40 Summary of On-Therapy Non-Fatal Serious Adverse Events (Safety Population)

AE by Preferred Term, n (%)	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Subjects with at least 1 SAE	1 (2%)	1 (2%)	0	0	2 (3%)	1 (2%)
Intestinal polyp[1]	0	0	0	0	0	1 (2%)
Cerebrovascular accident	0	0	0	0	1 (2%)	0
Hemiparesis	0	0	0	0	1 (2%)[2]	0
Ischaemic stroke	0	0	0	0	1 (2%)[2]	0
Laryngitis	0	1 (2%)	0	0	0	0
Gastroenteritis	1 (2%)	0	0	0	0	0

Data Source: Section 14, Table 12.10

1. The AE term 'intestinal polyp' has been clarified and is now known to be an event of 'diverticular perforation'
2. The events of hemiparesis and ischaemic stroke occurred in the same subject

Table 41 Listing of Subjects with On-Therapy Non-Fatal Serious Adverse Events (Safety Population)

Data Source: Listing 26

1. Relative to first dose of randomised study medication
2. Study number 925 = protocol number DPB100925
3. The AE term 'intestinal polyp' has been clarified and is now known to be an event of 'diverticular perforation

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8.3.2.3. Post-therapy Non-fatal Serious Adverse Events

There were no subjects with post-therapy, non-fatal SAEs.

8.4. Adverse Events Leading to Premature Discontinuation of Investigational Product and/or Study

8.4.1. Pre-therapy Adverse Events Leading to Withdrawal

Three subjects experienced an AE during the run-in period which resulted in withdrawal from the Main Phase of the study post randomisation: paraesthesia (placebo group), bladder neoplasm (placebo group), hypoaesthesia (2.5mg DEN group) (Section 14, Table 12.13).

8.4.2. On-therapy Adverse Events Leading to Withdrawal

A summary of on-therapy AEs which led to premature withdrawal of subjects from the Main Phase of the study is provided in Table 42. Three subjects (5%) in the placebo group, three subjects (5%) in the 2.5mg DEN group and one subject (2%) in the 30mg DEN group had AEs leading to withdrawal.

One AE led to the withdrawal of more than one subject: hyperglycaemia in the 2.5mg DEN group led to withdrawal of 2 subjects.

Table 42 Summary of Subject Withdrawals Due to On-Therapy Adverse Events (Safety Population)

AE by Preferred Term, n (%)		Denagliptin				
	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Subjects with at least 1 AE leading to withdrawal	3 (5%)	3 (5%)	0	0	1 (2%)	0
Cerebrovascular accident	0	0	0	0	1 (2%)	0
Hyperglycaemia	0	2 (3%)	0	0	0	0
Laryngitis	0	1 (2%)	0	0	0	0
Gastroenteritis	1 (2%)	0	0	0	0	0
Headache	1 (2%)	0	0	0	0	0
Ventricular extrasystoles	1 (2%)	0	0	0	0	0

Data Source: Section 14, Table 12.14

8.5. Other Relevant On-therapy Adverse Events

On-therapy AEs for additional safety consideration, i.e., those identified as being of clinical relevance in assessing the safety of DEN, were myalgia, hypertension, blood pressure increased, fluid retention and hypoglycaemia.

8.5.1. Myalgia

Two events of myalgia were reported, one in the placebo group of mild intensity and one in the 45mg DEN group of moderate intensity. The event of myalgia in the 45mg DEN group was considered to be related to study medication; there was no apparent association with increased CK-MB values for this subject (baseline: 2.3µg/L; Week 4: 3.4µg/L [early withdrawal visit; subject was withdrawn due to non-compliance with visit schedules]).

8.5.2. Hypertension/Blood Pressure Increased

Hypertension as an AE was reported in four subjects, one in the placebo group, two in the 7.5mg DEN group and one in the 45mg DEN group. Three of these subjects presented at baseline with cardiac/vascular disorders. The remaining subject, in the 7.5mg DEN group, experienced mild hypertension on Day 57 which was ongoing at study end. The hypertension did not lead to the subject's withdrawal from the study and was considered to be related to study medication. No on-therapy vital sign assessment for this subject was outside the range of clinical concern.

[redacted] The AE was mild in intensity, lasted for one day and considered to be unrelated to study medication.

On-therapy blood pressure values recorded during the study considered to be of potential clinical concern are detailed in Section 8.8.1.

8.5.3. Fluid Retention

One event of fluid retention was reported which was mild in intensity, occurring in the 45mg DEN group, and considered to be unrelated to study medication. No oedema-related AEs were reported in any treatment group.

8.5.4. Hypoglycaemia

Three subjects reported three hypoglycaemic events, all of which were mild in intensity and were not confirmed biochemically: one in the placebo group, two in the 15mg DEN group (Section 14, Tables 12.17, 12.18).

The single event of hypoglycaemia in the placebo group was not categorised as serious, did not result in subject withdrawal and was not considered to be related to study

medication. The two hypoglycaemic events in the 15mg DEN group were each single events, were not categorised as serious, were considered to be related to study medication, and did not result in subject withdrawal from the study.

8.6. Pregnancies

No subjects became pregnant during the study.

8.7. Clinical Laboratory Evaluations

Summaries of laboratory values at each visit and of changes from baseline at each visit for all subjects are provided in Section 14, Tables 12.19 and 12.20, respectively. Shifts from baseline with respect to the normal range (F2 flagged) and those outside the ranges of potential clinical concern (F3 flagged) are summarised in Section 14, Tables 12.21 and 12.22, respectively. Line graphs for selected laboratory parameters (ALT, AST, total bilirubin, haemoglobin) over time are provided in Section 14, Figure 12.1 to Figure 12.4. Box plots of maximum post baseline values for selected laboratory values (ALT, AST, total bilirubin, LDH, alkaline phosphatase, CK MB) are provided in Section 14, Figure 12.5 to Figure 12.10. Patient profiles for selected laboratory parameter post baseline data of potential clinical concern are provided in Section 14, Figure 12.11.

8.7.1. Laboratory Values over Time

8.7.1.1. Selected Laboratory Parameters

Bilirubin

Changes from baseline in mean direct bilirubin, indirect bilirubin and total bilirubin at Week 12 are summarised in Table 43. Mean values for all three parameters at Week 12 were similar or slightly lower than baseline across all treatment groups. No dose related trend was observed.

Table 43 Change from Baseline in Bilirubin Variables at Week 12 (Safety Population)

Bilirubin parameter, mean±SD	Placebo (N=64)		Denagliptin 2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Direct bilirubin (umol/L)												
Baseline	2.3±1.39	64	2.5±1.21	61	2.3±0.98	63	2.1±1.00	66	2.5±1.55	59	2.0±1.27	61
Week 12	2.2±1.24	49	2.3±1.10	45	2.1±0.99	54	1.9±1.08	58	2.4±1.26	56	1.9±1.05	54
Change[2]	-0.0±1.03	49	-0.2±0.90	45	0.0±0.66	54	-0.2±1.01	58	-0.1±1.29	55	-0.1±1.12	54
Indirect bilirubin (umol/L)												
Baseline	9.2±4.57	64	9.7±4.55	61	9.4±4.38	63	8.5±4.22	66	10.4±4.74	59	8.4±3.85	61
Week 12	8.6±4.39	49	9.5±4.53	45	8.9±3.99	54	8.3±3.35	58	9.3±4.02	56	7.9±3.73	54
Change[2]	-0.2±3.05	49	-0.2±3.13	45	-0.1±2.47	54	-0.0±2.87	58	-1.1±4.09	55	-0.7±2.94	54
Total bilirubin (umol/L)												
Baseline	11.4±5.55	64	12.2±5.49	61	11.7±5.07	63	10.6±4.99	66	12.9±5.84	59	10.4±4.85	61
Week 12	10.8±5.30	49	11.8±5.27	46	11.0±4.72	54	10.1±3.96	58	11.7±4.94	56	9.8±4.51	54
Change[2]	-0.2±3.55	49	-0.4±3.54	46	-0.1±2.83	54	-0.2±3.32	58	-1.2±4.83	55	-0.8±3.66	54

Data Source: Section 14, Tables 12.19, 12.20

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

AST and ALT

Changes from baseline in liver function variables at Week 12 are summarised in Table 44. At Week 12, decreases in mean ALT were observed across all treatment groups (Figure 10); no dose related trend was observed. Mean AST at Week 12 was similar or slightly lower than baseline across all treatment groups.

Table 44 Change from Baseline in Liver Function Variables at Week 12 (Safety Population)

LFT parameter, mean±SD	Placebo (N=64)		Denagliptin 2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
ALT (IU/L)		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	21.5±10.05	64	27.0±14.55	61	23.2±11.47	63	25.1±13.58	66	26.7±22.62	59	23.2±12.33	61
Week 12	19.8±8.49	49	23.6±10.79	46	21.4±9.85	54	23.8±14.13	58	20.2±9.52	56	22.7±14.75	54
Change[2]	-1.6±6.67	49	-3.7±10.56	46	-2.4±6.93	54	-1.2±9.01	58	-5.5±21.66	55	-0.5±10.97	54
AST (IU/L)												
Baseline	19.7±6.73	64	24.5±13.02	61	19.9±6.96	63	21.8±7.67	66	23.4±14.41	59	21.0±8.36	61
Week 12	18.8±5.55	49	21.8±7.27	46	20.1±7.65	54	21.7±9.38	58	20.5±10.39	56	21.2±10.67	54
Change[2]	-0.7±4.28	49	-2.6±8.90	46	-0.3±5.62	54	0.0±5.52	58	-2.2±10.02	55	0.5±6.97	54

Data Source: Section 14, Tables 12.19, 12.20

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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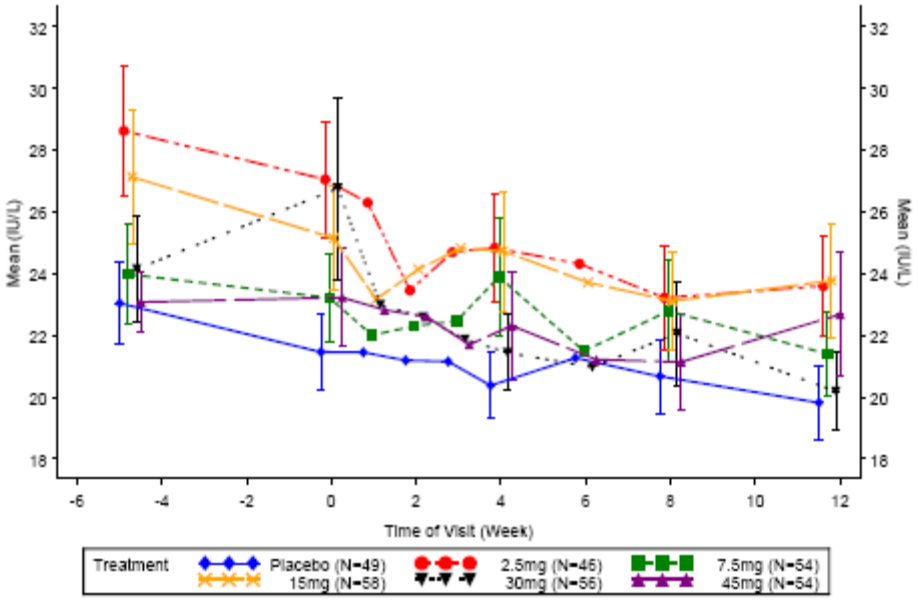
Figure 10 Mean (Plus and Minus SE) ALT (IU/L) by Visit (Safety Population)



Data Source: Section 14, Figure 12.1
NOTE: N is the number of subjects at Week 12. Week 0 shows all baseline values

Creatinine

Changes from baseline in mean creatinine at Week 12 are summarised in Table 45. At Week 12, no clinically relevant change from baseline in any treatment group was observed.

Table 45 Change from Baseline in Creatinine (micromole/L) at Week 12 (Safety Population)

Creatinine (umol/L), mean±SD	Placebo (N=64)		Denagliptin 2.5mg (N=61)		Denagliptin 7.5mg (N=63)		Denagliptin 15mg (N=66)		Denagliptin 30mg (N=60)		Denagliptin 45mg (N=61)	
		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	81.0±17.29	64	80.4±17.84	61	80.8±16.27	63	83.3±19.40	66	78.0±15.23	59	80.8±18.04	61
Week 12	82.1±20.31	49	80.8±20.07	46	82.1±16.41	54	86.1±20.21	58	79.0±15.95	56	81.0±15.35	54
Change[2]	0.1±13.66	49	0.7±9.42	46	1.2±7.08	54	1.4±7.95	58	1.4±8.15	55	-0.5±10.08	54

Data Source: Section 14, Tables 12.19, 12.20

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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Full Blood Count

Changes from baseline at Week 12 in haemoglobin are summarised in Table 46. At Week 12, no clinically relevant change from baseline in any treatment group was observed.

On review of changes from baseline in basophils, eosinophils, haematocrit, lymphocytes, monocytes, platelet count, red blood cell count, total neutrophils and white blood cell count no clinically relevant change from baseline in any treatment group was observed.

Table 46 Change from Baseline in Haemoglobin (%) at Week 12 (Safety Population)

Hb (%)			Denagliptin									
mean±SD	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	143.7±12.21	64	146.0±12.62	61	144.1±12.58	63	141.2±10.89	66	144.9±12.67	60	142.6±13.59	61
Week 12	142.2±9.97	45	145.8±13.46	48	143.1±10.55	52	139.6±11.87	59	145.5±14.60	53	142.1±14.22	54
Change[2]	-0.9±7.48	45	-0.8±10.71	48	-0.3±7.59	52	-1.5±5.87	59	0.0±10.53	53	-0.6±7.38	54

Data Source: Section 14, Tables 12.19, 12.20

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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8.7.1.2. Other Clinical Chemistry Variables

Summaries for other clinical chemistry variables are provided in Section 14, Tables 12.19 and 12.20. Results at Week 12 and mean changes from baseline at Week 12 were similar in all treatment groups.

8.7.2. Abnormalities of Potential Clinical Concern

Laboratory values considered to be clinically significant by the investigator were recorded as AEs in the eCRF and are presented in Section 8.2. The laboratory values considered by the sponsor to be of potential clinical concern (F3 flag) (see Section 5.8.7.5) are shown in Table 47.

Across all doses of DEN, low carbon dioxide/bicarbonate values of potential clinical concern were recorded in 0-10% of subjects compared to none in the placebo group. Across all doses of DEN, low calcium values of potential clinical concern were recorded in 2-12% of subjects compared to 5% in the placebo group. The incidence of all other F3 flagged parameters was low (≤ 5%) and/or similar across treatment groups.

One high F3 flagged AST value was recorded, occurring in the 30mg DEN group. No F3 flagged ALT values were recorded. Five high F3 flagged bilirubin (total) values were recorded: one in the placebo group, one in the 7.5mg DEN group, two in the 30mg DEN group and one in the 45mg DEN group.

Table 47 Summary of On-Therapy Laboratory Values of Potential Clinical Concern at any Time (Safety Population)

Laboratory parameter n (%)	High/ Low	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
Albumin	High	0	0	0	0	0	1 (2%)
AST	High	0	0	0	0	1 (2%)	0
Calcium	Low	3 (5%)	2 (3%)	5 (8%)	2 (3%)	1 (2%)	7 (12%)
CO2 content/bicarbonate	Low	0	3 (5%)	6 (10%)	2 (3%)	0	5 (8%)
Creatinine	High	0	0	0	1 (2%)	0	1 (2%)
Glucose	Low	0	0	1 (2%)	0	0	1 (2%)
Hct	High	2 (3%)	0	2 (3%)	0	2 (3%)	1 (2%)
	Low	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	0
Hb	High	2 (3%)	1 (2%)	3 (5%)	0	1 (2%)	1 (2%)
	Low	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	0
Phosphorus, inorganic	High	0	0	2 (3%)	0	0	0
Platelet count	Low	0	0	0	0	1 (2%)	0
Potassium	High	6 (10%)	3 (5%)	6 (10%)	4 (6%)	7 (12%)	8 (13%)
Sodium	High	0	0	0	1 (2%)	0	0
	Low	0	0	0	0	1 (2%)	2 (3%)
Total bilirubin	High	1 (2%)	0	1 (2%)	0	2 (3%)	1 (2%)
Uric acid	High	0	0	1 (2%)	0	0	0
WBC count	High	0	0	0	0	1 (2%)	1 (2%)

Data Source: Section 14, Table 12.22

Patient profiles of selected laboratory values (ALT, AST, Alkaline Phosphatase, Total Bilirubin) of potential clinical concern (post-baseline) are provided in Section 14, Figure 12.11. Box plots of maximum post-baseline values relative to ULN for ALT, AST, Bilirubin, Lactate Dehydrogenase and Alkaline Phosphatase are provided in Section 14, Figure 12.5 to Figure 12.9.

8.8. Other Safety Evaluations

8.8.1. Vital Signs

Summaries of vital signs variables at each visit and of changes from baseline at each visit are provided in Section 14, Tables 12.23 and 12.24, respectively.

The changes from baseline to Week 12 in vital signs are summarised in Table 48. At Week 12 there was no apparent trend in changes in mean SBP, DBP or HR with respect to dose of DEN. No clinically relevant changes from baseline were observed in any treatment group.

Table 48 Change from Baseline in Vital Signs at Week 24 (Safety Population)

Vital sign parameter, mean±SD	Placebo (N=64)	n[1]	Denagliptin 2.5mg (N=61)	n[1]	Denagliptin 7.5mg (N=63)	n[1]	Denagliptin 15mg (N=66)	n[1]	Denagliptin 30mg (N=60)	n[1]	Denagliptin 45mg (N=61)	n[1]
SBP (mmHg)												
Baseline	133.2±16.39	64	131.8±15.82	61	131.4±13.49	63	129.6±11.57	66	131.5±14.28	60	129.5±11.33	61
Week 12	134.4±16.54	49	135.6±15.44	48	130.1±15.80	55	129.1±12.18	60	133.2±15.99	56	131.4±12.69	56
Change[2]	-0.6±14.81	49	2.7±15.74	48	-1.2±10.84	55	-1.0±10.69	60	1.4±11.38	56	2.0±12.58	56
DBP (mmHg)												
Baseline	80.0±9.31	64	80.1±8.85	61	79.4±7.86	63	77.5±6.39	66	79.5±8.48	60	79.0±6.53	61
Week 12	79.7±9.24	49	81.5±8.06	48	78.7±9.62	55	76.4±7.83	60	80.6±9.54	56	79.2±7.07	56
Change[2]	-0.2±7.19	49	1.2±7.19	48	-0.4±7.52	55	-1.1±7.72	60	0.9±7.67	56	0.0±5.95	56
HR (bpm)												
Baseline	70.8±9.02	64	68.6±7.81	61	70.1±10.91	63	70.5±8.11	66	71.5±9.01	60	69.5±8.32	61
Week 12	72.3±9.31	49	71.3±9.32	48	70.2±10.77	55	70.4±8.60	60	73.2±8.79	56	68.9±9.37	55
Change[2]	0.4±9.00	49	1.9±6.96	48	0.3±8.38	55	0.3±8.12	60	1.6±8.07	56	-0.5±6.94	55

Data Source: Section 14, Tables 12.23, 12.24

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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The numbers of subjects with baseline shift flagging (F2) or values of potential clinical concern (F3) for vital signs at any on-therapy visit are presented in Table 49.

The proportions of subjects with F2 flags were no more than 7% in any treatment group for any of the blood pressure values and no more than 2% for heart rate. No apparent trend with respect to the proportion of F2 flags and dose of DEN was apparent. The incidence rate of F2 flags in the DEN groups was generally comparable to placebo.

The proportions of subjects with F3 flags were no more than 8% in any treatment group for any of the vital signs values. No apparent trend with respect to the proportion of F3 flags and dose of DEN was apparent. The incidence rate of F3 flags in the DEN groups was generally comparable to placebo.

Table 49 Summary of On-Therapy Vital Signs Results of Potential Clinical Concern at any Time (Safety Population)

Vital signs parameter		Denagliptin				
	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Baseline shift (F2 flag)						
SBP, n	62	60	62	63	59	60
>30mmHg increase	2 (3%)	4 (7%)	0	3 (5%)	3 (5%)	3 (5%)
>30mmHg decrease	4 (6%)	3 (5%)	0	2 (3%)	3 (5%)	1 (2%)
DBP, n	62	60	62	63	59	60
>20mmHg increase	3 (5%)	1 (2%)	1 (2%)	1 (2%)	2 (3%)	2 (3%)
>20mmHg decrease	3 (5%)	3 (5%)	0	3 (5%)	0	2 (3%)
HR, n	62	60	62	63	59	60
>30 bpm increase	1 (2%)	0	1 (2%)	0	1 (2%)	0
Value of potential clinical concern (F3 flag)						
SBP, n	62	60	62	63	59	60
>170 mmHg	5 (8%)	1 (2%)	3 (5%)	1 (2%)	1 (2%)	1 (2%)
<100 mmHg	1 (2%)	3 (5%)	2 (3%)	1 (2%)	1 (2%)	1 (2%)
DBP, n	62	60	62	63	59	60
<50 mmHg	0	1 (2%)	0	0	0	0
HR, n	62	60	62	63	59	60
<50 bpm	1 (2%)	0	3 (5%)	1 (2%)	0	3 (5%)

Data Source: Section 12, Tables 12.25, 12.26

A summary of urinalysis dipstick results is provided in Section 12, Table 12.27.

8.8.2. ECG

ECG values by visit are summarised in Section 14, Table 12.30 and change from baseline at Weeks 4 and 12 in Section 14, Table 12.31. No clinically relevant change in heart rate, PR interval, QRS interval, QT interval, QTc (Bazett) or QTc (Fridericia) were observed in any treatment group.

As shown in Table 50, a decrease in mean RR interval compared to baseline at Week 12 was observed for all DEN dose groups, the greatest decrease occurring in the 30mg DEN group. However, values were highly variable as indicated by the high SD for each group. Furthermore, no RR interval was categorised as being of potential clinical concern (F3 flag) (Table 51). None of the observed decreases in PR interval were considered to be of

clinical concern. Overall, the percentage of abnormal ECG values at Week 12 was lower in each of the DEN groups (range 24% to 35%) compared to placebo (40%) (Section 14, Table 12.32).

Few ECG values were flagged as being of potential clinical concern. Low HR values of potential clinical concern occurred with the highest frequency (≤5%) and with a similar incidence rate across treatment groups. One subject, in the 45mg DEN group, was recorded as having a high QTc (Bazett) and QTc (Fridericia) at baseline (534msec and 509msec, respectively) and at Week 4 (505msec and 503msec, respectively). The QTc values were below the cut-off for potential clinical concern at Week 12 (Bazett: 500msec; Fridericia: 497msec).

Only one change from baseline ECG value was flagged as being of potential clinical concern: one subject in the 15mg DEN group had an increase of >50% in QRS duration when the baseline value was ≤100msec recorded at baseline and Weeks 4, 6 and 12 (Section 14, Table 12.34). This subject did not report any associated AE.

Table 50 Change from Baseline in RR Interval at Week 12 (Safety Population)

RR interval, (msec) mean±SD	Placebo (N=64)	n[1]	Denagliptin 2.5mg (N=61)	n[1]	Denagliptin 7.5mg (N=63)	n[1]	Denagliptin 15mg (N=66)	n[1]	Denagliptin 30mg (N=60)	n[1]	Denagliptin 45mg (N=61)	n[1]
Baseline	904.4±134.5	64	898.7±105.6	61	911.0±160.8	63	882.6±114.4	65	877.9±124.3	60	920.2±150.3	61
Week 12	884.9±114.1	45	879.9±145.9	45	903.5±149.1	51	876.8±117.4	59	858.0±116.9	53	925.6±146.5	52
Change[2]	6.4±102.7	45	-5.6±117.4	45	-4.6±102.4	51	-4.1±118.9	58	-21.4±103.5	53	-2.2±1-4.0	52

Data Source: Section 14, Tables 12.30 and 12.31

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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Table 51 Summary of On-Therapy ECG Results of Potential Clinical Concern at any Time (Safety Population)

ECG parameter	Placebo (N=64)	Denagliptin 2.5mg (N=61)	Denagliptin 7.5mg (N=63)	Denagliptin 15mg (N=66)	Denagliptin 30mg (N=60)	Denagliptin 45mg (N=61)
HR, n	61	59	59	60	58	57
<50 bpm	3 (5%)	1 (2%)	3 (5%)	3 (5%)	1 (2%)	2 (4%)
QTc (Bazett)	61	59	59	60	58	57
>500msec	0	0	0	0	0	1 (2%)
QTc (Fridericia)	61	59	59	60	58	57
>500msec	0	0	0	0	0	1 (2%)

Data Source: Section 12, Table 12.33

8.8.3. Weight, BMI and Waist Circumference

Summaries of mean weight, hip circumference, waist circumference, waist:hip ratio and BMI at each visit and of change from baseline at each visit are provided in Section 14, Tables 12.28 and 12.29, respectively. Mean changes from baseline over time for weight is shown in Figure 11.

Changes from baseline at Week 12 in mean weight, BMI and waist circumference are shown in Table 52. A decrease from baseline in mean weight and BMI at Week 12 was observed across all DEN dose groups; no apparent trend with respect to dose of DEN was observed. The decreases in weight and BMI were generally similar to placebo. A similar trend was observed for waist circumference.

Table 52 Change from Baseline in Weight, BMI and Waist Circumference at Week 12 (Safety Population)

Parameter			Denagliptin									
mean±SD	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Weight (kg)		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	86.9±15.7	64	89.3±16.9	61	87.7±16.3	63	86.7±14.3	66	90.4±18.3	60	90.2±14.8	61
Week 12	87.0±16.4	49	88.6±18.6	48	88.1±16.5	55	87.1±14.2	60	89.5±18.6	56	89.2±14.6	56
Change[2]	-0.78±2.33	49	-0.96±2.87	48	-0.71±1.89	55	-0.36±2.01	60	-0.51±2.75	56	-0.50±2.42	56
BMI (kg)		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	30.55±4.84	64	31.45±4.68	61	30.76±4.77	63	30.57±4.08	66	31.51±4.62	60	31.45±4.17	61
Week 12	30.68±4.93	49	31.11±4.94	48	30.87±4.94	55	30.68±4.07	60	31.66±4.72	58	31.23±4.21	56
Change[2]	-0.28±0.83	49	-0.36±0.99	48	-0.25±0.68	55	-0.13±0.71	60	-0.20±0.96	56	-0.18±0.88	56
Waist circumference (cm)		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	103.5±12.5	64	104.7±11.2	61	103.8±11.6	63	102.2±9.7	66	106.1±12.5	60	104.6±11.0	61
Week 12	103.0±12.8	48	104.0±11.2	48	103.3±11.2	53	102.3±9.5	58	105.0±13.0	53	105.7±11.0	56
Change[2]	-1.1±4.90	48	-0.5±4.47	48	-1.0±3.26	53	-0.4±3.39	58	-0.1±4.78	53	1.2±7.60	56

Data Source: Section 14, Tables 12.28, 12.29

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

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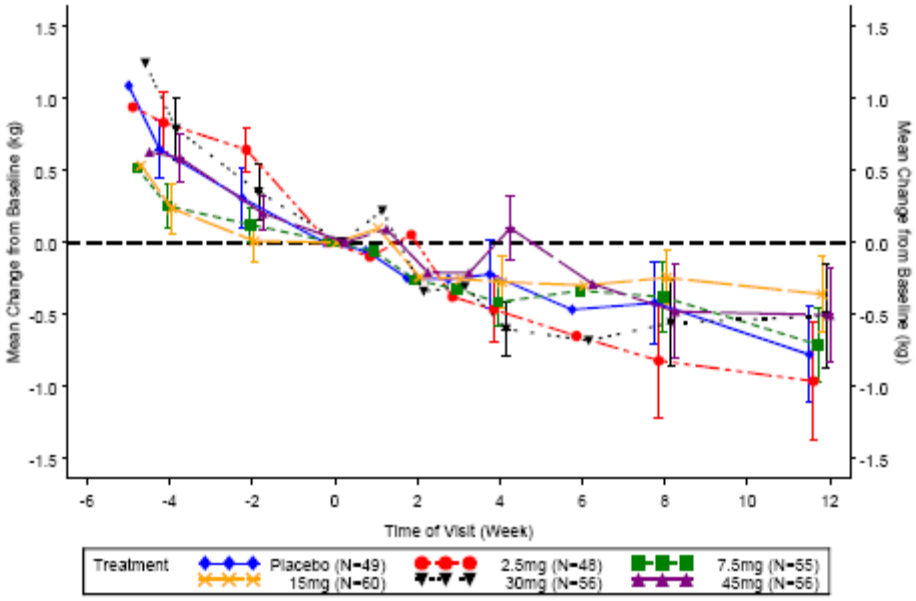
Figure 11 Mean Change from Baseline (Plus and Minus SE) in Weight (kg) by Visit (Safety Population)



Data Source: Section 14, Figure 12.15
NOTE: N is the number of subjects at Week 12

8.9. Safety Conclusions

- Overall, the incidence of on-therapy AEs in the DEN groups (range 32-42%) was similar to placebo (38%) and did not appear to be dose-related. The majority of AEs were mild to moderate in intensity (only eight subjects reported severe AEs) and there was a low rate of treatment-related AEs.
- The most frequently occurring AEs were nasopharyngitis in the 7.5mg DEN group (11%) and back pain and nausea in the 15mg DEN group (both 6%); no AE increased in incidence with increasing dose of DEN.
- Five subjects experienced six on-therapy non-fatal SAEs: one subject in each of the placebo, 2.5mg DEN and 45mg DEN groups and two in the 30mg DEN group. Only one SAE was considered to be related to study treatment (gastroenteritis in a placebo subject).
- Three subjects (5%) in the placebo group, three subjects (5%) in the 2.5mg DEN group and one subject (2%) in the 30mg DEN group had AEs leading to withdrawal.
- There was a low incidence of hypoglycaemia (one subject in the placebo group and two subjects in the 15mg DEN group). AEs of myalgia, hypertension, blood pressure increased and fluid retention were also infrequent for all treatment groups.
- No apparent trends were visible in ECGs, vital signs, haematology or clinical chemistry results. There were no detrimental effects on blood pressure.
- There was no visible difference from placebo in weight change; reductions were observed in all treatment groups.

9. BIOMARKER RESULTS

9.1. Exploratory Biomarker CK-MB

Changes from baseline at Week 12 in CK-MB are shown in Table 53. Small increases from baseline in CK-MB at Week 12 were observed across all DEN dose groups except the 15mg group; the greatest increase was observed in the 30mg DEN group (mean±SD; 0.32±1.47µg/L). Mean CK-MB was similar at baseline and Week 12 in the placebo group.

Table 53 Change from Baseline in CK-MB (microgrammes/L) at Week 12 (Safety Population)

CK-MB (µg/L) mean±SD	Placebo (N=64)		Denagliptin 2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
		n[1]		n[1]		n[1]		n[1]		n[1]		n[1]
Baseline	1.57±0.86	49	1.65±0.88	51	2.16±2.60	43	1.88±0.99	53	2.07±1.51	55	1.71±0.97	48
Week 12	1.66±0.57	36	1.66±0.78	34	1.98±1.41	39	1.86±1.01	50	2.30±2.43	45	1.86±1.26	41
Change[2]	-0.01±0.84	34	0.15±0.65	31	0.13±0.80	33	0.01±0.88	46	0.32±1.47	43	0.13±1.00	37

Data Source: Section 14, Tables 12.35. 12.36

1. Number of subjects with values at each visit; change from baseline calculated only for those subjects who had a baseline and Week 12 value
2. Change from baseline

NOTE: reference range = <5.1nmol/L.

The box plot of maximum post-baseline CK-MB values relative to ULN is provided in Section 14, Figure 12.10.

9.1.1. Exploratory Summary of cTnI

cTnI values at any time post baseline are shown in Table 54. Virtually all values across treatment groups were <0.2µg/L (reference range: 0-1.5µg/L).

[redacted]

[redacted] There were no AEs reported and no concomitant medications were taken by the subject.

[redacted] The ECG findings on this date were the same as at screen. The subject was asymptomatic at the time this sample was obtained. No other AEs were reported. [redacted]

Table 54 Summary of cTnI by Defined Categories Any Time Post Baseline (Safety Population)

cTnI (µg/L)		Denagliptin				
	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
n	61	60	62	64	59	57
<0.2	61 (100%)	59 (98%)	62 (100%)	64 (100%)	59 (100%)	56 (98%)
0.2 – 0.35	0	0	0	0	0	1 (2%)
>0.35 – 1.5	0	1 (2%)	0	0	0	0
>1.5	0	0	0	0	0	0

Data Source: Section 12, Table 12.37

9.2. Biomarker Conclusions

- Small increases from baseline in CK-MB at Week 12 were observed across all DEN dose groups except the 15mg group; the greatest increase was observed in the 30mg DEN group (mean±SD; 0.32±1.47µg/L). Mean CK-MB was similar at baseline and Week 12 in the placebo group.
- No clinically relevant changes in CK-MB were observed.
- No clinically relevant changes in cTnI were observed.

10. DISCUSSION AND CONCLUSIONS

10.1. Discussion

The currently available oral anti-diabetic medications, although highly effective in the medical management of patients with T2DM, are not optimal and are associated with specific side effects. There is therefore a need to investigate new agents with mechanisms that are different, yet complementary, to existing classes. GW823093 (Denagliptin; DEN) is a serine aminopeptidase, a potent and selective inhibitor of the dipeptidyl peptidase IV enzyme (DPP-IV) that is being developed for the treatment of T2DM. DPP-IV rapidly (terminal half-life [t1/2] <5 min) inactivates the incretin hormones glucagon like peptide-1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), which are secreted by cells in the gut in response to meal ingestion.

This Phase IIb dose-ranging study evaluated the dose-response, efficacy, safety and tolerability of a range of doses of DEN compared to placebo over a 12 week period in subjects with T2DM. A subsequent 12 week Extension Phase will evaluate the safety and tolerability and time course of glycaemic effects after an additional 12 weeks of dosing. This CSR presents data for the Main Phase only.

A total of 371 subjects were randomised, with stratification for gender and prior therapy, to receive placebo, 2.5mg, 7.5mg, 15mg, 30mg or 45mg DEN for 12 weeks. Demographic data were similar across treatment groups with respect to age, gender, race, weight, BMI and waist circumference. The mean age of subjects was 59.6 years, mean BMI 31.0kg/m^2 and mean waist circumference 104 cm. There was a similar proportion of male and female subjects participating in the trial. Across treatment groups, the mean duration of diabetes was 5.3 years, ranging from 0.0 to 35.6 years, reflecting a mixed prior therapy population. Forty-one percent of subjects were managed by diet and exercise compared to 59% who received monotherapy treatment; with a slightly lower percentage of diet and exercise subjects in the 15mg group. Mean baseline HbA1c overall was 7.90%, in the diet and exercise strata 7.98% and in the monotherapy strata 7.85%.

The study successfully demonstrated a statistically significant difference compared to placebo for the primary endpoint: reduction in HbA1c from baseline. Following 12 weeks of treatment, reductions compared to placebo in HbA1c were clinically and statistically significant for the 45mg (difference vs placebo: -0.84% [95% CI: -1.13, -0.55], $p<0.001$) and 30mg (difference vs placebo: -0.80% [95% CI: -1.09, -0.50], $p<0.001$) DEN groups. Statistically significant differences were also observed for the 15mg ($p=0.002$) and 7.5mg ($p<0.001$) DEN groups. The overall dose response profile supports achievement of glycaemic efficacy. Generally, the reductions in HbA1c were similar for the 30mg and 45mg DEN groups, and the 7.5mg group produced a slightly larger reduction than the 15mg group.

For subjects previously treated with monotherapy there was a worsening of HbA1c in the placebo group, which resulted in a greater decrease from baseline in HbA1c relative to placebo in subjects previously treated with monotherapy compared to diet and exercise.

Worthy of note was a greater decrease in HbA1c with increasing baseline HbA1c value and in subjects with a higher baseline BMI value. Decreases in HbA1c were similar in females and males.

The importance of tight glycaemic control in delaying the onset and slowing the progression of microvascular complications has been demonstrated in the Diabetes Control and Complications Trial (DCCT) and more recently in the UKPDS [DCCT, 1993; UKPDS 33, 1998; Stratton, 2000]. In the current study, the proportion of subjects who achieved a target HbA1c of less than 7% was slightly higher than placebo, however the difference did meet statistical significance (24% of subjects, odds ratio 3.24 [95% CI: 1.11, 9.52, p=0.032). Furthermore, in subjects receiving 30mg or 45mg DEN, 38% and 29% had a reduction in HbA1c of at least 0.7%, but the difference from placebo was not statistically significant.

The dose response in HbA1c reductions was mirrored by the decreases observed in FPG. FPG decreased rapidly over the first 4 weeks of treatment (except for the placebo and 2.5mg DEN groups), with no further decrease apparent over the following 8 weeks of treatment. In subjects receiving 30mg or 45mg DEN, 31% (odds ratio 3.24 [95% CI: 1.15, 9.13, p=0.026]) and 30% (odds ratio 3.00 [95% CI: 1.08, 8.30, p=0.034]) were responders in terms of reductions in FPG (i.e. ≥1.7mmol/L) after 12 weeks of treatment.

The study results for reductions in glycaemic parameters following treatment with DEN are consistent with reductions seen in studies with continuous GLP-1 infusion [Zander 2002] and with the GLP-1 agonist, exendin-4 [Fineman 2003].

The increases in insulin levels observed in this study have previously been reported in clinical studies of DPP-IV inhibitors [Mari 2005], and are consistent with the observed significant improvement in HOMA β-cell function at the higher doses of DEN, also documented in clinical studies with other DPP-IV inhibitors [Ristic 2005]. Additionally, 3- to 4-fold decreases relative to placebo in pro-insulin:insulin ratio were observed at the higher doses of DEN, an established marker of β-cell function. In type 2 diabetic subjects, the pro-insulin:insulin ratio has been directly correlated with the degree of hyperglycaemia, and, therefore, the degree of β-cell dysfunction [Kahn 1996].

In preclinical models GLP-1 has been shown to promote β-cell mass expansion and animal studies have shown DPP-IV inhibitors to improve islet survival and maintain β-cell mass and islet function [Riddle 2006]. These results suggest that DPP-IV inhibitors may have disease modifying potential, possibly by the prevention or delay in the worsening of glycaemic control, or by modulating the transition of impaired glucose tolerance to overt type 2 diabetes. This class of agents may thus be effective in the treatment of type 2 diabetes as monotherapy in the early stages of the disease, and later, if glycaemic control worsens, as part of combination therapy with existing anti-diabetic agents.

Improvements in glycaemia are usually associated with increases in body weight. However, at all doses of DEN, 12 weeks of treatment resulted in reductions in body weight which was also observed for subjects receiving placebo, as has previously been documented for other DPP-IV inhibitors [Ahrén 2004a; Zander 2002; Holst 1998].

Improvements in glycaemic control can often be compromised due to the risk of hypoglycaemia. However, DPP-IV inhibitors would not be expected to cause hypoglycaemia as GLP-1 is released in a glucose dependent manner. Consistent with this hypothesis, in this study, close monitoring of symptoms of hypoglycaemia during 12 weeks of treatment resulted in only three hypoglycaemic events being reported, two occurring on active therapy (15mg DEN group) and one on placebo. All events were mild in intensity. Importantly, no dose related increase in incidence was observed.

All doses of DEN had an acceptable safety profile. Overall, the rate of AEs in the denagliptin groups was similar to placebo. The incidence of AEs was highest in the 15mg DEN group (42%) and lowest in the 7.5mg and 30mg groups (both 32%); 38% of subjects reported AEs in the placebo group. No AE appeared to be dose-related. One on-therapy SAE was reported to be related to study drug, occurring in a subject from the placebo group. All doses of DEN were well tolerated; only 7 subjects withdrew due to an AE, three from the placebo group, three from the 2.5mg DEN group and one from the 30mg DEN group.

10.2. Conclusions

- The overall dose response profile supports achievement of glycemic efficacy with DEN. Similar clinically and statistically significant reductions in HbA1c compared to placebo occurred at the 30mg and 45mg doses of DEN (-0.80% and -0.84% respectively at week 12 ($p<0.001$)). The results for FPG and fructosamine were similar to that seen for HbA1c. A rapid onset of action was demonstrated. There were small statistically non-significant, non detrimental changes in serum lipids, fasting insulin, pro-insulin and pro-insulin:insulin ratio. However, although not statistically significant, there was a trend for clinical improvement in the pro-insulin:insulin ratio with DEN.
- A clinically meaningful improvement in HOMA BCF was observed in the 7.5mg, 15mg, 30mg and 45mg DEN groups, the greatest percent increases occurring in the 30mg and 45mg groups; HOMA BCF decreased slightly in the placebo group.
- Denagliptin was well tolerated with an acceptable safety profile. The incidence of on-therapy AEs in the DEN groups (range 32-42%) was similar to placebo (38%) and did not appear to be dose-related. The majority of AEs were mild to moderate in intensity and there was a low rate of treatment-related AEs. The most frequently reported events in the DEN-treated groups were nasopharynigitis (16 subjects, 5%), nausea (9 subjects, 3%) and headache (8 subjects, 3%). No subjects died. Five subjects experienced six on-therapy SAEs: one subject in each of the placebo, 2.5mg DEN and 45mg DEN groups and two in the 30mg DEN group. Seven subjects had AEs that led to early withdrawal from the study (3 subjects (5%) each in the placebo and 2.5mg DEN groups, and one subject (2%) in the 30mg DEN group)
- There was a very low incidence of hypoglycaemia and no apparent trends were visible in ECGs, vital signs, haematology or clinical chemistry results. There were no detrimental effects on blood pressure. There was no visible difference from placebo in weight change; reductions were observed in all treatment groups. No clinically relevant changes in CK-MB or cTnI were observed.

In summary, DEN at doses of 30mg and 45mg, produced clinically relevant reductions in HbA1c from baseline at week 12. A higher proportion of subjects in the 30mg and 45mg DEN dose groups achieved glycaemic targets and with improved beta cell function these two doses will potentially improve both the short and long term glycaemic control of patients with type 2 diabetes. Furthermore, at these doses DEN was well tolerated, there was no weight gain, hypoglycaemia or detrimental effects on lipids, blood pressure or other cardiovascular parameters.

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Table 10.1
Summary of Subject Disposition

	Placebo	2.5mg	7.5mg	15mg	30mg	45mg	Total
Entered Run-in							476
Randomised	64	61	62	63	59	62	371
Safety Population [1]	64	61	63	66	60	61	375
Intent-to-Treat Population	62	59	62	63	58	60	364
Completers	49	47	54	60	55	56	321
Per-Protocol Population	37	46	49	55	51	48	286

Note: Entered Run-In: Subjects who received run-in medication.
Randomised: Subjects randomised to study medication.
Safety Population: Subjects who received at least one dose of double-blind study medication.
Intent-to-Treat Population: Randomised subjects who received at least one dose of study medication, have a baseline assessment and have at least one corresponding on-therapy (whether scheduled or unscheduled) efficacy assessment.
Completers: As determined by the investigator.
[1] The number of subjects in the Safety population is greater than the number of subjects randomised because the Safety population includes subjects who took double-blind study medication during run-in.

[redacted]

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Table 10.2
Summary of Subject Disposition by Gender and Prior Therapy

	Placebo	2.5mg	7.5mg	15mg	30mg	45mg	Total
Randomised	64	61	62	63	59	62	371
Female, Diet & Exercise	14 (22%)	11 (18%)	13 (21%)	10 (16%)	12 (20%)	11 (18%)	71 (19%)
Male, Diet & Exercise	14 (22%)	13 (21%)	14 (23%)	14 (22%)	13 (22%)	14 (23%)	82 (22%)
Female, Monotherapy	18 (28%)	20 (33%)	18 (29%)	20 (32%)	19 (32%)	21 (34%)	116 (31%)
Male, Monotherapy	18 (28%)	17 (28%)	17 (27%)	19 (30%)	15 (25%)	16 (26%)	102 (27%)
Safety Population [1]	64	61	63	66	60	61	375
Female, Diet & Exercise	14 (22%)	11 (18%)	13 (21%)	10 (15%)	12 (20%)	11 (18%)	71 (19%)
Male, Diet & Exercise	14 (22%)	13 (21%)	14 (22%)	14 (21%)	13 (22%)	14 (23%)	82 (22%)
Female, Monotherapy	18 (28%)	20 (33%)	19 (30%)	23 (35%)	19 (32%)	21 (34%)	120 (32%)
Male, Monotherapy	18 (28%)	17 (28%)	17 (27%)	19 (29%)	16 (27%)	15 (25%)	102 (27%)
Intent-to-Treat Population	62	59	62	63	58	60	364
Female, Diet & Exercise	14 (23%)	10 (17%)	13 (21%)	10 (16%)	12 (21%)	11 (18%)	70 (19%)
Male, Diet & Exercise	14 (23%)	13 (22%)	14 (23%)	14 (22%)	13 (22%)	13 (22%)	81 (22%)
Female, Monotherapy	17 (27%)	19 (32%)	18 (29%)	20 (32%)	19 (33%)	21 (35%)	114 (31%)
Male, Monotherapy	17 (27%)	17 (29%)	17 (27%)	19 (30%)	14 (24%)	15 (25%)	99 (27%)
Completers	49	47	54	60	55	56	321
Female, Diet & Exercise	11 (22%)	8 (17%)	11 (20%)	9 (15%)	11 (20%)	11 (20%)	61 (19%)
Male, Diet & Exercise	12 (24%)	9 (19%)	10 (19%)	14 (23%)	13 (24%)	12 (21%)	70 (22%)
Female, Monotherapy	16 (33%)	15 (32%)	16 (30%)	20 (33%)	19 (35%)	19 (34%)	105 (33%)
Male, Monotherapy	10 (20%)	15 (32%)	17 (31%)	17 (28%)	12 (22%)	14 (25%)	85 (26%)

Note: Randomised: Subjects randomised to study medication.
Safety Population: Subjects who received at least one dose of double-blind study medication.
Intent-to-Treat Population: Randomised subjects who received at least one dose of study medication, have a baseline assessment and have at least one corresponding on-therapy (whether scheduled or unscheduled) efficacy assessment.
Completers: As determined by the investigator.
[1] The number of subjects in the Safety population is greater than the number of subjects randomised because the Safety population includes subjects who took double-blind study medication during run-in.

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Table 10.2
Summary of Subject Disposition by Gender and Prior Therapy

	Placebo	2.5mg	7.5mg	15mg	30mg	45mg	Total
Per-Protocol Population	37	46	49	55	51	48	286
Female, Diet & Exercise	9 (24%)	8 (17%)	10 (20%)	9 (16%)	10 (20%)	11 (23%)	57 (20%)
Male, Diet & Exercise	8 (22%)	8 (17%)	9 (18%)	13 (24%)	12 (24%)	10 (21%)	60 (21%)
Female, Monotherapy	12 (32%)	15 (33%)	16 (33%)	17 (31%)	18 (35%)	15 (31%)	93 (33%)
Male, Monotherapy	8 (22%)	15 (33%)	14 (29%)	16 (29%)	11 (22%)	12 (25%)	76 (27%)

Note: Randomised: Subjects randomised to study medication.
Safety Population: Subjects who received at least one dose of double-blind study medication.
Intent-to-Treat Population: Randomised subjects who received at least one dose of study medication, have a baseline assessment and have at least one corresponding on-therapy (whether scheduled or unscheduled) efficacy assessment.
Completers: As determined by the investigator.
[1] The number of subjects in the Safety population is greater than the number of subjects randomised because the Safety population includes subjects who took double-blind study medication during run-in.

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	Placebo			2.5mg			7.5mg			15mg		
			S	I	C	S	I	C	S	I	C	S	I	C
Canada	[redacted]	[redacted]	1	1	1	0	0	0	2	2	2	0	0	0
			1	1	0	0	0	0	1	1	1	1	1	1
			1	1	0	1	1	0	0	0	0	1	1	1
			1	1	1	0	0	0	0	0	0	0	0	0
			1	1	1	1	1	1	1	1	1	3	3	3
			2	2	2	0	0	0	0	0	0	1	1	1
			0	0	0	0	0	0	0	0	0	0	0	0
			1	1	1	1	1	1	0	0	0	1	1	1
			1	1	1	1	1	1	0	0	0	2	2	2
			1	1	0	0	0	0	0	0	0	1	1	1
Czech Republic			0	0	0	1	1	1	1	1	1	2	2	2
			2	2	2	3	3	3	3	3	3	0	0	0
			0	0	0	2	2	2	1	1	1	2	2	2
			0	0	0	1	1	1	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			1	1	1	2	2	2	2	2	2	2	2	2
			1	1	1	0	0	0	1	1	1	0	0	0
Finland			1	1	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	1	1	1	1	1	1
			0	0	0	0	0	0	0	0	0	0	0	0
Germany			2	2	2	1	1	0	1	1	1	2	2	2
			1	1	1	0	0	0	0	0	0	0	0	0
			1	1	1	0	0	0	2	2	2	2	2	2
			1	1	1	0	0	0	1	1	1	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	2	2	1	1	1	1	1	1	1

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	30mg			45mg			Total		
			S	I	C	S	I	C	S	I	C
Canada	[redacted]	[redacted]	3	3	3	2	2	2	8	8	8
			0	0	0	2	2	1	5	5	3
			1	1	1	0	0	0	4	4	2
			1	1	1	0	0	0	2	2	2
			2	2	2	0	0	0	8	8	8
			0	0	0	0	0	0	3	3	3
			0	0	0	1	1	1	1	1	1
			2	2	2	0	0	0	5	5	5
			0	0	0	0	0	0	4	4	4
			0	0	0	0	0	0	2	2	1
Czech Republic			1	1	1	2	2	2	7	7	7
			0	0	0	2	2	2	10	10	10
			0	0	0	1	1	1	6	6	6
			0	0	0	1	1	1	2	2	2
			2	2	2	1	1	1	4	4	4
			1	1	1	1	1	1	9	9	9
			1	0	0	0	0	0	3	2	2
Finland			1	1	1	1	1	1	3	3	2
			1	1	1	0	0	0	3	3	3
			0	0	0	1	0	1	1	0	1
Germany			0	0	0	1	1	1	7	7	6
			0	0	0	0	0	0	1	1	1
			2	2	2	2	2	2	9	9	9
			1	1	1	2	2	2	5	5	5
			1	1	1	0	0	0	1	1	1
			1	1	1	0	0	0	5	5	4

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	Placebo			2.5mg			7.5mg			15mg		
			S	I	C	S	I	C	S	I	C	S	I	C
Germany	[redacted]	[redacted]	1	1	1	2	2	2	3	3	3	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			1	1	1	0	0	0	0	0	0	0	0	0
			6	6	5	2	2	2	1	1	1	5	5	3
			4	4	4	1	1	1	1	1	1	1	1	0
			0	0	0	1	1	1	1	1	1	0	0	0
			1	1	1	0	0	0	0	0	0	1	1	1
			0	0	0	1	1	1	1	1	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			2	2	2	0	0	0	2	2	2	3	3	3
			0	0	0	0	0	0	2	2	2	0	0	0
			0	0	0	0	0	0	1	1	1	0	0	0
			1	1	1	0	0	0	3	3	2	1	1	1
			1	1	0	0	0	0	2	2	2	0	0	0
			0	0	0	1	1	0	0	0	0	0	0	0
			0	0	0	0	0	0	1	1	1	1	1	1
Greece			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	1	1	0	0	0	0	0	0	0
			2	1	0	0	0	0	1	1	1	2	2	2
			1	1	1	3	3	2	1	1	0	0	0	0
			0	0	0	1	1	0	0	0	0	2	1	1
			0	0	0	1	1	1	0	0	0	0	0	0
			1	1	1	0	0	0	0	0	0	1	1	1
Latvia			0	0	0	1	1	1	0	0	0	1	1	1

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	30mg			45mg			Total		
			S	I	C	S	I	C	S	I	C
Germany	[redacted]	[redacted]	2	2	2	3	3	3	11	11	11
			0	0	0	1	1	1	1	1	1
			1	1	1	0	0	0	1	1	1
			1	1	1	0	0	0	1	1	1
			0	0	0	0	0	0	1	1	1
			0	0	0	0	0	0	1	1	1
			2	2	2	2	2	2	18	18	15
			2	2	2	1	1	1	10	10	9
			0	0	0	0	0	0	2	2	2
			0	0	0	0	0	0	2	2	2
			0	0	0	0	0	0	2	2	1
			2	2	1	0	0	0	2	2	1
			2	2	2	1	1	0	10	10	9
			2	2	2	0	0	0	4	4	4
			1	1	1	0	0	0	2	2	2
			0	0	0	1	1	1	6	6	5
			0	0	0	0	0	0	3	3	2
			0	0	0	0	0	0	1	1	0
			0	0	0	0	0	0	2	2	2
Greece			0	0	0	1	1	1	1	1	1
			0	0	0	0	0	0	1	1	0
			2	2	2	1	1	1	8	7	6
			1	1	1	2	2	2	8	8	6
			0	0	0	0	0	0	3	2	1
			0	0	0	0	0	0	1	1	1
			0	0	0	1	1	1	3	3	3
Latvia			0	0	0	0	0	0	2	2	2

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	Placebo			2.5mg			7.5mg			15mg		
			S	I	C	S	I	C	S	I	C	S	I	C
Latvia	[redacted]	[redacted]	0	0	0	1	1	1	1	1	1	0	0	0
			0	0	0	1	1	1	1	1	1	0	0	0
			0	0	0	1	1	1	0	0	0	0	0	0
			0	0	0	0	0	0	1	0	0	4	2	2
			0	0	0	0	0	0	1	1	1	0	0	0
Romania			2	2	2	1	1	1	2	2	2	1	1	1
			3	3	2	0	0	0	1	1	1	2	2	2
			0	0	0	1	1	1	0	0	0	0	0	0
Sweden			0	0	0	0	0	0	1	1	1	3	3	3
			0	0	0	3	3	2	1	1	1	4	4	4
			2	1	1	6	6	5	2	2	2	0	0	0
United States			1	1	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			1	1	1	1	1	1	0	0	0	0	0	0
			1	1	0	0	0	0	1	1	1	1	1	1
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	1	1	1	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			0	0	0	0	0	0	4	4	2	0	0	0
			0	0	0	0	0	0	1	1	1	0	0	0
			0	0	0	1	1	0	1	1	1	0	0	0
			1	1	1	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			1	1	1	1	1	1	0	0	0	0	0	0
			0	0	0	2	2	2	0	0	0	0	0	0
			0	0	0	3	2	1	0	0	0	1	1	1

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	30mg			45mg			Total		
			S	I	C	S	I	C	S	I	C
Latvia	[redacted]	[redacted]	1	1	1	0	0	0	3	3	3
			1	1	1	1	1	1	4	4	4
			1	1	1	1	1	1	3	3	3
			0	0	0	1	1	1	6	3	3
			0	0	0	0	0	0	1	1	1
Romania			1	1	1	1	1	1	8	8	8
			2	2	2	1	1	1	9	9	8
			0	0	0	0	0	0	1	1	1
Sweden			0	0	0	2	2	2	6	6	6
			1	1	1	1	1	1	10	10	9
			2	2	2	3	3	3	15	14	13
United States			0	0	0	0	0	0	1	1	0
			2	2	2	0	0	0	3	3	3
			0	0	0	0	0	0	2	2	2
			0	0	0	1	1	1	4	4	3
			1	1	1	0	0	0	1	1	1
			0	0	0	0	0	0	1	1	1
			0	0	0	1	1	1	2	2	2
			0	0	0	0	0	0	4	4	2
			0	0	0	1	1	0	2	2	1
			0	0	0	2	2	2	4	4	3
			0	0	0	1	1	1	2	2	2
			0	0	0	1	1	1	2	2	2
			0	0	0	0	0	0	2	2	2
			2	2	1	1	1	1	5	5	4
			1	1	1	0	0	0	5	4	3

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	Placebo			2.5mg			7.5mg			15mg		
			S	I	C	S	I	C	S	I	C	S	I	C
United States	[redacted]	[redacted]	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1
			1	1	1	1	1	1	0	0	0	1	1	1
			0	0	0	2	2	2	2	2	1	2	2	2
			2	2	1	0	0	0	0	0	0	0	0	0
			2	2	2	0	0	0	1	1	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	1	1	1	1	1	1	0	0	0
			1	1	1	1	1	1	0	0	0	0	0	0
			1	1	1	0	0	0	0	0	0	0	0	0
			2	2	0	2	1	1	1	1	1	0	0	0
			1	1	1	0	0	0	1	1	0	0	0	0
			0	0	0	1	1	0	0	0	0	0	0	0
			1	1	1	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	1	1	1

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.3
Summary of Subject Disposition by Country

Country	Investigator's Last Name	Centre	30mg			45mg			Total		
			S	I	C	S	I	C	S	I	C
United States	[redacted]	[redacted]	1	1	1	0	0	0	1	1	1
			0	0	0	2	1	1	3	2	2
			0	0	0	2	2	2	5	5	5
			1	1	1	1	1	1	8	8	7
			1	1	0	0	0	0	3	3	1
			0	0	0	0	0	0	3	3	2
			1	1	0	0	0	0	1	1	0
			0	0	0	0	0	0	2	2	2
			0	0	0	0	0	0	2	2	2
			0	0	0	1	1	1	2	2	2
			0	0	0	1	1	0	6	5	2
			2	2	2	1	1	1	5	5	4
			0	0	0	0	0	0	1	1	0
			0	0	0	0	0	0	1	1	1
			0	0	0	0	0	0	1	1	1

Note:
S = Safety subjects
I = Intent-to-Treat subjects
C = Completed subjects

[redacted]

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Table 10.4
Summary of Screen and Run-In Failures

	Total (N=1687)
Total Number of Run-In and Screen Failures	1312 (78%)
Reason for Run-In or Screen Failure	
Adverse event	1 (<1%)
Lost to follow-up	8 (<1%)
Protocol violation	2 (<1%)
Subject decided to withdraw from study	48 (3%)
Prohibited medication use	10 (<1%)
Did not fulfil eligibility criteria	1197 (71%)
Non-compliance	0
Lack of Glycaemic Control	16 (<1%)
Other	26 (2%)
Missing	4 (<1%)

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Table 10.5
Summary of Study Conclusion

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Completion Status							
Completed	49 (77%)	47 (77%)	54 (86%)	60 (91%)	55 (92%)	56 (92%)	321 (86%)
Prematurely Withdrawn	15 (23%)	14 (23%)	9 (14%)	6 (9%)	5 (8%)	5 (8%)	54 (14%)
Reason for Premature Withdrawal							
Adverse event	5 (8%)	4 (7%)	0	0	1 (2%)	0	10 (3%)
Lost to follow-up	1 (2%)	0	2 (3%)	0	0	2 (3%)	5 (1%)
Protocol violation	0	2 (3%)	4 (6%)	2 (3%)	1 (2%)	1 (2%)	10 (3%)
Subject decided to withdraw from study	2 (3%)	2 (3%)	3 (5%)	0	0	1 (2%)	8 (2%)
Lack of efficacy	3 (5%)	0	0	1 (2%)	0	0	4 (1%)
Sponsor terminated study	0	0	0	0	0	0	0
Disease progression	0	0	0	0	0	0	0
Non-compliance	0	0	0	0	0	0	0
Insufficient therapeutic effect	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
Did not meet treatment eligibility criteria	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
Hypoglycaemic events (non-SAE)	0	0	0	0	0	0	0
Lack of Glycaemic Control	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
Other	1 (2%)	4 (7%)	0	2 (3%)	2 (3%)	1 (2%)	10 (3%)

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Table 10.6
Summary of Inclusion/Exclusion Criteria Deviations

Criterion	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)
Any criteria deviations	4 (6%)	3 (5%)	5 (8%)	4 (6%)
Inclusion criteria				
Subjects with T2DM at least 3 months preceeding screening demonstrated by fasting C-peptide level of >= 0.8 ng/ml at screening.	0	0	1 (2%)	0
Screening FPG >=7.8mmol/L and <=13.3mmol/L; pre-screen HbA1c >=7.0% and <=8.5% for subjects treated with oral monotherapy or >=7.5% and <=10.0% for subjects treated with diet/exercise only.	2 (3%)	1 (2%)	1 (2%)	3 (5%)
Body Mass Index (BMI) >= 24 (kg/m2) and <= 40 (kg/m2).	0	2 (3%)	3 (5%)	0
Exclusion criteria				
Subject has metabolic disease including Type I diabetes mellitus, uncorrected thyroid dysfunction or significant weight gain/loss of >5% total body weight within 3 months prior to screening.	0	0	1 (2%)	0
Received treatment with an investigational drug or participated in any other clinical trial during the previous 3 months.	0	0	0	1 (2%)
History of clinically significant cardiovascular disease.	2 (3%)	0	0	0
Fasting serum triglycerides >=4.5mmol/L at screening. If subject is receiving lipid-lowering therapy, must have been on the same dose for past 3 months.	0	0	0	0
Documented history of chronic or advanced hepato-biliary disease including history of, or positive results for hepatitis at screening and/or clinically significant hepatic enzyme elevation.	0	0	1 (2%)	1 (2%)

Note: 3 subjects in this table were mistakenly given randomised double-blind medication during the run-in period.
Deviations from Inclusion/Exclusion criteria are as determined by the investigator.

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Table 10.6
Summary of Inclusion/Exclusion Criteria Deviations

Criterion	30mg (N=60)	45mg (N=61)	Total (N=375)
Any criteria deviations	2 (3%)	3 (5%)	21 (6%)
Inclusion criteria			
Subjects with T2DM at least 3 months preceeding screening demonstrated by fasting C-peptide level of >= 0.8 ng/ml at screening.	0	0	1 (<1%)
Screening FPG >=7.8mmol/L and <=13.3mmol/L; pre-screen HbA1c >=7.0% and <=8.5% for subjects treated with oral monotherapy or >=7.5% and <=10.0% for subjects treated with diet/exercise only.	2 (3%)	2 (3%)	11 (3%)
Body Mass Index (BMI) >= 24 (kg/m2) and <= 40 (kg/m2).	0	0	5 (1%)
Exclusion criteria			
Subject has metabolic disease including Type I diabetes mellitus, uncorrected thyroid dysfunction or significant weight gain/loss of >5% total body weight within 3 months prior to screening.	0	0	1 (<1%)
Received treatment with an investigational drug or participated in any other clinical trial during the previous 3 months.	0	0	1 (<1%)
History of clinically significant cardiovascular disease.	0	0	2 (<1%)
Fasting serum triglycerides >=4.5mmol/L at screening. If subject is receiving lipid-lowering therapy, must have been on the same dose for past 3 months.	0	1 (2%)	1 (<1%)
Documented history of chronic or advanced hepato-biliary disease including history of, or positive results for hepatitis at screening and/or clinically significant hepatic enzyme elevation.	0	0	2 (<1%)

Note: 3 subjects in this table were mistakenly given randomised double-blind medication during the run-in period.
Deviations from Inclusion/Exclusion criteria are as determined by the investigator.

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Table 10.7
Summary of Major Deviations Leading to Exclusion from the Per Protocol Population

	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
Total number of major protocol deviators	25 (40%)	13 (22%)	13 (21%)	8 (13%)	7 (12%)	12 (20%)
Subject took prohibited concomitant medication	2 (3%)	1 (2%)	0	0	0	2 (3%)
Non-compliance with study medication	3 (5%)	1 (2%)	1 (2%)	0	2 (3%)	2 (3%)
Treatment was not taken according to protocol	0	0	0	0	1 (2%)	1 (2%)
Subject randomised to monotherapy with a washout period <28 days	4 (6%)	0	3 (5%)	2 (3%)	2 (3%)	1 (2%)
Subject systematically violated visit schedule	6 (10%)	2 (3%)	1 (2%)	5 (8%)	2 (3%)	2 (3%)
Subject with out-of-range HbA1c for inclusion criteria	5 (8%)	0	4 (6%)	1 (2%)	1 (2%)	1 (2%)
Subject does not have a week 12 HbA1c value	13 (21%)	11 (19%)	7 (11%)	3 (5%)	3 (5%)	7 (12%)

Note: Although subjects that do not have a week 12 HbA1c value are not major violators, they are excluded from the per protocol population.

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Table 10.8
Summary of Demographic Characteristics

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Age (y)	n	64	61	63	66	60	61	375
	Mean	60.8	58.6	60.4	59.9	58.8	59.2	59.6
	SD	10.89	9.54	12.41	7.97	9.95	7.85	9.87
	Median	63.0	59.0	64.0	59.5	60.0	60.0	61.0
	Min.	33	30	19	42	34	34	19
	Max.	75	75	75	73	75	74	75
	< 65	35	47	32	44	40	47	245
	>= 65	29	14	31	22	20	14	130
Sex	n	64	61	63	66	60	61	375
	Female	32 (50%)	31 (51%)	32 (51%)	33 (50%)	31 (52%)	32 (52%)	191 (51%)
	Male	32 (50%)	30 (49%)	31 (49%)	33 (50%)	29 (48%)	29 (48%)	184 (49%)
Ethnicity	n	64	61	63	66	60	61	375
	Hispanic or Latino	6 (9%)	5 (8%)	5 (8%)	1 (2%)	2 (3%)	4 (7%)	23 (6%)
	Not Hispanic or Latino	58 (91%)	56 (92%)	58 (92%)	65 (98%)	58 (97%)	57 (93%)	352 (94%)
Height (cm)	n	64	61	63	66	60	61	375
	Mean	168.7	168.2	168.7	168.2	169.0	169.3	168.7
	SD	9.41	9.35	9.17	10.35	10.68	10.21	9.82
	Median	169.0	170.0	168.0	167.5	168.0	168.0	168.0
	Min.	151	150	150	151	142	150	142
	Max.	196	187	198	191	198	193	198
Weight (kg)	n	64	61	63	66	60	61	375
	Mean	86.87	89.25	87.71	86.66	90.36	90.20	88.46
	SD	15.723	16.907	16.312	14.271	18.267	14.752	16.026
	Median	83.05	85.00	86.20	86.90	87.50	85.80	86.10
	Min.	59.0	52.9	56.1	53.0	57.8	62.5	52.9
	Max.	143.0	130.6	135.0	113.0	143.0	122.0	143.0

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Table 10.8
Summary of Demographic Characteristics

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
BMI (kg/m^2)	n	64	61	63	66	60	61	375
	Mean	30.55	31.45	30.76	30.57	31.51	31.45	31.04
	SD	4.839	4.679	4.773	4.081	4.624	4.170	4.525
	Median	29.62	30.86	30.38	30.43	30.96	31.14	30.61
	Min.	23.2	20.7	22.8	20.2	22.6	24.3	20.2
	Max.	39.6	40.8	41.2	39.6	39.8	40.1	41.2
	< 27	15	10	17	13	14	10	79
	27 - 30	20	16	12	15	7	14	84
	> 30	29	35	34	38	39	37	212
Baseline HbA1c (%)	n	64	58	60	63	58	59	362
	Mean	7.74	7.99	7.96	7.88	7.75	8.09	7.90
	SD	0.670	0.934	0.763	0.649	0.669	0.712	0.743
	Median	7.70	7.80	7.70	8.00	7.75	8.10	7.80
	Min.	6.1	6.4	6.6	6.5	6.4	6.7	6.1
	Max.	9.3	10.1	9.9	9.6	9.6	9.5	10.1
Baseline HbA1c (%) Diet & Exercise Strata	n	28	23	25	24	24	24	148
	Mean	7.70	8.08	8.15	7.87	8.00	8.12	7.98
	SD	0.635	0.880	0.835	0.469	0.694	0.707	0.720
	Median	7.70	7.70	7.70	7.90	8.00	8.15	7.80
	Min.	6.1	7.0	7.2	6.9	6.7	6.7	6.1
	Max.	9.3	9.8	9.7	8.6	9.6	9.5	9.8
Baseline HbA1c (%) Monotherapy Strata	n	36	35	35	39	34	35	214
	Mean	7.77	7.94	7.83	7.89	7.58	8.07	7.85
	SD	0.704	0.977	0.688	0.744	0.602	0.725	0.756
	Median	7.65	7.80	7.70	8.00	7.50	8.00	7.80
	Min.	6.6	6.4	6.6	6.5	6.4	6.8	6.4
	Max.	9.3	10.1	9.9	9.6	8.6	9.5	10.1

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Table 10.8
Summary of Demographic Characteristics

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Waist Circum. (cm)	n	64	61	63	66	60	61	375
	Mean	103.5	104.7	103.8	102.2	106.1	104.6	104.1
	SD	12.53	11.15	11.55	9.70	12.48	11.04	11.42
	Median	101.0	105.0	103.0	100.5	104.0	104.0	103.0
	Min.	82	74	82	84	82	72	72
	Max.	139	131	132	121	147	138	147
Hip Circum. (cm)	n	64	61	63	66	60	61	375
	Mean	108.5	110.2	108.9	108.1	110.4	111.6	109.6
	SD	11.44	9.32	11.05	9.70	10.80	9.98	10.42
	Median	106.0	111.0	108.0	108.0	108.0	109.0	108.0
	Min.	90	94	80	90	88	91	80
	Max.	137	136	136	135	137	135	137
Waist:Hip Ratio	n	64	61	63	66	60	61	375
	Mean	0.955	0.952	0.956	0.947	0.962	0.940	0.952
	SD	0.0781	0.0860	0.0805	0.0596	0.0761	0.0909	0.0787
	Median	0.949	0.962	0.952	0.949	0.955	0.943	0.951
	Min.	0.79	0.74	0.82	0.83	0.80	0.69	0.69
	Max.	1.12	1.21	1.16	1.11	1.15	1.12	1.21

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Table 10.9
Summary of Type II Diabetes Mellitus History

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Duration (yrs) [1]							
n	64	61	63	66	60	61	375
Mean	5.44	5.32	5.67	5.12	5.29	5.06	5.32
SD	4.580	4.630	5.999	4.826	5.064	4.223	4.892
Median	4.28	5.08	3.66	3.56	4.64	3.76	4.00
Min.	0.1	0.0	0.3	0.2	0.2	0.1	0.0
Max.	24.2	22.7	35.5	23.6	29.7	18.5	35.5
Pre-study treatment							
n	64	61	63	66	60	61	375
Diet & Exercise	28 (44%)	24 (39%)	27 (43%)	24 (36%)	25 (42%)	25 (41%)	153 (41%)
Monotherapy	36 (56%)	37 (61%)	36 (57%)	42 (64%)	35 (58%)	36 (59%)	222 (59%)

[1] If month is missing the first day of the year is used to calculate duration, otherwise the first of the month is used.

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Table 10.10
Summary of Selected Demographic Characteristics by Gender and Prior Therapy

	Treatment	Strata	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	Placebo	Female, Diet & Exercise	14	32.28	4.797	33.88	25.0	38.8
		Male, Diet & Exercise	14	30.63	5.148	29.31	24.2	39.5
		Female, Monotherapy	18	32.25	5.192	31.84	24.5	39.6
		Male, Monotherapy	18	27.44	2.487	27.44	23.2	31.5
	2.5mg	Female, Diet & Exercise	11	34.05	4.615	35.22	27.9	39.8
		Male, Diet & Exercise	13	30.73	5.384	30.12	24.3	40.4
		Female, Monotherapy	20	30.15	3.299	30.74	20.7	36.4
		Male, Monotherapy	17	31.84	5.172	30.15	24.1	40.8
	7.5mg	Female, Diet & Exercise	13	32.05	3.922	31.01	25.8	40.0
		Male, Diet & Exercise	14	29.55	3.517	28.68	24.8	34.8
		Female, Monotherapy	19	30.98	5.015	31.98	24.0	41.2
		Male, Monotherapy	17	30.53	5.970	30.38	22.8	39.4
	15mg	Female, Diet & Exercise	10	30.77	4.232	30.53	24.4	39.6
		Male, Diet & Exercise	14	29.43	3.808	29.20	24.1	36.6
		Female, Monotherapy	23	32.59	4.462	33.30	20.2	38.6
		Male, Monotherapy	19	28.88	2.669	29.86	24.5	33.7
	30mg	Female, Diet & Exercise	12	30.94	4.927	30.77	24.1	39.4
		Male, Diet & Exercise	13	31.23	4.667	31.01	25.9	39.4
		Female, Monotherapy	19	32.01	5.052	30.76	22.6	39.2
		Male, Monotherapy	16	31.59	4.153	31.02	23.7	39.8
	45mg	Female, Diet & Exercise	11	33.67	2.595	33.82	29.3	37.5
		Male, Diet & Exercise	14	30.48	4.377	29.03	26.0	38.9
		Female, Monotherapy	21	31.62	4.666	30.69	24.8	40.1
		Male, Monotherapy	15	30.49	3.871	28.75	24.3	37.2
Duration of Diabetes (yrs)[1]	Placebo	Female, Diet & Exercise	14	3.24	2.436	3.06	0.3	9.2
		Male, Diet & Exercise	14	4.00	3.540	3.40	0.1	11.0

[1] If month is missing the first day of the year is used to calculate duration, otherwise the first of the month is used.

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Table 10.10
Summary of Selected Demographic Characteristics by Gender and Prior Therapy

	Treatment	Strata	n	Mean	SD	Median	Min.	Max.
Duration of Diabetes (yrs)[1]	Placebo	Female, Monotherapy	18	5.61	5.364	4.19	0.4	24.2
		Male, Monotherapy	18	8.09	4.658	7.10	2.1	17.1
	2.5mg	Female, Diet & Exercise	11	5.37	3.365	5.40	1.3	13.7
		Male, Diet & Exercise	13	5.36	5.858	4.32	0.0	20.9
		Female, Monotherapy	20	4.71	5.087	3.62	0.3	22.7
		Male, Monotherapy	17	5.99	3.989	5.94	0.2	15.7
	7.5mg	Female, Diet & Exercise	13	3.49	2.633	3.76	0.3	8.0
		Male, Diet & Exercise	14	5.23	4.020	4.07	0.5	15.8
		Female, Monotherapy	19	8.96	8.969	4.40	2.1	35.5
		Male, Monotherapy	17	4.02	3.293	2.36	1.2	10.7
	15mg	Female, Diet & Exercise	10	4.53	6.939	2.25	0.3	23.6
		Male, Diet & Exercise	14	4.41	5.641	2.03	0.2	19.5
		Female, Monotherapy	23	4.61	3.070	3.75	0.4	10.6
		Male, Monotherapy	19	6.60	4.723	6.37	0.4	16.4
	30mg	Female, Diet & Exercise	12	2.95	2.565	2.34	0.3	8.2
		Male, Diet & Exercise	13	2.99	2.644	2.06	0.2	8.9
		Female, Monotherapy	19	7.85	6.811	6.69	1.1	29.7
		Male, Monotherapy	16	5.88	4.141	5.15	0.7	17.7
	45mg	Female, Diet & Exercise	11	3.21	2.290	2.94	0.6	7.5
		Male, Diet & Exercise	14	3.68	3.513	2.66	0.1	10.6
		Female, Monotherapy	21	6.94	5.110	5.45	0.7	18.5
		Male, Monotherapy	15	5.07	3.746	4.06	1.3	13.5

[1] If month is missing the first day of the year is used to calculate duration, otherwise the first of the month is used.

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Table 10.11
Summary of Baseline HbA1c (%) by Prior Therapy

	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)		Total (N=375)	
Total, n	64		58		60		63		58		59		362	
< 7.5%	21	(33%)	16	(28%)	16	(27%)	16	(25%)	19	(33%)	12	(20%)	100	(28%)
>=7.5% - <8%	21	(33%)	17	(29%)	19	(32%)	15	(24%)	14	(24%)	15	(25%)	101	(28%)
>=8% - <8.5%	13	(20%)	13	(22%)	12	(20%)	23	(37%)	18	(31%)	15	(25%)	94	(26%)
>=8.5%	9	(14%)	12	(21%)	13	(22%)	9	(14%)	7	(12%)	17	(29%)	67	(19%)
Diet & Exercise, n	28		23		25		24		24		24		148	
< 7.5%	8	(29%)	6	(26%)	6	(24%)	4	(17%)	5	(21%)	3	(13%)	32	(22%)
>=7.5% - <8%	12	(43%)	8	(35%)	8	(32%)	9	(38%)	5	(21%)	8	(33%)	50	(34%)
>=8% - <8.5%	6	(21%)	3	(13%)	3	(12%)	10	(42%)	8	(33%)	5	(21%)	35	(24%)
>=8.5%	2	(7%)	6	(26%)	8	(32%)	1	(4%)	6	(25%)	8	(33%)	31	(21%)
Monotherapy, n	36		35		35		39		34		35		214	
< 7.5%	13	(36%)	10	(29%)	10	(29%)	12	(31%)	14	(41%)	9	(26%)	68	(32%)
>=7.5% - <8%	9	(25%)	9	(26%)	11	(31%)	6	(15%)	9	(26%)	7	(20%)	51	(24%)
>=8% - <8.5%	7	(19%)	10	(29%)	9	(26%)	13	(33%)	10	(29%)	10	(29%)	59	(28%)
>=8.5%	7	(19%)	6	(17%)	5	(14%)	8	(21%)	1	(3%)	9	(26%)	36	(17%)

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Table 10.12
Summary of Race and Racial Combinations

Race	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
n	64	61	63	66	60	61	375
African American/African Heritage	5 (8%)	2 (3%)	5 (8%)	3 (5%)	1 (2%)	4 (7%)	20 (5%)
American Indian or Alaska Native	0	0	0	0	0	0	0
Asian	2 (3%)	0	1 (2%)	1 (2%)	6 (10%)	2 (3%)	12 (3%)
Central/South Asian Heritage	1 (2%)	0	1 (2%)	0	4 (7%)	2 (3%)	8 (2%)
Japanese/East Asian Heritage/ South East Asian Heritage	1 (2%)	0	0	1 (2%)	2 (3%)	0	4 (1%)
Native Hawaiian or other Pacific Islander	0	1 (2%)	0	0	0	0	1 (<1%)
White	57 (89%)	58 (95%)	57 (90%)	60 (91%)	53 (88%)	55 (90%)	340 (91%)
African American/African Heritage & White	0	0	0	1 (2%)	0	0	1 (<1%)
Asian & White	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.13
Summary of Race and Racial Combination Details

Race	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
n	64	61	63	66	60	61	375
African American/African Heritage	5 (8%)	2 (3%)	5 (8%)	3 (5%)	1 (2%)	4 (7%)	20 (5%)
American Indian or Alaska Native	0	0	0	0	0	0	0
Asian - Central/South Asian Heritage	1 (2%)	0	1 (2%)	0	4 (7%)	2 (3%)	8 (2%)
Asian - East Asian Heritage	0	0	0	0	1 (2%)	0	1 (<1%)
Asian - Japanese Heritage	0	0	0	0	0	0	0
Asian - South East Asian Heritage	1 (2%)	0	0	1 (2%)	1 (2%)	0	3 (<1%)
Asian - Mixed Race	0	0	0	0	0	0	0
Native Hawaiian or other Pacific Islander	0	1 (2%)	0	0	0	0	1 (<1%)
White - Arabic/North African Heritage	0	0	0	1 (2%)	2 (3%)	0	3 (<1%)
White - White/Caucasian/European Heritage	57 (89%)	58 (95%)	57 (90%)	59 (89%)	51 (85%)	55 (90%)	337 (90%)
White - Mixed Race	0	0	0	0	0	0	0
Mixed Race	0	0	0	2 (3%)	0	0	2 (<1%)

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Table 10.14
Summary of Substance Use

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Smoking History							
n	64	61	63	66	60	61	375
Never smoked	42 (66%)	39 (64%)	38 (60%)	45 (68%)	42 (70%)	40 (66%)	246 (66%)
Current smoker	10 (16%)	12 (20%)	10 (16%)	9 (14%)	12 (20%)	10 (16%)	63 (17%)
Former smoker	12 (19%)	10 (16%)	15 (24%)	12 (18%)	6 (10%)	11 (18%)	66 (18%)
Drink Alcohol							
n	64	61	63	66	60	60	374
Yes	26 (41%)	24 (39%)	19 (30%)	23 (35%)	21 (35%)	19 (32%)	132 (35%)
No	38 (59%)	37 (61%)	44 (70%)	43 (65%)	39 (65%)	41 (68%)	242 (65%)
Alcohol Units/Week							
n	26	24	19	23	21	19	132
Mean	5.1	4.1	3.4	5.1	3.5	3.4	4.2
SD	5.22	3.75	3.71	4.69	3.10	2.44	4.02
Median	2.5	3.0	2.0	3.0	2.0	2.0	2.5
Min.	0	1	0	0	1	1	0
Max.	21	14	14	18	12	7	21

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Table 10.15
Summary of Past Medical Conditions

Classification	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Any Condition	28 (44%)	32 (52%)	22 (35%)	21 (32%)	21 (35%)	28 (46%)	152 (41%)
Blood and lymphatic system disorders	0	0	0	1 (2%)	0	0	1 (<1%)
Cardiac disorders	2 (3%)	7 (11%)	3 (5%)	3 (5%)	4 (7%)	1 (2%)	20 (5%)
Ear and labyrinth disorders	1 (2%)	1 (2%)	1 (2%)	3 (5%)	0	3 (5%)	9 (2%)
Endocrine disorders	1 (2%)	1 (2%)	2 (3%)	1 (2%)	0	0	5 (1%)
Eye disorders	2 (3%)	1 (2%)	1 (2%)	0	2 (3%)	1 (2%)	7 (2%)
Gastrointestinal disorders	5 (8%)	3 (5%)	7 (11%)	2 (3%)	4 (7%)	8 (13%)	29 (8%)
Hepatobiliary disorders	4 (6%)	7 (11%)	0	5 (8%)	2 (3%)	3 (5%)	21 (6%)
Immune system disorders	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
Metabolism and nutrition disorders	0	2 (3%)	2 (3%)	2 (3%)	0	0	6 (2%)
Musculoskeletal and connective tissue disorders	3 (5%)	5 (8%)	5 (8%)	6 (9%)	2 (3%)	4 (7%)	25 (7%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (5%)	2 (3%)	5 (8%)	1 (2%)	3 (5%)	2 (3%)	16 (4%)
Nervous system disorders	2 (3%)	0	2 (3%)	2 (3%)	1 (2%)	1 (2%)	8 (2%)
Psychiatric disorders	4 (6%)	2 (3%)	4 (6%)	0	5 (8%)	3 (5%)	18 (5%)
Renal and urinary disorders	4 (6%)	1 (2%)	3 (5%)	3 (5%)	4 (7%)	2 (3%)	17 (5%)
Reproductive system and breast disorders	7 (11%)	2 (3%)	1 (2%)	2 (3%)	3 (5%)	5 (8%)	20 (5%)
Respiratory, thoracic and mediastinal disorders	0	4 (7%)	2 (3%)	2 (3%)	4 (7%)	1 (2%)	13 (3%)
Skin and subcutaneous tissue disorders	2 (3%)	3 (5%)	3 (5%)	2 (3%)	1 (2%)	2 (3%)	13 (3%)
Vascular disorders	0	5 (8%)	2 (3%)	1 (2%)	0	1 (2%)	9 (2%)
Infections and infestations	3 (5%)	2 (3%)	1 (2%)	1 (2%)	2 (3%)	2 (3%)	11 (3%)
Congenital, familial and genetic disorders	0	1 (2%)	0	0	0	0	1 (<1%)
General disorders and administration site conditions	2 (3%)	1 (2%)	2 (3%)	1 (2%)	0	2 (3%)	8 (2%)
Injury, poisoning and procedural complications	2 (3%)	2 (3%)	1 (2%)	2 (3%)	1 (2%)	1 (2%)	9 (2%)

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Table 10.16
Summary of Current Medical Conditions

Classification	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Any Condition	58 (91%)	56 (92%)	51 (81%)	59 (89%)	52 (87%)	54 (89%)	330 (88%)
Blood and lymphatic system disorders	0	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	5 (1%)
Cardiac disorders	24 (38%)	7 (11%)	12 (19%)	16 (24%)	14 (23%)	12 (20%)	85 (23%)
Ear and labyrinth disorders	4 (6%)	6 (10%)	1 (2%)	2 (3%)	3 (5%)	2 (3%)	18 (5%)
Endocrine disorders	17 (27%)	20 (33%)	18 (29%)	18 (27%)	20 (33%)	16 (26%)	109 (29%)
Eye disorders	13 (20%)	13 (21%)	4 (6%)	11 (17%)	10 (17%)	6 (10%)	57 (15%)
Gastrointestinal disorders	8 (13%)	9 (15%)	4 (6%)	12 (18%)	7 (12%)	7 (11%)	47 (13%)
Hepatobiliary disorders	1 (2%)	2 (3%)	0	1 (2%)	3 (5%)	1 (2%)	8 (2%)
Immune system disorders	0	2 (3%)	1 (2%)	2 (3%)	1 (2%)	1 (2%)	7 (2%)
Metabolism and nutrition disorders	44 (69%)	28 (46%)	37 (59%)	32 (48%)	33 (55%)	32 (52%)	206 (55%)
Musculoskeletal and connective tissue disorders	25 (39%)	12 (20%)	15 (24%)	17 (26%)	24 (40%)	17 (28%)	110 (29%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (2%)	0	0	1 (2%)	1 (2%)	2 (3%)	5 (1%)
Nervous system disorders	11 (17%)	10 (16%)	8 (13%)	5 (8%)	6 (10%)	4 (7%)	44 (12%)
Psychiatric disorders	5 (8%)	3 (5%)	2 (3%)	3 (5%)	3 (5%)	1 (2%)	17 (5%)
Renal and urinary disorders	9 (14%)	6 (10%)	2 (3%)	4 (6%)	6 (10%)	4 (7%)	31 (8%)
Reproductive system and breast disorders	6 (9%)	4 (7%)	2 (3%)	4 (6%)	4 (7%)	2 (3%)	22 (6%)
Respiratory, thoracic and mediastinal disorders	5 (8%)	2 (3%)	5 (8%)	4 (6%)	5 (8%)	9 (15%)	30 (8%)
Skin and subcutaneous tissue disorders	5 (8%)	6 (10%)	6 (10%)	7 (11%)	7 (12%)	4 (7%)	35 (9%)
Vascular disorders	42 (66%)	29 (48%)	30 (48%)	36 (55%)	35 (58%)	32 (52%)	204 (54%)
Infections and infestations	0	0	0	0	0	2 (3%)	2 (<1%)
Congenital, familial and genetic disorders	1 (2%)	1 (2%)	1 (2%)	0	0	1 (2%)	4 (1%)
General disorders and administration site conditions	3 (5%)	4 (7%)	4 (6%)	5 (8%)	6 (10%)	2 (3%)	24 (6%)
Injury, poisoning and procedural complications	0	0	1 (2%)	0	0	0	1 (<1%)

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Table 10.17
Summary of Past Diabetes Medical Conditions

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANY DIABETES MEDICAL CONDITION	3 (5%)	3 (5%)	3 (5%)	2 (3%)	2 (3%)	0	13 (3%)
Renal and urinary disorders							
Any condition	2 (3%)	2 (3%)	2 (3%)	0	2 (3%)	0	8 (2%)
Microalbuminuria	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)	0	4 (1%)
Proteinuria	1 (2%)	2 (3%)	0	0	1 (2%)	0	4 (1%)
Nephropathy	0	1 (2%)	1 (2%)	0	1 (2%)	0	3 (<1%)
Renal failure chronic	0	0	0	0	1 (2%)	0	1 (<1%)
Metabolism and nutrition disorders							
Any condition	0	3 (5%)	2 (3%)	1 (2%)	0	0	6 (2%)
Dyslipidaemia	0	3 (5%)	1 (2%)	1 (2%)	0	0	5 (1%)
Diabetic foot	0	0	1 (2%)	0	0	0	1 (<1%)
Nervous system disorders							
Any condition	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
Autonomic neuropathy	1 (2%)	0	0	0	0	0	1 (<1%)
Neuropathy peripheral	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.18
Summary of Current Diabetes Medical Conditions

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANY DIABETES MEDICAL CONDITION	39 (61%)	28 (46%)	32 (51%)	26 (39%)	29 (48%)	28 (46%)	182 (49%)
Metabolism and nutrition disorders							
Any condition	35 (55%)	24 (39%)	30 (48%)	22 (33%)	25 (42%)	27 (44%)	163 (43%)
Dyslipidaemia	35 (55%)	24 (39%)	30 (48%)	22 (33%)	25 (42%)	27 (44%)	163 (43%)
Nervous system disorders							
Any condition	9 (14%)	5 (8%)	5 (8%)	4 (6%)	3 (5%)	2 (3%)	28 (7%)
Neuropathy peripheral	9 (14%)	5 (8%)	5 (8%)	4 (6%)	3 (5%)	2 (3%)	28 (7%)
Renal and urinary disorders							
Any condition	2 (3%)	1 (2%)	1 (2%)	3 (5%)	1 (2%)	0	8 (2%)
Microalbuminuria	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)
Proteinuria	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
Nephropathy	0	0	0	1 (2%)	0	0	1 (<1%)
Eye disorders							
Any condition	0	0	1 (2%)	0	2 (3%)	0	3 (<1%)
Diabetic retinopathy	0	0	1 (2%)	0	2 (3%)	0	3 (<1%)

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Table 10.19
Summary of Past Cardiovascular Medical Conditions

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANY CARDIOVASCULAR MEDICAL CONDITION	5 (8%)	8 (13%)	7 (11%)	9 (14%)	5 (8%)	5 (8%)	39 (10%)
Cardiac disorders							
Any condition	2 (3%)	6 (10%)	6 (10%)	4 (6%)	2 (3%)	2 (3%)	22 (6%)
Myocardial infarction	1 (2%)	5 (8%)	2 (3%)	2 (3%)	2 (3%)	1 (2%)	13 (3%)
Myocardial ischaemia	1 (2%)	2 (3%)	2 (3%)	1 (2%)	1 (2%)	0	7 (2%)
Arrhythmia	1 (2%)	0	2 (3%)	0	0	1 (2%)	4 (1%)
Coronary artery disease	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)
Angina pectoris	0	0	0	2 (3%)	0	1 (2%)	3 (<1%)
Angina unstable	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
Cardiac failure	0	0	0	1 (2%)	0	0	1 (<1%)
Cardiac valve disease	0	0	0	1 (2%)	0	0	1 (<1%)
Vascular disorders							
Any condition	2 (3%)	2 (3%)	2 (3%)	1 (2%)	3 (5%)	1 (2%)	11 (3%)
Hypertension	1 (2%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0	8 (2%)
Peripheral vascular disorder	1 (2%)	1 (2%)	1 (2%)	0	0	1 (2%)	4 (1%)
General disorders and administration site conditions							
Any condition	1 (2%)	1 (2%)	0	2 (3%)	1 (2%)	1 (2%)	6 (2%)
Oedema	1 (2%)	1 (2%)	0	2 (3%)	1 (2%)	1 (2%)	6 (2%)
Nervous system disorders							
Any condition	0	0	1 (2%)	3 (5%)	1 (2%)	1 (2%)	6 (2%)
Cerebrovascular disorder	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	4 (1%)
Cerebrovascular accident	0	0	1 (2%)	1 (2%)	0	1 (2%)	3 (<1%)
Transient ischaemic attack	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)

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Table 10.20
Summary of Current Cardiovascular Medical Conditions

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANY CARDIOVASCULAR MEDICAL CONDITION	45 (70%)	31 (51%)	31 (49%)	34 (52%)	36 (60%)	34 (56%)	211 (56%)
Vascular disorders							
Any condition	42 (66%)	30 (49%)	30 (48%)	34 (52%)	35 (58%)	33 (54%)	204 (54%)
Hypertension	41 (64%)	30 (49%)	29 (46%)	33 (50%)	34 (57%)	33 (54%)	200 (53%)
Arteriosclerosis	4 (6%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	1 (2%)	14 (4%)
Peripheral vascular disorder	3 (5%)	0	3 (5%)	0	0	1 (2%)	7 (2%)
Cardiac disorders							
Any condition	12 (19%)	3 (5%)	5 (8%)	4 (6%)	1 (2%)	2 (3%)	27 (7%)
Coronary artery disease	5 (8%)	3 (5%)	1 (2%)	0	0	1 (2%)	10 (3%)
Myocardial ischaemia	4 (6%)	1 (2%)	1 (2%)	1 (2%)	0	2 (3%)	9 (2%)
Arrhythmia	4 (6%)	0	1 (2%)	1 (2%)	0	0	6 (2%)
Cardiac valve disease	2 (3%)	0	0	0	1 (2%)	0	3 (<1%)
Ventricular dysfunction	1 (2%)	0	2 (3%)	0	0	0	3 (<1%)
Angina pectoris	1 (2%)	0	1 (2%)	0	0	0	2 (<1%)
Ventricular hypertrophy	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
Cardiac failure	0	0	0	1 (2%)	0	0	1 (<1%)
General disorders and administration site conditions							
Any condition	1 (2%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	1 (2%)	11 (3%)
Oedema	1 (2%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	1 (2%)	11 (3%)
Nervous system disorders							
Any condition	0	0	1 (2%)	0	0	0	1 (<1%)
Cerebrovascular disorder	0	0	1 (2%)	0	0	0	1 (<1%)

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Table 10.21
Summary of Prior Anti-Diabetic Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Any medication	36 (56%)	37 (61%)	37 (59%)	42 (64%)	35 (58%)	38 (62%)	225 (60%)
ALIMENTARY TRACT AND METABOLISM							
Any medication	36 (56%)	37 (61%)	37 (59%)	42 (64%)	35 (58%)	38 (62%)	225 (60%)
DRUGS USED IN DIABETES							
Any medication	36 (56%)	37 (61%)	37 (59%)	42 (64%)	35 (58%)	38 (62%)	225 (60%)
METFORMIN	11 (17%)	11 (18%)	16 (25%)	13 (20%)	19 (32%)	15 (25%)	85 (23%)
METFORMIN HYDROCHLORIDE	11 (17%)	11 (18%)	10 (16%)	15 (23%)	10 (17%)	14 (23%)	71 (19%)
GLIBENCLAMIDE	3 (5%)	6 (10%)	3 (5%)	5 (8%)	2 (3%)	3 (5%)	22 (6%)
GLIMEPIRIDE	5 (8%)	3 (5%)	3 (5%)	5 (8%)	0	5 (8%)	21 (6%)
GLICLAZIDE	1 (2%)	3 (5%)	4 (6%)	3 (5%)	0	0	11 (3%)
GLIPIZIDE	4 (6%)	1 (2%)	1 (2%)	3 (5%)	2 (3%)	0	11 (3%)
REPAGLINIDE	0	2 (3%)	0	0	2 (3%)	0	4 (1%)
ACARBOSE	0	0	0	0	1 (2%)	0	1 (<1%)
BUFORMIN	0	0	0	1 (2%)	0	0	1 (<1%)
METFORMIN HYDROCHLORIDE+ROSIGLITAZONE	0	0	0	0	1 (2%)	0	1 (<1%)
NATEGLINIDE	0	0	0	0	0	1 (2%)	1 (<1%)
PIOGLITAZONE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
ROSIGLITAZONE MALEATE	0	0	0	0	1 (2%)	0	1 (<1%)
TOLBUTAMIDE	1 (2%)	0	0	0	0	0	1 (<1%)
VARIOUS							
Any medication	1 (2%)	0	0	0	0	0	1 (<1%)
DIAGNOSTIC AGENTS							
Any medication	1 (2%)	0	0	0	0	0	1 (<1%)
TOLBUTAMIDE	1 (2%)	0	0	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Any medication	50 (78%)	47 (77%)	46 (73%)	50 (76%)	43 (72%)	45 (74%)	281 (75%)
CARDIOVASCULAR SYSTEM							
Any medication	46 (72%)	33 (54%)	40 (63%)	37 (56%)	35 (58%)	35 (57%)	226 (60%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM							
Any medication	35 (55%)	23 (38%)	24 (38%)	27 (41%)	17 (28%)	24 (39%)	150 (40%)
RAMIPRIL	5 (8%)	2 (3%)	4 (6%)	5 (8%)	0	4 (7%)	20 (5%)
LISINOPRIL	8 (13%)	2 (3%)	2 (3%)	2 (3%)	1 (2%)	4 (7%)	19 (5%)
ENALAPRIL	4 (6%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	3 (5%)	14 (4%)
PERINDOPRIL	1 (2%)	3 (5%)	2 (3%)	4 (6%)	1 (2%)	2 (3%)	13 (3%)
HYDROCHLOROTHIAZIDE+VALSARTAN	1 (2%)	1 (2%)	1 (2%)	3 (5%)	3 (5%)	0	9 (2%)
VALSARTAN	2 (3%)	0	1 (2%)	2 (3%)	0	3 (5%)	8 (2%)
CANDESARTAN CILEXETIL	1 (2%)	3 (5%)	0	0	1 (2%)	0	5 (1%)
CAPTOPRIL	1 (2%)	0	0	2 (3%)	1 (2%)	1 (2%)	5 (1%)
ENALAPRIL MALEATE	1 (2%)	0	4 (6%)	0	0	0	5 (1%)
HYDROCHLOROTHIAZIDE+OLMESARTAN	1 (2%)	1 (2%)	2 (3%)	0	0	1 (2%)	5 (1%)
LOSARTAN POTASSIUM	1 (2%)	2 (3%)	1 (2%)	0	0	1 (2%)	5 (1%)
HYDROCHLOROTHIAZIDE+RAMIPRIL	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	4 (1%)
VERAPAMIL HYDROCHLORIDE+TRANDOLAPRIL	1 (2%)	1 (2%)	0	1 (2%)	0	1 (2%)	4 (1%)
CILAZAPRIL	0	1 (2%)	0	1 (2%)	1 (2%)	0	3 (<1%)
FOSINOPRIL SODIUM	0	1 (2%)	0	0	1 (2%)	1 (2%)	3 (<1%)
HYDROCHLOROTHIAZIDE+QUINAPRIL HYDROCHLORIDE	0	2 (3%)	0	0	1 (2%)	0	3 (<1%)
IRBESARTAN	2 (3%)	0	0	1 (2%)	0	0	3 (<1%)
LOSARTAN	1 (2%)	0	1 (2%)	0	1 (2%)	0	3 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL MALEATE	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
HYDROCHLOROTHIAZIDE+LOSARTAN POTASSIUM	0	2 (3%)	0	0	0	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
OLMESARTAN	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
TELMISARTAN	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
BENAZEPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
BENAZEPRIL HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
CANDESARTAN	1 (2%)	0	0	0	0	0	1 (<1%)
EPROSARTAN	0	0	0	1 (2%)	0	0	1 (<1%)
FELODIPINE+RAMIPRIL	1 (2%)	0	0	0	0	0	1 (<1%)
FOSINOPRIL	0	0	1 (2%)	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+CANDESARTAN CILEXETIL	0	1 (2%)	0	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+CAPTOPRIL	0	0	0	0	1 (2%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+EPROSARTAN MESILATE	0	0	0	0	1 (2%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+IRBESARTAN	0	0	0	0	0	1 (2%)	1 (<1%)
HYDROCHLOROTHIAZIDE+LISINOPRIL	0	0	1 (2%)	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+TELMISARTAN	1 (2%)	0	0	0	0	0	1 (<1%)
INDAPAMIDE+PERINDOPRIL ERBUMINE	0	0	0	1 (2%)	0	0	1 (<1%)
LISINOPRIL DIHYDRATE	0	0	0	1 (2%)	0	0	1 (<1%)
PIRETANIDE+RAMIPRIL	1 (2%)	0	0	0	0	0	1 (<1%)
QUINAPRIL	0	0	0	0	0	1 (2%)	1 (<1%)
SPIRAPRIL HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
TRANDOLAPRIL	0	0	0	0	0	1 (2%)	1 (<1%)
SERUM LIPID REDUCING AGENTS							
Any medication	24 (38%)	17 (28%)	19 (30%)	12 (18%)	12 (20%)	17 (28%)	101 (27%)
SIMVASTATIN	10 (16%)	6 (10%)	9 (14%)	5 (8%)	3 (5%)	5 (8%)	38 (10%)
ATORVASTATIN CALCIUM	6 (9%)	6 (10%)	4 (6%)	3 (5%)	2 (3%)	3 (5%)	24 (6%)
FENOFIBRATE	4 (6%)	0	3 (5%)	1 (2%)	1 (2%)	5 (8%)	14 (4%)
ROSUVASTATIN CALCIUM	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	2 (3%)	7 (2%)
LOVASTATIN	0	2 (3%)	2 (3%)	0	0	2 (3%)	6 (2%)
FLUVASTATIN SODIUM	0	1 (2%)	0	0	1 (2%)	2 (3%)	4 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
EZETIMIBE	1 (2%)	1 (2%)	0	0	1 (2%)	0	3 (<1%)
SIMVASTATIN+EZETIMIBE	0	0	0	1 (2%)	2 (3%)	0	3 (<1%)
ATORVASTATIN	0	0	0	2 (3%)	0	0	2 (<1%)
BEZAFIBRATE	0	0	0	0	0	1 (2%)	1 (<1%)
COLESEVELAM HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
FISH OIL	0	0	1 (2%)	0	0	0	1 (<1%)
GEMFIBROZIL	0	1 (2%)	0	0	0	0	1 (<1%)
NICOTINIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)
OMEGA-3 MARINE TRIGLYCERIDES	0	0	1 (2%)	0	0	0	1 (<1%)
PRAVASTATIN	1 (2%)	0	0	0	0	0	1 (<1%)
PRAVASTATIN SODIUM	0	0	0	1 (2%)	0	0	1 (<1%)
ROSUVASTATIN	1 (2%)	0	0	0	0	0	1 (<1%)
TOCOPHEROL+DOCOSAHEXANOIC ACID+EICOSAPENTAENOIC ACID	0	0	0	0	1 (2%)	0	1 (<1%)
BETA BLOCKING AGENTS							
Any medication	14 (22%)	12 (20%)	15 (24%)	9 (14%)	11 (18%)	14 (23%)	75 (20%)
METOPROLOL	6 (9%)	1 (2%)	3 (5%)	1 (2%)	4 (7%)	4 (7%)	19 (5%)
BETAXOLOL HYDROCHLORIDE	2 (3%)	3 (5%)	1 (2%)	2 (3%)	1 (2%)	0	9 (2%)
METOPROLOL SUCCINATE	0	3 (5%)	2 (3%)	1 (2%)	1 (2%)	2 (3%)	9 (2%)
ATENOLOL	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	3 (5%)	8 (2%)
METOPROLOL TARTRATE	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	1 (2%)	6 (2%)
BISOPROLOL	0	0	2 (3%)	0	0	2 (3%)	4 (1%)
CARVEDILOL	2 (3%)	0	1 (2%)	0	1 (2%)	0	4 (1%)
BISOPROLOL FUMARATE	1 (2%)	1 (2%)	1 (2%)	0	0	0	3 (<1%)
HYDROCHLOROTHIAZIDE+BISOPROLOL FUMARATE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
NEBIVOLOL HYDROCHLORIDE	0	0	0	1 (2%)	1 (2%)	1 (2%)	3 (<1%)
BETAXOLOL	1 (2%)	0	1 (2%)	0	0	0	2 (<1%)
CHLORTALIDONE+ATENOLOL	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
PROPRANOLOL	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
TIMOLOL	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
BOPINDOLOL MALONATE	0	0	0	0	0	1 (2%)	1 (<1%)
SOTALOL HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
TIMOLOL MALEATE	0	0	1 (2%)	0	0	0	1 (<1%)
DIURETICS							
Any medication	13 (20%)	7 (11%)	8 (13%)	5 (8%)	13 (22%)	11 (18%)	57 (15%)
HYDROCHLOROTHIAZIDE	4 (6%)	3 (5%)	3 (5%)	0	3 (5%)	5 (8%)	18 (5%)
INDAPAMIDE	4 (6%)	1 (2%)	2 (3%)	1 (2%)	4 (7%)	4 (7%)	16 (4%)
HYDROCHLOROTHIAZIDE+AMILORIDE HYDROCHLORIDE	0	2 (3%)	2 (3%)	3 (5%)	2 (3%)	1 (2%)	10 (3%)
FUROSEMIDE	1 (2%)	0	2 (3%)	0	2 (3%)	1 (2%)	6 (2%)
TORASEMIDE	2 (3%)	0	0	0	1 (2%)	0	3 (<1%)
PIRETANIDE	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
BENDROFLUMETHIAZIDE	0	0	0	0	0	1 (2%)	1 (<1%)
CHLORTALIDONE+AMILORIDE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
TRIAMTERENE+XIPAMIDE	1 (2%)	0	0	0	0	0	1 (<1%)
CALCIUM CHANNEL BLOCKERS							
Any medication	9 (14%)	3 (5%)	9 (14%)	10 (15%)	6 (10%)	7 (11%)	44 (12%)
AMLODIPINE BESILATE	5 (8%)	1 (2%)	4 (6%)	3 (5%)	3 (5%)	2 (3%)	18 (5%)
NITRENDIPINE	0	1 (2%)	3 (5%)	0	1 (2%)	0	5 (1%)
FELODIPINE	0	0	0	3 (5%)	0	1 (2%)	4 (1%)
NIFEDIPINE	3 (5%)	0	0	0	0	1 (2%)	4 (1%)
AMLODIPINE	0	0	1 (2%)	0	1 (2%)	1 (2%)	3 (<1%)
DILTIAZEM HYDROCHLORIDE	0	0	1 (2%)	1 (2%)	0	1 (2%)	3 (<1%)
VERAPAMIL	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
VERAPAMIL HYDROCHLORIDE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
ISRADIPINE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
DILTIAZEM	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIHYPERTENSIVES							
Any medication	2 (3%)	2 (3%)	1 (2%)	3 (5%)	5 (8%)	2 (3%)	15 (4%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
VERAPAMIL HYDROCHLORIDE+TRANDOLAPRIL	1 (2%)	1 (2%)	0	1 (2%)	0	1 (2%)	4 (1%)
DOXAZOSIN MESILATE	1 (2%)	0	0	0	2 (3%)	0	3 (<1%)
ISRADIPINE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
MOXONIDINE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DILTIAZEM	0	0	0	0	0	1 (2%)	1 (<1%)
HYDROCHLOROTHIAZIDE+EPROSARTAN MESILATE	0	0	0	0	1 (2%)	0	1 (<1%)
METHYLDOPA	0	1 (2%)	0	0	0	0	1 (<1%)
RILMENIDINE	0	1 (2%)	0	0	0	0	1 (<1%)
CARDIAC THERAPY							
Any medication	6 (9%)	0	4 (6%)	0	1 (2%)	0	11 (3%)
TRIMETAZIDINE HYDROCHLORIDE	3 (5%)	0	1 (2%)	0	0	0	4 (1%)
GLYCERYL TRINITRATE	1 (2%)	0	1 (2%)	0	1 (2%)	0	3 (<1%)
DIGOXIN	2 (3%)	0	0	0	0	0	2 (<1%)
ASPARTATE POTASSIUM+MAGNESIUM ASPARTATE	0	0	1 (2%)	0	0	0	1 (<1%)
INDOMETACIN	0	0	1 (2%)	0	0	0	1 (<1%)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
ISOSORBIDE DINITRATE	0	0	1 (2%)	0	0	0	1 (<1%)
METILDIGOXIN	1 (2%)	0	0	0	0	0	1 (<1%)
PROPAFENONE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
PERIPHERAL VASODILATORS							
Any medication	0	2 (3%)	1 (2%)	0	1 (2%)	0	4 (1%)
BETAHISTINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
NAFTIDROFURYL OXALATE	0	0	0	0	1 (2%)	0	1 (<1%)
NICERGOLINE	0	0	1 (2%)	0	0	0	1 (<1%)
NICOTINIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
VASOPROTECTIVES							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
ASCORBIC ACID+RUTOSIDE	0	0	0	0	1 (2%)	0	1 (<1%)
TRIBENOSIDE	0	0	0	0	1 (2%)	0	1 (<1%)
NERVOUS SYSTEM							
Any medication	22 (34%)	21 (34%)	15 (24%)	20 (30%)	15 (25%)	19 (31%)	112 (30%)
ANALGESICS							
Any medication	21 (33%)	14 (23%)	14 (22%)	19 (29%)	12 (20%)	17 (28%)	97 (26%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	13 (20%)	5 (8%)	10 (16%)	64 (17%)
PARACETAMOL	3 (5%)	2 (3%)	3 (5%)	8 (12%)	3 (5%)	6 (10%)	25 (7%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	5 (8%)	4 (7%)	2 (3%)	19 (5%)
ACETYLSALICYLIC ACID+CODEINE+PARACETAMOL+PHENOBARBITAL+CAFFEINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
CODEINE PHOSPHATE+PARACETAMOL	0	0	0	1 (2%)	0	0	1 (<1%)
CODEINE+PARACETAMOL	0	0	0	1 (2%)	0	0	1 (<1%)
DEXTROPROPOXYPHENE	0	0	0	0	0	1 (2%)	1 (<1%)
DEXTROPROPOXYPHENE HYDROCHLORIDE+PARACETAMOL	0	0	0	1 (2%)	0	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	1 (2%)	0	0	0	0	0	1 (<1%)
FLUPIRTINE MALEATE	0	0	0	1 (2%)	0	0	1 (<1%)
HYDROCODONE	0	0	1 (2%)	0	0	0	1 (<1%)
METAMIZOLE SODIUM	1 (2%)	0	0	0	0	0	1 (<1%)
PARACETAMOL+CAFFEINE	0	0	0	0	0	1 (2%)	1 (<1%)
RIZATRIPTAN BENZOATE	0	1 (2%)	0	0	0	0	1 (<1%)
TRAMADOL HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
TYLENOL #1 (NOS)	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
PSYCHOANALEPTICS							
Any medication	3 (5%)	6 (10%)	3 (5%)	3 (5%)	2 (3%)	2 (3%)	19 (5%)
PAROXETINE HYDROCHLORIDE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
VENLAFAXINE HYDROCHLORIDE	0	2 (3%)	1 (2%)	0	0	0	3 (<1%)
CITALOPRAM	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
CYCLOBENZAPRINE	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
SERTRALINE HYDROCHLORIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
AMITRIPTYLINE	0	0	0	1 (2%)	0	0	1 (<1%)
BUPROPION HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
DOXEPIN HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
DULOXETINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
FLUOXETINE HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
MIRTAZAPINE	0	0	0	1 (2%)	0	0	1 (<1%)
VENLAFAXINE	1 (2%)	0	0	0	0	0	1 (<1%)
VINPOCETINE	0	0	1 (2%)	0	0	0	1 (<1%)
PSYCHOLEPTICS							
Any medication	2 (3%)	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	6 (2%)
ALPRAZOLAM	1 (2%)	0	0	0	0	0	1 (<1%)
BROTIZOLAM	1 (2%)	0	0	0	0	0	1 (<1%)
CLONAZEPAM	0	0	0	0	0	1 (2%)	1 (<1%)
SLEEP MEDICATION (NOS)	0	0	0	0	1 (2%)	0	1 (<1%)
TETRAZEPAM	0	0	1 (2%)	0	0	0	1 (<1%)
ZOPICLONE	0	0	0	1 (2%)	0	0	1 (<1%)
ANTIEPILEPTICS							
Any medication	0	1 (2%)	0	1 (2%)	0	2 (3%)	4 (1%)
GABAPENTIN	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
CARBAMAZEPINE	0	1 (2%)	0	0	0	0	1 (<1%)
CLONAZEPAM	0	0	0	0	0	1 (2%)	1 (<1%)
OTHER NERVOUS SYSTEM DRUGS							
Any medication	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
BETAHISTINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
BUPROPION HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
ALIMENTARY TRACT AND METABOLISM							
Any medication	21 (33%)	16 (26%)	13 (21%)	23 (35%)	12 (20%)	15 (25%)	100 (27%)
STOMATOLOGICAL PREPARATIONS							
Any medication	17 (27%)	10 (16%)	9 (14%)	14 (21%)	5 (8%)	11 (18%)	66 (18%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	13 (20%)	5 (8%)	10 (16%)	64 (17%)
DOXYCYCLINE HYCLATE	0	0	0	0	0	1 (2%)	1 (<1%)
SODIUM FLUORIDE+MALIC ACID	0	0	0	1 (2%)	0	0	1 (<1%)
DRUGS FOR ACID RELATED DISORDERS							
Any medication	4 (6%)	3 (5%)	3 (5%)	6 (9%)	3 (5%)	3 (5%)	22 (6%)
OMEPRAZOLE	2 (3%)	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)	7 (2%)
PANTOPRAZOLE	1 (2%)	0	0	2 (3%)	1 (2%)	0	4 (1%)
ESOMEPRAZOLE MAGNESIUM	0	0	0	1 (2%)	1 (2%)	1 (2%)	3 (<1%)
FAMOTIDINE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
LANSOPRAZOLE	1 (2%)	0	0	2 (3%)	0	0	3 (<1%)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE GEL	0	0	0	1 (2%)	0	0	1 (<1%)
CALCIUM CARBONATE	0	0	1 (2%)	0	0	0	1 (<1%)
DIHYDROXYALUMINUM SODIUM CARBONATE	0	0	0	0	1 (2%)	0	1 (<1%)
NIZATIDINE	0	0	1 (2%)	0	0	0	1 (<1%)
PANTOPRAZOLE SODIUM	0	0	1 (2%)	0	0	0	1 (<1%)
RABEPRAZOLE SODIUM	1 (2%)	0	0	0	0	0	1 (<1%)
RANITIDINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
VITAMINS							
Any medication	0	5 (8%)	2 (3%)	5 (8%)	5 (8%)	1 (2%)	18 (5%)
VITAMINS NOS	0	4 (7%)	1 (2%)	2 (3%)	0	0	7 (2%)
ASCORBIC ACID	0	1 (2%)	1 (2%)	0	2 (3%)	0	4 (1%)
TOCOPHEROL	0	1 (2%)	1 (2%)	0	1 (2%)	0	3 (<1%)
VITAMIN D NOS	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
COD-LIVER OIL	0	0	0	1 (2%)	0	0	1 (<1%)
DIHYDROTACHYSTEROL	0	0	0	0	1 (2%)	0	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
IRON+VITAMINS NOS	0	0	1 (2%)	0	0	0	1 (<1%)
MINERALS NOS+VITAMINS NOS	0	0	0	1 (2%)	0	0	1 (<1%)
PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
THIAMINE HYDROCHLORIDE+PYRIDOXINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
TOCOPHEROL+DOCOSAHEXANOIC ACID+EICOSAPENTAENOIC ACID	0	0	0	0	1 (2%)	0	1 (<1%)
VITAMIN B SUBSTANCES NOS	0	0	1 (2%)	0	0	0	1 (<1%)
MINERAL SUPPLEMENTS							
Any medication	1 (2%)	2 (3%)	3 (5%)	2 (3%)	3 (5%)	0	11 (3%)
CALCIUM	0	1 (2%)	0	1 (2%)	2 (3%)	0	4 (1%)
ASCORBIC ACID+PYRIDOXINE HYDROCHLORIDE+CALCIUM CARBONATE+COLECALCIFEROL	0	1 (2%)	0	0	0	0	1 (<1%)
ASPARTATE POTASSIUM+MAGNESIUM ASPARTATE	0	0	1 (2%)	0	0	0	1 (<1%)
CALCIUM CARBONATE	0	0	1 (2%)	0	0	0	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL	0	1 (2%)	0	0	0	0	1 (<1%)
CALCIUM GLUCONATE+SODIUM MONOFLUOROPHOSPHATE+CALCIUM CITRATE	0	0	0	0	1 (2%)	0	1 (<1%)
CHROMIUM	0	0	0	0	1 (2%)	0	1 (<1%)
ERGOCALCIFEROL+CALCIUM	1 (2%)	0	0	0	0	0	1 (<1%)
MAGNESIUM	0	0	0	0	1 (2%)	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
POTASSIUM CHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
VANADYL SULPHATE	0	0	0	0	1 (2%)	0	1 (<1%)
ZINC+CALCIUM+MAGNESIUM	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIDIARRHEALS, INTESTINAL							
ANTIINFLAMMATORY/ANTIIN							
Any medication	1 (2%)	0	4 (6%)	1 (2%)	1 (2%)	1 (2%)	8 (2%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	0	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
LACTOBACILLUS ACIDOPHILUS	0	0	0	0	1 (2%)	0	1 (<1%)
LOPERAMIDE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
POLYCARBOPHIL CALCIUM	0	0	1 (2%)	0	0	0	1 (<1%)
LAXATIVES							
Any medication	1 (2%)	1 (2%)	1 (2%)	0	0	1 (2%)	4 (1%)
POLYCARBOPHIL CALCIUM	0	0	1 (2%)	0	0	0	1 (<1%)
POTASSIUM SULFATE	1 (2%)	0	0	0	0	0	1 (<1%)
SODIUM PHOSPHATE DIBASIC+SODIUM PHOSPHATE MONOBASIC	0	0	0	0	0	1 (2%)	1 (<1%)
STERCULIA	0	1 (2%)	0	0	0	0	1 (<1%)
ANTIEMETICS AND ANTINAUSEANTS							
Any medication	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
DIMENHYDRINATE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
SIBUTRAMINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
BILE AND LIVER THERAPY							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
LEVOGLUTAMIDE	0	0	0	0	1 (2%)	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
METOCLOPRAMIDE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
LEVOGLUTAMIDE	0	0	0	0	1 (2%)	0	1 (<1%)
BLOOD AND BLOOD FORMING ORGANS							
Any medication	18 (28%)	13 (21%)	10 (16%)	16 (24%)	7 (12%)	10 (16%)	74 (20%)
ANTITHROMBOTIC AGENTS							
Any medication	18 (28%)	10 (16%)	10 (16%)	15 (23%)	5 (8%)	10 (16%)	68 (18%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	13 (20%)	5 (8%)	10 (16%)	64 (17%)
CLOPIDOGREL BISULFATE	0	0	1 (2%)	1 (2%)	1 (2%)	0	3 (<1%)
ENOXAPARIN	0	0	0	1 (2%)	0	0	1 (<1%)
WARFARIN SODIUM	1 (2%)	0	0	0	0	0	1 (<1%)
ANTIANEMIC PREPARATIONS							
Any medication	0	4 (7%)	0	0	1 (2%)	0	5 (1%)
CYANOCOBALAMIN	0	3 (5%)	0	0	1 (2%)	0	4 (1%)
FOLIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS							
Any medication	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
POTASSIUM CHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
TYROSINE	0	0	0	0	1 (2%)	0	1 (<1%)
ANTIHEMORRHAGICS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
PHYTOMENADIONE	0	0	0	0	1 (2%)	0	1 (<1%)
MUSCULO-SKELETAL SYSTEM							
Any medication	10 (16%)	12 (20%)	12 (19%)	13 (20%)	8 (13%)	11 (18%)	66 (18%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS							
Any medication	7 (11%)	8 (13%)	10 (16%)	9 (14%)	8 (13%)	7 (11%)	49 (13%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	5 (8%)	4 (7%)	2 (3%)	19 (5%)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	2 (3%)	8 (2%)
NAPROXEN	0	3 (5%)	1 (2%)	0	0	0	4 (1%)
CELECOXIB	1 (2%)	0	0	1 (2%)	0	1 (2%)	3 (<1%)
DICLOFENAC SODIUM	0	0	2 (3%)	0	0	1 (2%)	3 (<1%)
GLUCOSAMINE	0	1 (2%)	1 (2%)	1 (2%)	0	0	3 (<1%)
MELOXICAM	1 (2%)	1 (2%)	0	0	0	1 (2%)	3 (<1%)
ACECLOFENAC	0	0	1 (2%)	0	0	0	1 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
DICLOFENAC SODIUM+MISOPROSTOL	1 (2%)	0	0	0	0	0	1 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
GLUCOSAMINE SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
INDOMETACIN	0	0	1 (2%)	0	0	0	1 (<1%)
KETOPROFEN	0	0	0	1 (2%)	0	0	1 (<1%)
LEFLUNOMIDE	0	1 (2%)	0	0	0	0	1 (<1%)
NABUMETONE	0	0	0	1 (2%)	0	0	1 (<1%)
NAPROXEN SODIUM	0	0	1 (2%)	0	0	0	1 (<1%)
ROFECOXIB	0	0	0	1 (2%)	0	0	1 (<1%)
TOLFENAMIC ACID	0	0	0	1 (2%)	0	0	1 (<1%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN							
Any medication	5 (8%)	4 (7%)	9 (14%)	6 (9%)	7 (12%)	5 (8%)	36 (10%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	5 (8%)	4 (7%)	2 (3%)	19 (5%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	2 (3%)	8 (2%)
NAPROXEN	0	3 (5%)	1 (2%)	0	0	0	4 (1%)
DICLOFENAC SODIUM	0	0	2 (3%)	0	0	1 (2%)	3 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
INDOMETACIN	0	0	1 (2%)	0	0	0	1 (<1%)
KETOPROFEN	0	0	0	1 (2%)	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
METHYL SALICYLATE+LEVOMENTHOL	1 (2%)	0	0	0	0	0	1 (<1%)
NAPROXEN SODIUM	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIGOUT PREPARATIONS							
Any medication	1 (2%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	3 (5%)	13 (3%)
ALLOPURINOL	1 (2%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	3 (5%)	13 (3%)
DRUGS FOR TREATMENT OF BONE DISEASES							
Any medication	2 (3%)	2 (3%)	0	1 (2%)	0	1 (2%)	6 (2%)
RISEDRONATE SODIUM	2 (3%)	1 (2%)	0	0	0	1 (2%)	4 (1%)
ALENDRONATE SODIUM	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
MUSCLE RELAXANTS							
Any medication	0	1 (2%)	2 (3%)	1 (2%)	0	2 (3%)	6 (2%)
CYCLOBENZAPRINE	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
ACETYLSALICYLIC ACID+DEXTROPROPOXYPHENE NAPSILATE+CHLORZOXAZONE	0	0	0	0	0	1 (2%)	1 (<1%)
NORGESIC (NOS)	0	0	0	0	0	1 (2%)	1 (<1%)
PARACETAMOL+METHOCARBAMOL	0	0	0	1 (2%)	0	0	1 (<1%)
TETRAZEPAM	0	0	1 (2%)	0	0	0	1 (<1%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL							
Any medication	0	1 (2%)	0	0	0	0	1 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
GENITO URINARY SYSTEM AND SEX HORMONES							
Any medication	6 (9%)	7 (11%)	7 (11%)	10 (15%)	8 (13%)	5 (8%)	43 (11%)
OTHER GYNECOLOGICALS							
Any medication	2 (3%)	4 (7%)	6 (10%)	5 (8%)	4 (7%)	2 (3%)	23 (6%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	5 (8%)	4 (7%)	2 (3%)	19 (5%)
NAPROXEN	0	3 (5%)	1 (2%)	0	0	0	4 (1%)
FENOTEROL HYDROBROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
NAPROXEN SODIUM	0	0	1 (2%)	0	0	0	1 (<1%)
UROLOGICALS							
Any medication	3 (5%)	3 (5%)	1 (2%)	1 (2%)	3 (5%)	1 (2%)	12 (3%)
TAMSULOSIN HYDROCHLORIDE	1 (2%)	0	0	0	1 (2%)	1 (2%)	3 (<1%)
DUTASTERIDE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
SILDENAFIL CITRATE	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
URTICA DIOICA+SERENOA REPENS+POPLAR BUDS	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
FINASTERIDE	0	0	0	0	1 (2%)	0	1 (<1%)
FURADONINE	0	1 (2%)	0	0	0	0	1 (<1%)
POTASSIUM AMINOBENZOATE	1 (2%)	0	0	0	0	0	1 (<1%)
SILDENAFIL	0	0	0	1 (2%)	0	0	1 (<1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM							
Any medication	1 (2%)	0	0	4 (6%)	0	1 (2%)	6 (2%)
ESTRADIOL VALERATE+MEDROXYPROGESTERONE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
ESTRIOL	1 (2%)	0	0	0	0	0	1 (<1%)
ETHINYLOESTRADIOL+CYPROTERONE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
ETHINYLOESTRADIOL+GESTODENE	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
NORETHISTERONE ACETATE+ESTRADIOL	0	0	0	0	0	1 (2%)	1 (<1%)
PROGESTERONE	0	0	0	1 (2%)	0	0	1 (<1%)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS							
Any medication	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	4 (1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
CICLOPIROX OLAMINE	0	0	1 (2%)	0	0	0	1 (<1%)
CLINDAMYCIN	0	0	0	1 (2%)	0	0	1 (<1%)
ECONAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
RESPIRATORY SYSTEM							
Any medication	2 (3%)	8 (13%)	10 (16%)	7 (11%)	5 (8%)	9 (15%)	41 (11%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES							
Any medication	0	2 (3%)	5 (8%)	2 (3%)	2 (3%)	6 (10%)	17 (5%)
FLUTICASONE PROPIONATE	0	0	1 (2%)	1 (2%)	1 (2%)	2 (3%)	5 (1%)
SALBUTAMOL	0	0	0	1 (2%)	1 (2%)	2 (3%)	4 (1%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	0	1 (2%)	1 (2%)	0	0	2 (3%)	4 (1%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	0	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
THEOPHYLLINE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
BUDESONIDE+FORMOTEROL FUMARATE	0	0	0	0	0	1 (2%)	1 (<1%)
FENOTEROL HYDROBROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
FLUNISOLIDE	0	0	0	0	0	1 (2%)	1 (<1%)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
SALMETEROL XINAFOATE	0	0	0	0	0	1 (2%)	1 (<1%)
NASAL PREPARATIONS							
Any medication	0	2 (3%)	6 (10%)	4 (6%)	1 (2%)	3 (5%)	16 (4%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
FLUTICASONE PROPIONATE	0	0	1 (2%)	1 (2%)	1 (2%)	2 (3%)	5 (1%)
MOMETASONE FUROATE	0	0	2 (3%)	1 (2%)	0	0	3 (<1%)
AZELASTINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	0	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
FLUNISOLIDE	0	0	0	0	0	1 (2%)	1 (<1%)
HYOSCINE METHONITRATE+PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
LEVOCABASTINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
MOMETASONE	0	1 (2%)	0	0	0	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
ANTIHISTAMINES FOR SYSTEMIC USE							
Any medication	2 (3%)	3 (5%)	4 (6%)	2 (3%)	2 (3%)	2 (3%)	15 (4%)
CETIRIZINE HYDROCHLORIDE	1 (2%)	0	2 (3%)	0	1 (2%)	0	4 (1%)
FEXOFENADINE HYDROCHLORIDE	1 (2%)	0	1 (2%)	0	0	1 (2%)	3 (<1%)
LORATADINE	0	3 (5%)	0	0	0	0	3 (<1%)
AZELASTINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
DIMENHYDRINATE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
CHLOROPYRAMINE HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
DIPHENHYDRAMINE	0	0	0	0	1 (2%)	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	1 (2%)	0	0	0	0	0	1 (<1%)
MECLOZINE HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+FEXOFENADINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
COUGH AND COLD PREPARATIONS							
Any medication	0	2 (3%)	3 (5%)	1 (2%)	1 (2%)	3 (5%)	10 (3%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
ACETYLCYSTEINE	0	0	0	0	0	1 (2%)	1 (<1%)
AMBROXOL HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
ETHYLMORPHINE HYDROCHLORIDE+SENEGA+COCILLANA	0	0	0	1 (2%)	0	0	1 (<1%)
HYDROCODONE	0	0	1 (2%)	0	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN+PSEUDOEPHEDRINE	0	1 (2%)	0	0	0	0	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+PSEUDOEPHEDRINE HYDROCHLORIDE+DOXYLAMINE SUCCINATE	0	0	1 (2%)	0	0	0	1 (<1%)
PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE+DOXYLAMINE SUCCINATE	0	0	1 (2%)	0	0	0	1 (<1%)
THROAT PREPARATIONS							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
SENSORY ORGANS							
Any medication	6 (9%)	6 (10%)	6 (10%)	6 (9%)	6 (10%)	7 (11%)	37 (10%)
OPHTHALMOLOGICALS							
Any medication	6 (9%)	6 (10%)	6 (10%)	6 (9%)	6 (10%)	7 (11%)	37 (10%)
BETAXOLOL HYDROCHLORIDE	2 (3%)	3 (5%)	1 (2%)	2 (3%)	1 (2%)	0	9 (2%)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	2 (3%)	8 (2%)
DICLOFENAC SODIUM	0	0	2 (3%)	0	0	1 (2%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
BETAXOLOL	1 (2%)	0	1 (2%)	0	0	0	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
LATANOPROST	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
TIMOLOL	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
ACETYLCYSTEINE	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
BRIMONIDINE TARTRATE	0	0	1 (2%)	0	0	0	1 (<1%)
BRINZOLAMIDE	0	1 (2%)	0	0	0	0	1 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
FLUOROMETHOLONE ACETATE	0	0	0	0	0	1 (2%)	1 (<1%)
INDOMETACIN	0	0	1 (2%)	0	0	0	1 (<1%)
LEVOBUNOLOL HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
LEVOCABASTINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
PHENIRAMINE MALEATE+NAPHAZOLINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
PROPYLENE GLYCOL+MACROGOL	1 (2%)	0	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
TIMOLOL MALEATE	0	0	1 (2%)	0	0	0	1 (<1%)
TIMOLOL MALEATE+LATANOPROST	0	1 (2%)	0	0	0	0	1 (<1%)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS							
Any medication	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
DERMATOLOGICALS							
Any medication	3 (5%)	2 (3%)	9 (14%)	8 (12%)	5 (8%)	4 (7%)	31 (8%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS							
Any medication	0	1 (2%)	5 (8%)	3 (5%)	1 (2%)	3 (5%)	13 (3%)
FLUTICASONE PROPIONATE	0	0	1 (2%)	1 (2%)	1 (2%)	2 (3%)	5 (1%)
MOMETASONE FUROATE	0	0	2 (3%)	1 (2%)	0	0	3 (<1%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	0	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
FLUOROMETHOLONE ACETATE	0	0	0	0	0	1 (2%)	1 (<1%)
MOMETASONE	0	1 (2%)	0	0	0	0	1 (<1%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS,							
Any medication	2 (3%)	0	1 (2%)	1 (2%)	1 (2%)	0	5 (1%)
CHLOROPYRAMINE HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
DIPHENHYDRAMINE	0	0	0	0	1 (2%)	0	1 (<1%)
DOXEPIN HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
METHYL SALICYLATE+LEVOMENTHOL	1 (2%)	0	0	0	0	0	1 (<1%)
ANTI-ACNE PREPARATIONS							
Any medication	0	0	0	3 (5%)	0	1 (2%)	4 (1%)
CLINDAMYCIN	0	0	0	1 (2%)	0	0	1 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
ETHINYLOESTRADIOL+CYPROTERONE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
FLUOROMETHOLONE ACETATE	0	0	0	0	0	1 (2%)	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
EMOLLIENTS AND PROTECTIVES							
Any medication	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)
TOCOPHEROL	0	1 (2%)	1 (2%)	0	1 (2%)	0	3 (<1%)
COD-LIVER OIL	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS							
Any medication	1 (2%)	0	2 (3%)	0	1 (2%)	0	4 (1%)
GLYCERYL TRINITRATE	1 (2%)	0	1 (2%)	0	1 (2%)	0	3 (<1%)
ISOSORBIDE DINITRATE	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIFUNGALS FOR DERMATOLOGICAL USE							
Any medication	0	0	2 (3%)	0	1 (2%)	0	3 (<1%)
CICLOPIROX OLAMINE	0	0	1 (2%)	0	0	0	1 (<1%)
ECONAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
TERBINAFINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGIC							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
OTHER DERMATOLOGICAL PREPARATIONS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
FINASTERIDE	0	0	0	0	1 (2%)	0	1 (<1%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES							
Any medication	4 (6%)	3 (5%)	4 (6%)	4 (6%)	5 (8%)	6 (10%)	26 (7%)
THYROID THERAPY							
Any medication	4 (6%)	3 (5%)	3 (5%)	4 (6%)	5 (8%)	6 (10%)	25 (7%)
LEVOTHYROXINE SODIUM	4 (6%)	1 (2%)	2 (3%)	3 (5%)	3 (5%)	4 (7%)	17 (5%)
LEVOTHYROXINE	0	2 (3%)	0	1 (2%)	1 (2%)	0	4 (1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
THIAMAZOLE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
CORTICOSTEROIDS FOR SYSTEMIC USE							
Any medication	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANTIINFECTIVES FOR SYSTEMIC USE							
Any medication	2 (3%)	4 (7%)	3 (5%)	6 (9%)	2 (3%)	5 (8%)	22 (6%)
ANTIBACTERIALS FOR SYSTEMIC USE							
Any medication	2 (3%)	3 (5%)	2 (3%)	4 (6%)	1 (2%)	5 (8%)	17 (5%)
AMOXICILLIN	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
ANTIBIOTICS NOS	0	0	0	0	0	1 (2%)	1 (<1%)
AZITHROMYCIN	0	1 (2%)	0	0	0	0	1 (<1%)
CEFALEXIN	0	0	0	0	0	1 (2%)	1 (<1%)
CEFAZOLIN	0	0	0	1 (2%)	0	0	1 (<1%)
CEFDINIR	0	0	1 (2%)	0	0	0	1 (<1%)
CEFUROXIME SODIUM	0	0	0	1 (2%)	0	0	1 (<1%)
CLINDAMYCIN	0	0	0	1 (2%)	0	0	1 (<1%)
DOXYCYCLINE	0	1 (2%)	0	0	0	0	1 (<1%)
DOXYCYCLINE HYCLATE	0	0	0	0	0	1 (2%)	1 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
FURADONINE	0	1 (2%)	0	0	0	0	1 (<1%)
PHENOXYMETHYLPENICILLIN	0	0	1 (2%)	0	0	0	1 (<1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	1 (2%)	0	0	0	0	1 (<1%)
VACCINES							
Any medication	0	1 (2%)	1 (2%)	2 (3%)	1 (2%)	0	5 (1%)
INFLUENZA VACCINE	0	0	1 (2%)	2 (3%)	1 (2%)	0	4 (1%)
TICK-BORNE ENCEPHALITIS VACCINE	0	1 (2%)	0	0	0	0	1 (<1%)
VARIOUS							
Any medication	0	1 (2%)	0	0	5 (8%)	2 (3%)	8 (2%)
ALL OTHER THERAPEUTIC PRODUCTS							
Any medication	0	1 (2%)	0	0	4 (7%)	2 (3%)	7 (2%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.22
Summary of Prior Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ACETYLCYSTEINE	0	0	0	0	0	1 (2%)	1 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
OENOTHERA BIENNIS	0	0	0	0	1 (2%)	0	1 (<1%)
VANADYL SULPHATE	0	0	0	0	1 (2%)	0	1 (<1%)
GENERAL NUTRIENTS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
TYROSINE	0	0	0	0	1 (2%)	0	1 (<1%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS							
Any medication	0	2 (3%)	0	0	0	0	2 (<1%)
IMMUNOSUPPRESSIVE AGENTS							
Any medication	0	2 (3%)	0	0	0	0	2 (<1%)
AZATHIOPRINE	0	1 (2%)	0	0	0	0	1 (<1%)
LEFLUNOMIDE	0	1 (2%)	0	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.23
Summary of Prior SU and Metformin Medications

ATC Level 2 ATC Level 4 Ingredient	Placebo (N=36)	2.5mg (N=37)	7.5mg (N=36)	15mg (N=42)	30mg (N=35)	45mg (N=36)	Total (N=222)
Any medication	36 (100%)	35 (95%)	36 (100%)	42 (100%)	33 (94%)	35 (97%)	217 (98%)
DRUGS USED IN DIABETES							
Any medication	36 (100%)	35 (95%)	36 (100%)	42 (100%)	33 (94%)	35 (97%)	217 (98%)
BIGUANIDES							
Any medication	22 (61%)	22 (59%)	25 (69%)	29 (69%)	29 (83%)	27 (75%)	154 (69%)
METFORMIN	11 (31%)	11 (30%)	15 (42%)	13 (31%)	19 (54%)	13 (36%)	82 (37%)
METFORMIN HYDROCHLORIDE	11 (31%)	11 (30%)	10 (28%)	15 (36%)	10 (29%)	14 (39%)	71 (32%)
BUFORMIN	0	0	0	1 (2%)	0	0	1 (<1%)
METFORMIN HYDROCHLORIDE+ROSIGLITAZONE	0	0	0	0	1 (3%)	0	1 (<1%)
SULFONAMIDES, UREA DERIVATIVES							
Any medication	14 (39%)	13 (35%)	11 (31%)	15 (36%)	4 (11%)	8 (22%)	65 (29%)
GLIBENCLAMIDE	3 (8%)	6 (16%)	3 (8%)	5 (12%)	2 (6%)	3 (8%)	22 (10%)
GLIMEPIRIDE	5 (14%)	3 (8%)	3 (8%)	5 (12%)	0	5 (14%)	21 (9%)
GLICLAZIDE	1 (3%)	3 (8%)	4 (11%)	3 (7%)	0	0	11 (5%)
GLIPIZIDE	4 (11%)	1 (3%)	1 (3%)	3 (7%)	2 (6%)	0	11 (5%)
TOLBUTAMIDE	1 (3%)	0	0	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.25
Summary of Study Medication Compliance

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Week 4							
Compliance since last visit							
n	64	61	63	66	60	61	311
0%	0	1 (2%)	0	0	0	0	1 (<1%)
>0% and <80%	1 (2%)	0	0	0	0	0	0
>=80% and <=120%	62 (97%)	60 (98%)	62 (98%)	65 (98%)	58 (97%)	59 (97%)	304 (98%)
>120%	0	0	0	0	0	0	0
Unknown	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)	2 (3%)	6 (2%)
Reason for non-compliance							
Adverse event	0	0	0	0	0	0	0
Dispensing error	0	0	0	0	0	0	0
Subject did not take medication according to the protocol	1 (2%)	0	0	0	1 (2%)	0	1 (<1%)
Other	0	1 (2%)	0	0	0	0	1 (<1%)

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Table 10.25
Summary of Study Medication Compliance

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Week 8							
Compliance since last visit							
n	56	55	58	60	58	57	288
0%	0	0	0	0	0	0	0
>0% and <80%	3 (5%)	3 (5%)	1 (2%)	0	2 (3%)	0	6 (2%)
>=80% and <=120%	51 (91%)	52 (95%)	56 (97%)	59 (98%)	56 (97%)	56 (98%)	279 (97%)
>120%	0	0	0	1 (2%)	0	0	1 (<1%)
Unknown	2 (4%)	0	1 (2%)	0	0	1 (2%)	2 (<1%)
Reason for non-compliance							
Adverse event	0	0	0	0	1 (2%)	0	1 (<1%)
Dispensing error	0	0	0	0	0	0	0
Subject did not take medication according to the protocol	1 (2%)	2 (4%)	1 (2%)	0	1 (2%)	0	4 (1%)
Other	2 (4%)	1 (2%)	0	1 (2%)	0	0	2 (<1%)

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Table 10.25
Summary of Study Medication Compliance

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Week 12							
Compliance since last visit							
n	51	48	56	60	56	56	276
0%	0	0	0	0	0	0	0
>0% and <80%	3 (6%)	0	1 (2%)	0	0	0	1 (<1%)
>=80% and <=120%	48 (94%)	48 (100%)	54 (96%)	59 (98%)	54 (96%)	56 (100%)	271 (98%)
>120%	0	0	0	1 (2%)	0	0	1 (<1%)
Unknown	0	0	1 (2%)	0	2 (4%)	0	3 (1%)
Reason for non-compliance							
Adverse event	0	0	0	0	0	0	0
Dispensing error	0	0	0	0	0	0	0
Subject did not take medication according to the protocol	1 (2%)	0	0	0	0	0	0
Other	2 (4%)	0	1 (2%)	1 (2%)	0	0	2 (<1%)

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
Any medication	54 (84%)	49 (80%)	48 (76%)	52 (79%)	42 (70%)	48 (79%)	293 (78%)
CARDIOVASCULAR SYSTEM							
Any medication	48 (75%)	35 (57%)	41 (65%)	39 (59%)	35 (58%)	36 (59%)	234 (62%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM							
Any medication	36 (56%)	25 (41%)	25 (40%)	28 (42%)	17 (28%)	24 (39%)	155 (41%)
RAMIPRIL	5 (8%)	3 (5%)	4 (6%)	6 (9%)	0	4 (7%)	22 (6%)
LISINOPRIL	8 (13%)	2 (3%)	2 (3%)	2 (3%)	1 (2%)	4 (7%)	19 (5%)
ENALAPRIL	4 (6%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	3 (5%)	14 (4%)
PERINDOPRIL	1 (2%)	3 (5%)	2 (3%)	4 (6%)	1 (2%)	1 (2%)	12 (3%)
HYDROCHLOROTHIAZIDE+VALSARTAN	1 (2%)	1 (2%)	1 (2%)	3 (5%)	3 (5%)	0	9 (2%)
VALSARTAN	1 (2%)	0	1 (2%)	2 (3%)	0	3 (5%)	7 (2%)
LOSARTAN POTASSIUM	1 (2%)	3 (5%)	1 (2%)	0	0	1 (2%)	6 (2%)
CANDESARTAN CILEXETIL	1 (2%)	3 (5%)	0	0	1 (2%)	0	5 (1%)
CAPTOPRIL	1 (2%)	0	0	2 (3%)	1 (2%)	1 (2%)	5 (1%)
ENALAPRIL MALEATE	1 (2%)	0	4 (6%)	0	0	0	5 (1%)
HYDROCHLOROTHIAZIDE+OLMESARTAN	1 (2%)	1 (2%)	2 (3%)	0	0	1 (2%)	5 (1%)
OLMESARTAN	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	0	5 (1%)
HYDROCHLOROTHIAZIDE+RAMIPRIL	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	4 (1%)
VERAPAMIL HYDROCHLORIDE+TRANDOLAPRIL	1 (2%)	1 (2%)	0	1 (2%)	0	1 (2%)	4 (1%)
CILAZAPRIL	0	1 (2%)	0	1 (2%)	1 (2%)	0	3 (<1%)
FOSINOPRIL SODIUM	0	1 (2%)	0	0	1 (2%)	1 (2%)	3 (<1%)
HYDROCHLOROTHIAZIDE+QUINAPRIL HYDROCHLORIDE	0	2 (3%)	0	0	1 (2%)	0	3 (<1%)
IRBESARTAN	2 (3%)	0	0	1 (2%)	0	0	3 (<1%)
LOSARTAN	1 (2%)	0	1 (2%)	0	1 (2%)	0	3 (<1%)
TELMISARTAN	2 (3%)	1 (2%)	0	0	0	0	3 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL MALEATE	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
HYDROCHLOROTHIAZIDE+IRBESARTAN	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
HYDROCHLOROTHIAZIDE+LOSARTAN POTASSIUM	0	2 (3%)	0	0	0	0	2 (<1%)
HYDROCHLOROTHIAZIDE+TELMISARTAN	2 (3%)	0	0	0	0	0	2 (<1%)
BENAZEPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
BENAZEPRIL HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
BENAZEPRIL HYDROCHLORIDE+AMLODIPINE BESILATE	1 (2%)	0	0	0	0	0	1 (<1%)
CANDESARTAN	1 (2%)	0	0	0	0	0	1 (<1%)
EPROSARTAN	0	0	0	1 (2%)	0	0	1 (<1%)
FELODIPINE+RAMIPRIL	1 (2%)	0	0	0	0	0	1 (<1%)
FOSINOPRIL	0	0	1 (2%)	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+CANDESARTAN CILEXETIL	0	1 (2%)	0	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+CAPTOPRIL	0	0	0	0	1 (2%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+EPROSARTAN MESILATE	0	0	0	0	1 (2%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+LISINOPRIL	0	0	1 (2%)	0	0	0	1 (<1%)
INDAPAMIDE+PERINDOPRIL ERBUMINE	0	0	0	1 (2%)	0	0	1 (<1%)
LISINOPRIL DIHYDRATE	0	0	0	1 (2%)	0	0	1 (<1%)
PIRETANIDE+RAMIPRIL	1 (2%)	0	0	0	0	0	1 (<1%)
QUINAPRIL	0	0	0	0	0	1 (2%)	1 (<1%)
SPIRAPRIL HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
TRANDOLAPRIL	0	0	0	0	0	1 (2%)	1 (<1%)
SERUM LIPID REDUCING AGENTS							
Any medication	25 (39%)	17 (28%)	19 (30%)	14 (21%)	13 (22%)	18 (30%)	106 (28%)
SIMVASTATIN	10 (16%)	5 (8%)	9 (14%)	5 (8%)	3 (5%)	5 (8%)	37 (10%)
ATORVASTATIN CALCIUM	6 (9%)	6 (10%)	4 (6%)	4 (6%)	3 (5%)	2 (3%)	25 (7%)
FENOFIBRATE	4 (6%)	0	3 (5%)	1 (2%)	1 (2%)	5 (8%)	14 (4%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ROSUVASTATIN CALCIUM	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	3 (5%)	8 (2%)
LOVASTATIN	1 (2%)	2 (3%)	2 (3%)	0	0	2 (3%)	7 (2%)
FLUVASTATIN SODIUM	0	1 (2%)	0	0	1 (2%)	2 (3%)	4 (1%)
EZETIMIBE	1 (2%)	1 (2%)	0	0	1 (2%)	0	3 (<1%)
SIMVASTATIN+EZETIMIBE	0	0	0	1 (2%)	2 (3%)	0	3 (<1%)
ATORVASTATIN	0	0	0	2 (3%)	0	0	2 (<1%)
FISH OIL	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
PRAVASTATIN	2 (3%)	0	0	0	0	0	2 (<1%)
BEZAFIBRATE	0	0	0	0	0	1 (2%)	1 (<1%)
COLESEVELAM HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
GEMFIBROZIL	0	1 (2%)	0	0	0	0	1 (<1%)
NICOTINIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)
OMEGA-3 MARINE TRIGLYCERIDES	0	0	1 (2%)	0	0	0	1 (<1%)
PRAVASTATIN SODIUM	0	0	0	1 (2%)	0	0	1 (<1%)
TOCOPHEROL+DOCOSAHEXANOIC ACID+EICOSAPENTAENOIC ACID	0	0	0	0	1 (2%)	0	1 (<1%)
BETA BLOCKING AGENTS							
Any medication	14 (22%)	13 (21%)	15 (24%)	9 (14%)	11 (18%)	14 (23%)	76 (20%)
METOPROLOL	6 (9%)	1 (2%)	3 (5%)	1 (2%)	4 (7%)	4 (7%)	19 (5%)
BETAXOLOL HYDROCHLORIDE	2 (3%)	3 (5%)	1 (2%)	2 (3%)	1 (2%)	0	9 (2%)
METOPROLOL SUCCINATE	0	3 (5%)	2 (3%)	1 (2%)	1 (2%)	2 (3%)	9 (2%)
ATENOLOL	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	3 (5%)	8 (2%)
METOPROLOL TARTRATE	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	1 (2%)	6 (2%)
BISOPROLOL	0	0	2 (3%)	0	0	2 (3%)	4 (1%)
CARVEDILOL	2 (3%)	0	1 (2%)	0	1 (2%)	0	4 (1%)
BISOPROLOL FUMARATE	1 (2%)	1 (2%)	1 (2%)	0	0	0	3 (<1%)
HYDROCHLOROTHIAZIDE+BISOPROLOL FUMARATE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
NEBIVOLOL HYDROCHLORIDE	0	0	0	1 (2%)	1 (2%)	1 (2%)	3 (<1%)
TIMOLOL	0	1 (2%)	0	1 (2%)	1 (2%)	0	3 (<1%)
BETAXOLOL	1 (2%)	0	1 (2%)	0	0	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
CHLORTALIDONE+ATENOLOL	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
PROPRANOLOL	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
ATROPINE SULFATE+AMOBARBITAL SODIUM+PROPRANOLOL HYDROCHLORIDE+ERGOT, PREPARED	0	1 (2%)	0	0	0	0	1 (<1%)
BOPINDOLOL MALONATE	0	0	0	0	0	1 (2%)	1 (<1%)
SOTALOL HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
TIMOLOL MALEATE	0	0	1 (2%)	0	0	0	1 (<1%)
DIURETICS							
Any medication	14 (22%)	8 (13%)	9 (14%)	5 (8%)	12 (20%)	11 (18%)	59 (16%)
HYDROCHLOROTHIAZIDE	5 (8%)	3 (5%)	3 (5%)	0	3 (5%)	5 (8%)	19 (5%)
INDAPAMIDE	4 (6%)	1 (2%)	3 (5%)	1 (2%)	4 (7%)	4 (7%)	17 (5%)
HYDROCHLOROTHIAZIDE+AMILORIDE HYDROCHLORIDE	0	2 (3%)	2 (3%)	3 (5%)	2 (3%)	1 (2%)	10 (3%)
FUROSEMIDE	1 (2%)	0	2 (3%)	0	2 (3%)	2 (3%)	7 (2%)
PIRETANIDE	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
TORASEMIDE	2 (3%)	0	0	0	0	0	2 (<1%)
BENDROFLUMETHIAZIDE	0	0	0	0	0	1 (2%)	1 (<1%)
CHLORTALIDONE+AMILORIDE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL	0	0	0	1 (2%)	0	0	1 (<1%)
ISOSORBIDE	0	1 (2%)	0	0	0	0	1 (<1%)
TRIAMTERENE+XIPAMIDE	1 (2%)	0	0	0	0	0	1 (<1%)
CALCIUM CHANNEL BLOCKERS							
Any medication	10 (16%)	3 (5%)	10 (16%)	10 (15%)	8 (13%)	7 (11%)	48 (13%)
AMLODIPINE BESILATE	5 (8%)	1 (2%)	4 (6%)	3 (5%)	3 (5%)	2 (3%)	18 (5%)
AMLODIPINE	1 (2%)	0	1 (2%)	0	2 (3%)	1 (2%)	5 (1%)
NITRENDIPINE	0	1 (2%)	3 (5%)	0	1 (2%)	0	5 (1%)
FELODIPINE	0	0	0	3 (5%)	0	1 (2%)	4 (1%)
NIFEDIPINE	3 (5%)	0	0	0	0	1 (2%)	4 (1%)
DILTIAZEM HYDROCHLORIDE	0	0	1 (2%)	1 (2%)	0	1 (2%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
VERAPAMIL	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
VERAPAMIL HYDROCHLORIDE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
ISRADIPINE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
DILTIAZEM	0	0	0	0	0	1 (2%)	1 (<1%)
LACIDIPINE	0	0	0	0	1 (2%)	0	1 (<1%)
LERCANIDIPINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIHYPERTENSIVES							
Any medication	2 (3%)	2 (3%)	1 (2%)	3 (5%)	5 (8%)	2 (3%)	15 (4%)
VERAPAMIL HYDROCHLORIDE+TRANDOLAPRIL	1 (2%)	1 (2%)	0	1 (2%)	0	1 (2%)	4 (1%)
DOXAZOSIN MESILATE	1 (2%)	0	0	0	2 (3%)	0	3 (<1%)
ISRADIPINE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
MOXONIDINE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DILTIAZEM	0	0	0	0	0	1 (2%)	1 (<1%)
HYDROCHLOROTHIAZIDE+EPROSARTAN MESILATE	0	0	0	0	1 (2%)	0	1 (<1%)
METHYLDOPA	0	1 (2%)	0	0	0	0	1 (<1%)
RILMENIDINE	0	1 (2%)	0	0	0	0	1 (<1%)
CARDIAC THERAPY							
Any medication	6 (9%)	0	5 (8%)	2 (3%)	1 (2%)	1 (2%)	15 (4%)
GLYCERYL TRINITRATE	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)
TRIMETAZIDINE HYDROCHLORIDE	3 (5%)	0	1 (2%)	0	0	0	4 (1%)
DIGOXIN	2 (3%)	0	0	0	0	0	2 (<1%)
INDOMETACIN	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
ASPARTATE POTASSIUM+MAGNESIUM ASPARTATE	0	0	1 (2%)	0	0	0	1 (<1%)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
ISOSORBIDE DINITRATE	0	0	1 (2%)	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
METILDIGOXIN	1 (2%)	0	0	0	0	0	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
PROPAFENONE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
VASOPROTECTIVES							
Any medication	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)	2 (3%)	7 (2%)
ASCORBIC ACID+RUTOSIDE	1 (2%)	0	0	0	1 (2%)	0	2 (<1%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
TRIBENOSIDE	0	0	0	0	1 (2%)	0	1 (<1%)
PERIPHERAL VASODILATORS							
Any medication	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	0	5 (1%)
NAFTIDROFURYL OXALATE	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
NICERGOLINE	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
BETAHISTINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
NICOTINIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)
PENTOXIFYLLINE	1 (2%)	0	0	0	0	0	1 (<1%)
NERVOUS SYSTEM							
Any medication	24 (38%)	21 (34%)	18 (29%)	20 (30%)	15 (25%)	24 (39%)	122 (33%)
ANALGESICS							
Any medication	23 (36%)	14 (23%)	14 (22%)	20 (30%)	12 (20%)	21 (34%)	104 (28%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	12 (18%)	5 (8%)	9 (15%)	62 (17%)
PARACETAMOL	3 (5%)	3 (5%)	2 (3%)	7 (11%)	1 (2%)	11 (18%)	27 (7%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	7 (11%)	5 (8%)	6 (10%)	26 (7%)
CODEINE+PARACETAMOL	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
METAMIZOLE SODIUM	1 (2%)	0	0	0	0	1 (2%)	2 (<1%)
TRAMADOL HYDROCHLORIDE	0	0	0	0	0	2 (3%)	2 (<1%)
ACETYLSALICYLIC ACID+ASCORBIC ACID	0	0	1 (2%)	0	0	0	1 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DEXTROPROPOXYPHENE	0	0	0	0	0	1 (2%)	1 (<1%)
DEXTROPROPOXYPHENE NAPSILATE	0	1 (2%)	0	0	0	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	1 (2%)	0	0	0	0	0	1 (<1%)
EXCEDRIN (NOS)	0	0	1 (2%)	0	0	0	1 (<1%)
HYDROCODONE	0	0	1 (2%)	0	0	0	1 (<1%)
PARACETAMOL+CAFFEINE	0	0	0	0	0	1 (2%)	1 (<1%)
PARACETAMOL+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
PARACETAMOL+HYDROCODONE BITARTRATE	0	0	0	0	0	1 (2%)	1 (<1%)
PARACETAMOL+OXYCODONE	0	1 (2%)	0	0	0	0	1 (<1%)
PETHIDINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
RIZATRIPTAN BENZOATE	0	1 (2%)	0	0	0	0	1 (<1%)
TYLENOL #1 (NOS)	0	0	0	1 (2%)	0	0	1 (<1%)
TYLENOL #3 (NOS)	0	0	0	0	1 (2%)	0	1 (<1%)
PSYCHOANALEPTICS							
Any medication	3 (5%)	7 (11%)	3 (5%)	4 (6%)	2 (3%)	3 (5%)	22 (6%)
CYCLOBENZAPRINE	0	2 (3%)	1 (2%)	0	0	0	3 (<1%)
PAROXETINE HYDROCHLORIDE	1 (2%)	1 (2%)	0	1 (2%)	0	0	3 (<1%)
VENLAFAXINE HYDROCHLORIDE	0	2 (3%)	1 (2%)	0	0	0	3 (<1%)
CITALOPRAM	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
CYCLOBENZAPRINE HYDROCHLORIDE	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
SERTRALINE HYDROCHLORIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
BUPROPION HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
DOXEPIN HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
DULOXETINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
FLUOXETINE HYDROCHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
MIRTAZAPINE	0	0	0	1 (2%)	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
VENLAFAXINE	1 (2%)	0	0	0	0	0	1 (<1%)
VINPOCETINE	0	0	1 (2%)	0	0	0	1 (<1%)
PSYCHOLEPTICS							
Any medication	1 (2%)	0	3 (5%)	1 (2%)	2 (3%)	1 (2%)	8 (2%)
ALPRAZOLAM	0	0	0	0	1 (2%)	0	1 (<1%)
BROTIZOLAM	1 (2%)	0	0	0	0	0	1 (<1%)
CLONAZEPAM	0	0	0	0	0	1 (2%)	1 (<1%)
FLUSPIRILENE	1 (2%)	0	0	0	0	0	1 (<1%)
HYDROXYZINE	0	0	1 (2%)	0	0	0	1 (<1%)
SLEEP MEDICATION (NOS)	0	0	0	0	1 (2%)	0	1 (<1%)
TETRAZEPAM	0	0	1 (2%)	0	0	0	1 (<1%)
ZIPRASIDONE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
ZOPICLONE	0	0	0	1 (2%)	0	0	1 (<1%)
ANTIEPILEPTICS							
Any medication	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	2 (3%)	6 (2%)
GABAPENTIN	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)	4 (1%)
CARBAMAZEPINE	0	1 (2%)	0	0	0	0	1 (<1%)
CLONAZEPAM	0	0	0	0	0	1 (2%)	1 (<1%)
ANESTHETICS							
Any medication	0	0	1 (2%)	0	0	2 (3%)	3 (<1%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
BUPIVACAINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
EPINEPHRINE HYDROCHLORIDE+ARTICAINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
OTHER NERVOUS SYSTEM DRUGS							
Any medication	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
BETAHISTINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
BUPROPION HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ALIMENTARY TRACT AND METABOLISM							
Any medication	23 (36%)	17 (28%)	17 (27%)	22 (33%)	14 (23%)	17 (28%)	110 (29%)
STOMATOLOGICAL PREPARATIONS							
Any medication	17 (27%)	10 (16%)	9 (14%)	13 (20%)	6 (10%)	12 (20%)	67 (18%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	12 (18%)	5 (8%)	9 (15%)	62 (17%)
CLOTRIMAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
DOXYCYCLINE HYCLATE	0	0	0	0	0	1 (2%)	1 (<1%)
METRONIDAZOLE	0	0	0	0	0	1 (2%)	1 (<1%)
SODIUM FLUORIDE+MALIC ACID	0	0	0	1 (2%)	0	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)
DRUGS FOR ACID RELATED DISORDERS							
Any medication	6 (9%)	5 (8%)	3 (5%)	5 (8%)	3 (5%)	3 (5%)	25 (7%)
OMEPRAZOLE	3 (5%)	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)	8 (2%)
ESOMEPRAZOLE MAGNESIUM	0	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	4 (1%)
FAMOTIDINE	2 (3%)	1 (2%)	0	1 (2%)	0	0	4 (1%)
LANSOPRAZOLE	1 (2%)	0	0	2 (3%)	0	0	3 (<1%)
PANTOPRAZOLE	1 (2%)	0	0	1 (2%)	1 (2%)	0	3 (<1%)
RANITIDINE HYDROCHLORIDE	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE GEL	0	0	0	1 (2%)	0	0	1 (<1%)
CALCIUM CARBONATE	0	0	1 (2%)	0	0	0	1 (<1%)
DIHYDROXYALUMINUM SODIUM CARBONATE	0	0	0	0	1 (2%)	0	1 (<1%)
NIZATIDINE	0	0	1 (2%)	0	0	0	1 (<1%)
PANTOPRAZOLE SODIUM	0	0	1 (2%)	0	0	0	1 (<1%)
RABEPRAZOLE	0	1 (2%)	0	0	0	0	1 (<1%)
RABEPRAZOLE SODIUM	1 (2%)	0	0	0	0	0	1 (<1%)
VITAMINS							
Any medication	0	5 (8%)	3 (5%)	5 (8%)	5 (8%)	1 (2%)	19 (5%)
VITAMINS NOS	0	4 (7%)	1 (2%)	1 (2%)	0	0	6 (2%)
ASCORBIC ACID	0	0	2 (3%)	0	2 (3%)	0	4 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
MINERALS NOS+VITAMINS NOS	0	0	0	2 (3%)	0	0	2 (<1%)
TOCOPHEROL	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
VITAMIN D NOS	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
COD-LIVER OIL	0	0	0	1 (2%)	0	0	1 (<1%)
DIHYDROTACHYSTEROL	0	0	0	0	1 (2%)	0	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
THIAMINE HYDROCHLORIDE+PYRIDOXINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
TOCOPHEROL+DOCOSAHEXANOIC ACID+EICOSAPENTAENOIC ACID	0	0	0	0	1 (2%)	0	1 (<1%)
VITAMIN B SUBSTANCES NOS	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIDIARRHEALS, INTESTINAL							
ANTIINFLAMMATORY/ANTIIN							
Any medication	1 (2%)	0	6 (10%)	2 (3%)	2 (3%)	2 (3%)	13 (3%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	1 (2%)	0	3 (<1%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
LACTOBACILLUS ACIDOPHILUS	0	0	0	0	1 (2%)	0	1 (<1%)
LOPERAMIDE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
POLYCARBOPHIL CALCIUM	0	0	1 (2%)	0	0	0	1 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
PREDNISONE	0	0	0	0	0	1 (2%)	1 (<1%)
MINERAL SUPPLEMENTS							
Any medication	1 (2%)	2 (3%)	3 (5%)	2 (3%)	3 (5%)	0	11 (3%)
CALCIUM	0	1 (2%)	0	1 (2%)	2 (3%)	0	4 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ASCORBIC ACID+PYRIDOXINE HYDROCHLORIDE+CALCIUM CARBONATE+COLECALCIFEROL	0	1 (2%)	0	0	0	0	1 (<1%)
ASPARTATE POTASSIUM+MAGNESIUM ASPARTATE	0	0	1 (2%)	0	0	0	1 (<1%)
CALCIUM CARBONATE	0	0	1 (2%)	0	0	0	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL	0	1 (2%)	0	0	0	0	1 (<1%)
CALCIUM GLUCONATE+SODIUM MONOFLUOROPHOSPHATE+CALCIUM CITRATE	0	0	0	0	1 (2%)	0	1 (<1%)
CHROMIUM	0	0	0	0	1 (2%)	0	1 (<1%)
ERGOCALCIFEROL+CALCIUM	1 (2%)	0	0	0	0	0	1 (<1%)
MAGNESIUM	0	0	0	0	1 (2%)	0	1 (<1%)
POTASSIUM CHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
VANADYL SULPHATE	0	0	0	0	1 (2%)	0	1 (<1%)
ZINC	0	0	1 (2%)	0	0	0	1 (<1%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS							
Any medication	1 (2%)	1 (2%)	0	0	2 (3%)	1 (2%)	5 (1%)
HYOSCINE BUTYLBROMIDE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
METOCLOPRAMIDE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
SPASMEX (NOS)	0	0	0	0	1 (2%)	0	1 (<1%)
TRIMEBUTINE	1 (2%)	0	0	0	0	0	1 (<1%)
LAXATIVES							
Any medication	1 (2%)	2 (3%)	1 (2%)	0	0	1 (2%)	5 (1%)
LACTULOSE	0	1 (2%)	0	0	0	0	1 (<1%)
POLYCARBOPHIL CALCIUM	0	0	1 (2%)	0	0	0	1 (<1%)
POTASSIUM SULFATE	1 (2%)	0	0	0	0	0	1 (<1%)
SODIUM PHOSPHATE DIBASIC+SODIUM PHOSPHATE MONOBASIC	0	0	0	0	0	1 (2%)	1 (<1%)
STERCULIA	0	1 (2%)	0	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANTIEMETICS AND ANTINAUSEANTS							
Any medication	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
DIMENHYDRINATE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
DRUGS USED IN DIABETES							
Any medication	2 (3%)	0	0	0	0	0	2 (<1%)
METFORMIN	1 (2%)	0	0	0	0	0	1 (<1%)
METFORMIN HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
SIBUTRAMINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
BILE AND LIVER THERAPY							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
LEVOGLUTAMIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DIGESTIVES, INCL. ENZYMES							
Any medication	1 (2%)	0	0	0	0	0	1 (<1%)
PANCREATIN	1 (2%)	0	0	0	0	0	1 (<1%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
LEVOGLUTAMIDE	0	0	0	0	1 (2%)	0	1 (<1%)
MUSCULO-SKELETAL SYSTEM							
Any medication	11 (17%)	11 (18%)	12 (19%)	15 (23%)	10 (17%)	19 (31%)	78 (21%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS							
Any medication	8 (13%)	7 (11%)	10 (16%)	13 (20%)	10 (17%)	15 (25%)	63 (17%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	7 (11%)	5 (8%)	6 (10%)	26 (7%)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	3 (5%)	9 (2%)
DICLOFENAC SODIUM	0	0	2 (3%)	3 (5%)	0	3 (5%)	8 (2%)
NAPROXEN	0	3 (5%)	1 (2%)	0	1 (2%)	0	5 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
CELECOXIB	1 (2%)	1 (2%)	0	1 (2%)	0	1 (2%)	4 (1%)
GLUCOSAMINE	0	1 (2%)	1 (2%)	1 (2%)	0	0	3 (<1%)
MELOXICAM	1 (2%)	1 (2%)	0	0	0	1 (2%)	3 (<1%)
NAPROXEN SODIUM	1 (2%)	0	1 (2%)	0	0	1 (2%)	3 (<1%)
INDOMETACIN	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
ACECLOFENAC	0	0	1 (2%)	0	0	0	1 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
DICLOFENAC SODIUM+MISOPROSTOL	1 (2%)	0	0	0	0	0	1 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
LEFLUNOMIDE	0	1 (2%)	0	0	0	0	1 (<1%)
NABUMETONE	0	0	0	1 (2%)	0	0	1 (<1%)
PIROXICAM	0	0	0	0	0	1 (2%)	1 (<1%)
ROFECOXIB	0	0	0	1 (2%)	0	0	1 (<1%)
TOLFENAMIC ACID	0	0	0	1 (2%)	0	0	1 (<1%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN							
Any medication	6 (9%)	4 (7%)	9 (14%)	12 (18%)	9 (15%)	13 (21%)	53 (14%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	7 (11%)	5 (8%)	6 (10%)	26 (7%)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	3 (5%)	9 (2%)
DICLOFENAC SODIUM	0	0	2 (3%)	3 (5%)	0	3 (5%)	8 (2%)
NAPROXEN	0	3 (5%)	1 (2%)	0	1 (2%)	0	5 (1%)
NAPROXEN SODIUM	1 (2%)	0	1 (2%)	0	0	1 (2%)	3 (<1%)
INDOMETACIN	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
METHYL SALICYLATE+LEVOMENTHOL	1 (2%)	0	0	0	0	0	1 (<1%)
PIROXICAM	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIGOUT PREPARATIONS							
Any medication	1 (2%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	3 (5%)	13 (3%)
ALLOPURINOL	1 (2%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	3 (5%)	13 (3%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
MUSCLE RELAXANTS							
Any medication	0	2 (3%)	2 (3%)	2 (3%)	0	3 (5%)	9 (2%)
CYCLOBENZAPRINE	0	2 (3%)	1 (2%)	0	0	0	3 (<1%)
CYCLOBENZAPRINE HYDROCHLORIDE	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
ACETYLSALICYLIC ACID+DEXTROPROPOXYPHENE NAPSILATE+CHLORZOXAZONE	0	0	0	0	0	1 (2%)	1 (<1%)
NORGESIC (NOS)	0	0	0	0	0	1 (2%)	1 (<1%)
PARACETAMOL+METHOCARBAMOL	0	0	0	1 (2%)	0	0	1 (<1%)
TETRAZEPAM	0	0	1 (2%)	0	0	0	1 (<1%)
DRUGS FOR TREATMENT OF BONE DISEASES							
Any medication	2 (3%)	2 (3%)	0	1 (2%)	0	1 (2%)	6 (2%)
RISEDRONATE SODIUM	2 (3%)	1 (2%)	0	0	0	1 (2%)	4 (1%)
ALENDRONATE SODIUM	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL							
Any medication	0	1 (2%)	0	0	0	0	1 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
BLOOD AND BLOOD FORMING ORGANS							
Any medication	18 (28%)	13 (21%)	11 (17%)	14 (21%)	7 (12%)	10 (16%)	73 (19%)
ANTITHROMBOTIC AGENTS							
Any medication	18 (28%)	10 (16%)	10 (16%)	13 (20%)	5 (8%)	9 (15%)	65 (17%)
ACETYLSALICYLIC ACID	17 (27%)	10 (16%)	9 (14%)	12 (18%)	5 (8%)	9 (15%)	62 (17%)
CLOPIDOGREL BISULFATE	0	0	1 (2%)	1 (2%)	2 (3%)	0	4 (1%)
WARFARIN SODIUM	1 (2%)	0	0	0	0	0	1 (<1%)
ANTIANEMIC PREPARATIONS							
Any medication	0	5 (8%)	1 (2%)	0	1 (2%)	1 (2%)	8 (2%)
CYANOCOBALAMIN	0	3 (5%)	0	0	1 (2%)	0	4 (1%)
IRON	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
FERROUS SULPHATE	0	1 (2%)	0	0	0	0	1 (<1%)
FOLIC ACID	0	1 (2%)	0	0	0	0	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS							
Any medication	0	0	0	2 (3%)	1 (2%)	0	3 (<1%)
POTASSIUM CHLORIDE	0	0	0	1 (2%)	0	0	1 (<1%)
SODIUM CITRATE	0	0	0	1 (2%)	0	0	1 (<1%)
TYROSINE	0	0	0	0	1 (2%)	0	1 (<1%)
ANTIHEMORRHAGICS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
PHYTOMENADIONE	0	0	0	0	1 (2%)	0	1 (<1%)
RESPIRATORY SYSTEM							
Any medication	7 (11%)	11 (18%)	16 (25%)	8 (12%)	7 (12%)	12 (20%)	61 (16%)
NASAL PREPARATIONS							
Any medication	1 (2%)	3 (5%)	7 (11%)	5 (8%)	2 (3%)	7 (11%)	25 (7%)
FLUTICASONE PROPIONATE	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)	9 (2%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	1 (2%)	0	3 (<1%)
MOMETASONE FUROATE	0	0	2 (3%)	1 (2%)	0	0	3 (<1%)
AZELASTINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
FLUNISOLIDE	0	0	0	0	0	1 (2%)	1 (<1%)
GUAIFENESIN+PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
HYOSCINE METHONITRATE+PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
MOMETASONE	0	1 (2%)	0	0	0	0	1 (<1%)
NAPHAZOLINE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
PSEUDOEPHEDRINE	0	0	0	0	0	1 (2%)	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+IBUPROFEN	0	1 (2%)	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)
COUGH AND COLD PREPARATIONS							
Any medication	4 (6%)	5 (8%)	5 (8%)	1 (2%)	2 (3%)	7 (11%)	24 (6%)
GUAIFENESIN	0	2 (3%)	1 (2%)	0	0	1 (2%)	4 (1%)
ACETYLCYSTEINE	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (2%)	0	0	0	0	1 (2%)	2 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+PSEUDOEPHEDRINE HYDROCHLORIDE+DOXYLAMINE SUCCINATE	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
AMBROXOL	1 (2%)	0	0	0	0	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE+EPHEDRINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
DEXTROMETHORPHAN	0	0	0	0	0	1 (2%)	1 (<1%)
GUAIFENESIN+DIPROPHYLLINE	0	0	0	0	1 (2%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
GUAIFENESIN+PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
HYDROCODONE	0	0	1 (2%)	0	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
NOSCAPINE	1 (2%)	0	0	0	0	0	1 (<1%)
PARACETAMOL+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN+PSEUDOEPHEDRINE	0	1 (2%)	0	0	0	0	1 (<1%)
TYLENOL COLD NOS	0	0	1 (2%)	0	0	0	1 (<1%)
VICKS VAPORUB NOS	0	0	0	0	0	1 (2%)	1 (<1%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES							
Any medication	0	3 (5%)	6 (10%)	3 (5%)	3 (5%)	7 (11%)	22 (6%)
FLUTICASONE PROPIONATE	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)	9 (2%)
SALBUTAMOL	0	0	1 (2%)	1 (2%)	1 (2%)	2 (3%)	5 (1%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	0	1 (2%)	2 (3%)	0	0	2 (3%)	5 (1%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	1 (2%)	0	3 (<1%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
THEOPHYLLINE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
BUDESONIDE+FORMOTEROL FUMARATE	0	0	0	0	0	1 (2%)	1 (<1%)
FENOTEROL HYDROBROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
FLUNISOLIDE	0	0	0	0	0	1 (2%)	1 (<1%)
IPRATROPIUM BROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
SALMETEROL XINAFOATE	0	0	0	0	0	1 (2%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANTIHISTAMINES FOR SYSTEMIC USE							
Any medication	3 (5%)	2 (3%)	5 (8%)	1 (2%)	2 (3%)	3 (5%)	16 (4%)
CETIRIZINE HYDROCHLORIDE	1 (2%)	0	2 (3%)	0	1 (2%)	0	4 (1%)
FEXOFENADINE HYDROCHLORIDE	1 (2%)	0	1 (2%)	0	0	1 (2%)	3 (<1%)
LORATADINE	0	2 (3%)	1 (2%)	0	0	0	3 (<1%)
AZELASTINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
DIMENHYDRINATE	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+FEXOFENADINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
BENADRYL (NOS)	1 (2%)	0	0	0	0	0	1 (<1%)
DIPHENHYDRAMINE	0	0	0	0	1 (2%)	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	1 (2%)	0	0	0	0	0	1 (<1%)
THROAT PREPARATIONS							
Any medication	0	0	3 (5%)	0	0	1 (2%)	4 (1%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
OTHER RESPIRATORY SYSTEM PRODUCTS							
Any medication	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
GENTIAN+PRIMULA VERIS+SAMBUCUS NIGRA+VERBENA OFFICINALIS+RUMEX ACETOSA	0	0	0	0	0	1 (2%)	1 (<1%)
TYLENOL SINUS (NOS)	0	0	0	1 (2%)	0	0	1 (<1%)
SENSORY ORGANS							
Any medication	8 (13%)	9 (15%)	10 (16%)	10 (15%)	7 (12%)	12 (20%)	56 (15%)
OPHTHALMOLOGICALS							
Any medication	8 (13%)	9 (15%)	10 (16%)	10 (15%)	7 (12%)	11 (18%)	55 (15%)
BETAXOLOL HYDROCHLORIDE	2 (3%)	3 (5%)	1 (2%)	2 (3%)	1 (2%)	0	9 (2%)
DICLOFENAC	1 (2%)	0	1 (2%)	1 (2%)	3 (5%)	3 (5%)	9 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
DICLOFENAC SODIUM	0	0	2 (3%)	3 (5%)	0	3 (5%)	8 (2%)
ACETYLCYSTEINE	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
TIMOLOL	0	1 (2%)	0	1 (2%)	1 (2%)	0	3 (<1%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
BETAXOLOL	1 (2%)	0	1 (2%)	0	0	0	2 (<1%)
CIPROFLOXACIN	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	2 (3%)	0	0	0	0	0	2 (<1%)
INDOMETACIN	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
LATANOPROST	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
METHYLPREDNISOLONE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
BRIMONIDINE TARTRATE	0	0	1 (2%)	0	0	0	1 (<1%)
BRINZOLAMIDE	0	1 (2%)	0	0	0	0	1 (<1%)
CLONIDINE	0	0	0	0	1 (2%)	0	1 (<1%)
CLONIDINE HYDROCHLORIDE	0	0	0	0	1 (2%)	0	1 (<1%)
DICLOFENAC DIETHYLAMINE	1 (2%)	0	0	0	0	0	1 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
HOMATROPINE	0	0	0	0	0	1 (2%)	1 (<1%)
ISOSORBIDE	0	1 (2%)	0	0	0	0	1 (<1%)
LEVOBUNOLOL HYDROCHLORIDE	0	0	0	0	0	1 (2%)	1 (<1%)
NAPHAZOLINE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
OFLOXACIN	0	0	0	1 (2%)	0	0	1 (<1%)
PHENIRAMINE MALEATE+NAPHAZOLINE HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
PIROXICAM	0	0	0	0	0	1 (2%)	1 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
PROPYLENE GLYCOL+MACROGOL	1 (2%)	0	0	0	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
TIMOLOL MALEATE	0	0	1 (2%)	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
TIMOLOL MALEATE+LATANOPROST	0	1 (2%)	0	0	0	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS							
Any medication	2 (3%)	1 (2%)	0	1 (2%)	0	1 (2%)	5 (1%)
CIPROFLOXACIN	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	2 (3%)	0	0	0	0	0	2 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+GENTAMICIN SULFATE	0	0	0	0	0	1 (2%)	1 (<1%)
GENITO URINARY SYSTEM AND SEX HORMONES							
Any medication	8 (13%)	7 (11%)	8 (13%)	11 (17%)	9 (15%)	9 (15%)	52 (14%)
OTHER GYNECOLOGICALS							
Any medication	3 (5%)	4 (7%)	6 (10%)	7 (11%)	6 (10%)	7 (11%)	33 (9%)
IBUPROFEN	2 (3%)	2 (3%)	4 (6%)	7 (11%)	5 (8%)	6 (10%)	26 (7%)
NAPROXEN	0	3 (5%)	1 (2%)	0	1 (2%)	0	5 (1%)
NAPROXEN SODIUM	1 (2%)	0	1 (2%)	0	0	1 (2%)	3 (<1%)
FENOTEROL HYDROBROMIDE	0	0	1 (2%)	0	0	0	1 (<1%)
UROLOGICALS							
Any medication	3 (5%)	2 (3%)	1 (2%)	1 (2%)	3 (5%)	1 (2%)	11 (3%)
TAMSULOSIN HYDROCHLORIDE	1 (2%)	0	0	0	1 (2%)	1 (2%)	3 (<1%)
DUTASTERIDE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
SILDENAFIL CITRATE	1 (2%)	1 (2%)	0	0	0	0	2 (<1%)
URTICA DIOICA+SERENOA REPENS+POPLAR BUDS	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
FINASTERIDE	0	0	0	0	1 (2%)	0	1 (<1%)
POTASSIUM AMINOBENZOATE	1 (2%)	0	0	0	0	0	1 (<1%)
SILDENAFIL	0	0	0	1 (2%)	0	0	1 (<1%)

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS							
Any medication	1 (2%)	1 (2%)	3 (5%)	1 (2%)	1 (2%)	1 (2%)	8 (2%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
CLINDAMYCIN	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
CICLOPIROX OLAMINE	0	0	1 (2%)	0	0	0	1 (<1%)
CLOTRIMAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
KETOCONAZOLE	0	1 (2%)	0	0	0	0	1 (<1%)
METRONIDAZOLE	0	0	0	0	0	1 (2%)	1 (<1%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM							
Any medication	1 (2%)	0	0	3 (5%)	0	1 (2%)	5 (1%)
ESTRADIOL	0	0	0	1 (2%)	0	0	1 (<1%)
VALERATE+MEDROXYPROGESTERONE ACETATE							
ESTRIOL	1 (2%)	0	0	0	0	0	1 (<1%)
ETHINYLOESTRADIOL+CYPROTERONE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
ETHINYLOESTRADIOL+GESTODENE	0	0	0	1 (2%)	0	0	1 (<1%)
NORETHISTERONE ACETATE+ESTRADIOL	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIINFECTIVES FOR SYSTEMIC USE							
Any medication	7 (11%)	7 (11%)	8 (13%)	8 (12%)	5 (8%)	11 (18%)	46 (12%)
ANTIBACTERIALS FOR SYSTEMIC USE							
Any medication	4 (6%)	3 (5%)	7 (11%)	7 (11%)	3 (5%)	11 (18%)	35 (9%)
AMOXICILLIN	0	0	1 (2%)	1 (2%)	0	3 (5%)	5 (1%)
CEFALEXIN	0	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	5 (1%)
AZITHROMYCIN	0	0	1 (2%)	0	1 (2%)	1 (2%)	3 (<1%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
CIPROFLOXACIN	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	2 (3%)	0	0	0	0	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
CLINDAMYCIN	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
DOXYCYCLINE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
LEVOFLOXACIN	0	0	0	0	0	2 (3%)	2 (<1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
AMOXICILLIN+CLAVULANATE POTASSIUM	0	0	0	1 (2%)	0	0	1 (<1%)
CEFADROXIL	0	0	1 (2%)	0	0	0	1 (<1%)
CEFDINIR	0	0	0	0	0	1 (2%)	1 (<1%)
CEFTRIAXONE	0	0	0	0	1 (2%)	0	1 (<1%)
CEFUROXIME AXETIL	0	0	0	0	0	1 (2%)	1 (<1%)
DOXYCYCLINE HYCLATE	0	0	0	0	0	1 (2%)	1 (<1%)
DOXYCYCLINE HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
ENOXACIN	0	0	0	0	1 (2%)	0	1 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
FOSFOMYCIN TROMETAMOL	0	0	1 (2%)	0	0	0	1 (<1%)
GATIFLOXACIN	0	0	0	0	0	1 (2%)	1 (<1%)
METRONIDAZOLE	0	0	0	0	0	1 (2%)	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	0	0	1 (2%)	0	0	0	1 (<1%)
OFLOXACIN	0	0	0	1 (2%)	0	0	1 (<1%)
SPIRAMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
SULFADIAZINE SILVER	0	0	1 (2%)	0	0	0	1 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	0	1 (2%)	0	0	0	0	1 (<1%)
TELITHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
VACCINES							
Any medication	3 (5%)	2 (3%)	2 (3%)	1 (2%)	1 (2%)	1 (2%)	10 (3%)
INFLUENZA VACCINE	0	2 (3%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)	6 (2%)
INFLUENZA VIRUS VACCINE INACTIVATED	3 (5%)	0	0	0	0	0	3 (<1%)
PNEUMOCOCCAL VACCINE	0	0	0	0	1 (2%)	0	1 (<1%)
TETANUS TOXOID	0	0	1 (2%)	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
ANTIMYCOTICS FOR SYSTEMIC USE							
Any medication	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
FLUCONAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
KETOCONAZOLE	0	1 (2%)	0	0	0	0	1 (<1%)
ANTIVIRALS FOR SYSTEMIC USE							
Any medication	0	1 (2%)	0	0	0	0	1 (<1%)
VALACICLOVIR HYDROCHLORIDE	0	1 (2%)	0	0	0	0	1 (<1%)
DERMATOLOGICALS							
Any medication	6 (9%)	4 (7%)	12 (19%)	9 (14%)	6 (10%)	7 (11%)	44 (12%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS							
Any medication	0	3 (5%)	5 (8%)	4 (6%)	2 (3%)	6 (10%)	20 (5%)
FLUTICASONE PROPIONATE	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)	9 (2%)
BECLOMETASONE DIPROPIONATE	0	0	2 (3%)	0	1 (2%)	0	3 (<1%)
MOMETASONE FUROATE	0	0	2 (3%)	1 (2%)	0	0	3 (<1%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
METHYLPREDNISOLONE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
MOMETASONE	0	1 (2%)	0	0	0	0	1 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS,							
Any medication	3 (5%)	0	3 (5%)	0	1 (2%)	1 (2%)	8 (2%)
LIDOCAINE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
BENADRYL (NOS)	1 (2%)	0	0	0	0	0	1 (<1%)
DIPHENHYDRAMINE	0	0	0	0	1 (2%)	0	1 (<1%)
DOXEPIN HYDROCHLORIDE	1 (2%)	0	0	0	0	0	1 (<1%)
LEVOMENTHOL	0	0	1 (2%)	0	0	0	1 (<1%)
METHYL SALICYLATE+LEVOMENTHOL	1 (2%)	0	0	0	0	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
PIMECROLIMUS	0	0	1 (2%)	0	0	0	1 (<1%)
ANTI-ACNE PREPARATIONS							
Any medication	1 (2%)	1 (2%)	0	3 (5%)	0	2 (3%)	7 (2%)
CLINDAMYCIN	1 (2%)	0	0	1 (2%)	0	0	2 (<1%)
METHYLPREDNISOLONE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
ERYTHROMYCIN	0	0	0	0	0	1 (2%)	1 (<1%)
ETHINYLOESTRADIOL+CYPROTERONE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
RETINOL	0	0	0	1 (2%)	0	0	1 (<1%)
ANTIFUNGALS FOR DERMATOLOGICAL USE							
Any medication	0	1 (2%)	2 (3%)	1 (2%)	2 (3%)	1 (2%)	7 (2%)
TERBINAFINE HYDROCHLORIDE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
CICLOPIROX OLAMINE	0	0	1 (2%)	0	0	0	1 (<1%)
CLOTRIMAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
FLUCONAZOLE	0	0	0	0	1 (2%)	0	1 (<1%)
KETOCONAZOLE	0	1 (2%)	0	0	0	0	1 (<1%)
MICONAZOLE NITRATE+FLUPREDNIDENE ACETATE	0	0	0	1 (2%)	0	0	1 (<1%)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS							
Any medication	1 (2%)	0	2 (3%)	1 (2%)	1 (2%)	0	5 (1%)
GLYCERYL TRINITRATE	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)
ISOSORBIDE DINITRATE	0	0	1 (2%)	0	0	0	1 (<1%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGIC							
Any medication	0	0	3 (5%)	0	0	1 (2%)	4 (1%)
ANTIBIOTICS NOS	0	0	2 (3%)	0	0	0	2 (<1%)
METRONIDAZOLE	0	0	0	0	0	1 (2%)	1 (<1%)
SULFADIAZINE SILVER	0	0	1 (2%)	0	0	0	1 (<1%)
EMOLLIENTS AND PROTECTIVES							
Any medication	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0	4 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
TOCOPHEROL	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
COD-LIVER OIL	0	0	0	1 (2%)	0	0	1 (<1%)
ZINC OXIDE+ICHTHAMMOL+GUAIAZULENE+BORIC ACID	1 (2%)	0	0	0	0	0	1 (<1%)
OTHER DERMATOLOGICAL PREPARATIONS							
Any medication	0	0	1 (2%)	0	1 (2%)	0	2 (<1%)
FINASTERIDE	0	0	0	0	1 (2%)	0	1 (<1%)
PIMECROLIMUS	0	0	1 (2%)	0	0	0	1 (<1%)
ANTISEPTICS AND DISINFECTANTS							
Any medication	1 (2%)	0	0	0	0	0	1 (<1%)
ZINC OXIDE+ICHTHAMMOL+GUAIAZULENE+BORIC ACID	1 (2%)	0	0	0	0	0	1 (<1%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES							
Any medication	4 (6%)	4 (7%)	4 (6%)	5 (8%)	6 (10%)	8 (13%)	31 (8%)
THYROID THERAPY							
Any medication	4 (6%)	3 (5%)	3 (5%)	4 (6%)	5 (8%)	6 (10%)	25 (7%)
LEVOTHYROXINE SODIUM	4 (6%)	1 (2%)	2 (3%)	3 (5%)	3 (5%)	4 (7%)	17 (5%)
LEVOTHYROXINE	0	2 (3%)	0	1 (2%)	1 (2%)	0	4 (1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
THIAMAZOLE	0	0	1 (2%)	0	0	1 (2%)	2 (<1%)
CORTICOSTEROIDS FOR SYSTEMIC USE							
Any medication	0	1 (2%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	8 (2%)
BETAMETHASONE	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
BUDESONIDE	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
METHYLPREDNISOLONE	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
PREDNISOLONE	0	0	0	0	0	1 (2%)	1 (<1%)
PREDNISONE	0	0	0	0	0	1 (2%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.24
Summary of Concomitant Medications

ATC Level 1 ATC Level 2 Ingredient	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	Total (N=375)
TRIAMCINOLONE ACETONIDE	0	0	0	0	0	1 (2%)	1 (<1%)
VARIOUS							
Any medication	0	3 (5%)	0	1 (2%)	5 (8%)	2 (3%)	11 (3%)
ALL OTHER THERAPEUTIC PRODUCTS							
Any medication	0	3 (5%)	0	1 (2%)	4 (7%)	2 (3%)	10 (3%)
ACETYLCYSTEINE	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
POTASSIUM IODIDE	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
CHONDROITIN SULFATE	0	1 (2%)	0	0	0	0	1 (<1%)
DIMETHYL SULFONE	0	0	0	0	1 (2%)	0	1 (<1%)
MEDICATION UNKNOWN	0	1 (2%)	0	0	0	0	1 (<1%)
OENOTHERA BIENNIS	0	0	0	0	1 (2%)	0	1 (<1%)
VANADYL SULPHATE	0	0	0	0	1 (2%)	0	1 (<1%)
GENERAL NUTRIENTS							
Any medication	0	0	0	0	1 (2%)	0	1 (<1%)
TYROSINE	0	0	0	0	1 (2%)	0	1 (<1%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS							
Any medication	0	2 (3%)	0	0	0	0	2 (<1%)
IMMUNOSUPPRESSIVE AGENTS							
Any medication	0	2 (3%)	0	0	0	0	2 (<1%)
AZATHIOPRINE	0	1 (2%)	0	0	0	0	1 (<1%)
LEFLUNOMIDE	0	1 (2%)	0	0	0	0	1 (<1%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENT							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
ANTIPROTOZOALS							
Any medication	0	0	0	0	0	1 (2%)	1 (<1%)
METRONIDAZOLE	0	0	0	0	0	1 (2%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

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Table 10.26
Summary of Overall Compliance

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
% of visits at which subject is compliant[1]							
n	64	61	63	66	60	61	311
Mean	93.0	96.5	96.0	97.5	95.3	95.9	96.3
SD	21.16	15.23	15.44	13.45	17.39	18.92	16.06
Median	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Min.	0	0	0	0	0	0	0
Max.	100	100	100	100	100	100	100

[1] Compliant visits are those at which subjects are >=80% and <=120% compliant

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Table 11.66 Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region (Intent-to-Treat with LOCF Population) 2092

Table 11.67 SAS Statistical Output for Table 11.66 Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region (Intent-to-Treat with LOCF Population) 2093

Table 11.68 Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region (Intent-to-Treat with LOCF Population) 2182

Table 11.69 SAS Statistical Output for Table 11.68 Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region (Intent-to-Treat with LOCF Population) 2183

Table 11.70 Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region (Intent-to-Treat with LOCF Population) 2272

Table 11.71 SAS Statistical Output for Table 11.70 Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region (Intent-to-Treat with LOCF Population) 2273

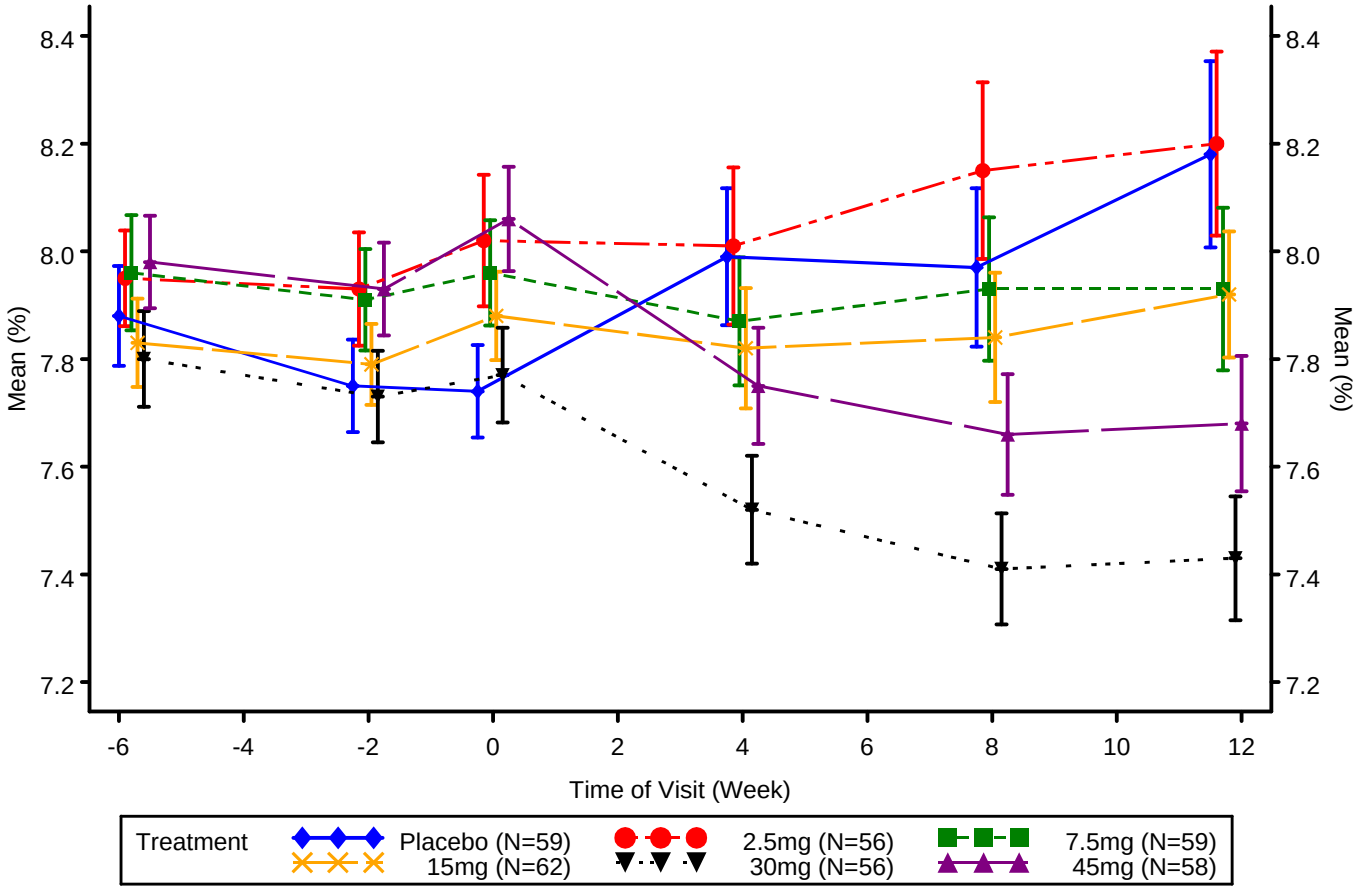
Table 11.72 Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region (Intent-to-Treat with LOCF Population) 2362

Table 11.73 SAS Statistical Output for Table 11.72 Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region (Intent-to-Treat with LOCF Population) 2363

Table 11.74 Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%%) at Week 12 by Region (Intent-to-Treat with LOCF Population) 2451

Table 11.75 Summary Statistics of Log-Transformed HOMA Beta Cell Function (%%) at Week 12 by Region (Intent-to-Treat with LOCF Population) 2453

Figure 11.1
Line Graph of Mean (+-SE) for HbA1c (%) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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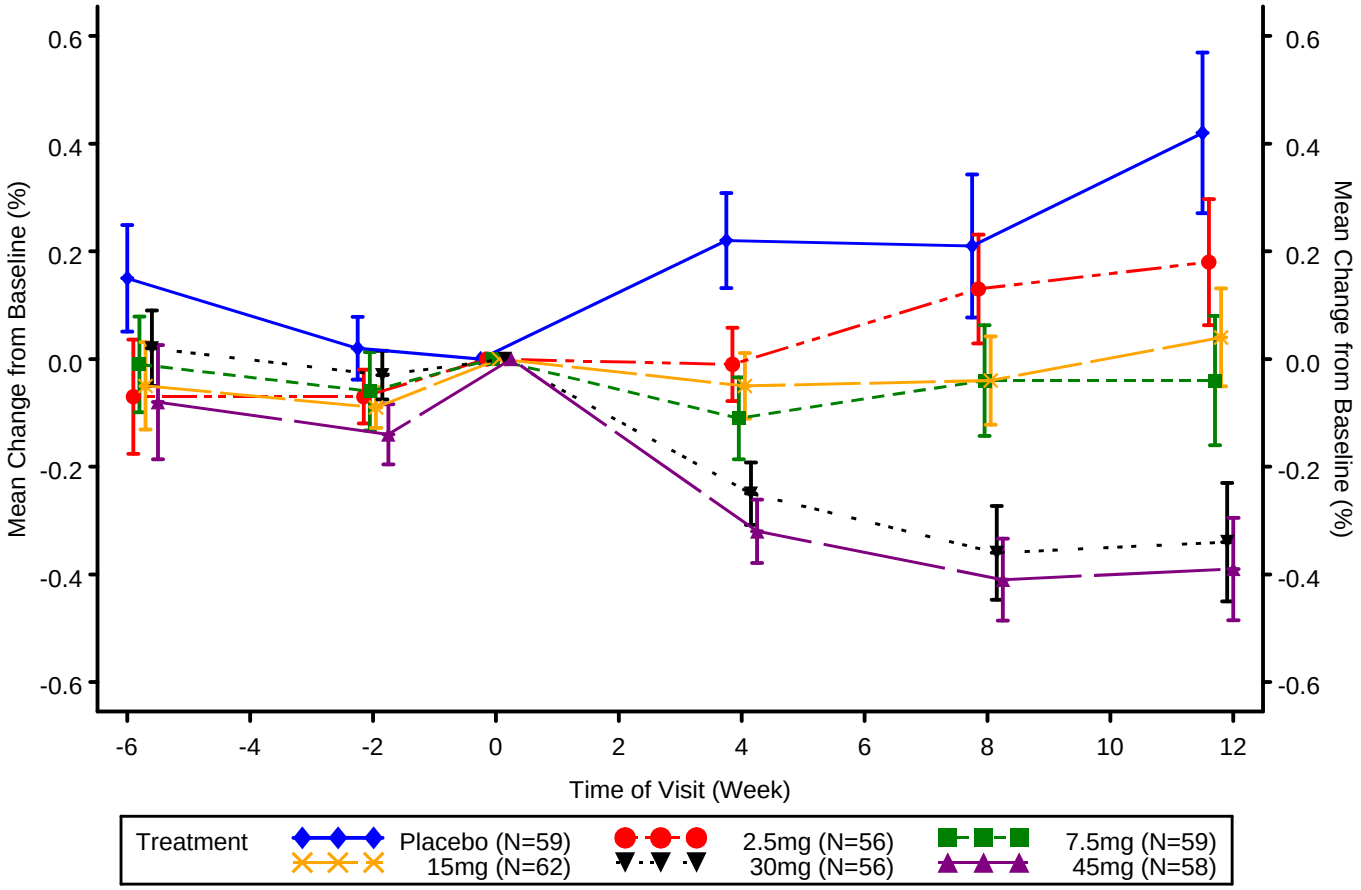
Figure 11.2
Line Graph of Mean Change from Baseline (+-SE) for HbA1c (%) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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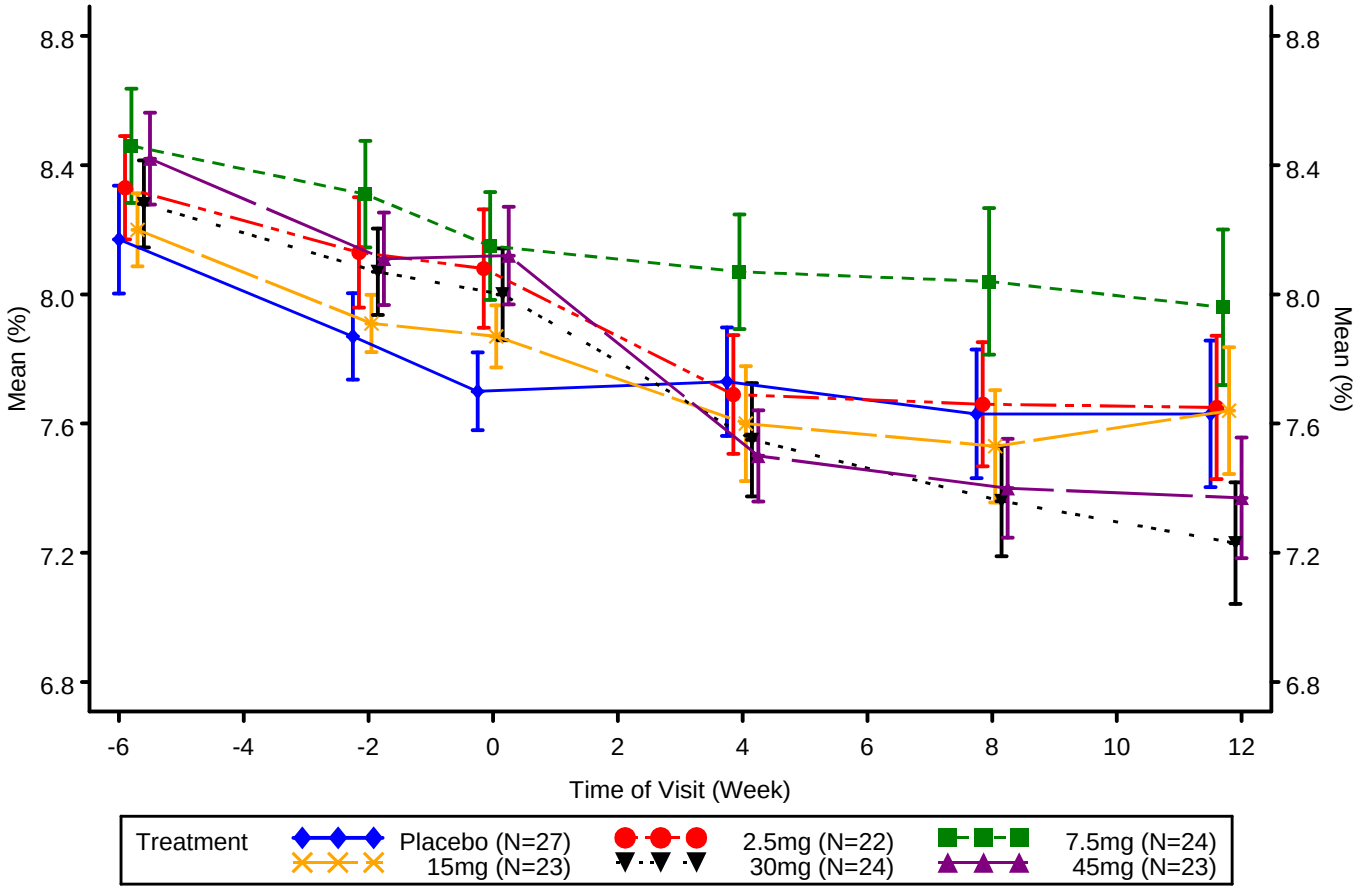
Figure 11.3
Line Graph of Mean (+-SE) for HbA1c (%) for Diet & Exercise Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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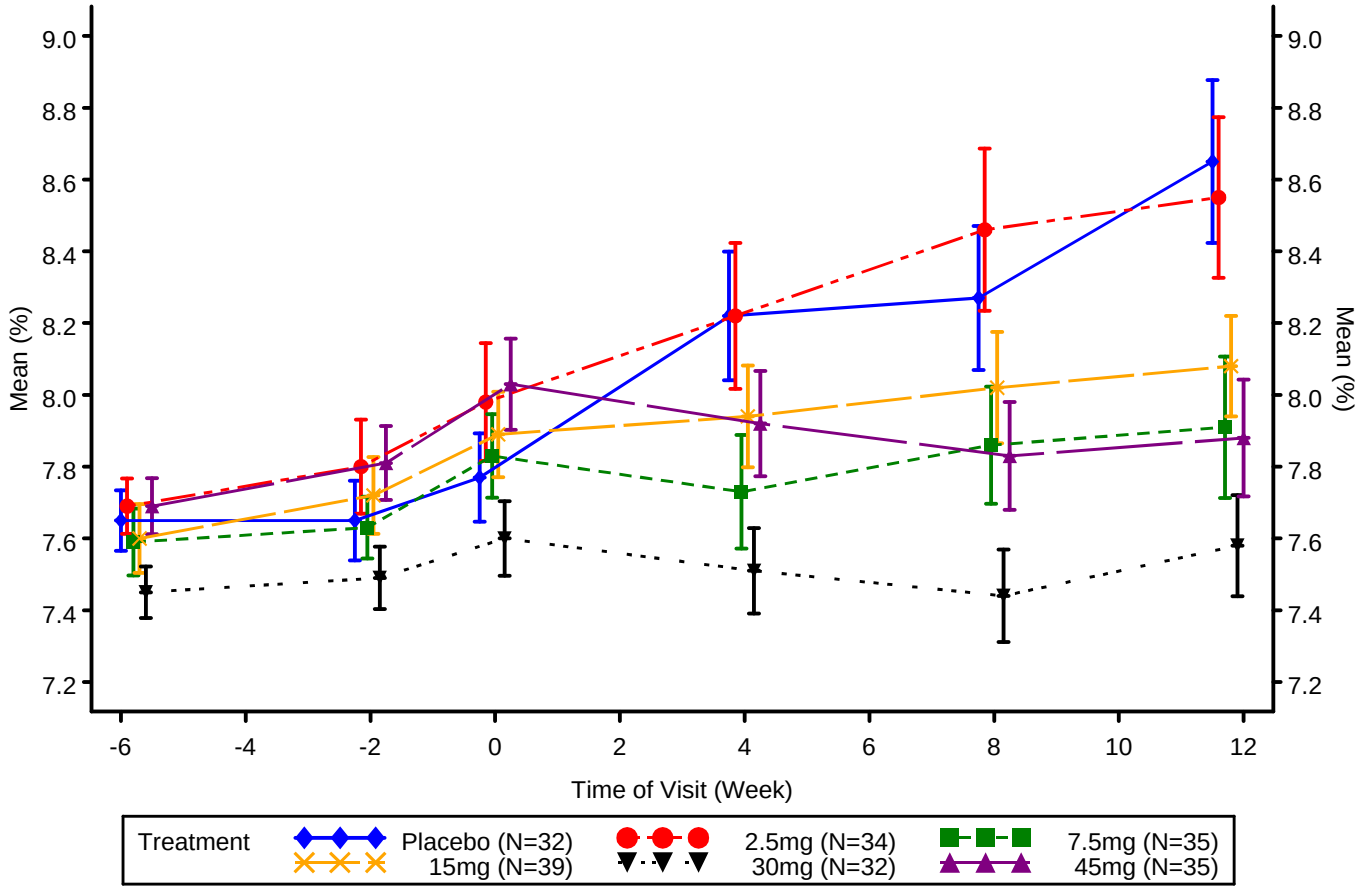
Figure 11.4
Line Graph of Mean (+-SE) for HbA1c (%) for Monotherapy Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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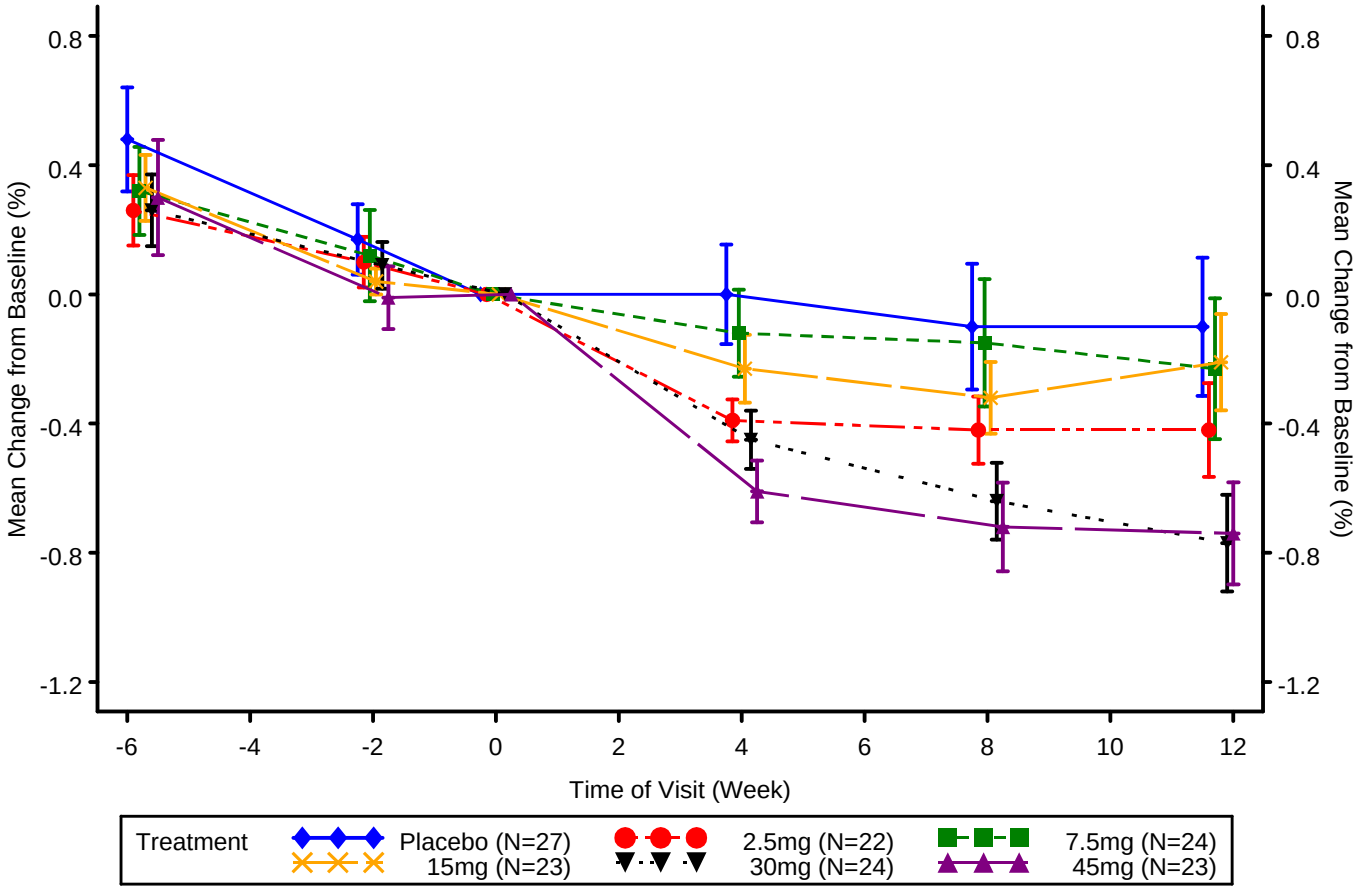
Figure 11.5
Line Graph of Mean Change from Baseline (+-SE) for HbA1c (%) for Diet & Exercise Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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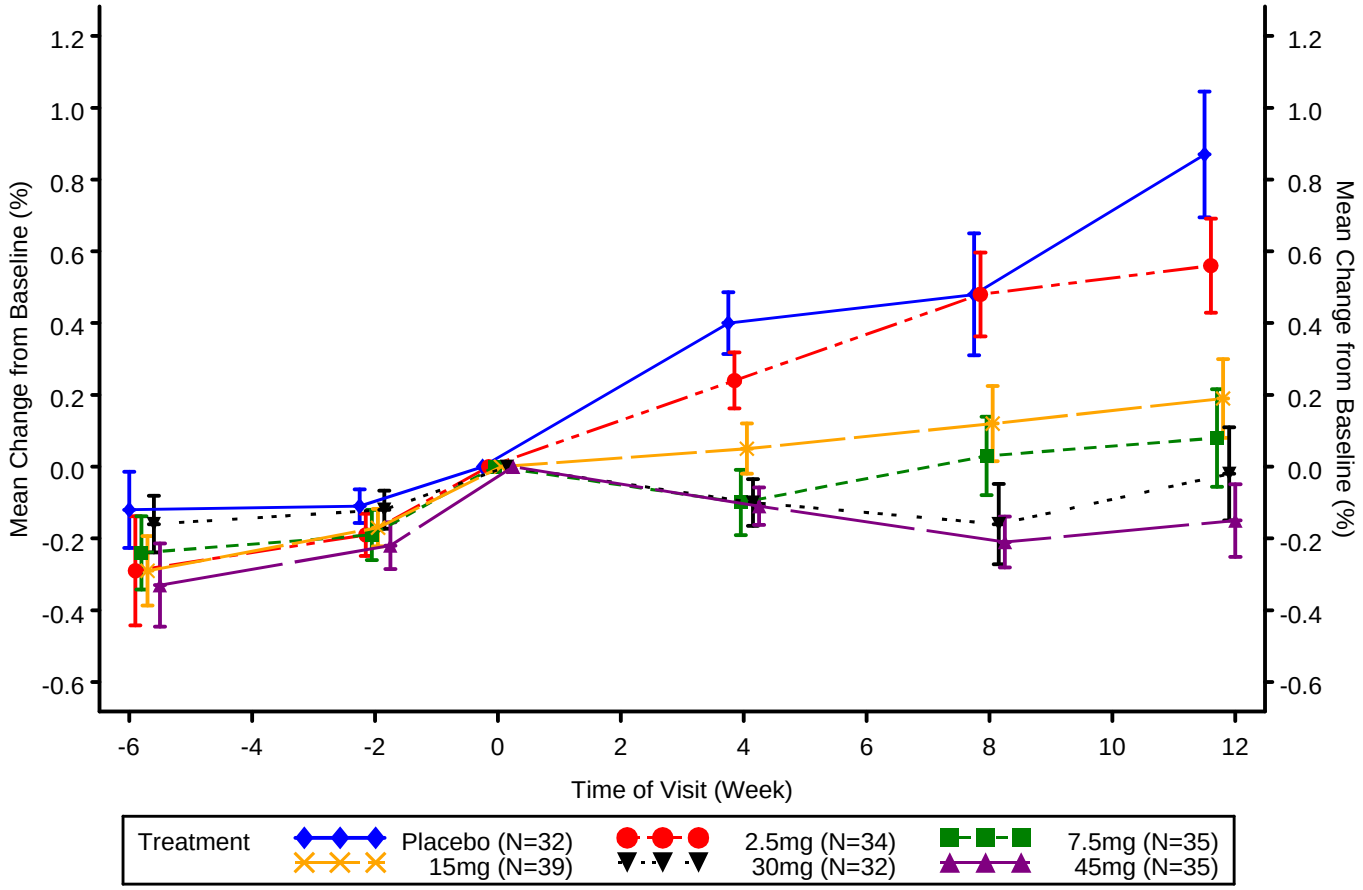
Figure 11.6
Line Graph of Mean Change from Baseline (+-SE) for HbA1c (%) for Monotherapy Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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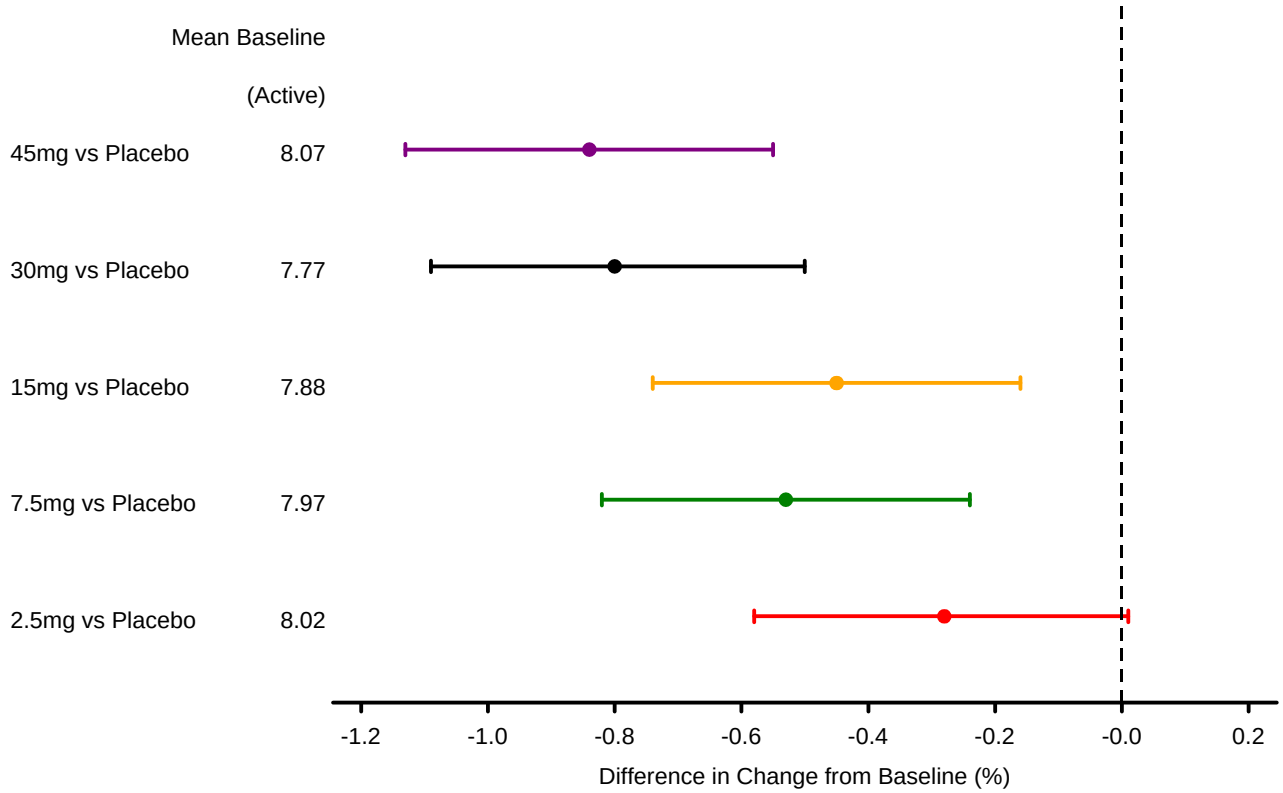
Figure 11.7
Figure of Treatment Difference in HbA1c (%) Change from Baseline to Week 12



Mean Baseline for Placebo = 7.76
Number of Subjects at Week 12 after LOCF: Placebo = 59, 2.5mg = 56, 7.5mg = 59, 15mg = 62, 30mg = 56, 45mg = 58

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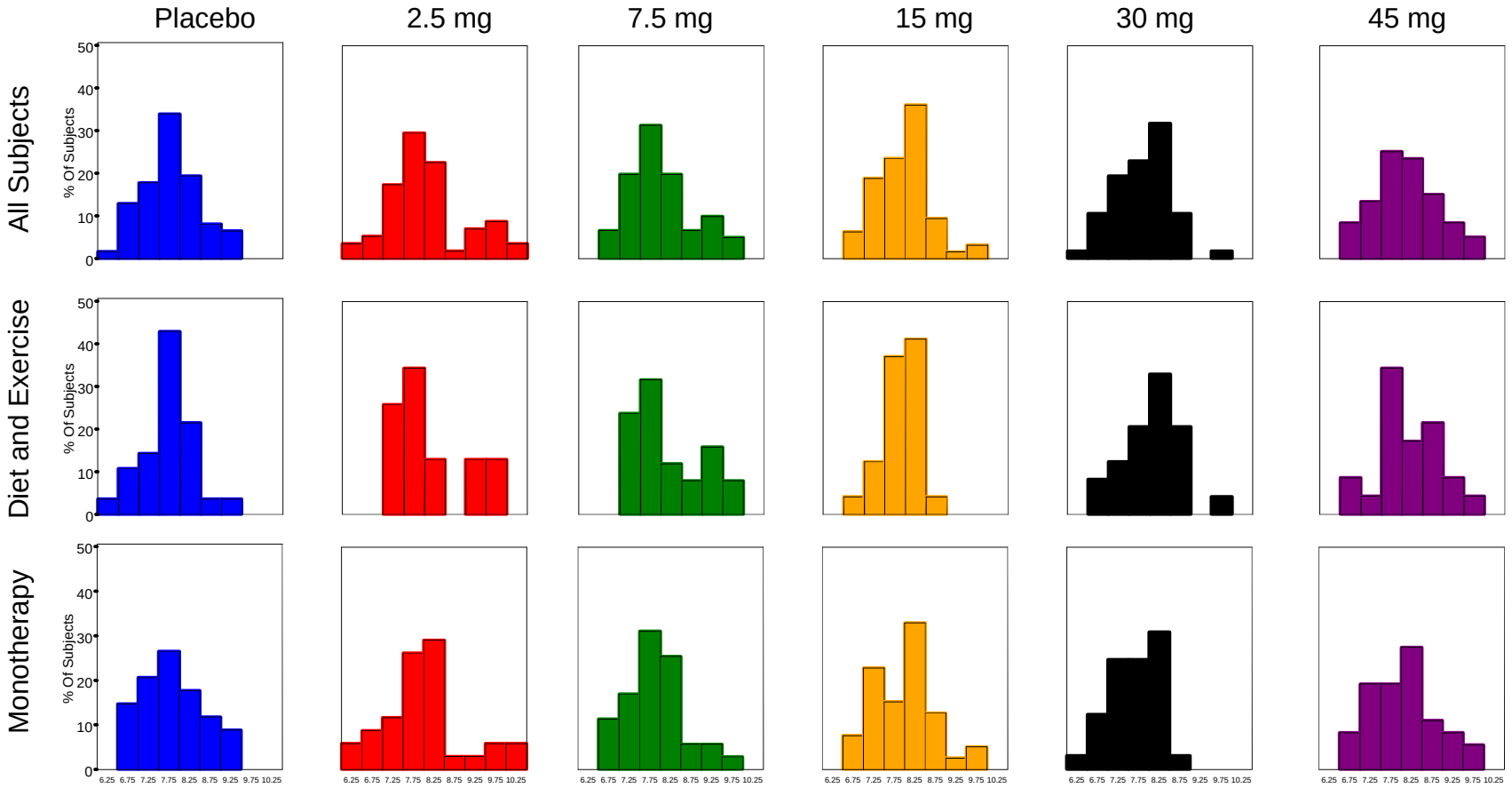
Figure 11.8
Distribution of Baseline HbA1c (%) by Treatment and Prior Therapy



[redacted]

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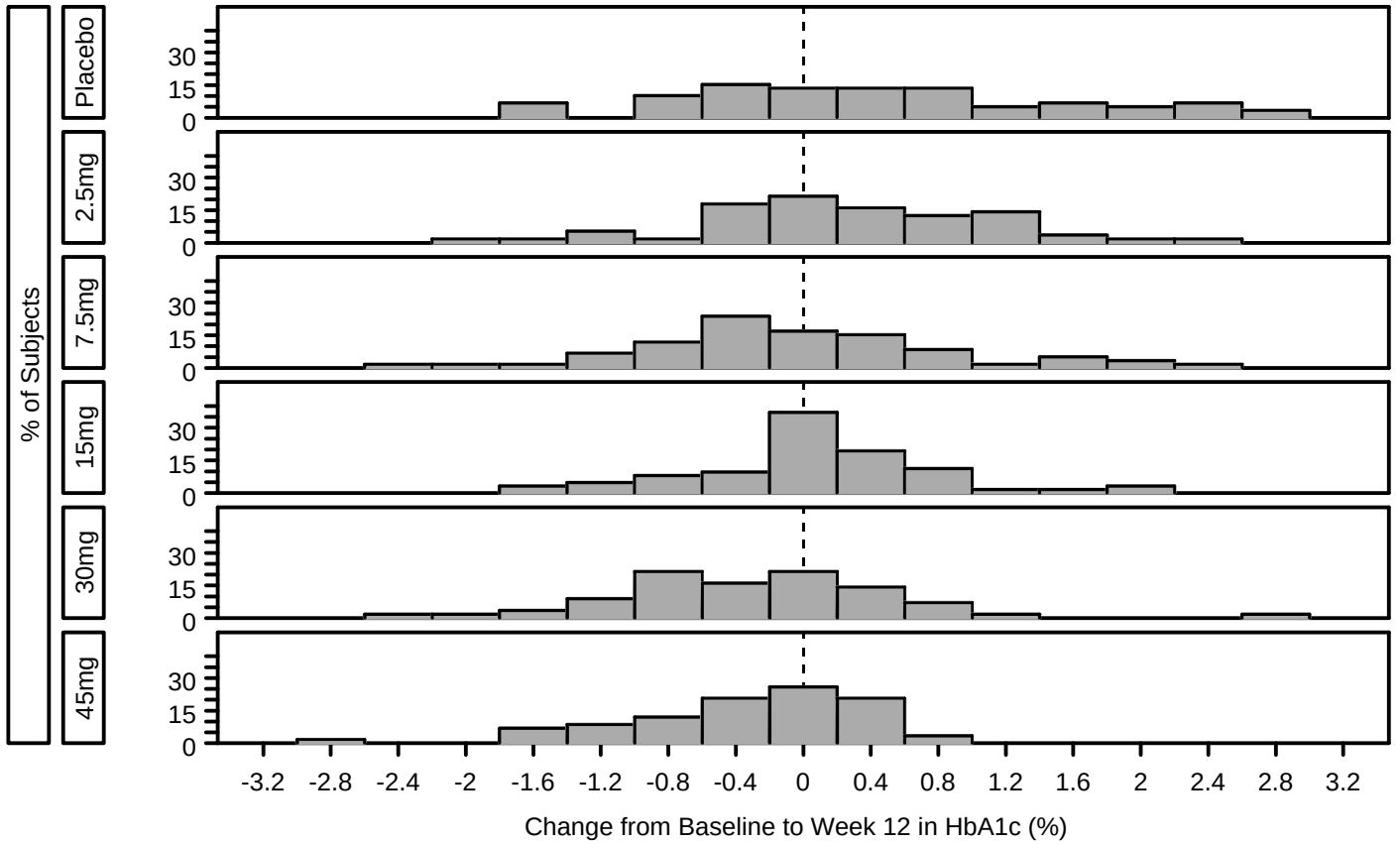
Figure 11.9
Distribution of Change from Baseline to Week 12 in HbA1c (%) by Treatment



[redacted]

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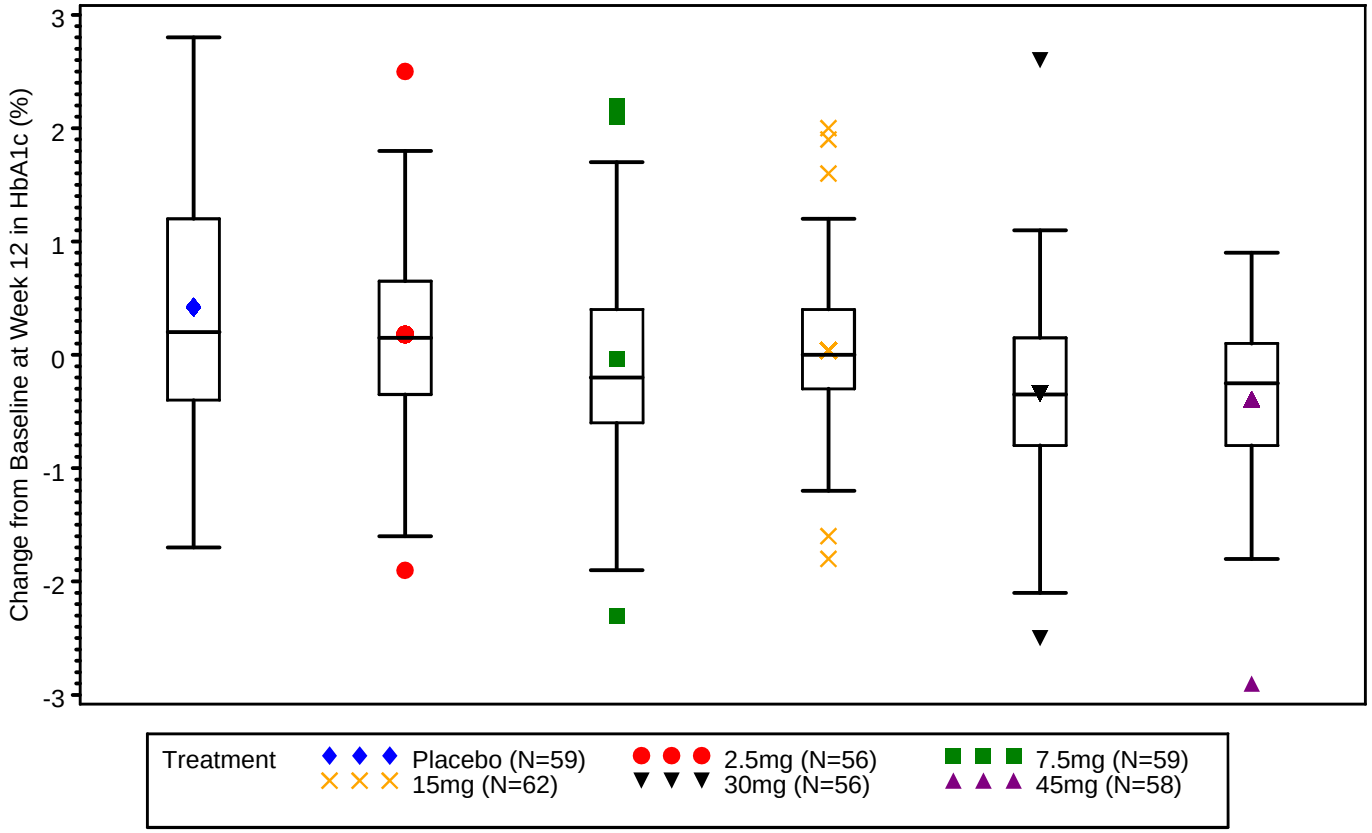
Figure 11.10
Boxplot of Change from Baseline at Week 12 in HbA1c (%) by Treatment



Note: N are number of subjects at Week 12 (after LOCF).

[redacted]

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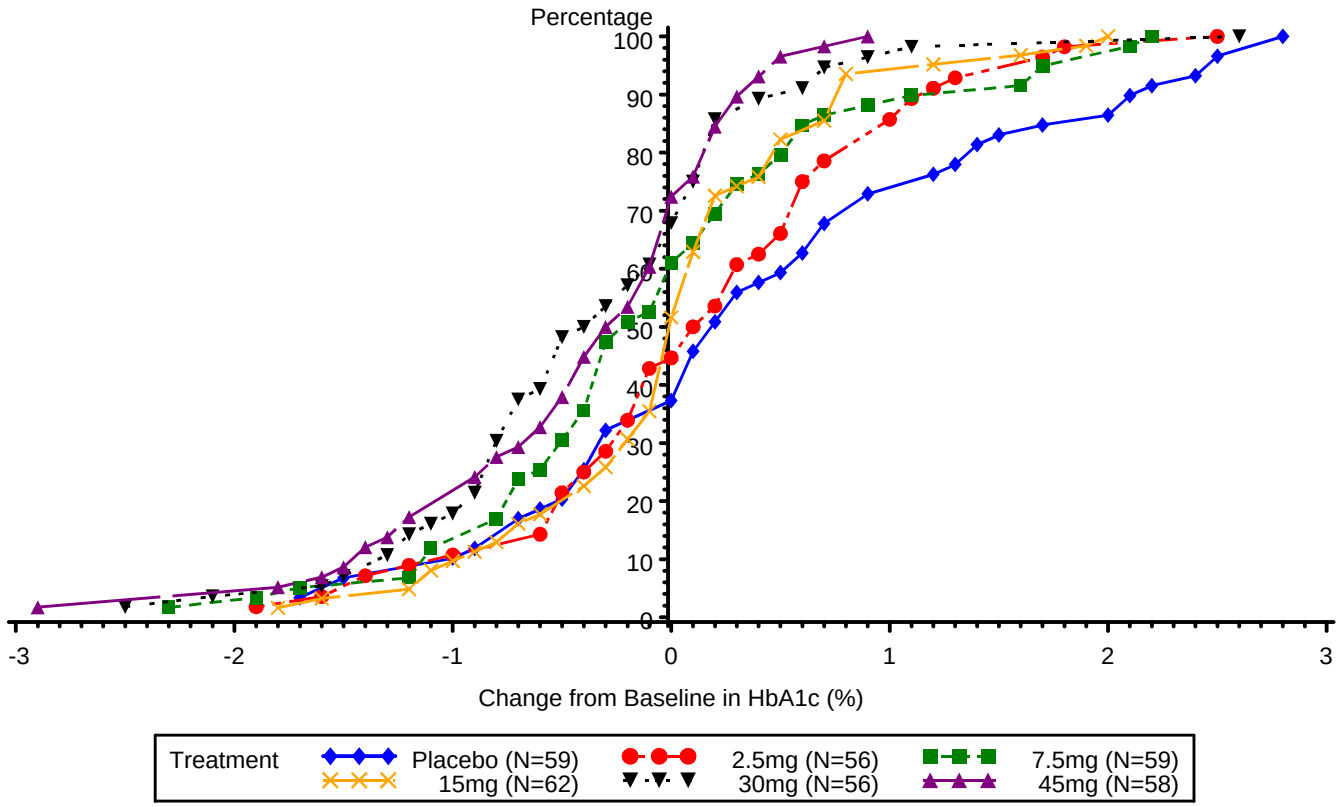
Figure 11.11
Cumulative Distribution Curve of Change from Baseline at Week 12 in HbA1c (%)



Note: N are number of subjects at Week 12 (after LOCF).

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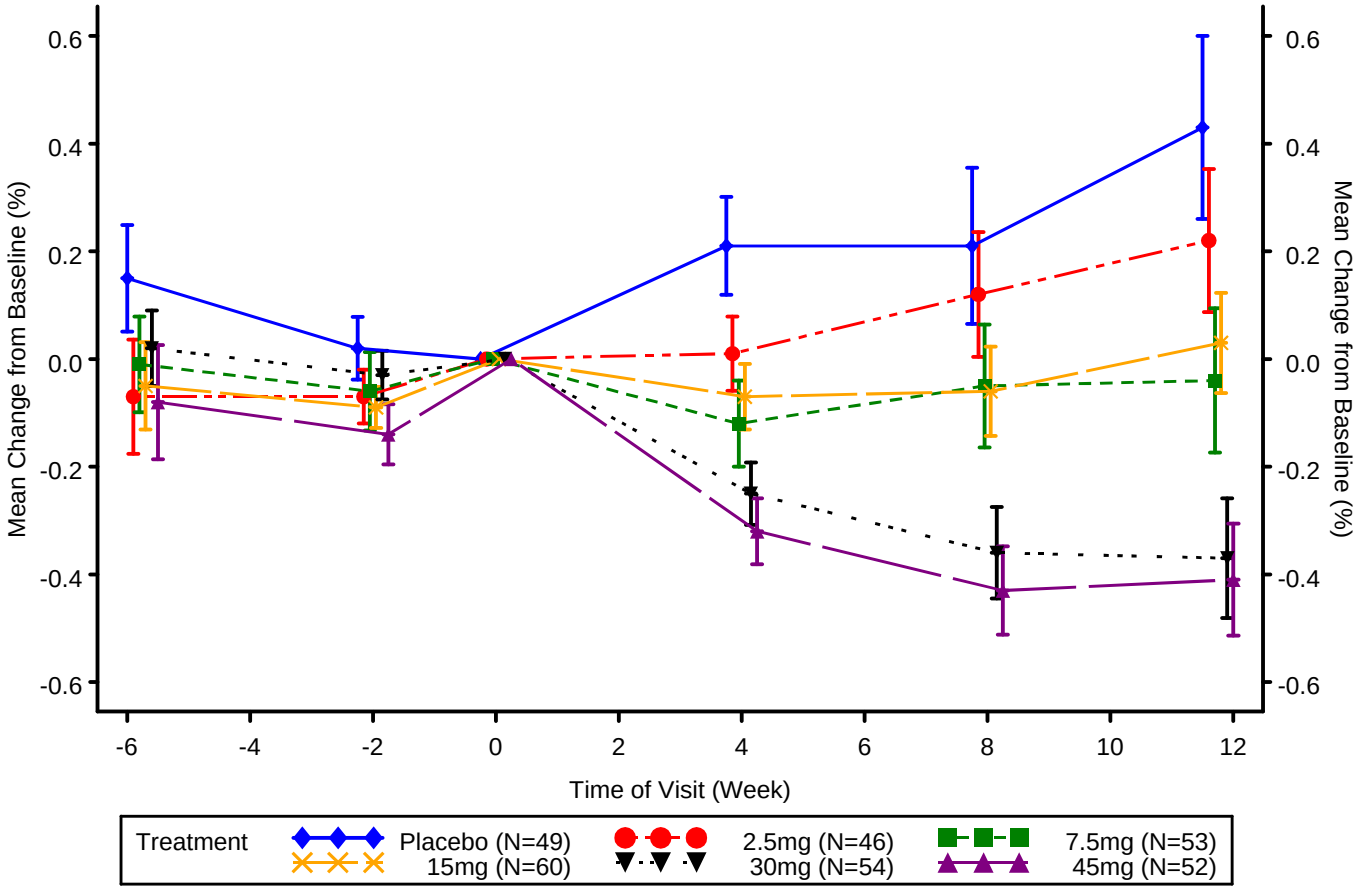
Figure 11.12
Line Graph of Mean Change from Baseline (+-SE) for HbA1c (%) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 without LOCF.

[redacted]

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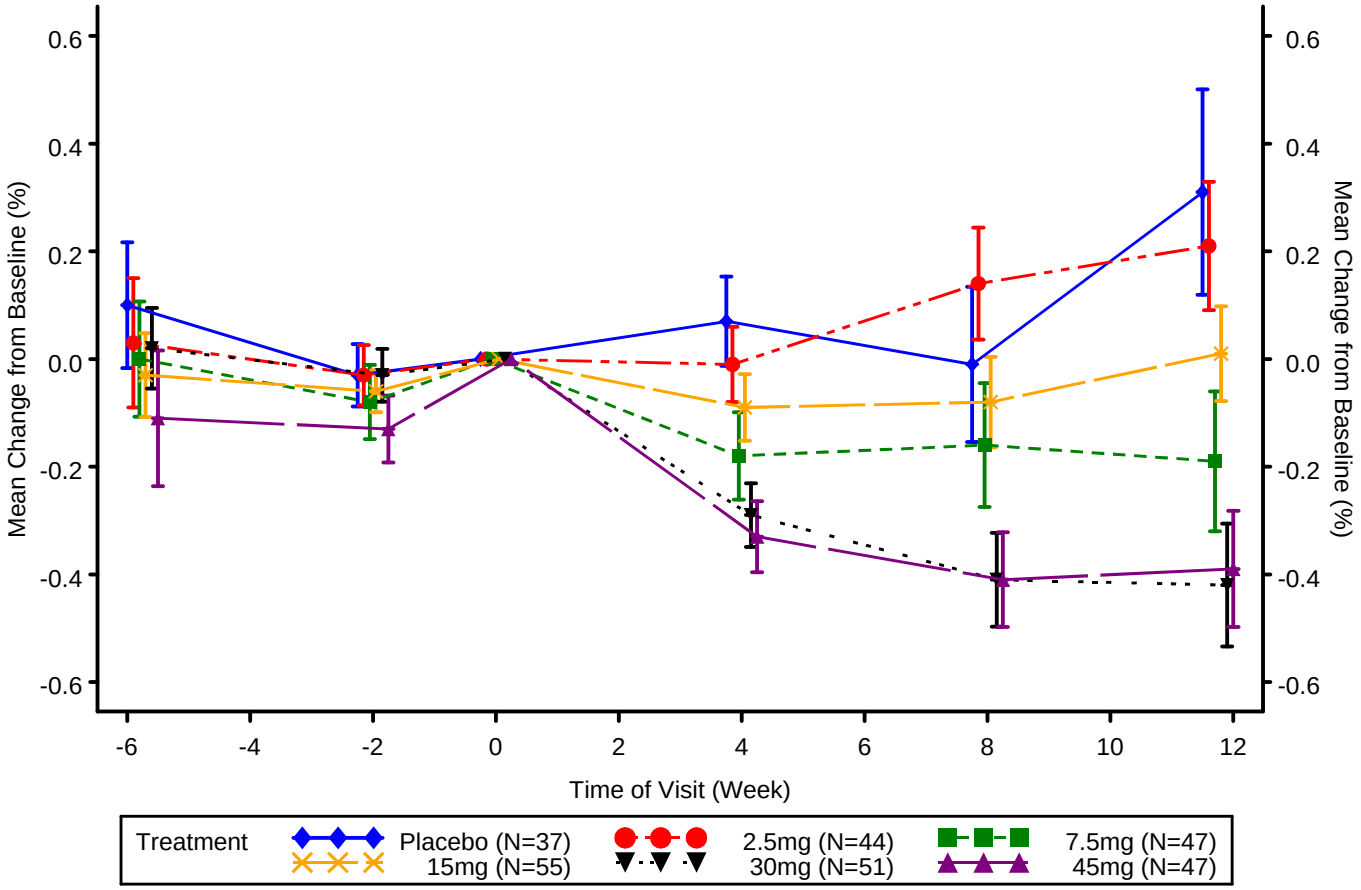
Figure 11.13
Line Graph of Mean Change from Baseline (+-SE) for HbA1c (%) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12.

[redacted]

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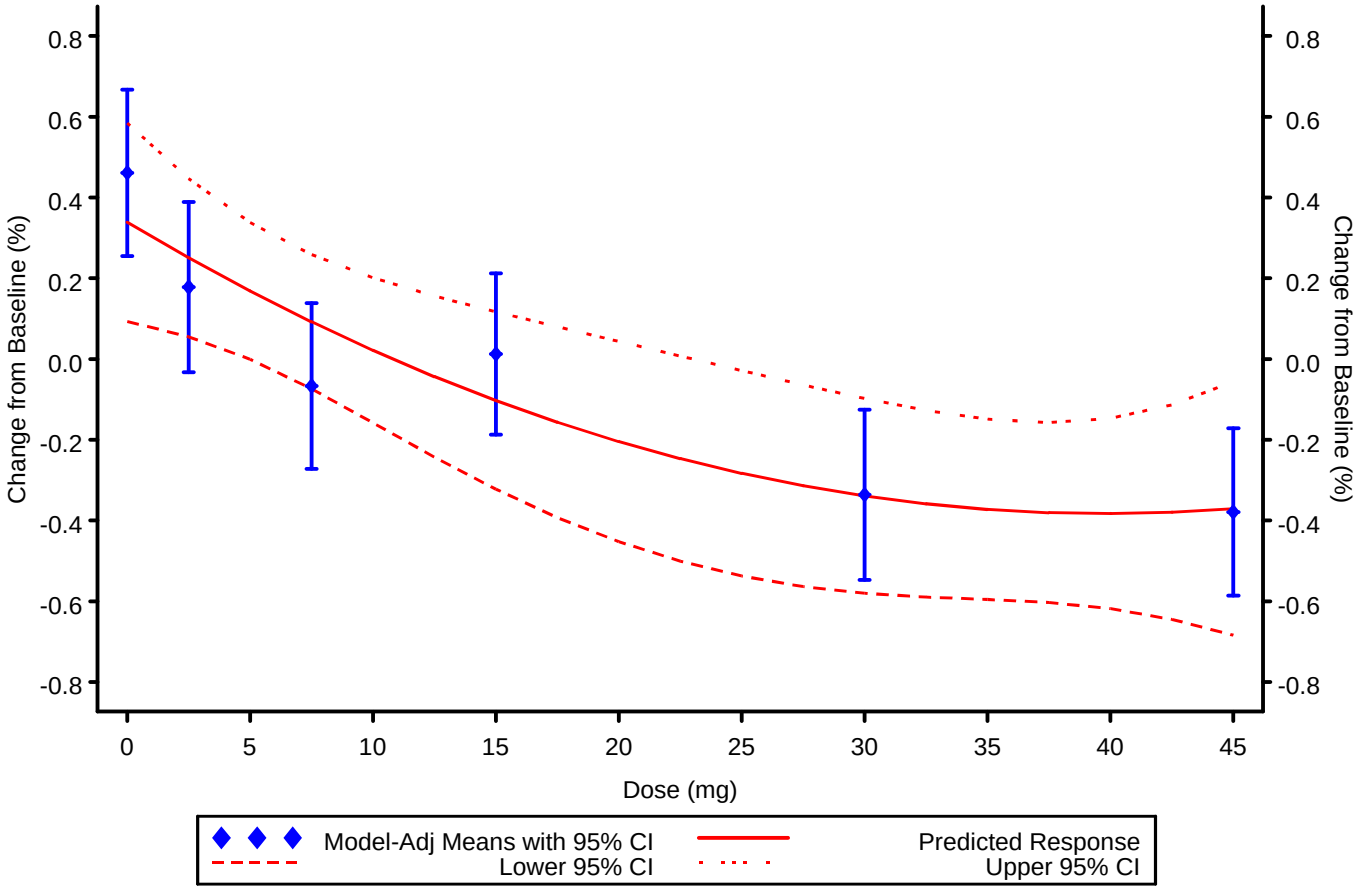
Figure 11.14
Figure of Predicted Dose-Response Curve for Change from Baseline in HbA1c (%) at Week 12



Linear: p<0.001, Quadratic: p=0.044, Cubic: p=0.438

[redacted]

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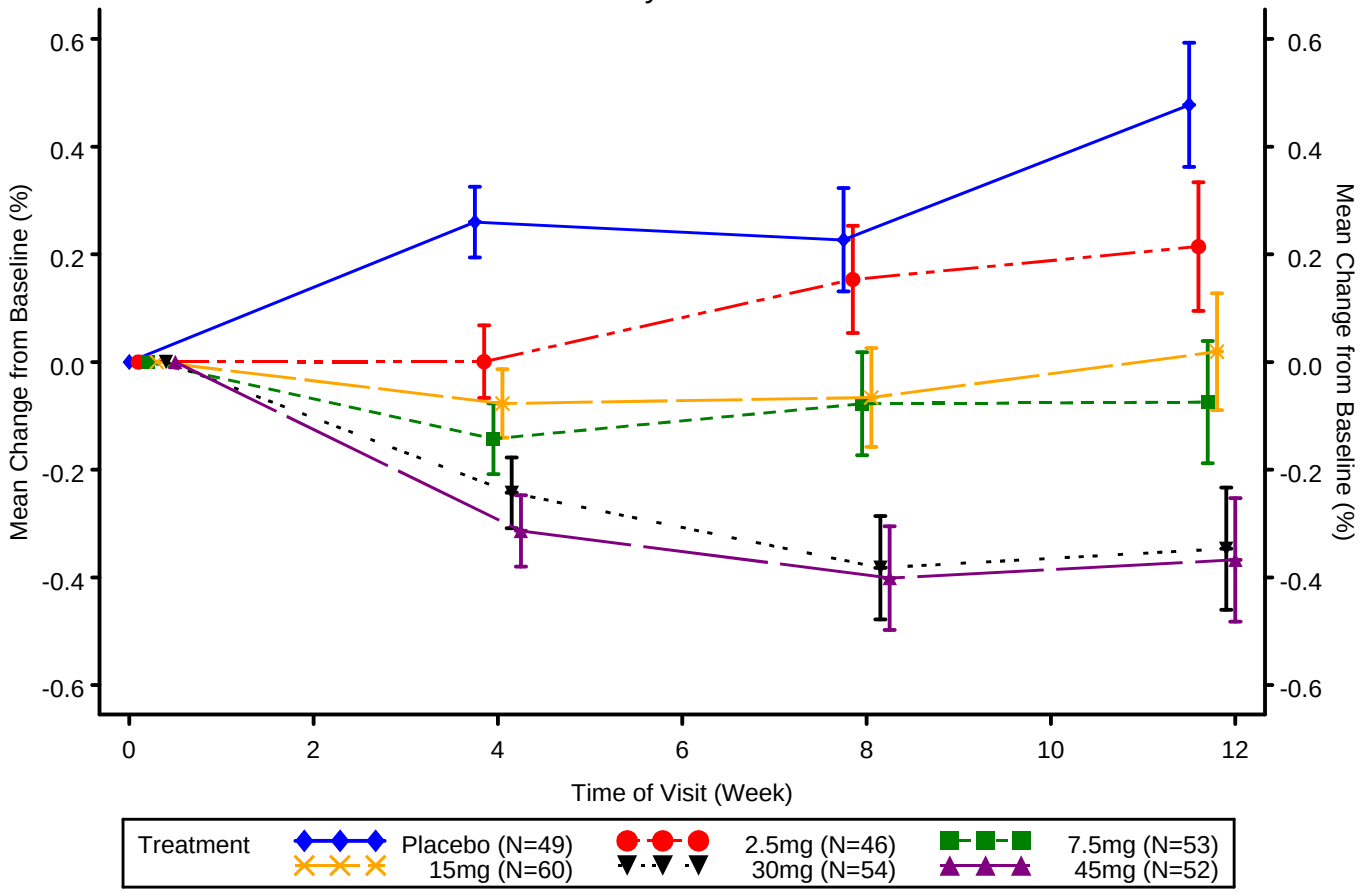
Figure 11.15
Line Graph of Repeated Measures Model-Adjusted Mean Change from Baseline (+-SE) for HbA1c (%) by Visit



Note: N are number of subjects at Week 12 without LOCF.

[redacted]

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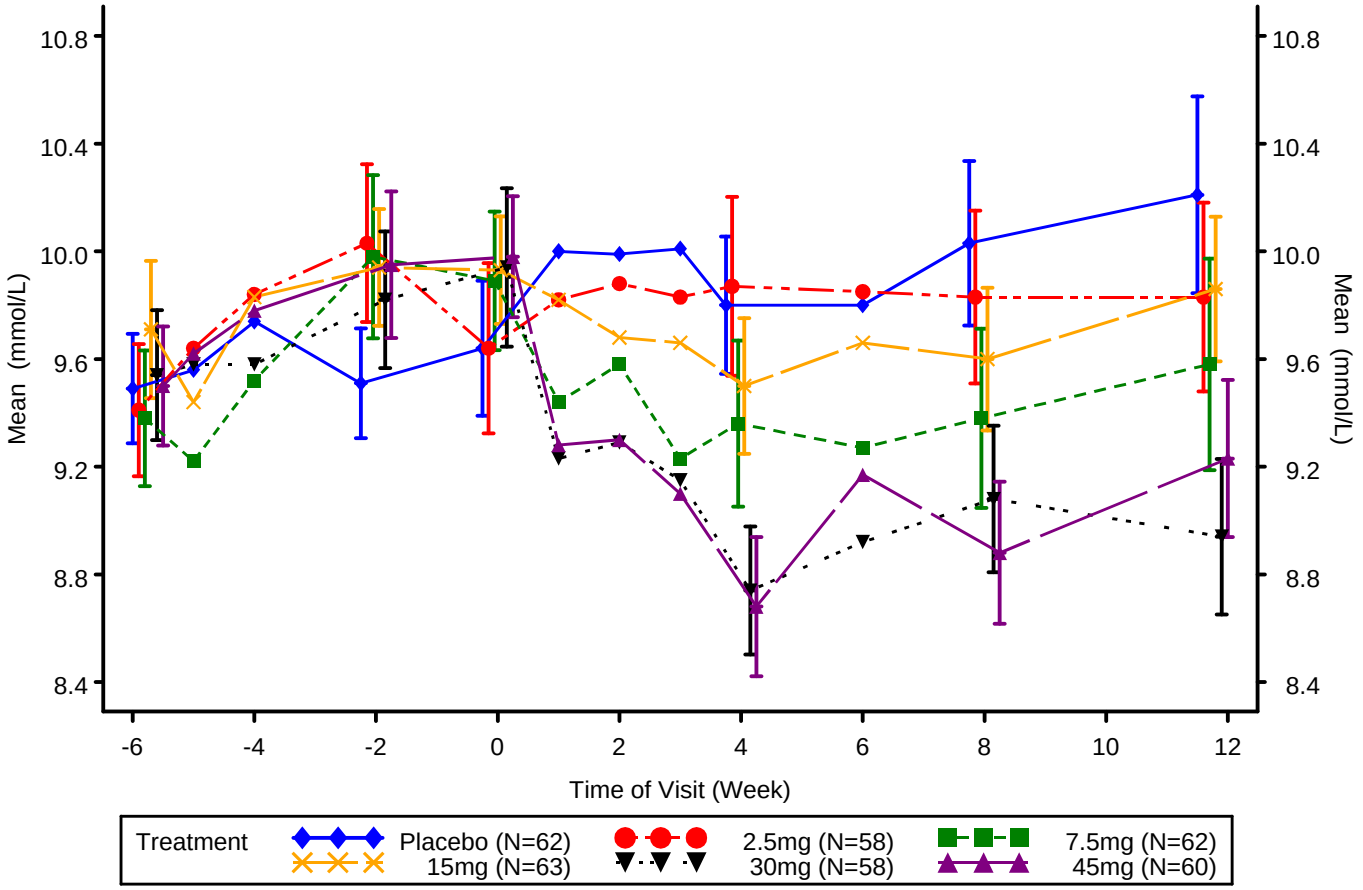
Figure 11.16
Line Graph of Mean (+-SE) for Fasting Plasma Glucose (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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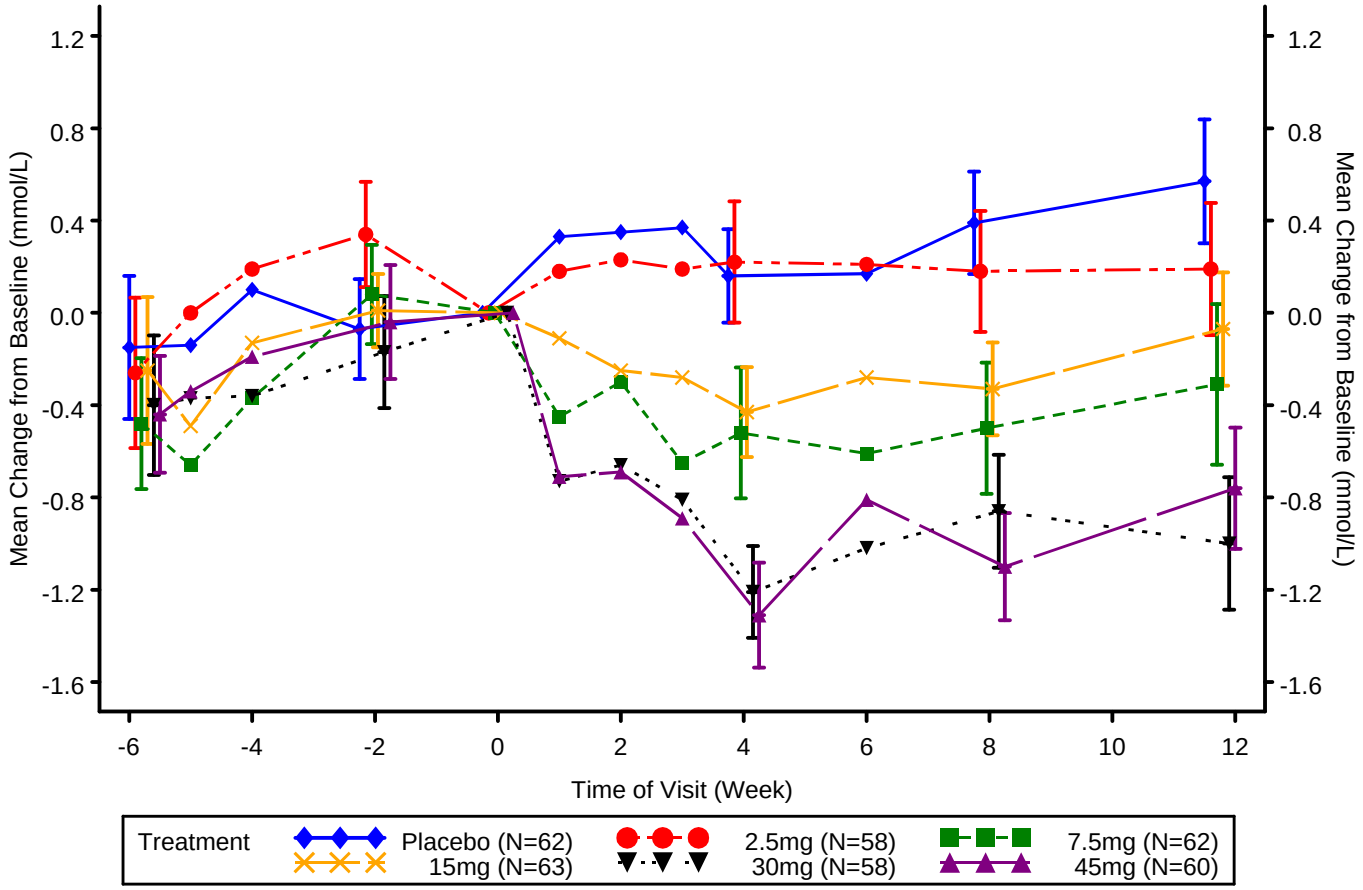
Figure 11.17
Line Graph of Mean Change from Baseline (+-SE) for Fasting Plasma Glucose (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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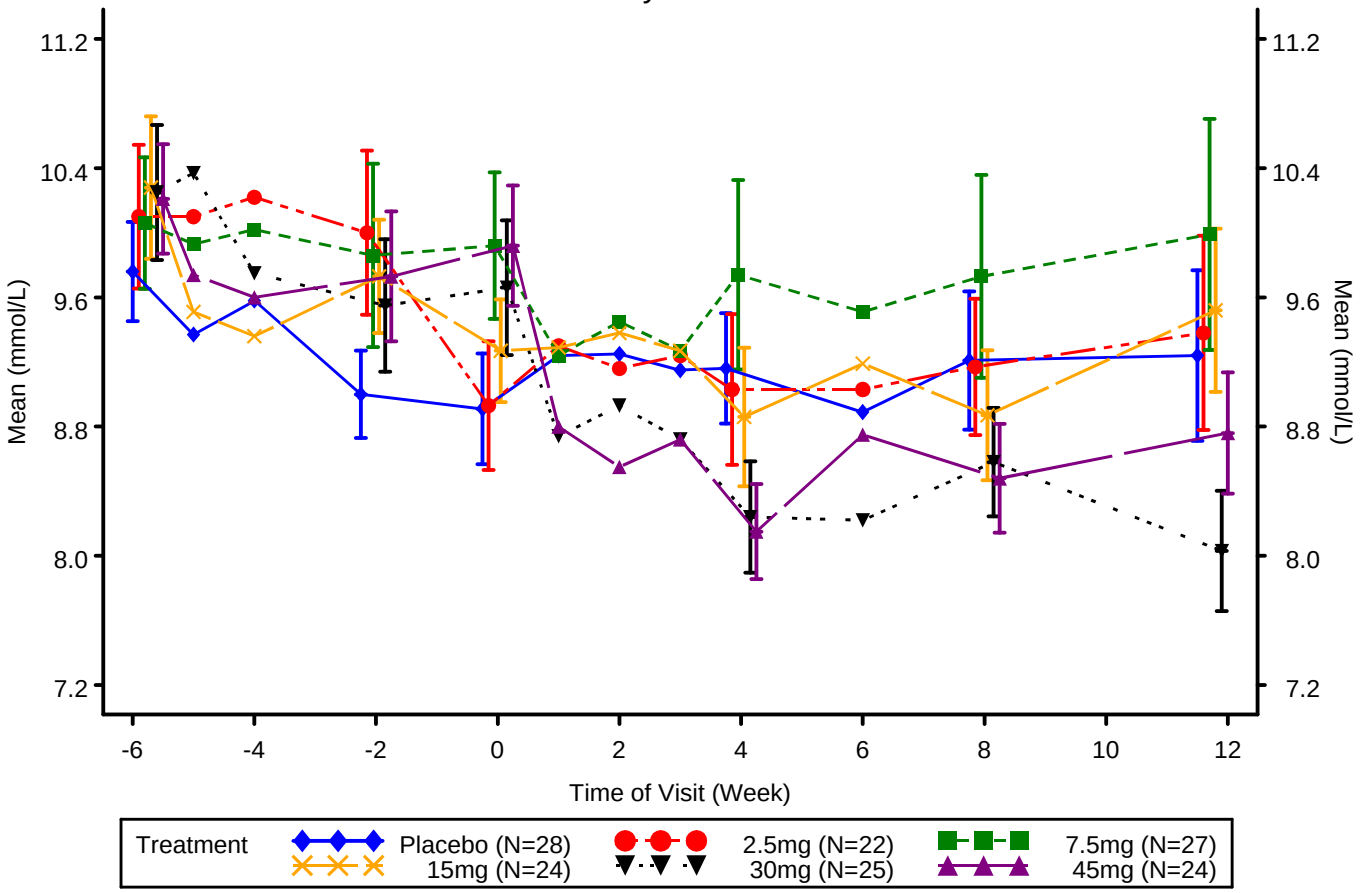
Figure 11.18
Line Graph of Mean (+-SE) for Fasting Plasma Glucose (mmol/L) for Diet & Exercise Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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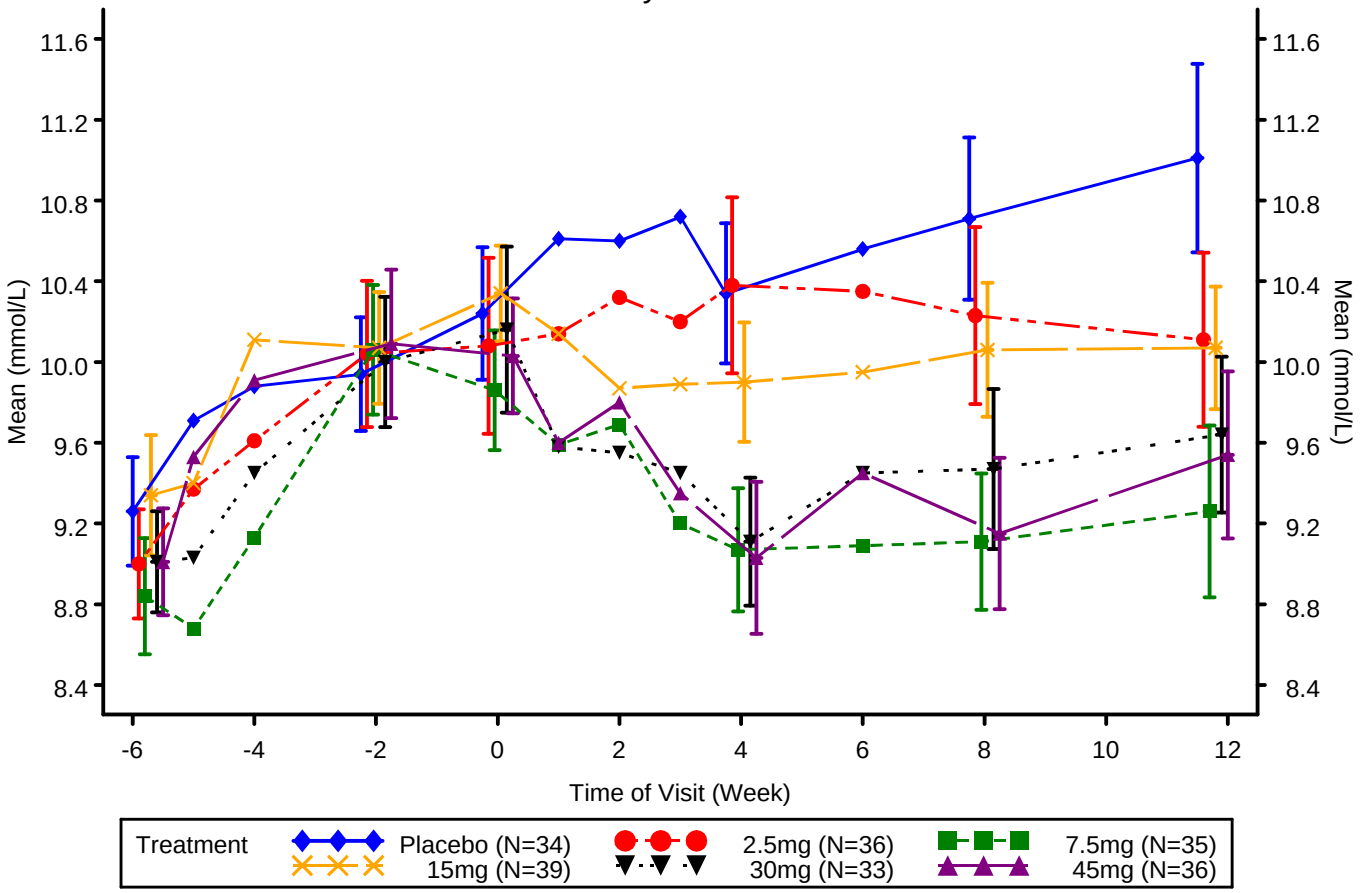
Figure 11.19
Line Graph of Mean (+-SE) for Fasting Plasma Glucose (mmol/L) for Monotherapy Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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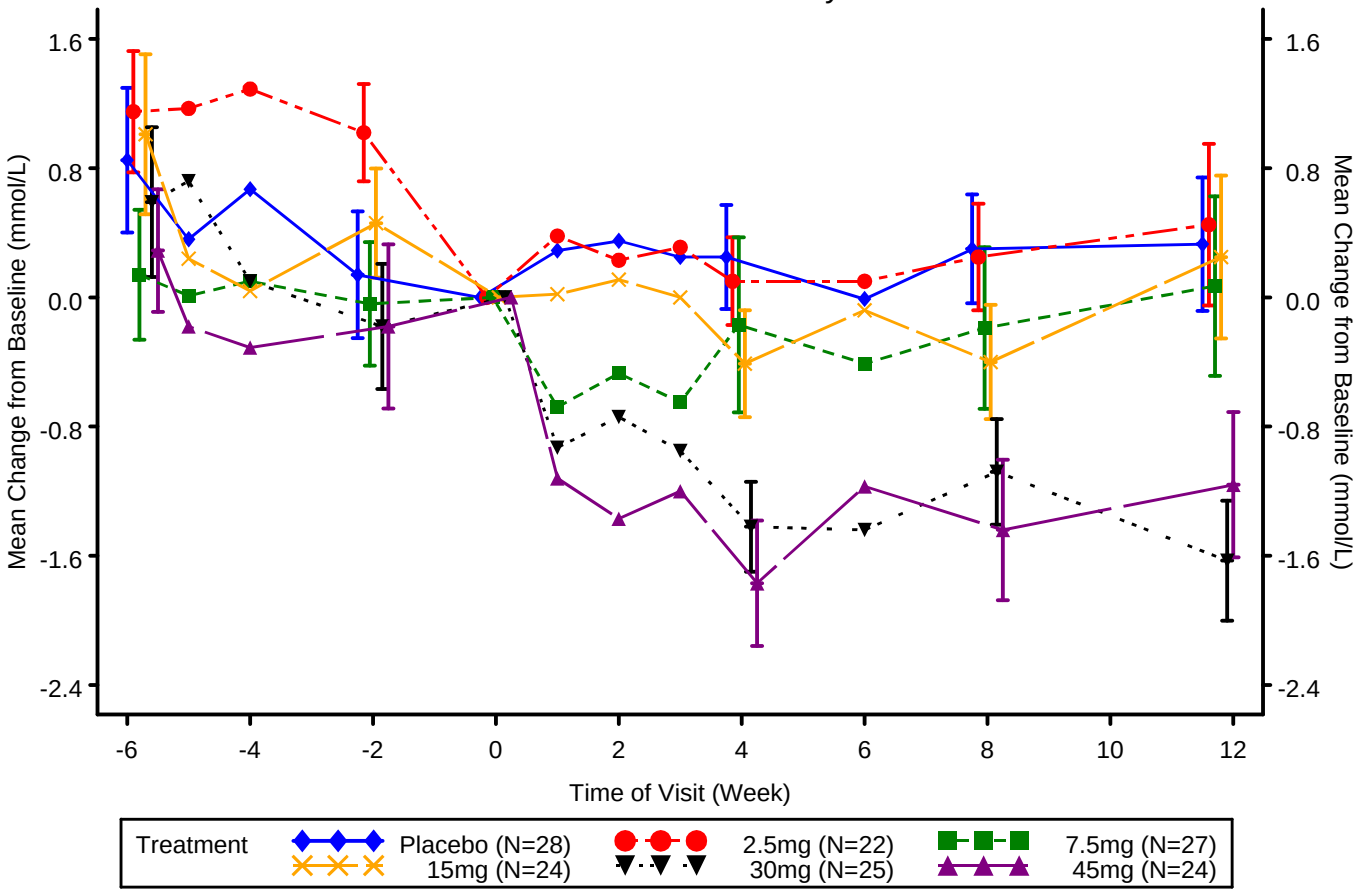
Figure 11.20
Line Graph of Mean Change from Baseline (+-SE) for Fasting Plasma Glucose (mmol/L)
for Diet & Exercise Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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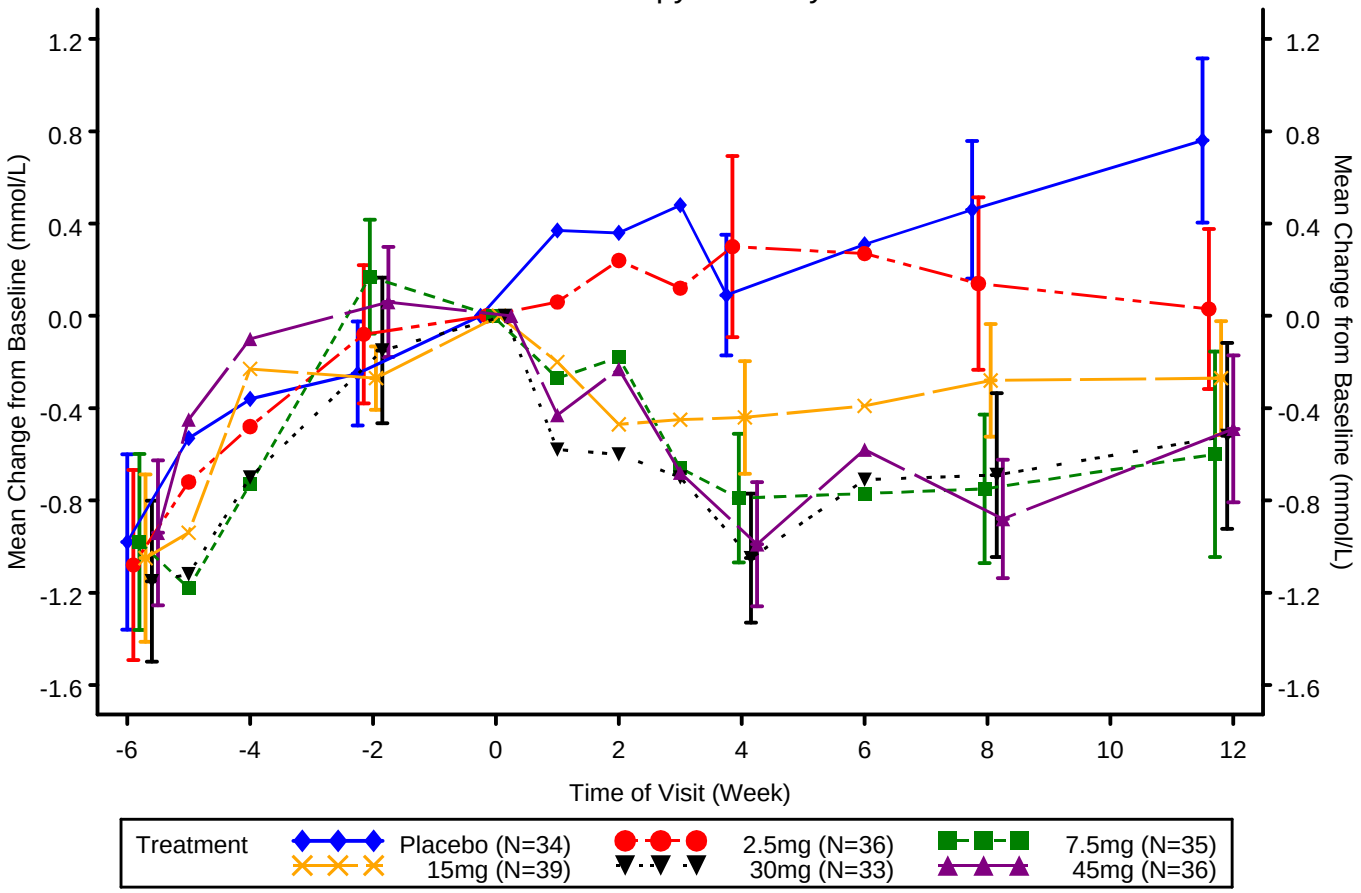
Figure 11.21
Line Graph of Mean Change from Baseline (+-SE) for Fasting Plasma Glucose (mmol/L)
for Monotherapy Strata by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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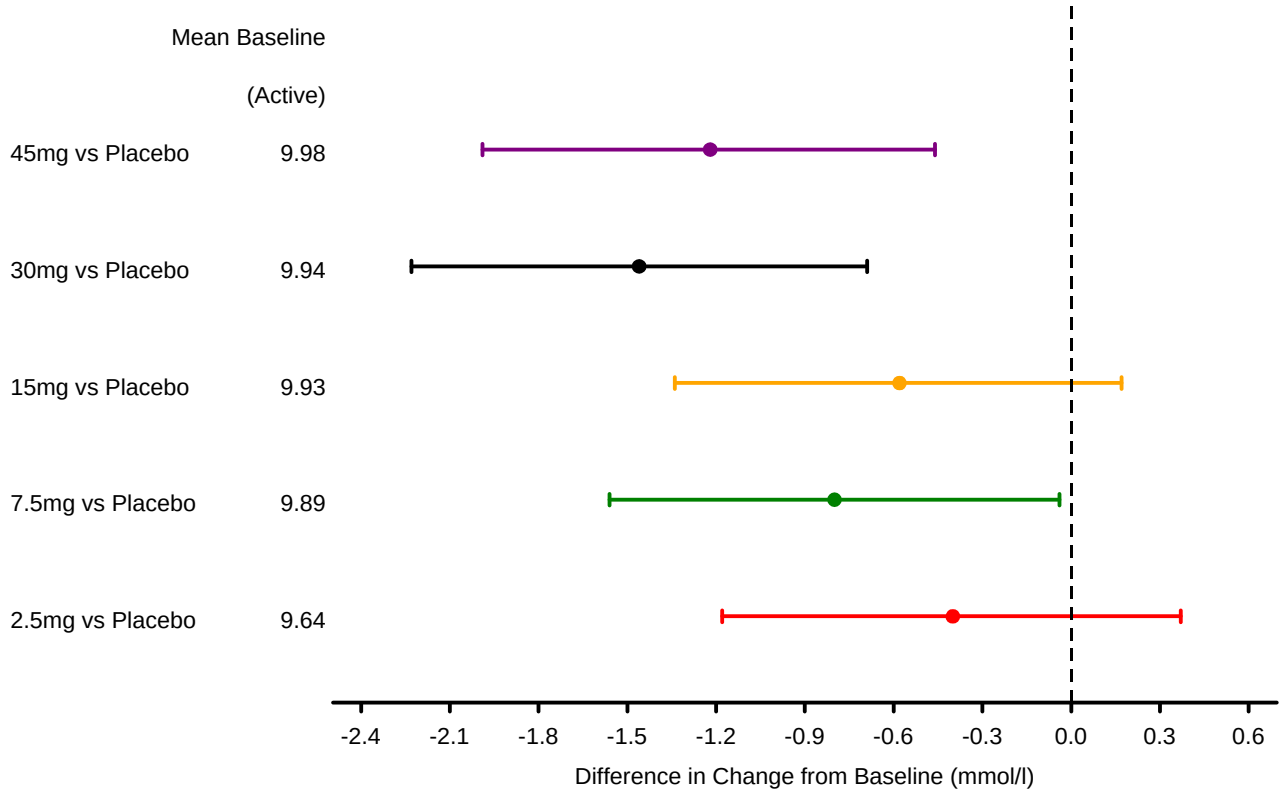
Figure 11.22
Figure of Treatment Difference in Fasting Plasma Glucose (mmol/l) Change from Baseline to Week 12



Mean Baseline for Placebo = 9.64
Number of Subjects at Week 12 after LOCF: Placebo = 62, 2.5mg = 58, 7.5mg = 62, 15mg = 63, 30mg = 58, 45mg = 60

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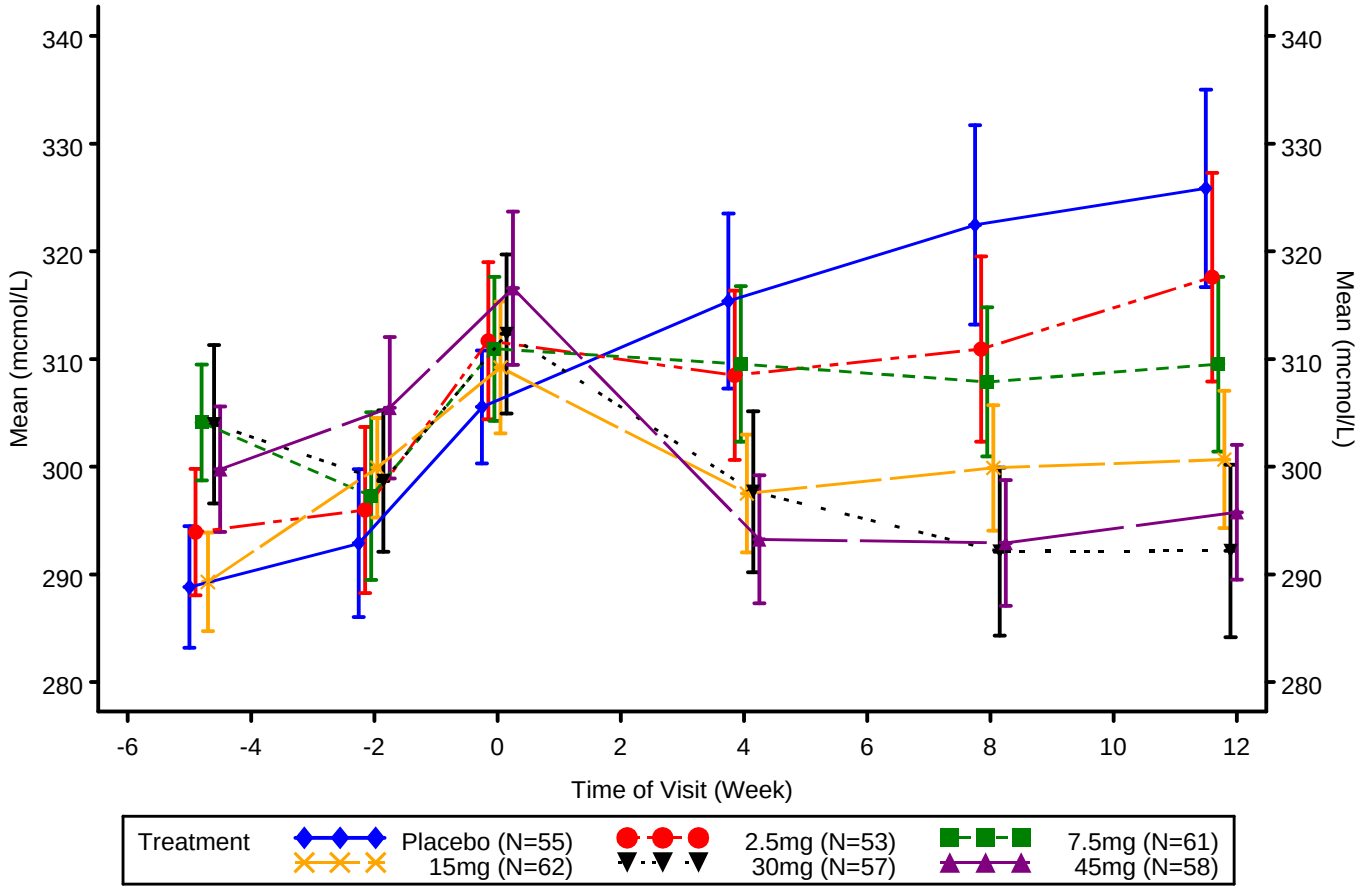
Figure 11.23
Line Graph of Mean (+-SE) for Fructosamine (mcmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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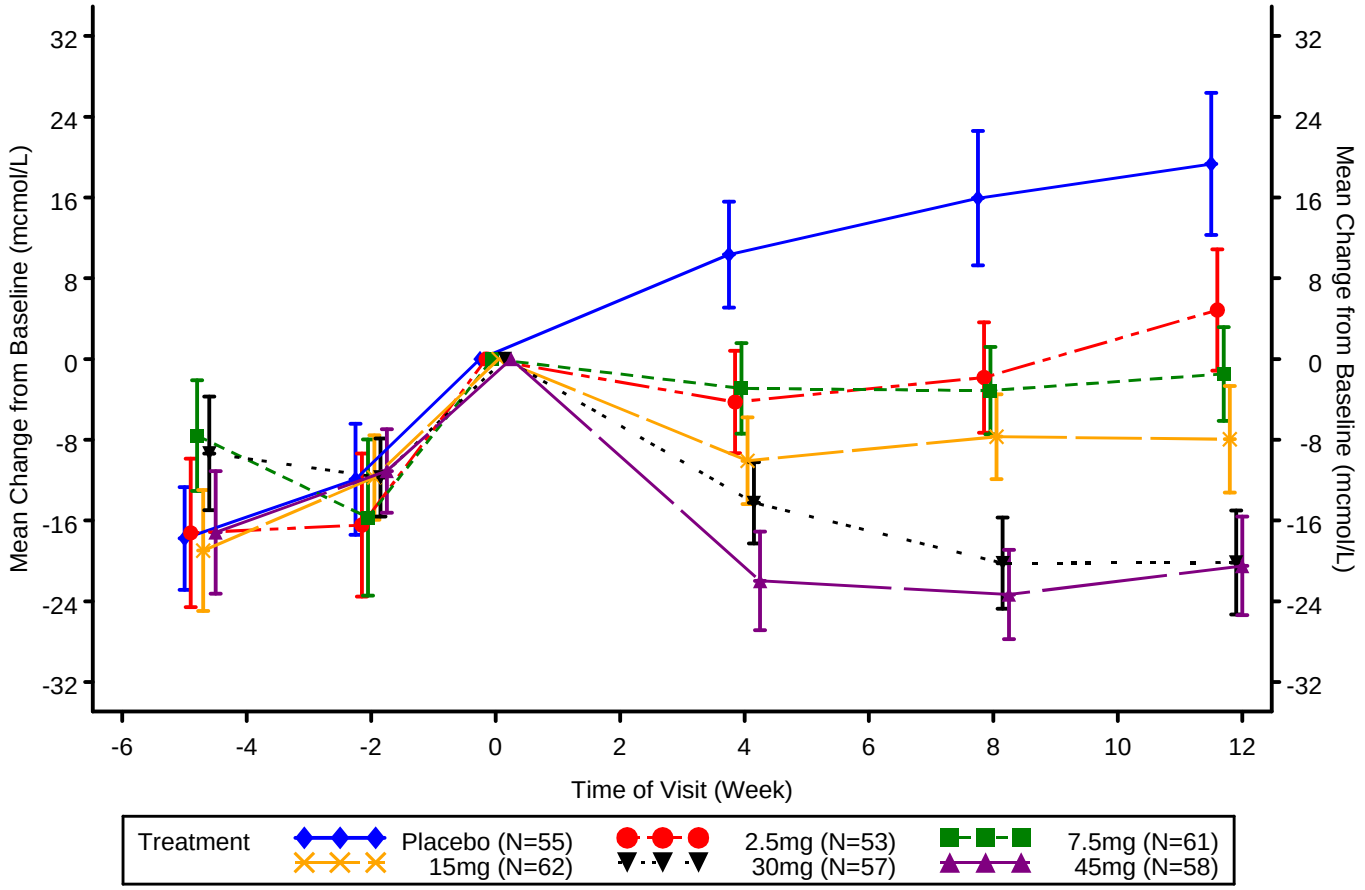
Figure 11.24
Line Graph of Mean Change from Baseline (+-SE) for Fructosamine (mcmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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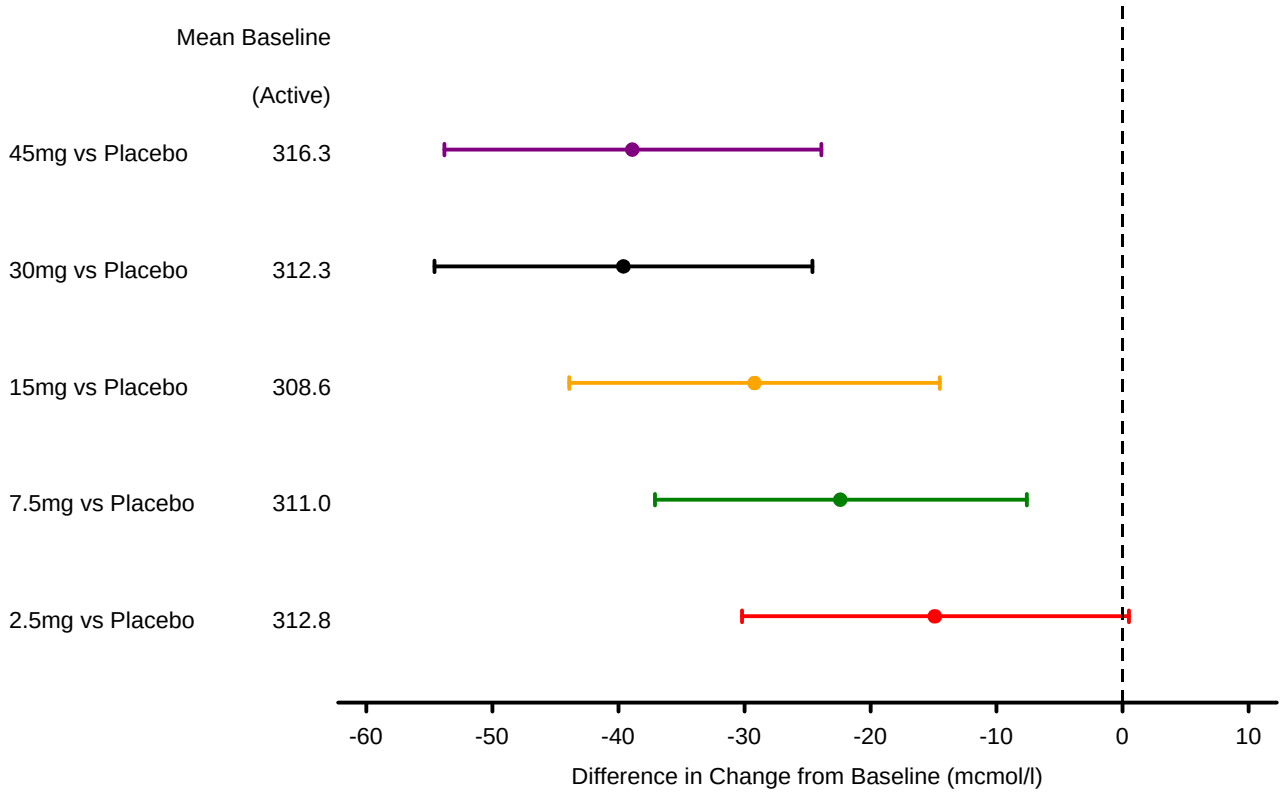
Figure 11.25
Figure of Treatment Difference in Fructosamine (mcmol/l) Change from Baseline to Week 12



Mean Baseline for Placebo = 306.5
Number of Subjects at Week 12 after LOCF: Placebo = 55, 2.5mg = 53, 7.5mg = 61, 15mg = 62, 30mg = 57, 45mg = 58

[redacted]

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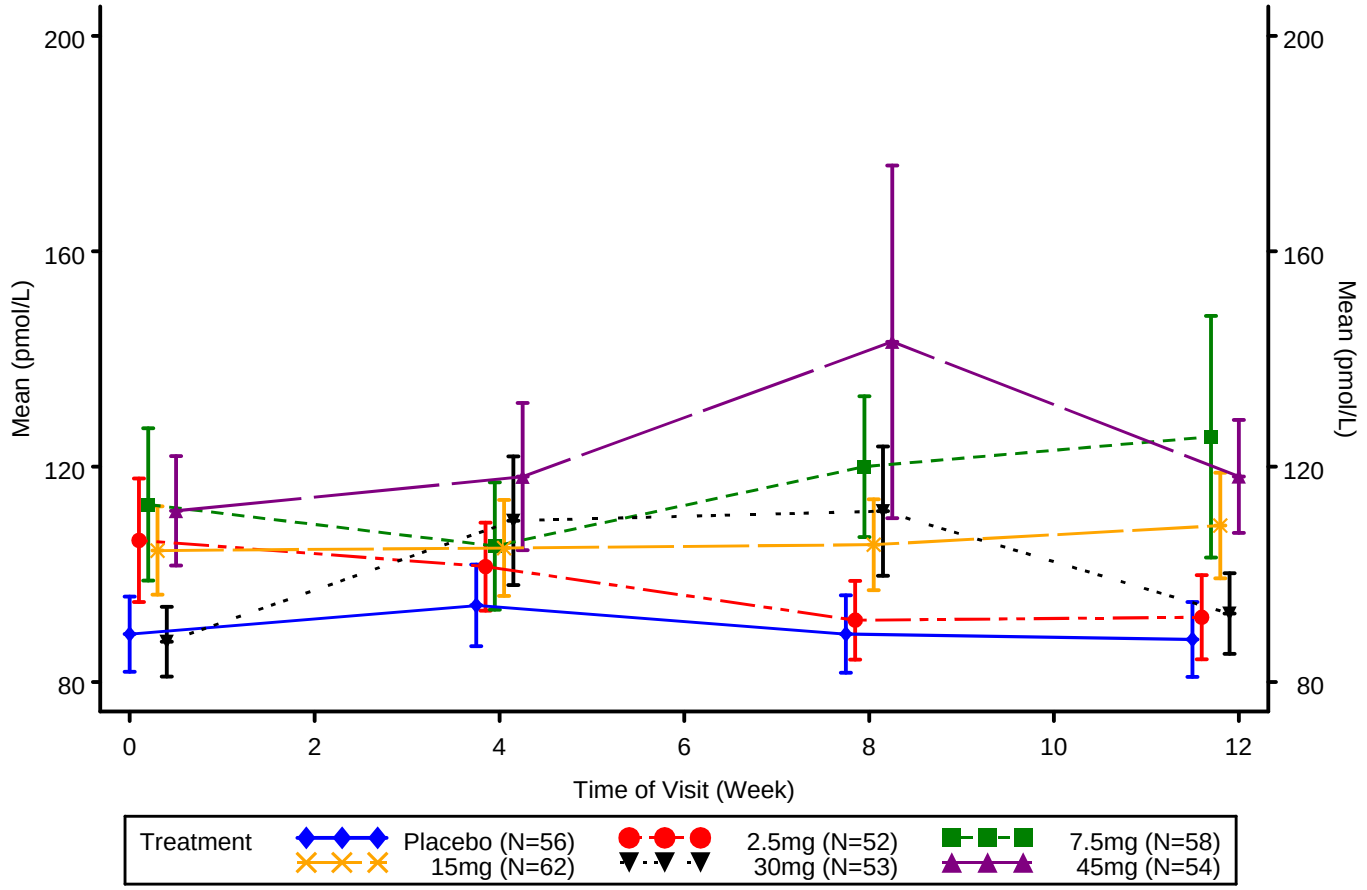
Figure 11.26
Line Graph of Mean (+-SE) for Fasting Serum Insulin (pmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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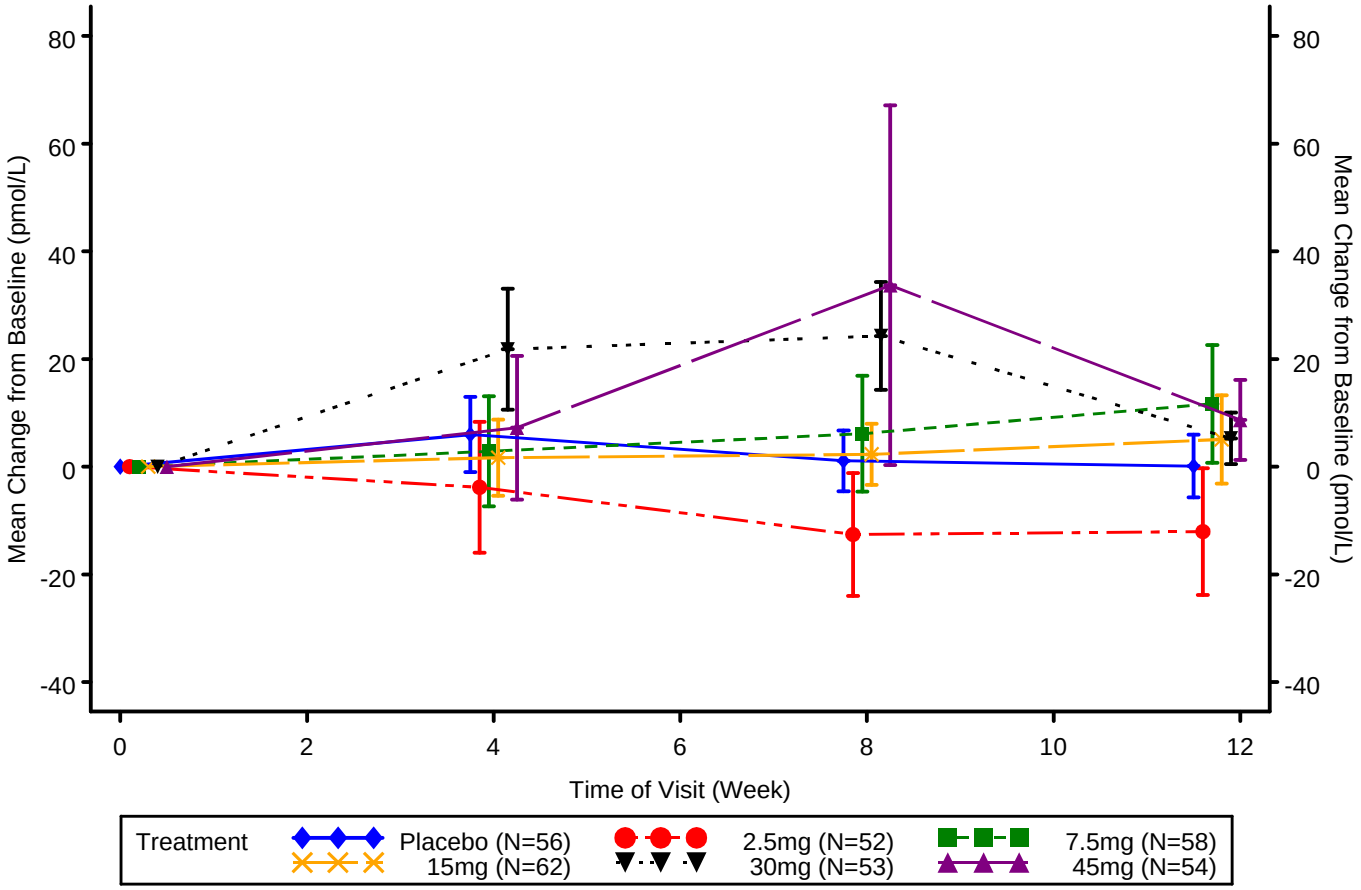
Figure 11.27
Line Graph of Mean Change from Baseline (+-SE) for Fasting Serum Insulin (pmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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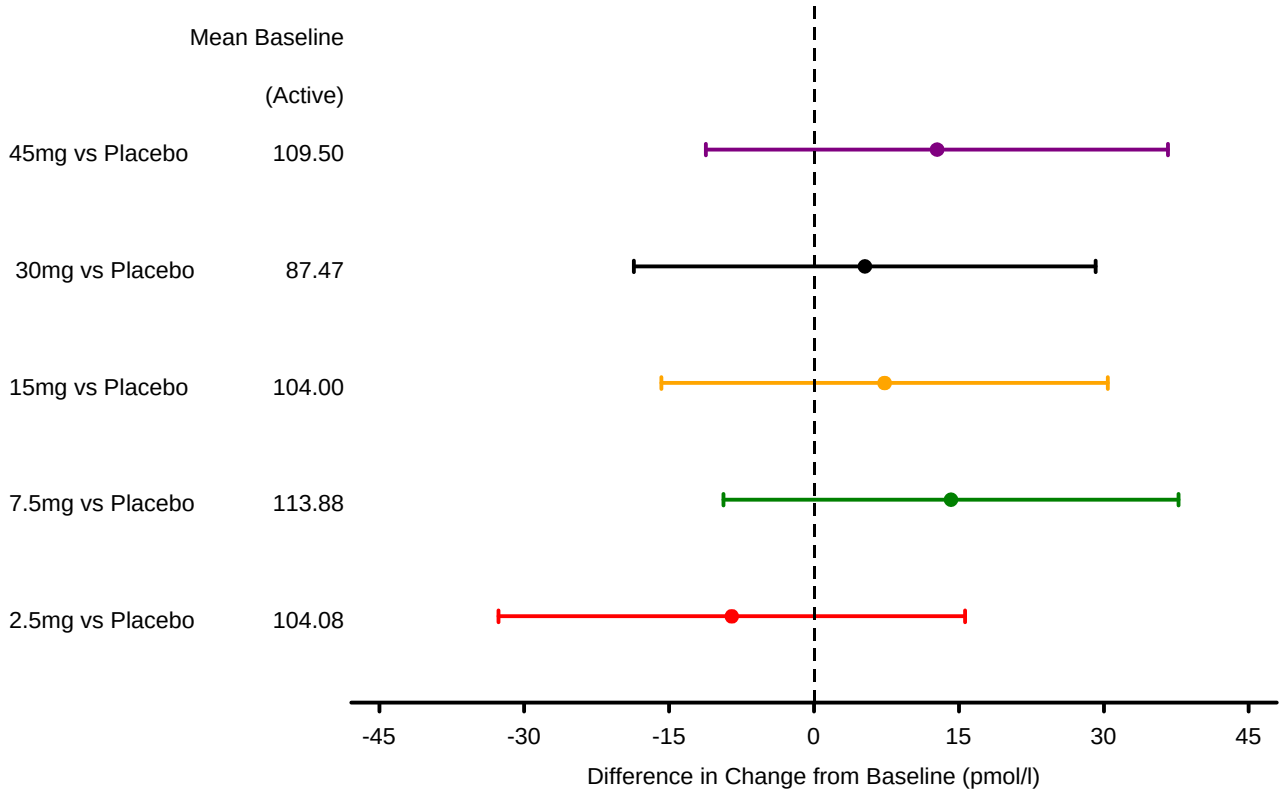
Figure 11.28
Figure of Treatment Difference in Fasting Serum Insulin (pmol/l) Change from Baseline to Week 12



Mean Baseline for Placebo = 87.81
Number of Subjects at Week 12 after LOCF: Placebo = 56, 2.5mg = 52, 7.5mg = 58, 15mg = 62, 30mg = 53, 45mg = 54

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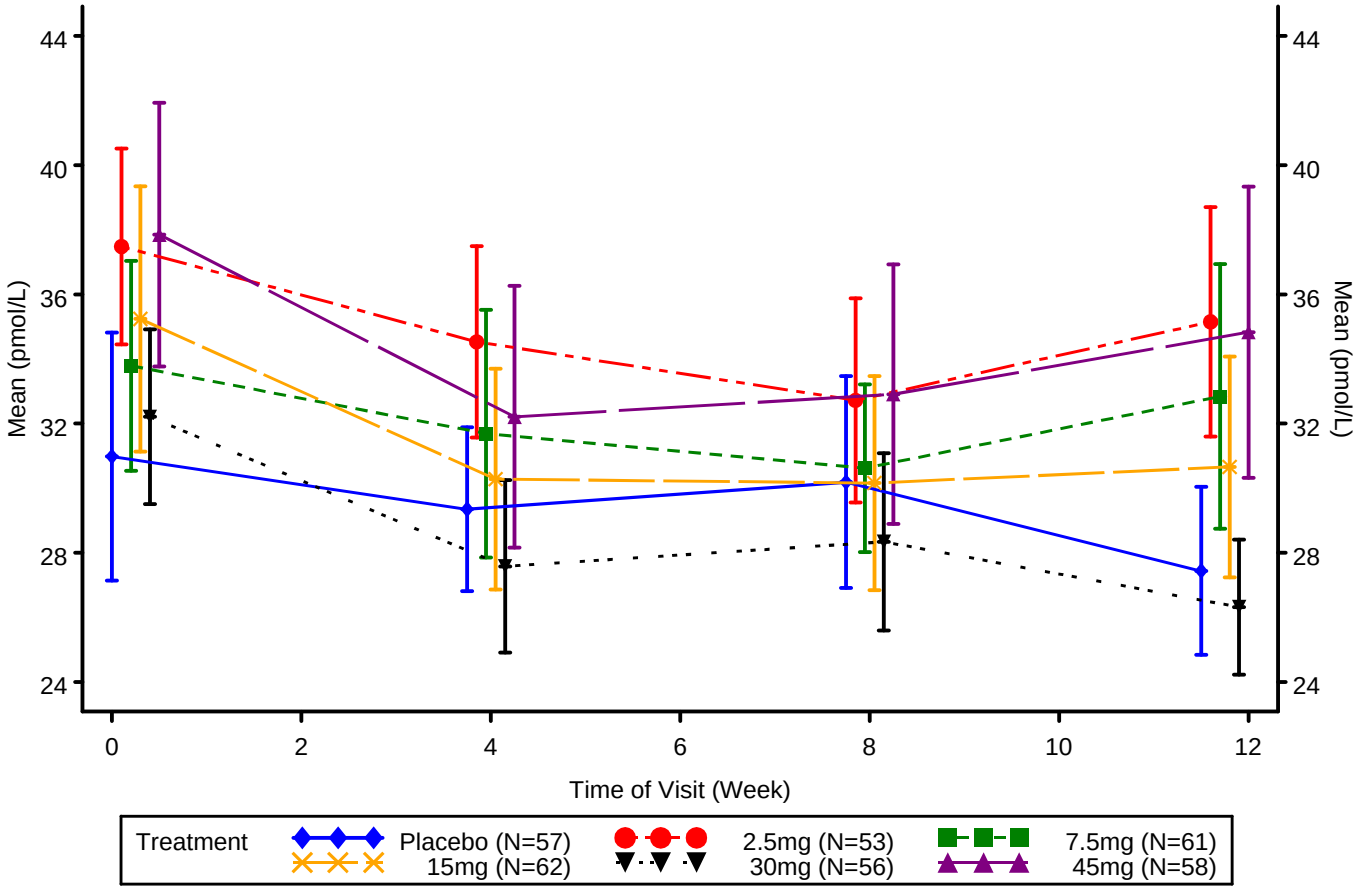
Figure 11.29
Line Graph of Mean (+-SE) for Pro-Insulin (pmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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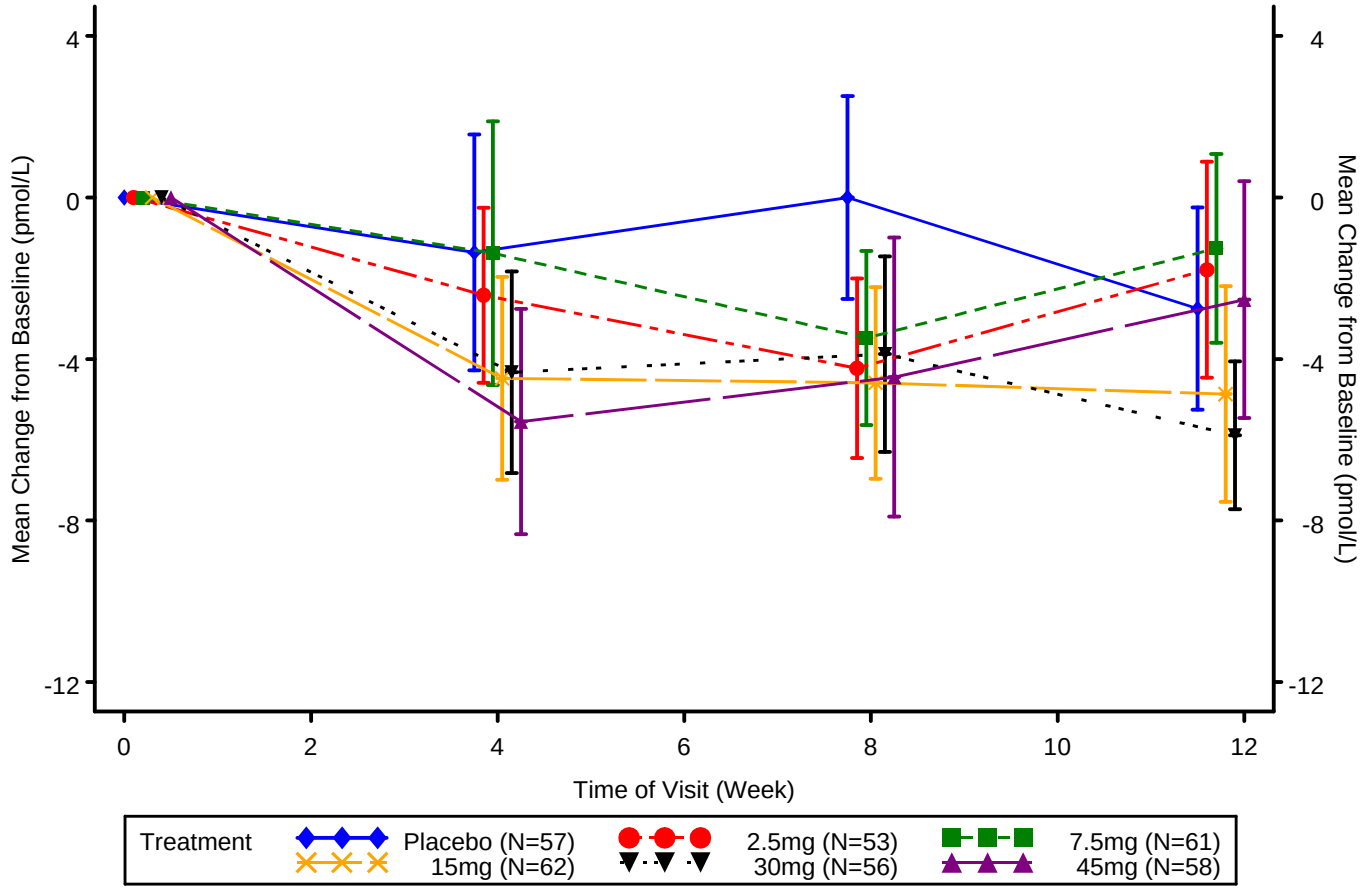
Figure 11.30
Line Graph of Mean Change from Baseline (+-SE) for Pro-Insulin (pmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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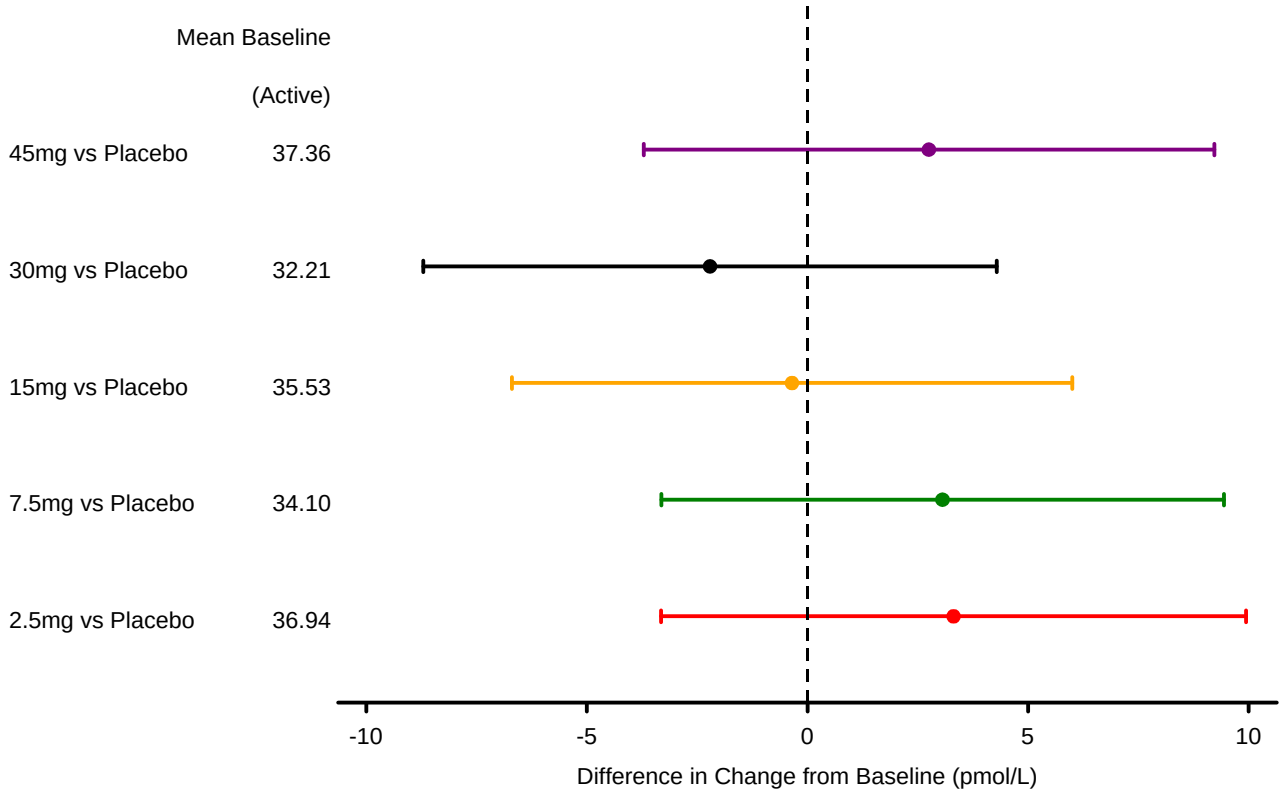
Figure 11.31
Figure of Treatment Difference in Pro-Insulin (pmol/L) Change from Baseline to Week 12



Mean Baseline for Placebo = 30.19
Number of Subjects at Week 12 after LOCF: Placebo = 57, 2.5mg = 53, 7.5mg = 61, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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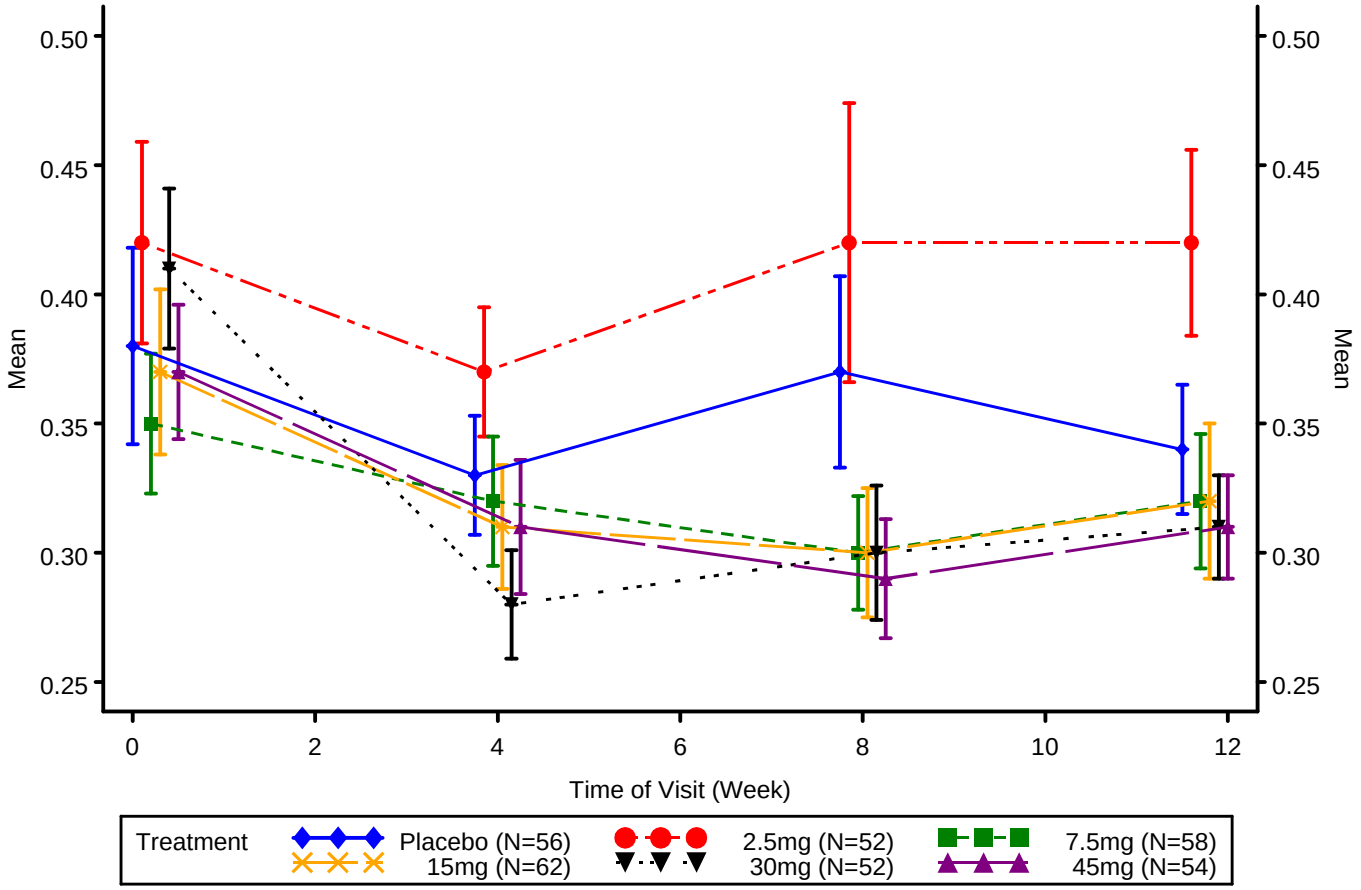
Figure 11.32
Line Graph of Mean (+-SE) for Pro-Insulin:Insulin Ratio by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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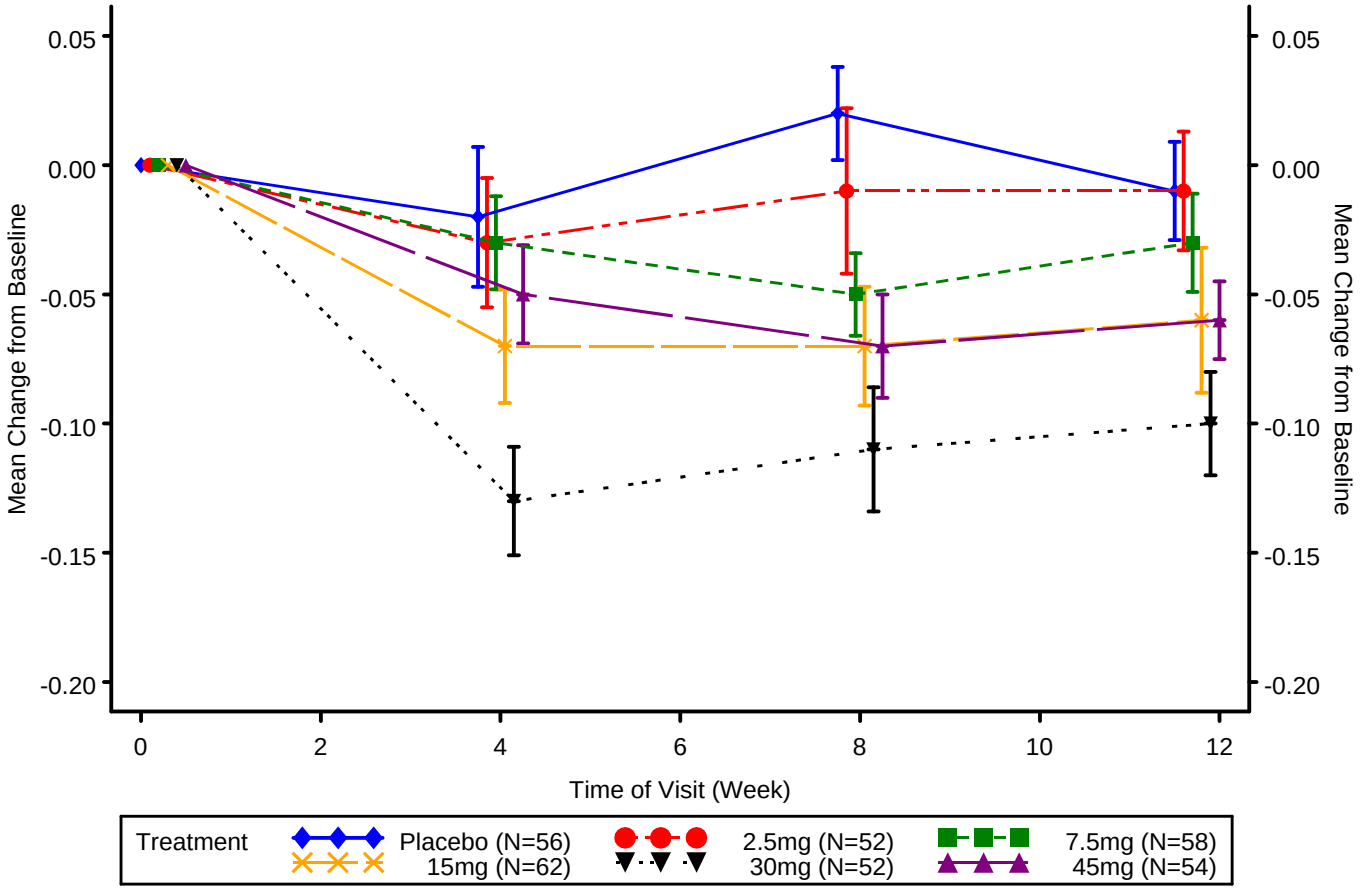
Figure 11.33
Line Graph of Mean Change from Baseline (+-SE) for Pro-Insulin:Insulin Ratio by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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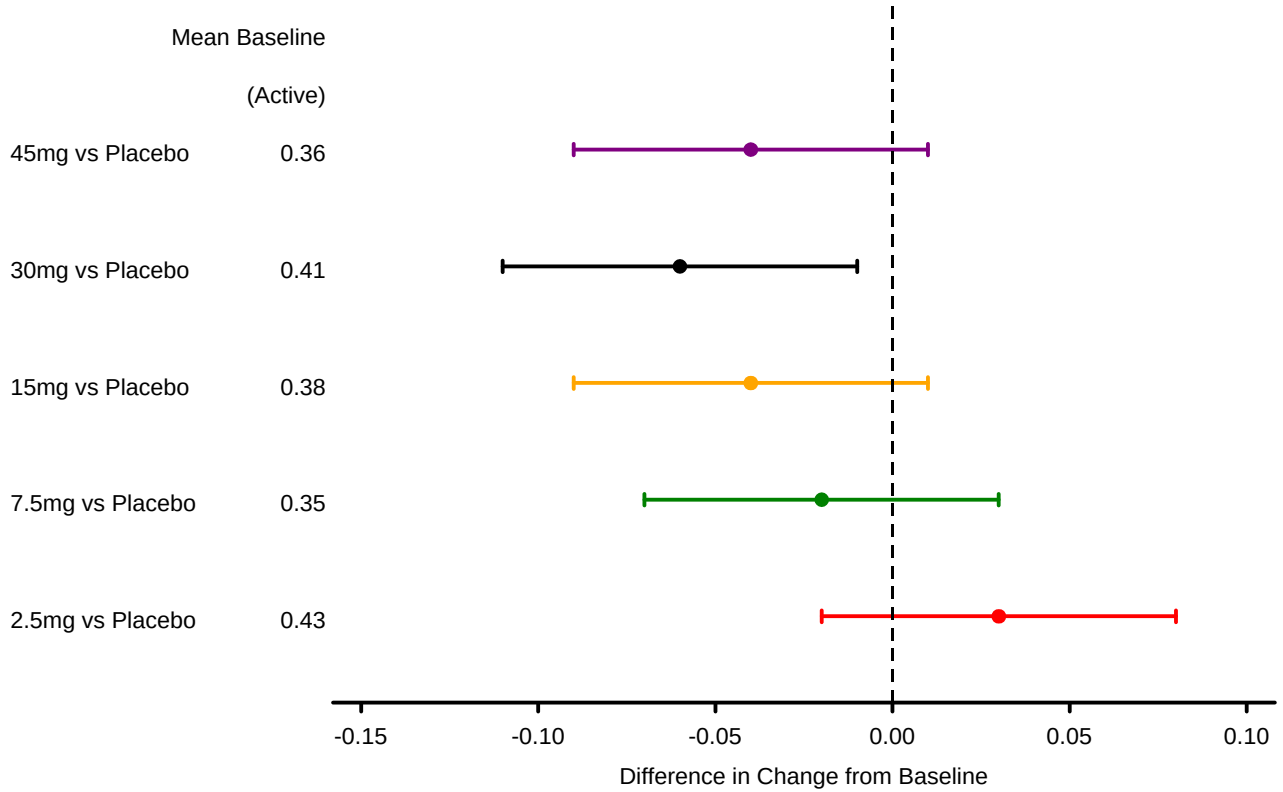
Figure 11.34
Figure of Treatment Difference in Pro-Insulin:Insulin Ratio Change from Baseline to Week 12



Mean Baseline for Placebo = 0.35
Number of Subjects at Week 12 after LOCF: Placebo = 56, 2.5mg = 52, 7.5mg = 58, 15mg = 62, 30mg = 52, 45mg = 54

[redacted]

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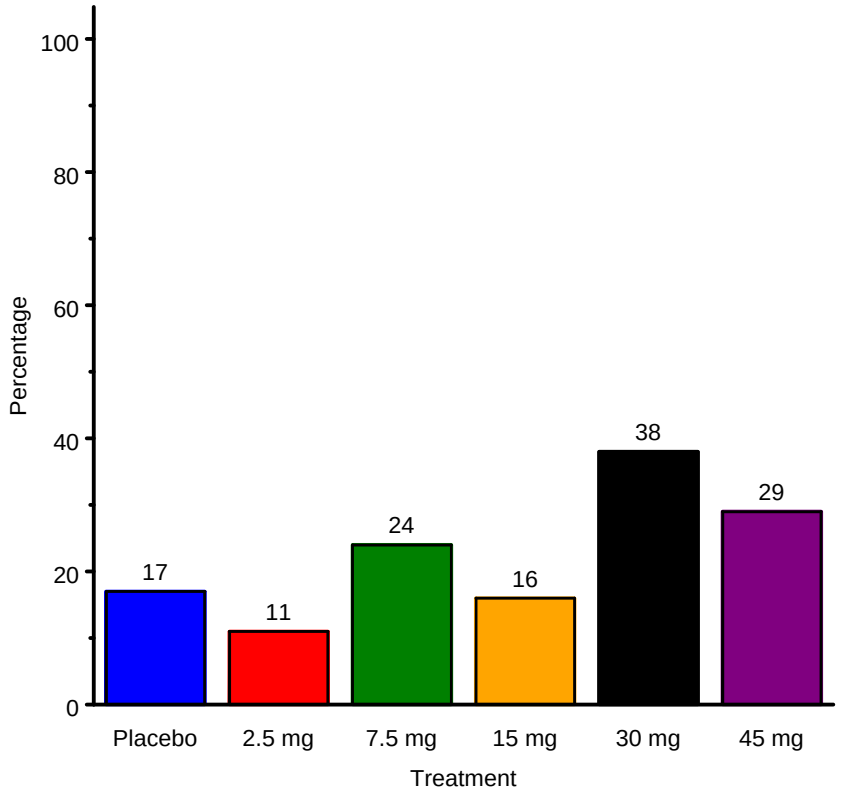
Figure 11.35
Figure of Percentage of Subjects with HbA1c Reduction from Baseline >= 0.7% at Week 12



Number of subjects at Week 12 after LOCF: Placebo = 59, 2.5mg = 56, 7.5mg = 59, 15mg = 62, 30mg = 56, 45mg = 58

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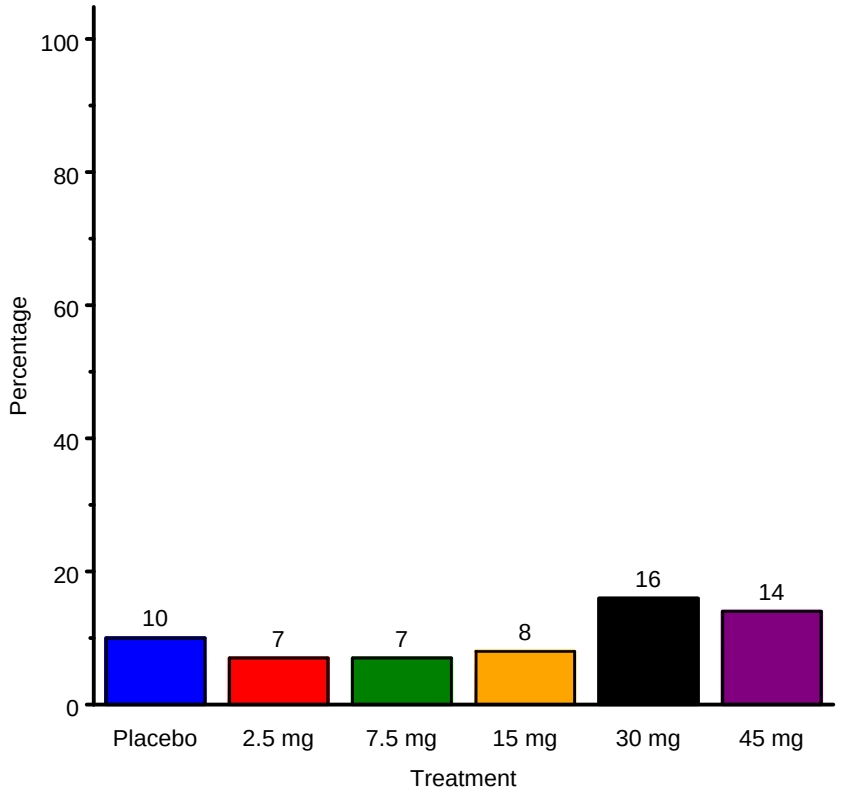
Figure 11.36
Figure of Percentage of Subjects with HbA1c <=6.5% at Week 12



Number of subjects at Week 12 after LOCF: Placebo = 59, 2.5mg = 56, 7.5mg = 59, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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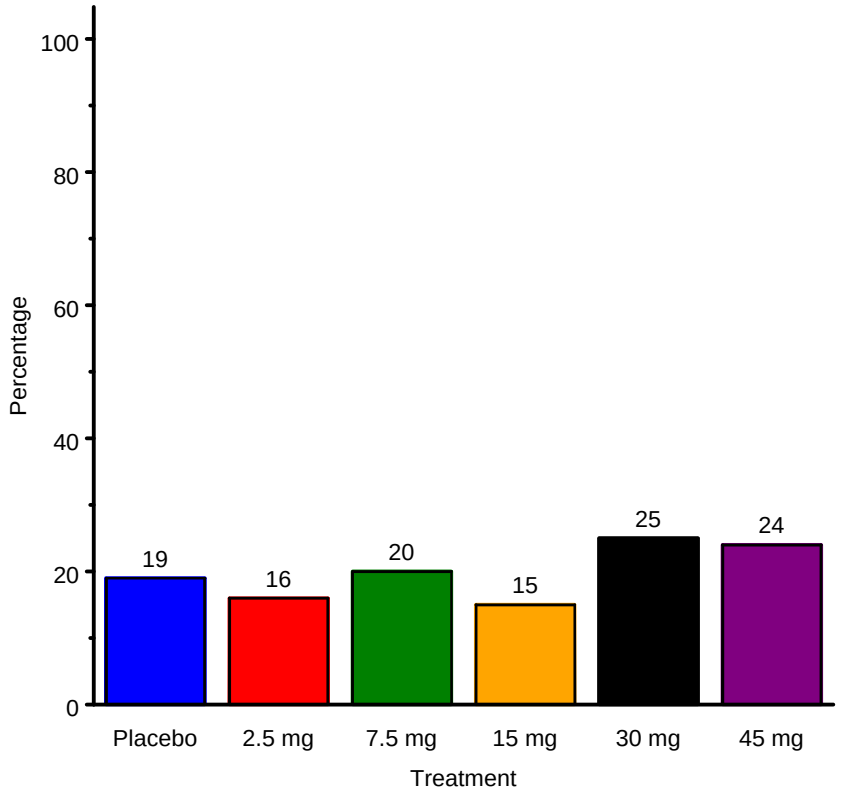
Figure 11.37
Figure of Percentage of Subjects with HbA1c <7% at Week 12



Number of subjects at Week 12 after LOCF: Placebo = 59, 2.5mg = 56, 7.5mg = 59, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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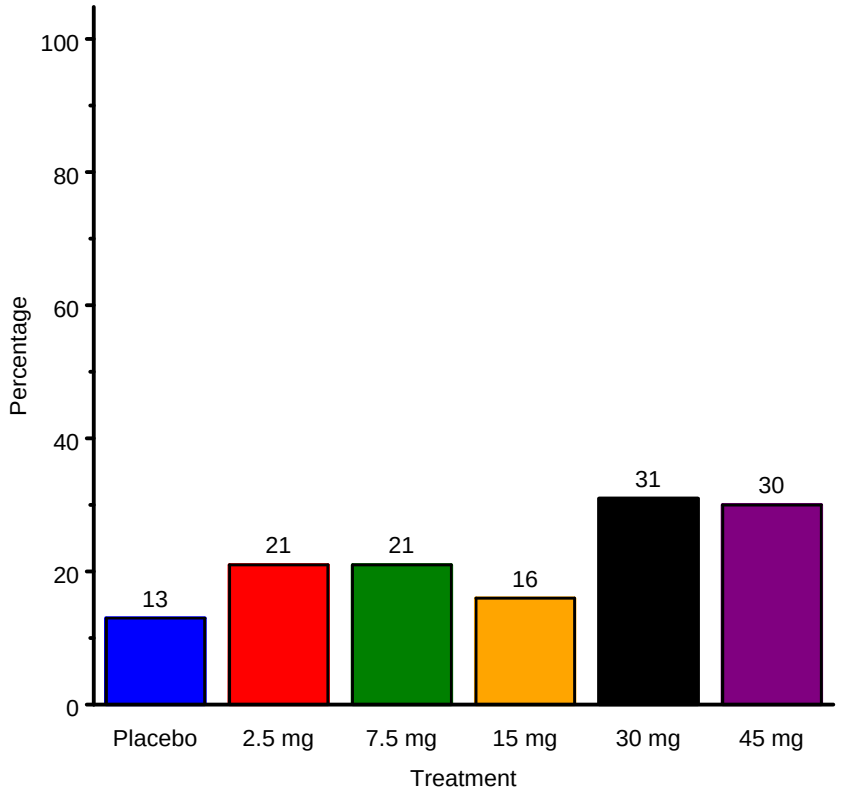
Figure 11.38
Figure of Percentage of Subjects with Fasting Plasma Glucose Reduction from Baseline >= 1.7 mmol/L at Week 12



Number of subjects at Week 12 after LOCF: Placebo = 62, 2.5mg = 58, 7.5mg = 62, 15mg = 63, 30mg = 58, 45mg = 60

[redacted]

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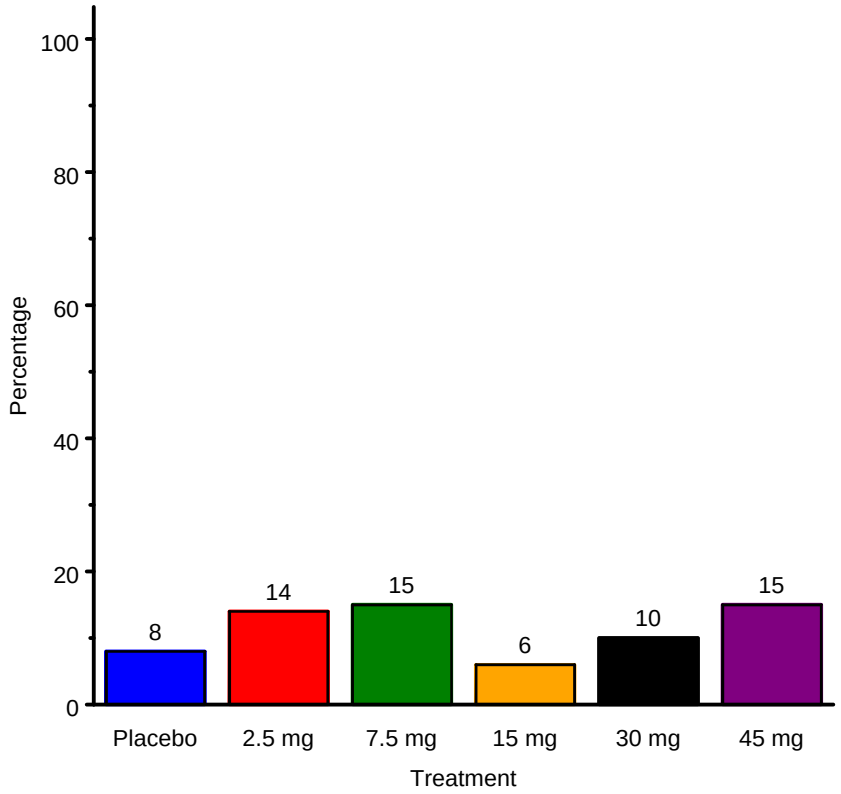
Figure 11.39
Figure of Percentage of Subjects with Fasting Plasma Glucose < 7mmol/L at Week 12



Number of subjects at Week 12 after LOCF: Placebo = 62, 2.5mg = 58, 7.5mg = 62, 15mg = 63, 30mg = 58, 45mg = 60

[redacted]

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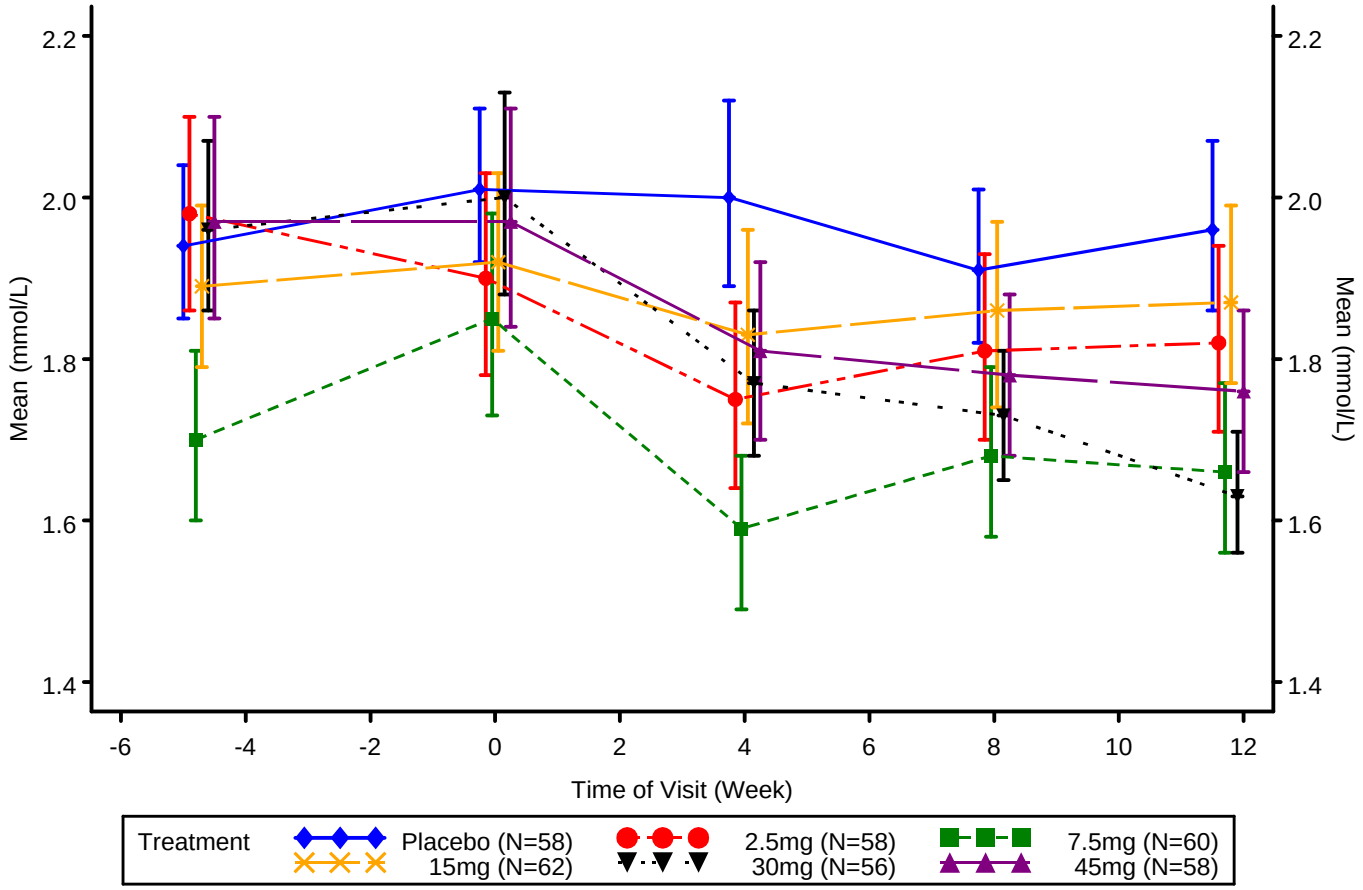
Figure 11.40
Line Graph of Geometric Mean (+-SE) for Triglycerides (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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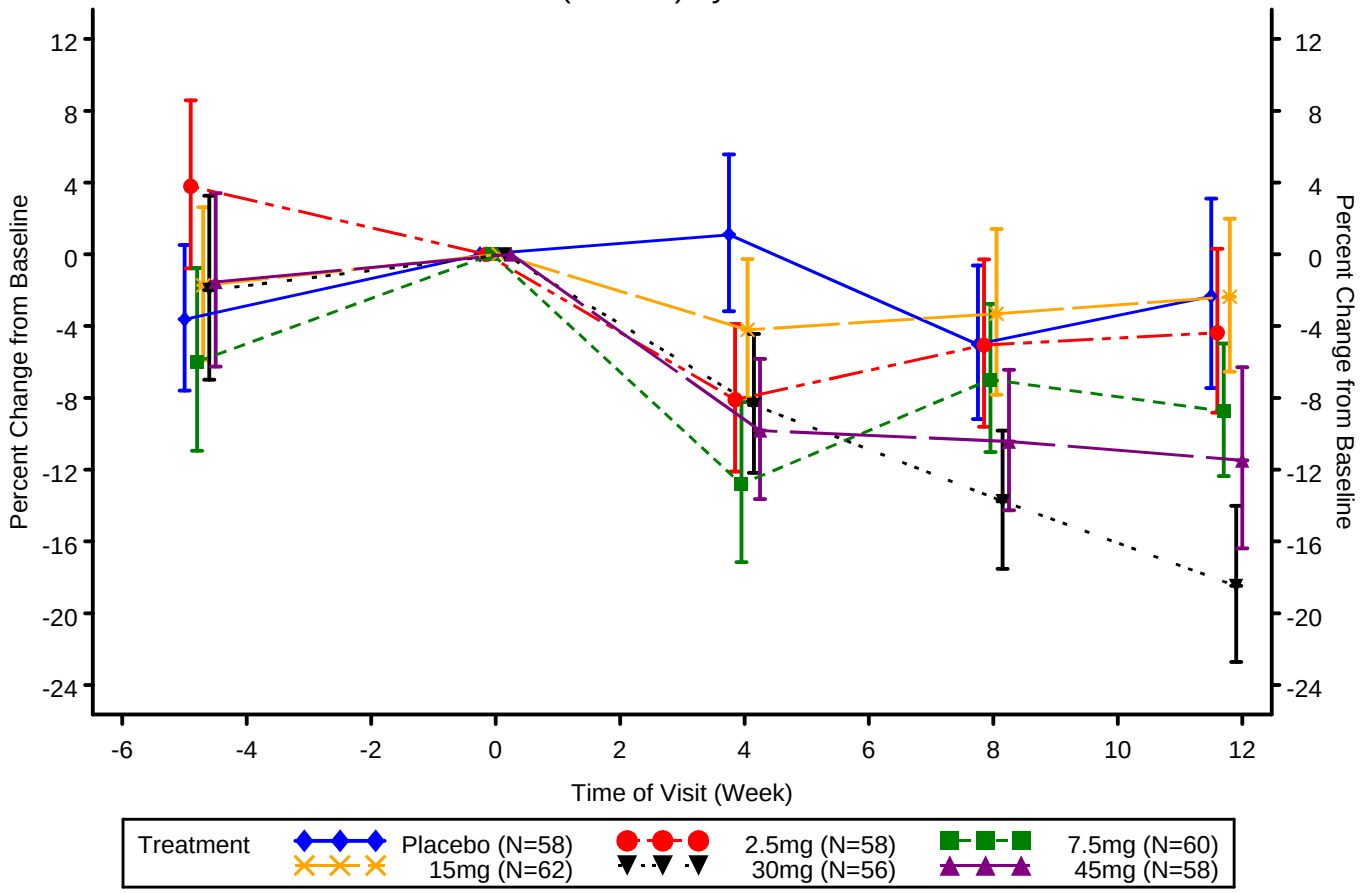
Figure 11.41
Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for Triglycerides (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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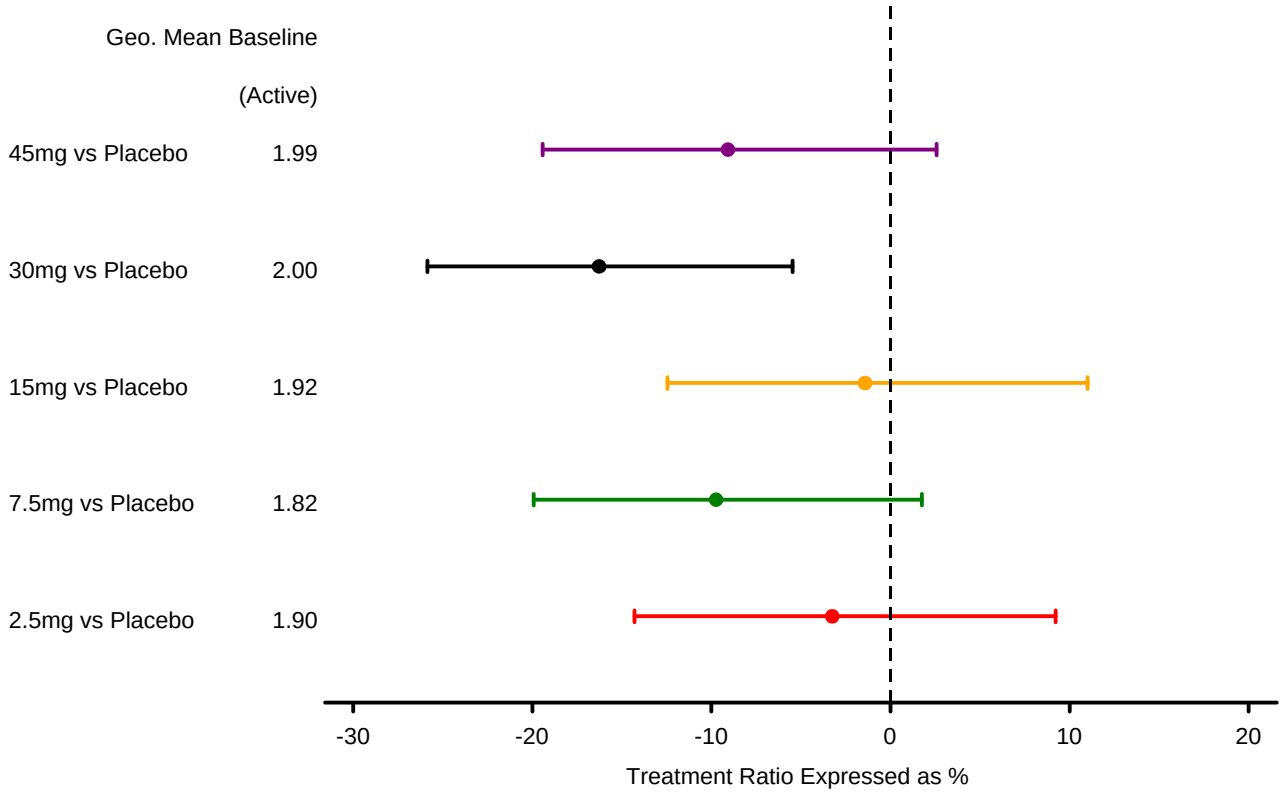
Figure 11.42
Figure of Treatment Ratio to Placebo Expressed as % Difference in Triglycerides (mmol/L) at Week 12



Geo. Mean Baseline for Placebo = 2.01
Number of Subjects at Week 12 after LOCF: Placebo = 58, 2.5mg = 58, 7.5mg = 60, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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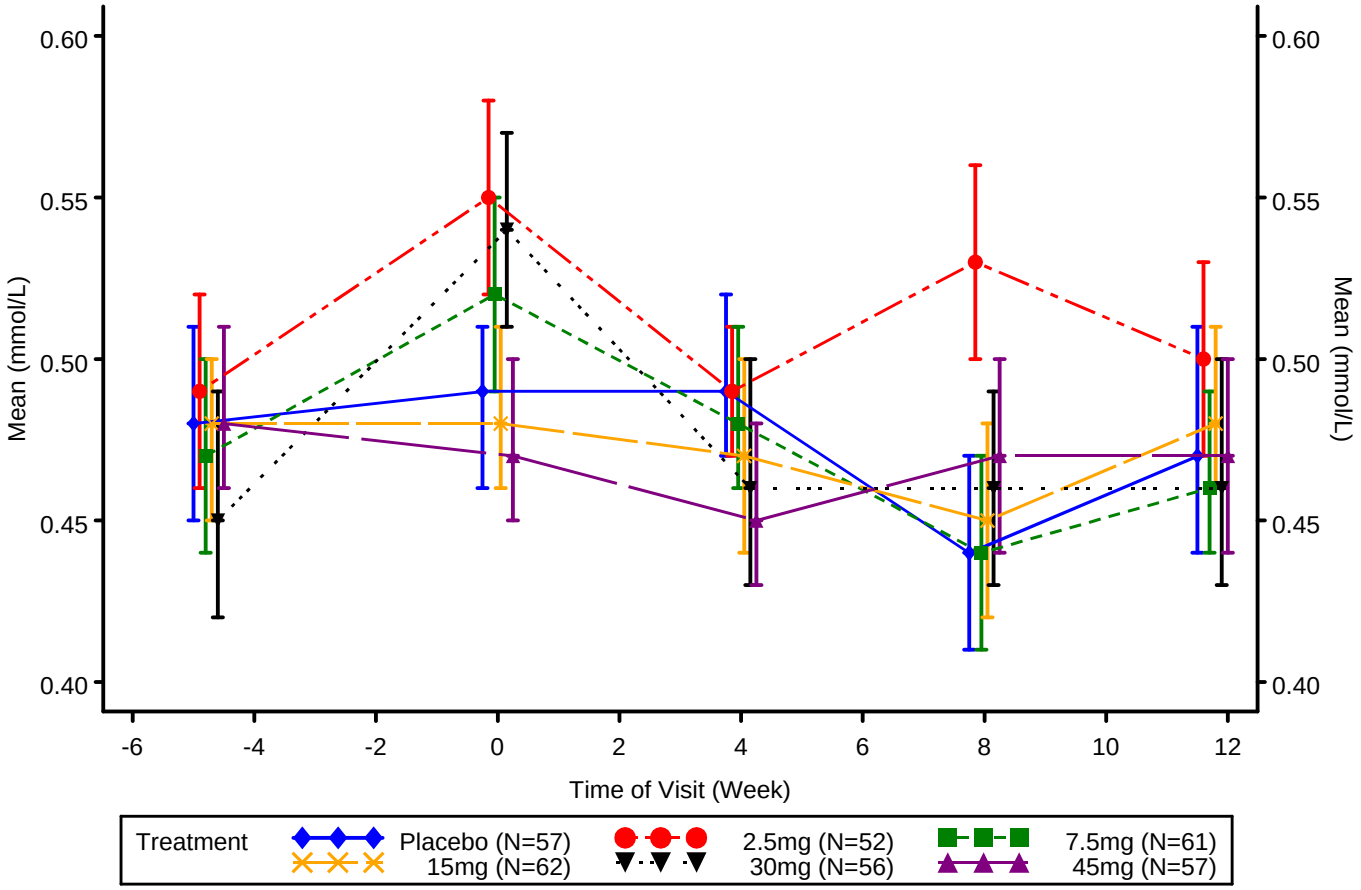
Figure 11.43
Line Graph of Geometric Mean (+-SE) for Free Fatty Acid (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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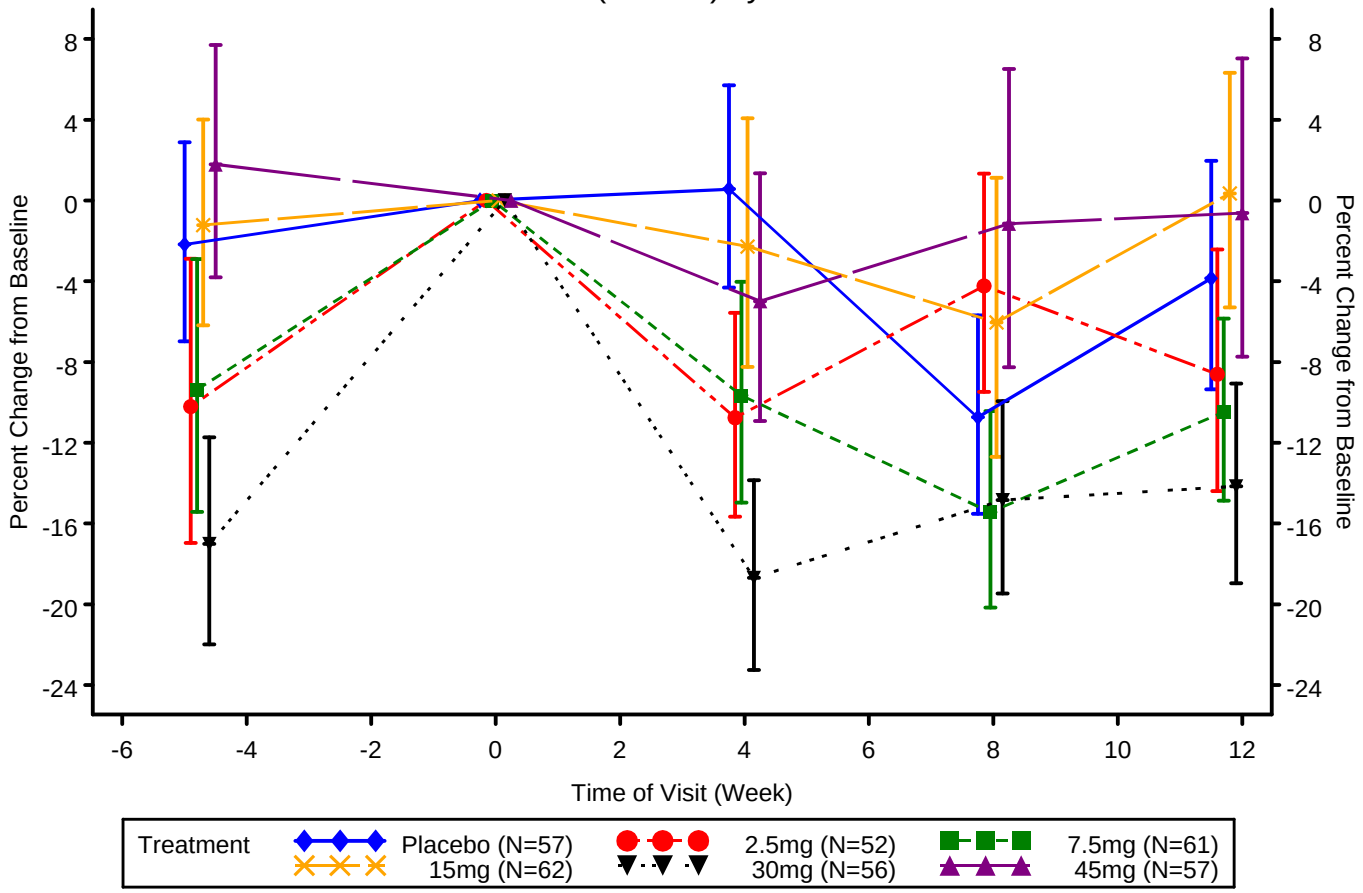
Figure 11.44
Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for Free Fatty Acid (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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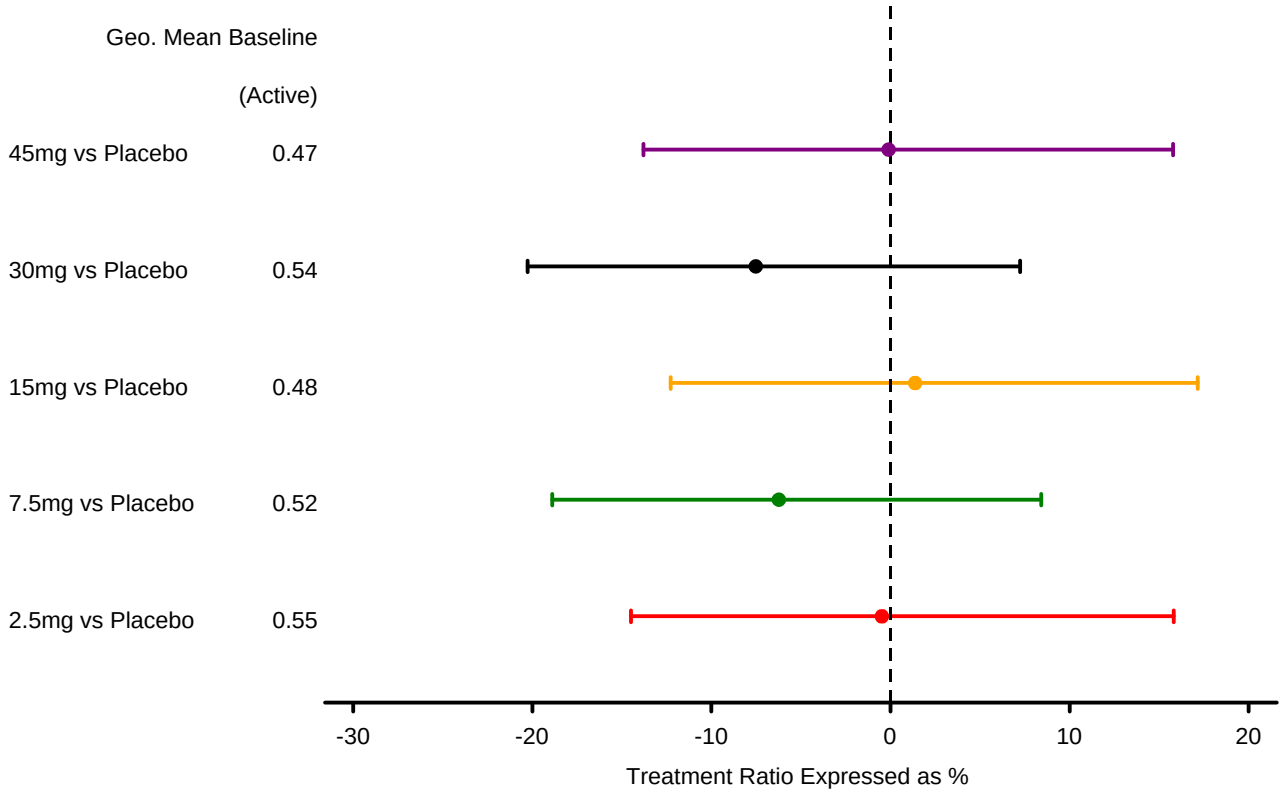
Figure 11.45
Figure of Treatment Ratio to Placebo Expressed as % Difference in Free Fatty Acid (mmol/L) at Week 12



Geo. Mean Baseline for Placebo = 0.49
Number of Subjects at Week 12 after LOCF: Placebo = 57, 2.5mg = 52, 7.5mg = 61, 15mg = 62, 30mg = 56, 45mg = 57

[redacted]

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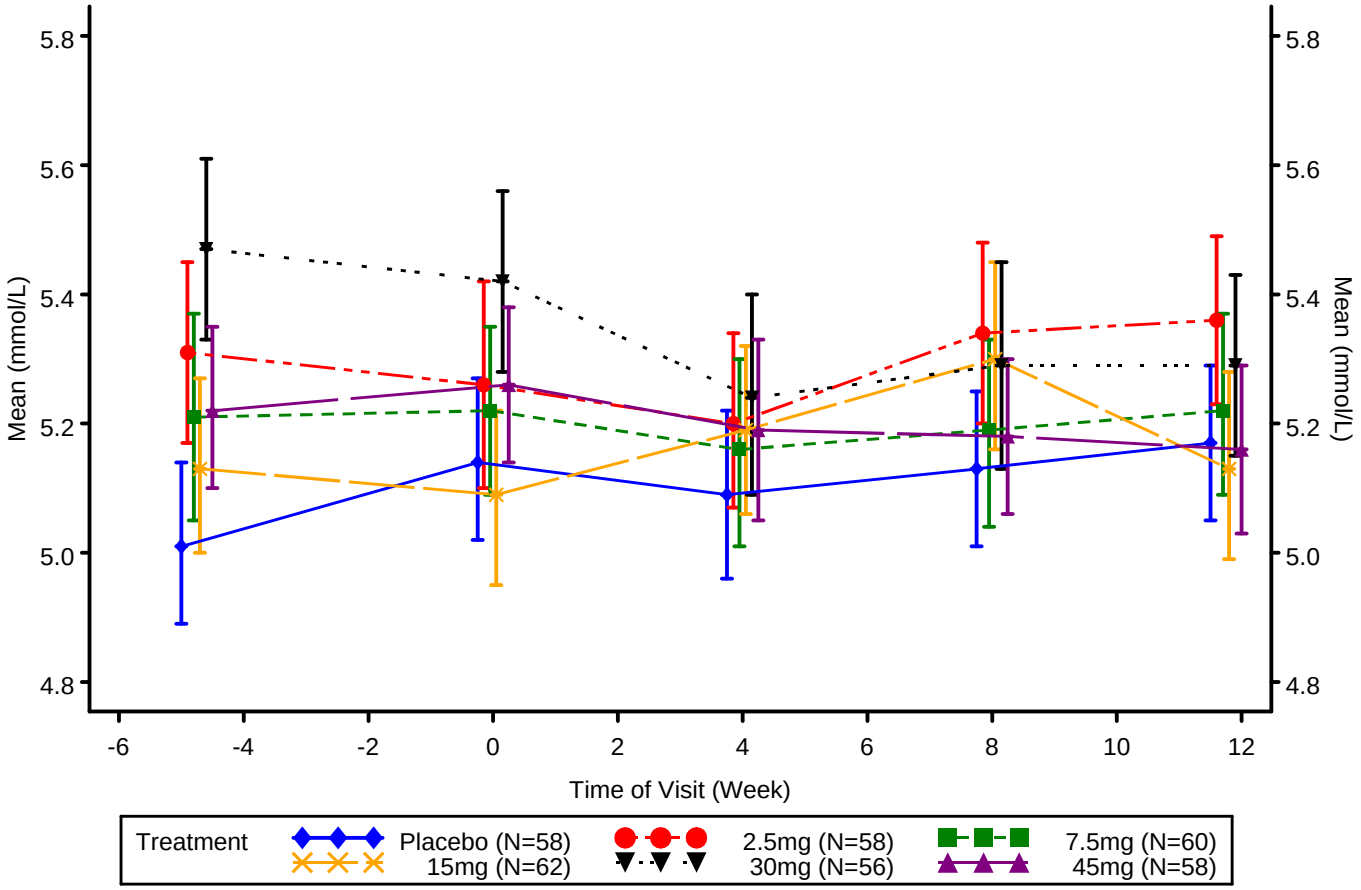
Figure 11.46
Line Graph of Geometric Mean (+-SE) for Total Cholesterol (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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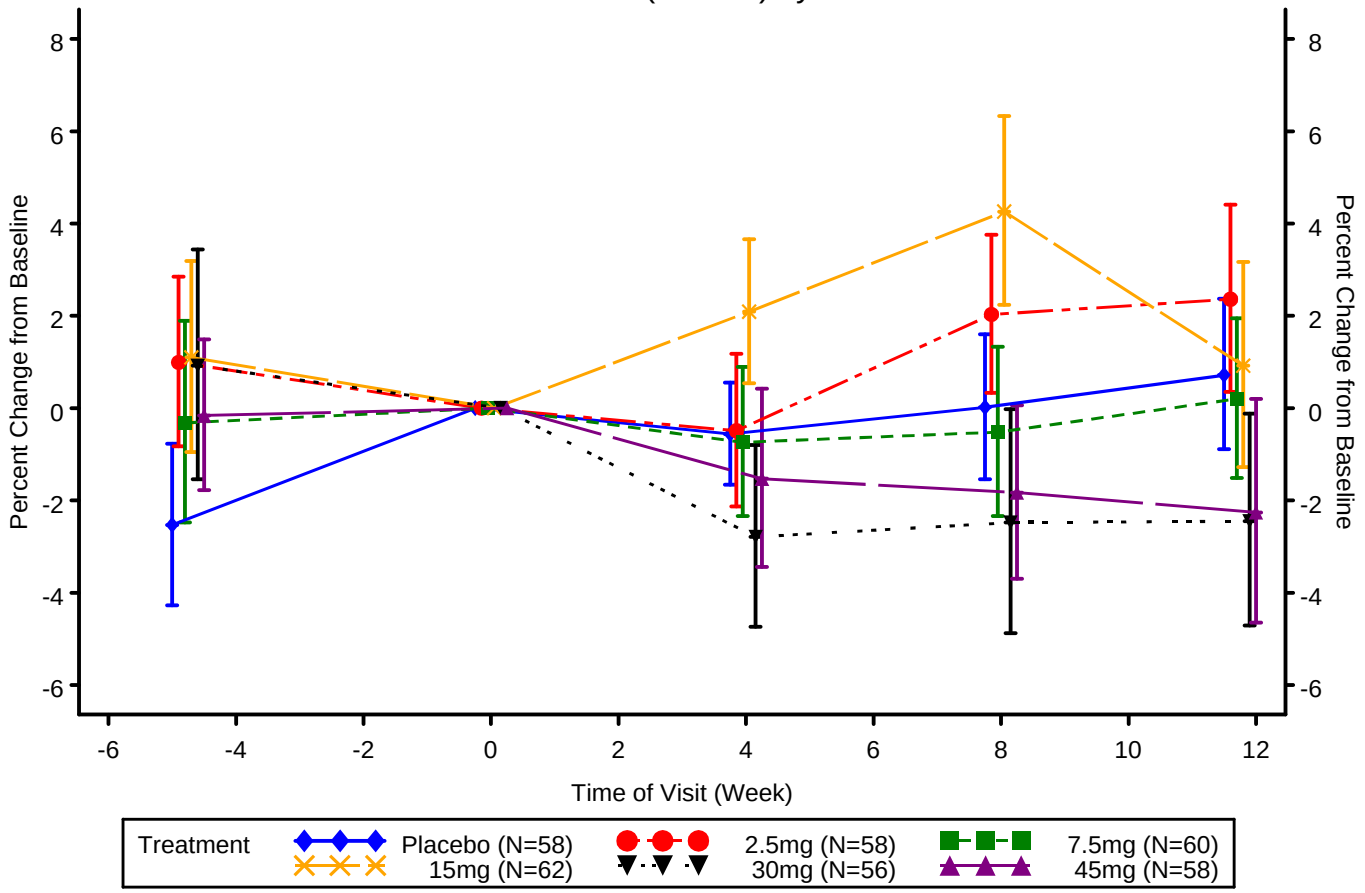
Figure 11.47
Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for Total Cholesterol (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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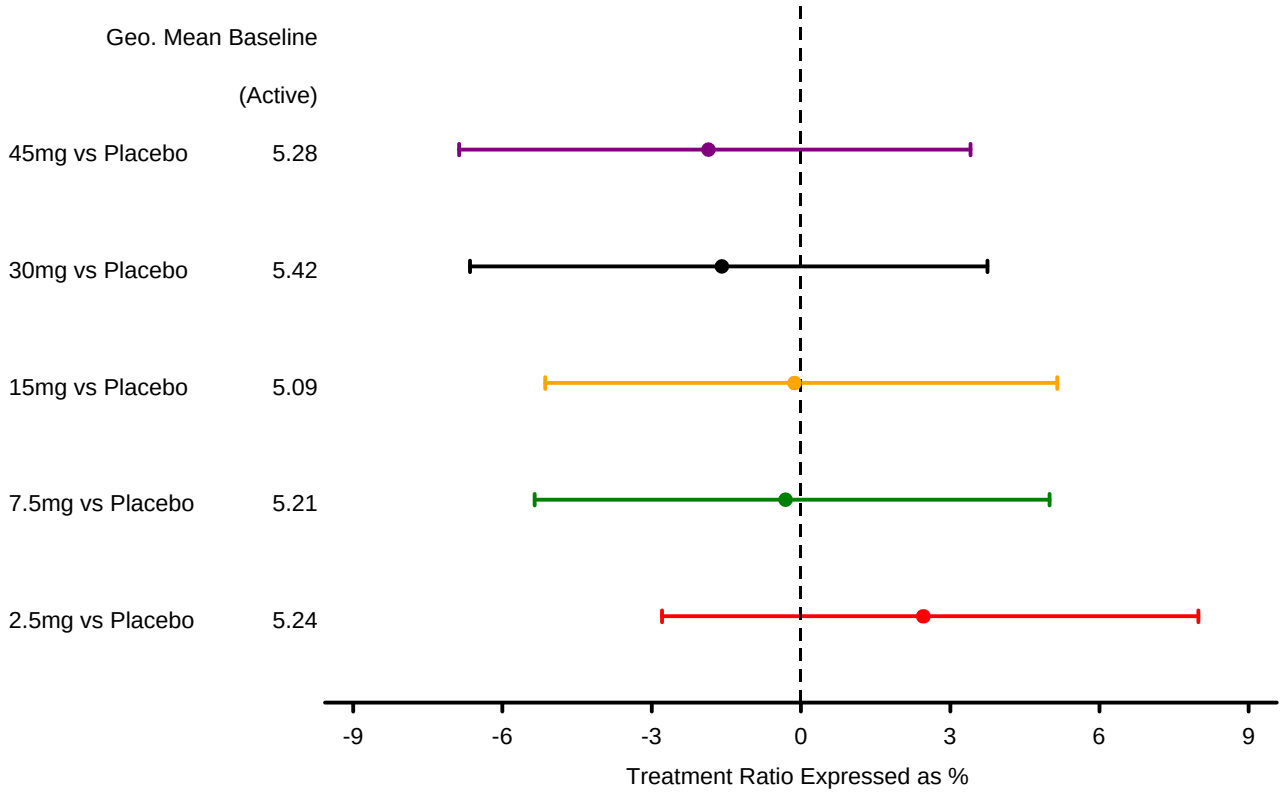
Figure 11.48
Figure of Treatment Ratio to Placebo Expressed as % Difference in Total Cholesterol (mmol/L) at Week 12



Geo. Mean Baseline for Placebo = 5.13
Number of Subjects at Week 12 after LOCF: Placebo = 58, 2.5mg = 58, 7.5mg = 60, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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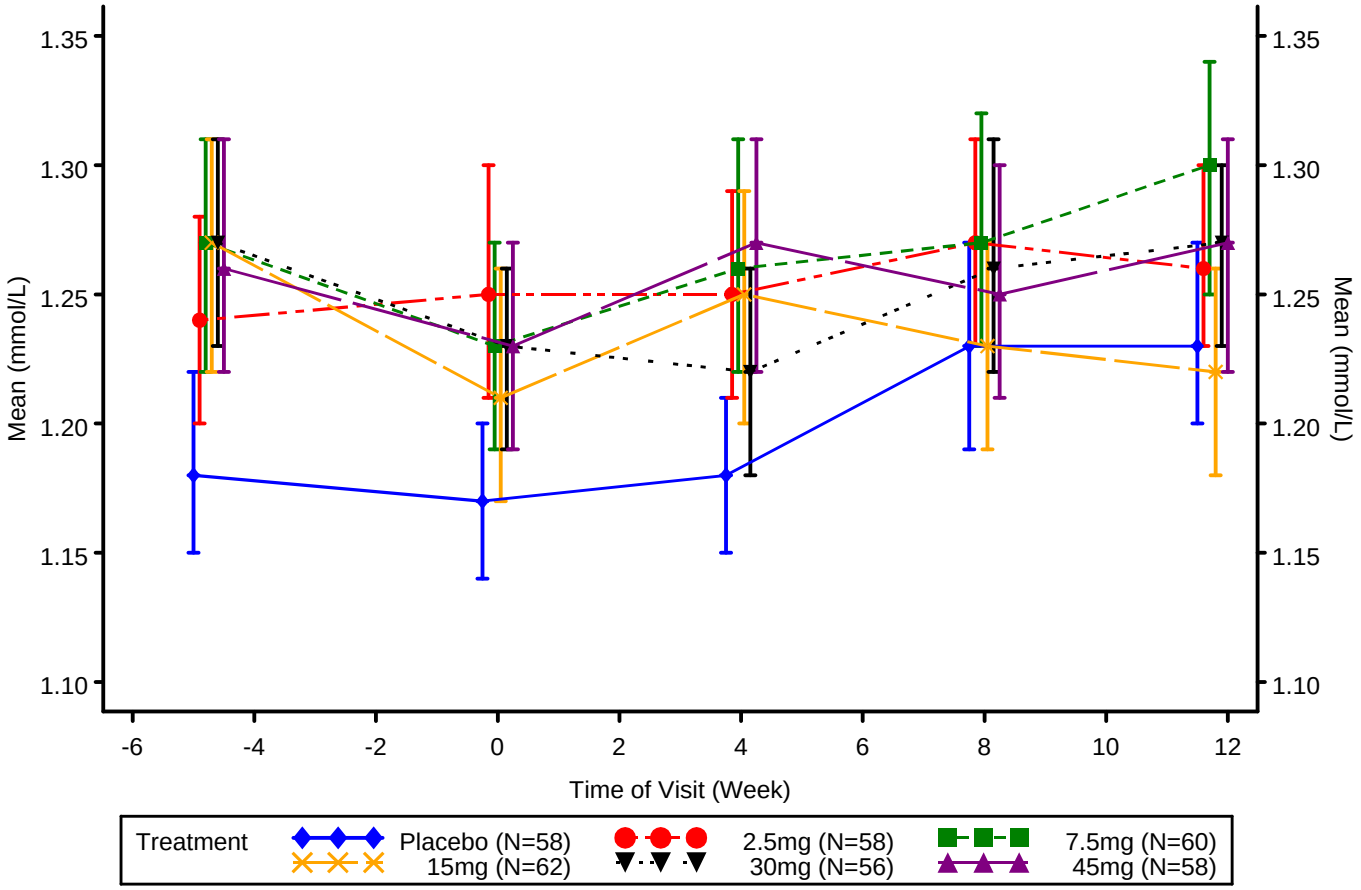
Figure 11.49
Line Graph of Geometric Mean (+-SE) for HDL-c (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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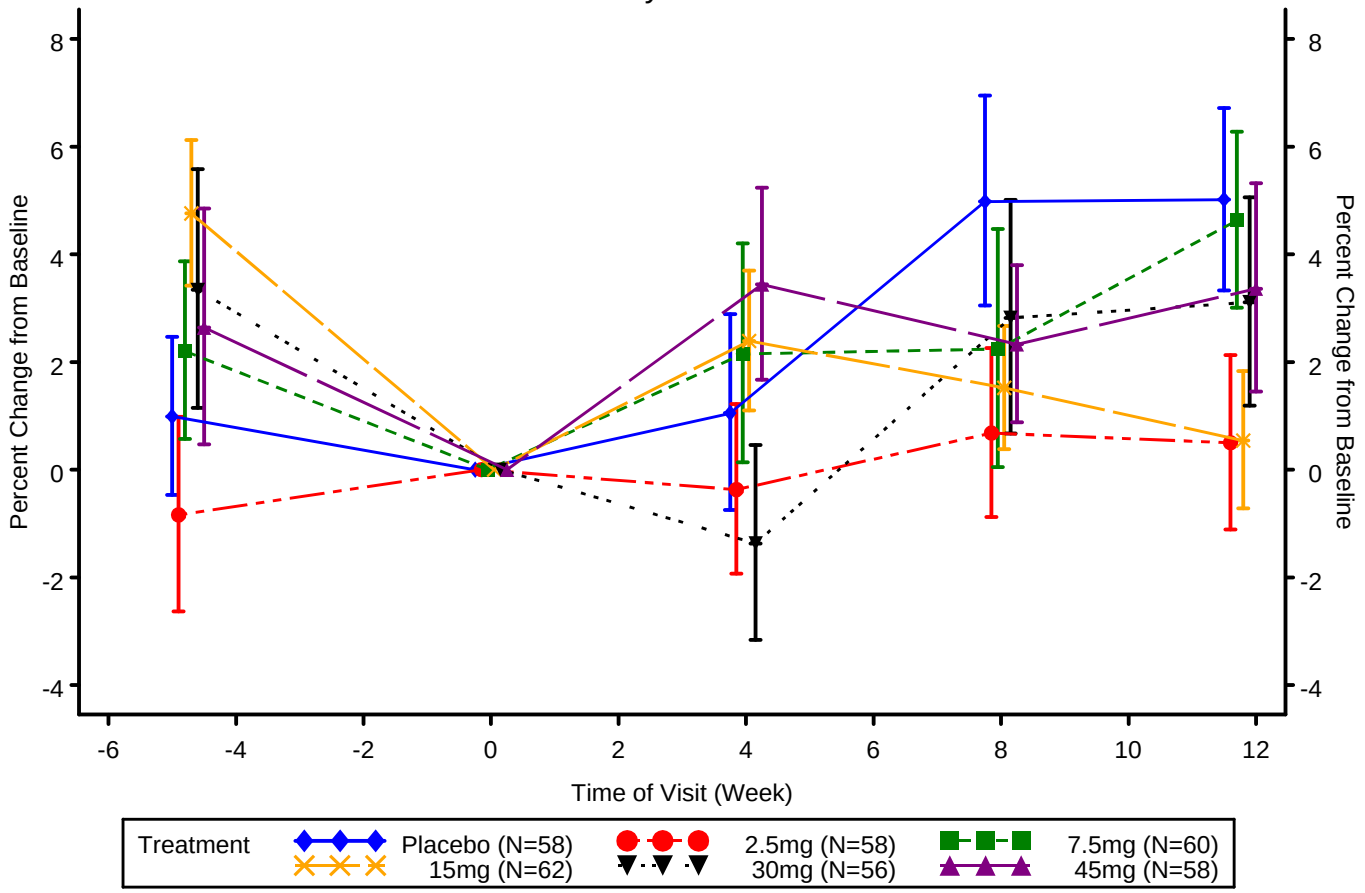
Figure 11.50
Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for HDL-c (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

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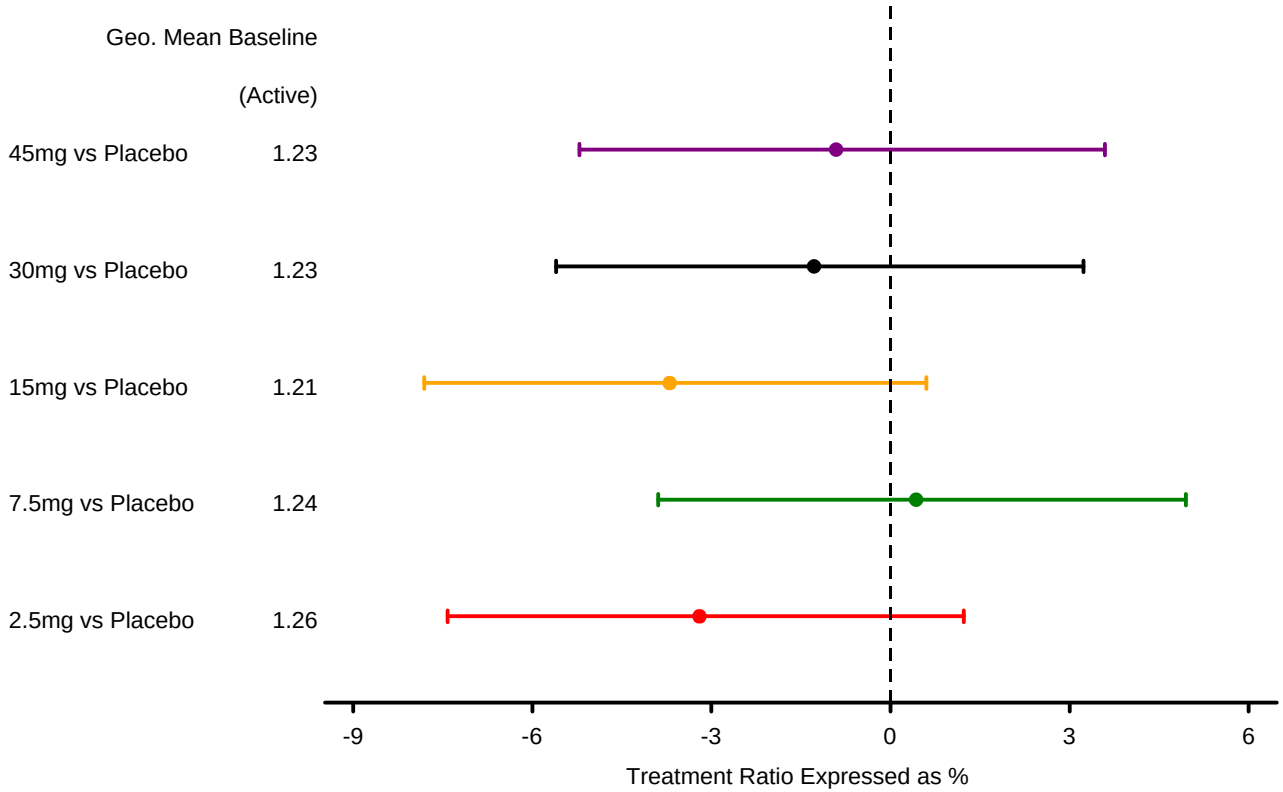
Figure 11.51
Figure of Treatment Ratio to Placebo Expressed as % Difference in HDL-c (mmol/L) at Week 12



Geo. Mean Baseline for Placebo = 1.17
Number of Subjects at Week 12 after LOCF: Placebo = 58, 2.5mg = 58, 7.5mg = 60, 15mg = 62, 30mg = 56, 45mg = 58

[redacted]

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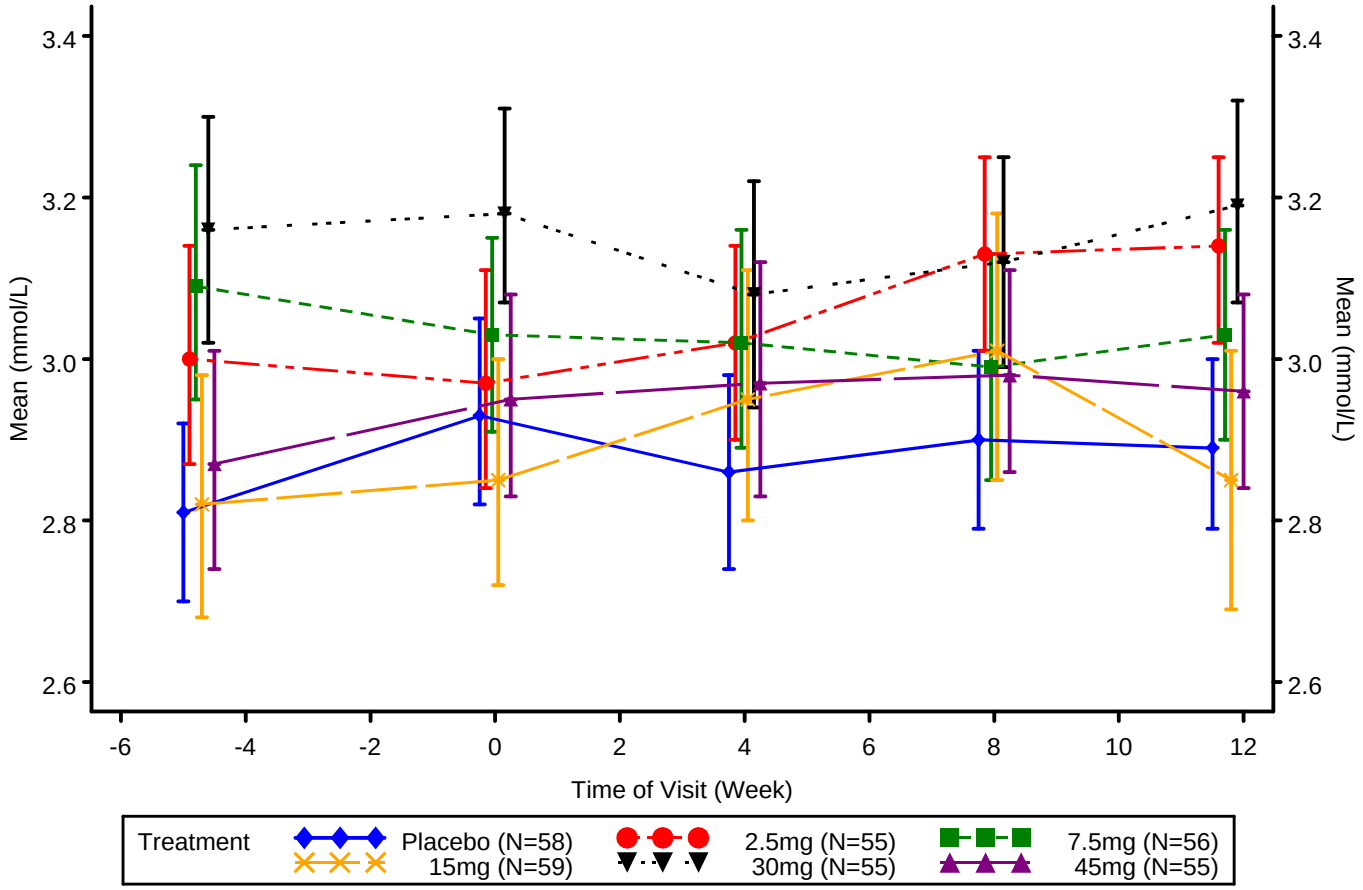
Figure 11.52
Line Graph of Geometric Mean (+-SE) for LDL-c (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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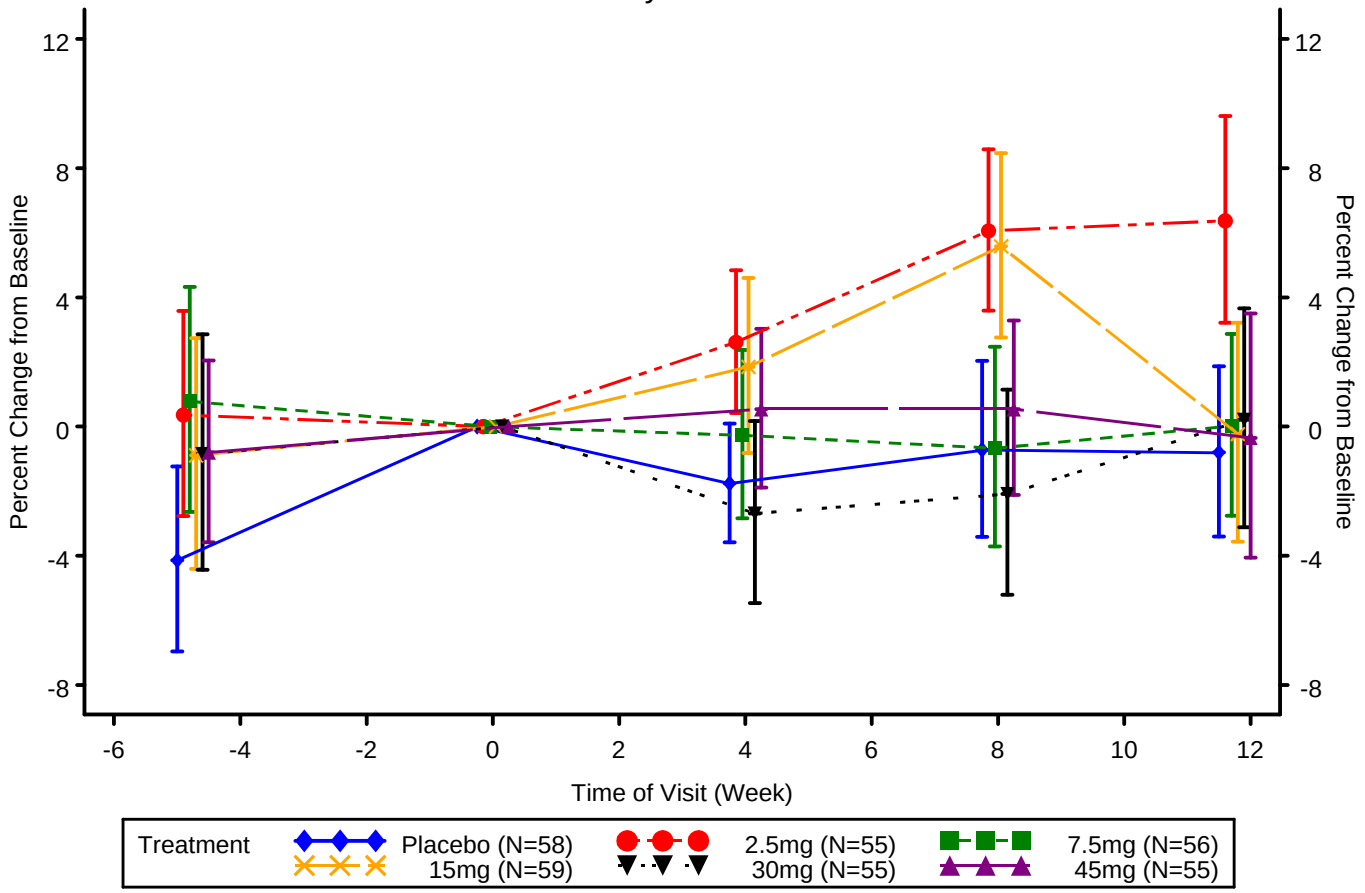
Figure 11.53
Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for LDL-c (mmol/L) by Visit



Note: Subjects shown at each visit are those with values at baseline and that visit.
N are number of subjects at Week 12 (after LOCF).

[redacted]

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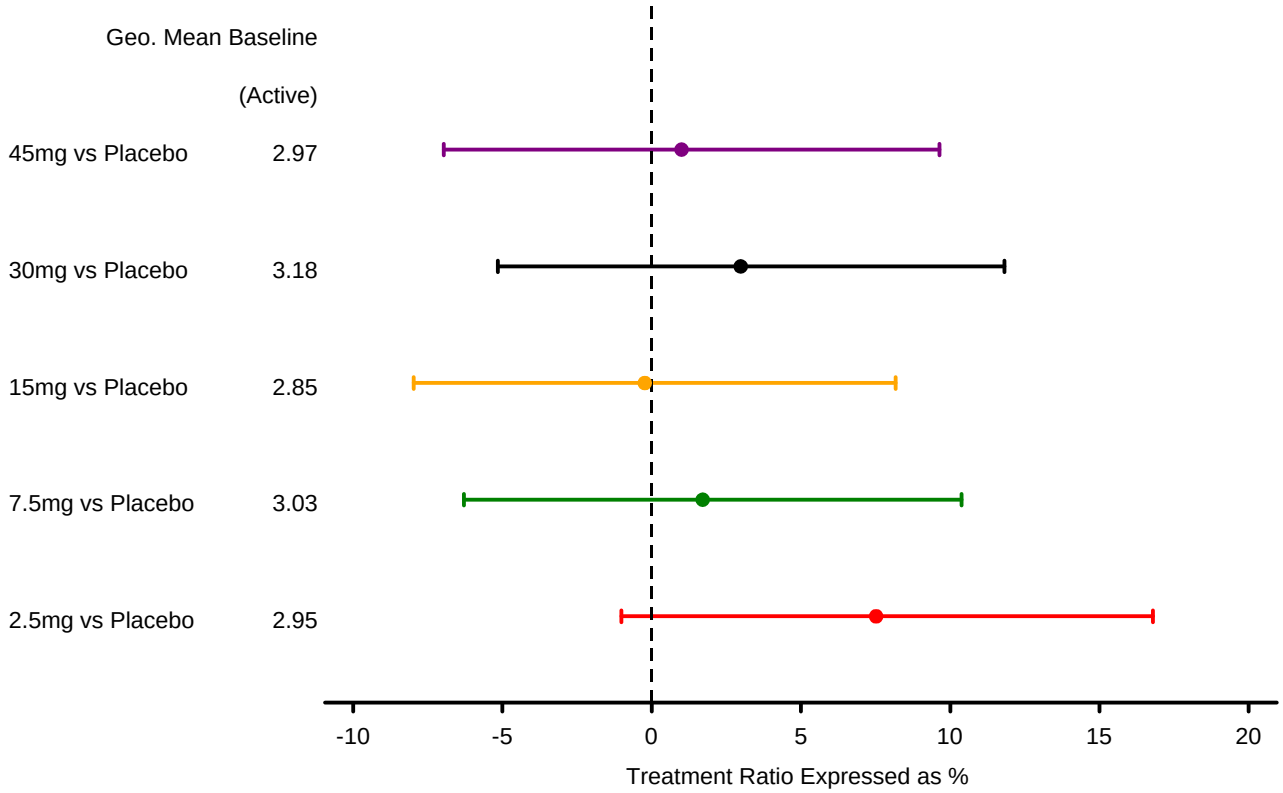
Figure 11.54
Figure of Treatment Ratio to Placebo Expressed as % Difference in LDL-c (mmol/L) at Week 12



Geo. Mean Baseline for Placebo = 2.92
Number of Subjects at Week 12 after LOCF: Placebo = 58, 2.5mg = 55, 7.5mg = 56, 15mg = 59, 30mg = 55, 45mg = 55

[redacted]

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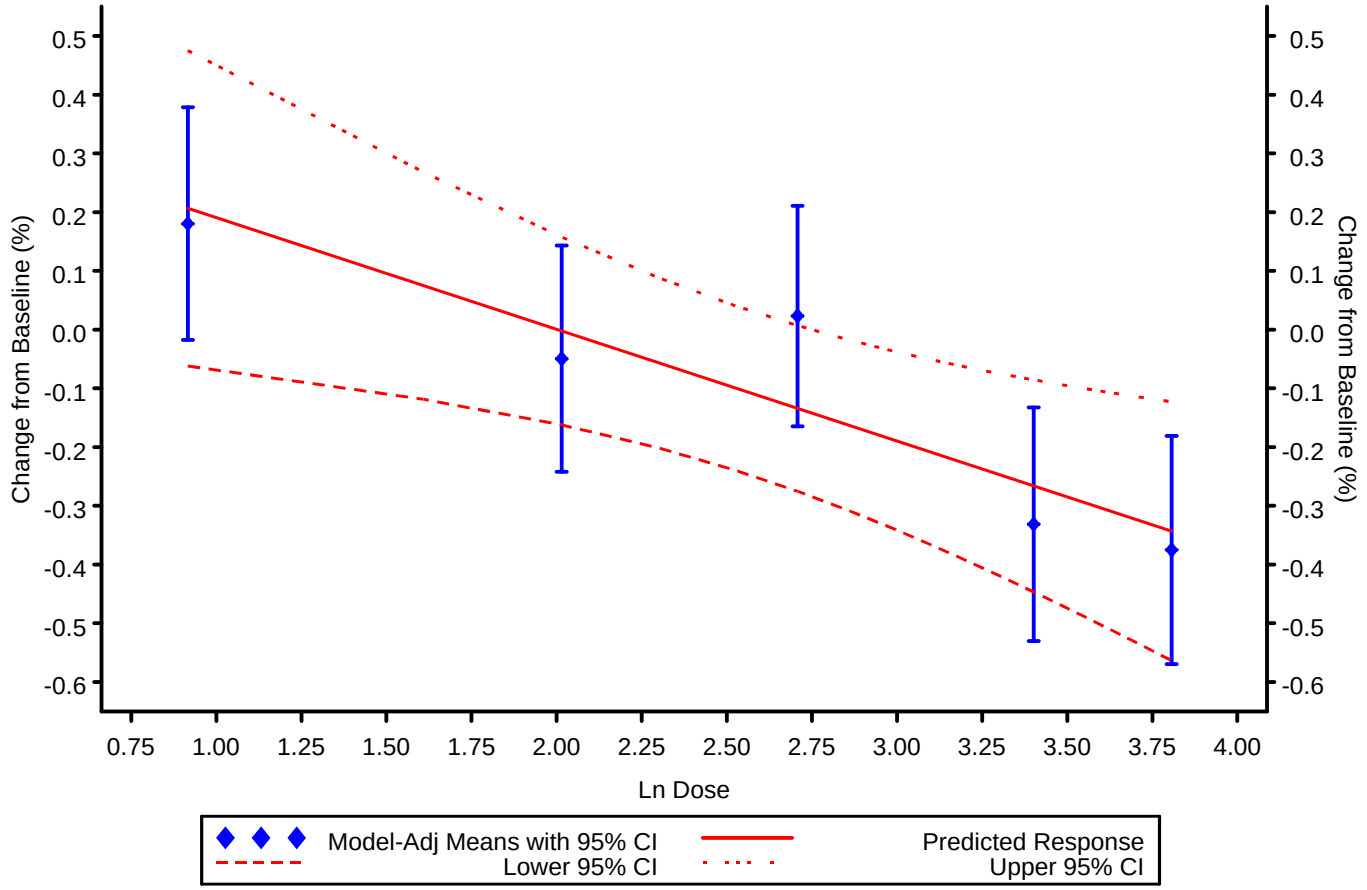
Figure 11.60
Exploratory Figure of Predicted Ln Dose-Response Curve for Change from Baseline in HbA1c (%) at Week 12



Linear: p<0.001, Quadratic: p=0.397, Cubic: p=0.537

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Week -6

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	57	60	63	55	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	7.74	8.02	7.96	7.88	7.78	8.06
	SD	0.683	0.918	0.763	0.649	0.664	0.741
	SE	0.087	0.122	0.098	0.082	0.090	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.80	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week -6	Mean	7.88	7.95	7.96	7.83	7.80	7.98
	SD	0.724	0.674	0.826	0.650	0.663	0.661
	SE	0.093	0.089	0.107	0.082	0.089	0.086
	Minimum	7.0	7.0	7.0	7.0	7.0	7.0
	Median	7.80	7.80	7.70	7.80	7.70	7.90
	Maximum	10.1	9.9	10.2	10.0	9.7	9.9
Change from Baseline	Mean	0.15	-0.07	-0.01	-0.05	0.02	-0.08
	SD	0.776	0.803	0.689	0.641	0.522	0.816
	SE	0.099	0.106	0.089	0.081	0.070	0.106
	Minimum	-1.6	-2.1	-1.7	-2.4	-1.4	-2.4
	Median	0.10	0.10	0.10	-0.10	0.10	-0.10
	Maximum	2.4	1.7	1.8	1.5	1.3	2.9

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Week -2

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	55	57	63	55	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	7.74	8.00	7.97	7.88	7.76	8.06
	SD	0.688	0.918	0.780	0.649	0.660	0.741
	SE	0.089	0.124	0.103	0.082	0.089	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.70	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week -2	Mean	7.75	7.93	7.91	7.79	7.73	7.93
	SD	0.668	0.782	0.713	0.593	0.628	0.658
	SE	0.086	0.105	0.094	0.075	0.085	0.086
	Minimum	5.9	6.5	6.6	6.6	6.4	6.5
	Median	7.70	7.90	7.70	7.80	7.60	7.90
	Maximum	9.4	10.1	9.9	9.2	9.8	9.5
Change from Baseline	Mean	0.02	-0.07	-0.06	-0.09	-0.03	-0.14
	SD	0.449	0.374	0.549	0.299	0.333	0.431
	SE	0.058	0.050	0.073	0.038	0.045	0.056
	Minimum	-0.7	-1.0	-1.2	-0.8	-0.8	-1.2
	Median	-0.05	0.00	0.00	-0.10	0.00	-0.10
	Maximum	1.8	0.7	2.2	0.6	0.9	1.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	57	60	63	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	7.74	8.02	7.96	7.88	7.77	8.06
	SD	0.678	0.918	0.763	0.649	0.660	0.741
	SE	0.086	0.122	0.098	0.082	0.088	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.75	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	56	59	61	56	57
Number (%) of Values Carried Forward		2 (3%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Mean	7.78	8.02	7.97	7.87	7.77	8.07
	SD	0.674	0.926	0.763	0.655	0.660	0.753
	SE	0.089	0.124	0.099	0.084	0.088	0.100
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	7.90	7.75	8.10
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week 4	Mean	7.99	8.01	7.87	7.82	7.52	7.75
	SD	0.966	1.093	0.915	0.876	0.751	0.812
	SE	0.127	0.146	0.119	0.112	0.100	0.108
	Minimum	6.3	6.3	6.1	6.0	5.8	5.9
	Median	7.80	7.70	7.80	8.00	7.50	7.80
	Maximum	10.6	11.4	9.9	10.4	9.4	9.7
Change from Baseline	Mean	0.22	-0.01	-0.11	-0.05	-0.25	-0.32
	SD	0.672	0.505	0.586	0.474	0.436	0.445
	SE	0.088	0.068	0.076	0.061	0.058	0.059
	Minimum	-1.1	-1.1	-1.1	-1.0	-1.6	-1.5
	Median	0.10	-0.10	-0.30	0.00	-0.30	-0.20
	Maximum	3.1	1.3	1.9	0.9	1.1	0.6

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		59	56	59	62	56	58
Number (%) of Values Carried Forward		6 (10%)	9 (16%)	6 (10%)	2 (3%)	2 (4%)	5 (9%)
Baseline	Mean	7.76	8.02	7.97	7.88	7.77	8.07
	SD	0.680	0.926	0.763	0.652	0.660	0.746
	SE	0.089	0.124	0.099	0.083	0.088	0.098
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	7.95	7.75	8.05
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week 8	Mean	7.97	8.15	7.93	7.84	7.41	7.66
	SD	1.129	1.229	1.021	0.944	0.772	0.850
	SE	0.147	0.164	0.133	0.120	0.103	0.112
	Minimum	6.2	6.1	6.2	6.2	6.1	5.5
	Median	7.80	7.80	7.80	7.90	7.40	7.75
	Maximum	11.2	12.0	10.3	10.4	9.4	9.8
Change from Baseline	Mean	0.21	0.13	-0.04	-0.04	-0.36	-0.41
	SD	1.019	0.753	0.789	0.645	0.653	0.579
	SE	0.133	0.101	0.103	0.082	0.087	0.076
	Minimum	-2.8	-1.6	-1.9	-1.4	-2.1	-1.8
	Median	0.00	0.00	-0.10	0.10	-0.40	-0.35
	Maximum	3.4	2.2	2.2	1.5	1.9	0.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.1
Summary Statistics for HbA1c (%) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		59	56	59	62	56	58
Number (%) of Values Carried Forward		10 (17%)	10 (18%)	6 (10%)	2 (3%)	2 (4%)	6 (10%)
Baseline	Mean	7.76	8.02	7.97	7.88	7.77	8.07
	SD	0.680	0.926	0.763	0.652	0.660	0.746
	SE	0.089	0.124	0.099	0.083	0.088	0.098
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	7.95	7.75	8.05
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week 12	Mean	8.18	8.20	7.93	7.92	7.43	7.68
	SD	1.331	1.278	1.160	0.918	0.864	0.963
	SE	0.173	0.171	0.151	0.117	0.115	0.126
	Minimum	6.2	6.3	6.2	6.0	5.5	5.8
	Median	7.90	7.75	7.60	7.90	7.35	7.65
	Maximum	11.8	11.8	11.0	10.4	9.7	9.9
Change from Baseline	Mean	0.42	0.18	-0.04	0.04	-0.34	-0.39
	SD	1.147	0.873	0.925	0.719	0.820	0.720
	SE	0.149	0.117	0.120	0.091	0.110	0.095
	Minimum	-1.7	-1.9	-2.3	-1.8	-2.5	-2.9
	Median	0.20	0.15	-0.20	0.00	-0.35	-0.25
	Maximum	2.8	2.5	2.2	2.0	2.6	0.9

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

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Population: Intent-to-Treat with LOCF

Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		59	56	59	62	56	58
Number (%) of Values Carried Forward		10 (17%)	10 (18%)	6 (10%)	2 (3%)	2 (4%)	6 (10%)
Baseline	Mean	7.76	8.02	7.97	7.88	7.77	8.07
	SD	0.680	0.926	0.763	0.652	0.660	0.746
Week 12	Mean	8.18	8.20	7.93	7.92	7.43	7.68
	SD	1.331	1.278	1.160	0.918	0.864	0.963
Chg from Baseline	Mean	0.42	0.18	-0.04	0.04	-0.34	-0.39
	SD	1.147	0.873	0.925	0.719	0.820	0.720
Model-Adj Chg [2]	Mean	0.46	0.18	-0.07	0.01	-0.34	-0.38
	SE	0.105	0.107	0.104	0.102	0.107	0.105
Diff from Pbo [2]	Mean		-0.28	-0.53	-0.45	-0.80	-0.84
	95% CI		-0.58,0.01	-0.82,-0.24	-0.74,-0.16	-1.09,-0.50	-1.13,-0.55
	p-val [3]		0.061	<0.001	0.002	<0.001	<0.001

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
p-values for interactions: trt*sex=0.514, trt*prior therapy=0.116, trt*region=0.056, trt*baseline=0.890

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	59	Sum Weights	59
Mean	7.76101695	Sum Observations	457.9
Std Deviation	0.68026794	Variance	0.46276447
Skewness	0.20337381	Kurtosis	0.09733738
Uncorrected SS	3580.61	Corrected SS	26.840339
Coeff Variation	8.76519071	Std Error Mean	0.08856334

Basic Statistical Measures

Location		Variability	
Mean	7.761017	Std Deviation	0.68027
Median	7.700000	Variance	0.46276
Mode	7.200000	Range	3.20000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 2 modes with a count of 6.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	87.63239	Pr > |t|	<.0001
Sign	M	29.5	Pr >= |M|	<.0001
Signed Rank	S	885	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.984811	Pr < W	0.6706
Kolmogorov-Smirnov	D	0.080074	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.046639	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.300023	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.3
99%	9.3
95%	9.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.6
75% Q3	8.2
50% Median	7.7
25% Q1	7.3
10%	6.9
5%	6.6
1%	6.1
0% Min	6.1

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.1	15	8.8	50
6.6	34	9.0	56
6.6	31	9.2	4
6.8	52	9.3	13
6.8	46	9.3	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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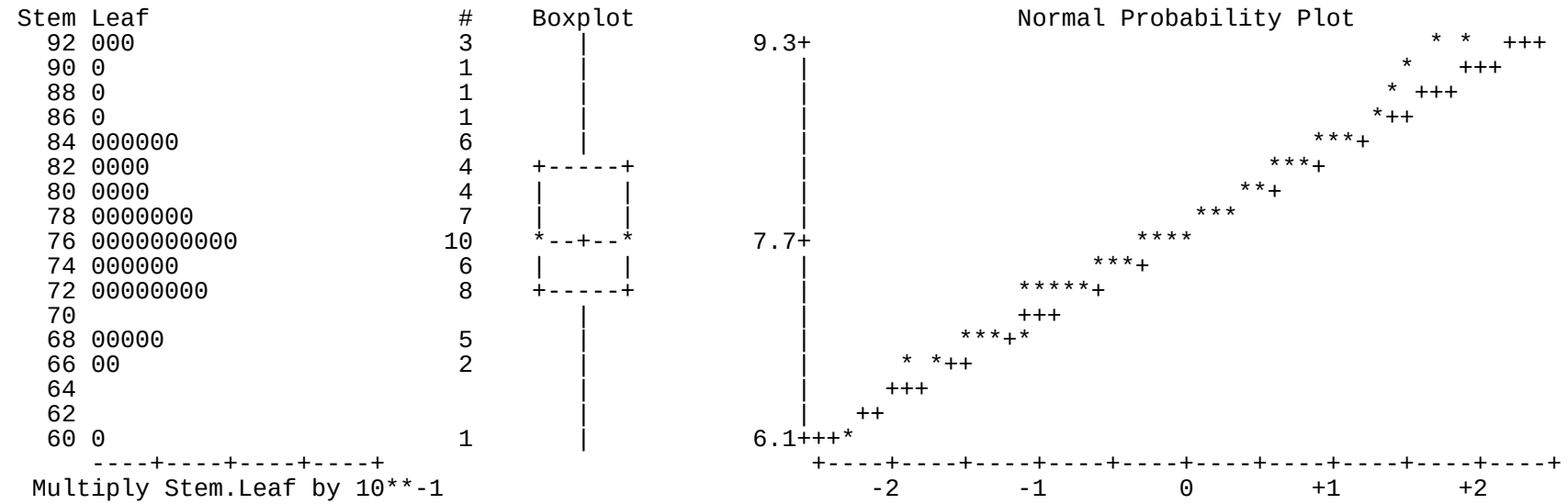
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	59	Sum Weights	59
Mean	8.18305085	Sum Observations	482.8
Std Deviation	1.33082196	Variance	1.77108708
Skewness	0.681579	Kurtosis	-0.0393501
Uncorrected SS	4053.5	Corrected SS	102.723051
Coeff Variation	16.2631515	Std Error Mean	0.17325826

Basic Statistical Measures

Location		Variability	
Mean	8.183051	Std Deviation	1.33082
Median	7.900000	Variance	1.77109
Mode	7.600000	Range	5.60000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	47.23036	Pr > |t|	<.0001
Sign	M	29.5	Pr >= |M|	<.0001

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	885	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.951159	Pr < W	0.0191
Kolmogorov-Smirnov	D	0.109055	Pr > D	0.0805
Cramer-von Mises	W-Sq	0.145847	Pr > W-Sq	0.0260
Anderson-Darling	A-Sq	0.852667	Pr > A-Sq	0.0268

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.8
99%	11.8
95%	10.6
90%	10.1
75% Q3	8.9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.9
25% Q1	7.2
10%	6.4
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	22	10.2	53
6.3	46	10.3	50
6.3	38	10.6	42
6.3	29	11.4	55
6.3	6	11.8	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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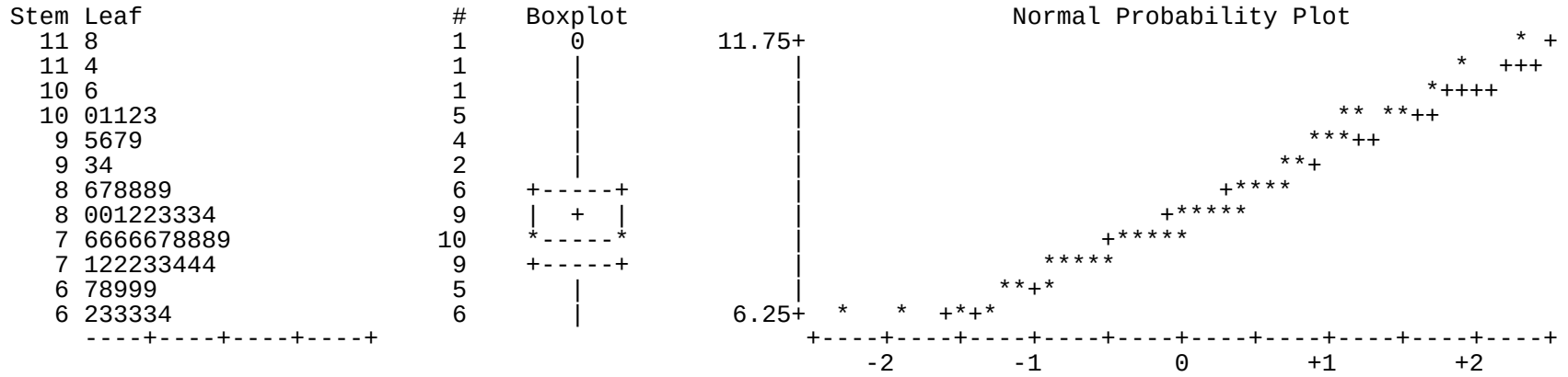
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	59	Sum Weights	59
Mean	0.4220339	Sum Observations	24.9
Std Deviation	1.14651914	Variance	1.31450614
Skewness	0.32654821	Kurtosis	-0.4579367
Uncorrected SS	86.75	Corrected SS	76.2413559
Coeff Variation	271.665178	Std Error Mean	0.14926408

Basic Statistical Measures

Location		Variability	
Mean	0.422034	Std Deviation	1.14652
Median	0.200000	Variance	1.31451
Mode	0.100000	Range	4.50000
		Interquartile Range	1.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.827431	Pr > |t|	0.0064
Sign	M	8.5	Pr >= |M|	0.0331

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	296.5	Pr >= |S|	0.0171

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.969348	Pr < W	0.1422
Kolmogorov-Smirnov	D	0.101705	Pr > D	0.1313
Cramer-von Mises	W-Sq	0.089519	Pr > W-Sq	0.1542
Anderson-Darling	A-Sq	0.550288	Pr > A-Sq	0.1537

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.8
99%	2.8
95%	2.5
90%	2.2
75% Q3	1.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.2
25% Q1	-0.4
10%	-1.0
5%	-1.5
1%	-1.7
0% Min	-1.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.7	13	2.4	53
-1.7	6	2.5	41
-1.5	38	2.5	52
-1.5	22	2.8	55
-1.0	48	2.8	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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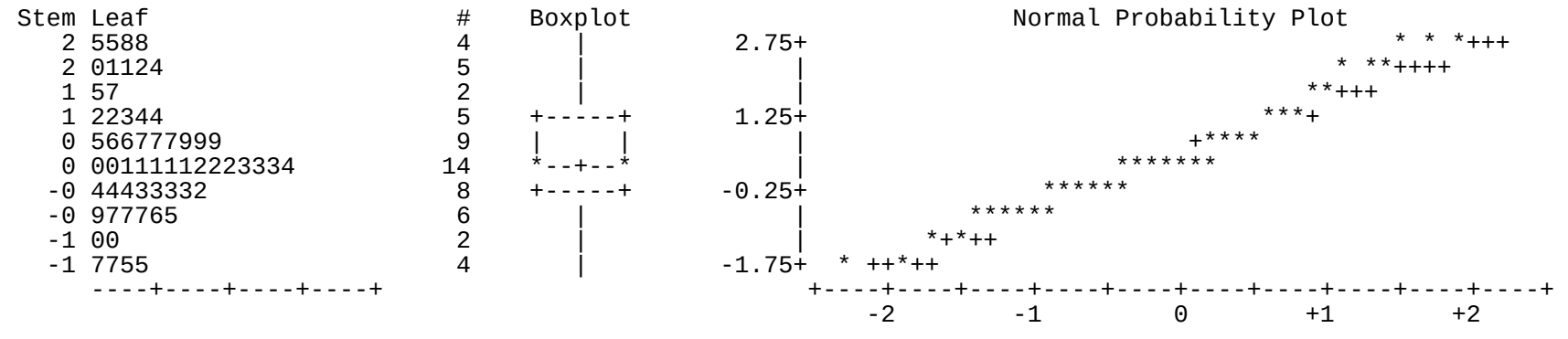
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	8.01964286	Sum Observations	449.1
Std Deviation	0.92626712	Variance	0.85797078
Skewness	0.6590068	Kurtosis	-0.2026908
Uncorrected SS	3648.81	Corrected SS	47.1883929
Coeff Variation	11.5499797	Std Error Mean	0.12377765

Basic Statistical Measures

Location		Variability	
Mean	8.019643	Std Deviation	0.92627
Median	7.800000	Variance	0.85797
Mode	7.700000	Range	3.70000
		Interquartile Range	1.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	64.79072	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.940166	Pr < W	0.0079
Kolmogorov-Smirnov	D	0.147292	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.224829	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.273697	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.1
99%	10.1
95%	9.8
90%	9.5
75% Q3	8.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.8
25% Q1	7.4
10%	7.0
5%	6.8
1%	6.4
0% Min	6.4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	49	9.7	1
6.4	30	9.8	7
6.8	40	9.8	36
6.8	24	10.1	3
6.9	46	10.1	43

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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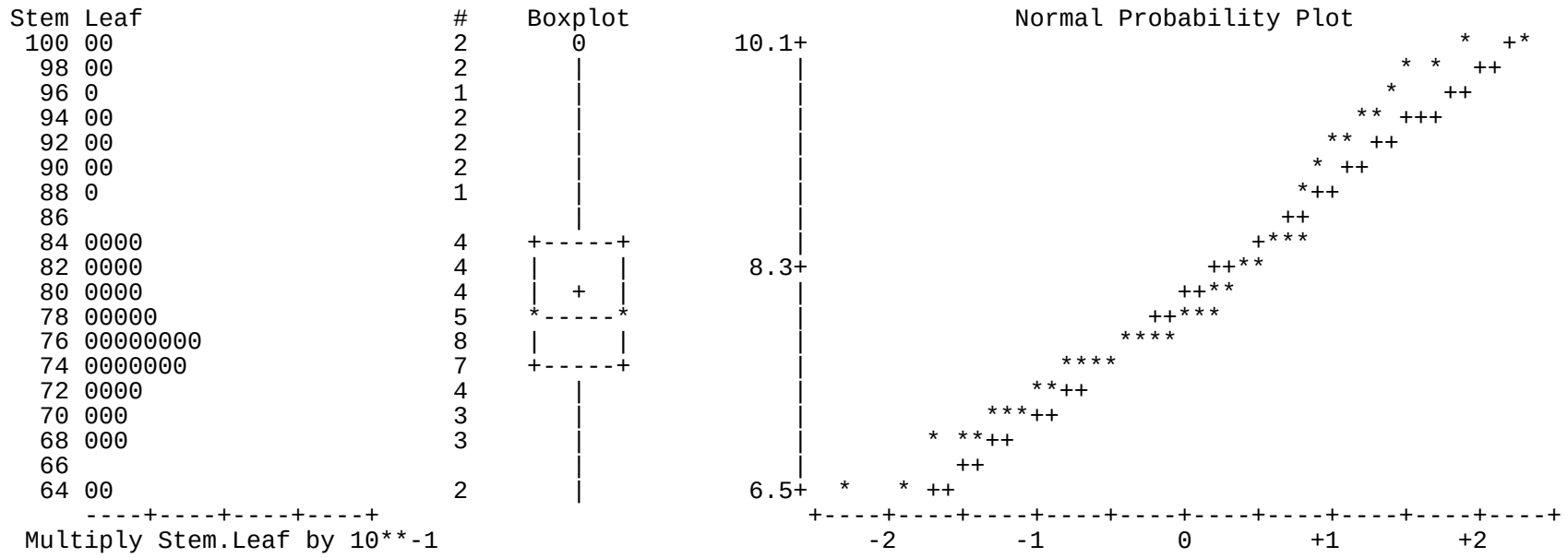
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	8.19642857	Sum Observations	459
Std Deviation	1.27806164	Variance	1.63344156
Skewness	0.72242577	Kurtosis	-0.0316652
Uncorrected SS	3852	Corrected SS	89.8392857
Coeff Variation	15.5929089	Std Error Mean	0.17078817

Basic Statistical Measures

Location		Variability	
Mean	8.196429	Std Deviation	1.27806
Median	7.750000	Variance	1.63344
Mode	7.600000	Range	5.50000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	47.99178	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.946007	Pr < W	0.0141
Kolmogorov-Smirnov	D	0.151148	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.175373	Pr > W-Sq	0.0105
Anderson-Darling	A-Sq	0.979045	Pr > A-Sq	0.0139

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.80
99%	11.80
95%	10.60
90%	10.10
75% Q3	9.00

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.30
10%	6.60
5%	6.50
1%	6.30
0% Min	6.30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	30	10.3	51
6.4	37	10.5	9
6.5	52	10.6	2
6.5	50	10.8	48
6.6	41	11.8	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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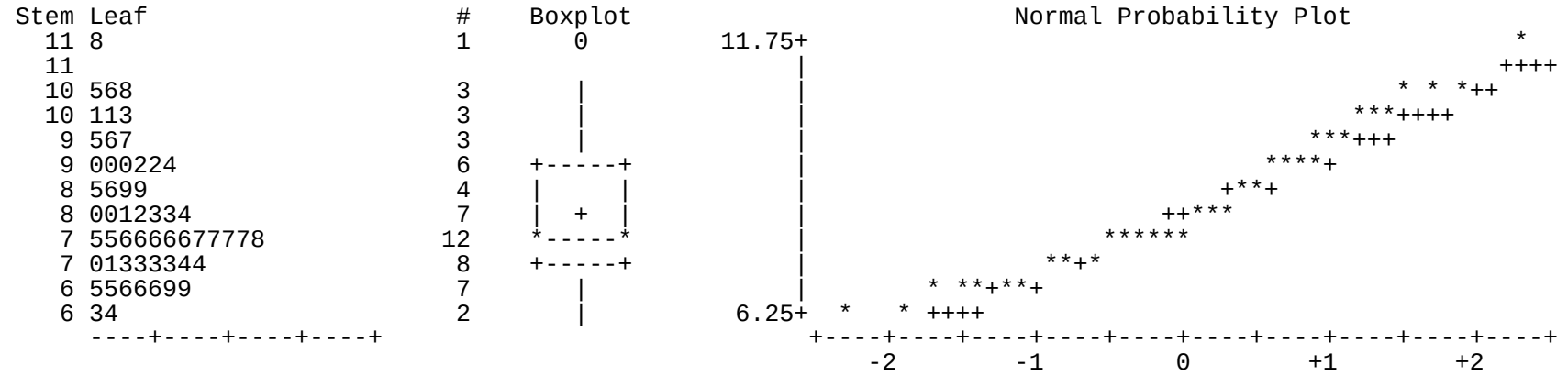
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	0.17678571	Sum Observations	9.9
Std Deviation	0.8728201	Variance	0.76181494
Skewness	0.03492776	Kurtosis	0.37836707
Uncorrected SS	43.65	Corrected SS	41.8998214
Coeff Variation	493.716423	Std Error Mean	0.11663549

Basic Statistical Measures

Location		Variability	
Mean	0.17679	Std Deviation	0.87282
Median	0.15000	Variance	0.76181
Mode	-0.50000	Range	4.40000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.515711	Pr > |t|	0.1353
Sign	M	3.5	Pr >= |M|	0.4188
Signed Rank	S	188	Pr >= |S|	0.1159

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.987046	Pr < W	0.8082
Kolmogorov-Smirnov	D	0.079598	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.044056	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.301937	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.50
99%	2.50
95%	1.70

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	1.20
75% Q3	0.65
50% Median	0.15
25% Q1	-0.35
10%	-1.00
5%	-1.40
1%	-1.90
0% Min	-1.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.9	54	1.3	53
-1.6	27	1.7	3
-1.4	41	1.7	48
-1.4	14	1.8	2
-1.2	50	2.5	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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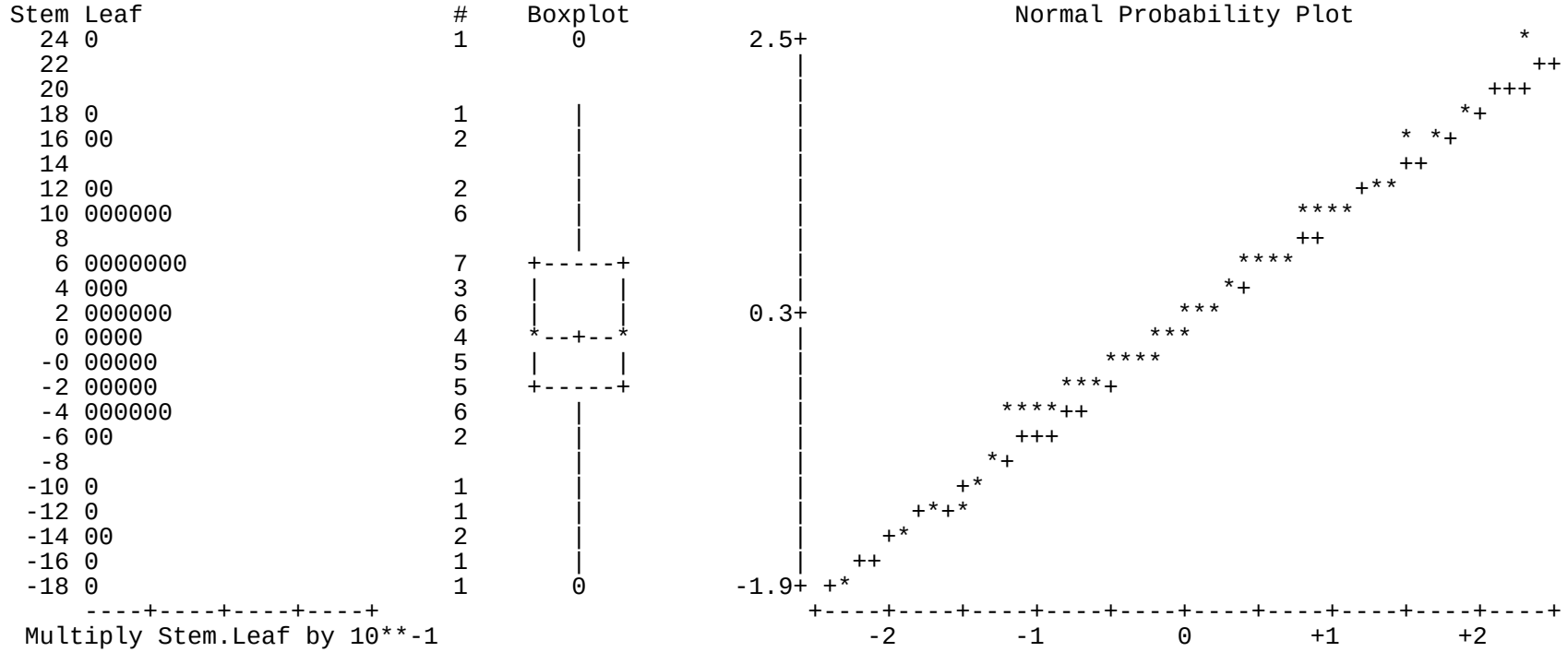
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	59	Sum Weights	59
Mean	7.97457627	Sum Observations	470.5
Std Deviation	0.76284251	Variance	0.5819287
Skewness	0.79881856	Kurtosis	0.13115947
Uncorrected SS	3785.79	Corrected SS	33.7518644
Coeff Variation	9.56593159	Std Error Mean	0.09931364

Basic Statistical Measures

Location		Variability	
Mean	7.974576	Std Deviation	0.76284
Median	7.700000	Variance	0.58193
Mode	7.600000	Range	3.30000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	80.29689	Pr > |t|	<.0001
Sign	M	29.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	885	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.929701	Pr < W	0.0021
Kolmogorov-Smirnov	D	0.165977	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.286814	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.648352	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.9
99%	9.9
95%	9.6
90%	9.3
75% Q3	8.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.4
10%	7.3
5%	6.9
1%	6.6
0% Min	6.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	29	9.4	27
6.7	23	9.4	45
6.9	41	9.6	31
6.9	10	9.7	30
7.2	22	9.9	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

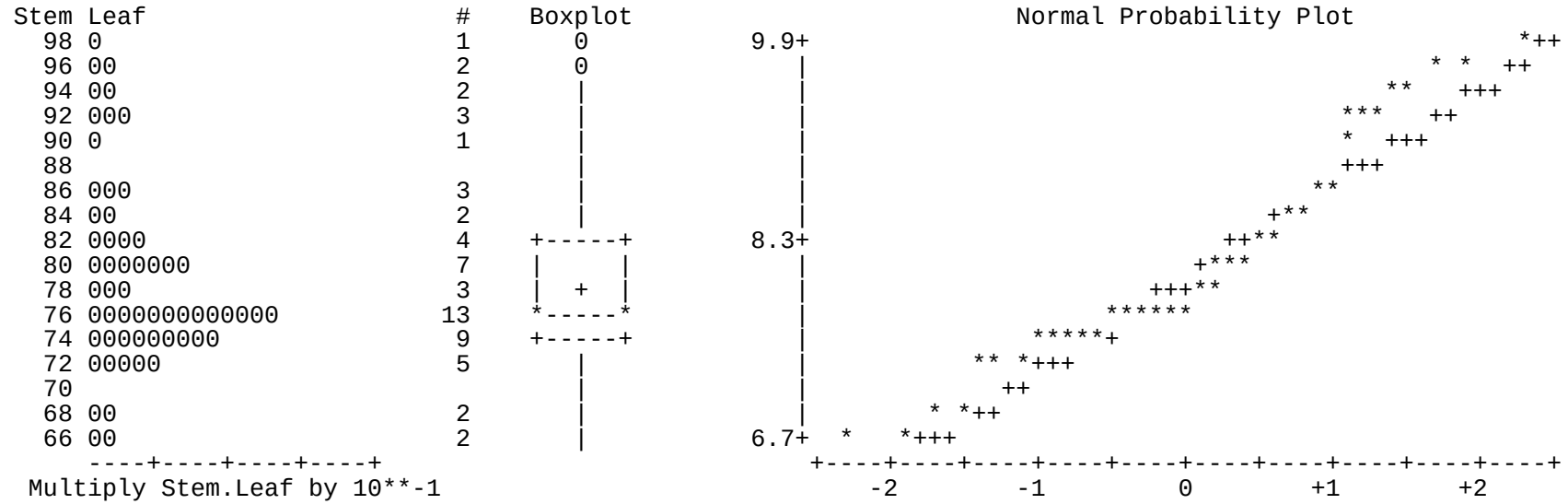

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	59	Sum Weights	59
Mean	7.93220339	Sum Observations	468
Std Deviation	1.15958385	Variance	1.34463472
Skewness	0.82354754	Kurtosis	0.11347167
Uncorrected SS	3790.26	Corrected SS	77.9888136
Coeff Variation	14.6186854	Std Error Mean	0.15096496

Basic Statistical Measures

Location		Variability	
Mean	7.932203	Std Deviation	1.15958
Median	7.600000	Variance	1.34463
Mode	7.600000	Range	4.80000
		Interquartile Range	1.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	52.54334	Pr > |t|	<.0001
Sign	M	29.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	885	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.937589	Pr < W 0.0046
Kolmogorov-Smirnov	D	0.15512	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.209916	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.200987	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.0
99%	11.0
95%	10.4
90%	9.8
75% Q3	8.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.6
25% Q1	7.1
10%	6.6
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	29	9.9	52
6.2	23	10.2	37
6.3	55	10.4	3
6.4	44	10.7	5
6.6	40	11.0	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

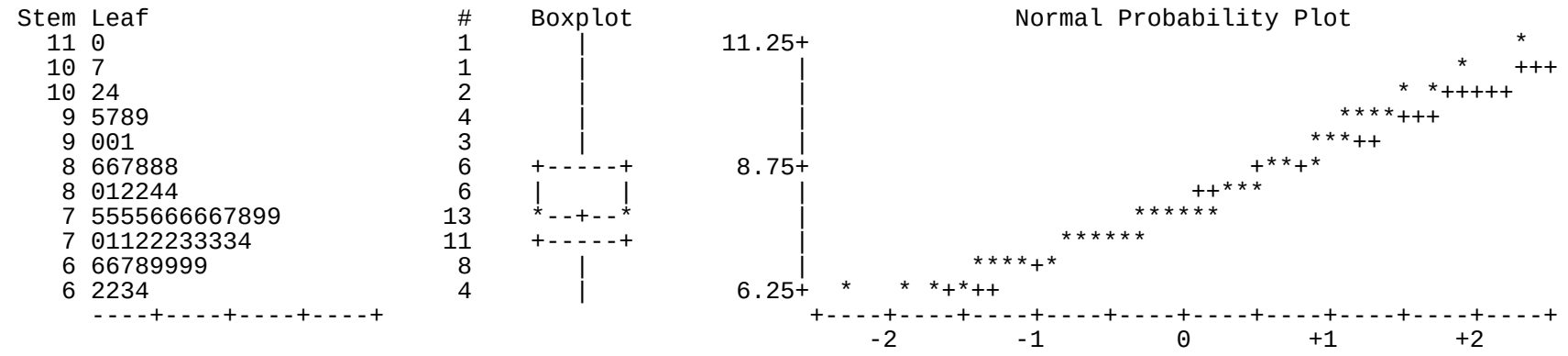

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	59	Sum Weights	59
Mean	-0.0423729	Sum Observations	-2.5
Std Deviation	0.92479325	Variance	0.85524255
Skewness	0.43586995	Kurtosis	0.75242253
Uncorrected SS	49.71	Corrected SS	49.6040678
Coeff Variation	-2182.5121	Std Error Mean	0.12039783

Basic Statistical Measures

Location		Variability	
Mean	-0.04237	Std Deviation	0.92479
Median	-0.20000	Variance	0.85524
Mode	-0.30000	Range	4.50000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.35194	Pr > |t|	0.7262
Sign	M	-4	Pr >= |M|	0.3409
Signed Rank	S	-109.5	Pr >= |S|	0.3504

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.958226	Pr < W	0.0412
Kolmogorov-Smirnov	D	0.101374	Pr > D	0.1342
Cramer-von Mises	W-Sq	0.146717	Pr > W-Sq	0.0250
Anderson-Darling	A-Sq	0.941482	Pr > A-Sq	0.0175

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.2
99%	2.2
95%	2.1

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	1.6
75% Q3	0.4
50% Median	-0.2
25% Q1	-0.6
10%	-1.1
5%	-1.7
1%	-2.3
0% Min	-2.3

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.3	49	1.7	5
-1.9	51	1.7	53
-1.7	44	2.1	3
-1.2	55	2.1	57
-1.1	40	2.2	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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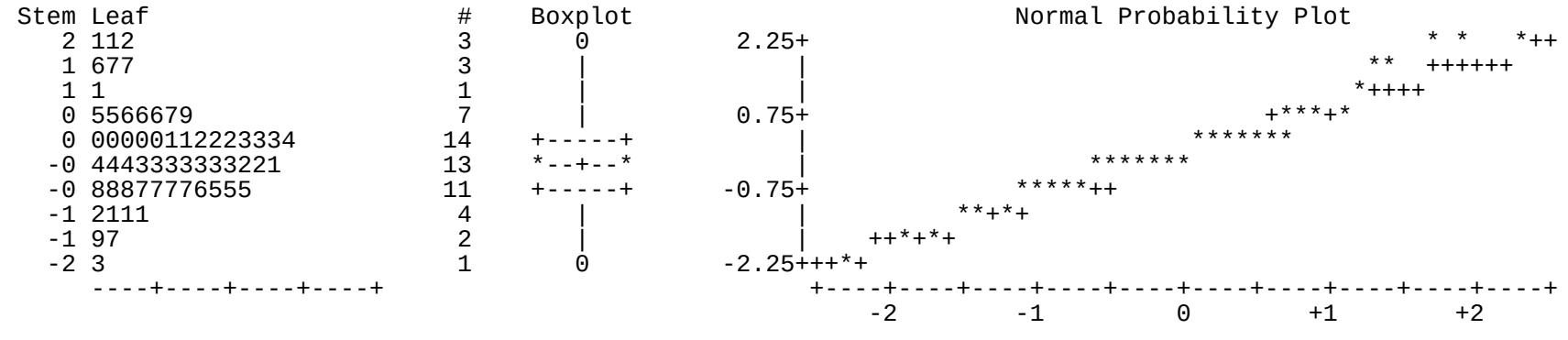
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	7.87741935	Sum Observations	488.4
Std Deviation	0.65196283	Variance	0.42505553
Skewness	0.24702869	Kurtosis	0.09897767
Uncorrected SS	3873.26	Corrected SS	25.9283871
Coeff Variation	8.27635037	Std Error Mean	0.08279936

Basic Statistical Measures

Location		Variability	
Mean	7.877419	Std Deviation	0.65196
Median	7.950000	Variance	0.42506
Mode	7.500000	Range	3.10000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	95.13865	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.985133	Pr < W	0.6566
Kolmogorov-Smirnov	D	0.089638	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.049149	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.297466	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.60
99%	9.60
95%	8.90
90%	8.60
75% Q3	8.30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.95
25% Q1	7.40
10%	7.10
5%	6.90
1%	6.50
0% Min	6.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	25	8.8	28
6.6	6	8.9	21
6.8	3	9.0	30
6.9	45	9.5	23
7.0	16	9.6	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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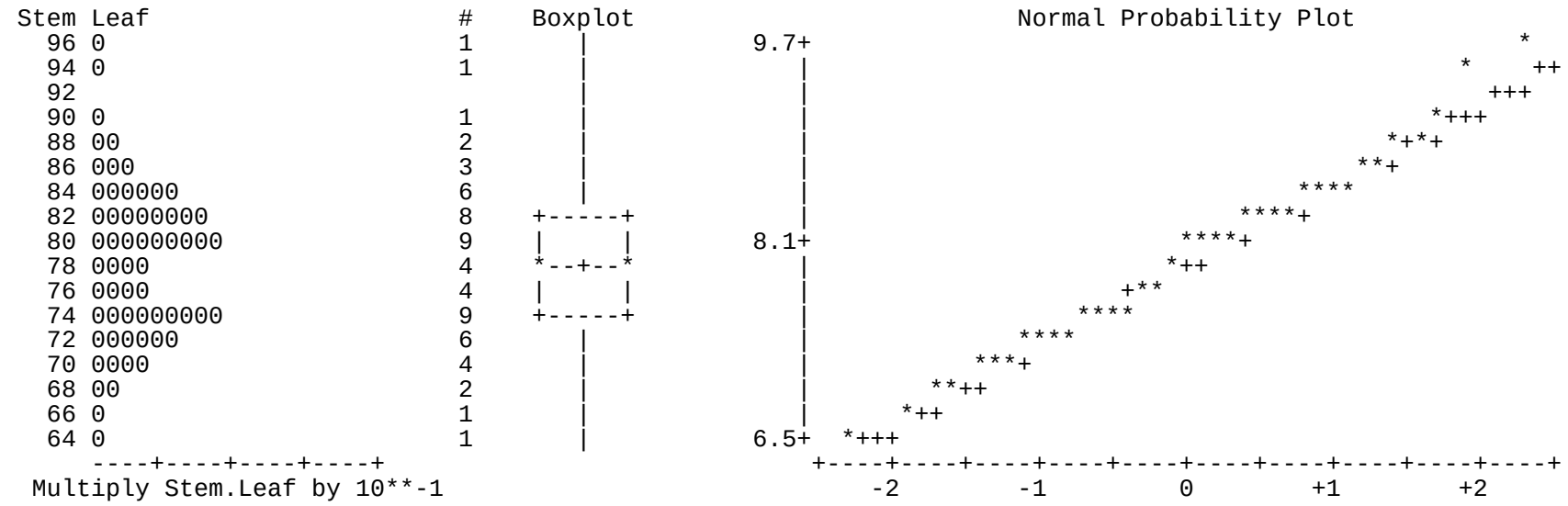
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	7.91774194	Sum Observations	490.9
Std Deviation	0.91821712	Variance	0.84312269
Skewness	0.30859783	Kurtosis	-0.0108206
Uncorrected SS	3938.25	Corrected SS	51.4304839
Coeff Variation	11.596957	Std Error Mean	0.11661369

Basic Statistical Measures

Location		Variability	
Mean	7.917742	Std Deviation	0.91822
Median	7.900000	Variance	0.84312
Mode	8.200000	Range	4.40000
		Interquartile Range	1.20000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	67.89719	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.987907	Pr < W	0.8021
Kolmogorov-Smirnov	D	0.062524	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.034954	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.220581	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.4
99%	10.4
95%	9.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	9.1
75% Q3	8.5
50% Median	7.9
25% Q1	7.3
10%	6.8
5%	6.5
1%	6.0
0% Min	6.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.0	33	9.3	17
6.4	50	9.5	4
6.4	25	9.5	54
6.5	45	10.0	18
6.5	36	10.4	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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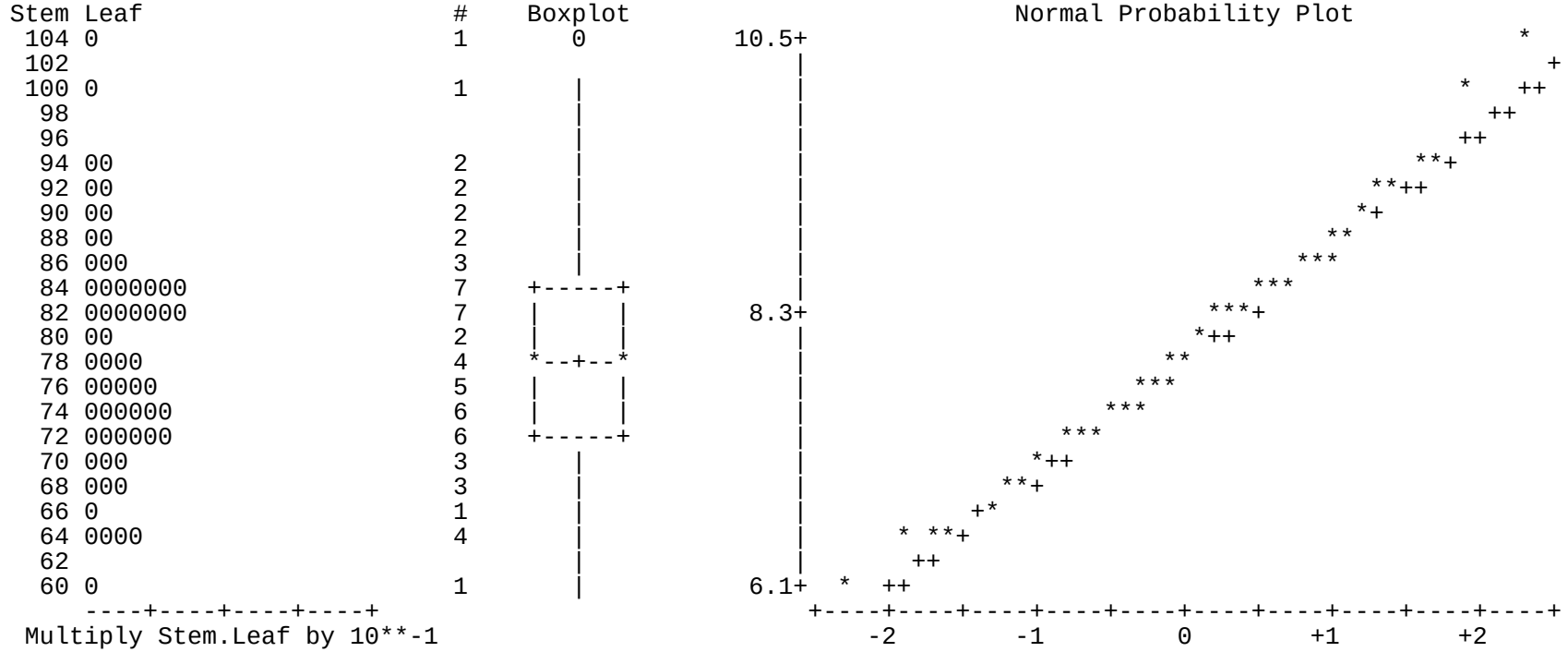
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	0.04032258	Sum Observations	2.5
Std Deviation	0.71871006	Variance	0.51654416
Skewness	0.1380459	Kurtosis	1.22010607
Uncorrected SS	31.61	Corrected SS	31.5091935
Coeff Variation	1782.40096	Std Error Mean	0.09127627

Basic Statistical Measures

Location		Variability	
Mean	0.040323	Std Deviation	0.71871
Median	0.000000	Variance	0.51654
Mode	0.000000	Range	3.80000
		Interquartile Range	0.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.441764	Pr > |t|	0.6602
Sign	M	4	Pr >= |M|	0.3317

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	61	Pr >= |S|	0.5831

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.957719	Pr < W	0.0319
Kolmogorov-Smirnov	D	0.137896	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.224456	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.14985	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.0
99%	2.0
95%	1.2
90%	0.8
75% Q3	0.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-0.3
10%	-0.9
5%	-1.1
1%	-1.8
0% Min	-1.8

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.8	23	0.8	60
-1.6	50	1.2	17
-1.2	48	1.6	4
-1.1	40	1.9	6
-1.1	33	2.0	18

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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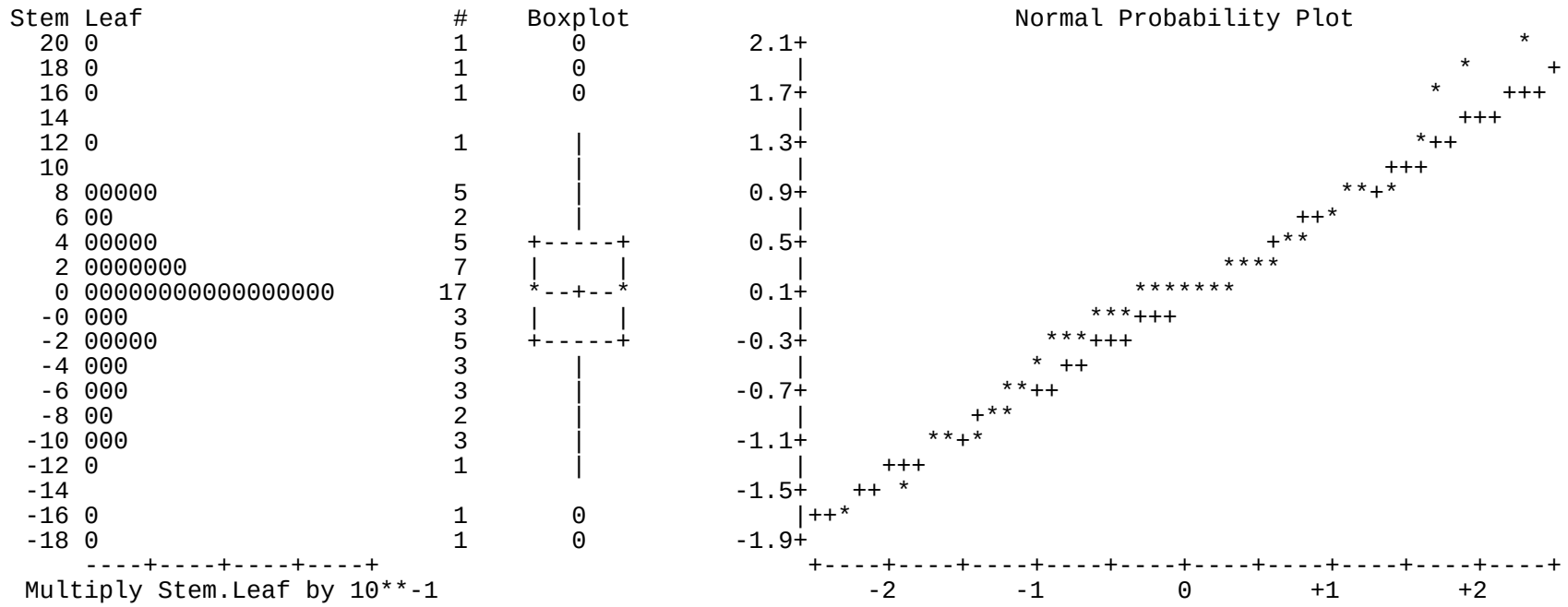
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	7.77321429	Sum Observations	435.3
Std Deviation	0.65988734	Variance	0.4354513
Skewness	0.09151171	Kurtosis	-0.2864215
Uncorrected SS	3407.63	Corrected SS	23.9498214
Coeff Variation	8.48924671	Std Error Mean	0.08818115

Basic Statistical Measures

Location		Variability	
Mean	7.773214	Std Deviation	0.65989
Median	7.750000	Variance	0.43545
Mode	8.400000	Range	3.20000
		Interquartile Range	1.05000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	88.15052	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.972988	Pr < W	0.2400
Kolmogorov-Smirnov	D	0.089146	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.077098	Pr > W-Sq	0.2277
Anderson-Darling	A-Sq	0.518992	Pr > A-Sq	0.1881

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.60
99%	9.60
95%	8.70
90%	8.60
75% Q3	8.35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.30
10%	6.80
5%	6.70
1%	6.40
0% Min	6.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	39	8.6	26
6.7	21	8.6	44
6.7	14	8.7	24
6.8	53	8.7	47
6.8	51	9.6	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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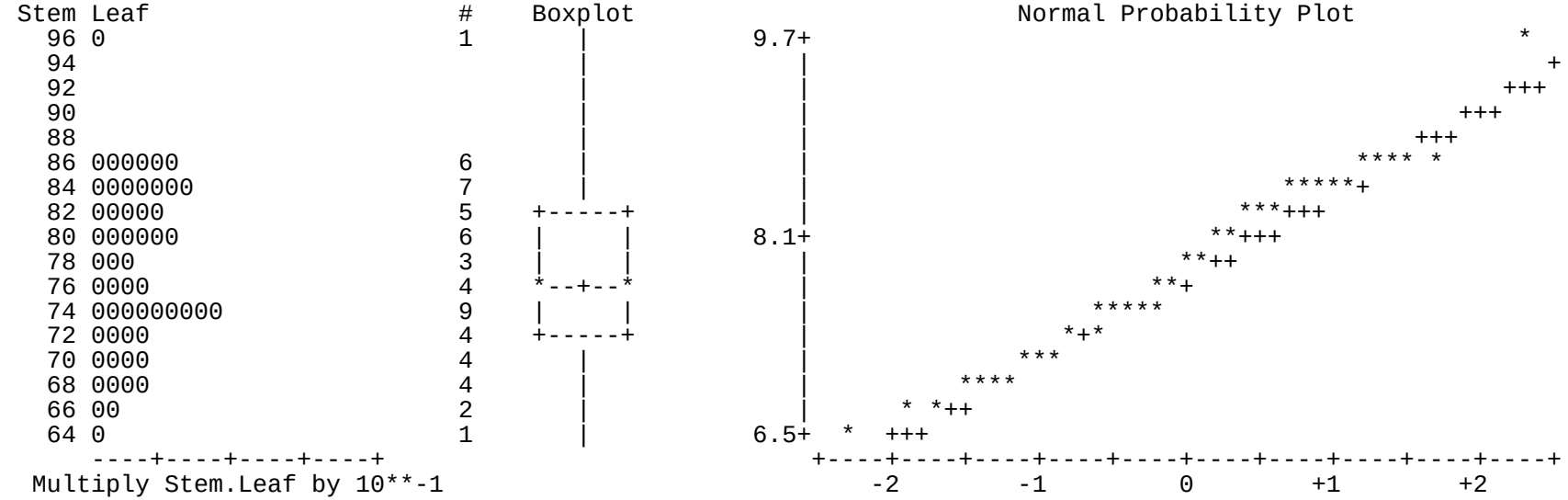
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	7.43214286	Sum Observations	416.2
Std Deviation	0.86405116	Variance	0.74658442
Skewness	0.38279917	Kurtosis	0.14494667
Uncorrected SS	3134.32	Corrected SS	41.0621429
Coeff Variation	11.6258686	Std Error Mean	0.11546369

Basic Statistical Measures

Location		Variability	
Mean	7.432143	Std Deviation	0.86405
Median	7.350000	Variance	0.74658
Mode	7.100000	Range	4.20000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	64.36779	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.981039	Pr < W	0.5213
Kolmogorov-Smirnov	D	0.111559	Pr > D	0.0820
Cramer-von Mises	W-Sq	0.077164	Pr > W-Sq	0.2273
Anderson-Darling	A-Sq	0.422634	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.70
99%	9.70
95%	8.90

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.60
75% Q3	7.95
50% Median	7.35
25% Q1	6.95
10%	6.30
5%	6.20
1%	5.50
0% Min	5.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	19	8.8	7
6.1	16	8.9	5
6.2	33	8.9	41
6.2	21	9.4	24
6.2	14	9.7	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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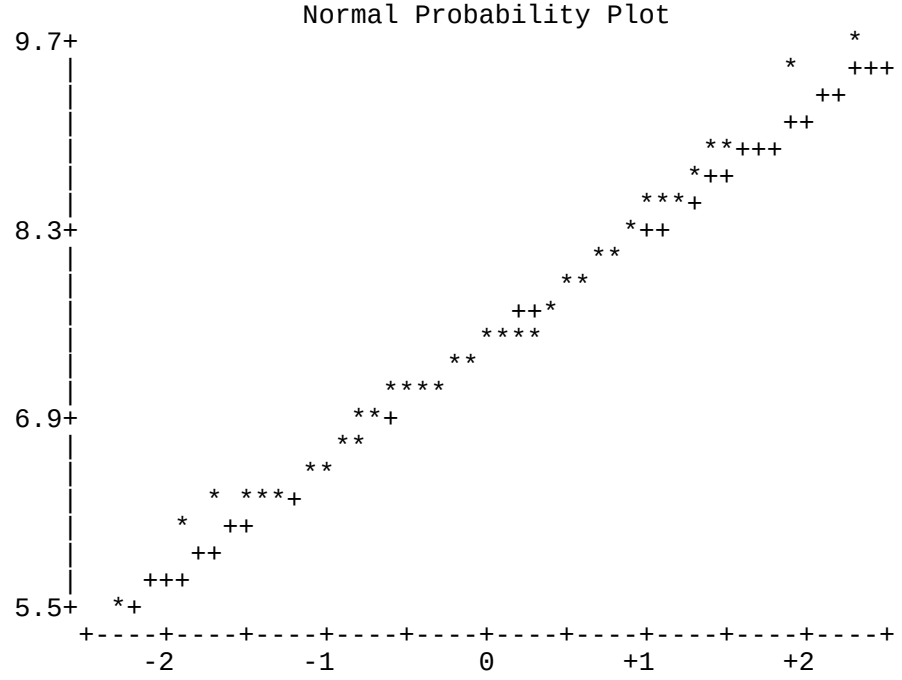
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
    96 0                     1       0
    94 0                     1       |
    92                               |
    90                               |
    88 000                   3       |
    86 0                     1       |
    84 000                   3       |
    82 00                    2       |
    80 000                   3       |
    78 0000                  4    +-----+
    76 00                    2    |     |
    74 00000000              8    |  +  |
    72 000000                6    *-----*
    70 00000000              8    |     |
    68 00                    2    +-----+
    66 000                   3       |
    64 00                    2       |
    62 00000                 5       |
    60 0                     1       |
    58                               |
    56                               |
    54 0                     1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.3410714	Sum Observations	-19.1
Std Deviation	0.81992833	Variance	0.67228247
Skewness	0.40598547	Kurtosis	2.45426732
Uncorrected SS	43.49	Corrected SS	36.9755357
Coeff Variation	-240.39784	Std Error Mean	0.10956753

Basic Statistical Measures

Location		Variability	
Mean	-0.34107	Std Deviation	0.81993
Median	-0.35000	Variance	0.67228
Mode	-0.50000	Range	5.10000
		Interquartile Range	0.95000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.11289	Pr > |t|	0.0029
Sign	M	-8	Pr >= |M|	0.0365

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-350.5	Pr >= |S|	0.0009

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.961266	Pr < W	0.0694
Kolmogorov-Smirnov	D	0.111802	Pr > D	0.0808
Cramer-von Mises	W-Sq	0.070726	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.512625	Pr > A-Sq	0.1952

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.60
99%	2.60
95%	0.90
90%	0.60
75% Q3	0.15

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.35
25% Q1	-0.80
10%	-1.30
5%	-1.60
1%	-2.50
0% Min	-2.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.5	19	0.7	39
-2.1	16	0.7	24
-1.6	47	0.9	5
-1.5	26	1.1	55
-1.3	48	2.6	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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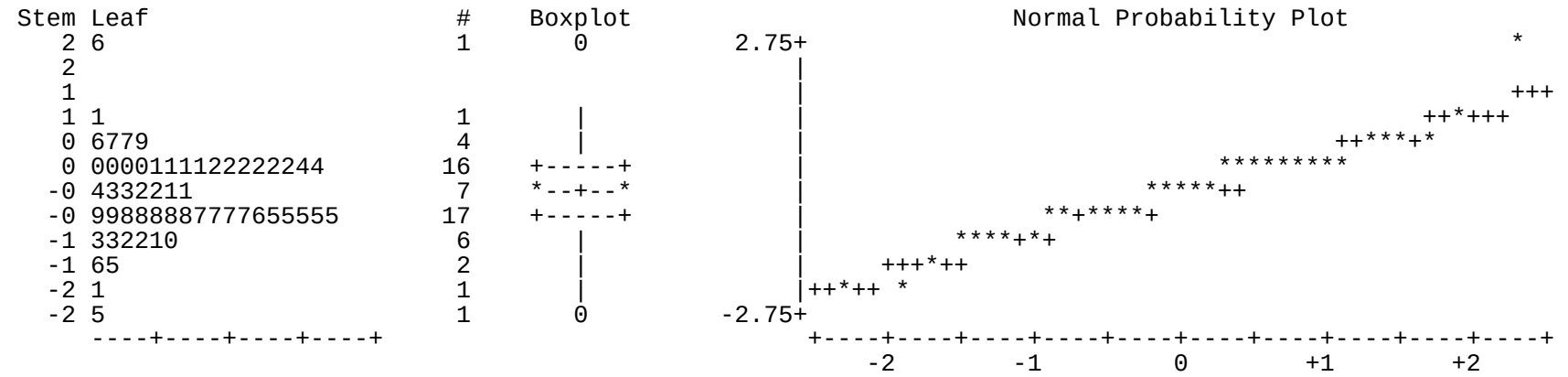
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	8.06724138	Sum Observations	467.9
Std Deviation	0.74630974	Variance	0.55697822
Skewness	-0.0072966	Kurtosis	-0.5029549
Uncorrected SS	3806.41	Corrected SS	31.7477586
Coeff Variation	9.25111448	Std Error Mean	0.09799527

Basic Statistical Measures

Location		Variability	
Mean	8.067241	Std Deviation	0.74631
Median	8.050000	Variance	0.55698
Mode	7.700000	Range	3.00000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	82.32276	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.984435	Pr < W	0.6620
Kolmogorov-Smirnov	D	0.054174	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.020498	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.165639	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.50
99%	9.50
95%	9.50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	9.10
75% Q3	8.60
50% Median	8.05
25% Q1	7.60
10%	7.10
5%	6.70
1%	6.50
0% Min	6.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	24	9.2	27
6.7	49	9.3	26
6.7	9	9.5	4
6.8	33	9.5	34
6.9	39	9.5	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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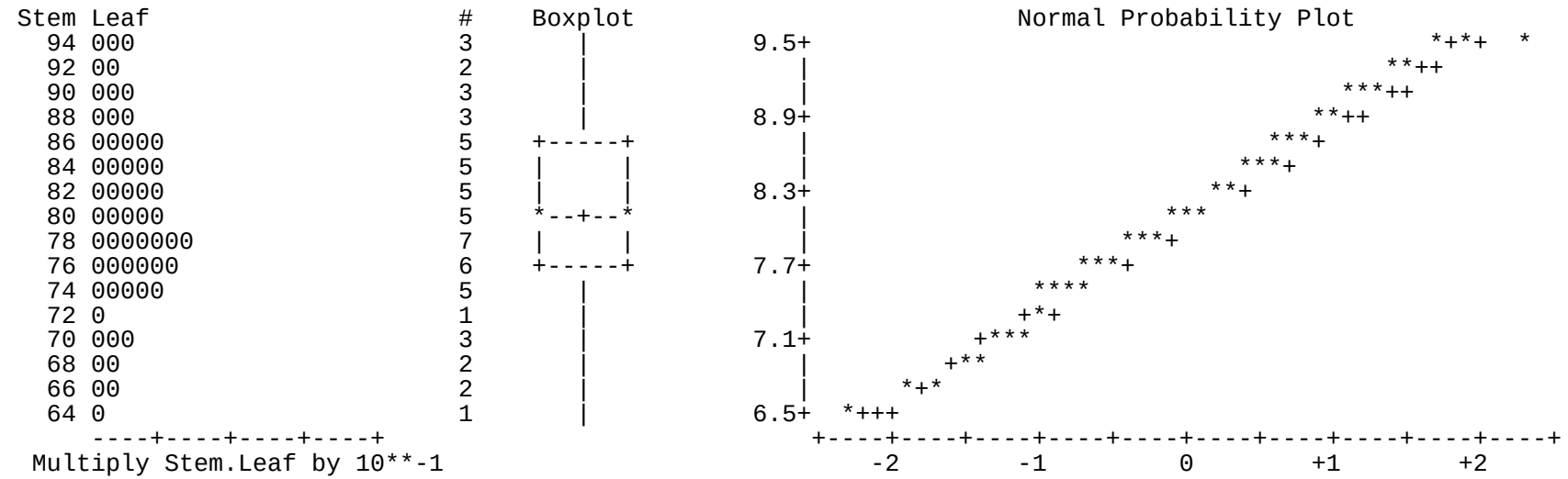
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	7.67931034	Sum Observations	445.4
Std Deviation	0.96295572	Variance	0.92728373
Skewness	0.27677237	Kurtosis	-0.2896889
Uncorrected SS	3473.22	Corrected SS	52.8551724
Coeff Variation	12.539612	Std Error Mean	0.12644228

Basic Statistical Measures

Location		Variability	
Mean	7.679310	Std Deviation	0.96296
Median	7.650000	Variance	0.92728
Mode	7.300000	Range	4.10000
		Interquartile Range	1.30000

NOTE: The mode displayed is the smallest of 3 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	60.73372	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.983809	Pr < W	0.6305
Kolmogorov-Smirnov	D	0.060794	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.024504	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.203363	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.90
99%	9.90
95%	9.70

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.90
75% Q3	8.30
50% Median	7.65
25% Q1	7.00
10%	6.50
5%	6.10
1%	5.80
0% Min	5.80

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.8	9	9.0	21
6.0	31	9.4	17
6.1	52	9.7	27
6.3	11	9.8	26
6.3	8	9.9	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

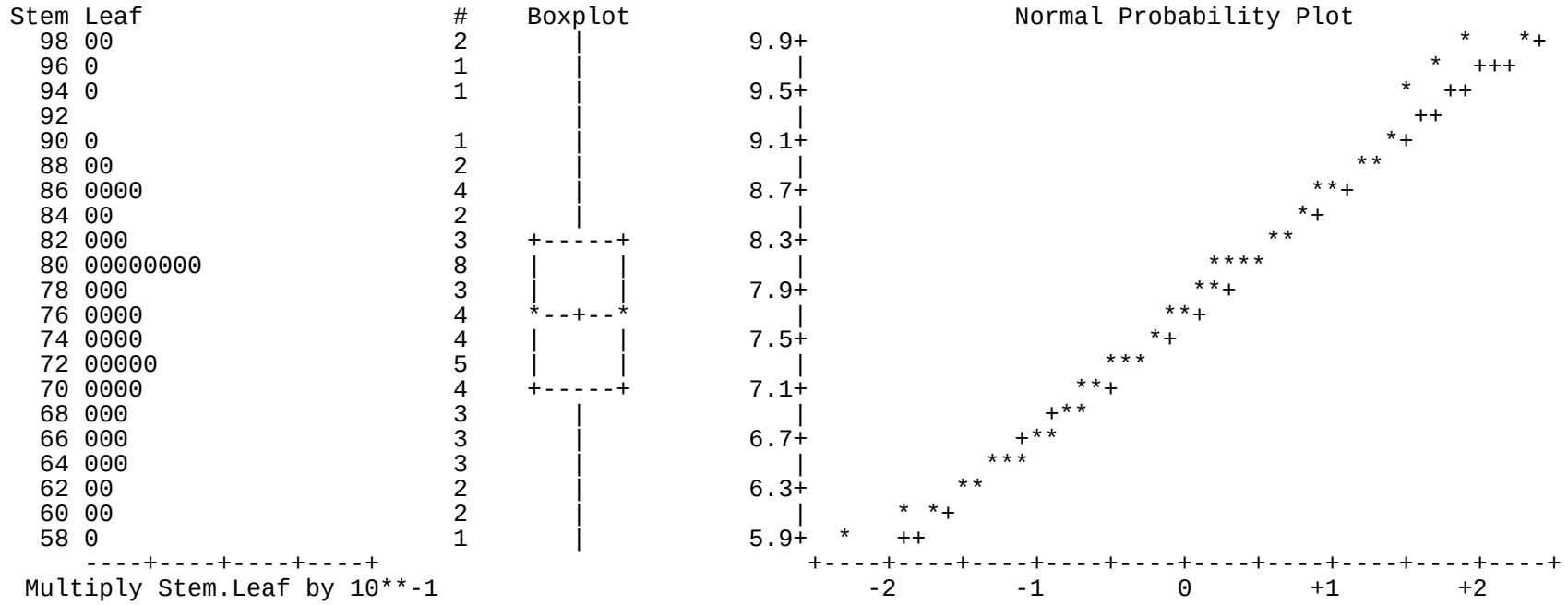

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.387931	Sum Observations	-22.5
Std Deviation	0.72039891	Variance	0.51897459
Skewness	-1.0073138	Kurtosis	1.40966231
Uncorrected SS	38.31	Corrected SS	29.5815517
Coeff Variation	-185.70283	Std Error Mean	0.09459301

Basic Statistical Measures

Location		Variability	
Mean	-0.38793	Std Deviation	0.72040
Median	-0.25000	Variance	0.51897
Mode	0.00000	Range	3.80000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-4.10105	Pr > |t|	0.0001
Sign	M	-9.5	Pr >= |M|	0.0110

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-389	Pr >= |S|	0.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.939405	Pr < W	0.0061
Kolmogorov-Smirnov	D	0.120822	Pr > D	0.0344
Cramer-von Mises	W-Sq	0.181951	Pr > W-Sq	0.0088
Anderson-Darling	A-Sq	1.037899	Pr > A-Sq	0.0093

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.90
99%	0.90
95%	0.50
90%	0.40
75% Q3	0.10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.25
25% Q1	-0.80
10%	-1.40
5%	-1.80
1%	-2.90
0% Min	-2.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.9	52	0.4	57
-1.8	19	0.5	26
-1.8	31	0.5	27
-1.6	8	0.7	54
-1.5	51	0.9	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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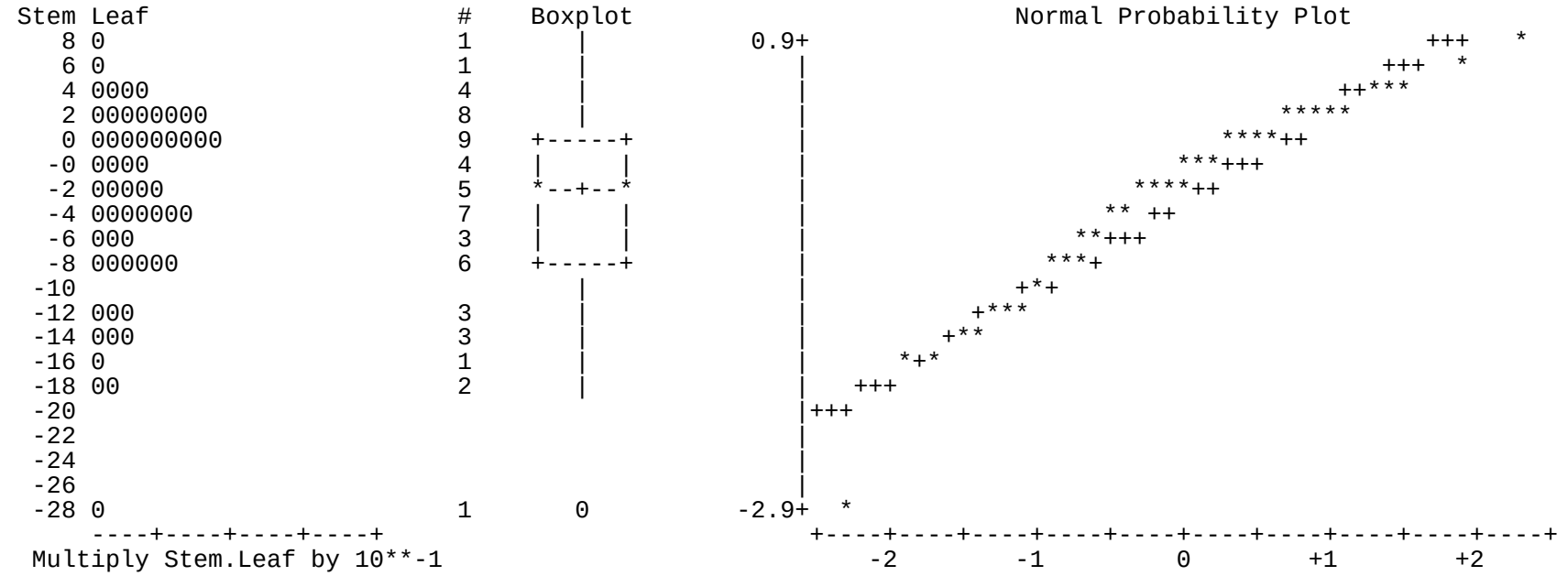
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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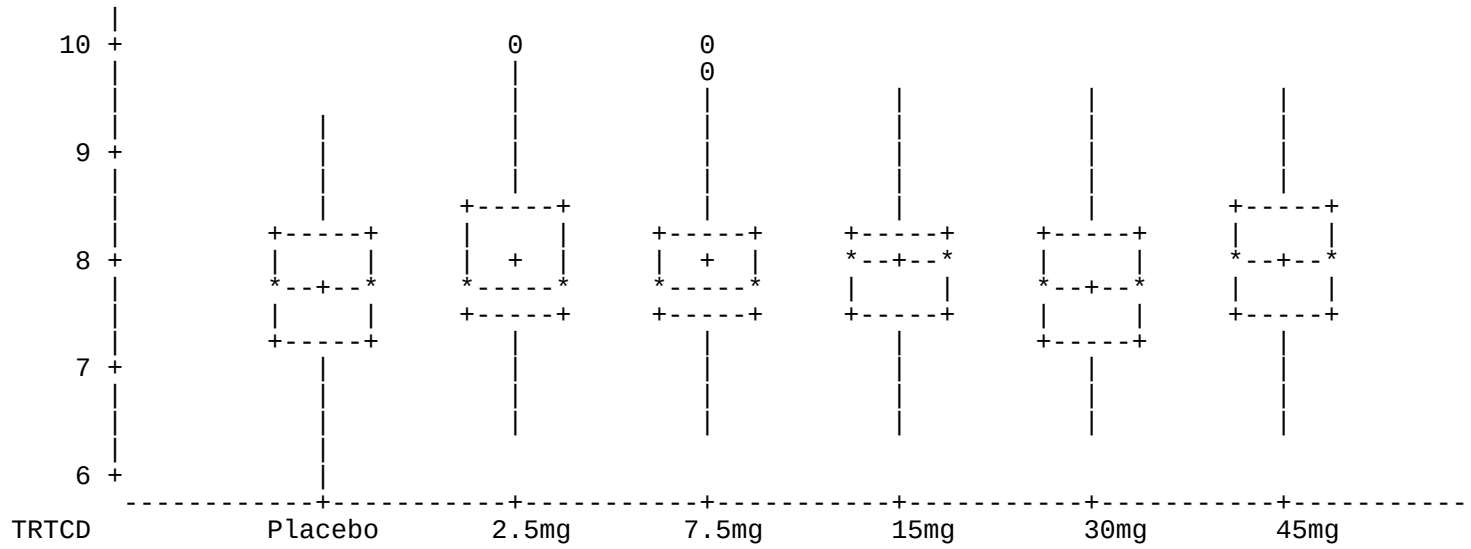
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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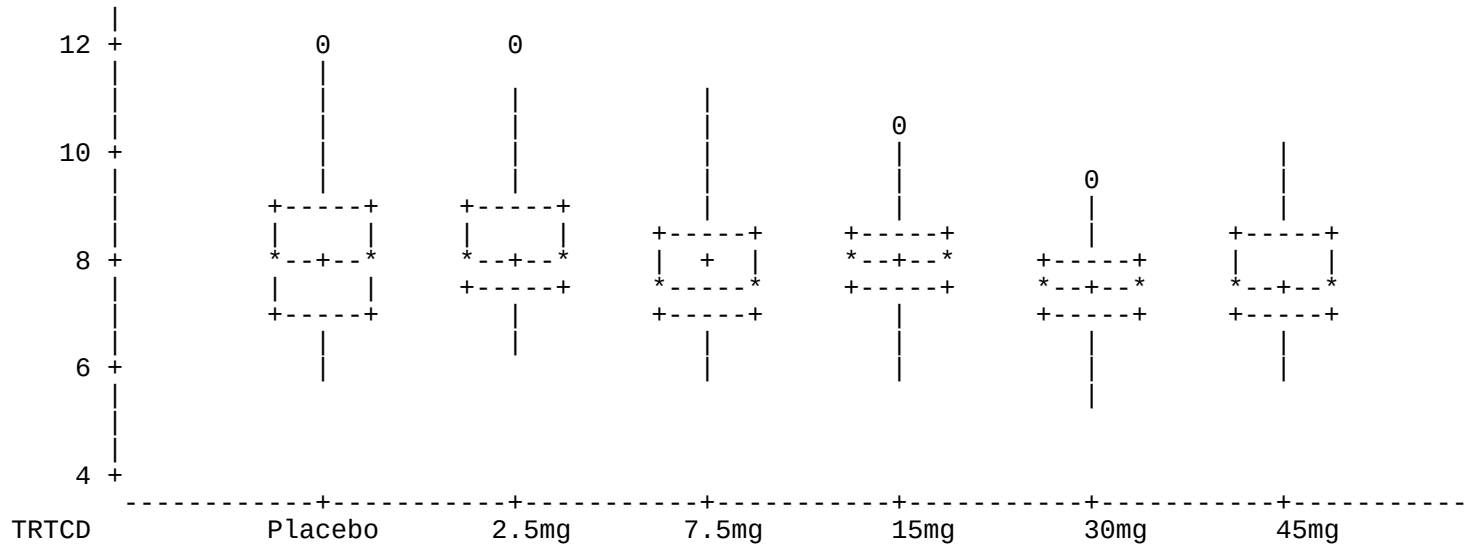
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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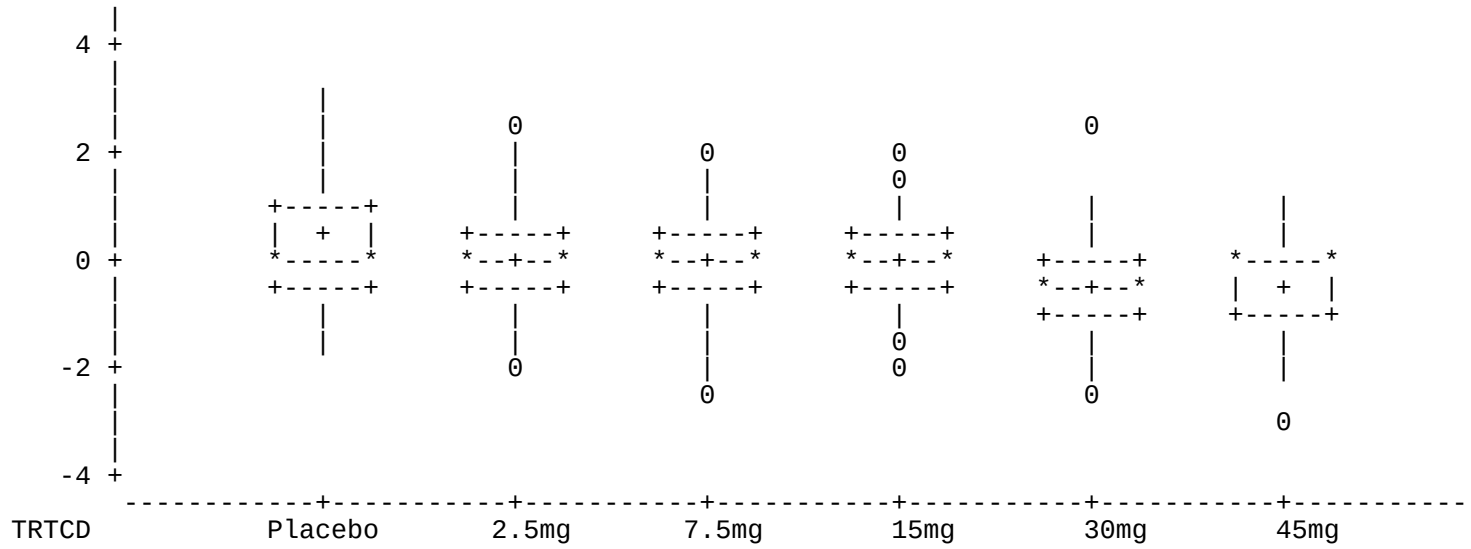
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6374	0.04896	13.02	<.0001	0.05	0.5514	0.7454

Fit Statistics

-2 Res Log Likelihood	856.3
AIC (smaller is better)	858.3
AICC (smaller is better)	858.3
BIC (smaller is better)	862.1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.5254	0.4818	339	1.09	0.2762
SEX	Female				-0.02282	0.08632	339	-0.26	0.7916
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.6532	0.08776	339	-7.44	<.0001
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	0.8399	0.1492	339	5.63	<.0001
TRTCD				2.5mg	0.5567	0.1497	339	3.72	0.0002
TRTCD				7.5mg	0.3120	0.1481	339	2.11	0.0358
TRTCD				15mg	0.3912	0.1464	339	2.67	0.0079
TRTCD				30mg	0.04267	0.1509	339	0.28	0.7775
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.4298	0.1009	339	-4.26	<.0001
REGIONCD			Eastern Europe		-0.1834	0.1072	339	-1.71	0.0879
REGIONCD			Western Europe		0				.
EFSTDBL					-0.05514	0.05839	339	-0.94	0.3457

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	339	0.07	0.7916
TRTTYPCD	1	339	55.40	<.0001
TRTCD	5	339	9.09	<.0001
REGIONCD	2	339	9.08	0.0001
EFSTDBL	1	339	0.89	0.3457

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2832	0.1508	339	-1.88	0.0612	0.05	-0.5798	0.01341
7.5mg vs Pbo	-0.5279	0.1481	339	-3.57	0.0004	0.05	-0.8192	-0.2366
15mg vs Pbo	-0.4487	0.1459	339	-3.08	0.0023	0.05	-0.7357	-0.1618
30mg vs Pbo	-0.7972	0.1491	339	-5.35	<.0001	0.05	-1.0904	-0.5040
45mg vs Pbo	-0.8399	0.1492	339	-5.63	<.0001	0.05	-1.1335	-0.5463

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.4971	0.4971	0.4971	0.4971	0.4971
SEX	Male				0.5029	0.5029	0.5029	0.5029	0.5029
TRTTYPCD		Diet & Exercise			0.4086	0.4086	0.4086	0.4086	0.4086
TRTTYPCD		Monotherapy			0.5914	0.5914	0.5914	0.5914	0.5914
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3257	0.3257	0.3257	0.3257	0.3257
REGIONCD			Eastern Europe		0.2714	0.2714	0.2714	0.2714	0.2714
REGIONCD			Western Europe		0.4029	0.4029	0.4029	0.4029	0.4029
EFSTDBL					7.9117	7.9117	7.9117	7.9117	7.9117

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.4971
SEX	Male				0.5029
TRTTYPCD		Diet & Exercise			0.4086
TRTTYPCD		Monotherapy			0.5914
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3257
REGIONCD			Eastern Europe		0.2714
REGIONCD			Western Europe		0.4029
EFSTDBL					7.9117

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.4611	0.1047	339	4.40	<.0001	0.05	0.2551	0.6671
TRTCD	2.5mg	WORK.EFF	0.1779	0.1073	339	1.66	0.0982	0.05	-0.03314	0.3890
TRTCD	7.5mg	WORK.EFF	-0.06680	0.1042	339	-0.64	0.5220	0.05	-0.2718	0.1382
TRTCD	15mg	WORK.EFF	0.01236	0.1015	339	0.12	0.9032	0.05	-0.1873	0.2120
TRTCD	30mg	WORK.EFF	-0.3361	0.1072	339	-3.14	0.0019	0.05	-0.5470	-0.1253
TRTCD	45mg	WORK.EFF	-0.3788	0.1053	339	-3.60	0.0004	0.05	-0.5860	-0.1716

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.2832	0.1508	339	1.88	0.0612	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.5279	0.1481	339	3.57	0.0004	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.4487	0.1459	339	3.08	0.0023	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.7972	0.1491	339	5.35	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.8399	0.1492	339	5.63	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.2447	0.1496	339	1.64	0.1027	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1656	0.1477	339	1.12	0.2629	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5141	0.1524	339	3.37	0.0008	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5567	0.1497	339	3.72	0.0002	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.07915	0.1455	339	-0.54	0.5868	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.2693	0.1497	339	1.80	0.0728	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.3120	0.1481	339	2.11	0.0358	0.05
TRTCD	15mg	30mg	WORK.EFF	0.3485	0.1476	339	2.36	0.0188	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3912	0.1464	339	2.67	0.0079	0.05
TRTCD	30mg	45mg	WORK.EFF	0.04267	0.1509	339	0.28	0.7775	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.01341	0.5798
TRTCD	Placebo	7.5mg	0.2366	0.8192
TRTCD	Placebo	15mg	0.1618	0.7357
TRTCD	Placebo	30mg	0.5040	1.0904
TRTCD	Placebo	45mg	0.5463	1.1335
TRTCD	2.5mg	7.5mg	-0.04948	0.5389
TRTCD	2.5mg	15mg	-0.1249	0.4560
TRTCD	2.5mg	30mg	0.2144	0.8137
TRTCD	2.5mg	45mg	0.2622	0.8513
TRTCD	7.5mg	15mg	-0.3654	0.2071

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.02504	0.5637
TRTCD	7.5mg	45mg	0.02078	0.6032
TRTCD	15mg	30mg	0.05807	0.6389
TRTCD	15mg	45mg	0.1033	0.6790
TRTCD	30mg	45mg	-0.2541	0.3394

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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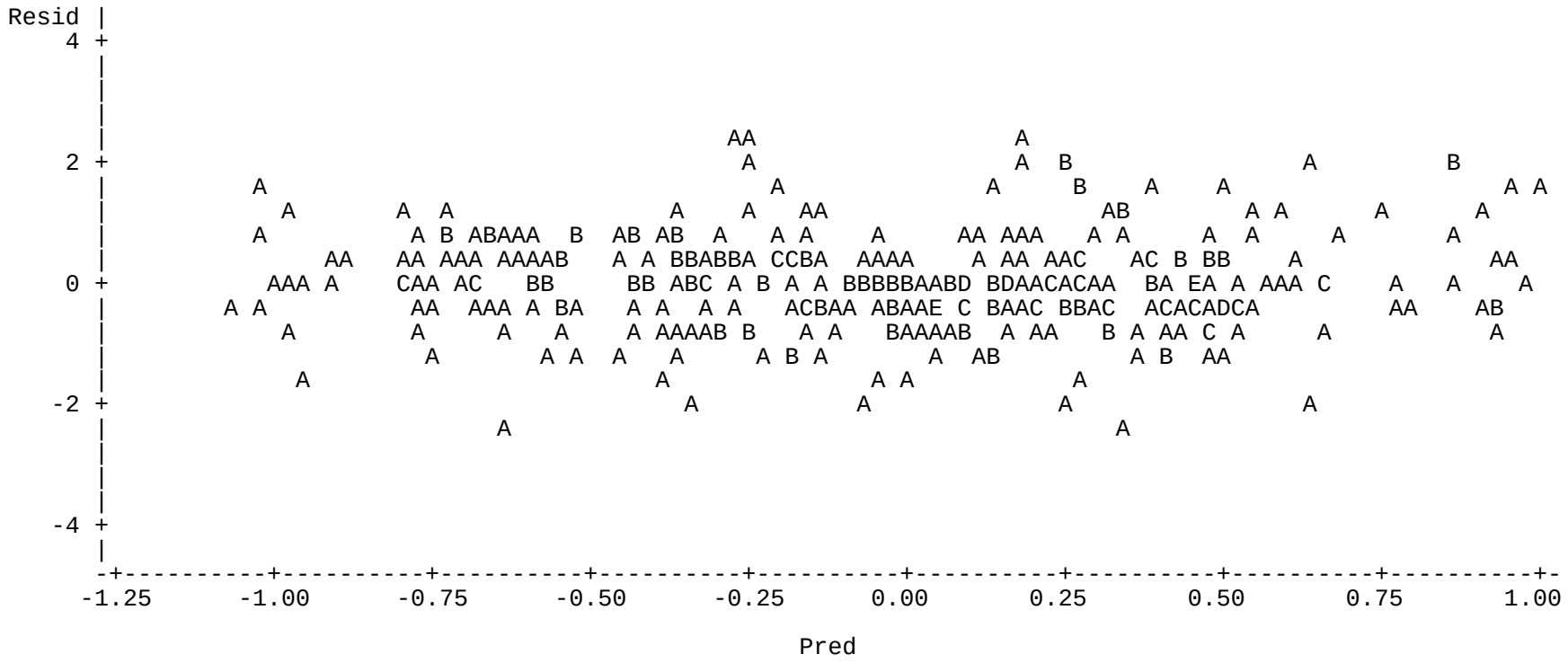
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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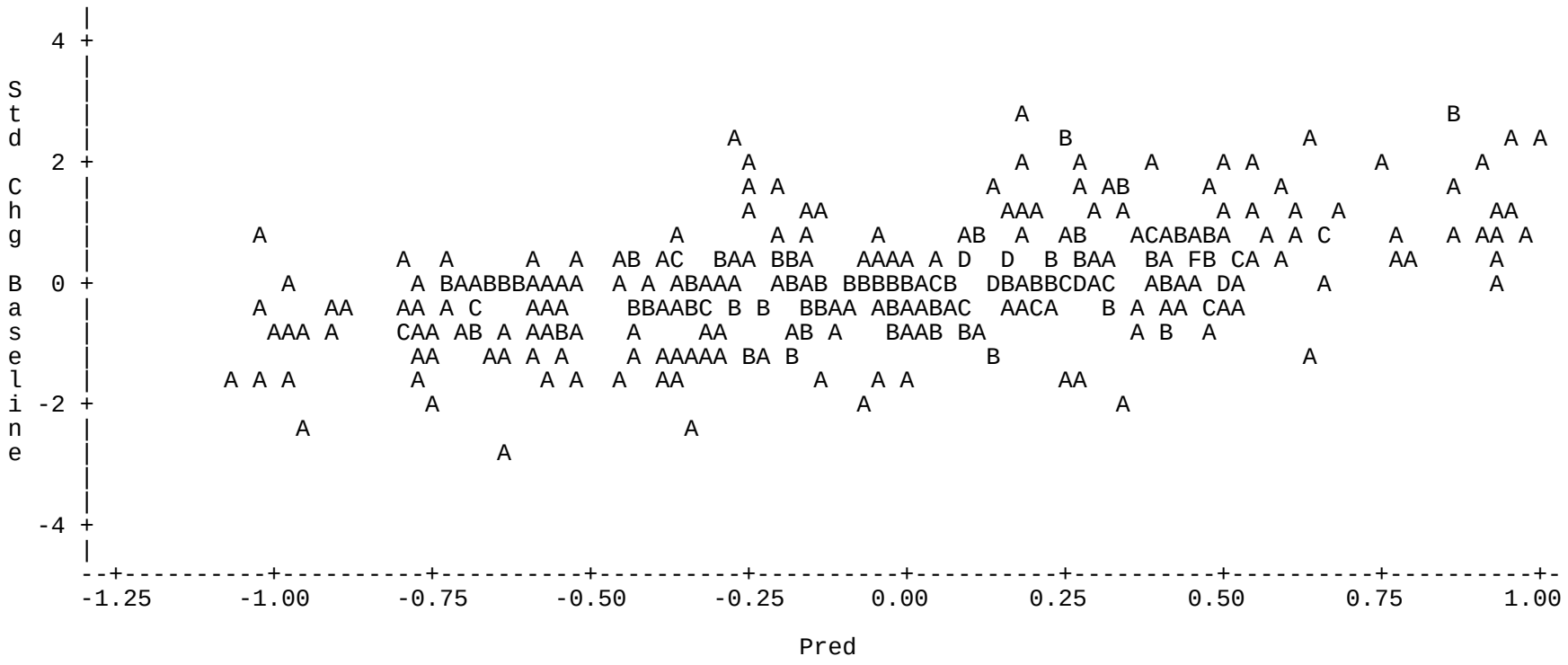
Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	350	Sum Weights	350
Mean	0	Sum Observations	0
Std Deviation	0.78687419	Variance	0.61917099
Skewness	0.28907545	Kurtosis	0.86778672
Uncorrected SS	216.090677	Corrected SS	216.090677
Coeff Variation		Std Error Mean	0.04206019

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.78687
Median	-0.04223	Variance	0.61917
Mode	0.04541	Range	4.71631
		Interquartile Range	0.86399

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-8	Pr >= |M|	0.4227
Signed Rank	S	-1241.5	Pr >= |S|	0.5130

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.981636	Pr < W	0.0002
Kolmogorov-Smirnov	D	0.058928	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.357161	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.118573	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.4631634
99%	2.1407770
95%	1.4179541
90%	0.9453450
75% Q3	0.4115800
50% Median	-0.0422261
25% Q1	-0.4524098
10%	-0.8747640
5%	-1.2182055
1%	-1.9541313
0% Min	-2.2531486

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-2.25315	298	1.95104	234
-2.24046	303	2.14078	327
-2.04109	236	2.34034	340
-1.95413	297	2.42335	320
-1.94820	40	2.46316	311

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Stem	Leaf	#	Boxplot
24	26	2	0
22	4	1	0
20	4	1	0
18	0733355	7	0
16	123	3	0
14	12157	5	|
12	66673558	8	|
10	0789023	7	|
8	0245791123345	13	|
6	02233345555578837789	20	|
4	01111334446888800112346	23	+-----+
2	000133344455566678900112234556778889	35	| |
0	000111133344555568889990000111233334466788	42	| + |
-0	9887766665444333222110998887777765543332221	44	*-----*
-2	998885332211088887777666666554443322211	39	| |
-4	995554322000999888866553332222110O	34	+-----+
-6	99997776655322097521	20	|
-8	98753965433221100	17	|
-10	87610009443	11	|
-12	6635542	7	|
-14	42	2	|
-16	869	3	0
-18	552	3	0
-20	4	1	0
-22	54	2	0

Multiply Stem.Leaf by 10**-1

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Table 11.3
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Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot

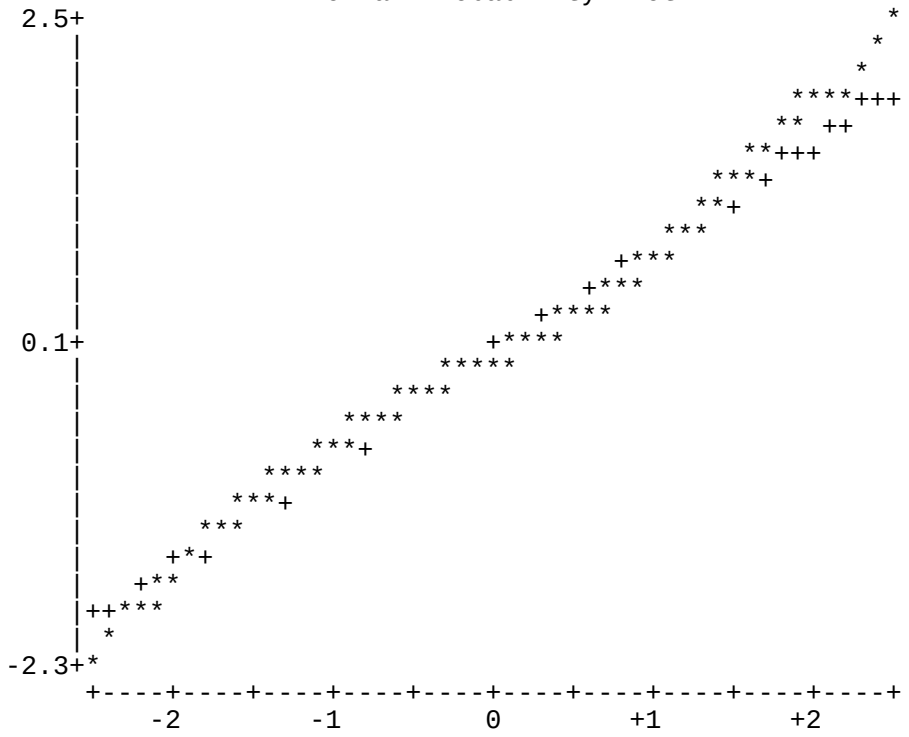

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

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Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6388	0.04943	12.92	<.0001	0.05	0.5520	0.7480

Fit Statistics

-2 Res Log Likelihood	856.6
AIC (smaller is better)	858.6
AICC (smaller is better)	858.6
BIC (smaller is better)	862.4

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.5866	0.4895	334	1.20	0.2316
SEX	Female				-0.1449	0.2112	334	-0.69	0.4932
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.6524	0.08791	334	-7.42	<.0001
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	0.9255	0.2130	334	4.35	<.0001
TRTCD				2.5mg	0.3636	0.2107	334	1.73	0.0854
TRTCD				7.5mg	0.2146	0.2101	334	1.02	0.3077
TRTCD				15mg	0.3132	0.2055	334	1.52	0.1285
TRTCD				30mg	-0.05154	0.2191	334	-0.24	0.8142
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.4178	0.1020	334	-4.10	<.0001
REGIONCD			Eastern Europe		-0.1922	0.1076	334	-1.79	0.0750
REGIONCD			Western Europe		0				.
EFSTDBL					-0.05509	0.05852	334	-0.94	0.3472
SEX*TRTCD	Female			Placebo	-0.1739	0.2964	334	-0.59	0.5578
SEX*TRTCD	Female			2.5mg	0.4035	0.3029	334	1.33	0.1837
SEX*TRTCD	Female			7.5mg	0.1921	0.2963	334	0.65	0.5173
SEX*TRTCD	Female			15mg	0.1532	0.2926	334	0.52	0.6009
SEX*TRTCD	Female			30mg	0.1785	0.3018	334	0.59	0.5546
SEX*TRTCD	Female			45mg	0				.
SEX*TRTCD	Male			Placebo	0				.
SEX*TRTCD	Male			2.5mg	0				.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male			7.5mg	0				.
SEX*TRTCD	Male			15mg	0				.
SEX*TRTCD	Male			30mg	0				.
SEX*TRTCD	Male			45mg	0				.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	334	0.05	0.8236
TRTTYPCD	1	334	55.07	<.0001
TRTCD	5	334	9.15	<.0001
REGIONCD	2	334	8.40	0.0003
EFSTDBL	1	334	0.89	0.3472
SEX*TRTCD	5	334	0.85	0.5140

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2732	0.1512	334	-1.81	0.0717	0.05	-0.5707	0.02425
7.5mg vs Pbo	-0.5279	0.1483	334	-3.56	0.0004	0.05	-0.8195	-0.2363
15mg vs Pbo	-0.4488	0.1462	334	-3.07	0.0023	0.05	-0.7363	-0.1612
30mg vs Pbo	-0.8009	0.1494	334	-5.36	<.0001	0.05	-1.0948	-0.5070
45mg vs Pbo	-0.8386	0.1495	334	-5.61	<.0001	0.05	-1.1326	-0.5446

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	Placebo	WORK.EFF	0.3028	0.1462	334	2.07	0.0391	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	Placebo	0.01518	0.5903

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	2.5mg	WORK.EFF	0.3183	0.1590	334	2.00	0.0462	0.05
SEX*TRTCD	Female	7.5mg	WORK.EFF	-0.04216	0.1487	334	-0.28	0.7769	0.05
SEX*TRTCD	Female	15mg	WORK.EFF	0.01756	0.1490	334	0.12	0.9062	0.05
SEX*TRTCD	Female	30mg	WORK.EFF	-0.3219	0.1463	334	-2.20	0.0284	0.05
SEX*TRTCD	Female	45mg	WORK.EFF	-0.4489	0.1471	334	-3.05	0.0025	0.05
SEX*TRTCD	Male	Placebo	WORK.EFF	0.6215	0.1494	334	4.16	<.0001	0.05
SEX*TRTCD	Male	2.5mg	WORK.EFF	0.05960	0.1463	334	0.41	0.6840	0.05
SEX*TRTCD	Male	7.5mg	WORK.EFF	-0.08937	0.1461	334	-0.61	0.5412	0.05
SEX*TRTCD	Male	15mg	WORK.EFF	0.009224	0.1394	334	0.07	0.9473	0.05
SEX*TRTCD	Male	30mg	WORK.EFF	-0.3556	0.1579	334	-2.25	0.0250	0.05
SEX*TRTCD	Male	45mg	WORK.EFF	-0.3040	0.1513	334	-2.01	0.0454	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	2.5mg	0.005432	0.6311
SEX*TRTCD	Female	7.5mg	-0.3346	0.2503
SEX*TRTCD	Female	15mg	-0.2755	0.3106
SEX*TRTCD	Female	30mg	-0.6096	-0.03420
SEX*TRTCD	Female	45mg	-0.7383	-0.1594

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Male	Placebo	0.3276	0.9154
SEX*TRTCD	Male	2.5mg	-0.2282	0.3474
SEX*TRTCD	Male	7.5mg	-0.3768	0.1981
SEX*TRTCD	Male	15mg	-0.2650	0.2835
SEX*TRTCD	Male	30mg	-0.6662	-0.04495
SEX*TRTCD	Male	45mg	-0.6017	-0.00633

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Female	2.5mg	WORK.EFF	-0.01553	0.2169	334	-0.07	0.9430
SEX*TRTCD	Female	Placebo	Female	7.5mg	WORK.EFF	0.3449	0.2087	334	1.65	0.0993
SEX*TRTCD	Female	Placebo	Female	15mg	WORK.EFF	0.2852	0.2087	334	1.37	0.1727
SEX*TRTCD	Female	Placebo	Female	30mg	WORK.EFF	0.6247	0.2067	334	3.02	0.0027
SEX*TRTCD	Female	Placebo	Female	45mg	WORK.EFF	0.7516	0.2080	334	3.61	0.0003
SEX*TRTCD	Female	Placebo	Male	Placebo	WORK.EFF	-0.3188	0.2083	334	-1.53	0.1269
SEX*TRTCD	Female	Placebo	Male	2.5mg	WORK.EFF	0.2431	0.2067	334	1.18	0.2403
SEX*TRTCD	Female	Placebo	Male	7.5mg	WORK.EFF	0.3921	0.2069	334	1.90	0.0589
SEX*TRTCD	Female	Placebo	Male	15mg	WORK.EFF	0.2935	0.2020	334	1.45	0.1471

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Male	30mg	WORK.EFF	0.6583	0.2145	334	3.07	0.0023
SEX*TRTCD	Female	Placebo	Male	45mg	WORK.EFF	0.6068	0.2106	334	2.88	0.0042
SEX*TRTCD	Female	2.5mg	Female	7.5mg	WORK.EFF	0.3604	0.2175	334	1.66	0.0984
SEX*TRTCD	Female	2.5mg	Female	15mg	WORK.EFF	0.3007	0.2179	334	1.38	0.1686
SEX*TRTCD	Female	2.5mg	Female	30mg	WORK.EFF	0.6402	0.2157	334	2.97	0.0032
SEX*TRTCD	Female	2.5mg	Female	45mg	WORK.EFF	0.7672	0.2157	334	3.56	0.0004
SEX*TRTCD	Female	2.5mg	Male	Placebo	WORK.EFF	-0.3033	0.2202	334	-1.38	0.1693
SEX*TRTCD	Female	2.5mg	Male	2.5mg	WORK.EFF	0.2587	0.2167	334	1.19	0.2335
SEX*TRTCD	Female	2.5mg	Male	7.5mg	WORK.EFF	0.4077	0.2157	334	1.89	0.0596
SEX*TRTCD	Female	2.5mg	Male	15mg	WORK.EFF	0.3091	0.2114	334	1.46	0.1447
SEX*TRTCD	Female	2.5mg	Male	30mg	WORK.EFF	0.6738	0.2264	334	2.98	0.0031
SEX*TRTCD	Female	2.5mg	Male	45mg	WORK.EFF	0.6223	0.2188	334	2.84	0.0047
SEX*TRTCD	Female	7.5mg	Female	15mg	WORK.EFF	-0.05972	0.2107	334	-0.28	0.7770
SEX*TRTCD	Female	7.5mg	Female	30mg	WORK.EFF	0.2798	0.2087	334	1.34	0.1809
SEX*TRTCD	Female	7.5mg	Female	45mg	WORK.EFF	0.4067	0.2091	334	1.95	0.0526
SEX*TRTCD	Female	7.5mg	Male	Placebo	WORK.EFF	-0.6637	0.2111	334	-3.14	0.0018
SEX*TRTCD	Female	7.5mg	Male	2.5mg	WORK.EFF	-0.1018	0.2088	334	-0.49	0.6263
SEX*TRTCD	Female	7.5mg	Male	7.5mg	WORK.EFF	0.04721	0.2082	334	0.23	0.8208
SEX*TRTCD	Female	7.5mg	Male	15mg	WORK.EFF	-0.05138	0.2036	334	-0.25	0.8009
SEX*TRTCD	Female	7.5mg	Male	30mg	WORK.EFF	0.3134	0.2170	334	1.44	0.1496
SEX*TRTCD	Female	7.5mg	Male	45mg	WORK.EFF	0.2619	0.2120	334	1.23	0.2177
SEX*TRTCD	Female	15mg	Female	30mg	WORK.EFF	0.3395	0.2088	334	1.63	0.1050
SEX*TRTCD	Female	15mg	Female	45mg	WORK.EFF	0.4664	0.2087	334	2.23	0.0261

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	15mg	Male	Placebo	WORK.EFF	-0.6040	0.2111	334	-2.86	0.0045
SEX*TRTCD	Female	15mg	Male	2.5mg	WORK.EFF	-0.04204	0.2085	334	-0.20	0.8403
SEX*TRTCD	Female	15mg	Male	7.5mg	WORK.EFF	0.1069	0.2090	334	0.51	0.6093
SEX*TRTCD	Female	15mg	Male	15mg	WORK.EFF	0.008338	0.2045	334	0.04	0.9675
SEX*TRTCD	Female	15mg	Male	30mg	WORK.EFF	0.3731	0.2172	334	1.72	0.0867
SEX*TRTCD	Female	15mg	Male	45mg	WORK.EFF	0.3216	0.2128	334	1.51	0.1317
SEX*TRTCD	Female	30mg	Female	45mg	WORK.EFF	0.1270	0.2080	334	0.61	0.5420
SEX*TRTCD	Female	30mg	Male	Placebo	WORK.EFF	-0.9435	0.2091	334	-4.51	<.0001
SEX*TRTCD	Female	30mg	Male	2.5mg	WORK.EFF	-0.3815	0.2072	334	-1.84	0.0665
SEX*TRTCD	Female	30mg	Male	7.5mg	WORK.EFF	-0.2325	0.2068	334	-1.12	0.2616
SEX*TRTCD	Female	30mg	Male	15mg	WORK.EFF	-0.3311	0.2018	334	-1.64	0.1018
SEX*TRTCD	Female	30mg	Male	30mg	WORK.EFF	0.03364	0.2154	334	0.16	0.8760
SEX*TRTCD	Female	30mg	Male	45mg	WORK.EFF	-0.01791	0.2104	334	-0.09	0.9322
SEX*TRTCD	Female	45mg	Male	Placebo	WORK.EFF	-1.0704	0.2107	334	-5.08	<.0001
SEX*TRTCD	Female	45mg	Male	2.5mg	WORK.EFF	-0.5085	0.2071	334	-2.46	0.0146
SEX*TRTCD	Female	45mg	Male	7.5mg	WORK.EFF	-0.3595	0.2075	334	-1.73	0.0840
SEX*TRTCD	Female	45mg	Male	15mg	WORK.EFF	-0.4581	0.2033	334	-2.25	0.0249
SEX*TRTCD	Female	45mg	Male	30mg	WORK.EFF	-0.09332	0.2167	334	-0.43	0.6670
SEX*TRTCD	Female	45mg	Male	45mg	WORK.EFF	-0.1449	0.2112	334	-0.69	0.4932
SEX*TRTCD	Male	Placebo	Male	2.5mg	WORK.EFF	0.5619	0.2088	334	2.69	0.0075
SEX*TRTCD	Male	Placebo	Male	7.5mg	WORK.EFF	0.7109	0.2092	334	3.40	0.0008
SEX*TRTCD	Male	Placebo	Male	15mg	WORK.EFF	0.6123	0.2043	334	3.00	0.0029
SEX*TRTCD	Male	Placebo	Male	30mg	WORK.EFF	0.9771	0.2160	334	4.52	<.0001

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male	Placebo	Male	45mg	WORK.EFF	0.9255	0.2130	334	4.35	<.0001
SEX*TRTCD	Male	2.5mg	Male	7.5mg	WORK.EFF	0.1490	0.2070	334	0.72	0.4722
SEX*TRTCD	Male	2.5mg	Male	15mg	WORK.EFF	0.05038	0.2025	334	0.25	0.8037
SEX*TRTCD	Male	2.5mg	Male	30mg	WORK.EFF	0.4152	0.2149	334	1.93	0.0542
SEX*TRTCD	Male	2.5mg	Male	45mg	WORK.EFF	0.3636	0.2107	334	1.73	0.0854
SEX*TRTCD	Male	7.5mg	Male	15mg	WORK.EFF	-0.09859	0.2017	334	-0.49	0.6254
SEX*TRTCD	Male	7.5mg	Male	30mg	WORK.EFF	0.2662	0.2153	334	1.24	0.2172
SEX*TRTCD	Male	7.5mg	Male	45mg	WORK.EFF	0.2146	0.2101	334	1.02	0.3077
SEX*TRTCD	Male	15mg	Male	30mg	WORK.EFF	0.3648	0.2106	334	1.73	0.0842
SEX*TRTCD	Male	15mg	Male	45mg	WORK.EFF	0.3132	0.2055	334	1.52	0.1285
SEX*TRTCD	Male	30mg	Male	45mg	WORK.EFF	-0.05154	0.2191	334	-0.24	0.8142

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Female	2.5mg	0.05	-0.4423	0.4112
SEX*TRTCD	Female	Placebo	Female	7.5mg	0.05	-0.06561	0.7554
SEX*TRTCD	Female	Placebo	Female	15mg	0.05	-0.1253	0.6957
SEX*TRTCD	Female	Placebo	Female	30mg	0.05	0.2181	1.0313
SEX*TRTCD	Female	Placebo	Female	45mg	0.05	0.3426	1.1607

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Male	Placebo	0.05	-0.7286	0.09102
SEX*TRTCD	Female	Placebo	Male	2.5mg	0.05	-0.1634	0.6497
SEX*TRTCD	Female	Placebo	Male	7.5mg	0.05	-0.01480	0.7990
SEX*TRTCD	Female	Placebo	Male	15mg	0.05	-0.1038	0.6909
SEX*TRTCD	Female	Placebo	Male	30mg	0.05	0.2364	1.0803
SEX*TRTCD	Female	Placebo	Male	45mg	0.05	0.1925	1.0211
SEX*TRTCD	Female	2.5mg	Female	7.5mg	0.05	-0.06741	0.7883
SEX*TRTCD	Female	2.5mg	Female	15mg	0.05	-0.1280	0.7294
SEX*TRTCD	Female	2.5mg	Female	30mg	0.05	0.2159	1.0645
SEX*TRTCD	Female	2.5mg	Female	45mg	0.05	0.3429	1.1915
SEX*TRTCD	Female	2.5mg	Male	Placebo	0.05	-0.7363	0.1298
SEX*TRTCD	Female	2.5mg	Male	2.5mg	0.05	-0.1677	0.6850
SEX*TRTCD	Female	2.5mg	Male	7.5mg	0.05	-0.01663	0.8319
SEX*TRTCD	Female	2.5mg	Male	15mg	0.05	-0.1068	0.7249
SEX*TRTCD	Female	2.5mg	Male	30mg	0.05	0.2286	1.1191
SEX*TRTCD	Female	2.5mg	Male	45mg	0.05	0.1918	1.0528
SEX*TRTCD	Female	7.5mg	Female	15mg	0.05	-0.4741	0.3547
SEX*TRTCD	Female	7.5mg	Female	30mg	0.05	-0.1307	0.6902
SEX*TRTCD	Female	7.5mg	Female	45mg	0.05	-0.00461	0.8180
SEX*TRTCD	Female	7.5mg	Male	Placebo	0.05	-1.0789	-0.2485
SEX*TRTCD	Female	7.5mg	Male	2.5mg	0.05	-0.5125	0.3089
SEX*TRTCD	Female	7.5mg	Male	7.5mg	0.05	-0.3624	0.4568
SEX*TRTCD	Female	7.5mg	Male	15mg	0.05	-0.4519	0.3492

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	7.5mg	Male	30mg	0.05	-0.1135	0.7402
SEX*TRTCD	Female	7.5mg	Male	45mg	0.05	-0.1552	0.6789
SEX*TRTCD	Female	15mg	Female	30mg	0.05	-0.07135	0.7503
SEX*TRTCD	Female	15mg	Female	45mg	0.05	0.05586	0.8770
SEX*TRTCD	Female	15mg	Male	Placebo	0.05	-1.0192	-0.1888
SEX*TRTCD	Female	15mg	Male	2.5mg	0.05	-0.4522	0.3681
SEX*TRTCD	Female	15mg	Male	7.5mg	0.05	-0.3043	0.5181
SEX*TRTCD	Female	15mg	Male	15mg	0.05	-0.3939	0.4106
SEX*TRTCD	Female	15mg	Male	30mg	0.05	-0.05410	0.8003
SEX*TRTCD	Female	15mg	Male	45mg	0.05	-0.09699	0.7401
SEX*TRTCD	Female	30mg	Female	45mg	0.05	-0.2822	0.5361
SEX*TRTCD	Female	30mg	Male	Placebo	0.05	-1.3547	-0.5322
SEX*TRTCD	Female	30mg	Male	2.5mg	0.05	-0.7891	0.02608
SEX*TRTCD	Female	30mg	Male	7.5mg	0.05	-0.6393	0.1742
SEX*TRTCD	Female	30mg	Male	15mg	0.05	-0.7282	0.06590
SEX*TRTCD	Female	30mg	Male	30mg	0.05	-0.3901	0.4574
SEX*TRTCD	Female	30mg	Male	45mg	0.05	-0.4317	0.3959
SEX*TRTCD	Female	45mg	Male	Placebo	0.05	-1.4848	-0.6560
SEX*TRTCD	Female	45mg	Male	2.5mg	0.05	-0.9158	-0.1012
SEX*TRTCD	Female	45mg	Male	7.5mg	0.05	-0.7676	0.04859
SEX*TRTCD	Female	45mg	Male	15mg	0.05	-0.8581	-0.05812
SEX*TRTCD	Female	45mg	Male	30mg	0.05	-0.5197	0.3330
SEX*TRTCD	Female	45mg	Male	45mg	0.05	-0.5603	0.2706

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Male	Placebo	Male	2.5mg	0.05	0.1512	0.9726
SEX*TRTCD	Male	Placebo	Male	7.5mg	0.05	0.2993	1.1225
SEX*TRTCD	Male	Placebo	Male	15mg	0.05	0.2104	1.0143
SEX*TRTCD	Male	Placebo	Male	30mg	0.05	0.5523	1.4019
SEX*TRTCD	Male	Placebo	Male	45mg	0.05	0.5065	1.3446
SEX*TRTCD	Male	2.5mg	Male	7.5mg	0.05	-0.2582	0.5561
SEX*TRTCD	Male	2.5mg	Male	15mg	0.05	-0.3480	0.4487
SEX*TRTCD	Male	2.5mg	Male	30mg	0.05	-0.00758	0.8379
SEX*TRTCD	Male	2.5mg	Male	45mg	0.05	-0.05093	0.7782
SEX*TRTCD	Male	7.5mg	Male	15mg	0.05	-0.4954	0.2983
SEX*TRTCD	Male	7.5mg	Male	30mg	0.05	-0.1573	0.6897
SEX*TRTCD	Male	7.5mg	Male	45mg	0.05	-0.1987	0.6279
SEX*TRTCD	Male	15mg	Male	30mg	0.05	-0.04951	0.7791
SEX*TRTCD	Male	15mg	Male	45mg	0.05	-0.09110	0.7176
SEX*TRTCD	Male	30mg	Male	45mg	0.05	-0.4826	0.3795

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6301	0.04876	12.92	<.0001	0.05	0.5445	0.7378

Fit Statistics

-2 Res Log Likelihood	851.8
AIC (smaller is better)	853.8
AICC (smaller is better)	853.8
BIC (smaller is better)	857.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.5878	0.4900	334	1.20
SEX	Female				-0.02279	0.08588	334	-0.27
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6520	0.2158	334	-3.02
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.9953	0.1948	334	5.11
TRTCD				2.5mg	0.6648	0.1927	334	3.45
TRTCD				7.5mg	0.1553	0.1911	334	0.81
TRTCD				15mg	0.3029	0.1857	334	1.63
TRTCD				30mg	0.05142	0.1963	334	0.26
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.4259	0.1009	334	-4.22
REGIONCD			Eastern Europe		-0.1561	0.1082	334	-1.44
REGIONCD			Western Europe		0			
EFSTDBL					-0.06413	0.05846	334	-1.10
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	-0.3398	0.2980	334	-1.14
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	-0.2791	0.3081	334	-0.91
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.3875	0.3034	334	1.28
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.2361	0.3016	334	0.78
TRTTYPCD*TRTCD		Diet & Exercise		30mg	-0.02180	0.3042	334	-0.07
TRTTYPCD*TRTCD		Diet & Exercise		45mg	0			
TRTTYPCD*TRTCD		Monotherapy		Placebo	0			
TRTTYPCD*TRTCD		Monotherapy		2.5mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.2312
SEX	Female				0.7909
SEX	Male				.
TRTTYPCD		Diet & Exercise			0.0027
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0006
TRTCD				7.5mg	0.4170
TRTCD				15mg	0.1037
TRTCD				30mg	0.7935
TRTCD				45mg	.
REGIONCD			US/Canada		<.0001
REGIONCD			Eastern Europe		0.1501
REGIONCD			Western Europe		.
EFSTDBL					0.2734
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	0.2550
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	0.3656
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.2025
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.4344
TRTTYPCD*TRTCD		Diet & Exercise		30mg	0.9429
TRTTYPCD*TRTCD		Diet & Exercise		45mg	.
TRTTYPCD*TRTCD		Monotherapy		Placebo	.
TRTTYPCD*TRTCD		Monotherapy		2.5mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTTYPCD*TRTCD		Monotherapy		7.5mg	0			
TRTTYPCD*TRTCD		Monotherapy		15mg	0			
TRTTYPCD*TRTCD		Monotherapy		30mg	0			
TRTTYPCD*TRTCD		Monotherapy		45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTTYPCD*TRTCD		Monotherapy		7.5mg	.
TRTTYPCD*TRTCD		Monotherapy		15mg	.
TRTTYPCD*TRTCD		Monotherapy		30mg	.
TRTTYPCD*TRTCD		Monotherapy		45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	334	0.07	0.7909
TRTTYPCD	1	334	56.23	<.0001
TRTCD	5	334	8.56	<.0001
REGIONCD	2	334	8.97	0.0002
EFSTDBL	1	334	1.20	0.2734
TRTTYPCD*TRTCD	5	334	1.78	0.1155

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.3001	0.1517	334	-1.98	0.0487	0.05	-0.5985	-0.00174
7.5mg vs Pbo	-0.4763	0.1488	334	-3.20	0.0015	0.05	-0.7690	-0.1836
15mg vs Pbo	-0.4044	0.1475	334	-2.74	0.0064	0.05	-0.6945	-0.1143
30mg vs Pbo	-0.7848	0.1492	334	-5.26	<.0001	0.05	-1.0784	-0.4913
45mg vs Pbo	-0.8254	0.1504	334	-5.49	<.0001	0.05	-1.1212	-0.5295

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	WORK.EFF	-0.1086	0.1532	334	-0.71	0.4788	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	WORK.EFF	-0.3784	0.1699	334	-2.23	0.0266	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	WORK.EFF	-0.2213	0.1632	334	-1.36	0.1761	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	WORK.EFF	-0.2251	0.1660	334	-1.36	0.1761	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	WORK.EFF	-0.7345	0.1624	334	-4.52	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	WORK.EFF	-0.7641	0.1675	334	-4.56	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	WORK.EFF	0.8832	0.1414	334	6.25	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	WORK.EFF	0.5527	0.1369	334	4.04	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	WORK.EFF	0.04323	0.1346	334	0.32	0.7482	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	WORK.EFF	0.1908	0.1273	334	1.50	0.1347	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	WORK.EFF	-0.06066	0.1423	334	-0.43	0.6701	0.05
TRTTYPCD*TRTCD	Monotherapy	45mg	WORK.EFF	-0.1121	0.1349	334	-0.83	0.4067	0.05

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	-0.4099	0.1927
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	-0.7127	-0.04416
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	-0.5424	0.09982
TRTTYPCD*TRTCD	Diet & Exercise	15mg	-0.5517	0.1015

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	30mg	-1.0539	-0.4150
TRTTYPCD*TRTCD	Diet & Exercise	45mg	-1.0936	-0.4346
TRTTYPCD*TRTCD	Monotherapy	Placebo	0.6050	1.1613
TRTTYPCD*TRTCD	Monotherapy	2.5mg	0.2833	0.8221
TRTTYPCD*TRTCD	Monotherapy	7.5mg	-0.2215	0.3079
TRTTYPCD*TRTCD	Monotherapy	15mg	-0.05951	0.4412
TRTTYPCD*TRTCD	Monotherapy	30mg	-0.3405	0.2192
TRTTYPCD*TRTCD	Monotherapy	45mg	-0.3774	0.1533

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	WORK.EFF	0.2698	0.2291	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	WORK.EFF	0.1127	0.2248	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	WORK.EFF	0.1165	0.2258	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	WORK.EFF	0.6258	0.2234	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	WORK.EFF	0.6555	0.2273	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	WORK.EFF	-0.9918	0.2082	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	WORK.EFF	-0.6613	0.2055	334

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	WORK.EFF	-0.1518	0.2037	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	WORK.EFF	-0.2995	0.1990	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	WORK.EFF	-0.04795	0.2084	334
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	WORK.EFF	0.003465	0.2045	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	WORK.EFF	-0.1571	0.2350	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	WORK.EFF	-0.1533	0.2375	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	WORK.EFF	0.3560	0.2345	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	WORK.EFF	0.3857	0.2380	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	WORK.EFF	-1.2616	0.2214	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	WORK.EFF	-0.9311	0.2181	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	WORK.EFF	-0.4216	0.2173	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	WORK.EFF	-0.5692	0.2123	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	WORK.EFF	-0.3177	0.2229	334
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	WORK.EFF	-0.2663	0.2166	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	WORK.EFF	0.003774	0.2325	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	WORK.EFF	0.5131	0.2303	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	WORK.EFF	0.5428	0.2337	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	WORK.EFF	-1.1045	0.2160	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	WORK.EFF	-0.7740	0.2134	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	WORK.EFF	-0.2645	0.2120	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	WORK.EFF	-0.4122	0.2074	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	WORK.EFF	-0.1606	0.2173	334
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	WORK.EFF	-0.1092	0.2111	334

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	WORK.EFF	0.5094	0.2326	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	WORK.EFF	0.5390	0.2365	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	WORK.EFF	-1.1083	0.2176	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	WORK.EFF	-0.7778	0.2158	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	WORK.EFF	-0.2683	0.2138	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	WORK.EFF	-0.4159	0.2095	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	WORK.EFF	-0.1644	0.2181	334
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	WORK.EFF	-0.1130	0.2140	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	WORK.EFF	0.02962	0.2327	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	WORK.EFF	-1.6176	0.2158	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	WORK.EFF	-1.2872	0.2120	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	WORK.EFF	-0.7777	0.2112	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	WORK.EFF	-0.9253	0.2062	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	WORK.EFF	-0.6738	0.2169	334
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	WORK.EFF	-0.6224	0.2109	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	WORK.EFF	-1.6473	0.2212	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	WORK.EFF	-1.3168	0.2147	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	WORK.EFF	-0.8073	0.2146	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	WORK.EFF	-0.9549	0.2099	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	WORK.EFF	-0.7034	0.2219	334
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	WORK.EFF	-0.6520	0.2158	334
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	WORK.EFF	0.3305	0.1981	334
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	WORK.EFF	0.8400	0.1955	334

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	WORK.EFF	0.6923	0.1906	334
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	WORK.EFF	0.9438	0.1991	334
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	WORK.EFF	0.9953	0.1948	334
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	WORK.EFF	0.5095	0.1917	334
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	WORK.EFF	0.3619	0.1865	334
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	WORK.EFF	0.6134	0.1986	334
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	WORK.EFF	0.6648	0.1927	334
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	WORK.EFF	-0.1476	0.1851	334
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	WORK.EFF	0.1039	0.1953	334
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	WORK.EFF	0.1553	0.1911	334
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	WORK.EFF	0.2515	0.1911	334
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	WORK.EFF	0.3029	0.1857	334
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	WORK.EFF	0.05142	0.1963	334

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	1.18	0.2398	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	0.50	0.6164	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	0.52	0.6064	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	2.80	0.0054	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	2.88	0.0042	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-4.76	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-3.22	0.0014	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-0.75	0.4565	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-1.50	0.1333	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.23	0.8181	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	0.02	0.9865	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	-0.67	0.5043	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.65	0.5190	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	1.52	0.1300	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	1.62	0.1062	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-5.70	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-4.27	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-1.94	0.0532	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-2.68	0.0077	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-1.43	0.1550	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-1.23	0.2198	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	0.02	0.9871	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	2.23	0.0265	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	2.32	0.0208	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-5.11	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-3.63	0.0003	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-1.25	0.2130	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-1.99	0.0477	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-0.74	0.4603	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-0.52	0.6052	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	2.19	0.0292	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	2.28	0.0233	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-5.09	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-3.60	0.0004	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-1.25	0.2104	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-1.99	0.0479	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.75	0.4515	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.53	0.5979	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	0.13	0.8988	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-7.50	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-6.07	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-3.68	0.0003	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-4.49	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-3.11	0.0021	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-2.95	0.0034	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-7.45	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-6.13	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-3.76	0.0002	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-4.55	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-3.17	0.0017	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-3.02	0.0027	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	1.67	0.0962	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	4.30	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	3.63	0.0003	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	4.74	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	5.11	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	2.66	0.0082	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	1.94	0.0532	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	3.09	0.0022	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	3.45	0.0006	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-0.80	0.4257	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	0.53	0.5952	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	0.81	0.4170	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	1.32	0.1891	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	1.63	0.1037	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	0.26	0.7935	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	-0.1809	0.7205
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	-0.3294	0.5548
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	-0.3278	0.5607
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	0.1865	1.0652
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	0.2083	1.1027
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-1.4014	-0.5822
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-1.0656	-0.2570
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-0.5525	0.2488
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-0.6909	0.09201
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.4578	0.3619
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	-0.3989	0.4058
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	-0.6194	0.3052
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.6205	0.3139
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	-0.1053	0.8174
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	-0.08260	0.8539
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-1.6971	-0.8261
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-1.3601	-0.5021
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-0.8491	0.005842
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-0.9869	-0.1516
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-0.7562	0.1208
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-0.6924	0.1598
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	-0.4536	0.4612
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	0.06008	0.9662

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	0.08298	1.0025
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-1.5294	-0.6796
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-1.1937	-0.3543
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-0.6816	0.1525
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-0.8202	-0.00413
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-0.5882	0.2669
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-0.5245	0.3061
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	0.05177	0.9670
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	0.07373	1.0043
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-1.5362	-0.6803
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-1.2023	-0.3532
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-0.6889	0.1523
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-0.8280	-0.00382
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.5935	0.2646
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.5340	0.3080
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	-0.4281	0.4874
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-2.0421	-1.1932
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-1.7043	-0.8700
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-1.1931	-0.3622
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-1.3308	-0.5198
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-1.1004	-0.2471
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-1.0373	-0.2075
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-2.0824	-1.2121

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-1.7391	-0.8945
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-1.2294	-0.3853
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-1.3678	-0.5420
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-1.1399	-0.2670
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-1.0764	-0.2275
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	-0.05919	0.7202
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	0.4554	1.2245
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	0.3174	1.0673
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	0.5522	1.3355
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	0.6120	1.3785
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	0.1324	0.8865
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	-0.00509	0.7288
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	0.2227	1.0040
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	0.2857	1.0439
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-0.5117	0.2165
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	-0.2803	0.4881
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	-0.2206	0.5312
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	-0.1245	0.6275
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	-0.06230	0.6681
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	-0.3346	0.4375

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	33
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6223	0.04852	12.83	<.0001	0.05	0.5372	0.7296

Fit Statistics

-2 Res Log Likelihood	844.6
AIC (smaller is better)	846.6
AICC (smaller is better)	846.6
BIC (smaller is better)	850.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.3560	0.5018	329	0.71
SEX	Female				-0.03158	0.08668	329	-0.36
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6231	0.08910	329	-6.99
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	1.4684	0.2364	329	6.21
TRTCD				2.5mg	0.6982	0.2498	329	2.79
TRTCD				7.5mg	0.4454	0.2281	329	1.95
TRTCD				15mg	0.6782	0.2341	329	2.90
TRTCD				30mg	0.3006	0.2376	329	1.27
TRTCD				45mg	0			
REGIONCD			US/Canada		0.07919	0.2508	329	0.32
REGIONCD			Eastern Europe		0.08378	0.2545	329	0.33
REGIONCD			Western Europe		0			
EFSTDBL					-0.06600	0.05855	329	-1.13
TRTCD*REGIONCD			US/Canada	Placebo	-1.0565	0.3404	329	-3.10
TRTCD*REGIONCD			Eastern Europe	Placebo	-1.1061	0.3769	329	-2.93
TRTCD*REGIONCD			Western Europe	Placebo	0			
TRTCD*REGIONCD			US/Canada	2.5mg	-0.4585	0.3671	329	-1.25
TRTCD*REGIONCD			Eastern Europe	2.5mg	-0.00965	0.3592	329	-0.03
TRTCD*REGIONCD			Western Europe	2.5mg	0			
TRTCD*REGIONCD			US/Canada	7.5mg	-0.2090	0.3525	329	-0.59
TRTCD*REGIONCD			Eastern Europe	7.5mg	-0.1358	0.3599	329	-0.38

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.4786
SEX	Female				0.7158
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0055
TRTCD				7.5mg	0.0517
TRTCD				15mg	0.0040
TRTCD				30mg	0.2067
TRTCD				45mg	.
REGIONCD			US/Canada		0.7524
REGIONCD			Eastern Europe		0.7422
REGIONCD			Western Europe		.
EFSTDBL					0.2605
TRTCD*REGIONCD			US/Canada	Placebo	0.0021
TRTCD*REGIONCD			Eastern Europe	Placebo	0.0036
TRTCD*REGIONCD			Western Europe	Placebo	.
TRTCD*REGIONCD			US/Canada	2.5mg	0.2125
TRTCD*REGIONCD			Eastern Europe	2.5mg	0.9786
TRTCD*REGIONCD			Western Europe	2.5mg	.
TRTCD*REGIONCD			US/Canada	7.5mg	0.5536
TRTCD*REGIONCD			Eastern Europe	7.5mg	0.7061

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTCD*REGIONCD			Western Europe	7.5mg	0			
TRTCD*REGIONCD			US/Canada	15mg	-0.6795	0.3444	329	-1.97
TRTCD*REGIONCD			Eastern Europe	15mg	-0.2091	0.3567	329	-0.59
TRTCD*REGIONCD			Western Europe	15mg	0			
TRTCD*REGIONCD			US/Canada	30mg	-0.5488	0.3503	329	-1.57
TRTCD*REGIONCD			Eastern Europe	30mg	-0.2621	0.3729	329	-0.70
TRTCD*REGIONCD			Western Europe	30mg	0			
TRTCD*REGIONCD			US/Canada	45mg	0			
TRTCD*REGIONCD			Eastern Europe	45mg	0			
TRTCD*REGIONCD			Western Europe	45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	7.5mg	.
TRTCD*REGIONCD			US/Canada	15mg	0.0493
TRTCD*REGIONCD			Eastern Europe	15mg	0.5581
TRTCD*REGIONCD			Western Europe	15mg	.
TRTCD*REGIONCD			US/Canada	30mg	0.1181
TRTCD*REGIONCD			Eastern Europe	30mg	0.4827

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	30mg	.
TRTCD*REGIONCD			US/Canada	45mg	.
TRTCD*REGIONCD			Eastern Europe	45mg	.
TRTCD*REGIONCD			Western Europe	45mg	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	329	0.13	0.7158
TRTTYPCD	1	329	48.91	<.0001
TRTCD	5	329	7.34	<.0001
REGIONCD	2	329	8.51	0.0002
EFSTDBL	1	329	1.27	0.2605
TRTCD*REGIONCD	10	329	1.82	0.0559

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2054	0.1524	329	-1.35	0.1786	0.05	-0.5051	0.09434
7.5mg vs Pbo	-0.4171	0.1529	329	-2.73	0.0067	0.05	-0.7179	-0.1162
15mg vs Pbo	-0.3656	0.1490	329	-2.45	0.0147	0.05	-0.6586	-0.07248
30mg vs Pbo	-0.7172	0.1534	329	-4.68	<.0001	0.05	-1.0189	-0.4154
45mg vs Pbo	-0.7475	0.1513	329	-4.94	<.0001	0.05	-1.0452	-0.4499

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	WORK.EFF	0.05461	0.1647	329	0.33	0.7403	0.05

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	-0.2693	0.3785

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	WORK.EFF	0.009632	0.2300	329	0.04	0.9666	0.05
TRTCD*REGIONCD	Western Europe	Placebo	WORK.EFF	1.0319	0.1611	329	6.40	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	WORK.EFF	-0.1175	0.1933	329	-0.61	0.5435	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	WORK.EFF	0.3359	0.1779	329	1.89	0.0599	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	WORK.EFF	0.2617	0.1815	329	1.44	0.1502	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	WORK.EFF	-0.1209	0.1975	329	-0.61	0.5409	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	WORK.EFF	-0.04311	0.2042	329	-0.21	0.8329	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	WORK.EFF	0.008915	0.1491	329	0.06	0.9524	0.05
TRTCD*REGIONCD	US/Canada	15mg	WORK.EFF	-0.3586	0.1768	329	-2.03	0.0433	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	WORK.EFF	0.1164	0.1921	329	0.61	0.5450	0.05
TRTCD*REGIONCD	Western Europe	15mg	WORK.EFF	0.2417	0.1583	329	1.53	0.1277	0.05
TRTCD*REGIONCD	US/Canada	30mg	WORK.EFF	-0.6054	0.1812	329	-3.34	0.0009	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	WORK.EFF	-0.3141	0.2210	329	-1.42	0.1561	0.05
TRTCD*REGIONCD	Western Europe	30mg	WORK.EFF	-0.1358	0.1624	329	-0.84	0.4035	0.05
TRTCD*REGIONCD	US/Canada	45mg	WORK.EFF	-0.3573	0.1827	329	-1.96	0.0513	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	WORK.EFF	-0.3527	0.1868	329	-1.89	0.0599	0.05
TRTCD*REGIONCD	Western Europe	45mg	WORK.EFF	-0.4365	0.1726	329	-2.53	0.0119	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	-0.4429	0.4621
TRTCD*REGIONCD	Western Europe	Placebo	0.7149	1.3489
TRTCD*REGIONCD	US/Canada	2.5mg	-0.4978	0.2627
TRTCD*REGIONCD	Eastern Europe	2.5mg	-0.01413	0.6859
TRTCD*REGIONCD	Western Europe	2.5mg	-0.09526	0.6187
TRTCD*REGIONCD	US/Canada	7.5mg	-0.5095	0.2677
TRTCD*REGIONCD	Eastern Europe	7.5mg	-0.4449	0.3586
TRTCD*REGIONCD	Western Europe	7.5mg	-0.2844	0.3022
TRTCD*REGIONCD	US/Canada	15mg	-0.7064	-0.01088
TRTCD*REGIONCD	Eastern Europe	15mg	-0.2615	0.4943
TRTCD*REGIONCD	Western Europe	15mg	-0.06969	0.5531
TRTCD*REGIONCD	US/Canada	30mg	-0.9618	-0.2490
TRTCD*REGIONCD	Eastern Europe	30mg	-0.7488	0.1206
TRTCD*REGIONCD	Western Europe	30mg	-0.4552	0.1836
TRTCD*REGIONCD	US/Canada	45mg	-0.7166	0.002075
TRTCD*REGIONCD	Eastern Europe	45mg	-0.7202	0.01483
TRTCD*REGIONCD	Western Europe	45mg	-0.7760	-0.09691

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	WORK.EFF	0.04498	0.2826	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	WORK.EFF	-0.9773	0.2302	329
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	WORK.EFF	0.1721	0.2535	329
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.2813	0.2429	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2071	0.2454	329
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	WORK.EFF	0.1755	0.2574	329
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.09773	0.2624	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	WORK.EFF	0.04570	0.2221	329
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	WORK.EFF	0.4132	0.2418	329
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	WORK.EFF	-0.06179	0.2527	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	WORK.EFF	-0.1871	0.2282	329
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	WORK.EFF	0.6600	0.2448	329
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	WORK.EFF	0.3687	0.2758	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	WORK.EFF	0.1904	0.2306	329
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	WORK.EFF	0.4119	0.2463	329
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	WORK.EFF	0.4073	0.2492	329
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	WORK.EFF	0.4911	0.2388	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	WORK.EFF	-1.0223	0.2803	329
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	WORK.EFF	0.1272	0.2994	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.3262	0.2924	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2521	0.2942	329
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	WORK.EFF	0.1305	0.3031	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.05275	0.3091	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	0.16	0.8736	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-4.25	<.0001	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	0.68	0.4975	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-1.16	0.2478	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-0.84	0.3992	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	0.68	0.4958	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	0.37	0.7098	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	0.21	0.8371	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	1.71	0.0884	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.24	0.8070	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-0.82	0.4128	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	2.70	0.0074	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	1.34	0.1822	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	0.83	0.4096	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	1.67	0.0954	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	1.63	0.1031	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	2.06	0.0405	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-3.65	0.0003	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	0.42	0.6713	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-1.12	0.2653	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.86	0.3922	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	0.43	0.6670	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	0.17	0.8646	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	-0.5109	0.6008
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-1.4302	-0.5244
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	-0.3265	0.6708
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-0.7592	0.1966
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-0.6898	0.2755
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	-0.3309	0.6819
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	-0.4185	0.6140
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	-0.3913	0.4827
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	-0.06251	0.8890
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.5589	0.4353
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-0.6360	0.2618
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	0.1785	1.1415
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	-0.1739	0.9113
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	-0.2633	0.6441
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	-0.07261	0.8964
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	-0.08293	0.8975
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	0.02133	0.9608
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-1.5738	-0.4708
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	-0.4619	0.7162
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-0.9014	0.2489
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.8309	0.3267
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	-0.4657	0.7268
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	-0.5553	0.6608

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	WORK.EFF	0.000717	0.2739	329
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	WORK.EFF	0.3683	0.2904	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	WORK.EFF	-0.1068	0.3005	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	WORK.EFF	-0.2321	0.2790	329
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	WORK.EFF	0.6150	0.2924	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	WORK.EFF	0.3237	0.3169	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	WORK.EFF	0.1454	0.2811	329
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	WORK.EFF	0.3669	0.2958	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	WORK.EFF	0.3623	0.2950	329
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	WORK.EFF	0.4461	0.2887	329
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	WORK.EFF	1.1495	0.2513	329
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	0.6960	0.2405	329
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	WORK.EFF	0.7702	0.2430	329
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	WORK.EFF	1.1528	0.2551	329
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	1.0750	0.2603	329
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	WORK.EFF	1.0230	0.2195	329
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	WORK.EFF	1.3905	0.2394	329
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	WORK.EFF	0.9155	0.2506	329
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	WORK.EFF	0.7902	0.2258	329
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	WORK.EFF	1.6373	0.2424	329
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	WORK.EFF	1.3460	0.2734	329
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	WORK.EFF	1.1677	0.2283	329
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	WORK.EFF	1.3892	0.2440	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	0.00	0.9979	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	1.27	0.2056	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.36	0.7226	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.83	0.4061	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	2.10	0.0362	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	1.02	0.3077	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	0.52	0.6052	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	1.24	0.2157	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	1.23	0.2203	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	1.54	0.1233	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	4.57	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	2.89	0.0041	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	3.17	0.0017	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	4.52	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	4.13	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	4.66	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	5.81	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	3.65	0.0003	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	3.50	0.0005	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	6.75	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	4.92	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	5.11	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	5.69	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	-0.5382	0.5396
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	-0.2030	0.9395
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.6978	0.4843
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.7810	0.3168
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	0.03976	1.1903
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	-0.2996	0.9471
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	-0.4075	0.6984
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	-0.2149	0.9487
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	-0.2181	0.9427
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	-0.1219	1.0141
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	0.6550	1.6439
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	0.2230	1.1691
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	0.2921	1.2482
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	0.6510	1.6546
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	0.5629	1.5872
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	0.5912	1.4549
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	0.9197	1.8614
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	0.4225	1.4086
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	0.3461	1.2343
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	1.1604	2.1142
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	0.8082	1.8839
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	0.7186	1.6169
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	0.9093	1.8691

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	WORK.EFF	1.3846	0.2467	329
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	WORK.EFF	1.4684	0.2364	329
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	WORK.EFF	-0.4534	0.2649	329
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	WORK.EFF	-0.3793	0.2657	329
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	WORK.EFF	0.003365	0.2765	329
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	WORK.EFF	-0.07442	0.2817	329
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	WORK.EFF	-0.1265	0.2440	329
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	WORK.EFF	0.2411	0.2630	329
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	WORK.EFF	-0.2339	0.2725	329
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	WORK.EFF	-0.3593	0.2485	329
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	WORK.EFF	0.4879	0.2641	329
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	WORK.EFF	0.1966	0.2947	329
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	WORK.EFF	0.01828	0.2519	329
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	WORK.EFF	0.2397	0.2681	329
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	WORK.EFF	0.2351	0.2683	329
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	WORK.EFF	0.3189	0.2592	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	WORK.EFF	0.07413	0.2533	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.4568	0.2656	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.3790	0.2701	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.3270	0.2322	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.6945	0.2498	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.2195	0.2619	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.09415	0.2392	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	5.61	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	6.21	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-1.71	0.0880	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-1.43	0.1544	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	0.01	0.9903	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	-0.26	0.7918	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	-0.52	0.6047	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	0.92	0.3601	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.86	0.3912	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-1.45	0.1491	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	1.85	0.0656	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	0.67	0.5053	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	0.07	0.9422	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	0.89	0.3720	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	0.88	0.3815	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	1.23	0.2195	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	0.29	0.7699	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	1.72	0.0864	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	1.40	0.1616	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	1.41	0.1601	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	2.78	0.0058	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	0.84	0.4027	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	0.39	0.6941	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	0.8993	1.8699
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	1.0033	1.9335
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-0.9746	0.06777
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-0.9019	0.1434
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	-0.5405	0.5472
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	-0.6286	0.4797
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	-0.6065	0.3536
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	-0.2764	0.7585
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.7700	0.3021
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-0.8480	0.1295
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	-0.03169	1.0074
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	-0.3832	0.7764
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	-0.4773	0.5138
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	-0.2878	0.7672
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	-0.2927	0.7630
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	-0.1910	0.8289
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	-0.4241	0.5724
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	-0.06573	0.9793
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	-0.1524	0.9104
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	-0.1298	0.7838
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	0.2030	1.1860
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	-0.2958	0.7347
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	-0.3764	0.5647

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	WORK.EFF	0.9413	0.2546	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.6500	0.2833	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.4717	0.2417	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.6931	0.2529	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.6886	0.2584	329
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.7723	0.2474	329
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.3826	0.2680	329
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.3049	0.2727	329
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.2528	0.2349	329
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.6204	0.2531	329
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.1453	0.2644	329
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.02002	0.2410	329
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	WORK.EFF	0.8671	0.2565	329
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.5759	0.2864	329
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.3976	0.2443	329
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.6190	0.2566	329
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.6144	0.2606	329
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.6982	0.2498	329
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	WORK.EFF	-0.07779	0.2843	329
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	WORK.EFF	-0.1298	0.2474	329
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	WORK.EFF	0.2377	0.2649	329
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.2373	0.2762	329
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	WORK.EFF	-0.3626	0.2532	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	3.70	0.0003	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	2.29	0.0224	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	1.95	0.0519	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	2.74	0.0065	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	2.66	0.0081	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	3.12	0.0020	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	1.43	0.1543	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	1.12	0.2644	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	1.08	0.2826	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	2.45	0.0147	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	0.55	0.5829	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	0.08	0.9339	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	3.38	0.0008	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	2.01	0.0452	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	1.63	0.1046	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	2.41	0.0164	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	2.36	0.0190	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	2.79	0.0055	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.27	0.7846	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.52	0.6002	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	0.90	0.3701	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-0.86	0.3909	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-1.43	0.1531	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	0.4405	1.4421
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	0.09273	1.2073
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	-0.00388	0.9473
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	0.1957	1.1906
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	0.1802	1.1970
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	0.2857	1.2590
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	-0.1446	0.9099
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	-0.2316	0.8413
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	-0.2093	0.7150
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	0.1226	1.1182
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	-0.3748	0.6655
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	-0.4541	0.4941
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	0.3625	1.3718
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	0.01241	1.1393
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	-0.08299	0.8781
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	0.1142	1.1239
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	0.1017	1.1271
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	0.2068	1.1897
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.6371	0.4815
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.6166	0.3569
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	-0.2833	0.7588
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-0.7807	0.3061
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-0.8608	0.1355

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	WORK.EFF	0.4845	0.2679	329
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	WORK.EFF	0.1932	0.2959	329
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	WORK.EFF	0.01491	0.2566	329
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	WORK.EFF	0.2364	0.2691	329
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	WORK.EFF	0.2318	0.2713	329
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	WORK.EFF	0.3156	0.2621	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	WORK.EFF	-0.05203	0.2530	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.3155	0.2700	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.1595	0.2798	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.2848	0.2585	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.5623	0.2732	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.2710	0.3020	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	WORK.EFF	0.09270	0.2609	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.3142	0.2730	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.3096	0.2776	329
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.3933	0.2669	329
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.3675	0.2313	329
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.1075	0.2433	329
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.2328	0.2175	329
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.6143	0.2346	329
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.3230	0.2664	329
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	WORK.EFF	0.1447	0.2205	329
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.3662	0.2359	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	1.81	0.0715	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	0.65	0.5142	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	0.06	0.9537	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	0.88	0.3804	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	0.85	0.3935	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	1.20	0.2295	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	-0.21	0.8372	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	1.17	0.2434	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.57	0.5691	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-1.10	0.2713	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	2.06	0.0404	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	0.90	0.3702	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	0.36	0.7226	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	1.15	0.2506	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	1.12	0.2655	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	1.47	0.1415	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	1.59	0.1129	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.44	0.6589	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-1.07	0.2851	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	2.62	0.0092	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	1.21	0.2262	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	0.66	0.5120	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	1.55	0.1216	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	-0.04259	1.0116
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	-0.3888	0.7752
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	-0.4898	0.5196
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	-0.2931	0.7658
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	-0.3019	0.7655
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	-0.2001	0.8312
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	-0.5497	0.4456
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	-0.2156	0.8467
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.7100	0.3910
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-0.7933	0.2237
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	0.02477	1.0998
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	-0.3231	0.8651
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	-0.4205	0.6059
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	-0.2228	0.8512
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	-0.2365	0.8556
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	-0.1317	0.9184
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	-0.08738	0.8225
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.5861	0.3711
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-0.6606	0.1950
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	0.1528	1.0758
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	-0.2011	0.8471
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	-0.2890	0.5785
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	-0.09792	0.8303

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.3616	0.2389	329
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.4454	0.2281	329
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	WORK.EFF	-0.4750	0.2613	329
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	WORK.EFF	-0.6004	0.2379	329
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	WORK.EFF	0.2468	0.2534	329
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	WORK.EFF	-0.04451	0.2823	329
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	WORK.EFF	-0.2228	0.2405	329
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	WORK.EFF	-0.00135	0.2534	329
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	WORK.EFF	-0.00594	0.2571	329
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	WORK.EFF	0.07784	0.2470	329
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	WORK.EFF	-0.1253	0.2488	329
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	WORK.EFF	0.7218	0.2643	329
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.4305	0.2941	329
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	WORK.EFF	0.2522	0.2504	329
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	WORK.EFF	0.4737	0.2646	329
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.4691	0.2691	329
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	WORK.EFF	0.5529	0.2583	329
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	WORK.EFF	0.8471	0.2402	329
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.5558	0.2727	329
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	WORK.EFF	0.3775	0.2265	329
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	WORK.EFF	0.5990	0.2427	329
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.5944	0.2448	329
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	WORK.EFF	0.6782	0.2341	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	1.51	0.1311	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	1.95	0.0517	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-1.82	0.0700	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-2.52	0.0121	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	0.97	0.3309	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	-0.16	0.8748	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.93	0.3550	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	-0.01	0.9957	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	-0.02	0.9816	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	0.32	0.7528	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.50	0.6148	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	2.73	0.0067	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	1.46	0.1441	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	1.01	0.3145	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	1.79	0.0744	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	1.74	0.0822	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	2.14	0.0331	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	3.53	0.0005	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	2.04	0.0423	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	1.67	0.0965	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	2.47	0.0141	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	2.43	0.0157	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	2.90	0.0040	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	-0.1083	0.8315
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	-0.00340	0.8941
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-0.9891	0.03910
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-1.0683	-0.1324
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	-0.2517	0.7453
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	-0.5998	0.5108
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.6960	0.2504
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	-0.4998	0.4971
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	-0.5118	0.4999
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	-0.4080	0.5637
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.6148	0.3641
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	0.2019	1.2417
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	-0.1480	1.0090
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	-0.2403	0.7447
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	-0.04688	0.9942
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	-0.06023	0.9984
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	0.04466	1.0611
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	0.3746	1.3197
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	0.01937	1.0923
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	-0.06798	0.8231
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	0.1216	1.0764
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	0.1129	1.0760
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	0.2176	1.1388

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	WORK.EFF	-0.2913	0.2859	329
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	WORK.EFF	-0.4696	0.2434	329
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	WORK.EFF	-0.2481	0.2580	329
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	WORK.EFF	-0.2527	0.2599	329
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	WORK.EFF	-0.1689	0.2502	329
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	WORK.EFF	-0.1783	0.2749	329
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	WORK.EFF	0.04316	0.2870	329
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.03857	0.2881	329
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	WORK.EFF	0.1223	0.2811	329
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	WORK.EFF	0.2215	0.2447	329
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.2169	0.2484	329
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	WORK.EFF	0.3006	0.2376	329
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	WORK.EFF	-0.00459	0.2623	329
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	WORK.EFF	0.07919	0.2508	329
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	WORK.EFF	0.08378	0.2545	329

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-1.02	0.3091	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-1.93	0.0545	0.05
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-0.96	0.3369	0.05
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-0.97	0.3316	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-0.68	0.5000	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.65	0.5171	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	0.15	0.8806	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	0.13	0.8936	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	0.44	0.6637	0.05
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	0.90	0.3662	0.05
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	0.87	0.3833	0.05
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	1.27	0.2067	0.05
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.02	0.9860	0.05
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	0.32	0.7524	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	0.33	0.7422	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-0.8538	0.2712
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-0.9484	0.009209
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-0.7557	0.2594
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-0.7640	0.2586
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-0.6612	0.3233
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.7191	0.3625
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	-0.5214	0.6077
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	-0.5282	0.6053
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	-0.4307	0.6754
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	-0.2600	0.7029
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	-0.2718	0.7055
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	-0.1669	0.7681
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.5206	0.5114
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	-0.4142	0.5725
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	-0.4168	0.5844

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	21
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6437	0.04981	12.92	<.0001	0.05	0.5562	0.7537

Fit Statistics

-2 Res Log Likelihood	862.9
AIC (smaller is better)	864.9
AICC (smaller is better)	864.9
BIC (smaller is better)	868.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.8872	1.1565	334	0.77
SEX	Female				-0.02158	0.08682	334	-0.25
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6489	0.08891	334	-7.30
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.2625	1.6706	334	0.16
TRTCD				2.5mg	-0.1839	1.4954	334	-0.12
TRTCD				7.5mg	-0.7953	1.6025	334	-0.50
TRTCD				15mg	0.3063	1.6998	334	0.18
TRTCD				30mg	0.8885	1.7343	334	0.51
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.4195	0.1022	334	-4.11
REGIONCD			Eastern Europe		-0.1784	0.1083	334	-1.65
REGIONCD			Western Europe		0			
EFSTDBL					-0.1009	0.1428	334	-0.71
EFSTDBL*TRTCD				Placebo	0.07254	0.2105	334	0.34
EFSTDBL*TRTCD				2.5mg	0.09210	0.1849	334	0.50
EFSTDBL*TRTCD				7.5mg	0.1384	0.1989	334	0.70
EFSTDBL*TRTCD				15mg	0.009718	0.2127	334	0.05
EFSTDBL*TRTCD				30mg	-0.1105	0.2187	334	-0.51
EFSTDBL*TRTCD				45mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.4435
SEX	Female				0.8038
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	0.8752
TRTCD				2.5mg	0.9022
TRTCD				7.5mg	0.6200
TRTCD				15mg	0.8571
TRTCD				30mg	0.6088
TRTCD				45mg	.
REGIONCD			US/Canada		<.0001
REGIONCD			Eastern Europe		0.1004
REGIONCD			Western Europe		.
EFSTDBL					0.4803
EFSTDBL*TRTCD				Placebo	0.7306
EFSTDBL*TRTCD				2.5mg	0.6188
EFSTDBL*TRTCD				7.5mg	0.4868
EFSTDBL*TRTCD				15mg	0.9636
EFSTDBL*TRTCD				30mg	0.6136
EFSTDBL*TRTCD				45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	334	0.06	0.8038
TRTTYPCD	1	334	53.27	<.0001
TRTCD	5	334	0.23	0.9501
REGIONCD	2	334	8.43	0.0003
EFSTDBL	1	334	1.24	0.2657
EFSTDBL*TRTCD	5	334	0.34	0.8899

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.4646	0.1075	334	4.32	<.0001	0.05	0.2532	0.6760
TRTCD	2.5mg	WORK.EFF	0.1728	0.1083	334	1.60	0.1116	0.05	-0.04029	0.3860
TRTCD	7.5mg	WORK.EFF	-0.07196	0.1050	334	-0.69	0.4938	0.05	-0.2786	0.1347
TRTCD	15mg	WORK.EFF	0.01134	0.1021	334	0.11	0.9117	0.05	-0.1896	0.2122
TRTCD	30mg	WORK.EFF	-0.3579	0.1098	334	-3.26	0.0012	0.05	-0.5739	-0.1419
TRTCD	45mg	WORK.EFF	-0.3719	0.1078	334	-3.45	0.0006	0.05	-0.5839	-0.1599

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.2918	0.1530	334	1.91	0.0575	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.5366	0.1504	334	3.57	0.0004	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.4533	0.1484	334	3.05	0.0024	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.8225	0.1533	334	5.37	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.8365	0.1524	334	5.49	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.2448	0.1511	334	1.62	0.1061	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1615	0.1488	334	1.09	0.2785	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5307	0.1545	334	3.43	0.0007	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5447	0.1525	334	3.57	0.0004	0.05
TRTCD	7.5mg	15mg	WORK.EFF	-0.08330	0.1465	334	-0.57	0.5700	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.2859	0.1520	334	1.88	0.0609	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.2999	0.1506	334	1.99	0.0473	0.05
TRTCD	15mg	30mg	WORK.EFF	0.3692	0.1501	334	2.46	0.0144	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3832	0.1484	334	2.58	0.0103	0.05
TRTCD	30mg	45mg	WORK.EFF	0.01402	0.1540	334	0.09	0.9275	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.3
SAS Statistical Output for Table 11.2
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.00929	0.5928
TRTCD	Placebo	7.5mg	0.2408	0.8323
TRTCD	Placebo	15mg	0.1614	0.7452
TRTCD	Placebo	30mg	0.5209	1.1240
TRTCD	Placebo	45mg	0.5366	1.1363
TRTCD	2.5mg	7.5mg	-0.05241	0.5420
TRTCD	2.5mg	15mg	-0.1312	0.4541
TRTCD	2.5mg	30mg	0.2267	0.8347
TRTCD	2.5mg	45mg	0.2446	0.8448
TRTCD	7.5mg	15mg	-0.3715	0.2049
TRTCD	7.5mg	30mg	-0.01316	0.5850
TRTCD	7.5mg	45mg	0.003640	0.5962
TRTCD	15mg	30mg	0.07384	0.6645
TRTCD	15mg	45mg	0.09122	0.6752
TRTCD	30mg	45mg	-0.2889	0.3169

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Week -6

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	57	60	63	55	59
Baseline	Mean	7.74	8.02	7.96	7.88	7.78	8.06
	SD	0.683	0.918	0.763	0.649	0.664	0.741
	SE	0.087	0.122	0.098	0.082	0.090	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.80	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week -6	Mean	7.88	7.95	7.96	7.83	7.80	7.98
	SD	0.724	0.674	0.826	0.650	0.663	0.661
	SE	0.093	0.089	0.107	0.082	0.089	0.086
	Minimum	7.0	7.0	7.0	7.0	7.0	7.0
	Median	7.80	7.80	7.70	7.80	7.70	7.90
	Maximum	10.1	9.9	10.2	10.0	9.7	9.9
Change from Baseline	Mean	0.15	-0.07	-0.01	-0.05	0.02	-0.08
	SD	0.776	0.803	0.689	0.641	0.522	0.816
	SE	0.099	0.106	0.089	0.081	0.070	0.106
	Minimum	-1.6	-2.1	-1.7	-2.4	-1.4	-2.4
	Median	0.10	0.10	0.10	-0.10	0.10	-0.10
	Maximum	2.4	1.7	1.8	1.5	1.3	2.9

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Week -2

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	55	57	63	55	59
Baseline	Mean	7.74	8.00	7.97	7.88	7.76	8.06
	SD	0.688	0.918	0.780	0.649	0.660	0.741
	SE	0.089	0.124	0.103	0.082	0.089	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.70	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week -2	Mean	7.75	7.93	7.91	7.79	7.73	7.93
	SD	0.668	0.782	0.713	0.593	0.628	0.658
	SE	0.086	0.105	0.094	0.075	0.085	0.086
	Minimum	5.9	6.5	6.6	6.6	6.4	6.5
	Median	7.70	7.90	7.70	7.80	7.60	7.90
	Maximum	9.4	10.1	9.9	9.2	9.8	9.5
Change from Baseline	Mean	0.02	-0.07	-0.06	-0.09	-0.03	-0.14
	SD	0.449	0.374	0.549	0.299	0.333	0.431
	SE	0.058	0.050	0.073	0.038	0.045	0.056
	Minimum	-0.7	-1.0	-1.2	-0.8	-0.8	-1.2
	Median	-0.05	0.00	0.00	-0.10	0.00	-0.10
	Maximum	1.8	0.7	2.2	0.6	0.9	1.0

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	57	60	63	56	59
Baseline	Mean	7.74	8.02	7.96	7.88	7.77	8.06
	SD	0.678	0.918	0.763	0.649	0.660	0.741
	SE	0.086	0.122	0.098	0.082	0.088	0.097
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.70	7.80	7.70	8.00	7.75	8.00
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	54	56	59	56	55
Baseline	Mean	7.78	8.05	7.95	7.84	7.77	8.11
	SD	0.680	0.927	0.747	0.625	0.660	0.729
	SE	0.091	0.126	0.100	0.081	0.088	0.098
	Minimum	6.1	6.4	6.6	6.5	6.4	6.7
	Median	7.70	7.80	7.70	7.90	7.75	8.10
	Maximum	9.3	10.1	9.9	9.5	9.6	9.5
Week 4	Mean	7.99	8.06	7.83	7.77	7.52	7.79
	SD	0.973	1.083	0.895	0.821	0.751	0.803
	SE	0.130	0.147	0.120	0.107	0.100	0.108
	Minimum	6.3	6.3	6.1	6.0	5.8	5.9
	Median	7.80	7.70	7.70	7.90	7.50	7.80
	Maximum	10.6	11.4	9.9	9.5	9.4	9.7
Change from Baseline	Mean	0.21	0.01	-0.12	-0.07	-0.25	-0.32
	SD	0.681	0.507	0.599	0.468	0.436	0.451
	SE	0.091	0.069	0.080	0.061	0.058	0.061
	Minimum	-1.1	-1.1	-1.1	-1.0	-1.6	-1.5
	Median	0.10	-0.05	-0.30	-0.10	-0.30	-0.20
	Maximum	3.1	1.3	1.9	0.9	1.1	0.6

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	47	53	60	54	53
Baseline	Mean	7.79	7.99	7.91	7.85	7.75	8.08
	SD	0.680	0.926	0.732	0.623	0.659	0.734
	SE	0.093	0.135	0.101	0.080	0.090	0.101
	Minimum	6.1	6.4	6.6	6.5	6.4	6.7
	Median	7.70	7.80	7.70	7.90	7.70	8.00
	Maximum	9.3	10.1	9.9	9.5	9.6	9.5
Week 8	Mean	8.00	8.11	7.86	7.79	7.39	7.65
	SD	1.132	1.206	1.015	0.898	0.724	0.854
	SE	0.156	0.176	0.139	0.116	0.098	0.117
	Minimum	6.2	6.1	6.2	6.2	6.1	5.5
	Median	7.80	7.80	7.70	7.85	7.40	7.70
	Maximum	11.2	12.0	10.3	10.1	9.0	9.8
Change from Baseline	Mean	0.21	0.12	-0.05	-0.06	-0.36	-0.43
	SD	1.059	0.795	0.832	0.646	0.627	0.600
	SE	0.145	0.116	0.114	0.083	0.085	0.082
	Minimum	-2.8	-1.6	-1.9	-1.4	-2.1	-1.8
	Median	0.00	0.00	-0.20	0.10	-0.40	-0.40
	Maximum	3.4	2.2	2.2	1.5	1.9	0.7

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.4
Summary Statistics for HbA1c (%) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		49	46	53	60	54	52
Baseline	Mean	7.79	7.97	7.92	7.85	7.76	8.10
	SD	0.639	0.915	0.729	0.623	0.659	0.746
	SE	0.091	0.135	0.100	0.080	0.090	0.104
	Minimum	6.1	6.4	6.6	6.5	6.4	6.7
	Median	7.70	7.75	7.70	7.90	7.75	8.10
	Maximum	9.3	10.1	9.9	9.5	9.6	9.5
Week 12	Mean	8.21	8.18	7.88	7.87	7.39	7.69
	SD	1.339	1.279	1.161	0.874	0.836	0.994
	SE	0.191	0.189	0.160	0.113	0.114	0.138
	Minimum	6.2	6.3	6.2	6.0	5.5	5.8
	Median	7.90	7.75	7.60	7.85	7.30	7.65
	Maximum	11.8	11.8	11.0	10.0	9.7	9.9
Change from Baseline	Mean	0.43	0.22	-0.04	0.03	-0.37	-0.41
	SD	1.192	0.902	0.973	0.724	0.819	0.753
	SE	0.170	0.133	0.134	0.093	0.111	0.104
	Minimum	-1.7	-1.9	-2.3	-1.8	-2.5	-2.9
	Median	0.20	0.15	-0.30	0.00	-0.45	-0.25
	Maximum	2.8	2.5	2.2	2.0	2.6	0.9

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Population: Intention-to-Treat without LOCF

Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		49	46	53	60	54	52
Baseline	Mean	7.79	7.97	7.92	7.85	7.76	8.10
	SD	0.639	0.915	0.729	0.623	0.659	0.746
Week 12	Mean	8.21	8.18	7.88	7.87	7.39	7.69
	SD	1.339	1.279	1.161	0.874	0.836	0.994
Chg from Baseline	Mean	0.43	0.22	-0.04	0.03	-0.37	-0.41
	SD	1.192	0.902	0.973	0.724	0.819	0.753
Model-Adj Chg [2]	Mean	0.47	0.21	-0.11	0.02	-0.36	-0.38
	SE	0.118	0.121	0.113	0.106	0.112	0.115
Diff from Pbo [2]	Mean		-0.26	-0.59	-0.46	-0.84	-0.85
	95% CI		-0.59,0.08	-0.91,-0.26	-0.77,-0.14	-1.16,-0.52	-1.18,-0.53
	p-val [3]		0.128	<0.001	0.004	<0.001	<0.001

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an heirarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
p-values for interactions: trt*sex=0.567, trt*prior therapy=0.311, trt*region=0.228, trt*baseline=0.802

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	49	Sum Weights	49
Mean	7.7877551	Sum Observations	381.6
Std Deviation	0.63856371	Variance	0.40776361
Skewness	0.16108154	Kurtosis	0.71813909
Uncorrected SS	2991.38	Corrected SS	19.5726531
Coeff Variation	8.19958636	Std Error Mean	0.09122339

Basic Statistical Measures

Location		Variability	
Mean	7.787755	Std Deviation	0.63856
Median	7.700000	Variance	0.40776
Mode	7.700000	Range	3.20000
		Interquartile Range	0.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	85.37016	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	612.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.978666	Pr < W	0.5107
Kolmogorov-Smirnov	D	0.103704	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.07307	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.425955	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.3
99%	9.3
95%	9.0
90%	8.6
75% Q3	8.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.5
10%	6.9
5%	6.9
1%	6.1
0% Min	6.1

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.1	14	8.6	46
6.6	27	8.8	42
6.9	45	9.0	47
6.9	11	9.3	12
6.9	10	9.3	18

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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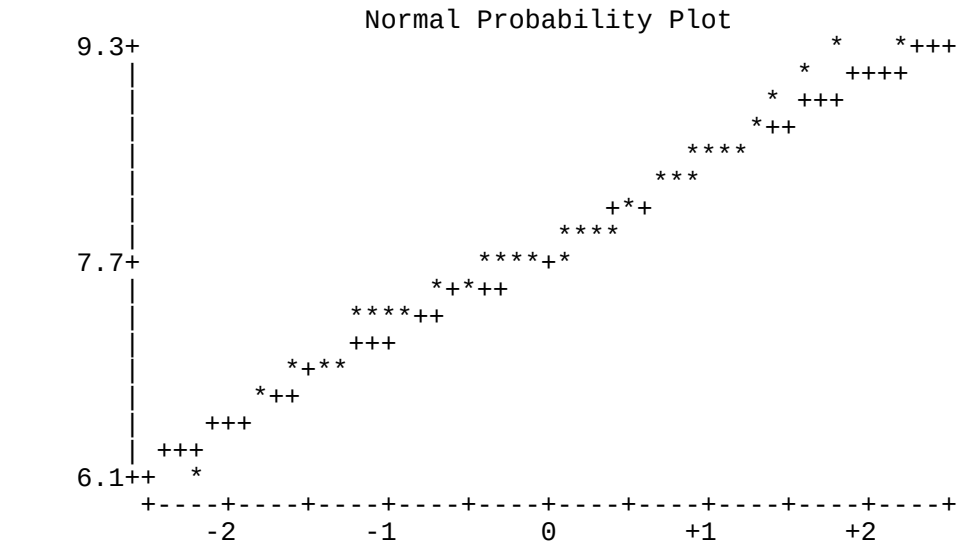
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
    92 00                    2       0
    90 0                     1       |
    88 0                     1       |
    86 0                     1       |
    84 0000                  4       |
    82 0000                  4    +-----+
    80 000                   3    |     |
    78 0000000               7    |     |
    76 0000000000           10    *--+--*
    74 00000                 5    +-----+
    72 000000                6       |
    70                               |
    68 000                   3       |
    66 0                     1       |
    64                               |
    62                               |
    60 0                     1       0
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	49	Sum Weights	49
Mean	8.21428571	Sum Observations	402.5
Std Deviation	1.33868717	Variance	1.79208333
Skewness	0.79519542	Kurtosis	0.14586137
Uncorrected SS	3392.27	Corrected SS	86.02
Coeff Variation	16.2970612	Std Error Mean	0.19124102

Basic Statistical Measures

Location		Variability	
Mean	8.214286	Std Deviation	1.33869
Median	7.900000	Variance	1.79208
Mode	7.600000	Range	5.60000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	42.95253	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	612.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.941229	Pr < W	0.0165
Kolmogorov-Smirnov	D	0.127535	Pr > D	0.0450
Cramer-von Mises	W-Sq	0.174709	Pr > W-Sq	0.0108
Anderson-Darling	A-Sq	0.971363	Pr > A-Sq	0.0144

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.8
99%	11.8
95%	10.6
90%	10.2
75% Q3	8.8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.9
25% Q1	7.3
10%	6.7
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	19	10.2	44
6.3	32	10.3	42
6.3	5	10.6	36
6.4	14	11.4	46
6.7	1	11.8	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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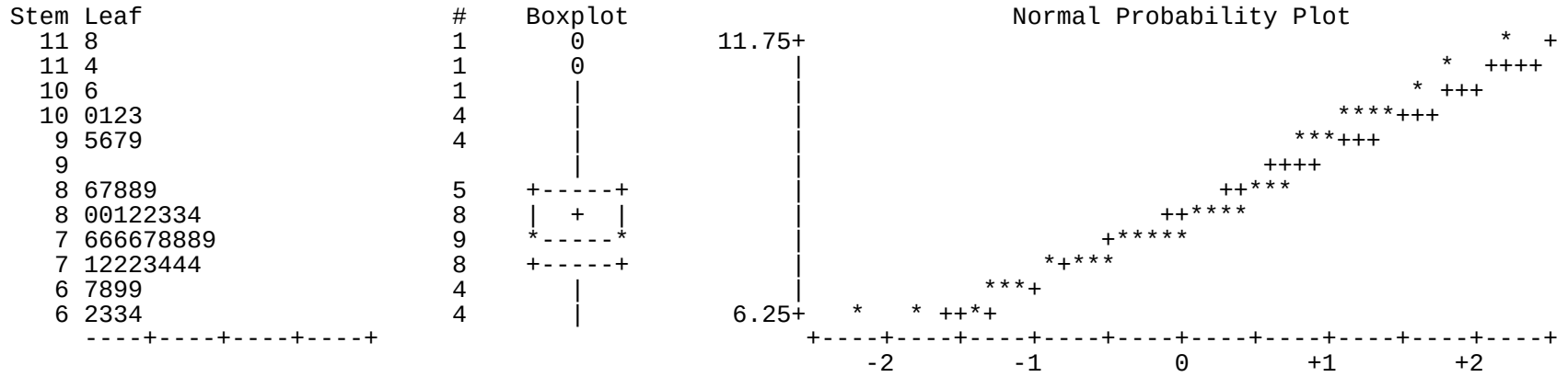
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	49	Sum Weights	49
Mean	0.42653061	Sum Observations	20.9
Std Deviation	1.19229742	Variance	1.42157313
Skewness	0.26686411	Kurtosis	-0.6123156
Uncorrected SS	77.15	Corrected SS	68.2355102
Coeff Variation	279.533844	Std Error Mean	0.1703282

Basic Statistical Measures

Location		Variability	
Mean	0.426531	Std Deviation	1.19230
Median	0.200000	Variance	1.42157
Mode	0.100000	Range	4.50000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.504169	Pr > |t|	0.0157
Sign	M	6.5	Pr >= |M|	0.0789

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	193	Pr >= |S|	0.0397

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.968593	Pr < W	0.2127
Kolmogorov-Smirnov	D	0.093278	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.076618	Pr > W-Sq	0.2300
Anderson-Darling	A-Sq	0.459374	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.8
99%	2.8
95%	2.5
90%	2.2
75% Q3	1.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.2
25% Q1	-0.4
10%	-1.0
5%	-1.5
1%	-1.7
0% Min	-1.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.7	12	2.2	36
-1.7	5	2.4	44
-1.5	32	2.5	35
-1.5	19	2.8	46
-1.0	40	2.8	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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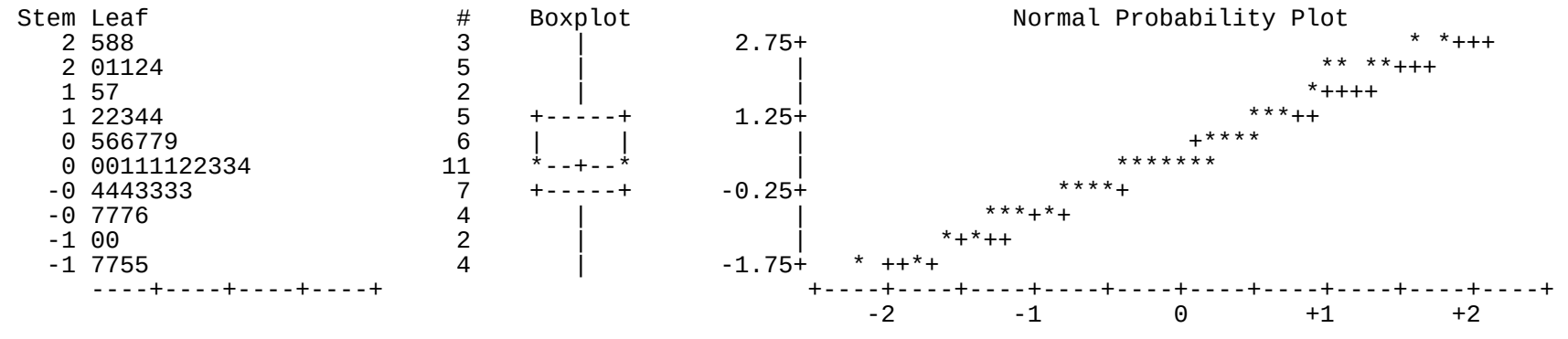
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	46	Sum Weights	46
Mean	7.96521739	Sum Observations	366.4
Std Deviation	0.91535479	Variance	0.8378744
Skewness	0.74361087	Kurtosis	0.16514125
Uncorrected SS	2956.16	Corrected SS	37.7043478
Coeff Variation	11.4918997	Std Error Mean	0.1349617

Basic Statistical Measures

Location		Variability	
Mean	7.965217	Std Deviation	0.91535
Median	7.750000	Variance	0.83787
Mode	7.500000	Range	3.70000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 4 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	59.01835	Pr > |t|	<.0001
Sign	M	23	Pr >= |M|	<.0001
Signed Rank	S	540.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.937342	Pr < W	0.0156
Kolmogorov-Smirnov	D	0.158575	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.191349	Pr > W-Sq	0.0066
Anderson-Darling	A-Sq	1.076483	Pr > A-Sq	0.0076

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.10
99%	10.10
95%	9.80

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	9.50
75% Q3	8.30
50% Median	7.75
25% Q1	7.40
10%	6.90
5%	6.80
1%	6.40
0% Min	6.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	39	9.5	16
6.4	23	9.7	1
6.8	32	9.8	29
6.8	19	10.1	3
6.9	37	10.1	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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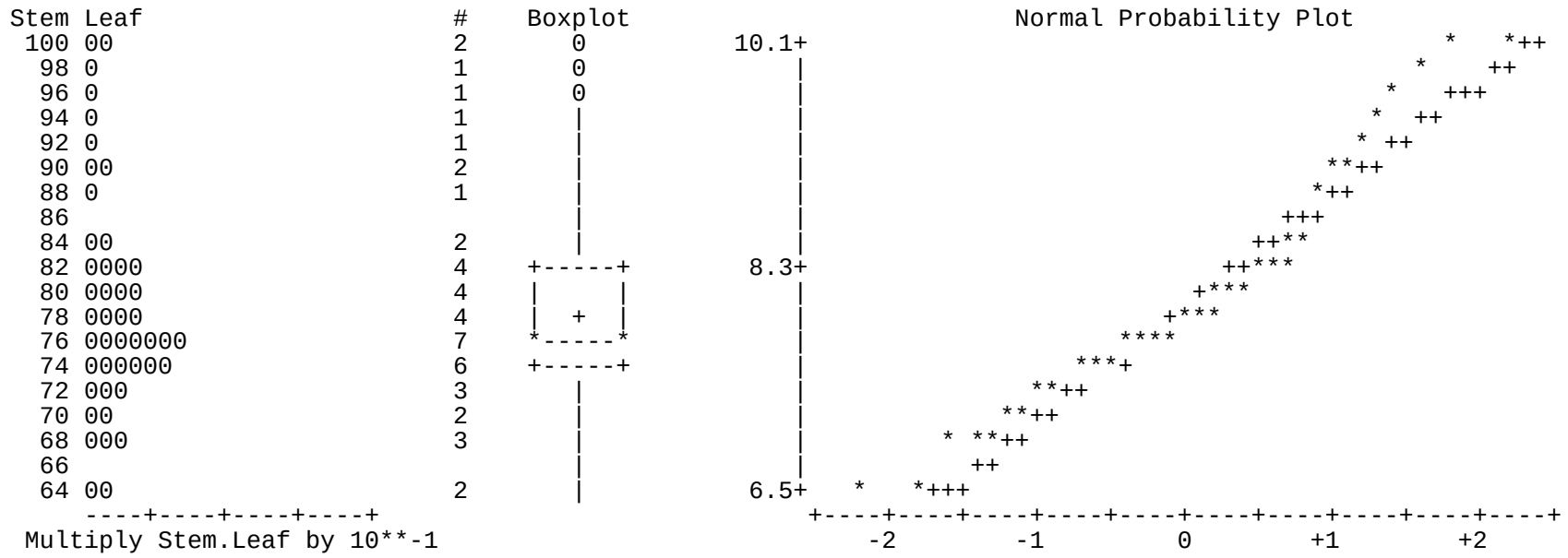
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	46	Sum Weights	46
Mean	8.1826087	Sum Observations	376.4
Std Deviation	1.27928875	Variance	1.63657971
Skewness	0.79356388	Kurtosis	0.22111005
Uncorrected SS	3153.58	Corrected SS	73.646087
Coeff Variation	15.6342409	Std Error Mean	0.18862084

Basic Statistical Measures

Location		Variability	
Mean	8.182609	Std Deviation	1.27929
Median	7.750000	Variance	1.63658
Mode	7.600000	Range	5.50000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	43.38126	Pr > |t|	<.0001
Sign	M	23	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	540.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.942981	Pr < W	0.0253
Kolmogorov-Smirnov	D	0.147005	Pr > D	0.0139
Cramer-von Mises	W-Sq	0.149376	Pr > W-Sq	0.0235
Anderson-Darling	A-Sq	0.83434	Pr > A-Sq	0.0300

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.80
99%	11.80
95%	10.60
90%	10.10
75% Q3	9.00

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.30
10%	6.60
5%	6.50
1%	6.30
0% Min	6.30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	23	10.1	4
6.5	42	10.3	41
6.5	40	10.6	2
6.6	33	10.8	38
6.6	32	11.8	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

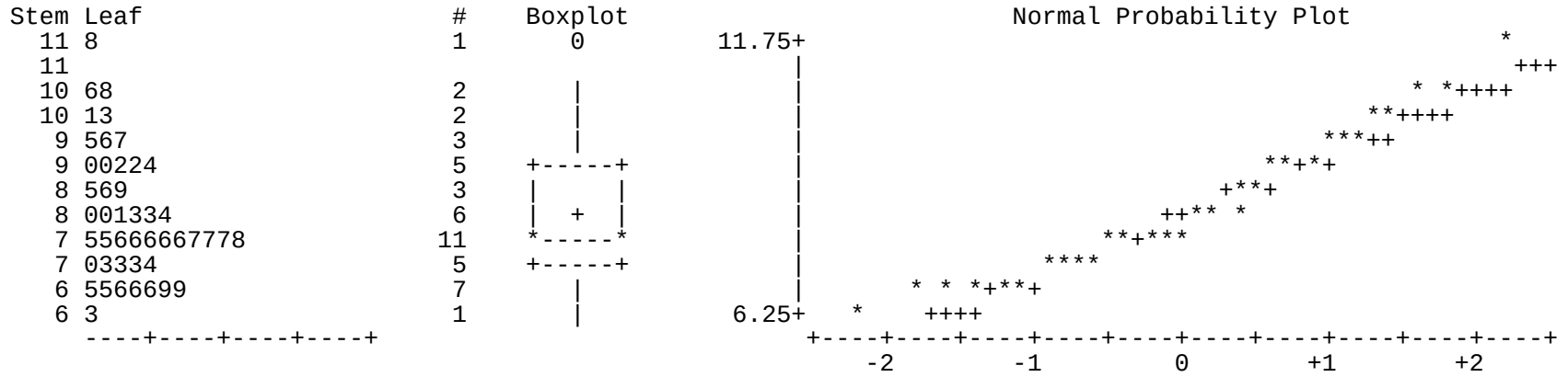

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	46	Sum Weights	46
Mean	0.2173913	Sum Observations	10
Std Deviation	0.90217129	Variance	0.81391304
Skewness	0.07456829	Kurtosis	0.23605263
Uncorrected SS	38.8	Corrected SS	36.626087
Coeff Variation	414.998795	Std Error Mean	0.1330179

Basic Statistical Measures

Location		Variability	
Mean	0.21739	Std Deviation	0.90217
Median	0.15000	Variance	0.81391
Mode	-0.50000	Range	4.40000
		Interquartile Range	1.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.634301	Pr > |t|	0.1092
Sign	M	3.5	Pr >= |M|	0.3713

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	140	Pr >= |S|	0.1149

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.989225	Pr < W	0.9431
Kolmogorov-Smirnov	D	0.082819	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.034468	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.229068	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.50
99%	2.50
95%	1.70
90%	1.30
75% Q3	0.70

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.15
25% Q1	-0.40
10%	-1.00
5%	-1.40
1%	-1.90
0% Min	-1.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.9	44	1.3	43
-1.4	33	1.7	3
-1.4	10	1.7	38
-1.2	40	1.8	2
-1.0	42	2.5	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

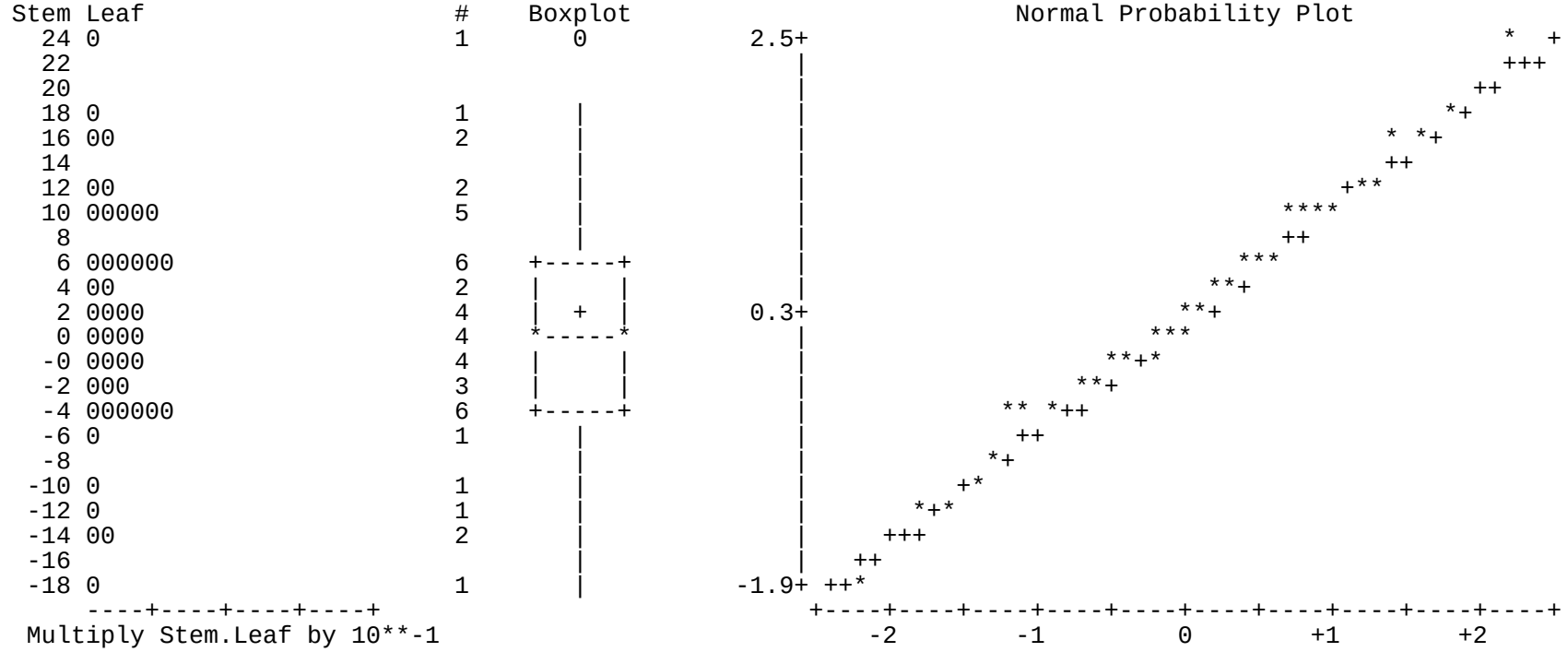

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	7.9245283	Sum Observations	420
Std Deviation	0.72877813	Variance	0.53111756
Skewness	0.87494764	Kurtosis	0.61335219
Uncorrected SS	3355.92	Corrected SS	27.6181132
Coeff Variation	9.19648592	Std Error Mean	0.10010537

Basic Statistical Measures

Location		Variability	
Mean	7.924528	Std Deviation	0.72878
Median	7.700000	Variance	0.53112
Mode	7.600000	Range	3.30000
		Interquartile Range	0.80000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	79.16187	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.930412	Pr < W	0.0042
Kolmogorov-Smirnov	D	0.168162	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.254725	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.443921	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.9
99%	9.9
95%	9.4
90%	9.2
75% Q3	8.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.5
10%	7.3
5%	6.9
1%	6.6
0% Min	6.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	26	9.2	44
6.7	22	9.3	45
6.9	37	9.4	25
6.9	9	9.7	27
7.2	21	9.9	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

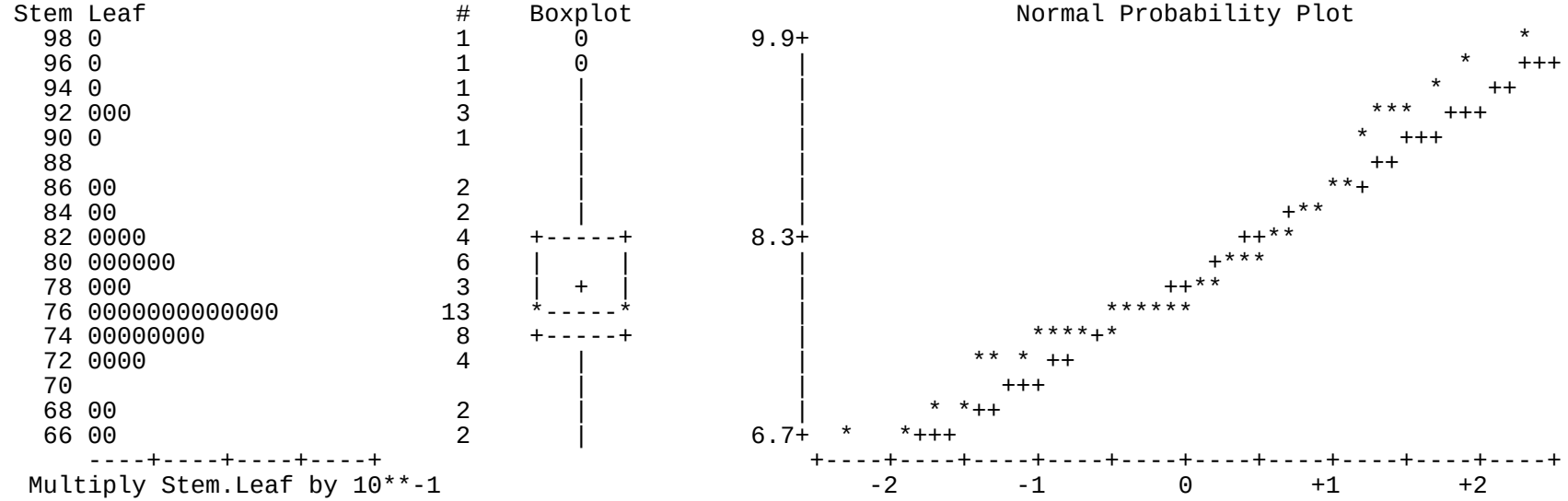

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	7.88113208	Sum Observations	417.7
Std Deviation	1.16140773	Variance	1.34886792
Skewness	0.94667847	Kurtosis	0.45232861
Uncorrected SS	3362.09	Corrected SS	70.1411321
Coeff Variation	14.7365597	Std Error Mean	0.15953162

Basic Statistical Measures

Location		Variability	
Mean	7.881132	Std Deviation	1.16141
Median	7.600000	Variance	1.34887
Mode	7.600000	Range	4.80000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	49.40169	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	715.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.924819	Pr < W 0.0025
Kolmogorov-Smirnov	D	0.161671	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.21929	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.285249	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.0
99%	11.0
95%	10.4
90%	9.8
75% Q3	8.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.6
25% Q1	7.1
10%	6.6
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	26	9.9	47
6.2	22	10.2	33
6.3	50	10.4	3
6.4	40	10.7	5
6.6	36	11.0	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
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Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

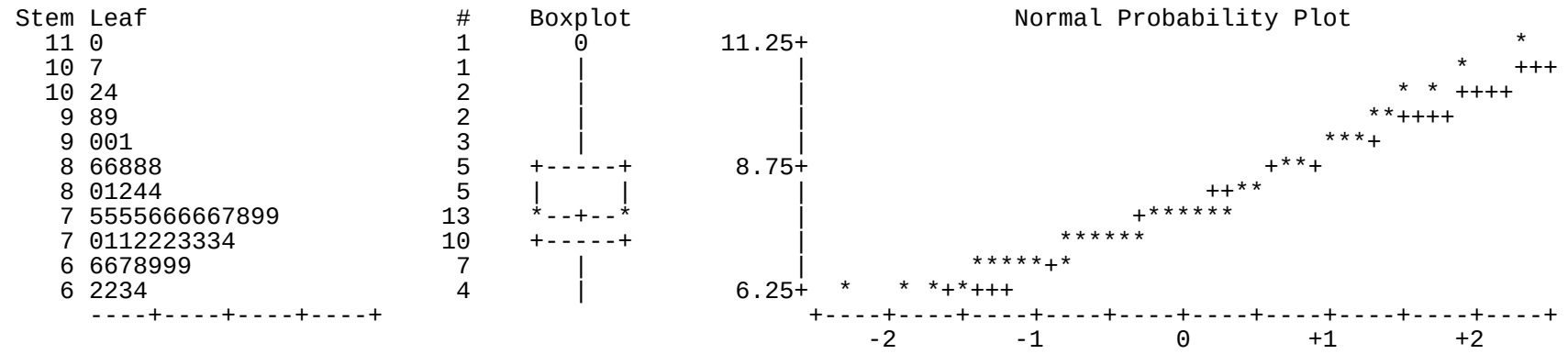

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	-0.0433962	Sum Observations	-2.3
Std Deviation	0.9732004	Variance	0.94711901
Skewness	0.42325382	Kurtosis	0.42191345
Uncorrected SS	49.35	Corrected SS	49.2501887
Coeff Variation	-2242.5922	Std Error Mean	0.13367936

Basic Statistical Measures

Location		Variability	
Mean	-0.04340	Std Deviation	0.97320
Median	-0.30000	Variance	0.94712
Mode	-0.30000	Range	4.50000
		Interquartile Range	1.20000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.32463	Pr > |t|	0.7468
Sign	M	-4	Pr >= |M|	0.3222

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-93.5	Pr >= |S|	0.3718

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.961567	Pr < W	0.0861
Kolmogorov-Smirnov	D	0.113417	Pr > D	0.0876
Cramer-von Mises	W-Sq	0.127093	Pr > W-Sq	0.0474
Anderson-Darling	A-Sq	0.796976	Pr > A-Sq	0.0382

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.2
99%	2.2
95%	2.1
90%	1.6
75% Q3	0.5

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.3
25% Q1	-0.7
10%	-1.1
5%	-1.7
1%	-2.3
0% Min	-2.3

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.3	44	1.7	5
-1.9	46	1.7	48
-1.7	40	2.1	3
-1.2	50	2.1	52
-1.1	36	2.2	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

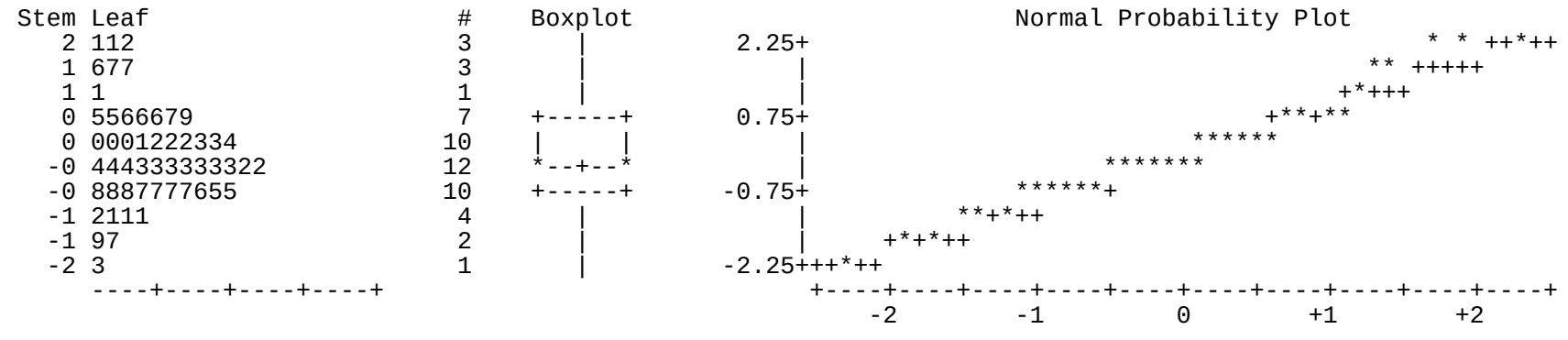

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	60	Sum Weights	60
Mean	7.84666667	Sum Observations	470.8
Std Deviation	0.62286018	Variance	0.3879548
Skewness	0.07556406	Kurtosis	-0.2067483
Uncorrected SS	3717.1	Corrected SS	22.8893333
Coeff Variation	7.93789523	Std Error Mean	0.0804109

Basic Statistical Measures

Location		Variability	
Mean	7.846667	Std Deviation	0.62286
Median	7.900000	Variance	0.38795
Mode	7.500000	Range	3.00000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	97.58212	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	915	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.989195	Pr < W	0.8743
Kolmogorov-Smirnov	D	0.094423	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.056313	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.29368	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.50
99%	9.50
95%	8.85
90%	8.60
75% Q3	8.30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.90
25% Q1	7.40
10%	7.05
5%	6.85
1%	6.50
0% Min	6.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	24	8.7	53
6.6	5	8.8	27
6.8	3	8.9	20
6.9	44	9.0	29
7.0	15	9.5	22

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

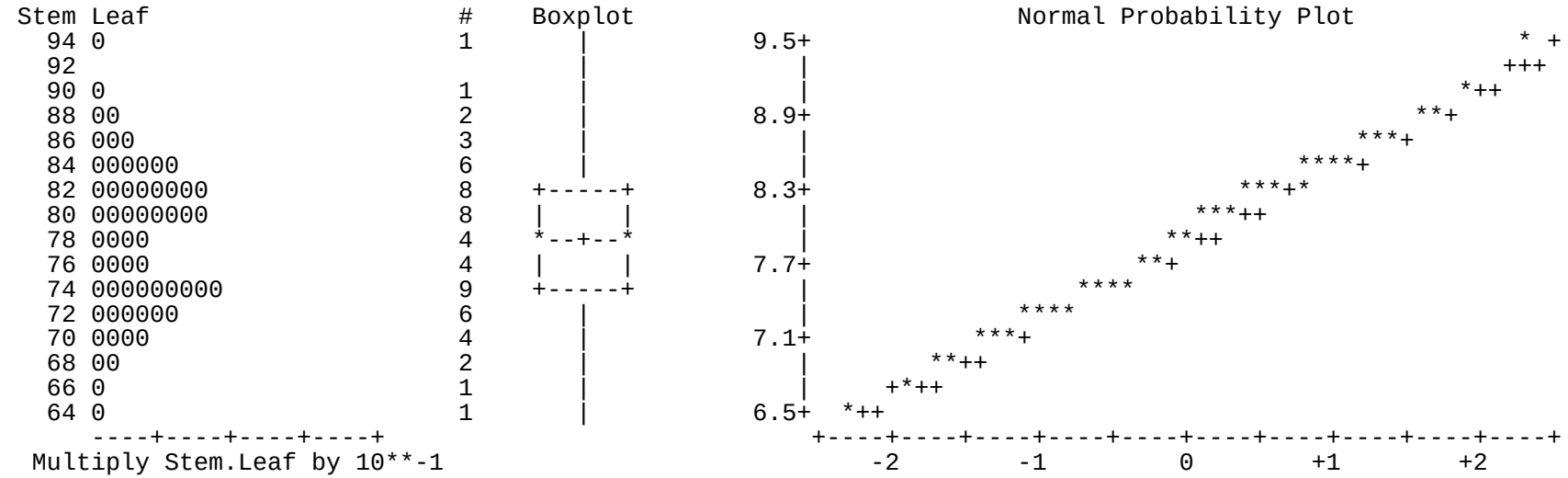

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	60	Sum Weights	60
Mean	7.87166667	Sum Observations	472.3
Std Deviation	0.87393357	Variance	0.76375989
Skewness	0.13188438	Kurtosis	-0.3963064
Uncorrected SS	3762.85	Corrected SS	45.0618333
Coeff Variation	11.1022685	Std Error Mean	0.11282434

Basic Statistical Measures

Location		Variability	
Mean	7.871667	Std Deviation	0.87393
Median	7.850000	Variance	0.76376
Mode	8.500000	Range	4.00000
		Interquartile Range	1.25000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	69.76922	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	915	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.990141	Pr < W	0.9106
Kolmogorov-Smirnov	D	0.064684	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.03579	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.203636	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.00
99%	10.00
95%	9.40
90%	9.05
75% Q3	8.50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.85
25% Q1	7.25
10%	6.75
5%	6.45
1%	6.00
0% Min	6.00

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.0	32	9.2	54
6.4	49	9.3	16
6.4	24	9.5	4
6.5	44	9.5	53
6.5	35	10.0	17

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

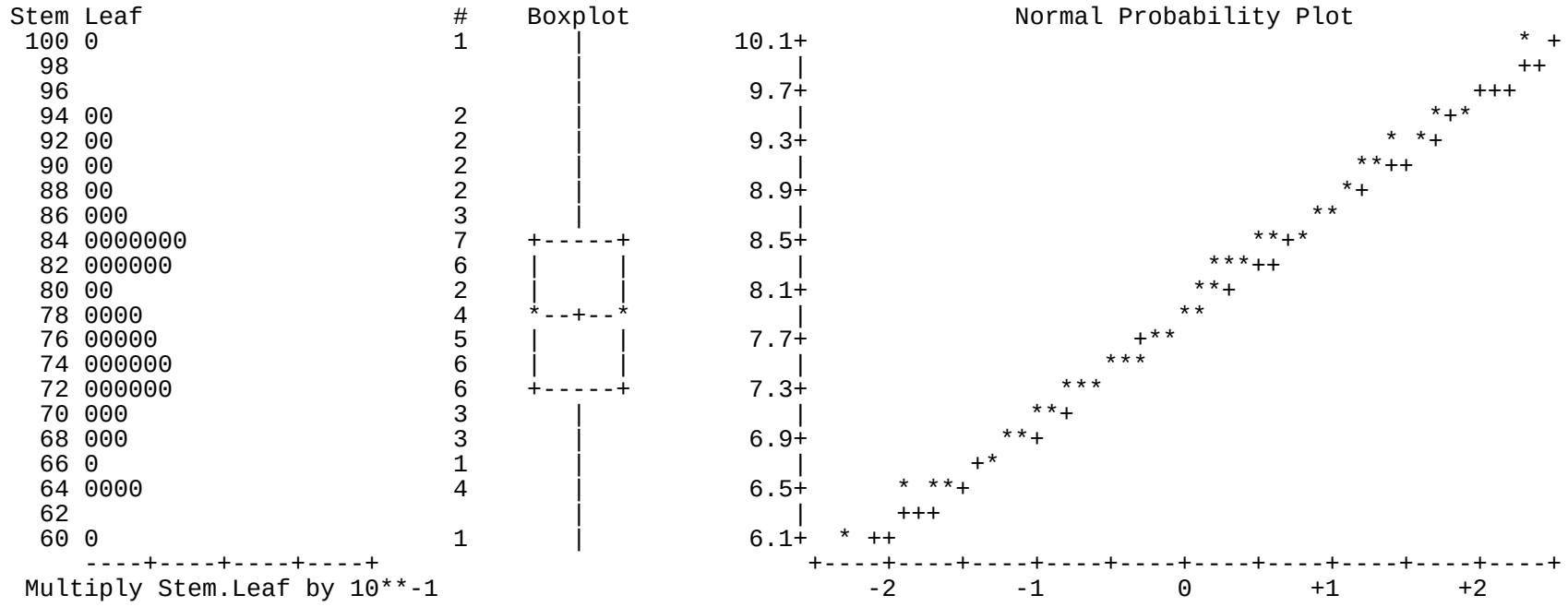

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	0.025	Sum Observations	1.5
Std Deviation	0.72360327	Variance	0.52360169
Skewness	0.18525453	Kurtosis	1.24755753
Uncorrected SS	30.93	Corrected SS	30.8925
Coeff Variation	2894.41309	Std Error Mean	0.09341678

Basic Statistical Measures

Location		Variability	
Mean	0.025000	Std Deviation	0.72360
Median	0.000000	Variance	0.52360
Mode	0.000000	Range	3.80000
		Interquartile Range	0.65000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.267618	Pr > |t|	0.7899
Sign	M	3	Pr >= |M|	0.4799

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	35	Pr >= |S|	0.7389

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.956202	Pr < W	0.0308
Kolmogorov-Smirnov	D	0.137783	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.225397	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.152507	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.00
99%	2.00
95%	1.40
90%	0.80
75% Q3	0.35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.00
25% Q1	-0.30
10%	-0.95
5%	-1.15
1%	-1.80
0% Min	-1.80

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.8	22	0.8	58
-1.6	49	1.2	16
-1.2	47	1.6	4
-1.1	39	1.9	5
-1.1	32	2.0	17

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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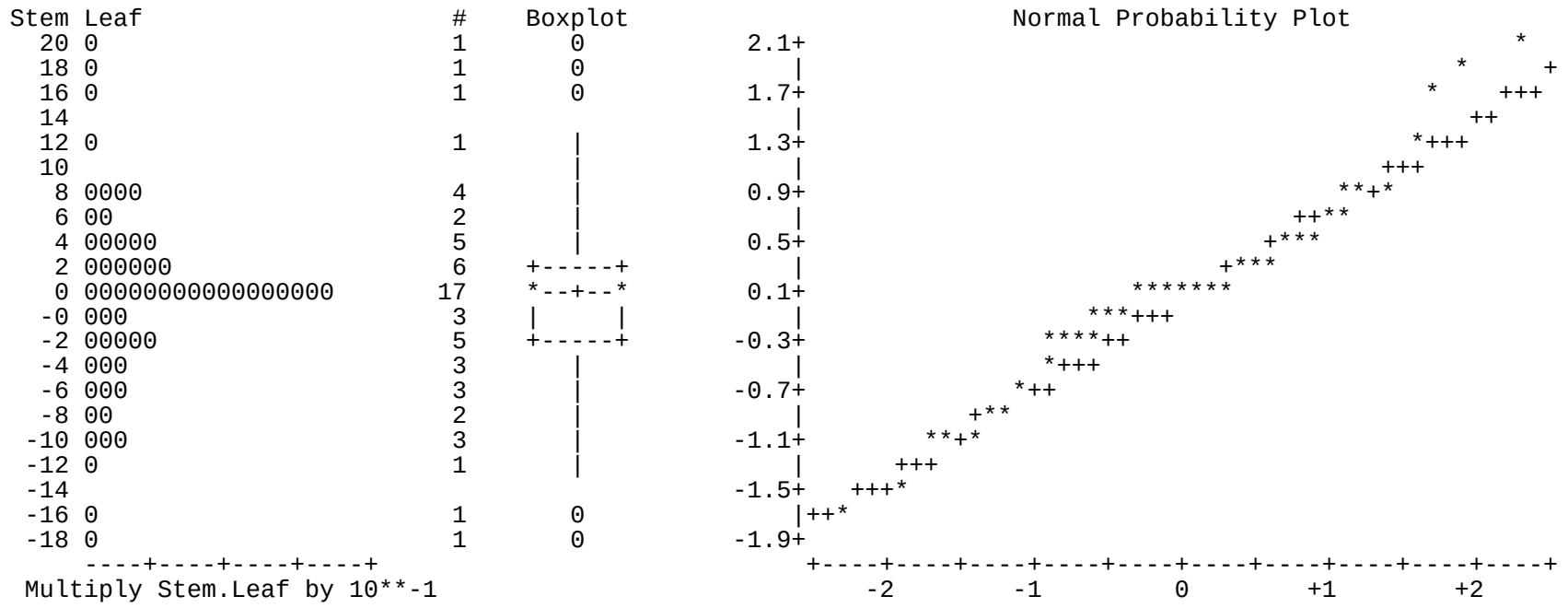
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	7.76111111	Sum Observations	419.1
Std Deviation	0.65887745	Variance	0.4341195
Skewness	0.09963428	Kurtosis	-0.231203
Uncorrected SS	3275.69	Corrected SS	23.0083333
Coeff Variation	8.48947326	Std Error Mean	0.08966186

Basic Statistical Measures

Location		Variability	
Mean	7.761111	Std Deviation	0.65888
Median	7.750000	Variance	0.43412
Mode	8.400000	Range	3.20000
		Interquartile Range	1.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	86.55978	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.971707	Pr < W	0.2290
Kolmogorov-Smirnov	D	0.085981	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.073474	Pr > W-Sq	0.2491
Anderson-Darling	A-Sq	0.512998	Pr > A-Sq	0.1945

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.60
99%	9.60
95%	8.60
90%	8.60
75% Q3	8.30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.30
10%	6.80
5%	6.70
1%	6.40
0% Min	6.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	38	8.6	7
6.7	21	8.6	25
6.7	14	8.6	43
6.8	51	8.7	46
6.8	49	9.6	40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

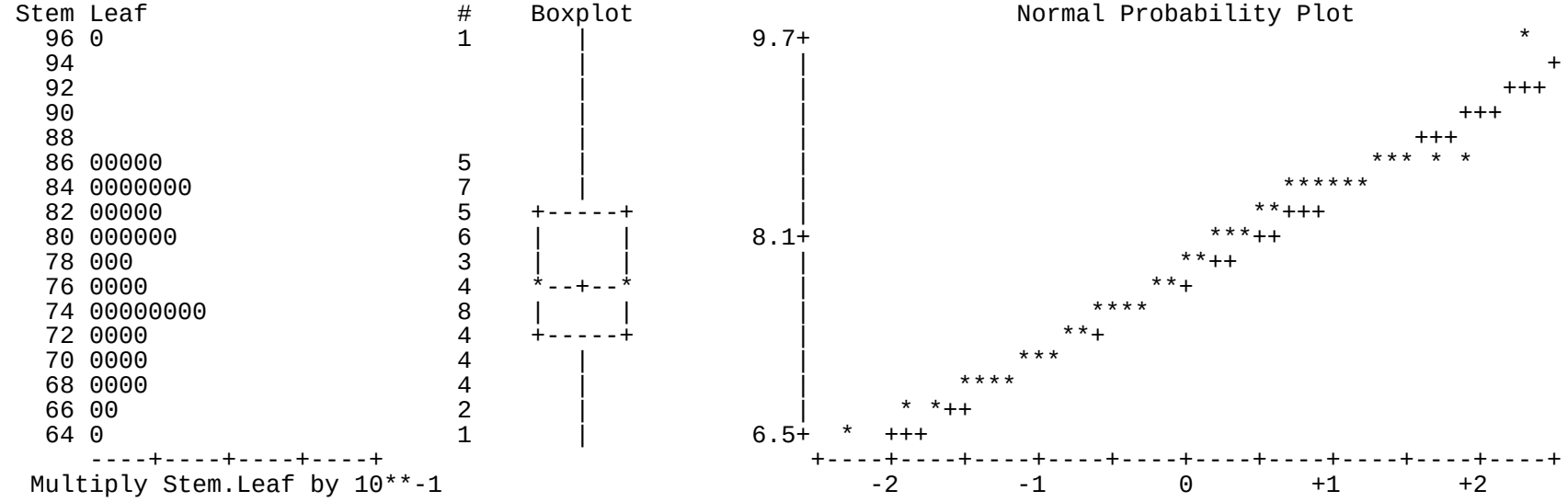

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	7.39074074	Sum Observations	399.1
Std Deviation	0.8358181	Variance	0.69859189
Skewness	0.33756447	Kurtosis	0.17470373
Uncorrected SS	2986.67	Corrected SS	37.0253704
Coeff Variation	11.3089896	Std Error Mean	0.11374044

Basic Statistical Measures

Location		Variability	
Mean	7.390741	Std Deviation	0.83582
Median	7.300000	Variance	0.69859
Mode	7.100000	Range	4.20000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	64.97901	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.982197	Pr < W	0.5988
Kolmogorov-Smirnov	D	0.114665	Pr > D	0.0765
Cramer-von Mises	W-Sq	0.075157	Pr > W-Sq	0.2391
Anderson-Darling	A-Sq	0.404342	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.7
99%	9.7
95%	8.9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.5
75% Q3	7.9
50% Median	7.3
25% Q1	6.9
10%	6.3
5%	6.2
1%	5.5
0% Min	5.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	19	8.6	15
6.1	16	8.8	7
6.2	32	8.9	5
6.2	21	8.9	40
6.2	14	9.7	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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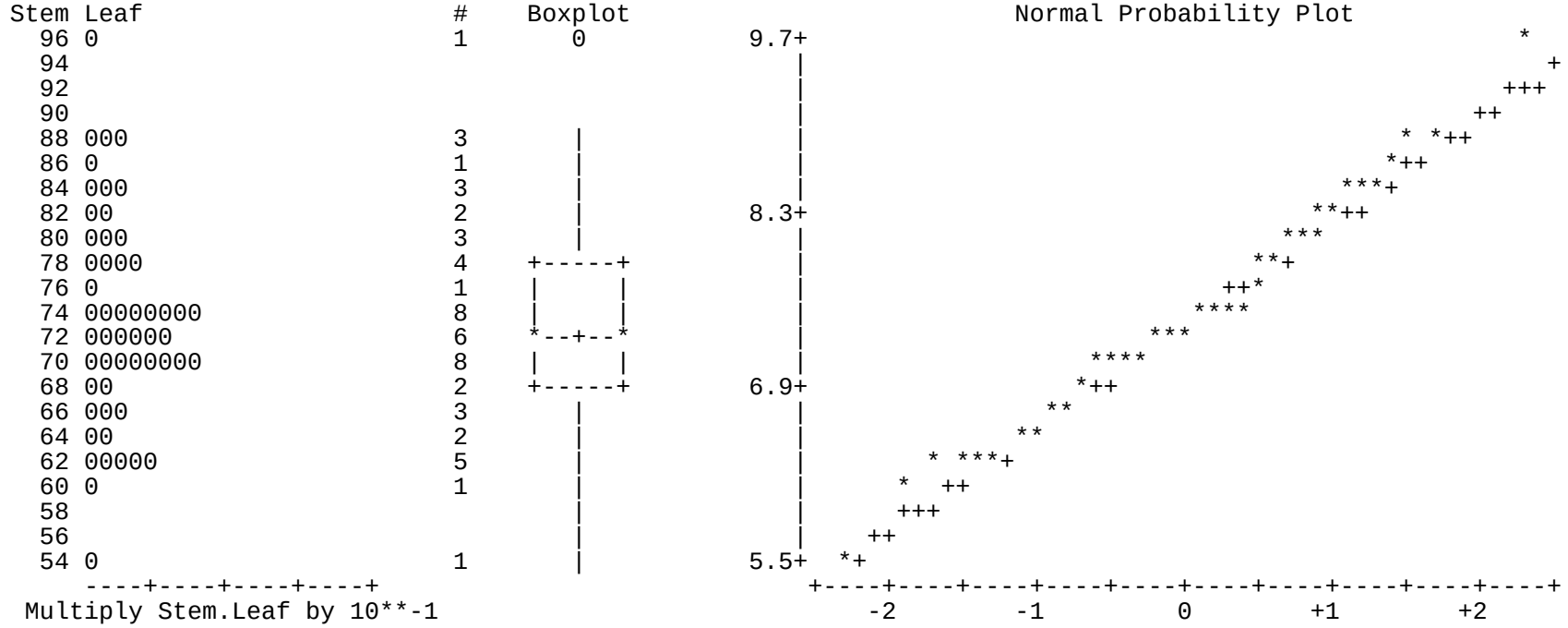
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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[redacted]

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	-0.3703704	Sum Observations	-20
Std Deviation	0.81902603	Variance	0.67080363
Skewness	0.48888543	Kurtosis	2.71742635
Uncorrected SS	42.96	Corrected SS	35.5525926
Coeff Variation	-221.13703	Std Error Mean	0.11145533

Basic Statistical Measures

Location		Variability	
Mean	-0.37037	Std Deviation	0.81903
Median	-0.45000	Variance	0.67080
Mode	-0.50000	Range	5.10000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.32304	Pr > |t|	0.0016
Sign	M	-9	Pr >= |M|	0.0153

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-354.5	Pr >= |S|	0.0003

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.956818	Pr < W	0.0497
Kolmogorov-Smirnov	D	0.113459	Pr > D	0.0824
Cramer-von Mises	W-Sq	0.075285	Pr > W-Sq	0.2383
Anderson-Darling	A-Sq	0.547335	Pr > A-Sq	0.1562

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.60
99%	2.60
95%	0.90
90%	0.40
75% Q3	0.10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.45
25% Q1	-0.80
10%	-1.30
5%	-1.60
1%	-2.50
0% Min	-2.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.5	19	0.6	45
-2.1	16	0.7	38
-1.6	46	0.9	5
-1.5	25	1.1	53
-1.3	47	2.6	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

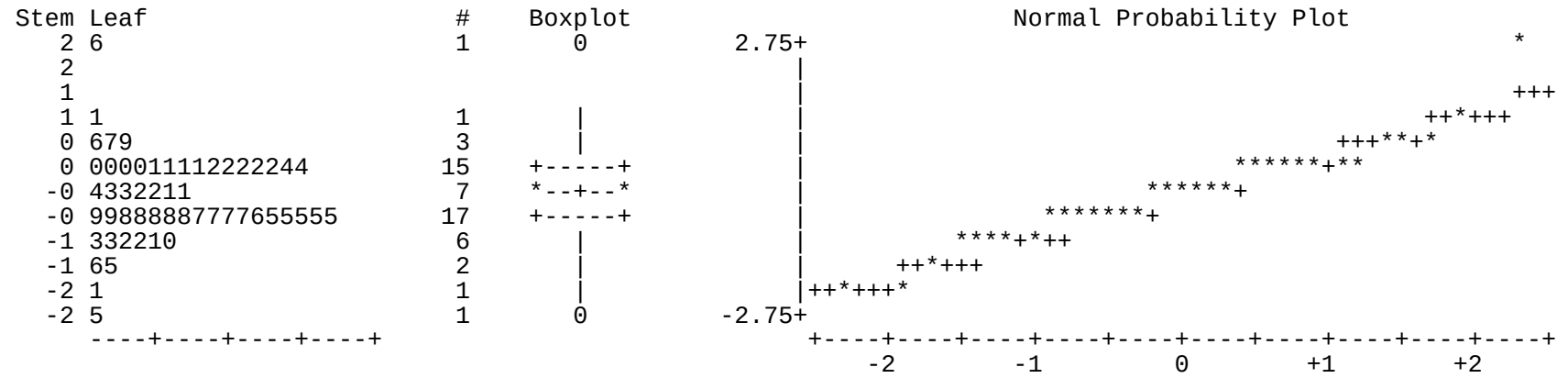

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	52	Sum Weights	52
Mean	8.10384615	Sum Observations	421.4
Std Deviation	0.74648498	Variance	0.55723982
Skewness	0.03490844	Kurtosis	-0.6479544
Uncorrected SS	3443.38	Corrected SS	28.4192308
Coeff Variation	9.21148997	Std Error Mean	0.10351884

Basic Statistical Measures

Location		Variability	
Mean	8.103846	Std Deviation	0.74648
Median	8.100000	Variance	0.55724
Mode	7.700000	Range	2.80000
		Interquartile Range	0.95000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	78.28378	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.979229	Pr < W	0.4936
Kolmogorov-Smirnov	D	0.051899	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.022029	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.184962	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.50
99%	9.50
95%	9.50
90%	9.10
75% Q3	8.60

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	8.10
25% Q1	7.65
10%	7.10
5%	6.80
1%	6.70
0% Min	6.70

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.7	45	9.2	26
6.7	9	9.3	25
6.8	30	9.5	4
6.9	36	9.5	31
7.1	39	9.5	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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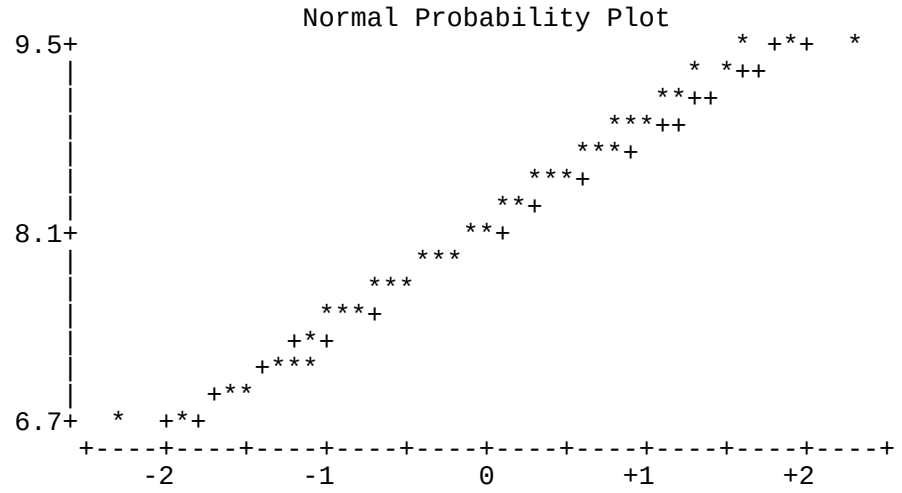
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                 #    Boxplot
    94 000                  3       |
    92 00                   2       |
    90 000                  3       |
    88 000                  3       |
    86 0000                 4    +-----+
    84 00000                5    |     |
    82 0000                 4    |     |
    80 00000                5    *--+--*
    78 00000                5    |     |
    76 000000               6    +-----+
    74 0000                 4       |
    72 0                    1       |
    70 000                  3       |
    68 00                   2       |
    66 00                   2       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	52	Sum Weights	52
Mean	7.69423077	Sum Observations	400.1
Std Deviation	0.99358994	Variance	0.98722097
Skewness	0.26914814	Kurtosis	-0.3835877
Uncorrected SS	3128.81	Corrected SS	50.3482692
Coeff Variation	12.9134408	Std Error Mean	0.13778613

Basic Statistical Measures

Location		Variability	
Mean	7.694231	Std Deviation	0.99359
Median	7.650000	Variance	0.98722
Mode	8.000000	Range	4.10000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	55.84184	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.982826	Pr < W	0.6519
Kolmogorov-Smirnov	D	0.06594	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.023193	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.192727	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.90
99%	9.90
95%	9.70
90%	8.90
75% Q3	8.40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.65
25% Q1	6.90
10%	6.50
5%	6.10
1%	5.80
0% Min	5.80

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.8	9	9.0	21
6.0	29	9.4	17
6.1	48	9.7	26
6.3	11	9.8	25
6.3	8	9.9	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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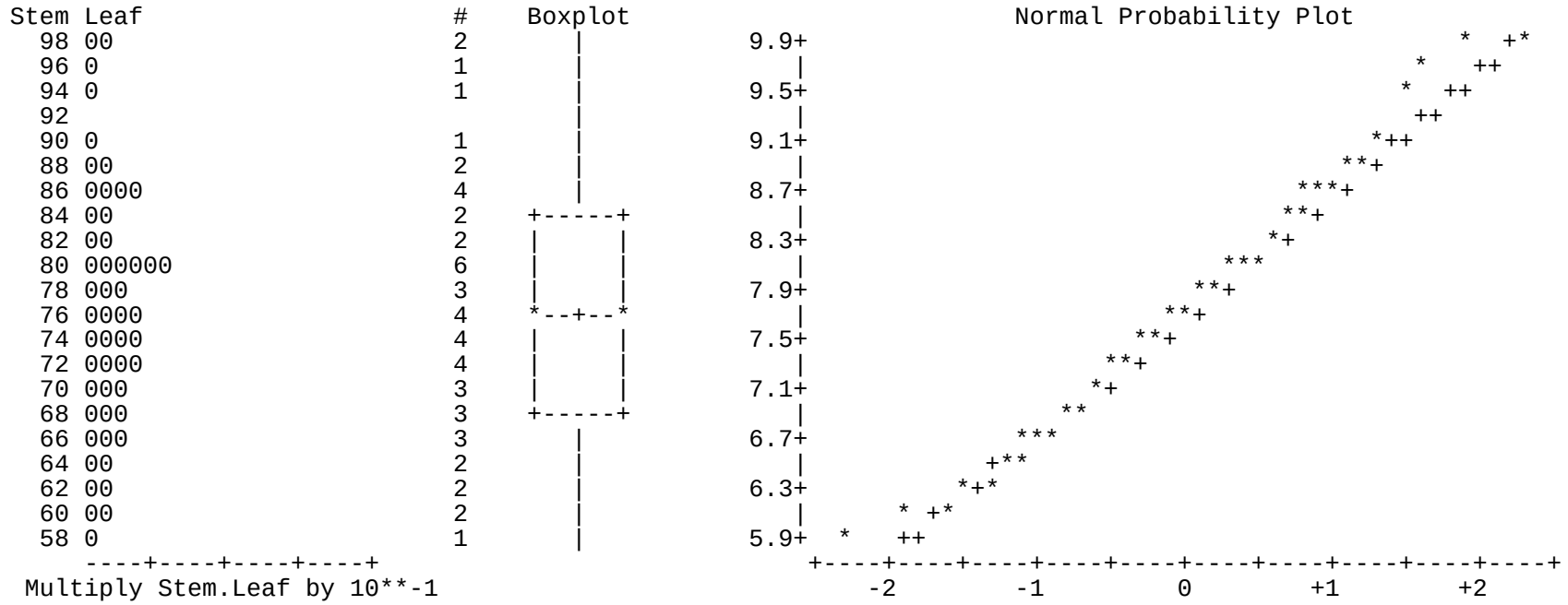
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	52	Sum Weights	52
Mean	-0.4096154	Sum Observations	-21.3
Std Deviation	0.75310068	Variance	0.56716063
Skewness	-0.9128616	Kurtosis	1.01944235
Uncorrected SS	37.65	Corrected SS	28.9251923
Coeff Variation	-183.85556	Std Error Mean	0.10443627

Basic Statistical Measures

Location		Variability	
Mean	-0.40962	Std Deviation	0.75310
Median	-0.25000	Variance	0.56716
Mode	0.00000	Range	3.80000
		Interquartile Range	1.05000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.92216	Pr > |t|	0.0003
Sign	M	-8	Pr >= |M|	0.0259

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-314	Pr >= |S|	0.0003

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.945027	Pr < W	0.0180
Kolmogorov-Smirnov	D	0.121046	Pr > D	0.0560
Cramer-von Mises	W-Sq	0.148529	Pr > W-Sq	0.0240
Anderson-Darling	A-Sq	0.856041	Pr > A-Sq	0.0258

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.90
99%	0.90
95%	0.50
90%	0.40
75% Q3	0.15

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.25
25% Q1	-0.90
10%	-1.40
5%	-1.80
1%	-2.90
0% Min	-2.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.9	48	0.4	52
-1.8	19	0.5	25
-1.8	29	0.5	26
-1.6	8	0.7	49
-1.5	47	0.9	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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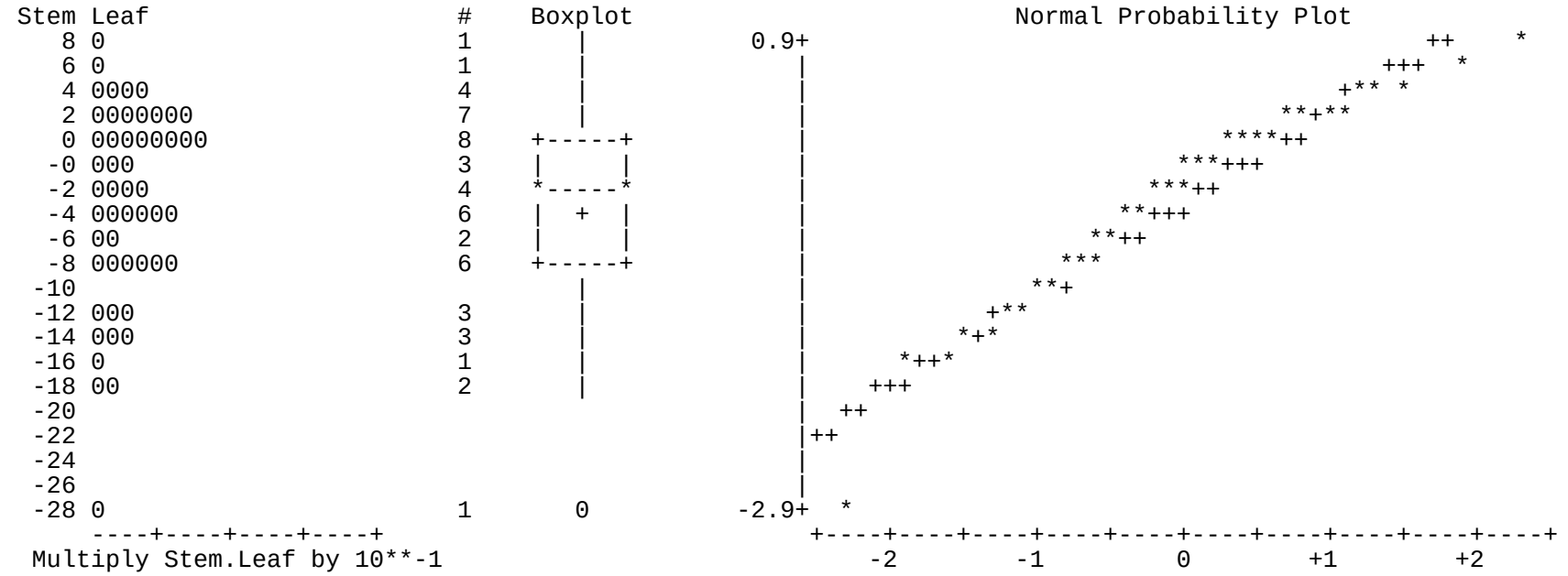
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots

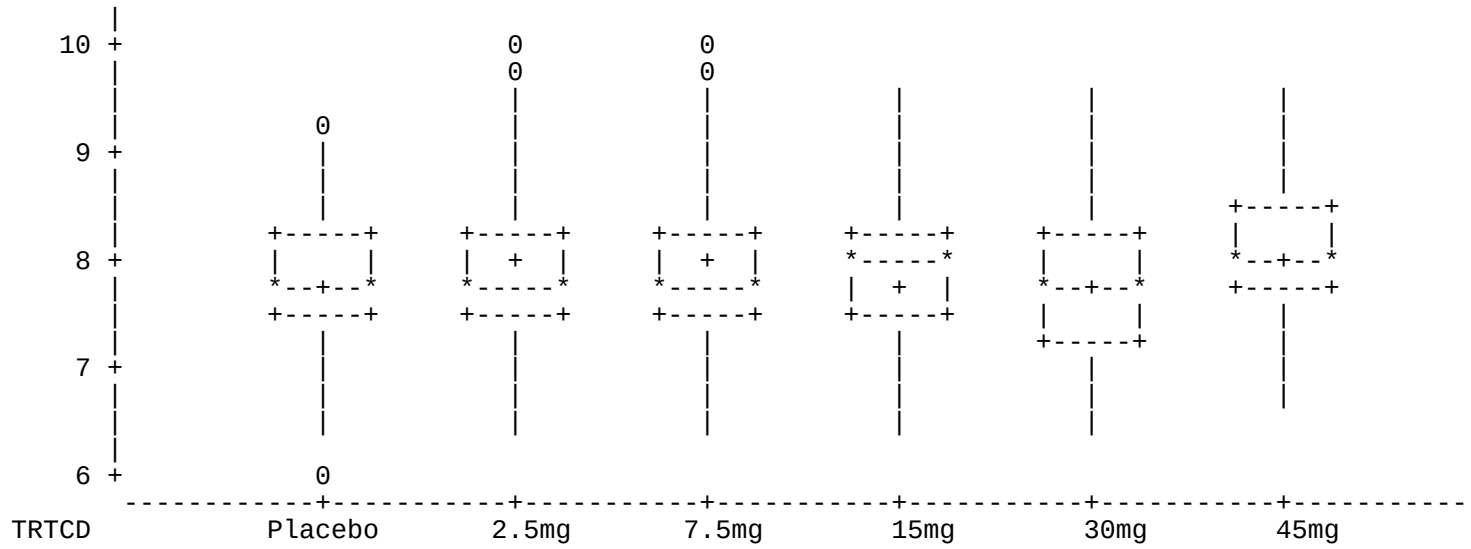

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots

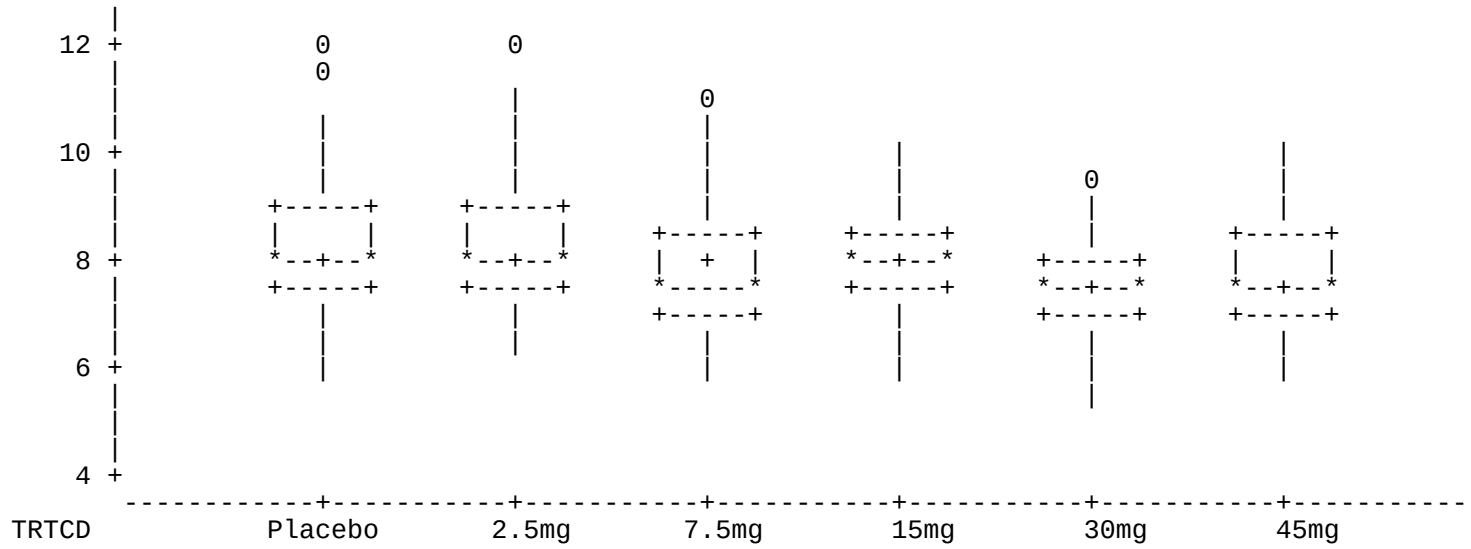

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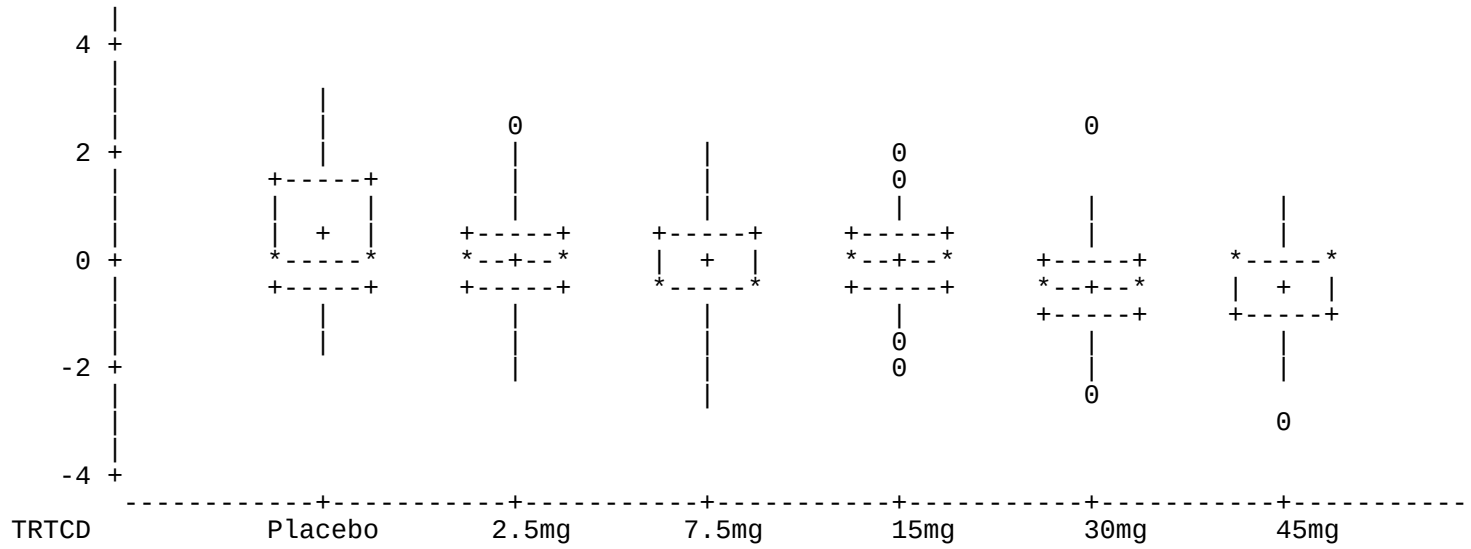
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	314
Observations Used	314
Observations Not Used	0
Total Observations	314

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6720	0.05460	12.31	<.0001	0.05	0.5767	0.7933

Fit Statistics

-2 Res Log Likelihood	785.0
AIC (smaller is better)	787.0
AICC (smaller is better)	787.0
BIC (smaller is better)	790.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.7076	0.5403	303	1.31	0.1913
SEX	Female				-0.01659	0.09360	303	-0.18	0.8594
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.6594	0.09559	303	-6.90	<.0001
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	0.8521	0.1655	303	5.15	<.0001
TRTCD				2.5mg	0.5922	0.1663	303	3.56	0.0004
TRTCD				7.5mg	0.2649	0.1611	303	1.64	0.1011
TRTCD				15mg	0.3967	0.1564	303	2.54	0.0117
TRTCD				30mg	0.01546	0.1613	303	0.10	0.9237
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.4662	0.1113	303	-4.19	<.0001
REGIONCD			Eastern Europe		-0.1925	0.1145	303	-1.68	0.0937
REGIONCD			Western Europe		0				.
EFSTDBL					-0.07755	0.06570	303	-1.18	0.2388

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	303	0.03	0.8594
TRTTYPCD	1	303	47.59	<.0001
TRTCD	5	303	8.28	<.0001
REGIONCD	2	303	8.78	0.0002
EFSTDBL	1	303	1.39	0.2388

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2599	0.1702	303	-1.53	0.1278	0.05	-0.5949	0.07504
7.5mg vs Pbo	-0.5873	0.1639	303	-3.58	0.0004	0.05	-0.9099	-0.2647
15mg vs Pbo	-0.4554	0.1586	303	-2.87	0.0044	0.05	-0.7674	-0.1434
30mg vs Pbo	-0.8367	0.1619	303	-5.17	<.0001	0.05	-1.1552	-0.5181
45mg vs Pbo	-0.8521	0.1655	303	-5.15	<.0001	0.05	-1.1777	-0.5265

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5127	0.5127	0.5127	0.5127	0.5127
SEX	Male				0.4873	0.4873	0.4873	0.4873	0.4873
TRTTYPCD		Diet & Exercise			0.4045	0.4045	0.4045	0.4045	0.4045
TRTTYPCD		Monotherapy			0.5955	0.5955	0.5955	0.5955	0.5955
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3089	0.3089	0.3089	0.3089	0.3089
REGIONCD			Eastern Europe		0.2834	0.2834	0.2834	0.2834	0.2834
REGIONCD			Western Europe		0.4076	0.4076	0.4076	0.4076	0.4076
EFSTDBL					7.8959	7.8959	7.8959	7.8959	7.8959

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5127
SEX	Male				0.4873
TRTTYPCD		Diet & Exercise			0.4045
TRTTYPCD		Monotherapy			0.5955
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3089
REGIONCD			Eastern Europe		0.2834
REGIONCD			Western Europe		0.4076
EFSTDBL					7.8959

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.4736	0.1180	303	4.01	<.0001	0.05	0.2414	0.7057
TRTCD	2.5mg	WORK.EFF	0.2136	0.1215	303	1.76	0.0796	0.05	-0.02540	0.4527
TRTCD	7.5mg	WORK.EFF	-0.1137	0.1132	303	-1.00	0.3160	0.05	-0.3365	0.1091
TRTCD	15mg	WORK.EFF	0.01813	0.1060	303	0.17	0.8643	0.05	-0.1904	0.2267
TRTCD	30mg	WORK.EFF	-0.3631	0.1121	303	-3.24	0.0013	0.05	-0.5837	-0.1425
TRTCD	45mg	WORK.EFF	-0.3786	0.1147	303	-3.30	0.0011	0.05	-0.6042	-0.1529

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.2599	0.1702	303	1.53	0.1278	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.5873	0.1639	303	3.58	0.0004	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.4554	0.1586	303	2.87	0.0044	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.8367	0.1619	303	5.17	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.8521	0.1655	303	5.15	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.3274	0.1662	303	1.97	0.0498	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1955	0.1611	303	1.21	0.2259	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5767	0.1659	303	3.48	0.0006	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5922	0.1663	303	3.56	0.0004	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.1318	0.1552	303	-0.85	0.3964	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.2494	0.1596	303	1.56	0.1191	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.2649	0.1611	303	1.64	0.1011	0.05
TRTCD	15mg	30mg	WORK.EFF	0.3812	0.1541	303	2.47	0.0139	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3967	0.1564	303	2.54	0.0117	0.05
TRTCD	30mg	45mg	WORK.EFF	0.01546	0.1613	303	0.10	0.9237	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.07504	0.5949
TRTCD	Placebo	7.5mg	0.2647	0.9099
TRTCD	Placebo	15mg	0.1434	0.7674
TRTCD	Placebo	30mg	0.5181	1.1552
TRTCD	Placebo	45mg	0.5265	1.1777
TRTCD	2.5mg	7.5mg	0.000330	0.6544
TRTCD	2.5mg	15mg	-0.1215	0.5126
TRTCD	2.5mg	30mg	0.2503	0.9032
TRTCD	2.5mg	45mg	0.2649	0.9195
TRTCD	7.5mg	15mg	-0.4373	0.1736

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.06458	0.5634
TRTCD	7.5mg	45mg	-0.05207	0.5818
TRTCD	15mg	30mg	0.07791	0.6846
TRTCD	15mg	45mg	0.08892	0.7045
TRTCD	30mg	45mg	-0.3019	0.3328

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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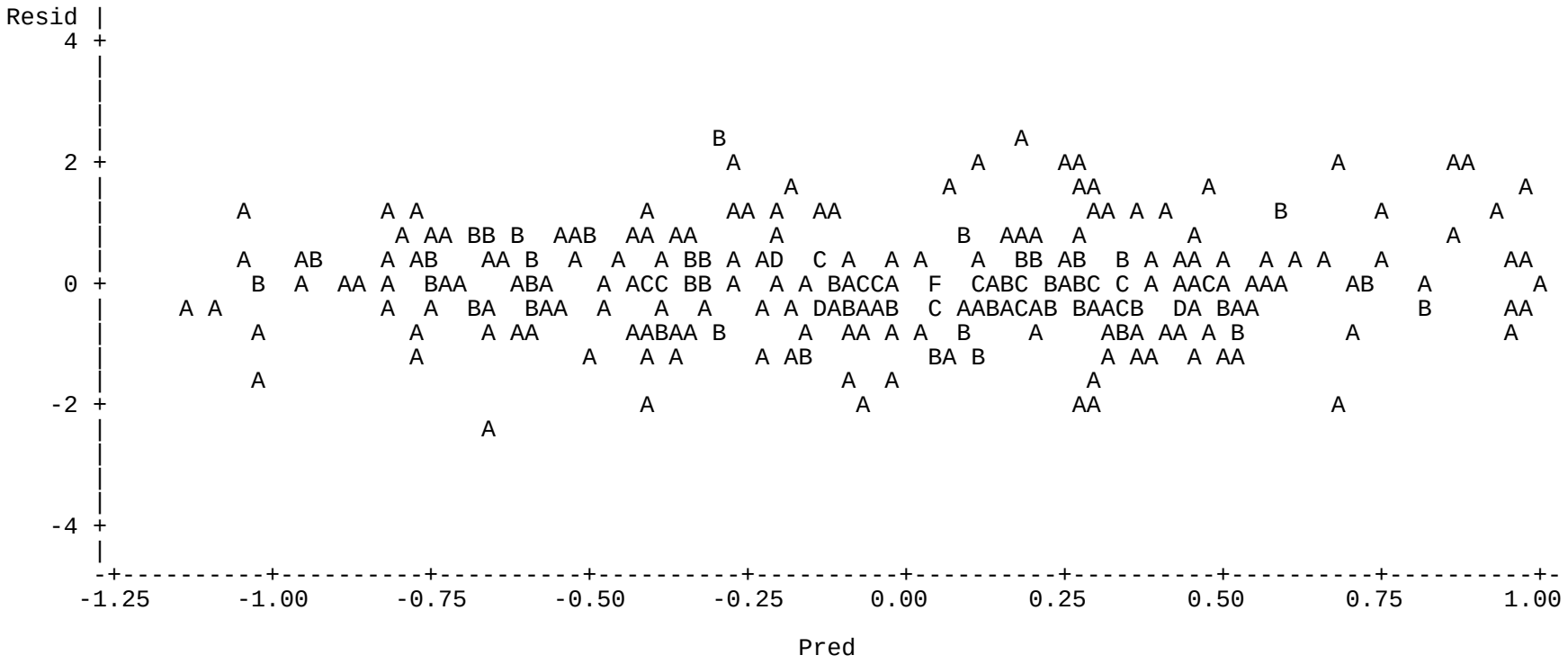
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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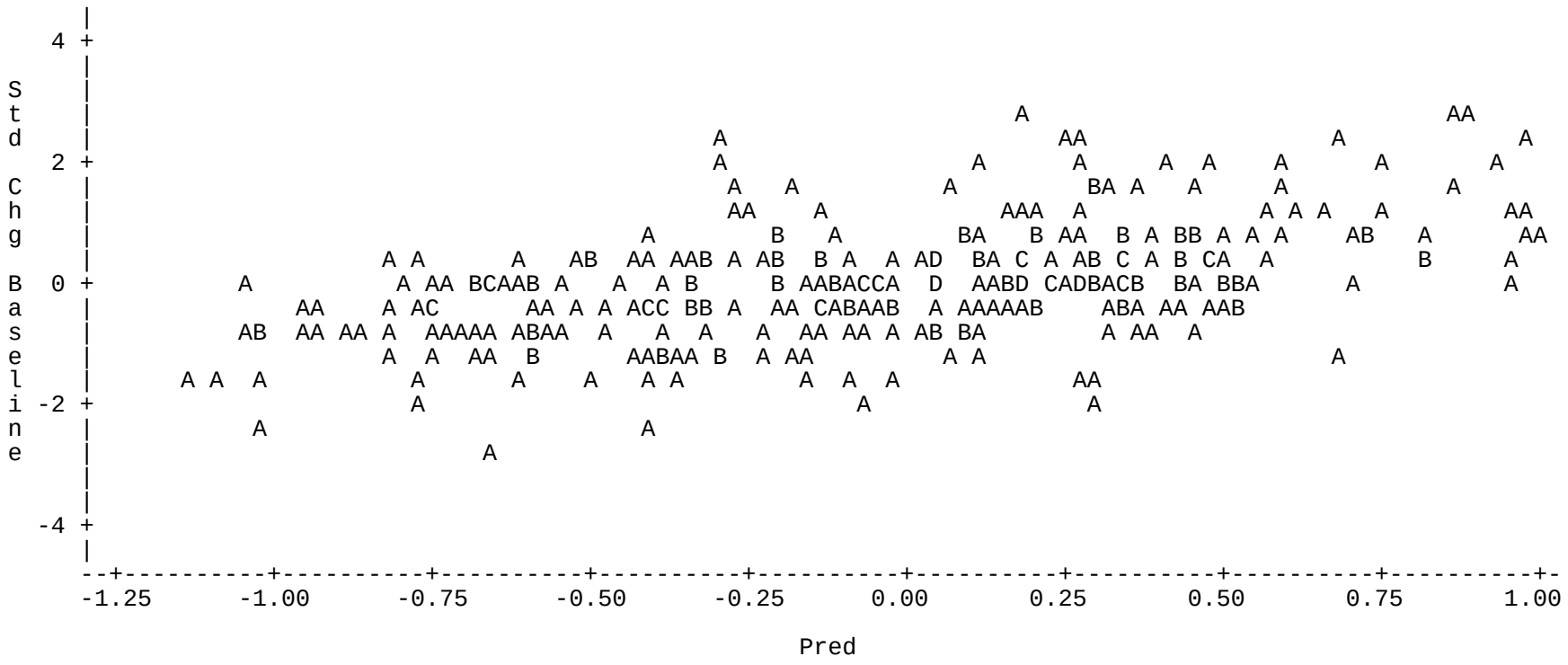
Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	314	Sum Weights	314
Mean	0	Sum Observations	0
Std Deviation	0.80657503	Variance	0.65056328
Skewness	0.30887216	Kurtosis	0.77496493
Uncorrected SS	203.626305	Corrected SS	203.626305
Coeff Variation		Std Error Mean	0.04551766

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.80658
Median	-0.05460	Variance	0.65056
Mode		Range	4.73433
		Interquartile Range	0.88357

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-7	Pr >= |M|	0.4632
Signed Rank	S	-1052.5	Pr >= |S|	0.5142

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.9825	Pr < W	0.0007
Kolmogorov-Smirnov	D	0.06395	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.31076	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.823955	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.5007162
99%	2.1212056
95%	1.4046122
90%	1.0230183
75% Q3	0.4221284
50% Median	-0.0545972
25% Q1	-0.4614371
10%	-0.9147943
5%	-1.2108436
1%	-1.9632840
0% Min	-2.2336143

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-2.23361	269	1.98040	13
-2.18886	274	2.12121	294
-2.07934	213	2.38412	306
-1.96328	37	2.42760	289
-1.88296	268	2.50072	281

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Stem	Leaf	#	Boxplot
24	30	2	0
22	8	1	0
20	2	1	0
18	224588	6	0
16	1338	4	0
14	03	2	|
12	601155899	9	|
10	012371157	9	|
8	00124569122449	14	|
6	01145667833	11	|
4	11223344678999011234679	23	+-----+
2	12223344555679911124445567 99	28	| |
0	011222334445556678888002223444555566779	40	| + |
-0	9888888766644332222100999999988765432110	40	*-----*
-2	887774433229887777554444332 21	29	| |
-4	876663211111099876655554332 1111000	34	+-----+
-6	9988865544333211022	19	|
-8	9410963322110	13	|
-10	9875211964430	13	|
-12	842231	6	|
-14	8	1	|
-16	07	2	|
-18	6830	4	0
-20	98	2	0
-22	3	1	0

----+----+----+----+----+----+----+----+
Multiply Stem.Leaf by 10**-1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
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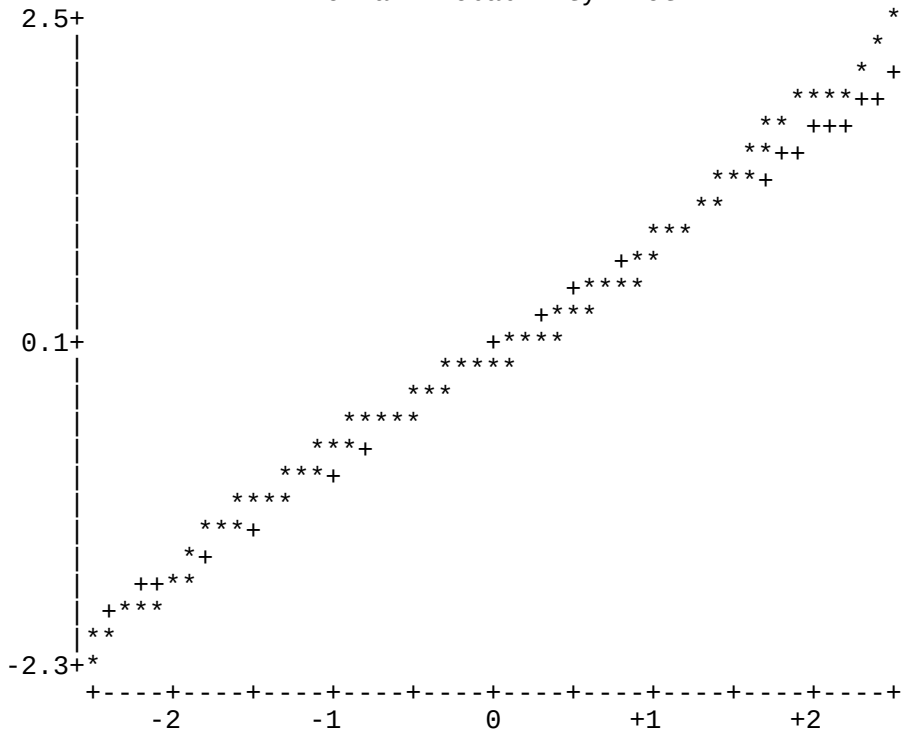
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
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Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	314
Observations Used	314
Observations Not Used	0
Total Observations	314

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6745	0.05526	12.21	<.0001	0.05	0.5781	0.7974

Fit Statistics

-2 Res Log Likelihood	784.9
AIC (smaller is better)	786.9
AICC (smaller is better)	786.9
BIC (smaller is better)	790.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.7284	0.5487	298	1.33	0.1854
SEX	Female				-0.08189	0.2301	298	-0.36	0.7222
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.6682	0.09595	298	-6.96	<.0001
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	1.0168	0.2425	298	4.19	<.0001
TRTCD				2.5mg	0.4438	0.2364	298	1.88	0.0614
TRTCD				7.5mg	0.1511	0.2307	298	0.65	0.5132
TRTCD				15mg	0.3446	0.2214	298	1.56	0.1207
TRTCD				30mg	-0.01088	0.2351	298	-0.05	0.9631
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.4628	0.1129	298	-4.10	<.0001
REGIONCD			Eastern Europe		-0.1982	0.1151	298	-1.72	0.0860
REGIONCD			Western Europe		0				.
EFSTDBL					-0.07535	0.06589	298	-1.14	0.2537
SEX*TRTCD	Female			Placebo	-0.2951	0.3298	298	-0.89	0.3717
SEX*TRTCD	Female			2.5mg	0.3046	0.3369	298	0.90	0.3666
SEX*TRTCD	Female			7.5mg	0.2213	0.3222	298	0.69	0.4929
SEX*TRTCD	Female			15mg	0.1023	0.3117	298	0.33	0.7429
SEX*TRTCD	Female			30mg	0.05126	0.3233	298	0.16	0.8741
SEX*TRTCD	Female			45mg	0				.
SEX*TRTCD	Male			Placebo	0				.
SEX*TRTCD	Male			2.5mg	0				.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male			7.5mg	0				.
SEX*TRTCD	Male			15mg	0				.
SEX*TRTCD	Male			30mg	0				.
SEX*TRTCD	Male			45mg	0				.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	298	0.04	0.8499
TRTTYPCD	1	298	48.50	<.0001
TRTCD	5	298	8.49	<.0001
REGIONCD	2	298	8.40	0.0003
EFSTDBL	1	298	1.31	0.2537
SEX*TRTCD	5	298	0.78	0.5666

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2732	0.1709	298	-1.60	0.1110	0.05	-0.6096	0.06318
7.5mg vs Pbo	-0.6076	0.1647	298	-3.69	0.0003	0.05	-0.9317	-0.2834
15mg vs Pbo	-0.4735	0.1592	298	-2.97	0.0032	0.05	-0.7869	-0.1602
30mg vs Pbo	-0.8545	0.1628	298	-5.25	<.0001	0.05	-1.1749	-0.5341
45mg vs Pbo	-0.8693	0.1662	298	-5.23	<.0001	0.05	-1.1964	-0.5421

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	Placebo	WORK.EFF	0.3038	0.1582	298	1.92	0.0558	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	Placebo	-0.00758	0.6152

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	2.5mg	WORK.EFF	0.3305	0.1768	298	1.87	0.0625	0.05
SEX*TRTCD	Female	7.5mg	WORK.EFF	-0.04559	0.1587	298	-0.29	0.7741	0.05
SEX*TRTCD	Female	15mg	WORK.EFF	0.02902	0.1532	298	0.19	0.8499	0.05
SEX*TRTCD	Female	30mg	WORK.EFF	-0.3775	0.1530	298	-2.47	0.0142	0.05
SEX*TRTCD	Female	45mg	WORK.EFF	-0.4179	0.1600	298	-2.61	0.0095	0.05
SEX*TRTCD	Male	Placebo	WORK.EFF	0.6808	0.1766	298	3.86	0.0001	0.05
SEX*TRTCD	Male	2.5mg	WORK.EFF	0.1077	0.1681	298	0.64	0.5220	0.05
SEX*TRTCD	Male	7.5mg	WORK.EFF	-0.1850	0.1615	298	-1.15	0.2529	0.05
SEX*TRTCD	Male	15mg	WORK.EFF	0.008569	0.1478	298	0.06	0.9538	0.05
SEX*TRTCD	Male	30mg	WORK.EFF	-0.3469	0.1658	298	-2.09	0.0372	0.05
SEX*TRTCD	Male	45mg	WORK.EFF	-0.3360	0.1652	298	-2.03	0.0429	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	2.5mg	-0.01738	0.6783
SEX*TRTCD	Female	7.5mg	-0.3578	0.2667
SEX*TRTCD	Female	15mg	-0.2724	0.3305
SEX*TRTCD	Female	30mg	-0.6786	-0.07645
SEX*TRTCD	Female	45mg	-0.7328	-0.1030

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Male	Placebo	0.3333	1.0282
SEX*TRTCD	Male	2.5mg	-0.2230	0.4385
SEX*TRTCD	Male	7.5mg	-0.5027	0.1328
SEX*TRTCD	Male	15mg	-0.2823	0.2995
SEX*TRTCD	Male	30mg	-0.6731	-0.02067
SEX*TRTCD	Male	45mg	-0.6612	-0.01084

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Female	2.5mg	WORK.EFF	-0.02663	0.2380	298	-0.11	0.9110
SEX*TRTCD	Female	Placebo	Female	7.5mg	WORK.EFF	0.3494	0.2242	298	1.56	0.1201
SEX*TRTCD	Female	Placebo	Female	15mg	WORK.EFF	0.2748	0.2202	298	1.25	0.2131
SEX*TRTCD	Female	Placebo	Female	30mg	WORK.EFF	0.6814	0.2201	298	3.10	0.0022
SEX*TRTCD	Female	Placebo	Female	45mg	WORK.EFF	0.7217	0.2256	298	3.20	0.0015
SEX*TRTCD	Female	Placebo	Male	Placebo	WORK.EFF	-0.3770	0.2366	298	-1.59	0.1121
SEX*TRTCD	Female	Placebo	Male	2.5mg	WORK.EFF	0.1961	0.2308	298	0.85	0.3963
SEX*TRTCD	Female	Placebo	Male	7.5mg	WORK.EFF	0.4888	0.2260	298	2.16	0.0314
SEX*TRTCD	Female	Placebo	Male	15mg	WORK.EFF	0.2953	0.2164	298	1.36	0.1735

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Male	30mg	WORK.EFF	0.6507	0.2285	298	2.85	0.0047
SEX*TRTCD	Female	Placebo	Male	45mg	WORK.EFF	0.6398	0.2291	298	2.79	0.0056
SEX*TRTCD	Female	2.5mg	Female	7.5mg	WORK.EFF	0.3761	0.2373	298	1.58	0.1142
SEX*TRTCD	Female	2.5mg	Female	15mg	WORK.EFF	0.3014	0.2340	298	1.29	0.1987
SEX*TRTCD	Female	2.5mg	Female	30mg	WORK.EFF	0.7080	0.2332	298	3.04	0.0026
SEX*TRTCD	Female	2.5mg	Female	45mg	WORK.EFF	0.7484	0.2376	298	3.15	0.0018
SEX*TRTCD	Female	2.5mg	Male	Placebo	WORK.EFF	-0.3503	0.2514	298	-1.39	0.1646
SEX*TRTCD	Female	2.5mg	Male	2.5mg	WORK.EFF	0.2227	0.2443	298	0.91	0.3626
SEX*TRTCD	Female	2.5mg	Male	7.5mg	WORK.EFF	0.5154	0.2393	298	2.15	0.0321
SEX*TRTCD	Female	2.5mg	Male	15mg	WORK.EFF	0.3219	0.2305	298	1.40	0.1636
SEX*TRTCD	Female	2.5mg	Male	30mg	WORK.EFF	0.6774	0.2444	298	2.77	0.0059
SEX*TRTCD	Female	2.5mg	Male	45mg	WORK.EFF	0.6665	0.2410	298	2.77	0.0060
SEX*TRTCD	Female	7.5mg	Female	15mg	WORK.EFF	-0.07461	0.2210	298	-0.34	0.7358
SEX*TRTCD	Female	7.5mg	Female	30mg	WORK.EFF	0.3319	0.2205	298	1.51	0.1333
SEX*TRTCD	Female	7.5mg	Female	45mg	WORK.EFF	0.3723	0.2253	298	1.65	0.0995
SEX*TRTCD	Female	7.5mg	Male	Placebo	WORK.EFF	-0.7264	0.2382	298	-3.05	0.0025
SEX*TRTCD	Female	7.5mg	Male	2.5mg	WORK.EFF	-0.1533	0.2314	298	-0.66	0.5082
SEX*TRTCD	Female	7.5mg	Male	7.5mg	WORK.EFF	0.1394	0.2259	298	0.62	0.5377
SEX*TRTCD	Female	7.5mg	Male	15mg	WORK.EFF	-0.05416	0.2169	298	-0.25	0.8030
SEX*TRTCD	Female	7.5mg	Male	30mg	WORK.EFF	0.3013	0.2300	298	1.31	0.1913
SEX*TRTCD	Female	7.5mg	Male	45mg	WORK.EFF	0.2904	0.2284	298	1.27	0.2046
SEX*TRTCD	Female	15mg	Female	30mg	WORK.EFF	0.4065	0.2167	298	1.88	0.0616
SEX*TRTCD	Female	15mg	Female	45mg	WORK.EFF	0.4469	0.2207	298	2.03	0.0437

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	15mg	Male	Placebo	WORK.EFF	-0.6518	0.2339	298	-2.79	0.0057
SEX*TRTCD	Female	15mg	Male	2.5mg	WORK.EFF	-0.07872	0.2268	298	-0.35	0.7287
SEX*TRTCD	Female	15mg	Male	7.5mg	WORK.EFF	0.2140	0.2228	298	0.96	0.3377
SEX*TRTCD	Female	15mg	Male	15mg	WORK.EFF	0.02045	0.2134	298	0.10	0.9237
SEX*TRTCD	Female	15mg	Male	30mg	WORK.EFF	0.3759	0.2256	298	1.67	0.0967
SEX*TRTCD	Female	15mg	Male	45mg	WORK.EFF	0.3650	0.2263	298	1.61	0.1077
SEX*TRTCD	Female	30mg	Female	45mg	WORK.EFF	0.04038	0.2223	298	0.18	0.8559
SEX*TRTCD	Female	30mg	Male	Placebo	WORK.EFF	-1.0583	0.2337	298	-4.53	<.0001
SEX*TRTCD	Female	30mg	Male	2.5mg	WORK.EFF	-0.4853	0.2277	298	-2.13	0.0339
SEX*TRTCD	Female	30mg	Male	7.5mg	WORK.EFF	-0.1926	0.2221	298	-0.87	0.3867
SEX*TRTCD	Female	30mg	Male	15mg	WORK.EFF	-0.3861	0.2124	298	-1.82	0.0701
SEX*TRTCD	Female	30mg	Male	30mg	WORK.EFF	-0.03063	0.2259	298	-0.14	0.8922
SEX*TRTCD	Female	30mg	Male	45mg	WORK.EFF	-0.04151	0.2250	298	-0.18	0.8538
SEX*TRTCD	Female	45mg	Male	Placebo	WORK.EFF	-1.0987	0.2394	298	-4.59	<.0001
SEX*TRTCD	Female	45mg	Male	2.5mg	WORK.EFF	-0.5256	0.2311	298	-2.27	0.0237
SEX*TRTCD	Female	45mg	Male	7.5mg	WORK.EFF	-0.2330	0.2280	298	-1.02	0.3077
SEX*TRTCD	Female	45mg	Male	15mg	WORK.EFF	-0.4265	0.2188	298	-1.95	0.0522
SEX*TRTCD	Female	45mg	Male	30mg	WORK.EFF	-0.07102	0.2313	298	-0.31	0.7591
SEX*TRTCD	Female	45mg	Male	45mg	WORK.EFF	-0.08189	0.2301	298	-0.36	0.7222
SEX*TRTCD	Male	Placebo	Male	2.5mg	WORK.EFF	0.5731	0.2437	298	2.35	0.0193
SEX*TRTCD	Male	Placebo	Male	7.5mg	WORK.EFF	0.8658	0.2397	298	3.61	0.0004
SEX*TRTCD	Male	Placebo	Male	15mg	WORK.EFF	0.6722	0.2298	298	2.92	0.0037
SEX*TRTCD	Male	Placebo	Male	30mg	WORK.EFF	1.0277	0.2403	298	4.28	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male	Placebo	Male	45mg	WORK.EFF	1.0168	0.2425	298	4.19	<.0001
SEX*TRTCD	Male	2.5mg	Male	7.5mg	WORK.EFF	0.2927	0.2334	298	1.25	0.2109
SEX*TRTCD	Male	2.5mg	Male	15mg	WORK.EFF	0.09917	0.2243	298	0.44	0.6587
SEX*TRTCD	Male	2.5mg	Male	30mg	WORK.EFF	0.4546	0.2357	298	1.93	0.0547
SEX*TRTCD	Male	2.5mg	Male	45mg	WORK.EFF	0.4438	0.2364	298	1.88	0.0614
SEX*TRTCD	Male	7.5mg	Male	15mg	WORK.EFF	-0.1935	0.2187	298	-0.88	0.3770
SEX*TRTCD	Male	7.5mg	Male	30mg	WORK.EFF	0.1619	0.2317	298	0.70	0.4852
SEX*TRTCD	Male	7.5mg	Male	45mg	WORK.EFF	0.1511	0.2307	298	0.65	0.5132
SEX*TRTCD	Male	15mg	Male	30mg	WORK.EFF	0.3555	0.2219	298	1.60	0.1102
SEX*TRTCD	Male	15mg	Male	45mg	WORK.EFF	0.3446	0.2214	298	1.56	0.1207
SEX*TRTCD	Male	30mg	Male	45mg	WORK.EFF	-0.01088	0.2351	298	-0.05	0.9631

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Female	2.5mg	0.05	-0.4949	0.4417
SEX*TRTCD	Female	Placebo	Female	7.5mg	0.05	-0.09171	0.7905
SEX*TRTCD	Female	Placebo	Female	15mg	0.05	-0.1586	0.7082
SEX*TRTCD	Female	Placebo	Female	30mg	0.05	0.2482	1.1146
SEX*TRTCD	Female	Placebo	Female	45mg	0.05	0.2778	1.1656

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Male	Placebo	0.05	-0.8425	0.08857
SEX*TRTCD	Female	Placebo	Male	2.5mg	0.05	-0.2582	0.6504
SEX*TRTCD	Female	Placebo	Male	7.5mg	0.05	0.04400	0.9336
SEX*TRTCD	Female	Placebo	Male	15mg	0.05	-0.1307	0.7212
SEX*TRTCD	Female	Placebo	Male	30mg	0.05	0.2010	1.1004
SEX*TRTCD	Female	Placebo	Male	45mg	0.05	0.1890	1.0907
SEX*TRTCD	Female	2.5mg	Female	7.5mg	0.05	-0.09102	0.8431
SEX*TRTCD	Female	2.5mg	Female	15mg	0.05	-0.1591	0.7619
SEX*TRTCD	Female	2.5mg	Female	30mg	0.05	0.2490	1.1669
SEX*TRTCD	Female	2.5mg	Female	45mg	0.05	0.2807	1.2160
SEX*TRTCD	Female	2.5mg	Male	Placebo	0.05	-0.8451	0.1445
SEX*TRTCD	Female	2.5mg	Male	2.5mg	0.05	-0.2580	0.7035
SEX*TRTCD	Female	2.5mg	Male	7.5mg	0.05	0.04447	0.9864
SEX*TRTCD	Female	2.5mg	Male	15mg	0.05	-0.1317	0.7755
SEX*TRTCD	Female	2.5mg	Male	30mg	0.05	0.1964	1.1583
SEX*TRTCD	Female	2.5mg	Male	45mg	0.05	0.1923	1.1407
SEX*TRTCD	Female	7.5mg	Female	15mg	0.05	-0.5094	0.3602
SEX*TRTCD	Female	7.5mg	Female	30mg	0.05	-0.1020	0.7659
SEX*TRTCD	Female	7.5mg	Female	45mg	0.05	-0.07113	0.8158
SEX*TRTCD	Female	7.5mg	Male	Placebo	0.05	-1.1951	-0.2577
SEX*TRTCD	Female	7.5mg	Male	2.5mg	0.05	-0.6088	0.3021
SEX*TRTCD	Female	7.5mg	Male	7.5mg	0.05	-0.3051	0.5839
SEX*TRTCD	Female	7.5mg	Male	15mg	0.05	-0.4810	0.3727

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	7.5mg	Male	30mg	0.05	-0.1514	0.7540
SEX*TRTCD	Female	7.5mg	Male	45mg	0.05	-0.1591	0.7400
SEX*TRTCD	Female	15mg	Female	30mg	0.05	-0.01986	0.8330
SEX*TRTCD	Female	15mg	Female	45mg	0.05	0.01264	0.8812
SEX*TRTCD	Female	15mg	Male	Placebo	0.05	-1.1121	-0.1914
SEX*TRTCD	Female	15mg	Male	2.5mg	0.05	-0.5250	0.3676
SEX*TRTCD	Female	15mg	Male	7.5mg	0.05	-0.2245	0.6525
SEX*TRTCD	Female	15mg	Male	15mg	0.05	-0.3994	0.4403
SEX*TRTCD	Female	15mg	Male	30mg	0.05	-0.06807	0.8199
SEX*TRTCD	Female	15mg	Male	45mg	0.05	-0.08023	0.8103
SEX*TRTCD	Female	30mg	Female	45mg	0.05	-0.3970	0.4778
SEX*TRTCD	Female	30mg	Male	Placebo	0.05	-1.5183	-0.5984
SEX*TRTCD	Female	30mg	Male	2.5mg	0.05	-0.9334	-0.03712
SEX*TRTCD	Female	30mg	Male	7.5mg	0.05	-0.6297	0.2446
SEX*TRTCD	Female	30mg	Male	15mg	0.05	-0.8040	0.03186
SEX*TRTCD	Female	30mg	Male	30mg	0.05	-0.4753	0.4140
SEX*TRTCD	Female	30mg	Male	45mg	0.05	-0.4843	0.4013
SEX*TRTCD	Female	45mg	Male	Placebo	0.05	-1.5698	-0.6276
SEX*TRTCD	Female	45mg	Male	2.5mg	0.05	-0.9805	-0.07076
SEX*TRTCD	Female	45mg	Male	7.5mg	0.05	-0.6816	0.2157
SEX*TRTCD	Female	45mg	Male	15mg	0.05	-0.8571	0.004111
SEX*TRTCD	Female	45mg	Male	30mg	0.05	-0.5262	0.3842
SEX*TRTCD	Female	45mg	Male	45mg	0.05	-0.5348	0.3710

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Male	Placebo	Male	2.5mg	0.05	0.09350	1.0526
SEX*TRTCD	Male	Placebo	Male	7.5mg	0.05	0.3940	1.3375
SEX*TRTCD	Male	Placebo	Male	15mg	0.05	0.2199	1.1245
SEX*TRTCD	Male	Placebo	Male	30mg	0.05	0.5549	1.5005
SEX*TRTCD	Male	Placebo	Male	45mg	0.05	0.5396	1.4940
SEX*TRTCD	Male	2.5mg	Male	7.5mg	0.05	-0.1667	0.7521
SEX*TRTCD	Male	2.5mg	Male	15mg	0.05	-0.3422	0.5405
SEX*TRTCD	Male	2.5mg	Male	30mg	0.05	-0.00931	0.9186
SEX*TRTCD	Male	2.5mg	Male	45mg	0.05	-0.02140	0.9089
SEX*TRTCD	Male	7.5mg	Male	15mg	0.05	-0.6240	0.2370
SEX*TRTCD	Male	7.5mg	Male	30mg	0.05	-0.2941	0.6179
SEX*TRTCD	Male	7.5mg	Male	45mg	0.05	-0.3030	0.6052
SEX*TRTCD	Male	15mg	Male	30mg	0.05	-0.08121	0.7921
SEX*TRTCD	Male	15mg	Male	45mg	0.05	-0.09114	0.7803
SEX*TRTCD	Male	30mg	Male	45mg	0.05	-0.4735	0.4517

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	314
Observations Used	314
Observations Not Used	0
Total Observations	314

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6699	0.05488	12.21	<.0001	0.05	0.5741	0.7919

Fit Statistics

-2 Res Log Likelihood	782.6
AIC (smaller is better)	784.6
AICC (smaller is better)	784.6
BIC (smaller is better)	788.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.7085	0.5544	298	1.28
SEX	Female				-0.02175	0.09366	298	-0.23
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6877	0.2324	298	-2.96
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.9814	0.2206	298	4.45
TRTCD				2.5mg	0.6719	0.2149	298	3.13
TRTCD				7.5mg	0.1367	0.2068	298	0.66
TRTCD				15mg	0.2895	0.2023	298	1.43
TRTCD				30mg	0.04122	0.2126	298	0.19
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.4639	0.1115	298	-4.16
REGIONCD			Eastern Europe		-0.1646	0.1162	298	-1.42
REGIONCD			Western Europe		0			
EFSTDBL					-0.07713	0.06598	298	-1.17
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	-0.2638	0.3287	298	-0.80
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	-0.2220	0.3434	298	-0.65
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.3592	0.3326	298	1.08
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.2808	0.3199	298	0.88
TRTTYPCD*TRTCD		Diet & Exercise		30mg	-0.05307	0.3239	298	-0.16
TRTTYPCD*TRTCD		Diet & Exercise		45mg	0			
TRTTYPCD*TRTCD		Monotherapy		Placebo	0			
TRTTYPCD*TRTCD		Monotherapy		2.5mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.2022
SEX	Female				0.8165
SEX	Male				.
TRTTYPCD		Diet & Exercise			0.0033
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0019
TRTCD				7.5mg	0.5091
TRTCD				15mg	0.1534
TRTCD				30mg	0.8464
TRTCD				45mg	.
REGIONCD			US/Canada		<.0001
REGIONCD			Eastern Europe		0.1576
REGIONCD			Western Europe		.
EFSTDBL					0.2434
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	0.4228
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	0.5185
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.2811
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.3807
TRTTYPCD*TRTCD		Diet & Exercise		30mg	0.8700
TRTTYPCD*TRTCD		Diet & Exercise		45mg	.
TRTTYPCD*TRTCD		Monotherapy		Placebo	.
TRTTYPCD*TRTCD		Monotherapy		2.5mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTTYPCD*TRTCD		Monotherapy		7.5mg	0			
TRTTYPCD*TRTCD		Monotherapy		15mg	0			
TRTTYPCD*TRTCD		Monotherapy		30mg	0			
TRTTYPCD*TRTCD		Monotherapy		45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTTYPCD*TRTCD		Monotherapy		7.5mg	.
TRTTYPCD*TRTCD		Monotherapy		15mg	.
TRTTYPCD*TRTCD		Monotherapy		30mg	.
TRTTYPCD*TRTCD		Monotherapy		45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	298	0.05	0.8165
TRTTYPCD	1	298	49.05	<.0001
TRTCD	5	298	7.90	<.0001
REGIONCD	2	298	8.70	0.0002
EFSTDBL	1	298	1.37	0.2434
TRTTYPCD*TRTCD	5	298	1.20	0.3115

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.2885	0.1729	298	-1.67	0.0961	0.05	-0.6287	0.05163
7.5mg vs Pbo	-0.5331	0.1668	298	-3.20	0.0015	0.05	-0.8613	-0.2049
15mg vs Pbo	-0.4195	0.1602	298	-2.62	0.0093	0.05	-0.7347	-0.1044
30mg vs Pbo	-0.8347	0.1626	298	-5.13	<.0001	0.05	-1.1547	-0.5148
45mg vs Pbo	-0.8494	0.1664	298	-5.11	<.0001	0.05	-1.1769	-0.5220

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	WORK.EFF	-0.07184	0.1709	298	-0.42	0.6744	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	WORK.EFF	-0.3394	0.1995	298	-1.70	0.0899	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	WORK.EFF	-0.2935	0.1892	298	-1.55	0.1219	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	WORK.EFF	-0.2190	0.1714	298	-1.28	0.2022	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	WORK.EFF	-0.8012	0.1711	298	-4.68	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	WORK.EFF	-0.7894	0.1769	298	-4.46	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	WORK.EFF	0.8797	0.1618	298	5.44	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	WORK.EFF	0.5702	0.1527	298	3.73	0.0002	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	WORK.EFF	0.03508	0.1408	298	0.25	0.8035	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	WORK.EFF	0.1878	0.1349	298	1.39	0.1648	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	WORK.EFF	-0.06042	0.1491	298	-0.41	0.6855	0.05
TRTTYPCD*TRTCD	Monotherapy	45mg	WORK.EFF	-0.1016	0.1504	298	-0.68	0.4997	0.05

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	-0.4081	0.2644
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	-0.7320	0.05312
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	-0.6657	0.07878
TRTTYPCD*TRTCD	Diet & Exercise	15mg	-0.5563	0.1182

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	30mg	-1.1378	-0.4645
TRTTYPCD*TRTCD	Diet & Exercise	45mg	-1.1375	-0.4412
TRTTYPCD*TRTCD	Monotherapy	Placebo	0.5613	1.1981
TRTTYPCD*TRTCD	Monotherapy	2.5mg	0.2697	0.8708
TRTTYPCD*TRTCD	Monotherapy	7.5mg	-0.2421	0.3122
TRTTYPCD*TRTCD	Monotherapy	15mg	-0.07764	0.4533
TRTTYPCD*TRTCD	Monotherapy	30mg	-0.3538	0.2329
TRTTYPCD*TRTCD	Monotherapy	45mg	-0.3976	0.1944

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	WORK.EFF	0.2676	0.2631	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	WORK.EFF	0.2216	0.2551	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	WORK.EFF	0.1472	0.2417	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	WORK.EFF	0.7294	0.2420	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	WORK.EFF	0.7175	0.2464	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	WORK.EFF	-0.9516	0.2351	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	WORK.EFF	-0.6421	0.2292	298

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	WORK.EFF	-0.1069	0.2212	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	WORK.EFF	-0.2597	0.2177	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	WORK.EFF	-0.01142	0.2261	298
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	WORK.EFF	0.02980	0.2281	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	WORK.EFF	-0.04598	0.2742	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	WORK.EFF	-0.1204	0.2630	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	WORK.EFF	0.4618	0.2622	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	WORK.EFF	0.4499	0.2656	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	WORK.EFF	-1.2192	0.2575	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	WORK.EFF	-0.9097	0.2513	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	WORK.EFF	-0.3745	0.2447	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	WORK.EFF	-0.5273	0.2410	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	WORK.EFF	-0.2790	0.2507	298
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	WORK.EFF	-0.2378	0.2488	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	WORK.EFF	-0.07443	0.2548	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	WORK.EFF	0.5077	0.2555	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	WORK.EFF	0.4959	0.2591	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	WORK.EFF	-1.1732	0.2488	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	WORK.EFF	-0.8637	0.2442	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	WORK.EFF	-0.3285	0.2359	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	WORK.EFF	-0.4813	0.2332	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	WORK.EFF	-0.2330	0.2410	298
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	WORK.EFF	-0.1918	0.2409	298

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	WORK.EFF	0.5822	0.2424	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	WORK.EFF	0.5703	0.2472	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	WORK.EFF	-1.0987	0.2354	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	WORK.EFF	-0.7893	0.2300	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	WORK.EFF	-0.2541	0.2219	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	WORK.EFF	-0.4069	0.2186	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	WORK.EFF	-0.1586	0.2266	298
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	WORK.EFF	-0.1174	0.2281	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	WORK.EFF	-0.01185	0.2454	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	WORK.EFF	-1.6809	0.2360	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	WORK.EFF	-1.3714	0.2288	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	WORK.EFF	-0.8363	0.2218	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	WORK.EFF	-0.9890	0.2176	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	WORK.EFF	-0.7408	0.2280	298
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	WORK.EFF	-0.6996	0.2275	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	WORK.EFF	-1.6691	0.2421	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	WORK.EFF	-1.3596	0.2326	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	WORK.EFF	-0.8244	0.2255	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	WORK.EFF	-0.9772	0.2223	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	WORK.EFF	-0.7289	0.2339	298
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	WORK.EFF	-0.6877	0.2324	298
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	WORK.EFF	0.3095	0.2233	298
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	WORK.EFF	0.8446	0.2149	298

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	WORK.EFF	0.6919	0.2107	298
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	WORK.EFF	0.9401	0.2182	298
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	WORK.EFF	0.9814	0.2206	298
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	WORK.EFF	0.5352	0.2075	298
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	WORK.EFF	0.3824	0.2032	298
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	WORK.EFF	0.6307	0.2141	298
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	WORK.EFF	0.6719	0.2149	298
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	WORK.EFF	-0.1528	0.1950	298
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	WORK.EFF	0.09550	0.2048	298
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	WORK.EFF	0.1367	0.2068	298
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	WORK.EFF	0.2483	0.2012	298
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	WORK.EFF	0.2895	0.2023	298
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	WORK.EFF	0.04122	0.2126	298

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	1.02	0.3100	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	0.87	0.3858	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	0.61	0.5430	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	3.01	0.0028	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	2.91	0.0039	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-4.05	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-2.80	0.0054	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-0.48	0.6293	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-1.19	0.2339	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.05	0.9597	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	0.13	0.8961	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	-0.17	0.8669	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.46	0.6475	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	1.76	0.0793	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	1.69	0.0914	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-4.73	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-3.62	0.0003	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-1.53	0.1269	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-2.19	0.0295	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-1.11	0.2667	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-0.96	0.3399	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	-0.29	0.7704	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	1.99	0.0478	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	1.91	0.0566	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-4.72	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-3.54	0.0005	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-1.39	0.1647	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-2.06	0.0399	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-0.97	0.3344	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-0.80	0.4264	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	2.40	0.0169	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	2.31	0.0217	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-4.67	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-3.43	0.0007	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-1.15	0.2530	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-1.86	0.0636	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.70	0.4846	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.51	0.6072	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	-0.05	0.9615	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-7.12	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-5.99	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-3.77	0.0002	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-4.55	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-3.25	0.0013	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-3.07	0.0023	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-6.90	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-5.85	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-3.66	0.0003	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-4.40	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-3.12	0.0020	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-2.96	0.0033	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	1.39	0.1668	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	3.93	0.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	3.28	0.0011	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	4.31	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	4.45	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	2.58	0.0104	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	1.88	0.0608	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	2.95	0.0035	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	3.13	0.0019	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-0.78	0.4341	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	0.47	0.6413	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	0.66	0.5091	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	1.23	0.2181	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	1.43	0.1534	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	0.19	0.8464	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	-0.2503	0.7855
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	-0.2805	0.7237
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	-0.3284	0.6228
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	0.2531	1.2056
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	0.2325	1.2025
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-1.4142	-0.4889
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-1.0931	-0.1911
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-0.5423	0.3285
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-0.6881	0.1688
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.4563	0.4335
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	-0.4191	0.4787
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	-0.5856	0.4937
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.6381	0.3972
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	-0.05427	0.9778
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	-0.07283	0.9726
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-1.7259	-0.7124
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-1.4042	-0.4151
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-0.8560	0.1070
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-1.0016	-0.05301
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-0.7725	0.2144
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-0.7274	0.2518
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	-0.5759	0.4271
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	0.004957	1.0105

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	-0.01392	1.0057
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-1.6628	-0.6835
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-1.3443	-0.3831
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-0.7928	0.1357
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-0.9402	-0.02237
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-0.7074	0.2413
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-0.6658	0.2822
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	0.1052	1.0591
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	0.08391	1.0567
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-1.5620	-0.6354
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-1.2420	-0.3366
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-0.6908	0.1826
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-0.8370	0.02322
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.6046	0.2874
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.5664	0.3316
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	-0.4947	0.4710
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-2.1453	-1.2165
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-1.8218	-0.9211
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-1.2728	-0.3997
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-1.4172	-0.5608
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-1.1894	-0.2922
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-1.1473	-0.2518
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-2.1454	-1.1927

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-1.8173	-0.9019
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-1.2683	-0.3806
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-1.4146	-0.5398
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-1.1892	-0.2687
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-1.1450	-0.2304
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	-0.1300	0.7489
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	0.4216	1.2676
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	0.2772	1.1065
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	0.5106	1.3696
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	0.5473	1.4154
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	0.1269	0.9435
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	-0.01749	0.7823
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	0.2093	1.0520
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	0.2489	1.0948
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-0.5366	0.2310
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	-0.3075	0.4985
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	-0.2703	0.5437
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	-0.1476	0.6442
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	-0.1085	0.6875
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	-0.3772	0.4596

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	33
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	314
Observations Used	314
Observations Not Used	0
Total Observations	314

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6654	0.05497	12.10	<.0001	0.05	0.5695	0.7878

Fit Statistics

-2 Res Log Likelihood	776.7
AIC (smaller is better)	778.7
AICC (smaller is better)	778.7
BIC (smaller is better)	782.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.5346	0.5678	293	0.94
SEX	Female				-0.03778	0.09497	293	-0.40
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6411	0.09747	293	-6.58
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	1.4259	0.2603	293	5.48
TRTCD				2.5mg	0.6789	0.2820	293	2.41
TRTCD				7.5mg	0.3987	0.2453	293	1.63
TRTCD				15mg	0.6402	0.2543	293	2.52
TRTCD				30mg	0.2601	0.2559	293	1.02
TRTCD				45mg	0			
REGIONCD			US/Canada		0.005744	0.2845	293	0.02
REGIONCD			Eastern Europe		0.05700	0.2696	293	0.21
REGIONCD			Western Europe		0			
EFSTDBL					-0.08326	0.06642	293	-1.25
TRTCD*REGIONCD			US/Canada	Placebo	-0.9786	0.3871	293	-2.53
TRTCD*REGIONCD			Eastern Europe	Placebo	-1.0682	0.4127	293	-2.59
TRTCD*REGIONCD			Western Europe	Placebo	0			
TRTCD*REGIONCD			US/Canada	2.5mg	-0.3313	0.4185	293	-0.79
TRTCD*REGIONCD			Eastern Europe	2.5mg	0.000257	0.3962	293	0.00
TRTCD*REGIONCD			Western Europe	2.5mg	0			
TRTCD*REGIONCD			US/Canada	7.5mg	-0.1918	0.4015	293	-0.48
TRTCD*REGIONCD			Eastern Europe	7.5mg	-0.1542	0.3822	293	-0.40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.3473
SEX	Female				0.6911
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0167
TRTCD				7.5mg	0.1051
TRTCD				15mg	0.0124
TRTCD				30mg	0.3103
TRTCD				45mg	.
REGIONCD			US/Canada		0.9839
REGIONCD			Eastern Europe		0.8327
REGIONCD			Western Europe		.
EFSTDBL					0.2110
TRTCD*REGIONCD			US/Canada	Placebo	0.0120
TRTCD*REGIONCD			Eastern Europe	Placebo	0.0101
TRTCD*REGIONCD			Western Europe	Placebo	.
TRTCD*REGIONCD			US/Canada	2.5mg	0.4293
TRTCD*REGIONCD			Eastern Europe	2.5mg	0.9995
TRTCD*REGIONCD			Western Europe	2.5mg	.
TRTCD*REGIONCD			US/Canada	7.5mg	0.6332
TRTCD*REGIONCD			Eastern Europe	7.5mg	0.6869

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTCD*REGIONCD			Western Europe	7.5mg	0			
TRTCD*REGIONCD			US/Canada	15mg	-0.5970	0.3770	293	-1.58
TRTCD*REGIONCD			Eastern Europe	15mg	-0.1819	0.3770	293	-0.48
TRTCD*REGIONCD			Western Europe	15mg	0			
TRTCD*REGIONCD			US/Canada	30mg	-0.5644	0.3854	293	-1.46
TRTCD*REGIONCD			Eastern Europe	30mg	-0.2204	0.3916	293	-0.56
TRTCD*REGIONCD			Western Europe	30mg	0			
TRTCD*REGIONCD			US/Canada	45mg	0			
TRTCD*REGIONCD			Eastern Europe	45mg	0			
TRTCD*REGIONCD			Western Europe	45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	7.5mg	.
TRTCD*REGIONCD			US/Canada	15mg	0.1143
TRTCD*REGIONCD			Eastern Europe	15mg	0.6298
TRTCD*REGIONCD			Western Europe	15mg	.
TRTCD*REGIONCD			US/Canada	30mg	0.1442
TRTCD*REGIONCD			Eastern Europe	30mg	0.5741

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	30mg	.
TRTCD*REGIONCD			US/Canada	45mg	.
TRTCD*REGIONCD			Eastern Europe	45mg	.
TRTCD*REGIONCD			Western Europe	45mg	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	293	0.16	0.6911
TRTTYPCD	1	293	43.27	<.0001
TRTCD	5	293	6.46	<.0001
REGIONCD	2	293	7.70	0.0006
EFSTDBL	1	293	1.57	0.2110
TRTCD*REGIONCD	10	293	1.30	0.2279

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1750	0.1732	293	-1.01	0.3131	0.05	-0.5159	0.1659
7.5mg vs Pbo	-0.4602	0.1721	293	-2.67	0.0079	0.05	-0.7990	-0.1215
15mg vs Pbo	-0.3630	0.1629	293	-2.23	0.0266	0.05	-0.6835	-0.04247
30mg vs Pbo	-0.7450	0.1675	293	-4.45	<.0001	0.05	-1.0746	-0.4154
45mg vs Pbo	-0.7436	0.1691	293	-4.40	<.0001	0.05	-1.0765	-0.4107

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	WORK.EFF	0.05146	0.1923	293	0.27	0.7892	0.05

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	-0.3270	0.4299

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	WORK.EFF	0.01319	0.2598	293	0.05	0.9595	0.05
TRTCD*REGIONCD	Western Europe	Placebo	WORK.EFF	1.0244	0.1785	293	5.74	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	WORK.EFF	-0.04811	0.2195	293	-0.22	0.8267	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	WORK.EFF	0.3347	0.1995	293	1.68	0.0944	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	WORK.EFF	0.2774	0.2108	293	1.32	0.1892	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	WORK.EFF	-0.1888	0.2357	293	-0.80	0.4236	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	WORK.EFF	-0.1000	0.2188	293	-0.46	0.6479	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	WORK.EFF	-0.00279	0.1570	293	-0.02	0.9858	0.05
TRTCD*REGIONCD	US/Canada	15mg	WORK.EFF	-0.3526	0.1828	293	-1.93	0.0548	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	WORK.EFF	0.1138	0.1987	293	0.57	0.5671	0.05
TRTCD*REGIONCD	Western Europe	15mg	WORK.EFF	0.2387	0.1709	293	1.40	0.1635	0.05
TRTCD*REGIONCD	US/Canada	30mg	WORK.EFF	-0.7000	0.1927	293	-3.63	0.0003	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	WORK.EFF	-0.3047	0.2286	293	-1.33	0.1836	0.05
TRTCD*REGIONCD	Western Europe	30mg	WORK.EFF	-0.1414	0.1714	293	-0.82	0.4102	0.05
TRTCD*REGIONCD	US/Canada	45mg	WORK.EFF	-0.3958	0.2136	293	-1.85	0.0650	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	WORK.EFF	-0.3445	0.1933	293	-1.78	0.0758	0.05
TRTCD*REGIONCD	Western Europe	45mg	WORK.EFF	-0.4015	0.1883	293	-2.13	0.0338	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	-0.4982	0.5246
TRTCD*REGIONCD	Western Europe	Placebo	0.6731	1.3756
TRTCD*REGIONCD	US/Canada	2.5mg	-0.4802	0.3840
TRTCD*REGIONCD	Eastern Europe	2.5mg	-0.05788	0.7272
TRTCD*REGIONCD	Western Europe	2.5mg	-0.1374	0.6922
TRTCD*REGIONCD	US/Canada	7.5mg	-0.6527	0.2750
TRTCD*REGIONCD	Eastern Europe	7.5mg	-0.5307	0.3306
TRTCD*REGIONCD	Western Europe	7.5mg	-0.3118	0.3062
TRTCD*REGIONCD	US/Canada	15mg	-0.7124	0.007235
TRTCD*REGIONCD	Eastern Europe	15mg	-0.2772	0.5049
TRTCD*REGIONCD	Western Europe	15mg	-0.09762	0.5751
TRTCD*REGIONCD	US/Canada	30mg	-1.0792	-0.3208
TRTCD*REGIONCD	Eastern Europe	30mg	-0.7547	0.1452
TRTCD*REGIONCD	Western Europe	30mg	-0.4788	0.1960
TRTCD*REGIONCD	US/Canada	45mg	-0.8162	0.02471
TRTCD*REGIONCD	Eastern Europe	45mg	-0.7250	0.03596
TRTCD*REGIONCD	Western Europe	45mg	-0.7722	-0.03085

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	WORK.EFF	0.03826	0.3234	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	WORK.EFF	-0.9729	0.2624	293
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	WORK.EFF	0.09957	0.2918	293
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.2832	0.2770	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2260	0.2853	293
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	WORK.EFF	0.2403	0.3041	293
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.1515	0.2912	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	WORK.EFF	0.05425	0.2482	293
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	WORK.EFF	0.4040	0.2653	293
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	WORK.EFF	-0.06238	0.2764	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	WORK.EFF	-0.1873	0.2573	293
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	WORK.EFF	0.7514	0.2722	293
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	WORK.EFF	0.3562	0.2989	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	WORK.EFF	0.1928	0.2576	293
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	WORK.EFF	0.4472	0.2873	293
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	WORK.EFF	0.3960	0.2728	293
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	WORK.EFF	0.4530	0.2690	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	WORK.EFF	-1.0112	0.3140	293
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	WORK.EFF	0.06131	0.3397	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.3215	0.3292	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2642	0.3352	293
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	WORK.EFF	0.2020	0.3514	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.1132	0.3410	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	0.12	0.9059	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-3.71	0.0003	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	0.34	0.7332	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-1.02	0.3074	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-0.79	0.4290	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	0.79	0.4301	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	0.52	0.6033	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	0.22	0.8272	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	1.52	0.1289	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.23	0.8216	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-0.73	0.4672	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	2.76	0.0061	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	1.19	0.2344	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	0.75	0.4547	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	1.56	0.1207	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	1.45	0.1477	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	1.68	0.0933	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-3.22	0.0014	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	0.18	0.8569	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-0.98	0.3296	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.79	0.4313	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	0.57	0.5658	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	0.33	0.7401	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	-0.5983	0.6748
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-1.4894	-0.4564
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	-0.4747	0.6738
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-0.8283	0.2619
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-0.7874	0.3355
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	-0.3583	0.8389
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	-0.4216	0.7245
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	-0.4343	0.5428
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	-0.1182	0.9262
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.6064	0.4816
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-0.6936	0.3191
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	0.2158	1.2871
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	-0.2322	0.9446
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	-0.3142	0.6998
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	-0.1183	1.0127
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	-0.1409	0.9328
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	-0.07652	0.9824
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-1.6291	-0.3932
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	-0.6072	0.7298
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-0.9694	0.3265
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.9240	0.3956
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	-0.4896	0.8936
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	-0.5579	0.7844

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	WORK.EFF	0.01599	0.3035	293
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	WORK.EFF	0.3658	0.3182	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	WORK.EFF	-0.1006	0.3277	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	WORK.EFF	-0.2255	0.3102	293
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	WORK.EFF	0.7132	0.3234	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	WORK.EFF	0.3179	0.3442	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	WORK.EFF	0.1546	0.3105	293
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	WORK.EFF	0.4090	0.3385	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	WORK.EFF	0.3577	0.3229	293
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	WORK.EFF	0.4147	0.3224	293
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	WORK.EFF	1.0725	0.2829	293
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	0.6897	0.2683	293
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	WORK.EFF	0.7469	0.2765	293
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	WORK.EFF	1.2132	0.2959	293
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	1.1244	0.2830	293
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	WORK.EFF	1.0271	0.2376	293
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	WORK.EFF	1.3769	0.2556	293
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	WORK.EFF	0.9105	0.2674	293
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	WORK.EFF	0.7856	0.2468	293
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	WORK.EFF	1.7243	0.2627	293
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	WORK.EFF	1.3291	0.2890	293
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	WORK.EFF	1.1657	0.2470	293
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	WORK.EFF	1.4201	0.2792	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	0.05	0.9580	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	1.15	0.2512	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.31	0.7590	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.73	0.4677	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	2.21	0.0282	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	0.92	0.3564	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	0.50	0.6190	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	1.21	0.2280	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	1.11	0.2689	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	1.29	0.1994	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	3.79	0.0002	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	2.57	0.0106	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	2.70	0.0073	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	4.10	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	3.97	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	4.32	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	5.39	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	3.41	0.0008	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	3.18	0.0016	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	6.56	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	4.60	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	4.72	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	5.09	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	-0.5813	0.6133
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	-0.2604	0.9919
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.7456	0.5443
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.8360	0.3849
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	0.07676	1.3496
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	-0.3595	0.9954
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	-0.4565	0.7656
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	-0.2573	1.0752
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	-0.2778	0.9932
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	-0.2198	1.0492
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	0.5157	1.6292
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	0.1617	1.2177
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	0.2027	1.2912
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	0.6308	1.7956
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	0.5675	1.6813
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	0.5595	1.4948
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	0.8739	1.8800
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	0.3843	1.4368
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	0.2999	1.2713
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	1.2074	2.2413
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	0.7604	1.8978
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	0.6795	1.6519
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	0.8707	1.9695

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	WORK.EFF	1.3689	0.2627	293
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	WORK.EFF	1.4259	0.2603	293
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	WORK.EFF	-0.3828	0.2985	293
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	WORK.EFF	-0.3255	0.3044	293
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	WORK.EFF	0.1407	0.3224	293
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.05192	0.3101	293
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	WORK.EFF	-0.04532	0.2699	293
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	WORK.EFF	0.3044	0.2868	293
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	WORK.EFF	-0.1620	0.2955	293
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	WORK.EFF	-0.2868	0.2768	293
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	WORK.EFF	0.6519	0.2911	293
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	WORK.EFF	0.2566	0.3185	293
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	WORK.EFF	0.09326	0.2776	293
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	WORK.EFF	0.3476	0.3089	293
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	WORK.EFF	0.2964	0.2925	293
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	WORK.EFF	0.3534	0.2891	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	WORK.EFF	0.05725	0.2899	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.5235	0.3082	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.4347	0.2953	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.3374	0.2539	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.6872	0.2695	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.2208	0.2816	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.09592	0.2642	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	5.21	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	5.48	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-1.28	0.2008	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-1.07	0.2858	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	0.44	0.6628	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	0.17	0.8671	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	-0.17	0.8668	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	1.06	0.2893	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.55	0.5841	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-1.04	0.3009	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	2.24	0.0259	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	0.81	0.4211	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	0.34	0.7372	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	1.13	0.2613	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	1.01	0.3118	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	1.22	0.2225	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	0.20	0.8436	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	1.70	0.0905	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	1.47	0.1421	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	1.33	0.1848	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	2.55	0.0113	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	0.78	0.4336	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	0.36	0.7168	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	0.8519	1.8858
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	0.9136	1.9381
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-0.9703	0.2047
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-0.9246	0.2735
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	-0.4939	0.7753
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	-0.5583	0.6622
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	-0.5765	0.4858
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	-0.2600	0.8688
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.7436	0.4197
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-0.8316	0.2579
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	0.07904	1.2247
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	-0.3703	0.8835
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	-0.4531	0.6397
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	-0.2603	0.9556
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	-0.2794	0.8721
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	-0.2155	0.9223
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	-0.5132	0.6277
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	-0.08309	1.1301
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	-0.1465	1.0159
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	-0.1622	0.8371
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	0.1568	1.2176
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	-0.3334	0.7751
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	-0.4241	0.6159

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	WORK.EFF	1.0346	0.2782	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.6394	0.3031	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.4760	0.2640	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.7304	0.2892	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.6792	0.2783	293
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.7362	0.2738	293
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.4663	0.3160	293
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.3774	0.3037	293
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.2802	0.2629	293
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.6300	0.2789	293
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.1636	0.2897	293
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.03867	0.2715	293
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	WORK.EFF	0.9774	0.2855	293
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.5821	0.3114	293
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.4188	0.2722	293
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.6732	0.2998	293
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.6219	0.2860	293
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.6789	0.2820	293
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	WORK.EFF	-0.08881	0.3216	293
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	WORK.EFF	-0.1861	0.2832	293
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	WORK.EFF	0.1637	0.2980	293
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.3027	0.3085	293
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	WORK.EFF	-0.4276	0.2914	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	3.72	0.0002	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	2.11	0.0358	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	1.80	0.0724	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	2.53	0.0121	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	2.44	0.0153	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	2.69	0.0076	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	1.48	0.1411	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	1.24	0.2149	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	1.07	0.2873	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	2.26	0.0246	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	0.56	0.5728	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	0.14	0.8868	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	3.42	0.0007	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	1.87	0.0625	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	1.54	0.1250	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	2.25	0.0255	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	2.17	0.0304	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	2.41	0.0167	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.28	0.7826	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.66	0.5117	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	0.55	0.5832	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-0.98	0.3273	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-1.47	0.1433	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	0.4872	1.5821
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	0.04282	1.2360
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	-0.04360	0.9957
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	0.1612	1.2996
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	0.1315	1.2269
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	0.1973	1.2750
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	-0.1556	1.0881
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	-0.2202	0.9751
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	-0.2371	0.7975
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	0.08105	1.1789
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	-0.4067	0.7338
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	-0.4956	0.5729
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	0.4155	1.5393
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	-0.03066	1.1950
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	-0.1169	0.9545
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	0.08307	1.2633
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	0.05910	1.1847
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	0.1238	1.2340
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.7217	0.5440
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.7434	0.3713
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	-0.4228	0.7502
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-0.9099	0.3045
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-1.0011	0.1459

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	WORK.EFF	0.5111	0.3045	293
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	WORK.EFF	0.1159	0.3284	293
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	WORK.EFF	-0.04747	0.2921	293
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	WORK.EFF	0.2069	0.3175	293
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	WORK.EFF	0.1557	0.3046	293
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	WORK.EFF	0.2127	0.3011	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	WORK.EFF	-0.09724	0.2693	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.2525	0.2851	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.2139	0.2946	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.3388	0.2781	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.6000	0.2917	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.2047	0.3179	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	WORK.EFF	0.04134	0.2775	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.2957	0.3046	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.2445	0.2932	293
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.3015	0.2885	293
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.3498	0.2410	293
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.1166	0.2532	293
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.2415	0.2320	293
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.6972	0.2485	293
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.3020	0.2773	293
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	WORK.EFF	0.1386	0.2324	293
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.3930	0.2652	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	1.68	0.0942	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	0.35	0.7244	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	-0.16	0.8710	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	0.65	0.5152	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	0.51	0.6098	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	0.71	0.4806	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	-0.36	0.7183	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	0.89	0.3765	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.73	0.4684	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-1.22	0.2242	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	2.06	0.0406	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	0.64	0.5201	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	0.15	0.8817	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	0.97	0.3324	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	0.83	0.4051	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	1.04	0.2969	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	1.45	0.1477	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.46	0.6455	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-1.04	0.2988	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	2.81	0.0054	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	1.09	0.2770	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	0.60	0.5514	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	1.48	0.1395	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	-0.08805	1.1103
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	-0.5304	0.7622
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	-0.6223	0.5274
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	-0.4181	0.8319
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	-0.4439	0.7552
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	-0.3800	0.8053
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	-0.6273	0.4328
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	-0.3085	0.8136
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.7936	0.3659
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-0.8861	0.2086
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	0.02582	1.1741
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	-0.4209	0.8303
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	-0.5049	0.5876
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	-0.3037	0.8951
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	-0.3326	0.8215
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	-0.2663	0.8693
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	-0.1245	0.8241
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.6150	0.3818
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-0.6982	0.2151
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	0.2081	1.1863
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	-0.2437	0.8476
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	-0.3188	0.5959
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	-0.1289	0.9149

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.3417	0.2490	293
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.3987	0.2453	293
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	WORK.EFF	-0.4664	0.2704	293
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	WORK.EFF	-0.5913	0.2510	293
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	WORK.EFF	0.3474	0.2661	293
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	WORK.EFF	-0.04782	0.2920	293
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	WORK.EFF	-0.2112	0.2513	293
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	WORK.EFF	0.04320	0.2798	293
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	WORK.EFF	-0.00805	0.2660	293
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	WORK.EFF	0.04894	0.2623	293
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	WORK.EFF	-0.1249	0.2620	293
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	WORK.EFF	0.8138	0.2767	293
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.4186	0.3044	293
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	WORK.EFF	0.2552	0.2613	293
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	WORK.EFF	0.5096	0.2915	293
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.4583	0.2785	293
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	WORK.EFF	0.5153	0.2740	293
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	WORK.EFF	0.9387	0.2568	293
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.5435	0.2859	293
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	WORK.EFF	0.3801	0.2415	293
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	WORK.EFF	0.6345	0.2757	293
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.5832	0.2576	293
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	WORK.EFF	0.6402	0.2543	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	1.37	0.1710	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	1.63	0.1051	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-1.73	0.0856	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-2.36	0.0191	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	1.31	0.1927	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	-0.16	0.8701	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.84	0.4014	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	0.15	0.8774	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	-0.03	0.9759	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	0.19	0.8521	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.48	0.6340	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	2.94	0.0035	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	1.37	0.1702	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	0.98	0.3296	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	1.75	0.0815	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	1.65	0.1009	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	1.88	0.0610	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	3.66	0.0003	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	1.90	0.0583	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	1.57	0.1166	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	2.30	0.0221	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	2.26	0.0243	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	2.52	0.0124	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	-0.1484	0.8318
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	-0.08401	0.8814
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-0.9985	0.06572
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-1.0853	-0.09728
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	-0.1762	0.8711
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	-0.6226	0.5269
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.7058	0.2834
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	-0.5075	0.5939
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	-0.5315	0.5154
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	-0.4673	0.5652
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.6406	0.3908
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	0.2693	1.3584
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	-0.1806	1.0177
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	-0.2591	0.7695
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	-0.06420	1.0834
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	-0.08972	1.0064
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	-0.02393	1.0546
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	0.4333	1.4442
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	-0.01923	1.1062
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	-0.09524	0.8555
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	0.09182	1.1772
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	0.07623	1.0903
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	0.1397	1.1408

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	WORK.EFF	-0.3952	0.2997	293
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	WORK.EFF	-0.5586	0.2578	293
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	WORK.EFF	-0.3042	0.2890	293
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	WORK.EFF	-0.3555	0.2727	293
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	WORK.EFF	-0.2985	0.2690	293
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	WORK.EFF	-0.1634	0.2864	293
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	WORK.EFF	0.09102	0.3126	293
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.03976	0.2980	293
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	WORK.EFF	0.09676	0.2973	293
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	WORK.EFF	0.2544	0.2748	293
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.2031	0.2593	293
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	WORK.EFF	0.2601	0.2559	293
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	WORK.EFF	-0.05125	0.2892	293
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	WORK.EFF	0.005744	0.2845	293
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	WORK.EFF	0.05700	0.2696	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-1.32	0.1883	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-2.17	0.0310	0.05
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-1.05	0.2933	0.05
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-1.30	0.1934	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-1.11	0.2681	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.57	0.5688	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	0.29	0.7712	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	0.13	0.8939	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	0.33	0.7451	0.05
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	0.93	0.3554	0.05
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	0.78	0.4341	0.05
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	1.02	0.3103	0.05
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.18	0.8595	0.05
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	0.02	0.9839	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	0.21	0.8327	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-0.9851	0.1946
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-1.0660	-0.05125
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-0.8730	0.2645
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-0.8922	0.1812
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-0.8279	0.2310
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.7270	0.4003
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	-0.5243	0.7063
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	-0.5468	0.6263
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	-0.4884	0.6819
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	-0.2865	0.7952
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	-0.3073	0.7135
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	-0.2436	0.7638
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.6205	0.5180
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	-0.5542	0.5657
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	-0.4736	0.5876

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	21
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	314
Observations Used	314
Observations Not Used	0
Total Observations	314

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.6780	0.05555	12.21	<.0001	0.05	0.5811	0.8015

Fit Statistics

-2 Res Log Likelihood	789.9
AIC (smaller is better)	791.9
AICC (smaller is better)	791.9
BIC (smaller is better)	795.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.9829	1.2627	298	0.78
SEX	Female				-0.01740	0.09418	298	-0.18
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6535	0.09656	298	-6.77
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.1056	1.9227	298	0.05
TRTCD				2.5mg	-0.4759	1.6664	298	-0.29
TRTCD				7.5mg	-0.5082	1.7755	298	-0.29
TRTCD				15mg	0.4573	1.8509	298	0.25
TRTCD				30mg	1.3276	1.8527	298	0.72
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.4514	0.1126	298	-4.01
REGIONCD			Eastern Europe		-0.1843	0.1158	298	-1.59
REGIONCD			Western Europe		0			
EFSTDBL					-0.1127	0.1550	298	-0.73
EFSTDBL*TRTCD				Placebo	0.09441	0.2419	298	0.39
EFSTDBL*TRTCD				2.5mg	0.1335	0.2061	298	0.65
EFSTDBL*TRTCD				7.5mg	0.09700	0.2206	298	0.44
EFSTDBL*TRTCD				15mg	-0.00887	0.2316	298	-0.04
EFSTDBL*TRTCD				30mg	-0.1706	0.2331	298	-0.73
EFSTDBL*TRTCD				45mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.4369
SEX	Female				0.8535
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	0.9563
TRTCD				2.5mg	0.7754
TRTCD				7.5mg	0.7749
TRTCD				15mg	0.8050
TRTCD				30mg	0.4742
TRTCD				45mg	.
REGIONCD			US/Canada		<.0001
REGIONCD			Eastern Europe		0.1124
REGIONCD			Western Europe		.
EFSTDBL					0.4680
EFSTDBL*TRTCD				Placebo	0.6967
EFSTDBL*TRTCD				2.5mg	0.5178
EFSTDBL*TRTCD				7.5mg	0.6604
EFSTDBL*TRTCD				15mg	0.9695
EFSTDBL*TRTCD				30mg	0.4648
EFSTDBL*TRTCD				45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	298	0.03	0.8535
TRTTYPCD	1	298	45.80	<.0001
TRTCD	5	298	0.29	0.9206
REGIONCD	2	298	8.04	0.0004
EFSTDBL	1	298	1.71	0.1914
EFSTDBL*TRTCD	5	298	0.47	0.8019

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.4794	0.1201	298	3.99	<.0001	0.05	0.2431	0.7157
TRTCD	2.5mg	WORK.EFF	0.2064	0.1223	298	1.69	0.0925	0.05	-0.03424	0.4470
TRTCD	7.5mg	WORK.EFF	-0.1138	0.1138	298	-1.00	0.3180	0.05	-0.3378	0.1101
TRTCD	15mg	WORK.EFF	0.01571	0.1067	298	0.15	0.8831	0.05	-0.1944	0.2258
TRTCD	30mg	WORK.EFF	-0.3909	0.1146	298	-3.41	0.0007	0.05	-0.6165	-0.1654
TRTCD	45mg	WORK.EFF	-0.3716	0.1189	298	-3.12	0.0020	0.05	-0.6057	-0.1375

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.2730	0.1720	298	1.59	0.1135	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.5932	0.1658	298	3.58	0.0004	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.4637	0.1607	298	2.88	0.0042	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.8703	0.1655	298	5.26	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.8510	0.1695	298	5.02	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.3202	0.1673	298	1.91	0.0565	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1906	0.1621	298	1.18	0.2405	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5973	0.1679	298	3.56	0.0004	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5779	0.1702	298	3.40	0.0008	0.05
TRTCD	7.5mg	15mg	WORK.EFF	-0.1295	0.1562	298	-0.83	0.4075	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.2771	0.1618	298	1.71	0.0878	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.2577	0.1648	298	1.56	0.1188	0.05
TRTCD	15mg	30mg	WORK.EFF	0.4066	0.1567	298	2.60	0.0099	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3873	0.1598	298	2.42	0.0160	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.01935	0.1653	298	-0.12	0.9069	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.6
SAS Statistical Output for Table 11.5
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.06548	0.6116
TRTCD	Placebo	7.5mg	0.2670	0.9195
TRTCD	Placebo	15mg	0.1474	0.7800
TRTCD	Placebo	30mg	0.5447	1.1960
TRTCD	Placebo	45mg	0.5175	1.1845
TRTCD	2.5mg	7.5mg	-0.00894	0.6493
TRTCD	2.5mg	15mg	-0.1284	0.5097
TRTCD	2.5mg	30mg	0.2669	0.9276
TRTCD	2.5mg	45mg	0.2431	0.9128
TRTCD	7.5mg	15mg	-0.4369	0.1778
TRTCD	7.5mg	30mg	-0.04132	0.5955
TRTCD	7.5mg	45mg	-0.06653	0.5820
TRTCD	15mg	30mg	0.09831	0.7150
TRTCD	15mg	45mg	0.07276	0.7018
TRTCD	30mg	45mg	-0.3447	0.3060

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Week -6

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		36	44	47	55	50	47
Baseline	Mean	7.87	7.94	7.90	7.84	7.79	8.09
	SD	0.606	0.917	0.707	0.600	0.676	0.779
	SE	0.101	0.138	0.103	0.081	0.096	0.114
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.80	7.70	7.70	7.90	7.85	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5
Week -6	Mean	7.97	7.97	7.90	7.81	7.81	7.98
	SD	0.714	0.699	0.787	0.594	0.641	0.676
	SE	0.119	0.105	0.115	0.080	0.091	0.099
	Minimum	7.0	7.0	7.0	7.0	7.0	7.0
	Median	7.80	7.90	7.70	7.80	7.70	7.90
	Maximum	10.0	9.9	10.0	9.4	9.7	9.9
Change from Baseline	Mean	0.10	0.03	0.00	-0.03	0.02	-0.11
	SD	0.700	0.794	0.736	0.580	0.532	0.865
	SE	0.117	0.120	0.107	0.078	0.075	0.126
	Minimum	-1.6	-2.1	-1.7	-1.1	-1.4	-2.4
	Median	0.05	0.20	0.10	-0.10	0.10	-0.10
	Maximum	2.3	1.7	1.8	1.5	1.3	2.9

[1]Number of subjects with a value at baseline and at specified visit

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Week -2

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		36	44	46	55	50	47
Baseline	Mean	7.88	7.94	7.91	7.84	7.77	8.09
	SD	0.606	0.917	0.712	0.600	0.673	0.779
	SE	0.101	0.138	0.105	0.081	0.095	0.114
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.85	7.70	7.70	7.90	7.80	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5
Week -2	Mean	7.84	7.91	7.83	7.78	7.74	7.96
	SD	0.591	0.808	0.628	0.550	0.645	0.703
	SE	0.099	0.122	0.093	0.074	0.091	0.103
	Minimum	6.9	6.5	6.6	6.8	6.4	6.5
	Median	7.90	7.90	7.70	7.80	7.70	7.80
	Maximum	9.4	10.1	9.8	9.2	9.8	9.5
Change from Baseline	Mean	-0.03	-0.03	-0.08	-0.06	-0.03	-0.13
	SD	0.351	0.368	0.470	0.286	0.346	0.428
	SE	0.058	0.056	0.069	0.039	0.049	0.062
	Minimum	-0.7	-1.0	-1.2	-0.8	-0.8	-1.2
	Median	-0.05	0.00	0.00	0.00	0.00	-0.10
	Maximum	0.7	0.7	0.9	0.6	0.9	0.9

[1]Number of subjects with a value at baseline and at specified visit

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Baseline

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		37	44	47	55	51	47
Baseline	Mean	7.87	7.94	7.90	7.84	7.78	8.09
	SD	0.598	0.917	0.707	0.600	0.672	0.779
	SE	0.098	0.138	0.103	0.081	0.094	0.114
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.80	7.70	7.70	7.90	7.80	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5

[1]Number of subjects with a value at baseline and at specified visit

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Week 4

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		37	44	47	54	51	47
Baseline	Mean	7.87	7.94	7.90	7.83	7.78	8.09
	SD	0.598	0.917	0.707	0.603	0.672	0.779
	SE	0.098	0.138	0.103	0.082	0.094	0.114
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.80	7.70	7.70	7.90	7.80	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5
Week 4	Mean	7.94	7.93	7.72	7.74	7.49	7.75
	SD	0.801	1.070	0.849	0.841	0.739	0.849
	SE	0.132	0.161	0.124	0.114	0.104	0.124
	Minimum	6.8	6.3	6.1	6.0	5.8	5.9
	Median	7.80	7.65	7.50	7.85	7.50	7.80
	Maximum	10.1	11.4	9.9	9.5	9.3	9.7
Change from Baseline	Mean	0.07	-0.01	-0.18	-0.09	-0.29	-0.33
	SD	0.507	0.463	0.558	0.459	0.422	0.451
	SE	0.083	0.070	0.081	0.062	0.059	0.066
	Minimum	-0.8	-1.0	-1.1	-1.0	-1.6	-1.5
	Median	0.00	-0.10	-0.30	-0.10	-0.30	-0.20
	Maximum	1.3	1.3	1.6	0.9	1.1	0.4

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Week 8

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		37	44	46	55	50	46
Baseline	Mean	7.87	7.94	7.90	7.84	7.78	8.07
	SD	0.598	0.917	0.715	0.600	0.678	0.781
	SE	0.098	0.138	0.105	0.081	0.096	0.115
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.80	7.70	7.70	7.90	7.80	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5
Week 8	Mean	7.86	8.08	7.74	7.76	7.37	7.66
	SD	0.895	1.212	0.929	0.926	0.742	0.896
	SE	0.147	0.183	0.137	0.125	0.105	0.132
	Minimum	6.5	6.1	6.2	6.2	6.1	5.5
	Median	7.70	7.75	7.60	7.80	7.40	7.75
	Maximum	10.7	12.0	10.0	10.1	9.0	9.8
Change from Baseline	Mean	-0.01	0.14	-0.16	-0.08	-0.41	-0.41
	SD	0.873	0.691	0.777	0.626	0.618	0.599
	SE	0.144	0.104	0.115	0.084	0.087	0.088
	Minimum	-2.8	-1.3	-1.9	-1.3	-2.1	-1.8
	Median	-0.10	0.00	-0.30	0.00	-0.50	-0.30
	Maximum	2.1	1.9	1.8	1.5	1.9	0.7

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.7
Summary Statistics for HbA1c (%) by Visit

Visit: Week 12

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		37	44	47	55	51	47
Baseline	Mean	7.87	7.94	7.90	7.84	7.78	8.09
	SD	0.598	0.917	0.707	0.600	0.672	0.779
	SE	0.098	0.138	0.103	0.081	0.094	0.114
	Minimum	6.6	6.4	6.6	6.5	6.4	6.7
	Median	7.80	7.70	7.70	7.90	7.80	8.00
	Maximum	9.3	10.1	9.7	9.0	9.6	9.5
Week 12	Mean	8.18	8.15	7.71	7.84	7.36	7.70
	SD	1.254	1.261	1.040	0.858	0.846	1.008
	SE	0.206	0.190	0.152	0.116	0.118	0.147
	Minimum	6.3	6.3	6.2	6.0	5.5	5.8
	Median	7.80	7.75	7.50	7.90	7.30	7.60
	Maximum	11.4	11.8	10.7	9.5	9.7	9.9
Change from Baseline	Mean	0.31	0.21	-0.19	0.01	-0.42	-0.39
	SD	1.159	0.791	0.893	0.653	0.812	0.737
	SE	0.191	0.119	0.130	0.088	0.114	0.108
	Minimum	-1.7	-1.4	-2.3	-1.6	-2.5	-2.9
	Median	0.10	0.15	-0.30	0.00	-0.50	-0.20
	Maximum	2.8	1.8	2.1	1.9	2.6	0.7

[1]Number of subjects with a value at baseline and at specified visit

[redacted]

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Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

		Placebo (N=37)	2.5mg (N=46)	7.5mg (N=49)	15mg (N=55)	30mg (N=51)	45mg (N=48)
n [1]		37	44	47	55	51	47
Baseline	Mean	7.87	7.94	7.90	7.84	7.78	8.09
	SD	0.598	0.917	0.707	0.600	0.672	0.779
Week 12	Mean	8.18	8.15	7.71	7.84	7.36	7.70
	SD	1.254	1.261	1.040	0.858	0.846	1.008
Chg from Baseline	Mean	0.31	0.21	-0.19	0.01	-0.42	-0.39
	SD	1.159	0.791	0.893	0.653	0.812	0.737
Model-Adj Chg [2]	Mean	0.35	0.20	-0.25	0.01	-0.39	-0.37
	SE	0.124	0.114	0.110	0.101	0.105	0.110
Diff from Pbo [2]	Mean		-0.16	-0.60	-0.35	-0.75	-0.73
	95% CI		-0.49,0.18	-0.93,-0.28	-0.66,-0.03	-1.06,-0.43	-1.05,-0.40
	p-val [3]		0.355	<0.001	0.031	<0.001	<0.001

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
p-values for interactions: trt*sex=0.573, trt*prior therapy=0.382, trt*region=0.211, trt*baseline=0.595

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	37	Sum Weights	37
Mean	7.87297297	Sum Observations	291.3
Std Deviation	0.59798209	Variance	0.35758258
Skewness	0.37937314	Kurtosis	0.53217749
Uncorrected SS	2306.27	Corrected SS	12.872973
Coeff Variation	7.59537845	Std Error Mean	0.09830765

Basic Statistical Measures

Location		Variability	
Mean	7.872973	Std Deviation	0.59798
Median	7.800000	Variance	0.35758
Mode	7.700000	Range	2.70000
		Interquartile Range	0.70000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	80.08505	Pr > |t|	<.0001
Sign	M	18.5	Pr >= |M|	<.0001
Signed Rank	S	351.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.975412	Pr < W	0.5733
Kolmogorov-Smirnov	D	0.103597	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.048605	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.320928	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.3
99%	9.3
95%	9.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.6
75% Q3	8.2
50% Median	7.8
25% Q1	7.5
10%	7.2
5%	6.9
1%	6.6
0% Min	6.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	21	8.5	20
6.9	11	8.6	37
6.9	10	8.8	35
7.2	23	9.3	12
7.2	2	9.3	15

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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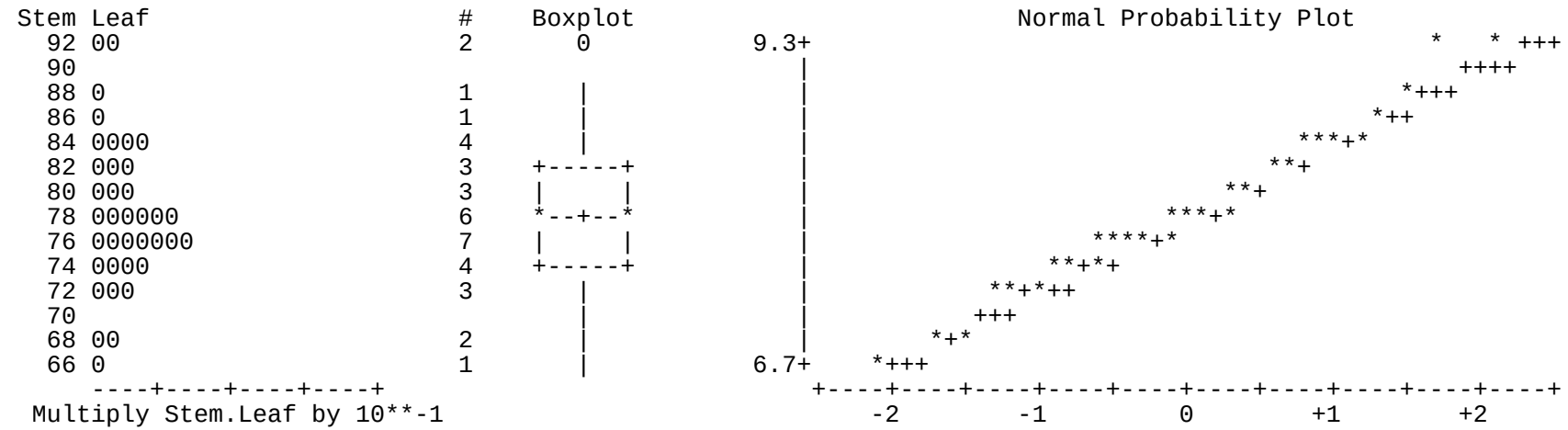
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	37	Sum Weights	37
Mean	8.17837838	Sum Observations	302.6
Std Deviation	1.25435577	Variance	1.57340841
Skewness	0.80542856	Kurtosis	-0.0250664
Uncorrected SS	2531.42	Corrected SS	56.6427027
Coeff Variation	15.3374632	Std Error Mean	0.20621482

Basic Statistical Measures

Location		Variability	
Mean	8.178378	Std Deviation	1.25436
Median	7.800000	Variance	1.57341
Mode	7.600000	Range	5.10000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	39.65951	Pr > |t|	<.0001
Sign	M	18.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	351.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.931119	Pr < W	0.0243
Kolmogorov-Smirnov	D	0.159082	Pr > D	0.0188
Cramer-von Mises	W-Sq	0.185974	Pr > W-Sq	0.0077
Anderson-Darling	A-Sq	1.005878	Pr > A-Sq	0.0107

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.4
99%	11.4
95%	10.6
90%	10.1
75% Q3	8.8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.8
25% Q1	7.3
10%	6.9
5%	6.3
1%	6.3
0% Min	6.3

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	26	10.0	9
6.3	5	10.1	29
6.7	1	10.3	35
6.9	23	10.6	30
6.9	19	11.4	37

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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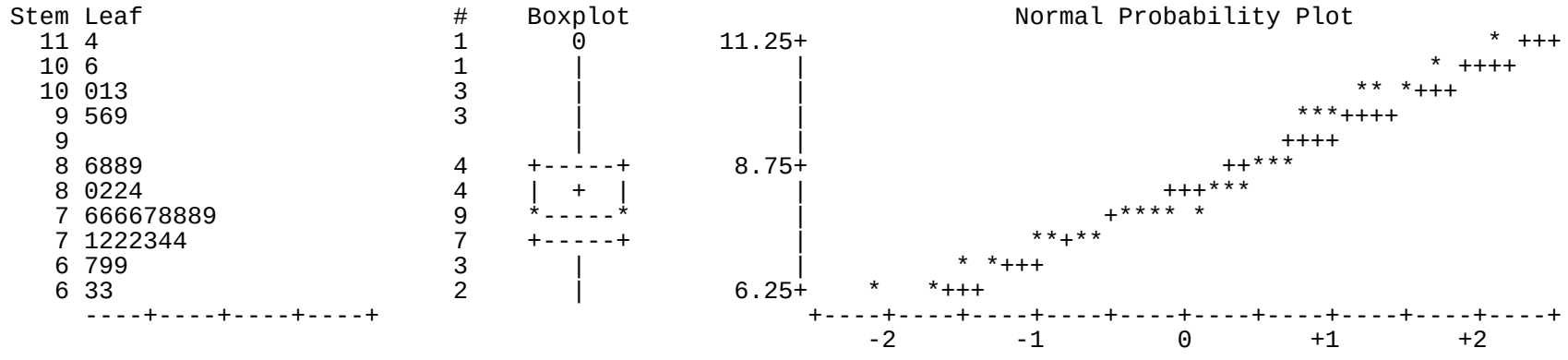
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	37	Sum Weights	37
Mean	0.30540541	Sum Observations	11.3
Std Deviation	1.15948886	Variance	1.34441441
Skewness	0.36547598	Kurtosis	-0.4387375
Uncorrected SS	51.85	Corrected SS	48.3989189
Coeff Variation	379.655644	Std Error Mean	0.19061879

Basic Statistical Measures

Location		Variability	
Mean	0.305405	Std Deviation	1.15949
Median	0.100000	Variance	1.34441
Mode	0.100000	Range	4.50000
		Interquartile Range	1.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.602179	Pr > |t|	0.1179
Sign	M	4	Pr >= |M|	0.2430

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	74.5	Pr >= |S|	0.2471

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.967185	Pr < W	0.3374
Kolmogorov-Smirnov	D	0.103784	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.077359	Pr > W-Sq	0.2241
Anderson-Darling	A-Sq	0.434607	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.8
99%	2.8
95%	2.5
90%	2.1
75% Q3	1.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.1
25% Q1	-0.4
10%	-1.0
5%	-1.7
1%	-1.7
0% Min	-1.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.7	12	2.0	36
-1.7	5	2.1	9
-1.5	26	2.2	30
-1.0	33	2.5	29
-1.0	1	2.8	37

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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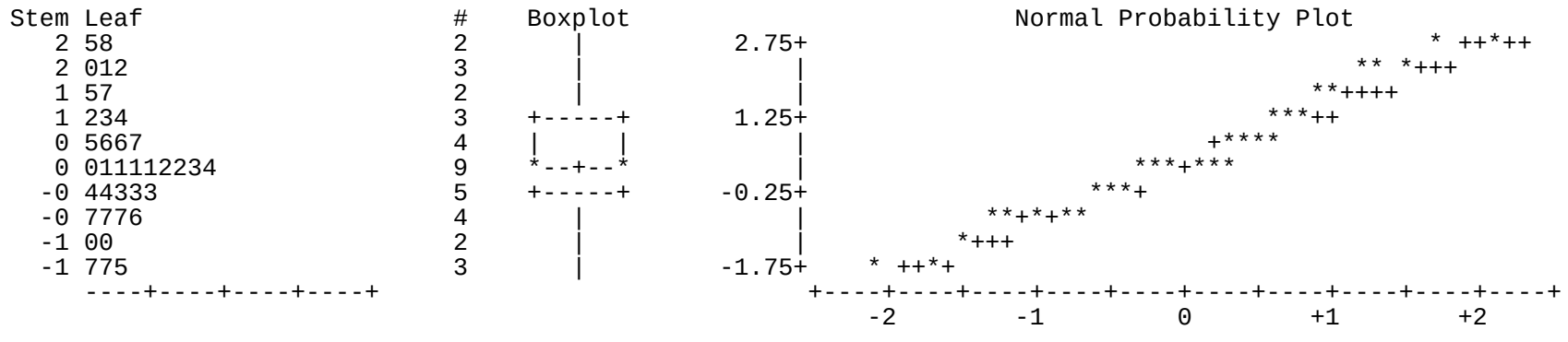
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	44	Sum Weights	44
Mean	7.94090909	Sum Observations	349.4
Std Deviation	0.91659587	Variance	0.84014799
Skewness	0.80059466	Kurtosis	0.3148621
Uncorrected SS	2810.68	Corrected SS	36.1263636
Coeff Variation	11.542707	Std Error Mean	0.13818203

Basic Statistical Measures

Location		Variability	
Mean	7.940909	Std Deviation	0.91660
Median	7.700000	Variance	0.84015
Mode	7.500000	Range	3.70000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 3 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	57.46702	Pr > |t|	<.0001
Sign	M	22	Pr >= |M|	<.0001
Signed Rank	S	495	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.932109	Pr < W	0.0124
Kolmogorov-Smirnov	D	0.151998	Pr > D	0.0117
Cramer-von Mises	W-Sq	0.185411	Pr > W-Sq	0.0079
Anderson-Darling	A-Sq	1.082883	Pr > A-Sq	0.0073

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.1
99%	10.1
95%	9.8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	9.5
75% Q3	8.3
50% Median	7.7
25% Q1	7.4
10%	6.9
5%	6.8
1%	6.4
0% Min	6.4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	39	9.5	16
6.4	23	9.7	1
6.8	32	9.8	29
6.8	19	10.1	3
6.9	37	10.1	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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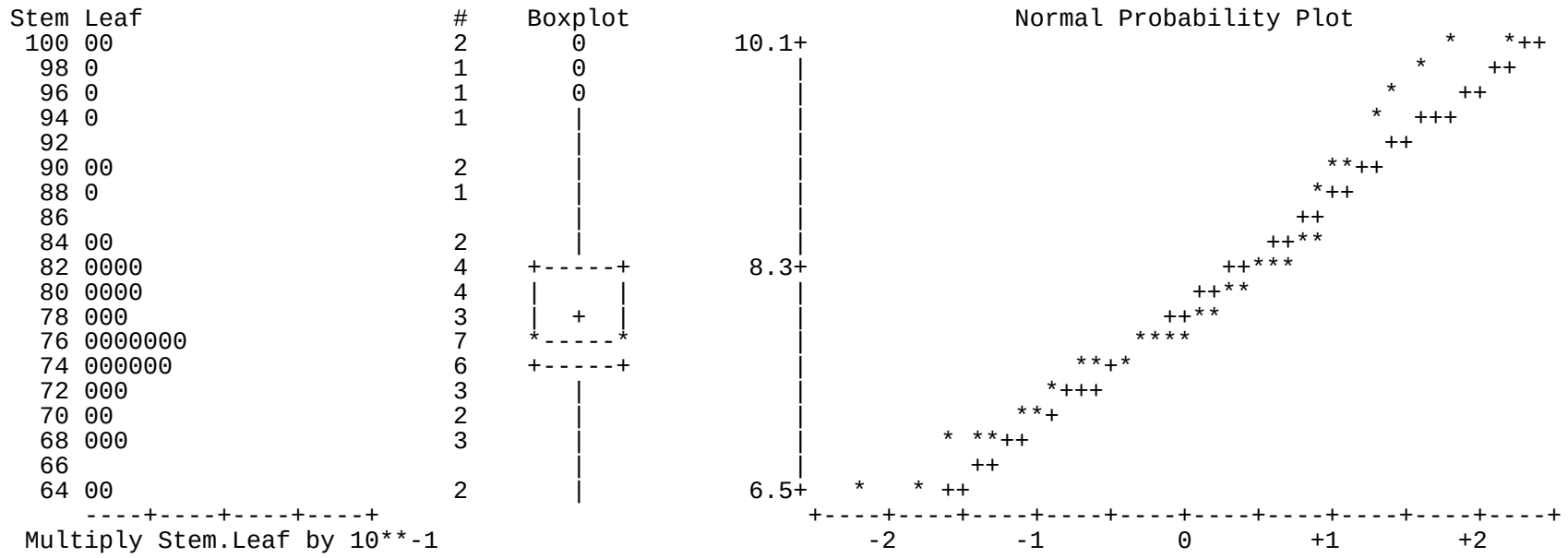
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	44	Sum Weights	44
Mean	8.15454545	Sum Observations	358.8
Std Deviation	1.26075919	Variance	1.58951374
Skewness	0.83234563	Kurtosis	0.46870376
Uncorrected SS	2994.2	Corrected SS	68.3490909
Coeff Variation	15.4608151	Std Error Mean	0.1900666

Basic Statistical Measures

Location		Variability	
Mean	8.154545	Std Deviation	1.26076
Median	7.750000	Variance	1.58951
Mode	7.600000	Range	5.50000
		Interquartile Range	1.65000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	42.90362	Pr > |t|	<.0001
Sign	M	22	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	495	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.942986	Pr < W	0.0303
Kolmogorov-Smirnov	D	0.140776	Pr > D	0.0269
Cramer-von Mises	W-Sq	0.13028	Pr > W-Sq	0.0435
Anderson-Darling	A-Sq	0.749272	Pr > A-Sq	0.0477

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.80
99%	11.80
95%	10.60
90%	9.70
75% Q3	9.00

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.35
10%	6.60
5%	6.50
1%	6.30
0% Min	6.30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	23	9.7	29
6.5	41	10.1	4
6.5	40	10.6	2
6.6	33	10.8	38
6.6	32	11.8	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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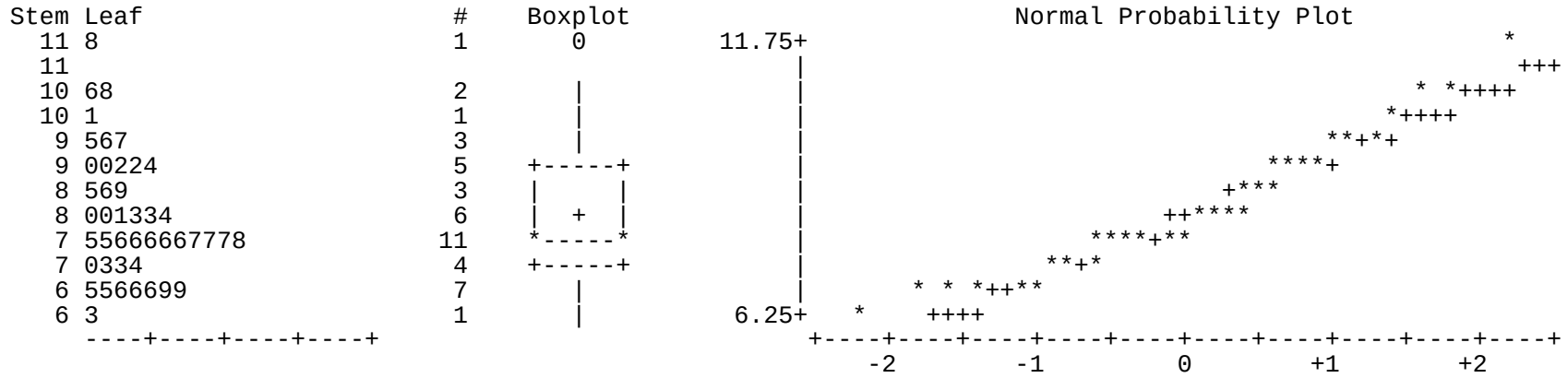
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	44	Sum Weights	44
Mean	0.21363636	Sum Observations	9.4
Std Deviation	0.79140467	Variance	0.62632135
Skewness	0.01278596	Kurtosis	-0.3121685
Uncorrected SS	28.94	Corrected SS	26.9318182
Coeff Variation	370.44474	Std Error Mean	0.11930874

Basic Statistical Measures

Location		Variability	
Mean	0.21364	Std Deviation	0.79140
Median	0.15000	Variance	0.62632
Mode	-0.50000	Range	3.20000
		Interquartile Range	1.05000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.790618	Pr > |t|	0.0804
Sign	M	3.5	Pr >= |M|	0.3604

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	139.5	Pr >= |S|	0.0922

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.980364	Pr < W	0.6481
Kolmogorov-Smirnov	D	0.069963	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.03124	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.233774	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.80
99%	1.80
95%	1.70
90%	1.20
75% Q3	0.70

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.15
25% Q1	-0.35
10%	-0.60
5%	-1.20
1%	-1.40
0% Min	-1.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.4	33	1.2	39
-1.4	10	1.3	42
-1.2	40	1.7	3
-1.0	41	1.7	38
-0.6	8	1.8	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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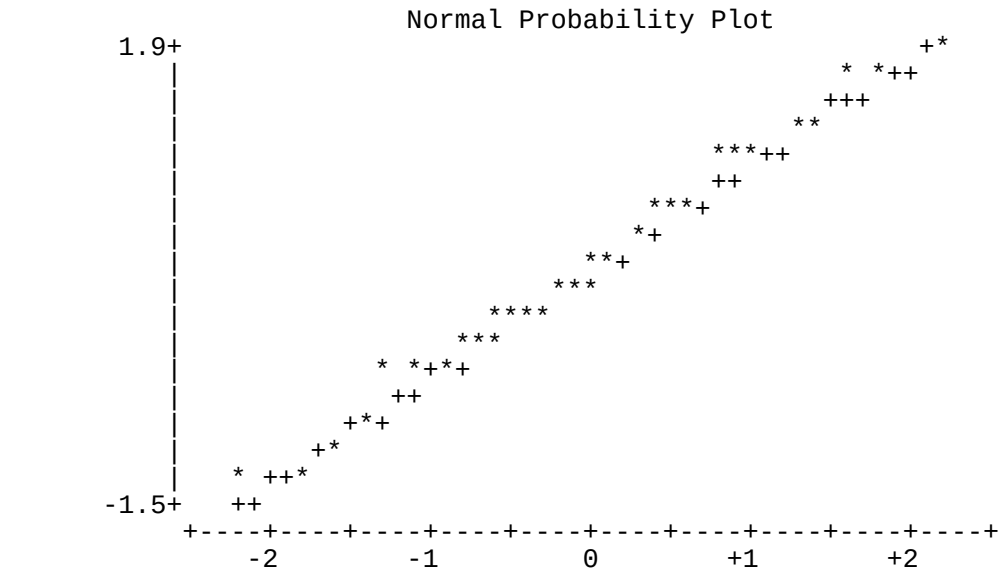
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
Stem Leaf                     #    Boxplot
  18 0                        1       |
  16 00                       2       |
  14                                  |
  12 00                       2       |
  10 00000                    5       |
   8                                  |
   6 000000                   6    +-----+
   4 00                       2    |     |
   2 0000                     4    |  +  |
   0 0000                     4    *-----*
  -0 0000                     4    |     |
  -2 000                      3    +-----+
  -4 000000                   6       |
  -6 0                        1       |
  -8                                  |
 -10 0                        1       |
 -12 0                        1       |
 -14 00                       2       |
     ----+----+----+----+
 Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	47	Sum Weights	47
Mean	7.9	Sum Observations	371.3
Std Deviation	0.70710678	Variance	0.5
Skewness	0.72710253	Kurtosis	0.27236047
Uncorrected SS	2956.27	Corrected SS	23
Coeff Variation	8.95071875	Std Error Mean	0.10314212

Basic Statistical Measures

Location		Variability	
Mean	7.900000	Std Deviation	0.70711
Median	7.700000	Variance	0.50000
Mode	7.600000	Range	3.10000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	76.59334	Pr > |t|	<.0001
Sign	M	23.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	564	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.938673	Pr < W	0.0159
Kolmogorov-Smirnov	D	0.164543	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.210528	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.184518	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.7
99%	9.7
95%	9.3
90%	9.2
75% Q3	8.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.4
10%	7.3
5%	6.9
1%	6.6
0% Min	6.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	25	9.2	4
6.7	21	9.2	41
6.9	35	9.3	42
6.9	9	9.4	24
7.3	32	9.7	26

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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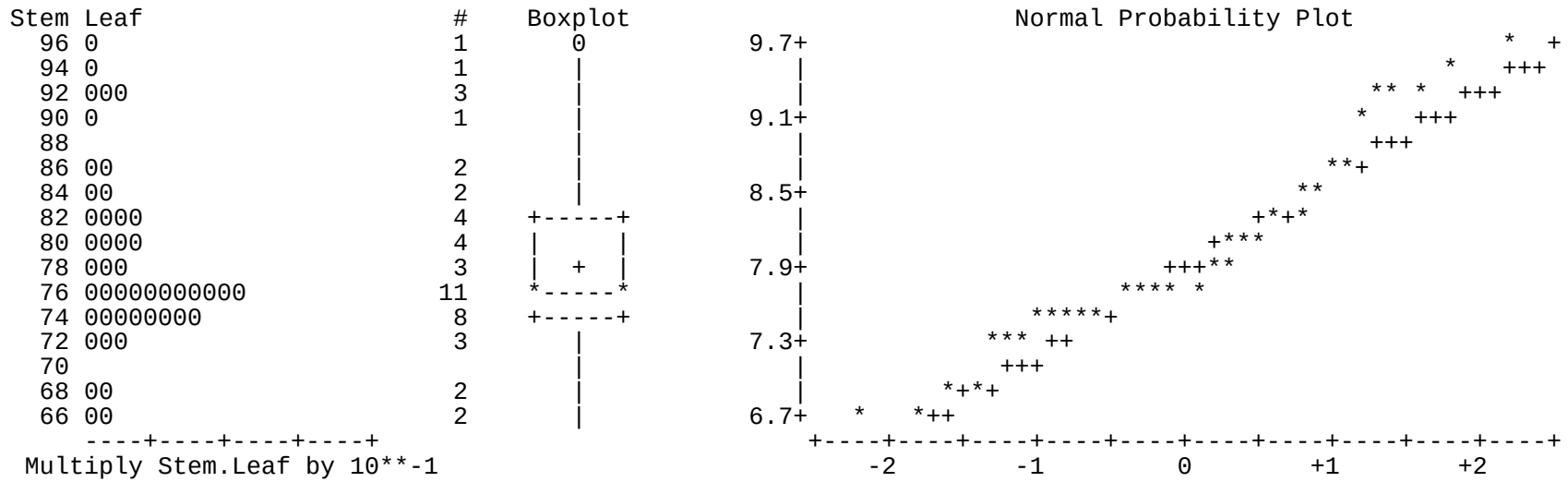
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	47	Sum Weights	47
Mean	7.71489362	Sum Observations	362.6
Std Deviation	1.04027144	Variance	1.08216466
Skewness	1.06934086	Kurtosis	1.18206878
Uncorrected SS	2847.2	Corrected SS	49.7795745
Coeff Variation	13.4839375	Std Error Mean	0.15173918

Basic Statistical Measures

Location		Variability	
Mean	7.714894	Std Deviation	1.04027
Median	7.500000	Variance	1.08216
Mode	7.600000	Range	4.50000
		Interquartile Range	1.20000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	50.84312	Pr > |t|	<.0001
Sign	M	23.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	564	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.920117	Pr < W	0.0034
Kolmogorov-Smirnov	D	0.160993	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.180364	Pr > W-Sq	0.0091
Anderson-Darling	A-Sq	1.084727	Pr > A-Sq	0.0073

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.7
99%	10.7
95%	10.2
90%	9.0
75% Q3	8.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.5
25% Q1	7.0
10%	6.6
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	25	9.0	33
6.2	21	9.1	44
6.3	46	10.2	31
6.4	37	10.4	3
6.6	34	10.7	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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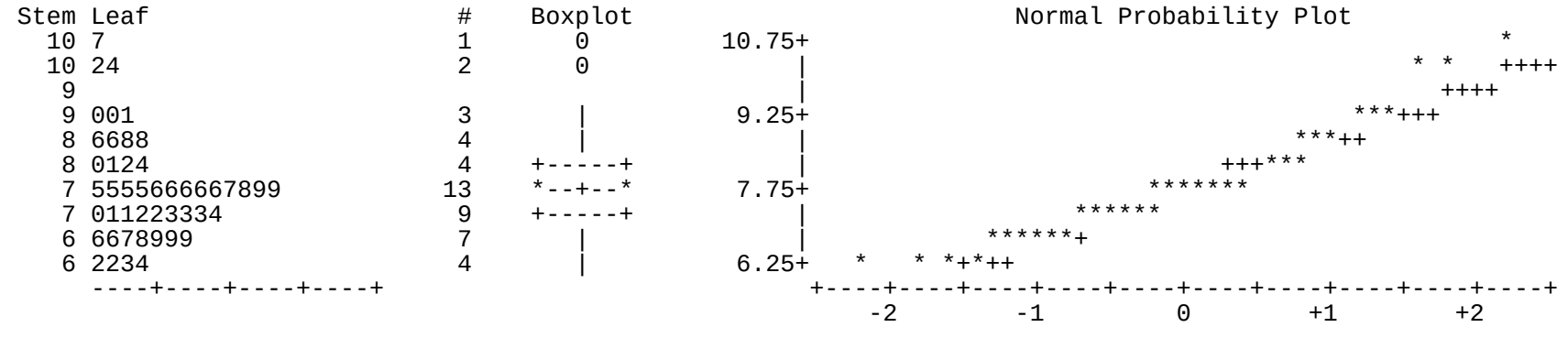
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	47	Sum Weights	47
Mean	-0.1851064	Sum Observations	-8.7
Std Deviation	0.89320593	Variance	0.79781684
Skewness	0.38785828	Kurtosis	0.83100064
Uncorrected SS	38.31	Corrected SS	36.6995745
Coeff Variation	-482.53654	Std Error Mean	0.13028748

Basic Statistical Measures

Location		Variability	
Mean	-0.18511	Std Deviation	0.89321
Median	-0.30000	Variance	0.79782
Mode	-0.30000	Range	4.40000
		Interquartile Range	1.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.42075	Pr > |t|	0.1621
Sign	M	-6.5	Pr >= |M|	0.0725

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-168.5	Pr >= |S|	0.0561

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.9625	Pr < W	0.1352
Kolmogorov-Smirnov	D	0.125643	Pr > D	0.0627
Cramer-von Mises	W-Sq	0.117529	Pr > W-Sq	0.0664
Anderson-Darling	A-Sq	0.725259	Pr > A-Sq	0.0560

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.1
99%	2.1
95%	1.7
90%	0.9
75% Q3	0.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.3
25% Q1	-0.7
10%	-1.1
5%	-1.7
1%	-2.3
0% Min	-2.3

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.3	41	0.9	29
-1.9	43	1.6	31
-1.7	37	1.7	5
-1.2	46	1.7	44
-1.1	34	2.1	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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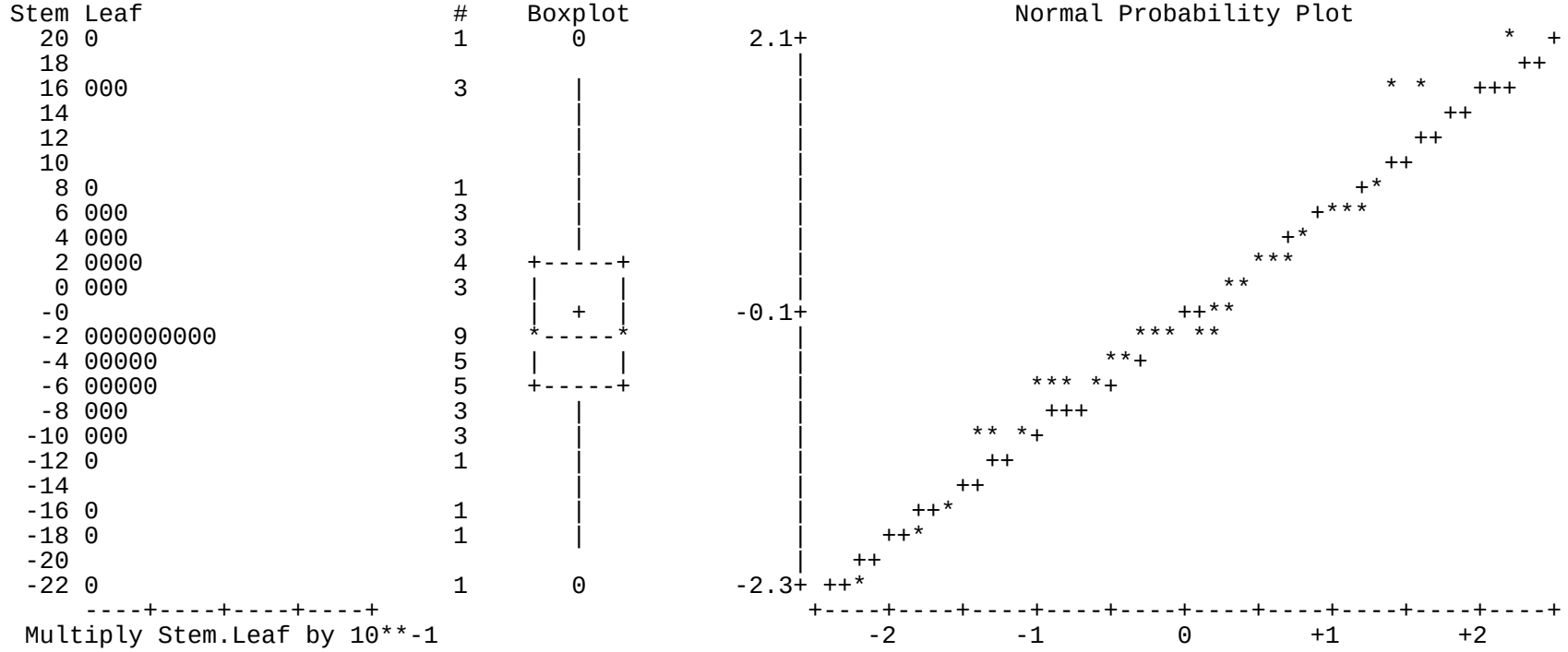
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	55	Sum Weights	55
Mean	7.83818182	Sum Observations	431.1
Std Deviation	0.60045998	Variance	0.36055219
Skewness	-0.2336504	Kurtosis	-0.6421475
Uncorrected SS	3398.51	Corrected SS	19.4698182
Coeff Variation	7.66070493	Std Error Mean	0.08096601

Basic Statistical Measures

Location		Variability	
Mean	7.838182	Std Deviation	0.60046
Median	7.900000	Variance	0.36055
Mode	7.500000	Range	2.50000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 3 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	96.8083	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	770	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.979707	Pr < W	0.4755
Kolmogorov-Smirnov	D	0.097133	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.077106	Pr > W-Sq	0.2276
Anderson-Darling	A-Sq	0.406774	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.0
99%	9.0
95%	8.8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.6
75% Q3	8.3
50% Median	7.9
25% Q1	7.4
10%	7.0
5%	6.8
1%	6.5
0% Min	6.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	22	8.6	43
6.6	5	8.7	51
6.8	3	8.8	25
6.9	42	8.9	19
7.0	15	9.0	27

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
    90 0                     1       |
    88 00                    2       |
    86 000                   3       |
    84 000000                6       |
    82 00000000              8    +-----+
    80 0000000               7    |     |
    78 0000                  4    *--+--*
    76 0000                  4    |     |
    74 0000000               7    +-----+
    72 00000                 5       |
    70 0000                  4       |
    68 00                    2       |
    66 0                     1       |
    64 0                     1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```

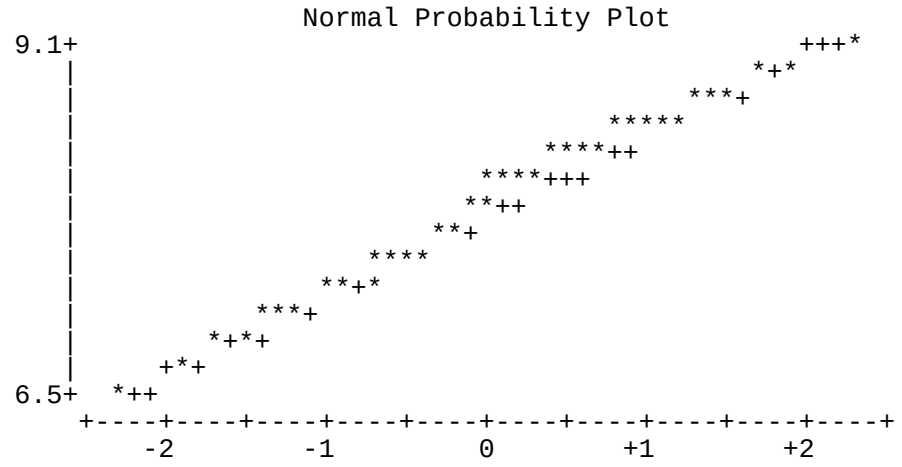

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	55	Sum Weights	55
Mean	7.84363636	Sum Observations	431.4
Std Deviation	0.85845763	Variance	0.73694949
Skewness	-0.0315348	Kurtosis	-0.7041848
Uncorrected SS	3423.54	Corrected SS	39.7952727
Coeff Variation	10.9446382	Std Error Mean	0.1157544

Basic Statistical Measures

Location		Variability	
Mean	7.843636	Std Deviation	0.85846
Median	7.900000	Variance	0.73695
Mode	8.500000	Range	3.50000
		Interquartile Range	1.30000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	67.76102	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	770	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.982364	Pr < W	0.5946
Kolmogorov-Smirnov	D	0.079155	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.049914	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.282767	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.5
99%	9.5
95%	9.3
90%	9.0
75% Q3	8.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.9
25% Q1	7.2
10%	6.7
5%	6.4
1%	6.0
0% Min	6.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.0	30	9.1	2
6.4	47	9.2	52
6.4	22	9.3	16
6.5	42	9.5	4
6.5	33	9.5	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
    94 00                    2        |
    92 00                    2        |
    90 00                    2        |
    88 00                    2        |
    86 000                   3        |
    84 0000000               7    +-----+
    82 00000                 5    |     |
    80 00                    2    |     |
    78 0000                  4    *--+--*
    76 000                   3    |     |
    74 000000                6    |     |
    72 00000                 5    +-----+
    70 000                   3        |
    68 000                   3        |
    66 0                     1        |
    64 0000                  4        |
    62                               |
    60 0                     1        |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```

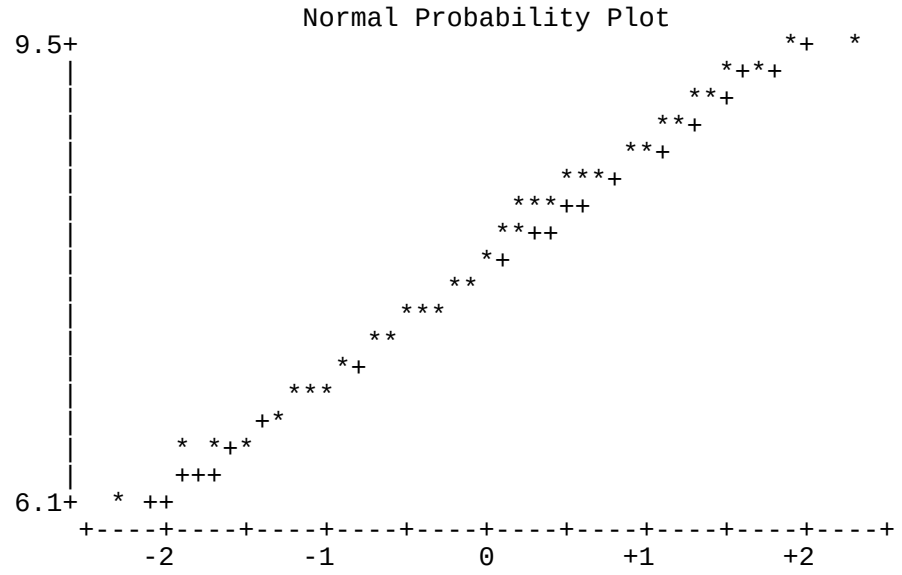

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	0.00545455	Sum Observations	0.3
Std Deviation	0.65274866	Variance	0.42608081
Skewness	0.22501161	Kurtosis	1.14779993
Uncorrected SS	23.01	Corrected SS	23.0083636
Coeff Variation	11967.0587	Std Error Mean	0.08801661

Basic Statistical Measures

Location		Variability	
Mean	0.005455	Std Deviation	0.65275
Median	0.000000	Variance	0.42608
Mode	0.000000	Range	3.50000
		Interquartile Range	0.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.061972	Pr > |t|	0.9508
Sign	M	2	Pr >= |M|	0.6587

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	8	Pr >= |S|	0.9314

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.964239	Pr < W	0.1009
Kolmogorov-Smirnov	D	0.128291	Pr > D	0.0232
Cramer-von Mises	W-Sq	0.17614	Pr > W-Sq	0.0101
Anderson-Darling	A-Sq	0.889044	Pr > A-Sq	0.0223

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9
99%	1.9
95%	1.2
90%	0.8
75% Q3	0.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-0.3
10%	-0.9
5%	-1.1
1%	-1.6
0% Min	-1.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.6	47	0.8	17
-1.2	45	0.8	51
-1.1	37	1.2	16
-1.1	30	1.6	4
-1.0	25	1.9	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

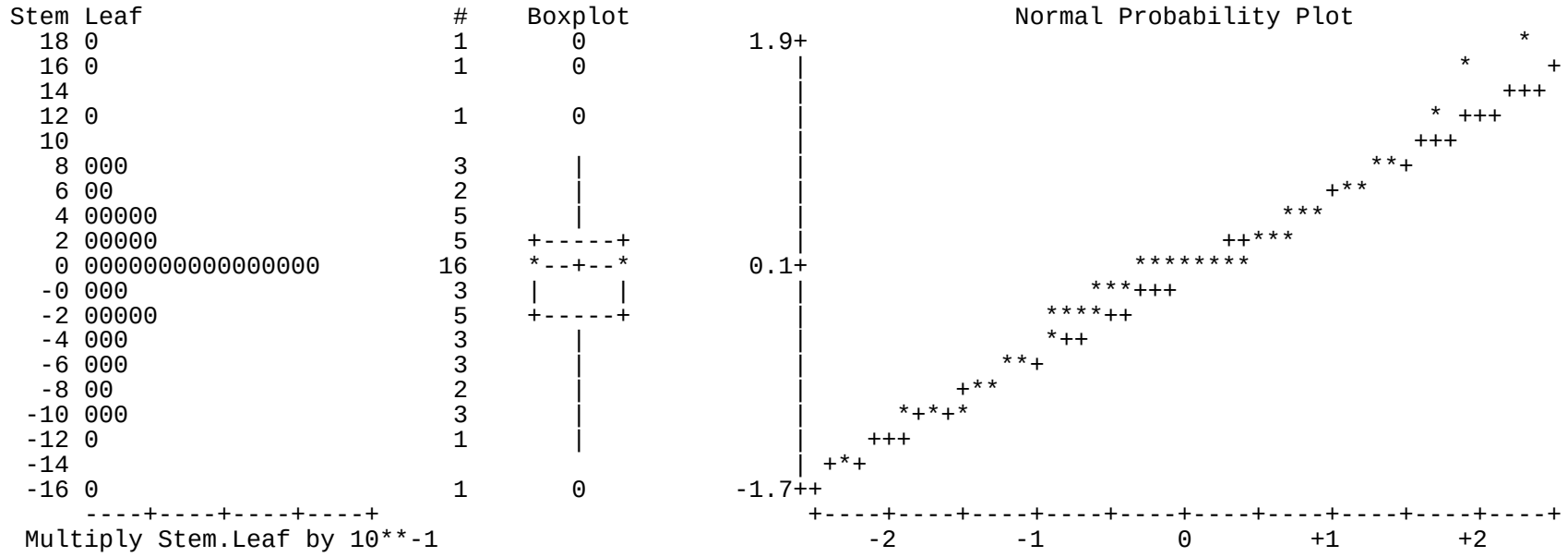

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	51	Sum Weights	51
Mean	7.78039216	Sum Observations	396.8
Std Deviation	0.67172006	Variance	0.45120784
Skewness	0.02372711	Kurtosis	-0.2964944
Uncorrected SS	3109.82	Corrected SS	22.5603922
Coeff Variation	8.63349879	Std Error Mean	0.09405962

Basic Statistical Measures

Location		Variability	
Mean	7.780392	Std Deviation	0.67172
Median	7.800000	Variance	0.45121
Mode	8.400000	Range	3.20000
		Interquartile Range	1.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	82.71766	Pr > |t|	<.0001
Sign	M	25.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	663	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.96748	Pr < W	0.1735
Kolmogorov-Smirnov	D	0.098729	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.086552	Pr > W-Sq	0.1712
Anderson-Darling	A-Sq	0.591092	Pr > A-Sq	0.1219

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.6
99%	9.6
95%	8.6
90%	8.6
75% Q3	8.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.8
25% Q1	7.3
10%	6.8
5%	6.7
1%	6.4
0% Min	6.4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	38	8.6	7
6.7	21	8.6	25
6.7	14	8.6	42
6.8	49	8.7	45
6.8	48	9.6	39

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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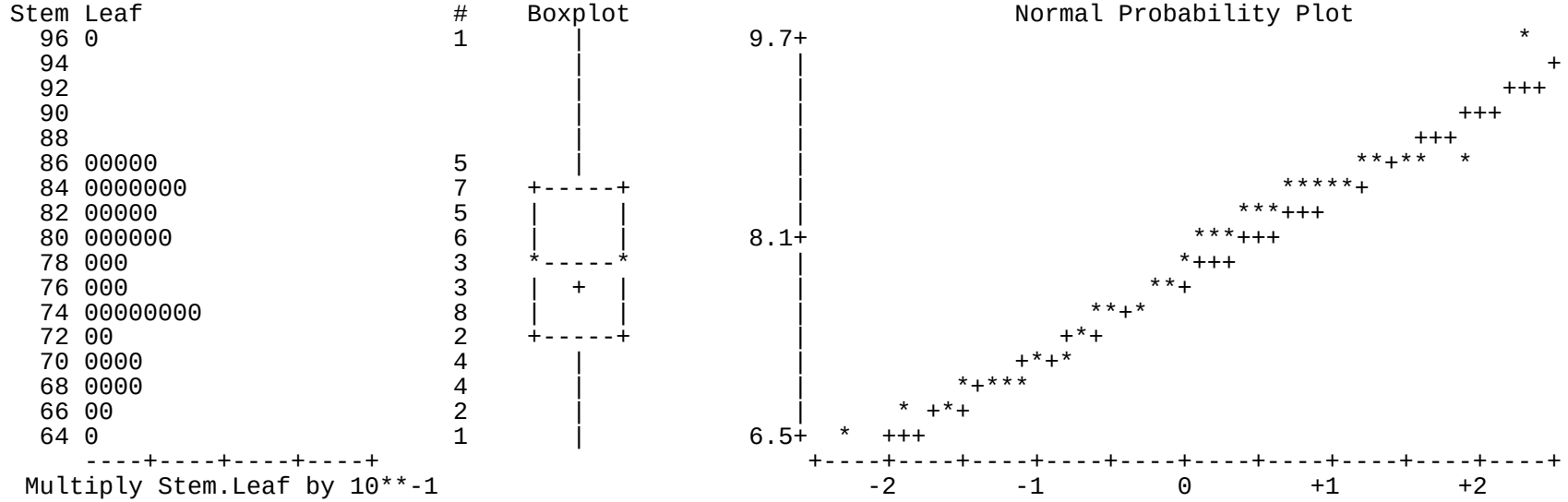
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	51	Sum Weights	51
Mean	7.36470588	Sum Observations	375.6
Std Deviation	0.84612612	Variance	0.71592941
Skewness	0.40413175	Kurtosis	0.2183241
Uncorrected SS	2801.98	Corrected SS	35.7964706
Coeff Variation	11.4889329	Std Error Mean	0.11848136

Basic Statistical Measures

Location		Variability	
Mean	7.364706	Std Deviation	0.84613
Median	7.300000	Variance	0.71593
Mode	7.100000	Range	4.20000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

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[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	62.1592	Pr > |t|	<.0001
Sign	M	25.5	Pr >= |M|	<.0001
Signed Rank	S	663	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.978727	Pr < W	0.4863
Kolmogorov-Smirnov	D	0.122755	Pr > D	0.0533
Cramer-von Mises	W-Sq	0.082848	Pr > W-Sq	0.1932
Anderson-Darling	A-Sq	0.447191	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.7
99%	9.7
95%	8.9

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.5
75% Q3	7.9
50% Median	7.3
25% Q1	6.9
10%	6.3
5%	6.2
1%	5.5
0% Min	5.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	19	8.6	15
6.1	16	8.8	7
6.2	32	8.9	5
6.2	21	8.9	39
6.2	14	9.7	50

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

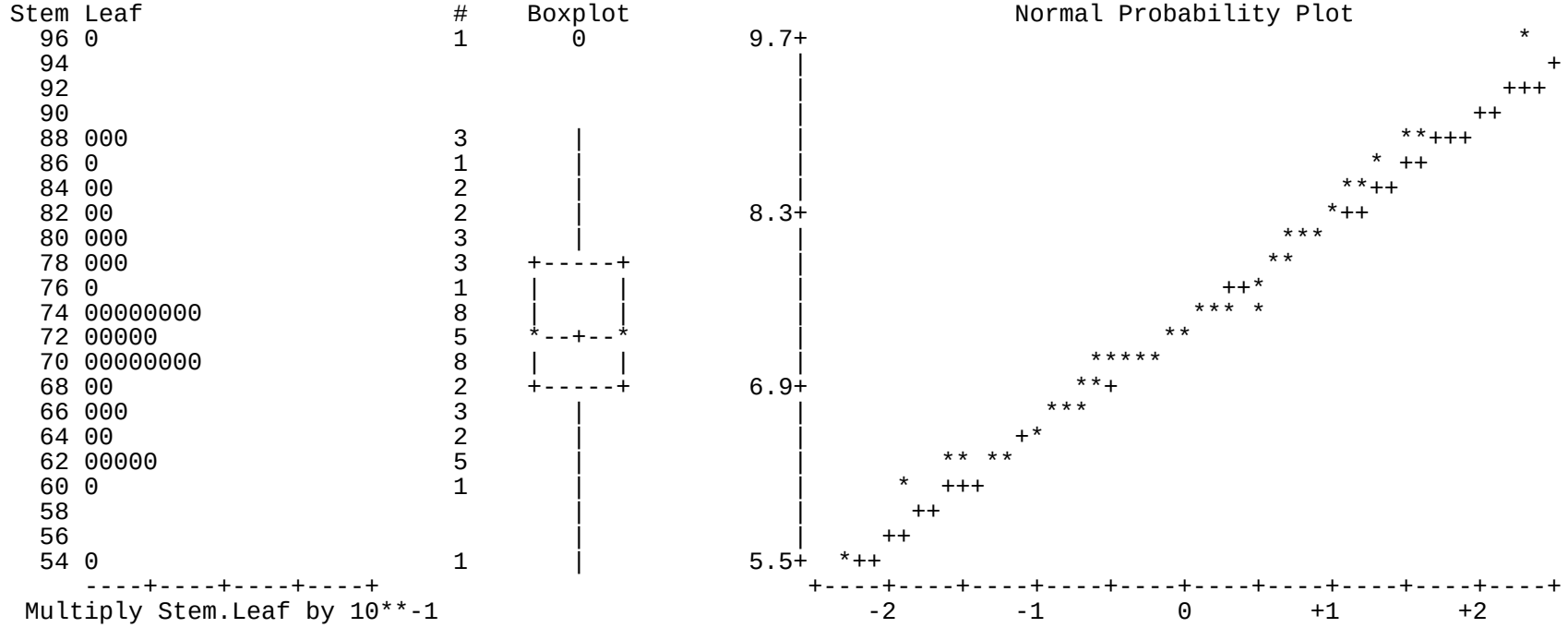

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	51	Sum Weights	51
Mean	-0.4156863	Sum Observations	-21.2
Std Deviation	0.81151033	Variance	0.65854902
Skewness	0.57864973	Kurtosis	3.21125562
Uncorrected SS	41.74	Corrected SS	32.927451
Coeff Variation	-195.22183	Std Error Mean	0.11363418

Basic Statistical Measures

Location		Variability	
Mean	-0.41569	Std Deviation	0.81151
Median	-0.50000	Variance	0.65855
Mode	-0.50000	Range	5.10000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.65811	Pr > |t|	0.0006
Sign	M	-10	Pr >= |M|	0.0055

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-362.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.947898	Pr < W 0.0258
Kolmogorov-Smirnov	D	0.106371	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.0722	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq	0.561265	Pr > A-Sq 0.1436

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.6
99%	2.6
95%	0.7
90%	0.4
75% Q3	0.1

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.5
25% Q1	-0.8
10%	-1.3
5%	-1.6
1%	-2.5
0% Min	-2.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.5	19	0.4	49
-2.1	16	0.6	44
-1.6	45	0.7	38
-1.5	25	0.9	5
-1.3	46	2.6	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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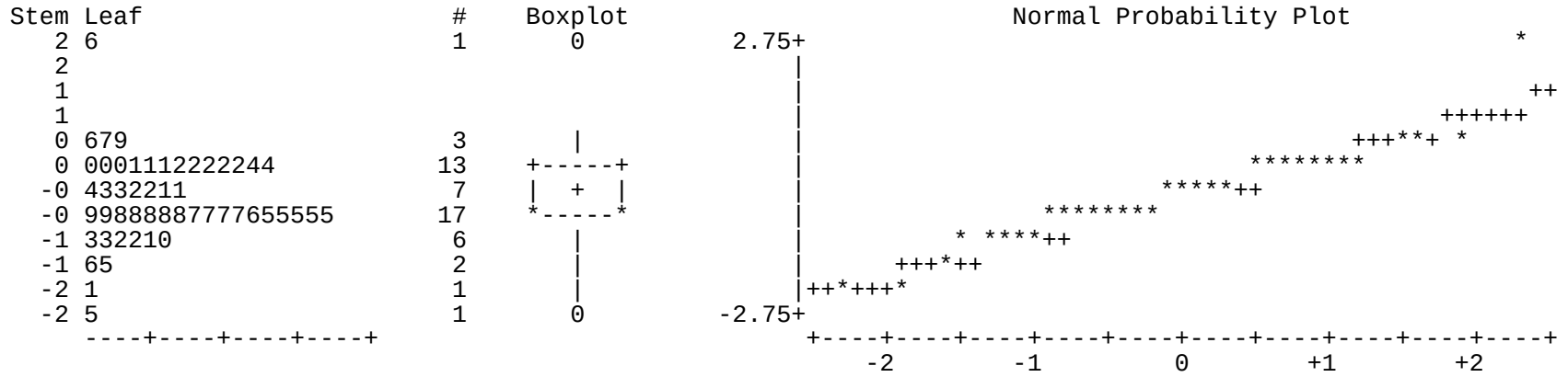
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	47	Sum Weights	47
Mean	8.08723404	Sum Observations	380.1
Std Deviation	0.7792463	Variance	0.60722479
Skewness	0.0904919	Kurtosis	-0.8103343
Uncorrected SS	3101.89	Corrected SS	27.9323404
Coeff Variation	9.63551065	Std Error Mean	0.11366475

Basic Statistical Measures

Location		Variability	
Mean	8.087234	Std Deviation	0.77925
Median	8.000000	Variance	0.60722
Mode	7.700000	Range	2.80000
		Interquartile Range	1.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	71.14988	Pr > |t|	<.0001
Sign	M	23.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	564	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.972359	Pr < W	0.3248
Kolmogorov-Smirnov	D	0.073361	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.037695	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.269866	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.5
99%	9.5
95%	9.5
90%	9.2
75% Q3	8.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	8.0
25% Q1	7.5
10%	7.1
5%	6.8
1%	6.7
0% Min	6.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.7	42	9.2	23
6.7	8	9.3	22
6.8	27	9.5	4
6.9	33	9.5	28
7.1	36	9.5	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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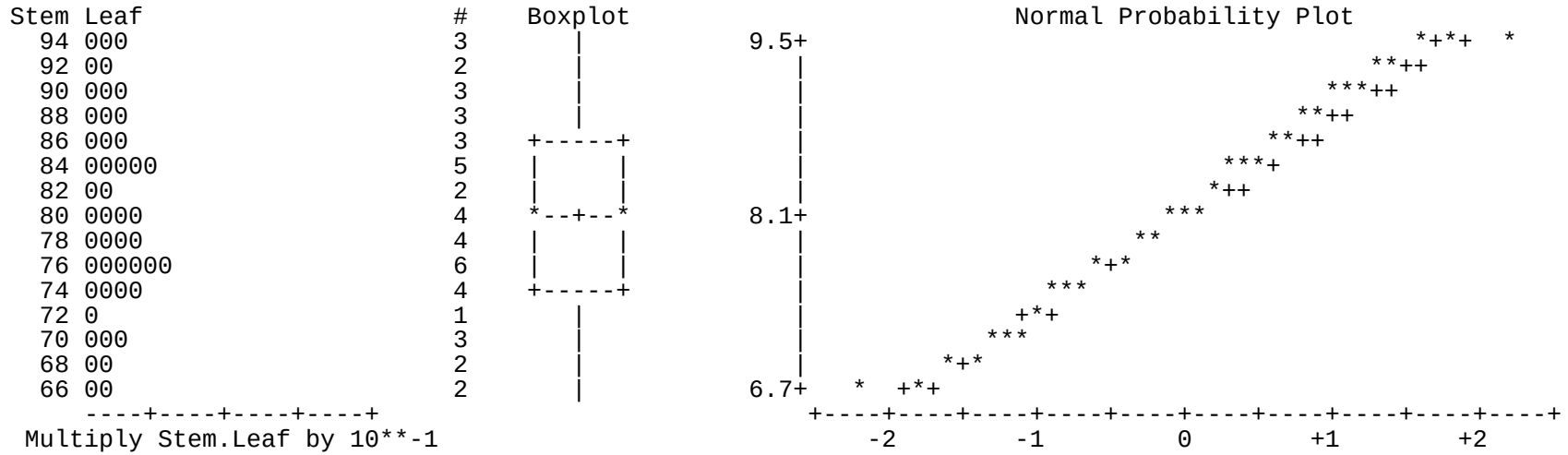
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	47	Sum Weights	47
Mean	7.69574468	Sum Observations	361.7
Std Deviation	1.00821785	Variance	1.01650324
Skewness	0.27451636	Kurtosis	-0.3623326
Uncorrected SS	2830.31	Corrected SS	46.7591489
Coeff Variation	13.1009785	Std Error Mean	0.14706369

Basic Statistical Measures

Location		Variability	
Mean	7.695745	Std Deviation	1.00822
Median	7.600000	Variance	1.01650
Mode	6.700000	Range	4.10000
		Interquartile Range	1.70000

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	52.32933	Pr > |t|	<.0001
Sign	M	23.5	Pr >= |M|	<.0001
Signed Rank	S	564	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.980703	Pr < W	0.6215
Kolmogorov-Smirnov	D	0.068168	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.024028	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.205228	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.9
99%	9.9
95%	9.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.9
75% Q3	8.5
50% Median	7.6
25% Q1	6.8
10%	6.3
5%	6.1
1%	5.8
0% Min	5.8

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.8	8	8.9	21
6.0	26	9.4	16
6.1	45	9.7	23
6.3	10	9.8	22
6.3	7	9.9	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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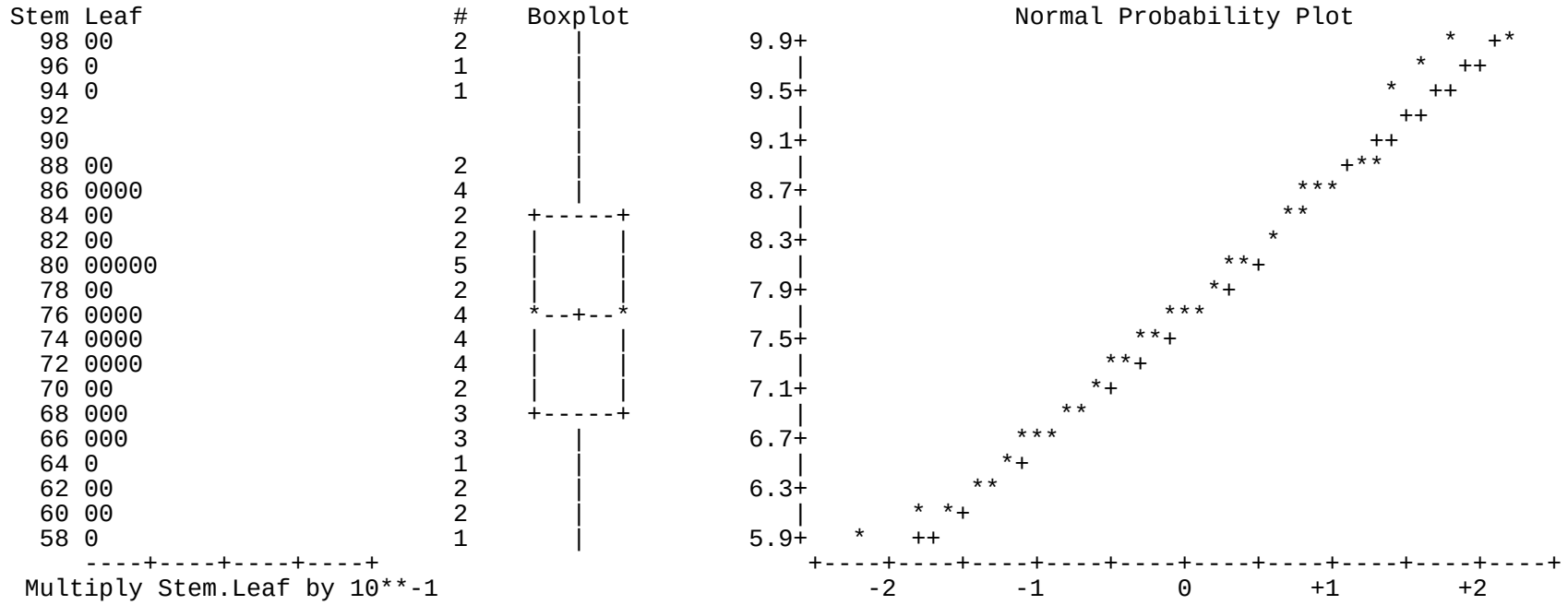
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	47	Sum Weights	47
Mean	-0.3914894	Sum Observations	-18.4
Std Deviation	0.73745443	Variance	0.54383904
Skewness	-1.1297133	Kurtosis	1.48412477
Uncorrected SS	32.22	Corrected SS	25.0165957
Coeff Variation	-188.37151	Std Error Mean	0.10756878

Basic Statistical Measures

Location		Variability	
Mean	-0.39149	Std Deviation	0.73745
Median	-0.20000	Variance	0.54384
Mode	0.00000	Range	3.60000
		Interquartile Range	1.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.63943	Pr > |t|	0.0007
Sign	M	-6.5	Pr >= |M|	0.0596

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-238	Pr >= |S|	0.0012

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.914672	Pr < W	0.0022
Kolmogorov-Smirnov	D	0.143038	Pr > D	0.0171
Cramer-von Mises	W-Sq	0.214463	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.208468	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7
99%	0.7
95%	0.5
90%	0.4
75% Q3	0.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.2
25% Q1	-0.9
10%	-1.4
5%	-1.6
1%	-2.9
0% Min	-2.9

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.9	45	0.4	25
-1.8	26	0.4	47
-1.6	7	0.5	22
-1.5	44	0.5	23
-1.4	12	0.7	46

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

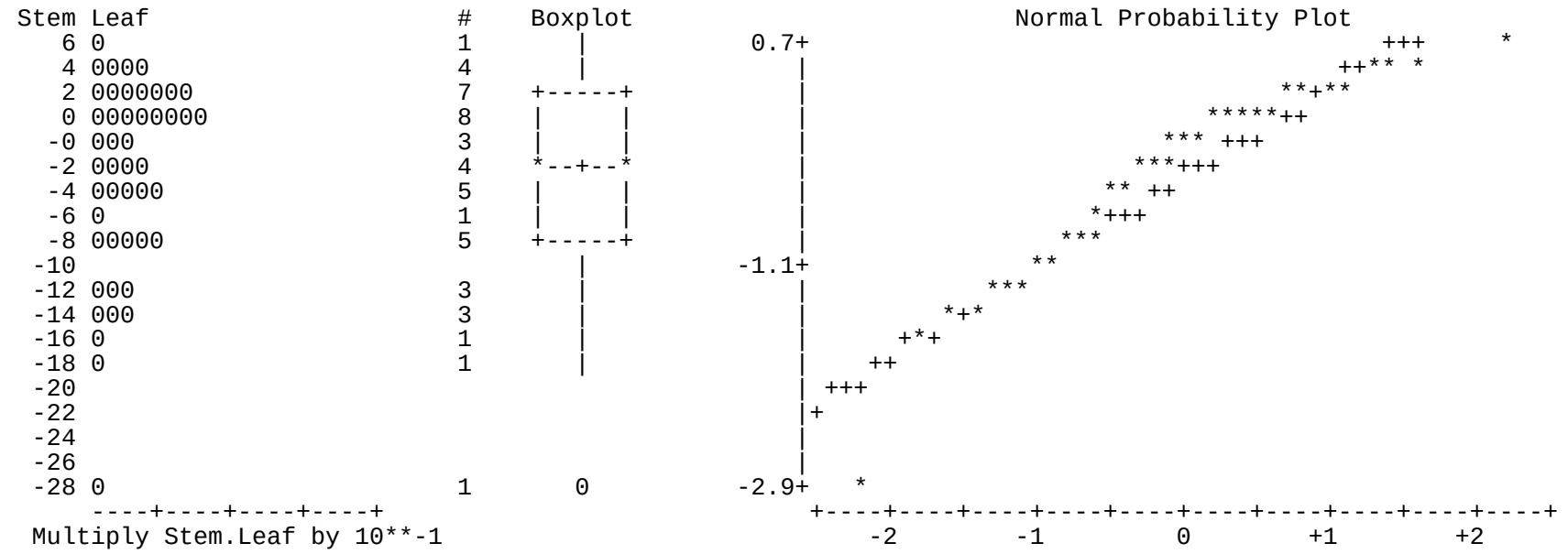

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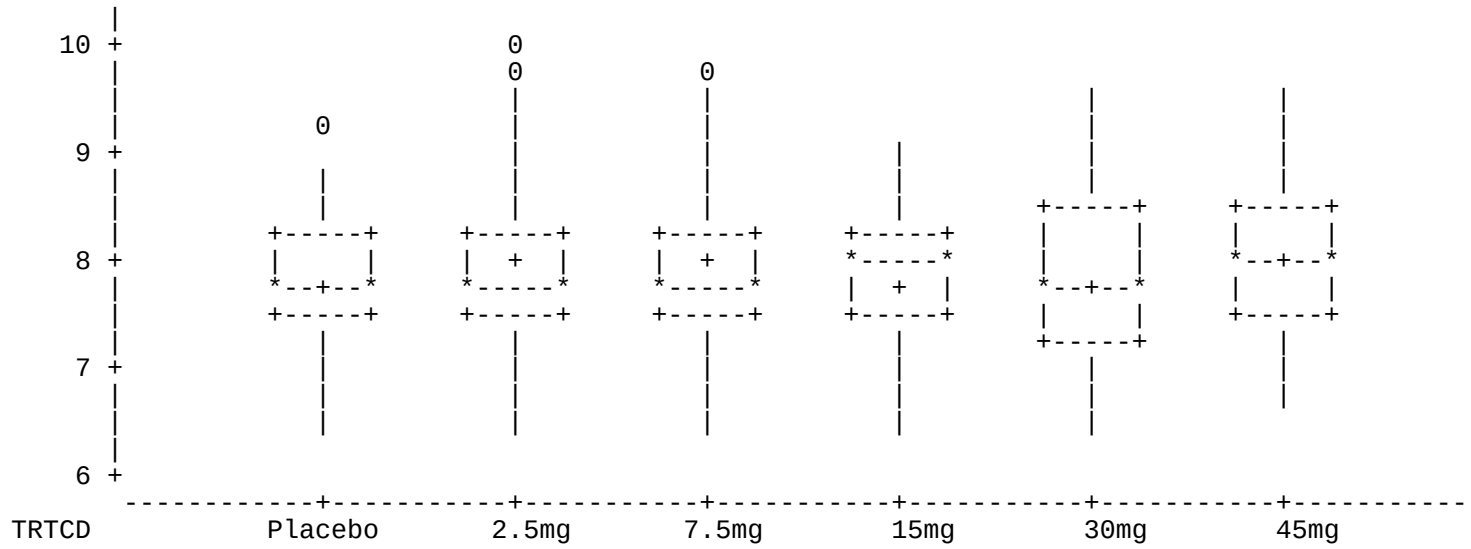
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



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[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots

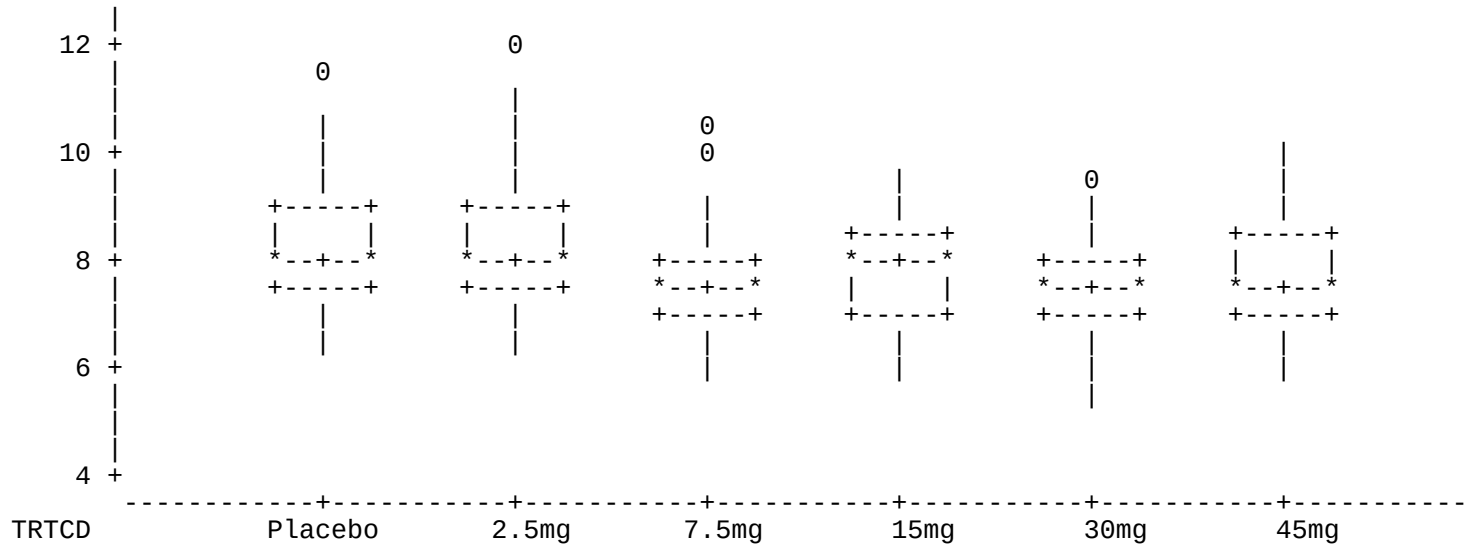

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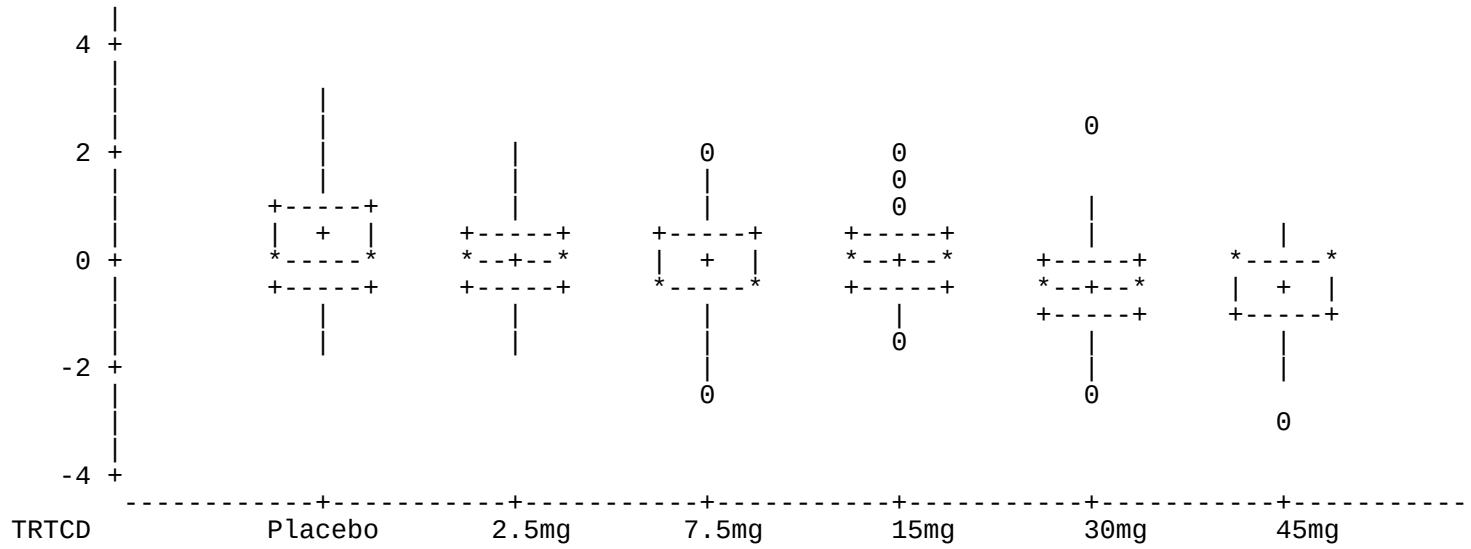
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	281
Observations Used	281
Observations Not Used	0
Total Observations	281

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5619	0.04836	11.62	<.0001	0.05	0.4779	0.6701

Fit Statistics

-2 Res Log Likelihood	654.9
AIC (smaller is better)	656.9
AICC (smaller is better)	656.9
BIC (smaller is better)	660.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.5408	0.5227	270	1.03	0.3018
SEX	Female				-0.07660	0.09055	270	-0.85	0.3983
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.6983	0.09247	270	-7.55	<.0001
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.7251	0.1659	270	4.37	<.0001
TRTCD				2.5mg	0.5690	0.1578	270	3.61	0.0004
TRTCD				7.5mg	0.1241	0.1556	270	0.80	0.4256
TRTCD				15mg	0.3784	0.1500	270	2.52	0.0122
TRTCD				30mg	-0.01991	0.1533	270	-0.13	0.8967
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.3861	0.1083	270	-3.56	0.0004
REGIONCD			Eastern Europe		-0.1298	0.1098	270	-1.18	0.2383
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.05449	0.06382	270	-0.85	0.3940

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	270	0.72	0.3983
TRTTYPCD	1	270	57.02	<.0001
TRTCD	5	270	7.44	<.0001
REGIONCD	2	270	6.45	0.0018
EFSTDBL	1	270	0.73	0.3940

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1561	0.1684	270	-0.93	0.3548	0.05	-0.4878	0.1755
7.5mg vs Pbo	-0.6010	0.1655	270	-3.63	0.0003	0.05	-0.9268	-0.2752
15mg vs Pbo	-0.3467	0.1598	270	-2.17	0.0309	0.05	-0.6614	-0.03207
30mg vs Pbo	-0.7450	0.1620	270	-4.60	<.0001	0.05	-1.0640	-0.4261
45mg vs Pbo	-0.7251	0.1659	270	-4.37	<.0001	0.05	-1.0517	-0.3986

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5196	0.5196	0.5196	0.5196	0.5196
SEX	Male				0.4804	0.4804	0.4804	0.4804	0.4804
TRTTYPCD		Diet & Exercise			0.4057	0.4057	0.4057	0.4057	0.4057
TRTTYPCD		Monotherapy			0.5943	0.5943	0.5943	0.5943	0.5943
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3132	0.3132	0.3132	0.3132	0.3132
REGIONCD			Eastern Europe		0.3025	0.3025	0.3025	0.3025	0.3025
REGIONCD			Western Europe		0.3843	0.3843	0.3843	0.3843	0.3843
EFSTDBL					7.9004	7.9004	7.9004	7.9004	7.9004

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5196
SEX	Male				0.4804
TRTTYPCD		Diet & Exercise			0.4057
TRTTYPCD		Monotherapy			0.5943
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3132
REGIONCD			Eastern Europe		0.3025
REGIONCD			Western Europe		0.3843
EFSTDBL					7.9004

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.3522	0.1236	270	2.85	0.0047	0.05	0.1088	0.5956
TRTCD	2.5mg	WORK.EFF	0.1961	0.1136	270	1.73	0.0855	0.05	-0.02760	0.4197
TRTCD	7.5mg	WORK.EFF	-0.2488	0.1099	270	-2.26	0.0244	0.05	-0.4652	-0.03246
TRTCD	15mg	WORK.EFF	0.005466	0.1013	270	0.05	0.9570	0.05	-0.1939	0.2048
TRTCD	30mg	WORK.EFF	-0.3929	0.1055	270	-3.72	0.0002	0.05	-0.6005	-0.1852
TRTCD	45mg	WORK.EFF	-0.3729	0.1101	270	-3.39	0.0008	0.05	-0.5897	-0.1561

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.1561	0.1684	270	0.93	0.3548	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.6010	0.1655	270	3.63	0.0003	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.3467	0.1598	270	2.17	0.0309	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.7450	0.1620	270	4.60	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.7251	0.1659	270	4.37	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.4449	0.1584	270	2.81	0.0053	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1906	0.1521	270	1.25	0.2113	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5889	0.1555	270	3.79	0.0002	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5690	0.1578	270	3.61	0.0004	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.2543	0.1496	270	-1.70	0.0904	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.1440	0.1525	270	0.94	0.3456	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.1241	0.1556	270	0.80	0.4256	0.05
TRTCD	15mg	30mg	WORK.EFF	0.3983	0.1460	270	2.73	0.0068	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3784	0.1500	270	2.52	0.0122	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.01991	0.1533	270	-0.13	0.8967	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1755	0.4878
TRTCD	Placebo	7.5mg	0.2752	0.9268
TRTCD	Placebo	15mg	0.03207	0.6614
TRTCD	Placebo	30mg	0.4261	1.0640
TRTCD	Placebo	45mg	0.3986	1.0517
TRTCD	2.5mg	7.5mg	0.1330	0.7567
TRTCD	2.5mg	15mg	-0.1089	0.4900
TRTCD	2.5mg	30mg	0.2827	0.8951
TRTCD	2.5mg	45mg	0.2584	0.8796
TRTCD	7.5mg	15mg	-0.5489	0.04035

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.1561	0.4442
TRTCD	7.5mg	45mg	-0.1821	0.4304
TRTCD	15mg	30mg	0.1108	0.6859
TRTCD	15mg	45mg	0.08314	0.6737
TRTCD	30mg	45mg	-0.3216	0.2818

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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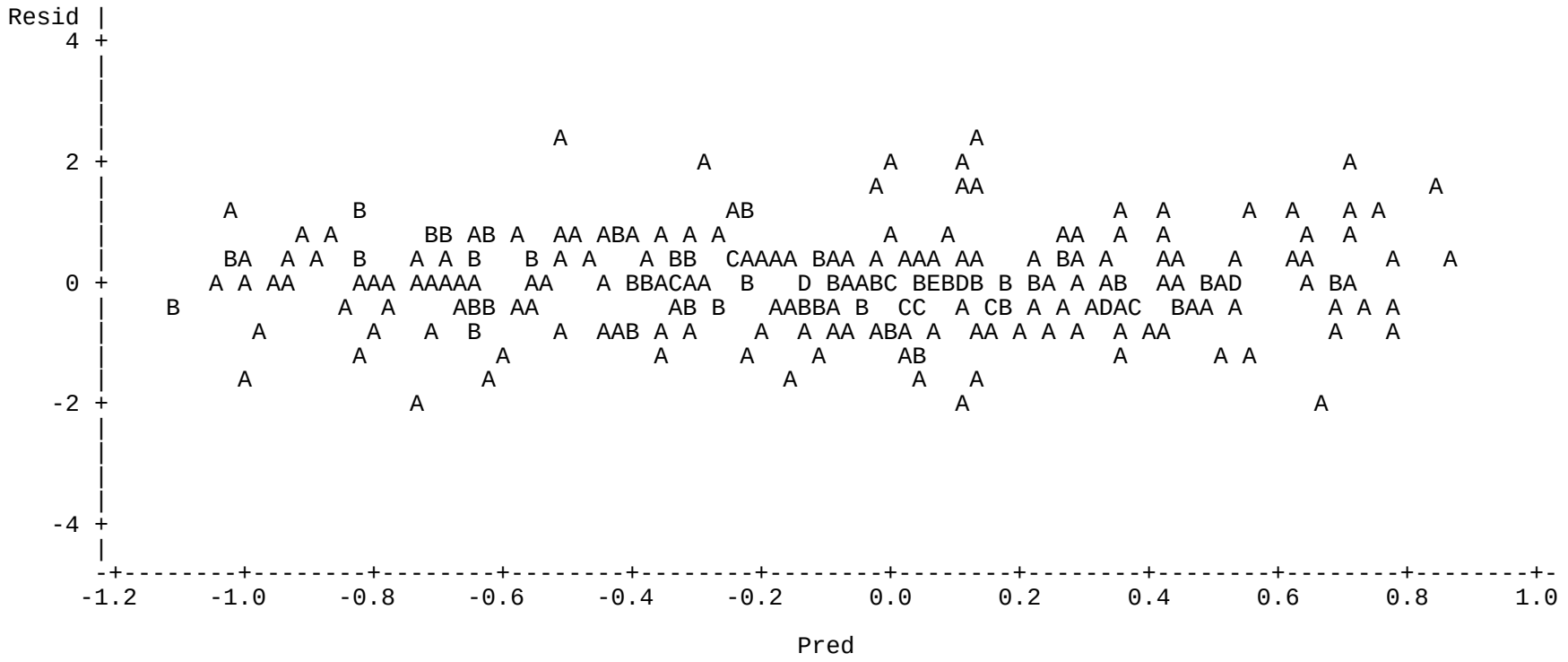
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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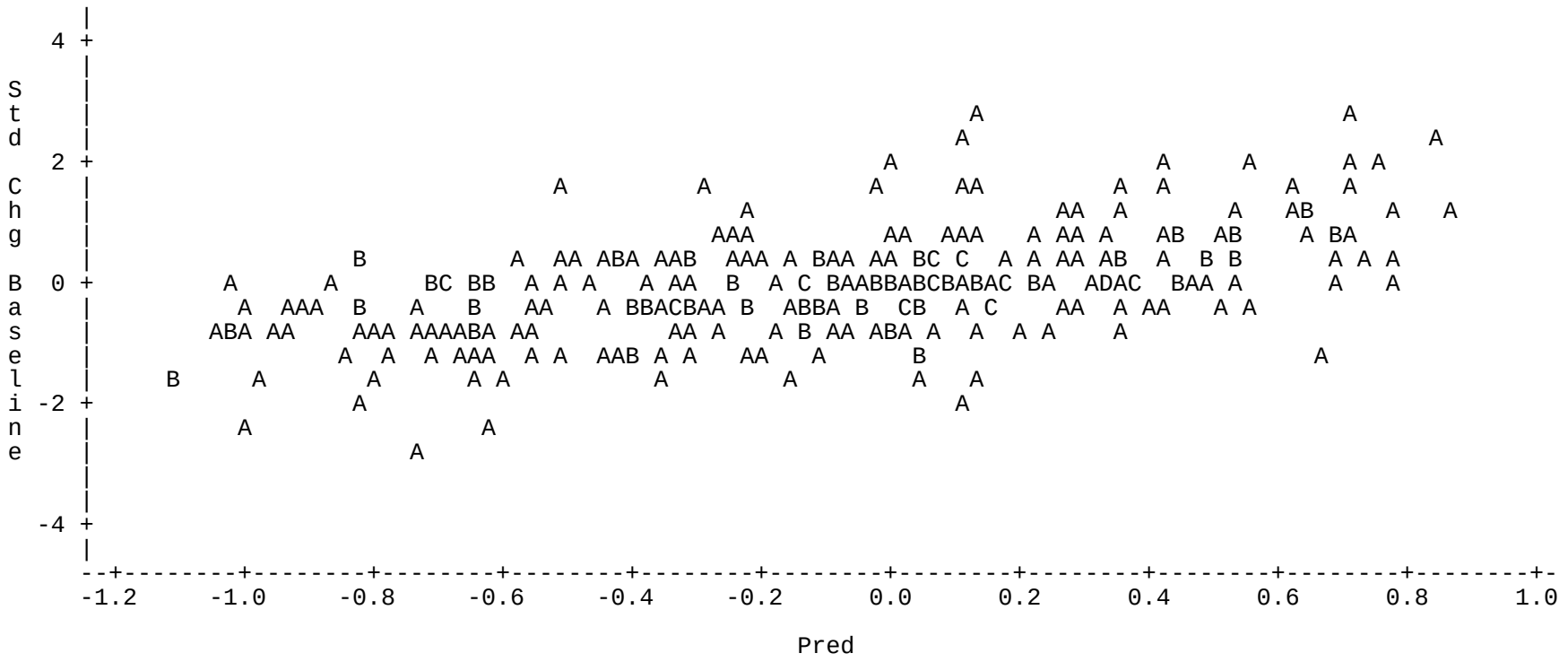
Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	281	Sum Weights	281
Mean	0	Sum Observations	0
Std Deviation	0.73606421	Variance	0.54179053
Skewness	0.25869225	Kurtosis	1.04271988
Uncorrected SS	151.701347	Corrected SS	151.701347
Coeff Variation		Std Error Mean	0.04390991

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.73606
Median	-0.02765	Variance	0.54179
Mode		Range	4.64153
		Interquartile Range	0.85324

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-6.5	Pr >= |M|	0.4741
Signed Rank	S	-582.5	Pr >= |S|	0.6700

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.984063	Pr < W	0.0032
Kolmogorov-Smirnov	D	0.055013	Pr > D	0.0377
Cramer-von Mises	W-Sq	0.195772	Pr > W-Sq	0.0061
Anderson-Darling	A-Sq	1.227654	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.465995
99%	2.093706
95%	1.241141
90%	0.865263
75% Q3	0.410621
50% Median	-0.027649
25% Q1	-0.442618
10%	-0.861286
5%	-1.110532
1%	-2.019721
0% Min	-2.175535

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-2.17554	252	2.07928	273
-2.07388	200	2.09004	198
-2.01972	257	2.09371	13
-1.75516	36	2.21315	265
-1.68877	251	2.46599	269

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Stem	Leaf	#	Boxplot
24	7	1	0
22	1	1	0
20	899	3	0
18	9	1	0
16	53	2	0
14	86	2	|
12	1244589	7	|
10	049223	6	|
8	112345790237	12	|
6	001112558990689	15	|
4	1123334456778990223478	22	+-----+
2	12267889011122234455556778	26	| |
0	11112222346788899900233344455557779	36	| + |
-0	888877665544432220099998877655444332222 11	41	*-----*
-2	99988766643332199888875554433 21	31	| |
-4	766554422108777555543321	25	+-----+
-6	97211098886652	14	|
-8	98544330965311100	17	|
-10	7310662	7	|
-12	9764	4	|
-14	50	2	|
-16	694	3	0
-18			
-20	872	3	0

----+----+----+----+----+----+----+----+-
Multiply Stem.Leaf by 10**-1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
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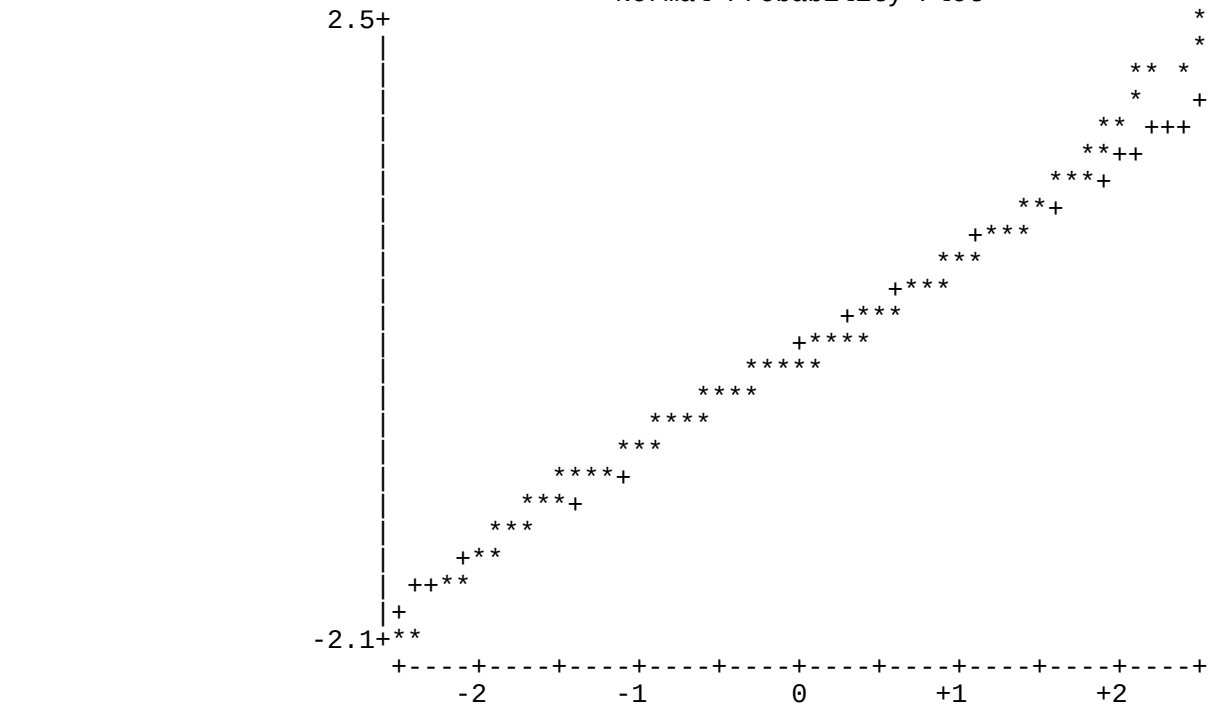
Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	281
Observations Used	281
Observations Not Used	0
Total Observations	281

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5643	0.04902	11.51	<.0001	0.05	0.4793	0.6742

Fit Statistics

-2 Res Log Likelihood	655.1
AIC (smaller is better)	657.1
AICC (smaller is better)	657.1
BIC (smaller is better)	660.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.5415	0.5308	265	1.02	0.3087
SEX	Female				-0.1380	0.2211	265	-0.62	0.5331
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.7029	0.09286	265	-7.57	<.0001
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	0.9141	0.2484	265	3.68	0.0003
TRTCD				2.5mg	0.4664	0.2256	265	2.07	0.0397
TRTCD				7.5mg	-0.01398	0.2269	265	-0.06	0.9509
TRTCD				15mg	0.3586	0.2129	265	1.68	0.0932
TRTCD				30mg	-0.08314	0.2266	265	-0.37	0.7139
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.3845	0.1104	265	-3.48	0.0006
REGIONCD			Eastern Europe		-0.1405	0.1105	265	-1.27	0.2050
REGIONCD			Western Europe		0				.
EFSTDBL					-0.04987	0.06411	265	-0.78	0.4373
SEX*TRTCD	Female			Placebo	-0.3296	0.3343	265	-0.99	0.3251
SEX*TRTCD	Female			2.5mg	0.2091	0.3189	265	0.66	0.5125
SEX*TRTCD	Female			7.5mg	0.2591	0.3120	265	0.83	0.4070
SEX*TRTCD	Female			15mg	0.03447	0.2991	265	0.12	0.9083
SEX*TRTCD	Female			30mg	0.1174	0.3082	265	0.38	0.7036
SEX*TRTCD	Female			45mg	0				.
SEX*TRTCD	Male			Placebo	0				.
SEX*TRTCD	Male			2.5mg	0				.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male			7.5mg	0				.
SEX*TRTCD	Male			15mg	0				.
SEX*TRTCD	Male			30mg	0				.
SEX*TRTCD	Male			45mg	0				.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	265	0.96	0.3283
TRTTYPCD	1	265	57.29	<.0001
TRTCD	5	265	7.72	<.0001
REGIONCD	2	265	6.11	0.0026
EFSTDBL	1	265	0.61	0.4373
SEX*TRTCD	5	265	0.77	0.5734

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1784	0.1695	265	-1.05	0.2936	0.05	-0.5121	0.1554
7.5mg vs Pbo	-0.6338	0.1669	265	-3.80	0.0002	0.05	-0.9624	-0.3051
15mg vs Pbo	-0.3735	0.1609	265	-2.32	0.0210	0.05	-0.6903	-0.05669
30mg vs Pbo	-0.7738	0.1635	265	-4.73	<.0001	0.05	-1.0957	-0.4518
45mg vs Pbo	-0.7494	0.1672	265	-4.48	<.0001	0.05	-1.0786	-0.4201

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	Placebo	WORK.EFF	0.1460	0.1642	265	0.89	0.3748	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	Placebo	-0.1773	0.4693

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
SEX*TRTCD	Female	2.5mg	WORK.EFF	0.2370	0.1655	265	1.43	0.1534	0.05
SEX*TRTCD	Female	7.5mg	WORK.EFF	-0.1934	0.1510	265	-1.28	0.2012	0.05
SEX*TRTCD	Female	15mg	WORK.EFF	-0.04546	0.1482	265	-0.31	0.7593	0.05
SEX*TRTCD	Female	30mg	WORK.EFF	-0.4043	0.1425	265	-2.84	0.0049	0.05
SEX*TRTCD	Female	45mg	WORK.EFF	-0.4386	0.1518	265	-2.89	0.0042	0.05
SEX*TRTCD	Male	Placebo	WORK.EFF	0.6136	0.1886	265	3.25	0.0013	0.05
SEX*TRTCD	Male	2.5mg	WORK.EFF	0.1659	0.1572	265	1.06	0.2923	0.05
SEX*TRTCD	Male	7.5mg	WORK.EFF	-0.3145	0.1603	265	-1.96	0.0509	0.05
SEX*TRTCD	Male	15mg	WORK.EFF	0.05809	0.1401	265	0.41	0.6787	0.05
SEX*TRTCD	Male	30mg	WORK.EFF	-0.3837	0.1584	265	-2.42	0.0161	0.05
SEX*TRTCD	Male	45mg	WORK.EFF	-0.3006	0.1608	265	-1.87	0.0627	0.05

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Female	2.5mg	-0.08891	0.5629
SEX*TRTCD	Female	7.5mg	-0.4906	0.1038
SEX*TRTCD	Female	15mg	-0.3373	0.2464
SEX*TRTCD	Female	30mg	-0.6848	-0.1238
SEX*TRTCD	Female	45mg	-0.7375	-0.1397

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Least Squares Means

Effect	Sex	Randomized treatment code	Lower	Upper
SEX*TRTCD	Male	Placebo	0.2422	0.9850
SEX*TRTCD	Male	2.5mg	-0.1436	0.4754
SEX*TRTCD	Male	7.5mg	-0.6302	0.001173
SEX*TRTCD	Male	15mg	-0.2178	0.3339
SEX*TRTCD	Male	30mg	-0.6956	-0.07175
SEX*TRTCD	Male	45mg	-0.6171	0.01598

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Female	2.5mg	WORK.EFF	-0.09099	0.2336	265	-0.39	0.6973
SEX*TRTCD	Female	Placebo	Female	7.5mg	WORK.EFF	0.3394	0.2226	265	1.52	0.1286
SEX*TRTCD	Female	Placebo	Female	15mg	WORK.EFF	0.1914	0.2215	265	0.86	0.3883
SEX*TRTCD	Female	Placebo	Female	30mg	WORK.EFF	0.5503	0.2176	265	2.53	0.0120
SEX*TRTCD	Female	Placebo	Female	45mg	WORK.EFF	0.5846	0.2238	265	2.61	0.0095
SEX*TRTCD	Female	Placebo	Male	Placebo	WORK.EFF	-0.4676	0.2502	265	-1.87	0.0628
SEX*TRTCD	Female	Placebo	Male	2.5mg	WORK.EFF	-0.01989	0.2275	265	-0.09	0.9304
SEX*TRTCD	Female	Placebo	Male	7.5mg	WORK.EFF	0.4605	0.2293	265	2.01	0.0456
SEX*TRTCD	Female	Placebo	Male	15mg	WORK.EFF	0.08789	0.2157	265	0.41	0.6840

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	Placebo	Male	30mg	WORK.EFF	0.5297	0.2279	265	2.32	0.0209
SEX*TRTCD	Female	Placebo	Male	45mg	WORK.EFF	0.4465	0.2296	265	1.94	0.0528
SEX*TRTCD	Female	2.5mg	Female	7.5mg	WORK.EFF	0.4304	0.2239	265	1.92	0.0557
SEX*TRTCD	Female	2.5mg	Female	15mg	WORK.EFF	0.2824	0.2226	265	1.27	0.2056
SEX*TRTCD	Female	2.5mg	Female	30mg	WORK.EFF	0.6413	0.2179	265	2.94	0.0035
SEX*TRTCD	Female	2.5mg	Female	45mg	WORK.EFF	0.6756	0.2237	265	3.02	0.0028
SEX*TRTCD	Female	2.5mg	Male	Placebo	WORK.EFF	-0.3766	0.2518	265	-1.50	0.1359
SEX*TRTCD	Female	2.5mg	Male	2.5mg	WORK.EFF	0.07110	0.2287	265	0.31	0.7561
SEX*TRTCD	Female	2.5mg	Male	7.5mg	WORK.EFF	0.5515	0.2306	265	2.39	0.0175
SEX*TRTCD	Female	2.5mg	Male	15mg	WORK.EFF	0.1789	0.2169	265	0.82	0.4103
SEX*TRTCD	Female	2.5mg	Male	30mg	WORK.EFF	0.6207	0.2312	265	2.69	0.0077
SEX*TRTCD	Female	2.5mg	Male	45mg	WORK.EFF	0.5375	0.2300	265	2.34	0.0202
SEX*TRTCD	Female	7.5mg	Female	15mg	WORK.EFF	-0.1479	0.2123	265	-0.70	0.4865
SEX*TRTCD	Female	7.5mg	Female	30mg	WORK.EFF	0.2109	0.2074	265	1.02	0.3100
SEX*TRTCD	Female	7.5mg	Female	45mg	WORK.EFF	0.2452	0.2144	265	1.14	0.2538
SEX*TRTCD	Female	7.5mg	Male	Placebo	WORK.EFF	-0.8070	0.2424	265	-3.33	0.0010
SEX*TRTCD	Female	7.5mg	Male	2.5mg	WORK.EFF	-0.3593	0.2185	265	-1.64	0.1013
SEX*TRTCD	Female	7.5mg	Male	7.5mg	WORK.EFF	0.1211	0.2198	265	0.55	0.5820
SEX*TRTCD	Female	7.5mg	Male	15mg	WORK.EFF	-0.2515	0.2057	265	-1.22	0.2225
SEX*TRTCD	Female	7.5mg	Male	30mg	WORK.EFF	0.1903	0.2196	265	0.87	0.3870
SEX*TRTCD	Female	7.5mg	Male	45mg	WORK.EFF	0.1071	0.2199	265	0.49	0.6265
SEX*TRTCD	Female	15mg	Female	30mg	WORK.EFF	0.3588	0.2060	265	1.74	0.0826
SEX*TRTCD	Female	15mg	Female	45mg	WORK.EFF	0.3931	0.2114	265	1.86	0.0641

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Female	15mg	Male	Placebo	WORK.EFF	-0.6591	0.2394	265	-2.75	0.0063
SEX*TRTCD	Female	15mg	Male	2.5mg	WORK.EFF	-0.2113	0.2151	265	-0.98	0.3267
SEX*TRTCD	Female	15mg	Male	7.5mg	WORK.EFF	0.2691	0.2186	265	1.23	0.2195
SEX*TRTCD	Female	15mg	Male	15mg	WORK.EFF	-0.1036	0.2047	265	-0.51	0.6134
SEX*TRTCD	Female	15mg	Male	30mg	WORK.EFF	0.3382	0.2164	265	1.56	0.1192
SEX*TRTCD	Female	15mg	Male	45mg	WORK.EFF	0.2551	0.2196	265	1.16	0.2464
SEX*TRTCD	Female	30mg	Female	45mg	WORK.EFF	0.03427	0.2090	265	0.16	0.8699
SEX*TRTCD	Female	30mg	Male	Placebo	WORK.EFF	-1.0179	0.2365	265	-4.30	<.0001
SEX*TRTCD	Female	30mg	Male	2.5mg	WORK.EFF	-0.5702	0.2124	265	-2.68	0.0077
SEX*TRTCD	Female	30mg	Male	7.5mg	WORK.EFF	-0.08977	0.2143	265	-0.42	0.6756
SEX*TRTCD	Female	30mg	Male	15mg	WORK.EFF	-0.4624	0.1993	265	-2.32	0.0211
SEX*TRTCD	Female	30mg	Male	30mg	WORK.EFF	-0.02061	0.2136	265	-0.10	0.9232
SEX*TRTCD	Female	30mg	Male	45mg	WORK.EFF	-0.1038	0.2146	265	-0.48	0.6292
SEX*TRTCD	Female	45mg	Male	Placebo	WORK.EFF	-1.0522	0.2426	265	-4.34	<.0001
SEX*TRTCD	Female	45mg	Male	2.5mg	WORK.EFF	-0.6044	0.2181	265	-2.77	0.0060
SEX*TRTCD	Female	45mg	Male	7.5mg	WORK.EFF	-0.1240	0.2212	265	-0.56	0.5754
SEX*TRTCD	Female	45mg	Male	15mg	WORK.EFF	-0.4967	0.2078	265	-2.39	0.0175
SEX*TRTCD	Female	45mg	Male	30mg	WORK.EFF	-0.05488	0.2202	265	-0.25	0.8034
SEX*TRTCD	Female	45mg	Male	45mg	WORK.EFF	-0.1380	0.2211	265	-0.62	0.5331
SEX*TRTCD	Male	Placebo	Male	2.5mg	WORK.EFF	0.4477	0.2451	265	1.83	0.0689
SEX*TRTCD	Male	Placebo	Male	7.5mg	WORK.EFF	0.9281	0.2479	265	3.74	0.0002
SEX*TRTCD	Male	Placebo	Male	15mg	WORK.EFF	0.5555	0.2348	265	2.37	0.0187
SEX*TRTCD	Male	Placebo	Male	30mg	WORK.EFF	0.9973	0.2448	265	4.07	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|
SEX*TRTCD	Male	Placebo	Male	45mg	WORK.EFF	0.9141	0.2484	265	3.68	0.0003
SEX*TRTCD	Male	2.5mg	Male	7.5mg	WORK.EFF	0.4804	0.2247	265	2.14	0.0334
SEX*TRTCD	Male	2.5mg	Male	15mg	WORK.EFF	0.1078	0.2111	265	0.51	0.6101
SEX*TRTCD	Male	2.5mg	Male	30mg	WORK.EFF	0.5496	0.2226	265	2.47	0.0142
SEX*TRTCD	Male	2.5mg	Male	45mg	WORK.EFF	0.4664	0.2256	265	2.07	0.0397
SEX*TRTCD	Male	7.5mg	Male	15mg	WORK.EFF	-0.3726	0.2127	265	-1.75	0.0810
SEX*TRTCD	Male	7.5mg	Male	30mg	WORK.EFF	0.06917	0.2256	265	0.31	0.7594
SEX*TRTCD	Male	7.5mg	Male	45mg	WORK.EFF	-0.01398	0.2269	265	-0.06	0.9509
SEX*TRTCD	Male	15mg	Male	30mg	WORK.EFF	0.4418	0.2114	265	2.09	0.0376
SEX*TRTCD	Male	15mg	Male	45mg	WORK.EFF	0.3586	0.2129	265	1.68	0.0932
SEX*TRTCD	Male	30mg	Male	45mg	WORK.EFF	-0.08314	0.2266	265	-0.37	0.7139

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Female	2.5mg	0.05	-0.5510	0.3690
SEX*TRTCD	Female	Placebo	Female	7.5mg	0.05	-0.09892	0.7777
SEX*TRTCD	Female	Placebo	Female	15mg	0.05	-0.2447	0.6276
SEX*TRTCD	Female	Placebo	Female	30mg	0.05	0.1219	0.9787
SEX*TRTCD	Female	Placebo	Female	45mg	0.05	0.1439	1.0252

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	Placebo	Male	Placebo	0.05	-0.9603	0.02506
SEX*TRTCD	Female	Placebo	Male	2.5mg	0.05	-0.4679	0.4281
SEX*TRTCD	Female	Placebo	Male	7.5mg	0.05	0.009019	0.9120
SEX*TRTCD	Female	Placebo	Male	15mg	0.05	-0.3369	0.5126
SEX*TRTCD	Female	Placebo	Male	30mg	0.05	0.08089	0.9785
SEX*TRTCD	Female	Placebo	Male	45mg	0.05	-0.00551	0.8986
SEX*TRTCD	Female	2.5mg	Female	7.5mg	0.05	-0.01055	0.8713
SEX*TRTCD	Female	2.5mg	Female	15mg	0.05	-0.1558	0.7207
SEX*TRTCD	Female	2.5mg	Female	30mg	0.05	0.2122	1.0703
SEX*TRTCD	Female	2.5mg	Female	45mg	0.05	0.2351	1.1160
SEX*TRTCD	Female	2.5mg	Male	Placebo	0.05	-0.8724	0.1191
SEX*TRTCD	Female	2.5mg	Male	2.5mg	0.05	-0.3792	0.5214
SEX*TRTCD	Female	2.5mg	Male	7.5mg	0.05	0.09740	1.0056
SEX*TRTCD	Female	2.5mg	Male	15mg	0.05	-0.2482	0.6060
SEX*TRTCD	Female	2.5mg	Male	30mg	0.05	0.1655	1.0758
SEX*TRTCD	Female	2.5mg	Male	45mg	0.05	0.08466	0.9904
SEX*TRTCD	Female	7.5mg	Female	15mg	0.05	-0.5660	0.2701
SEX*TRTCD	Female	7.5mg	Female	30mg	0.05	-0.1974	0.6192
SEX*TRTCD	Female	7.5mg	Female	45mg	0.05	-0.1769	0.6673
SEX*TRTCD	Female	7.5mg	Male	Placebo	0.05	-1.2843	-0.3297
SEX*TRTCD	Female	7.5mg	Male	2.5mg	0.05	-0.7895	0.07091
SEX*TRTCD	Female	7.5mg	Male	7.5mg	0.05	-0.3116	0.5538
SEX*TRTCD	Female	7.5mg	Male	15mg	0.05	-0.6565	0.1535

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Female	7.5mg	Male	30mg	0.05	-0.2421	0.6226
SEX*TRTCD	Female	7.5mg	Male	45mg	0.05	-0.3259	0.5402
SEX*TRTCD	Female	15mg	Female	30mg	0.05	-0.04669	0.7644
SEX*TRTCD	Female	15mg	Female	45mg	0.05	-0.02321	0.8094
SEX*TRTCD	Female	15mg	Male	Placebo	0.05	-1.1304	-0.1877
SEX*TRTCD	Female	15mg	Male	2.5mg	0.05	-0.6348	0.2121
SEX*TRTCD	Female	15mg	Male	7.5mg	0.05	-0.1614	0.6995
SEX*TRTCD	Female	15mg	Male	15mg	0.05	-0.5067	0.2995
SEX*TRTCD	Female	15mg	Male	30mg	0.05	-0.08779	0.7643
SEX*TRTCD	Female	15mg	Male	45mg	0.05	-0.1773	0.6875
SEX*TRTCD	Female	30mg	Female	45mg	0.05	-0.3772	0.4457
SEX*TRTCD	Female	30mg	Male	Placebo	0.05	-1.4837	-0.5521
SEX*TRTCD	Female	30mg	Male	2.5mg	0.05	-0.9884	-0.1520
SEX*TRTCD	Female	30mg	Male	7.5mg	0.05	-0.5117	0.3322
SEX*TRTCD	Female	30mg	Male	15mg	0.05	-0.8548	-0.07001
SEX*TRTCD	Female	30mg	Male	30mg	0.05	-0.4413	0.4000
SEX*TRTCD	Female	30mg	Male	45mg	0.05	-0.5263	0.3188
SEX*TRTCD	Female	45mg	Male	Placebo	0.05	-1.5298	-0.5745
SEX*TRTCD	Female	45mg	Male	2.5mg	0.05	-1.0339	-0.1750
SEX*TRTCD	Female	45mg	Male	7.5mg	0.05	-0.5596	0.3115
SEX*TRTCD	Female	45mg	Male	15mg	0.05	-0.9058	-0.08756
SEX*TRTCD	Female	45mg	Male	30mg	0.05	-0.4884	0.3787
SEX*TRTCD	Female	45mg	Male	45mg	0.05	-0.5734	0.2974

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - sex*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Sex	Randomized treatment code	Sex	Randomized treatment code	Alpha	Lower	Upper
SEX*TRTCD	Male	Placebo	Male	2.5mg	0.05	-0.03495	0.9304
SEX*TRTCD	Male	Placebo	Male	7.5mg	0.05	0.4401	1.4161
SEX*TRTCD	Male	Placebo	Male	15mg	0.05	0.09315	1.0178
SEX*TRTCD	Male	Placebo	Male	30mg	0.05	0.5152	1.4794
SEX*TRTCD	Male	Placebo	Male	45mg	0.05	0.4250	1.4033
SEX*TRTCD	Male	2.5mg	Male	7.5mg	0.05	0.03797	0.9228
SEX*TRTCD	Male	2.5mg	Male	15mg	0.05	-0.3079	0.5235
SEX*TRTCD	Male	2.5mg	Male	30mg	0.05	0.1112	0.9879
SEX*TRTCD	Male	2.5mg	Male	45mg	0.05	0.02218	0.9107
SEX*TRTCD	Male	7.5mg	Male	15mg	0.05	-0.7915	0.04625
SEX*TRTCD	Male	7.5mg	Male	30mg	0.05	-0.3750	0.5134
SEX*TRTCD	Male	7.5mg	Male	45mg	0.05	-0.4608	0.4328
SEX*TRTCD	Male	15mg	Male	30mg	0.05	0.02562	0.8580
SEX*TRTCD	Male	15mg	Male	45mg	0.05	-0.06048	0.7778
SEX*TRTCD	Male	30mg	Male	45mg	0.05	-0.5292	0.3629

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	27
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	281
Observations Used	281
Observations Not Used	0
Total Observations	281

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5612	0.04876	11.51	<.0001	0.05	0.4767	0.6705

Fit Statistics

-2 Res Log Likelihood	653.5
AIC (smaller is better)	655.5
AICC (smaller is better)	655.5
BIC (smaller is better)	659.1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.5298	0.5395	265	0.98
SEX	Female				-0.07915	0.09074	265	-0.87
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.7352	0.2228	265	-3.30
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.8987	0.2222	265	4.04
TRTCD				2.5mg	0.5709	0.2037	265	2.80
TRTCD				7.5mg	0.05213	0.2007	265	0.26
TRTCD				15mg	0.2490	0.1956	265	1.27
TRTCD				30mg	0.002989	0.2032	265	0.01
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.3863	0.1087	265	-3.55
REGIONCD			Eastern Europe		-0.1030	0.1114	265	-0.92
REGIONCD			Western Europe		0			
EFSTDBL					-0.05220	0.06420	265	-0.81
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	-0.3669	0.3324	265	-1.10
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	-0.01283	0.3256	265	-0.04
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.2000	0.3214	265	0.62
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.3270	0.3054	265	1.07
TRTTYPCD*TRTCD		Diet & Exercise		30mg	-0.04421	0.3084	265	-0.14
TRTTYPCD*TRTCD		Diet & Exercise		45mg	0			
TRTTYPCD*TRTCD		Monotherapy		Placebo	0			
TRTTYPCD*TRTCD		Monotherapy		2.5mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.3270
SEX	Female				0.3838
SEX	Male				.
TRTTYPCD		Diet & Exercise			0.0011
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0054
TRTCD				7.5mg	0.7953
TRTCD				15mg	0.2042
TRTCD				30mg	0.9883
TRTCD				45mg	.
REGIONCD			US/Canada		0.0004
REGIONCD			Eastern Europe		0.3558
REGIONCD			Western Europe		.
EFSTDBL					0.4169
TRTTYPCD*TRTCD		Diet & Exercise		Placebo	0.2707
TRTTYPCD*TRTCD		Diet & Exercise		2.5mg	0.9686
TRTTYPCD*TRTCD		Diet & Exercise		7.5mg	0.5342
TRTTYPCD*TRTCD		Diet & Exercise		15mg	0.2852
TRTTYPCD*TRTCD		Diet & Exercise		30mg	0.8861
TRTTYPCD*TRTCD		Diet & Exercise		45mg	.
TRTTYPCD*TRTCD		Monotherapy		Placebo	.
TRTTYPCD*TRTCD		Monotherapy		2.5mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTTYPCD*TRTCD		Monotherapy		7.5mg	0			
TRTTYPCD*TRTCD		Monotherapy		15mg	0			
TRTTYPCD*TRTCD		Monotherapy		30mg	0			
TRTTYPCD*TRTCD		Monotherapy		45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTTYPCD*TRTCD		Monotherapy		7.5mg	.
TRTTYPCD*TRTCD		Monotherapy		15mg	.
TRTTYPCD*TRTCD		Monotherapy		30mg	.
TRTTYPCD*TRTCD		Monotherapy		45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	265	0.76	0.3838
TRTTYPCD	1	265	59.46	<.0001
TRTCD	5	265	7.10	<.0001
REGIONCD	2	265	6.57	0.0016
EFSTDBL	1	265	0.66	0.4169
TRTTYPCD*TRTCD	5	265	1.06	0.3823

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1508	0.1713	265	-0.88	0.3795	0.05	-0.4880	0.1865
7.5mg vs Pbo	-0.5631	0.1684	265	-3.34	0.0009	0.05	-0.8946	-0.2316
15mg vs Pbo	-0.3028	0.1612	265	-1.88	0.0615	0.05	-0.6203	0.01469
30mg vs Pbo	-0.7344	0.1629	265	-4.51	<.0001	0.05	-1.0550	-0.4137
45mg vs Pbo	-0.7153	0.1669	265	-4.29	<.0001	0.05	-1.0439	-0.3867

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	WORK.EFF	-0.2793	0.1818	265	-1.54	0.1256	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	WORK.EFF	-0.2531	0.1879	265	-1.35	0.1793	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	WORK.EFF	-0.5590	0.1831	265	-3.05	0.0025	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	WORK.EFF	-0.2352	0.1604	265	-1.47	0.1438	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	WORK.EFF	-0.8524	0.1603	265	-5.32	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	WORK.EFF	-0.8112	0.1692	265	-4.79	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	WORK.EFF	0.8228	0.1683	265	4.89	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	WORK.EFF	0.4950	0.1423	265	3.48	0.0006	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	WORK.EFF	-0.02379	0.1375	265	-0.17	0.8628	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	WORK.EFF	0.1731	0.1308	265	1.32	0.1868	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	WORK.EFF	-0.07293	0.1413	265	-0.52	0.6061	0.05
TRTTYPCD*TRTCD	Monotherapy	45mg	WORK.EFF	-0.07592	0.1449	265	-0.52	0.6009	0.05

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	-0.6373	0.07864
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	-0.6231	0.1170
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	-0.9196	-0.1985
TRTTYPCD*TRTCD	Diet & Exercise	15mg	-0.5510	0.08068

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	30mg	-1.1679	-0.5368
TRTTYPCD*TRTCD	Diet & Exercise	45mg	-1.1443	-0.4780
TRTTYPCD*TRTCD	Monotherapy	Placebo	0.4914	1.1542
TRTTYPCD*TRTCD	Monotherapy	2.5mg	0.2147	0.7753
TRTTYPCD*TRTCD	Monotherapy	7.5mg	-0.2946	0.2470
TRTTYPCD*TRTCD	Monotherapy	15mg	-0.08440	0.4306
TRTTYPCD*TRTCD	Monotherapy	30mg	-0.3511	0.2052
TRTTYPCD*TRTCD	Monotherapy	45mg	-0.3613	0.2095

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	WORK.EFF	-0.02627	0.2613	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	WORK.EFF	0.2797	0.2575	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	WORK.EFF	-0.04414	0.2425	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	WORK.EFF	0.5730	0.2424	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	WORK.EFF	0.5318	0.2481	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	WORK.EFF	-1.1021	0.2479	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	WORK.EFF	-0.7743	0.2311	265

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	WORK.EFF	-0.2555	0.2281	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	WORK.EFF	-0.4524	0.2242	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	WORK.EFF	-0.2064	0.2306	265
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	WORK.EFF	-0.2034	0.2322	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	WORK.EFF	0.3060	0.2618	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	WORK.EFF	-0.01788	0.2471	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	WORK.EFF	0.5993	0.2464	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	WORK.EFF	0.5581	0.2525	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	WORK.EFF	-1.0759	0.2527	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	WORK.EFF	-0.7481	0.2358	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	WORK.EFF	-0.2293	0.2337	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	WORK.EFF	-0.4261	0.2291	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	WORK.EFF	-0.1801	0.2364	265
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	WORK.EFF	-0.1771	0.2365	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	WORK.EFF	-0.3238	0.2430	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	WORK.EFF	0.2934	0.2436	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	WORK.EFF	0.2521	0.2494	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	WORK.EFF	-1.3818	0.2489	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	WORK.EFF	-1.0540	0.2330	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	WORK.EFF	-0.5352	0.2295	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	WORK.EFF	-0.7321	0.2260	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	WORK.EFF	-0.4861	0.2317	265
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	WORK.EFF	-0.4831	0.2325	265

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	WORK.EFF	0.6172	0.2269	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	WORK.EFF	0.5760	0.2341	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	WORK.EFF	-1.0580	0.2323	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	WORK.EFF	-0.7302	0.2149	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	WORK.EFF	-0.2114	0.2115	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	WORK.EFF	-0.4083	0.2073	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	WORK.EFF	-0.1623	0.2134	265
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	WORK.EFF	-0.1593	0.2162	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	WORK.EFF	-0.04122	0.2325	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	WORK.EFF	-1.6752	0.2329	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	WORK.EFF	-1.3474	0.2138	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	WORK.EFF	-0.8286	0.2118	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	WORK.EFF	-1.0255	0.2066	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	WORK.EFF	-0.7794	0.2149	265
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	WORK.EFF	-0.7765	0.2158	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	WORK.EFF	-1.6340	0.2401	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	WORK.EFF	-1.3062	0.2202	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	WORK.EFF	-0.7874	0.2178	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	WORK.EFF	-0.9842	0.2137	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	WORK.EFF	-0.7382	0.2224	265
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	WORK.EFF	-0.7352	0.2228	265
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	WORK.EFF	0.3278	0.2210	265
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	WORK.EFF	0.8466	0.2173	265

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	WORK.EFF	0.6497	0.2131	265
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	WORK.EFF	0.8957	0.2181	265
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	WORK.EFF	0.8987	0.2222	265
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	WORK.EFF	0.5188	0.1978	265
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	WORK.EFF	0.3219	0.1927	265
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	WORK.EFF	0.5679	0.2014	265
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	WORK.EFF	0.5709	0.2037	265
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	WORK.EFF	-0.1969	0.1897	265
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	WORK.EFF	0.04914	0.1963	265
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	WORK.EFF	0.05213	0.2007	265
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	WORK.EFF	0.2460	0.1925	265
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	WORK.EFF	0.2490	0.1956	265
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	WORK.EFF	0.002989	0.2032	265

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	-0.10	0.9200	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	1.09	0.2785	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	-0.18	0.8557	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	2.36	0.0188	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	2.14	0.0330	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-4.45	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-3.35	0.0009	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-1.12	0.2636	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-2.02	0.0446	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.90	0.3715	0.05
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	-0.88	0.3818	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	1.17	0.2436	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.07	0.9424	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	2.43	0.0157	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	2.21	0.0279	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-4.26	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-3.17	0.0017	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-0.98	0.3276	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-1.86	0.0640	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-0.76	0.4467	0.05
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-0.75	0.4545	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	-1.33	0.1837	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	1.20	0.2296	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	1.01	0.3129	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-5.55	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-4.52	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-2.33	0.0204	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-3.24	0.0013	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-2.10	0.0369	0.05
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-2.08	0.0387	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	2.72	0.0070	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	2.46	0.0145	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-4.55	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-3.40	0.0008	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-1.00	0.3184	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-1.97	0.0499	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.76	0.4477	0.05
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.74	0.4619	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	-0.18	0.8594	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-7.19	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-6.30	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-3.91	0.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-4.96	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-3.63	0.0003	0.05
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-3.60	0.0004	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-6.80	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-5.93	<.0001	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-3.61	0.0004	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-4.61	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-3.32	0.0010	0.05
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-3.30	0.0011	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	1.48	0.1393	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	3.90	0.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	3.05	0.0025	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	4.11	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	4.04	<.0001	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	2.62	0.0092	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	1.67	0.0960	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	2.82	0.0052	0.05
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	2.80	0.0054	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-1.04	0.3004	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	0.25	0.8026	0.05
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	0.26	0.7953	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	1.28	0.2024	0.05
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	1.27	0.2042	0.05
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	0.01	0.9883	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	2.5mg	-0.5407	0.4881
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	7.5mg	-0.2274	0.7868
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	15mg	-0.5216	0.4333
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	30mg	0.09582	1.0503
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Diet & Exercise	45mg	0.04328	1.0204
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	Placebo	-1.5903	-0.6140
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	2.5mg	-1.2293	-0.3193
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	7.5mg	-0.7046	0.1936
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	15mg	-0.8938	-0.01102
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	30mg	-0.6604	0.2476
TRTTYPCD*TRTCD	Diet & Exercise	Placebo	Monotherapy	45mg	-0.6606	0.2538
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	7.5mg	-0.2095	0.8214
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	15mg	-0.5045	0.4687
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	30mg	0.1142	1.0844
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Diet & Exercise	45mg	0.06102	1.0552
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	Placebo	-1.5734	-0.5783
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	2.5mg	-1.2123	-0.2839
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	7.5mg	-0.6895	0.2310
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	15mg	-0.8772	0.02490
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	30mg	-0.6455	0.2852
TRTTYPCD*TRTCD	Diet & Exercise	2.5mg	Monotherapy	45mg	-0.6428	0.2885
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	15mg	-0.8022	0.1545
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	30mg	-0.1863	0.7731

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Diet & Exercise	45mg	-0.2389	0.7432
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	Placebo	-1.8718	-0.8918
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	2.5mg	-1.5129	-0.5952
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	7.5mg	-0.9871	-0.08339
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	15mg	-1.1770	-0.2872
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	30mg	-0.9423	-0.02987
TRTTYPCD*TRTCD	Diet & Exercise	7.5mg	Monotherapy	45mg	-0.9408	-0.02540
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	30mg	0.1705	1.0639
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Diet & Exercise	45mg	0.1151	1.0368
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	Placebo	-1.5153	-0.6007
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	2.5mg	-1.1533	-0.3070
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	7.5mg	-0.6278	0.2050
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	15mg	-0.8164	-0.00016
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	30mg	-0.5824	0.2579
TRTTYPCD*TRTCD	Diet & Exercise	15mg	Monotherapy	45mg	-0.5849	0.2664
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Diet & Exercise	45mg	-0.4990	0.4166
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	Placebo	-2.1338	-1.2165
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	2.5mg	-1.7683	-0.9264
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	7.5mg	-1.2456	-0.4115
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	15mg	-1.4322	-0.6187
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	30mg	-1.2026	-0.3563
TRTTYPCD*TRTCD	Diet & Exercise	30mg	Monotherapy	45mg	-1.2014	-0.3515
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	Placebo	-2.1067	-1.1612

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - trttypcd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Pre-study treatment code	Randomized treatment code	Pre-study treatment code	Randomized treatment code	Lower	Upper
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	2.5mg	-1.7397	-0.8727
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	7.5mg	-1.2162	-0.3585
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	15mg	-1.4050	-0.5634
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	30mg	-1.1762	-0.3002
TRTTYPCD*TRTCD	Diet & Exercise	45mg	Monotherapy	45mg	-1.1739	-0.2966
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	2.5mg	-0.1074	0.7630
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	7.5mg	0.4187	1.2745
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	15mg	0.2301	1.0694
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	30mg	0.4663	1.3252
TRTTYPCD*TRTCD	Monotherapy	Placebo	Monotherapy	45mg	0.4612	1.3362
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	7.5mg	0.1294	0.9082
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	15mg	-0.05746	0.7013
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	30mg	0.1714	0.9645
TRTTYPCD*TRTCD	Monotherapy	2.5mg	Monotherapy	45mg	0.1699	0.9720
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	15mg	-0.5704	0.1767
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	30mg	-0.3374	0.4357
TRTTYPCD*TRTCD	Monotherapy	7.5mg	Monotherapy	45mg	-0.3430	0.4473
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	30mg	-0.1331	0.6251
TRTTYPCD*TRTCD	Monotherapy	15mg	Monotherapy	45mg	-0.1362	0.6342
TRTTYPCD*TRTCD	Monotherapy	30mg	Monotherapy	45mg	-0.3970	0.4030

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	33
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	281
Observations Used	281
Observations Not Used	0
Total Observations	281

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5549	0.04867	11.40	<.0001	0.05	0.4707	0.6642

Fit Statistics

-2 Res Log Likelihood	647.0
AIC (smaller is better)	649.0
AICC (smaller is better)	649.0
BIC (smaller is better)	652.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.4257	0.5490	260	0.78
SEX	Female				-0.1056	0.09213	260	-1.15
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6880	0.09409	260	-7.31
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	1.3082	0.2657	260	4.92
TRTCD				2.5mg	0.6428	0.2748	260	2.34
TRTCD				7.5mg	0.1516	0.2393	260	0.63
TRTCD				15mg	0.6233	0.2470	260	2.52
TRTCD				30mg	0.1858	0.2484	260	0.75
TRTCD				45mg	0			
REGIONCD			US/Canada		0.03355	0.2762	260	0.12
REGIONCD			Eastern Europe		0.05098	0.2568	260	0.20
REGIONCD			Western Europe		0			
EFSTDBL					-0.06133	0.06441	260	-0.95
TRTCD*REGIONCD			US/Canada	Placebo	-0.9966	0.3963	260	-2.51
TRTCD*REGIONCD			Eastern Europe	Placebo	-1.0017	0.4056	260	-2.47
TRTCD*REGIONCD			Western Europe	Placebo	0			
TRTCD*REGIONCD			US/Canada	2.5mg	-0.3427	0.4003	260	-0.86
TRTCD*REGIONCD			Eastern Europe	2.5mg	0.02948	0.3773	260	0.08
TRTCD*REGIONCD			Western Europe	2.5mg	0			
TRTCD*REGIONCD			US/Canada	7.5mg	-0.09456	0.3894	260	-0.24
TRTCD*REGIONCD			Eastern Europe	7.5mg	0.09871	0.3659	260	0.27

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.4388
SEX	Female				0.2528
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	<.0001
TRTCD				2.5mg	0.0201
TRTCD				7.5mg	0.5270
TRTCD				15mg	0.0122
TRTCD				30mg	0.4552
TRTCD				45mg	.
REGIONCD			US/Canada		0.9034
REGIONCD			Eastern Europe		0.8428
REGIONCD			Western Europe		.
EFSTDBL					0.3419
TRTCD*REGIONCD			US/Canada	Placebo	0.0125
TRTCD*REGIONCD			Eastern Europe	Placebo	0.0142
TRTCD*REGIONCD			Western Europe	Placebo	.
TRTCD*REGIONCD			US/Canada	2.5mg	0.3928
TRTCD*REGIONCD			Eastern Europe	2.5mg	0.9378
TRTCD*REGIONCD			Western Europe	2.5mg	.
TRTCD*REGIONCD			US/Canada	7.5mg	0.8084
TRTCD*REGIONCD			Eastern Europe	7.5mg	0.7876

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
TRTCD*REGIONCD			Western Europe	7.5mg	0			
TRTCD*REGIONCD			US/Canada	15mg	-0.5273	0.3639	260	-1.45
TRTCD*REGIONCD			Eastern Europe	15mg	-0.2819	0.3600	260	-0.78
TRTCD*REGIONCD			Western Europe	15mg	0			
TRTCD*REGIONCD			US/Canada	30mg	-0.5338	0.3693	260	-1.45
TRTCD*REGIONCD			Eastern Europe	30mg	-0.1244	0.3701	260	-0.34
TRTCD*REGIONCD			Western Europe	30mg	0			
TRTCD*REGIONCD			US/Canada	45mg	0			
TRTCD*REGIONCD			Eastern Europe	45mg	0			
TRTCD*REGIONCD			Western Europe	45mg	0			

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	7.5mg	.
TRTCD*REGIONCD			US/Canada	15mg	0.1485
TRTCD*REGIONCD			Eastern Europe	15mg	0.4343
TRTCD*REGIONCD			Western Europe	15mg	.
TRTCD*REGIONCD			US/Canada	30mg	0.1495
TRTCD*REGIONCD			Eastern Europe	30mg	0.7371

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
TRTCD*REGIONCD			Western Europe	30mg	.
TRTCD*REGIONCD			US/Canada	45mg	.
TRTCD*REGIONCD			Eastern Europe	45mg	.
TRTCD*REGIONCD			Western Europe	45mg	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	260	1.31	0.2528
TRTTYPCD	1	260	53.47	<.0001
TRTCD	5	260	6.06	<.0001
REGIONCD	2	260	6.15	0.0025
EFSTDBL	1	260	0.91	0.3419
TRTCD*REGIONCD	10	260	1.34	0.2108

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1037	0.1694	260	-0.61	0.5409	0.05	-0.4373	0.2298
7.5mg vs Pbo	-0.4891	0.1699	260	-2.88	0.0043	0.05	-0.8238	-0.1545
15mg vs Pbo	-0.2885	0.1613	260	-1.79	0.0748	0.05	-0.6061	0.02907
30mg vs Pbo	-0.6757	0.1642	260	-4.11	<.0001	0.05	-0.9991	-0.3523
45mg vs Pbo	-0.6421	0.1673	260	-3.84	0.0002	0.05	-0.9716	-0.3126

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	WORK.EFF	-0.04765	0.2067	260	-0.23	0.8179	0.05

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	-0.4547	0.3595

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	WORK.EFF	-0.03531	0.2490	260	-0.14	0.8874	0.05
TRTCD*REGIONCD	Western Europe	Placebo	WORK.EFF	0.9154	0.1930	260	4.74	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	WORK.EFF	-0.05914	0.2007	260	-0.29	0.7685	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	WORK.EFF	0.3305	0.1823	260	1.81	0.0710	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	WORK.EFF	0.2500	0.2067	260	1.21	0.2276	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	WORK.EFF	-0.3022	0.2247	260	-1.34	0.1799	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	WORK.EFF	-0.09153	0.2073	260	-0.44	0.6593	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	WORK.EFF	-0.2412	0.1554	260	-1.55	0.1218	0.05
TRTCD*REGIONCD	US/Canada	15mg	WORK.EFF	-0.2632	0.1713	260	-1.54	0.1255	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	WORK.EFF	-0.00039	0.1871	260	-0.00	0.9983	0.05
TRTCD*REGIONCD	Western Europe	15mg	WORK.EFF	0.2305	0.1676	260	1.38	0.1703	0.05
TRTCD*REGIONCD	US/Canada	30mg	WORK.EFF	-0.7072	0.1760	260	-4.02	<.0001	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	WORK.EFF	-0.2804	0.2089	260	-1.34	0.1807	0.05
TRTCD*REGIONCD	Western Europe	30mg	WORK.EFF	-0.2070	0.1677	260	-1.23	0.2183	0.05
TRTCD*REGIONCD	US/Canada	45mg	WORK.EFF	-0.3592	0.2090	260	-1.72	0.0868	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	WORK.EFF	-0.3418	0.1815	260	-1.88	0.0607	0.05
TRTCD*REGIONCD	Western Europe	45mg	WORK.EFF	-0.3928	0.1816	260	-2.16	0.0315	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Least Squares Means

Effect	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	-0.5256	0.4550
TRTCD*REGIONCD	Western Europe	Placebo	0.5354	1.2954
TRTCD*REGIONCD	US/Canada	2.5mg	-0.4544	0.3361
TRTCD*REGIONCD	Eastern Europe	2.5mg	-0.02852	0.6894
TRTCD*REGIONCD	Western Europe	2.5mg	-0.1570	0.6570
TRTCD*REGIONCD	US/Canada	7.5mg	-0.7448	0.1403
TRTCD*REGIONCD	Eastern Europe	7.5mg	-0.4998	0.3168
TRTCD*REGIONCD	Western Europe	7.5mg	-0.5472	0.06478
TRTCD*REGIONCD	US/Canada	15mg	-0.6004	0.07399
TRTCD*REGIONCD	Eastern Europe	15mg	-0.3689	0.3681
TRTCD*REGIONCD	Western Europe	15mg	-0.09957	0.5606
TRTCD*REGIONCD	US/Canada	30mg	-1.0539	-0.3606
TRTCD*REGIONCD	Eastern Europe	30mg	-0.6918	0.1310
TRTCD*REGIONCD	Western Europe	30mg	-0.5373	0.1233
TRTCD*REGIONCD	US/Canada	45mg	-0.7707	0.05224
TRTCD*REGIONCD	Eastern Europe	45mg	-0.6992	0.01554
TRTCD*REGIONCD	Western Europe	45mg	-0.7504	-0.03515

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	WORK.EFF	-0.01234	0.3240	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	WORK.EFF	-0.9631	0.2832	260
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	WORK.EFF	0.01150	0.2880	260
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.3781	0.2755	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2976	0.2922	260
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	WORK.EFF	0.2546	0.3053	260
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.04388	0.2926	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	WORK.EFF	0.1936	0.2587	260
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	WORK.EFF	0.2156	0.2686	260
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	WORK.EFF	-0.04726	0.2787	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	WORK.EFF	-0.2782	0.2660	260
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	WORK.EFF	0.6596	0.2714	260
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	WORK.EFF	0.2328	0.2945	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	WORK.EFF	0.1594	0.2665	260
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	WORK.EFF	0.3116	0.2938	260
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	WORK.EFF	0.2942	0.2753	260
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	WORK.EFF	0.3452	0.2747	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	WORK.EFF	-0.9507	0.3144	260
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	WORK.EFF	0.02384	0.3195	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	-0.3658	0.3096	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	WORK.EFF	-0.2853	0.3239	260
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	WORK.EFF	0.2669	0.3352	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	0.05622	0.3250	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	-0.04	0.9696	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-3.40	0.0008	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	0.04	0.9682	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-1.37	0.1711	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-1.02	0.3093	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	0.83	0.4052	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	0.15	0.8809	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	0.75	0.4550	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	0.80	0.4230	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.17	0.8655	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-1.05	0.2967	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	2.43	0.0158	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	0.79	0.4301	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	0.60	0.5504	0.05
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	1.06	0.2898	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	1.07	0.2862	0.05
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	1.26	0.2101	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-3.02	0.0027	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	0.07	0.9406	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-1.18	0.2386	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.88	0.3792	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	0.80	0.4266	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	0.17	0.8628	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	Placebo	-0.6503	0.6256
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	Placebo	-1.5207	-0.4055
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	2.5mg	-0.5556	0.5786
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	2.5mg	-0.9205	0.1643
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	2.5mg	-0.8730	0.2777
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	7.5mg	-0.3466	0.8558
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	7.5mg	-0.5323	0.6201
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	7.5mg	-0.3159	0.7031
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	15mg	-0.3134	0.7445
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	15mg	-0.5961	0.5016
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	15mg	-0.8020	0.2457
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	30mg	0.1252	1.1940
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	30mg	-0.3472	0.8127
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	30mg	-0.3654	0.6841
TRTCD*REGIONCD	US/Canada	Placebo	US/Canada	45mg	-0.2669	0.8901
TRTCD*REGIONCD	US/Canada	Placebo	Eastern Europe	45mg	-0.2479	0.8362
TRTCD*REGIONCD	US/Canada	Placebo	Western Europe	45mg	-0.1958	0.8861
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	Placebo	-1.5699	-0.3315
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	2.5mg	-0.6053	0.6530
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	2.5mg	-0.9755	0.2440
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	2.5mg	-0.9230	0.3524
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	7.5mg	-0.3932	0.9270
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	7.5mg	-0.5836	0.6961

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	WORK.EFF	0.2059	0.2935	260
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	WORK.EFF	0.2279	0.3021	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	WORK.EFF	-0.03491	0.3120	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	WORK.EFF	-0.2658	0.2997	260
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	WORK.EFF	0.6719	0.3048	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	WORK.EFF	0.2451	0.3238	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	WORK.EFF	0.1717	0.3000	260
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	WORK.EFF	0.3239	0.3264	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	WORK.EFF	0.3065	0.3073	260
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	WORK.EFF	0.3575	0.3089	260
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	WORK.EFF	0.9746	0.2793	260
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	WORK.EFF	0.5850	0.2654	260
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	WORK.EFF	0.6654	0.2831	260
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	WORK.EFF	1.2176	0.2964	260
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	WORK.EFF	1.0069	0.2836	260
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	WORK.EFF	1.1566	0.2475	260
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	WORK.EFF	1.1786	0.2575	260
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	WORK.EFF	0.9158	0.2694	260
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	WORK.EFF	0.6849	0.2561	260
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	WORK.EFF	1.6226	0.2617	260
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	WORK.EFF	1.1958	0.2828	260
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	WORK.EFF	1.1224	0.2555	260
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	WORK.EFF	1.2747	0.2843	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	0.70	0.4835	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	0.75	0.4513	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.11	0.9110	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.89	0.3759	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	2.20	0.0284	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	0.76	0.4498	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	0.57	0.5676	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	0.99	0.3219	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	1.00	0.3195	0.05
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	1.16	0.2482	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	3.49	0.0006	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	2.20	0.0284	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	2.35	0.0195	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	4.11	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	3.55	0.0005	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	4.67	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	4.58	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	3.40	0.0008	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	2.67	0.0080	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	6.20	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	4.23	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	4.39	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	4.48	<.0001	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	7.5mg	-0.3720	0.7838
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	15mg	-0.3670	0.8229
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	15mg	-0.6492	0.5794
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	15mg	-0.8560	0.3243
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	30mg	0.07168	1.2722
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	30mg	-0.3926	0.8828
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	30mg	-0.4190	0.7624
TRTCD*REGIONCD	Eastern Europe	Placebo	US/Canada	45mg	-0.3187	0.9666
TRTCD*REGIONCD	Eastern Europe	Placebo	Eastern Europe	45mg	-0.2986	0.9117
TRTCD*REGIONCD	Eastern Europe	Placebo	Western Europe	45mg	-0.2508	0.9658
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	2.5mg	0.4246	1.5245
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	2.5mg	0.06238	1.1075
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	2.5mg	0.1079	1.2229
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	7.5mg	0.6341	1.8012
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	7.5mg	0.4485	1.5654
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	7.5mg	0.6692	1.6441
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	15mg	0.6717	1.6856
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	15mg	0.3853	1.4464
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	15mg	0.1806	1.1892
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	30mg	1.1073	2.1380
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	30mg	0.6389	1.7527
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	30mg	0.6193	1.6256
TRTCD*REGIONCD	Western Europe	Placebo	US/Canada	45mg	0.7148	1.8346

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	WORK.EFF	1.2572	0.2644	260
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	WORK.EFF	1.3082	0.2657	260
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	WORK.EFF	-0.3896	0.2731	260
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	WORK.EFF	-0.3091	0.2879	260
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	WORK.EFF	0.2431	0.3008	260
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.03238	0.2891	260
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	WORK.EFF	0.1821	0.2541	260
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	WORK.EFF	0.2041	0.2649	260
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	WORK.EFF	-0.05875	0.2735	260
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	WORK.EFF	-0.2897	0.2598	260
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	WORK.EFF	0.6481	0.2659	260
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	WORK.EFF	0.2213	0.2913	260
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	WORK.EFF	0.1479	0.2609	260
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	WORK.EFF	0.3001	0.2921	260
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	WORK.EFF	0.2827	0.2706	260
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	WORK.EFF	0.3337	0.2707	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	WORK.EFF	0.08046	0.2756	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.6327	0.2899	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.4220	0.2750	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.5717	0.2394	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.5937	0.2495	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.3309	0.2616	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.09994	0.2492	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	4.75	<.0001	0.05
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	4.92	<.0001	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-1.43	0.1549	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-1.07	0.2838	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	0.81	0.4198	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	0.11	0.9109	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	0.72	0.4744	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	0.77	0.4417	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.21	0.8301	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-1.11	0.2660	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	2.44	0.0154	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	0.76	0.4482	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	0.57	0.5714	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	1.03	0.3051	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	1.04	0.2972	0.05
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	1.23	0.2189	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	0.29	0.7706	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	2.18	0.0300	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	1.53	0.1261	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	2.39	0.0177	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	2.38	0.0180	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	1.26	0.2070	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	0.40	0.6888	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	Placebo	Eastern Europe	45mg	0.7365	1.7779
TRTCD*REGIONCD	Western Europe	Placebo	Western Europe	45mg	0.7849	1.8315
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	2.5mg	-0.9274	0.1482
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	2.5mg	-0.8760	0.2577
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	7.5mg	-0.3492	0.8354
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	7.5mg	-0.5369	0.6016
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	7.5mg	-0.3184	0.6825
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	15mg	-0.3175	0.7256
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	15mg	-0.5973	0.4798
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	15mg	-0.8013	0.2220
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	30mg	0.1246	1.1716
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	30mg	-0.3523	0.7949
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	30mg	-0.3660	0.6617
TRTCD*REGIONCD	US/Canada	2.5mg	US/Canada	45mg	-0.2750	0.8752
TRTCD*REGIONCD	US/Canada	2.5mg	Eastern Europe	45mg	-0.2502	0.8155
TRTCD*REGIONCD	US/Canada	2.5mg	Western Europe	45mg	-0.1995	0.8668
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	2.5mg	-0.4622	0.6232
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	7.5mg	0.06184	1.2035
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	7.5mg	-0.1195	0.9635
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	7.5mg	0.1002	1.0431
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	15mg	0.1024	1.0849
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	15mg	-0.1842	0.8459
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	15mg	-0.3908	0.5907

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	WORK.EFF	1.0377	0.2543	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.6109	0.2772	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.5375	0.2485	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.6897	0.2746	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.6723	0.2579	260
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.7233	0.2566	260
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	WORK.EFF	0.5522	0.3053	260
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	WORK.EFF	0.3415	0.2926	260
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	WORK.EFF	0.4912	0.2587	260
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	WORK.EFF	0.5132	0.2686	260
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	WORK.EFF	0.2504	0.2786	260
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	WORK.EFF	0.01947	0.2659	260
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	WORK.EFF	0.9572	0.2713	260
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	WORK.EFF	0.5304	0.2945	260
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	WORK.EFF	0.4570	0.2663	260
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	WORK.EFF	0.6092	0.2939	260
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	WORK.EFF	0.5918	0.2752	260
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	WORK.EFF	0.6428	0.2748	260
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	WORK.EFF	-0.2107	0.3061	260
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	WORK.EFF	-0.06100	0.2733	260
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	WORK.EFF	-0.03899	0.2828	260
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.3018	0.2924	260
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	WORK.EFF	-0.5327	0.2799	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	4.08	<.0001	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	2.20	0.0284	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	2.16	0.0315	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	2.51	0.0126	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	2.61	0.0097	0.05
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	2.82	0.0052	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	1.81	0.0716	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	1.17	0.2443	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	1.90	0.0587	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	1.91	0.0572	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	0.90	0.3696	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	0.07	0.9417	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	3.53	0.0005	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	1.80	0.0729	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	1.72	0.0873	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	2.07	0.0392	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	2.15	0.0325	0.05
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	2.34	0.0201	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.69	0.4918	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.22	0.8236	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	-0.14	0.8904	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-1.03	0.3030	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-1.90	0.0581	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	30mg	0.5369	1.5385
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	30mg	0.06510	1.1566
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	30mg	0.04808	1.0269
TRTCD*REGIONCD	Eastern Europe	2.5mg	US/Canada	45mg	0.1490	1.2304
TRTCD*REGIONCD	Eastern Europe	2.5mg	Eastern Europe	45mg	0.1645	1.1800
TRTCD*REGIONCD	Eastern Europe	2.5mg	Western Europe	45mg	0.2179	1.2286
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	7.5mg	-0.04892	1.1534
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	7.5mg	-0.2347	0.9178
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	7.5mg	-0.01818	1.0006
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	15mg	-0.01573	1.0422
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	15mg	-0.2982	0.7990
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	15mg	-0.5042	0.5432
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	30mg	0.4230	1.4915
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	30mg	-0.04949	1.1103
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	30mg	-0.06739	0.9814
TRTCD*REGIONCD	Western Europe	2.5mg	US/Canada	45mg	0.03045	1.1880
TRTCD*REGIONCD	Western Europe	2.5mg	Eastern Europe	45mg	0.04985	1.1338
TRTCD*REGIONCD	Western Europe	2.5mg	Western Europe	45mg	0.1016	1.1840
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	7.5mg	-0.8134	0.3920
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	7.5mg	-0.5992	0.4772
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	15mg	-0.5958	0.5178
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	15mg	-0.8777	0.2740
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	15mg	-1.0838	0.01835

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	WORK.EFF	0.4050	0.2852	260
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	WORK.EFF	-0.02182	0.3070	260
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	WORK.EFF	-0.09521	0.2805	260
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	WORK.EFF	0.05702	0.3075	260
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	WORK.EFF	0.03959	0.2886	260
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	WORK.EFF	0.09058	0.2889	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	WORK.EFF	0.1497	0.2591	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.1717	0.2689	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.09114	0.2786	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.3220	0.2674	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.6157	0.2723	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.1889	0.2954	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	WORK.EFF	0.1155	0.2665	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.2677	0.2930	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.2503	0.2765	260
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.3013	0.2753	260
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	WORK.EFF	0.02201	0.2311	260
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	WORK.EFF	-0.2408	0.2433	260
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	WORK.EFF	-0.4717	0.2289	260
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	WORK.EFF	0.4660	0.2350	260
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	WORK.EFF	0.03919	0.2601	260
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	WORK.EFF	-0.03421	0.2285	260
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	WORK.EFF	0.1180	0.2602	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	1.42	0.1567	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	-0.07	0.9434	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	-0.34	0.7346	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	0.19	0.8530	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	0.14	0.8910	0.05
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	0.31	0.7541	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	0.58	0.5639	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	0.64	0.5237	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.33	0.7439	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-1.20	0.2295	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	2.26	0.0246	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	0.64	0.5231	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	0.43	0.6651	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	0.91	0.3617	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	0.91	0.3663	0.05
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	1.09	0.2749	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	0.10	0.9242	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.99	0.3231	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-2.06	0.0403	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	1.98	0.0484	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	0.15	0.8804	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	-0.15	0.8811	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	0.45	0.6505	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	30mg	-0.1565	0.9665
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	30mg	-0.6263	0.5827
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	30mg	-0.6476	0.4571
TRTCD*REGIONCD	US/Canada	7.5mg	US/Canada	45mg	-0.5486	0.6626
TRTCD*REGIONCD	US/Canada	7.5mg	Eastern Europe	45mg	-0.5288	0.6079
TRTCD*REGIONCD	US/Canada	7.5mg	Western Europe	45mg	-0.4782	0.6594
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	7.5mg	-0.3604	0.6598
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	15mg	-0.3578	0.7012
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	15mg	-0.6398	0.4576
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	15mg	-0.8485	0.2044
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	30mg	0.07946	1.1519
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	30mg	-0.3928	0.7706
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	30mg	-0.4093	0.6403
TRTCD*REGIONCD	Eastern Europe	7.5mg	US/Canada	45mg	-0.3092	0.8446
TRTCD*REGIONCD	Eastern Europe	7.5mg	Eastern Europe	45mg	-0.2943	0.7948
TRTCD*REGIONCD	Eastern Europe	7.5mg	Western Europe	45mg	-0.2409	0.8434
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	15mg	-0.4330	0.4771
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	15mg	-0.7198	0.2382
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	15mg	-0.9224	-0.02109
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	30mg	0.003215	0.9288
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	30mg	-0.4730	0.5513
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	30mg	-0.4841	0.4156
TRTCD*REGIONCD	Western Europe	7.5mg	US/Canada	45mg	-0.3944	0.6304

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	WORK.EFF	0.1006	0.2390	260
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	WORK.EFF	0.1516	0.2393	260
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	WORK.EFF	-0.2628	0.2542	260
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	WORK.EFF	-0.4937	0.2403	260
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	WORK.EFF	0.4440	0.2461	260
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	WORK.EFF	0.01718	0.2691	260
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	WORK.EFF	-0.05622	0.2399	260
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	WORK.EFF	0.09602	0.2694	260
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	WORK.EFF	0.07858	0.2493	260
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	WORK.EFF	0.1296	0.2498	260
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	WORK.EFF	-0.2309	0.2510	260
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	WORK.EFF	0.7068	0.2566	260
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.2800	0.2822	260
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	WORK.EFF	0.2066	0.2503	260
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	WORK.EFF	0.3589	0.2807	260
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.3414	0.2617	260
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	WORK.EFF	0.3924	0.2609	260
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	WORK.EFF	0.9378	0.2421	260
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	WORK.EFF	0.5109	0.2685	260
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	WORK.EFF	0.4375	0.2371	260
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	WORK.EFF	0.5898	0.2698	260
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	WORK.EFF	0.5723	0.2466	260
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	WORK.EFF	0.6233	0.2470	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	0.42	0.6741	0.05
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	0.63	0.5270	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-1.03	0.3021	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-2.05	0.0409	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	1.80	0.0724	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	0.06	0.9492	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.23	0.8149	0.05
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	0.36	0.7219	0.05
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	0.32	0.7529	0.05
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	0.52	0.6045	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.92	0.3585	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	2.75	0.0063	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	0.99	0.3219	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	0.83	0.4099	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	1.28	0.2022	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	1.30	0.1931	0.05
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	1.50	0.1338	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	3.87	0.0001	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	1.90	0.0582	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	1.85	0.0662	0.05
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	2.19	0.0297	0.05
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	2.32	0.0210	0.05
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	2.52	0.0122	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	Western Europe	7.5mg	Eastern Europe	45mg	-0.3700	0.5712
TRTCD*REGIONCD	Western Europe	7.5mg	Western Europe	45mg	-0.3196	0.6228
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	15mg	-0.7633	0.2377
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	15mg	-0.9670	-0.02051
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	30mg	-0.04064	0.9286
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	30mg	-0.5128	0.5471
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	30mg	-0.5286	0.4162
TRTCD*REGIONCD	US/Canada	15mg	US/Canada	45mg	-0.4345	0.6266
TRTCD*REGIONCD	US/Canada	15mg	Eastern Europe	45mg	-0.4124	0.5696
TRTCD*REGIONCD	US/Canada	15mg	Western Europe	45mg	-0.3624	0.6215
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	15mg	-0.7252	0.2634
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	30mg	0.2015	1.2122
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	30mg	-0.2756	0.8356
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	30mg	-0.2863	0.6995
TRTCD*REGIONCD	Eastern Europe	15mg	US/Canada	45mg	-0.1939	0.9116
TRTCD*REGIONCD	Eastern Europe	15mg	Eastern Europe	45mg	-0.1738	0.8567
TRTCD*REGIONCD	Eastern Europe	15mg	Western Europe	45mg	-0.1214	0.9062
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	30mg	0.4610	1.4145
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	30mg	-0.01788	1.0397
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	30mg	-0.02942	0.9045
TRTCD*REGIONCD	Western Europe	15mg	US/Canada	45mg	0.05841	1.1211
TRTCD*REGIONCD	Western Europe	15mg	Eastern Europe	45mg	0.08683	1.0578
TRTCD*REGIONCD	Western Europe	15mg	Western Europe	45mg	0.1370	1.1097

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Margins	Estimate	Standard Error	DF
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	WORK.EFF	-0.4268	0.2740	260
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	WORK.EFF	-0.5002	0.2432	260
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	WORK.EFF	-0.3480	0.2744	260
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	WORK.EFF	-0.3654	0.2527	260
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	WORK.EFF	-0.3144	0.2527	260
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	WORK.EFF	-0.07340	0.2683	260
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	WORK.EFF	0.07884	0.2955	260
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.06141	0.2754	260
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	WORK.EFF	0.1124	0.2778	260
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	WORK.EFF	0.1522	0.2687	260
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	WORK.EFF	0.1348	0.2477	260
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	WORK.EFF	0.1858	0.2484	260
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	WORK.EFF	-0.01743	0.2777	260
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	WORK.EFF	0.03355	0.2762	260
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	WORK.EFF	0.05098	0.2568	260

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	t Value	Pr > |t|	Alpha
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-1.56	0.1205	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-2.06	0.0407	0.05
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-1.27	0.2058	0.05
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-1.45	0.1493	0.05
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-1.24	0.2145	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.27	0.7847	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	0.27	0.7898	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	0.22	0.8237	0.05
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	0.40	0.6861	0.05
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	0.57	0.5714	0.05
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	0.54	0.5868	0.05
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	0.75	0.4552	0.05
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.06	0.9500	0.05
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	0.12	0.9034	0.05
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	0.20	0.8428	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - regioncd*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Region code	Randomized treatment code	Region code	Randomized treatment code	Lower	Upper
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	30mg	-0.9663	0.1127
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	30mg	-0.9791	-0.02137
TRTCD*REGIONCD	US/Canada	30mg	US/Canada	45mg	-0.8883	0.1923
TRTCD*REGIONCD	US/Canada	30mg	Eastern Europe	45mg	-0.8630	0.1321
TRTCD*REGIONCD	US/Canada	30mg	Western Europe	45mg	-0.8120	0.1831
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	30mg	-0.6018	0.4550
TRTCD*REGIONCD	Eastern Europe	30mg	US/Canada	45mg	-0.5030	0.6607
TRTCD*REGIONCD	Eastern Europe	30mg	Eastern Europe	45mg	-0.4808	0.6037
TRTCD*REGIONCD	Eastern Europe	30mg	Western Europe	45mg	-0.4345	0.6593
TRTCD*REGIONCD	Western Europe	30mg	US/Canada	45mg	-0.3768	0.6813
TRTCD*REGIONCD	Western Europe	30mg	Eastern Europe	45mg	-0.3530	0.6227
TRTCD*REGIONCD	Western Europe	30mg	Western Europe	45mg	-0.3034	0.6750
TRTCD*REGIONCD	US/Canada	45mg	Eastern Europe	45mg	-0.5642	0.5294
TRTCD*REGIONCD	US/Canada	45mg	Western Europe	45mg	-0.5103	0.5774
TRTCD*REGIONCD	Eastern Europe	45mg	Western Europe	45mg	-0.4547	0.5567

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	21
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Dimensions

Max Obs Per Subject	281
Observations Used	281
Observations Not Used	0
Total Observations	281

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5646	0.04905	11.51	<.0001	0.05	0.4796	0.6745

Fit Statistics

-2 Res Log Likelihood	658.6
AIC (smaller is better)	660.6
AICC (smaller is better)	660.6
BIC (smaller is better)	664.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value
Intercept					0.9527	1.1626	265	0.82
SEX	Female				-0.07910	0.09109	265	-0.87
SEX	Male				0			
TRTTYPCD		Diet & Exercise			-0.6899	0.09333	265	-7.39
TRTTYPCD		Monotherapy			0			
TRTCD				Placebo	0.2185	2.0211	265	0.11
TRTCD				2.5mg	-1.0922	1.5410	265	-0.71
TRTCD				7.5mg	-0.07885	1.7088	265	-0.05
TRTCD				15mg	-0.4702	1.7695	265	-0.27
TRTCD				30mg	1.2534	1.7102	265	0.73
TRTCD				45mg	0			
REGIONCD			US/Canada		-0.3712	0.1091	265	-3.40
REGIONCD			Eastern Europe		-0.1262	0.1108	265	-1.14
REGIONCD			Western Europe		0			
EFSTDBL					-0.1064	0.1429	265	-0.74
EFSTDBL*TRTCD				Placebo	0.06282	0.2537	265	0.25
EFSTDBL*TRTCD				2.5mg	0.2082	0.1910	265	1.09
EFSTDBL*TRTCD				7.5mg	0.02465	0.2130	265	0.12
EFSTDBL*TRTCD				15mg	0.1065	0.2220	265	0.48
EFSTDBL*TRTCD				30mg	-0.1658	0.2150	265	-0.77
EFSTDBL*TRTCD				45mg	0			

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Pr > |t|
Intercept					0.4132
SEX	Female				0.3860
SEX	Male				.
TRTTYPCD		Diet & Exercise			<.0001
TRTTYPCD		Monotherapy			.
TRTCD				Placebo	0.9140
TRTCD				2.5mg	0.4791
TRTCD				7.5mg	0.9632
TRTCD				15mg	0.7907
TRTCD				30mg	0.4643
TRTCD				45mg	.
REGIONCD			US/Canada		0.0008
REGIONCD			Eastern Europe		0.2560
REGIONCD			Western Europe		.
EFSTDBL					0.4573
EFSTDBL*TRTCD				Placebo	0.8046
EFSTDBL*TRTCD				2.5mg	0.2768
EFSTDBL*TRTCD				7.5mg	0.9079
EFSTDBL*TRTCD				15mg	0.6318
EFSTDBL*TRTCD				30mg	0.4413
EFSTDBL*TRTCD				45mg	.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	265	0.75	0.3860
TRTTYPCD	1	265	54.64	<.0001
TRTCD	5	265	0.46	0.8082
REGIONCD	2	265	5.86	0.0032
EFSTDBL	1	265	0.99	0.3214
EFSTDBL*TRTCD	5	265	0.74	0.5946

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.3518	0.1241	265	2.84	0.0049	0.05	0.1075	0.5961
TRTCD	2.5mg	WORK.EFF	0.1896	0.1139	265	1.66	0.0973	0.05	-0.03476	0.4139
TRTCD	7.5mg	WORK.EFF	-0.2471	0.1102	265	-2.24	0.0257	0.05	-0.4641	-0.03024
TRTCD	15mg	WORK.EFF	0.008354	0.1020	265	0.08	0.9348	0.05	-0.1925	0.2092
TRTCD	30mg	WORK.EFF	-0.4195	0.1072	265	-3.91	0.0001	0.05	-0.6305	-0.2085
TRTCD	45mg	WORK.EFF	-0.3631	0.1131	265	-3.21	0.0015	0.05	-0.5857	-0.1404

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.1622	0.1690	265	0.96	0.3380	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.5989	0.1660	265	3.61	0.0004	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.3434	0.1606	265	2.14	0.0334	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.7713	0.1635	265	4.72	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.7149	0.1681	265	4.25	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.4367	0.1588	265	2.75	0.0064	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1812	0.1528	265	1.19	0.2366	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.6091	0.1567	265	3.89	0.0001	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5526	0.1602	265	3.45	0.0007	0.05
TRTCD	7.5mg	15mg	WORK.EFF	-0.2555	0.1504	265	-1.70	0.0904	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.1724	0.1539	265	1.12	0.2638	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.1159	0.1580	265	0.73	0.4637	0.05
TRTCD	15mg	30mg	WORK.EFF	0.4279	0.1479	265	2.89	0.0041	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3714	0.1524	265	2.44	0.0154	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.05648	0.1560	265	-0.36	0.7175	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.9
SAS Statistical Output for Table 11.8
Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output for Each Treatment x Covariate - efstdbl*treatment

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1705	0.4949
TRTCD	Placebo	7.5mg	0.2721	0.9258
TRTCD	Placebo	15mg	0.02715	0.6597
TRTCD	Placebo	30mg	0.4494	1.0933
TRTCD	Placebo	45mg	0.3838	1.0459
TRTCD	2.5mg	7.5mg	0.1240	0.7495
TRTCD	2.5mg	15mg	-0.1196	0.4821
TRTCD	2.5mg	30mg	0.3006	0.9177
TRTCD	2.5mg	45mg	0.2372	0.8681
TRTCD	7.5mg	15mg	-0.5515	0.04054
TRTCD	7.5mg	30mg	-0.1307	0.4755
TRTCD	7.5mg	45mg	-0.1951	0.4269
TRTCD	15mg	30mg	0.1367	0.7191
TRTCD	15mg	45mg	0.07139	0.6714
TRTCD	30mg	45mg	-0.3635	0.2506

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.10
Summary Statistics for HbA1c (%) at Week 12 by Region

Region: Eastern Europe

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		12	21	16	17	13	18
n [1]		12	20	15	17	13	18
Number (%) of Values Carried Forward		2 (17%)	3 (15%)	1 (7%)	0	0	0
Baseline	Mean	7.60	8.20	8.01	7.76	7.95	7.98
	SD	0.882	1.072	0.693	0.472	0.655	0.791
	SE	0.255	0.240	0.179	0.114	0.182	0.186
	Minimum	6.1	6.4	7.2	6.8	7.0	6.7
	Median	7.65	8.05	7.70	8.00	7.90	8.00
	Maximum	9.3	10.1	9.4	8.4	9.6	9.5
Week 12	Mean	7.47	8.58	8.05	7.99	7.49	7.49
	SD	0.974	1.381	1.252	0.958	0.748	0.958
	SE	0.281	0.309	0.323	0.232	0.207	0.226
	Minimum	6.3	6.6	6.4	6.4	6.1	5.8
	Median	7.35	8.25	7.80	8.10	7.40	7.70
	Maximum	10.0	11.8	10.7	10.0	8.9	9.4
Change from Baseline	Mean	-0.13	0.38	0.04	0.24	-0.45	-0.48
	SD	0.990	0.817	0.971	0.818	0.673	0.576
	SE	0.286	0.183	0.251	0.198	0.187	0.136
	Minimum	-1.7	-1.4	-1.7	-1.6	-2.1	-1.6
	Median	-0.25	0.45	0.00	0.20	-0.20	-0.40
	Maximum	2.1	1.8	2.1	2.0	0.4	0.3

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.10
Summary Statistics for HbA1c (%) at Week 12 by Region

Region: US/Canada

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		26	18	18	20	20	21
n [1]		23	17	16	20	19	19
Number (%) of Values Carried Forward		5 (22%)	3 (18%)	4 (25%)	0	1 (5%)	4 (21%)
Baseline	Mean	7.79	7.70	8.06	8.04	7.89	8.13
	SD	0.641	0.843	1.051	0.758	0.627	0.781
	SE	0.134	0.205	0.263	0.169	0.144	0.179
	Minimum	6.6	6.4	6.6	6.5	6.7	6.5
	Median	7.70	7.60	7.65	8.20	8.10	8.10
	Maximum	9.3	9.8	9.9	9.5	8.7	9.5
Week 12	Mean	7.87	7.53	7.87	7.68	7.25	7.88
	SD	0.999	1.034	1.288	0.806	0.929	1.180
	SE	0.208	0.251	0.322	0.180	0.213	0.271
	Minimum	6.2	6.3	6.2	6.0	5.5	6.0
	Median	7.70	7.40	7.50	7.75	7.20	7.50
	Maximum	9.7	9.7	11.0	9.0	9.4	9.9
Change from Baseline	Mean	0.07	-0.17	-0.19	-0.37	-0.64	-0.25
	SD	0.809	0.656	0.538	0.521	0.698	0.825
	SE	0.169	0.159	0.134	0.117	0.160	0.189
	Minimum	-1.5	-1.6	-0.8	-1.8	-2.5	-1.8
	Median	0.10	-0.20	-0.30	-0.20	-0.60	0.00
	Maximum	2.1	1.1	1.1	0.2	0.7	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.10
Summary Statistics for HbA1c (%) at Week 12 by Region

Region: Western Europe

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		24	20	28	26	25	21
n [1]		24	19	28	25	24	21
Number (%) of Values Carried Forward		3 (13%)	4 (21%)	1 (4%)	2 (8%)	1 (4%)	2 (10%)
Baseline	Mean	7.81	8.12	7.91	7.83	7.59	8.09
	SD	0.620	0.796	0.615	0.666	0.667	0.704
	SE	0.127	0.183	0.116	0.133	0.136	0.154
	Minimum	6.8	7.0	6.9	6.6	6.4	6.8
	Median	7.75	7.80	7.80	7.80	7.50	8.00
	Maximum	9.2	9.8	9.3	9.6	8.7	9.5
Week 12	Mean	8.85	8.39	7.91	8.06	7.55	7.66
	SD	1.493	1.187	1.069	0.971	0.880	0.735
	SE	0.305	0.272	0.202	0.194	0.180	0.160
	Minimum	6.3	6.5	6.3	6.5	6.2	6.1
	Median	8.70	8.30	7.55	8.10	7.35	7.60
	Maximum	11.8	10.8	10.2	10.4	9.7	8.8
Change from Baseline	Mean	1.03	0.27	0.00	0.23	-0.04	-0.43
	SD	1.244	1.035	1.082	0.671	0.903	0.746
	SE	0.254	0.237	0.204	0.134	0.184	0.163
	Minimum	-1.7	-1.9	-2.3	-1.2	-1.6	-2.9
	Median	1.05	0.30	0.00	0.20	0.05	-0.30
	Maximum	2.8	2.5	2.2	1.9	2.6	0.7

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.11
Summary Statistics for HbA1c (%) at Week 12 by Gender

Gender: Female

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		31	29	31	30	31	32
n [1]		30	26	29	29	30	30
Number (%) of Values Carried Forward		3 (10%)	4 (15%)	2 (7%)	0	1 (3%)	3 (10%)
Baseline	Mean	7.79	8.09	7.98	7.90	7.79	8.16
	SD	0.719	0.996	0.755	0.591	0.605	0.683
	SE	0.131	0.195	0.140	0.110	0.110	0.125
	Minimum	6.1	6.8	6.6	6.9	6.4	6.8
	Median	7.70	7.75	7.70	8.00	7.80	8.10
	Maximum	9.3	10.1	9.9	9.0	8.7	9.5
Week 12	Mean	8.08	8.47	7.98	7.94	7.49	7.71
	SD	1.200	1.317	1.348	0.897	0.803	1.078
	SE	0.219	0.258	0.250	0.166	0.147	0.197
	Minimum	6.3	6.5	6.2	6.0	6.1	6.1
	Median	7.80	8.00	7.60	8.10	7.40	7.45
	Maximum	11.4	11.8	11.0	10.0	9.4	9.9
Change from Baseline	Mean	0.28	0.38	0.00	0.04	-0.30	-0.45
	SD	1.071	0.846	1.113	0.690	0.725	0.854
	SE	0.196	0.166	0.207	0.128	0.132	0.156
	Minimum	-1.7	-1.4	-2.3	-1.1	-2.1	-2.9
	Median	0.10	0.30	-0.30	0.00	-0.15	-0.35
	Maximum	2.8	2.5	2.2	2.0	0.9	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

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Table 11.11
Summary Statistics for HbA1c (%) at Week 12 by Gender

Gender: Male

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		31	30	31	33	27	28
n [1]		29	30	30	33	26	28
Number (%) of Values Carried Forward		7 (24%)	6 (20%)	4 (13%)	2 (6%)	1 (4%)	3 (11%)
Baseline	Mean	7.73	7.96	7.97	7.86	7.76	7.97
	SD	0.649	0.874	0.783	0.710	0.730	0.809
	SE	0.121	0.160	0.143	0.124	0.143	0.153
	Minimum	6.6	6.4	6.7	6.5	6.7	6.5
	Median	7.70	7.80	7.70	7.90	7.55	7.95
	Maximum	9.2	9.8	9.6	9.6	9.6	9.5
Week 12	Mean	8.29	7.96	7.89	7.90	7.37	7.65
	SD	1.467	1.216	0.965	0.950	0.941	0.841
	SE	0.272	0.222	0.176	0.165	0.185	0.159
	Minimum	6.2	6.3	6.2	6.4	5.5	5.8
	Median	8.20	7.55	7.75	7.70	7.25	7.85
	Maximum	11.8	10.8	9.8	10.4	9.7	8.9
Change from Baseline	Mean	0.57	0.00	-0.08	0.04	-0.39	-0.32
	SD	1.222	0.872	0.715	0.754	0.930	0.551
	SE	0.227	0.159	0.131	0.131	0.182	0.104
	Minimum	-1.5	-1.9	-1.7	-1.8	-2.5	-1.8
	Median	0.60	-0.10	0.00	0.10	-0.50	-0.15
	Maximum	2.8	1.7	2.1	1.9	2.6	0.7

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.12
Summary Statistics for HbA1c (%) at Week 12 by Prior Therapy

Prior Therapy: Diet & Exercise

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		28	23	27	24	25	24
n [1]		27	22	24	23	24	23
Number (%) of Values Carried Forward		4 (15%)	5 (23%)	5 (21%)	0	1 (4%)	1 (4%)
Baseline	Mean	7.73	8.08	8.19	7.85	8.00	8.12
	SD	0.627	0.900	0.829	0.471	0.694	0.723
	SE	0.121	0.192	0.169	0.098	0.142	0.151
	Minimum	6.1	7.0	7.3	6.9	6.7	6.7
	Median	7.70	7.70	7.70	7.90	8.00	8.20
	Maximum	9.3	9.8	9.7	8.6	9.6	9.5
Week 12	Mean	7.63	7.65	7.96	7.64	7.23	7.37
	SD	1.181	1.042	1.178	0.938	0.921	0.895
	SE	0.227	0.222	0.241	0.196	0.188	0.187
	Minimum	6.2	6.4	6.3	6.0	5.5	5.8
	Median	7.40	7.40	7.45	7.70	7.10	7.50
	Maximum	10.6	10.1	9.9	9.5	9.4	8.8
Change from Baseline	Mean	-0.10	-0.42	-0.23	-0.21	-0.77	-0.74
	SD	1.114	0.680	1.070	0.716	0.736	0.757
	SE	0.214	0.145	0.218	0.149	0.150	0.158
	Minimum	-1.7	-1.9	-2.3	-1.6	-2.5	-2.9
	Median	-0.30	-0.35	-0.30	-0.20	-0.75	-0.50
	Maximum	2.4	1.0	2.2	1.6	0.7	0.3

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

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Table 11.12
Summary Statistics for HbA1c (%) at Week 12 by Prior Therapy

Prior Therapy: Monotherapy

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		34	36	35	39	33	36
n [1]		32	34	35	39	32	35
Number (%) of Values Carried Forward		6 (19%)	5 (15%)	1 (3%)	2 (5%)	1 (3%)	5 (14%)
Baseline	Mean	7.79	7.98	7.83	7.89	7.60	8.03
	SD	0.731	0.954	0.688	0.744	0.588	0.770
	SE	0.129	0.164	0.116	0.119	0.104	0.130
	Minimum	6.6	6.4	6.6	6.5	6.4	6.5
	Median	7.65	7.85	7.70	8.00	7.50	8.00
	Maximum	9.3	10.1	9.9	9.6	8.6	9.5
Week 12	Mean	8.65	8.55	7.91	8.08	7.58	7.88
	SD	1.283	1.307	1.163	0.877	0.800	0.966
	SE	0.227	0.224	0.197	0.140	0.141	0.163
	Minimum	6.9	6.3	6.2	6.4	6.2	6.5
	Median	8.35	8.30	7.60	8.10	7.45	7.70
	Maximum	11.8	11.8	11.0	10.4	9.7	9.9
Change from Baseline	Mean	0.87	0.56	0.08	0.19	-0.02	-0.15
	SD	0.988	0.762	0.803	0.686	0.735	0.598
	SE	0.175	0.131	0.136	0.110	0.130	0.101
	Minimum	-0.7	-1.4	-1.9	-1.8	-1.2	-1.8
	Median	0.70	0.60	0.00	0.10	0.00	0.00
	Maximum	2.8	2.5	2.1	2.0	2.6	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.13
Summary Statistics for HbA1c (%) at Week 12 by Baseline HbA1c

Baseline HbA1c: <7.5%

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		20	15	16	16	18	13
n [1]		18	15	15	16	18	13
Number (%) of Values Carried Forward		6 (33%)	3 (20%)	2 (13%)	0	0	2 (15%)
Baseline	Mean	7.01	7.05	7.19	7.08	7.03	7.06
	SD	0.341	0.336	0.276	0.269	0.297	0.315
	SE	0.080	0.087	0.071	0.067	0.070	0.087
	Minimum	6.1	6.4	6.6	6.5	6.4	6.5
	Median	7.20	7.10	7.30	7.15	7.10	7.10
	Maximum	7.4	7.4	7.4	7.4	7.4	7.4
Week 12	Mean	7.41	7.27	7.27	7.11	7.04	6.92
	SD	0.821	0.554	0.744	0.572	0.872	0.490
	SE	0.193	0.143	0.192	0.143	0.206	0.136
	Minimum	6.3	6.3	6.2	6.0	6.2	5.8
	Median	7.25	7.30	7.20	7.20	6.95	7.00
	Maximum	9.3	8.3	9.1	8.5	9.7	7.6
Change from Baseline	Mean	0.39	0.22	0.07	0.03	0.01	-0.15
	SD	0.803	0.606	0.630	0.665	0.834	0.318
	SE	0.189	0.157	0.163	0.166	0.197	0.088
	Minimum	-0.9	-0.6	-0.7	-1.1	-0.9	-0.9
	Median	0.30	0.10	0.00	-0.05	-0.05	0.00
	Maximum	2.5	1.3	1.7	1.9	2.6	0.2

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.13
Summary Statistics for HbA1c (%) at Week 12 by Baseline HbA1c

Baseline HbA1c: 7.5-8.5%

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		36	30	32	39	31	30
n [1]		35	29	32	38	31	29
Number (%) of Values Carried Forward		3 (9%)	4 (14%)	1 (3%)	1 (3%)	1 (3%)	3 (10%)
Baseline	Mean	7.93	7.91	7.88	7.98	7.98	8.01
	SD	0.327	0.321	0.295	0.320	0.342	0.284
	SE	0.055	0.060	0.052	0.052	0.061	0.053
	Minimum	7.5	7.5	7.5	7.5	7.5	7.5
	Median	7.90	7.80	7.80	8.00	8.00	8.00
	Maximum	8.5	8.4	8.5	8.5	8.4	8.5
Week 12	Mean	8.27	8.06	7.85	8.07	7.51	7.62
	SD	1.184	0.981	0.984	0.794	0.750	0.815
	SE	0.200	0.182	0.174	0.129	0.135	0.151
	Minimum	6.2	6.5	6.3	6.4	5.5	6.0
	Median	8.20	8.00	7.60	8.20	7.50	7.80
	Maximum	10.6	10.3	10.4	10.0	8.9	9.0
Change from Baseline	Mean	0.34	0.14	-0.03	0.09	-0.46	-0.39
	SD	1.178	0.827	0.912	0.717	0.752	0.693
	SE	0.199	0.153	0.161	0.116	0.135	0.129
	Minimum	-1.7	-1.4	-1.7	-1.6	-2.5	-1.8
	Median	0.10	0.20	-0.25	0.10	-0.40	-0.40
	Maximum	2.5	2.5	2.2	2.0	0.9	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.13
Summary Statistics for HbA1c (%) at Week 12 by Baseline HbA1c

Baseline HbA1c: >8.5%

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		6	12	12	8	7	16
n [1]		6	12	12	8	7	16
Number (%) of Values Carried Forward		1 (17%)	3 (25%)	3 (25%)	1 (13%)	1 (14%)	1 (6%)
Baseline	Mean	9.03	9.50	9.22	8.96	8.77	8.98
	SD	0.288	0.413	0.426	0.389	0.368	0.337
	SE	0.117	0.119	0.123	0.138	0.139	0.084
	Minimum	8.6	8.8	8.6	8.6	8.6	8.6
	Median	9.10	9.50	9.25	8.85	8.60	8.95
	Maximum	9.3	10.1	9.9	9.6	9.6	9.5
Week 12	Mean	10.02	9.70	8.99	8.81	8.07	8.40
	SD	1.566	1.276	1.344	0.874	0.957	1.013
	SE	0.639	0.368	0.388	0.309	0.362	0.253
	Minimum	7.6	7.3	6.7	7.7	7.1	6.1
	Median	10.20	9.90	8.90	8.75	7.90	8.25
	Maximum	11.8	11.8	11.0	10.4	9.4	9.9
Change from Baseline	Mean	0.98	0.20	-0.23	-0.15	-0.70	-0.58
	SD	1.788	1.263	1.266	0.885	0.874	0.951
	SE	0.730	0.365	0.366	0.313	0.330	0.238
	Minimum	-1.7	-1.9	-2.3	-1.8	-1.6	-2.9
	Median	1.20	0.10	-0.30	0.05	-0.70	-0.55
	Maximum	2.8	1.8	1.7	0.8	0.7	0.5

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.14
Summary Statistics for HbA1c (%) at Week 12 by Baseline BMI

Baseline BMI: <27 kg/m^2

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		15	10	16	12	14	10
n [1]		14	10	16	12	13	10
Number (%) of Values Carried Forward		1 (7%)	2 (20%)	1 (6%)	1 (8%)	0	2 (20%)
Baseline	Mean	7.56	7.74	8.08	7.87	7.99	8.07
	SD	0.821	0.624	0.928	0.584	0.832	0.759
	SE	0.219	0.197	0.232	0.168	0.231	0.240
	Minimum	6.1	7.0	6.7	6.5	6.8	6.9
	Median	7.35	7.70	7.65	7.95	8.20	8.15
	Maximum	8.8	9.1	9.9	8.7	9.6	9.3
Week 12	Mean	8.03	8.06	7.99	7.92	7.82	8.10
	SD	1.162	0.951	1.373	0.928	0.995	0.914
	SE	0.311	0.301	0.343	0.268	0.276	0.289
	Minimum	6.4	6.9	6.2	6.4	6.7	6.7
	Median	7.85	7.90	7.75	7.90	7.40	8.20
	Maximum	10.3	10.1	11.0	9.5	9.7	9.8
Change from Baseline	Mean	0.47	0.32	-0.09	0.05	-0.18	0.03
	SD	0.779	0.641	0.898	0.532	1.019	0.231
	SE	0.208	0.203	0.225	0.153	0.283	0.073
	Minimum	-1.0	-0.5	-1.7	-1.1	-1.5	-0.3
	Median	0.60	0.60	-0.30	0.10	-0.20	0.00
	Maximum	1.7	1.3	2.1	0.8	2.6	0.5

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.14
Summary Statistics for HbA1c (%) at Week 12 by Baseline BMI

Baseline BMI: 27-30 kg/m^2

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		18	16	12	15	7	14
n [1]		18	15	11	14	7	14
Number (%) of Values Carried Forward		7 (39%)	3 (20%)	3 (27%)	0	0	0
Baseline	Mean	7.77	8.11	8.10	7.64	7.74	8.04
	SD	0.618	1.165	0.707	0.692	0.741	0.664
	SE	0.146	0.301	0.213	0.185	0.280	0.177
	Minimum	6.6	6.4	7.3	6.6	6.7	6.8
	Median	7.75	7.60	7.90	7.40	7.70	8.00
	Maximum	9.2	10.1	9.4	9.0	8.6	9.1
Week 12	Mean	8.18	8.29	8.68	7.73	7.57	7.59
	SD	1.522	1.501	1.365	0.837	0.923	0.874
	SE	0.359	0.388	0.412	0.224	0.349	0.234
	Minimum	6.3	6.5	6.9	6.4	6.2	6.0
	Median	7.80	7.80	8.80	7.45	7.90	7.75
	Maximum	10.6	11.8	10.7	9.3	8.4	9.4
Change from Baseline	Mean	0.41	0.18	0.58	0.09	-0.17	-0.44
	SD	1.246	0.887	1.059	0.811	0.725	0.524
	SE	0.294	0.229	0.319	0.217	0.274	0.140
	Minimum	-1.7	-1.4	-0.8	-1.6	-0.8	-1.8
	Median	0.15	0.30	0.30	0.00	-0.50	-0.40
	Maximum	2.5	1.7	2.1	1.9	1.1	0.3

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.14
Summary Statistics for HbA1c (%) at Week 12 by Baseline BMI

Baseline BMI: >30 kg/m^2

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		29	33	34	36	37	36
n [1]		27	31	32	36	36	34
Number (%) of Values Carried Forward		2 (7%)	5 (16%)	2 (6%)	1 (3%)	2 (6%)	4 (12%)
Baseline	Mean	7.86	8.07	7.88	7.98	7.70	8.08
	SD	0.643	0.889	0.700	0.650	0.574	0.794
	SE	0.124	0.160	0.124	0.108	0.096	0.136
	Minimum	6.8	6.4	6.6	6.8	6.4	6.5
	Median	7.70	8.00	7.70	8.00	7.65	8.05
	Maximum	9.3	9.8	9.7	9.6	8.7	9.5
Week 12	Mean	8.26	8.20	7.65	7.99	7.27	7.59
	SD	1.320	1.289	0.847	0.958	0.775	1.004
	SE	0.254	0.232	0.150	0.160	0.129	0.172
	Minimum	6.2	6.3	6.2	6.0	5.5	5.8
	Median	8.00	7.70	7.55	8.00	7.25	7.50
	Maximum	11.8	10.8	9.9	10.4	9.4	9.9
Change from Baseline	Mean	0.40	0.13	-0.23	0.02	-0.43	-0.49
	SD	1.270	0.947	0.819	0.752	0.765	0.842
	SE	0.244	0.170	0.145	0.125	0.128	0.144
	Minimum	-1.7	-1.9	-2.3	-1.8	-2.5	-2.9
	Median	0.10	0.10	-0.25	0.00	-0.30	-0.35
	Maximum	2.8	2.5	2.2	2.0	0.9	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	54	56	60	56	56
Baseline	Mean	7.76	8.05	7.95	7.85	7.77	8.11
	SD	0.687	0.927	0.747	0.623	0.660	0.723
Week 12	Mean	8.21	8.18	7.88	7.87	7.39	7.69
	SD	1.339	1.279	1.161	0.874	0.836	0.994
Model-Adj Chg [2]	Mean	0.48	0.21	-0.07	0.02	-0.35	-0.37
	SE	0.115	0.119	0.114	0.108	0.113	0.115
Diff from Pbo [2]	Mean		-0.26	-0.55	-0.46	-0.82	-0.85
	95% CI		-0.59,0.06	-0.87,-0.23	-0.77,-0.15	-1.14,-0.51	-1.17,-0.52
	p-val[3]		0.115	<0.001	0.004	<0.001	<0.001

[1]Number of subjects with a value of HbA1c at baseline and at least one other post-baseline visit.
[2]Based on Model: Change = Baseline + Gender + Region + Prior Therapy + Treatment + Visit + Treatment*Visit + Baseline*Visit (repeated values over time). An unstructured variance-covariance structure was specified to account for repeated measures within the same subject.
[3]A closed test procedure will be used. Tests will be peformed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	57	Sum Weights	57
Mean	7.76491228	Sum Observations	442.6
Std Deviation	0.68673431	Variance	0.47160401
Skewness	0.19522354	Kurtosis	0.07939465
Uncorrected SS	3463.16	Corrected SS	26.4098246
Coeff Variation	8.84407039	Std Error Mean	0.09096018

Basic Statistical Measures

Location		Variability	
Mean	7.764912	Std Deviation	0.68673
Median	7.700000	Variance	0.47160
Mode	7.700000	Range	3.20000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	85.36606	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	826.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.3
99%	9.3
95%	9.2
90%	8.6
75% Q3	8.2
50% Median	7.7
25% Q1	7.3
10%	6.9
5%	6.6
1%	6.1
0% Min	6.1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.1	15	8.8	49
6.6	33	9.0	55
6.6	30	9.2	4
6.8	51	9.3	13
6.8	45	9.3	20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	8.05185185	Sum Observations	434.8
Std Deviation	0.9273091	Variance	0.85990217
Skewness	0.60946137	Kurtosis	-0.2365639
Uncorrected SS	3546.52	Corrected SS	45.5748148
Coeff Variation	11.5167183	Std Error Mean	0.12619078

Basic Statistical Measures

Location		Variability	
Mean	8.051852	Std Deviation	0.92731
Median	7.800000	Variance	0.85990
Mode	7.700000	Range	3.70000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	63.80697	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.1
99%	10.1
95%	9.8
90%	9.5
75% Q3	8.4
50% Median	7.8
25% Q1	7.5
10%	7.0
5%	6.8
1%	6.4
0% Min	6.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	47	9.7	1
6.4	29	9.8	7
6.8	38	9.8	35
6.8	24	10.1	3
6.9	44	10.1	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	7.94821429	Sum Observations	445.1
Std Deviation	0.74711349	Variance	0.55817857
Skewness	0.87390365	Kurtosis	0.44884588
Uncorrected SS	3568.45	Corrected SS	30.6998214
Coeff Variation	9.39976536	Std Error Mean	0.09983724

Basic Statistical Measures

Location		Variability	
Mean	7.948214	Std Deviation	0.74711
Median	7.700000	Variance	0.55818
Mode	7.600000	Range	3.30000
		Interquartile Range	0.85000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	79.61172	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.90
99%	9.90
95%	9.60
90%	9.20
75% Q3	8.30
50% Median	7.70
25% Q1	7.45
10%	7.30
5%	6.90
1%	6.60
0% Min	6.60

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	28	9.3	48
6.7	22	9.4	26
6.9	40	9.6	30
6.9	9	9.7	29
7.2	21	9.9	33

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	60	Sum Weights	60
Mean	7.84666667	Sum Observations	470.8
Std Deviation	0.62286018	Variance	0.3879548
Skewness	0.07556406	Kurtosis	-0.2067483
Uncorrected SS	3717.1	Corrected SS	22.8893333
Coeff Variation	7.93789523	Std Error Mean	0.0804109

Basic Statistical Measures

Location		Variability	
Mean	7.846667	Std Deviation	0.62286
Median	7.900000	Variance	0.38795
Mode	7.500000	Range	3.00000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	97.58212	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	915	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.50
99%	9.50
95%	8.85
90%	8.60
75% Q3	8.30
50% Median	7.90
25% Q1	7.40
10%	7.05
5%	6.85
1%	6.50
0% Min	6.50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	24	8.7	53
6.6	5	8.8	27
6.8	3	8.9	20
6.9	44	9.0	29
7.0	15	9.5	22

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	7.77321429	Sum Observations	435.3
Std Deviation	0.65988734	Variance	0.4354513
Skewness	0.09151171	Kurtosis	-0.2864215
Uncorrected SS	3407.63	Corrected SS	23.9498214
Coeff Variation	8.48924671	Std Error Mean	0.08818115

Basic Statistical Measures

Location		Variability	
Mean	7.773214	Std Deviation	0.65989
Median	7.750000	Variance	0.43545
Mode	8.400000	Range	3.20000
		Interquartile Range	1.05000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	88.15052	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.60
99%	9.60
95%	8.70
90%	8.60
75% Q3	8.35
50% Median	7.75
25% Q1	7.30
10%	6.80
5%	6.70
1%	6.40
0% Min	6.40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	39	8.6	26
6.7	21	8.6	44
6.7	14	8.7	24
6.8	53	8.7	47
6.8	51	9.6	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	8.10714286	Sum Observations	454
Std Deviation	0.72308861	Variance	0.52285714
Skewness	0.02661945	Kurtosis	-0.5175518
Uncorrected SS	3709.4	Corrected SS	28.7571429
Coeff Variation	8.9191547	Std Error Mean	0.09662678

Basic Statistical Measures

Location		Variability	
Mean	8.107143	Std Deviation	0.72309
Median	8.100000	Variance	0.52286
Mode	7.700000	Range	2.80000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	83.90161	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.5
99%	9.5
95%	9.5
90%	9.1
75% Q3	8.6
50% Median	8.1
25% Q1	7.7
10%	7.1
5%	6.8
1%	6.7
0% Min	6.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Baseline Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.7	48	9.2	26
6.7	9	9.3	25
6.8	32	9.5	4
6.9	38	9.5	33
7.1	42	9.5	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	49	Sum Weights	49
Mean	8.21428571	Sum Observations	402.5
Std Deviation	1.33868717	Variance	1.79208333
Skewness	0.79519542	Kurtosis	0.14586137
Uncorrected SS	3392.27	Corrected SS	86.02
Coeff Variation	16.2970612	Std Error Mean	0.19124102

Basic Statistical Measures

Location		Variability	
Mean	8.214286	Std Deviation	1.33869
Median	7.900000	Variance	1.79208
Mode	7.600000	Range	5.60000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	42.95253	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	612.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.8
99%	11.8
95%	10.6
90%	10.2
75% Q3	8.8
50% Median	7.9
25% Q1	7.3
10%	6.7
5%	6.3
1%	6.2
0% Min	6.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	19	10.2	44
6.3	32	10.3	42
6.3	5	10.6	36
6.4	14	11.4	46
6.7	1	11.8	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	46	Sum Weights	46
Mean	8.1826087	Sum Observations	376.4
Std Deviation	1.27928875	Variance	1.63657971
Skewness	0.79356388	Kurtosis	0.22111005
Uncorrected SS	3153.58	Corrected SS	73.646087
Coeff Variation	15.6342409	Std Error Mean	0.18862084

Basic Statistical Measures

Location		Variability	
Mean	8.182609	Std Deviation	1.27929
Median	7.750000	Variance	1.63658
Mode	7.600000	Range	5.50000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	43.38126	Pr > |t|	<.0001
Sign	M	23	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	540.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.80
99%	11.80
95%	10.60
90%	10.10
75% Q3	9.00
50% Median	7.75
25% Q1	7.30
10%	6.60
5%	6.50
1%	6.30
0% Min	6.30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=2.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	23	10.1	4
6.5	42	10.3	41
6.5	40	10.6	2
6.6	33	10.8	38
6.6	32	11.8	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	7.88113208	Sum Observations	417.7
Std Deviation	1.16140773	Variance	1.34886792
Skewness	0.94667847	Kurtosis	0.45232861
Uncorrected SS	3362.09	Corrected SS	70.1411321
Coeff Variation	14.7365597	Std Error Mean	0.15953162

Basic Statistical Measures

Location		Variability	
Mean	7.881132	Std Deviation	1.16141
Median	7.600000	Variance	1.34887
Mode	7.600000	Range	4.80000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	49.40169	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.0
99%	11.0
95%	10.4
90%	9.8
75% Q3	8.6
50% Median	7.6
25% Q1	7.1
10%	6.6
5%	6.3
1%	6.2
0% Min	6.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=7.5 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	26	9.9	47
6.2	22	10.2	33
6.3	50	10.4	3
6.4	40	10.7	5
6.6	36	11.0	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	60	Sum Weights	60
Mean	7.87166667	Sum Observations	472.3
Std Deviation	0.87393357	Variance	0.76375989
Skewness	0.13188438	Kurtosis	-0.3963064
Uncorrected SS	3762.85	Corrected SS	45.0618333
Coeff Variation	11.1022685	Std Error Mean	0.11282434

Basic Statistical Measures

Location		Variability	
Mean	7.871667	Std Deviation	0.87393
Median	7.850000	Variance	0.76376
Mode	8.500000	Range	4.00000
		Interquartile Range	1.25000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	69.76922	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	915	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.00
99%	10.00
95%	9.40
90%	9.05
75% Q3	8.50
50% Median	7.85
25% Q1	7.25
10%	6.75
5%	6.45
1%	6.00
0% Min	6.00

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=15 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.0	32	9.2	54
6.4	49	9.3	16
6.4	24	9.5	4
6.5	44	9.5	53
6.5	35	10.0	17

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	7.39074074	Sum Observations	399.1
Std Deviation	0.8358181	Variance	0.69859189
Skewness	0.33756447	Kurtosis	0.17470373
Uncorrected SS	2986.67	Corrected SS	37.0253704
Coeff Variation	11.3089896	Std Error Mean	0.11374044

Basic Statistical Measures

Location		Variability	
Mean	7.390741	Std Deviation	0.83582
Median	7.300000	Variance	0.69859
Mode	7.100000	Range	4.20000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	64.97901	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	742.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.7
99%	9.7
95%	8.9
90%	8.5
75% Q3	7.9
50% Median	7.3
25% Q1	6.9
10%	6.3
5%	6.2
1%	5.5
0% Min	5.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=30 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	19	8.6	15
6.1	16	8.8	7
6.2	32	8.9	5
6.2	21	8.9	40
6.2	14	9.7	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	52	Sum Weights	52
Mean	7.69423077	Sum Observations	400.1
Std Deviation	0.99358994	Variance	0.98722097
Skewness	0.26914814	Kurtosis	-0.3835877
Uncorrected SS	3128.81	Corrected SS	50.3482692
Coeff Variation	12.9134408	Std Error Mean	0.13778613

Basic Statistical Measures

Location		Variability	
Mean	7.694231	Std Deviation	0.99359
Median	7.650000	Variance	0.98722
Mode	8.000000	Range	4.10000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	55.84184	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	689	Pr >= |S| <.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.90
99%	9.90
95%	9.70
90%	8.90
75% Q3	8.40
50% Median	7.65
25% Q1	6.90
10%	6.50
5%	6.10
1%	5.80
0% Min	5.80

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Summary Statistics Output for Week 12 Visit

---------- Randomized treatment code=45 mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.8	9	9.0	21
6.0	29	9.4	17
6.1	48	9.7	26
6.3	11	9.8	25
6.3	8	9.9	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFFMIXED
Dependent Variable	STDCHGBL
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Prasad-Rao-Jeske-Kackar-Harville
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SEX	2	F M
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5 mg 7.5 mg 15 mg 30 mg 45 mg
REGIONCD	3	US/Canada Eastern Europe Western Europe
avisnum	3	Week 4 Week 8 Week 12

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Covariance Parameters	6
Columns in X	39
Columns in Z	0
Subjects	339
Max Obs Per Subject	3
Observations Used	970
Observations Not Used	0
Total Observations	970

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	2061.07448355	
1	2	1321.68511437	0.00031093
2	1	1321.61904059	0.00000044
3	1	1321.61894899	0.00000000

Convergence criteria met.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	0.2403
UN(2,1)	SUBJID	0.2771
UN(2,2)	SUBJID	0.5042
UN(3,1)	SUBJID	0.2789
UN(3,2)	SUBJID	0.4973
UN(3,3)	SUBJID	0.7023

Fit Statistics

-2 Res Log Likelihood	1321.6
AIC (smaller is better)	1333.6
AICC (smaller is better)	1333.7
BIC (smaller is better)	1356.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
5	739.46	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Estimate	Standard Error	DF
Intercept						0.6634	0.5351	320
SEX	F					0.06835	0.05354	325
SEX	M					0		
TRTTYPCD		Diet & Exercise				-0.3369	0.05459	325
TRTTYPCD		Monotherapy				0		
TRTCD				Placebo		0.8453	0.1631	320
TRTCD				2.5 mg		0.5820	0.1648	321
TRTCD				7.5 mg		0.2930	0.1612	313
TRTCD				15 mg		0.3866	0.1579	309
TRTCD				30 mg		0.02075	0.1619	312
TRTCD				45 mg		0		
REGIONCD			US/Canada			-0.2592	0.06306	325
REGIONCD			Eastern Europe			-0.1218	0.06606	324
REGIONCD			Western Europe			0		
BLHBA1C						-0.1030	0.06465	322
avisnum					Week 4	-0.7783	0.4041	314
avisnum					Week 8	-0.01806	0.3026	305
avisnum					Week 12	0		
TRTCD*avisnum				Placebo	Week 4	-0.2717	0.1231	315
TRTCD*avisnum				Placebo	Week 8	-0.2169	0.09257	306
TRTCD*avisnum				Placebo	Week 12	0		
TRTCD*avisnum				2.5 mg	Week 4	-0.2677	0.1250	312

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha
Intercept						1.24	0.2160	0.05
SEX	F					1.28	0.2026	0.05
SEX	M						.	
TRTTYPCD		Diet & Exercise				-6.17	<.0001	0.05
TRTTYPCD		Monotherapy					.	
TRTCD				Placebo		5.18	<.0001	0.05
TRTCD				2.5 mg		3.53	0.0005	0.05
TRTCD				7.5 mg		1.82	0.0701	0.05
TRTCD				15 mg		2.45	0.0149	0.05
TRTCD				30 mg		0.13	0.8981	0.05
TRTCD				45 mg			.	
REGIONCD			US/Canada			-4.11	<.0001	0.05
REGIONCD			Eastern Europe			-1.84	0.0661	0.05
REGIONCD			Western Europe				.	
BLHBA1C						-1.59	0.1122	0.05
avisnum					Week 4	-1.93	0.0550	0.05
avisnum					Week 8	-0.06	0.9524	0.05
avisnum					Week 12		.	
TRTCD*avisnum				Placebo	Week 4	-2.21	0.0280	0.05
TRTCD*avisnum				Placebo	Week 8	-2.34	0.0198	0.05
TRTCD*avisnum				Placebo	Week 12		.	
TRTCD*avisnum				2.5 mg	Week 4	-2.14	0.0330	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Lower	Upper
Intercept						-0.3895	1.7162
SEX	F					-0.03698	0.1737
SEX	M						
TRTTYPCD		Diet & Exercise				-0.4443	-0.2295
TRTTYPCD		Monotherapy					
TRTCD				Placebo		0.5244	1.1662
TRTCD				2.5 mg		0.2577	0.9062
TRTCD				7.5 mg		-0.02417	0.6101
TRTCD				15 mg		0.07592	0.6973
TRTCD				30 mg		-0.2977	0.3392
TRTCD				45 mg			
REGIONCD			US/Canada			-0.3833	-0.1352
REGIONCD			Eastern Europe			-0.2518	0.008143
REGIONCD			Western Europe				
BLHBA1C						-0.2302	0.02422
avisnum					Week 4	-1.5733	0.01671
avisnum					Week 8	-0.6134	0.5773
avisnum					Week 12		
TRTCD*avisnum				Placebo	Week 4	-0.5138	-0.02958
TRTCD*avisnum				Placebo	Week 8	-0.3990	-0.03473
TRTCD*avisnum				Placebo	Week 12		
TRTCD*avisnum				2.5 mg	Week 4	-0.5136	-0.02182

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Estimate	Standard Error	DF
TRTCD*avisnum				2.5 mg	Week 8	-0.02734	0.09352	307
TRTCD*avisnum				2.5 mg	Week 12	0		
TRTCD*avisnum				7.5 mg	Week 4	-0.1220	0.1207	311
TRTCD*avisnum				7.5 mg	Week 8	0.03077	0.09050	308
TRTCD*avisnum				7.5 mg	Week 12	0		
TRTCD*avisnum				15 mg	Week 4	-0.1501	0.1179	311
TRTCD*avisnum				15 mg	Week 8	-0.05129	0.08791	307
TRTCD*avisnum				15 mg	Week 12	0		
TRTCD*avisnum				30 mg	Week 4	0.04991	0.1210	311
TRTCD*avisnum				30 mg	Week 8	-0.00164	0.09070	308
TRTCD*avisnum				30 mg	Week 12	0		
TRTCD*avisnum				45 mg	Week 4	0		
TRTCD*avisnum				45 mg	Week 8	0		
TRTCD*avisnum				45 mg	Week 12	0		
BLHBA1C*avisnum					Week 4	0.1053	0.04875	313
BLHBA1C*avisnum					Week 8	-0.00199	0.03652	306
BLHBA1C*avisnum					Week 12	0		

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha
TRTCD*avisnum				2.5 mg	Week 8	-0.29	0.7703	0.05
TRTCD*avisnum				2.5 mg	Week 12		.	
TRTCD*avisnum				7.5 mg	Week 4	-1.01	0.3133	0.05
TRTCD*avisnum				7.5 mg	Week 8	0.34	0.7341	0.05
TRTCD*avisnum				7.5 mg	Week 12		.	
TRTCD*avisnum				15 mg	Week 4	-1.27	0.2039	0.05
TRTCD*avisnum				15 mg	Week 8	-0.58	0.5600	0.05
TRTCD*avisnum				15 mg	Week 12		.	
TRTCD*avisnum				30 mg	Week 4	0.41	0.6804	0.05
TRTCD*avisnum				30 mg	Week 8	-0.02	0.9856	0.05
TRTCD*avisnum				30 mg	Week 12		.	
TRTCD*avisnum				45 mg	Week 4		.	
TRTCD*avisnum				45 mg	Week 8		.	
TRTCD*avisnum				45 mg	Week 12		.	
BLHBA1C*avisnum					Week 4	2.16	0.0315	0.05
BLHBA1C*avisnum					Week 8	-0.05	0.9565	0.05
BLHBA1C*avisnum					Week 12		.	

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Lower	Upper
TRTCD*avisnum				2.5 mg	Week 8	-0.2114	0.1567
TRTCD*avisnum				2.5 mg	Week 12		
TRTCD*avisnum				7.5 mg	Week 4	-0.3595	0.1156
TRTCD*avisnum				7.5 mg	Week 8	-0.1473	0.2088
TRTCD*avisnum				7.5 mg	Week 12		
TRTCD*avisnum				15 mg	Week 4	-0.3820	0.08188
TRTCD*avisnum				15 mg	Week 8	-0.2243	0.1217
TRTCD*avisnum				15 mg	Week 12		
TRTCD*avisnum				30 mg	Week 4	-0.1882	0.2880
TRTCD*avisnum				30 mg	Week 8	-0.1801	0.1768
TRTCD*avisnum				30 mg	Week 12		
TRTCD*avisnum				45 mg	Week 4		
TRTCD*avisnum				45 mg	Week 8		
TRTCD*avisnum				45 mg	Week 12		
BLHBA1C*avisnum					Week 4	0.009403	0.2012
BLHBA1C*avisnum					Week 8	-0.07385	0.06986
BLHBA1C*avisnum					Week 12		

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	325	1.63	0.2026
TRTTYPCD	1	325	38.07	<.0001
TRTCD	5	318	9.49	<.0001
REGIONCD	2	324	8.45	0.0003
BLHBA1C	1	324	2.05	0.1531
avisnum	2	309	4.94	0.0077
TRTCD*avisnum	10	458	2.40	0.0088
BLHBA1C*avisnum	2	309	4.98	0.0074

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row1	Row2	Row3	Row4
Intercept						1	1	1	1
SEX	F					0.5103	0.5103	0.5103	0.5103
SEX	M					0.4897	0.4897	0.4897	0.4897
TRTTYPCD		Diet & Exercise				0.4052	0.4052	0.4052	0.4052
TRTTYPCD		Monotherapy				0.5948	0.5948	0.5948	0.5948
TRTCD				Placebo		1	1	1	
TRTCD				2.5 mg					1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row1	Row2	Row3	Row4
TRTCD				7.5 mg					
TRTCD				15 mg					
TRTCD				30 mg					
TRTCD				45 mg					
REGIONCD			US/Canada			0.3134	0.3134	0.3134	0.3134
REGIONCD			Eastern Europe			0.2825	0.2825	0.2825	0.2825
REGIONCD			Western Europe			0.4041	0.4041	0.4041	0.4041
BLHBA1C						7.9018	7.9018	7.9018	7.9018
avisnum					Week 4	1			1
avisnum					Week 8		1		
avisnum					Week 12			1	
TRTCD*avisnum				Placebo	Week 4	1			
TRTCD*avisnum				Placebo	Week 8		1		
TRTCD*avisnum				Placebo	Week 12			1	
TRTCD*avisnum				2.5 mg	Week 4				1
TRTCD*avisnum				2.5 mg	Week 8				
TRTCD*avisnum				2.5 mg	Week 12				
TRTCD*avisnum				7.5 mg	Week 4				
TRTCD*avisnum				7.5 mg	Week 8				
TRTCD*avisnum				7.5 mg	Week 12				
TRTCD*avisnum				15 mg	Week 4				
TRTCD*avisnum				15 mg	Week 8				

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row1	Row2	Row3	Row4
TRTCD*avisnum				15 mg	Week 12				
TRTCD*avisnum				30 mg	Week 4				
TRTCD*avisnum				30 mg	Week 8				
TRTCD*avisnum				30 mg	Week 12				
TRTCD*avisnum				45 mg	Week 4				
TRTCD*avisnum				45 mg	Week 8				
TRTCD*avisnum				45 mg	Week 12				
BLHBA1C*avisnum					Week 4	7.9018			7.9018
BLHBA1C*avisnum					Week 8		7.9018		
BLHBA1C*avisnum					Week 12			7.9018	

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row5	Row6	Row7	Row8
Intercept						1	1	1	1
SEX	F					0.5103	0.5103	0.5103	0.5103
SEX	M					0.4897	0.4897	0.4897	0.4897
TRTTYPCD		Diet & Exercise				0.4052	0.4052	0.4052	0.4052

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row5	Row6	Row7	Row8
TRTTYPCD		Monotherapy				0.5948	0.5948	0.5948	0.5948
TRTCD				Placebo					
TRTCD				2.5 mg		1	1		
TRTCD				7.5 mg				1	1
TRTCD				15 mg					
TRTCD				30 mg					
TRTCD				45 mg					
REGIONCD			US/Canada			0.3134	0.3134	0.3134	0.3134
REGIONCD			Eastern Europe			0.2825	0.2825	0.2825	0.2825
REGIONCD			Western Europe			0.4041	0.4041	0.4041	0.4041
BLHBA1C						7.9018	7.9018	7.9018	7.9018
avisnum					Week 4			1	
avisnum					Week 8	1			1
avisnum					Week 12		1		
TRTCD*avisnum				Placebo	Week 4				
TRTCD*avisnum				Placebo	Week 8				
TRTCD*avisnum				Placebo	Week 12				
TRTCD*avisnum				2.5 mg	Week 4				
TRTCD*avisnum				2.5 mg	Week 8	1			
TRTCD*avisnum				2.5 mg	Week 12		1		
TRTCD*avisnum				7.5 mg	Week 4			1	
TRTCD*avisnum				7.5 mg	Week 8				1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row5	Row6	Row7	Row8
TRTCD*avisnum				7.5 mg	Week 12				
TRTCD*avisnum				15 mg	Week 4				
TRTCD*avisnum				15 mg	Week 8				
TRTCD*avisnum				15 mg	Week 12				
TRTCD*avisnum				30 mg	Week 4				
TRTCD*avisnum				30 mg	Week 8				
TRTCD*avisnum				30 mg	Week 12				
TRTCD*avisnum				45 mg	Week 4				
TRTCD*avisnum				45 mg	Week 8				
TRTCD*avisnum				45 mg	Week 12				
BLHBA1C*avisnum					Week 4			7.9018	
BLHBA1C*avisnum					Week 8	7.9018			7.9018
BLHBA1C*avisnum					Week 12		7.9018		

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row9	Row10	Row11	Row12
Intercept						1	1	1	1
SEX	F					0.5103	0.5103	0.5103	0.5103
SEX	M					0.4897	0.4897	0.4897	0.4897
TRTTYPCD		Diet & Exercise				0.4052	0.4052	0.4052	0.4052
TRTTYPCD		Monotherapy				0.5948	0.5948	0.5948	0.5948
TRTCD				Placebo					
TRTCD				2.5 mg					
TRTCD				7.5 mg		1			
TRTCD				15 mg			1	1	1
TRTCD				30 mg					
TRTCD				45 mg					
REGIONCD			US/Canada			0.3134	0.3134	0.3134	0.3134
REGIONCD			Eastern Europe			0.2825	0.2825	0.2825	0.2825
REGIONCD			Western Europe			0.4041	0.4041	0.4041	0.4041
BLHBA1C						7.9018	7.9018	7.9018	7.9018
avisnum					Week 4		1		
avisnum					Week 8			1	
avisnum					Week 12	1			1
TRTCD*avisnum				Placebo	Week 4				
TRTCD*avisnum				Placebo	Week 8				
TRTCD*avisnum				Placebo	Week 12				
TRTCD*avisnum				2.5 mg	Week 4				

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row9	Row10	Row11	Row12
TRTCD*avisnum				2.5 mg	Week 8				
TRTCD*avisnum				2.5 mg	Week 12				
TRTCD*avisnum				7.5 mg	Week 4				
TRTCD*avisnum				7.5 mg	Week 8				
TRTCD*avisnum				7.5 mg	Week 12	1			
TRTCD*avisnum				15 mg	Week 4		1		
TRTCD*avisnum				15 mg	Week 8			1	
TRTCD*avisnum				15 mg	Week 12				1
TRTCD*avisnum				30 mg	Week 4				
TRTCD*avisnum				30 mg	Week 8				
TRTCD*avisnum				30 mg	Week 12				
TRTCD*avisnum				45 mg	Week 4				
TRTCD*avisnum				45 mg	Week 8				
TRTCD*avisnum				45 mg	Week 12				
BLHBA1C*avisnum					Week 4		7.9018		
BLHBA1C*avisnum					Week 8			7.9018	
BLHBA1C*avisnum					Week 12	7.9018			7.9018

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row13	Row14	Row15	Row16
Intercept						1	1	1	1
SEX	F					0.5103	0.5103	0.5103	0.5103
SEX	M					0.4897	0.4897	0.4897	0.4897
TRTTYPCD		Diet & Exercise				0.4052	0.4052	0.4052	0.4052
TRTTYPCD		Monotherapy				0.5948	0.5948	0.5948	0.5948
TRTCD				Placebo					
TRTCD				2.5 mg					
TRTCD				7.5 mg					
TRTCD				15 mg					
TRTCD				30 mg		1	1	1	
TRTCD				45 mg					1
REGIONCD			US/Canada			0.3134	0.3134	0.3134	0.3134
REGIONCD			Eastern Europe			0.2825	0.2825	0.2825	0.2825
REGIONCD			Western Europe			0.4041	0.4041	0.4041	0.4041
BLHBA1C						7.9018	7.9018	7.9018	7.9018
avisnum					Week 4	1			1
avisnum					Week 8		1		
avisnum					Week 12			1	
TRTCD*avisnum				Placebo	Week 4				
TRTCD*avisnum				Placebo	Week 8				
TRTCD*avisnum				Placebo	Week 12				
TRTCD*avisnum				2.5 mg	Week 4				

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row13	Row14	Row15	Row16
TRTCD*avisnum				2.5 mg	Week 8				
TRTCD*avisnum				2.5 mg	Week 12				
TRTCD*avisnum				7.5 mg	Week 4				
TRTCD*avisnum				7.5 mg	Week 8				
TRTCD*avisnum				7.5 mg	Week 12				
TRTCD*avisnum				15 mg	Week 4				
TRTCD*avisnum				15 mg	Week 8				
TRTCD*avisnum				15 mg	Week 12				
TRTCD*avisnum				30 mg	Week 4	1			
TRTCD*avisnum				30 mg	Week 8		1		
TRTCD*avisnum				30 mg	Week 12			1	
TRTCD*avisnum				45 mg	Week 4				1
TRTCD*avisnum				45 mg	Week 8				
TRTCD*avisnum				45 mg	Week 12				
BLHBA1C*avisnum					Week 4	7.9018			7.9018
BLHBA1C*avisnum					Week 8		7.9018		
BLHBA1C*avisnum					Week 12			7.9018	

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row17	Row18
Intercept						1	1
SEX	F					0.5103	0.5103
SEX	M					0.4897	0.4897
TRTTYPCD		Diet & Exercise				0.4052	0.4052
TRTTYPCD		Monotherapy				0.5948	0.5948
TRTCD				Placebo			
TRTCD				2.5 mg			
TRTCD				7.5 mg			
TRTCD				15 mg			
TRTCD				30 mg			
TRTCD				45 mg		1	1
REGIONCD			US/Canada			0.3134	0.3134
REGIONCD			Eastern Europe			0.2825	0.2825
REGIONCD			Western Europe			0.4041	0.4041
BLHBA1C						7.9018	7.9018
avisnum					Week 4		
avisnum					Week 8	1	
avisnum					Week 12		1
TRTCD*avisnum				Placebo	Week 4		
TRTCD*avisnum				Placebo	Week 8		
TRTCD*avisnum				Placebo	Week 12		
TRTCD*avisnum				2.5 mg	Week 4		

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD*avisnum Least Squares Means Using WORK.EFFMIXED Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Visit number for reporting	Row17	Row18
TRTCD*avisnum				2.5 mg	Week 8		
TRTCD*avisnum				2.5 mg	Week 12		
TRTCD*avisnum				7.5 mg	Week 4		
TRTCD*avisnum				7.5 mg	Week 8		
TRTCD*avisnum				7.5 mg	Week 12		
TRTCD*avisnum				15 mg	Week 4		
TRTCD*avisnum				15 mg	Week 8		
TRTCD*avisnum				15 mg	Week 12		
TRTCD*avisnum				30 mg	Week 4		
TRTCD*avisnum				30 mg	Week 8		
TRTCD*avisnum				30 mg	Week 12		
TRTCD*avisnum				45 mg	Week 4		
TRTCD*avisnum				45 mg	Week 8	1	
TRTCD*avisnum				45 mg	Week 12		1
BLHBA1C*avisnum					Week 4		
BLHBA1C*avisnum					Week 8	7.9018	
BLHBA1C*avisnum					Week 12		7.9018

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD*avisnum	Placebo	Week 4	WORK.EFFMIXED	0.2599	0.06564	326	3.96	<.0001	0.05
TRTCD*avisnum	Placebo	Week 8	WORK.EFFMIXED	0.2271	0.09582	322	2.37	0.0184	0.05
TRTCD*avisnum	Placebo	Week 12	WORK.EFFMIXED	0.4778	0.1152	326	4.15	<.0001	0.05
TRTCD*avisnum	2.5 mg	Week 4	WORK.EFFMIXED	0.000633	0.06725	323	0.01	0.9925	0.05
TRTCD*avisnum	2.5 mg	Week 8	WORK.EFFMIXED	0.1533	0.09971	332	1.54	0.1251	0.05
TRTCD*avisnum	2.5 mg	Week 12	WORK.EFFMIXED	0.2145	0.1194	327	1.80	0.0734	0.05
TRTCD*avisnum	7.5 mg	Week 4	WORK.EFFMIXED	-0.1426	0.06570	323	-2.17	0.0307	0.05
TRTCD*avisnum	7.5 mg	Week 8	WORK.EFFMIXED	-0.07759	0.09585	318	-0.81	0.4188	0.05
TRTCD*avisnum	7.5 mg	Week 12	WORK.EFFMIXED	-0.07454	0.1135	312	-0.66	0.5120	0.05
TRTCD*avisnum	15 mg	Week 4	WORK.EFFMIXED	-0.07712	0.06357	326	-1.21	0.2260	0.05
TRTCD*avisnum	15 mg	Week 8	WORK.EFFMIXED	-0.06602	0.09174	310	-0.72	0.4723	0.05
TRTCD*avisnum	15 mg	Week 12	WORK.EFFMIXED	0.01909	0.1083	303	0.18	0.8601	0.05
TRTCD*avisnum	30 mg	Week 4	WORK.EFFMIXED	-0.2430	0.06581	323	-3.69	0.0003	0.05
TRTCD*avisnum	30 mg	Week 8	WORK.EFFMIXED	-0.3822	0.09577	315	-3.99	<.0001	0.05
TRTCD*avisnum	30 mg	Week 12	WORK.EFFMIXED	-0.3467	0.1133	309	-3.06	0.0024	0.05
TRTCD*avisnum	45 mg	Week 4	WORK.EFFMIXED	-0.3136	0.06624	326	-4.74	<.0001	0.05
TRTCD*avisnum	45 mg	Week 8	WORK.EFFMIXED	-0.4013	0.09636	317	-4.16	<.0001	0.05
TRTCD*avisnum	45 mg	Week 12	WORK.EFFMIXED	-0.3675	0.1145	314	-3.21	0.0015	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Lower	Upper
TRTCD*avisnum	Placebo	Week 4	0.1308	0.3891
TRTCD*avisnum	Placebo	Week 8	0.03855	0.4156
TRTCD*avisnum	Placebo	Week 12	0.2512	0.7043
TRTCD*avisnum	2.5 mg	Week 4	-0.1317	0.1329
TRTCD*avisnum	2.5 mg	Week 8	-0.04285	0.3494
TRTCD*avisnum	2.5 mg	Week 12	-0.02041	0.4493
TRTCD*avisnum	7.5 mg	Week 4	-0.2719	-0.01336
TRTCD*avisnum	7.5 mg	Week 8	-0.2662	0.1110
TRTCD*avisnum	7.5 mg	Week 12	-0.2980	0.1489
TRTCD*avisnum	15 mg	Week 4	-0.2022	0.04794
TRTCD*avisnum	15 mg	Week 8	-0.2465	0.1145
TRTCD*avisnum	15 mg	Week 12	-0.1940	0.2321
TRTCD*avisnum	30 mg	Week 4	-0.3724	-0.1135
TRTCD*avisnum	30 mg	Week 8	-0.5706	-0.1938
TRTCD*avisnum	30 mg	Week 12	-0.5696	-0.1239
TRTCD*avisnum	45 mg	Week 4	-0.4439	-0.1833
TRTCD*avisnum	45 mg	Week 8	-0.5909	-0.2117
TRTCD*avisnum	45 mg	Week 12	-0.5929	-0.1421

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	Placebo	Week 4	Placebo	Week 8	WORK.EFFMIXED	0.03288	0.06025	313
TRTCD*avisnum	Placebo	Week 4	Placebo	Week 12	WORK.EFFMIXED	-0.2178	0.08742	318
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 4	WORK.EFFMIXED	0.2593	0.09463	324
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 8	WORK.EFFMIXED	0.1066	0.1200	396
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 12	WORK.EFFMIXED	0.04549	0.1367	411
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 4	WORK.EFFMIXED	0.4026	0.09307	324
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 8	WORK.EFFMIXED	0.3375	0.1163	385
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 12	WORK.EFFMIXED	0.3345	0.1313	398
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 4	WORK.EFFMIXED	0.3371	0.09130	326
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 8	WORK.EFFMIXED	0.3260	0.1127	380
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 12	WORK.EFFMIXED	0.2408	0.1265	393
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 4	WORK.EFFMIXED	0.5029	0.09246	324
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 8	WORK.EFFMIXED	0.6421	0.1157	382
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 12	WORK.EFFMIXED	0.6067	0.1305	394
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 4	WORK.EFFMIXED	0.5736	0.09373	326
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.6613	0.1170	383
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.6274	0.1324	399
TRTCD*avisnum	Placebo	Week 8	Placebo	Week 12	WORK.EFFMIXED	-0.2507	0.06591	305
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 4	WORK.EFFMIXED	0.2264	0.1176	389
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 8	WORK.EFFMIXED	0.07377	0.1389	327
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 12	WORK.EFFMIXED	0.01261	0.1536	384
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 4	WORK.EFFMIXED	0.3697	0.1164	387

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	Placebo	Week 4	Placebo	Week 8	0.55	0.5857	0.05	-0.08568	0.1514
TRTCD*avisnum	Placebo	Week 4	Placebo	Week 12	-2.49	0.0132	0.05	-0.3898	-0.04583
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 4	2.74	0.0065	0.05	0.07314	0.4455
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 8	0.89	0.3745	0.05	-0.1292	0.3425
TRTCD*avisnum	Placebo	Week 4	2.5 mg	Week 12	0.33	0.7396	0.05	-0.2233	0.3143
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 4	4.33	<.0001	0.05	0.2195	0.5857
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 8	2.90	0.0039	0.05	0.1088	0.5663
TRTCD*avisnum	Placebo	Week 4	7.5 mg	Week 12	2.55	0.0112	0.05	0.07636	0.5926
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 4	3.69	0.0003	0.05	0.1574	0.5167
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 8	2.89	0.0040	0.05	0.1043	0.5476
TRTCD*avisnum	Placebo	Week 4	15 mg	Week 12	1.90	0.0577	0.05	-0.00790	0.4896
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 4	5.44	<.0001	0.05	0.3210	0.6848
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 8	5.55	<.0001	0.05	0.4148	0.8695
TRTCD*avisnum	Placebo	Week 4	30 mg	Week 12	4.65	<.0001	0.05	0.3501	0.8633
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 4	6.12	<.0001	0.05	0.3892	0.7580
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 8	5.65	<.0001	0.05	0.4311	0.8914
TRTCD*avisnum	Placebo	Week 4	45 mg	Week 12	4.74	<.0001	0.05	0.3671	0.8878
TRTCD*avisnum	Placebo	Week 8	Placebo	Week 12	-3.80	0.0002	0.05	-0.3804	-0.1210
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 4	1.92	0.0550	0.05	-0.00485	0.4577
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 8	0.53	0.5957	0.05	-0.1995	0.3470
TRTCD*avisnum	Placebo	Week 8	2.5 mg	Week 12	0.08	0.9346	0.05	-0.2895	0.3147
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 4	3.18	0.0016	0.05	0.1409	0.5984

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 8	WORK.EFFMIXED	0.3047	0.1357	320
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 12	WORK.EFFMIXED	0.3016	0.1487	372
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 4	WORK.EFFMIXED	0.3042	0.1149	387
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 8	WORK.EFFMIXED	0.2931	0.1325	316
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 12	WORK.EFFMIXED	0.2080	0.1444	367
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 4	WORK.EFFMIXED	0.4700	0.1158	387
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 8	WORK.EFFMIXED	0.6093	0.1349	318
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 12	WORK.EFFMIXED	0.5738	0.1479	369
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 4	WORK.EFFMIXED	0.5407	0.1169	388
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 8	WORK.EFFMIXED	0.6284	0.1365	320
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 12	WORK.EFFMIXED	0.5946	0.1499	373
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 4	WORK.EFFMIXED	0.4771	0.1339	414
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 8	WORK.EFFMIXED	0.3245	0.1529	389
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 12	WORK.EFFMIXED	0.2633	0.1664	327
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 4	WORK.EFFMIXED	0.6204	0.1327	411
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 8	WORK.EFFMIXED	0.5554	0.1500	382
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 12	WORK.EFFMIXED	0.5523	0.1619	319
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 4	WORK.EFFMIXED	0.5549	0.1315	409
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 8	WORK.EFFMIXED	0.5438	0.1471	378
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 12	WORK.EFFMIXED	0.4587	0.1579	315
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 4	WORK.EFFMIXED	0.7207	0.1323	411
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 8	WORK.EFFMIXED	0.8600	0.1493	380

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 8	2.25	0.0254	0.05	0.03769	0.5716
TRTCD*avisnum	Placebo	Week 8	7.5 mg	Week 12	2.03	0.0433	0.05	0.009169	0.5940
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 4	2.65	0.0084	0.05	0.07827	0.5301
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 8	2.21	0.0277	0.05	0.03239	0.5538
TRTCD*avisnum	Placebo	Week 8	15 mg	Week 12	1.44	0.1508	0.05	-0.07606	0.4920
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 4	4.06	<.0001	0.05	0.2423	0.6977
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 8	4.52	<.0001	0.05	0.3438	0.8747
TRTCD*avisnum	Placebo	Week 8	30 mg	Week 12	3.88	0.0001	0.05	0.2830	0.8646
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 4	4.62	<.0001	0.05	0.3108	0.7706
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 8	4.60	<.0001	0.05	0.3599	0.8969
TRTCD*avisnum	Placebo	Week 8	45 mg	Week 12	3.97	<.0001	0.05	0.2998	0.8893
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 4	3.56	0.0004	0.05	0.2140	0.7403
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 8	2.12	0.0344	0.05	0.02390	0.6250
TRTCD*avisnum	Placebo	Week 12	2.5 mg	Week 12	1.58	0.1146	0.05	-0.06411	0.5907
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 4	4.67	<.0001	0.05	0.3595	0.8813
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 8	3.70	0.0002	0.05	0.2605	0.8502
TRTCD*avisnum	Placebo	Week 12	7.5 mg	Week 12	3.41	0.0007	0.05	0.2338	0.8708
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 4	4.22	<.0001	0.05	0.2965	0.8133
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 8	3.70	0.0003	0.05	0.2546	0.8330
TRTCD*avisnum	Placebo	Week 12	15 mg	Week 12	2.91	0.0039	0.05	0.1480	0.7693
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 4	5.45	<.0001	0.05	0.4608	0.9807
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 8	5.76	<.0001	0.05	0.5664	1.1535

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 12	WORK.EFFMIXED	0.8245	0.1610	316
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 4	WORK.EFFMIXED	0.7914	0.1332	412
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 8	WORK.EFFMIXED	0.8791	0.1507	381
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 12	WORK.EFFMIXED	0.8453	0.1631	320
TRTCD*avisnum	2.5 mg	Week 4	2.5 mg	Week 8	WORK.EFFMIXED	-0.1527	0.06362	311
TRTCD*avisnum	2.5 mg	Week 4	2.5 mg	Week 12	WORK.EFFMIXED	-0.2138	0.09105	311
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 4	WORK.EFFMIXED	0.1432	0.09398	323
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 8	WORK.EFFMIXED	0.07823	0.1171	385
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 12	WORK.EFFMIXED	0.07517	0.1319	400
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 4	WORK.EFFMIXED	0.07775	0.09258	324
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 8	WORK.EFFMIXED	0.06665	0.1138	380
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 12	WORK.EFFMIXED	-0.01846	0.1275	394
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 4	WORK.EFFMIXED	0.2436	0.09465	323
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 8	WORK.EFFMIXED	0.3828	0.1175	382
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 12	WORK.EFFMIXED	0.3474	0.1322	396
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 4	WORK.EFFMIXED	0.3143	0.09378	324
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.4020	0.1170	385
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.3681	0.1324	401
TRTCD*avisnum	2.5 mg	Week 8	2.5 mg	Week 12	WORK.EFFMIXED	-0.06116	0.06793	305
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 4	WORK.EFFMIXED	0.2959	0.1194	395
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 8	WORK.EFFMIXED	0.2309	0.1382	326
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 12	WORK.EFFMIXED	0.2278	0.1511	379

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	Placebo	Week 12	30 mg	Week 12	5.12	<.0001	0.05	0.5078	1.1412
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 4	5.94	<.0001	0.05	0.5295	1.0533
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 8	5.83	<.0001	0.05	0.5828	1.1754
TRTCD*avisnum	Placebo	Week 12	45 mg	Week 12	5.18	<.0001	0.05	0.5244	1.1662
TRTCD*avisnum	2.5 mg	Week 4	2.5 mg	Week 8	-2.40	0.0170	0.05	-0.2778	-0.02748
TRTCD*avisnum	2.5 mg	Week 4	2.5 mg	Week 12	-2.35	0.0195	0.05	-0.3930	-0.03466
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 4	1.52	0.1284	0.05	-0.04164	0.3281
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 8	0.67	0.5044	0.05	-0.1519	0.3084
TRTCD*avisnum	2.5 mg	Week 4	7.5 mg	Week 12	0.57	0.5692	0.05	-0.1842	0.3345
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 4	0.84	0.4016	0.05	-0.1044	0.2599
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 8	0.59	0.5585	0.05	-0.1571	0.2904
TRTCD*avisnum	2.5 mg	Week 4	15 mg	Week 12	-0.14	0.8850	0.05	-0.2691	0.2322
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 4	2.57	0.0105	0.05	0.05739	0.4298
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 8	3.26	0.0012	0.05	0.1518	0.6139
TRTCD*avisnum	2.5 mg	Week 4	30 mg	Week 12	2.63	0.0089	0.05	0.08754	0.6072
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 4	3.35	0.0009	0.05	0.1298	0.4988
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 8	3.44	0.0007	0.05	0.1720	0.6319
TRTCD*avisnum	2.5 mg	Week 4	45 mg	Week 12	2.78	0.0057	0.05	0.1079	0.6283
TRTCD*avisnum	2.5 mg	Week 8	2.5 mg	Week 12	-0.90	0.3687	0.05	-0.1948	0.07251
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 4	2.48	0.0136	0.05	0.06126	0.5306
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 8	1.67	0.0959	0.05	-0.04108	0.5029
TRTCD*avisnum	2.5 mg	Week 8	7.5 mg	Week 12	1.51	0.1323	0.05	-0.06917	0.5248

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 4	WORK.EFFMIXED	0.2304	0.1183	393
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 8	WORK.EFFMIXED	0.2193	0.1356	321
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 12	WORK.EFFMIXED	0.1342	0.1473	372
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 4	WORK.EFFMIXED	0.3963	0.1199	395
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 8	WORK.EFFMIXED	0.5355	0.1388	324
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 12	WORK.EFFMIXED	0.5000	0.1514	376
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 4	WORK.EFFMIXED	0.4669	0.1192	397
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 8	WORK.EFFMIXED	0.5546	0.1380	325
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 12	WORK.EFFMIXED	0.5208	0.1513	380
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 4	WORK.EFFMIXED	0.3571	0.1362	411
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 8	WORK.EFFMIXED	0.2920	0.1530	384
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 12	WORK.EFFMIXED	0.2890	0.1647	320
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 4	WORK.EFFMIXED	0.2916	0.1353	406
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 8	WORK.EFFMIXED	0.2805	0.1507	378
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 12	WORK.EFFMIXED	0.1954	0.1613	316
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 4	WORK.EFFMIXED	0.4574	0.1367	410
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 8	WORK.EFFMIXED	0.5967	0.1536	382
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 12	WORK.EFFMIXED	0.5612	0.1651	319
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 4	WORK.EFFMIXED	0.5281	0.1361	412
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 8	WORK.EFFMIXED	0.6158	0.1528	384
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 12	WORK.EFFMIXED	0.5820	0.1648	321
TRTCD*avisnum	7.5 mg	Week 4	7.5 mg	Week 8	WORK.EFFMIXED	-0.06502	0.05965	312

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 4	1.95	0.0522	0.05	-0.00216	0.4630
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 8	1.62	0.1068	0.05	-0.04747	0.4861
TRTCD*avisnum	2.5 mg	Week 8	15 mg	Week 12	0.91	0.3628	0.05	-0.1554	0.4238
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 4	3.30	0.0010	0.05	0.1604	0.6321
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 8	3.86	0.0001	0.05	0.2624	0.8086
TRTCD*avisnum	2.5 mg	Week 8	30 mg	Week 12	3.30	0.0011	0.05	0.2023	0.7978
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 4	3.92	0.0001	0.05	0.2326	0.7012
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 8	4.02	<.0001	0.05	0.2831	0.8261
TRTCD*avisnum	2.5 mg	Week 8	45 mg	Week 12	3.44	0.0006	0.05	0.2233	0.8182
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 4	2.62	0.0091	0.05	0.08929	0.6248
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 8	1.91	0.0571	0.05	-0.00886	0.5930
TRTCD*avisnum	2.5 mg	Week 12	7.5 mg	Week 12	1.75	0.0803	0.05	-0.03502	0.6130
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 4	2.16	0.0317	0.05	0.02561	0.5575
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 8	1.86	0.0634	0.05	-0.01577	0.5767
TRTCD*avisnum	2.5 mg	Week 12	15 mg	Week 12	1.21	0.2267	0.05	-0.1220	0.5127
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 4	3.35	0.0009	0.05	0.1886	0.7262
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 8	3.89	0.0001	0.05	0.2947	0.8986
TRTCD*avisnum	2.5 mg	Week 12	30 mg	Week 12	3.40	0.0008	0.05	0.2364	0.8860
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 4	3.88	0.0001	0.05	0.2606	0.7955
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 8	4.03	<.0001	0.05	0.3153	0.9163
TRTCD*avisnum	2.5 mg	Week 12	45 mg	Week 12	3.53	0.0005	0.05	0.2577	0.9062
TRTCD*avisnum	7.5 mg	Week 4	7.5 mg	Week 8	-1.09	0.2765	0.05	-0.1824	0.05235

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	7.5 mg	Week 4	7.5 mg	Week 12	WORK.EFFMIXED	-0.06808	0.08485	310
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 4	WORK.EFFMIXED	-0.06550	0.09150	324
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 8	WORK.EFFMIXED	-0.07660	0.1129	379
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 12	WORK.EFFMIXED	-0.1617	0.1267	392
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 4	WORK.EFFMIXED	0.1004	0.09307	323
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 8	WORK.EFFMIXED	0.2396	0.1162	381
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 12	WORK.EFFMIXED	0.2041	0.1310	393
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 4	WORK.EFFMIXED	0.1710	0.09326	325
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.2587	0.1166	383
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.2249	0.1320	399
TRTCD*avisnum	7.5 mg	Week 8	7.5 mg	Week 12	WORK.EFFMIXED	-0.00306	0.06353	308
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 4	WORK.EFFMIXED	-0.00047	0.1151	383
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 8	WORK.EFFMIXED	-0.01158	0.1328	315
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 12	WORK.EFFMIXED	-0.09669	0.1447	365
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 4	WORK.EFFMIXED	0.1654	0.1163	384
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 8	WORK.EFFMIXED	0.3046	0.1356	317
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 12	WORK.EFFMIXED	0.2692	0.1485	368
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 4	WORK.EFFMIXED	0.2360	0.1165	386
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 8	WORK.EFFMIXED	0.3237	0.1358	318
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 12	WORK.EFFMIXED	0.2899	0.1493	373
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 4	WORK.EFFMIXED	0.002580	0.1302	394
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 8	WORK.EFFMIXED	-0.00852	0.1460	366

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	7.5 mg	Week 4	7.5 mg	Week 12	-0.80	0.4230	0.05	-0.2350	0.09887
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 4	-0.72	0.4746	0.05	-0.2455	0.1145
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 8	-0.68	0.4980	0.05	-0.2986	0.1454
TRTCD*avisnum	7.5 mg	Week 4	15 mg	Week 12	-1.28	0.2026	0.05	-0.4108	0.08741
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 4	1.08	0.2817	0.05	-0.08275	0.2834
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 8	2.06	0.0399	0.05	0.01109	0.4681
TRTCD*avisnum	7.5 mg	Week 4	30 mg	Week 12	1.56	0.1200	0.05	-0.05345	0.4617
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 4	1.83	0.0676	0.05	-0.01246	0.3545
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 8	2.22	0.0271	0.05	0.02951	0.4879
TRTCD*avisnum	7.5 mg	Week 4	45 mg	Week 12	1.70	0.0892	0.05	-0.03463	0.4844
TRTCD*avisnum	7.5 mg	Week 8	7.5 mg	Week 12	-0.05	0.9617	0.05	-0.1281	0.1220
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 4	-0.00	0.9967	0.05	-0.2267	0.2258
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 8	-0.09	0.9306	0.05	-0.2728	0.2496
TRTCD*avisnum	7.5 mg	Week 8	15 mg	Week 12	-0.67	0.5043	0.05	-0.3812	0.1878
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 4	1.42	0.1560	0.05	-0.06336	0.3941
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 8	2.25	0.0253	0.05	0.03786	0.5714
TRTCD*avisnum	7.5 mg	Week 8	30 mg	Week 12	1.81	0.0707	0.05	-0.02280	0.5611
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 4	2.03	0.0434	0.05	0.007041	0.4650
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 8	2.38	0.0177	0.05	0.05649	0.5910
TRTCD*avisnum	7.5 mg	Week 8	45 mg	Week 12	1.94	0.0529	0.05	-0.00364	0.5835
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 4	0.02	0.9842	0.05	-0.2534	0.2585
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 8	-0.06	0.9535	0.05	-0.2957	0.2787

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 12	WORK.EFFMIXED	-0.09363	0.1570	308
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 4	WORK.EFFMIXED	0.1684	0.1313	397
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 8	WORK.EFFMIXED	0.3077	0.1486	369
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 12	WORK.EFFMIXED	0.2722	0.1605	310
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 4	WORK.EFFMIXED	0.2391	0.1314	399
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 8	WORK.EFFMIXED	0.3268	0.1488	371
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 12	WORK.EFFMIXED	0.2930	0.1612	313
TRTCD*avisnum	15 mg	Week 4	15 mg	Week 8	WORK.EFFMIXED	-0.01110	0.05658	312
TRTCD*avisnum	15 mg	Week 4	15 mg	Week 12	WORK.EFFMIXED	-0.09621	0.08029	309
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 4	WORK.EFFMIXED	0.1659	0.09145	324
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 8	WORK.EFFMIXED	0.3051	0.1149	380
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 12	WORK.EFFMIXED	0.2696	0.1299	391
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 4	WORK.EFFMIXED	0.2365	0.09195	326
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.3242	0.1156	381
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.2904	0.1311	395
TRTCD*avisnum	15 mg	Week 8	15 mg	Week 12	WORK.EFFMIXED	-0.08511	0.05944	305
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 4	WORK.EFFMIXED	0.1770	0.1128	379
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 8	WORK.EFFMIXED	0.3162	0.1325	313
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 12	WORK.EFFMIXED	0.2807	0.1457	363
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 4	WORK.EFFMIXED	0.2476	0.1133	380
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 8	WORK.EFFMIXED	0.3353	0.1333	314
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 12	WORK.EFFMIXED	0.3015	0.1470	367

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	7.5 mg	Week 12	15 mg	Week 12	-0.60	0.5513	0.05	-0.4025	0.2152
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 4	1.28	0.2003	0.05	-0.08970	0.4266
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 8	2.07	0.0391	0.05	0.01542	0.5999
TRTCD*avisnum	7.5 mg	Week 12	30 mg	Week 12	1.70	0.0909	0.05	-0.04357	0.5880
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 4	1.82	0.0696	0.05	-0.01926	0.4974
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 8	2.20	0.0287	0.05	0.03410	0.6195
TRTCD*avisnum	7.5 mg	Week 12	45 mg	Week 12	1.82	0.0701	0.05	-0.02417	0.6101
TRTCD*avisnum	15 mg	Week 4	15 mg	Week 8	-0.20	0.8446	0.05	-0.1224	0.1002
TRTCD*avisnum	15 mg	Week 4	15 mg	Week 12	-1.20	0.2317	0.05	-0.2542	0.06177
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 4	1.81	0.0707	0.05	-0.01406	0.3458
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 8	2.66	0.0083	0.05	0.07917	0.5310
TRTCD*avisnum	15 mg	Week 4	30 mg	Week 12	2.08	0.0385	0.05	0.01433	0.5249
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 4	2.57	0.0105	0.05	0.05562	0.4174
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 8	2.81	0.0053	0.05	0.09699	0.5514
TRTCD*avisnum	15 mg	Week 4	45 mg	Week 12	2.21	0.0273	0.05	0.03261	0.5481
TRTCD*avisnum	15 mg	Week 8	15 mg	Week 12	-1.43	0.1532	0.05	-0.2021	0.03186
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 4	1.57	0.1177	0.05	-0.04493	0.3988
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 8	2.39	0.0176	0.05	0.05551	0.5769
TRTCD*avisnum	15 mg	Week 8	30 mg	Week 12	1.93	0.0547	0.05	-0.00570	0.5672
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 4	2.19	0.0294	0.05	0.02487	0.4703
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 8	2.52	0.0124	0.05	0.07310	0.5975
TRTCD*avisnum	15 mg	Week 8	45 mg	Week 12	2.05	0.0409	0.05	0.01251	0.5905

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	Margins	Estimate	Standard Error	DF
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 4	WORK.EFFMIXED	0.2621	0.1266	393
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 8	WORK.EFFMIXED	0.4013	0.1444	363
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 12	WORK.EFFMIXED	0.3658	0.1565	306
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 4	WORK.EFFMIXED	0.3327	0.1270	393
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 8	WORK.EFFMIXED	0.4204	0.1451	364
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 12	WORK.EFFMIXED	0.3866	0.1579	309
TRTCD*avisnum	30 mg	Week 4	30 mg	Week 8	WORK.EFFMIXED	0.1392	0.05932	312
TRTCD*avisnum	30 mg	Week 4	30 mg	Week 12	WORK.EFFMIXED	0.1038	0.08435	310
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 4	WORK.EFFMIXED	0.07066	0.09385	325
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.1584	0.1171	382
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.1245	0.1325	398
TRTCD*avisnum	30 mg	Week 8	30 mg	Week 12	WORK.EFFMIXED	-0.03546	0.06314	308
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 4	WORK.EFFMIXED	-0.06858	0.1169	382
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 8	WORK.EFFMIXED	0.01911	0.1365	317
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 12	WORK.EFFMIXED	-0.01471	0.1499	370
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 4	WORK.EFFMIXED	-0.03312	0.1316	394
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 8	WORK.EFFMIXED	0.05457	0.1493	367
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 12	WORK.EFFMIXED	0.02075	0.1619	312
TRTCD*avisnum	45 mg	Week 4	45 mg	Week 8	WORK.EFFMIXED	0.08769	0.06026	315
TRTCD*avisnum	45 mg	Week 4	45 mg	Week 12	WORK.EFFMIXED	0.05387	0.08601	312
TRTCD*avisnum	45 mg	Week 8	45 mg	Week 12	WORK.EFFMIXED	-0.03382	0.06454	308

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.16
SAS Statistical Output for Table 11.15
Repeated Measures Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Visit number for reporting	Randomized treatment code	Visit number for reporting	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 4	2.07	0.0392	0.05	0.01307	0.5111
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 8	2.78	0.0057	0.05	0.1173	0.6853
TRTCD*avisnum	15 mg	Week 12	30 mg	Week 12	2.34	0.0201	0.05	0.05784	0.6738
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 4	2.62	0.0092	0.05	0.08296	0.5825
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 8	2.90	0.0040	0.05	0.1350	0.7058
TRTCD*avisnum	15 mg	Week 12	45 mg	Week 12	2.45	0.0149	0.05	0.07592	0.6973
TRTCD*avisnum	30 mg	Week 4	30 mg	Week 8	2.35	0.0195	0.05	0.02251	0.2560
TRTCD*avisnum	30 mg	Week 4	30 mg	Week 12	1.23	0.2195	0.05	-0.06220	0.2698
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 4	0.75	0.4521	0.05	-0.1140	0.2553
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 8	1.35	0.1771	0.05	-0.07191	0.3886
TRTCD*avisnum	30 mg	Week 4	45 mg	Week 12	0.94	0.3478	0.05	-0.1359	0.3850
TRTCD*avisnum	30 mg	Week 8	30 mg	Week 12	-0.56	0.5748	0.05	-0.1597	0.08878
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 4	-0.59	0.5577	0.05	-0.2984	0.1612
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 8	0.14	0.8887	0.05	-0.2494	0.2877
TRTCD*avisnum	30 mg	Week 8	45 mg	Week 12	-0.10	0.9219	0.05	-0.3094	0.2800
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 4	-0.25	0.8014	0.05	-0.2919	0.2256
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 8	0.37	0.7149	0.05	-0.2390	0.3481
TRTCD*avisnum	30 mg	Week 12	45 mg	Week 12	0.13	0.8981	0.05	-0.2977	0.3392
TRTCD*avisnum	45 mg	Week 4	45 mg	Week 8	1.46	0.1466	0.05	-0.03087	0.2063
TRTCD*avisnum	45 mg	Week 4	45 mg	Week 12	0.63	0.5315	0.05	-0.1154	0.2231
TRTCD*avisnum	45 mg	Week 8	45 mg	Week 12	-0.52	0.6006	0.05	-0.1608	0.09317

Trttypcd is the prior therapy variable, Regioncd is the region variable, Blhba1c is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week -6

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	57	61	62	58	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.64	9.67	9.86	9.96	9.94	9.94
	SD	1.972	2.426	2.030	1.589	2.241	1.723
	SE	0.251	0.321	0.260	0.202	0.294	0.224
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.80	9.90	9.65	9.90
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week -6	Mean	9.49	9.41	9.38	9.71	9.54	9.50
	SD	1.600	1.848	1.966	2.007	1.839	1.700
	SE	0.203	0.245	0.252	0.255	0.241	0.221
	Minimum	5.7	5.4	6.4	6.6	6.0	6.1
	Median	9.45	9.50	9.10	9.50	9.25	9.20
	Maximum	13.2	15.0	14.3	17.5	14.5	14.9
Change from Baseline	Mean	-0.15	-0.26	-0.48	-0.25	-0.40	-0.44
	SD	2.444	2.459	2.220	2.505	2.298	1.941
	SE	0.310	0.326	0.284	0.318	0.302	0.253
	Minimum	-6.2	-5.8	-5.3	-5.5	-7.3	-4.4
	Median	0.05	-0.20	-0.40	-0.70	-0.25	-0.50
	Maximum	4.9	5.8	4.4	8.6	4.8	4.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	58	62	63	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.70	9.64	9.89	9.93	9.95	9.95
	SD	1.935	2.410	2.024	1.588	2.260	1.743
	SE	0.248	0.316	0.257	0.200	0.302	0.227
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.40	9.20	9.85	9.90	9.65	9.90
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week -5	Mean	9.56	9.64	9.22	9.44	9.58	9.62
	SD	1.639	1.675	1.645	1.685	1.795	1.696
	SE	0.210	0.220	0.209	0.212	0.240	0.221
	Minimum	6.8	6.4	5.7	6.8	6.2	6.1
	Median	9.20	9.50	9.20	9.20	9.20	9.20
	Maximum	15.8	13.2	13.3	14.8	14.2	14.9
Change from Baseline	Mean	-0.14	0.00	-0.66	-0.49	-0.37	-0.34
	SD	2.118	2.265	2.130	2.066	2.125	2.008
	SE	0.271	0.297	0.271	0.260	0.284	0.261
	Minimum	-6.7	-7.1	-6.4	-4.3	-7.9	-4.4
	Median	0.00	0.30	-0.20	-0.90	-0.30	-0.70
	Maximum	6.4	3.2	4.6	5.1	4.7	4.3

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week -4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	62	58	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.64	9.64	9.89	9.96	9.94	9.97
	SD	1.972	2.410	2.024	1.586	2.241	1.755
	SE	0.251	0.316	0.257	0.201	0.294	0.229
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.90
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week -4	Mean	9.74	9.84	9.52	9.83	9.58	9.78
	SD	1.928	1.974	1.820	1.444	1.404	1.360
	SE	0.245	0.259	0.231	0.183	0.184	0.177
	Minimum	6.7	6.6	6.2	6.9	6.1	6.1
	Median	9.30	9.60	9.55	9.65	9.50	9.80
	Maximum	15.9	15.9	14.4	13.9	12.0	12.8
Change from Baseline	Mean	0.10	0.19	-0.37	-0.13	-0.36	-0.19
	SD	2.193	2.076	2.209	1.481	1.890	1.744
	SE	0.279	0.273	0.281	0.188	0.248	0.227
	Minimum	-5.6	-3.6	-5.2	-3.7	-8.2	-4.1
	Median	0.15	0.30	-0.10	-0.15	0.00	-0.20
	Maximum	8.2	6.7	5.0	4.2	3.3	4.3

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week -2

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		59	55	60	63	56	60
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.58	9.68	9.90	9.93	9.98	9.98
	SD	1.980	2.462	2.053	1.588	2.269	1.743
	SE	0.258	0.332	0.265	0.200	0.303	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.20	9.20	9.85	9.90	9.75	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week -2	Mean	9.51	10.03	9.98	9.94	9.82	9.95
	SD	1.569	2.176	2.350	1.719	1.898	2.106
	SE	0.204	0.293	0.303	0.217	0.254	0.272
	Minimum	6.6	6.5	4.7	6.8	6.6	4.6
	Median	9.20	9.60	9.65	9.80	9.50	9.60
	Maximum	13.6	17.3	17.0	15.7	14.2	15.2
Change from Baseline	Mean	-0.07	0.34	0.08	0.01	-0.17	-0.04
	SD	1.662	1.692	1.669	1.263	1.815	1.910
	SE	0.216	0.228	0.215	0.159	0.243	0.247
	Minimum	-5.7	-3.7	-4.3	-2.8	-6.0	-8.9
	Median	0.10	0.20	0.00	0.10	0.05	0.00
	Maximum	5.7	6.8	3.7	3.9	4.6	4.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
	SE	0.251	0.316	0.257	0.200	0.294	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 1

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	58	62	63	57	60
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	9.67	9.64	9.89	9.93	9.95	9.98
	SD	1.973	2.410	2.024	1.588	2.259	1.743
	SE	0.253	0.316	0.257	0.200	0.299	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.40	9.20	9.85	9.90	9.70	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 1	Mean	10.00	9.82	9.44	9.82	9.23	9.28
	SD	2.357	2.364	2.110	1.871	2.022	1.886
	SE	0.302	0.310	0.268	0.236	0.268	0.243
	Minimum	4.1	4.8	4.3	6.3	6.2	5.7
	Median	9.40	9.45	9.25	9.70	9.20	9.10
	Maximum	15.8	15.7	16.1	15.2	17.0	15.2
Change from Baseline	Mean	0.33	0.18	-0.45	-0.11	-0.73	-0.71
	SD	1.247	2.178	1.462	1.782	1.088	1.605
	SE	0.160	0.286	0.186	0.224	0.144	0.207
	Minimum	-2.9	-9.2	-6.5	-4.6	-3.7	-6.5
	Median	0.40	0.15	-0.40	-0.50	-0.60	-0.50
	Maximum	3.1	6.6	2.6	5.2	1.9	3.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 2

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	57	60
Number (%) of Values Carried Forward		2 (3%)	0	2 (3%)	0	0	1 (2%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.95	9.98
	SD	1.972	2.410	2.024	1.588	2.259	1.743
	SE	0.251	0.316	0.257	0.200	0.299	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.70	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 2	Mean	9.99	9.88	9.58	9.68	9.29	9.30
	SD	2.157	2.488	2.185	1.793	2.045	2.224
	SE	0.274	0.327	0.277	0.226	0.271	0.287
	Minimum	6.4	5.8	4.7	6.3	5.7	2.3
	Median	9.55	9.65	9.60	9.30	9.10	9.15
	Maximum	17.2	15.3	16.1	14.1	16.5	15.3
Change from Baseline	Mean	0.35	0.23	-0.30	-0.25	-0.66	-0.69
	SD	1.385	2.113	1.575	1.460	1.514	2.043
	SE	0.176	0.277	0.200	0.184	0.201	0.264
	Minimum	-2.7	-7.5	-6.1	-2.8	-5.0	-11.2
	Median	0.05	0.10	-0.15	-0.40	-0.50	-0.45
	Maximum	4.6	5.7	3.7	4.0	3.0	2.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 3

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	57	60
Number (%) of Values Carried Forward		7 (11%)	1 (2%)	3 (5%)	3 (5%)	1 (2%)	5 (8%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.95	9.98
	SD	1.972	2.410	2.024	1.588	2.259	1.743
	SE	0.251	0.316	0.257	0.200	0.299	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.70	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 3	Mean	10.01	9.83	9.23	9.66	9.15	9.10
	SD	2.268	2.350	2.243	1.942	2.095	2.200
	SE	0.288	0.309	0.285	0.245	0.277	0.284
	Minimum	4.9	5.8	4.8	6.6	6.3	5.7
	Median	9.60	9.90	9.20	9.40	8.80	8.75
	Maximum	17.4	16.8	16.1	14.2	15.5	16.0
Change from Baseline	Mean	0.37	0.19	-0.65	-0.28	-0.81	-0.89
	SD	1.442	1.975	1.814	1.603	1.591	1.844
	SE	0.183	0.259	0.230	0.202	0.211	0.238
	Minimum	-4.2	-7.4	-8.1	-4.9	-6.8	-5.5
	Median	0.25	0.30	-0.45	-0.20	-0.60	-0.95
	Maximum	4.6	6.7	2.8	4.0	4.1	4.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		6 (10%)	6 (10%)	5 (8%)	3 (5%)	1 (2%)	4 (7%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
	SE	0.251	0.316	0.257	0.200	0.294	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 4	Mean	9.80	9.87	9.36	9.50	8.74	8.68
	SD	2.004	2.530	2.428	1.997	1.816	2.008
	SE	0.255	0.332	0.308	0.252	0.238	0.259
	Minimum	5.7	4.7	3.1	5.9	5.0	4.9
	Median	9.50	10.00	9.25	9.20	8.40	8.55
	Maximum	15.3	15.8	16.1	14.6	12.5	14.2
Change from Baseline	Mean	0.16	0.22	-0.52	-0.43	-1.21	-1.31
	SD	1.595	2.005	2.235	1.548	1.514	1.764
	SE	0.203	0.263	0.284	0.195	0.199	0.228
	Minimum	-4.1	-5.5	-8.0	-5.4	-6.6	-8.4
	Median	0.15	0.00	-0.30	-0.50	-0.90	-1.05
	Maximum	5.0	6.7	7.0	4.2	1.1	2.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 6

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		9 (15%)	8 (14%)	5 (8%)	3 (5%)	1 (2%)	6 (10%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
	SE	0.251	0.316	0.257	0.200	0.294	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 6	Mean	9.80	9.85	9.27	9.66	8.92	9.17
	SD	2.239	2.567	2.485	1.892	1.953	2.246
	SE	0.284	0.337	0.316	0.238	0.256	0.290
	Minimum	5.5	5.0	4.7	6.3	5.2	4.6
	Median	9.40	9.50	9.10	9.40	8.70	9.05
	Maximum	15.7	16.3	16.1	15.5	13.6	14.2
Change from Baseline	Mean	0.17	0.21	-0.61	-0.28	-1.02	-0.81
	SD	1.507	2.149	2.139	1.420	1.657	1.882
	SE	0.191	0.282	0.272	0.179	0.218	0.243
	Minimum	-3.5	-7.1	-7.6	-3.4	-5.6	-6.2
	Median	0.15	0.00	-0.55	-0.40	-0.70	-0.85
	Maximum	4.5	7.3	6.5	3.7	2.0	3.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		9 (15%)	12 (21%)	6 (10%)	3 (5%)	2 (3%)	5 (8%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
	SE	0.251	0.316	0.257	0.200	0.294	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 8	Mean	10.03	9.83	9.38	9.60	9.08	8.88
	SD	2.411	2.441	2.621	2.103	2.074	2.043
	SE	0.306	0.321	0.333	0.265	0.272	0.264
	Minimum	5.4	5.0	5.1	6.1	5.8	5.3
	Median	9.55	9.70	8.90	9.30	8.85	8.55
	Maximum	15.5	15.4	16.6	14.4	14.1	14.4
Change from Baseline	Mean	0.39	0.18	-0.50	-0.33	-0.86	-1.10
	SD	1.745	1.996	2.235	1.593	1.869	1.801
	SE	0.222	0.262	0.284	0.201	0.245	0.233
	Minimum	-2.6	-5.6	-7.1	-3.6	-6.3	-8.2
	Median	0.20	0.00	-0.45	-0.50	-0.60	-0.90
	Maximum	5.4	5.0	6.5	3.9	4.8	3.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.17
Summary Statistics for Fasting Plasma Glucose (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		13 (21%)	11 (19%)	9 (15%)	4 (6%)	2 (3%)	6 (10%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
	SE	0.251	0.316	0.257	0.200	0.294	0.225
	Minimum	5.5	5.7	5.5	6.8	6.4	5.5
	Median	9.35	9.20	9.85	9.90	9.65	9.95
	Maximum	15.8	16.7	15.6	15.0	18.7	13.5
Week 12	Mean	10.21	9.83	9.58	9.86	8.94	9.23
	SD	2.875	2.675	3.094	2.137	2.203	2.265
	SE	0.365	0.351	0.393	0.269	0.289	0.292
	Minimum	5.2	5.2	4.1	6.2	4.2	5.5
	Median	9.55	9.15	9.00	9.20	8.45	9.20
	Maximum	17.7	16.1	19.0	15.8	15.8	15.1
Change from Baseline	Mean	0.57	0.19	-0.31	-0.07	-1.00	-0.76
	SD	2.120	2.176	2.743	1.945	2.184	2.039
	SE	0.269	0.286	0.348	0.245	0.287	0.263
	Minimum	-3.9	-4.8	-8.6	-3.2	-7.8	-6.9
	Median	0.15	0.00	-0.10	-0.30	-0.65	-0.55
	Maximum	5.4	6.8	8.0	6.9	4.4	4.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.18
Summary Statistics for Fasting Plasma Glucose (mmol/L) at Week 12 by Prior Therapy

Prior Therapy: Diet & Exercise

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		28	23	27	24	25	24
n [1]		28	22	27	24	25	24
Number (%) of Values Carried Forward		5 (18%)	6 (27%)	8 (30%)	1 (4%)	1 (4%)	1 (4%)
Baseline	Mean	8.91	8.93	9.92	9.27	9.66	9.92
	SD	1.817	1.871	2.358	1.559	2.083	1.823
	SE	0.343	0.399	0.454	0.318	0.417	0.372
	Minimum	5.5	5.8	5.5	6.8	6.4	5.5
	Median	8.80	8.75	10.00	9.05	9.30	9.80
	Maximum	14.5	14.5	15.6	12.6	15.3	13.5
Week 12	Mean	9.24	9.38	9.99	9.52	8.03	8.76
	SD	2.795	2.817	3.719	2.479	1.858	1.836
	SE	0.528	0.601	0.716	0.506	0.372	0.375
	Minimum	5.2	5.2	4.1	6.5	4.2	5.5
	Median	8.70	8.45	9.40	9.00	7.90	8.60
	Maximum	17.7	16.1	19.0	15.8	11.8	12.7
Change from Baseline	Mean	0.33	0.45	0.07	0.25	-1.63	-1.16
	SD	2.183	2.351	2.884	2.468	1.857	2.204
	SE	0.413	0.501	0.555	0.504	0.371	0.450
	Minimum	-3.9	-2.8	-5.1	-3.2	-5.1	-6.9
	Median	-0.15	0.00	-0.10	-0.20	-1.20	-0.75
	Maximum	5.1	6.8	8.0	6.9	1.7	2.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.18
Summary Statistics for Fasting Plasma Glucose (mmol/L) at Week 12 by Prior Therapy

Prior Therapy: Monotherapy

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		34	36	35	39	33	36
n [1]		34	36	35	39	33	36
Number (%) of Values Carried Forward		8 (24%)	5 (14%)	1 (3%)	3 (8%)	1 (3%)	5 (14%)
Baseline	Mean	10.24	10.08	9.86	10.34	10.16	10.03
	SD	1.914	2.615	1.760	1.483	2.362	1.712
	SE	0.328	0.436	0.297	0.237	0.411	0.285
	Minimum	6.5	5.7	6.7	7.8	6.4	5.9
	Median	9.95	9.85	9.60	10.20	9.80	10.10
	Maximum	15.8	16.7	13.9	15.0	18.7	13.5
Week 12	Mean	11.01	10.11	9.26	10.07	9.64	9.54
	SD	2.725	2.584	2.522	1.901	2.216	2.487
	SE	0.467	0.431	0.426	0.304	0.386	0.414
	Minimum	6.2	6.1	4.3	6.2	6.5	5.6
	Median	10.35	9.80	8.60	9.70	9.20	9.50
	Maximum	16.7	15.4	15.3	15.5	15.8	15.1
Change from Baseline	Mean	0.76	0.03	-0.60	-0.27	-0.52	-0.49
	SD	2.078	2.079	2.633	1.542	2.316	1.906
	SE	0.356	0.347	0.445	0.247	0.403	0.318
	Minimum	-2.8	-4.8	-8.6	-3.0	-7.8	-4.3
	Median	0.60	0.20	-0.10	-0.30	-0.20	-0.45
	Maximum	5.4	4.2	5.2	5.1	4.4	4.4

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	58	62	63	58	60
Number (%) of Values Carried Forward		13 (21%)	11 (19%)	9 (15%)	4 (6%)	2 (3%)	6 (10%)
Baseline	Mean	9.64	9.64	9.89	9.93	9.94	9.98
	SD	1.972	2.410	2.024	1.588	2.241	1.743
Week 12	Mean	10.21	9.83	9.58	9.86	8.94	9.23
	SD	2.875	2.675	3.094	2.137	2.203	2.265
Chg from Baseline	Mean	0.57	0.19	-0.31	-0.07	-1.00	-0.76
	SD	2.120	2.176	2.743	1.945	2.184	2.039
Model-Adj Chg [2]	Mean	0.52	0.11	-0.28	-0.07	-0.95	-0.71
	SE	0.273	0.282	0.272	0.270	0.281	0.276
Diff from Pbo [2]	Mean		-0.40	-0.80	-0.58	-1.46	-1.22
	95% CI		-1.18,0.37	-1.56,-0.04	-1.34,0.17	-2.23,-0.69	-1.99,-0.46
	p-val [3]		0.306	0.039	0.130	<0.001	0.002

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	9.63870968	Sum Observations	597.6
Std Deviation	1.97246246	Variance	3.89060814
Skewness	0.70301778	Kurtosis	0.91637334
Uncorrected SS	5997.42	Corrected SS	237.327097
Coeff Variation	20.4639679	Std Error Mean	0.25050298

Basic Statistical Measures

Location		Variability	
Mean	9.638710	Std Deviation	1.97246
Median	9.350000	Variance	3.89061
Mode	9.000000	Range	10.30000
		Interquartile Range	2.20000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	38.47742	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.961642	Pr < W	0.0501
Kolmogorov-Smirnov	D	0.104753	Pr > D	0.0894
Cramer-von Mises	W-Sq	0.154537	Pr > W-Sq	0.0211
Anderson-Darling	A-Sq	0.867247	Pr > A-Sq	0.0245

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.80
99%	15.80
95%	12.80
90%	12.60
75% Q3	10.50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.35
25% Q1	8.30
10%	7.80
5%	6.60
1%	5.50
0% Min	5.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	6	12.7	60
6.1	22	12.8	55
6.5	12	13.0	21
6.6	1	14.5	56
7.0	29	15.8	20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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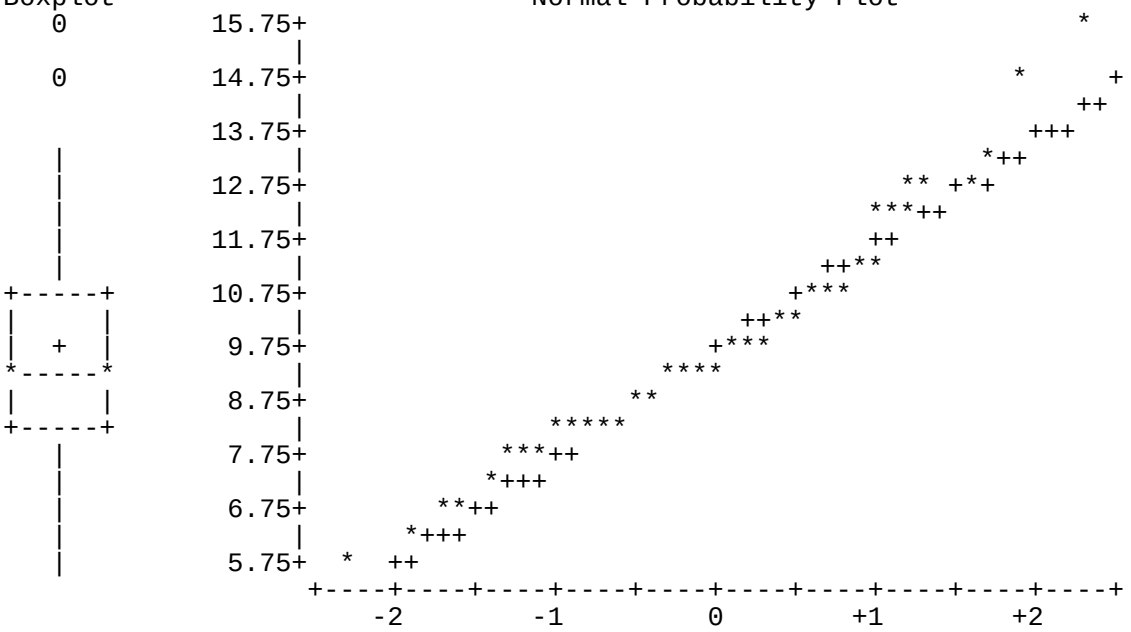
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                     #    Boxplot
    15 8                        1       0
    15                                  |
    14 5                        1       0
    14                                  |
    13                                  |
    13 0                        1       |
    12 6778                     4       |
    12 114                      3       |
    11                                  |
    11 33                       2       |
    10 55789                    5    +-----+
    10 00233                    5    |     |
     9 5577889                  7    |  +  |
     9 00001222344             11    *-----*
     8 5669                     4    |     |
     8 001223344                9    +-----+
     7 7889                     4       |
     7 0                        1       |
     6 56                       2       |
     6 1                        1       |
     5 5                        1       |
       ----+----+----+----+
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	10.2064516	Sum Observations	632.8
Std Deviation	2.87452753	Variance	8.26290851
Skewness	0.74712127	Kurtosis	-0.1482474
Uncorrected SS	6962.68	Corrected SS	504.037419
Coeff Variation	28.1638285	Std Error Mean	0.36506536

Basic Statistical Measures

Location		Variability	
Mean	10.20645	Std Deviation	2.87453
Median	9.55000	Variance	8.26291
Mode	9.70000	Range	12.50000
		Interquartile Range	3.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	27.95787	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	976.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.938912	Pr < W 0.0040
Kolmogorov-Smirnov	D	0.1667	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.270771	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.477654	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	17.70
99%	17.70
95%	15.30
90%	14.80
75% Q3	12.20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.55
25% Q1	8.30
10%	7.30
5%	6.40
1%	5.20
0% Min	5.20

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.2	22	15.0	57
6.2	31	15.3	60
6.3	1	15.8	42
6.4	6	16.7	26
6.6	44	17.7	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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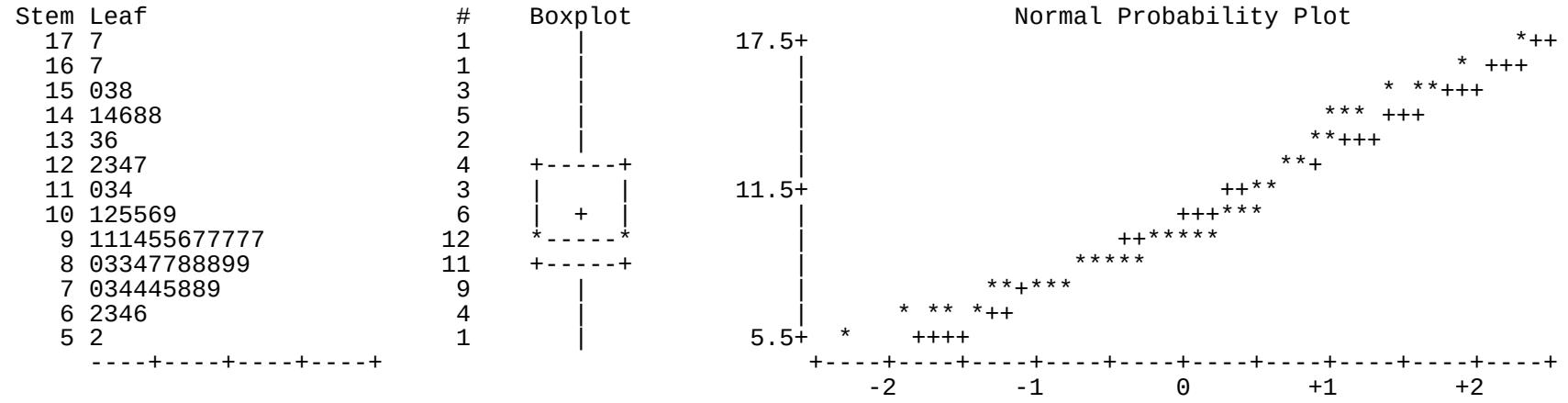
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	0.56774194	Sum Observations	35.2
Std Deviation	2.1199114	Variance	4.49402433
Skewness	0.57961133	Kurtosis	-0.1153607
Uncorrected SS	294.12	Corrected SS	274.135484
Coeff Variation	373.393484	Std Error Mean	0.26922902

Basic Statistical Measures

Location		Variability	
Mean	0.567742	Std Deviation	2.11991
Median	0.150000	Variance	4.49402
Mode	0.600000	Range	9.30000
		Interquartile Range	2.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.108769	Pr > |t|	0.0391
Sign	M	2	Pr >= |M|	0.6989

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	208.5	Pr >= |S|	0.1258

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.953798	Pr < W	0.0204
Kolmogorov-Smirnov	D	0.142813	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.19532	Pr > W-Sq	0.0059
Anderson-Darling	A-Sq	1.112865	Pr > A-Sq	0.0063

Quantiles (Definition 5)

Quantile	Estimate
100% Max	5.40
99%	5.40
95%	4.90
90%	3.60
75% Q3	1.50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.15
25% Q1	-0.90
10%	-1.70
5%	-2.30
1%	-3.90
0% Min	-3.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-3.9	56	4.6	26
-2.8	21	4.9	55
-2.6	13	5.0	42
-2.3	48	5.1	27
-1.8	44	5.4	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot                        Normal Probability Plot
      5 014                      3       0          5.25+                                  * * ++*
      4 69                       2       |             |                                 * *  ++
      4 0                        1       |             |                                *   ++
      3 556                      3       |             |                              ** +++
      3 4                        1       |             |                             * ++
      2 69                       2       |             |                           **+
      2 44                       2       |             |                         +*+
      1 59                       2    +-----+          |                       ++*
      1 0011                     4    |     |          |                     ++**
      0 5666677899              10    |  +  |     0.75+                   +****
      0 0012                     4    *-----*          |                +**
     -0 44433211                 8    |     |          |             *****
     -0 999655                   6    +-----+          |          ***
     -1 44400                    5       |             |        *++
     -1 88776                    5       |             |     ****+
     -2 3                        1       |             |    * ++
     -2 86                       2       |             |  * *++
     -3                                  |             |  +++
     -3 9                        1       |       -3.75+  * ++
        ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+
                                                         -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	9.64482759	Sum Observations	559.4
Std Deviation	2.41037032	Variance	5.80988506
Skewness	0.97033548	Kurtosis	1.09428776
Uncorrected SS	5726.48	Corrected SS	331.163448
Coeff Variation	24.9913261	Std Error Mean	0.31649713

Basic Statistical Measures

Location		Variability	
Mean	9.644828	Std Deviation	2.41037
Median	9.200000	Variance	5.80989
Mode	9.200000	Range	11.00000
		Interquartile Range	2.60000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	30.47367	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.93839	Pr < W	0.0055
Kolmogorov-Smirnov	D	0.115816	Pr > D	0.0508
Cramer-von Mises	W-Sq	0.155198	Pr > W-Sq	0.0207
Anderson-Darling	A-Sq	0.974575	Pr > A-Sq	0.0144

Quantiles (Definition 5)

Quantile	Estimate
100% Max	16.7
99%	16.7
95%	14.9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	12.7
75% Q3	10.6
50% Median	9.2
25% Q1	8.0
10%	6.7
5%	6.3
1%	5.7
0% Min	5.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.7	41	13.2	48
5.8	37	14.5	55
6.3	51	14.9	49
6.4	44	16.4	8
6.7	39	16.7	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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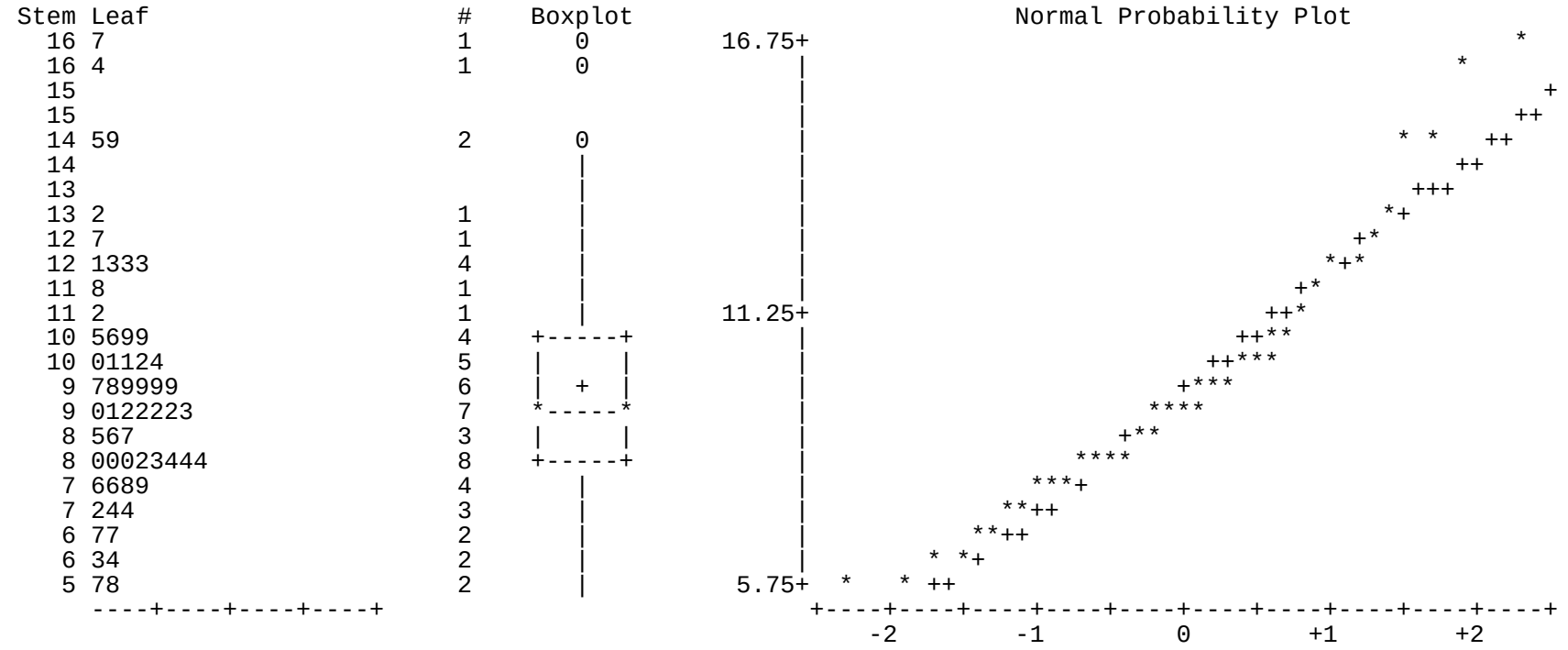
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	9.83275862	Sum Observations	570.3
Std Deviation	2.67453147	Variance	7.15311857
Skewness	0.55136606	Kurtosis	-0.4750474
Uncorrected SS	6015.35	Corrected SS	407.727759
Coeff Variation	27.2002148	Std Error Mean	0.35118319

Basic Statistical Measures

Location		Variability	
Mean	9.832759	Std Deviation	2.67453
Median	9.150000	Variance	7.15312
Mode	7.800000	Range	10.90000
		Interquartile Range	3.90000

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	27.99894	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.956795	Pr < W	0.0377
Kolmogorov-Smirnov	D	0.113428	Pr > D	0.0629
Cramer-von Mises	W-Sq	0.136228	Pr > W-Sq	0.0370
Anderson-Darling	A-Sq	0.805773	Pr > A-Sq	0.0366

Quantiles (Definition 5)

Quantile	Estimate
100% Max	16.10
99%	16.10
95%	15.40

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	13.90
75% Q3	11.70
50% Median	9.15
25% Q1	7.80
10%	6.70
5%	6.20
1%	5.20
0% Min	5.20

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.2	53	14.5	35
6.1	41	14.7	48
6.2	39	15.4	10
6.3	51	15.4	38
6.4	42	16.1	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

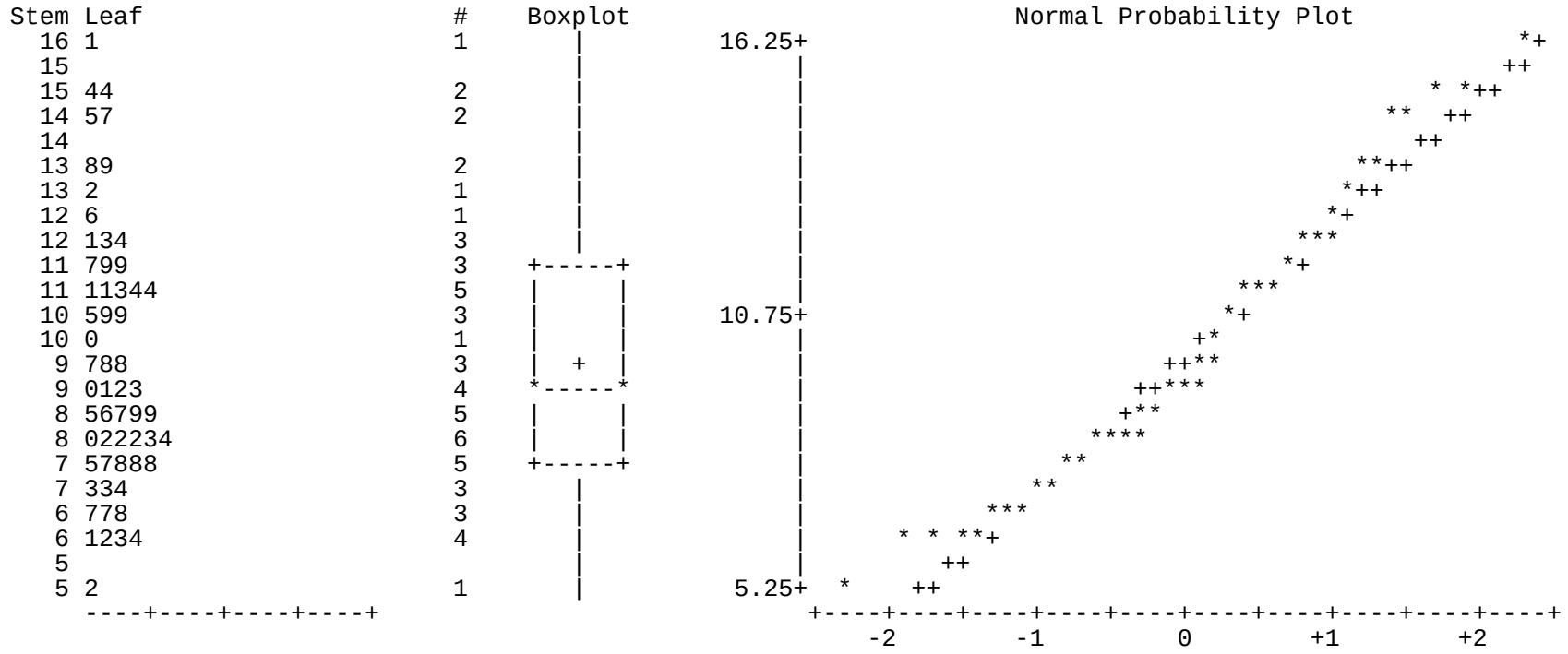

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.18793103	Sum Observations	10.9
Std Deviation	2.17579004	Variance	4.73406231
Skewness	0.60823354	Kurtosis	1.17159065
Uncorrected SS	271.89	Corrected SS	269.841552
Coeff Variation	1157.75984	Std Error Mean	0.28569523

Basic Statistical Measures

Location		Variability	
Mean	0.187931	Std Deviation	2.17579
Median	0.000000	Variance	4.73406
Mode	0.000000	Range	11.60000
		Interquartile Range	2.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.657802	Pr > |t|	0.5133
Sign	M	0.5	Pr >= |M|	1.0000

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	30	Pr >= |S|	0.7934

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.967273	Pr < W	0.1188
Kolmogorov-Smirnov	D	0.080907	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.055761	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.44808	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	6.8
99%	6.8
95%	4.2
90%	2.7
75% Q3	1.5

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-1.1
10%	-2.6
5%	-2.8
1%	-4.8
0% Min	-4.8

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-4.8	9	2.9	25
-3.0	34	3.1	54
-2.8	53	4.2	7
-2.7	14	6.2	38
-2.6	55	6.8	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

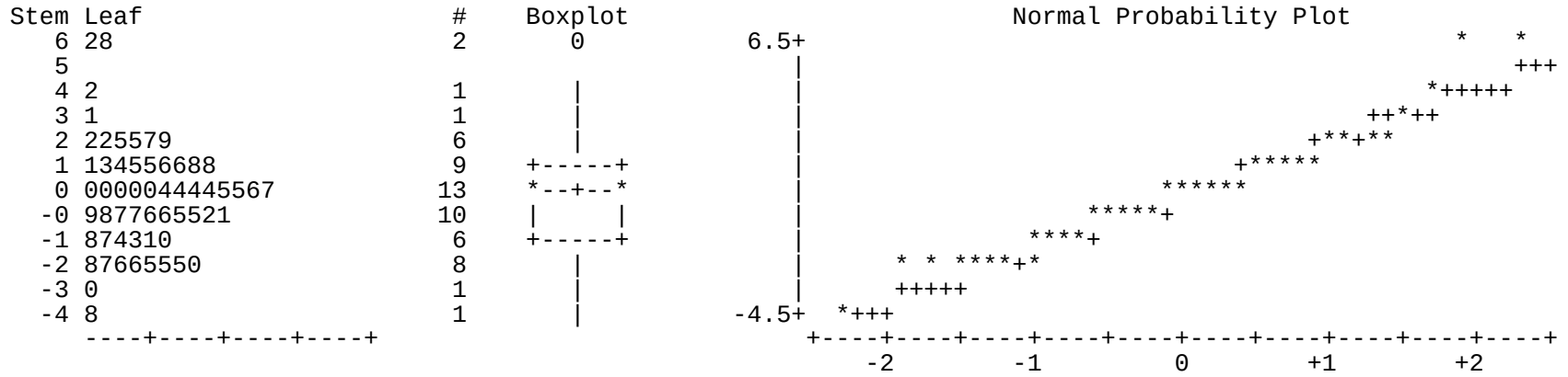

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	9.88709677	Sum Observations	613
Std Deviation	2.02407509	Variance	4.09687996
Skewness	0.13526768	Kurtosis	0.37952303
Uncorrected SS	6310.7	Corrected SS	249.909677
Coeff Variation	20.4718851	Std Error Mean	0.25705779

Basic Statistical Measures

Location		Variability	
Mean	9.887097	Std Deviation	2.02408
Median	9.850000	Variance	4.09688
Mode	8.300000	Range	10.10000
		Interquartile Range	2.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	38.46254	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.987362	Pr < W	0.7746
Kolmogorov-Smirnov	D	0.087147	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.046529	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.271468	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.60
99%	15.60
95%	13.00
90%	12.20
75% Q3	11.20

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.85
25% Q1	8.80
10%	7.40
5%	6.70
1%	5.50
0% Min	5.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	52	12.9	32
5.5	49	13.0	5
5.7	29	13.3	51
6.7	23	13.9	3
6.9	10	15.6	47

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

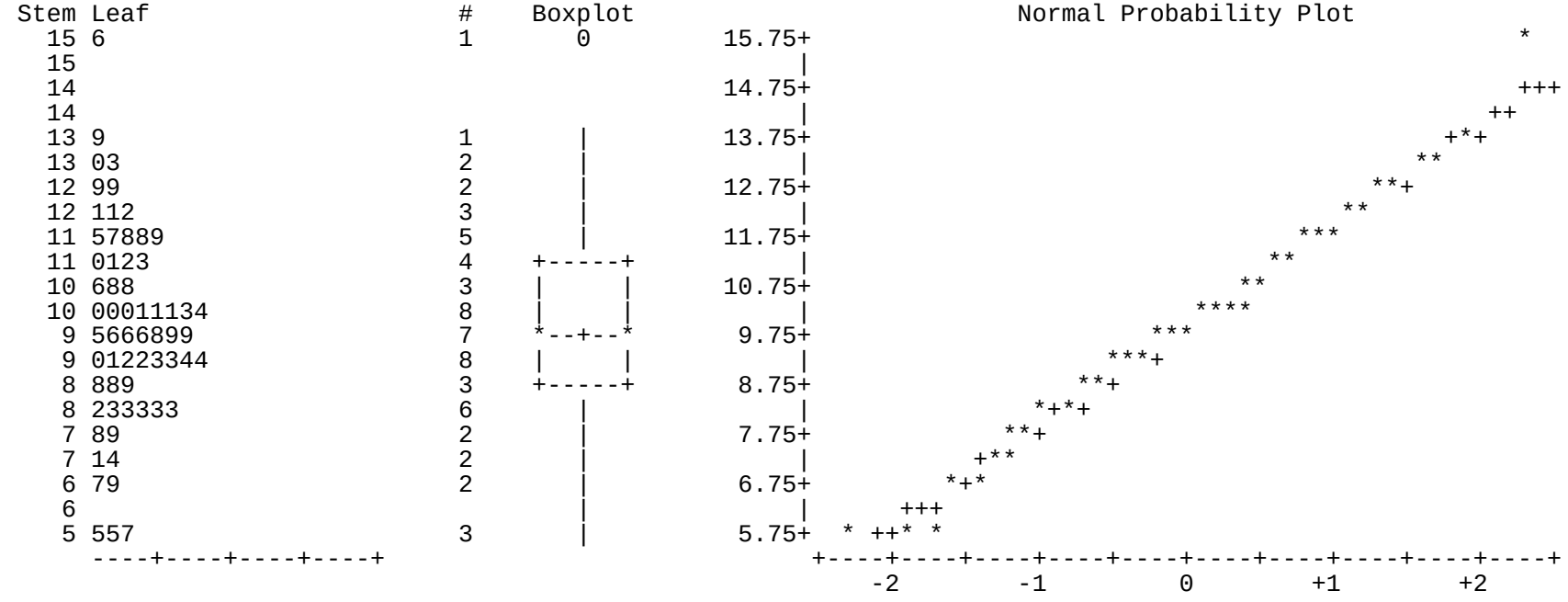

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	9.58064516	Sum Observations	594
Std Deviation	3.09440737	Variance	9.57535695
Skewness	0.74443778	Kurtosis	0.38868253
Uncorrected SS	6275	Corrected SS	584.096774
Coeff Variation	32.2985281	Std Error Mean	0.39299013

Basic Statistical Measures

Location		Variability	
Mean	9.580645	Std Deviation	3.09441
Median	9.000000	Variance	9.57536
Mode	7.200000	Range	14.90000
		Interquartile Range	3.60000

NOTE: The mode displayed is the smallest of 15 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	24.37884	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.953025	Pr < W	0.0187
Kolmogorov-Smirnov	D	0.120191	Pr > D	0.0244
Cramer-von Mises	W-Sq	0.214441	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.115101	Pr > A-Sq	0.0062

Quantiles (Definition 5)

Quantile	Estimate
100% Max	19.0
99%	19.0
95%	14.8

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	14.3
75% Q3	11.3
50% Median	9.0
25% Q1	7.7
10%	6.4
5%	5.3
1%	4.1
0% Min	4.1

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
4.1	49	14.8	3
4.3	12	14.8	33
4.7	52	15.3	39
5.3	5	16.1	47
5.7	40	19.0	55

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

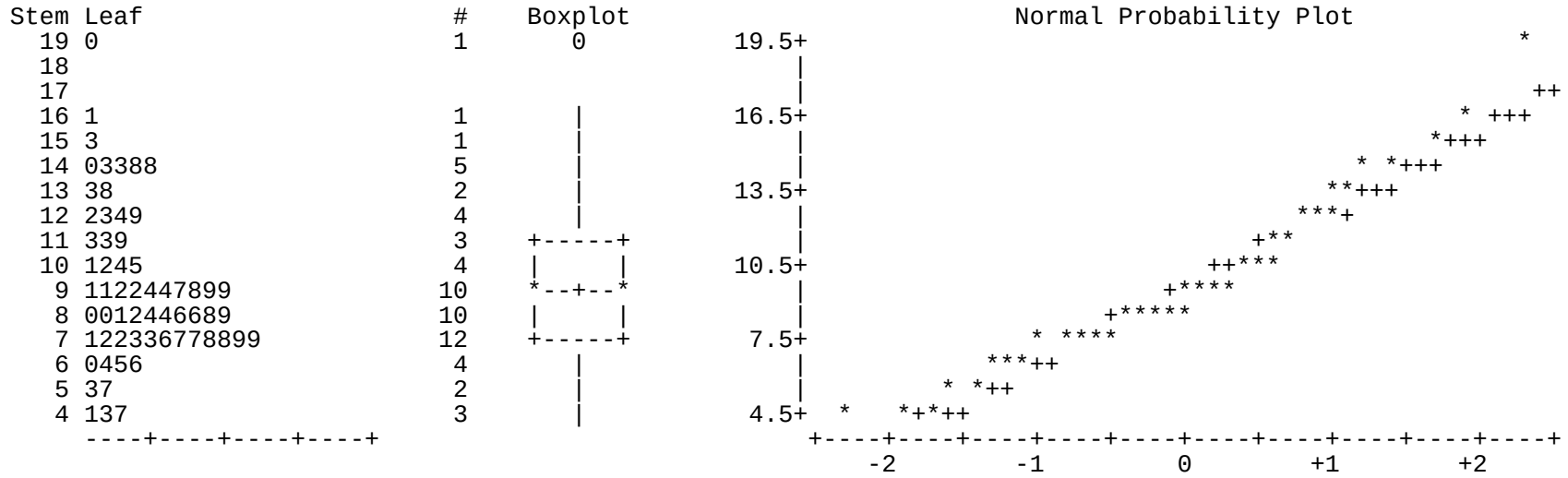

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-0.3064516	Sum Observations	-19
Std Deviation	2.74273233	Variance	7.52258065
Skewness	-0.0551311	Kurtosis	2.51688914
Uncorrected SS	464.7	Corrected SS	458.877419
Coeff Variation	-894.99687	Std Error Mean	0.34832735

Basic Statistical Measures

Location		Variability	
Mean	-0.30645	Std Deviation	2.74273
Median	-0.10000	Variance	7.52258
Mode	1.00000	Range	16.60000
		Interquartile Range	2.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.87978	Pr > |t|	0.3824
Sign	M	-2	Pr >= |M|	0.6989

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-155	Pr >= |S| 0.2572

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.937119	Pr < W 0.0034
Kolmogorov-Smirnov	D	0.158887	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.24811	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.445829	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	8.0
99%	8.0
95%	3.6
90%	3.0
75% Q3	0.8

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.1
25% Q1	-1.6
10%	-3.0
5%	-5.0
1%	-8.6
0% Min	-8.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-8.6	12	3.2	18
-7.7	5	3.6	60
-5.1	40	5.2	39
-5.0	46	6.5	33
-4.2	44	8.0	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

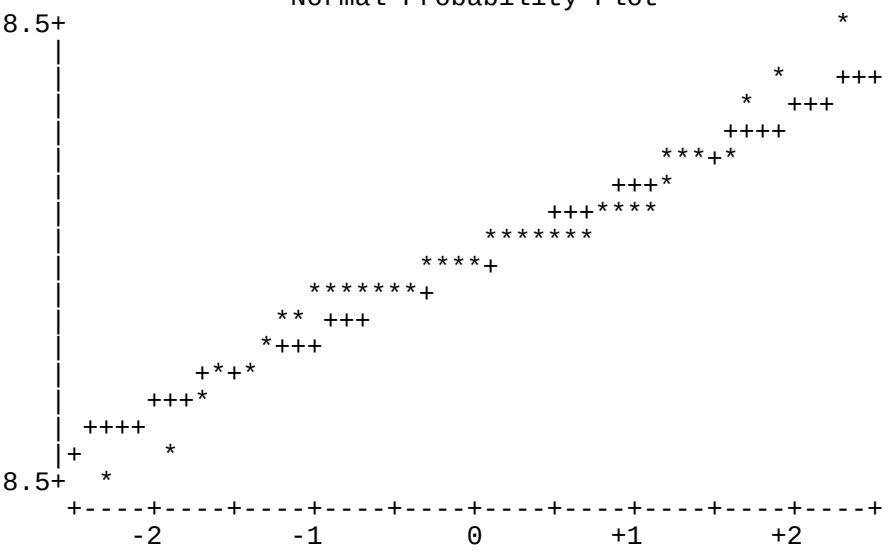
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                #    Boxplot
     8 0                   1       *
     7
     6 5                   1       0
     5 2                   1       0
     4
     3 0126                4       |
     2 1                   1       |
     1 000119              6       |
     0 0012224455677889   16    +-----+
    -0 988654211           9    *--+--*
    -1 9976665443310      13    +-----+
    -2 660                 3       |
    -3 30                  2       |
    -4 2                   1       |
    -5 10                  2       |
    -6
    -7 7                   1       0
    -8 6                   1       0
       ----+----+----+----+
```

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	63	Sum Weights	63
Mean	9.93333333	Sum Observations	625.8
Std Deviation	1.5884665	Variance	2.52322581
Skewness	0.34135068	Kurtosis	0.48870693
Uncorrected SS	6372.72	Corrected SS	156.44
Coeff Variation	15.9912734	Std Error Mean	0.20012797

Basic Statistical Measures

Location		Variability	
Mean	9.933333	Std Deviation	1.58847
Median	9.900000	Variance	2.52323
Mode	8.700000	Range	8.20000
		Interquartile Range	2.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	49.63491	Pr > |t|	<.0001
Sign	M	31.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	1008	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.976582	Pr < W	0.2722
Kolmogorov-Smirnov	D	0.060223	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.048724	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.355708	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.0
99%	15.0
95%	12.1
90%	11.8
75% Q3	11.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.9
25% Q1	8.8
10%	8.2
5%	7.3
1%	6.8
0% Min	6.8

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.8	45	12.1	42
6.8	33	12.1	43
6.9	63	12.3	8
7.3	40	12.6	7
7.8	9	15.0	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

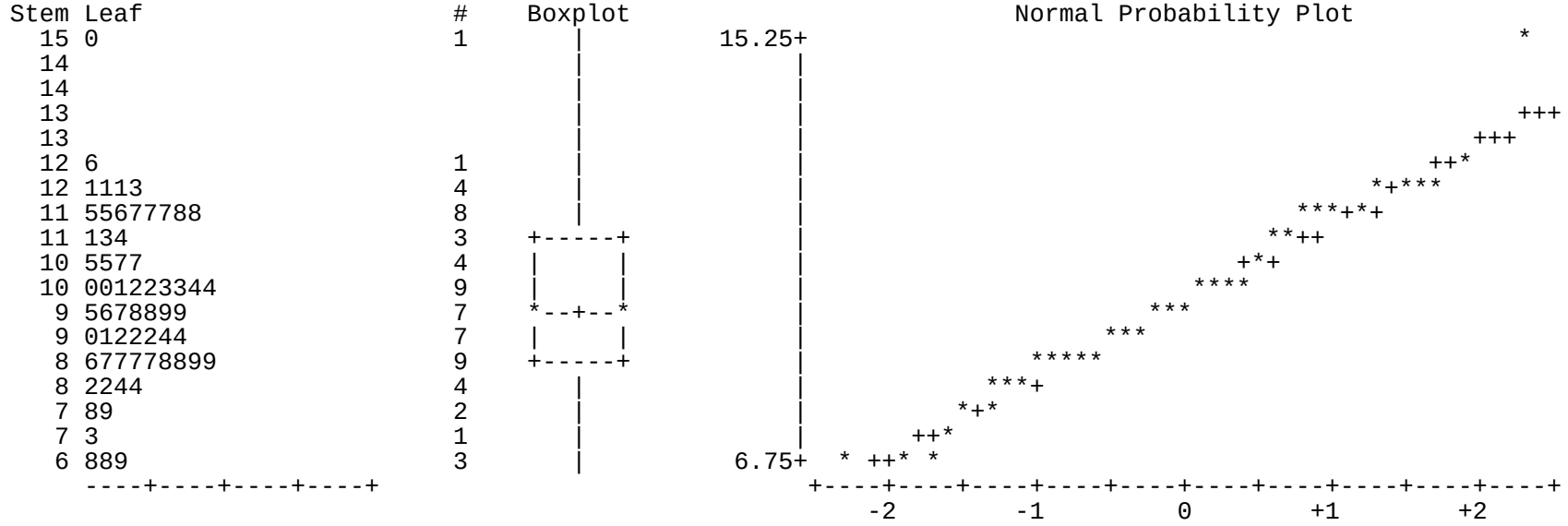

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	63	Sum Weights	63
Mean	9.86031746	Sum Observations	621.2
Std Deviation	2.13658906	Variance	4.5650128
Skewness	0.84422143	Kurtosis	0.4990486
Uncorrected SS	6408.26	Corrected SS	283.030794
Coeff Variation	21.6685626	Std Error Mean	0.26918492

Basic Statistical Measures

Location		Variability	
Mean	9.860317	Std Deviation	2.13659
Median	9.200000	Variance	4.56501
Mode	9.000000	Range	9.60000
		Interquartile Range	2.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	36.63027	Pr > |t|	<.0001
Sign	M	31.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	1008	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.942361	Pr < W 0.0053
Kolmogorov-Smirnov	D	0.131089	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.213391	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.200776	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.8
99%	15.8
95%	13.2
90%	12.9
75% Q3	11.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.2
25% Q1	8.5
10%	7.6
5%	6.9
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	9	13.1	61
6.5	45	13.2	56
6.6	33	14.9	4
6.9	53	15.5	18
7.6	60	15.8	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

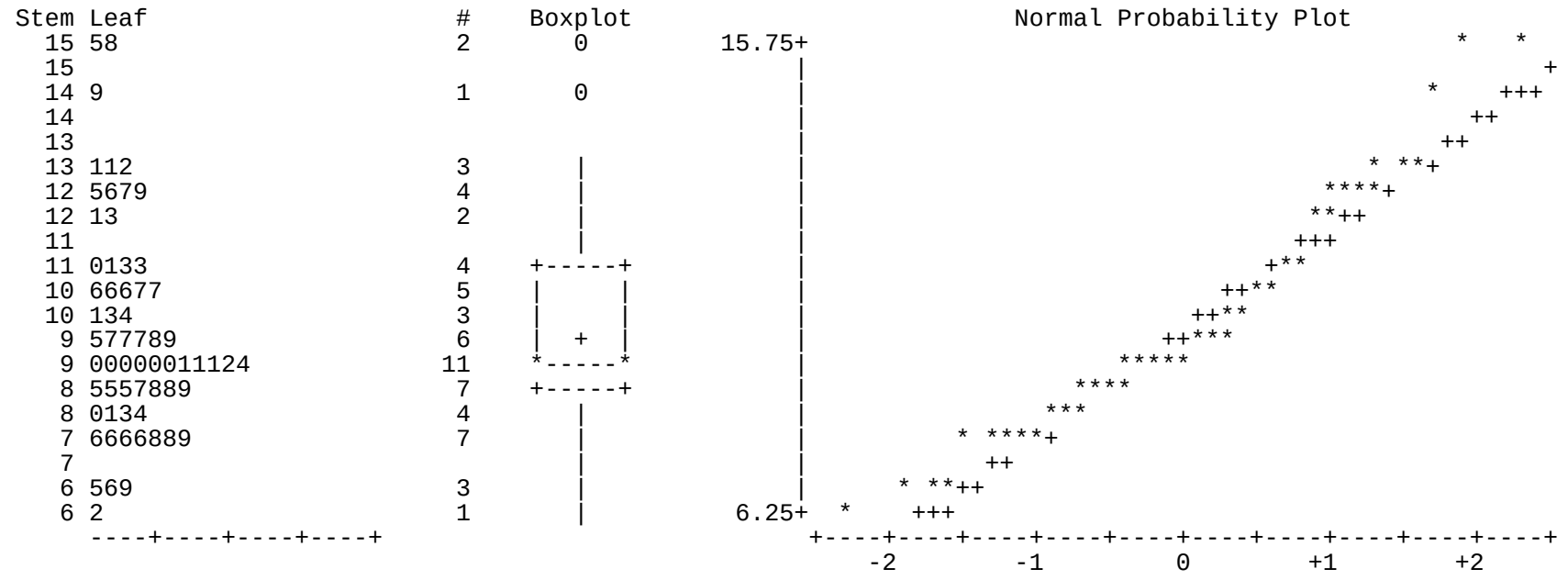

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	63	Sum Weights	63
Mean	-0.0730159	Sum Observations	-4.6
Std Deviation	1.94473701	Variance	3.78200205
Skewness	1.42392317	Kurtosis	3.06579023
Uncorrected SS	234.82	Corrected SS	234.484127
Coeff Variation	-2663.4442	Std Error Mean	0.24501383

Basic Statistical Measures

Location		Variability	
Mean	-0.07302	Std Deviation	1.94474
Median	-0.30000	Variance	3.78200
Mode	0.00000	Range	10.10000
		Interquartile Range	2.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.29801	Pr > |t|	0.7667
Sign	M	-8	Pr >= |M|	0.0479

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-176.5	Pr >= |S|	0.1738

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.889234	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.152144	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.305038	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.895711	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	6.9
99%	6.9
95%	4.4
90%	2.0
75% Q3	0.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.3
25% Q1	-1.4
10%	-2.2
5%	-2.8
1%	-3.2
0% Min	-3.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-3.2	53	2.6	3
-3.0	28	4.4	63
-2.9	48	5.1	18
-2.8	23	5.5	4
-2.5	35	6.9	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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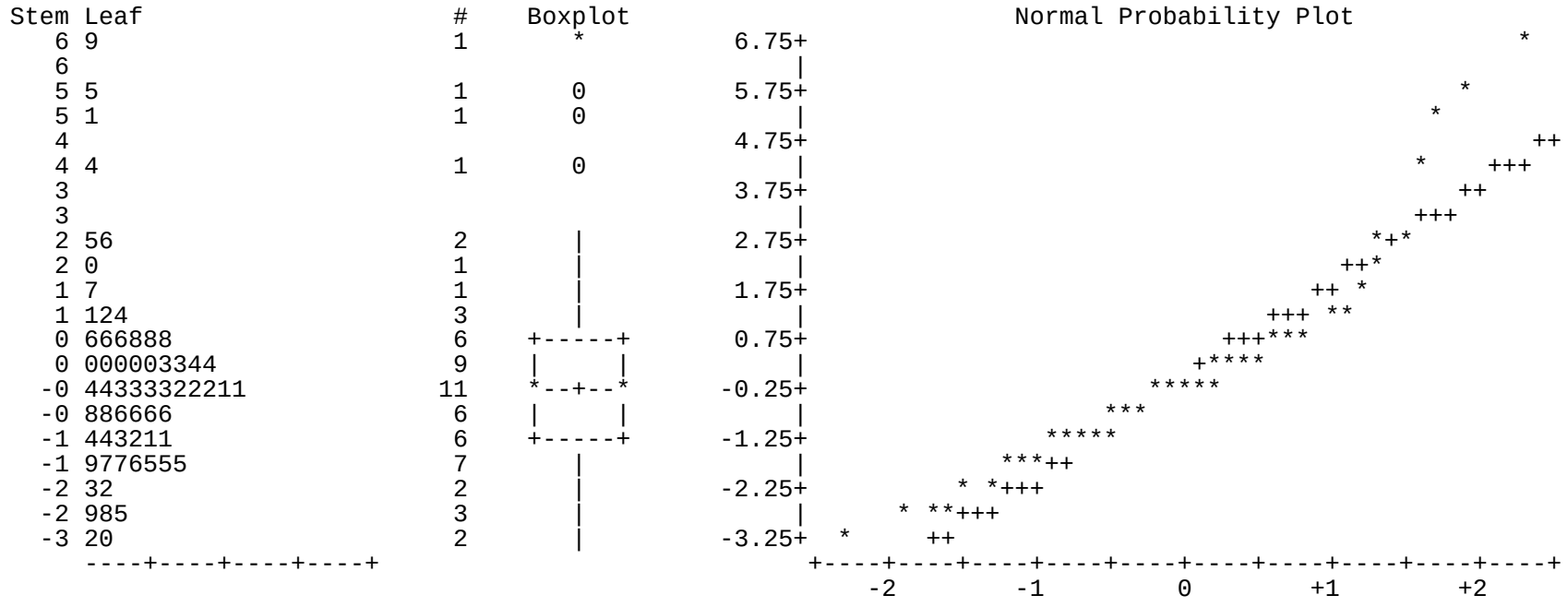
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	9.94137931	Sum Observations	576.6
Std Deviation	2.24085154	Variance	5.02141561
Skewness	1.2544441	Kurtosis	3.08977484
Uncorrected SS	6018.42	Corrected SS	286.22069
Coeff Variation	22.5406502	Std Error Mean	0.29423822

Basic Statistical Measures

Location		Variability	
Mean	9.94138	Std Deviation	2.24085
Median	9.65000	Variance	5.02142
Mode	10.40000	Range	12.30000
		Interquartile Range	2.80000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	33.78684	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.92717	Pr < W	0.0019
Kolmogorov-Smirnov	D	0.091331	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.103888	Pr > W-Sq	0.0982
Anderson-Darling	A-Sq	0.739589	Pr > A-Sq	0.0510

Quantiles (Definition 5)

Quantile	Estimate
100% Max	18.70
99%	18.70
95%	13.50
90%	12.70
75% Q3	11.10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.65
25% Q1	8.30
10%	7.30
5%	7.00
1%	6.40
0% Min	6.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	55	13.5	5
6.4	34	13.5	24
7.0	53	13.5	25
7.0	14	15.3	43
7.2	37	18.7	7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

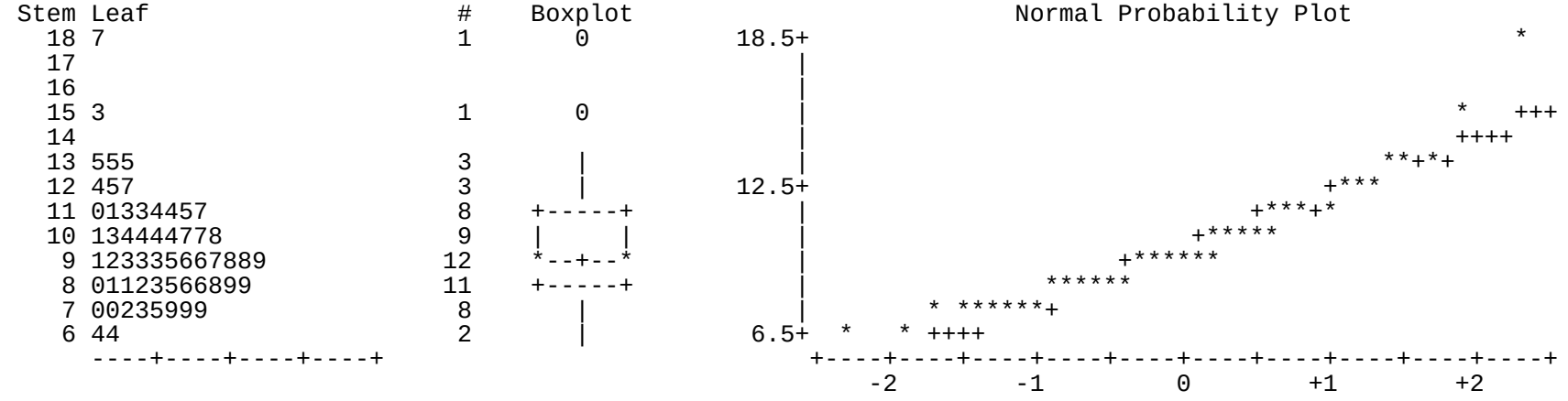

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	8.94310345	Sum Observations	518.7
Std Deviation	2.20343528	Variance	4.85512704
Skewness	0.63343107	Kurtosis	0.96322141
Uncorrected SS	4915.53	Corrected SS	276.742241
Coeff Variation	24.6383741	Std Error Mean	0.28932523

Basic Statistical Measures

Location		Variability	
Mean	8.943103	Std Deviation	2.20344
Median	8.450000	Variance	4.85513
Mode	7.700000	Range	11.60000
		Interquartile Range	2.70000

NOTE: The mode displayed is the smallest of 3 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	30.91021	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.961554	Pr < W	0.0633
Kolmogorov-Smirnov	D	0.125319	Pr > D	0.0227
Cramer-von Mises	W-Sq	0.166207	Pr > W-Sq	0.0152
Anderson-Darling	A-Sq	0.877857	Pr > A-Sq	0.0234

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.80
99%	15.80
95%	12.50

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[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	12.30
75% Q3	10.30
50% Median	8.45
25% Q1	7.60
10%	6.80
5%	5.70
1%	4.20
0% Min	4.20

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
4.2	38	12.3	30
4.4	39	12.4	48
5.7	34	12.5	52
5.8	18	14.1	56
6.5	55	15.8	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

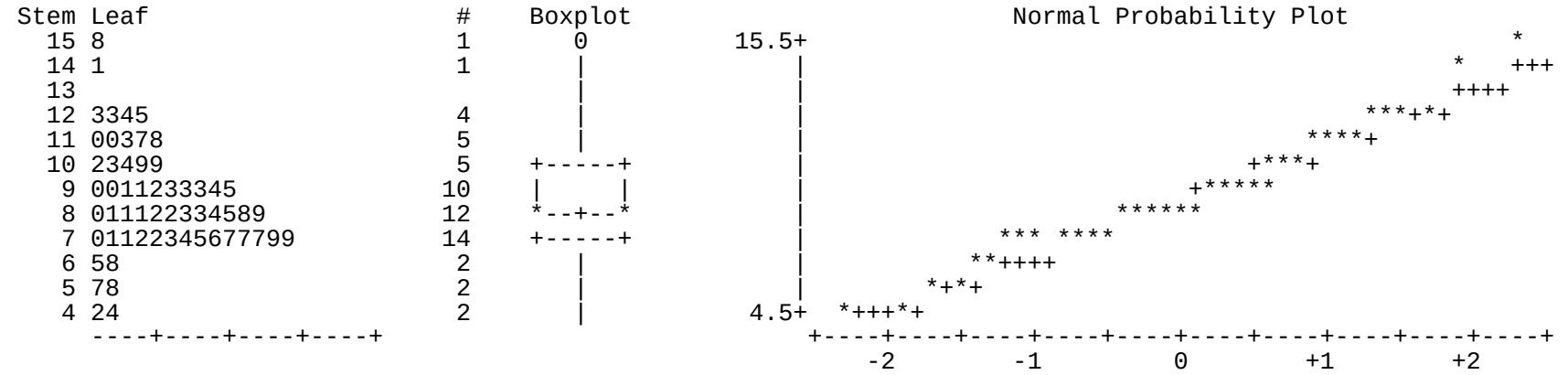

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.9982759	Sum Observations	-57.9
Std Deviation	2.18379128	Variance	4.76894434
Skewness	-0.7078689	Kurtosis	1.29859494
Uncorrected SS	329.63	Corrected SS	271.829828
Coeff Variation	-218.75629	Std Error Mean	0.28674584

Basic Statistical Measures

Location		Variability	
Mean	-0.99828	Std Deviation	2.18379
Median	-0.65000	Variance	4.76894
Mode	0.10000	Range	12.20000
		Interquartile Range	2.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.4814	Pr > |t|	0.0010
Sign	M	-9	Pr >= |M|	0.0222

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-386	Pr >= |S| 0.0011

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.956799	Pr < W 0.0377
Kolmogorov-Smirnov	D	0.135614	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.159567	Pr > W-Sq 0.0185
Anderson-Darling	A-Sq	0.898573	Pr > A-Sq 0.0215

Quantiles (Definition 5)

Quantile	Estimate
100% Max	4.40
99%	4.40
95%	2.00
90%	1.20
75% Q3	0.30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.65
25% Q1	-2.10
10%	-3.60
5%	-5.10
1%	-7.80
0% Min	-7.80

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-7.8	7	1.3	32
-6.7	24	1.7	19
-5.1	38	2.0	48
-4.3	49	2.4	56
-3.7	28	4.4	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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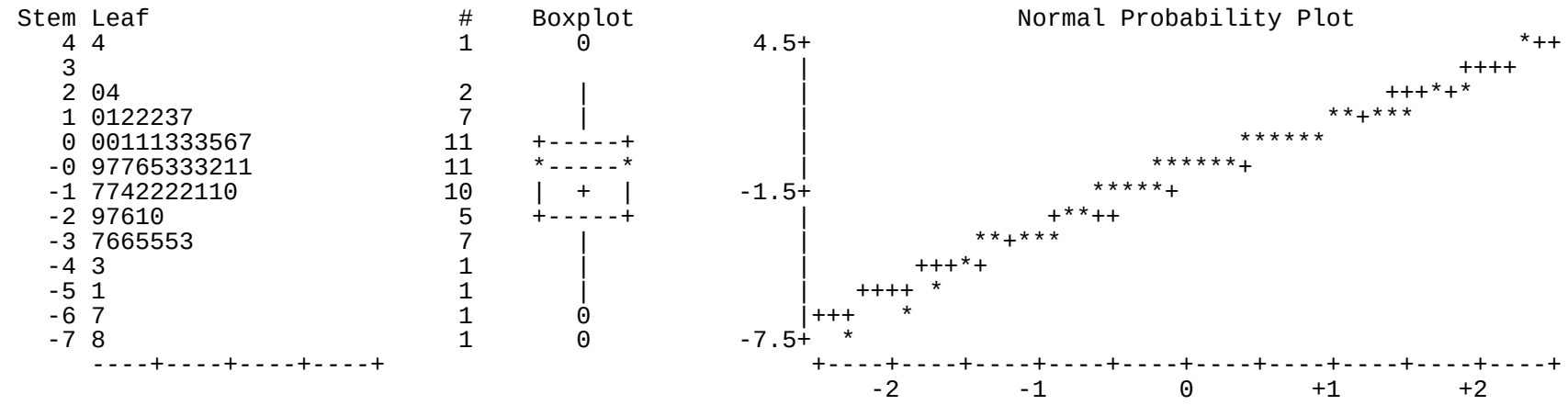
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	60	Sum Weights	60
Mean	9.98333333	Sum Observations	599
Std Deviation	1.74289518	Variance	3.03768362
Skewness	-0.2309367	Kurtosis	0.10626687
Uncorrected SS	6159.24	Corrected SS	179.223333
Coeff Variation	17.4580486	Std Error Mean	0.2250068

Basic Statistical Measures

Location		Variability	
Mean	9.983333	Std Deviation	1.74290
Median	9.950000	Variance	3.03768
Mode	9.800000	Range	8.00000
		Interquartile Range	2.45000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	44.36903	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	915	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.984423	Pr < W	0.6401
Kolmogorov-Smirnov	D	0.050549	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.021642	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.217298	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	13.50
99%	13.50
95%	12.55
90%	12.45
75% Q3	11.20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.95
25% Q1	8.75
10%	8.00
5%	6.75
1%	5.50
0% Min	5.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	9	12.5	17
5.9	26	12.5	60
6.4	11	12.6	3
7.1	41	13.5	29
7.9	55	13.5	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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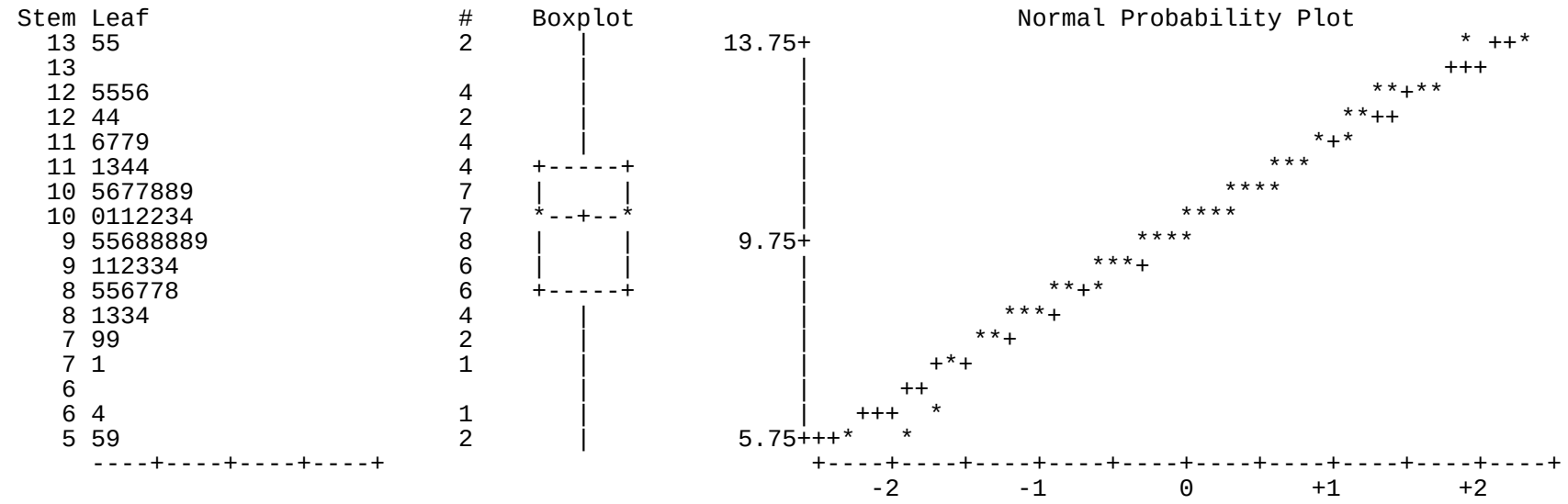
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	60	Sum Weights	60
Mean	9.22666667	Sum Observations	553.6
Std Deviation	2.26520225	Variance	5.13114124
Skewness	0.33009356	Kurtosis	-0.4258043
Uncorrected SS	5410.62	Corrected SS	302.737333
Coeff Variation	24.5506024	Std Error Mean	0.29243635

Basic Statistical Measures

Location		Variability	
Mean	9.226667	Std Deviation	2.26520
Median	9.200000	Variance	5.13114
Mode	9.200000	Range	9.60000
		Interquartile Range	3.40000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	31.55102	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001
Signed Rank	S	915	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.975555	Pr < W	0.2700
Kolmogorov-Smirnov	D	0.075756	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.048642	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.338587	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	15.10
99%	15.10
95%	12.60

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	12.30
75% Q3	10.80
50% Median	9.20
25% Q1	7.40
10%	6.30
5%	5.65
1%	5.50
0% Min	5.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	36	12.4	28
5.6	20	12.5	4
5.6	9	12.7	48
5.7	26	14.2	19
5.8	37	15.1	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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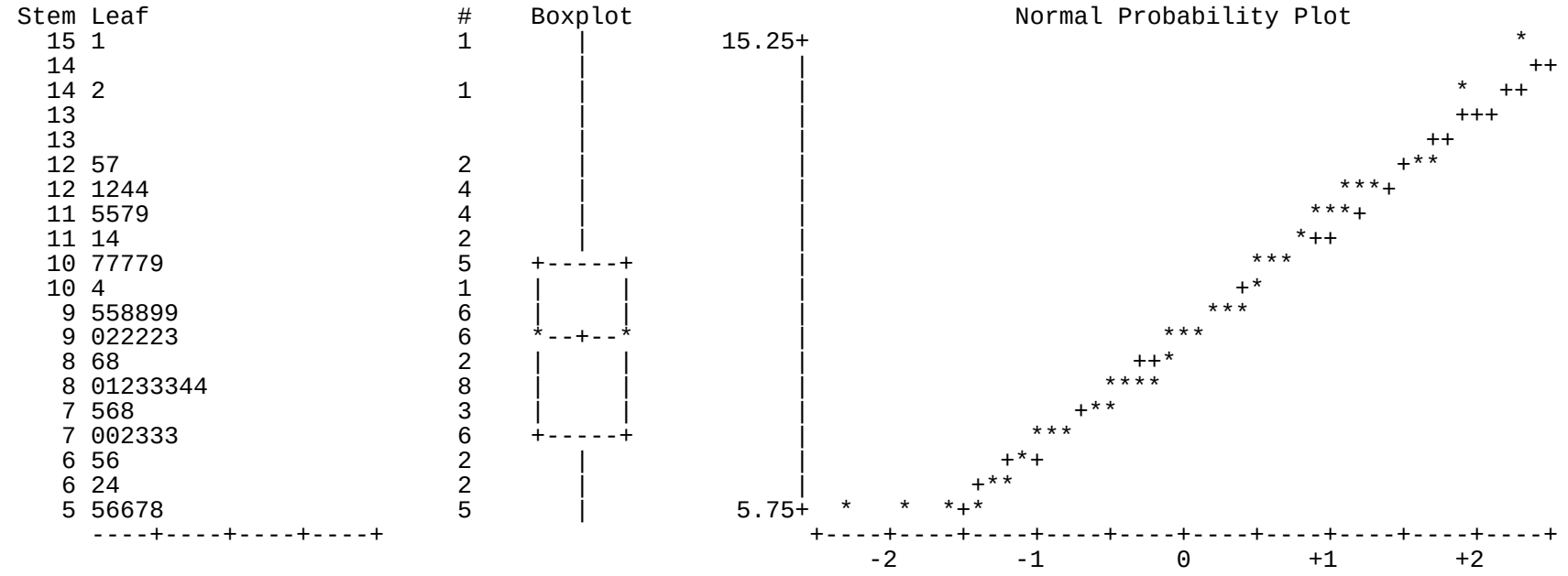
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	-0.7566667	Sum Observations	-45.4
Std Deviation	2.03947207	Variance	4.15944633
Skewness	-0.5071118	Kurtosis	1.46712409
Uncorrected SS	279.76	Corrected SS	245.407333
Coeff Variation	-269.53375	Std Error Mean	0.26329471

Basic Statistical Measures

Location		Variability	
Mean	-0.75667	Std Deviation	2.03947
Median	-0.55000	Variance	4.15945
Mode	0.10000	Range	11.30000
		Interquartile Range	1.85000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.87384	Pr > |t|	0.0056
Sign	M	-9.5	Pr >= |M|	0.0163

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-358	Pr >= |S|	0.0036

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.968914	Pr < W	0.1291
Kolmogorov-Smirnov	D	0.103894	Pr > D	0.1044
Cramer-von Mises	W-Sq	0.092501	Pr > W-Sq	0.1413
Anderson-Darling	A-Sq	0.574854	Pr > A-Sq	0.1347

Quantiles (Definition 5)

Quantile	Estimate
100% Max	4.40
99%	4.40
95%	2.35
90%	1.65
75% Q3	0.10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.55
25% Q1	-1.75
10%	-3.25
5%	-4.15
1%	-6.90
0% Min	-6.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-6.9	36	2.2	4
-6.5	54	2.3	19
-4.3	42	2.4	24
-4.0	20	2.9	48
-3.5	37	4.4	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

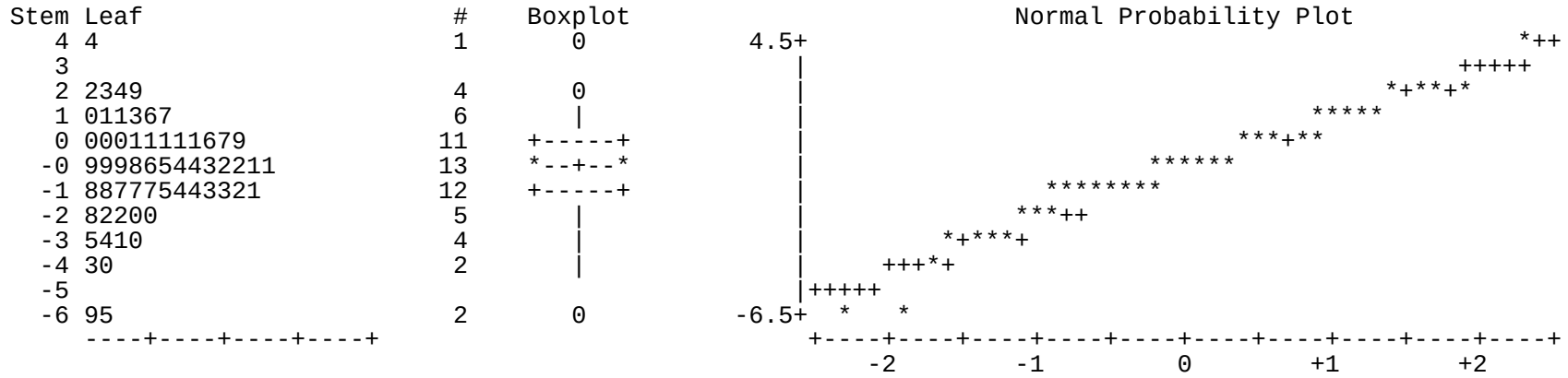

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots

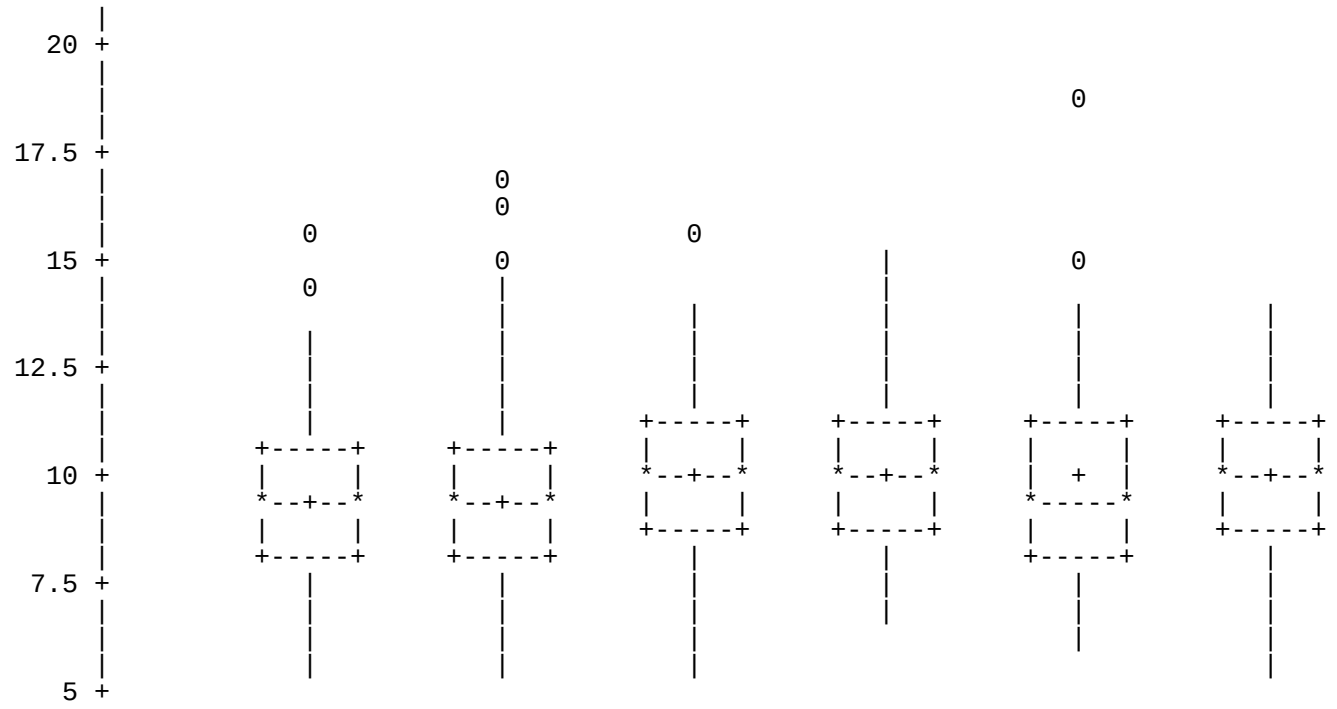

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots

TRTCD	Placebo	2.5mg	7.5mg	15mg	30mg	45mg

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
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Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots

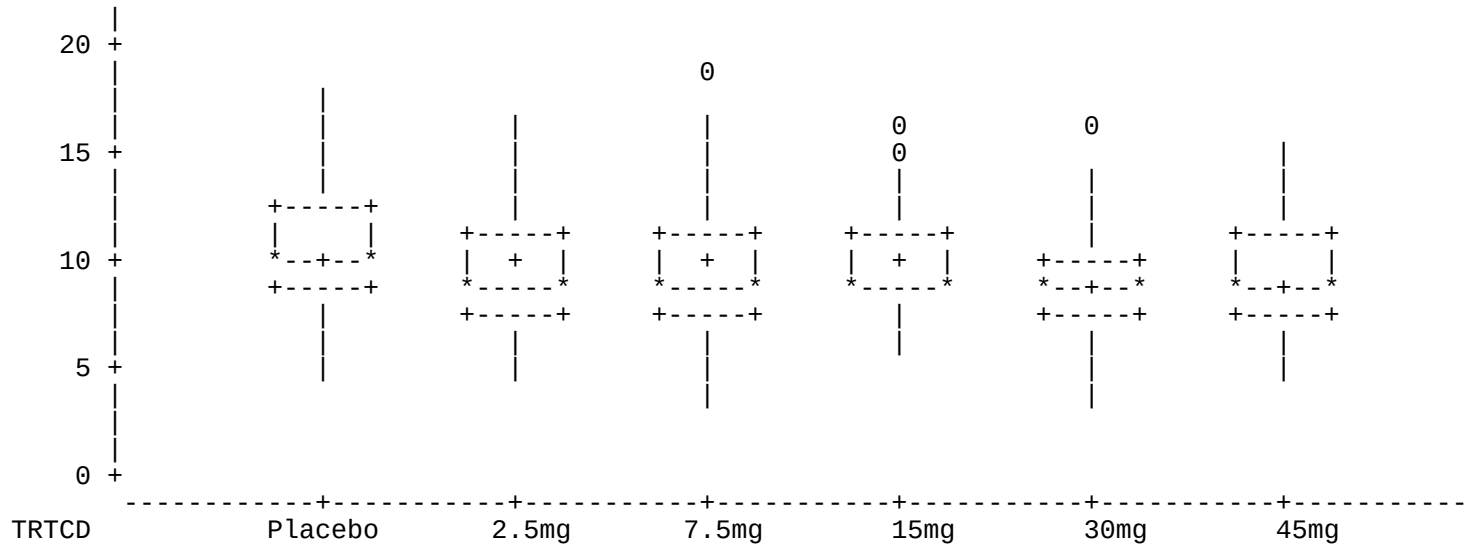

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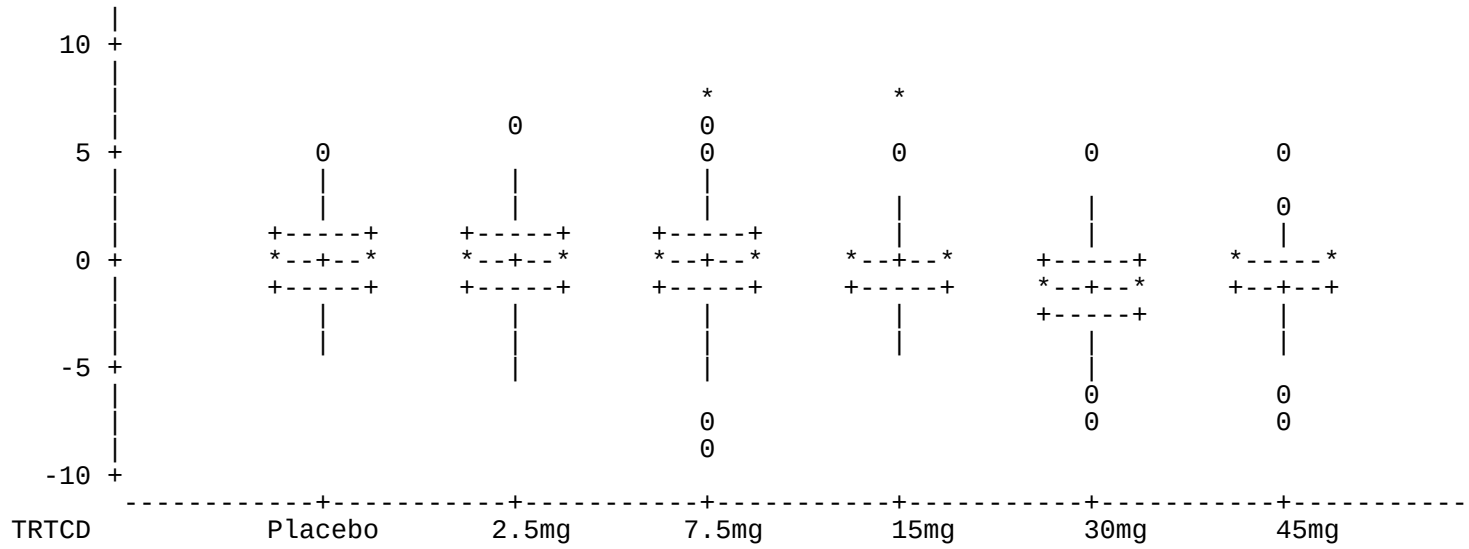
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	363
Observations Used	363
Observations Not Used	0
Total Observations	363

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	4.5670	0.3442	13.27	<.0001	0.05	3.9608	5.3246

Fit Statistics

-2 Res Log Likelihood	1582.8
AIC (smaller is better)	1584.8
AICC (smaller is better)	1584.8
BIC (smaller is better)	1588.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					2.5706	0.6848	352	3.75	0.0002
SEX	Female				-0.4399	0.2258	352	-1.95	0.0522
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.3354	0.2323	352	-1.44	0.1496
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	1.2248	0.3886	352	3.15	0.0018
TRTCD				2.5mg	0.8212	0.3946	352	2.08	0.0381
TRTCD				7.5mg	0.4274	0.3879	352	1.10	0.2713
TRTCD				15mg	0.6425	0.3860	352	1.66	0.0969
TRTCD				30mg	-0.2368	0.3942	352	-0.60	0.5484
TRTCD				45mg	0			.	
REGIONCD			US/Canada		0.09513	0.2642	352	0.36	0.7190
REGIONCD			Eastern Europe		0.07963	0.2835	352	0.28	0.7790
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.3021	0.05721	352	-5.28	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	352	3.80	0.0522
TRTTYPCD	1	352	2.09	0.1496
TRTCD	5	352	3.77	0.0024
REGIONCD	2	352	0.07	0.9281
EFSTDBL	1	352	27.88	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.4036	0.3934	352	-1.03	0.3056	0.05	-1.1773	0.3701
7.5mg vs Pbo	-0.7974	0.3853	352	-2.07	0.0392	0.05	-1.5552	-0.03970
15mg vs Pbo	-0.5823	0.3838	352	-1.52	0.1301	0.05	-1.3372	0.1726
30mg vs Pbo	-1.4617	0.3912	352	-3.74	0.0002	0.05	-2.2310	-0.6923
45mg vs Pbo	-1.2248	0.3886	352	-3.15	0.0018	0.05	-1.9891	-0.4606

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5069	0.5069	0.5069	0.5069	0.5069
SEX	Male				0.4931	0.4931	0.4931	0.4931	0.4931
TRTTYPCD		Diet & Exercise			0.4132	0.4132	0.4132	0.4132	0.4132
TRTTYPCD		Monotherapy			0.5868	0.5868	0.5868	0.5868	0.5868
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3361	0.3361	0.3361	0.3361	0.3361
REGIONCD			Eastern Europe		0.2672	0.2672	0.2672	0.2672	0.2672
REGIONCD			Western Europe		0.3967	0.3967	0.3967	0.3967	0.3967
EFSTDBL					9.8386	9.8386	9.8386	9.8386	9.8386

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5069
SEX	Male				0.4931
TRTTYPCD		Diet & Exercise			0.4132
TRTTYPCD		Monotherapy			0.5868
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3361
REGIONCD			Eastern Europe		0.2672
REGIONCD			Western Europe		0.3967
EFSTDBL					9.8386

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.5152	0.2727	352	1.89	0.0597	0.05	-0.02109	1.0514
TRTCD	2.5mg	WORK.EFF	0.1115	0.2821	352	0.40	0.6928	0.05	-0.4433	0.6664
TRTCD	7.5mg	WORK.EFF	-0.2823	0.2718	352	-1.04	0.2998	0.05	-0.8169	0.2523
TRTCD	15mg	WORK.EFF	-0.06715	0.2695	352	-0.25	0.8034	0.05	-0.5972	0.4629
TRTCD	30mg	WORK.EFF	-0.9465	0.2811	352	-3.37	0.0008	0.05	-1.4993	-0.3938
TRTCD	45mg	WORK.EFF	-0.7097	0.2763	352	-2.57	0.0106	0.05	-1.2531	-0.1663

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.4036	0.3934	352	1.03	0.3056	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.7974	0.3853	352	2.07	0.0392	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.5823	0.3838	352	1.52	0.1301	0.05
TRTCD	Placebo	30mg	WORK.EFF	1.4617	0.3912	352	3.74	0.0002	0.05
TRTCD	Placebo	45mg	WORK.EFF	1.2248	0.3886	352	3.15	0.0018	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.3938	0.3921	352	1.00	0.3159	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1787	0.3900	352	0.46	0.6471	0.05
TRTCD	2.5mg	30mg	WORK.EFF	1.0580	0.3993	352	2.65	0.0084	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.8212	0.3946	352	2.08	0.0381	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.2151	0.3827	352	-0.56	0.5744	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.6642	0.3907	352	1.70	0.0900	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.4274	0.3879	352	1.10	0.2713	0.05
TRTCD	15mg	30mg	WORK.EFF	0.8794	0.3895	352	2.26	0.0246	0.05
TRTCD	15mg	45mg	WORK.EFF	0.6425	0.3860	352	1.66	0.0969	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.2368	0.3942	352	-0.60	0.5484	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.3701	1.1773
TRTCD	Placebo	7.5mg	0.03970	1.5552
TRTCD	Placebo	15mg	-0.1726	1.3372
TRTCD	Placebo	30mg	0.6923	2.2310
TRTCD	Placebo	45mg	0.4606	1.9891
TRTCD	2.5mg	7.5mg	-0.3773	1.1650
TRTCD	2.5mg	15mg	-0.5883	0.9457
TRTCD	2.5mg	30mg	0.2728	1.8433
TRTCD	2.5mg	45mg	0.04516	1.5973
TRTCD	7.5mg	15mg	-0.9678	0.5375

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.1042	1.4327
TRTCD	7.5mg	45mg	-0.3355	1.1903
TRTCD	15mg	30mg	0.1132	1.6455
TRTCD	15mg	45mg	-0.1166	1.4017
TRTCD	30mg	45mg	-1.0122	0.5385

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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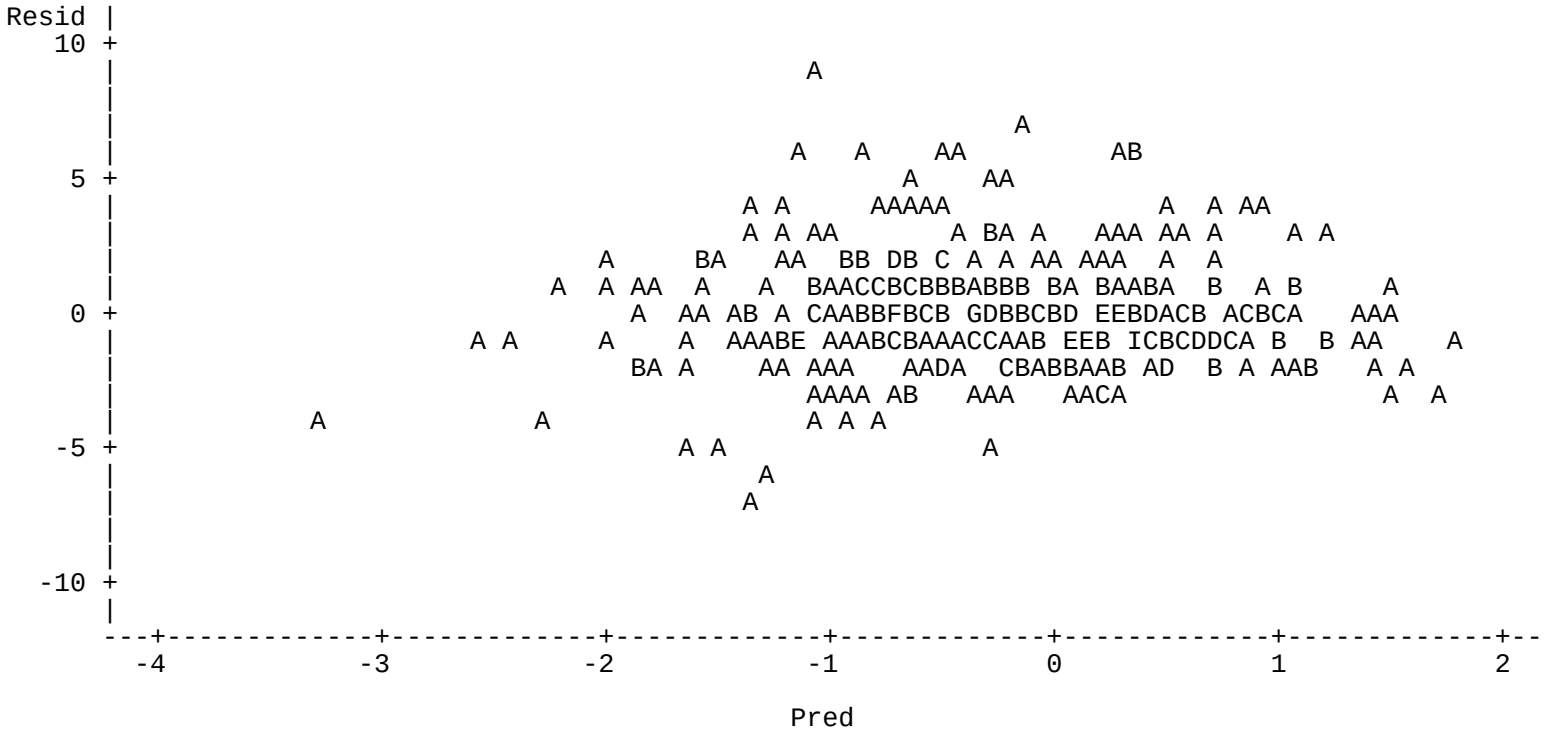
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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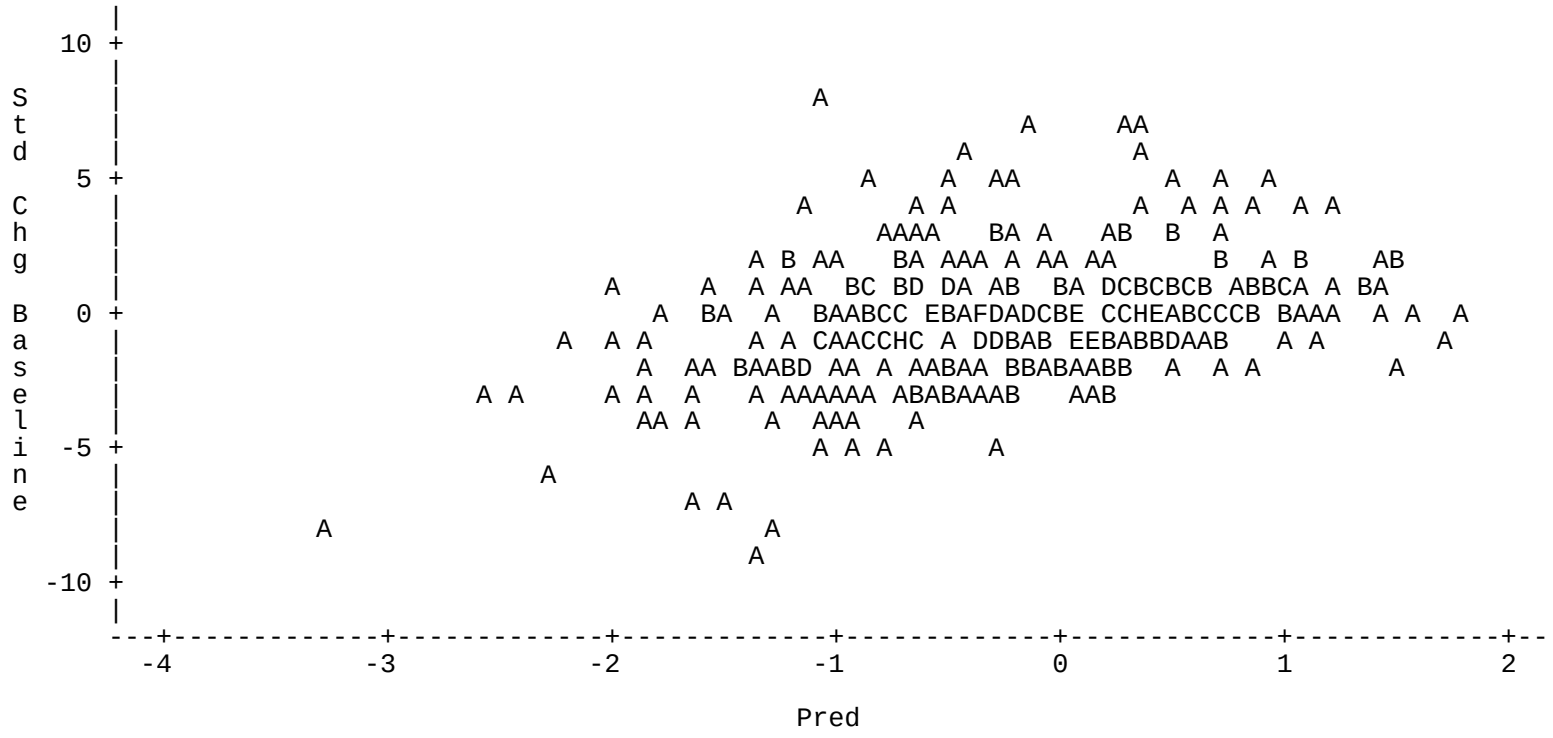
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	363	Sum Weights	363
Mean	0	Sum Observations	0
Std Deviation	2.10732598	Variance	4.4408228
Skewness	0.60666627	Kurtosis	1.93389614
Uncorrected SS	1607.57785	Corrected SS	1607.57785
Coeff Variation		Std Error Mean	0.11060593

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	2.10733
Median	-0.20150	Variance	4.44082
Mode		Range	16.36145
		Interquartile Range	2.17684

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-19.5	Pr >= |M|	0.0460
Signed Rank	S	-2706	Pr >= |S|	0.1765

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.962281	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.086279	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.754267	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.203216	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.100072
99%	6.249444
95%	3.725439
90%	2.587123
75% Q3	0.928336
50% Median	-0.201498
25% Q1	-1.248506
10%	-2.318643
5%	-2.980046
1%	-5.050946
0% Min	-7.261373

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-7.26137	51	5.90164	25
-6.41079	22	6.24944	172
-5.38955	228	6.47320	21
-5.05095	156	7.05548	141
-4.53676	52	9.10007	321

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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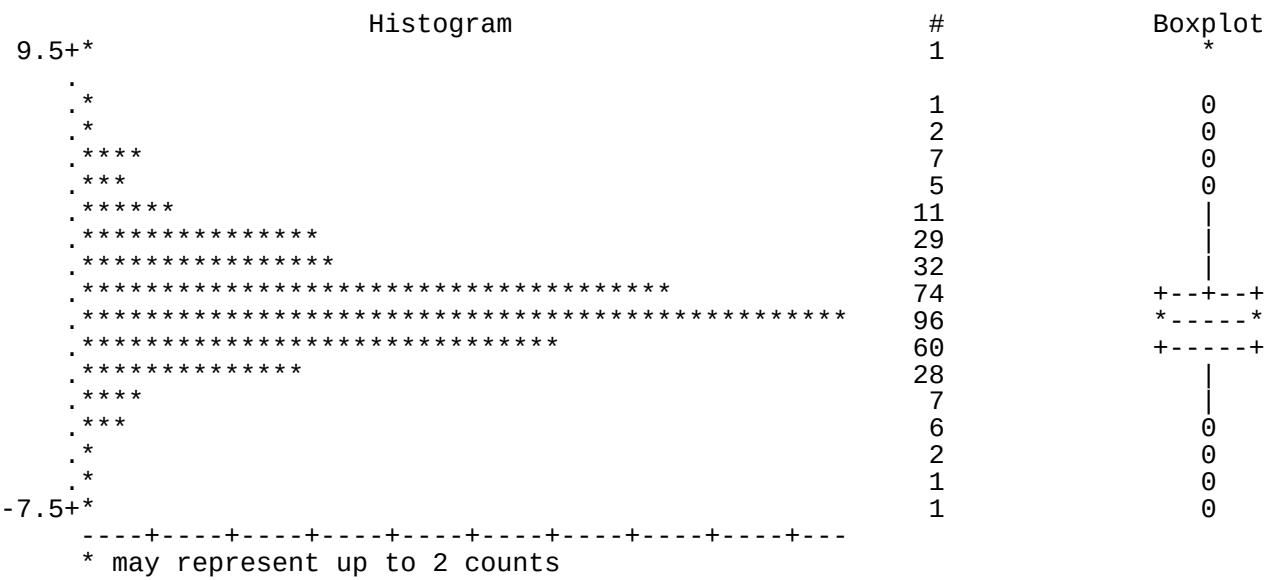
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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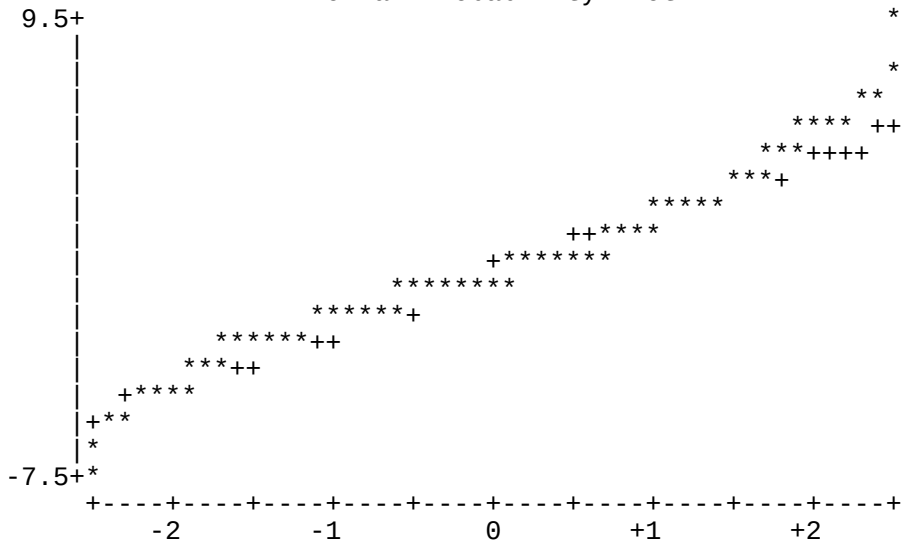
Table 11.20
SAS Statistical Output for Table 11.19
Analysis of Change in Fasting Plasma Glucose (mmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	53	61	62	55	58
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	306.6	311.2	311.7	308.3	313.3	316.9
	SD	39.51	53.97	52.79	48.46	56.23	55.07
	SE	5.23	7.41	6.76	6.15	7.58	7.23
	Minimum	236	219	214	227	194	219
	Median	306.0	299.0	306.0	294.0	310.0	311.0
	Maximum	406	508	458	461	448	521
Week -5	Mean	288.8	293.9	304.1	289.3	303.9	299.8
	SD	42.67	42.74	41.96	36.03	54.58	44.36
	SE	5.65	5.87	5.37	4.58	7.36	5.82
	Minimum	217	212	189	191	169	193
	Median	283.0	302.0	305.0	288.0	299.0	298.0
	Maximum	409	381	423	382	462	415
Change from Baseline	Mean	-17.8	-17.2	-7.6	-19.0	-9.3	-17.2
	SD	38.40	53.51	42.87	47.20	41.72	46.27
	SE	5.09	7.35	5.49	5.99	5.63	6.08
	Minimum	-118	-192	-102	-270	-98	-164
	Median	-17.0	-16.0	-1.0	-11.5	-5.0	-13.5
	Maximum	73	77	98	51	81	102

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Week -2

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	53	56	60	54	58
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	304.8	312.4	313.0	311.6	310.4	316.6
	SD	40.21	53.83	54.02	48.23	55.91	55.14
	SE	5.52	7.39	7.22	6.23	7.61	7.24
	Minimum	236	219	214	240	194	219
	Median	299.0	304.0	306.5	301.0	309.5	309.0
	Maximum	406	508	458	461	448	521
Week -2	Mean	292.9	296.0	297.3	299.9	298.7	305.5
	SD	49.94	56.15	58.34	35.73	48.30	49.93
	SE	6.86	7.71	7.80	4.61	6.57	6.56
	Minimum	71	52	19	235	197	204
	Median	293.0	298.0	304.0	297.0	297.0	305.0
	Maximum	391	415	415	386	398	477
Change from Baseline	Mean	-11.9	-16.5	-15.7	-11.7	-11.7	-11.1
	SD	40.09	51.52	57.97	32.42	28.45	31.49
	SE	5.51	7.08	7.75	4.19	3.87	4.13
	Minimum	-238	-283	-331	-105	-76	-105
	Median	-5.0	-8.0	-9.0	-9.5	-11.5	-12.5
	Maximum	52	82	105	57	37	95

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	54	62	63	57	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	305.6	311.7	311.0	309.2	312.3	316.6
	SD	39.96	53.60	52.67	48.63	55.74	54.66
	SE	5.25	7.29	6.69	6.13	7.38	7.12
	Minimum	236	219	214	227	194	219
	Median	302.5	301.5	305.0	295.0	310.0	310.0
	Maximum	406	508	458	461	448	521

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	53	58	61	53	56
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Mean	305.0	312.8	312.4	307.6	311.9	315.2
	SD	38.71	53.53	53.92	48.53	51.19	54.98
	SE	5.32	7.35	7.08	6.21	7.03	7.35
	Minimum	246	219	214	227	194	219
	Median	299.0	304.0	305.0	293.0	310.0	309.0
	Maximum	406	508	458	461	424	521
Week 4	Mean	315.4	308.5	309.5	297.5	297.7	293.3
	SD	59.11	57.24	54.99	42.72	54.44	44.44
	SE	8.12	7.86	7.22	5.47	7.48	5.94
	Minimum	229	188	213	229	193	224
	Median	303.0	307.0	294.0	293.0	283.0	288.0
	Maximum	510	496	460	462	462	420
Change from Baseline	Mean	10.3	-4.3	-2.9	-10.1	-14.2	-22.0
	SD	38.09	37.01	34.08	33.64	29.38	36.58
	SE	5.23	5.08	4.48	4.31	4.04	4.89
	Minimum	-82	-163	-134	-114	-96	-122
	Median	12.0	-3.0	-1.0	-5.0	-14.0	-17.5
	Maximum	106	89	89	57	48	53

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		55	53	61	61	57	58
Number (%) of Values Carried Forward		6 (11%)	10 (19%)	8 (13%)	2 (3%)	3 (5%)	10 (17%)
Baseline	Mean	306.5	312.8	311.0	307.6	312.3	316.3
	SD	39.25	53.53	53.11	48.53	55.74	55.08
	SE	5.29	7.35	6.80	6.21	7.38	7.23
	Minimum	246	219	214	227	194	219
	Median	306.0	304.0	304.0	293.0	310.0	309.0
	Maximum	406	508	458	461	448	521
Week 8	Mean	322.5	310.9	307.9	299.9	292.1	292.9
	SD	68.69	62.69	54.07	45.49	58.84	44.47
	SE	9.26	8.61	6.92	5.82	7.79	5.84
	Minimum	211	208	210	226	186	209
	Median	308.0	299.0	294.0	294.0	287.0	289.5
	Maximum	582	529	460	462	462	409
Change from Baseline	Mean	15.9	-1.8	-3.1	-7.7	-20.2	-23.3
	SD	49.33	39.87	33.88	32.84	34.06	33.65
	SE	6.65	5.48	4.34	4.21	4.51	4.42
	Minimum	-64	-163	-82	-90	-96	-118
	Median	9.0	-4.0	0.0	-9.0	-22.0	-16.0
	Maximum	211	92	131	49	88	33

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.21
Summary Statistics for Fructosamine (mcmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		55	53	61	62	57	58
Number (%) of Values Carried Forward		10 (18%)	11 (21%)	10 (16%)	3 (5%)	6 (11%)	7 (12%)
Baseline	Mean	306.5	312.8	311.0	308.6	312.3	316.3
	SD	39.25	53.53	53.11	48.80	55.74	55.08
	SE	5.29	7.35	6.80	6.20	7.38	7.23
	Minimum	246	219	214	227	194	219
	Median	306.0	304.0	304.0	294.0	310.0	309.0
	Maximum	406	508	458	461	448	521
Week 12	Mean	325.9	317.6	309.5	300.7	292.2	295.8
	SD	67.96	70.50	63.36	50.20	60.45	47.62
	SE	9.16	9.68	8.11	6.37	8.01	6.25
	Minimum	216	208	198	225	176	189
	Median	315.0	306.0	300.0	288.5	281.0	298.0
	Maximum	567	599	508	462	462	415
Change from Baseline	Mean	19.3	4.8	-1.5	-8.0	-20.2	-20.5
	SD	52.14	43.78	36.34	41.58	38.85	37.22
	SE	7.03	6.01	4.65	5.28	5.15	4.89
	Minimum	-75	-163	-82	-116	-106	-117
	Median	7.0	-1.0	-2.0	-5.5	-18.0	-14.0
	Maximum	196	125	101	116	75	53

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		55	53	61	62	57	58
Number (%) of Values Carried Forward		10 (18%)	11 (21%)	10 (16%)	3 (5%)	6 (11%)	7 (12%)
Baseline	Mean	306.5	312.8	311.0	308.6	312.3	316.3
	SD	39.25	53.53	53.11	48.80	55.74	55.08
Week 12	Mean	325.9	317.6	309.5	300.7	292.2	295.8
	SD	67.96	70.50	63.36	50.20	60.45	47.62
Chg from Baseline	Mean	19.3	4.8	-1.5	-8.0	-20.2	-20.5
	SD	52.14	43.78	36.34	41.58	38.85	37.22
Model-Adj Chg [2]	Mean	19.9	5.0	-2.5	-9.3	-19.7	-19.0
	SE	5.44	5.55	5.16	5.12	5.34	5.29
Diff from Pbo [2]	Mean		-14.9	-22.4	-29.2	-39.6	-38.9
	95% CI		-30.2,0.5	-37.1,-7.6	-43.9,-14.5	-54.6,-24.6	-53.8,-23.9
	p-val [3]		0.057	0.003	<0.001	<0.001	<0.001

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	55	Sum Weights	55
Mean	306.527273	Sum Observations	16859
Std Deviation	39.2503147	Variance	1540.58721
Skewness	0.41178294	Kurtosis	-0.5299909
Uncorrected SS	5250935	Corrected SS	83191.7091
Coeff Variation	12.804836	Std Error Mean	5.29251136

Basic Statistical Measures

Location		Variability	
Mean	306.5273	Std Deviation	39.25031
Median	306.0000	Variance	1541
Mode	317.0000	Range	160.00000
		Interquartile Range	58.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	57.91717	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	770	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.965996	Pr < W	0.1213
Kolmogorov-Smirnov	D	0.079744	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.060831	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.456235	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	406
99%	406
95%	378
90%	361
75% Q3	334

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	306
25% Q1	276
10%	256
5%	253
1%	246
0% Min	246

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
246	6	371	53
247	31	372	45
253	1	378	42
254	20	379	27
255	21	406	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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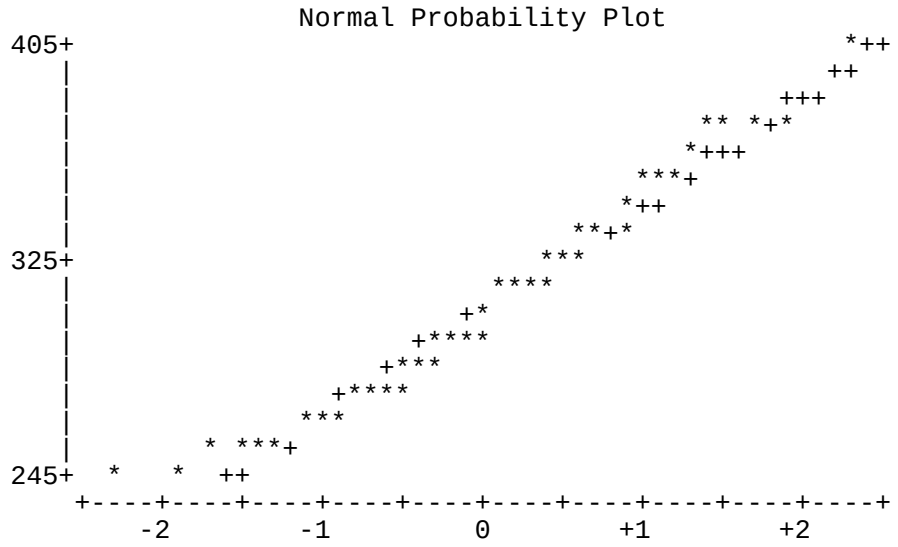
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                #    Boxplot
    40 6                   1       |
    39                             |
    38                             |
    37 1289                4       |
    36 1                   1       |
    35 167                 3       |
    34 7                   1       |
    33 44668               5    +-----+
    32 0258                4    |     |
    31 0477779             7    |     |
    30 69                  2    *--+--*
    29 133479              6    |     |
    28 3689                4    |     |
    27 136778              6    +-----+
    26 0046                4       |
    25 34566               5       |
    24 67                  2       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	55	Sum Weights	55
Mean	325.854545	Sum Observations	17922
Std Deviation	67.955437	Variance	4617.94141
Skewness	1.11997552	Kurtosis	2.17223257
Uncorrected SS	6089334	Corrected SS	249368.836
Coeff Variation	20.8545309	Std Error Mean	9.16310925

Basic Statistical Measures

Location		Variability	
Mean	325.8545	Std Deviation	67.95544
Median	315.0000	Variance	4618
Mode	289.0000	Range	351.00000
		Interquartile Range	87.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	35.56157	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	770	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.933717	Pr < W	0.0047
Kolmogorov-Smirnov	D	0.090726	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.098987	Pr > W-Sq	0.1158
Anderson-Darling	A-Sq	0.704924	Pr > A-Sq	0.0653

Quantiles (Definition 5)

Quantile	Estimate
100% Max	567
99%	567
95%	434
90%	406
75% Q3	369

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	315
25% Q1	282
10%	249
5%	234
1%	216
0% Min	216

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
216	35	415	50
232	20	417	39
234	26	434	8
237	17	510	14
242	16	567	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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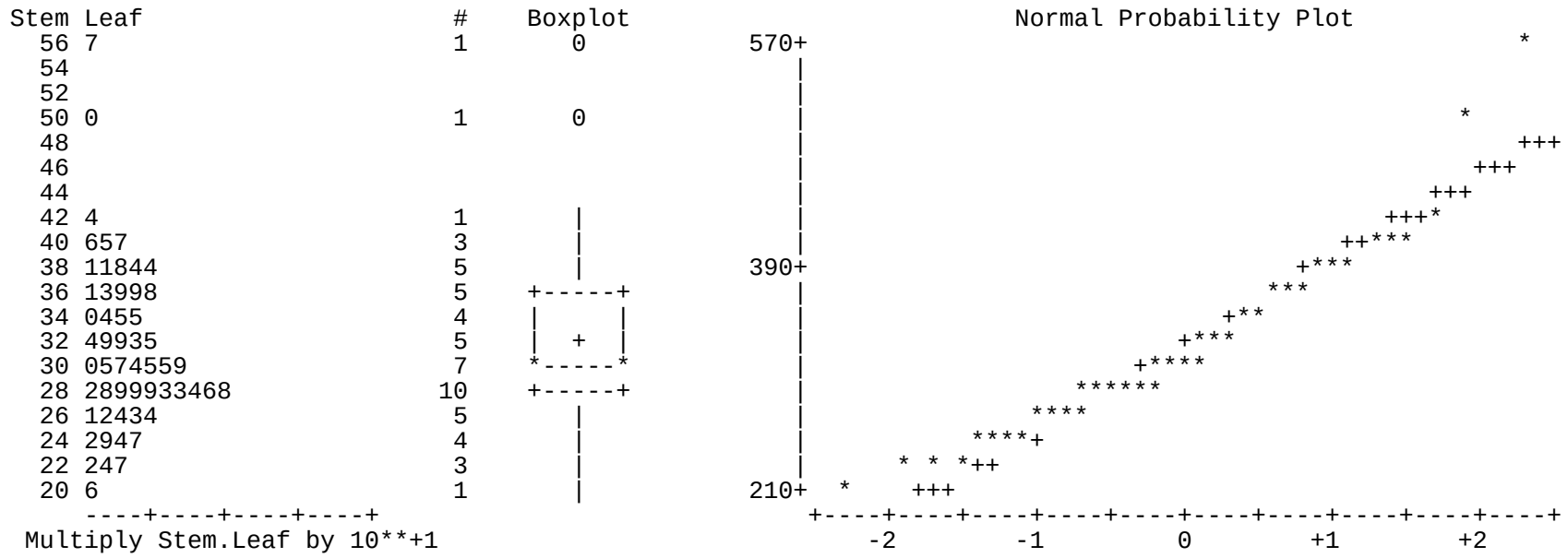
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	19.3272727	Sum Observations	1063
Std Deviation	52.1365922	Variance	2718.22424
Skewness	0.9507576	Kurtosis	1.46563564
Uncorrected SS	167329	Corrected SS	146784.109
Coeff Variation	269.756592	Std Error Mean	7.03009665

Basic Statistical Measures

Location		Variability	
Mean	19.32727	Std Deviation	52.13659
Median	7.00000	Variance	2718
Mode	-4.00000	Range	271.00000
		Interquartile Range	64.00000

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.749219	Pr > |t|	0.0081
Sign	M	7	Pr >= |M|	0.0759
Signed Rank	S	279	Pr >= |S|	0.0148

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.94544	Pr < W	0.0145
Kolmogorov-Smirnov	D	0.13702	Pr > D	0.0108
Cramer-von Mises	W-Sq	0.192028	Pr > W-Sq	0.0066
Anderson-Darling	A-Sq	0.965202	Pr > A-Sq	0.0152

Quantiles (Definition 5)

Quantile	Estimate
100% Max	196
99%	196
95%	113

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	89
75% Q3	54
50% Median	7
25% Q1	-10
10%	-44
5%	-54
1%	-75
0% Min	-75

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-75	19	100	8
-61	34	104	14
-54	17	113	52
-49	42	138	50
-47	16	196	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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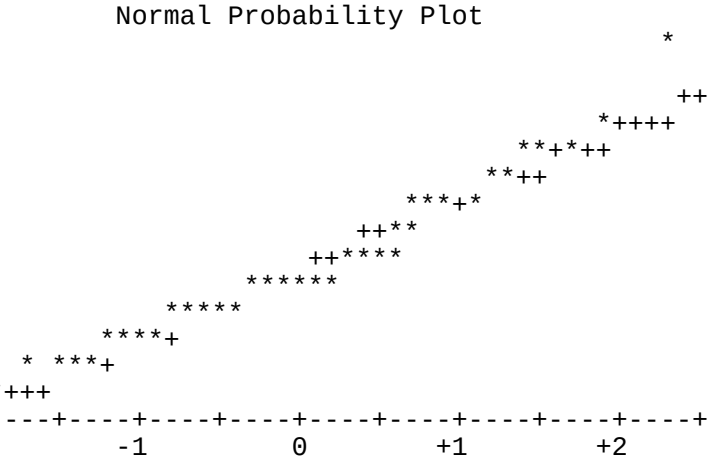
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                  #    Boxplot
    18 6                     1       0
    16                              |
    14                              |
    12 8                     1      |
    10 043                   3      |
     8 09                    2      |
     6 346992                6      |
     4 34                    2    +-----+
     2 0334737               7    |     |
     0 0124556701147        13    *--+--*
    -0 930744211             9    +-----+
    -2 32182                 5      |
    -4 4974                  4      |
    -6 51                    2      |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	312.754717	Sum Observations	16576
Std Deviation	53.5306906	Variance	2865.53483
Skewness	1.32082893	Kurtosis	3.46329472
Uncorrected SS	5333230	Corrected SS	149007.811
Coeff Variation	17.1158699	Std Error Mean	7.35300585

Basic Statistical Measures

Location		Variability	
Mean	312.7547	Std Deviation	53.53069
Median	304.0000	Variance	2866
Mode	234.0000	Range	289.00000
		Interquartile Range	52.00000

NOTE: The mode displayed is the smallest of 11 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	42.53427	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.909664	Pr < W	0.0007
Kolmogorov-Smirnov	D	0.11245	Pr > D	0.0923
Cramer-von Mises	W-Sq	0.142223	Pr > W-Sq	0.0300
Anderson-Darling	A-Sq	1.012191	Pr > A-Sq	0.0107

Quantiles (Definition 5)

Quantile	Estimate
100% Max	508
99%	508
95%	401

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	371
75% Q3	335
50% Median	304
25% Q1	283
10%	254
5%	234
1%	219
0% Min	219

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
219	7	375	5
234	36	375	9
234	16	401	40
236	50	476	8
248	37	508	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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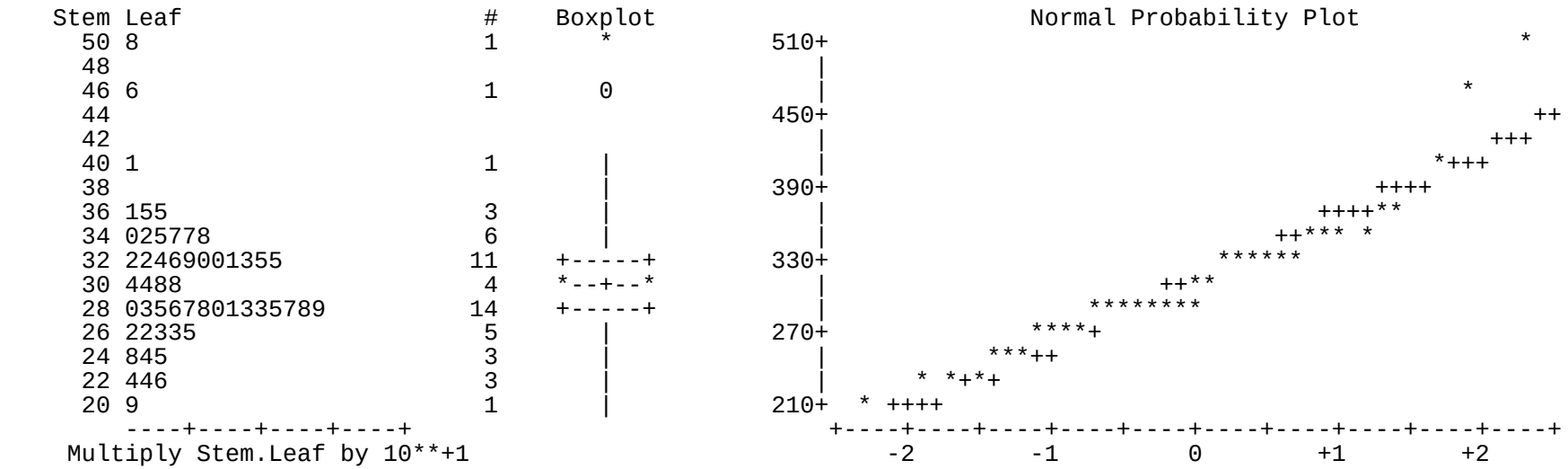
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	317.603774	Sum Observations	16833
Std Deviation	70.5043206	Variance	4970.85922
Skewness	1.76755774	Kurtosis	4.8849746
Uncorrected SS	5604709	Corrected SS	258484.679
Coeff Variation	22.1988296	Std Error Mean	9.68451323

Basic Statistical Measures

Location		Variability	
Mean	317.6038	Std Deviation	70.50432
Median	306.0000	Variance	4971
Mode	236.0000	Range	391.00000
		Interquartile Range	67.00000

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	32.79502	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.868771	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.141248	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.249307	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.586209	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	599
99%	599
95%	451

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	391
75% Q3	341
50% Median	306
25% Q1	274
10%	247
5%	228
1%	208
0% Min	208

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
208	49	396	5
225	37	404	34
228	7	451	48
236	38	529	8
236	36	599	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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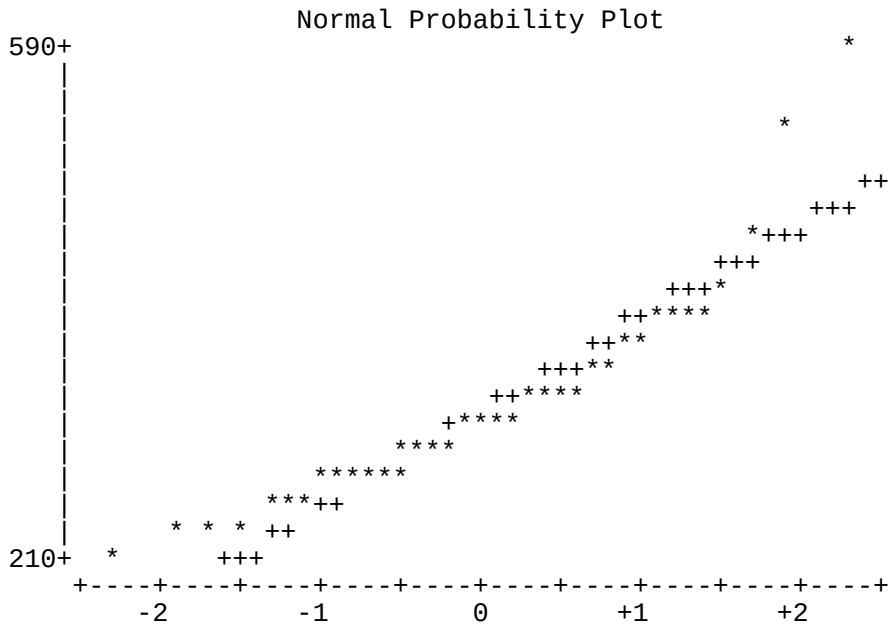
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                #    Boxplot
    58 9                   1       *
    56                              |
    54                              |
    52 9                   1       0
    50                              |
    48                              |
    46                              |
    44 1                   1       0
    42                              |
    40 4                   1       |
    38 6916                4       |
    36 12                  2       |
    34 1457                4    +-----+
    32 890356              6    |     |
    30 366900299           9    *--+--*
    28 11288199            8    |     |
    26 69033467            8    +-----+
    24 779                 3       |
    22 5866                4       |
    20 8                   1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	4.8490566	Sum Observations	257
Std Deviation	43.7753866	Variance	1916.28447
Skewness	-0.1594114	Kurtosis	4.58633485
Uncorrected SS	100893	Corrected SS	99646.7925
Coeff Variation	902.760891	Std Error Mean	6.01301179

Basic Statistical Measures

Location		Variability	
Mean	4.8491	Std Deviation	43.77539
Median	-1.0000	Variance	1916
Mode	-34.0000	Range	288.00000
		Interquartile Range	42.00000

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.806427	Pr > |t|	0.4237
Sign	M	-0.5	Pr >= |M|	1.0000
Signed Rank	S	68.5	Pr >= |S|	0.5492

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.894499	Pr < W	0.0002
Kolmogorov-Smirnov	D	0.123393	Pr > D	0.0431
Cramer-von Mises	W-Sq	0.179408	Pr > W-Sq	0.0093
Anderson-Darling	A-Sq	1.350025	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	125
99%	125
95%	91

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	53
75% Q3	25
50% Median	-1
25% Q1	-17
10%	-34
5%	-41
1%	-163
0% Min	-163

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-163	49	54	32
-42	13	64	34
-41	42	91	4
-37	38	125	48
-34	31	125	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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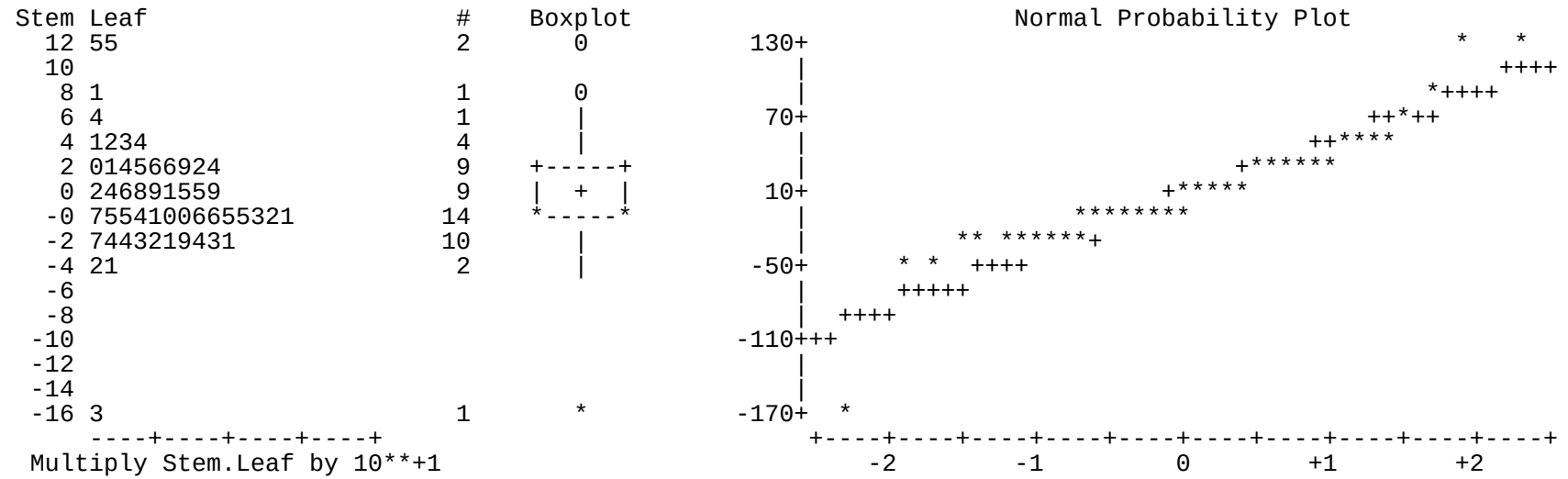
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	61	Sum Weights	61
Mean	311	Sum Observations	18971
Std Deviation	53.109635	Variance	2820.63333
Skewness	0.44985121	Kurtosis	0.16018938
Uncorrected SS	6069219	Corrected SS	169238
Coeff Variation	17.0770531	Std Error Mean	6.79999196

Basic Statistical Measures

Location		Variability	
Mean	311.0000	Std Deviation	53.10964
Median	304.0000	Variance	2821
Mode	288.0000	Range	244.00000
		Interquartile Range	65.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	45.73535	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	945.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.973396	Pr < W	0.2048
Kolmogorov-Smirnov	D	0.105184	Pr > D	0.0915
Cramer-von Mises	W-Sq	0.0999	Pr > W-Sq	0.1126
Anderson-Darling	A-Sq	0.546892	Pr > A-Sq	0.1578

Quantiles (Definition 5)

Quantile	Estimate
100% Max	458
99%	458
95%	406
90%	383
75% Q3	348

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	304
25% Q1	283
10%	240
5%	224
1%	214
0% Min	214

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
214	9	404	4
216	22	406	5
224	13	411	36
224	12	423	35
226	51	458	46

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

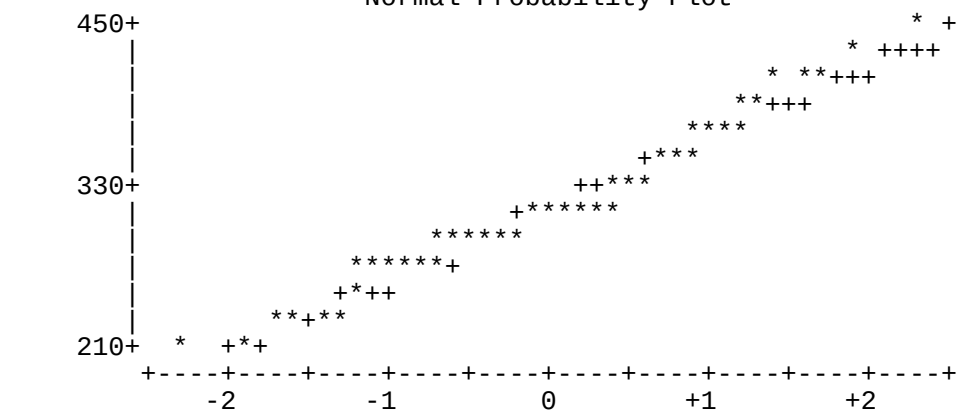
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Stem	Leaf	#	Boxplot
44	8	1	0
42	3	1	
40	461	3	
38	34	2	
36	2450	4	
34	88905	5	+-----+
32	03689	5	| |
30	1344678992469	13	*--+--*
28	366688880068	12	+-----+
26	12469078	8	
24	0	1	
22	4465	4	
20	46	2	

Multiply Stem.Leaf by 10**+1



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	61	Sum Weights	61
Mean	309.52459	Sum Observations	18881
Std Deviation	63.3644502	Variance	4015.05355
Skewness	0.93007819	Kurtosis	1.12548354
Uncorrected SS	6085037	Corrected SS	240903.213
Coeff Variation	20.47154	Std Error Mean	8.11298651

Basic Statistical Measures

Location		Variability	
Mean	309.5246	Std Deviation	63.36445
Median	300.0000	Variance	4015
Mode	304.0000	Range	310.00000
		Interquartile Range	74.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	38.15174	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	945.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.943174	Pr < W 0.0069
Kolmogorov-Smirnov	D	0.135322	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.194078	Pr > W-Sq 0.0062
Anderson-Darling	A-Sq	1.105366	Pr > A-Sq 0.0066

Quantiles (Definition 5)

Quantile	Estimate
100% Max	508
99%	508
95%	437
90%	388
75% Q3	340

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	300
25% Q1	266
10%	250
5%	216
1%	198
0% Min	198

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
198	39	427	3
201	13	437	59
216	57	456	5
216	22	460	46
228	12	508	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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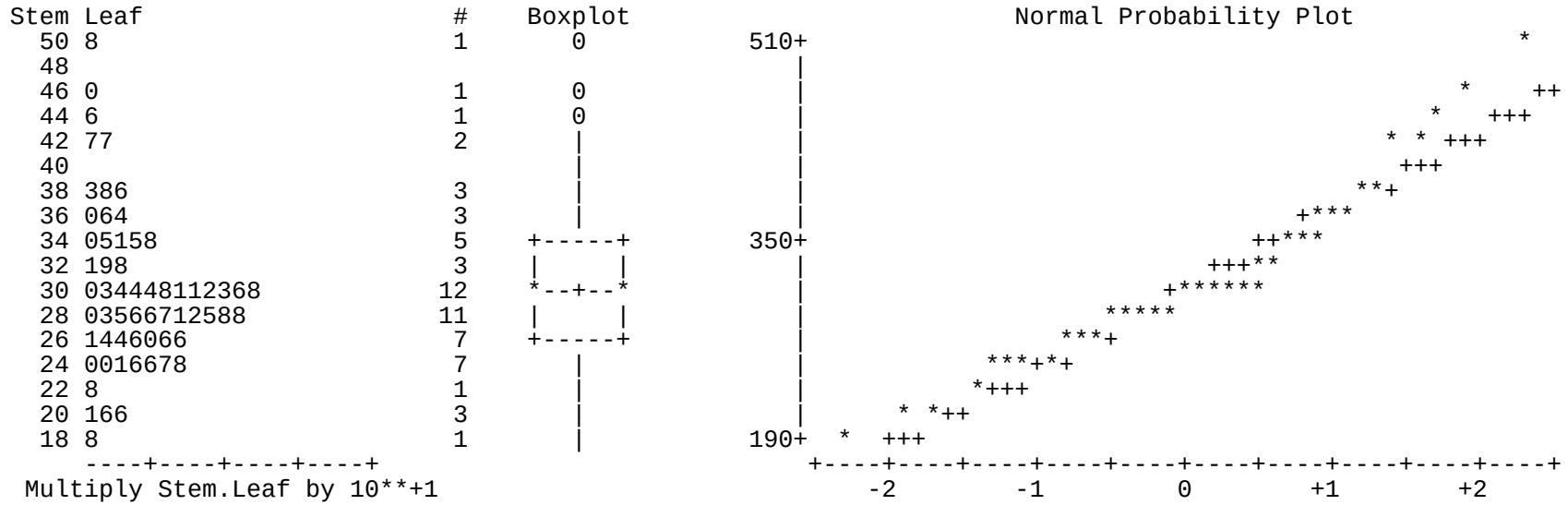
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	61	Sum Weights	61
Mean	-1.4754098	Sum Observations	-90
Std Deviation	36.3398801	Variance	1320.58689
Skewness	0.77906918	Kurtosis	1.03137772
Uncorrected SS	79368	Corrected SS	79235.2131
Coeff Variation	-2463.0363	Std Error Mean	4.65284486

Basic Statistical Measures

Location		Variability	
Mean	-1.47541	Std Deviation	36.33988
Median	-2.00000	Variance	1321
Mode	2.00000	Range	183.00000
		Interquartile Range	39.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.3171	Pr > |t|	0.7523
Sign	M	-3	Pr >= |M|	0.5118

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-138	Pr >= |S|	0.2891

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.942448	Pr < W	0.0064
Kolmogorov-Smirnov	D	0.128642	Pr > D	0.0133
Cramer-von Mises	W-Sq	0.198236	Pr > W-Sq	0.0052
Anderson-Darling	A-Sq	1.253234	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	101
99%	101
95%	77
90%	50
75% Q3	13

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-2
25% Q1	-26
10%	-37
5%	-46
1%	-82
0% Min	-82

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-82	54	65	3
-72	39	77	9
-46	43	85	35
-46	2	87	51
-40	53	101	59

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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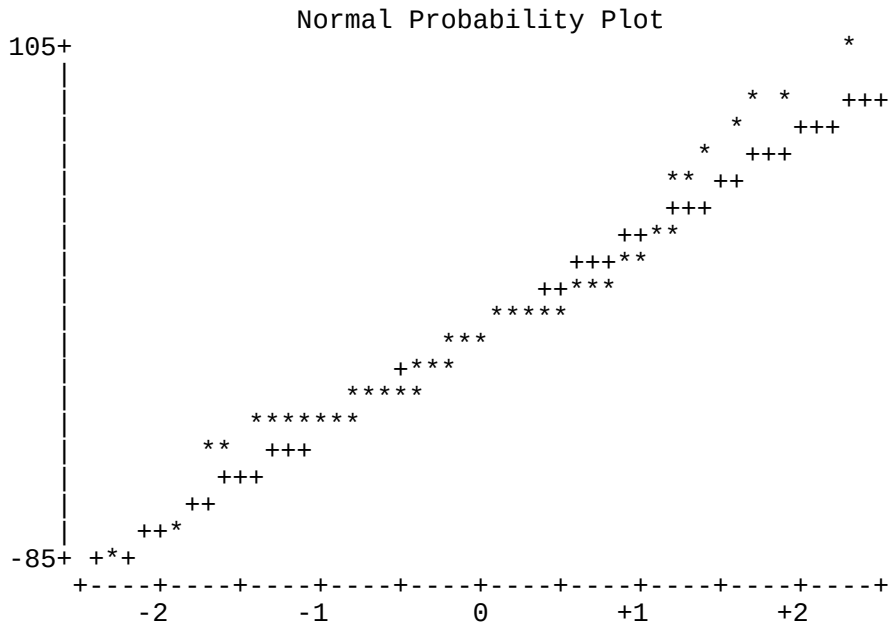
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                     #    Boxplot
    10 1                        1       0
     9                                  |
     8 57                       2       0
     7 7                        1       0
     6 5                        1       |
     5 05                       2       |
     4                                  |
     3 19                       2       |
     2 145                      3       |
     1 023358                   6    +-----+
     0 00012222347             11    |     |
    -0 8653322                  7    *--+--*
    -1 9876                     4    |     |
    -2 86654321                 8    +-----+
    -3 87743221                 8       |
    -4 660                      3       |
    -5                                  |
    -6                                  |
    -7 2                        1       |
    -8 2                        1       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	308.612903	Sum Observations	19134
Std Deviation	48.7967867	Variance	2381.12639
Skewness	0.98417966	Kurtosis	1.01357061
Uncorrected SS	6050248	Corrected SS	145248.71
Coeff Variation	15.8116482	Std Error Mean	6.1971981

Basic Statistical Measures

Location		Variability	
Mean	308.6129	Std Deviation	48.79679
Median	294.0000	Variance	2381
Mode	262.0000	Range	234.00000
		Interquartile Range	73.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	49.79878	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.929886	Pr < W	0.0016
Kolmogorov-Smirnov	D	0.125996	Pr > D	0.0157
Cramer-von Mises	W-Sq	0.216051	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.262466	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	461
99%	461
95%	382

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	367
75% Q3	346
50% Median	294
25% Q1	273
10%	262
5%	250
1%	227
0% Min	227

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
227	36	376	52
240	38	382	2
246	13	399	23
250	62	452	21
256	45	461	56

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[redacted]

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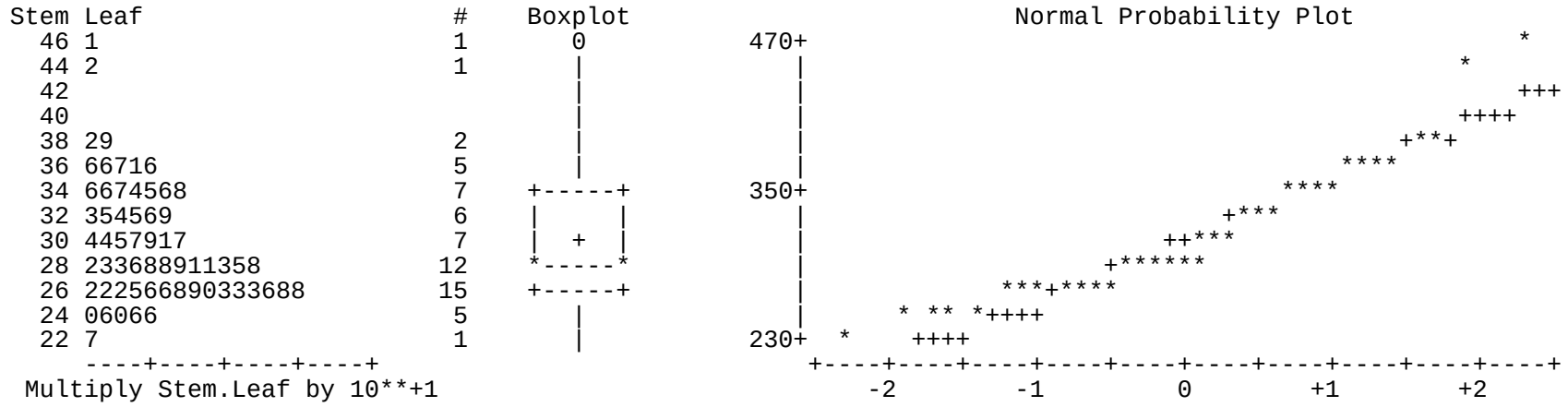
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	300.66129	Sum Observations	18641
Std Deviation	50.196644	Variance	2519.70307
Skewness	0.94498403	Kurtosis	1.01130359
Uncorrected SS	5758329	Corrected SS	153701.887
Coeff Variation	16.6954129	Std Error Mean	6.37498016

Basic Statistical Measures

Location		Variability	
Mean	300.6613	Std Deviation	50.19664
Median	288.5000	Variance	2520
Mode	242.0000	Range	237.00000
		Interquartile Range	60.00000

NOTE: The mode displayed is the smallest of 11 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	47.1627	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.942795	Pr < W	0.0061
Kolmogorov-Smirnov	D	0.125847	Pr > D	0.0160
Cramer-von Mises	W-Sq	0.159613	Pr > W-Sq	0.0186
Anderson-Darling	A-Sq	0.933501	Pr > A-Sq	0.0183

Quantiles (Definition 5)

Quantile	Estimate
100% Max	462.0
99%	462.0
95%	394.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	367.0
75% Q3	326.0
50% Median	288.5
25% Q1	266.0
10%	242.0
5%	229.0
1%	225.0
0% Min	225.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
225	33	378	42
226	47	394	4
227	15	394	17
229	45	432	8
235	25	462	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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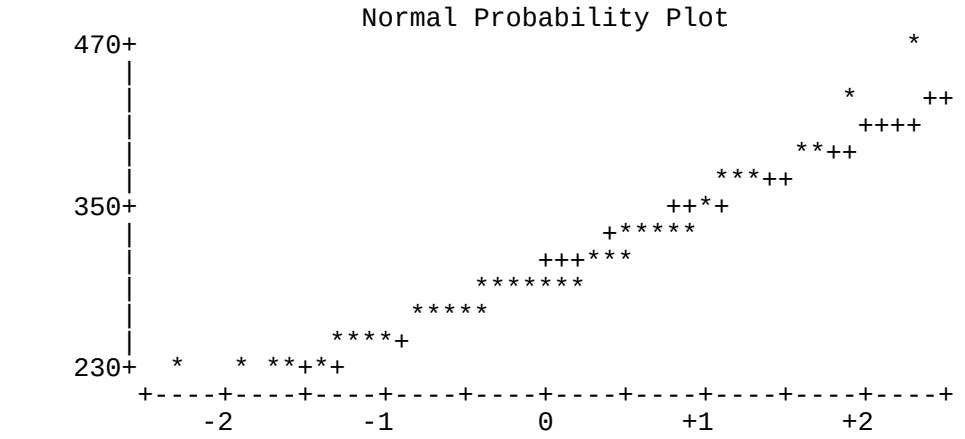
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
    46 2                     1       0
    44                       0
    42 2                     1       0
    40                       0
    38 44                    2       |
    36 05788                 5       |
    34 51                    2       |
    32 34561669              8    +-----+
    30 490234                6    |  +  |
    28 0113466778993677     16    *-----*
    26 012689018             9    +-----+
    24 2226677               7       |
    22 56795                 5       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-7.9516129	Sum Observations	-493
Std Deviation	41.5847653	Variance	1729.2927
Skewness	0.07617046	Kurtosis	1.09690283
Uncorrected SS	109407	Corrected SS	105486.855
Coeff Variation	-522.97271	Std Error Mean	5.28127047

Basic Statistical Measures

Location		Variability	
Mean	-7.9516	Std Deviation	41.58477
Median	-5.5000	Variance	1729
Mode	-12.0000	Range	232.00000
		Interquartile Range	42.00000

NOTE: The mode displayed is the smallest of 11 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.50563	Pr > |t|	0.1373
Sign	M	-7.5	Pr >= |M|	0.0722
Signed Rank	S	-226	Pr >= |S|	0.1050

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.972515	Pr < W	0.1778
Kolmogorov-Smirnov	D	0.109683	Pr > D	0.0636
Cramer-von Mises	W-Sq	0.149883	Pr > W-Sq	0.0235
Anderson-Darling	A-Sq	0.784012	Pr > A-Sq	0.0413

Quantiles (Definition 5)

Quantile	Estimate
100% Max	116.0
99%	116.0
95%	65.0

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	34.0
75% Q3	16.0
50% Median	-5.5
25% Q1	-26.0
10%	-67.0
5%	-71.0
1%	-116.0
0% Min	-116.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-116	21	43	3
-93	52	65	8
-87	23	69	24
-71	28	84	18
-70	29	116	4

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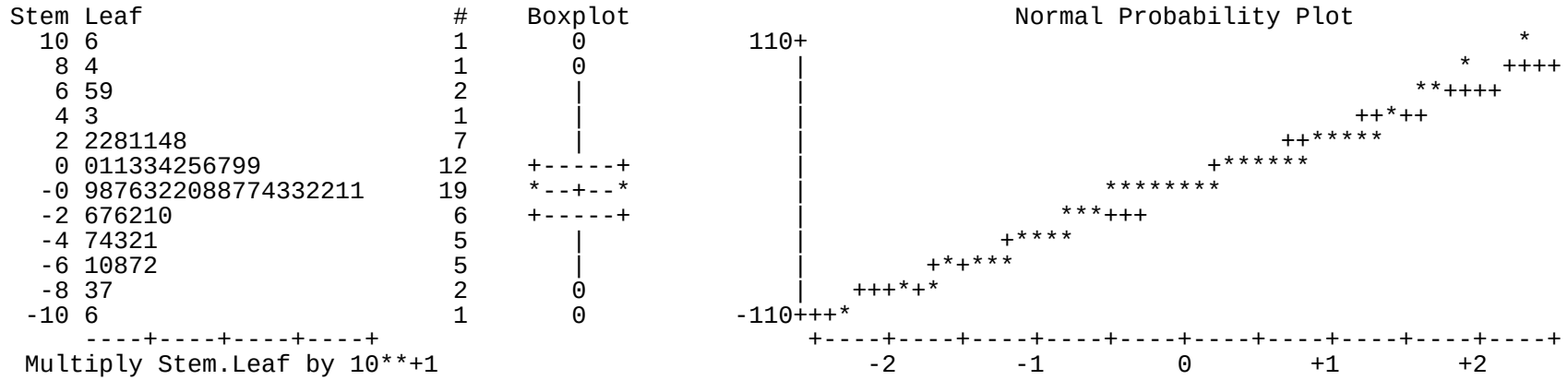
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	57	Sum Weights	57
Mean	312.333333	Sum Observations	17803
Std Deviation	55.7373731	Variance	3106.65476
Skewness	0.14959013	Kurtosis	-0.1688434
Uncorrected SS	5734443	Corrected SS	173972.667
Coeff Variation	17.845477	Std Error Mean	7.38259542

Basic Statistical Measures

Location		Variability	
Mean	312.3333	Std Deviation	55.73737
Median	310.0000	Variance	3107
Mode	279.0000	Range	254.00000
		Interquartile Range	70.00000

NOTE: The mode displayed is the smallest of 5 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	42.30671	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.986578	Pr < W	0.7780
Kolmogorov-Smirnov	D	0.091079	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.057899	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.319034	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	448
99%	448
95%	410

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	389
75% Q3	349
50% Median	310
25% Q1	279
10%	248
5%	214
1%	194
0% Min	194

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
194	33	391	23
204	37	393	7
214	38	410	42
218	2	424	24
226	50	448	18

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                     #    Boxplot
    44 8                        1       |
    42 4                        1       |
    40 0                        1       |
    38 13913                    5       |
    36 70148                    5       |
    34 295                      3    +-----+
    32 0025686                  7    |     |
    30 11349002678             11    *--+--*
    28 3588378                  7    |     |
    26 2361899                  7    +-----+
    24 8268                     4       |
    22 6                        1       |
    20 448                      3       |
    18 4                        1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```

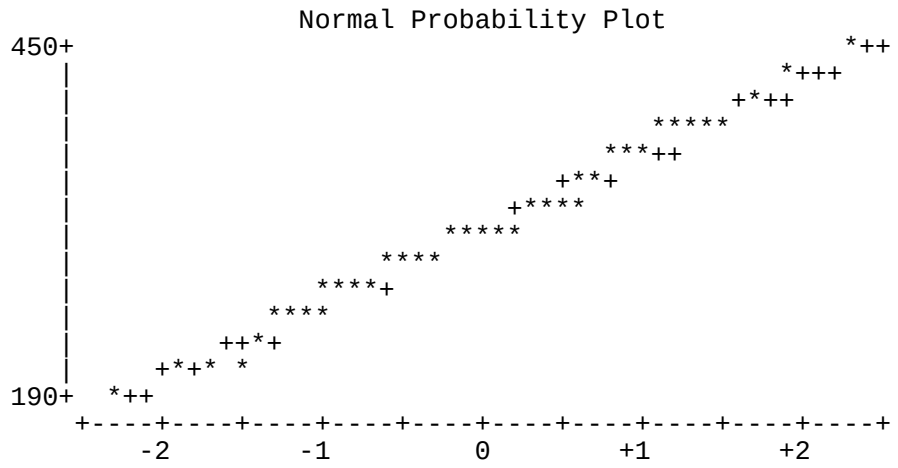

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	57	Sum Weights	57
Mean	292.175439	Sum Observations	16654
Std Deviation	60.4471797	Variance	3653.86153
Skewness	0.74647433	Kurtosis	0.64434112
Uncorrected SS	5070506	Corrected SS	204616.246
Coeff Variation	20.6886588	Std Error Mean	8.00642454

Basic Statistical Measures

Location		Variability	
Mean	292.1754	Std Deviation	60.44718
Median	281.0000	Variance	3654
Mode	293.0000	Range	286.00000
		Interquartile Range	67.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	36.49262	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.955297	Pr < W	0.0344
Kolmogorov-Smirnov	D	0.126137	Pr > D	0.0231
Cramer-von Mises	W-Sq	0.171393	Pr > W-Sq	0.0126
Anderson-Darling	A-Sq	0.930534	Pr > A-Sq	0.0185

Quantiles (Definition 5)

Quantile	Estimate
100% Max	462
99%	462
95%	401
90%	391
75% Q3	323

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[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	281
25% Q1	256
10%	221
5%	197
1%	176
0% Min	176

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
176	33	394	42
193	38	398	56
197	19	401	51
205	2	448	18
221	43	462	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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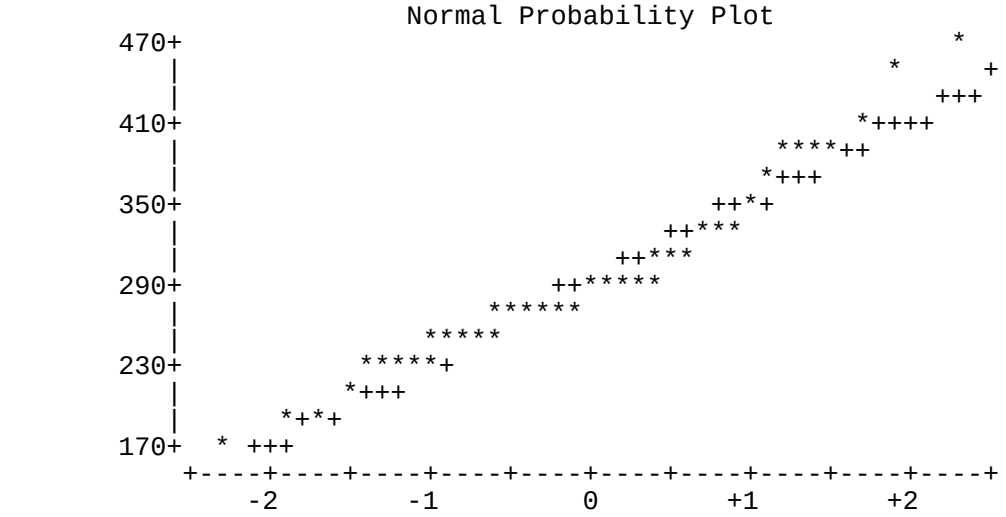
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                #    Boxplot
    46 2                   1       0
    44 8                   1       0
    42                             |
    40 1                   1       |
    38 3148                4       |
    36 7                   1       |
    34 45                  2       |
    32 37035               5   +-----+
    30 14799               5   |     |
    28 0112473339         10   *--+--*
    26 12315566788        11   |     |
    24 1168469             7   +-----+
    22 11028               5       |
    20 5                   1       |
    18 37                  2       |
    16 6                   1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



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[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	57	Sum Weights	57
Mean	-20.157895	Sum Observations	-1149
Std Deviation	38.8498894	Variance	1509.31391
Skewness	0.23375232	Kurtosis	-0.2884472
Uncorrected SS	107683	Corrected SS	84521.5789
Coeff Variation	-192.72791	Std Error Mean	5.14579356

Basic Statistical Measures

Location		Variability	
Mean	-20.1579	Std Deviation	38.84989
Median	-18.0000	Variance	1509
Mode	-62.0000	Range	181.00000
		Interquartile Range	54.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.91735	Pr > |t|	0.0002
Sign	M	-11.5	Pr >= |M|	0.0027

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-418.5	Pr >= |S|	0.0002

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.983715	Pr < W	0.6369
Kolmogorov-Smirnov	D	0.099049	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.040647	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.32788	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	75
99%	75
95%	50
90%	29
75% Q3	5

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[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-18
25% Q1	-49
10%	-67
5%	-68
1%	-106
0% Min	-106

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-106	19	38	24
-90	14	41	29
-68	23	50	50
-68	20	62	56
-67	48	75	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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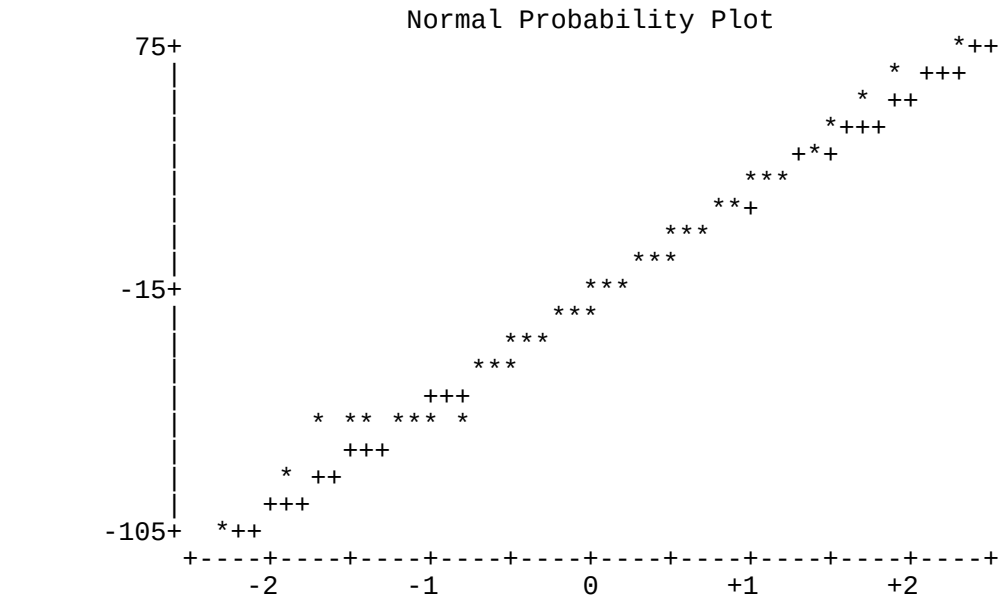
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                     #    Boxplot
     7 5                        1       |
     6 2                        1       |
     5 0                        1       |
     4 1                        1       |
     3 8                        1       |
     2 03499                    5       |
     1 07                       2       |
     0 005577                   6    +-----+
    -0 54                       2    |     |
    -1 877631100                9    *-----*
    -2 9751                     4    |  +  |
    -3 876622                   6    |     |
    -4 9731                     4    +-----+
    -5                                  |
    -6 887754322211            12       |
    -7                                  |
    -8                                  |
    -9 0                        1       |
   -10 6                        1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	316.258621	Sum Observations	18343
Std Deviation	55.0838469	Variance	3034.23019
Skewness	1.00595257	Kurtosis	2.56421072
Uncorrected SS	5974083	Corrected SS	172951.121
Coeff Variation	17.4173424	Std Error Mean	7.23286344

Basic Statistical Measures

Location		Variability	
Mean	316.2586	Std Deviation	55.08385
Median	309.0000	Variance	3034
Mode	295.0000	Range	302.00000
		Interquartile Range	51.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	43.72523	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.937727	Pr < W	0.0052
Kolmogorov-Smirnov	D	0.122396	Pr > D	0.0293
Cramer-von Mises	W-Sq	0.144348	Pr > W-Sq	0.0277
Anderson-Darling	A-Sq	0.853986	Pr > A-Sq	0.0265

Quantiles (Definition 5)

Quantile	Estimate
100% Max	521
99%	521
95%	403
90%	391
75% Q3	338

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	309
25% Q1	287
10%	246
5%	226
1%	219
0% Min	219

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
219	35	394	30
224	36	395	18
226	53	403	27
231	9	451	28
236	25	521	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
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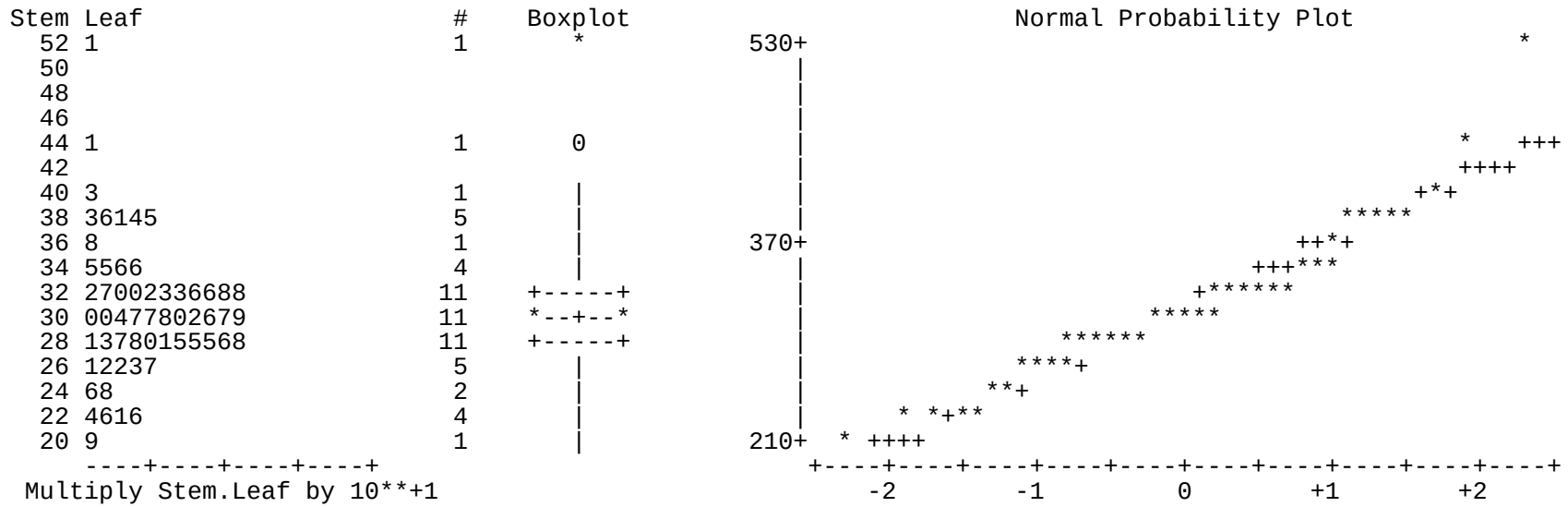
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	295.758621	Sum Observations	17154
Std Deviation	47.6188487	Variance	2267.55475
Skewness	0.3060877	Kurtosis	0.04282321
Uncorrected SS	5202694	Corrected SS	129250.621
Coeff Variation	16.1005784	Std Error Mean	6.25266116

Basic Statistical Measures

Location		Variability	
Mean	295.7586	Std Deviation	47.61885
Median	298.0000	Variance	2268
Mode	231.0000	Range	226.00000
		Interquartile Range	62.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	47.30124	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.97853	Pr < W	0.3920
Kolmogorov-Smirnov	D	0.062687	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.039091	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.360483	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	415
99%	415
95%	386
90%	355
75% Q3	324

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	298
25% Q1	262
10%	231
5%	229
1%	189
0% Min	189

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
189	36	381	30
228	53	383	28
229	51	386	26
230	25	404	4
231	35	415	27

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                 #    Boxplot
    40 45                   2       |
    38 136                  3       |
    36                              |
    34 055                  3       |
    32 044551469            9    +-----+
    30 0348003446          10    |     |
    28 3668856889          10    *--+--*
    26 12268133             8    +-----+
    24 04909                5       |
    22 8901111              7       |
    20                              |
    18 9                    1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```

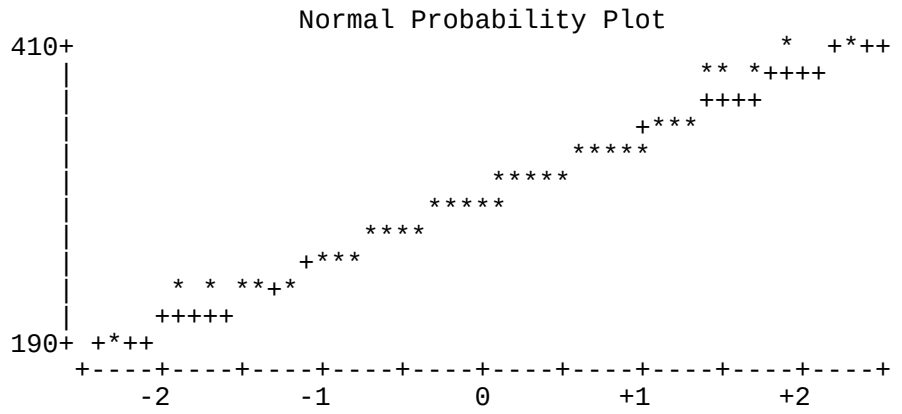

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-20.5	Sum Observations	-1189
Std Deviation	37.2230121	Variance	1385.55263
Skewness	-0.6725195	Kurtosis	0.74828012
Uncorrected SS	103351	Corrected SS	78976.5
Coeff Variation	-181.57567	Std Error Mean	4.88762094

Basic Statistical Measures

Location		Variability	
Mean	-20.5000	Std Deviation	37.22301
Median	-14.0000	Variance	1386
Mode	-7.0000	Range	170.00000
		Interquartile Range	37.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-4.19427	Pr > |t|	<.0001
Sign	M	-13	Pr >= |M|	0.0009

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-495	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.957846	Pr < W	0.0422
Kolmogorov-Smirnov	D	0.107058	Pr > D	0.0953
Cramer-von Mises	W-Sq	0.109929	Pr > W-Sq	0.0844
Anderson-Darling	A-Sq	0.722427	Pr > A-Sq	0.0582

Quantiles (Definition 5)

Quantile	Estimate
100% Max	53
99%	53
95%	42
90%	23
75% Q3	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-14
25% Q1	-35
10%	-68
5%	-113
1%	-117
0% Min	-117

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-117	4	23	33
-116	51	27	42
-113	52	42	14
-86	19	48	47
-85	18	53	26

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Table 11.23
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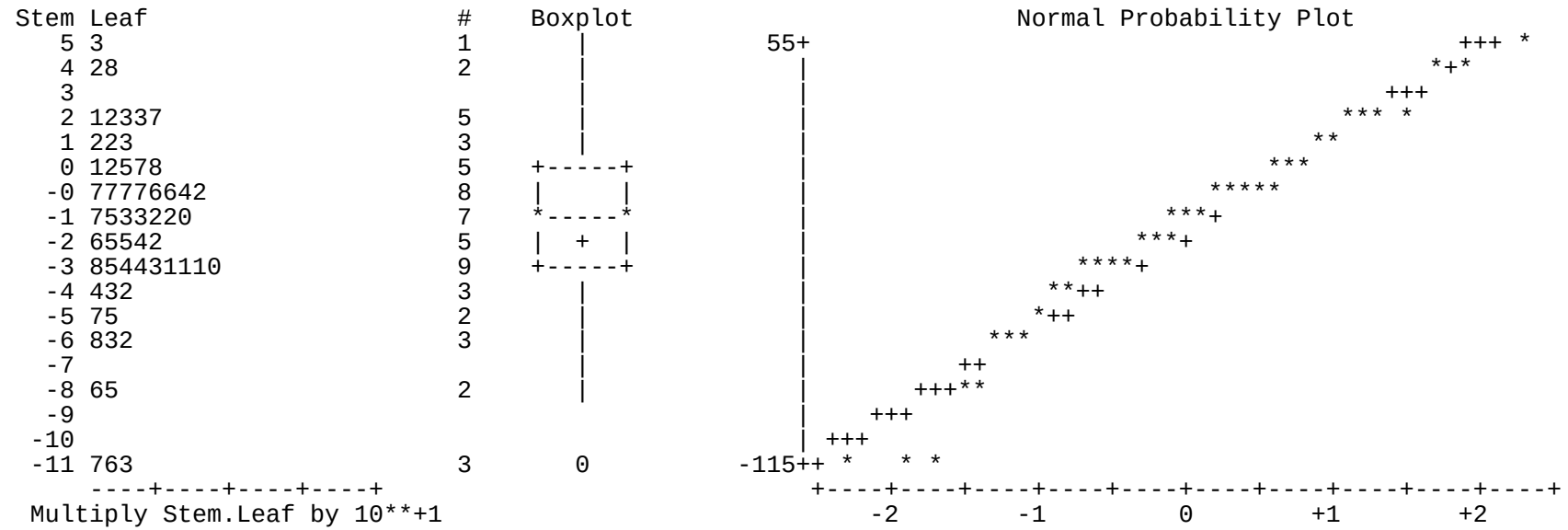
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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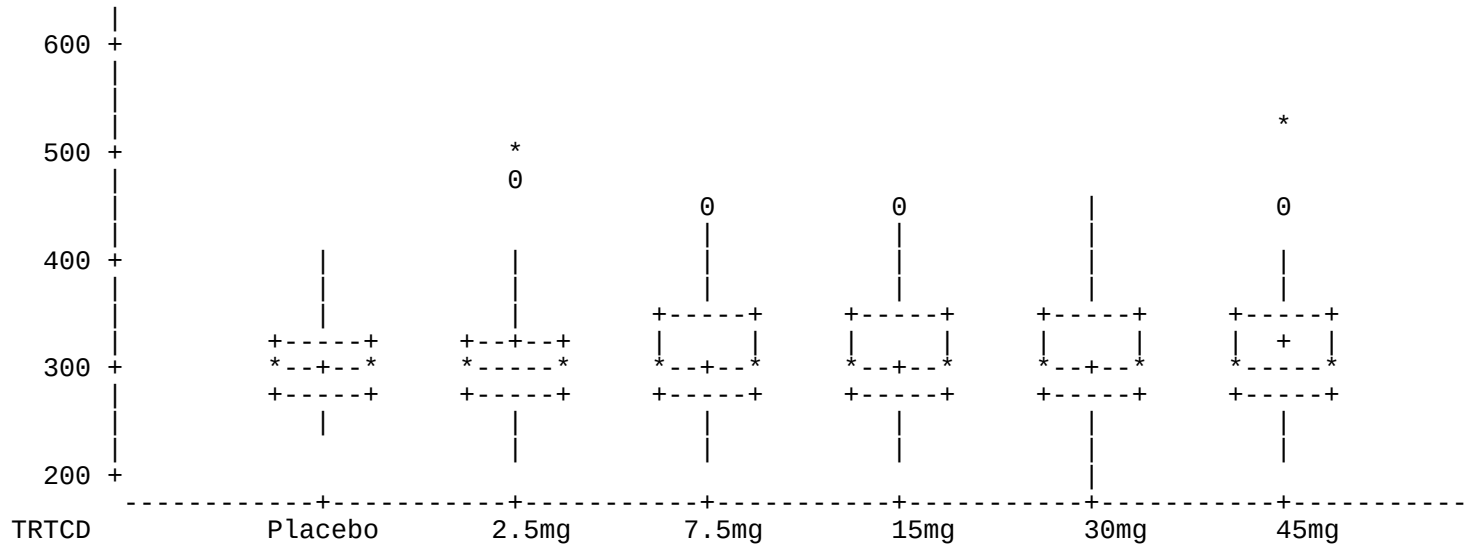
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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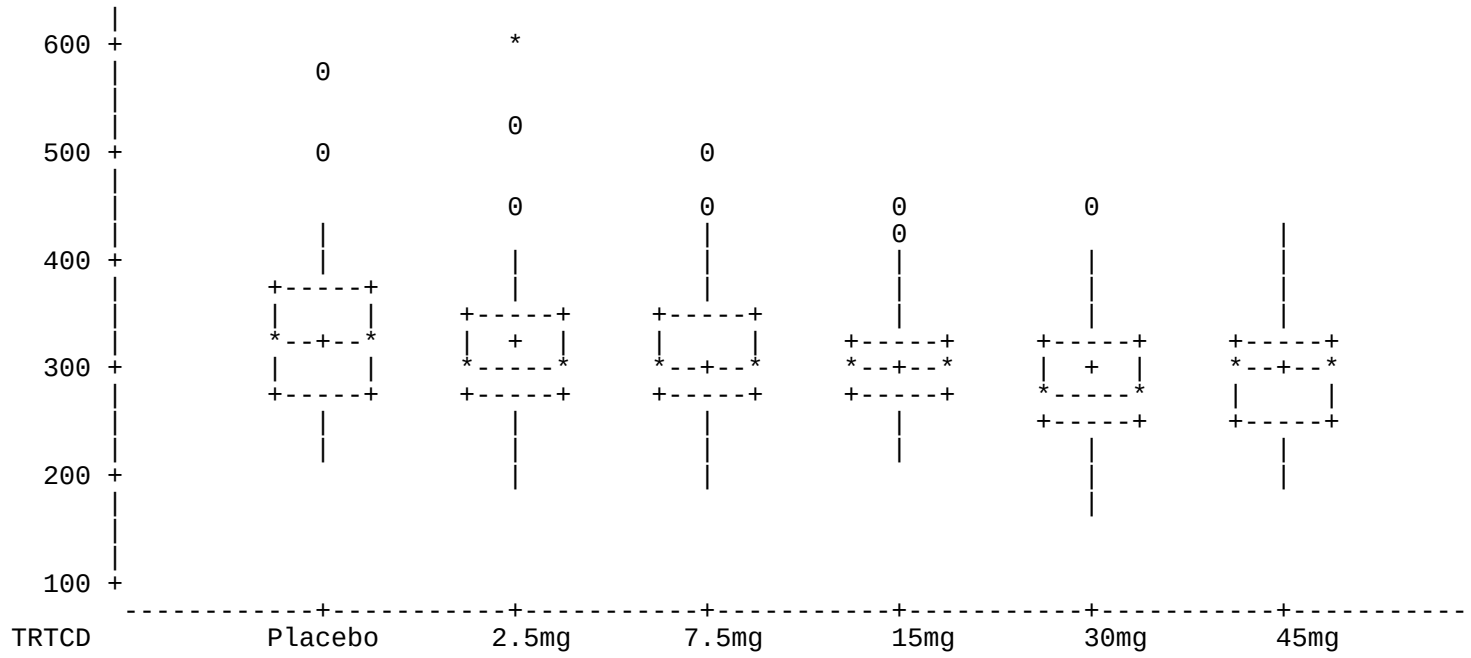
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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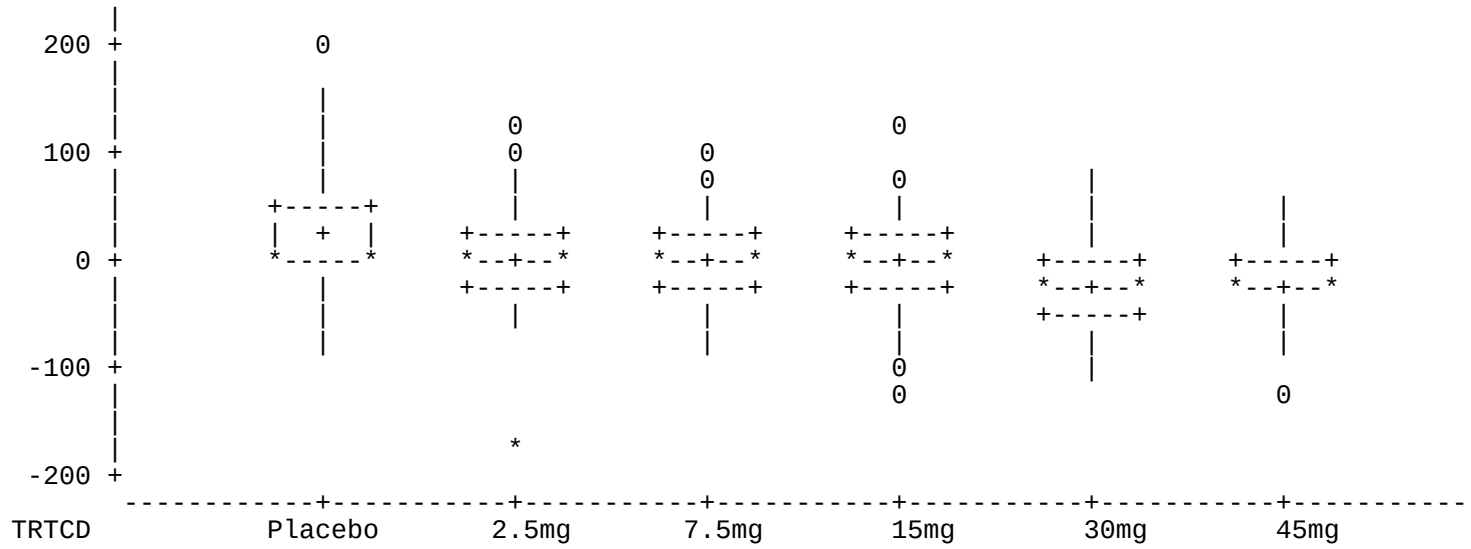
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	346
Observations Used	346
Observations Not Used	0
Total Observations	346

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	1619.10	125.10	12.94	<.0001	0.05	1399.38	1895.25

Fit Statistics

-2 Res Log Likelihood	3481.4
AIC (smaller is better)	3483.4
AICC (smaller is better)	3483.4
BIC (smaller is better)	3487.2

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					42.5777	15.4073	335	2.76	0.0060
SEX	Female				-11.2968	4.3817	335	-2.58	0.0104
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-9.2286	4.4939	335	-2.05	0.0408
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	38.8883	7.5977	335	5.12	<.0001
TRTCD				2.5mg	24.0366	7.6591	335	3.14	0.0019
TRTCD				7.5mg	16.5239	7.4003	335	2.23	0.0262
TRTCD				15mg	9.7162	7.3711	335	1.32	0.1884
TRTCD				30mg	-0.7198	7.5207	335	-0.10	0.9238
TRTCD				45mg	0				.
REGIONCD			US/Canada		-16.5477	5.1766	335	-3.20	0.0015
REGIONCD			Eastern Europe		-5.8004	5.5031	335	-1.05	0.2926
REGIONCD			Western Europe		0				.
EFSTDBL					-0.1445	0.04395	335	-3.29	0.0011

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	335	6.65	0.0104
TRTTYPCD	1	335	4.22	0.0408
TRTCD	5	335	7.95	<.0001
REGIONCD	2	335	5.20	0.0060
EFSTDBL	1	335	10.82	0.0011

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-14.8517	7.7906	335	-1.91	0.0575	0.05	-30.1762	0.4729
7.5mg vs Pbo	-22.3643	7.5075	335	-2.98	0.0031	0.05	-37.1322	-7.5965
15mg vs Pbo	-29.1721	7.4759	335	-3.90	0.0001	0.05	-43.8776	-14.4665
30mg vs Pbo	-39.6080	7.6200	335	-5.20	<.0001	0.05	-54.5971	-24.6190
45mg vs Pbo	-38.8883	7.5977	335	-5.12	<.0001	0.05	-53.8336	-23.9429

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5058	0.5058	0.5058	0.5058	0.5058
SEX	Male				0.4942	0.4942	0.4942	0.4942	0.4942
TRTTYPCD		Diet & Exercise			0.4162	0.4162	0.4162	0.4162	0.4162
TRTTYPCD		Monotherapy			0.5838	0.5838	0.5838	0.5838	0.5838
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3295	0.3295	0.3295	0.3295	0.3295
REGIONCD			Eastern Europe		0.2775	0.2775	0.2775	0.2775	0.2775
REGIONCD			Western Europe		0.3931	0.3931	0.3931	0.3931	0.3931
EFSTDBL					311.23	311.23	311.23	311.23	311.23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5058
SEX	Male				0.4942
TRTTYPCD		Diet & Exercise			0.4162
TRTTYPCD		Monotherapy			0.5838
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3295
REGIONCD			Eastern Europe		0.2775
REGIONCD			Western Europe		0.3931
EFSTDBL					311.23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	19.8619	5.4435	335	3.65	0.0003	0.05	9.1541	30.5696
TRTCD	2.5mg	WORK.EFF	5.0102	5.5504	335	0.90	0.3673	0.05	-5.9079	15.9283
TRTCD	7.5mg	WORK.EFF	-2.5025	5.1616	335	-0.48	0.6281	0.05	-12.6556	7.6507
TRTCD	15mg	WORK.EFF	-9.3102	5.1199	335	-1.82	0.0699	0.05	-19.3814	0.7610
TRTCD	30mg	WORK.EFF	-19.7462	5.3406	335	-3.70	0.0003	0.05	-30.2515	-9.2409
TRTCD	45mg	WORK.EFF	-19.0264	5.2926	335	-3.59	0.0004	0.05	-29.4373	-8.6154

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	14.8517	7.7906	335	1.91	0.0575	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	22.3643	7.5075	335	2.98	0.0031	0.05
TRTCD	Placebo	15mg	WORK.EFF	29.1721	7.4759	335	3.90	0.0001	0.05
TRTCD	Placebo	30mg	WORK.EFF	39.6080	7.6200	335	5.20	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	38.8883	7.5977	335	5.12	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	7.5127	7.5875	335	0.99	0.3228	0.05
TRTCD	2.5mg	15mg	WORK.EFF	14.3204	7.5493	335	1.90	0.0587	0.05
TRTCD	2.5mg	30mg	WORK.EFF	24.7564	7.7219	335	3.21	0.0015	0.05
TRTCD	2.5mg	45mg	WORK.EFF	24.0366	7.6591	335	3.14	0.0019	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	6.8077	7.2696	335	0.94	0.3497	0.05
TRTCD	7.5mg	30mg	WORK.EFF	17.2437	7.4212	335	2.32	0.0207	0.05
TRTCD	7.5mg	45mg	WORK.EFF	16.5239	7.4003	335	2.23	0.0262	0.05
TRTCD	15mg	30mg	WORK.EFF	10.4360	7.4051	335	1.41	0.1597	0.05
TRTCD	15mg	45mg	WORK.EFF	9.7162	7.3711	335	1.32	0.1884	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.7198	7.5207	335	-0.10	0.9238	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.4729	30.1762
TRTCD	Placebo	7.5mg	7.5965	37.1322
TRTCD	Placebo	15mg	14.4665	43.8776
TRTCD	Placebo	30mg	24.6190	54.5971
TRTCD	Placebo	45mg	23.9429	53.8336
TRTCD	2.5mg	7.5mg	-7.4124	22.4377
TRTCD	2.5mg	15mg	-0.5295	29.1703
TRTCD	2.5mg	30mg	9.5669	39.9459
TRTCD	2.5mg	45mg	8.9707	39.1025
TRTCD	7.5mg	15mg	-7.4920	21.1075

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	2.6457	31.8418
TRTCD	7.5mg	45mg	1.9671	31.0808
TRTCD	15mg	30mg	-4.1303	25.0023
TRTCD	15mg	45mg	-4.7833	24.2157
TRTCD	30mg	45mg	-15.5136	14.0740

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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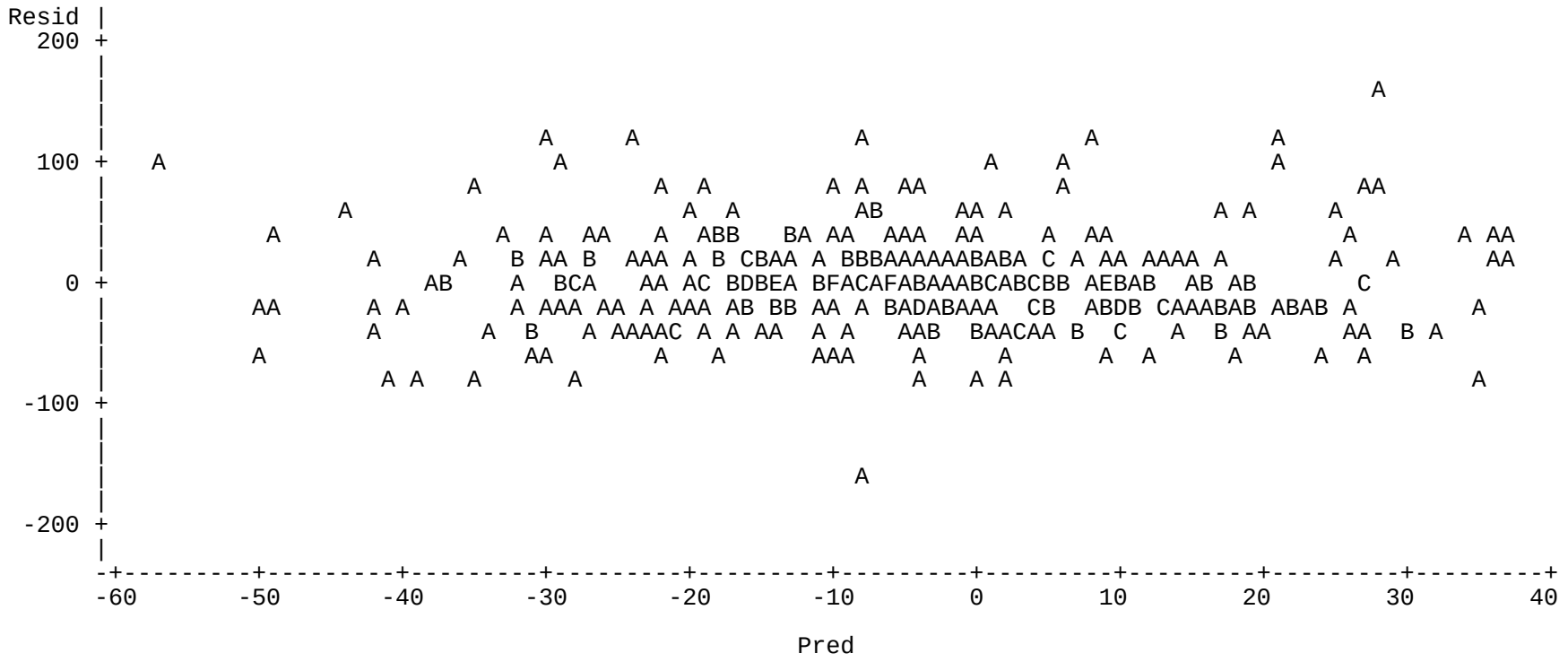
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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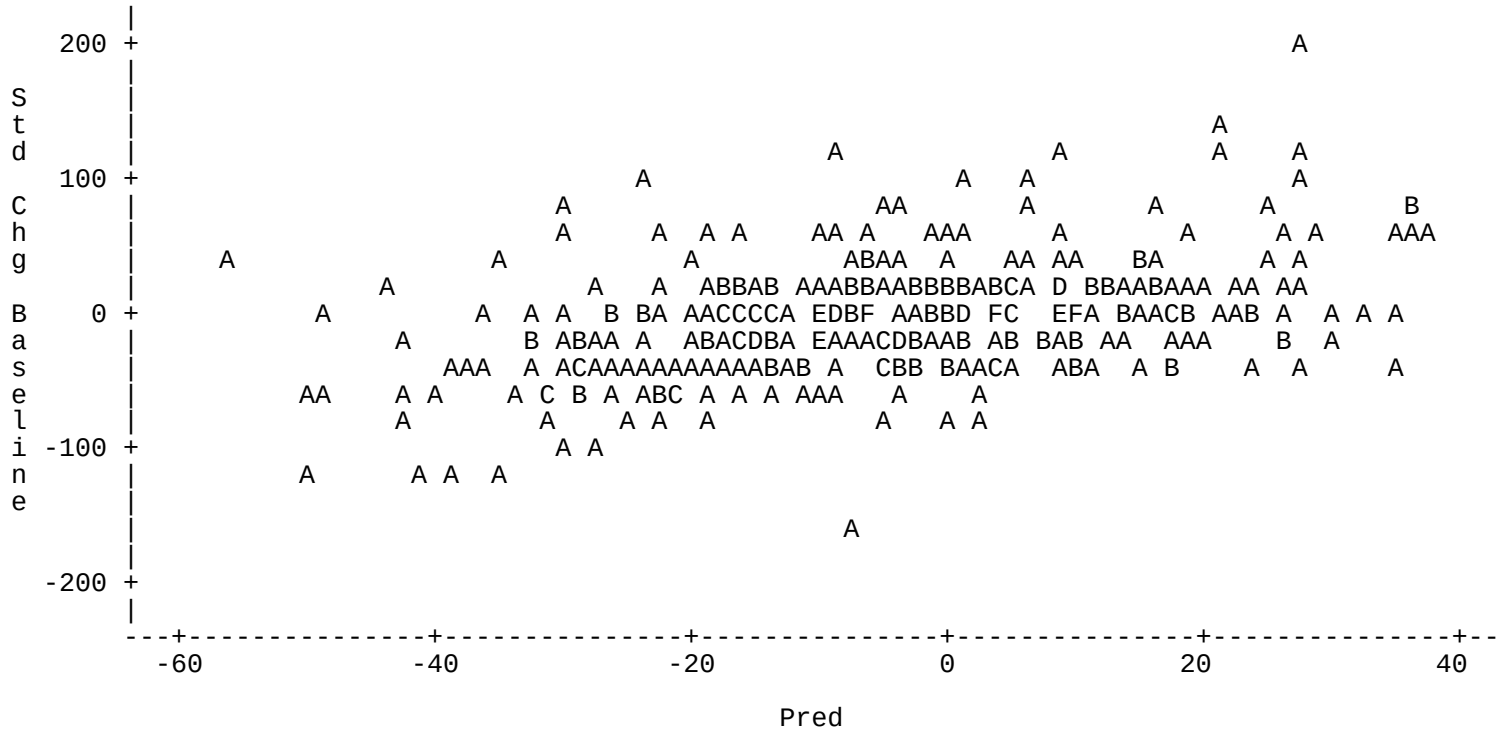
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	346	Sum Weights	346
Mean	0	Sum Observations	0
Std Deviation	39.6505899	Variance	1572.16928
Skewness	0.59565222	Kurtosis	1.82662007
Uncorrected SS	542398.402	Corrected SS	542398.402
Coeff Variation		Std Error Mean	2.13162892

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	39.65059
Median	-2.45790	Variance	1572
Mode		Range	323.62287
		Interquartile Range	43.01197

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-7	Pr >= |M|	0.4847
Signed Rank	S	-2045.5	Pr >= |S|	0.2726

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.966555	Pr < W		<0.0001
Kolmogorov-Smirnov	D	0.074466	Pr > D		<0.0100
Cramer-von Mises	W-Sq	0.457184	Pr > W-Sq		<0.0050
Anderson-Darling	A-Sq	2.877756	Pr > A-Sq		<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	168.1616
99%	116.8054
95%	75.1047
90%	48.6762
75% Q3	18.8421
50% Median	-2.4579
25% Q1	-24.1699
10%	-43.9724
5%	-57.1135
1%	-78.6547
0% Min	-155.4613

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-155.4613	297	114.914	15
-85.6023	91	116.805	294
-80.8639	289	117.099	324
-78.6547	219	124.416	25
-78.4674	17	168.162	331

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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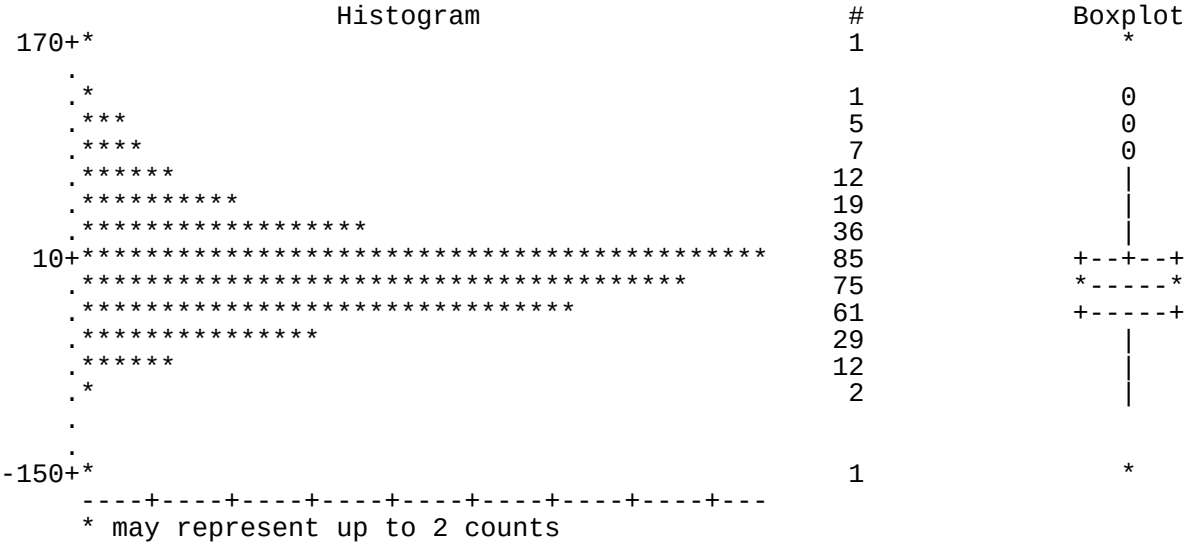
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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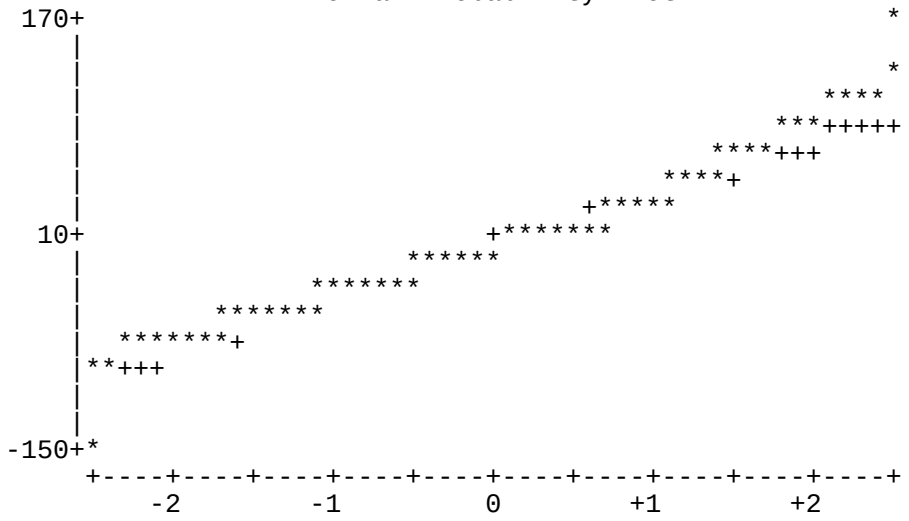
Table 11.23
SAS Statistical Output for Table 11.22
Analysis of Change in Fructosamine (mcmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.24
Summary Statistics for Fasting Serum Insulin (pmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	53	59	63	53	56
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	88.90	106.31	112.97	104.41	87.47	111.80
	SD	54.047	83.548	108.726	65.099	47.167	76.021
	SE	6.977	11.476	14.155	8.202	6.479	10.159
	Minimum	14.4	28.9	18.0	21.7	21.7	21.7
	Median	86.60	86.60	93.80	84.00	79.40	85.30
	Maximum	267.0	577.4	786.7	303.1	223.7	414.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.24
Summary Statistics for Fasting Serum Insulin (pmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	51	55	61	49	52
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Mean	88.27	105.27	102.41	103.22	88.16	110.92
	SD	52.637	83.134	64.051	65.801	47.707	74.593
	SE	7.230	11.641	8.637	8.425	6.815	10.344
	Minimum	14.4	28.9	18.0	21.7	21.7	21.7
	Median	86.60	86.60	93.80	79.40	79.40	86.60
	Maximum	267.0	577.4	375.3	303.1	223.7	414.0
Week 4	Mean	94.24	101.45	105.26	104.89	109.96	118.14
	SD	55.133	58.387	87.523	69.702	83.542	98.616
	SE	7.573	8.176	11.802	8.924	11.935	13.676
	Minimum	24.0	21.7	18.0	28.9	28.9	21.7
	Median	79.40	84.00	86.60	86.60	84.00	91.90
	Maximum	288.7	288.7	498.0	368.1	438.0	635.1
Change from Baseline	Mean	5.97	-3.83	2.85	1.67	21.80	7.23
	SD	50.769	86.792	75.790	55.221	78.596	96.413
	SE	6.974	12.153	10.219	7.070	11.228	13.370
	Minimum	-101.0	-519.7	-194.9	-144.0	-72.0	-120.0
	Median	0.00	0.00	-6.00	-6.00	7.20	-3.60
	Maximum	245.4	223.7	354.0	204.0	390.0	613.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.24
Summary Statistics for Fasting Serum Insulin (pmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	61	53	54
Number (%) of Values Carried Forward		6 (11%)	11 (21%)	8 (14%)	3 (5%)	3 (6%)	10 (19%)
Baseline	Mean	87.81	104.08	113.88	103.22	87.47	109.50
	SD	52.405	82.762	109.447	65.801	47.167	73.545
	SE	7.003	11.477	14.371	8.425	6.479	10.008
	Minimum	14.4	28.9	18.0	21.7	21.7	21.7
	Median	85.30	83.00	93.80	79.40	79.40	85.30
	Maximum	267.0	577.4	786.7	303.1	223.7	414.0
Week 8	Mean	88.92	91.49	120.01	105.51	111.74	143.20
	SD	53.920	52.794	99.580	65.878	87.419	240.766
	SE	7.205	7.321	13.075	8.435	12.008	32.764
	Minimum	14.4	14.4	21.7	21.7	14.4	21.7
	Median	84.00	81.70	93.80	84.00	84.00	105.00
	Maximum	303.1	210.0	541.3	303.1	447.5	1818.7
Change from Baseline	Mean	1.10	-12.59	6.12	2.29	24.27	33.69
	SD	42.239	82.225	81.880	44.507	72.846	245.550
	SE	5.644	11.403	10.751	5.699	10.006	33.415
	Minimum	-115.4	-534.1	-245.4	-114.0	-60.0	-144.0
	Median	0.00	-3.00	3.00	0.00	7.20	3.00
	Maximum	144.3	129.9	375.3	186.0	353.6	1768.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.24
Summary Statistics for Fasting Serum Insulin (pmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	62	53	54
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	10 (17%)	3 (5%)	4 (8%)	6 (11%)
Baseline	Mean	87.81	104.08	113.88	104.00	87.47	109.50
	SD	52.405	82.762	109.447	65.548	47.167	73.545
	SE	7.003	11.477	14.371	8.325	6.479	10.008
	Minimum	14.4	28.9	18.0	21.7	21.7	21.7
	Median	85.30	83.00	93.80	81.70	79.40	85.30
	Maximum	267.0	577.4	786.7	303.1	223.7	414.0
Week 12	Mean	87.92	92.03	125.56	109.06	92.72	118.19
	SD	52.139	56.337	171.032	77.356	54.696	77.105
	SE	6.967	7.813	22.458	9.824	7.513	10.493
	Minimum	21.7	14.4	18.0	18.0	28.9	21.7
	Median	79.40	81.70	91.90	93.80	79.40	97.90
	Maximum	274.2	245.4	1306.3	353.6	288.7	378.0
Change from Baseline	Mean	0.11	-12.06	11.68	5.06	5.25	8.69
	SD	43.662	85.045	83.280	64.407	34.801	54.605
	SE	5.835	11.794	10.935	8.180	4.780	7.431
	Minimum	-158.8	-526.9	-180.4	-126.0	-108.0	-120.0
	Median	0.00	-7.20	9.60	0.00	0.00	0.00
	Maximum	144.3	173.2	519.6	312.0	115.4	144.3

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	62	53	54
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	10 (17%)	3 (5%)	4 (8%)	6 (11%)
Baseline	Mean	87.81	104.08	113.88	104.00	87.47	109.50
	SD	52.405	82.762	109.447	65.548	47.167	73.545
Week 12	Mean	87.92	92.03	125.56	109.06	92.72	118.19
	SD	52.139	56.337	171.032	77.356	54.696	77.105
Chg from Baseline	Mean	0.11	-12.06	11.68	5.06	5.25	8.69
	SD	43.662	85.045	83.280	64.407	34.801	54.605
Model-Adj Chg [2]	Mean	-2.04	-10.55	12.14	5.27	3.23	10.70
	SE	8.514	8.804	8.355	8.057	8.732	8.641
Diff from Pbo [2]	Mean		-8.51	14.18	7.31	5.27	12.74
	95% CI		-32.66,15.65	-9.37,37.72	-15.79,30.42	-18.64,29.17	-11.18,36.65
	p-val [3]		0.489	0.237	0.534	0.665	0.295

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	87.8125	Sum Observations	4917.5
Std Deviation	52.4045247	Variance	2746.2342
Skewness	1.12725714	Kurtosis	1.75917501
Uncorrected SS	582860.85	Corrected SS	151042.881
Coeff Variation	59.6777505	Std Error Mean	7.00284917

Basic Statistical Measures

Location		Variability	
Mean	87.81250	Std Deviation	52.40452
Median	85.30000	Variance	2746
Mode	43.30000	Range	252.60000
		Interquartile Range	66.25000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.53954	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.920084	Pr < W	0.0012
Kolmogorov-Smirnov	D	0.134352	Pr > D	0.0129
Cramer-von Mises	W-Sq	0.150777	Pr > W-Sq	0.0229
Anderson-Darling	A-Sq	1.05634	Pr > A-Sq	0.0085

Quantiles (Definition 5)

Quantile	Estimate
100% Max	267.00
99%	267.00
95%	209.30
90%	144.30
75% Q3	111.90

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	85.30
25% Q1	45.65
10%	28.90
5%	18.00
1%	14.40
0% Min	14.40

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	55	158.8	38
18.0	30	192.0	19
18.0	14	209.3	8
21.7	43	209.3	12
21.7	6	267.0	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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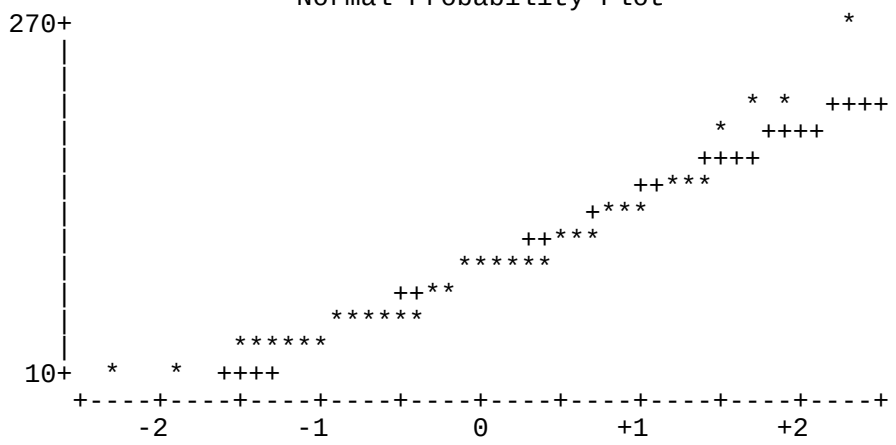
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
    26 7                     1       0
    24                              |
    22                              |
    20 99                    2      |
    18 2                     1      |
    16                              |
    14 449                   3      |
    12 36088                 5      |
    10 22866                 5   +-----+
     8 4477044446666        13   *--+--*
     6 028999                6   |     |
     4 33333800448          11   +-----+
     2 229066                6      |
     0 488                   3      |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	87.9196429	Sum Observations	4923.5
Std Deviation	52.1387499	Variance	2718.44924
Skewness	1.80881063	Kurtosis	4.07493773
Uncorrected SS	582387.07	Corrected SS	149514.708
Coeff Variation	59.3027317	Std Error Mean	6.96733353

Basic Statistical Measures

Location		Variability	
Mean	87.91964	Std Deviation	52.13875
Median	79.40000	Variance	2718
Mode	79.40000	Range	252.50000
		Interquartile Range	47.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.61884	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.834078	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.187226	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.419464	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.528117	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	274.2
99%	274.2
95%	223.7
90%	156.0
75% Q3	101.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	54.1
10%	30.0
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	53	166.0	3
24.0	14	168.0	20
28.9	43	223.7	12
28.9	9	259.8	44
30.0	30	274.2	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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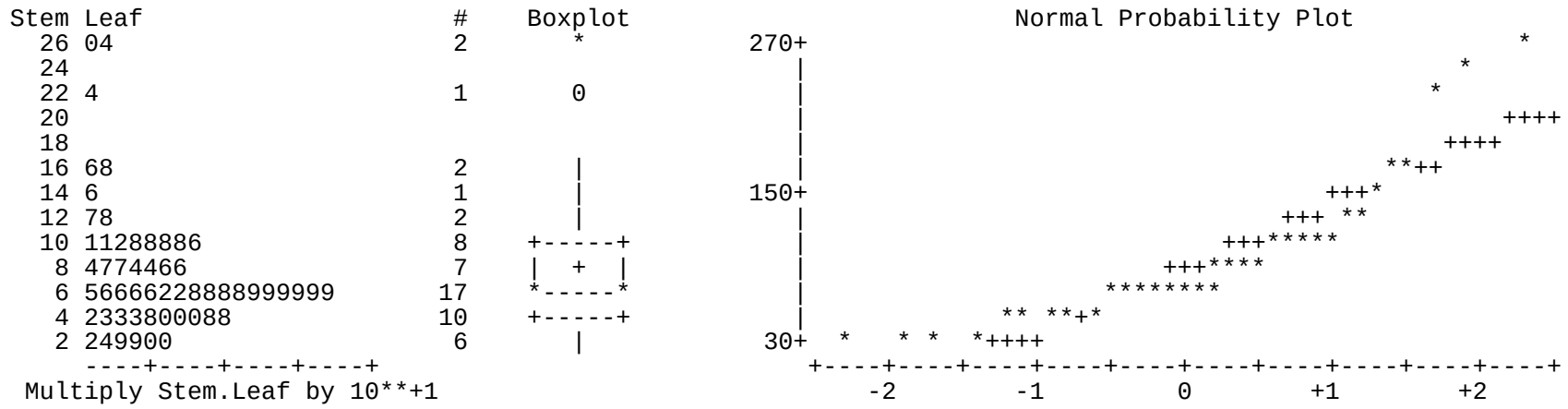
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	0.10714286	Sum Observations	6
Std Deviation	43.6617447	Variance	1906.34795
Skewness	0.04361822	Kurtosis	5.22041797
Uncorrected SS	104849.78	Corrected SS	104849.137
Coeff Variation	40750.9617	Std Error Mean	5.83454605

Basic Statistical Measures

Location		Variability	
Mean	0.107143	Std Deviation	43.66174
Median	0.000000	Variance	1906
Mode	0.000000	Range	303.10000
		Interquartile Range	39.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.018364	Pr > |t|	0.9854
Sign	M	-1.5	Pr >= |M|	0.7798

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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-17.5	Pr >= |S|	0.8716

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.878211	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.132049	Pr > D	0.0162
Cramer-von Mises	W-Sq	0.279429	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.889421	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	50.5
90%	42.0
75% Q3	21.6

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-18.0
10%	-36.1
5%	-50.5
1%	-158.8
0% Min	-158.8

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-158.8	8	43.3	36
-101.0	3	48.0	23
-50.5	38	50.5	37
-43.3	4	129.9	51
-36.1	54	144.3	44

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot
     14 4                        1       *
     12 0                        1       0
     10
      8
      6
      4 2380                     4       |
      2 222249066                9    +-----+
      0 00000666772248          14    *--+--*
     -0 888444277777766         15    +-----+
     -2 66666004                 8       |
     -4 03                       2       |
     -6
     -8
    -10 1                        1       0
    -12
    -14 9                        1       *
        ----+----+----+----+
    Multiply Stem.Leaf by 10**+1
```

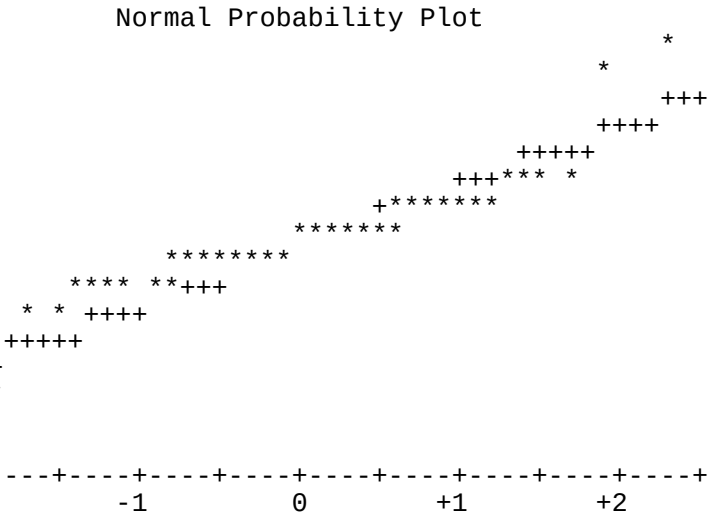

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	52	Sum Weights	52
Mean	104.082692	Sum Observations	5412.3
Std Deviation	82.7622385	Variance	6849.58813
Skewness	3.84832752	Kurtosis	20.7140137
Uncorrected SS	912655.75	Corrected SS	349328.994
Coeff Variation	79.515851	Std Error Mean	11.4770575

Basic Statistical Measures

Location		Variability	
Mean	104.0827	Std Deviation	82.76224
Median	83.0000	Variance	6850
Mode	65.0000	Range	548.50000
		Interquartile Range	69.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.068761	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.653697	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.181829	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.534971	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.419285	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	577.40
99%	577.40
95%	194.90
90%	186.00
75% Q3	127.95

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	83.00
25% Q1	58.85
10%	43.30
5%	30.00
1%	28.90
0% Min	28.90

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	18	186.0	35
28.9	5	192.0	52
30.0	36	194.9	20
36.1	42	216.0	31
43.3	45	577.4	4

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

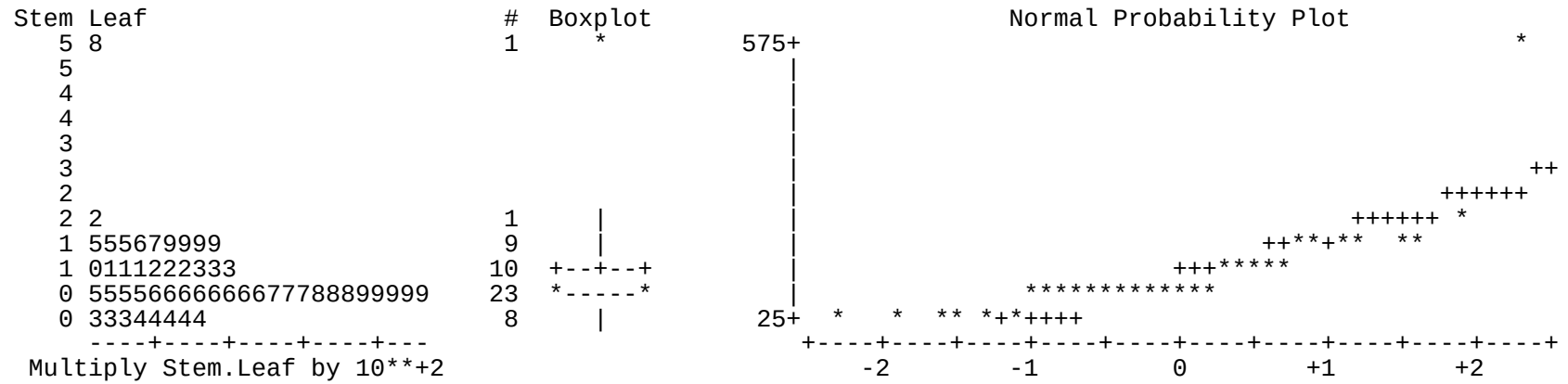

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	52	Sum Weights	52
Mean	92.0269231	Sum Observations	4785.4
Std Deviation	56.3374048	Variance	3173.90318
Skewness	0.93401227	Kurtosis	0.16359883
Uncorrected SS	602254.7	Corrected SS	161869.062
Coeff Variation	61.2183945	Std Error Mean	7.81259238

Basic Statistical Measures

Location		Variability	
Mean	92.02692	Std Deviation	56.33740
Median	81.70000	Variance	3174
Mode	36.10000	Range	231.00000
		Interquartile Range	66.25000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.77931	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.913468	Pr < W	0.0011
Kolmogorov-Smirnov	D	0.136348	Pr > D	0.0170
Cramer-von Mises	W-Sq	0.24267	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.48823	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	245.40
99%	245.40
95%	204.00

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	173.20
75% Q3	115.50
50% Median	81.70
25% Q1	49.25
10%	36.10
5%	28.90
1%	14.40
0% Min	14.40

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	45	180.0	31
21.7	15	202.1	50
28.9	42	204.0	35
28.9	18	222.0	26
36.1	48	245.4	49

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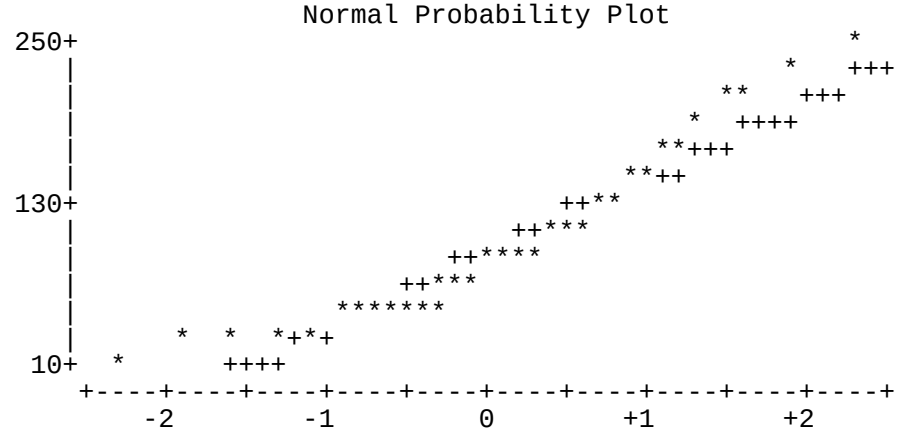
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
    24 5                     1       0
    22 2                     1       0
    20 24                    2       |
    18 0                     1       |
    16 263                   3       |
    14 99                    2       |
    12 328                   3       |
    10 188888                6    +-----+
     8 4447746               7    *--+--*
     6 622899                6    |     |
     4 33380000048          11    +-----+
     2 29966666              8       |
     0 4                     1       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	52	Sum Weights	52
Mean	-12.055769	Sum Observations	-626.9
Std Deviation	85.0451078	Variance	7232.67036
Skewness	-4.2763511	Kurtosis	27.1037491
Uncorrected SS	376423.95	Corrected SS	368866.188
Coeff Variation	-705.43079	Std Error Mean	11.7936345

Basic Statistical Measures

Location		Variability	
Mean	-12.0558	Std Deviation	85.04511
Median	-7.2000	Variance	7233
Mode	7.2000	Range	700.10000
		Interquartile Range	45.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.02223	Pr > |t|	0.3115
Sign	M	-4	Pr >= |M|	0.3222

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-125.5	Pr >= |S|	0.2292

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.578716	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.27331	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.995397	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	5.516677	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	173.2
99%	173.2
95%	72.0
90%	43.3
75% Q3	16.2

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-7.2
25% Q1	-28.9
10%	-43.3
5%	-79.4
1%	-526.9
0% Min	-526.9

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-526.9	4	50.5	13
-115.5	48	54.0	36
-79.4	37	72.0	26
-78.0	28	93.8	50
-50.5	40	173.2	49

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

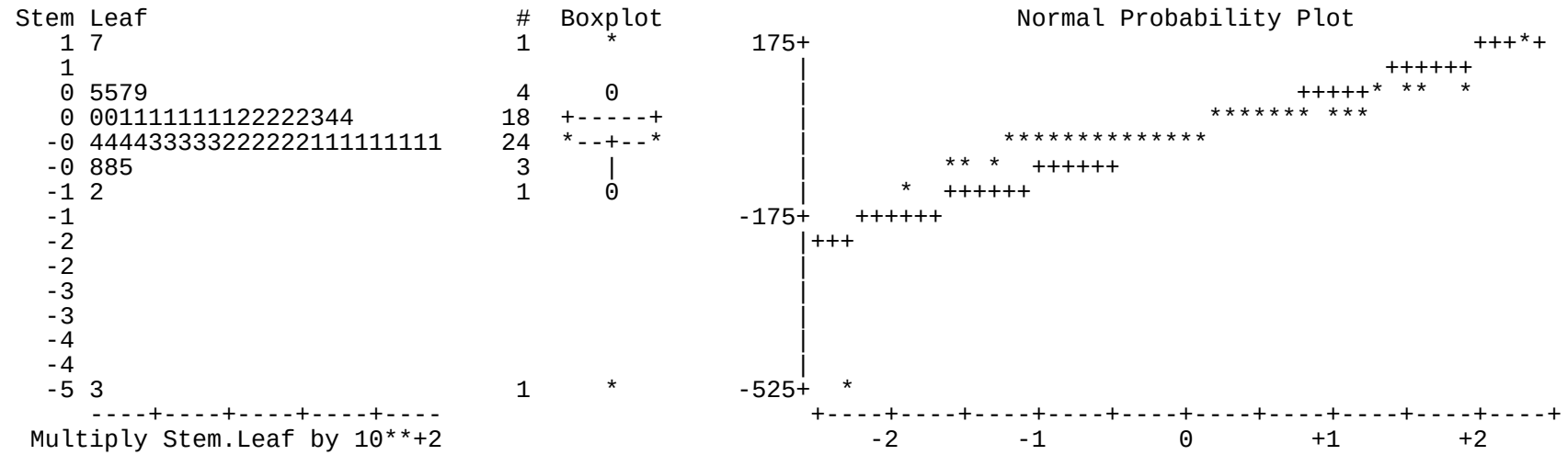

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	113.884483	Sum Observations	6605.3
Std Deviation	109.446616	Variance	11978.5617
Skewness	4.44723777	Kurtosis	25.4726168
Uncorrected SS	1435019.19	Corrected SS	682778.016
Coeff Variation	96.1031855	Std Error Mean	14.3710447

Basic Statistical Measures

Location		Variability	
Mean	113.8845	Std Deviation	109.44662
Median	93.8000	Variance	11979
Mode	93.8000	Range	768.70000
		Interquartile Range	57.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.924579	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.580754	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.243763	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.023524	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	5.742319	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	786.7
99%	786.7
95%	245.4
90%	202.1
75% Q3	122.7

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	93.8
25% Q1	65.0
10%	28.9
5%	24.0
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
18.0	58	209.3	12
18.0	28	223.7	19
24.0	33	245.4	37
24.0	31	375.3	20
28.9	46	786.7	10

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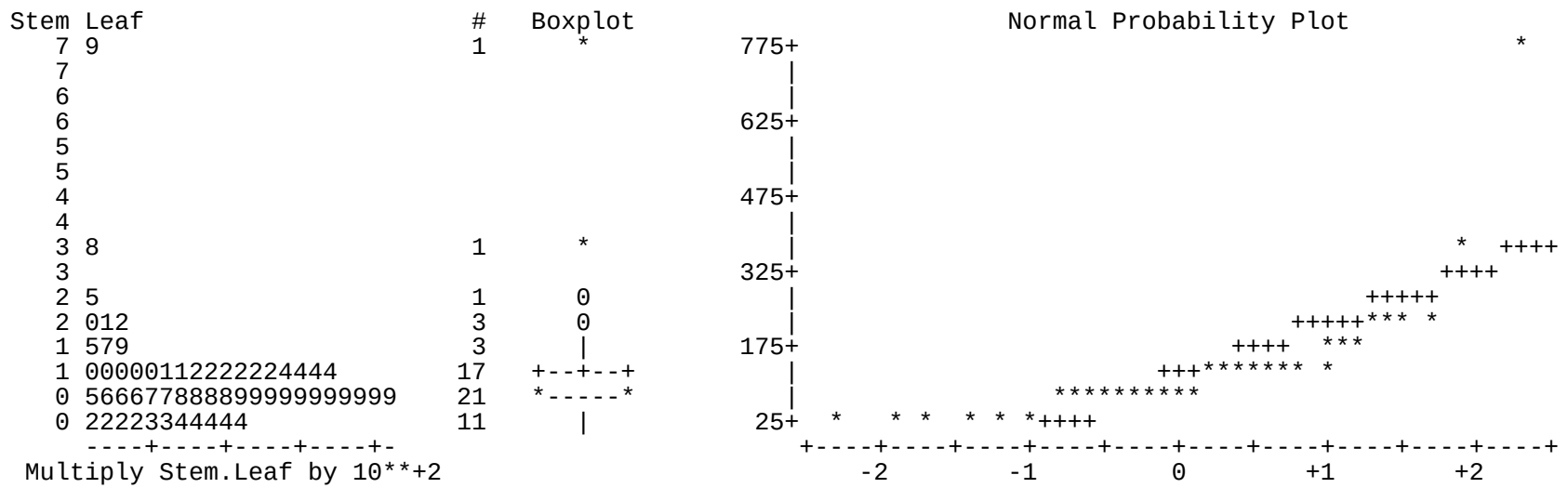
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	125.562069	Sum Observations	7282.6
Std Deviation	171.032386	Variance	29252.0771
Skewness	5.99099136	Kurtosis	41.1816934
Uncorrected SS	2581786.72	Corrected SS	1667368.4
Coeff Variation	136.213418	Std Error Mean	22.4576525

Basic Statistical Measures

Location		Variability	
Mean	125.5621	Std Deviation	171.03239
Median	91.9000	Variance	29252
Mode	108.3000	Range	1288
		Interquartile Range	62.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.591059	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.417414	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.265296	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.563713	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	8.607387	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1306.3
99%	1306.3
95%	288.7
90%	230.9
75% Q3	122.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	91.9
25% Q1	60.0
10%	36.1
5%	24.0
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		-----Highest----	
Value	Obs	Value	Obs
18.0	33	238.2	36
21.7	46	252.0	27
24.0	35	288.7	19
30.0	28	288.7	20
36.0	31	1306.3	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Stem	Leaf	#	Boxplot
13	1	1	*
12			
11			
10			
9			
8			
7			
6			
5			
4			
3			
2	0334599	7	0
1	00111111122466688	17	+--+--+
0	22234444445566666677788899999999	33	*-----*

Multiply Stem.Leaf by 10**+2

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Normal Probability Plot

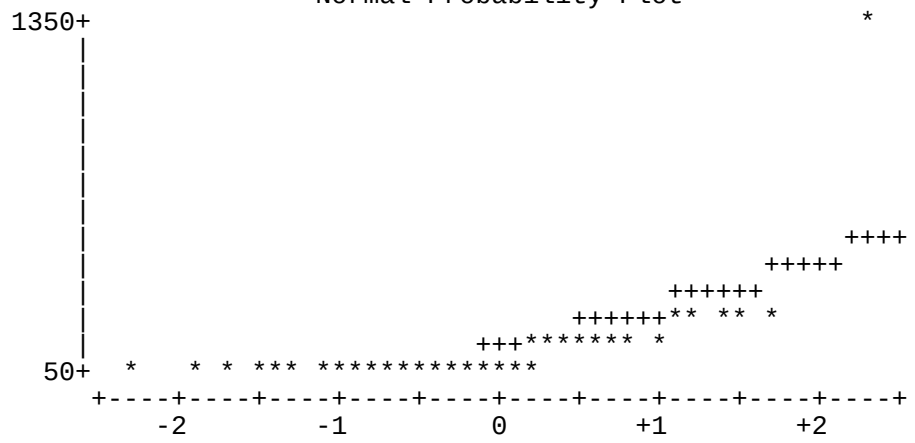

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	11.6775862	Sum Observations	677.3
Std Deviation	83.2800645	Variance	6935.56914
Skewness	3.88402379	Kurtosis	24.5854545
Uncorrected SS	403236.67	Corrected SS	395327.441
Coeff Variation	713.161633	Std Error Mean	10.9352082

Basic Statistical Measures

Location		Variability	
Mean	11.67759	Std Deviation	83.28006
Median	9.60000	Variance	6936
Mode	12.00000	Range	700.00000
		Interquartile Range	57.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.067889	Pr > |t|	0.2901
Sign	M	3	Pr >= |M|	0.5044

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	120	Pr >= |S|	0.3320

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.64868	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.206035	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.740968	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.36043	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	519.6
99%	519.6
95%	108.0
90%	64.9
75% Q3	28.9

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	9.6
25% Q1	-28.8
10%	-50.5
5%	-79.4
1%	-180.4
0% Min	-180.4

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-180.4	37	65.0	19
-86.6	20	93.9	36
-79.4	44	108.0	27
-64.9	6	115.4	8
-57.8	21	519.6	10

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Table 11.26
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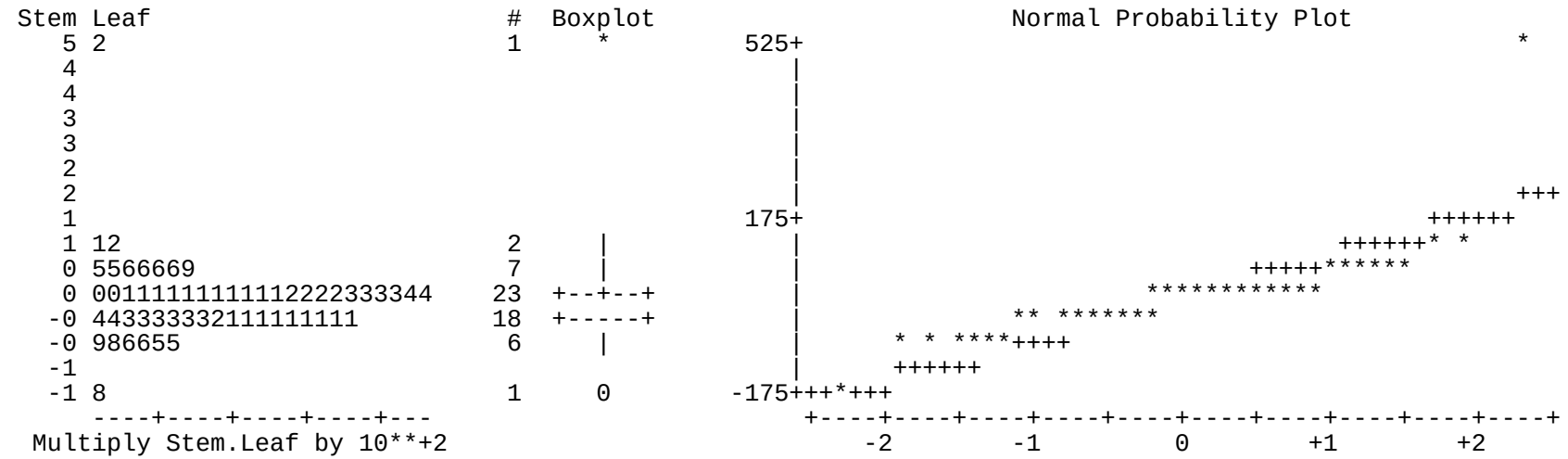
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	104.003226	Sum Observations	6448.2
Std Deviation	65.5480726	Variance	4296.54983
Skewness	1.19442387	Kurtosis	0.67276904
Uncorrected SS	932723.14	Corrected SS	262089.539
Coeff Variation	63.025038	Std Error Mean	8.32461355

Basic Statistical Measures

Location		Variability	
Mean	104.0032	Std Deviation	65.54807
Median	81.7000	Variance	4297
Mode	57.7000	Range	281.40000
		Interquartile Range	74.30000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.49346	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.871149	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.177621	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.505965	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.872388	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	303.1
99%	303.1
95%	240.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	216.5
75% Q3	132.0
50% Median	81.7
25% Q1	57.7
10%	42.0
5%	36.1
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	54	234.0	35
28.9	50	240.0	24
36.0	62	240.0	31
36.1	58	252.6	57
36.1	15	303.1	48

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
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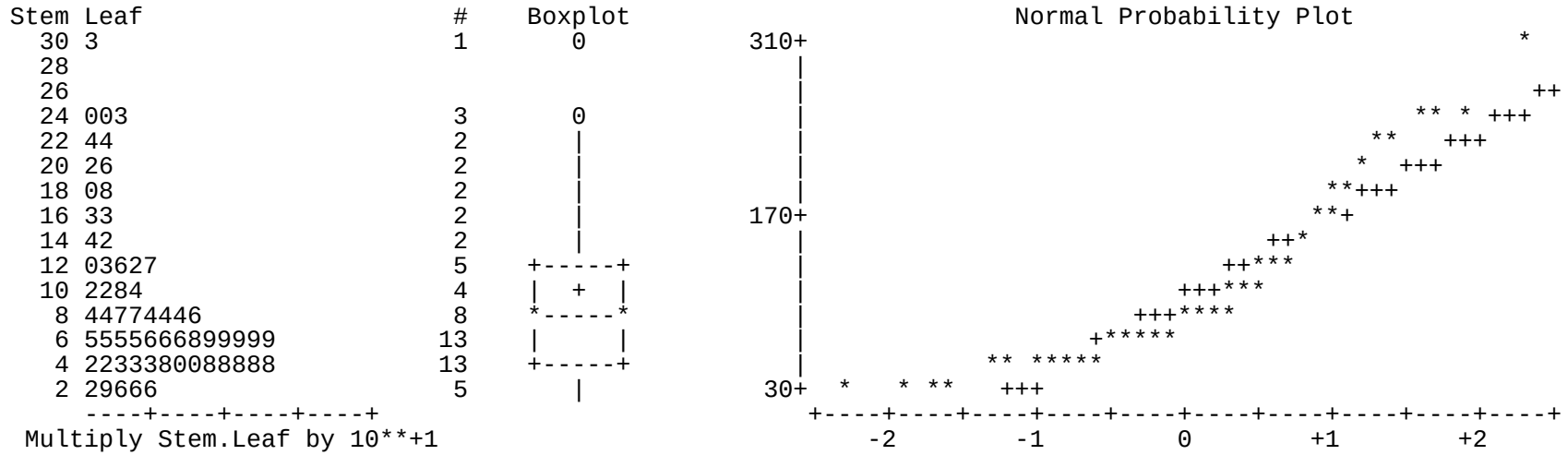
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	109.059677	Sum Observations	6761.7
Std Deviation	77.3563851	Variance	5984.01031
Skewness	1.78540819	Kurtosis	3.06415177
Uncorrected SS	1102453.45	Corrected SS	365024.629
Coeff Variation	70.9303263	Std Error Mean	9.82427073

Basic Statistical Measures

Location		Variability	
Mean	109.0597	Std Deviation	77.35639
Median	93.8000	Variance	5984
Mode	43.3000	Range	335.60000
		Interquartile Range	68.30000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.10105	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.804531	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.197466	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.585123	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.681018	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	353.6
99%	353.6
95%	310.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	187.6
75% Q3	126.0
50% Median	93.8
25% Q1	57.7
10%	43.3
5%	36.1
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
18.0	28	281.5	48
21.7	15	310.3	60
30.0	32	330.0	31
36.1	53	348.0	62
43.3	58	353.6	13

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

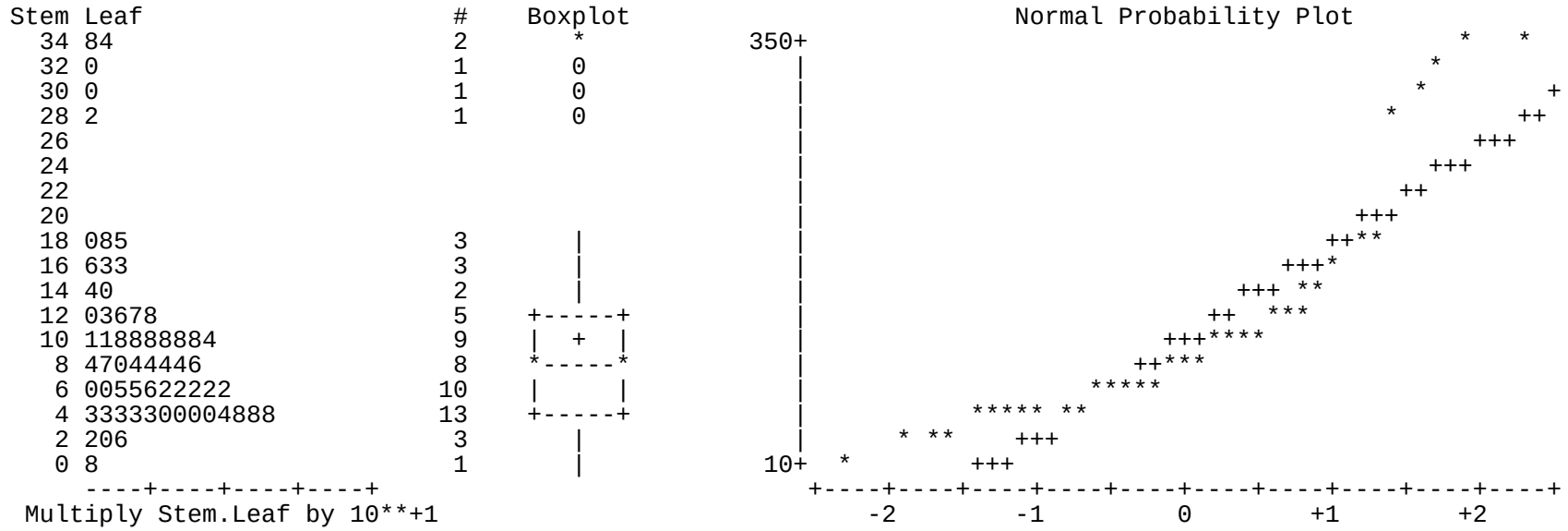

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	5.05645161	Sum Observations	313.5
Std Deviation	64.40748	Variance	4148.32348
Skewness	1.80316805	Kurtosis	7.66725614
Uncorrected SS	254632.93	Corrected SS	253047.732
Coeff Variation	1273.76834	Std Error Mean	8.17975814

Basic Statistical Measures

Location		Variability	
Mean	5.056452	Std Deviation	64.40748
Median	0.000000	Variance	4148
Mode	0.000000	Range	438.00000
		Interquartile Range	52.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.618166	Pr > |t|	0.5388
Sign	M	1	Pr >= |M|	0.8939

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	6.5	Pr >= |S|	0.9583

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.870817	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.142397	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.286471	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.626122	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	312.0
99%	312.0
95%	108.3
90%	72.0
75% Q3	24.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-28.9
10%	-72.1
5%	-79.4
1%	-126.0
0% Min	-126.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-126.0	24	90.0	31
-93.8	18	108.3	46
-84.0	35	129.9	60
-79.4	57	129.9	13
-79.3	2	312.0	62

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

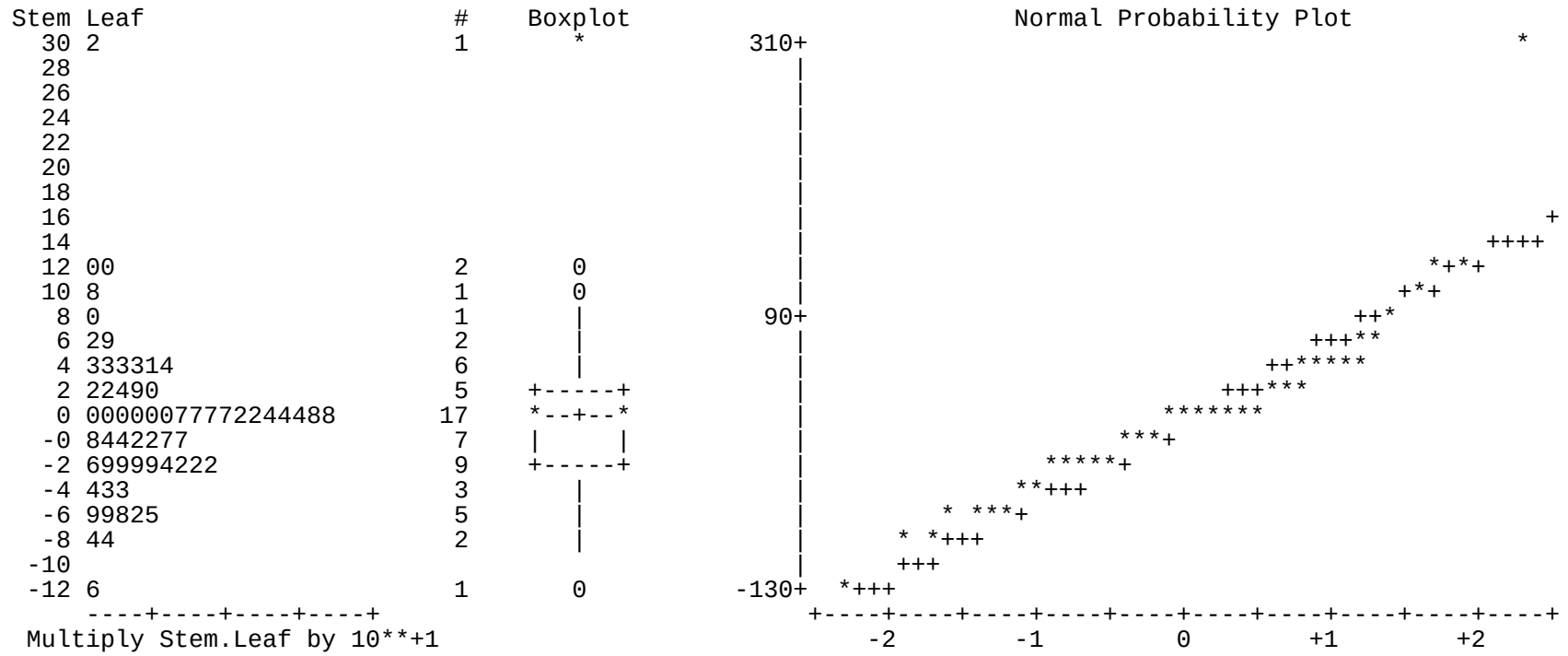

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	87.4716981	Sum Observations	4636
Std Deviation	47.1672612	Variance	2224.75053
Skewness	0.8721686	Kurtosis	0.44488262
Uncorrected SS	521205.82	Corrected SS	115687.028
Coeff Variation	53.9228827	Std Error Mean	6.4789216

Basic Statistical Measures

Location		Variability	
Mean	87.47170	Std Deviation	47.16726
Median	79.40000	Variance	2225
Mode	21.70000	Range	202.00000
		Interquartile Range	60.30000

NOTE: The mode displayed is the smallest of 7 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.50097	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.938233	Pr < W	0.0086
Kolmogorov-Smirnov	D	0.096241	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.126238	Pr > W-Sq	0.0484
Anderson-Darling	A-Sq	0.866945	Pr > A-Sq	0.0244

Quantiles (Definition 5)

Quantile	Estimate
100% Max	223.7
99%	223.7
95%	192.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	158.8
75% Q3	108.3
50% Median	79.4
25% Q1	48.0
10%	36.1
5%	21.7
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	51	158.8	45
21.7	38	162.0	31
21.7	16	192.0	28
30.0	29	194.9	48
36.1	43	223.7	7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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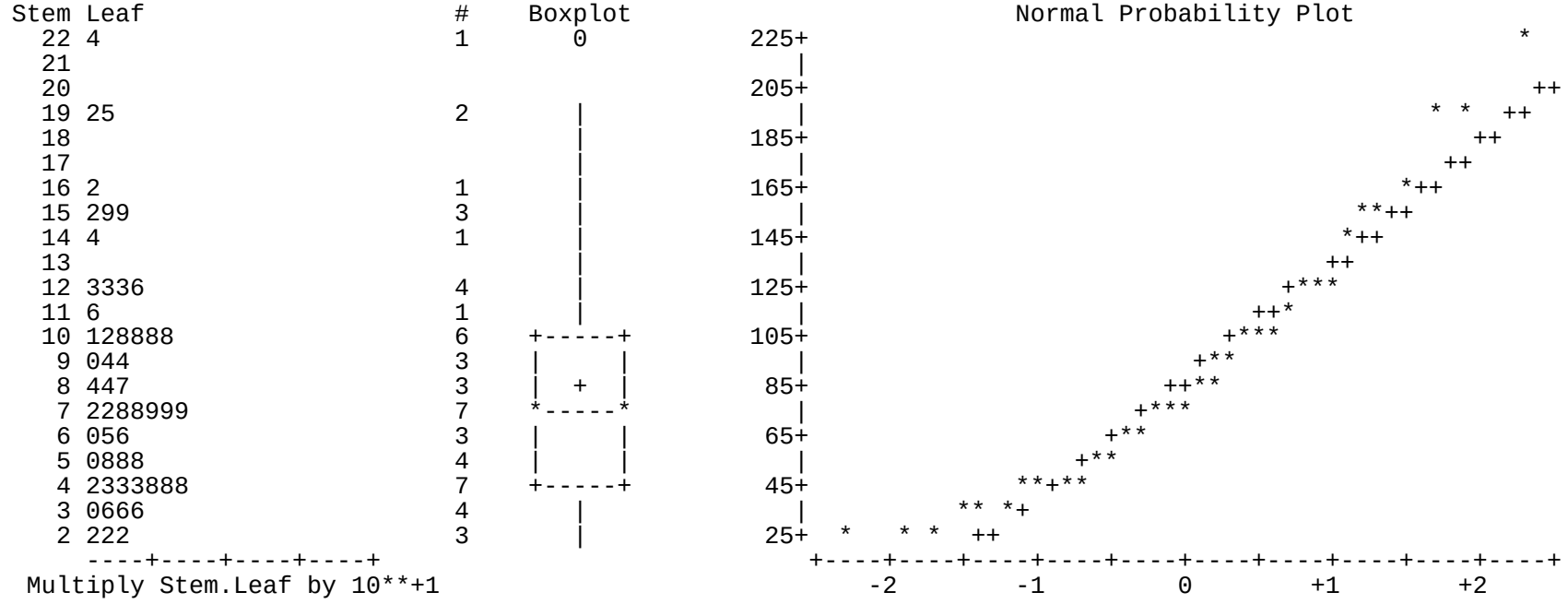
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	92.7169811	Sum Observations	4914
Std Deviation	54.6963356	Variance	2991.68913
Skewness	1.42649568	Kurtosis	2.38074031
Uncorrected SS	611179.08	Corrected SS	155567.835
Coeff Variation	58.9927918	Std Error Mean	7.51311951

Basic Statistical Measures

Location		Variability	
Mean	92.71698	Std Deviation	54.69634
Median	79.40000	Variance	2992
Mode	57.70000	Range	259.80000
		Interquartile Range	66.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.34068	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.88092	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.133611	Pr > D	0.0190
Cramer-von Mises	W-Sq	0.266053	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.66376	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	288.7
99%	288.7
95%	216.5
90%	158.8
75% Q3	120.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	54.0
10%	36.1
5%	30.0
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	51	173.2	48
28.9	16	187.6	45
30.0	21	216.5	49
36.0	17	223.7	5
36.1	14	288.7	7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

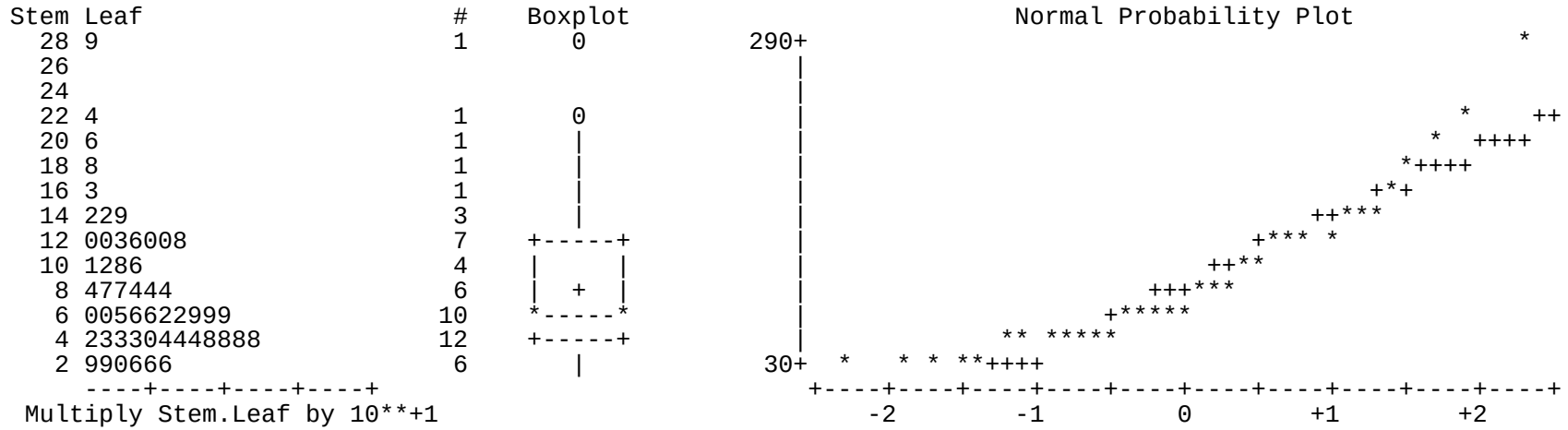

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	5.24528302	Sum Observations	278
Std Deviation	34.8014067	Variance	1211.13791
Skewness	-0.0452468	Kurtosis	2.89070746
Uncorrected SS	64437.36	Corrected SS	62979.1713
Coeff Variation	663.480056	Std Error Mean	4.78034085

Basic Statistical Measures

Location		Variability	
Mean	5.245283	Std Deviation	34.80141
Median	0.000000	Variance	1211
Mode	0.000000	Range	223.40000
		Interquartile Range	27.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.097261	Pr > |t|	0.2776
Sign	M	4	Pr >= |M|	0.2800

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	116.5	Pr >= |S|	0.1471

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.939847	Pr < W	0.0101
Kolmogorov-Smirnov	D	0.136837	Pr > D	0.0145
Cramer-von Mises	W-Sq	0.235252	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.23429	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	115.4
99%	115.4
95%	65.0
90%	43.3
75% Q3	21.6

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-6.0
10%	-36.1
5%	-54.0
1%	-108.0
0% Min	-108.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-108.0	31	50.5	4
-66.0	28	57.7	35
-54.0	22	65.0	7
-43.3	2	72.2	49
-36.1	15	115.4	5

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot
     10 5                        1       *
      8                                  |
      6 52                        2       0
      4 308                       3       |
      2 2224999006               10    +-----+
      0 00000000000677777748     20    *--+--*
     -0 8884476666               10    +-----+
     -2 662                      3       |
     -4 43                       2       0
     -6 6                        1       0
     -8                                  |
    -10 8                        1       *
        ----+----+----+----+
    Multiply Stem.Leaf by 10**+1
```

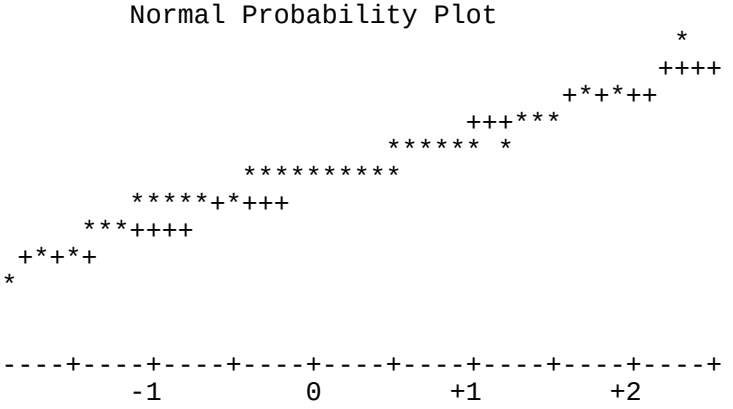

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	109.503704	Sum Observations	5913.2
Std Deviation	73.5452882	Variance	5408.90942
Skewness	1.78982276	Kurtosis	4.62344705
Uncorrected SS	934189.5	Corrected SS	286672.199
Coeff Variation	67.1623751	Std Error Mean	10.0082461

Basic Statistical Measures

Location		Variability	
Mean	109.5037	Std Deviation	73.54529
Median	85.3000	Variance	5409
Mode	79.4000	Range	392.30000
		Interquartile Range	93.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.94135	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.851532	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.160125	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.343273	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.994545	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	414.0
99%	414.0
95%	245.4
90%	180.4
75% Q3	151.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	85.3
25% Q1	57.7
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	33	209.3	39
24.0	27	234.0	32
28.9	12	245.4	45
36.0	31	288.0	22
36.1	34	414.0	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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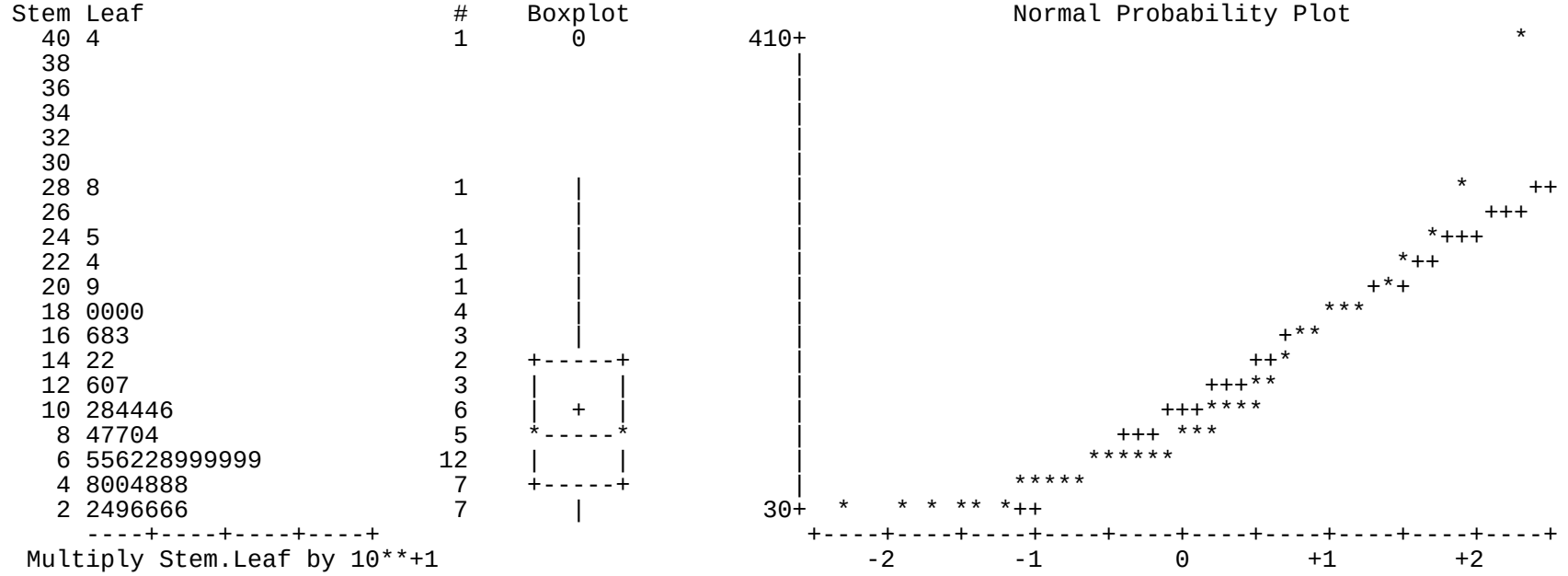
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	118.190741	Sum Observations	6382.3
Std Deviation	77.1053806	Variance	5945.23972
Skewness	1.34865912	Kurtosis	1.85118313
Uncorrected SS	1069426.47	Corrected SS	315097.705
Coeff Variation	65.238089	Std Error Mean	10.4927133

Basic Statistical Measures

Location		Variability	
Mean	118.1907	Std Deviation	77.10538
Median	97.9000	Variance	5945
Mode	65.0000	Range	356.30000
		Interquartile Range	93.80000

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.26408	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.887662	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.162146	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.296117	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.743382	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	378.0
99%	378.0
95%	294.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	223.7
75% Q3	158.8
50% Median	97.9
25% Q1	65.0
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	2	234.0	54
28.9	15	245.4	42
28.9	12	294.0	24
36.0	18	317.5	39
36.1	37	378.0	22

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

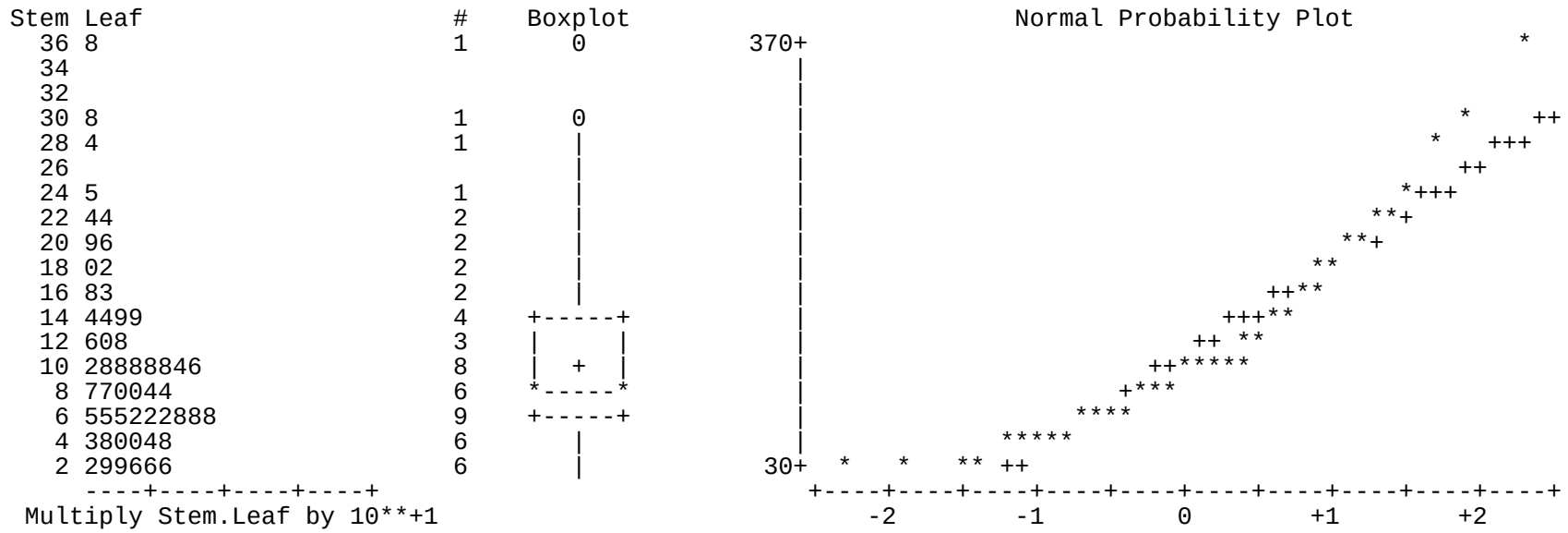

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	8.68703704	Sum Observations	469.1
Std Deviation	54.6047653	Variance	2981.68039
Skewness	0.32787033	Kurtosis	0.4523146
Uncorrected SS	162104.15	Corrected SS	158029.061
Coeff Variation	628.577558	Std Error Mean	7.43076736

Basic Statistical Measures

Location		Variability	
Mean	8.687037	Std Deviation	54.60477
Median	0.000000	Variance	2982
Mode	0.000000	Range	264.30000
		Interquartile Range	57.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.169063	Pr > |t|	0.2476
Sign	M	0.5	Pr >= |M|	1.0000

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	84.5	Pr >= |S|	0.3768

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.967999	Pr < W	0.1572
Kolmogorov-Smirnov	D	0.118756	Pr > D	0.0564
Cramer-von Mises	W-Sq	0.163375	Pr > W-Sq	0.0166
Anderson-Darling	A-Sq	0.833395	Pr > A-Sq	0.0307

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	122.6
90%	86.6
75% Q3	36.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-21.6
10%	-65.0
5%	-79.4
1%	-120.0
0% Min	-120.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-120.0	24	90.0	22
-96.0	32	108.2	39
-79.4	10	122.6	33
-78.0	18	126.0	54
-66.0	21	144.3	38

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

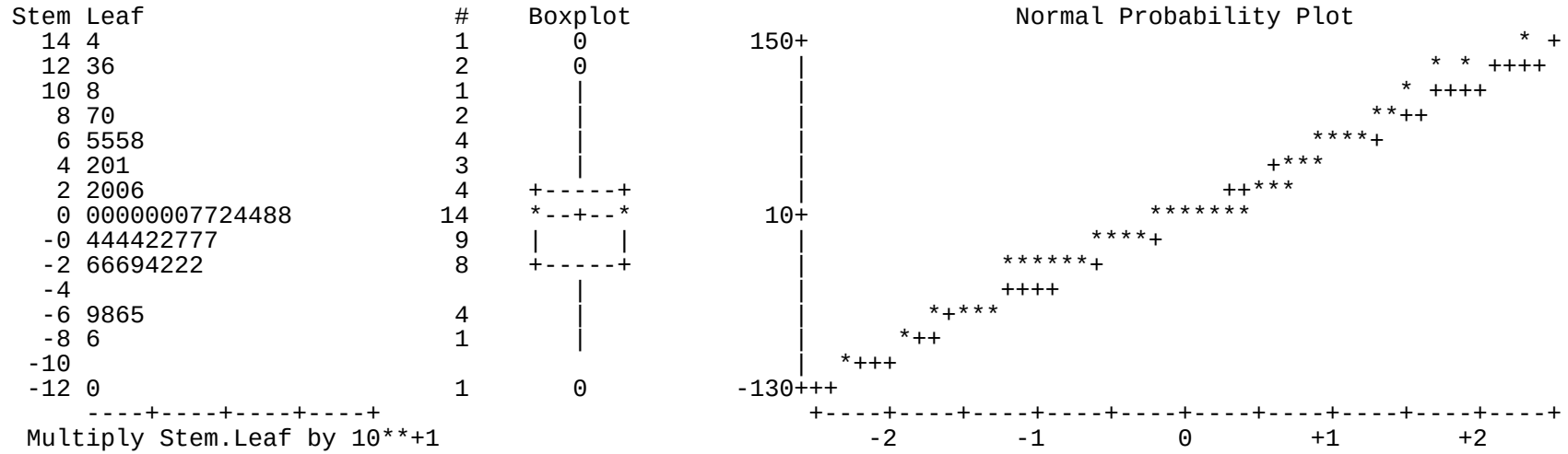

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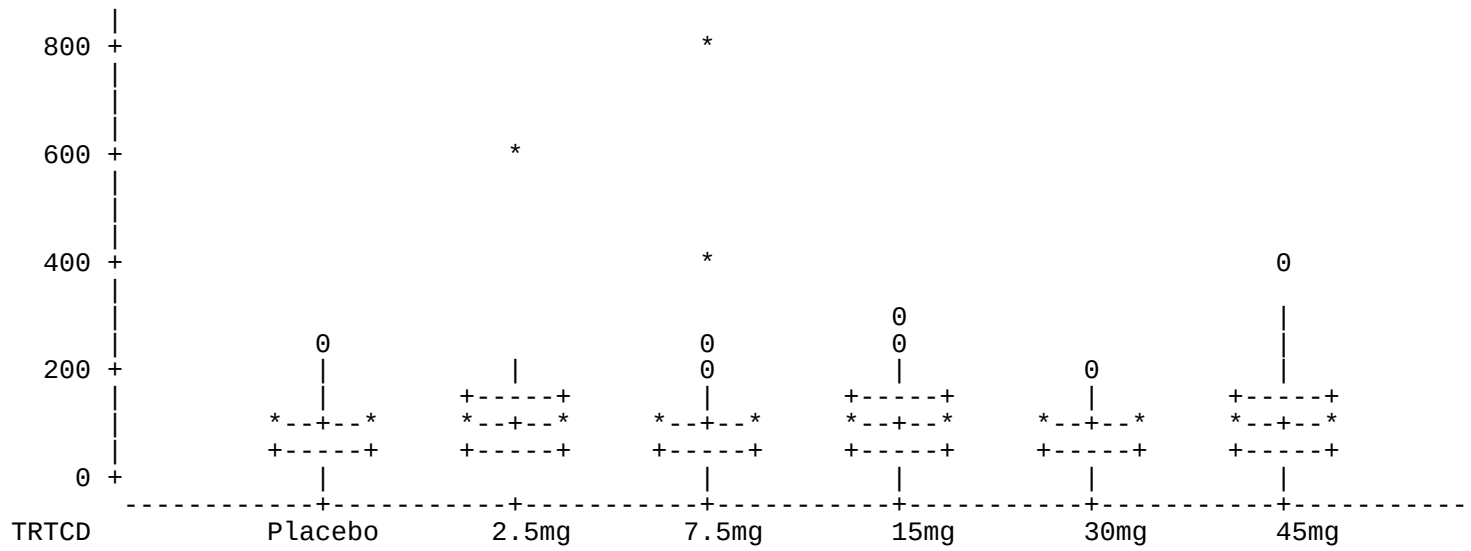
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



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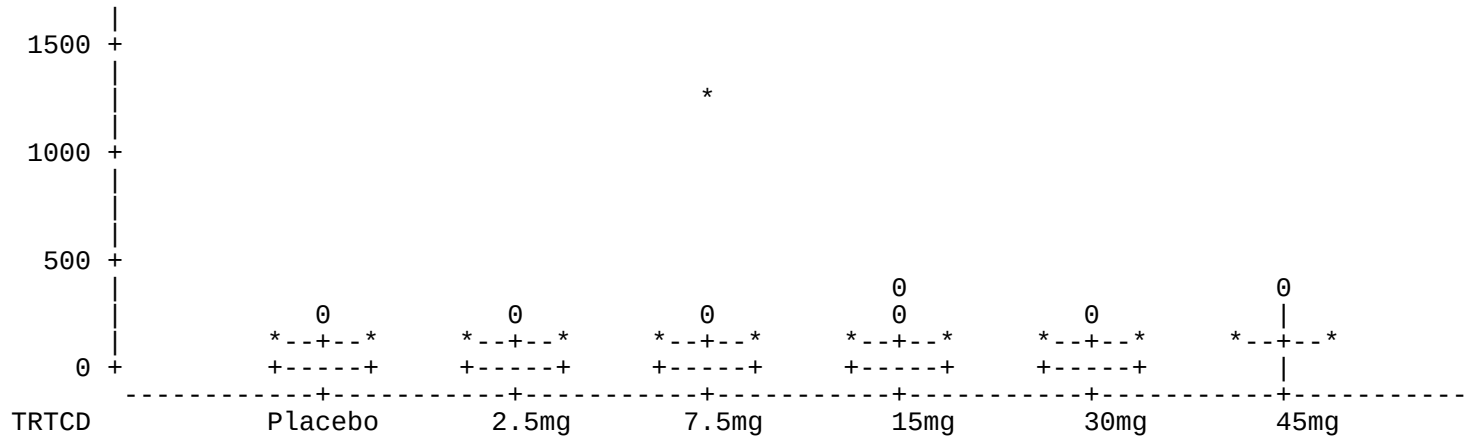
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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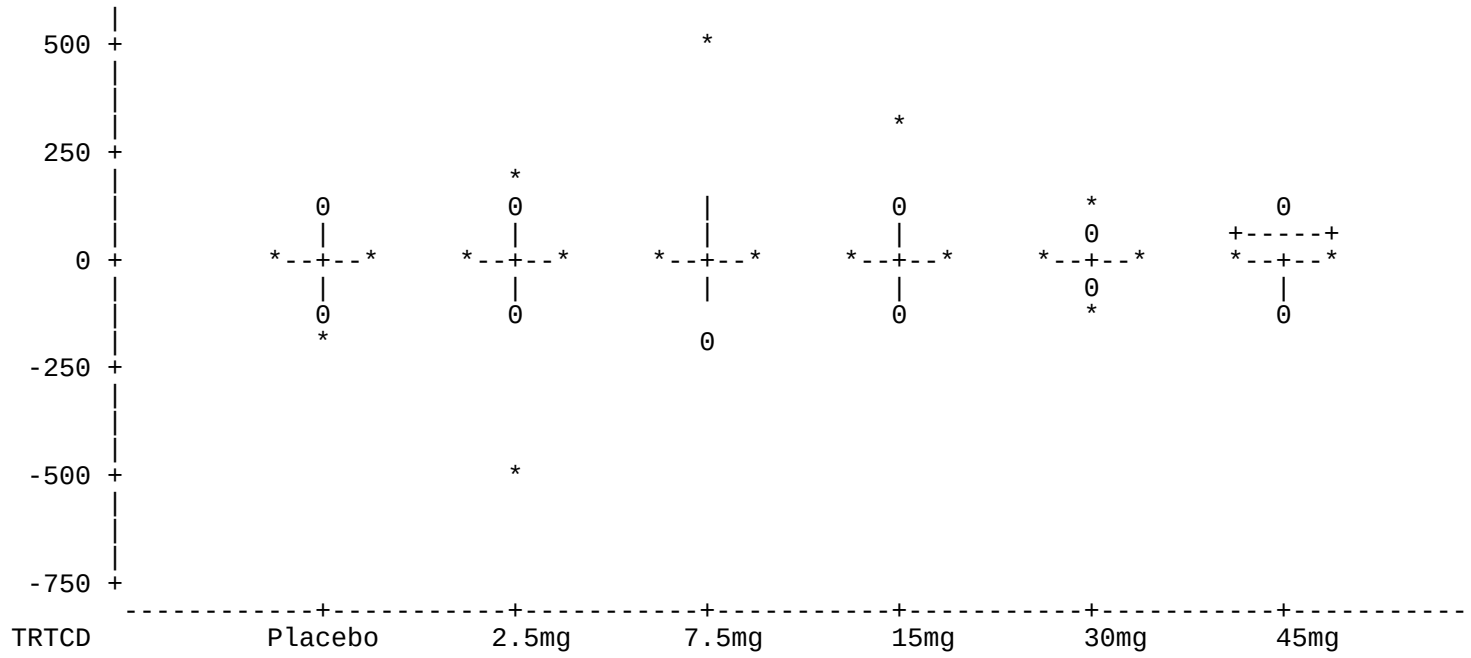
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	335
Observations Used	335
Observations Not Used	0
Total Observations	335

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	4010.40	315.09	12.73	<.0001	0.05	3457.99	4707.39

Fit Statistics

-2 Res Log Likelihood	3663.2
AIC (smaller is better)	3665.2
AICC (smaller is better)	3665.2
BIC (smaller is better)	3669.0

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					29.1345	11.8842	324	2.45	0.0148
SEX	Female				-3.5336	6.9954	324	-0.51	0.6138
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			5.8434	7.0691	324	0.83	0.4091
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	-12.7360	12.1546	324	-1.05	0.2955
TRTCD				2.5mg	-21.2417	12.3143	324	-1.72	0.0855
TRTCD				7.5mg	1.4411	12.0204	324	0.12	0.9046
TRTCD				15mg	-5.4212	11.8140	324	-0.46	0.6466
TRTCD				30mg	-7.4687	12.3149	324	-0.61	0.5446
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-9.9901	8.1959	324	-1.22	0.2238
REGIONCD			Eastern Europe		-19.2645	8.7166	324	-2.21	0.0278
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.1026	0.04671	324	-2.20	0.0288

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	324	0.26	0.6138
TRTTYPCD	1	324	0.68	0.4091
TRTCD	5	324	0.96	0.4448
REGIONCD	2	324	2.48	0.0857
EFSTDBL	1	324	4.82	0.0288

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-8.5057	12.2766	324	-0.69	0.4889	0.05	-32.6575	15.6461
7.5mg vs Pbo	14.1771	11.9684	324	1.18	0.2371	0.05	-9.3684	37.7226
15mg vs Pbo	7.3148	11.7446	324	0.62	0.5338	0.05	-15.7906	30.4202
30mg vs Pbo	5.2673	12.1503	324	0.43	0.6649	0.05	-18.6361	29.1707
45mg vs Pbo	12.7360	12.1546	324	1.05	0.2955	0.05	-11.1759	36.6480

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.4985	0.4985	0.4985	0.4985	0.4985
SEX	Male				0.5015	0.5015	0.5015	0.5015	0.5015
TRTTYPCD		Diet & Exercise			0.4209	0.4209	0.4209	0.4209	0.4209
TRTTYPCD		Monotherapy			0.5791	0.5791	0.5791	0.5791	0.5791
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3403	0.3403	0.3403	0.3403	0.3403
REGIONCD			Eastern Europe		0.2776	0.2776	0.2776	0.2776	0.2776
REGIONCD			Western Europe		0.3821	0.3821	0.3821	0.3821	0.3821
EFSTDBL					101.29	101.29	101.29	101.29	101.29

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.4985
SEX	Male				0.5015
TRTTYPCD		Diet & Exercise			0.4209
TRTTYPCD		Monotherapy			0.5791
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3403
REGIONCD			Eastern Europe		0.2776
REGIONCD			Western Europe		0.3821
EFSTDBL					101.29

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-2.0400	8.5140	324	-0.24	0.8108	0.05	-18.7897	14.7097
TRTCD	2.5mg	WORK.EFF	-10.5457	8.8037	324	-1.20	0.2318	0.05	-27.8654	6.7740
TRTCD	7.5mg	WORK.EFF	12.1371	8.3548	324	1.45	0.1473	0.05	-4.2994	28.5735
TRTCD	15mg	WORK.EFF	5.2748	8.0569	324	0.65	0.5131	0.05	-10.5756	21.1252
TRTCD	30mg	WORK.EFF	3.2273	8.7324	324	0.37	0.7119	0.05	-13.9521	20.4066
TRTCD	45mg	WORK.EFF	10.6960	8.6412	324	1.24	0.2167	0.05	-6.3039	27.6959

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	8.5057	12.2766	324	0.69	0.4889	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	-14.1771	11.9684	324	-1.18	0.2371	0.05
TRTCD	Placebo	15mg	WORK.EFF	-7.3148	11.7446	324	-0.62	0.5338	0.05
TRTCD	Placebo	30mg	WORK.EFF	-5.2673	12.1503	324	-0.43	0.6649	0.05
TRTCD	Placebo	45mg	WORK.EFF	-12.7360	12.1546	324	-1.05	0.2955	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	-22.6828	12.1407	324	-1.87	0.0626	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-15.8205	11.9275	324	-1.33	0.1856	0.05
TRTCD	2.5mg	30mg	WORK.EFF	-13.7730	12.4249	324	-1.11	0.2685	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-21.2417	12.3143	324	-1.72	0.0855	0.05

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	6.8623	11.5986	324	0.59	0.5545	0.05
TRTCD	7.5mg	30mg	WORK.EFF	8.9098	12.1081	324	0.74	0.4624	0.05
TRTCD	7.5mg	45mg	WORK.EFF	1.4411	12.0204	324	0.12	0.9046	0.05
TRTCD	15mg	30mg	WORK.EFF	2.0475	11.8957	324	0.17	0.8634	0.05
TRTCD	15mg	45mg	WORK.EFF	-5.4212	11.8140	324	-0.46	0.6466	0.05
TRTCD	30mg	45mg	WORK.EFF	-7.4687	12.3149	324	-0.61	0.5446	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-15.6461	32.6575
TRTCD	Placebo	7.5mg	-37.7226	9.3684
TRTCD	Placebo	15mg	-30.4202	15.7906
TRTCD	Placebo	30mg	-29.1707	18.6361
TRTCD	Placebo	45mg	-36.6480	11.1759
TRTCD	2.5mg	7.5mg	-46.5673	1.2018
TRTCD	2.5mg	15mg	-39.2856	7.6446
TRTCD	2.5mg	30mg	-38.2167	10.6707
TRTCD	2.5mg	45mg	-45.4678	2.9844
TRTCD	7.5mg	15mg	-15.9558	29.6804

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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-14.9106	32.7302
TRTCD	7.5mg	45mg	-22.2069	25.0890
TRTCD	15mg	30mg	-21.3550	25.4500
TRTCD	15mg	45mg	-28.6630	17.8206
TRTCD	30mg	45mg	-31.6960	16.7586

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.

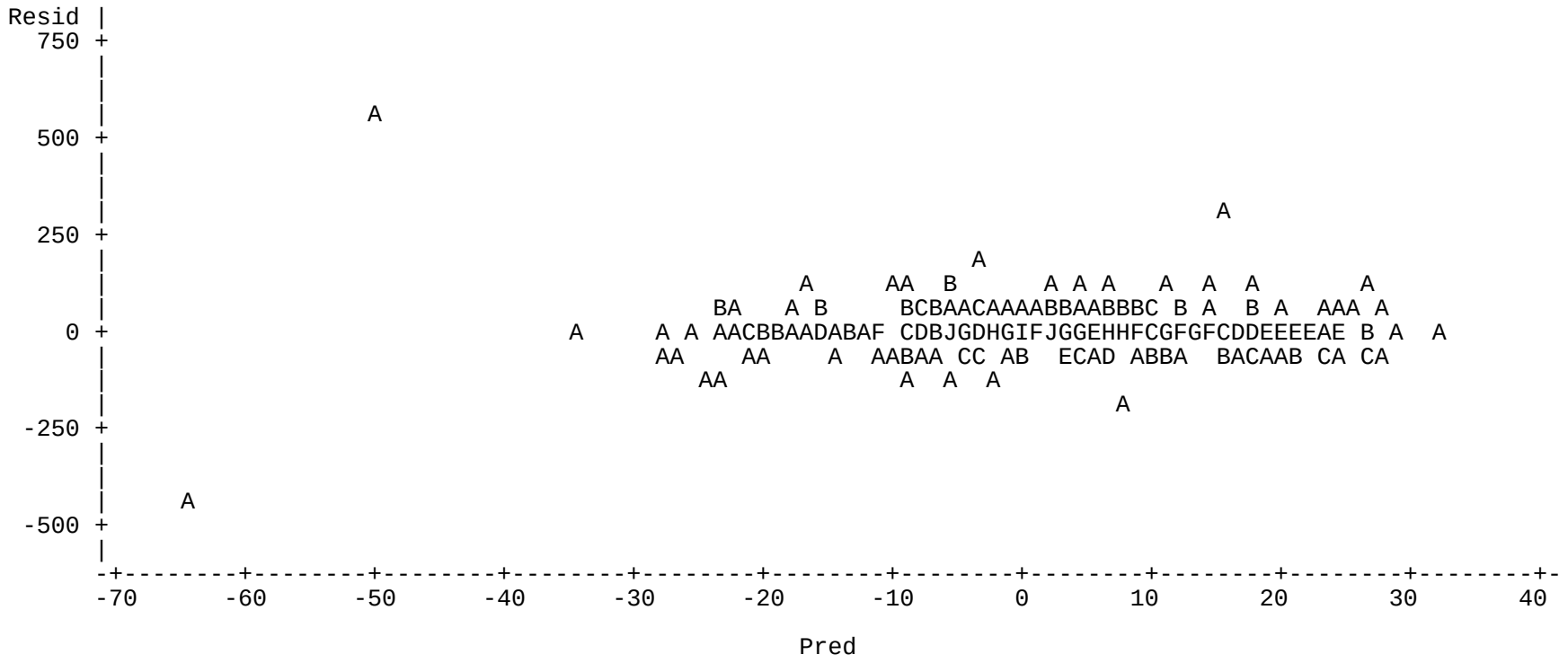

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Table 11.26
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

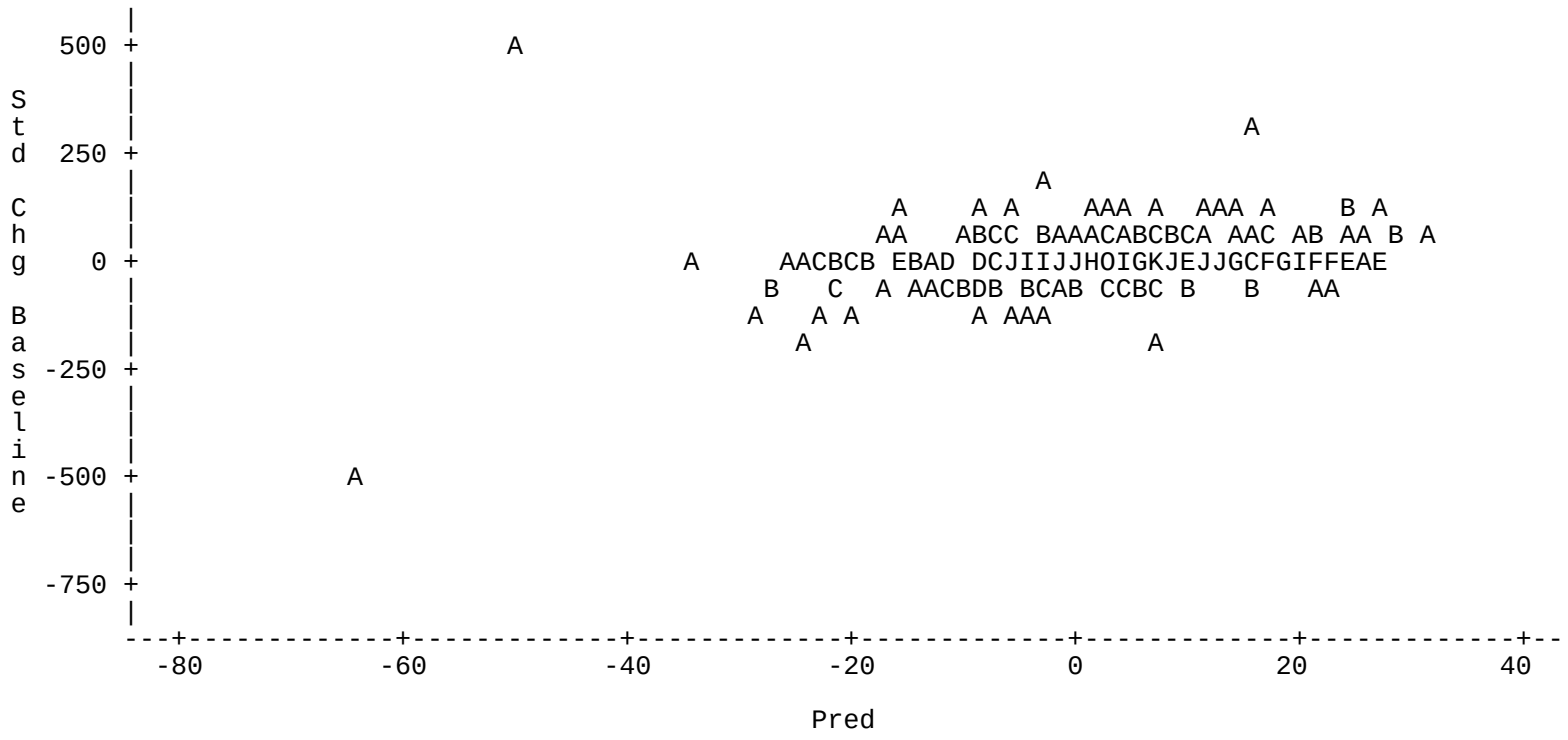

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	335	Sum Weights	335
Mean	0	Sum Observations	0
Std Deviation	62.3725274	Variance	3890.33218
Skewness	1.51628652	Kurtosis	30.3672587
Uncorrected SS	1299370.95	Corrected SS	1299370.95
Coeff Variation		Std Error Mean	3.40777521

Basic Statistical Measures

Location		Variability	
Mean	0.0000	Std Deviation	62.37253
Median	-4.2778	Variance	3890
Mode	-44.8166	Range	1032
		Interquartile Range	43.43056

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-16.5	Pr >= |M|	0.0802
Signed Rank	S	-2473	Pr >= |S|	0.1636

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.744168	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.154499	Pr > D	<0.0100
Cramer-von Mises	W-Sq	2.575494	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	14.47521	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	569.71144
99%	153.16874
95%	91.17148
90%	52.00521
75% Q3	19.24575
50% Median	-4.27782
25% Q1	-24.18481
10%	-52.28273
5%	-73.05927
1%	-117.41774
0% Min	-462.15133

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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-462.151	20	146.085	62
-188.116	218	153.169	237
-134.467	60	176.246	295
-117.418	129	296.126	335
-110.154	286	569.711	36

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[redacted]

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Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

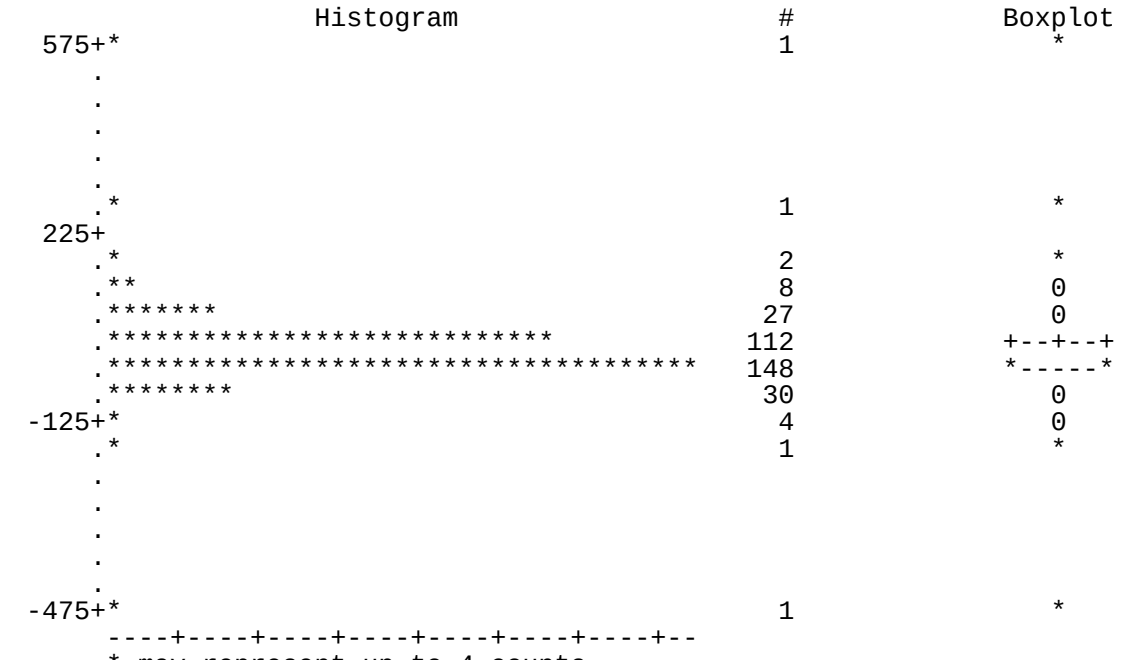

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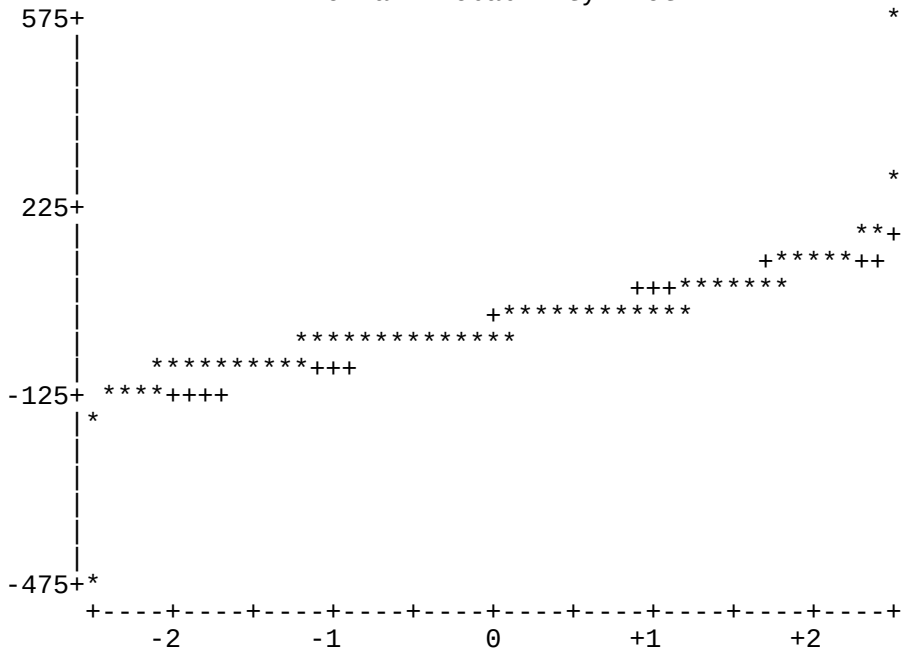
Table 11.26
SAS Statistical Output for Table 11.25
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.27
Summary Statistics for Pro-Insulin (pmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	54	62	63	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	30.98	37.48	33.79	35.24	32.21	37.85
	SD	29.761	22.266	25.595	32.611	20.247	31.356
	SE	3.842	3.030	3.251	4.109	2.706	4.082
	Minimum	5.0	9.0	4.0	8.0	5.0	2.0
	Median	22.00	30.50	25.50	27.00	29.00	28.00
	Maximum	166.0	94.0	128.0	184.0	85.0	154.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.27
Summary Statistics for Pro-Insulin (pmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		55	53	58	61	52	56
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Mean	30.71	36.94	33.07	34.75	31.90	37.77
	SD	30.576	22.122	22.987	32.483	19.309	31.895
	SE	4.123	3.039	3.018	4.159	2.678	4.262
	Minimum	5.0	9.0	4.0	8.0	7.0	2.0
	Median	20.00	30.00	26.50	27.00	29.00	28.50
	Maximum	166.0	94.0	113.0	184.0	85.0	154.0
Week 4	Mean	29.35	34.53	31.69	30.28	27.58	32.21
	SD	18.793	21.540	29.189	26.668	19.240	30.309
	SE	2.534	2.959	3.833	3.414	2.668	4.050
	Minimum	6.0	4.0	4.0	7.0	5.0	5.0
	Median	24.00	27.00	24.00	22.00	24.50	21.50
	Maximum	83.0	88.0	177.0	139.0	109.0	139.0
Change from Baseline	Mean	-1.36	-2.42	-1.38	-4.48	-4.33	-5.55
	SD	21.662	15.774	24.872	19.604	18.011	20.885
	SE	2.921	2.167	3.266	2.510	2.498	2.791
	Minimum	-88.0	-63.0	-43.0	-64.0	-39.0	-78.0
	Median	1.00	0.00	-2.00	-3.00	-4.00	-6.00
	Maximum	73.0	55.0	104.0	42.0	95.0	65.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.27
Summary Statistics for Pro-Insulin (pmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	53	61	61	56	58
Number (%) of Values Carried Forward		6 (11%)	10 (19%)	8 (13%)	2 (3%)	3 (5%)	10 (17%)
Baseline	Mean	30.19	36.94	34.10	34.75	32.21	37.36
	SD	30.187	22.122	25.691	32.483	20.247	31.405
	SE	3.998	3.039	3.289	4.159	2.706	4.124
	Minimum	5.0	9.0	4.0	8.0	5.0	2.0
	Median	20.00	30.00	26.00	27.00	29.00	27.50
	Maximum	166.0	94.0	128.0	184.0	85.0	154.0
Week 8	Mean	30.19	32.72	30.62	30.16	28.34	32.91
	SD	24.761	23.001	20.260	25.866	20.550	30.589
	SE	3.280	3.159	2.594	3.312	2.746	4.017
	Minimum	7.0	4.0	4.0	3.0	6.0	5.0
	Median	26.00	26.00	25.00	21.00	21.00	22.50
	Maximum	132.0	121.0	96.0	150.0	93.0	162.0
Change from Baseline	Mean	0.00	-4.23	-3.48	-4.59	-3.88	-4.45
	SD	18.948	16.204	16.865	18.539	18.139	26.313
	SE	2.510	2.226	2.159	2.374	2.424	3.455
	Minimum	-95.0	-63.0	-78.0	-86.0	-72.0	-74.0
	Median	1.00	-3.00	-3.00	-3.00	-4.00	-4.00
	Maximum	65.0	39.0	32.0	37.0	56.0	137.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.27
Summary Statistics for Pro-Insulin (pmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	53	61	62	56	58
Number (%) of Values Carried Forward		10 (18%)	11 (21%)	11 (18%)	4 (6%)	6 (11%)	7 (12%)
Baseline	Mean	30.19	36.94	34.10	35.53	32.21	37.36
	SD	30.187	22.122	25.691	32.793	20.247	31.405
	SE	3.998	3.039	3.289	4.165	2.706	4.124
	Minimum	5.0	9.0	4.0	8.0	5.0	2.0
	Median	20.00	30.00	26.00	27.50	29.00	27.50
	Maximum	166.0	94.0	128.0	184.0	85.0	154.0
Week 12	Mean	27.44	35.15	32.84	30.66	26.32	34.83
	SD	19.621	25.865	31.971	26.904	15.637	34.327
	SE	2.599	3.553	4.094	3.417	2.090	4.507
	Minimum	5.0	4.0	4.0	6.0	6.0	7.0
	Median	25.00	26.00	24.00	24.00	23.50	25.00
	Maximum	118.0	126.0	208.0	175.0	77.0	214.0
Change from Baseline	Mean	-2.75	-1.79	-1.26	-4.87	-5.89	-2.53
	SD	18.901	19.482	18.268	21.035	13.728	22.318
	SE	2.504	2.676	2.339	2.671	1.834	2.930
	Minimum	-107.0	-63.0	-50.0	-96.0	-45.0	-84.0
	Median	-1.00	0.00	-2.00	-2.00	-4.00	-3.50
	Maximum	38.0	44.0	80.0	65.0	36.0	82.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	53	61	62	56	58
Number (%) of Values Carried Forward		10 (18%)	11 (21%)	11 (18%)	4 (6%)	6 (11%)	7 (12%)
Baseline	Mean	30.19	36.94	34.10	35.53	32.21	37.36
	SD	30.187	22.122	25.691	32.793	20.247	31.405
Week 12	Mean	27.44	35.15	32.84	30.66	26.32	34.83
	SD	19.621	25.865	31.971	26.904	15.637	34.327
Chg from Baseline	Mean	-2.75	-1.79	-1.26	-4.87	-5.89	-2.53
	SD	18.901	19.482	18.268	21.035	13.728	22.318
Model-Adj Chg [2]	Mean	-4.28	-0.97	-1.21	-4.63	-6.49	-1.53
	SE	2.332	2.418	2.248	2.228	2.348	2.307
Diff from Pbo [2]	Mean		3.31	3.06	-0.35	-2.21	2.75
	95% CI		-3.32,9.94	-3.31,9.44	-6.70,6.00	-8.71,4.29	-3.71,9.22
	p-val [3]		0.327	0.345	0.914	0.504	0.403

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	57	Sum Weights	57
Mean	30.1929825	Sum Observations	1721
Std Deviation	30.1865856	Variance	911.22995
Skewness	2.86107671	Kurtosis	9.81463519
Uncorrected SS	102991	Corrected SS	51028.8772
Coeff Variation	99.9788134	Std Error Mean	3.99831094

Basic Statistical Measures

Location		Variability	
Mean	30.19298	Std Deviation	30.18659
Median	20.00000	Variance	911.22995
Mode	20.00000	Range	161.00000
		Interquartile Range	19.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.551434	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.678973	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.243874	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.930624	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	5.167444	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	166
99%	166
95%	75

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	67
75% Q3	33
50% Median	20
25% Q1	14
10%	9
5%	6
1%	5
0% Min	5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5	25	67	55
6	29	71	20
6	7	75	9
7	15	147	3
8	44	166	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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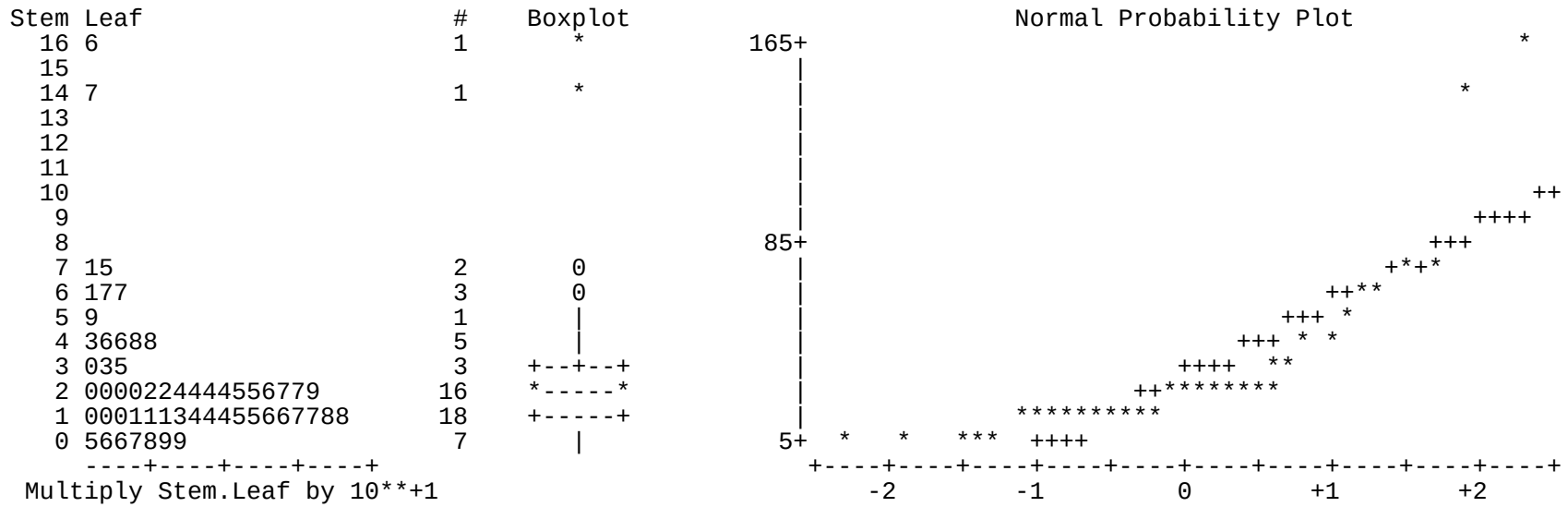
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	57	Sum Weights	57
Mean	27.4385965	Sum Observations	1564
Std Deviation	19.6214328	Variance	385.000627
Skewness	2.21409137	Kurtosis	7.39654499
Uncorrected SS	64474	Corrected SS	21560.0351
Coeff Variation	71.5103371	Std Error Mean	2.59892227

Basic Statistical Measures

Location		Variability	
Mean	27.43860	Std Deviation	19.62143
Median	25.00000	Variance	385.00063
Mode	12.00000	Range	113.00000
		Interquartile Range	22.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.55768	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.811694	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.152498	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.365573	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.336927	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	118
99%	118
95%	68

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	48
75% Q3	35
50% Median	25
25% Q1	13
10%	10
5%	8
1%	5
0% Min	5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5	29	59	5
7	15	59	55
8	44	68	21
8	37	74	13
8	7	118	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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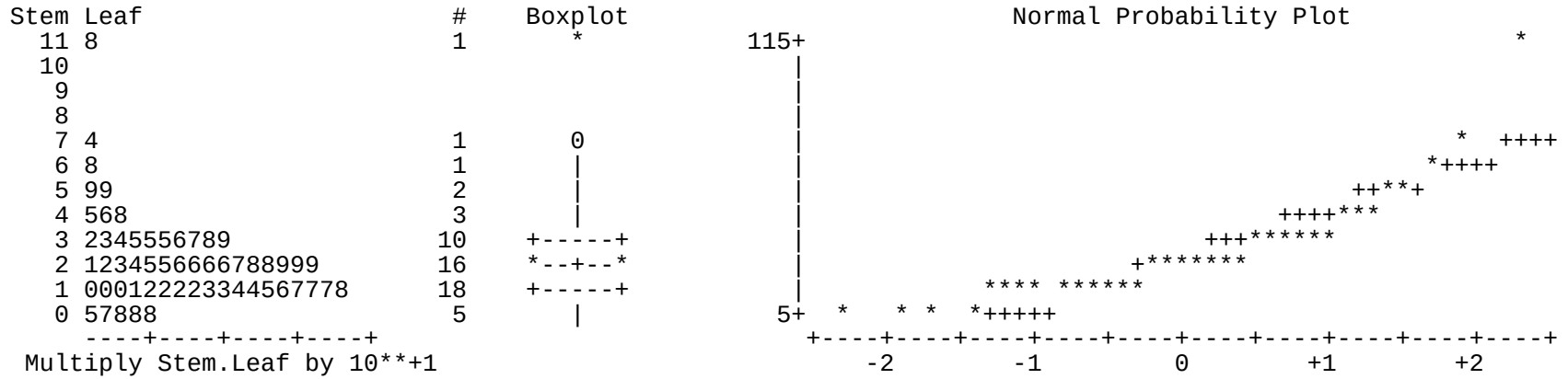
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	57	Sum Weights	57
Mean	-2.754386	Sum Observations	-157
Std Deviation	18.9013234	Variance	357.260025
Skewness	-3.166537	Kurtosis	16.4665666
Uncorrected SS	20439	Corrected SS	20006.5614
Coeff Variation	-686.22639	Std Error Mean	2.50354144

Basic Statistical Measures

Location		Variability	
Mean	-2.75439	Std Deviation	18.90132
Median	-1.00000	Variance	357.26003
Mode	-3.00000	Range	145.00000
		Interquartile Range	10.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.1002	Pr > |t|	0.2760
Sign	M	-2.5	Pr >= |M|	0.5831

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-13	Pr >= |S|	0.9096

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.707765	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.228114	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.826914	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.394083	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	38
99%	38
95%	16
90%	10
75% Q3	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-1
25% Q1	-4
10%	-19
5%	-34
1%	-107
0% Min	-107

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-107	5	11	57
-43	9	15	52
-34	20	16	45
-29	3	22	23
-26	49	38	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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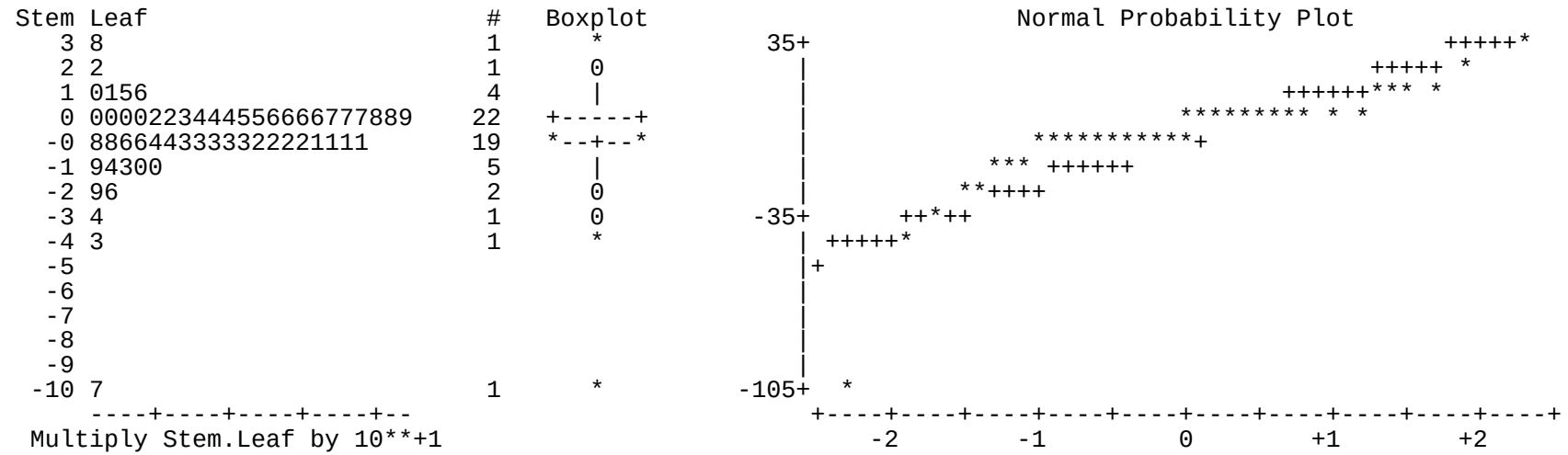
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	36.9433962	Sum Observations	1958
Std Deviation	22.1215307	Variance	489.362119
Skewness	0.99864442	Kurtosis	0.22567438
Uncorrected SS	97782	Corrected SS	25446.8302
Coeff Variation	59.8795263	Std Error Mean	3.03862593

Basic Statistical Measures

Location		Variability	
Mean	36.94340	Std Deviation	22.12153
Median	30.00000	Variance	489.36212
Mode	22.00000	Range	85.00000
		Interquartile Range	28.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.15793	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.901296	Pr < W	0.0004
Kolmogorov-Smirnov	D	0.136779	Pr > D	0.0146
Cramer-von Mises	W-Sq	0.276063	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.678416	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	94
99%	94
95%	83

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	67
75% Q3	50
50% Median	30
25% Q1	22
10%	14
5%	11
1%	9
0% Min	9

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
9	5	78	46
10	11	81	21
11	26	83	27
13	6	92	36
14	24	94	31

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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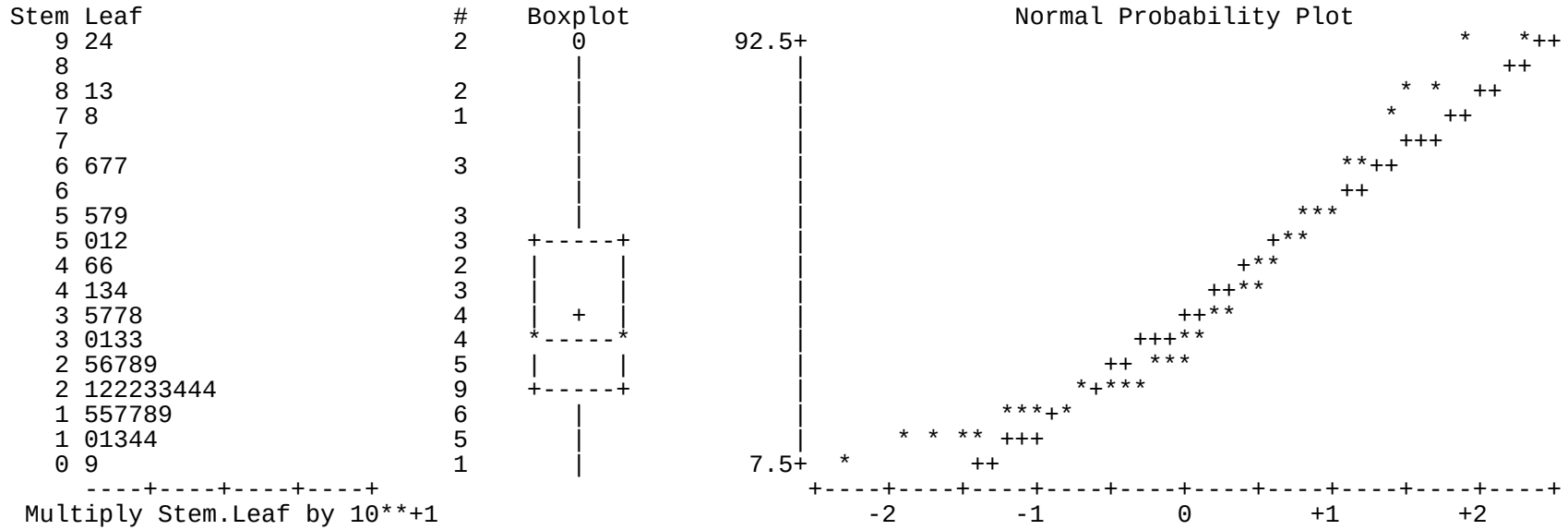
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	35.1509434	Sum Observations	1863
Std Deviation	25.8653289	Variance	669.015239
Skewness	1.71172105	Kurtosis	3.37145305
Uncorrected SS	100275	Corrected SS	34788.7925
Coeff Variation	73.5835981	Std Error Mean	3.55287617

Basic Statistical Measures

Location		Variability	
Mean	35.15094	Std Deviation	25.86533
Median	26.00000	Variance	669.01524
Mode	25.00000	Range	122.00000
		Interquartile Range	27.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.893658	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.84334	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.15197	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.355856	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.240812	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	126
99%	126
95%	96
90%	67
75% Q3	44

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	26
25% Q1	17
10%	12
5%	9
1%	4
0% Min	4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
4	49	69	31
6	11	75	50
9	43	96	33
9	5	116	36
12	26	126	27

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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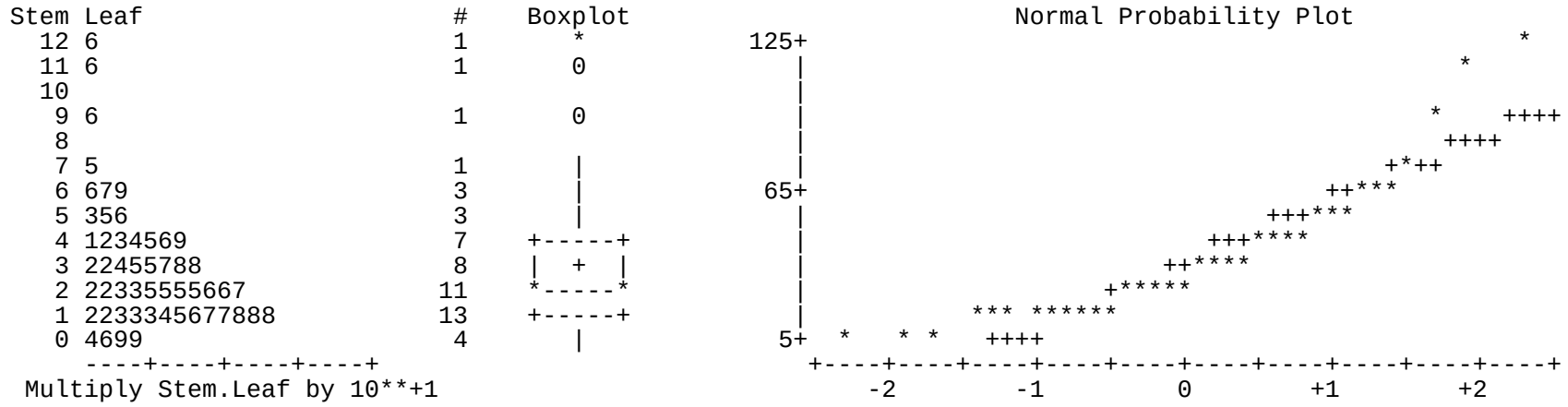
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	-1.7924528	Sum Observations	-95
Std Deviation	19.4821008	Variance	379.55225
Skewness	-0.3554308	Kurtosis	2.29717002
Uncorrected SS	19907	Corrected SS	19736.717
Coeff Variation	-1086.8961	Std Error Mean	2.67607235

Basic Statistical Measures

Location		Variability	
Mean	-1.79245	Std Deviation	19.48210
Median	0.00000	Variance	379.55225
Mode	0.00000	Range	107.00000
		Interquartile Range	15.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.66981	Pr > |t|	0.5059
Sign	M	-2	Pr >= |M|	0.6655
Signed Rank	S	-84.5	Pr >= |S|	0.3916

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.930738	Pr < W	0.0043
Kolmogorov-Smirnov	D	0.130347	Pr > D	0.0235
Cramer-von Mises	W-Sq	0.251377	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.393314	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	44
99%	44
95%	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	21
75% Q3	6
50% Median	0
25% Q1	-9
10%	-22
5%	-34
1%	-63
0% Min	-63

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-63	49	21	51
-53	46	24	36
-34	38	41	33
-31	48	43	27
-25	31	44	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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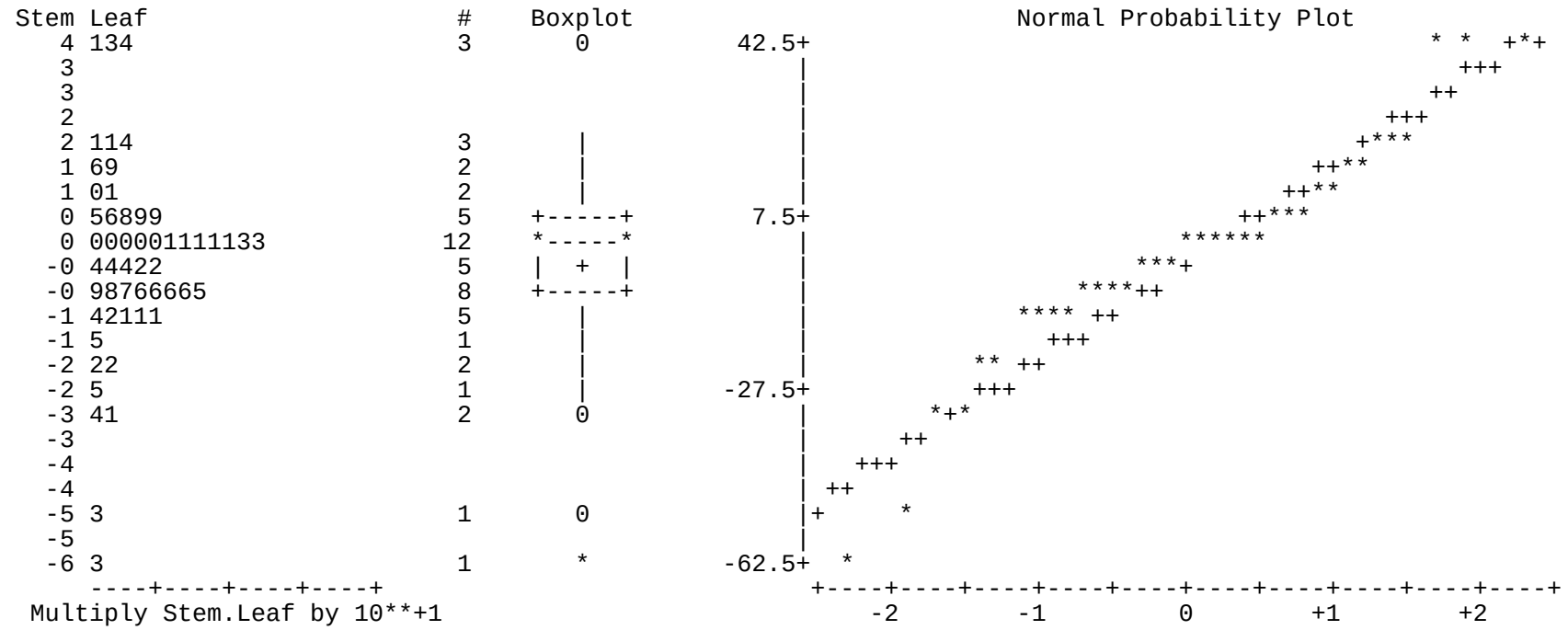
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	61	Sum Weights	61
Mean	34.0983607	Sum Observations	2080
Std Deviation	25.6909225	Variance	660.023497
Skewness	1.57412819	Kurtosis	2.94393912
Uncorrected SS	110526	Corrected SS	39601.4098
Coeff Variation	75.3435707	Std Error Mean	3.28938556

Basic Statistical Measures

Location		Variability	
Mean	34.09836	Std Deviation	25.69092
Median	26.00000	Variance	660.02350
Mode	14.00000	Range	124.00000
		Interquartile Range	29.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.36618	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	945.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.861152	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.133431	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.356798	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.20744	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	128
99%	128
95%	73
90%	68
75% Q3	44

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	26
25% Q1	15
10%	10
5%	7
1%	4
0% Min	4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
4	32	70	55
6	51	73	28
6	12	93	44
7	9	113	14
8	23	128	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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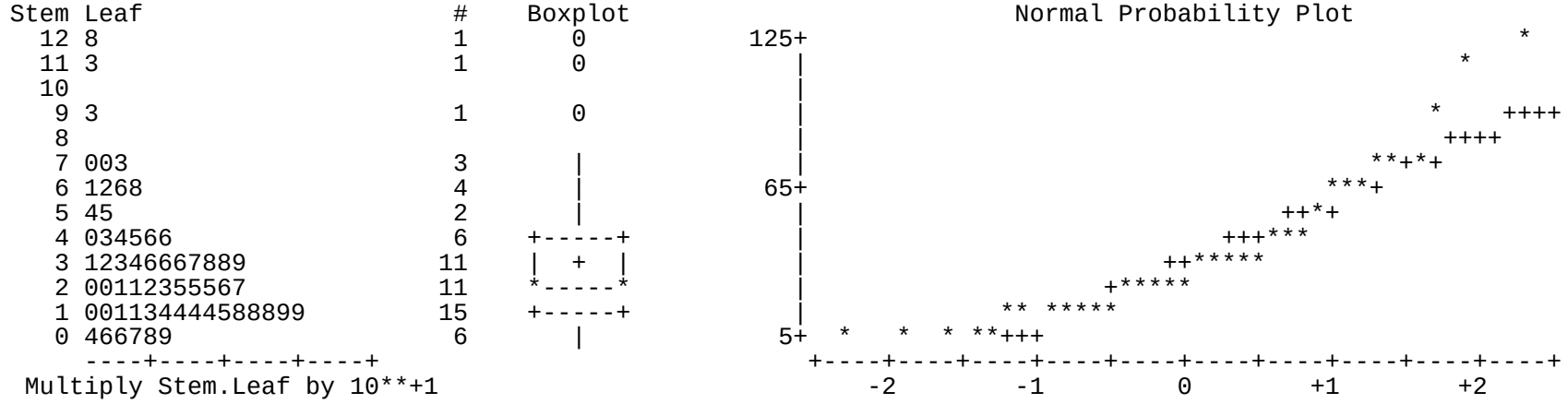
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	61	Sum Weights	61
Mean	32.8360656	Sum Observations	2003
Std Deviation	31.9714353	Variance	1022.17268
Skewness	3.20952749	Kurtosis	14.5354409
Uncorrected SS	127101	Corrected SS	61330.3607
Coeff Variation	97.3668275	Std Error Mean	4.09352283

Basic Statistical Measures

Location		Variability	
Mean	32.83607	Std Deviation	31.97144
Median	24.00000	Variance	1022
Mode	27.00000	Range	204.00000
		Interquartile Range	25.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.021469	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	945.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.694918	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.232247	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.830908	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.551665	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	208
99%	208
95%	87
90%	65
75% Q3	40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	24
25% Q1	15
10%	8
5%	7
1%	4
0% Min	4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
4	32	72	5
4	12	87	14
7	57	90	20
7	43	107	28
7	37	208	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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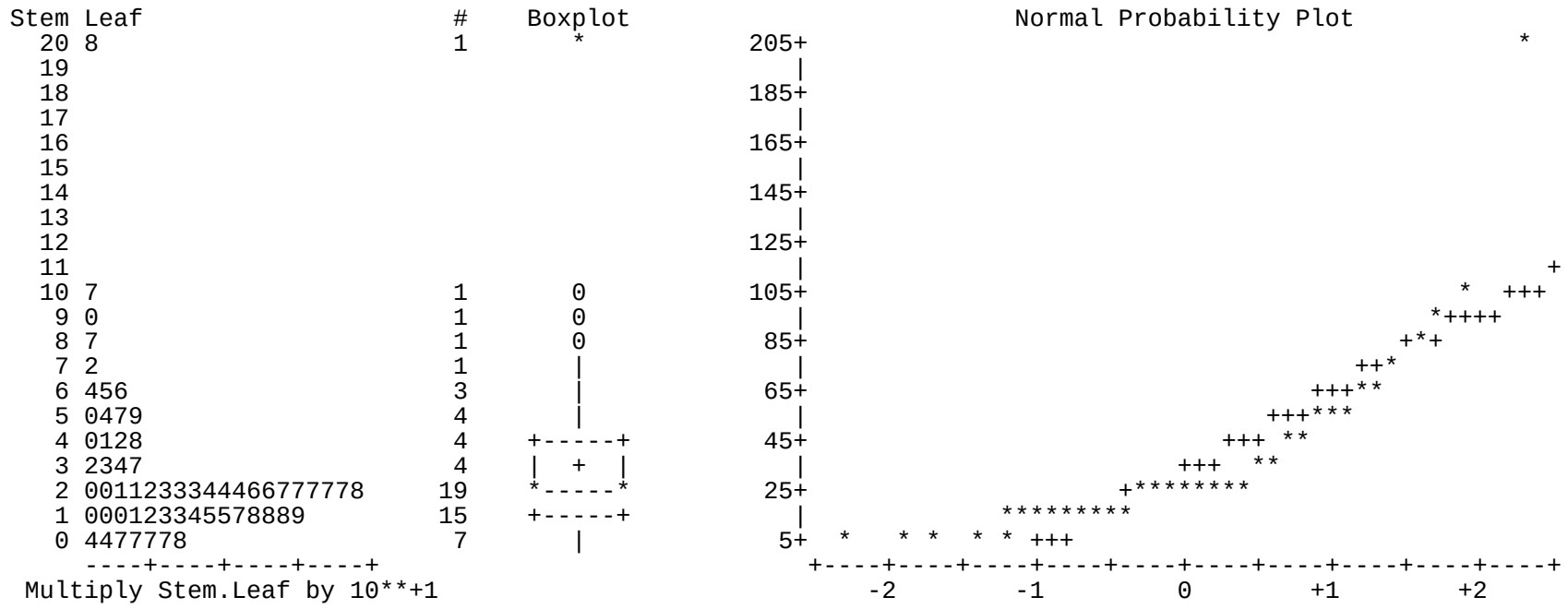
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	61	Sum Weights	61
Mean	-1.2622951	Sum Observations	-77
Std Deviation	18.26828	Variance	333.730055
Skewness	0.91530565	Kurtosis	6.76791744
Uncorrected SS	20121	Corrected SS	20023.8033
Coeff Variation	-1447.2274	Std Error Mean	2.33901357

Basic Statistical Measures

Location		Variability	
Mean	-1.26230	Std Deviation	18.26828
Median	-2.00000	Variance	333.73005
Mode	-4.00000	Range	130.00000
		Interquartile Range	11.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 6.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.53967	Pr > |t|	0.5914
Sign	M	-5.5	Pr >= |M|	0.1770
Signed Rank	S	-123	Pr >= |S|	0.3067

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.861942	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.155616	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.473723	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.521905	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	80
99%	80
95%	20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	17
75% Q3	4
50% Median	-2
25% Q1	-7
10%	-17
5%	-28
1%	-50
0% Min	-50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-50	41	18	8
-49	55	20	20
-35	39	28	51
-28	44	34	28
-26	14	80	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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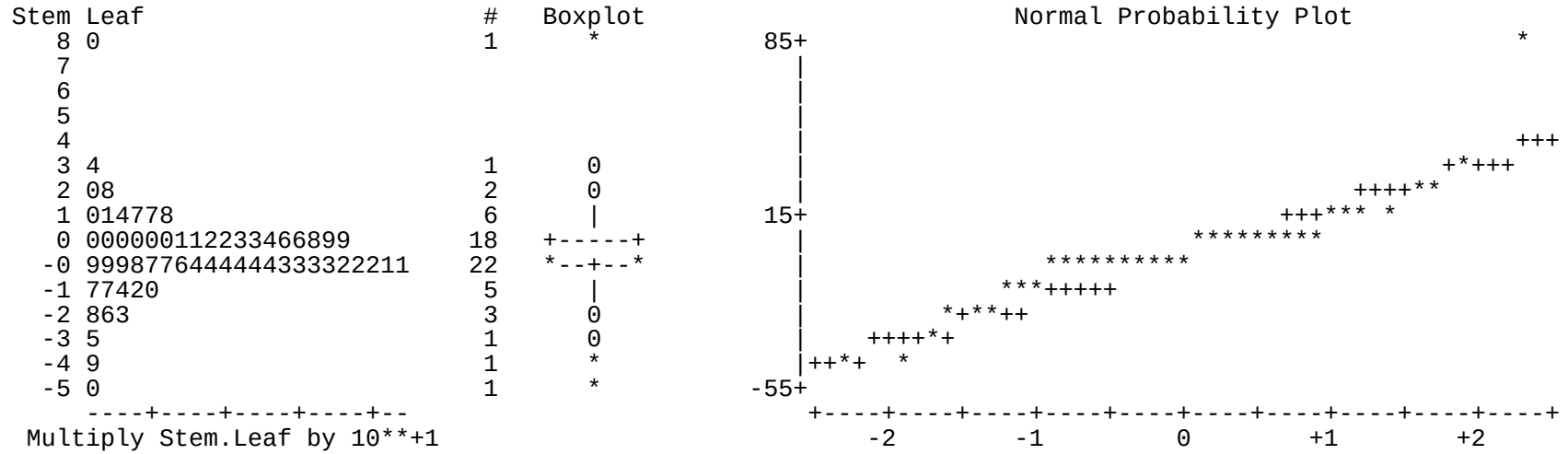
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	35.5322581	Sum Observations	2203
Std Deviation	32.7933009	Variance	1075.40058
Skewness	2.89421357	Kurtosis	9.78425841
Uncorrected SS	143877	Corrected SS	65599.4355
Coeff Variation	92.291632	Std Error Mean	4.16475337

Basic Statistical Measures

Location		Variability	
Mean	35.53226	Std Deviation	32.79330
Median	27.50000	Variance	1075
Mode	29.00000	Range	176.00000
		Interquartile Range	20.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.53166	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.672903	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.252374	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.076497	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	5.907534	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	184.0
99%	184.0
95%	86.0
90%	71.0
75% Q3	36.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	27.5
25% Q1	16.0
10%	12.0
5%	10.0
1%	8.0
0% Min	8.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
8	32	83	7
8	15	86	31
10	45	109	33
10	27	166	35
11	59	184	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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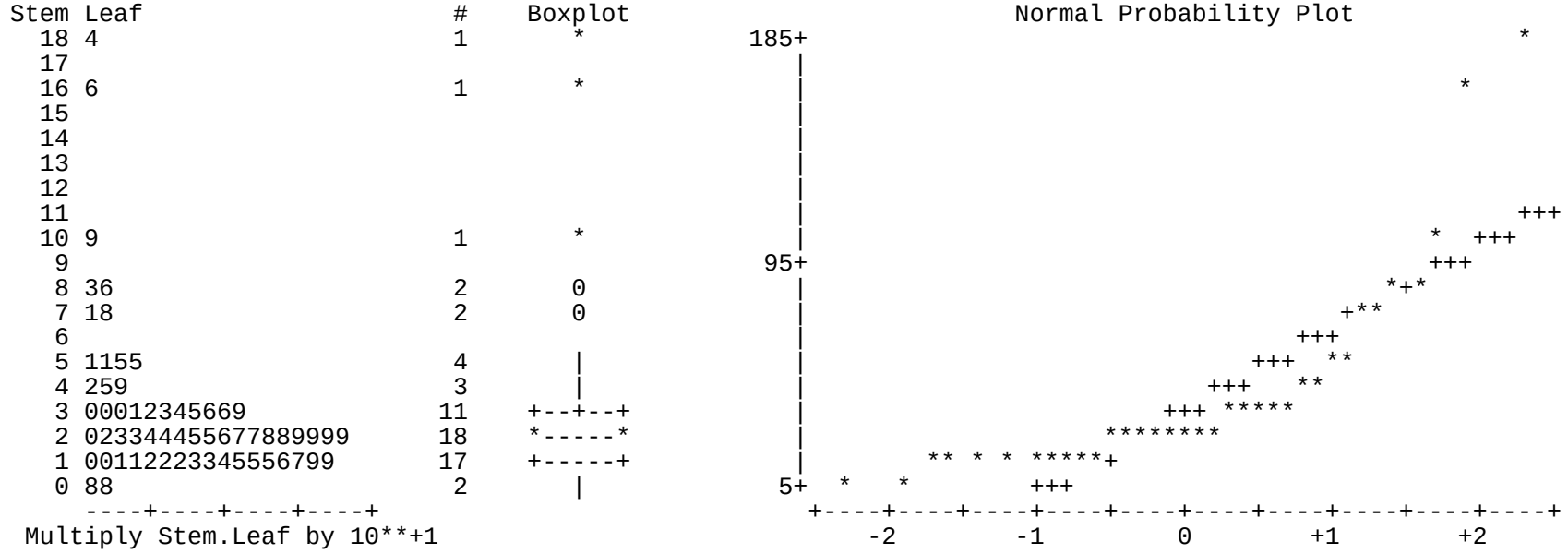
Population: Intent-to-Treat with LOCF

Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	30.6612903	Sum Observations	1901
Std Deviation	26.9035579	Variance	723.801428
Skewness	3.14363442	Kurtosis	13.531415
Uncorrected SS	102439	Corrected SS	44151.8871
Coeff Variation	87.7443761	Std Error Mean	3.41675527

Basic Statistical Measures

Location		Variability	
Mean	30.66129	Std Deviation	26.90356
Median	24.00000	Variance	723.80143
Mode	29.00000	Range	169.00000
		Interquartile Range	21.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.973803	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.696739	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.204655	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.820341	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.632295	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	175
99%	175
95%	73
90%	61
75% Q3	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	24
25% Q1	14
10%	11
5%	9
1%	6
0% Min	6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6	32	70	35
6	15	73	31
9	59	74	47
9	45	107	62
9	20	175	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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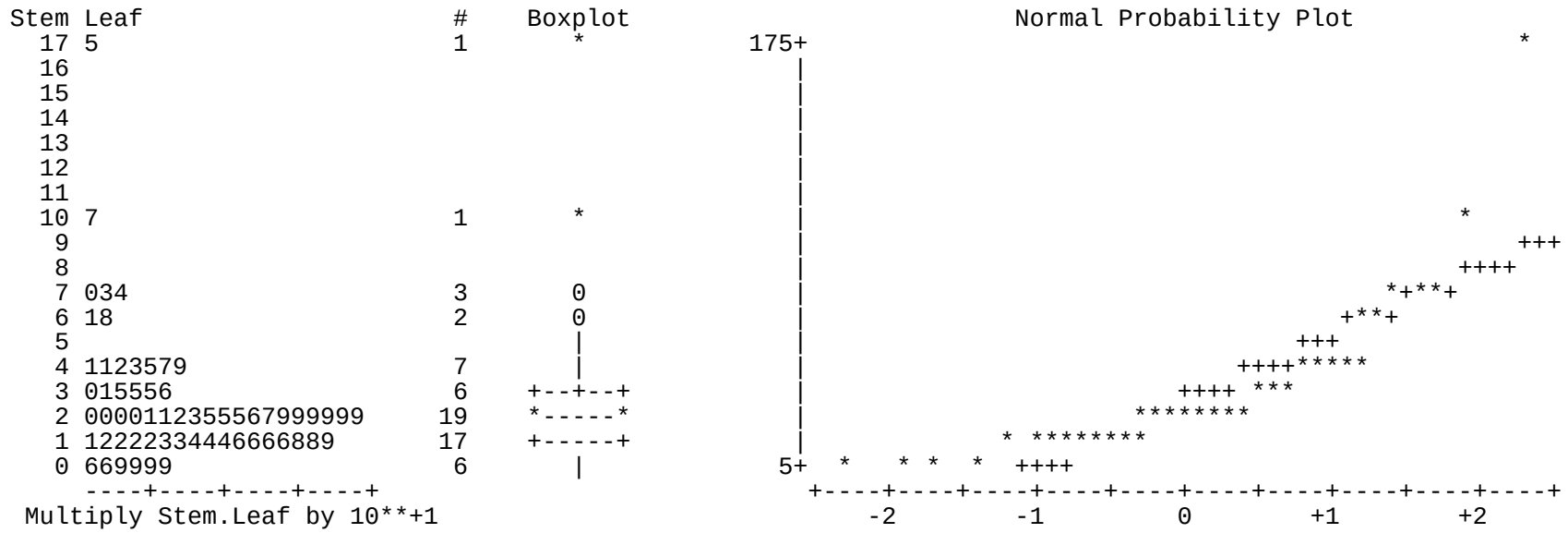
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-4.8709677	Sum Observations	-302
Std Deviation	21.0350869	Variance	442.474881
Skewness	-1.4918251	Kurtosis	8.26011893
Uncorrected SS	28462	Corrected SS	26990.9677
Coeff Variation	-431.84615	Std Error Mean	2.67145871

Basic Statistical Measures

Location		Variability	
Mean	-4.87097	Std Deviation	21.03509
Median	-2.00000	Variance	442.47488
Mode	0.00000	Range	161.00000
		Interquartile Range	12.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.82334	Pr > |t|	0.0732
Sign	M	-7.5	Pr >= |M|	0.0627
Signed Rank	S	-268	Pr >= |S|	0.0318

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.779691	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.207964	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.804789	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.417785	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	65
99%	65
95%	15

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	11
75% Q3	2
50% Median	-2
25% Q1	-10
10%	-20
5%	-34
1%	-96
0% Min	-96

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-96	35	15	4
-74	33	15	26
-52	42	20	46
-34	7	25	36
-26	24	65	62

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

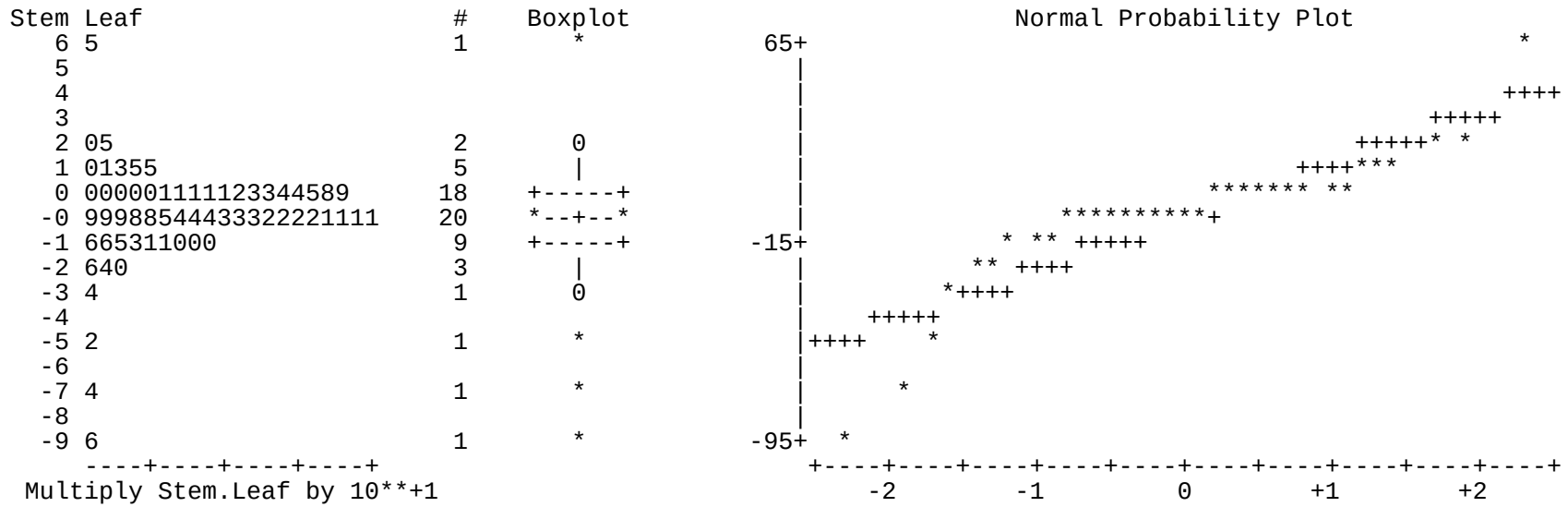

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	32.2142857	Sum Observations	1804
Std Deviation	20.2473022	Variance	409.953247
Skewness	1.04797718	Kurtosis	0.6149156
Uncorrected SS	80662	Corrected SS	22547.4286
Coeff Variation	62.8519359	Std Error Mean	2.70565957

Basic Statistical Measures

Location		Variability	
Mean	32.21429	Std Deviation	20.24730
Median	29.00000	Variance	409.95325
Mode	14.00000	Range	80.00000
		Interquartile Range	27.50000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.90626	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.902052	Pr < W	0.0003
Kolmogorov-Smirnov	D	0.105999	Pr > D	0.1168
Cramer-von Mises	W-Sq	0.206247	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.537618	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	85.0
99%	85.0
95%	78.0

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	59.0
75% Q3	42.5
50% Median	29.0
25% Q1	15.0
10%	13.0
5%	8.0
1%	5.0
0% Min	5.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5	37	76	6
7	3	78	5
8	46	78	44
8	36	83	52
10	53	85	10

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
     8 5                     1       0
     8 3                     1       |
     7 688                   3       |
     7                               |
     6                               |
     6                               |
     5 59                    2       |
     5 12                    2       |
     4 679                   3       |
     4 0144                  4    +-----+
     3 555899                6    |     |
     3 011123                6    |  +  |
     2 6678                  4    *-----*
     2 11234                 5    |     |
     1 55556689              8    +-----+
     1 0334444               7       |
     0 5788                  4       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```

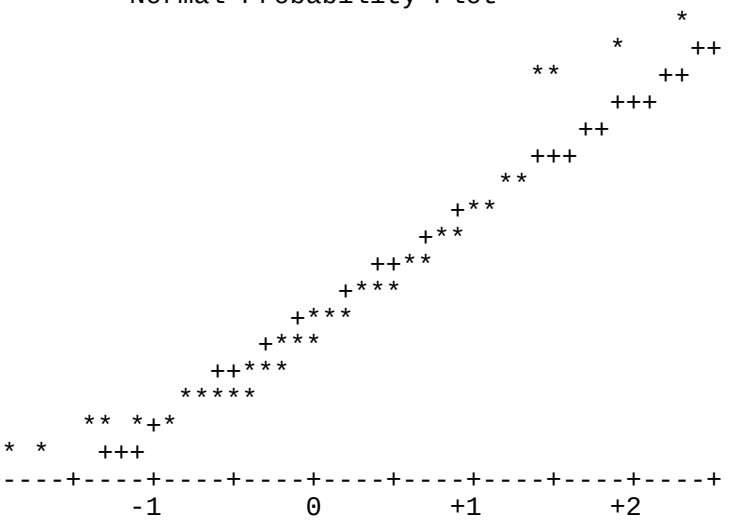

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	26.3214286	Sum Observations	1474
Std Deviation	15.636911	Variance	244.512987
Skewness	1.1228534	Kurtosis	1.35440531
Uncorrected SS	52246	Corrected SS	13448.2143
Coeff Variation	59.4075318	Std Error Mean	2.08957013

Basic Statistical Measures

Location		Variability	
Mean	26.32143	Std Deviation	15.63691
Median	23.50000	Variance	244.51299
Mode	12.00000	Range	71.00000
		Interquartile Range	22.50000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.59658	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.906921	Pr < W	0.0004
Kolmogorov-Smirnov	D	0.131266	Pr > D	0.0173
Cramer-von Mises	W-Sq	0.193277	Pr > W-Sq	0.0063
Anderson-Darling	A-Sq	1.335768	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	77.0
99%	77.0
95%	58.0

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Table 11.29
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Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	47.0
75% Q3	36.0
50% Median	23.5
25% Q1	13.5
10%	10.0
5%	8.0
1%	6.0
0% Min	6.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6	3	47	52
7	53	49	11
8	23	58	29
9	24	70	6
9	17	77	5

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[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

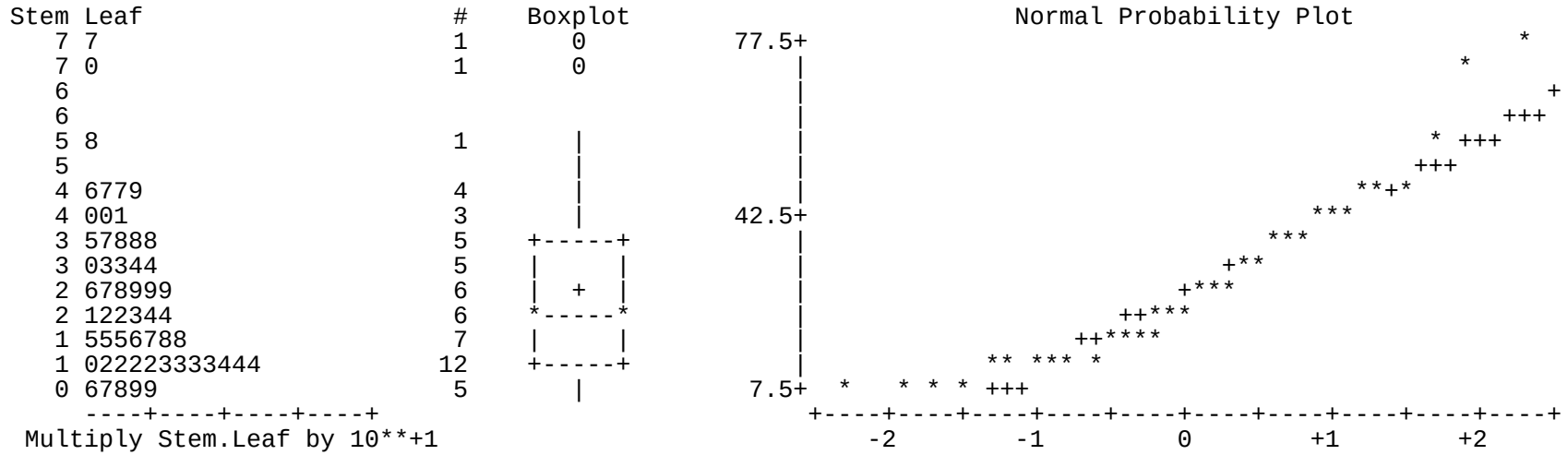

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-5.8928571	Sum Observations	-330
Std Deviation	13.7281113	Variance	188.461039
Skewness	-0.5220269	Kurtosis	2.40899273
Uncorrected SS	12310	Corrected SS	10365.3571
Coeff Variation	-232.96189	Std Error Mean	1.83449603

Basic Statistical Measures

Location		Variability	
Mean	-5.89286	Std Deviation	13.72811
Median	-4.00000	Variance	188.46104
Mode	-5.00000	Range	81.00000
		Interquartile Range	10.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.21225	Pr > |t|	0.0022
Sign	M	-13	Pr >= |M|	0.0005

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-402	Pr >= |S| 0.0003

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.910581	Pr < W 0.0005
Kolmogorov-Smirnov	D	0.175458	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.401215	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	2.081579	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	36.0
99%	36.0
95%	11.0
90%	7.0
75% Q3	0.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-4.0
25% Q1	-9.5
10%	-24.0
5%	-36.0
1%	-45.0
0% Min	-45.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-45	10	8	49
-44	44	9	31
-36	52	11	27
-27	23	20	38
-27	16	36	37

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Table 11.29
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Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

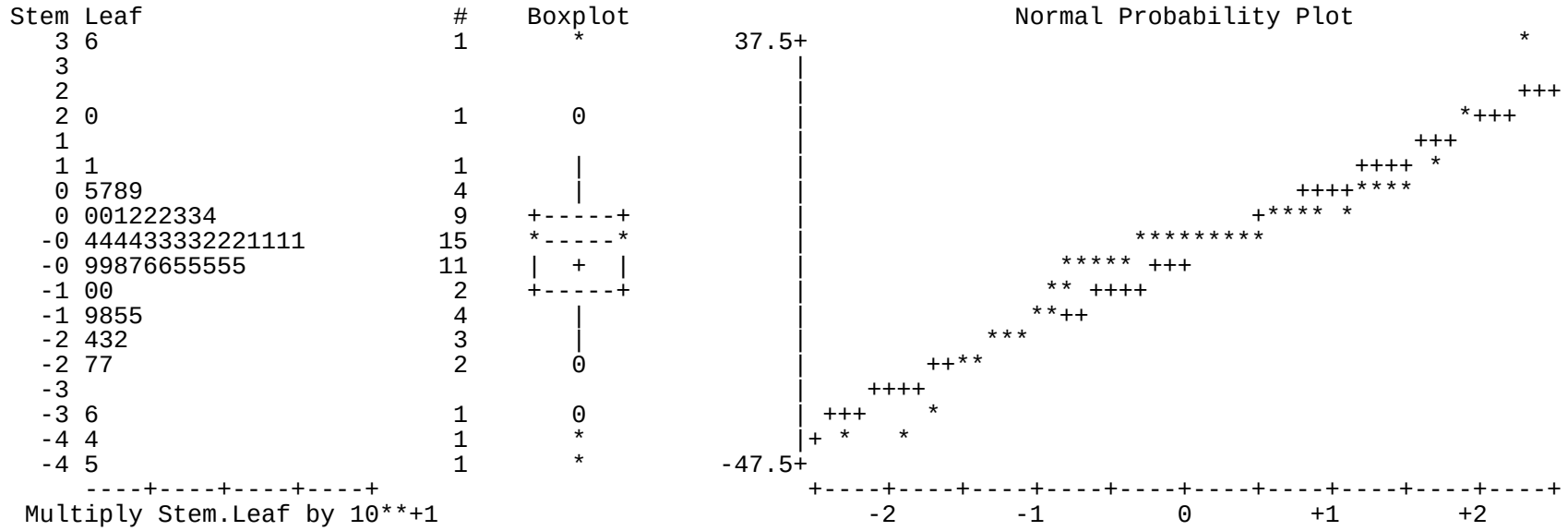

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	37.362069	Sum Observations	2167
Std Deviation	31.4054964	Variance	986.305203
Skewness	1.94210155	Kurtosis	4.07943673
Uncorrected SS	137183	Corrected SS	56219.3966
Coeff Variation	84.0571661	Std Error Mean	4.1237437

Basic Statistical Measures

Location		Variability	
Mean	37.36207	Std Deviation	31.40550
Median	27.50000	Variance	986.30520
Mode	25.00000	Range	152.00000
		Interquartile Range	30.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.060231	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.799327	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.19527	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.586178	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.480537	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	154.0
99%	154.0
95%	119.0
90%	72.0
75% Q3	47.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	27.5
25% Q1	17.0
10%	11.0
5%	6.0
1%	2.0
0% Min	2.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
2	35	74	22
5	2	115	33
6	36	119	10
6	32	132	23
9	50	154	48

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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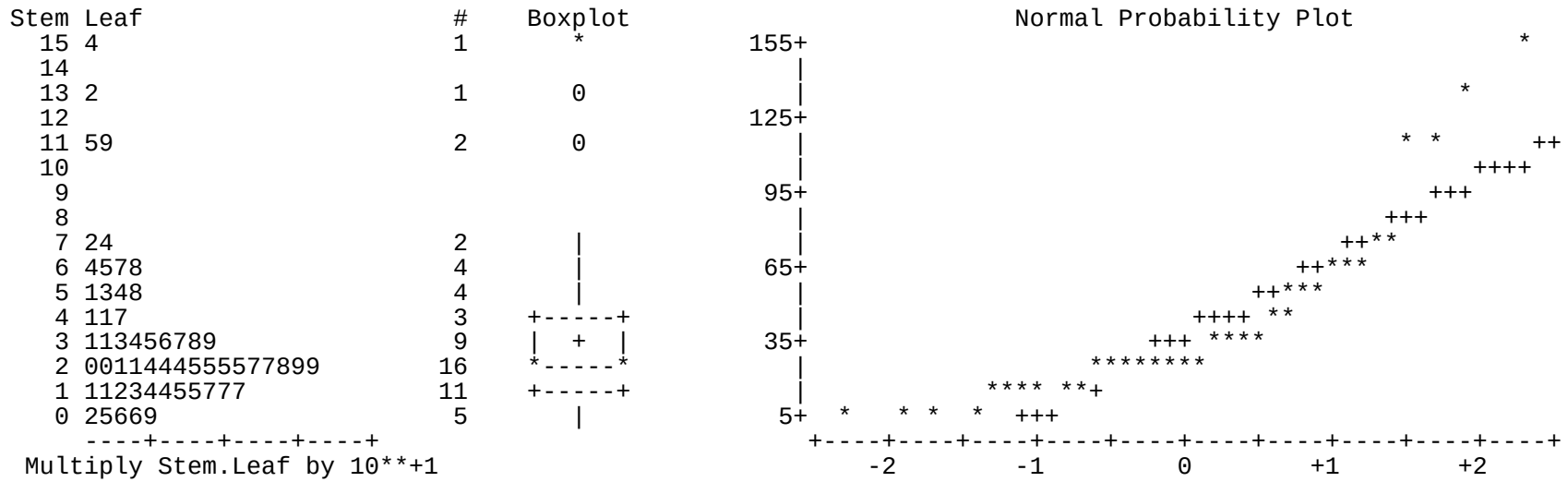
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	34.8275862	Sum Observations	2020
Std Deviation	34.3271863	Variance	1178.35572
Skewness	2.95733171	Kurtosis	12.4016618
Uncorrected SS	137518	Corrected SS	67166.2759
Coeff Variation	98.5632081	Std Error Mean	4.50738038

Basic Statistical Measures

Location		Variability	
Mean	34.82759	Std Deviation	34.32719
Median	25.00000	Variance	1178
Mode	8.00000	Range	207.00000
		Interquartile Range	31.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.726791	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.710677	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.208781	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.723654	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.061956	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	214
99%	214
95%	97
90%	76
75% Q3	43

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	25
25% Q1	12
10%	8
5%	8
1%	7
0% Min	7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
7	40	78	58
7	2	83	33
8	53	97	48
8	35	114	26
8	32	214	23

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

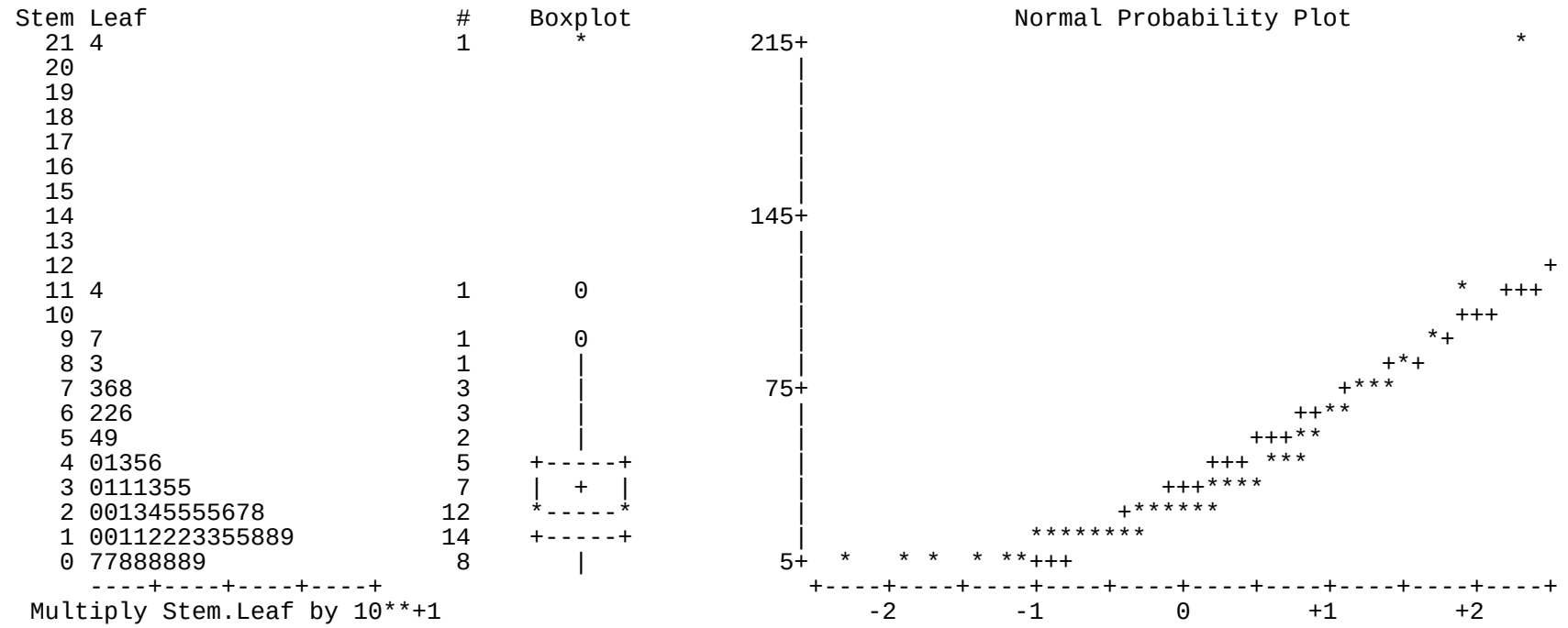

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-2.5344828	Sum Observations	-147
Std Deviation	22.3176553	Variance	498.077737
Skewness	0.04616921	Kurtosis	6.14917563
Uncorrected SS	28763	Corrected SS	28390.431
Coeff Variation	-880.56055	Std Error Mean	2.93045171

Basic Statistical Measures

Location		Variability	
Mean	-2.53448	Std Deviation	22.31766
Median	-3.50000	Variance	498.07774
Mode	-4.00000	Range	166.00000
		Interquartile Range	13.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.86488	Pr > |t|	0.3907
Sign	M	-4.5	Pr >= |M|	0.2892

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-196	Pr >= |S|	0.1198

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.845068	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.19668	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.588103	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.158612	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	82.0
99%	82.0
95%	34.0
90%	19.0
75% Q3	4.0

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-3.5
25% Q1	-9.0
10%	-21.0
5%	-43.0
1%	-84.0
0% Min	-84.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-84	10	22	47
-57	48	25	58
-43	53	34	43
-32	33	50	26
-23	52	82	23

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

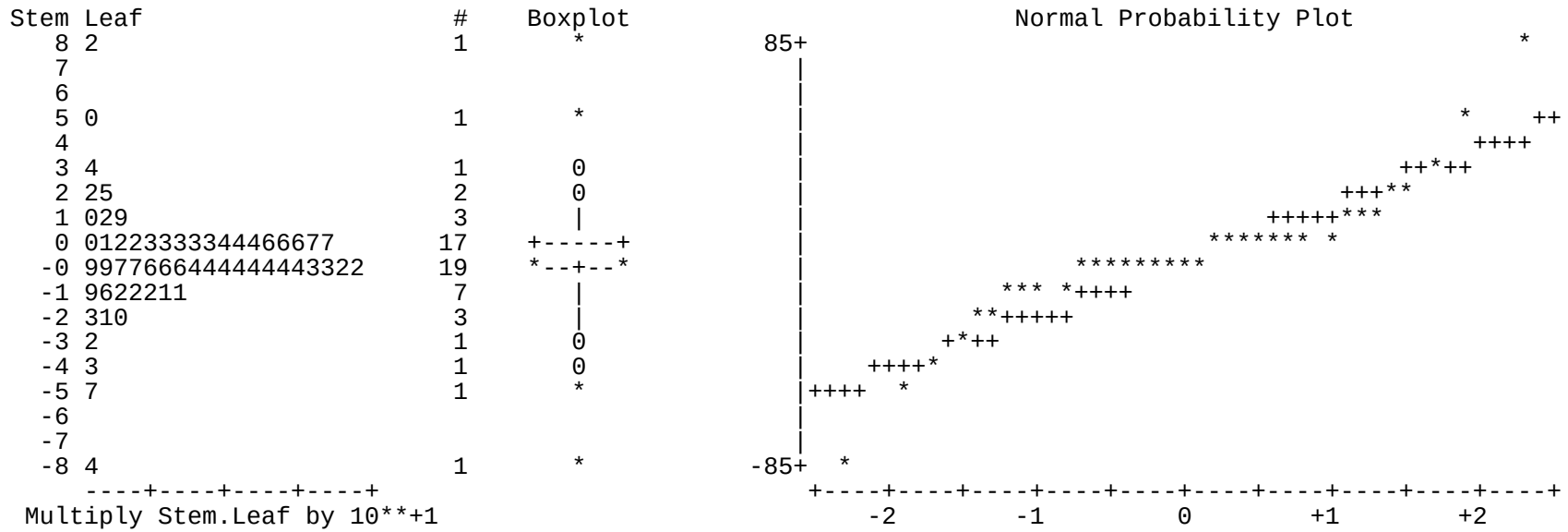

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots

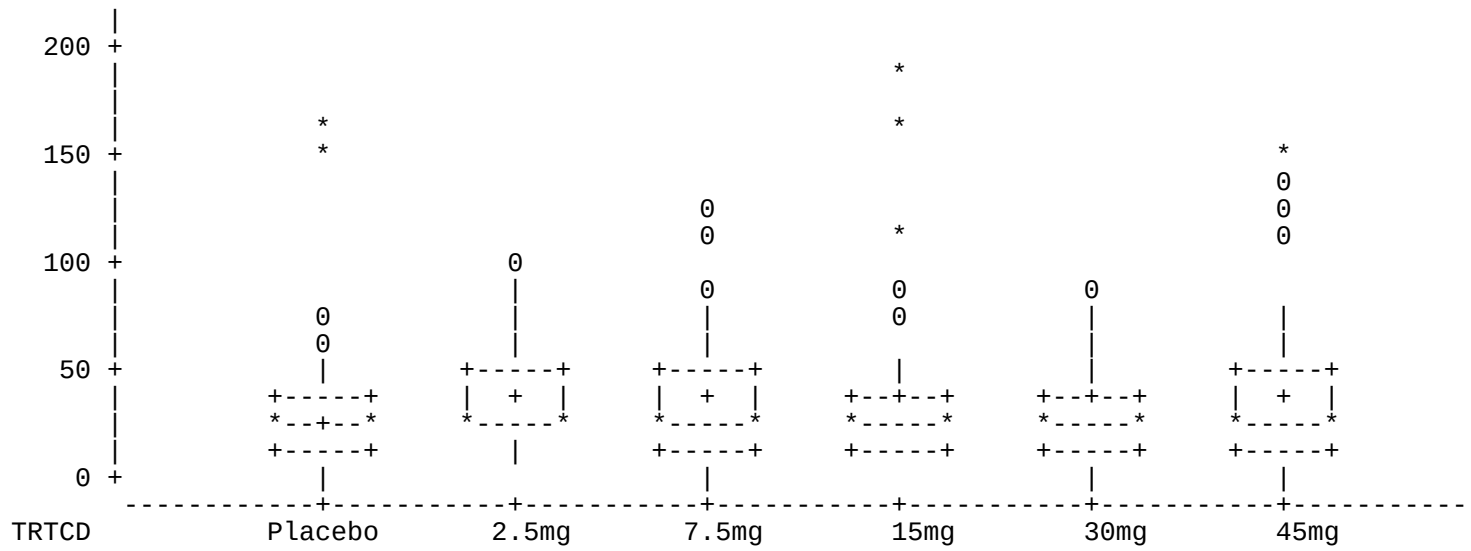

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots

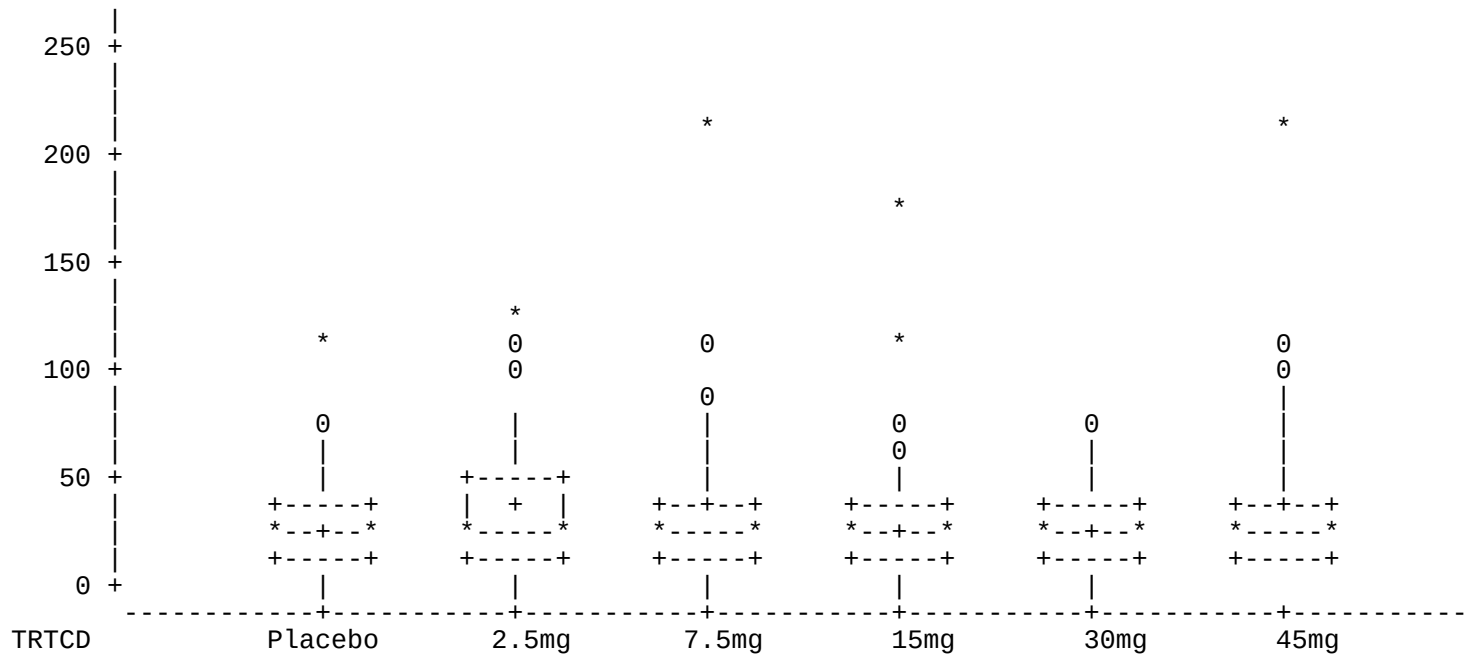

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots

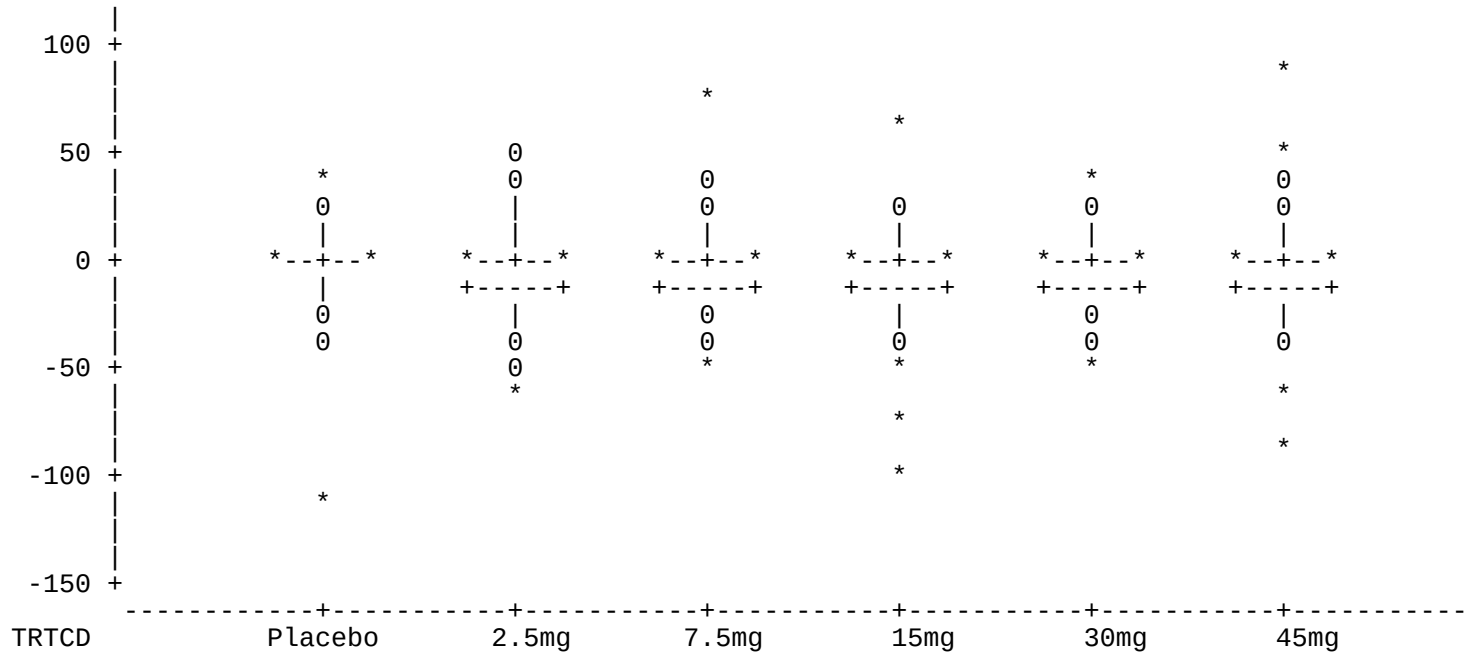

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	347
Observations Used	347
Observations Not Used	0
Total Observations	347

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	307.06	23.6901	12.96	<.0001	0.05	265.44	359.34

Fit Statistics

-2 Res Log Likelihood	2931.8
AIC (smaller is better)	2933.8
AICC (smaller is better)	2933.8
BIC (smaller is better)	2937.7

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					9.4971	3.2094	336	2.96	0.0033
SEX	Female				-3.6707	1.9019	336	-1.93	0.0544
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.1345	1.9222	336	-0.07	0.9442
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	-2.7510	3.2867	336	-0.84	0.4032
TRTCD				2.5mg	0.5585	3.3339	336	0.17	0.8671
TRTCD				7.5mg	0.3127	3.2242	336	0.10	0.9228
TRTCD				15mg	-3.1009	3.2073	336	-0.97	0.3343
TRTCD				30mg	-4.9625	3.2962	336	-1.51	0.1331
TRTCD				45mg	0			.	
REGIONCD			US/Canada		3.0480	2.2203	336	1.37	0.1707
REGIONCD			Eastern Europe		-1.8868	2.3743	336	-0.79	0.4274
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.2805	0.03439	336	-8.16	<.0001

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	336	3.72	0.0544
TRTTYPCD	1	336	0.00	0.9442
TRTCD	5	336	0.94	0.4525
REGIONCD	2	336	2.13	0.1203
EFSTDBL	1	336	66.51	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	3.3095	3.3689	336	0.98	0.3266	0.05	-3.3173	9.9363
7.5mg vs Pbo	3.0637	3.2412	336	0.95	0.3452	0.05	-3.3118	9.4392
15mg vs Pbo	-0.3499	3.2305	336	-0.11	0.9138	0.05	-6.7044	6.0046
30mg vs Pbo	-2.2115	3.3028	336	-0.67	0.5036	0.05	-8.7082	4.2852
45mg vs Pbo	2.7510	3.2867	336	0.84	0.4032	0.05	-3.7141	9.2161

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.4986	0.4986	0.4986	0.4986	0.4986
SEX	Male				0.5014	0.5014	0.5014	0.5014	0.5014
TRTTYPCD		Diet & Exercise			0.415	0.415	0.415	0.415	0.415
TRTTYPCD		Monotherapy			0.585	0.585	0.585	0.585	0.585
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3343	0.3343	0.3343	0.3343	0.3343
REGIONCD			Eastern Europe		0.2709	0.2709	0.2709	0.2709	0.2709
REGIONCD			Western Europe		0.3948	0.3948	0.3948	0.3948	0.3948
EFSTDBL					34.389	34.389	34.389	34.389	34.389

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.4986
SEX	Male				0.5014
TRTTYPCD		Diet & Exercise			0.415
TRTTYPCD		Monotherapy			0.585
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3343
REGIONCD			Eastern Europe		0.2709
REGIONCD			Western Europe		0.3948
EFSTDBL					34.389

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Table 11.29
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Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-4.2776	2.3324	336	-1.83	0.0675	0.05	-8.8655	0.3104
TRTCD	2.5mg	WORK.EFF	-0.9680	2.4176	336	-0.40	0.6891	0.05	-5.7235	3.7875
TRTCD	7.5mg	WORK.EFF	-1.2139	2.2477	336	-0.54	0.5895	0.05	-5.6352	3.2075
TRTCD	15mg	WORK.EFF	-4.6274	2.2284	336	-2.08	0.0386	0.05	-9.0108	-0.2440
TRTCD	30mg	WORK.EFF	-6.4891	2.3478	336	-2.76	0.0060	0.05	-11.1073	-1.8709
TRTCD	45mg	WORK.EFF	-1.5266	2.3065	336	-0.66	0.5085	0.05	-6.0637	3.0105

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-3.3095	3.3689	336	-0.98	0.3266	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	-3.0637	3.2412	336	-0.95	0.3452	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.3499	3.2305	336	0.11	0.9138	0.05
TRTCD	Placebo	30mg	WORK.EFF	2.2115	3.3028	336	0.67	0.5036	0.05
TRTCD	Placebo	45mg	WORK.EFF	-2.7510	3.2867	336	-0.84	0.4032	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.2458	3.3047	336	0.07	0.9407	0.05
TRTCD	2.5mg	15mg	WORK.EFF	3.6594	3.2854	336	1.11	0.2662	0.05
TRTCD	2.5mg	30mg	WORK.EFF	5.5210	3.3811	336	1.63	0.1034	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5585	3.3339	336	0.17	0.8671	0.05

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	3.4136	3.1649	336	1.08	0.2816	0.05
TRTCD	7.5mg	30mg	WORK.EFF	5.2752	3.2477	336	1.62	0.1052	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.3127	3.2242	336	0.10	0.9228	0.05
TRTCD	15mg	30mg	WORK.EFF	1.8616	3.2393	336	0.57	0.5659	0.05
TRTCD	15mg	45mg	WORK.EFF	-3.1009	3.2073	336	-0.97	0.3343	0.05
TRTCD	30mg	45mg	WORK.EFF	-4.9625	3.2962	336	-1.51	0.1331	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-9.9363	3.3173
TRTCD	Placebo	7.5mg	-9.4392	3.3118
TRTCD	Placebo	15mg	-6.0046	6.7044
TRTCD	Placebo	30mg	-4.2852	8.7082
TRTCD	Placebo	45mg	-9.2161	3.7141
TRTCD	2.5mg	7.5mg	-6.2546	6.7463
TRTCD	2.5mg	15mg	-2.8032	10.1220
TRTCD	2.5mg	30mg	-1.1298	12.1718
TRTCD	2.5mg	45mg	-5.9994	7.1165
TRTCD	7.5mg	15mg	-2.8119	9.6391

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-1.1131	11.6635
TRTCD	7.5mg	45mg	-6.0294	6.6548
TRTCD	15mg	30mg	-4.5102	8.2335
TRTCD	15mg	45mg	-9.4098	3.2081
TRTCD	30mg	45mg	-11.4462	1.5212

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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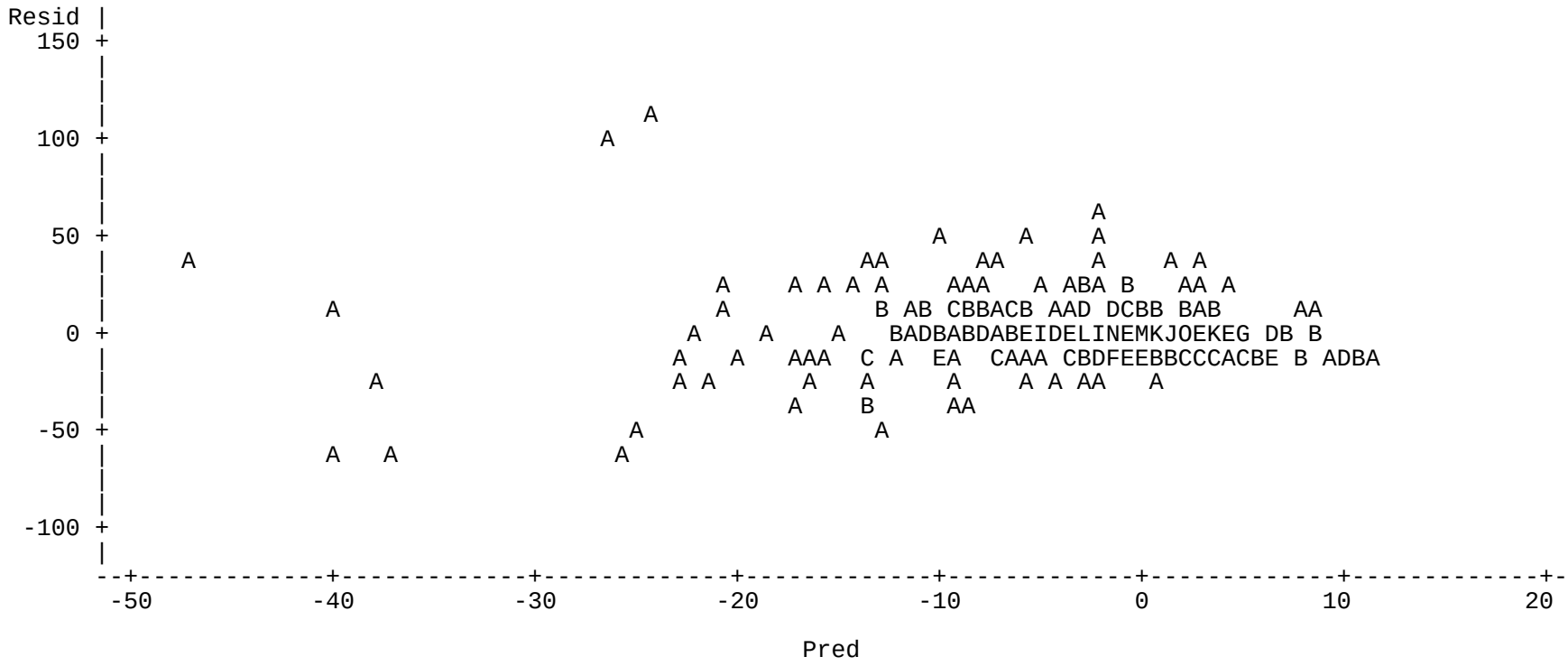
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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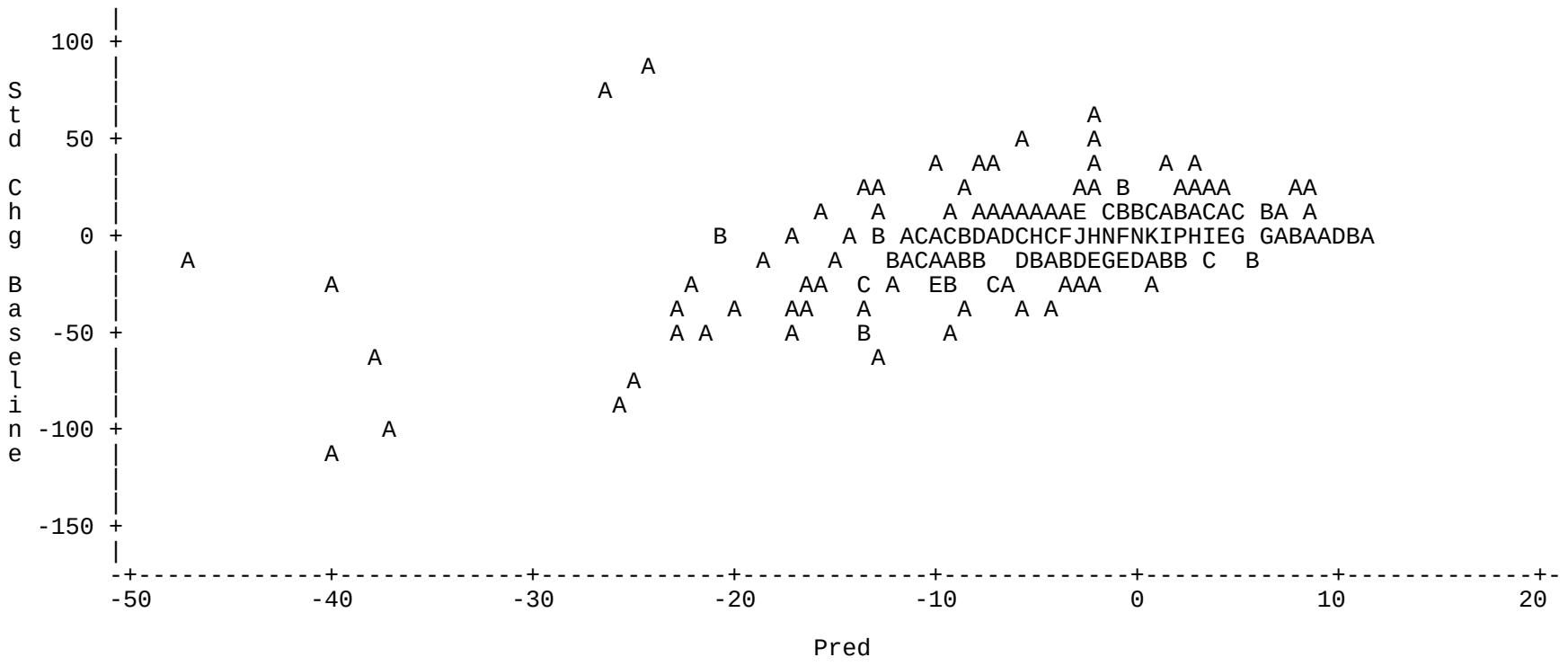
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	347	Sum Weights	347
Mean	0	Sum Observations	0
Std Deviation	17.26801	Variance	298.184168
Skewness	1.34860603	Kurtosis	9.95898765
Uncorrected SS	103171.722	Corrected SS	103171.722
Coeff Variation		Std Error Mean	0.92699534

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	17.26801
Median	-1.31299	Variance	298.18417
Mode		Range	173.66451
		Interquartile Range	12.18374

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-22.5	Pr >= |M|	0.0180
Signed Rank	S	-3097	Pr >= |S|	0.0978

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.845482	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.147385	Pr > D	<0.0100
Cramer-von Mises	W-Sq	2.33191	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	12.95475	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	106.47885
99%	55.40591
95%	25.70110
90%	16.90502
75% Q3	4.92158
50% Median	-1.31299
25% Q1	-7.26216
10%	-13.75431
5%	-20.24004
1%	-50.45795
0% Min	-67.18566

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		------Highest-----	
Value	Obs	Value	Obs
-67.1857	34	53.1766	137
-58.7493	212	55.4059	151
-58.2327	60	67.4706	347
-50.4579	298	106.0922	38
-49.0662	203	106.4789	135

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

```
                    Histogram                       #             Boxplot
105+*                                               2                *
   .
   .
   .
   .*                                               1                *
   .*                                               2                *
   .**                                              4                0
   .**                                              5                0
   .*****                                          13                0
   .**********                                     31                |
   .******************************                 93               +--+--+
   .*******************************************   133               *-----*
   .***************                                44                |
   .***                                             9                0
   .**                                              4                0
   .*                                               2                0
   .*                                               3                *
-65+*                                               1                *
    ----+----+----+----+----+----+----+----+----+----+
    * may represent up to 3 counts
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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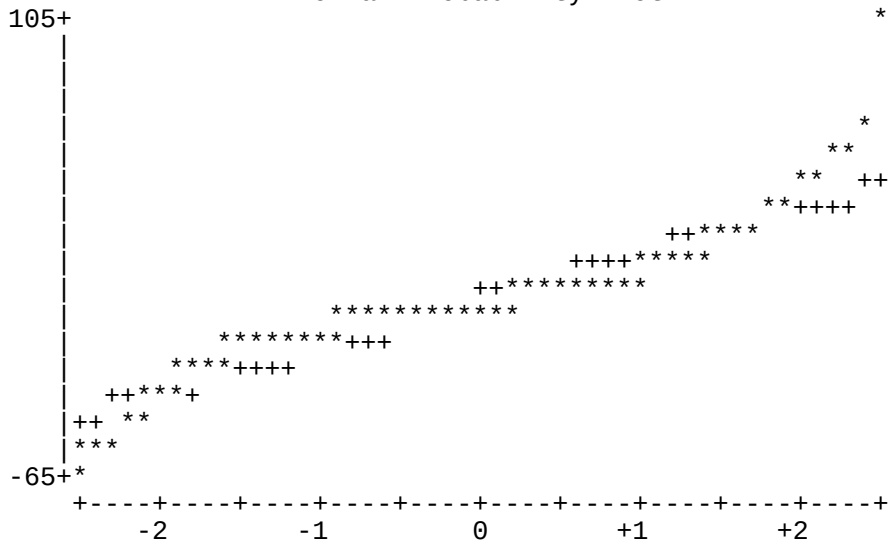
Table 11.29
SAS Statistical Output for Table 11.28
Analysis of Change in Pro-Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.30
Summary Statistics for Pro-Insulin:Insulin Ratio by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	53	59	63	52	56
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	0.38	0.42	0.35	0.37	0.41	0.37
	SD	0.297	0.286	0.205	0.253	0.224	0.192
	SE	0.038	0.039	0.027	0.032	0.031	0.026
	Minimum	0.1	0.0	0.1	0.1	0.1	0.1
	Median	0.31	0.37	0.29	0.30	0.34	0.35
	Maximum	1.8	1.8	0.9	1.2	1.0	1.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.30
Summary Statistics for Pro-Insulin:Insulin Ratio by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	51	55	61	48	52
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Mean	0.35	0.40	0.36	0.38	0.40	0.36
	SD	0.248	0.214	0.207	0.254	0.214	0.177
	SE	0.034	0.030	0.028	0.033	0.031	0.024
	Minimum	0.1	0.0	0.1	0.1	0.1	0.1
	Median	0.30	0.37	0.31	0.30	0.33	0.35
	Maximum	1.8	1.3	0.9	1.2	1.0	0.8
Week 4	Mean	0.33	0.37	0.32	0.31	0.28	0.31
	SD	0.170	0.178	0.186	0.191	0.148	0.190
	SE	0.023	0.025	0.025	0.024	0.021	0.026
	Minimum	0.1	0.1	0.0	0.1	0.1	0.0
	Median	0.31	0.36	0.27	0.27	0.25	0.28
	Maximum	1.1	1.0	0.9	0.9	0.7	1.0
Change from Baseline	Mean	-0.02	-0.03	-0.03	-0.07	-0.13	-0.05
	SD	0.197	0.176	0.137	0.169	0.146	0.137
	SE	0.027	0.025	0.018	0.022	0.021	0.019
	Minimum	-1.2	-0.9	-0.4	-0.7	-0.6	-0.4
	Median	0.00	0.00	-0.04	-0.03	-0.11	-0.04
	Maximum	0.4	0.3	0.3	0.5	0.1	0.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.30
Summary Statistics for Pro-Insulin:Insulin Ratio by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	61	52	54
Number (%) of Values Carried Forward		6 (11%)	11 (21%)	8 (14%)	3 (5%)	3 (6%)	10 (19%)
Baseline	Mean	0.35	0.43	0.35	0.38	0.41	0.36
	SD	0.242	0.288	0.206	0.254	0.224	0.173
	SE	0.032	0.040	0.027	0.033	0.031	0.024
	Minimum	0.1	0.0	0.1	0.1	0.1	0.1
	Median	0.30	0.38	0.29	0.30	0.34	0.35
	Maximum	1.8	1.8	0.9	1.2	1.0	0.8
Week 8	Mean	0.37	0.42	0.30	0.30	0.30	0.29
	SD	0.273	0.389	0.169	0.192	0.190	0.171
	SE	0.037	0.054	0.022	0.025	0.026	0.023
	Minimum	0.1	0.1	0.1	0.1	0.0	0.0
	Median	0.32	0.36	0.26	0.26	0.25	0.24
	Maximum	2.0	2.8	0.9	1.0	1.1	0.9
Change from Baseline	Mean	0.02	-0.01	-0.05	-0.07	-0.11	-0.07
	SD	0.133	0.229	0.120	0.177	0.174	0.150
	SE	0.018	0.032	0.016	0.023	0.024	0.020
	Minimum	-0.4	-0.8	-0.4	-0.7	-0.5	-0.4
	Median	0.01	-0.04	-0.05	-0.04	-0.05	-0.05
	Maximum	0.5	1.0	0.3	0.3	0.4	0.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.30
Summary Statistics for Pro-Insulin:Insulin Ratio by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	62	52	54
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	11 (19%)	4 (6%)	4 (8%)	6 (11%)
Baseline	Mean	0.35	0.43	0.35	0.38	0.41	0.36
	SD	0.242	0.288	0.206	0.253	0.224	0.173
	SE	0.032	0.040	0.027	0.032	0.031	0.024
	Minimum	0.1	0.0	0.1	0.1	0.1	0.1
	Median	0.30	0.38	0.29	0.30	0.34	0.35
	Maximum	1.8	1.8	0.9	1.2	1.0	0.8
Week 12	Mean	0.34	0.42	0.32	0.32	0.31	0.31
	SD	0.191	0.258	0.201	0.234	0.145	0.144
	SE	0.025	0.036	0.026	0.030	0.020	0.020
	Minimum	0.1	0.1	0.1	0.1	0.1	0.0
	Median	0.31	0.36	0.25	0.26	0.30	0.29
	Maximum	1.2	1.7	1.1	1.6	0.8	0.6
Change from Baseline	Mean	-0.01	-0.01	-0.03	-0.06	-0.10	-0.06
	SD	0.139	0.165	0.145	0.219	0.147	0.107
	SE	0.019	0.023	0.019	0.028	0.020	0.015
	Minimum	-0.6	-0.8	-0.4	-0.9	-0.4	-0.4
	Median	0.00	0.00	-0.05	-0.04	-0.08	-0.05
	Maximum	0.3	0.3	0.6	0.6	0.2	0.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)

[redacted]

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Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	52	58	62	52	54
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	11 (19%)	4 (6%)	4 (8%)	6 (11%)
Baseline	Mean	0.35	0.43	0.35	0.38	0.41	0.36
	SD	0.242	0.288	0.206	0.253	0.224	0.173
Week 12	Mean	0.34	0.42	0.32	0.32	0.31	0.31
	SD	0.191	0.258	0.201	0.234	0.145	0.144
Chg from Baseline	Mean	-0.01	-0.01	-0.03	-0.06	-0.10	-0.06
	SD	0.139	0.165	0.145	0.219	0.147	0.107
Model-Adj Chg [2]	Mean	-0.02	0.01	-0.04	-0.06	-0.08	-0.06
	SE	0.018	0.019	0.018	0.017	0.018	0.018
Diff from Pbo [2]	Mean		0.03	-0.02	-0.04	-0.06	-0.04
	95% CI		-0.02,0.08	-0.07,0.03	-0.09,0.01	-0.11,-0.01	-0.09,0.01
	p-val [3]		0.286	0.457	0.136	0.021	0.094

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be appplied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	0.34783137	Sum Observations	19.4785565
Std Deviation	0.24170894	Variance	0.05842321
Skewness	3.88598735	Kurtosis	21.5783506
Uncorrected SS	9.98852958	Corrected SS	3.21327666
Coeff Variation	69.4902657	Std Error Mean	0.03229972

Basic Statistical Measures

Location		Variability	
Mean	0.347831	Std Deviation	0.24171
Median	0.302267	Variance	0.05842
Mode	0.166667	Range	1.69180
		Interquartile Range	0.19939

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.76887	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.666338	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.176514	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.565958	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.530488	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.7697228
99%	1.7697228
95%	0.7043880
90%	0.5117271
75% Q3	0.4213048

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3022670
25% Q1	0.2219144
10%	0.1666667
5%	0.1041667
1%	0.0779221
0% Min	0.0779221

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0779221	13	0.515781	54
0.0865801	44	0.550562	3
0.1041667	24	0.704388	40
0.1041667	21	0.763889	55
0.1386001	51	1.769723	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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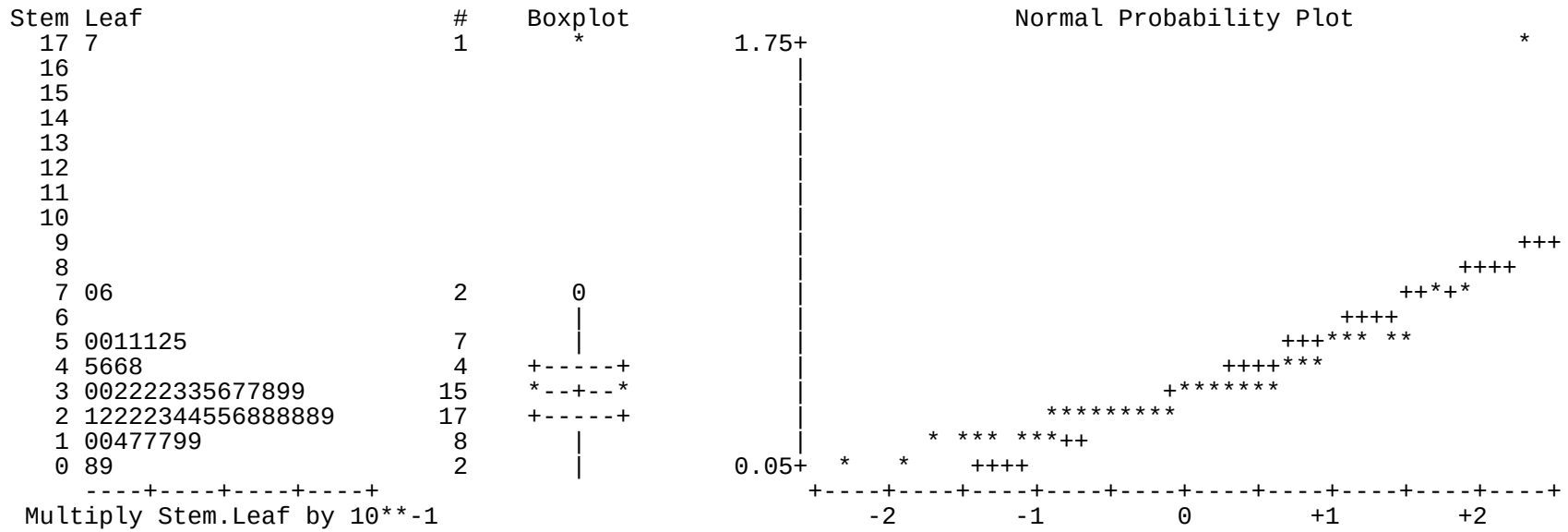
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	0.33526934	Sum Observations	18.7750829
Std Deviation	0.19071375	Variance	0.03637174
Skewness	1.83928521	Kurtosis	5.44221708
Uncorrected SS	8.29515503	Corrected SS	2.00044545
Coeff Variation	56.8837444	Std Error Mean	0.0254852

Basic Statistical Measures

Location		Variability	
Mean	0.335269	Std Deviation	0.19071
Median	0.308608	Variance	0.03637
Mode	0.327456	Range	1.07594
		Interquartile Range	0.20298

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.15545	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.856656	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.139106	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.289339	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.754904	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1683168
99%	1.1683168
95%	0.6585789
90%	0.6045340
75% Q3	0.3986858

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3086081
25% Q1	0.1957071
10%	0.1662050
5%	0.1212121
1%	0.0923788
0% Min	0.0923788

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0923788	36	0.628998	54
0.1000770	44	0.633663	8
0.1212121	13	0.658579	49
0.1276441	51	0.710843	3
0.1282051	21	1.168317	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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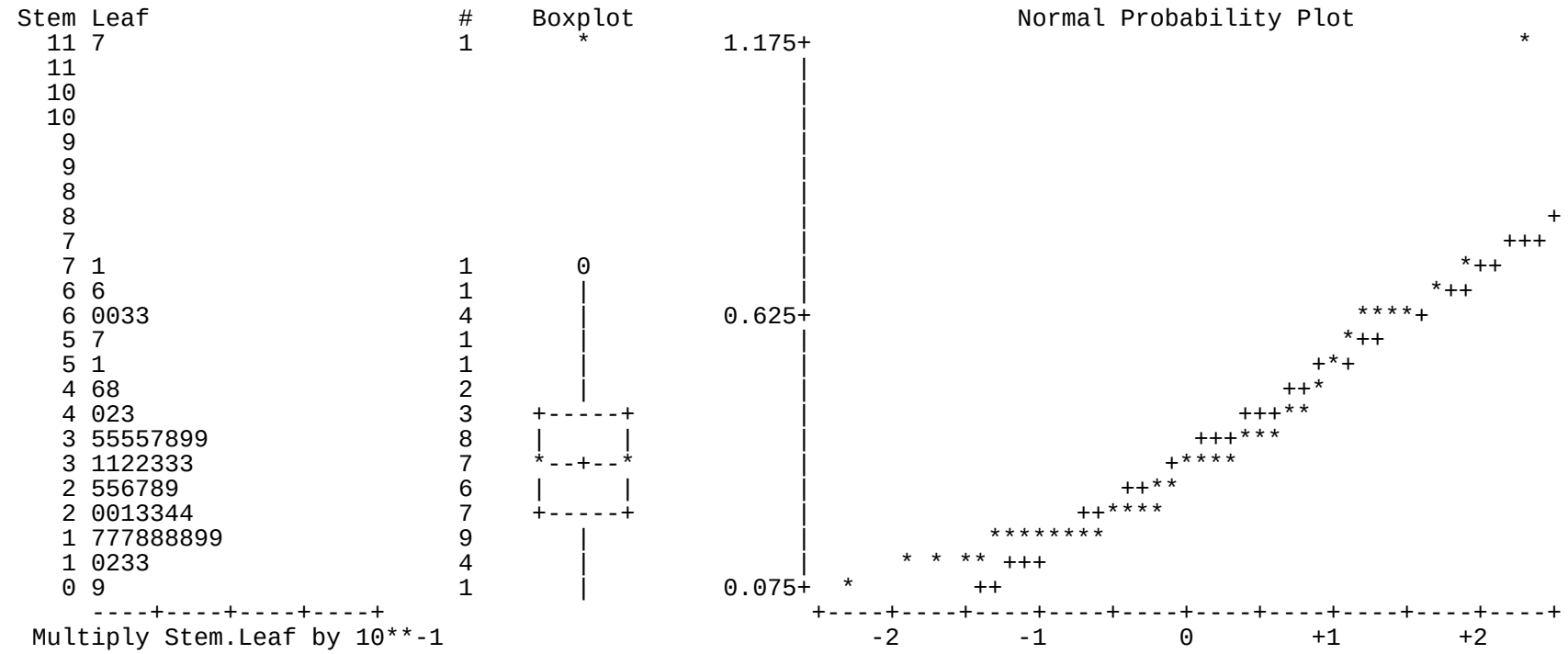
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.012562	Sum Observations	-0.7034737
Std Deviation	0.13863541	Variance	0.01921978
Skewness	-1.4254175	Kurtosis	5.39988862
Uncorrected SS	1.06592478	Corrected SS	1.05708773
Coeff Variation	-1103.6068	Std Error Mean	0.01852594

Basic Statistical Measures

Location		Variability	
Mean	-0.01256	Std Deviation	0.13864
Median	0.00216	Variance	0.01922
Mode	0.00000	Range	0.87673
		Interquartile Range	0.16414

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.67808	Pr > |t|	0.5006
Sign	M	1	Pr >= |M|	0.8919

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[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-38.5	Pr >= |S|	0.7436

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.90032	Pr < W	0.0002
Kolmogorov-Smirnov	D	0.121604	Pr > D	0.0385
Cramer-von Mises	W-Sq	0.137137	Pr > W-Sq	0.0360
Anderson-Darling	A-Sq	1.035744	Pr > A-Sq	0.0094

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2753261
99%	0.2753261
95%	0.1873706
90%	0.1410256
75% Q3	0.0725967

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0021645
25% Q1	-0.0915432
10%	-0.1326122
5%	-0.2309469
1%	-0.6014060
0% Min	-0.6014060

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.601406	4	0.146852	49
-0.371279	55	0.160282	3
-0.230947	36	0.187371	20
-0.151515	29	0.229167	22
-0.134438	2	0.275326	8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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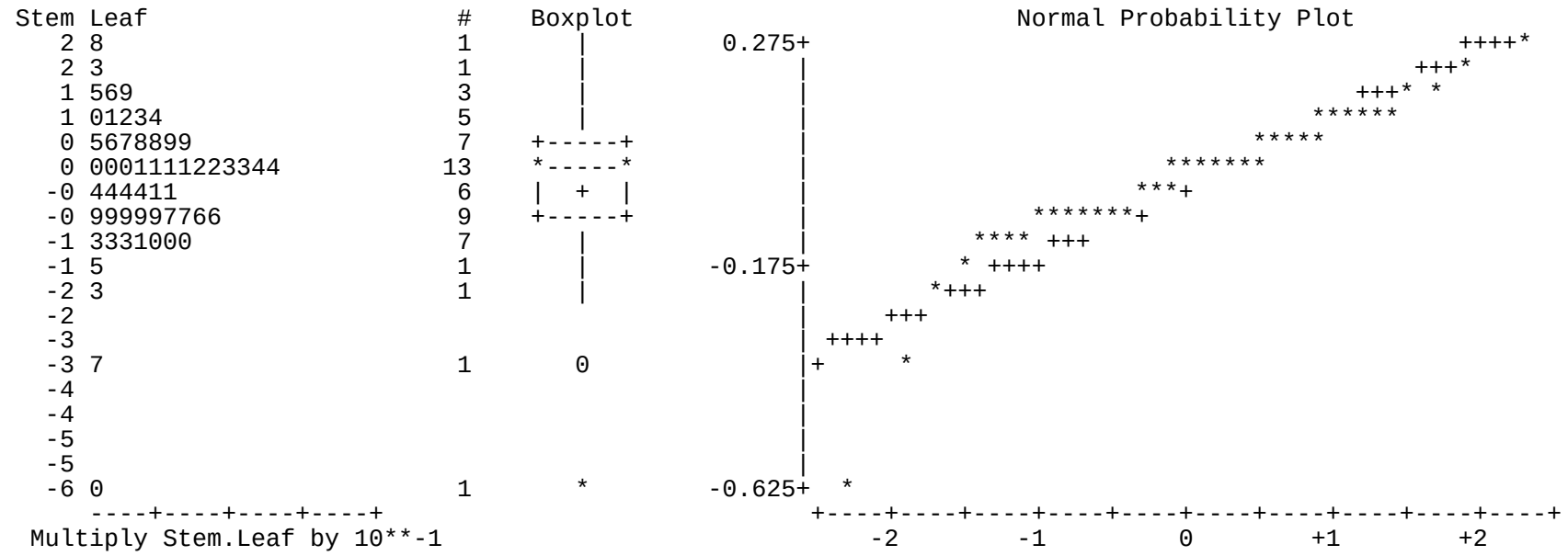
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	52	Sum Weights	52
Mean	0.42682022	Sum Observations	22.1946517
Std Deviation	0.28785314	Variance	0.08285943
Skewness	2.82536774	Kurtosis	10.617459
Uncorrected SS	13.6989572	Corrected SS	4.22583099
Coeff Variation	67.4413079	Std Error Mean	0.03991805

Basic Statistical Measures

Location		Variability	
Mean	0.426820	Std Deviation	0.28785
Median	0.376738	Variance	0.08286
Mode	0.508083	Range	1.77194
		Interquartile Range	0.22383

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.69241	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.732079	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.215777	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.631715	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.666346	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.8013857
99%	1.8013857
95%	1.0444444
90%	0.6615385
75% Q3	0.4940651

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3767381
25% Q1	0.2702374
10%	0.1980198
5%	0.1616628
1%	0.0294423
0% Min	0.0294423

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0294423	4	0.732673	3
0.1555556	23	0.762125	15
0.1616628	43	1.044444	30
0.1833333	25	1.266667	36
0.1939058	12	1.801386	45

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
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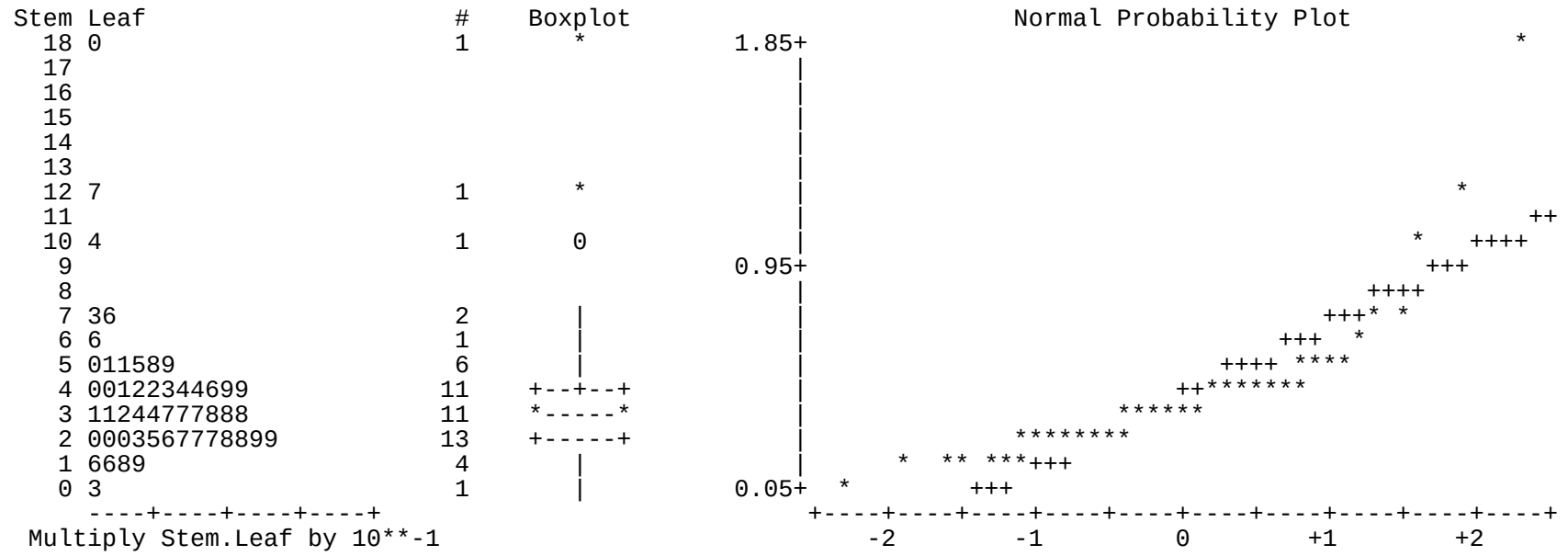
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	52	Sum Weights	52
Mean	0.41737825	Sum Observations	21.7036691
Std Deviation	0.25839855	Variance	0.06676981
Skewness	2.91378323	Kurtosis	12.8188157
Uncorrected SS	12.4639	Corrected SS	3.40526045
Coeff Variation	61.9099228	Std Error Mean	0.03583343

Basic Statistical Measures

Location		Variability	
Mean	0.417378	Std Deviation	0.25840
Median	0.360111	Variance	0.06677
Mode	0.360111	Range	1.63212
		Interquartile Range	0.25137

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.64773	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.756455	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.152522	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.381938	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.477698	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.736111
99%	1.736111
95%	0.821429
90%	0.618652
75% Q3	0.508823

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.360111
25% Q1	0.257448
10%	0.205556
5%	0.156971
1%	0.103986
0% Min	0.103986

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.103986	10	0.633663	44
0.110803	48	0.727273	32
0.156971	9	0.821429	30
0.166667	23	1.013825	15
0.196305	37	1.736111	45

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
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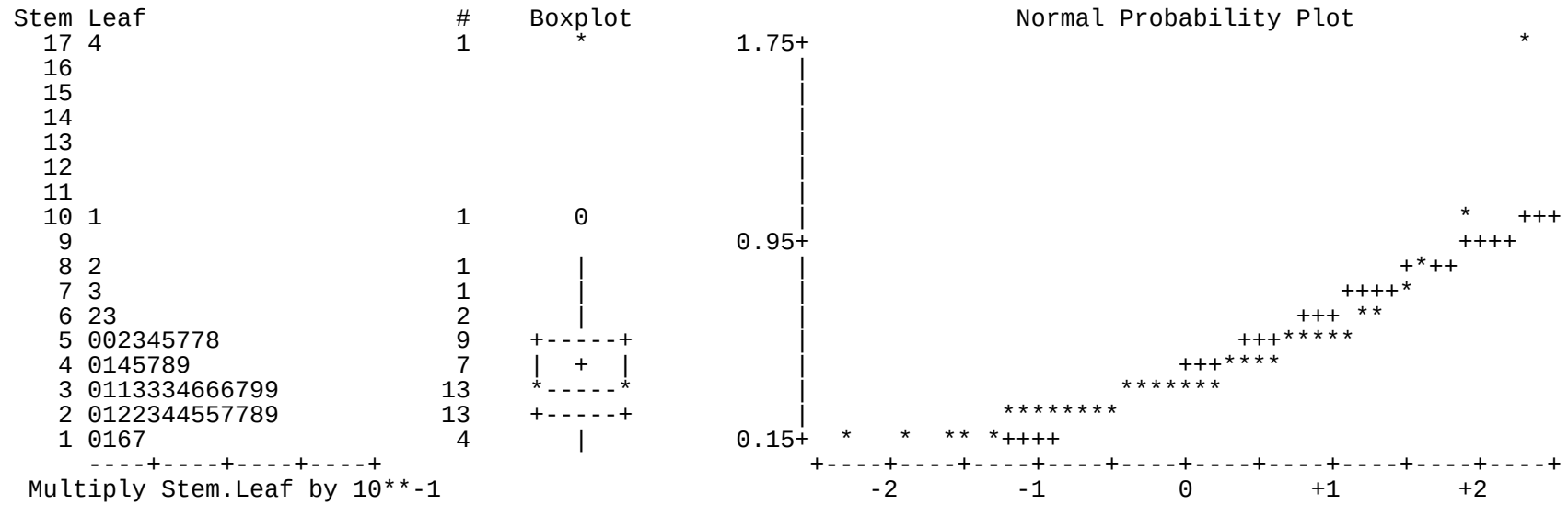
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	52	Sum Weights	52
Mean	-0.009442	Sum Observations	-0.4909825
Std Deviation	0.16471657	Variance	0.02713155
Skewness	-1.8900155	Kurtosis	8.7045696
Uncorrected SS	1.38834485	Corrected SS	1.38370901
Coeff Variation	-1744.5145	Std Error Mean	0.02284208

Basic Statistical Measures

Location		Variability	
Mean	-0.00944	Std Deviation	0.16472
Median	0.00091	Variance	0.02713
Mode		Range	1.10556
		Interquartile Range	0.14068

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.41336	Pr > |t|	0.6811
Sign	M	0	Pr >= |M|	1.0000

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[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	8	Pr >= |S|	0.9428

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.851927	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.130708	Pr > D	0.0247
Cramer-von Mises	W-Sq	0.270349	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.616756	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.326993316
99%	0.326993316
95%	0.251700173
90%	0.158119658
75% Q3	0.072280929

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Table 11.32
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.000908389
25% Q1	-0.068398372
10%	-0.158175001
5%	-0.237623762
1%	-0.778571429
0% Min	-0.778571429

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.778571	36	0.158333	33
-0.331149	48	0.189964	28
-0.237624	3	0.251700	15
-0.223016	30	0.290765	32
-0.166051	47	0.326993	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

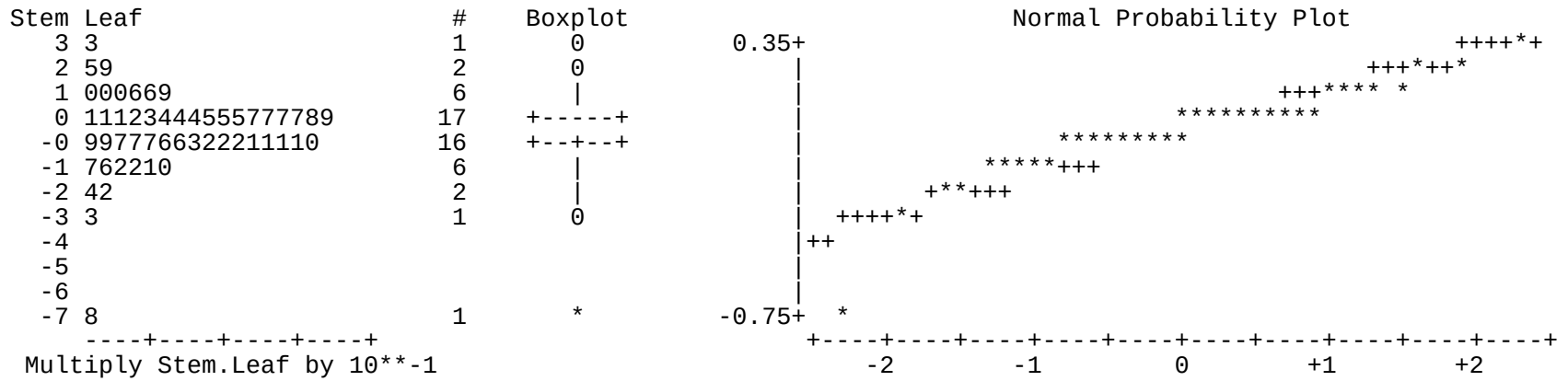

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	0.34987157	Sum Observations	20.2925512
Std Deviation	0.20587819	Variance	0.04238583
Skewness	1.24519166	Kurtosis	0.79917945
Uncorrected SS	9.51577892	Corrected SS	2.41599214
Coeff Variation	58.8439306	Std Error Mean	0.02703313

Basic Statistical Measures

Location		Variability	
Mean	0.349872	Std Deviation	0.20588
Median	0.292853	Variance	0.04239
Mode	0.500000	Range	0.84538
		Interquartile Range	0.22477

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.94233	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.863465	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.169944	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.436856	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.728393	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9209454
99%	0.9209454
95%	0.8312343
90%	0.7612457
75% Q3	0.4166667

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.2928531
25% Q1	0.1918977
10%	0.1625366
5%	0.1296296
1%	0.0755668
0% Min	0.0755668

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0755668	48	0.762565	55
0.1172708	41	0.785714	57
0.1296296	25	0.831234	5
0.1386139	54	0.833333	28
0.1616628	9	0.920945	13

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

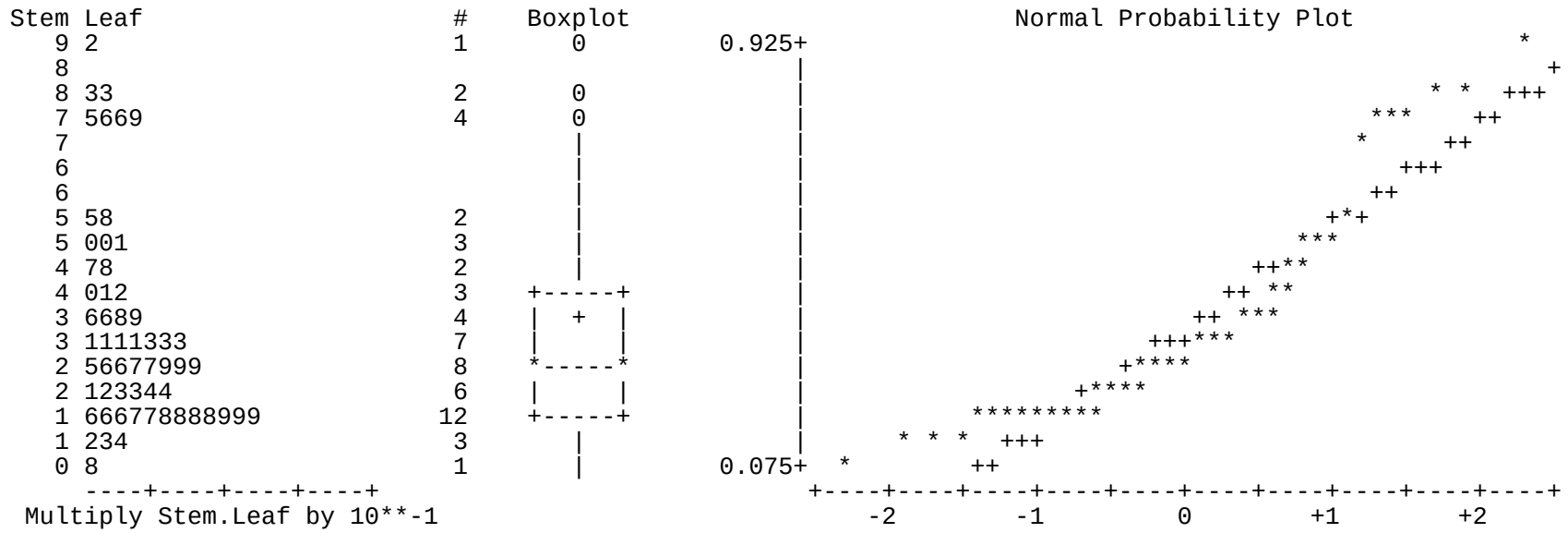

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	0.31695667	Sum Observations	18.3834868
Std Deviation	0.20102767	Variance	0.04041212
Skewness	2.02442499	Kurtosis	4.89317474
Uncorrected SS	8.13025973	Corrected SS	2.30349101
Coeff Variation	63.4243376	Std Error Mean	0.02639623

Basic Statistical Measures

Location		Variability	
Mean	0.316957	Std Deviation	0.20103
Median	0.253722	Variance	0.04041
Mode	0.173310	Range	1.05037
		Interquartile Range	0.17563

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.00765	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.79872	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.218781	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.644483	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.536535	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1250000
99%	1.1250000
95%	0.8613861

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.5666667
75% Q3	0.3627451
50% Median	0.2537224
25% Q1	0.1871102
10%	0.1419753
5%	0.1111111
1%	0.0746269
0% Min	0.0746269

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0746269	54	0.567867	55
0.1076923	41	0.599078	46
0.1111111	31	0.861386	13
0.1230769	37	0.906801	5
0.1296296	22	1.125000	35

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

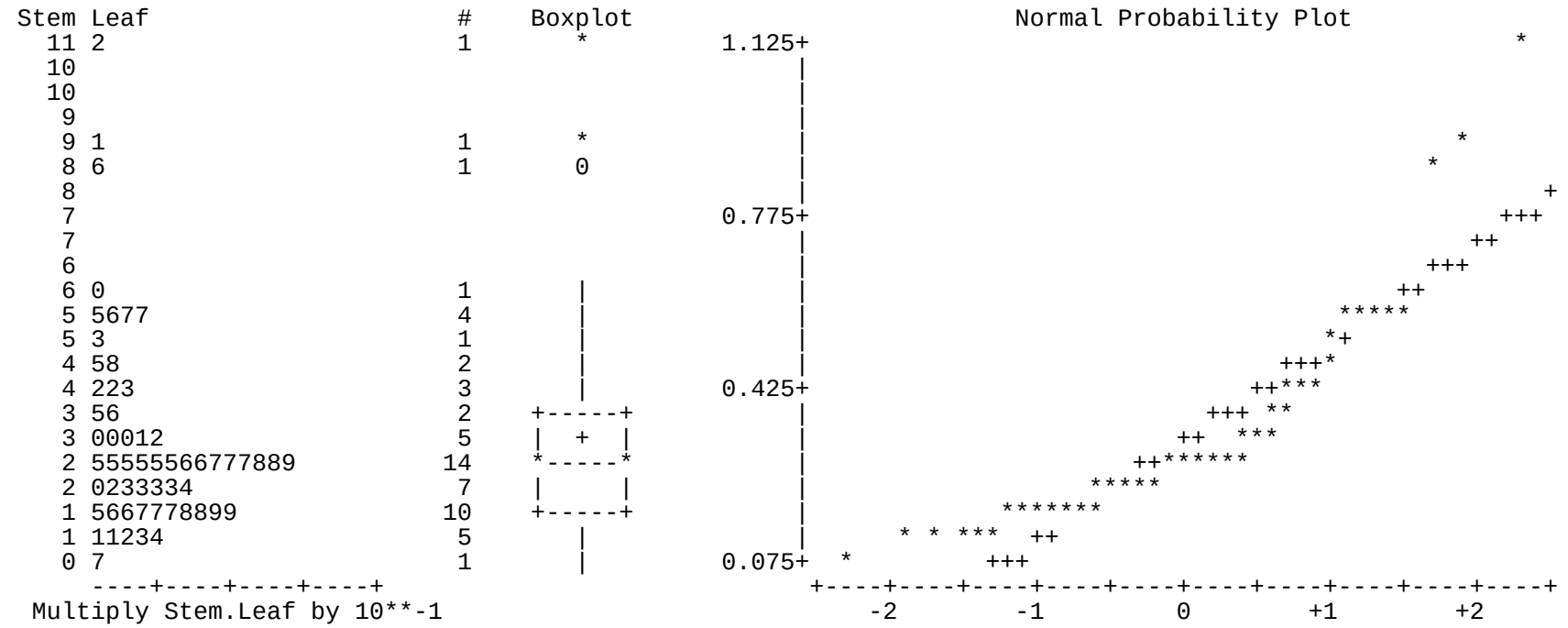

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0329149	Sum Observations	-1.9090644
Std Deviation	0.14518258	Variance	0.02107798
Skewness	1.19765479	Kurtosis	4.96719942
Uncorrected SS	1.26428159	Corrected SS	1.20144491
Coeff Variation	-441.08462	Std Error Mean	0.01906341

Basic Statistical Measures

Location		Variability	
Mean	-0.03291	Std Deviation	0.14518
Median	-0.05137	Variance	0.02108
Mode		Range	0.93193
		Interquartile Range	0.15049

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.7266	Pr > |t|	0.0897
Sign	M	-9.5	Pr >= |M|	0.0163

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-304.5	Pr >= |S|	0.0142

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.913721	Pr < W	0.0005
Kolmogorov-Smirnov	D	0.107875	Pr > D	0.0911
Cramer-von Mises	W-Sq	0.169429	Pr > W-Sq	0.0136
Anderson-Darling	A-Sq	1.074473	Pr > A-Sq	0.0078

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5795455
99%	0.5795455
95%	0.2188055
90%	0.1063348
75% Q3	0.0418278

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0513719
25% Q1	-0.1086602
10%	-0.1946980
5%	-0.2666667
1%	-0.3523810
0% Min	-0.3523810

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.352381	57	0.120370	25
-0.305035	39	0.138889	33
-0.266667	28	0.218806	48
-0.261280	52	0.298593	6
-0.250000	58	0.579545	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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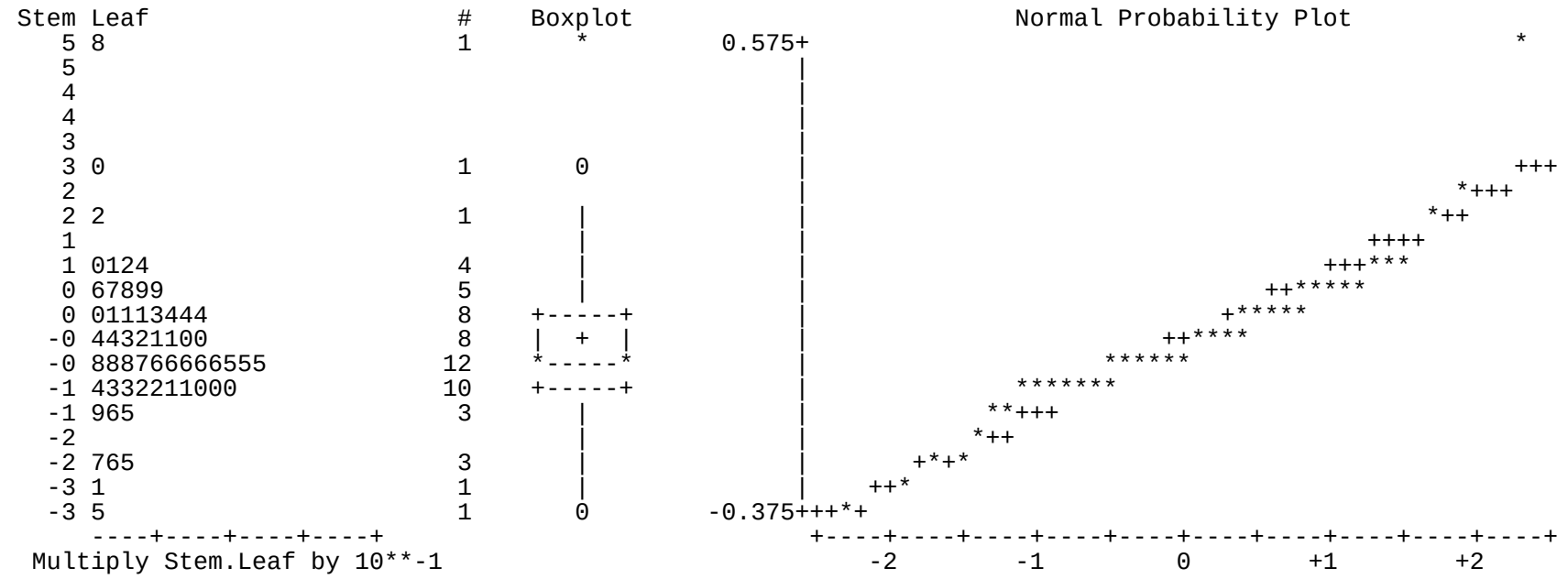
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	62	Sum Weights	62
Mean	0.37816935	Sum Observations	23.4464998
Std Deviation	0.2530204	Variance	0.06401932
Skewness	1.51734914	Kurtosis	1.80704229
Uncorrected SS	12.7719263	Corrected SS	3.90517867
Coeff Variation	66.9066382	Std Error Mean	0.03213362

Basic Statistical Measures

Location		Variability	
Mean	0.378169	Std Deviation	0.25302
Median	0.304400	Variance	0.06402
Mode	0.138539	Range	1.05582
		Interquartile Range	0.25934

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.76865	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.830188	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.19509	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.558934	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.379996	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.166667
99%	1.166667
95%	0.980810

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.750000
75% Q3	0.461894
50% Median	0.304400
25% Q1	0.202559
10%	0.138539
5%	0.134108
1%	0.110847
0% Min	0.110847

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.110847	57	0.95614	33
0.121212	32	0.98081	2
0.127451	51	1.00990	17
0.134108	13	1.05991	54
0.138504	40	1.16667	62

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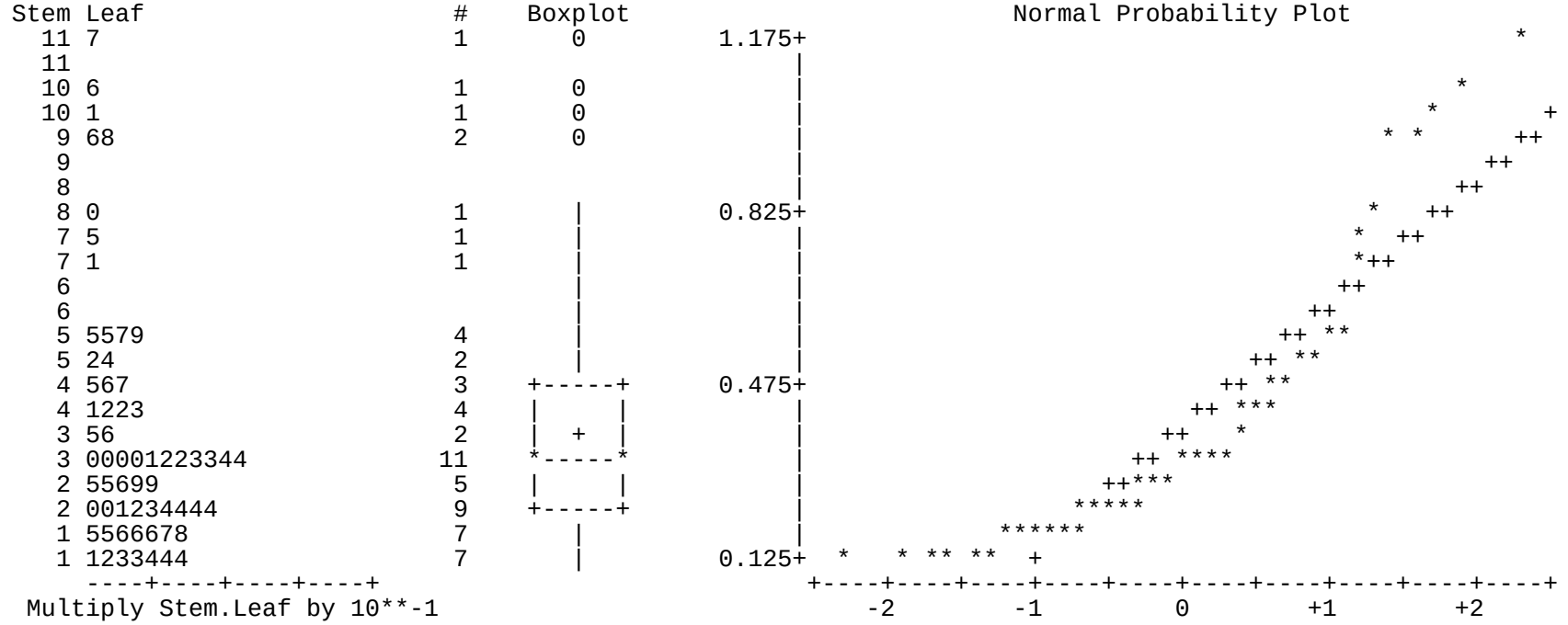
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	62	Sum Weights	62
Mean	0.32130912	Sum Observations	19.9211653
Std Deviation	0.23357548	Variance	0.0545575
Skewness	3.261353	Kurtosis	15.1837735
Uncorrected SS	9.72885982	Corrected SS	3.32800776
Coeff Variation	72.6949425	Std Error Mean	0.02966412

Basic Statistical Measures

Location		Variability	
Mean	0.321309	Std Deviation	0.23358
Median	0.262037	Variance	0.05456
Mode	0.167436	Range	1.53104
		Interquartile Range	0.18056

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.83158	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.708715	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.20778	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.683912	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.997538	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.6158818
99%	1.6158818
95%	0.6666667

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.5148515
75% Q3	0.3750000
50% Median	0.2620370
25% Q1	0.1944444
10%	0.1384615
5%	0.1039261
1%	0.0848416
0% Min	0.0848416

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0848416	13	0.583333	33
0.0888099	48	0.666667	29
0.0977995	12	0.808314	17
0.1039261	20	0.888889	28
0.1287129	11	1.615882	2

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

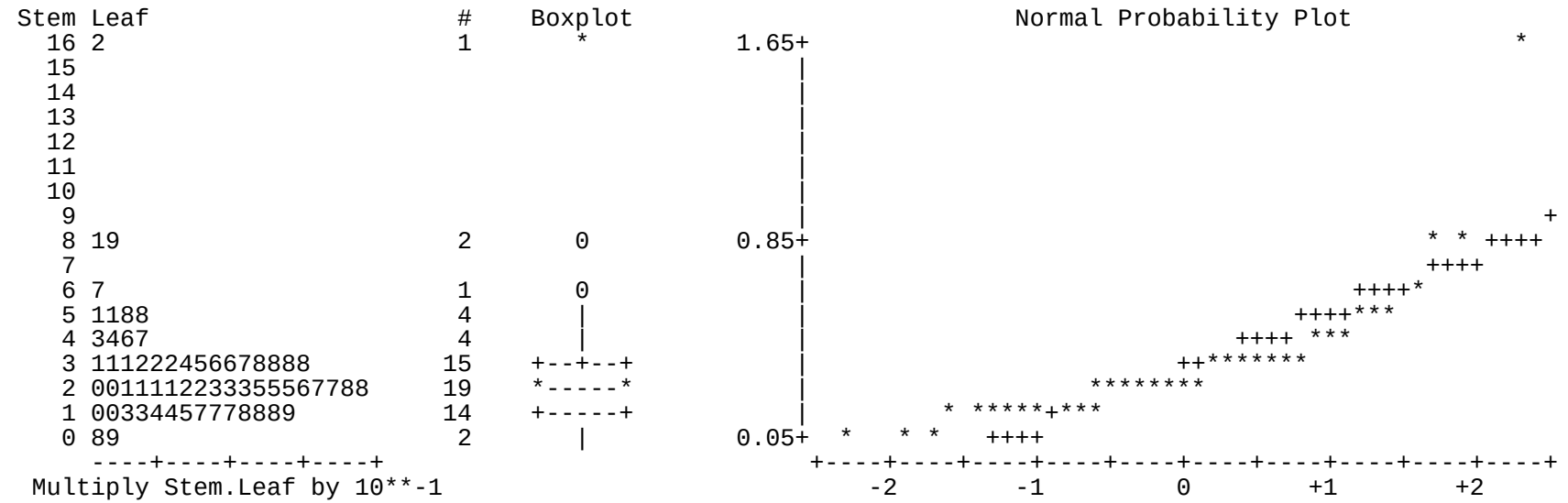

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-0.0568602	Sum Observations	-3.5253344
Std Deviation	0.21906947	Variance	0.04799143
Skewness	-0.3869089	Kurtosis	5.74019641
Uncorrected SS	3.12792873	Corrected SS	2.9274774
Coeff Variation	-385.27713	Std Error Mean	0.02782185

Basic Statistical Measures

Location		Variability	
Mean	-0.05686	Std Deviation	0.21907
Median	-0.03507	Variance	0.04799
Mode		Range	1.49808
		Interquartile Range	0.17735

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.04373	Pr > |t|	0.0453
Sign	M	-10	Pr >= |M|	0.0151

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-360.5	Pr >= |S|	0.0103

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.835313	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.170487	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.514094	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.131245	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6388889
99%	0.6388889
95%	0.1395224
90%	0.0792079
75% Q3	0.0402256

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0350686
25% Q1	-0.1371212
10%	-0.2427350
5%	-0.3728070
1%	-0.8591954
0% Min	-0.8591954

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.859195	62	0.113780	4
-0.736831	54	0.139522	6
-0.376984	30	0.154943	18
-0.372807	33	0.635072	2
-0.341430	58	0.638889	28

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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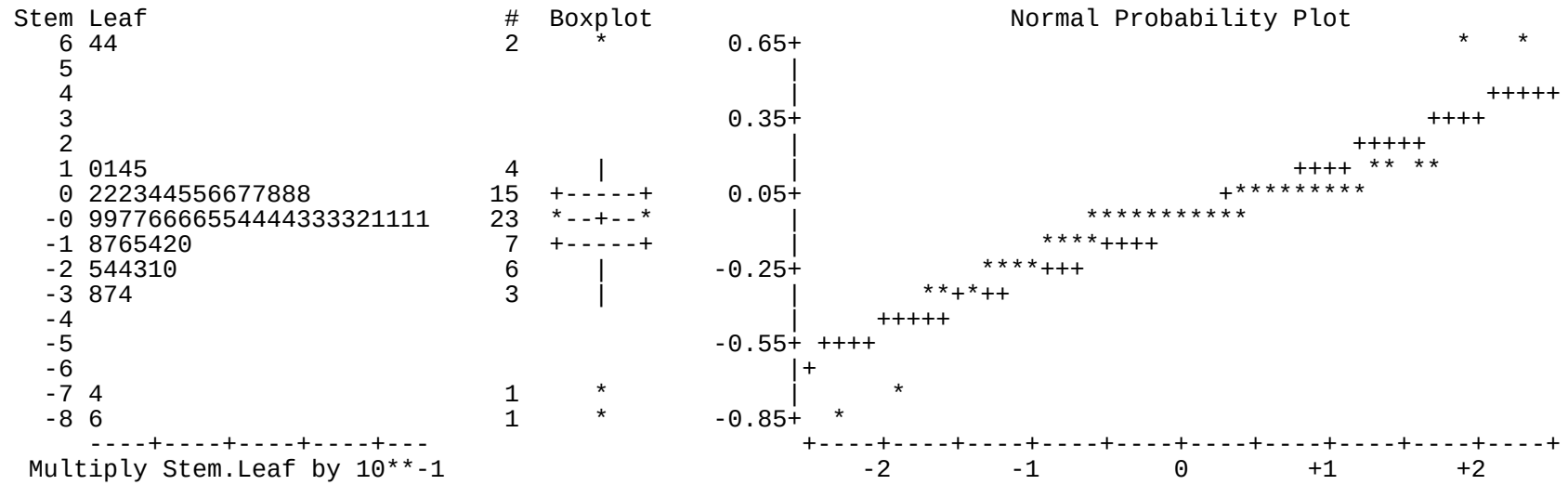
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	52	Sum Weights	52
Mean	0.40994993	Sum Observations	21.3173965
Std Deviation	0.22369033	Variance	0.05003737
Skewness	0.68312299	Kurtosis	-0.4499537
Uncorrected SS	11.2909709	Corrected SS	2.55190566
Coeff Variation	54.5652816	Std Error Mean	0.03102027

Basic Statistical Measures

Location		Variability	
Mean	0.409950	Std Deviation	0.22369
Median	0.336213	Variance	0.05004
Mode	0.277778	Range	0.91312
		Interquartile Range	0.35639

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.21555	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.930104	Pr < W	0.0045
Kolmogorov-Smirnov	D	0.150715	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.238283	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.352147	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9823678
99%	0.9823678
95%	0.8125000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.7017544
75% Q3	0.5903979
50% Median	0.3362133
25% Q1	0.2340067
10%	0.1666667
5%	0.1334017
1%	0.0692521
0% Min	0.0692521

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0692521	35	0.715935	8
0.1303993	1	0.733333	33
0.1334017	47	0.812500	32
0.1538462	49	0.904762	17
0.1616628	3	0.982368	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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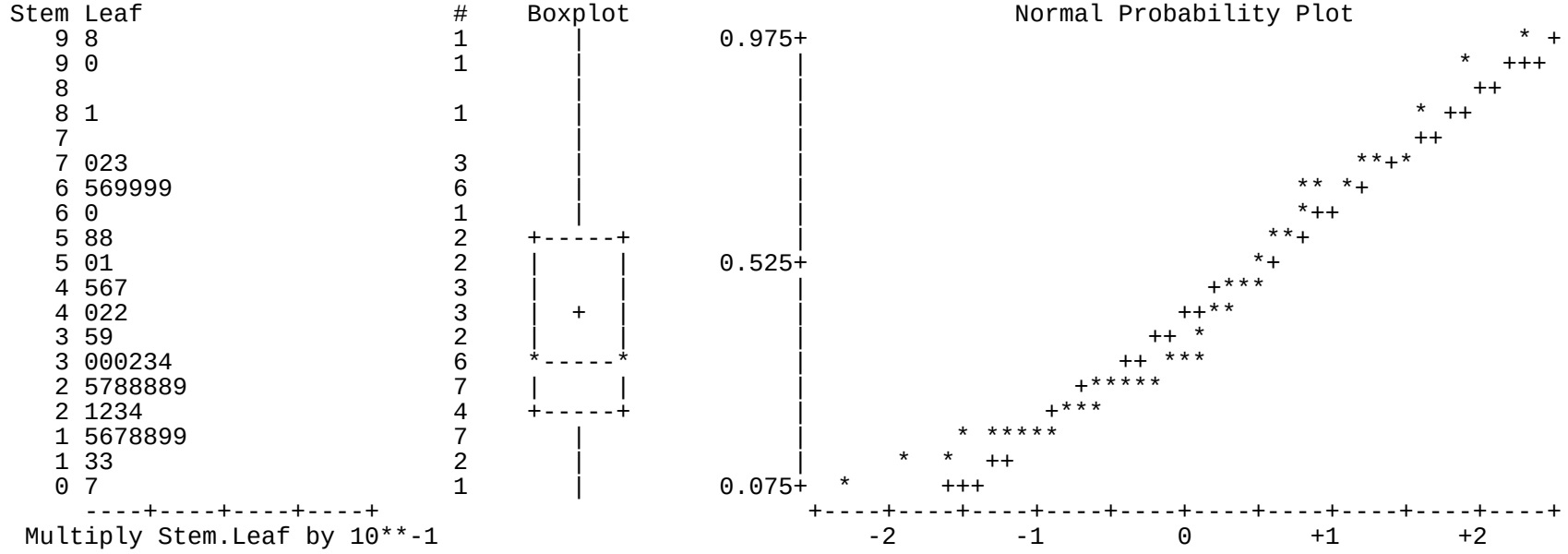
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	52	Sum Weights	52
Mean	0.31410096	Sum Observations	16.3332501
Std Deviation	0.14501871	Variance	0.02103043
Skewness	0.98954442	Kurtosis	1.4968418
Uncorrected SS	6.20284135	Corrected SS	1.07255175
Coeff Variation	46.1694575	Std Error Mean	0.02011048

Basic Statistical Measures

Location		Variability	
Mean	0.314101	Std Deviation	0.14502
Median	0.295701	Variance	0.02103
Mode	0.242634	Range	0.72472
		Interquartile Range	0.19109

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	15.61877	Pr > |t|	<.0001
Sign	M	26	Pr >= |M|	<.0001
Signed Rank	S	689	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.944243	Pr < W	0.0167
Kolmogorov-Smirnov	D	0.111339	Pr > D	0.1047
Cramer-von Mises	W-Sq	0.110558	Pr > W-Sq	0.0827
Anderson-Darling	A-Sq	0.697227	Pr > A-Sq	0.0682

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8055556
99%	0.8055556
95%	0.5927637

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.5037783
75% Q3	0.3982537
50% Median	0.2957010
25% Q1	0.2071591
10%	0.1492537
5%	0.1111111
1%	0.0808314
0% Min	0.0808314

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0808314	49	0.537037	32
0.0977995	1	0.583333	33
0.1111111	22	0.592764	4
0.1316245	7	0.600462	8
0.1385681	3	0.805556	17

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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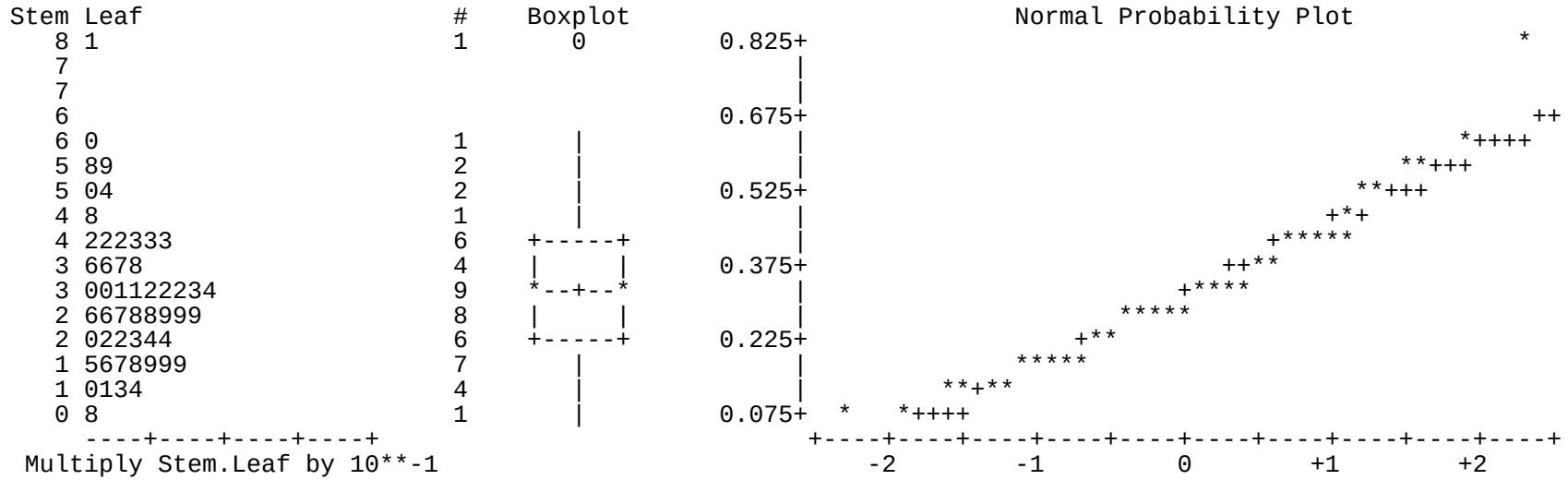
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	52	Sum Weights	52
Mean	-0.095849	Sum Observations	-4.9841463
Std Deviation	0.14679398	Variance	0.02154847
Skewness	-0.2662796	Kurtosis	-0.1266029
Uncorrected SS	1.57669732	Corrected SS	1.09897203
Coeff Variation	-153.15134	Std Error Mean	0.02035666

Basic Statistical Measures

Location		Variability	
Mean	-0.09585	Std Deviation	0.14679
Median	-0.07967	Variance	0.02155
Mode		Range	0.67527
		Interquartile Range	0.17951

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-4.70848	Pr > |t|	<.0001
Sign	M	-13.5	Pr >= |M|	0.0002

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-436	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.983231	Pr < W 0.6706
Kolmogorov-Smirnov	D	0.088547	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.05559	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq	0.340235	Pr > A-Sq >0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.24637533
99%	0.24637533
95%	0.11904762
90%	0.08804563
75% Q3	-0.00160256

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.07966567
25% Q1	-0.18111355
10%	-0.28468775
5%	-0.38883530
1%	-0.42889429
0% Min	-0.42889429

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.428894	9	0.104055	45
-0.389604	4	0.117110	52
-0.388835	5	0.119048	34
-0.358101	48	0.142728	36
-0.287660	16	0.246375	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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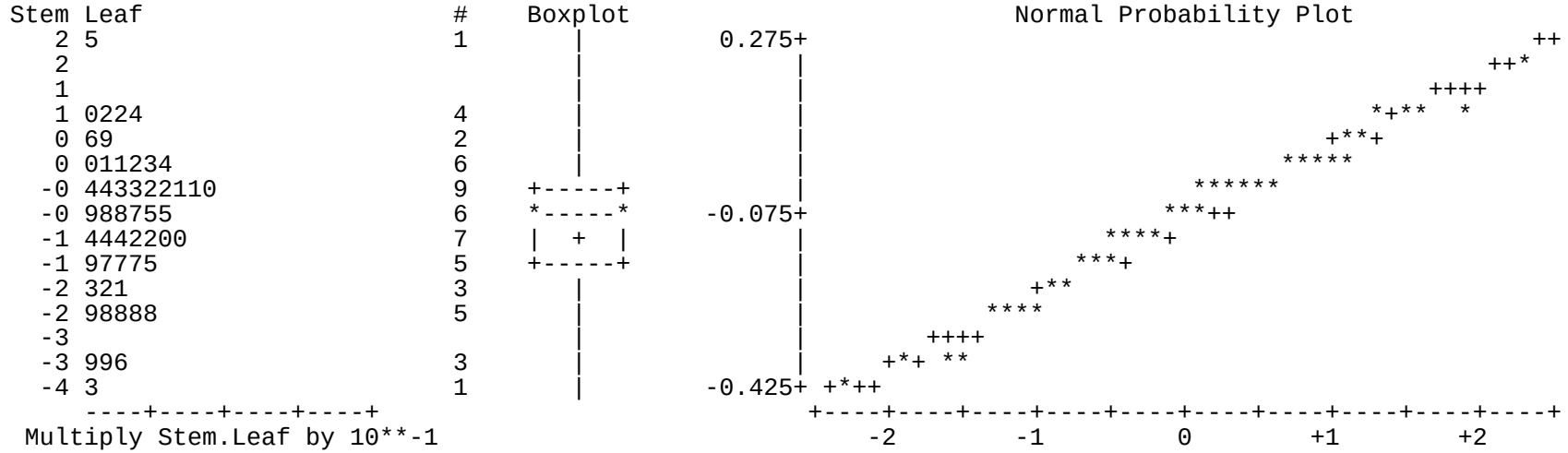
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	0.36279536	Sum Observations	19.5909495
Std Deviation	0.17322337	Variance	0.03000634
Skewness	0.54652294	Kurtosis	-0.1830308
Uncorrected SS	8.69784136	Corrected SS	1.59033578
Coeff Variation	47.7468534	Std Error Mean	0.02357271

Basic Statistical Measures

Location		Variability	
Mean	0.362795	Std Deviation	0.17322
Median	0.349850	Variance	0.03001
Mode		Range	0.75155
		Interquartile Range	0.25400

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	15.39048	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	742.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.969172	Pr < W 0.1772
Kolmogorov-Smirnov	D	0.087997	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.067958	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq	0.467365	Pr > A-Sq 0.2454

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.809524
99%	0.809524
95%	0.692521
90%	0.627547
75% Q3	0.484765

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.349850
25% Q1	0.230769
10%	0.138539
5%	0.113350
1%	0.057971
0% Min	0.057971

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.057971	24	0.656863	30
0.111111	48	0.687067	10
0.113350	47	0.692521	34
0.123997	14	0.708333	27
0.138504	2	0.809524	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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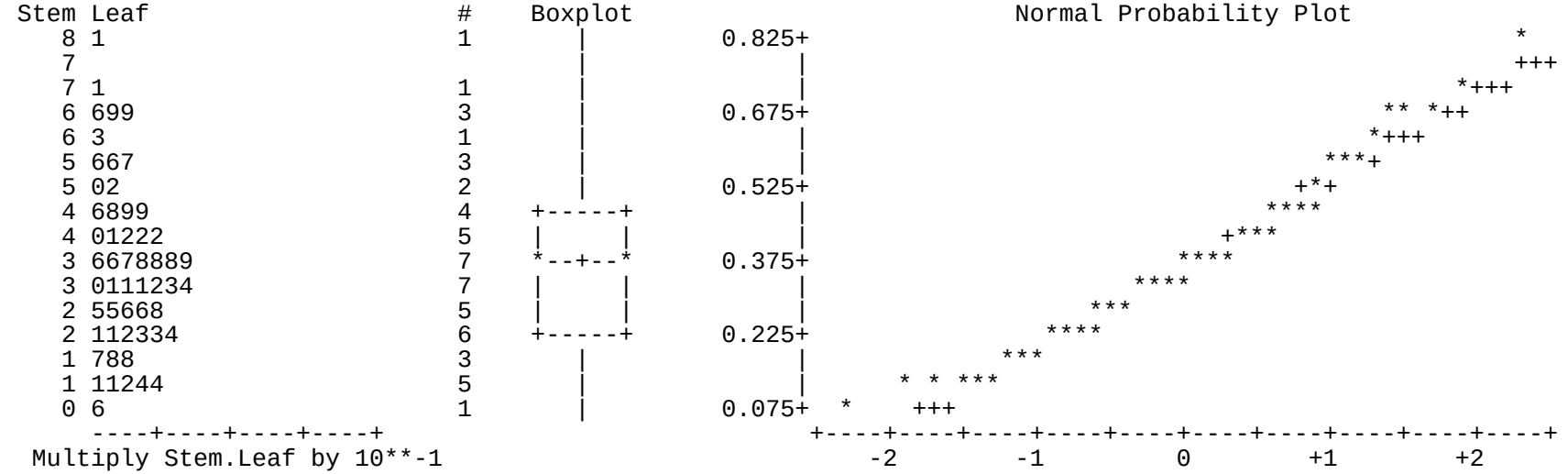
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	0.30621241	Sum Observations	16.5354702
Std Deviation	0.14366719	Variance	0.02064026
Skewness	0.41679268	Kurtosis	-0.6175902
Uncorrected SS	6.15730001	Corrected SS	1.09393379
Coeff Variation	46.9174925	Std Error Mean	0.01955063

Basic Statistical Measures

Location		Variability	
Mean	0.306212	Std Deviation	0.14367
Median	0.286639	Variance	0.02064
Mode		Range	0.56703
		Interquartile Range	0.20427

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	15.66254	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.962768	Pr < W	0.0917
Kolmogorov-Smirnov	D	0.107659	Pr > D	0.1187
Cramer-von Mises	W-Sq	0.098433	Pr > W-Sq	0.1179
Anderson-Darling	A-Sq	0.6436	Pr > A-Sq	0.0909

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6078431
99%	0.6078431
95%	0.5937500
90%	0.5111111
75% Q3	0.3888889

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.2866395
25% Q1	0.1846154
10%	0.1443418
5%	0.1015697
1%	0.0408163
0% Min	0.0408163

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0408163	24	0.514851	7
0.0793651	48	0.566138	22
0.1015697	14	0.593750	25
0.1230769	8	0.601449	32
0.1341082	38	0.607843	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
     6 01                    2       |
     5 79                    2       |
     5 0111                  4       |
     4 567                   3       |
     4 3                     1       |
     3 7778899               7    +-----+
     3 1222334               7    |  +  |
     2 888899                6    *-----*
     2 12233                 5    |     |
     1 57778888999          11    +-----+
     1 0234                  4       |
     0 8                     1       |
     0 4                     1       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**-1
```

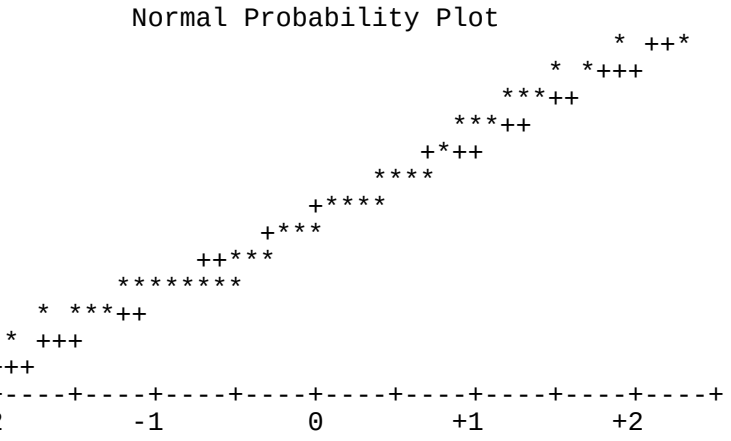

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	-0.0565829	Sum Observations	-3.0554792
Std Deviation	0.10698375	Variance	0.01144552
Skewness	-0.785471	Kurtosis	1.36682766
Uncorrected SS	0.77950073	Corrected SS	0.6066127
Coeff Variation	-189.07419	Std Error Mean	0.01455864

Basic Statistical Measures

Location		Variability	
Mean	-0.05658	Std Deviation	0.10698
Median	-0.04871	Variance	0.01145
Mode	0.00000	Range	0.55327
		Interquartile Range	0.11431

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.88655	Pr > |t|	0.0003
Sign	M	-10	Pr >= |M|	0.0078

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-392	Pr >= |S|	0.0002

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.953729	Pr < W	0.0362
Kolmogorov-Smirnov	D	0.115516	Pr > D	0.0723
Cramer-von Mises	W-Sq	0.119377	Pr > W-Sq	0.0625
Anderson-Darling	A-Sq	0.772997	Pr > A-Sq	0.0433

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.18407649
99%	0.18407649
95%	0.10780423
90%	0.06257310
75% Q3	0.00794694

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.04871031
25% Q1	-0.10636778
10%	-0.20168067
5%	-0.31393265
1%	-0.36919514
0% Min	-0.36919514

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.369195	34	0.0712653	47
-0.337963	27	0.0793451	5
-0.313933	10	0.1078042	22
-0.205942	38	0.1099963	32
-0.202579	51	0.1840765	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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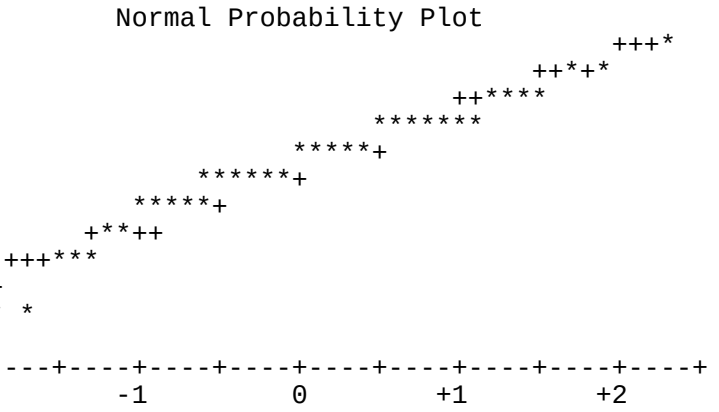
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                     #    Boxplot
     1 8                        1       0
     1 11                       2       |
     0 5678                     4       |
     0 00011112234             11    +-----+
    -0 44332220                 8    |     |
    -0 9998866655555           13    *--+--*
    -1 433210                   6    +-----+
    -1 665                      3       |
    -2 100                      3       |
    -2
    -3 41                       2       0
    -3 7                        1       0
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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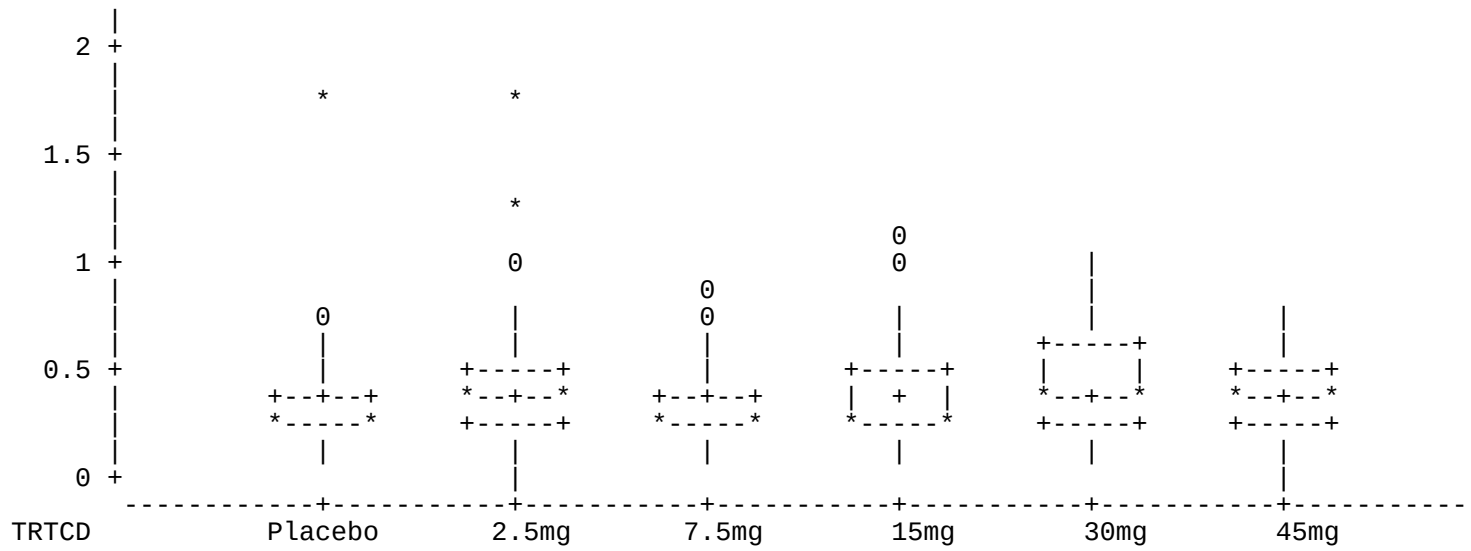
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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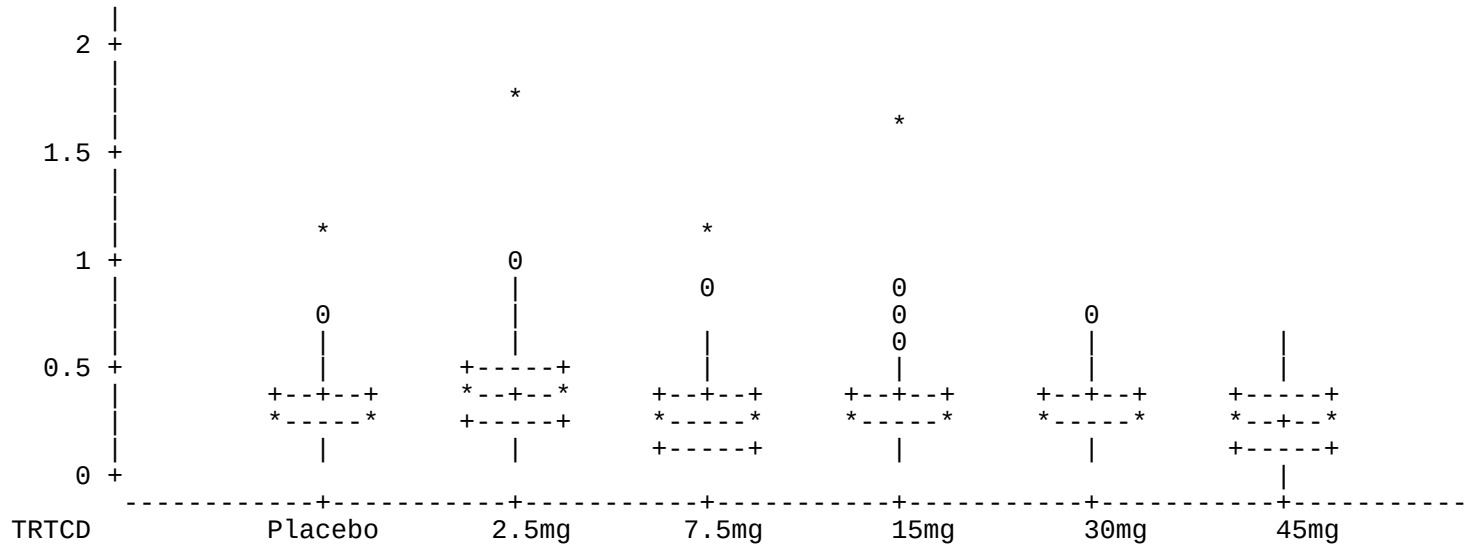
Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



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[redacted]

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots

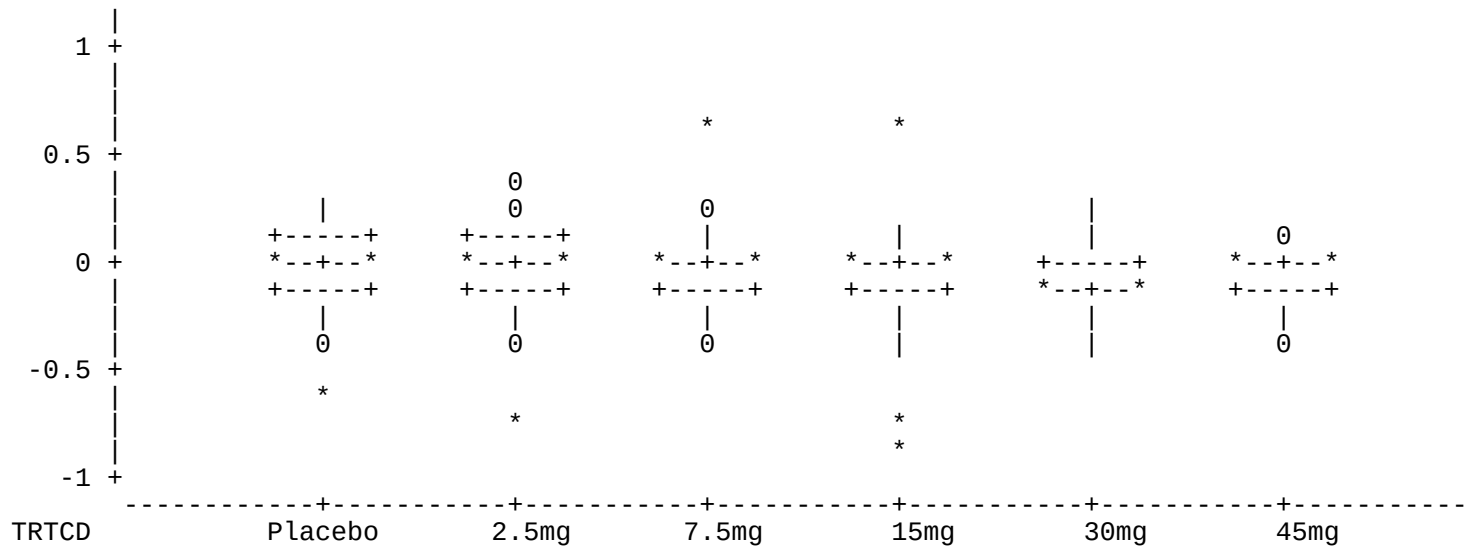

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	334
Observations Used	334
Observations Not Used	0
Total Observations	334

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.01766	0.001390	12.71	<.0001	0.05	0.01522	0.02074

Fit Statistics

-2 Res Log Likelihood	-343.1
AIC (smaller is better)	-341.1
AICC (smaller is better)	-341.1
BIC (smaller is better)	-337.3

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.08491	0.02685	323	3.16	0.0017
SEX	Female				-0.02556	0.01496	323	-1.71	0.0886
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.03561	0.01498	323	-2.38	0.0180
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.04276	0.02542	323	1.68	0.0935
TRTCD				2.5mg	0.07036	0.02591	323	2.72	0.0070
TRTCD				7.5mg	0.02416	0.02522	323	0.96	0.3390
TRTCD				15mg	0.006028	0.02479	323	0.24	0.8080
TRTCD				30mg	-0.01669	0.02593	323	-0.64	0.5202
TRTCD				45mg	0			.	
REGIONCD			US/Canada		0.02995	0.01720	323	1.74	0.0826
REGIONCD			Eastern Europe		0.04042	0.01835	323	2.20	0.0283
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.3791	0.03226	323	-11.75	<.0001

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	323	2.92	0.0886
TRTTYPCD	1	323	5.65	0.0180
TRTCD	5	323	3.00	0.0116
REGIONCD	2	323	2.79	0.0631
EFSTDBL	1	323	138.10	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	0.02760	0.02582	323	1.07	0.2859	0.05	-0.02320	0.07840
7.5mg vs Pbo	-0.01860	0.02498	323	-0.74	0.4571	0.05	-0.06775	0.03055
15mg vs Pbo	-0.03673	0.02460	323	-1.49	0.1364	0.05	-0.08512	0.01167
30mg vs Pbo	-0.05945	0.02570	323	-2.31	0.0213	0.05	-0.1100	-0.00889
45mg vs Pbo	-0.04276	0.02542	323	-1.68	0.0935	0.05	-0.09276	0.007252

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.497	0.497	0.497	0.497	0.497
SEX	Male				0.503	0.503	0.503	0.503	0.503
TRTTYPCD		Diet & Exercise			0.4192	0.4192	0.4192	0.4192	0.4192
TRTTYPCD		Monotherapy			0.5808	0.5808	0.5808	0.5808	0.5808
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3413	0.3413	0.3413	0.3413	0.3413
REGIONCD			Eastern Europe		0.2754	0.2754	0.2754	0.2754	0.2754
REGIONCD			Western Europe		0.3832	0.3832	0.3832	0.3832	0.3832
EFSTDBL					0.3782	0.3782	0.3782	0.3782	0.3782

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.497
SEX	Male				0.503
TRTTYPCD		Diet & Exercise			0.4192
TRTTYPCD		Monotherapy			0.5808
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3413
REGIONCD			Eastern Europe		0.2754
REGIONCD			Western Europe		0.3832
EFSTDBL					0.3782

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.02200	0.01784	323	-1.23	0.2183	0.05	-0.05709	0.01309
TRTCD	2.5mg	WORK.EFF	0.005602	0.01854	323	0.30	0.7627	0.05	-0.03086	0.04207
TRTCD	7.5mg	WORK.EFF	-0.04060	0.01751	323	-2.32	0.0211	0.05	-0.07505	-0.00615
TRTCD	15mg	WORK.EFF	-0.05873	0.01690	323	-3.47	0.0006	0.05	-0.09198	-0.02547
TRTCD	30mg	WORK.EFF	-0.08145	0.01848	323	-4.41	<.0001	0.05	-0.1178	-0.04509
TRTCD	45mg	WORK.EFF	-0.06475	0.01812	323	-3.57	0.0004	0.05	-0.1004	-0.02910

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-0.02760	0.02582	323	-1.07	0.2859	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.01860	0.02498	323	0.74	0.4571	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.03673	0.02460	323	1.49	0.1364	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.05945	0.02570	323	2.31	0.0213	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.04276	0.02542	323	1.68	0.0935	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.04620	0.02557	323	1.81	0.0717	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.06433	0.02509	323	2.56	0.0108	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.08705	0.02616	323	3.33	0.0010	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.07036	0.02591	323	2.72	0.0070	0.05

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	0.01813	0.02433	323	0.74	0.4568	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.04085	0.02548	323	1.60	0.1099	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.02416	0.02522	323	0.96	0.3390	0.05
TRTCD	15mg	30mg	WORK.EFF	0.02272	0.02506	323	0.91	0.3653	0.05
TRTCD	15mg	45mg	WORK.EFF	0.006028	0.02479	323	0.24	0.8080	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.01669	0.02593	323	-0.64	0.5202	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.07840	0.02320
TRTCD	Placebo	7.5mg	-0.03055	0.06775
TRTCD	Placebo	15mg	-0.01167	0.08512
TRTCD	Placebo	30mg	0.008890	0.1100
TRTCD	Placebo	45mg	-0.00725	0.09276
TRTCD	2.5mg	7.5mg	-0.00410	0.09651
TRTCD	2.5mg	15mg	0.01497	0.1137
TRTCD	2.5mg	30mg	0.03559	0.1385
TRTCD	2.5mg	45mg	0.01938	0.1213
TRTCD	7.5mg	15mg	-0.02974	0.06600

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.00928	0.09098
TRTCD	7.5mg	45mg	-0.02547	0.07378
TRTCD	15mg	30mg	-0.02658	0.07202
TRTCD	15mg	45mg	-0.04274	0.05480
TRTCD	30mg	45mg	-0.06770	0.03432

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.

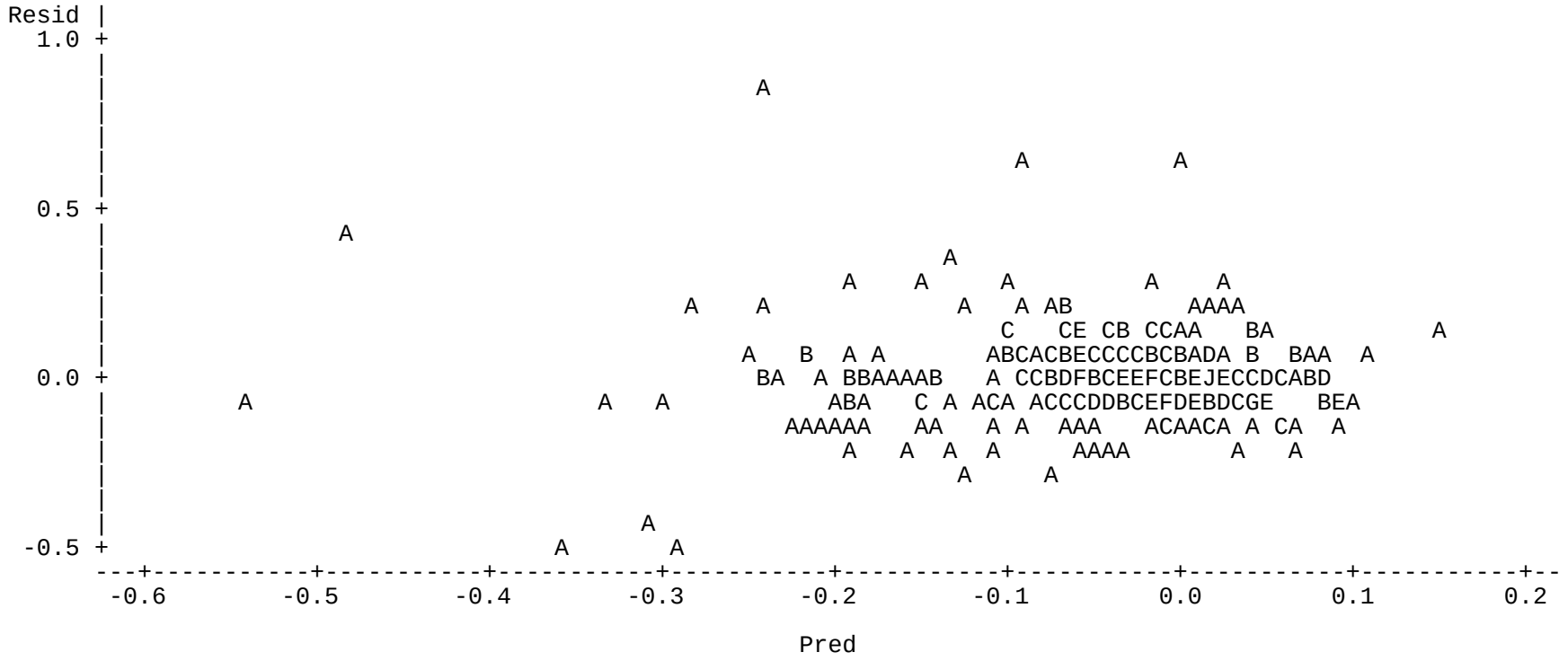

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

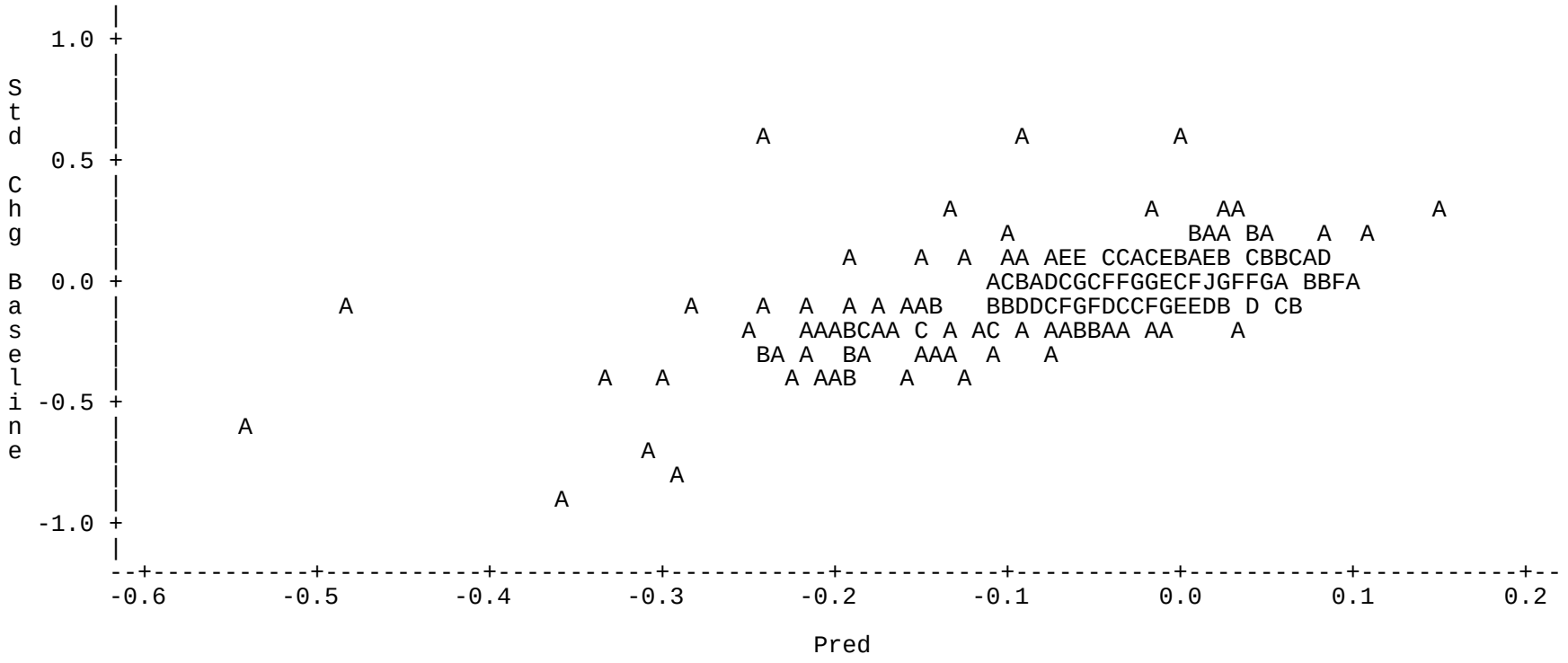

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	334	Sum Weights	334
Mean	0	Sum Observations	0
Std Deviation	0.13088222	Variance	0.01713016
Skewness	1.52280085	Kurtosis	10.1309066
Uncorrected SS	5.70434215	Corrected SS	5.70434215
Coeff Variation		Std Error Mean	0.00716156

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.13088
Median	-0.01602	Variance	0.01713
Mode		Range	1.37772
		Interquartile Range	0.11821

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-18	Pr >= |M|	0.0553
Signed Rank	S	-2711.5	Pr >= |S|	0.1249

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.867237	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.104381	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.340064	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	7.876621	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8755590
99%	0.4219757
95%	0.1995673
90%	0.1364953
75% Q3	0.0523942
50% Median	-0.0160178
25% Q1	-0.0658167
10%	-0.1276410
5%	-0.1654459
1%	-0.2576871
0% Min	-0.5021626

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Table 11.32
SAS Statistical Output for Table 11.31
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.502163	334	0.385369	85
-0.483569	204	0.421976	270
-0.425941	300	0.638348	179
-0.257687	285	0.672888	186
-0.255667	182	0.875559	8

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[redacted]

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Table 11.32
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Residual Plots

The UNIVARIATE Procedure
Variable: Resid

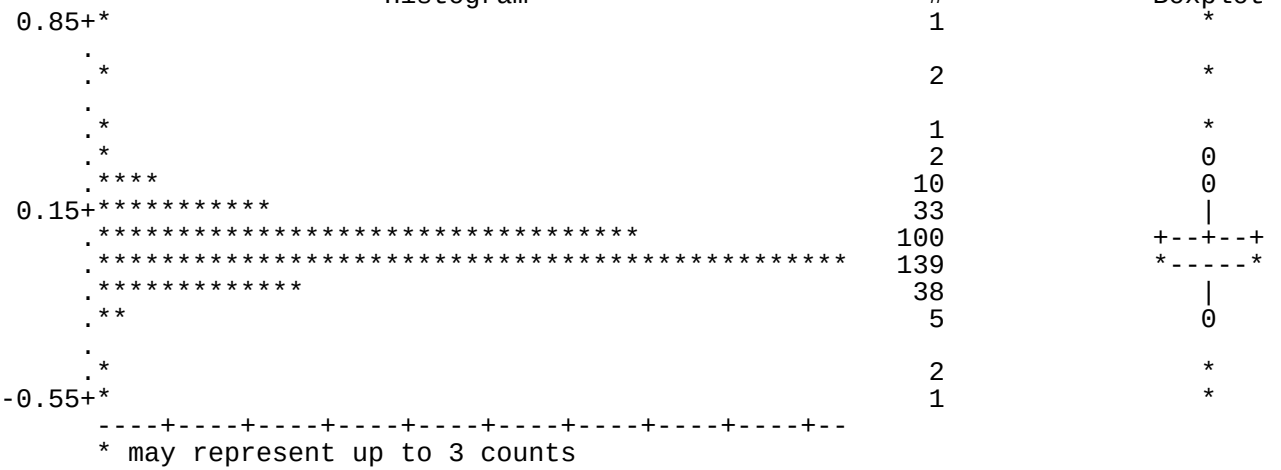

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Table 11.32
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot

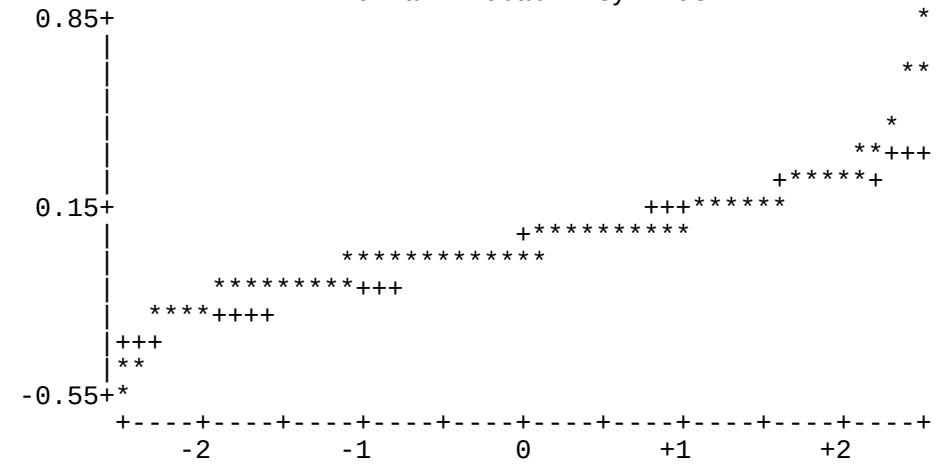

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Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Visit: Week 12	Placebo (N=62)		2.5mg (N=59)		7.5mg (N=62)		15mg (N=63)		30mg (N=58)		45mg (N=60)	
n [1]	59		56		59		62		56		58	
Number (%) of Values Carried Forward	10	(17%)	10	(18%)	6	(10%)	2	(3%)	2	(4%)	6	(10%)
Subjects with:												
HbA1c <=6.5%	6	(10%)	4	(7%)	4	(7%)	5	(8%)	9	(16%)	8	(14%)
6.5< HbA1c <7%	5	(8%)	5	(9%)	8	(14%)	4	(6%)	5	(9%)	6	(10%)
7=< HbA1c <=8%	21	(36%)	22	(39%)	25	(42%)	24	(39%)	31	(55%)	24	(41%)
HbA1c >8%	27	(46%)	25	(45%)	22	(37%)	29	(47%)	11	(20%)	20	(34%)
Increase or no reduction	39	(66%)	32	(57%)	28	(47%)	40	(65%)	22	(39%)	23	(40%)
Reduction 0 - <0.7%	10	(17%)	18	(32%)	17	(29%)	12	(19%)	13	(23%)	18	(31%)
Reduction 0.7 - <1.5%	6	(10%)	4	(7%)	11	(19%)	8	(13%)	17	(30%)	12	(21%)
Reduction >=1.5%	4	(7%)	2	(4%)	3	(5%)	2	(3%)	4	(7%)	5	(9%)

[1]Number of subjects with a value at baseline and at specified visit.
[2]Odds (Odds=Baseline+Gender+PriorTherapy+Treat) of having Hba1c <=6.5% at Week 12 on Active vs Placebo.
[3]Odds of having Hba1c <7% at Week 12 on Active vs Placebo.
[4]Odds of having Hba1c >=0.7% decrease from baseline at Week 12 on Active vs Placebo.
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
Percentages are based on 'Number of Subjects' by treatment group.

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Population: Intent-to-Treat with LOCF

Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Visit: Week 12	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]	59	56	59	62	56	58
Number (%) of Values Carried Forward	10 (17%)	10 (18%)	6 (10%)	2 (3%)	2 (4%)	6 (10%)
Responders (<=6.5%)	6 (10%)	4 (7%)	4 (7%)	5 (8%)	9 (16%)	8 (14%)
Odds Ratio to Placebo [2]		0.92	1.15	1.20	2.68	3.24
95% CI		0.21,3.95	0.27,4.92	0.30,4.83	0.74,9.77	0.85,12.37
p-val[5]		0.909	0.852	0.795	0.135	0.085
Responders (<7%)	11 (19%)	9 (16%)	12 (20%)	9 (15%)	14 (25%)	14 (24%)
Odds Ratio to Placebo [3]		1.10	1.99	1.04	2.15	3.24
95% CI		0.36,3.36	0.69,5.76	0.35,3.13	0.76,6.13	1.11,9.52
p-val[5]		0.866	0.202	0.941	0.152	0.032
Responders (>=0.7%)	10 (17%)	6 (11%)	14 (24%)	10 (16%)	21 (38%)	17 (29%)
Odds Ratio to Placebo [4]		0.46	1.43	1.01	3.65	2.00
95% CI		0.14,1.50	0.53,3.85	0.36,2.78	1.41,9.48	0.76,5.24
p-val[5]		0.198	0.481	0.991	0.008	0.161

[1]Number of subjects with a value at baseline and at specified visit.
[2]Odds (Odds=Baseline+Gender+PriorTherapy+Treat) of having Hba1c <=6.5% at Week 12 on Active vs Placebo.
[3]Odds of having Hba1c <7% at Week 12 on Active vs Placebo.
[4]Odds of having Hba1c >=0.7% decrease from baseline at Week 12 on Active vs Placebo.
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
Percentages are based on 'Number of Subjects' by treatment group.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency counts of the number of subjects with values at baseline and specified visit

The FREQ Procedure

Table of AVISNUM by TRTCD

AVISNUM(Visit number for reporting) TRTCD(Randomized treatment code)

Frequency / Percent / Row Pct / Col Pct	Placebo	2.5mg	7.5mg	15mg	30mg	45mg	Total
120	59	56	59	62	56	58	350
	16.86	16.00	16.86	17.71	16.00	16.57	100.00
	16.86	16.00	16.86	17.71	16.00	16.57	
	100.00	100.00	100.00	100.00	100.00	100.00	
Total	59	56	59	62	56	58	350
	16.86	16.00	16.86	17.71	16.00	16.57	100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency counts for the number of observations carried forward

The FREQ Procedure

Table 1 of TRTCD by EFLOCFIN
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)
EFLOCFIN(Carry forward value indicator (1=Y,0=N))

Frequency Percent Row Pct Col Pct	0	1	Total
Placebo	49 14.00 83.05 15.61	10 2.86 16.95 27.78	59 16.86
2.5mg	46 13.14 82.14 14.65	10 2.86 17.86 27.78	56 16.00
7.5mg	53 15.14 89.83 16.88	6 1.71 10.17 16.67	59 16.86
Total	314 89.71	36 10.29	350 100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency counts for the number of observations carried forward

The FREQ Procedure

Table 1 of TRTCD by EFLOCFIN
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)
EFLOCFIN(Carry forward value indicator (1=Y,0=N))

Frequency / Percent / Row Pct / Col Pct	0	1	Total
15mg	60	2	62
	17.14	0.57	17.71
	96.77	3.23	
	19.11	5.56	
30mg	54	2	56
	15.43	0.57	16.00
	96.43	3.57	
	17.20	5.56	
45mg	52	6	58
	14.86	1.71	16.57
	89.66	10.34	
	16.56	16.67	
Total	314	36	350
	89.71	10.29	100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency counts for the HbA1c categories

The FREQ Procedure

Table 1 of TRTCD by hba1cfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) hba1cfl(HbA1c responder flag)

Frequency Percent Row Pct Col Pct	HbA1c <= 6.5%	6.5< HbA 1c <7%	7<= Hba1 c <=8%	HbA1c >8 %	Total
Placebo	6 1.71 10.17 16.67	5 1.43 8.47 15.15	21 6.00 35.59 14.29	27 7.71 45.76 20.15	59 16.86
2.5mg	4 1.14 7.14 11.11	5 1.43 8.93 15.15	22 6.29 39.29 14.97	25 7.14 44.64 18.66	56 16.00
7.5mg	4 1.14 6.78 11.11	8 2.29 13.56 24.24	25 7.14 42.37 17.01	22 6.29 37.29 16.42	59 16.86
Total	36 10.29	33 9.43	147 42.00	134 38.29	350 100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency counts for the HbA1c categories

The FREQ Procedure

Table 1 of TRTCD by hba1cfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) hba1cfl(HbA1c responder flag)

Frequency Percent Row Pct Col Pct	HbA1c <= 6.5%	6.5< HbA 1c <7%	7<= Hba1 c <=8%	HbA1c >8 %	Total
15mg	5 1.43 8.06 13.89	4 1.14 6.45 12.12	24 6.86 38.71 16.33	29 8.29 46.77 21.64	62 17.71
30mg	9 2.57 16.07 25.00	5 1.43 8.93 15.15	31 8.86 55.36 21.09	11 3.14 19.64 8.21	56 16.00
45mg	8 2.29 13.79 22.22	6 1.71 10.34 18.18	24 6.86 41.38 16.33	20 5.71 34.48 14.93	58 16.57
Total	36 10.29	33 9.43	147 42.00	134 38.29	350 100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency count for the HbA1c reduction categories

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl(Reduction flag)

Frequency / Percent / Row Pct / Col Pct	Increase or no reduction	Reduction 0 - <0.7%	Reduction 0.7 - <1.5%	Reduction >=1.5%	Total
Placebo	39	10	6	4	59
	11.14	2.86	1.71	1.14	16.86
	66.10	16.95	10.17	6.78	
	21.20	11.36	10.34	20.00	
2.5mg	32	18	4	2	56
	9.14	5.14	1.14	0.57	16.00
	57.14	32.14	7.14	3.57	
	17.39	20.45	6.90	10.00	
Total	184	88	58	20	350
	52.57	25.14	16.57	5.71	100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency count for the HbA1c reduction categories

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl(Reduction flag)

Frequency Percent Row Pct Col Pct	Increase or no reduction	Reduction 0 - <0.7%	Reduction 0.7 - <1.5%	Reduction >=1.5%	Total
7.5mg	28 8.00 47.46 15.22	17 4.86 28.81 19.32	11 3.14 18.64 18.97	3 0.86 5.08 15.00	59 16.86
15mg	40 11.43 64.52 21.74	12 3.43 19.35 13.64	8 2.29 12.90 13.79	2 0.57 3.23 10.00	62 17.71
Total	184 52.57	88 25.14	58 16.57	20 5.71	350 100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Frequency count for the HbA1c reduction categories

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl(Reduction flag)

Frequency Percent Row Pct Col Pct	Increase or no reduction	Reduction 0 - <0.7%	Reduction 0.7 - <1.5%	Reduction >=1.5%	Total
30mg	22 6.29 39.29 11.96	13 3.71 23.21 14.77	17 4.86 30.36 29.31	4 1.14 7.14 20.00	56 16.00
45mg	23 6.57 39.66 12.50	18 5.14 31.03 20.45	12 3.43 20.69 20.69	5 1.43 8.62 25.00	58 16.57
Total	184 52.57	88 25.14	58 16.57	20 5.71	350 100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Model Information

Data Set	WORK.EFF	
Response Variable	a7fl	Responders flag (<7%)
Number of Response Levels	2	
Number of Observations	350	
Model	binary logit	
Optimization Technique	Fisher's scoring	

Response Profile

Ordered Value	a7fl	Total Frequency
1	Responder	69
2	Non responder	281

Probability modeled is a7fl='Responder'.

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
TRTCD	Placebo	0	0	0	0	0
	2.5mg	1	0	0	0	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
	7.5mg	0	1	0	0	0
	15mg	0	0	1	0	0
	30mg	0	0	0	1	0
	45mg	0	0	0	0	1
SEX	Female	1				
	Male	0				
TRTTYPCD	Diet & Exercise	1				
	Monotherapy	0				

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	349.491	275.269
SC	353.349	309.990
-2 Log L	347.491	257.269

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	90.2226	8	<.0001
Score	71.8987	8	<.0001
Wald	53.5935	8	<.0001

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
TRTCD	5	7.4948	0.1864
SEX	1	0.0476	0.8273
TRTTYPCD	1	31.0762	<.0001
EFSTDBL	1	42.6595	<.0001

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Exp(Est)
Intercept		1	13.2069	2.3204	32.3946	<.0001	544086.0
TRTCD	2.5mg	1	0.0962	0.5689	0.0286	0.8657	1.101
TRTCD	7.5mg	1	0.6902	0.5411	1.6270	0.2021	1.994
TRTCD	15mg	1	0.0416	0.5603	0.0055	0.9408	1.042
TRTCD	30mg	1	0.7661	0.5342	2.0564	0.1516	2.151
TRTCD	45mg	1	1.1767	0.5494	4.5872	0.0322	3.244
SEX	Female	1	-0.0688	0.3152	0.0476	0.8273	0.934
TRTTYPCD	Diet & Exercise	1	1.9646	0.3524	31.0762	<.0001	7.132
EFSTDBL		1	-2.0923	0.3204	42.6595	<.0001	0.123

Odds Ratio Estimates

Effect			Point Estimate	95% Wald Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.101	0.361	3.357
TRTCD	7.5mg	vs Placebo	1.994	0.690	5.759
TRTCD	15mg	vs Placebo	1.042	0.348	3.126
TRTCD	30mg	vs Placebo	2.151	0.755	6.129
TRTCD	45mg	vs Placebo	3.244	1.105	9.521
SEX	Female	vs Male	0.934	0.503	1.732
TRTTYPCD	Diet & Exercise	vs Monotherapy	7.132	3.575	14.229
EFSTDBL			0.123	0.066	0.231

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	83.7	Somers' D	0.677
Percent Discordant	16.0	Gamma	0.679
Percent Tied	0.3	Tau-a	0.215
Pairs	19389	c	0.838

Profile Likelihood Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.101	0.356	3.377
TRTCD	7.5mg	vs Placebo	1.0000	1.994	0.695	5.887
TRTCD	15mg	vs Placebo	1.0000	1.042	0.343	3.145
TRTCD	30mg	vs Placebo	1.0000	2.151	0.763	6.279
TRTCD	45mg	vs Placebo	1.0000	3.244	1.122	9.807
SEX	Female vs Male		1.0000	0.934	0.502	1.734
TRTTYPCD	Diet & Exercise vs Monotherapy		1.0000	7.132	3.660	14.651
EFSTDBL			1.0000	0.123	0.063	0.223

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.101	0.361	3.357
TRTCD	7.5mg	vs Placebo	1.0000	1.994	0.690	5.759
TRTCD	15mg	vs Placebo	1.0000	1.042	0.348	3.126

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Wald Confidence Interval for Adjusted Odds Ratios

Effect		Unit	Estimate	95% Confidence Limits	
TRTCD	30mg vs Placebo	1.0000	2.151	0.755	6.129
TRTCD	45mg vs Placebo	1.0000	3.244	1.105	9.521
SEX	Female vs Male	1.0000	0.934	0.503	1.732
TRTTYPCD	Diet & Exercise vs Monotherapy	1.0000	7.132	3.575	14.229
EFSTDBL		1.0000	0.123	0.066	0.231

Coefficients of Contrast 2.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	1
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Coefficients of Contrast 7.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	1
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 15mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	1
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Coefficients of Contrast 30mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	1
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 45mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	1
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

The LOGISTIC Procedure

Contrast Test Results

Contrast	DF	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	1	0.0286	0.8657
7.5mg vs Placebo	1	1.6270	0.2021
15mg vs Placebo	1	0.0055	0.9408
30mg vs Placebo	1	2.0564	0.1516
45mg vs Placebo	1	4.5872	0.0322

Contrast Rows Estimation and Testing Results

Contrast	Type	Row	Estimate	Standard Error	Alpha	Lower Limit	Upper Limit	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	PARM	1	0.0962	0.5689	0.05	-1.0188	1.2111	0.0286	0.8657
2.5mg vs Placebo	EXP	1	1.1010	0.6263	0.05	0.3610	3.3573	0.0286	0.8657
7.5mg vs Placebo	PARM	1	0.6902	0.5411	0.05	-0.3704	1.7508	1.6270	0.2021
7.5mg vs Placebo	EXP	1	1.9942	1.0791	0.05	0.6905	5.7592	1.6270	0.2021
15mg vs Placebo	PARM	1	0.0416	0.5603	0.05	-1.0566	1.1398	0.0055	0.9408
15mg vs Placebo	EXP	1	1.0425	0.5841	0.05	0.3476	3.1263	0.0055	0.9408
30mg vs Placebo	PARM	1	0.7661	0.5342	0.05	-0.2810	1.8131	2.0564	0.1516
30mg vs Placebo	EXP	1	2.1513	1.1492	0.05	0.7551	6.1293	2.0564	0.1516
45mg vs Placebo	PARM	1	1.1767	0.5494	0.05	0.0999	2.2535	4.5872	0.0322
45mg vs Placebo	EXP	1	3.2435	1.7820	0.05	1.1050	9.5205	4.5872	0.0322

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <7 category

Obs	Variable	Class Val0	Prob ChiSq
1	TRTCD	2.5mg	0.8657
2	TRTCD	7.5mg	0.2021
3	TRTCD	15mg	0.9408
4	TRTCD	30mg	0.1516
5	TRTCD	45mg	0.0322

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Model Information

Data Set	WORK.EFF	
Response Variable	a65fl	Responders flag (<=6.5%)
Number of Response Levels	2	
Number of Observations	350	
Model	binary logit	
Optimization Technique	Fisher's scoring	

Response Profile

Ordered Value	a65fl	Total Frequency
1	Responder	36
2	Non responder	314

Probability modeled is a65fl='Responder'.

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
TRTCD	Placebo	0	0	0	0	0
	2.5mg	1	0	0	0	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
	7.5mg	0	1	0	0	0
	15mg	0	0	1	0	0
	30mg	0	0	0	1	0
	45mg	0	0	0	0	1
SEX	Female	1				
	Male	0				
TRTTYPCD	Diet & Exercise	1				
	Monotherapy	0				

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	233.921	188.494
SC	237.779	223.216
-2 Log L	231.921	170.494

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	61.4267	8	<.0001
Score	48.8942	8	<.0001
Wald	36.2925	8	<.0001

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
TRTCD	5	6.2036	0.2869
SEX	1	0.1564	0.6925
TRTTYPCD	1	19.4721	<.0001
EFSTDBL	1	28.0131	<.0001

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Exp(Est)
Intercept		1	13.2868	2.9880	19.7738	<.0001	589380.5
TRTCD	2.5mg	1	-0.0854	0.7443	0.0132	0.9086	0.918
TRTCD	7.5mg	1	0.1386	0.7421	0.0349	0.8519	1.149
TRTCD	15mg	1	0.1848	0.7095	0.0678	0.7946	1.203
TRTCD	30mg	1	0.9858	0.6600	2.2306	0.1353	2.680
TRTCD	45mg	1	1.1768	0.6829	2.9690	0.0849	3.244
SEX	Female	1	-0.1606	0.4060	0.1564	0.6925	0.852
TRTTYPCD	Diet & Exercise	1	2.0404	0.4624	19.4721	<.0001	7.694
EFSTDBL		1	-2.2317	0.4217	28.0131	<.0001	0.107

Odds Ratio Estimates

Effect			Point Estimate	95% Wald Confidence Limits	
TRTCD	2.5mg	vs Placebo	0.918	0.213	3.949
TRTCD	7.5mg	vs Placebo	1.149	0.268	4.919
TRTCD	15mg	vs Placebo	1.203	0.299	4.833
TRTCD	30mg	vs Placebo	2.680	0.735	9.771
TRTCD	45mg	vs Placebo	3.244	0.851	12.370
SEX	Female	vs Male	0.852	0.384	1.887
TRTTYPCD	Diet & Exercise	vs Monotherapy	7.694	3.109	19.043
EFSTDBL			0.107	0.047	0.245

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	85.2	Somers' D	0.709
Percent Discordant	14.4	Gamma	0.711
Percent Tied	0.4	Tau-a	0.131
Pairs	11304	c	0.854

Profile Likelihood Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	0.918	0.200	3.945
TRTCD	7.5mg	vs Placebo	1.0000	1.149	0.252	4.947
TRTCD	15mg	vs Placebo	1.0000	1.203	0.290	4.948
TRTCD	30mg	vs Placebo	1.0000	2.680	0.755	10.397
TRTCD	45mg	vs Placebo	1.0000	3.244	0.869	13.124
SEX	Female vs Male		1.0000	0.852	0.380	1.887
TRTTYPCD	Diet & Exercise vs Monotherapy		1.0000	7.694	3.243	20.146
EFSTDBL			1.0000	0.107	0.044	0.231

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	0.918	0.213	3.949
TRTCD	7.5mg	vs Placebo	1.0000	1.149	0.268	4.919
TRTCD	15mg	vs Placebo	1.0000	1.203	0.299	4.833

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	30mg	vs Placebo	1.0000	2.680	0.735	9.771
TRTCD	45mg	vs Placebo	1.0000	3.244	0.851	12.370
SEX	Female	vs Male	1.0000	0.852	0.384	1.887
TRTTYPCD	Diet & Exercise	vs Monotherapy	1.0000	7.694	3.109	19.043
EFSTDBL			1.0000	0.107	0.047	0.245

Coefficients of Contrast 2.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	1
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Coefficients of Contrast 7.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	1
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 15mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	1
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Coefficients of Contrast 30mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	1
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 45mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	1
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

The LOGISTIC Procedure

Contrast Test Results

Contrast	DF	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	1	0.0132	0.9086
7.5mg vs Placebo	1	0.0349	0.8519
15mg vs Placebo	1	0.0678	0.7946
30mg vs Placebo	1	2.2306	0.1353
45mg vs Placebo	1	2.9690	0.0849

Contrast Rows Estimation and Testing Results

Contrast	Type	Row	Estimate	Standard Error	Alpha	Lower Limit	Upper Limit	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	PARM	1	-0.0854	0.7443	0.05	-1.5442	1.3733	0.0132	0.9086
2.5mg vs Placebo	EXP	1	0.9181	0.6833	0.05	0.2135	3.9485	0.0132	0.9086
7.5mg vs Placebo	PARM	1	0.1386	0.7421	0.05	-1.3160	1.5931	0.0349	0.8519
7.5mg vs Placebo	EXP	1	1.1486	0.8524	0.05	0.2682	4.9192	0.0349	0.8519
15mg vs Placebo	PARM	1	0.1848	0.7095	0.05	-1.2059	1.5754	0.0678	0.7946
15mg vs Placebo	EXP	1	1.2029	0.8535	0.05	0.2994	4.8328	0.0678	0.7946
30mg vs Placebo	PARM	1	0.9858	0.6600	0.05	-0.3079	2.2794	2.2306	0.1353
30mg vs Placebo	EXP	1	2.6798	1.7687	0.05	0.7350	9.7705	2.2306	0.1353
45mg vs Placebo	PARM	1	1.1768	0.6829	0.05	-0.1618	2.5153	2.9690	0.0849
45mg vs Placebo	EXP	1	3.2438	2.2154	0.05	0.8506	12.3704	2.9690	0.0849

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistical regression Model for the HbA1c <=6.5 category

Obs	Variable	Class Val0	Prob ChiSq
1	TRTCD	2.5mg	0.9086
2	TRTCD	7.5mg	0.8519
3	TRTCD	15mg	0.7946
4	TRTCD	30mg	0.1353
5	TRTCD	45mg	0.0849

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Model Information

Data Set	WORK.EFF	
Response Variable	r07fl	Responders flag (>=0.7%)
Number of Response Levels	2	
Number of Observations	350	
Model	binary logit	
Optimization Technique	Fisher's scoring	

Response Profile

Ordered Value	r07fl	Total Frequency
1	Responder	78
2	Non responder	272

Probability modeled is r07fl='Responder'.

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
TRTCD	Placebo	0	0	0	0	0
	2.5mg	1	0	0	0	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
	7.5mg	0	1	0	0	0
	15mg	0	0	1	0	0
	30mg	0	0	0	1	0
	45mg	0	0	0	0	1
SEX	Female	1				
	Male	0				
TRTTYPCD	Diet & Exercise	1				
	Monotherapy	0				

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	373.350	319.061
SC	377.208	353.782
-2 Log L	371.350	301.061

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	70.2892	8	<.0001
Score	66.4800	8	<.0001
Wald	53.0394	8	<.0001

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
TRTCD	5	16.9934	0.0045
SEX	1	0.0436	0.8347
TRTTYPCD	1	33.2244	<.0001
EFSTDBL	1	12.8272	0.0003

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Exp(Est)
Intercept		1	-8.3042	1.6808	24.4102	<.0001	0.000
TRTCD	2.5mg	1	-0.7735	0.6007	1.6579	0.1979	0.461
TRTCD	7.5mg	1	0.3560	0.5056	0.4959	0.4813	1.428
TRTCD	15mg	1	0.00573	0.5196	0.0001	0.9912	1.006
TRTCD	30mg	1	1.2951	0.4869	7.0743	0.0078	3.651
TRTCD	45mg	1	0.6907	0.4923	1.9683	0.1606	1.995
SEX	Female	1	-0.0607	0.2910	0.0436	0.8347	0.941
TRTTYPCD	Diet & Exercise	1	1.7360	0.3012	33.2244	<.0001	5.674
EFSTDBL		1	0.7286	0.2034	12.8272	0.0003	2.072

Odds Ratio Estimates

Effect			Point Estimate	95% Wald Confidence Limits	
TRTCD	2.5mg	vs Placebo	0.461	0.142	1.498
TRTCD	7.5mg	vs Placebo	1.428	0.530	3.846
TRTCD	15mg	vs Placebo	1.006	0.363	2.785
TRTCD	30mg	vs Placebo	3.651	1.406	9.482
TRTCD	45mg	vs Placebo	1.995	0.760	5.236
SEX	Female	vs Male	0.941	0.532	1.665
TRTTYPCD	Diet & Exercise	vs Monotherapy	5.674	3.145	10.239
EFSTDBL			2.072	1.391	3.087

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	79.1	Somers' D	0.586
Percent Discordant	20.5	Gamma	0.588
Percent Tied	0.4	Tau-a	0.204
Pairs	21216	c	0.793

Profile Likelihood Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	0.461	0.134	1.461
TRTCD	7.5mg	vs Placebo	1.0000	1.428	0.532	3.918
TRTCD	15mg	vs Placebo	1.0000	1.006	0.360	2.814
TRTCD	30mg	vs Placebo	1.0000	3.651	1.436	9.798
TRTCD	45mg	vs Placebo	1.0000	1.995	0.770	5.373
SEX	Female	vs Male	1.0000	0.941	0.531	1.667
TRTTYPCD	Diet & Exercise	vs Monotherapy	1.0000	5.674	3.190	10.429
EFSTDBL			1.0000	2.072	1.398	3.112

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	0.461	0.142	1.498
TRTCD	7.5mg	vs Placebo	1.0000	1.428	0.530	3.846
TRTCD	15mg	vs Placebo	1.0000	1.006	0.363	2.785

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	30mg	vs Placebo	1.0000	3.651	1.406	9.482
TRTCD	45mg	vs Placebo	1.0000	1.995	0.760	5.236
SEX	Female	vs Male	1.0000	0.941	0.532	1.665
TRTTYPCD	Diet & Exercise	vs Monotherapy	1.0000	5.674	3.145	10.239
EFSTDBL			1.0000	2.072	1.391	3.087

Coefficients of Contrast 2.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	1
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Coefficients of Contrast 7.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	1
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 15mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	1
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Coefficients of Contrast 30mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	1
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 45mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	1
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

The LOGISTIC Procedure

Contrast Test Results

Contrast	DF	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	1	1.6579	0.1979
7.5mg vs Placebo	1	0.4959	0.4813
15mg vs Placebo	1	0.0001	0.9912
30mg vs Placebo	1	7.0743	0.0078
45mg vs Placebo	1	1.9683	0.1606

Contrast Rows Estimation and Testing Results

Contrast	Type	Row	Estimate	Standard Error	Alpha	Lower Limit	Upper Limit	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	PARM	1	-0.7735	0.6007	0.05	-1.9508	0.4039	1.6579	0.1979
2.5mg vs Placebo	EXP	1	0.4614	0.2772	0.05	0.1422	1.4976	1.6579	0.1979
7.5mg vs Placebo	PARM	1	0.3560	0.5056	0.05	-0.6349	1.3470	0.4959	0.4813
7.5mg vs Placebo	EXP	1	1.4277	0.7218	0.05	0.5300	3.8458	0.4959	0.4813
15mg vs Placebo	PARM	1	0.00573	0.5196	0.05	-1.0126	1.0241	0.0001	0.9912
15mg vs Placebo	EXP	1	1.0057	0.5226	0.05	0.3633	2.7846	0.0001	0.9912
30mg vs Placebo	PARM	1	1.2951	0.4869	0.05	0.3407	2.2494	7.0743	0.0078
30mg vs Placebo	EXP	1	3.6512	1.7778	0.05	1.4060	9.4820	7.0743	0.0078
45mg vs Placebo	PARM	1	0.6907	0.4923	0.05	-0.2742	1.6555	1.9683	0.1606
45mg vs Placebo	EXP	1	1.9950	0.9821	0.05	0.7602	5.2358	1.9683	0.1606

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.34
SAS Statistical Output for Table 11.33
Analysis of the Proportion of HbA1c Responders at Week 12

Logistic Model Output
Logistic regression Model for the HbA1c reduction >=0.7 category

Obs	Variable	Class Val0	Prob ChiSq
1	TRTCD	2.5mg	0.1979
2	TRTCD	7.5mg	0.4813
3	TRTCD	15mg	0.9912
4	TRTCD	30mg	0.0078
5	TRTCD	45mg	0.1606

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.35
Analysis of the Proportion of Fasting Plasma Glucose Responders at Week 12

Visit: Week 12	Placebo (N=62)		2.5mg (N=59)		7.5mg (N=62)		15mg (N=63)		30mg (N=58)		45mg (N=60)	
n [1]	62		58		62		63		58		60	
Number (%) of Values Carried Forward	13	(21%)	11	(19%)	9	(15%)	4	(6%)	2	(3%)	6	(10%)
Subjects with:												
FPG <7mmol/L	5	(8%)	8	(14%)	9	(15%)	4	(6%)	6	(10%)	9	(15%)
7=< FPG <7.8mmol/L	6	(10%)	5	(9%)	8	(13%)	4	(6%)	12	(21%)	8	(13%)
FPG >=7.8mmol/L	51	(82%)	45	(78%)	45	(73%)	55	(87%)	40	(69%)	43	(72%)
Increase or no reduction	34	(55%)	32	(55%)	30	(48%)	26	(41%)	21	(36%)	22	(37%)
Reduction 0 - <1.7mmol/L	20	(32%)	14	(24%)	19	(31%)	27	(43%)	19	(33%)	20	(33%)
Reduction 1.7 - <2.2mmol/L	4	(6%)	3	(5%)	4	(6%)	3	(5%)	4	(7%)	7	(12%)
Reduction 2.2 - <2.8mmol/L	2	(3%)	6	(10%)	2	(3%)	3	(5%)	2	(3%)	2	(3%)
Reduction >=2.8mmol/L	2	(3%)	3	(5%)	7	(11%)	4	(6%)	12	(21%)	9	(15%)

[1]Number of subjects with a value at baseline and at specified visit.
[2]Odds (Odds=Baseline+Gender+PriorTherapy+Treat) of having FPG < 7mmol/L at Week 12 on Active vs Placebo.
[3]Odds of having FPG >=1.7mmol/L decrease from baseline at Week 12 on Active vs Placebo.
[4]A closed test procedure will be used. Tests will be performed in a hierarchical manner, that is, tests will be applied sequentially where testing does not procede to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
Percentages are based on 'Number of Subjects' by treatment group.

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Table 11.35
Analysis of the Proportion of Fasting Plasma Glucose Responders at Week 12

Visit: Week 12	Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]	62	58	62	63	58	60
Number (%) of Values Carried Forward	13 (21%)	11 (19%)	9 (15%)	4 (6%)	2 (3%)	6 (10%)
Responders (<7mmol/L)	5 (8%)	8 (14%)	9 (15%)	4 (6%)	6 (10%)	9 (15%)
Odds Ratio to Placebo [2]		1.77	2.57	1.09	1.56	3.14
95% CI		0.50,6.30	0.72,9.11	0.26,4.62	0.41,5.91	0.89,11.14
p-val[4]		0.380	0.145	0.906	0.509	0.077
Responders (>=1.7mmol/L)	8 (13%)	12 (21%)	13 (21%)	10 (16%)	18 (31%)	18 (30%)
Odds Ratio to Placebo [3]		1.90	1.59	1.35	3.24	3.00
95% CI		0.63,5.72	0.55,4.62	0.45,4.00	1.15,9.13	1.08,8.30
p-val[4]		0.254	0.396	0.590	0.026	0.034

[1]Number of subjects with a value at baseline and at specified visit.
[2]Odds (Odds=Baseline+Gender+PriorTherapy+Treat) of having FPG < 7mmol/L at Week 12 on Active vs Placebo.
[3]Odds of having FPG >=1.7mmol/L decrease from baseline at Week 12 on Active vs Placebo.
[4]A closed test procedure will be used. Tests will be performed in a hierarchical manner, that is, tests will be applied sequentially where testing does not procede to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.
Percentages are based on 'Number of Subjects' by treatment group.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the number of subjects with values at baseline and specified visit

The FREQ Procedure

Table of AVISNUM by TRTCD

AVISNUM(Visit number for reporting) TRTCD(Randomized treatment code)

Frequency Percent Row Pct Col Pct	Placebo	2.5mg	7.5mg	15mg	30mg	45mg	Total
120	62	58	62	63	58	60	363
	17.08	15.98	17.08	17.36	15.98	16.53	100.00
	17.08	15.98	17.08	17.36	15.98	16.53	
	100.00	100.00	100.00	100.00	100.00	100.00	
Total	62	58	62	63	58	60	363
	17.08	15.98	17.08	17.36	15.98	16.53	100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency count of number of observations carried forward

The FREQ Procedure

Table 1 of TRTCD by EFLOCFIN
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)
EFLOCFIN(Carry forward value indicator (1=Y,0=N))

Frequency / Percent / Row Pct / Col Pct	0	1	Total
Placebo	49	13	62
	13.50	3.58	17.08
	79.03	20.97	
	15.41	28.89	
2.5mg	47	11	58
	12.95	3.03	15.98
	81.03	18.97	
	14.78	24.44	
7.5mg	53	9	62
	14.60	2.48	17.08
	85.48	14.52	
	16.67	20.00	
Total	318	45	363
	87.60	12.40	100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency count of number of observations carried forward

The FREQ Procedure

Table 1 of TRTCD by EFLOCFIN
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)
EFLOCFIN(Carry forward value indicator (1=Y,0=N))

Frequency / Percent / Row Pct / Col Pct	0	1	Total
15mg	59	4	63
	16.25	1.10	17.36
	93.65	6.35	
	18.55	8.89	
30mg	56	2	58
	15.43	0.55	15.98
	96.55	3.45	
	17.61	4.44	
45mg	54	6	60
	14.88	1.65	16.53
	90.00	10.00	
	16.98	13.33	
Total	318	45	363
	87.60	12.40	100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the categories of FPG

The FREQ Procedure

Table 1 of TRTCD by fpgfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)

TRTCD	fpgfl: FPG <7mmol/L	fpgfl: 7=< FPG <7.8mmol/L	fpgfl: FPG >=7.8mmol/L	Total
Placebo	5	6	51	62
	1.38	1.65	14.05	17.08
	8.06	9.68	82.26	
	12.20	13.95	18.28	
2.5mg	8	5	45	58
	2.20	1.38	12.40	15.98
	13.79	8.62	77.59	
	19.51	11.63	16.13	
7.5mg	9	8	45	62
	2.48	2.20	12.40	17.08
	14.52	12.90	72.58	
	21.95	18.60	16.13	
Total	41	43	279	363
	11.29	11.85	76.86	100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the categories of FPG

The FREQ Procedure

Table 1 of TRTCD by fpgfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code)

fpgfl Frequency Percent Row Pct Col Pct	FPG <7mmol/L	7=< FPG <7.8mmol/L	FPG >=7.8mmol/L	Total
15mg	4 1.10 6.35 9.76	4 1.10 6.35 9.30	55 15.15 87.30 19.71	63 17.36
30mg	6 1.65 10.34 14.63	12 3.31 20.69 27.91	40 11.02 68.97 14.34	58 15.98
45mg	9 2.48 15.00 21.95	8 2.20 13.33 18.60	43 11.85 71.67 15.41	60 16.53
Total	41 11.29	43 11.85	279 76.86	363 100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the reduction categories of FPG

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl

Frequency Percent Row Pct Col Pct	Increase/no reduction	Reduction 0 - <1.7mmol/L	Reduction 1.7 - <2.2mmol/L	Reduction 2.2 - <2.8mmol/L	Reduction >=2.8mmol/L	Total
Placebo	34 9.37 54.84 20.61	20 5.51 32.26 16.81	4 1.10 6.45 16.00	2 0.55 3.23 11.76	2 0.55 3.23 5.41	62 17.08
2.5mg	32 8.82 55.17 19.39	14 3.86 24.14 11.76	3 0.83 5.17 12.00	6 1.65 10.34 35.29	3 0.83 5.17 8.11	58 15.98
Total	165 45.45	119 32.78	25 6.89	17 4.68	37 10.19	363 100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the reduction categories of FPG

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl

Frequency / Percent / Row Pct / Col Pct	Increase/no reduction	Reduction 0 - <1.7mmol/L	Reduction 1.7 - <2.2mmol/L	Reduction 2.2 - <2.8mmol/L	Reduction >=2.8mmol/L	Total
7.5mg	30	19	4	2	7	62
	8.26	5.23	1.10	0.55	1.93	17.08
	48.39	30.65	6.45	3.23	11.29	
	18.18	15.97	16.00	11.76	18.92	
15mg	26	27	3	3	4	63
	7.16	7.44	0.83	0.83	1.10	17.36
	41.27	42.86	4.76	4.76	6.35	
	15.76	22.69	12.00	17.65	10.81	
Total	165	119	25	17	37	363
	45.45	32.78	6.89	4.68	10.19	100.00

(Continued)

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Frequency counts for the reduction categories of FPG

The FREQ Procedure

Table 1 of TRTCD by redfl
Controlling for AVISNUM=120

TRTCD(Randomized treatment code) redfl

Frequency / Percent / Row Pct / Col Pct	Increase/no reduction	Reduction 0 - <1.7mmol/L	Reduction 1.7 - <2.2mmol/L	Reduction 2.2 - <2.8mmol/L	Reduction >=2.8mmol/L	Total
30mg	21	19	4	2	12	58
	5.79	5.23	1.10	0.55	3.31	15.98
	36.21	32.76	6.90	3.45	20.69	
	12.73	15.97	16.00	11.76	32.43	
45mg	22	20	7	2	9	60
	6.06	5.51	1.93	0.55	2.48	16.53
	36.67	33.33	11.67	3.33	15.00	
	13.33	16.81	28.00	11.76	24.32	
Total	165	119	25	17	37	363
	45.45	32.78	6.89	4.68	10.19	100.00

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Model Information

Data Set	WORK.EFF	
Response Variable	a7fl	Responders (<7mmol/L)/Non Responders
Number of Response Levels	2	
Number of Observations	363	
Model	binary logit	
Optimization Technique	Fisher's scoring	

Response Profile

Ordered Value	a7fl	Total Frequency
1	Responders	41
2	Non-Responders	322

Probability modeled is a7fl='Responders'.

Class Level Information

Class	Value	Design Variables				
		1	2	3	4	5
TRTCD	Placebo	0	0	0	0	0
	2.5mg	1	0	0	0	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
	7.5mg	0	1	0	0	0
	15mg	0	0	1	0	0
	30mg	0	0	0	1	0
	45mg	0	0	0	0	1
SEX	Female	1				
	Male	0				
TRTTYPCD	Diet & Exercise	1				
	Monotherapy	0				

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	258.012	225.877
SC	261.907	260.927
-2 Log L	256.012	207.877

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	48.1352	8	<.0001
Score	40.1464	8	<.0001
Wald	34.7872	8	<.0001

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
TRTCD	5	4.9043	0.4277
SEX	1	0.7504	0.3863
TRTTYPCD	1	1.2681	0.2601
EFSTDBL	1	29.0890	<.0001

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Exp(Est)
Intercept		1	3.0575	1.1847	6.6607	0.0099	21.273
TRTCD	2.5mg	1	0.5692	0.6484	0.7706	0.3800	1.767
TRTCD	7.5mg	1	0.9423	0.6466	2.1237	0.1450	2.566
TRTCD	15mg	1	0.0872	0.7359	0.0140	0.9057	1.091
TRTCD	30mg	1	0.4475	0.6783	0.4353	0.5094	1.564
TRTCD	45mg	1	1.1443	0.6461	3.1369	0.0765	3.140
SEX	Female	1	0.3165	0.3654	0.7504	0.3863	1.372
TRTTYPCD	Diet & Exercise	1	0.4143	0.3679	1.2681	0.2601	1.513
EFSTDBL		1	-0.6713	0.1245	29.0890	<.0001	0.511

Odds Ratio Estimates

Effect			Point Estimate	95% Wald Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.767	0.496	6.297
TRTCD	7.5mg	vs Placebo	2.566	0.722	9.113
TRTCD	15mg	vs Placebo	1.091	0.258	4.616
TRTCD	30mg	vs Placebo	1.564	0.414	5.911
TRTCD	45mg	vs Placebo	3.140	0.885	11.141
SEX	Female	vs Male	1.372	0.671	2.809
TRTTYPCD	Diet & Exercise	vs Monotherapy	1.513	0.736	3.112
EFSTDBL			0.511	0.400	0.652

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	78.0	Somers' D	0.566
Percent Discordant	21.5	Gamma	0.569
Percent Tied	0.5	Tau-a	0.114
Pairs	13202	c	0.783

Profile Likelihood Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.767	0.505	6.708
TRTCD	7.5mg	vs Placebo	1.0000	2.566	0.744	9.794
TRTCD	15mg	vs Placebo	1.0000	1.091	0.242	4.687
TRTCD	30mg	vs Placebo	1.0000	1.564	0.412	6.206
TRTCD	45mg	vs Placebo	1.0000	3.140	0.916	12.010
SEX	Female vs Male		1.0000	1.372	0.673	2.843
TRTTYPCD	Diet & Exercise vs Monotherapy		1.0000	1.513	0.735	3.137
EFSTDBL			1.0000	0.511	0.395	0.644

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.767	0.496	6.297
TRTCD	7.5mg	vs Placebo	1.0000	2.566	0.722	9.113
TRTCD	15mg	vs Placebo	1.0000	1.091	0.258	4.616

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Wald Confidence Interval for Adjusted Odds Ratios

Effect		Unit	Estimate	95% Confidence Limits	
TRTCD	30mg vs Placebo	1.0000	1.564	0.414	5.911
TRTCD	45mg vs Placebo	1.0000	3.140	0.885	11.141
SEX	Female vs Male	1.0000	1.372	0.671	2.809
TRTTYPCD	Diet & Exercise vs Monotherapy	1.0000	1.513	0.736	3.112
EFSTDBL		1.0000	0.511	0.400	0.652

Coefficients of Contrast 2.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	1
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Coefficients of Contrast 7.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	1
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 15mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	1
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Coefficients of Contrast 30mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	1
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 45mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	1
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Logistic regression model for the FPG < 7 category

The LOGISTIC Procedure

Contrast Test Results

Contrast	DF	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	1	0.7706	0.3800
7.5mg vs Placebo	1	2.1237	0.1450
15mg vs Placebo	1	0.0140	0.9057
30mg vs Placebo	1	0.4353	0.5094
45mg vs Placebo	1	3.1369	0.0765

Contrast Rows Estimation and Testing Results

Contrast	Type	Row	Estimate	Standard Error	Alpha	Lower Limit	Upper Limit	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	PARM	1	0.5692	0.6484	0.05	-0.7017	1.8401	0.7706	0.3800
2.5mg vs Placebo	EXP	1	1.7669	1.1457	0.05	0.4957	6.2974	0.7706	0.3800
7.5mg vs Placebo	PARM	1	0.9423	0.6466	0.05	-0.3250	2.2097	2.1237	0.1450
7.5mg vs Placebo	EXP	1	2.5660	1.6593	0.05	0.7225	9.1133	2.1237	0.1450
15mg vs Placebo	PARM	1	0.0872	0.7359	0.05	-1.3552	1.5296	0.0140	0.9057
15mg vs Placebo	EXP	1	1.0911	0.8030	0.05	0.2579	4.6163	0.0140	0.9057
30mg vs Placebo	PARM	1	0.4475	0.6783	0.05	-0.8819	1.7769	0.4353	0.5094
30mg vs Placebo	EXP	1	1.5644	1.0611	0.05	0.4140	5.9115	0.4353	0.5094
45mg vs Placebo	PARM	1	1.1443	0.6461	0.05	-0.1220	2.4107	3.1369	0.0765
45mg vs Placebo	EXP	1	3.1403	2.0290	0.05	0.8851	11.1413	3.1369	0.0765

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Model Information

Data Set	WORK.EFF	
Response Variable	r17fl	Responders (>1.7mmol/L)/Non Responders
Number of Response Levels	2	
Number of Observations	363	
Model	binary logit	
Optimization Technique	Fisher's scoring	

Response Profile

Ordered Value	r17fl	Total Frequency
1	Responders	79
2	Non-Responders	284

Probability modeled is r17fl='Responders'.

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
TRTCD	Placebo	0	0	0	0	0
	2.5mg	1	0	0	0	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

[redacted]

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Class Level Information

		Design Variables				
Class	Value	1	2	3	4	5
	7.5mg	0	1	0	0	0
	15mg	0	0	1	0	0
	30mg	0	0	0	1	0
	45mg	0	0	0	0	1
SEX	Female	1				
	Male	0				
TRTTYPCD	Diet & Exercise	1				
	Monotherapy	0				

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

[redacted]

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	382.346	324.462
SC	386.241	359.512
-2 Log L	380.346	306.462

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	73.8841	8	<.0001
Score	71.3030	8	<.0001
Wald	52.0614	8	<.0001

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
TRTCD	5	8.2476	0.1431
SEX	1	1.0332	0.3094
TRTTYPCD	1	9.2191	0.0024
EFSTDBL	1	44.6928	<.0001

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Exp(Est)
Intercept		1	-8.3336	1.0718	60.4588	<.0001	0.000
TRTCD	2.5mg	1	0.6413	0.5622	1.3010	0.2540	1.899
TRTCD	7.5mg	1	0.4630	0.5449	0.7218	0.3955	1.589
TRTCD	15mg	1	0.2991	0.5548	0.2907	0.5898	1.349
TRTCD	30mg	1	1.1743	0.5292	4.9245	0.0265	3.236
TRTCD	45mg	1	1.0984	0.5194	4.4730	0.0344	2.999
SEX	Female	1	0.2964	0.2916	1.0332	0.3094	1.345
TRTTYPCD	Diet & Exercise	1	0.9183	0.3024	9.2191	0.0024	2.505
EFSTDBL		1	0.5680	0.0850	44.6928	<.0001	1.765

Odds Ratio Estimates

Effect			Point Estimate	95% Wald Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.899	0.631	5.716
TRTCD	7.5mg	vs Placebo	1.589	0.546	4.623
TRTCD	15mg	vs Placebo	1.349	0.455	4.000
TRTCD	30mg	vs Placebo	3.236	1.147	9.130
TRTCD	45mg	vs Placebo	2.999	1.084	8.301
SEX	Female	vs Male	1.345	0.759	2.382
TRTTYPCD	Diet & Exercise	vs Monotherapy	2.505	1.385	4.532
EFSTDBL			1.765	1.494	2.085

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	79.7	Somers' D	0.596
Percent Discordant	20.0	Gamma	0.599
Percent Tied	0.3	Tau-a	0.204
Pairs	22436	c	0.798

Profile Likelihood Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.899	0.637	5.904
TRTCD	7.5mg	vs Placebo	1.0000	1.589	0.553	4.786
TRTCD	15mg	vs Placebo	1.0000	1.349	0.457	4.123
TRTCD	30mg	vs Placebo	1.0000	3.236	1.180	9.571
TRTCD	45mg	vs Placebo	1.0000	2.999	1.116	8.709
SEX	Female vs Male		1.0000	1.345	0.762	2.398
TRTTYPCD	Diet & Exercise vs Monotherapy		1.0000	2.505	1.394	4.579
EFSTDBL			1.0000	1.765	1.506	2.104

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	2.5mg	vs Placebo	1.0000	1.899	0.631	5.716
TRTCD	7.5mg	vs Placebo	1.0000	1.589	0.546	4.623
TRTCD	15mg	vs Placebo	1.0000	1.349	0.455	4.000

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Wald Confidence Interval for Adjusted Odds Ratios

Effect			Unit	Estimate	95% Confidence Limits	
TRTCD	30mg	vs Placebo	1.0000	3.236	1.147	9.130
TRTCD	45mg	vs Placebo	1.0000	2.999	1.084	8.301
SEX	Female	vs Male	1.0000	1.345	0.759	2.382
TRTTYPCD	Diet & Exercise	vs Monotherapy	1.0000	2.505	1.385	4.532
EFSTDBL			1.0000	1.765	1.494	2.085

Coefficients of Contrast 2.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	1
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Coefficients of Contrast 7.5mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	1
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 15mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	1
TRTCD30mg	0
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Coefficients of Contrast 30mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	1
TRTCD45mg	0
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Coefficients of Contrast 45mg vs Placebo

Parameter	Row1
Intercept	0
TRTCD2_5mg	0
TRTCD7_5mg	0
TRTCD15mg	0
TRTCD30mg	0
TRTCD45mg	1
SEXFemale	0
TRTTYPCDDiet___Exercise	0
EFSTDBL	0

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Table 11.36
SAS Statistical Output for Table 11.35
Analysis of the Proportion of Fasting Glucose Responders at Week 12

Logistic Model Output
Lgistic regression model for the FPG reduction >=1.7 category

The LOGISTIC Procedure

Contrast Test Results

Contrast	DF	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	1	1.3010	0.2540
7.5mg vs Placebo	1	0.7218	0.3955
15mg vs Placebo	1	0.2907	0.5898
30mg vs Placebo	1	4.9245	0.0265
45mg vs Placebo	1	4.4730	0.0344

Contrast Rows Estimation and Testing Results

Contrast	Type	Row	Estimate	Standard Error	Alpha	Lower Limit	Upper Limit	Wald Chi-Square	Pr > ChiSq
2.5mg vs Placebo	PARM	1	0.6413	0.5622	0.05	-0.4607	1.7432	1.3010	0.2540
2.5mg vs Placebo	EXP	1	1.8989	1.0676	0.05	0.6309	5.7157	1.3010	0.2540
7.5mg vs Placebo	PARM	1	0.4630	0.5449	0.05	-0.6050	1.5310	0.7218	0.3955
7.5mg vs Placebo	EXP	1	1.5888	0.8658	0.05	0.5460	4.6227	0.7218	0.3955
15mg vs Placebo	PARM	1	0.2991	0.5548	0.05	-0.7882	1.3864	0.2907	0.5898
15mg vs Placebo	EXP	1	1.3486	0.7482	0.05	0.4547	4.0004	0.2907	0.5898
30mg vs Placebo	PARM	1	1.1743	0.5292	0.05	0.1371	2.2115	4.9245	0.0265
30mg vs Placebo	EXP	1	3.2360	1.7124	0.05	1.1470	9.1295	4.9245	0.0265
45mg vs Placebo	PARM	1	1.0984	0.5194	0.05	0.0805	2.1163	4.4730	0.0344
45mg vs Placebo	EXP	1	2.9994	1.5577	0.05	1.0838	8.3005	4.4730	0.0344

Trttypcd is the prior therapy variable and Efstdbl is the baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.37
Summary Statistics of Log-Transformed Triglycerides (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	60	61	56	57
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	2.01	1.90	1.81	1.92	2.00	2.00
	CV (%) [2]	37.439	53.618	54.029	48.043	49.865	54.535
Week -5	Geo Mean	1.94	1.98	1.70	1.89	1.96	1.97
	CV (%) [2]	39.311	49.470	50.125	44.725	40.330	51.284
	Geo Mean - SE[3]	1.85	1.86	1.60	1.79	1.86	1.85
	Geo Mean + SE[3]	2.04	2.10	1.81	1.99	2.07	2.10
	Minimum	0.6	0.8	0.7	0.5	0.7	0.6
	Median	2.04	1.86	1.64	1.93	1.99	1.98
	Maximum	4.4	6.8	5.5	4.2	4.2	5.3
Ratio to Baseline (%) [4]	Geo Mean	-3.62	3.79	-5.99	-1.73	-1.99	-1.54
	Geo Mean - SE[3]	-7.60	-0.79	-10.95	-5.90	-6.99	-6.25
	Geo Mean + SE[3]	0.52	8.58	-0.76	2.63	3.27	3.40
	Minimum	-67.4	-62.7	-89.6	-61.6	-81.2	-63.9
	Median	-1.82	7.41	-3.83	7.44	-1.21	0.00
	Maximum	110.6	89.6	179.3	91.3	169.7	145.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.37
Summary Statistics of Log-Transformed Triglycerides (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	61	62	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	2.01	1.90	1.85	1.92	2.00	1.97
	CV (%) [2]	37.439	53.618	57.122	47.607	49.865	54.681
	Geo Mean - SE[3]	1.92	1.78	1.73	1.81	1.88	1.84
	Geo Mean + SE[3]	2.11	2.03	1.98	2.03	2.13	2.11
	Minimum	1.0	0.7	0.8	0.7	0.8	0.8
	Median	2.10	1.82	1.72	1.80	1.91	1.91
	Maximum	4.0	7.0	8.4	5.0	20.4	7.3

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.37
Summary Statistics of Log-Transformed Triglycerides (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	57	58	61	53	57
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	4 (7%)	2 (3%)	0	2 (4%)
Baseline	Geo Mean	1.98	1.90	1.82	1.91	1.93	2.00
	CV (%) [2]	38.109	54.695	56.351	47.944	36.921	54.775
Week 4	Geo Mean	2.00	1.75	1.59	1.83	1.77	1.81
	CV (%) [2]	44.970	51.381	47.871	54.763	37.683	47.671
	Geo Mean - SE[3]	1.89	1.64	1.49	1.72	1.68	1.70
	Geo Mean + SE[3]	2.12	1.87	1.68	1.96	1.86	1.92
	Minimum	0.8	0.6	0.7	0.5	0.7	0.9
	Median	1.93	1.74	1.55	1.61	1.69	1.75
	Maximum	5.6	11.2	5.2	5.4	3.9	6.1
Ratio to Baseline (%) [4]	Geo Mean	1.10	-8.10	-12.80	-4.21	-8.39	-9.82
	Geo Mean - SE[3]	-3.17	-12.11	-17.15	-8.00	-12.18	-13.64
	Geo Mean + SE[3]	5.57	-3.89	-8.23	-0.26	-4.44	-5.83
	Minimum	-56.9	-51.8	-83.6	-77.6	-52.6	-63.8
	Median	-1.60	-10.71	-9.12	-3.97	-10.50	-9.86
	Maximum	146.9	93.8	143.3	105.1	298.7	82.1

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.37
Summary Statistics of Log-Transformed Triglycerides (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	59	62	56	58
Number (%) of Values Carried Forward		9 (16%)	13 (22%)	7 (12%)	2 (3%)	2 (4%)	9 (16%)
Baseline	Geo Mean	2.01	1.90	1.81	1.92	2.00	1.99
	CV (%) [2]	38.362	54.148	56.008	47.607	49.865	54.802
Week 8	Geo Mean	1.91	1.81	1.68	1.86	1.73	1.78
	CV (%) [2]	39.110	51.365	48.933	51.903	37.177	43.633
	Geo Mean - SE[3]	1.82	1.70	1.58	1.74	1.65	1.68
	Geo Mean + SE[3]	2.01	1.93	1.79	1.97	1.81	1.88
	Minimum	0.8	0.7	0.7	0.9	0.9	0.8
	Median	1.93	1.78	1.58	1.69	1.72	1.64
	Maximum	4.4	11.2	9.8	11.2	4.3	4.7
Ratio to Baseline (%) [4]	Geo Mean	-5.00	-5.06	-6.98	-3.31	-13.76	-10.43
	Geo Mean - SE[3]	-9.19	-9.61	-11.01	-7.82	-17.53	-14.26
	Geo Mean + SE[3]	-0.62	-0.29	-2.77	1.42	-9.82	-6.43
	Minimum	-59.8	-78.8	-51.2	-68.0	-80.2	-63.8
	Median	0.00	0.39	-9.29	-0.81	-10.93	-8.22
	Maximum	150.3	125.5	139.2	473.3	87.1	89.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.37
Summary Statistics of Log-Transformed Triglycerides (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	60	62	56	58
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)	4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	2.01	1.90	1.82	1.92	2.00	1.99
	CV (%) [2]	38.362	54.148	55.857	47.607	49.865	54.802
Week 12	Geo Mean	1.96	1.82	1.66	1.87	1.63	1.76
	CV (%) [2]	44.599	48.890	51.163	49.921	33.755	44.378
	Geo Mean - SE[3]	1.86	1.71	1.56	1.77	1.56	1.66
	Geo Mean + SE[3]	2.07	1.94	1.77	1.99	1.71	1.86
	Minimum	0.8	0.7	0.7	0.6	0.8	0.7
	Median	2.06	1.83	1.52	1.85	1.68	1.67
	Maximum	5.3	11.2	7.5	7.0	4.0	4.1
Ratio to Baseline (%) [4]	Geo Mean	-2.33	-4.37	-8.74	-2.37	-18.48	-11.48
	Geo Mean - SE[3]	-7.46	-8.83	-12.35	-6.54	-22.72	-16.38
	Geo Mean + SE[3]	3.10	0.31	-4.98	1.99	-14.01	-6.30
	Minimum	-72.2	-68.3	-59.8	-60.8	-90.4	-63.8
	Median	4.37	2.19	-6.05	-3.42	-14.48	-15.74
	Maximum	203.4	96.1	74.7	261.0	72.4	221.6

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		58	58	60
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)
Baseline	Geo Mean	2.01	1.90	1.82
	CV (%) [2]	38.362	54.148	55.857
Week 12	Geo Mean	1.96	1.82	1.66
	CV (%) [2]	44.599	48.890	51.163
Ratio to Baseline (% chg) [3]	Geo Mean	-2.33	-4.37	-8.74
	Geo Mean -SE,+SE	-7.46,3.10	-8.83,0.31	-12.35,-4.98
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-1.42	-4.62	-11.02
	Geo Mean -SE,+SE	-5.61,2.96	-8.67,-0.39	-14.73,-7.14
Ratio to Baseline (% diff) [4]	Geo Mean		-3.25	-9.74
	95% CI		-14.30,9.22	-19.93,1.75
	p-val[5]		0.592	0.094

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant trestment difference are for descriptive purposes only.

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Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	56	58
Number (%) of Values Carried Forward		4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	1.92	2.00	1.99
	CV (%) [2]	47.607	49.865	54.802
Week 12	Geo Mean	1.87	1.63	1.76
	CV (%) [2]	49.921	33.755	44.378
Ratio to Baseline (% chg) [3]	Geo Mean	-2.37	-18.48	-11.48
	Geo Mean -SE,+SE	-6.54,1.99	-22.72,-14.01	-16.38,-6.30
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-2.82	-17.46	-10.37
	Geo Mean -SE,+SE	-6.80,1.33	-21.02,-13.74	-14.17,-6.40
Ratio to Baseline (% diff) [4]	Geo Mean	-1.42	-16.27	-9.08
	95% CI	-12.46,11.01	-25.85,-5.46	-19.42,2.58
	p-val[5]	0.813	0.004	0.122

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant trestment difference are for descriptive purposes only.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.69746417	Sum Observations	40.452922
Std Deviation	0.37052937	Variance	0.13729201
Skewness	-0.1289534	Kurtosis	-0.9219668
Uncorrected SS	36.0401085	Corrected SS	7.82564475
Coeff Variation	53.1252189	Std Error Mean	0.04865289

Basic Statistical Measures

Location		Variability	
Mean	0.69746	Std Deviation	0.37053
Median	0.74194	Variance	0.13729
Mode	-0.04082	Range	1.43210
		Interquartile Range	0.62169

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	14.33551	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	852.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.3912819
99%	1.3912819
95%	1.2354715
90%	1.1969482
75% Q3	0.9932518
50% Median	0.7419373
25% Q1	0.3715636
10%	0.1988509
5%	0.0953102
1%	-0.0408220
0% Min	-0.0408220

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.0408220	46	1.20597	56
-0.0408220	30	1.22378	52
0.0953102	20	1.23547	13
0.1222176	1	1.32442	12
0.1739533	50	1.39128	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.67393852	Sum Observations	39.0884339
Std Deviation	0.42592093	Variance	0.18140864
Skewness	-0.0153206	Kurtosis	0.0836027
Uncorrected SS	36.6834936	Corrected SS	10.3402925
Coeff Variation	63.1987817	Std Error Mean	0.05592616

Basic Statistical Measures

Location		Variability	
Mean	0.673939	Std Deviation	0.42592
Median	0.722706	Variance	0.18141
Mode	0.652325	Range	1.95161
		Interquartile Range	0.50948

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.05051	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	831.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.663926
99%	1.663926
95%	1.521699
90%	1.308333
75% Q3	0.908259
50% Median	0.722706
25% Q1	0.398776
10%	0.076961
5%	-0.105361
1%	-0.287682
0% Min	-0.287682

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2876821	38	1.31103	10
-0.1743534	17	1.33763	42
-0.1053605	47	1.52170	49
-0.0725707	11	1.59737	26
0.0392207	30	1.66393	32

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0235257	Sum Observations	-1.3644881
Std Deviation	0.41132744	Variance	0.16919026
Skewness	-0.1288074	Kurtosis	1.44504155
Uncorrected SS	9.67594557	Corrected SS	9.64384509
Coeff Variation	-1748.4206	Std Error Mean	0.05400994

Basic Statistical Measures

Location		Variability	
Mean	-0.02353	Std Deviation	0.41133
Median	0.04272	Variance	0.16919
Mode		Range	2.39097
		Interquartile Range	0.45180

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.43558	Pr > |t|	0.6648
Sign	M	3	Pr >= |M|	0.5118

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-53.5	Pr >= |S|	0.6824

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1100410
99%	1.1100410
95%	0.7820005
90%	0.4476979
75% Q3	0.1803817
50% Median	0.0427168
25% Q1	-0.2714216
10%	-0.4653632
5%	-0.7092333
1%	-1.2809338
0% Min	-1.2809338

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SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.280934	38	0.459532	46
-0.911769	51	0.710691	1
-0.709233	12	0.782001	26
-0.618184	56	0.798208	10
-0.594707	48	1.110041	32

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.64407911	Sum Observations	37.3565881
Std Deviation	0.50707344	Variance	0.25712348
Skewness	0.36361561	Kurtosis	-0.0631007
Uncorrected SS	38.716636	Corrected SS	14.6560381
Coeff Variation	78.7284416	Std Error Mean	0.066582

Basic Statistical Measures

Location		Variability	
Mean	0.64408	Std Deviation	0.50707
Median	0.59884	Variance	0.25712
Mode	-0.04082	Range	2.26347
		Interquartile Range	0.74639

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.673471	Pr > |t|	<.0001
Sign	M	24	Pr >= |M|	<.0001
Signed Rank	S	805.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9487632
99%	1.9487632
95%	1.7509375
90%	1.2809338
75% Q3	0.9932518
50% Median	0.5988365
25% Q1	0.2468601
10%	0.0198026
5%	-0.1053605
1%	-0.3147107
0% Min	-0.3147107

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.314711	23	1.28647	7
-0.248461	49	1.34025	48
-0.105361	18	1.75094	29
-0.040822	37	1.81808	35
-0.040822	6	1.94876	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.5994289	Sum Observations	34.766876
Std Deviation	0.46295085	Variance	0.21432349
Skewness	1.12314836	Kurtosis	3.2308218
Uncorrected SS	33.0567091	Corrected SS	12.216439
Coeff Variation	77.2319876	Std Error Mean	0.06078842

Basic Statistical Measures

Location		Variability	
Mean	0.599429	Std Deviation	0.46295
Median	0.601576	Variance	0.21432
Mode	0.482426	Range	2.71344
		Interquartile Range	0.55639

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.860905	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	826.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.4123360
99%	2.4123360
95%	1.5810384
90%	1.0647107
75% Q3	0.8415672
50% Median	0.6015762
25% Q1	0.2851789
10%	0.0953102
5%	-0.0304592
1%	-0.3011051
0% Min	-0.3011051

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3011051	41	1.25846	34
-0.1984509	33	1.28647	26
-0.0304592	22	1.58104	57
-0.0202027	49	1.59331	35
0.0582689	15	2.41234	29

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0446502	Sum Observations	-2.5897121
Std Deviation	0.36393212	Variance	0.13244659
Skewness	-0.3531351	Kurtosis	0.45556602
Uncorrected SS	7.6650866	Corrected SS	7.54945541
Coeff Variation	-815.07373	Std Error Mean	0.04778663

Basic Statistical Measures

Location		Variability	
Mean	-0.04465	Std Deviation	0.36393
Median	0.02168	Variance	0.13245
Mode		Range	1.82241
		Interquartile Range	0.45636

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.93437	Pr > |t|	0.3541
Sign	M	2	Pr >= |M|	0.6940

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-93.5	Pr >= |S|	0.4739

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6735387
99%	0.6735387
95%	0.6613985
90%	0.3537637
75% Q3	0.2031651
50% Median	0.0216752
25% Q1	-0.2531959
10%	-0.5445367
5%	-0.6273006
1%	-1.1488741
0% Min	-1.1488741

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.148874	22	0.410021	23
-0.690302	34	0.545917	19
-0.627301	48	0.661398	29
-0.626136	16	0.664748	57
-0.597837	56	0.673539	9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	60	Sum Weights	60
Mean	0.60044853	Sum Observations	36.0269117
Std Deviation	0.5211046	Variance	0.27155
Skewness	1.064056	Kurtosis	1.43487253
Uncorrected SS	37.6537562	Corrected SS	16.0214502
Coeff Variation	86.78589	Std Error Mean	0.06727431

Basic Statistical Measures

Location		Variability	
Mean	0.600449	Std Deviation	0.52110
Median	0.527574	Variance	0.27155
Mode	0.131028	Range	2.36038
		Interquartile Range	0.56671

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.925376	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001
Signed Rank	S	842	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.12465388
99%	2.12465388
95%	1.90905173
90%	1.18922647
75% Q3	0.81727985
50% Median	0.52757396
25% Q1	0.25056943
10%	0.00990131
5%	-0.15680773
1%	-0.23572233
0% Min	-0.23572233

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2357223	50	1.36609	24
-0.1863296	22	1.85942	39
-0.1743534	27	1.95869	53
-0.1392621	41	1.98238	38
-0.0202027	35	2.12465	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	60	Sum Weights	60
Mean	0.50899533	Sum Observations	30.5397197
Std Deviation	0.48219587	Variance	0.23251286
Skewness	0.83305927	Kurtosis	0.59683532
Uncorrected SS	29.2628335	Corrected SS	13.7182588
Coeff Variation	94.7348331	Std Error Mean	0.06225122

Basic Statistical Measures

Location		Variability	
Mean	0.508995	Std Deviation	0.48220
Median	0.418710	Variance	0.23251
Mode	0.418710	Range	2.34607
		Interquartile Range	0.60826

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.176472	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	847	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.0175661
99%	2.0175661
95%	1.3871436
90%	1.2294310
75% Q3	0.7649375
50% Median	0.4187103
25% Q1	0.1566749
10%	0.0246807
5%	-0.0833816
1%	-0.3285041
0% Min	-0.3285041

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3285041	29	1.27536	20
-0.3011051	27	1.31103	53
-0.0833816	44	1.46326	10
-0.0833816	6	1.58104	38
-0.0618754	23	2.01757	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	-0.0914532	Sum Observations	-5.487192
Std Deviation	0.31245654	Variance	0.09762909
Skewness	-0.3741847	Kurtosis	-0.1117725
Uncorrected SS	6.26193751	Corrected SS	5.76011624
Coeff Variation	-341.65731	Std Error Mean	0.04033797

Basic Statistical Measures

Location		Variability	
Mean	-0.09145	Std Deviation	0.31246
Median	-0.06243	Variance	0.09763
Mode	-0.35341	Range	1.46929
		Interquartile Range	0.40951

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.26717	Pr > |t|	0.0271
Sign	M	-5	Pr >= |M|	0.2451

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-265	Pr >= |S|	0.0502

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5579724
99%	0.5579724
95%	0.3937657
90%	0.3185823
75% Q3	0.1091968
50% Median	-0.0624251
25% Q1	-0.3003119
10%	-0.5226379
5%	-0.6626722
1%	-0.9113197
0% Min	-0.9113197

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.911320	54	0.367982	10
-0.682297	52	0.371564	12
-0.677691	39	0.415968	3
-0.647653	53	0.434573	50
-0.608730	42	0.557972	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	62	Sum Weights	62
Mean	0.65217619	Sum Observations	40.4349236
Std Deviation	0.4519763	Variance	0.20428257
Skewness	0.30469255	Kurtosis	-0.7010581
Uncorrected SS	38.8319312	Corrected SS	12.4612369
Coeff Variation	69.3027904	Std Error Mean	0.05740105

Basic Statistical Measures

Location		Variability	
Mean	0.652176	Std Deviation	0.45198
Median	0.587771	Variance	0.20428
Mode	0.113329	Range	1.91054
		Interquartile Range	0.73337

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.36175	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	925.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.609438
99%	1.609438
95%	1.401183
90%	1.249902
75% Q3	1.026042
50% Median	0.587771
25% Q1	0.292670
10%	0.122218
5%	0.000000
1%	-0.301105
0% Min	-0.301105

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3011051	54	1.40118	19
-0.0408220	51	1.40118	42
-0.0100503	16	1.51732	41
0.0000000	25	1.57691	35
0.1133287	59	1.60944	61

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	62	Sum Weights	62
Mean	0.62820009	Sum Observations	38.9484054
Std Deviation	0.47171158	Variance	0.22251182
Skewness	0.40118999	Kurtosis	0.41856206
Uncorrected SS	38.0406126	Corrected SS	13.573221
Coeff Variation	75.0893854	Std Error Mean	0.05990743

Basic Statistical Measures

Location		Variability	
Mean	0.628200	Std Deviation	0.47171
Median	0.612476	Variance	0.22251
Mode	0.165514	Range	2.51373
		Interquartile Range	0.59784

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.48618	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	937.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9516082
99%	1.9516082
95%	1.4586150
90%	1.2470323
75% Q3	0.8754687
50% Median	0.6124756
25% Q1	0.2776317
10%	0.1043600
5%	-0.0304592
1%	-0.5621189
0% Min	-0.5621189

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.5621189	54	1.43031	60
-0.1392621	53	1.45862	61
-0.0618754	52	1.53471	35
-0.0304592	5	1.60944	62
0.0582689	23	1.95161	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-0.0239761	Sum Observations	-1.4865182
Std Deviation	0.34363691	Variance	0.11808632
Skewness	0.48303777	Kurtosis	3.19147898
Uncorrected SS	7.23890664	Corrected SS	7.20326573
Coeff Variation	-1433.2477	Std Error Mean	0.04364193

Basic Statistical Measures

Location		Variability	
Mean	-0.02398	Std Deviation	0.34364
Median	-0.03483	Variance	0.11809
Mode		Range	2.22123
		Interquartile Range	0.39209

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.54938	Pr > |t|	0.5847
Sign	M	-1.5	Pr >= |M|	0.7982

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-97	Pr >= |S|	0.4905

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.2837788
99%	1.2837788
95%	0.3988426
90%	0.2618408
75% Q3	0.1678809
50% Median	-0.0348339
25% Q1	-0.2242125
10%	-0.3837723
5%	-0.4920056
1%	-0.9374490
0% Min	-0.9374490

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.937449	42	0.332134	46
-0.801950	53	0.398843	43
-0.696155	18	0.546544	44
-0.492006	47	0.725670	62
-0.470004	41	1.283779	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	56	Sum Weights	56
Mean	0.69483406	Sum Observations	38.9107073
Std Deviation	0.47123352	Variance	0.22206103
Skewness	2.01438218	Kurtosis	9.78657743
Uncorrected SS	39.2498413	Corrected SS	12.2133566
Coeff Variation	67.819577	Std Error Mean	0.06297123

Basic Statistical Measures

Location		Variability	
Mean	0.694834	Std Deviation	0.47123
Median	0.647103	Variance	0.22206
Mode	0.797507	Range	3.28997
		Interquartile Range	0.53556

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.03415	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	787	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	3.0155349
99%	3.0155349
95%	1.3190856
90%	1.1505720
75% Q3	0.9341287
50% Median	0.6471032
25% Q1	0.3985734
10%	0.2311117
5%	-0.0202027
1%	-0.2744368
0% Min	-0.2744368

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2744368	38	1.23547	5
-0.0618754	21	1.28093	56
-0.0202027	46	1.31909	32
0.1570037	49	1.35067	10
0.2151114	29	3.01553	23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	56	Sum Weights	56
Mean	0.49047251	Sum Observations	27.4664604
Std Deviation	0.32848619	Variance	0.10790318
Skewness	0.0433858	Kurtosis	0.23595389
Uncorrected SS	19.4062183	Corrected SS	5.93467463
Coeff Variation	66.9734149	Std Error Mean	0.04389581

Basic Statistical Measures

Location		Variability	
Mean	0.490473	Std Deviation	0.32849
Median	0.515809	Variance	0.10790
Mode	0.270027	Range	1.65823
		Interquartile Range	0.41809

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.17356	Pr > |t|	<.0001
Sign	M	23	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	772	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.3837912
99%	1.3837912
95%	1.0986123
90%	0.8544153
75% Q3	0.6881220
50% Median	0.5158087
25% Q1	0.2700271
10%	0.1133287
5%	-0.0943107
1%	-0.2744368
0% Min	-0.2744368

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.2744368	21	0.924259	10
-0.0943107	46	0.955511	35
-0.0943107	6	1.098612	32
-0.0833816	7	1.111858	8
-0.0618754	14	1.383791	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.2043616	Sum Observations	-11.444247
Std Deviation	0.39984379	Variance	0.15987505
Skewness	-2.7459514	Kurtosis	14.2564117
Uncorrected SS	11.131892	Corrected SS	8.79312793
Coeff Variation	-195.65509	Std Error Mean	0.05343137

Basic Statistical Measures

Location		Variability	
Mean	-0.20436	Std Deviation	0.39984
Median	-0.15649	Variance	0.15988
Mode		Range	2.88705
		Interquartile Range	0.36334

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.82475	Pr > |t|	0.0003
Sign	M	-15	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-503	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5444640
99%	0.5444640
95%	0.3155169
90%	0.1483198
75% Q3	-0.0183767
50% Median	-0.1564924
25% Q1	-0.3817202
10%	-0.5195784
5%	-0.6264558
1%	-2.3425904
0% Min	-2.3425904

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-2.342590	23	0.211970	52
-0.933990	16	0.300105	37
-0.626456	25	0.315517	29
-0.596205	7	0.367725	35
-0.586604	14	0.544464	38

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.68595465	Sum Observations	39.7853696
Std Deviation	0.5124609	Variance	0.26261617
Skewness	0.33230772	Kurtosis	-0.5566411
Uncorrected SS	42.2600811	Corrected SS	14.9691219
Coeff Variation	74.7076941	Std Error Mean	0.06728941

Basic Statistical Measures

Location		Variability	
Mean	0.685955	Std Deviation	0.51246
Median	0.649714	Variance	0.26262
Mode	0.285179	Range	2.18358
		Interquartile Range	0.80235

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.19409	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	830.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9851309
99%	1.9851309
95%	1.6389967
90%	1.3376292
75% Q3	1.0647107
50% Median	0.6497142
25% Q1	0.2623643
10%	0.0582689
5%	-0.0833816
1%	-0.1984509
0% Min	-0.1984509

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.1984509	45	1.38128	39
-0.1165338	9	1.38629	3
-0.0833816	30	1.63900	43
-0.0304592	52	1.79509	33
0.0198026	15	1.98513	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.56396668	Sum Observations	32.7100673
Std Deviation	0.42399586	Variance	0.17977249
Skewness	0.00189389	Kurtosis	-0.5236126
Uncorrected SS	28.6944197	Corrected SS	10.2470318
Coeff Variation	75.1810124	Std Error Mean	0.05567338

Basic Statistical Measures

Location		Variability	
Mean	0.563967	Std Deviation	0.42400
Median	0.512824	Variance	0.17977
Mode	0.058269	Range	1.83933
		Interquartile Range	0.64589

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.12992	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	804.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.4085450
99%	1.4085450
95%	1.2178757
90%	1.1216776
75% Q3	0.9082586
50% Median	0.5128236
25% Q1	0.2623643
10%	0.0582689
5%	-0.1743534
1%	-0.4307829
0% Min	-0.4307829

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.4307829	1	1.13783	52
-0.3011051	28	1.19996	34
-0.1743534	50	1.21788	23
-0.0100503	9	1.39624	26
0.0582689	42	1.40854	46

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.121988	Sum Observations	-7.0753023
Std Deviation	0.43364457	Variance	0.18804761
Skewness	0.34117599	Kurtosis	0.52768489
Uncorrected SS	11.5818155	Corrected SS	10.7187137
Coeff Variation	-355.48141	Std Error Mean	0.05694032

Basic Statistical Measures

Location		Variability	
Mean	-0.12199	Std Deviation	0.43364
Median	-0.17123	Variance	0.18805
Mode		Range	2.18405
		Interquartile Range	0.49756

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.14238	Pr > |t|	0.0364
Sign	M	-6	Pr >= |M|	0.1480

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-291.5	Pr >= |S|	0.0227

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.168292
99%	1.168292
95%	0.589861
90%	0.448025
75% Q3	0.111591
50% Median	-0.171234
25% Q1	-0.385971
10%	-0.652873
5%	-0.886519
1%	-1.015762
0% Min	-1.015762

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.015762	33	0.451985	22
-0.955511	1	0.491281	21
-0.886519	10	0.589861	35
-0.793128	43	0.842443	36
-0.723762	39	1.168292	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	352
Observations Used	352
Observations Not Used	0
Total Observations	352

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.1084	0.008303	13.06	<.0001	0.05	0.09382	0.1267

Fit Statistics

-2 Res Log Likelihood	256.2
AIC (smaller is better)	258.2
AICC (smaller is better)	258.2
BIC (smaller is better)	262.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.1867	0.06083	341	3.07	0.0023
SEX	Female				-0.04959	0.03541	341	-1.40	0.1623
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			0.02162	0.03600	341	0.60	0.5485
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.09521	0.06135	341	1.55	0.1216
TRTCD				2.5mg	0.06217	0.06124	341	1.02	0.3107
TRTCD				7.5mg	-0.00725	0.06084	341	-0.12	0.9052
TRTCD				15mg	0.08089	0.06025	341	1.34	0.1803
TRTCD				30mg	-0.08241	0.06186	341	-1.33	0.1837
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.01019	0.04142	341	-0.25	0.8059
REGIONCD			Eastern Europe		-0.05575	0.04424	341	-1.26	0.2085
REGIONCD			Western Europe		0			.	
EFLOGBL					-0.3954	0.03735	341	-10.59	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	341	1.96	0.1623
TRTTYPCD	1	341	0.36	0.5485
TRTCD	5	341	2.40	0.0372
REGIONCD	2	341	0.85	0.4302
EFLOGBL	1	341	112.08	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.03304	0.06164	341	-0.54	0.5923	0.05	-0.1543	0.08821
7.5mg vs Pbo	-0.1025	0.06092	341	-1.68	0.0935	0.05	-0.2223	0.01737
15mg vs Pbo	-0.01433	0.06038	341	-0.24	0.8126	0.05	-0.1331	0.1044
30mg vs Pbo	-0.1776	0.06176	341	-2.88	0.0043	0.05	-0.2991	-0.05613
45mg vs Pbo	-0.09521	0.06135	341	-1.55	0.1216	0.05	-0.2159	0.02546

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5028	0.5028	0.5028	0.5028	0.5028
SEX	Male				0.4972	0.4972	0.4972	0.4972	0.4972
TRTTYPCD		Diet & Exercise			0.4063	0.4063	0.4063	0.4063	0.4063
TRTTYPCD		Monotherapy			0.5938	0.5938	0.5938	0.5938	0.5938
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3295	0.3295	0.3295	0.3295	0.3295
REGIONCD			Eastern Europe		0.2699	0.2699	0.2699	0.2699	0.2699
REGIONCD			Western Europe		0.4006	0.4006	0.4006	0.4006	0.4006
EFLOGBL					0.6618	0.6618	0.6618	0.6618	0.6618

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5028
SEX	Male				0.4972
TRTTYPCD		Diet & Exercise			0.4063
TRTTYPCD		Monotherapy			0.5938
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3295
REGIONCD			Eastern Europe		0.2699
REGIONCD			Western Europe		0.4006
EFLOGBL					0.6618

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.01428	0.04342	341	-0.33	0.7425	0.05	-0.09969	0.07113
TRTCD	2.5mg	WORK.EFF	-0.04732	0.04342	341	-1.09	0.2766	0.05	-0.1327	0.03809
TRTCD	7.5mg	WORK.EFF	-0.1167	0.04262	341	-2.74	0.0065	0.05	-0.2006	-0.03291
TRTCD	15mg	WORK.EFF	-0.02861	0.04186	341	-0.68	0.4949	0.05	-0.1109	0.05373
TRTCD	30mg	WORK.EFF	-0.1919	0.04412	341	-4.35	<.0001	0.05	-0.2787	-0.1051
TRTCD	45mg	WORK.EFF	-0.1095	0.04330	341	-2.53	0.0119	0.05	-0.1947	-0.02432

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.03304	0.06164	341	0.54	0.5923	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.1025	0.06092	341	1.68	0.0935	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.01433	0.06038	341	0.24	0.8126	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.1776	0.06176	341	2.88	0.0043	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.09521	0.06135	341	1.55	0.1216	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.06943	0.06084	341	1.14	0.2547	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-0.01871	0.06025	341	-0.31	0.7563	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.1446	0.06209	341	2.33	0.0205	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.06217	0.06124	341	1.02	0.3107	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.08814	0.05973	341	-1.48	0.1410	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.07515	0.06137	341	1.22	0.2215	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-0.00725	0.06084	341	-0.12	0.9052	0.05
TRTCD	15mg	30mg	WORK.EFF	0.1633	0.06088	341	2.68	0.0077	0.05
TRTCD	15mg	45mg	WORK.EFF	0.08089	0.06025	341	1.34	0.1803	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.08241	0.06186	341	-1.33	0.1837	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.08821	0.1543
TRTCD	Placebo	7.5mg	-0.01737	0.2223
TRTCD	Placebo	15mg	-0.1044	0.1331
TRTCD	Placebo	30mg	0.05613	0.2991
TRTCD	Placebo	45mg	-0.02546	0.2159
TRTCD	2.5mg	7.5mg	-0.05025	0.1891
TRTCD	2.5mg	15mg	-0.1372	0.09981
TRTCD	2.5mg	30mg	0.02244	0.2667
TRTCD	2.5mg	45mg	-0.05829	0.1826
TRTCD	7.5mg	15mg	-0.2056	0.02934

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.04555	0.1959
TRTCD	7.5mg	45mg	-0.1269	0.1124
TRTCD	15mg	30mg	0.04353	0.2830
TRTCD	15mg	45mg	-0.03762	0.1994
TRTCD	30mg	45mg	-0.2041	0.03927

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
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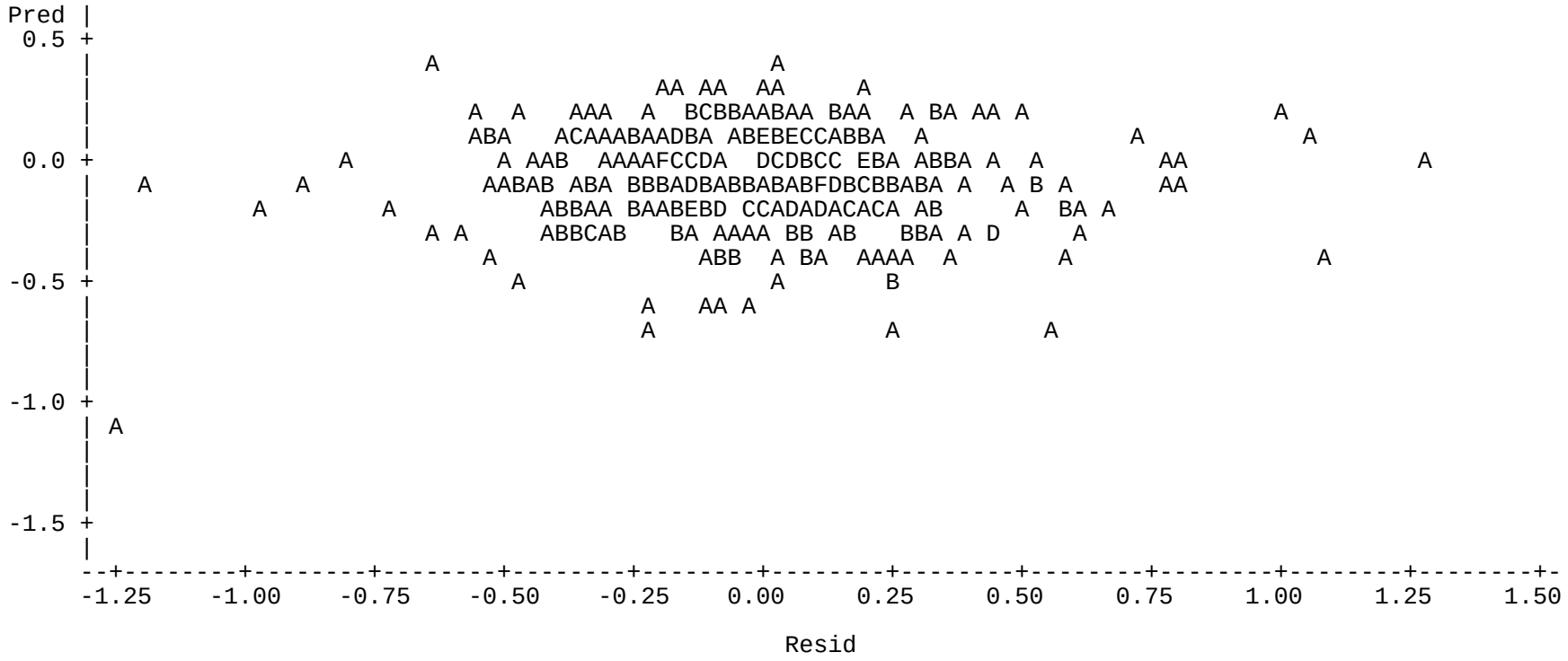
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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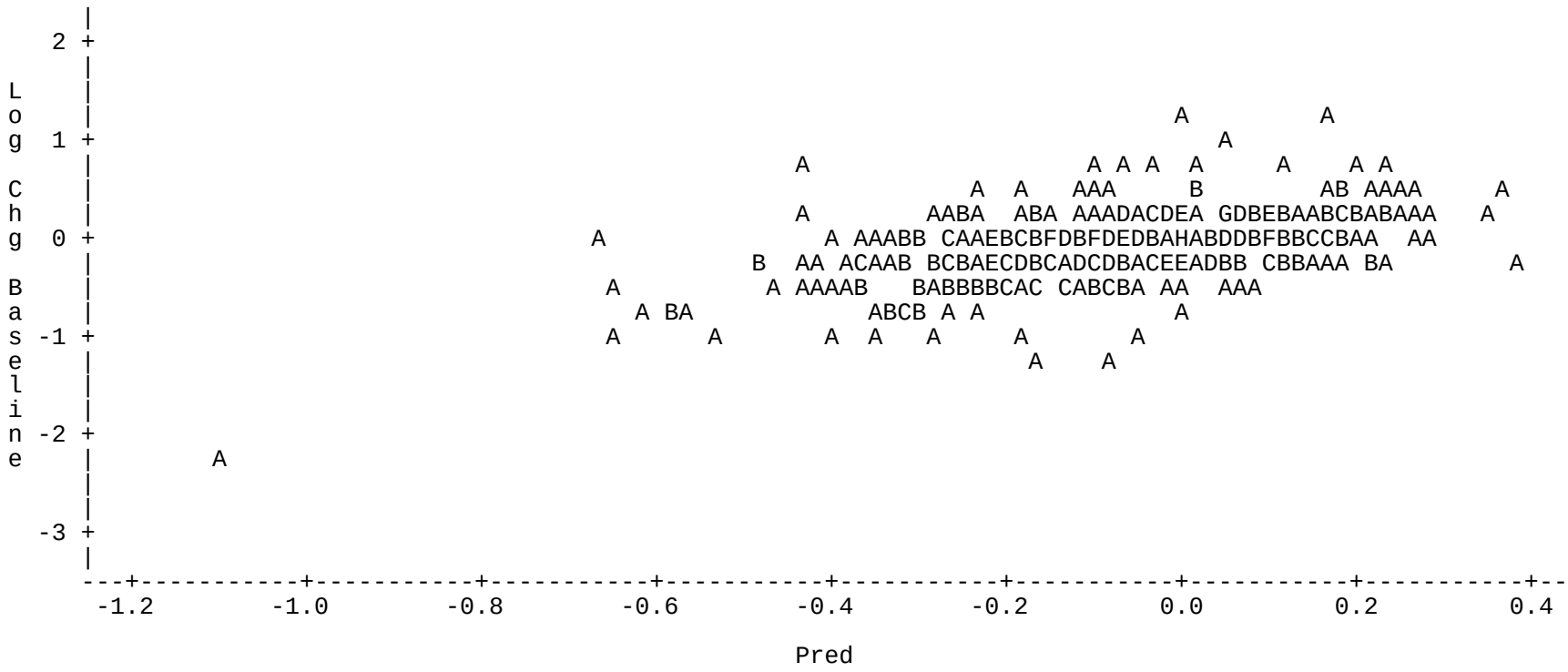
Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	352	Sum Weights	352
Mean	0	Sum Observations	0
Std Deviation	0.32454798	Variance	0.10533139
Skewness	0.12063583	Kurtosis	1.96294028
Uncorrected SS	36.9713189	Corrected SS	36.9713189
Coeff Variation		Std Error Mean	0.01729847

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.32455
Median	0.00194	Variance	0.10533
Mode	-0.39201	Range	2.52463
		Interquartile Range	0.36556

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	1	Pr >= |M|	0.9575
Signed Rank	S	-396	Pr >= |S|	0.8361

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.97686	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.053761	Pr > D	0.0146
Cramer-von Mises	W-Sq	0.22205	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.544047	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.28019773
99%	0.99746729
95%	0.53013875
90%	0.35957878
75% Q3	0.17997566
50% Median	0.00194399
25% Q1	-0.18558909
10%	-0.37575157
5%	-0.48723417
1%	-0.90066080
0% Min	-1.24443219

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.244432	154	0.810991	175
-1.191794	226	0.997467	299
-0.977208	99	1.057268	200
-0.900661	2	1.093344	135
-0.807564	313	1.280198	36

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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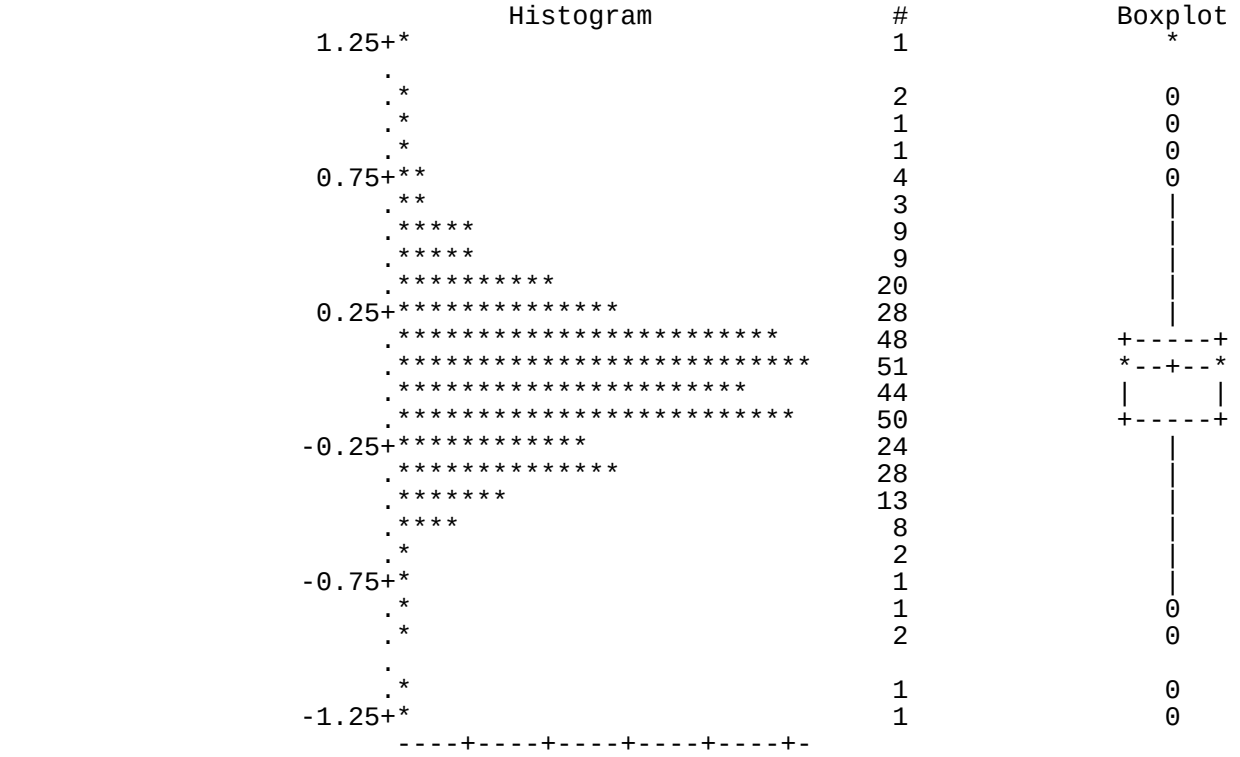
Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

* may represent up to 2 counts

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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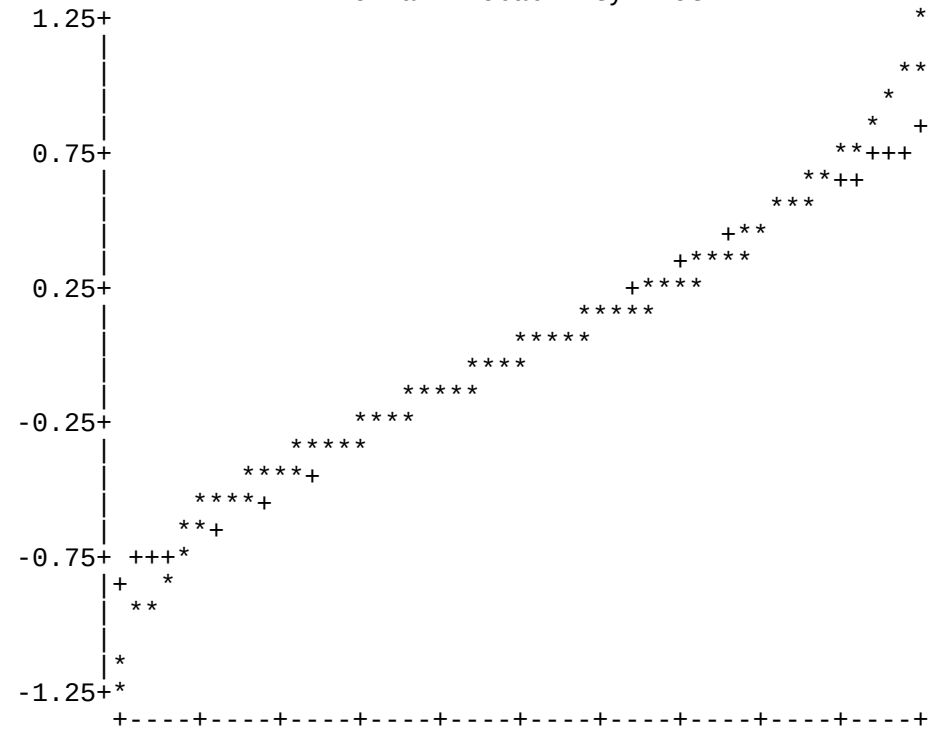
Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.39
SAS Statistical Output for Table 11.38
Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

-2 -1 0 +1 +2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.40
Summary Statistics of Log-Transformed Free Fatty Acid (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	52	60	62	54	57
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	0.49	0.55	0.51	0.48	0.55	0.48
	CV (%) [2]	42.605	44.474	48.177	49.413	40.934	42.127
Week -5	Geo Mean	0.48	0.49	0.47	0.48	0.45	0.48
	CV (%) [2]	44.221	49.397	52.700	45.288	64.849	39.094
	Geo Mean - SE[3]	0.45	0.46	0.44	0.45	0.42	0.46
	Geo Mean + SE[3]	0.51	0.52	0.50	0.50	0.49	0.51
	Minimum	0.1	0.1	0.1	0.2	0.1	0.1
	Median	0.51	0.49	0.48	0.49	0.53	0.50
	Maximum	1.0	1.3	1.2	0.9	1.0	1.1
Ratio to Baseline (%) [4]	Geo Mean	-2.18	-10.21	-9.37	-1.22	-17.01	1.79
	Geo Mean - SE[3]	-6.98	-16.97	-15.42	-6.19	-21.98	-3.80
	Geo Mean + SE[3]	2.88	-2.89	-2.90	4.01	-11.73	7.71
	Minimum	-50.8	-83.9	-82.8	-64.0	-78.8	-79.3
	Median	-4.44	-6.74	-7.20	-3.17	-6.66	0.00
	Maximum	170.4	180.0	172.0	237.5	114.3	136.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.40
Summary Statistics of Log-Transformed Free Fatty Acid (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		60	53	62	63	56	58
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	0.49	0.55	0.52	0.48	0.54	0.47
	CV (%) [2]	42.025	44.143	47.591	48.970	41.288	41.762
	Geo Mean - SE[3]	0.46	0.52	0.49	0.46	0.51	0.45
	Geo Mean + SE[3]	0.51	0.58	0.55	0.51	0.57	0.50
	Minimum	0.2	0.2	0.1	0.2	0.2	0.2
	Median	0.49	0.59	0.55	0.50	0.57	0.47
	Maximum	1.2	1.1	1.2	1.1	1.3	1.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.40
Summary Statistics of Log-Transformed Free Fatty Acid (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		55	52	57	61	52	55
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	3 (5%)	2 (3%)	0	2 (4%)
Baseline	Geo Mean	0.49	0.55	0.53	0.48	0.57	0.48
	CV (%) [2]	41.921	44.600	46.744	49.526	36.271	40.444
Week 4	Geo Mean	0.49	0.49	0.48	0.47	0.46	0.45
	CV (%) [2]	45.740	37.599	44.187	50.355	56.006	50.332
	Geo Mean - SE[3]	0.47	0.47	0.46	0.44	0.43	0.43
	Geo Mean + SE[3]	0.52	0.51	0.51	0.50	0.50	0.48
	Minimum	0.2	0.2	0.2	0.1	0.1	0.1
	Median	0.47	0.47	0.50	0.51	0.51	0.46
	Maximum	1.3	1.7	1.0	1.0	1.2	1.2
Ratio to Baseline (%) [4]	Geo Mean	0.57	-10.76	-9.66	-2.28	-18.69	-4.99
	Geo Mean - SE[3]	-4.32	-15.67	-14.97	-8.25	-23.26	-10.92
	Geo Mean + SE[3]	5.71	-5.56	-4.02	4.08	-13.86	1.34
	Minimum	-59.8	-67.0	-83.2	-78.0	-67.0	-68.1
	Median	-4.26	-10.22	-12.28	-2.63	-17.50	-2.94
	Maximum	207.4	236.0	305.6	240.0	88.1	368.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.40
Summary Statistics of Log-Transformed Free Fatty Acid (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	52	61	61	56	57
Number (%) of Values Carried Forward		7 (12%)	10 (19%)	7 (11%)	2 (3%)	3 (5%)	10 (18%)
Baseline	Geo Mean	0.49	0.55	0.52	0.48	0.54	0.47
	CV (%) [2]	41.719	44.600	48.021	49.526	41.288	42.164
Week 8	Geo Mean	0.44	0.53	0.44	0.45	0.46	0.47
	CV (%) [2]	54.344	41.921	51.168	53.896	50.802	44.834
	Geo Mean - SE[3]	0.41	0.50	0.41	0.42	0.43	0.44
	Geo Mean + SE[3]	0.47	0.56	0.47	0.48	0.49	0.50
	Minimum	0.1	0.2	0.2	0.1	0.1	0.2
	Median	0.46	0.54	0.47	0.51	0.47	0.47
	Maximum	1.1	1.3	1.2	1.1	1.0	1.3
Ratio to Baseline (%) [4]	Geo Mean	-10.74	-4.23	-15.44	-6.04	-14.84	-1.15
	Geo Mean - SE[3]	-15.52	-9.48	-20.17	-12.70	-19.47	-8.26
	Geo Mean + SE[3]	-5.69	1.33	-10.43	1.13	-9.94	6.51
	Minimum	-80.0	-79.3	-79.0	-84.0	-79.1	-62.3
	Median	-11.83	1.72	-16.07	-5.71	-11.65	-7.89
	Maximum	133.3	72.2	196.6	175.0	180.0	452.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.40
Summary Statistics of Log-Transformed Free Fatty Acid (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		57	52	61	62	56	57
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	10 (16%)	4 (6%)	6 (11%)	7 (12%)
Baseline	Geo Mean	0.49	0.55	0.52	0.48	0.54	0.47
	CV (%) [2]	41.719	44.600	48.021	49.126	41.288	42.164
Week 12	Geo Mean	0.47	0.50	0.46	0.48	0.46	0.47
	CV (%) [2]	56.266	41.667	48.448	42.623	53.820	46.149
	Geo Mean - SE[3]	0.44	0.47	0.44	0.46	0.43	0.44
	Geo Mean + SE[3]	0.51	0.53	0.49	0.51	0.50	0.50
	Minimum	0.1	0.2	0.2	0.2	0.1	0.1
	Median	0.47	0.48	0.50	0.52	0.49	0.47
	Maximum	1.2	1.2	1.6	0.8	1.2	1.2
Ratio to Baseline (%) [4]	Geo Mean	-3.86	-8.61	-10.48	0.35	-14.16	-0.62
	Geo Mean - SE[3]	-9.35	-14.40	-14.87	-5.29	-18.96	-7.73
	Geo Mean + SE[3]	1.96	-2.43	-5.85	6.32	-9.07	7.04
	Minimum	-80.0	-64.9	-63.8	-60.0	-72.5	-68.2
	Median	-4.88	-2.55	-7.02	0.96	-12.53	-6.12
	Maximum	214.8	172.7	148.3	233.3	135.7	368.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		57	52	61
Number (%) of Values Carried Forward		10 (18%)	12 (23%)	10 (16%)
Baseline	Geo Mean	0.49	0.55	0.52
	CV (%) [2]	41.719	44.600	48.021
Week 12	Geo Mean	0.47	0.50	0.46
	CV (%) [2]	56.266	41.667	48.448
Ratio to Baseline (% chg) [3]	Geo Mean	-3.86	-8.61	-10.48
	Geo Mean -SE,+SE	-9.35,1.96	-14.40,-2.43	-14.87,-5.85
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-4.14	-4.61	-10.11
	Geo Mean -SE,+SE	-9.09,1.08	-9.78,0.86	-14.60,-5.39
Ratio to Baseline (% diff) [4]	Geo Mean		-0.48	-6.23
	95% CI		-14.49,15.82	-18.89,8.42
	p-val[5]		0.950	0.384

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significnat. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	56	57
Number (%) of Values Carried Forward		4 (6%)	6 (11%)	7 (12%)
Baseline	Geo Mean	0.48	0.54	0.47
	CV (%) [2]	49.126	41.288	42.164
Week 12	Geo Mean	0.48	0.46	0.47
	CV (%) [2]	42.623	53.820	46.149
Ratio to Baseline (% chg) [3]	Geo Mean	0.35	-14.16	-0.62
	Geo Mean -SE,+SE	-5.29,6.32	-18.96,-9.07	-7.73,7.04
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-2.82	-11.35	-4.25
	Geo Mean -SE,+SE	-7.64,2.24	-15.97,-6.48	-9.19,0.97
Ratio to Baseline (% diff) [4]	Geo Mean	1.38	-7.52	-0.11
	95% CI	-12.27,17.15	-20.26,7.24	-13.80,15.77
	p-val[5]	0.853	0.300	0.989

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significnat. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	57	Sum Weights	57
Mean	-0.7067809	Sum Observations	-40.286513
Std Deviation	0.40056869	Variance	0.16045528
Skewness	0.11290452	Kurtosis	-0.7074323
Uncorrected SS	37.4592351	Corrected SS	8.98549541
Coeff Variation	-56.675084	Std Error Mean	0.05305662

Basic Statistical Measures

Location		Variability	
Mean	-0.70678	Std Deviation	0.40057
Median	-0.71335	Variance	0.16046
Mode	-1.13943	Range	1.63519
		Interquartile Range	0.52130

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-13.3213	Pr > |t|	<.0001
Sign	M	-27.5	Pr >= |M|	<.0001
Signed Rank	S	-818.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.1655144
99%	0.1655144
95%	-0.0618754
90%	-0.1053605
75% Q3	-0.4462871
50% Median	-0.7133499
25% Q1	-0.9675840
10%	-1.2378744
5%	-1.3862944
1%	-1.4696760
0% Min	-1.4696760

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.46968	28	-0.0833816	42
-1.46968	9	-0.0725707	35
-1.38629	15	-0.0618754	53
-1.30933	19	-0.0202027	56
-1.23787	16	0.1655144	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	57	Sum Weights	57
Mean	-0.7461642	Sum Observations	-42.531357
Std Deviation	0.52444305	Variance	0.27504052
Skewness	-0.8382087	Kurtosis	2.07663244
Uncorrected SS	47.1376437	Corrected SS	15.402269
Coeff Variation	-70.285211	Std Error Mean	0.06946418

Basic Statistical Measures

Location		Variability	
Mean	-0.74616	Std Deviation	0.52444
Median	-0.75502	Variance	0.27504
Mode	-0.79851	Range	2.83321
		Interquartile Range	0.64934

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-10.7417	Pr > |t|	<.0001
Sign	M	-25	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	-787	Pr >= |S| <.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.17395331
99%	0.17395331
95%	0.00995033
90%	-0.05129329
75% Q3	-0.40047757
50% Median	-0.75502258
25% Q1	-1.04982212
10%	-1.27296568
5%	-1.66073121
1%	-2.65926004
0% Min	-2.65926004

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-------Highest------	
Value	Obs	Value	Obs
-2.65926	45	-0.05129329	47
-1.96611	21	0.00000000	56
-1.66073	15	0.00995033	39
-1.34707	28	0.03922071	6
-1.30933	22	0.17395331	49

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	57	Sum Weights	57
Mean	-0.0393832	Sum Observations	-2.244844
Std Deviation	0.44362051	Variance	0.19679916
Skewness	-0.8022897	Kurtosis	3.40145797
Uncorrected SS	11.1091622	Corrected SS	11.020753
Coeff Variation	-1126.4199	Std Error Mean	0.05875897

Basic Statistical Measures

Location		Variability	
Mean	-0.03938	Std Deviation	0.44362
Median	-0.05001	Variance	0.19680
Mode		Range	2.75625
		Interquartile Range	0.50555

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.67025	Pr > |t|	0.5055
Sign	M	-0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-61	Pr >= |S|	0.6321

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1468144
99%	1.1468144
95%	0.7472144
90%	0.3409266
75% Q3	0.2311117
50% Median	-0.0500104
25% Q1	-0.2744368
10%	-0.4054651
5%	-0.7366323
1%	-1.6094379
0% Min	-1.6094379

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.609438	45	0.366625	39
-1.368276	21	0.417735	38
-0.736632	53	0.747214	11
-0.595983	22	0.815750	9
-0.554997	10	1.146814	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	52	Sum Weights	52
Mean	-0.6006894	Sum Observations	-31.235847
Std Deviation	0.42593007	Variance	0.18141642
Skewness	-0.5444427	Kurtosis	0.23516603
Uncorrected SS	28.0152783	Corrected SS	9.25223764
Coeff Variation	-70.906878	Std Error Mean	0.05906587

Basic Statistical Measures

Location		Variability	
Mean	-0.60069	Std Deviation	0.42593
Median	-0.54607	Variance	0.18142
Mode	-1.02165	Range	2.00148
		Interquartile Range	0.66709

NOTE: The mode displayed is the smallest of 3 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-10.1698	Pr > |t|	<.0001
Sign	M	-23	Pr >= |M|	<.0001
Signed Rank	S	-678	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.10436002
99%	0.10436002
95%	0.00995033
90%	-0.08338161
75% Q3	-0.27452342
50% Median	-0.54606666
25% Q1	-0.94160854
10%	-1.10866262
5%	-1.34707365
1%	-1.89711998
0% Min	-1.89711998

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-------Highest------	
Value	Obs	Value	Obs
-1.89712	28	-0.05129329	14
-1.38629	24	-0.05129329	17
-1.34707	42	0.00995033	4
-1.23787	27	0.00995033	30
-1.10866	34	0.10436002	48

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	52	Sum Weights	52
Mean	-0.6907276	Sum Observations	-35.917837
Std Deviation	0.40010868	Variance	0.16008696
Skewness	0.04020106	Kurtosis	-0.3449155
Uncorrected SS	32.9738773	Corrected SS	8.16443493
Coeff Variation	-57.925681	Std Error Mean	0.05548509

Basic Statistical Measures

Location		Variability	
Mean	-0.69073	Std Deviation	0.40011
Median	-0.73419	Variance	0.16009
Mode	-1.02165	Range	1.81645
		Interquartile Range	0.55195

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-12.4489	Pr > |t|	<.0001
Sign	M	-23	Pr >= |M|	<.0001
Signed Rank	S	-680	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2070142
99%	0.2070142
95%	0.0198026
90%	-0.1863296
75% Q3	-0.4156302
50% Median	-0.7341862
25% Q1	-0.9675840
10%	-1.2378744
5%	-1.3470736
1%	-1.6094379
0% Min	-1.6094379

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.60944	27	-0.1165338	21
-1.38629	13	-0.1053605	19
-1.34707	28	0.0198026	1
-1.27297	42	0.0487902	47
-1.27297	24	0.2070142	49

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	52	Sum Weights	52
Mean	-0.0900383	Sum Observations	-4.6819902
Std Deviation	0.471529	Variance	0.22233959
Skewness	-0.0185754	Kurtosis	0.12686438
Uncorrected SS	11.7608776	Corrected SS	11.3393193
Coeff Variation	-523.69841	Std Error Mean	0.06538931

Basic Statistical Measures

Location		Variability	
Mean	-0.09004	Std Deviation	0.47153
Median	-0.02581	Variance	0.22234
Mode	0.00000	Range	2.04927
		Interquartile Range	0.51913

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.37696	Pr > |t|	0.1745
Sign	M	-2	Pr >= |M|	0.6718
Signed Rank	S	-134.5	Pr >= |S|	0.1971

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.003302
99%	1.003302
95%	0.900161
90%	0.381935
75% Q3	0.161614
50% Median	-0.025809
25% Q1	-0.357518
10%	-0.788457
5%	-1.031602
1%	-1.045969
0% Min	-1.045969

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.045969	48	0.497838	1
-1.031921	7	0.550046	28
-1.031602	30	0.900161	49
-0.821980	41	0.905117	21
-0.788457	16	1.003302	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	61	Sum Weights	61
Mean	-0.6557429	Sum Observations	-40.000319
Std Deviation	0.45552614	Variance	0.20750407
Skewness	-0.5633869	Kurtosis	0.22095056
Uncorrected SS	38.6801703	Corrected SS	12.450244
Coeff Variation	-69.467183	Std Error Mean	0.05832415

Basic Statistical Measures

Location		Variability	
Mean	-0.65574	Std Deviation	0.45553
Median	-0.59784	Variance	0.20750
Mode	-0.27444	Range	2.14007
		Interquartile Range	0.61310

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-11.2431	Pr > |t|	<.0001
Sign	M	-27.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-927.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.173953
99%	0.173953
95%	-0.040822
90%	-0.105361
75% Q3	-0.328504
50% Median	-0.597837
25% Q1	-0.941609
10%	-1.237874
5%	-1.386294
1%	-1.966113
0% Min	-1.966113

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.96611	37	-0.0725707	43
-1.71480	22	-0.0408220	16
-1.56065	10	0.0676586	17
-1.38629	29	0.1484200	2
-1.34707	32	0.1739533	12

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	61	Sum Weights	61
Mean	-0.7664	Sum Observations	-46.750399
Std Deviation	0.45917733	Variance	0.21084382
Skewness	-0.0940963	Kurtosis	-0.4027581
Uncorrected SS	48.4801337	Corrected SS	12.6506293
Coeff Variation	-59.913537	Std Error Mean	0.05879163

Basic Statistical Measures

Location		Variability	
Mean	-0.76640	Std Deviation	0.45918
Median	-0.69315	Variance	0.21084
Mode	-1.34707	Range	2.23569
		Interquartile Range	0.78552

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-13.0359	Pr > |t|	<.0001
Sign	M	-29.5	Pr >= |M|	<.0001
Signed Rank	S	-926.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.463734
99%	0.463734
95%	-0.223144
90%	-0.261365
75% Q3	-0.385662
50% Median	-0.693147
25% Q1	-1.171183
10%	-1.386294
5%	-1.427116
1%	-1.771957
0% Min	-1.771957

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.77196	34	-0.2231436	5
-1.66073	26	-0.2231436	18
-1.46968	29	-0.0943107	16
-1.42712	61	-0.0833816	3
-1.42712	51	0.4637340	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	61	Sum Weights	61
Mean	-0.110657	Sum Observations	-6.7500798
Std Deviation	0.3931436	Variance	0.15456189
Skewness	-0.0461619	Kurtosis	-0.0151141
Uncorrected SS	10.0206572	Corrected SS	9.27371334
Coeff Variation	-355.28113	Std Error Mean	0.05033688

Basic Statistical Measures

Location		Variability	
Mean	-0.11066	Std Deviation	0.39314
Median	-0.07276	Variance	0.15456
Mode		Range	1.92630
		Interquartile Range	0.58192

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.19833	Pr > |t|	0.0318
Sign	M	-6.5	Pr >= |M|	0.1237

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-262.5	Pr >= |S|	0.0587

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9093703
99%	0.9093703
95%	0.3513979
90%	0.2876821
75% Q3	0.1764564
50% Median	-0.0727594
25% Q1	-0.4054651
10%	-0.6380874
5%	-0.7717903
1%	-1.0169343
0% Min	-1.0169343

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.016934	34	0.328504	22
-0.810930	61	0.351398	45
-0.775385	53	0.448025	23
-0.771790	12	0.794930	37
-0.767255	38	0.909370	39

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	62	Sum Weights	62
Mean	-0.7333835	Sum Observations	-45.46978
Std Deviation	0.46495829	Variance	0.21618621
Skewness	-0.34798	Kurtosis	-0.2506763
Uncorrected SS	46.5341474	Corrected SS	13.1873589
Coeff Variation	-63.399062	Std Error Mean	0.05904976

Basic Statistical Measures

Location		Variability	
Mean	-0.73338	Std Deviation	0.46496
Median	-0.72408	Variance	0.21619
Mode	-0.96758	Range	1.98330
		Interquartile Range	0.52130

NOTE: The mode displayed is the smallest of 5 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-12.4198	Pr > |t|	<.0001
Sign	M	-28	Pr >= |M|	<.0001
Signed Rank	S	-965.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.0861777
99%	0.0861777
95%	-0.0408220
90%	-0.0833816
75% Q3	-0.4462871
50% Median	-0.7240849
25% Q1	-0.9675840
10%	-1.4271164
5%	-1.6094379
1%	-1.8971200
0% Min	-1.8971200

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-------Highest------	
Value	Obs	Value	Obs
-1.89712	24	-0.08338161	60
-1.66073	31	-0.04082199	18
-1.60944	62	0.00995033	1
-1.60944	23	0.04879016	19
-1.56065	54	0.08617770	28

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	62	Sum Weights	62
Mean	-0.7299144	Sum Observations	-45.254694
Std Deviation	0.40857325	Variance	0.1669321
Skewness	-1.0363581	Kurtosis	0.59557217
Uncorrected SS	43.2149126	Corrected SS	10.1828583
Coeff Variation	-55.975501	Std Error Mean	0.05188886

Basic Statistical Measures

Location		Variability	
Mean	-0.72991	Std Deviation	0.40857
Median	-0.65393	Variance	0.16693
Mode	-0.86750	Range	1.63413
		Interquartile Range	0.45199

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-14.0669	Pr > |t|	<.0001
Sign	M	-31	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-976.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	-0.198451
99%	-0.198451
95%	-0.235722
90%	-0.274437
75% Q3	-0.415515
50% Median	-0.653926
25% Q1	-0.867501
10%	-1.347074
5%	-1.609438
1%	-1.832581
0% Min	-1.832581

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		------Highest-----	
Value	Obs	Value	Obs
-1.83258	62	-0.248461	37
-1.77196	25	-0.235722	6
-1.60944	42	-0.223144	1
-1.60944	39	-0.223144	13
-1.60944	27	-0.198451	59

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	0.00346912	Sum Observations	0.21508549
Std Deviation	0.45507742	Variance	0.20709546
Skewness	0.2491737	Kurtosis	-0.1027879
Uncorrected SS	12.633569	Corrected SS	12.6328229
Coeff Variation	13117.9464	Std Error Mean	0.05779489

Basic Statistical Measures

Location		Variability	
Mean	0.00347	Std Deviation	0.45508
Median	0.00907	Variance	0.20710
Mode	-0.07411	Range	2.12026
		Interquartile Range	0.61594

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.060025	Pr > |t|	0.9523
Sign	M	0	Pr >= |M|	1.0000
Signed Rank	S	-12.5	Pr >= |S|	0.9310

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.2039728
99%	1.2039728
95%	0.7178398
90%	0.5877867
75% Q3	0.3136576
50% Median	0.0090711
25% Q1	-0.3022809
10%	-0.6035350
5%	-0.7055697
1%	-0.9162907
0% Min	-0.9162907

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.916291	42	0.617161	55
-0.804373	25	0.717840	59
-0.721056	28	0.885519	13
-0.705570	41	1.011601	40
-0.667829	39	1.203973	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	56	Sum Weights	56
Mean	-0.6147105	Sum Observations	-34.423785
Std Deviation	0.3967439	Variance	0.15740572
Skewness	-0.4015447	Kurtosis	0.03381697
Uncorrected SS	29.8179755	Corrected SS	8.65731473
Coeff Variation	-64.54159	Std Error Mean	0.05301713

Basic Statistical Measures

Location		Variability	
Mean	-0.61471	Std Deviation	0.39674
Median	-0.57097	Variance	0.15741
Mode	-0.52763	Range	1.89184
		Interquartile Range	0.46534

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-11.5946	Pr > |t|	<.0001
Sign	M	-26	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-785	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2311117
99%	0.2311117
95%	-0.0202027
90%	-0.0943107
75% Q3	-0.3566749
50% Median	-0.5709687
25% Q1	-0.8220147
10%	-1.1711830
5%	-1.3470736
1%	-1.6607312
0% Min	-1.6607312

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.66073	18	-0.0943107	39
-1.38629	37	-0.0408220	10
-1.34707	52	-0.0202027	5
-1.27297	38	0.1133287	55
-1.27297	27	0.2311117	23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	56	Sum Weights	56
Mean	-0.7673472	Sum Observations	-42.971443
Std Deviation	0.50435741	Variance	0.2543764
Skewness	-0.6850996	Kurtosis	0.30882033
Uncorrected SS	46.9647188	Corrected SS	13.990702
Coeff Variation	-65.727406	Std Error Mean	0.06739759

Basic Statistical Measures

Location		Variability	
Mean	-0.76735	Std Deviation	0.50436
Median	-0.72408	Variance	0.25438
Mode	-1.30933	Range	2.45959
		Interquartile Range	0.67822

NOTE: The mode displayed is the smallest of 3 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-11.3854	Pr > |t|	<.0001
Sign	M	-27	Pr >= |M|	<.0001
Signed Rank	S	-792	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.157004
99%	0.157004
95%	-0.105361
90%	-0.150823
75% Q3	-0.415515
50% Median	-0.724085
25% Q1	-1.093736
10%	-1.427116
5%	-1.609438
1%	-2.302585
0% Min	-2.302585

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-2.30259	27	-0.1278334	13
-1.83258	3	-0.1053605	5
-1.60944	48	-0.1053605	44
-1.60944	36	-0.0943107	50
-1.46968	37	0.1570037	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.1526367	Sum Observations	-8.5476579
Std Deviation	0.43078337	Variance	0.18557431
Skewness	-0.4447426	Kurtosis	0.42381468
Uncorrected SS	11.5112739	Corrected SS	10.2065872
Coeff Variation	-282.22782	Std Error Mean	0.05756585

Basic Statistical Measures

Location		Variability	
Mean	-0.15264	Std Deviation	0.43078
Median	-0.13391	Variance	0.18557
Mode	-0.13815	Range	2.14943
		Interquartile Range	0.45425

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.65152	Pr > |t|	0.0104
Sign	M	-8	Pr >= |M|	0.0440

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-280.5	Pr >= |S|	0.0207

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.857450
99%	0.857450
95%	0.447014
90%	0.313658
75% Q3	0.132231
50% Median	-0.133914
25% Q1	-0.322015
10%	-0.819441
5%	-0.974560
1%	-1.291984
0% Min	-1.291984

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.291984	6	0.356675	43
-1.029619	27	0.383725	50
-0.974560	48	0.447014	54
-0.965081	3	0.708185	29
-0.832909	36	0.857450	38

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	57	Sum Weights	57
Mean	-0.7464134	Sum Observations	-42.545563
Std Deviation	0.40451089	Variance	0.16362906
Skewness	-0.0023227	Kurtosis	-0.0047744
Uncorrected SS	40.919805	Corrected SS	9.1632275
Coeff Variation	-54.19395	Std Error Mean	0.05357878

Basic Statistical Measures

Location		Variability	
Mean	-0.74641	Std Deviation	0.40451
Median	-0.77653	Variance	0.16363
Mode	-1.07881	Range	1.90954
		Interquartile Range	0.52130

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-13.9311	Pr > |t|	<.0001
Sign	M	-27.5	Pr >= |M|	<.0001
Signed Rank	S	-816.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.300105
99%	0.300105
95%	-0.127833
90%	-0.198451
75% Q3	-0.446287
50% Median	-0.776529
25% Q1	-0.967584
10%	-1.386294
5%	-1.514128
1%	-1.609438
0% Min	-1.609438

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		------Highest-----	
Value	Obs	Value	Obs
-1.60944	40	-0.186330	37
-1.56065	45	-0.162519	11
-1.51413	5	-0.127833	43
-1.46968	35	-0.040822	54
-1.38629	53	0.300105	49

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	57	Sum Weights	57
Mean	-0.7526411	Sum Observations	-42.900543
Std Deviation	0.43939937	Variance	0.19307181
Skewness	-0.2602861	Kurtosis	0.03961632
Uncorrected SS	43.100733	Corrected SS	10.8120213
Coeff Variation	-58.380996	Std Error Mean	0.05819987

Basic Statistical Measures

Location		Variability	
Mean	-0.75264	Std Deviation	0.43940
Median	-0.75502	Variance	0.19307
Mode	-1.02165	Range	2.12312
		Interquartile Range	0.55962

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-12.932	Pr > |t|	<.0001
Sign	M	-26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-821.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.1570037
99%	0.1570037
95%	-0.0725707
90%	-0.2357223
75% Q3	-0.4620355
50% Median	-0.7550226
25% Q1	-1.0216512
10%	-1.3470736
5%	-1.4696760
1%	-1.9661129
0% Min	-1.9661129

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		------Highest------	
Value	Obs	Value	Obs
-1.96611	40	-0.2107210	46
-1.60944	32	-0.1984509	49
-1.46968	5	-0.0725707	45
-1.42712	21	0.1397619	52
-1.38629	9	0.1570037	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	57	Sum Weights	57
Mean	-0.0062277	Sum Observations	-0.3549799
Std Deviation	0.56032314	Variance	0.31396202
Skewness	0.83113008	Kurtosis	1.37145905
Uncorrected SS	17.5840839	Corrected SS	17.5818732
Coeff Variation	-8997.2478	Std Error Mean	0.07421661

Basic Statistical Measures

Location		Variability	
Mean	-0.00623	Std Deviation	0.56032
Median	-0.06318	Variance	0.31396
Mode	0.60825	Range	2.69011
		Interquartile Range	0.59909

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.08391	Pr > |t|	0.9334
Sign	M	-3.5	Pr >= |M|	0.4270

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-95	Pr >= |S|	0.4552

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.5432981
99%	1.5432981
95%	1.4880771
90%	0.7602865
75% Q3	0.2326223
50% Median	-0.0631789
25% Q1	-0.3664630
10%	-0.5436154
5%	-0.9745596
1%	-1.1468144
0% Min	-1.1468144

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.146814	11	0.783531	46
-1.041454	21	0.830348	30
-0.974560	32	1.488077	45
-0.714201	54	1.526056	52
-0.590868	2	1.543298	53

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	345
Observations Used	345
Observations Not Used	0
Total Observations	345

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.1593	0.01233	12.92	<.0001	0.05	0.1377	0.1866

Fit Statistics

-2 Res Log Likelihood	379.9
AIC (smaller is better)	381.9
AICC (smaller is better)	381.9
BIC (smaller is better)	385.7

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					-0.3938	0.07640	334	-5.15	<.0001
SEX	Female				0.09708	0.04405	334	2.20	0.0282
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.04241	0.04404	334	-0.96	0.3362
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.001067	0.07498	334	0.01	0.9887
TRTCD				2.5mg	-0.00377	0.07701	334	-0.05	0.9609
TRTCD				7.5mg	-0.06322	0.07382	334	-0.86	0.3924
TRTCD				15mg	0.01473	0.07336	334	0.20	0.8410
TRTCD				30mg	-0.07713	0.07555	334	-1.02	0.3080
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.1830	0.05200	334	-3.52	0.0005
REGIONCD			Eastern Europe		-0.03512	0.05428	334	-0.65	0.5181
REGIONCD			Western Europe		0			.	
EFLOGBL					-0.5747	0.05321	334	-10.80	<.0001

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	334	4.86	0.0282
TRTTYPCD	1	334	0.93	0.3362
TRTCD	5	334	0.54	0.7485
REGIONCD	2	334	6.64	0.0015
EFLOGBL	1	334	116.68	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.00484	0.07711	334	-0.06	0.9500	0.05	-0.1565	0.1468
7.5mg vs Pbo	-0.06428	0.07378	334	-0.87	0.3842	0.05	-0.2094	0.08084
15mg vs Pbo	0.01366	0.07351	334	0.19	0.8527	0.05	-0.1309	0.1583
30mg vs Pbo	-0.07820	0.07531	334	-1.04	0.2998	0.05	-0.2263	0.06994
45mg vs Pbo	-0.00107	0.07498	334	-0.01	0.9887	0.05	-0.1486	0.1464

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5014	0.5014	0.5014	0.5014	0.5014
SEX	Male				0.4986	0.4986	0.4986	0.4986	0.4986
TRTTYPCD		Diet & Exercise			0.4145	0.4145	0.4145	0.4145	0.4145
TRTTYPCD		Monotherapy			0.5855	0.5855	0.5855	0.5855	0.5855
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3333	0.3333	0.3333	0.3333	0.3333
REGIONCD			Eastern Europe		0.2696	0.2696	0.2696	0.2696	0.2696
REGIONCD			Western Europe		0.3971	0.3971	0.3971	0.3971	0.3971
EFLOGBL					-0.678	-0.678	-0.678	-0.678	-0.678

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5014
SEX	Male				0.4986
TRTTYPCD		Diet & Exercise			0.4145
TRTTYPCD		Monotherapy			0.5855
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3333
REGIONCD			Eastern Europe		0.2696
REGIONCD			Western Europe		0.3971
EFLOGBL					-0.678

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.04231	0.05303	334	-0.80	0.4255	0.05	-0.1466	0.06200
TRTCD	2.5mg	WORK.EFF	-0.04716	0.05571	334	-0.85	0.3979	0.05	-0.1567	0.06243
TRTCD	7.5mg	WORK.EFF	-0.1066	0.05120	334	-2.08	0.0381	0.05	-0.2073	-0.00588
TRTCD	15mg	WORK.EFF	-0.02865	0.05084	334	-0.56	0.5734	0.05	-0.1287	0.07136
TRTCD	30mg	WORK.EFF	-0.1205	0.05353	334	-2.25	0.0250	0.05	-0.2258	-0.01521
TRTCD	45mg	WORK.EFF	-0.04338	0.05304	334	-0.82	0.4140	0.05	-0.1477	0.06095

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.004842	0.07711	334	0.06	0.9500	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.06428	0.07378	334	0.87	0.3842	0.05
TRTCD	Placebo	15mg	WORK.EFF	-0.01366	0.07351	334	-0.19	0.8527	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.07820	0.07531	334	1.04	0.2998	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.001067	0.07498	334	0.01	0.9887	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.05944	0.07569	334	0.79	0.4328	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-0.01850	0.07554	334	-0.24	0.8067	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.07336	0.07729	334	0.95	0.3432	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-0.00377	0.07701	334	-0.05	0.9609	0.05

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.07794	0.07218	334	-1.08	0.2810	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.01392	0.07401	334	0.19	0.8510	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-0.06322	0.07382	334	-0.86	0.3924	0.05
TRTCD	15mg	30mg	WORK.EFF	0.09186	0.07399	334	1.24	0.2153	0.05
TRTCD	15mg	45mg	WORK.EFF	0.01473	0.07336	334	0.20	0.8410	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.07713	0.07555	334	-1.02	0.3080	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1468	0.1565
TRTCD	Placebo	7.5mg	-0.08084	0.2094
TRTCD	Placebo	15mg	-0.1583	0.1309
TRTCD	Placebo	30mg	-0.06994	0.2263
TRTCD	Placebo	45mg	-0.1464	0.1486
TRTCD	2.5mg	7.5mg	-0.08945	0.2083
TRTCD	2.5mg	15mg	-0.1671	0.1301
TRTCD	2.5mg	30mg	-0.07868	0.2254
TRTCD	2.5mg	45mg	-0.1553	0.1477
TRTCD	7.5mg	15mg	-0.2199	0.06404

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.1317	0.1595
TRTCD	7.5mg	45mg	-0.2084	0.08200
TRTCD	15mg	30mg	-0.05369	0.2374
TRTCD	15mg	45mg	-0.1296	0.1590
TRTCD	30mg	45mg	-0.2257	0.07148

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.

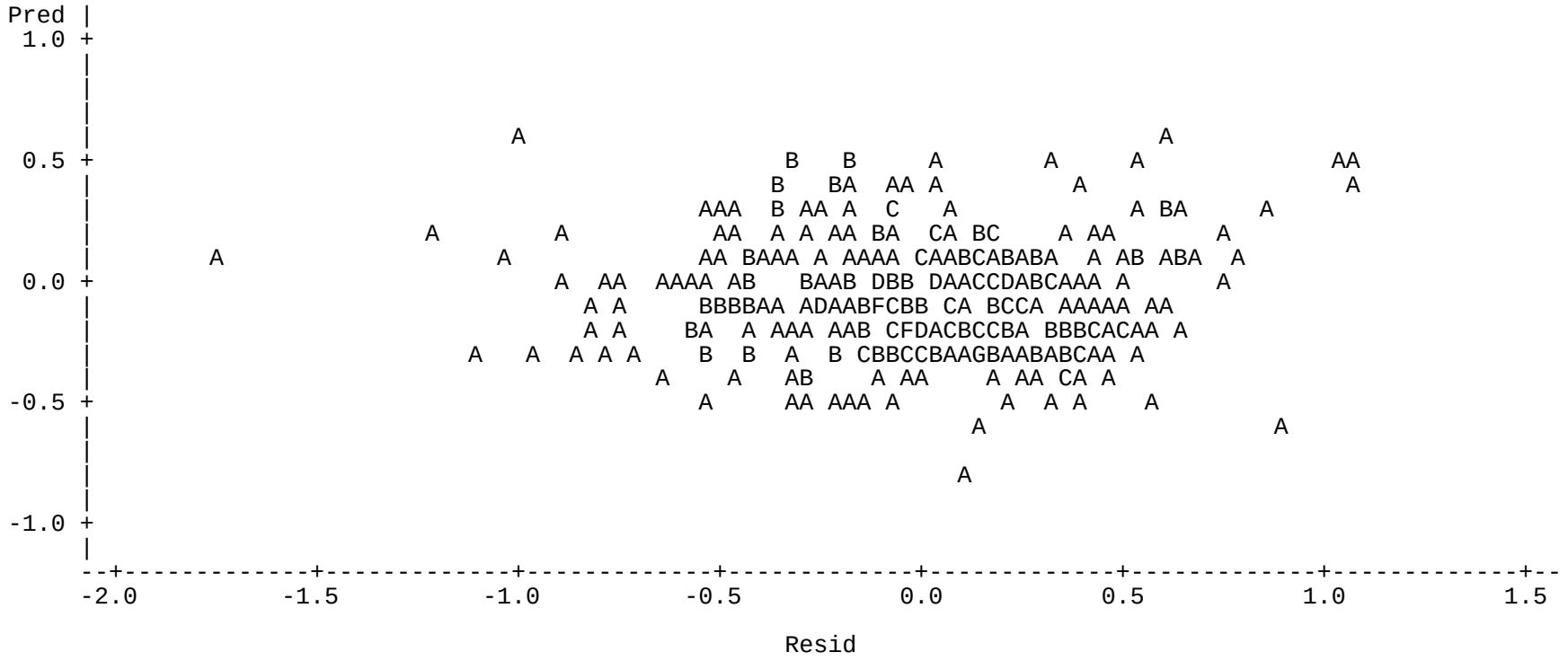

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

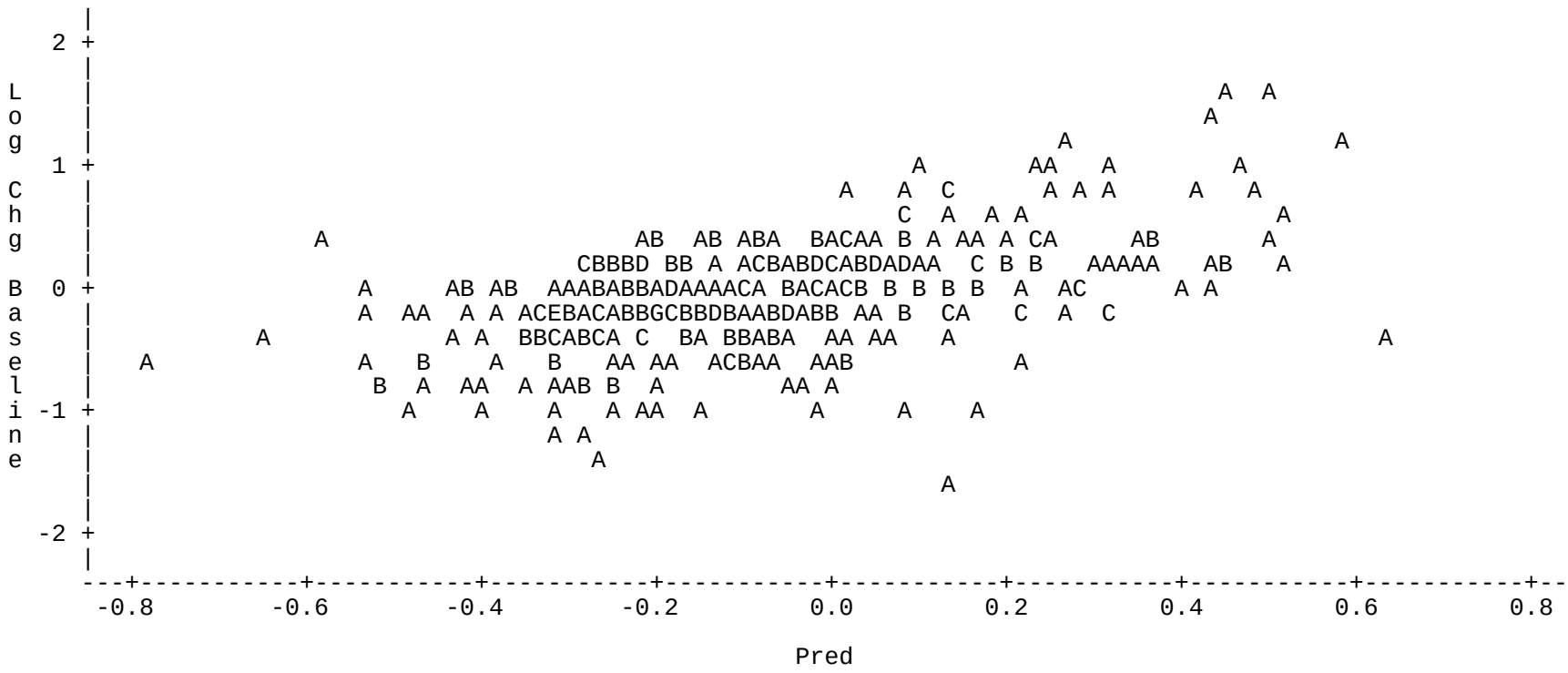

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	345	Sum Weights	345
Mean	0	Sum Observations	0
Std Deviation	0.39332515	Variance	0.15470467
Skewness	-0.4252492	Kurtosis	1.09294421
Uncorrected SS	53.2184075	Corrected SS	53.2184075
Coeff Variation		Std Error Mean	0.02117591

Basic Statistical Measures

Location		Variability	
Mean	0.000000	Std Deviation	0.39333
Median	0.014891	Variance	0.15470
Mode	0.526196	Range	2.81097
		Interquartile Range	0.47241

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	4.5	Pr >= |M|	0.6667
Signed Rank	S	1063.5	Pr >= |S|	0.5669

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.986685	Pr < W	0.0029
Kolmogorov-Smirnov	D	0.045372	Pr > D	0.0833
Cramer-von Mises	W-Sq	0.134202	Pr > W-Sq	0.0405
Anderson-Darling	A-Sq	0.835365	Pr > A-Sq	0.0324

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.0684112
99%	0.8927446
95%	0.6002465
90%	0.4731876
75% Q3	0.2491868
50% Median	0.0148914
25% Q1	-0.2232242
10%	-0.5024949
5%	-0.6430929
1%	-1.0474179
0% Min	-1.7425616

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.742562	247	0.872890	143
-1.204441	170	0.892745	12
-1.093777	146	1.043239	313
-1.047418	26	1.062426	265
-0.984984	244	1.068411	295

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

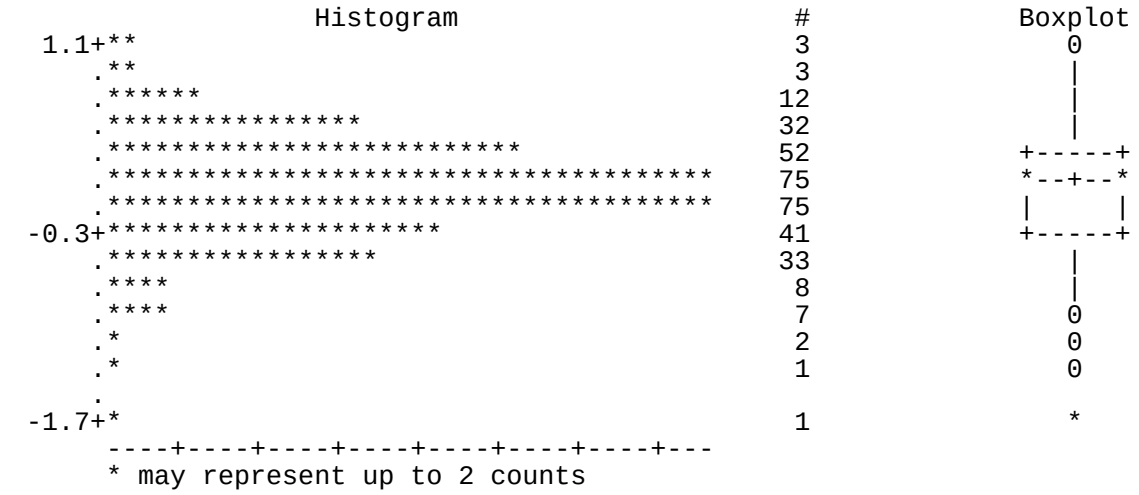

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Table 11.42
SAS Statistical Output for Table 11.41
Analysis of Log-Transformed Free Fatty Acid (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot

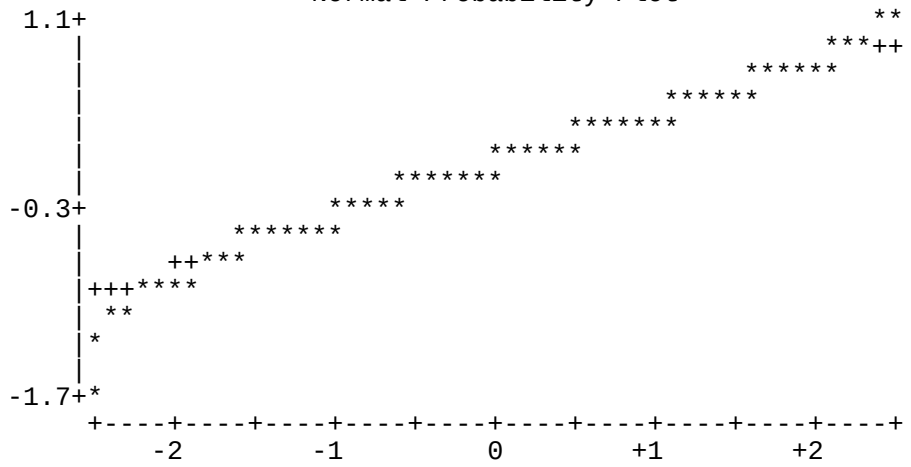

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Table 11.43
Summary Statistics of Log-Transformed Total Cholesterol (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	60	61	56	57
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	5.14	5.26	5.23	5.08	5.42	5.23
	CV (%) [2]	19.814	23.711	19.783	21.270	19.976	17.423
Week -5	Geo Mean	5.01	5.31	5.21	5.13	5.47	5.22
	CV (%) [2]	19.277	20.600	24.260	20.569	19.370	18.682
	Geo Mean - SE[3]	4.89	5.17	5.05	5.00	5.33	5.10
	Geo Mean + SE[3]	5.14	5.45	5.37	5.27	5.61	5.35
	Minimum	2.9	3.5	2.7	3.2	3.1	2.8
	Median	5.26	5.25	5.38	5.15	5.56	5.25
	Maximum	6.9	8.4	8.2	8.2	7.9	7.2
Ratio to Baseline (%) [4]	Geo Mean	-2.53	0.99	-0.32	1.10	0.92	-0.16
	Geo Mean - SE[3]	-4.27	-0.83	-2.48	-0.95	-1.54	-1.78
	Geo Mean + SE[3]	-0.77	2.85	1.89	3.19	3.44	1.49
	Minimum	-42.0	-33.0	-42.8	-37.2	-36.5	-21.8
	Median	-2.63	2.10	-0.15	1.59	0.70	-2.09
	Maximum	61.2	48.5	60.0	64.6	154.6	52.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.43
Summary Statistics of Log-Transformed Total Cholesterol (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	61	62	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	5.14	5.26	5.22	5.09	5.42	5.26
	CV (%) [2]	19.814	23.711	19.621	21.132	19.976	18.000
	Geo Mean - SE[3]	5.02	5.10	5.09	4.95	5.28	5.14
	Geo Mean + SE[3]	5.27	5.42	5.35	5.22	5.56	5.38
	Minimum	3.0	3.4	3.7	3.1	2.8	2.7
	Median	5.25	5.36	5.32	5.10	5.45	5.30
	Maximum	7.2	8.6	7.5	7.9	8.7	7.9

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.43
Summary Statistics of Log-Transformed Total Cholesterol (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	57	59	61	53	57
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	4 (7%)	2 (3%)	0	2 (4%)
Baseline	Geo Mean	5.12	5.22	5.19	5.09	5.39	5.27
	CV (%) [2]	19.916	23.834	19.674	21.311	20.346	18.093
Week 4	Geo Mean	5.09	5.20	5.16	5.19	5.24	5.19
	CV (%) [2]	19.297	19.731	22.142	19.703	21.638	19.970
	Geo Mean - SE[3]	4.96	5.07	5.01	5.06	5.09	5.05
	Geo Mean + SE[3]	5.22	5.34	5.30	5.32	5.40	5.33
	Minimum	3.1	3.2	2.9	3.1	3.0	2.9
	Median	5.12	5.10	5.35	5.23	5.31	5.19
	Maximum	7.9	8.1	7.2	8.6	8.7	7.1
Ratio to Baseline (%) [4]	Geo Mean	-0.56	-0.49	-0.74	2.09	-2.79	-1.53
	Geo Mean - SE[3]	-1.66	-2.13	-2.34	0.54	-4.74	-3.44
	Geo Mean + SE[3]	0.55	1.18	0.89	3.66	-0.80	0.42
	Minimum	-18.4	-27.2	-38.8	-28.5	-33.0	-43.5
	Median	-0.63	1.41	0.81	0.00	-2.56	-1.16
	Maximum	23.5	37.0	26.3	41.5	89.7	63.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.43
Summary Statistics of Log-Transformed Total Cholesterol (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	60	62	56	58
Number (%) of Values Carried Forward		9 (16%)	13 (22%)	8 (13%)	2 (3%)	2 (4%)	9 (16%)
Baseline	Geo Mean	5.13	5.24	5.21	5.09	5.42	5.28
	CV (%) [2]	19.694	23.677	19.747	21.132	19.976	17.954
Week 8	Geo Mean	5.13	5.34	5.19	5.30	5.29	5.18
	CV (%) [2]	18.004	20.261	21.909	21.849	22.640	17.906
	Geo Mean - SE[3]	5.01	5.20	5.04	5.16	5.13	5.06
	Geo Mean + SE[3]	5.25	5.48	5.33	5.45	5.45	5.30
	Minimum	3.1	3.5	3.4	2.8	2.3	3.0
	Median	5.25	5.30	5.29	5.36	5.41	5.24
	Maximum	7.1	8.2	7.8	8.0	8.7	7.3
Ratio to Baseline (%) [4]	Geo Mean	0.02	2.03	-0.52	4.26	-2.48	-1.83
	Geo Mean - SE[3]	-1.54	0.33	-2.34	2.24	-4.88	-3.70
	Geo Mean + SE[3]	1.60	3.76	1.33	6.33	-0.02	0.06
	Minimum	-27.2	-21.0	-30.7	-20.2	-48.2	-43.5
	Median	-1.79	0.26	-0.19	2.13	-1.38	0.92
	Maximum	45.1	43.2	87.0	124.3	79.6	24.6

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.43
Summary Statistics of Log-Transformed Total Cholesterol (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	60	62	56	58
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)	4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	5.13	5.24	5.21	5.09	5.42	5.28
	CV (%) [2]	19.694	23.677	19.747	21.132	19.976	17.954
Week 12	Geo Mean	5.17	5.36	5.22	5.13	5.29	5.16
	CV (%) [2]	18.062	18.329	21.031	21.909	20.457	19.323
	Geo Mean - SE[3]	5.05	5.23	5.09	4.99	5.15	5.03
	Geo Mean + SE[3]	5.29	5.49	5.37	5.28	5.43	5.29
	Minimum	3.0	3.6	3.1	3.2	2.9	2.8
	Median	5.27	5.40	5.33	5.10	5.46	5.09
	Maximum	7.0	8.1	8.1	8.4	8.7	7.2
Ratio to Baseline (%) [4]	Geo Mean	0.72	2.36	0.20	0.92	-2.45	-2.26
	Geo Mean - SE[3]	-0.89	0.35	-1.51	-1.28	-4.71	-4.65
	Geo Mean + SE[3]	2.37	4.41	1.95	3.17	-0.12	0.20
	Minimum	-23.7	-35.3	-35.0	-46.9	-45.7	-43.5
	Median	1.38	1.89	0.41	-0.09	-0.56	-0.23
	Maximum	48.2	56.8	43.6	110.4	76.2	68.1

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		58	58	60
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)
Baseline	Geo Mean	5.13	5.24	5.21
	CV (%) [2]	19.694	23.677	19.747
Week 12	Geo Mean	5.17	5.36	5.22
	CV (%) [2]	18.062	18.329	21.031
Ratio to Baseline (% chg) [3]	Geo Mean	0.72	2.36	0.20
	Geo Mean -SE,+SE	-0.89,2.37	0.35,4.41	-1.51,1.95
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	0.17	2.63	-0.14
	Geo Mean -SE,+SE	-1.70,2.07	0.72,4.58	-1.97,1.72
Ratio to Baseline (% diff) [4]	Geo Mean		2.46	-0.31
	95% CI		-2.79,7.99	-5.35,5.00
	p-val[5]		0.364	0.906

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significnat. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	56	58
Number (%) of Values Carried Forward		4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	5.09	5.42	5.28
	CV (%) [2]	21.132	19.976	17.954
Week 12	Geo Mean	5.13	5.29	5.16
	CV (%) [2]	21.909	20.457	19.323
Ratio to Baseline (% chg) [3]	Geo Mean	0.92	-2.45	-2.26
	Geo Mean -SE,+SE	-1.28,3.17	-4.71,-0.12	-4.65,0.20
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	0.04	-1.42	-1.70
	Geo Mean -SE,+SE	-1.76,1.88	-3.29,0.49	-3.52,0.17
Ratio to Baseline (% diff) [4]	Geo Mean	-0.13	-1.59	-1.86
	95% CI	-5.14,5.15	-6.65,3.75	-6.87,3.41
	p-val[5]	0.961	0.552	0.481

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significnat. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	1.63481254	Sum Observations	94.8191275
Std Deviation	0.19507017	Variance	0.03805237
Skewness	-0.7672397	Kurtosis	0.39774285
Uncorrected SS	157.180484	Corrected SS	2.16898518
Coeff Variation	11.9322654	Std Error Mean	0.02561397

Basic Statistical Measures

Location		Variability	
Mean	1.634813	Std Deviation	0.19507
Median	1.657264	Variance	0.03805
Mode	1.740466	Range	0.87264
		Interquartile Range	0.20817

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	63.82504	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.95445
99%	1.95445
95%	1.93874
90%	1.86408
75% Q3	1.75786
50% Median	1.65726
25% Q1	1.54969
10%	1.29473
5%	1.23837
1%	1.08181
0% Min	1.08181

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.08181	30	1.86563	7
1.21194	47	1.87026	43
1.23837	31	1.93874	50
1.25276	36	1.95303	26
1.29473	34	1.95445	12

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	1.64203338	Sum Observations	95.2379363
Std Deviation	0.17916889	Variance	0.03210149
Skewness	-0.6390614	Kurtosis	0.52467046
Uncorrected SS	158.213656	Corrected SS	1.82978494
Coeff Variation	10.9114034	Std Error Mean	0.02352603

Basic Statistical Measures

Location		Variability	
Mean	1.642033	Std Deviation	0.17917
Median	1.661077	Variance	0.03210
Mode	1.458615	Range	0.83548
		Interquartile Range	0.24773

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	69.79646	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.94734
99%	1.94734
95%	1.93442
90%	1.85317
75% Q3	1.78675
50% Median	1.66108
25% Q1	1.53902
10%	1.43508
5%	1.28093
1%	1.11186
0% Min	1.11186

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.11186	47	1.85630	49
1.20896	30	1.89462	37
1.28093	31	1.93442	51
1.31103	4	1.94305	54
1.41099	34	1.94734	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.00722084	Sum Observations	0.41880875
Std Deviation	0.12307402	Variance	0.01514721
Skewness	0.62361301	Kurtosis	1.87453958
Uncorrected SS	0.86641536	Corrected SS	0.86339121
Coeff Variation	1704.42787	Std Error Mean	0.01616041

Basic Statistical Measures

Location		Variability	
Mean	0.007221	Std Deviation	0.12307
Median	0.013713	Variance	0.01515
Mode		Range	0.66392
		Interquartile Range	0.13958

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.446823	Pr > |t|	0.6567
Sign	M	2	Pr >= |M|	0.6940

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	19.5	Pr >= |S|	0.8815

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.3936307
99%	0.3936307
95%	0.2058521
90%	0.1403574
75% Q3	0.0677182
50% Median	0.0137129
25% Q1	-0.0718585
10%	-0.1361322
5%	-0.1445183
1%	-0.2702903
0% Min	-0.2702903

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.270290	24	0.162961	37
-0.269273	38	0.181317	58
-0.144518	12	0.205852	36
-0.138150	40	0.372069	51
-0.136576	26	0.393631	32

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	1.65546209	Sum Observations	96.0168014
Std Deviation	0.2335446	Variance	0.05454308
Skewness	0.15798541	Kurtosis	-0.6433448
Uncorrected SS	162.061131	Corrected SS	3.10895564
Coeff Variation	14.1075174	Std Error Mean	0.03066591

Basic Statistical Measures

Location		Variability	
Mean	1.655462	Std Deviation	0.23354
Median	1.678030	Variance	0.05454
Mode	1.458615	Range	0.94280
		Interquartile Range	0.34309

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	53.98379	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.15176
99%	2.15176
95%	2.08939
90%	2.00418
75% Q3	1.80171
50% Median	1.67803
25% Q1	1.45862
10%	1.37372
5%	1.25562
1%	1.20896
0% Min	1.20896

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.20896	30	2.02815	45
1.25276	32	2.03732	48
1.25562	21	2.08939	46
1.28093	17	2.11626	34
1.30833	41	2.15176	4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	1.67879257	Sum Observations	97.369969
Std Deviation	0.18177717	Variance	0.03304294
Skewness	-0.0632832	Kurtosis	-0.3530174
Uncorrected SS	165.347428	Corrected SS	1.88344754
Coeff Variation	10.8278517	Std Error Mean	0.02386851

Basic Statistical Measures

Location		Variability	
Mean	1.678793	Std Deviation	0.18178
Median	1.686399	Variance	0.03304
Mode	1.410987	Range	0.80016
		Interquartile Range	0.25202

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	70.33503	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.08939
99%	2.08939
95%	1.96711
90%	1.95019
75% Q3	1.80171
50% Median	1.68640
25% Q1	1.54969
10%	1.42311
5%	1.36354
1%	1.28923
0% Min	1.28923

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.28923	22	1.96291	7
1.29473	33	1.96711	34
1.36354	21	1.96711	53
1.41099	32	2.00418	46
1.41099	28	2.08939	16

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.02333048	Sum Observations	1.35316759
Std Deviation	0.15081356	Variance	0.02274473
Skewness	0.1089588	Kurtosis	1.23648807
Uncorrected SS	1.32801966	Corrected SS	1.29644962
Coeff Variation	646.423	Std Error Mean	0.01980279

Basic Statistical Measures

Location		Variability	
Mean	0.023330	Std Deviation	0.15081
Median	0.018692	Variance	0.02274
Mode		Range	0.88590
		Interquartile Range	0.18686

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.178141	Pr > |t|	0.2436
Sign	M	3.5	Pr >= |M|	0.4270

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	135.5	Pr >= |S|	0.2856

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.4497379
99%	0.4497379
95%	0.3148107
90%	0.2126623
75% Q3	0.1079213
50% Median	0.0186920
25% Q1	-0.0789432
10%	-0.1491432
5%	-0.1823216
1%	-0.4361641
0% Min	-0.4361641

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.436164	4	0.214148	30
-0.235607	48	0.226646	53
-0.182322	51	0.314811	29
-0.170221	35	0.351745	9
-0.152969	22	0.449738	58

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	60	Sum Weights	60
Mean	1.65133514	Sum Observations	99.0801084
Std Deviation	0.19558886	Variance	0.038255
Skewness	-0.037316	Kurtosis	-1.1769552
Uncorrected SS	165.87151	Corrected SS	2.25704512
Coeff Variation	11.8442862	Std Error Mean	0.02525041

Basic Statistical Measures

Location		Variability	
Mean	1.651335	Std Deviation	0.19559
Median	1.666752	Variance	0.03826
Mode	1.348073	Range	0.71751
		Interquartile Range	0.33272

NOTE: The mode displayed is the smallest of 7 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	65.39834	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001
Signed Rank	S	915	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.01223
99%	2.01223
95%	1.92844
90%	1.89084
75% Q3	1.81319
50% Median	1.66675
25% Q1	1.48047
10%	1.39127
5%	1.34807
1%	1.29473
0% Min	1.29473

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.29473	27	1.89762	51
1.29746	21	1.90954	36
1.34807	28	1.94734	11
1.34807	10	2.00956	3
1.38128	9	2.01223	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	60	Sum Weights	60
Mean	1.65334748	Sum Observations	99.2008487
Std Deviation	0.2080424	Variance	0.04328164
Skewness	-0.2605971	Kurtosis	-0.3533634
Uncorrected SS	166.56709	Corrected SS	2.55361669
Coeff Variation	12.5831018	Std Error Mean	0.02685816

Basic Statistical Measures

Location		Variability	
Mean	1.653347	Std Deviation	0.20804
Median	1.672314	Variance	0.04328
Mode	1.458615	Range	0.97186
		Interquartile Range	0.33989

NOTE: The mode displayed is the smallest of 7 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	61.55848	Pr > |t|	<.0001
Sign	M	30	Pr >= |M|	<.0001
Signed Rank	S	915	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.09679
99%	2.09679
95%	1.94874
90%	1.91168
75% Q3	1.81808
50% Median	1.67231
25% Q1	1.47818
10%	1.38598
5%	1.30153
1%	1.12493
0% Min	1.12493

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.12493	49	1.92862	58
1.22083	47	1.94162	18
1.29473	27	1.95586	51
1.30833	21	2.02551	3
1.35067	43	2.09679	57

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	0.00201234	Sum Observations	0.12074033
Std Deviation	0.13364158	Variance	0.01786007
Skewness	-0.2636598	Kurtosis	1.66945393
Uncorrected SS	1.05398715	Corrected SS	1.05374418
Coeff Variation	6641.10715	Std Error Mean	0.01725305

Basic Statistical Measures

Location		Variability	
Mean	0.002012	Std Deviation	0.13364
Median	0.004049	Variance	0.01786
Mode		Range	0.79316
		Interquartile Range	0.13897

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.116637	Pr > |t|	0.9075
Sign	M	0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	22.5	Pr >= |S|	0.8668

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.36205262
99%	0.36205262
95%	0.19838247
90%	0.13856961
75% Q3	0.08957186
50% Median	0.00404861
25% Q1	-0.04940100
10%	-0.17635479
5%	-0.22287026
1%	-0.43110754
0% Min	-0.43110754

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.431108	49	0.143334	5
-0.260077	19	0.154868	18
-0.228439	47	0.241897	12
-0.217301	25	0.310155	10
-0.186586	34	0.362053	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	62	Sum Weights	62
Mean	1.62653642	Sum Observations	100.845258
Std Deviation	0.20901824	Variance	0.04368863
Skewness	-0.3366608	Kurtosis	0.54522255
Uncorrected SS	166.693492	Corrected SS	2.66500615
Coeff Variation	12.850511	Std Error Mean	0.02654534

Basic Statistical Measures

Location		Variability	
Mean	1.626536	Std Deviation	0.20902
Median	1.629241	Variance	0.04369
Mode	1.536867	Range	0.95299
		Interquartile Range	0.21307

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	61.27389	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.06813
99%	2.06813
95%	1.97408
90%	1.90658
75% Q3	1.73695
50% Median	1.62924
25% Q1	1.52388
10%	1.39872
5%	1.17865
1%	1.11514
0% Min	1.11514

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.11514	44	1.92716	60
1.12493	49	1.97408	22
1.12817	6	2.00148	29
1.17865	28	2.04769	27
1.35067	5	2.06813	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	62	Sum Weights	62
Mean	1.63571431	Sum Observations	101.414287
Std Deviation	0.21652518	Variance	0.04688315
Skewness	0.09188157	Kurtosis	-0.143733
Uncorrected SS	168.744672	Corrected SS	2.85987245
Coeff Variation	13.2373473	Std Error Mean	0.02749873

Basic Statistical Measures

Location		Variability	
Mean	1.635714	Std Deviation	0.21653
Median	1.629239	Variance	0.04688
Mode	1.348073	Range	0.97845
		Interquartile Range	0.26495

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	59.48328	Pr > |t|	<.0001
Sign	M	31	Pr >= |M|	<.0001
Signed Rank	S	976.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.12585
99%	2.12585
95%	1.98100
90%	1.94305
75% Q3	1.75786
50% Median	1.62924
25% Q1	1.49290
10%	1.34807
5%	1.30563
1%	1.14740
0% Min	1.14740

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.14740	50	1.95586	10
1.20297	44	1.98100	19
1.26695	18	2.06686	29
1.30563	49	2.07944	27
1.30833	28	2.12585	8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	0.00917788	Sum Observations	0.56902878
Std Deviation	0.17349142	Variance	0.03009927
Skewness	0.51658988	Kurtosis	6.98667274
Uncorrected SS	1.84127815	Corrected SS	1.83605567
Coeff Variation	1890.32056	Std Error Mean	0.02203343

Basic Statistical Measures

Location		Variability	
Mean	0.00918	Std Deviation	0.17349
Median	-0.00089	Variance	0.03010
Mode		Range	1.37730
		Interquartile Range	0.13896

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.416544	Pr > |t|	0.6785
Sign	M	-0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	32.5	Pr >= |S|	0.8176

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.743631086
99%	0.743631086
95%	0.234931507
90%	0.192531116
75% Q3	0.067822596
50% Median	-0.000890472
25% Q1	-0.071132987
10%	-0.157836014
5%	-0.205799438
1%	-0.633666271
0% Min	-0.633666271

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.633666	18	0.219273	8
-0.290060	50	0.234932	16
-0.210295	23	0.235677	40
-0.205799	14	0.367725	25
-0.194156	52	0.743631	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	56	Sum Weights	56
Mean	1.69004185	Sum Observations	94.6423438
Std Deviation	0.19780517	Variance	0.03912688
Skewness	-0.5610094	Kurtosis	1.94839659
Uncorrected SS	162.101501	Corrected SS	2.1519786
Coeff Variation	11.7041578	Std Error Mean	0.02643283

Basic Statistical Measures

Location		Variability	
Mean	1.690042	Std Deviation	0.19781
Median	1.695574	Variance	0.03913
Mode	1.492904	Range	1.12313
		Interquartile Range	0.22867

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	63.93723	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.15987
99%	2.15987
95%	2.06051
90%	1.88707
75% Q3	1.81074
50% Median	1.69557
25% Q1	1.58206
10%	1.49290
5%	1.29473
1%	1.03674
0% Min	1.03674

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.03674	38	1.89010	12
1.19695	14	1.96711	31
1.29473	25	2.06051	24
1.44692	21	2.09433	10
1.49290	34	2.15987	42

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	56	Sum Weights	56
Mean	1.66527116	Sum Observations	93.2551848
Std Deviation	0.20247476	Variance	0.04099603
Skewness	-0.3644959	Kurtosis	0.95694028
Uncorrected SS	157.549951	Corrected SS	2.25478146
Coeff Variation	12.1586658	Std Error Mean	0.02705683

Basic Statistical Measures

Location		Variability	
Mean	1.665271	Std Deviation	0.20247
Median	1.696532	Variance	0.04100
Mode	1.492904	Range	1.10901
		Interquartile Range	0.26454

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	61.54717	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.16332
99%	2.16332
95%	1.98787
90%	1.91398
75% Q3	1.78841
50% Median	1.69653
25% Q1	1.52388
10%	1.45161
5%	1.28093
1%	1.05431
0% Min	1.05431

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.05431	14	1.92862	12
1.19392	18	1.93730	8
1.28093	25	1.98787	31
1.43270	45	2.04898	10
1.43508	32	2.16332	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.0247707	Sum Observations	-1.3871589
Std Deviation	0.17602866	Variance	0.03098609
Skewness	-0.3070329	Kurtosis	3.70658789
Uncorrected SS	1.73859581	Corrected SS	1.70423492
Coeff Variation	-710.63269	Std Error Mean	0.02352282

Basic Statistical Measures

Location		Variability	
Mean	-0.02477	Std Deviation	0.17603
Median	-0.00565	Variance	0.03099
Mode		Range	1.17686
		Interquartile Range	0.16841

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.05305	Pr > |t|	0.2969
Sign	M	-0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-108	Pr >= |S|	0.3703

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.56668296
99%	0.56668296
95%	0.22354109
90%	0.10669550
75% Q3	0.05040541
50% Median	-0.00564978
25% Q1	-0.11800025
10%	-0.19145404
5%	-0.39786051
1%	-0.61018088
0% Min	-0.61018088

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.610181	42	0.113641	1
-0.445074	18	0.130654	8
-0.397861	23	0.223541	3
-0.295623	49	0.334998	37
-0.272047	45	0.566683	38

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	1.6630697	Sum Observations	96.4580427
Std Deviation	0.17811593	Variance	0.03172528
Skewness	-0.66853	Kurtosis	2.07378725
Uncorrected SS	162.22479	Corrected SS	1.80834121
Coeff Variation	10.71007	Std Error Mean	0.02338777

Basic Statistical Measures

Location		Variability	
Mean	1.663070	Std Deviation	0.17812
Median	1.672402	Variance	0.03173
Mode	1.599388	Range	1.05988
		Interquartile Range	0.26073

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	71.10853	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.06051
99%	2.06051
95%	1.93152
90%	1.85942
75% Q3	1.80829
50% Median	1.67240
25% Q1	1.54756
10%	1.44692
5%	1.42070
1%	1.00063
0% Min	1.00063

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.00063	1	1.85942	38
1.40610	16	1.90658	53
1.42070	52	1.93152	33
1.43031	10	1.98787	21
1.43508	51	2.06051	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	1.64026128	Sum Observations	95.135154
Std Deviation	0.19146034	Variance	0.03665706
Skewness	-0.3811839	Kurtosis	0.48085077
Uncorrected SS	158.135962	Corrected SS	2.08945245
Coeff Variation	11.6725512	Std Error Mean	0.02513997

Basic Statistical Measures

Location		Variability	
Mean	1.640261	Std Deviation	0.19146
Median	1.627276	Variance	0.03666
Mode	1.360977	Range	0.93443
		Interquartile Range	0.23605

NOTE: The mode displayed is the smallest of 7 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	65.24515	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.97824
99%	1.97824
95%	1.94448
90%	1.93152
75% Q3	1.76644
50% Median	1.62728
25% Q1	1.53039
10%	1.37372
5%	1.33500
1%	1.04380
0% Min	1.04380

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
1.04380	1	1.94018	52
1.30563	48	1.94305	53
1.33500	28	1.94448	17
1.36098	57	1.96851	46
1.36098	33	1.97824	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0228084	Sum Observations	-1.3228887
Std Deviation	0.18893977	Variance	0.03569824
Skewness	-0.127884	Kurtosis	2.39866077
Uncorrected SS	2.06497253	Corrected SS	2.03479952
Coeff Variation	-828.3771	Std Error Mean	0.02480901

Basic Statistical Measures

Location		Variability	
Mean	-0.02281	Std Deviation	0.18894
Median	-0.00234	Variance	0.03570
Mode		Range	1.09003
		Interquartile Range	0.18634

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.91936	Pr > |t|	0.3618
Sign	M	-0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-102.5	Pr >= |S|	0.4203

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.51948369
99%	0.51948369
95%	0.19013410
90%	0.14557489
75% Q3	0.07786032
50% Median	-0.00234192
25% Q1	-0.10848064
10%	-0.23841102
5%	-0.45886588
1%	-0.57054486
0% Min	-0.57054486

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.570545	33	0.156405	13
-0.461818	21	0.180858	2
-0.458866	20	0.190134	15
-0.327090	54	0.517301	35
-0.254234	28	0.519484	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	352
Observations Used	352
Observations Not Used	0
Total Observations	352

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.02040	0.001562	13.06	<.0001	0.05	0.01765	0.02384

Fit Statistics

-2 Res Log Likelihood	-315.3
AIC (smaller is better)	-313.3
AICC (smaller is better)	-313.3
BIC (smaller is better)	-309.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.5769	0.06842	341	8.43	<.0001
SEX	Female				0.01553	0.01555	341	1.00	0.3187
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			0.003587	0.01565	341	0.23	0.8188
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.01878	0.02662	341	0.71	0.4810
TRTCD				2.5mg	0.04308	0.02656	341	1.62	0.1057
TRTCD				7.5mg	0.01565	0.02635	341	0.59	0.5529
TRTCD				15mg	0.01752	0.02616	341	0.67	0.5036
TRTCD				30mg	0.002786	0.02685	341	0.10	0.9174
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.05957	0.01801	341	-3.31	0.0010
REGIONCD			Eastern Europe		-0.03874	0.01922	341	-2.02	0.0446
REGIONCD			Western Europe		0			.	
EFLOGBL					-0.3467	0.03898	341	-8.90	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	341	1.00	0.3187
TRTTYPCD	1	341	0.05	0.8188
TRTCD	5	341	0.66	0.6551
REGIONCD	2	341	5.71	0.0036
EFLOGBL	1	341	79.13	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	0.02430	0.02672	341	0.91	0.3638	0.05	-0.02827	0.07687
7.5mg vs Pbo	-0.00313	0.02638	341	-0.12	0.9057	0.05	-0.05501	0.04875
15mg vs Pbo	-0.00127	0.02618	341	-0.05	0.9615	0.05	-0.05276	0.05023
30mg vs Pbo	-0.01600	0.02685	341	-0.60	0.5518	0.05	-0.06882	0.03682
45mg vs Pbo	-0.01878	0.02662	341	-0.71	0.4810	0.05	-0.07114	0.03358

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
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Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5028	0.5028	0.5028	0.5028	0.5028
SEX	Male				0.4972	0.4972	0.4972	0.4972	0.4972
TRTTYPCD		Diet & Exercise			0.4063	0.4063	0.4063	0.4063	0.4063
TRTTYPCD		Monotherapy			0.5938	0.5938	0.5938	0.5938	0.5938
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3295	0.3295	0.3295	0.3295	0.3295
REGIONCD			Eastern Europe		0.2699	0.2699	0.2699	0.2699	0.2699
REGIONCD			Western Europe		0.4006	0.4006	0.4006	0.4006	0.4006
EFLOGBL					1.653	1.653	1.653	1.653	1.653

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5028
SEX	Male				0.4972
TRTTYPCD		Diet & Exercise			0.4063
TRTTYPCD		Monotherapy			0.5938
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3295
REGIONCD			Eastern Europe		0.2699
REGIONCD			Western Europe		0.4006
EFLOGBL					1.653

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.001686	0.01883	341	0.09	0.9287	0.05	-0.03535	0.03872
TRTCD	2.5mg	WORK.EFF	0.02599	0.01883	341	1.38	0.1685	0.05	-0.01106	0.06303
TRTCD	7.5mg	WORK.EFF	-0.00144	0.01846	341	-0.08	0.9378	0.05	-0.03775	0.03487
TRTCD	15mg	WORK.EFF	0.000420	0.01818	341	0.02	0.9816	0.05	-0.03535	0.03619
TRTCD	30mg	WORK.EFF	-0.01431	0.01918	341	-0.75	0.4562	0.05	-0.05204	0.02342
TRTCD	45mg	WORK.EFF	-0.01710	0.01878	341	-0.91	0.3633	0.05	-0.05403	0.01984

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-0.02430	0.02672	341	-0.91	0.3638	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.003128	0.02638	341	0.12	0.9057	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.001266	0.02618	341	0.05	0.9615	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.01600	0.02685	341	0.60	0.5518	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.01878	0.02662	341	0.71	0.4810	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.02743	0.02638	341	1.04	0.2992	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.02557	0.02615	341	0.98	0.3289	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.04030	0.02696	341	1.49	0.1359	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.04308	0.02656	341	1.62	0.1057	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.00186	0.02591	341	-0.07	0.9428	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.01287	0.02662	341	0.48	0.6291	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.01565	0.02635	341	0.59	0.5529	0.05
TRTCD	15mg	30mg	WORK.EFF	0.01473	0.02651	341	0.56	0.5788	0.05
TRTCD	15mg	45mg	WORK.EFF	0.01752	0.02616	341	0.67	0.5036	0.05
TRTCD	30mg	45mg	WORK.EFF	0.002786	0.02685	341	0.10	0.9174	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.07687	0.02827
TRTCD	Placebo	7.5mg	-0.04875	0.05501
TRTCD	Placebo	15mg	-0.05023	0.05276
TRTCD	Placebo	30mg	-0.03682	0.06882
TRTCD	Placebo	45mg	-0.03358	0.07114
TRTCD	2.5mg	7.5mg	-0.02446	0.07932
TRTCD	2.5mg	15mg	-0.02587	0.07701
TRTCD	2.5mg	30mg	-0.01273	0.09333
TRTCD	2.5mg	45mg	-0.00915	0.09532
TRTCD	7.5mg	15mg	-0.05282	0.04910

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.03948	0.06522
TRTCD	7.5mg	45mg	-0.03618	0.06749
TRTCD	15mg	30mg	-0.03741	0.06687
TRTCD	15mg	45mg	-0.03394	0.06897
TRTCD	30mg	45mg	-0.05003	0.05560

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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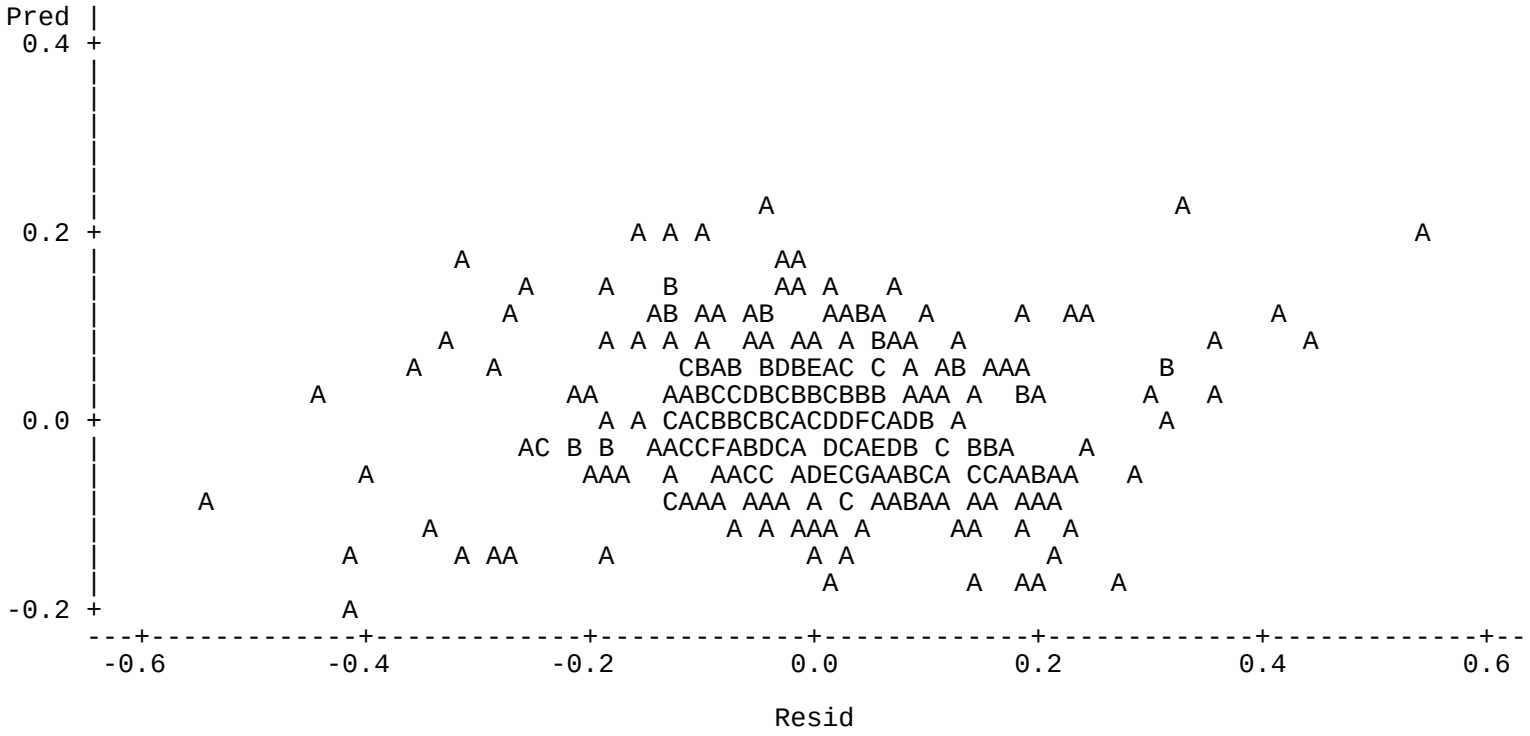
Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

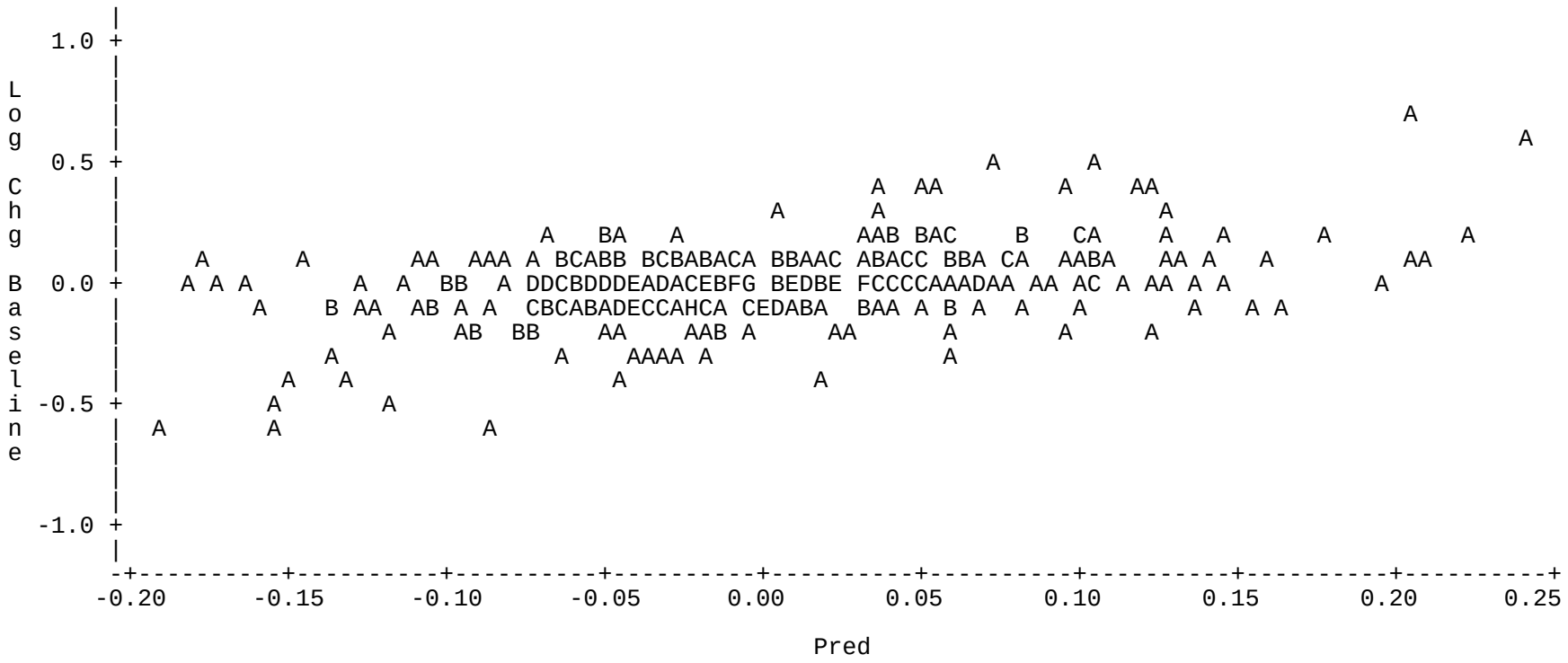

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	352	Sum Weights	352
Mean	0	Sum Observations	0
Std Deviation	0.14076678	Variance	0.01981529
Skewness	-0.0863517	Kurtosis	1.76943867
Uncorrected SS	6.95516545	Corrected SS	6.95516545
Coeff Variation		Std Error Mean	0.00750289

Basic Statistical Measures

Location		Variability	
Mean	0.000000	Std Deviation	0.14077
Median	0.004084	Variance	0.01982
Mode		Range	1.08625
		Interquartile Range	0.15615

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	5	Pr >= |M|	0.6315
Signed Rank	S	91	Pr >= |S|	0.9621

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.976734	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.062565	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.363469	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.254458	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.54040534
99%	0.35923337
95%	0.21033740
90%	0.17471479
75% Q3	0.07431185
50% Median	0.00408392
25% Q1	-0.08183572
10%	-0.14749052
5%	-0.24099845
1%	-0.41773717
0% Min	-0.54584551

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.545846	115	0.355213	351
-0.448965	288	0.359233	200
-0.418131	205	0.416090	299
-0.417737	266	0.443386	224
-0.400462	119	0.540405	36

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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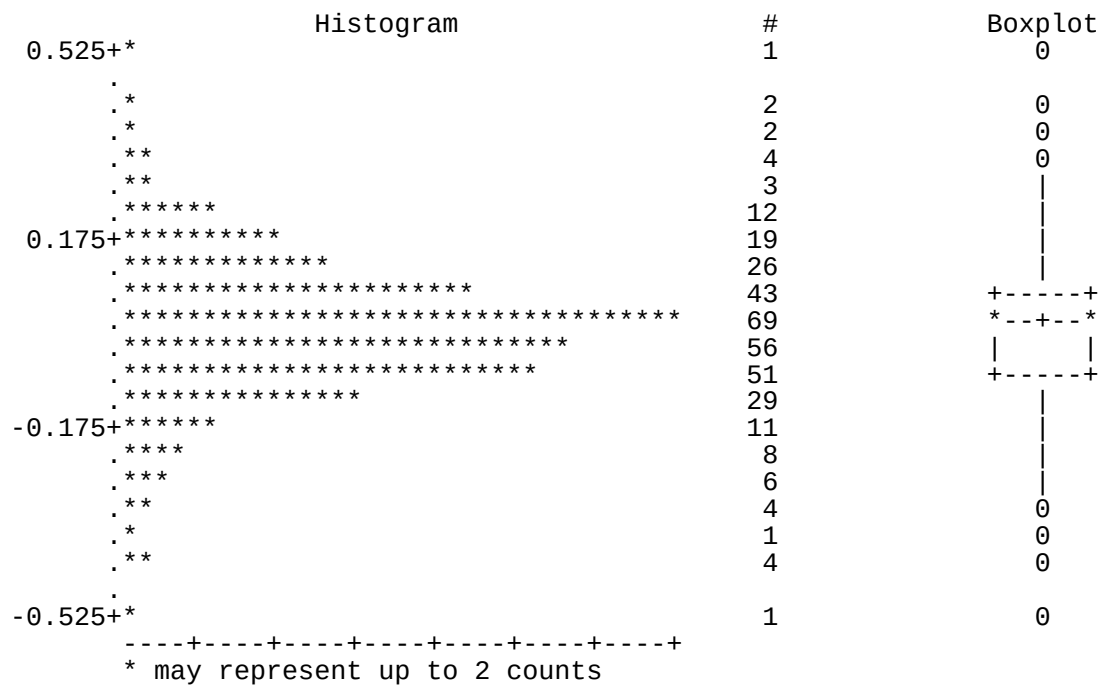
Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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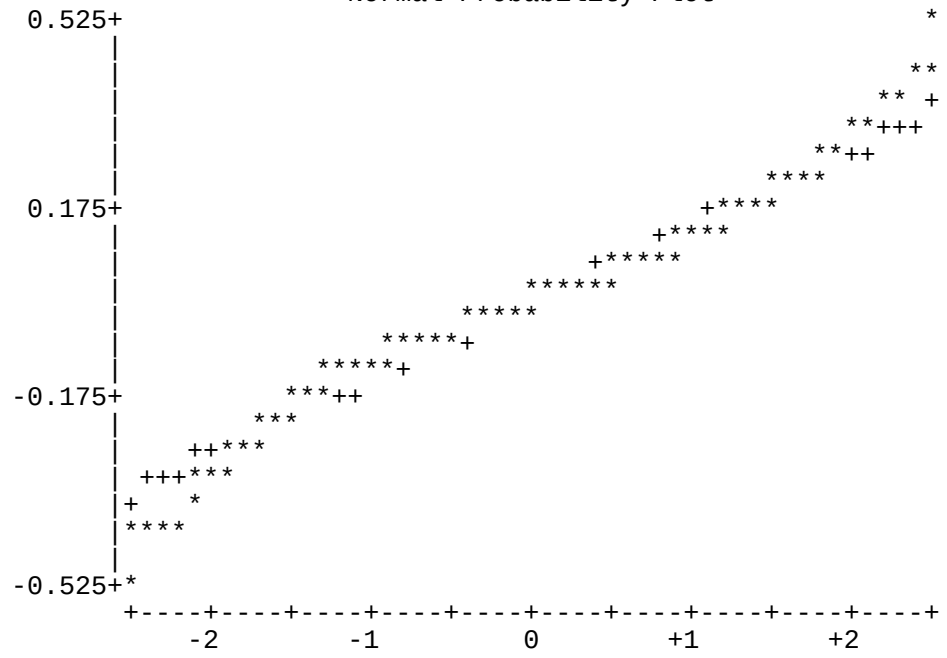
Table 11.45
SAS Statistical Output for Table 11.44
Analysis of Log-Transformed Total Cholesterol (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.46
Summary Statistics of Log-Transformed HDL-c (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	60	61	56	57
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	1.17	1.25	1.24	1.21	1.23	1.23
	CV (%) [2]	20.479	26.808	26.697	27.533	22.626	26.262
Week -5	Geo Mean	1.18	1.24	1.27	1.27	1.27	1.26
	CV (%) [2]	22.311	25.246	26.820	25.596	25.149	27.823
	Geo Mean - SE[3]	1.15	1.20	1.22	1.22	1.23	1.22
	Geo Mean + SE[3]	1.22	1.28	1.31	1.31	1.31	1.31
	Minimum	0.8	0.7	0.7	0.7	0.7	0.8
	Median	1.15	1.19	1.26	1.25	1.26	1.27
	Maximum	2.2	2.0	2.1	2.2	3.1	2.2
Ratio to Baseline (%) [4]	Geo Mean	0.99	-0.84	2.20	4.76	3.34	2.64
	Geo Mean - SE[3]	-0.47	-2.63	0.57	3.42	1.15	0.47
	Geo Mean + SE[3]	2.47	0.98	3.87	6.12	5.58	4.85
	Minimum	-20.4	-43.1	-28.4	-16.7	-25.7	-40.9
	Median	0.00	0.00	1.94	4.08	1.43	2.91
	Maximum	38.7	42.9	45.0	32.8	119.8	122.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.46
Summary Statistics of Log-Transformed HDL-c (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	59	61	62	56	59
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	1.17	1.25	1.23	1.21	1.23	1.23
	CV (%) [2]	20.479	26.808	26.850	27.571	22.626	25.865
	Geo Mean - SE[3]	1.14	1.21	1.19	1.17	1.19	1.19
	Geo Mean + SE[3]	1.20	1.30	1.27	1.26	1.26	1.27
	Minimum	0.6	0.7	0.7	0.6	0.8	0.7
	Median	1.15	1.25	1.20	1.23	1.23	1.26
	Maximum	2.1	2.1	2.0	2.2	2.1	2.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.46
Summary Statistics of Log-Transformed HDL-c (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	57	58	61	53	57
Number (%) of Values Carried Forward		2 (4%)	2 (4%)	4 (7%)	2 (3%)	0	2 (4%)
Baseline	Geo Mean	1.17	1.25	1.24	1.22	1.24	1.22
	CV (%) [2]	21.117	26.382	26.281	27.686	22.847	26.298
Week 4	Geo Mean	1.18	1.25	1.26	1.25	1.22	1.27
	CV (%) [2]	20.786	24.091	26.718	28.039	24.196	27.800
	Geo Mean - SE[3]	1.15	1.21	1.22	1.20	1.18	1.22
	Geo Mean + SE[3]	1.21	1.29	1.31	1.29	1.26	1.31
	Minimum	0.9	0.7	0.7	0.6	0.7	0.8
	Median	1.16	1.25	1.29	1.29	1.24	1.30
	Maximum	2.2	2.0	2.2	2.4	2.0	2.5
Ratio to Baseline (%) [4]	Geo Mean	1.05	-0.37	2.15	2.39	-1.37	3.44
	Geo Mean - SE[3]	-0.75	-1.93	0.14	1.10	-3.16	1.67
	Geo Mean + SE[3]	2.89	1.22	4.20	3.70	0.46	5.24
	Minimum	-44.3	-39.5	-27.7	-13.6	-39.2	-29.0
	Median	0.00	-0.70	1.94	0.00	0.00	2.86
	Maximum	65.0	35.7	115.0	58.6	39.4	79.6

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.46
Summary Statistics of Log-Transformed HDL-c (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	59	62	56	58
Number (%) of Values Carried Forward		9 (16%)	13 (22%)	7 (12%)	2 (3%)	2 (4%)	9 (16%)
Baseline	Geo Mean	1.17	1.26	1.24	1.21	1.23	1.23
	CV (%) [2]	20.951	26.663	26.560	27.571	22.626	26.066
Week 8	Geo Mean	1.23	1.27	1.27	1.23	1.26	1.25
	CV (%) [2]	23.194	23.407	29.162	26.579	28.368	26.040
	Geo Mean - SE[3]	1.19	1.23	1.23	1.19	1.22	1.21
	Geo Mean + SE[3]	1.27	1.31	1.32	1.27	1.31	1.30
	Minimum	0.8	0.7	0.6	0.6	0.6	0.8
	Median	1.19	1.27	1.27	1.24	1.29	1.27
	Maximum	2.6	2.1	2.3	2.4	2.7	2.3
Ratio to Baseline (%) [4]	Geo Mean	4.98	0.68	2.24	1.52	2.82	2.33
	Geo Mean - SE[3]	3.05	-0.88	0.05	0.38	0.67	0.88
	Geo Mean + SE[3]	6.95	2.26	4.47	2.67	5.01	3.80
	Minimum	-39.9	-27.7	-55.5	-14.4	-33.7	-20.8
	Median	5.39	0.33	3.85	1.00	2.27	2.69
	Maximum	65.0	35.7	57.0	28.7	71.8	30.6

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.46
Summary Statistics of Log-Transformed HDL-c (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	58	60	62	56	58
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)	4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	1.17	1.26	1.24	1.21	1.23	1.23
	CV (%) [2]	20.951	26.663	26.613	27.571	22.626	26.066
Week 12	Geo Mean	1.23	1.26	1.30	1.22	1.27	1.27
	CV (%) [2]	22.200	22.666	27.145	27.649	23.282	26.001
	Geo Mean - SE[3]	1.20	1.23	1.25	1.18	1.23	1.22
	Geo Mean + SE[3]	1.27	1.30	1.34	1.26	1.30	1.31
	Minimum	0.9	0.7	0.7	0.6	0.7	0.8
	Median	1.24	1.30	1.30	1.19	1.26	1.26
	Maximum	2.4	1.9	2.2	2.4	2.4	2.2
Ratio to Baseline (%) [4]	Geo Mean	5.02	0.50	4.63	0.54	3.11	3.36
	Geo Mean - SE[3]	3.33	-1.11	3.01	-0.72	1.19	1.45
	Geo Mean + SE[3]	6.72	2.13	6.28	1.83	5.06	5.32
	Minimum	-17.5	-34.6	-18.5	-25.0	-35.8	-36.5
	Median	4.91	0.00	4.26	0.33	3.09	3.23
	Maximum	56.7	35.7	57.0	33.3	44.2	69.4

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		58	58	60
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)
Baseline	Geo Mean	1.17	1.26	1.24
	CV (%) [2]	20.951	26.663	26.613
Week 12	Geo Mean	1.23	1.26	1.30
	CV (%) [2]	22.200	22.666	27.145
Ratio to Baseline (% chg) [3]	Geo Mean	5.02	0.50	4.63
	Geo Mean -SE,+SE	3.33,6.72	-1.11,2.13	3.01,6.28
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	4.36	1.03	4.81
	Geo Mean -SE,+SE	2.71,6.04	-0.58,2.65	3.18,6.46
Ratio to Baseline (% diff) [4]	Geo Mean		-3.20	0.43
	95% CI		-7.42,1.23	-3.89,4.95
	p-val[5]		0.154	0.848

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	56	58
Number (%) of Values Carried Forward		4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	1.21	1.23	1.23
	CV (%) [2]	27.571	22.626	26.066
Week 12	Geo Mean	1.22	1.27	1.27
	CV (%) [2]	27.649	23.282	26.001
Ratio to Baseline (% chg) [3]	Geo Mean	0.54	3.11	3.36
	Geo Mean -SE,+SE	-0.72,1.83	1.19,5.06	1.45,5.32
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	0.50	3.02	3.42
	Geo Mean -SE,+SE	-1.04,2.06	1.37,4.71	1.78,5.07
Ratio to Baseline (% diff) [4]	Geo Mean	-3.70	-1.28	-0.91
	95% CI	-7.81,0.60	-5.60,3.23	-5.21,3.59
	p-val[5]	0.090	0.570	0.687

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.15906525	Sum Observations	9.22578456
Std Deviation	0.20725975	Variance	0.0429566
Skewness	-0.0649537	Kurtosis	1.4187842
Uncorrected SS	3.91602807	Corrected SS	2.44852633
Coeff Variation	130.298569	Std Error Mean	0.02721454

Basic Statistical Measures

Location		Variability	
Mean	0.159065	Std Deviation	0.20726
Median	0.139762	Variance	0.04296
Mode	0.048790	Range	1.25276
		Interquartile Range	0.22124

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.844863	Pr > |t|	<.0001
Sign	M	19	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	608	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7419373
99%	0.7419373
95%	0.5007753
90%	0.4574248
75% Q3	0.2700271
50% Median	0.1397619
25% Q1	0.0487902
10%	-0.0725707
5%	-0.1625189
1%	-0.5108256
0% Min	-0.5108256

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.510826	5	0.470004	8
-0.186330	53	0.476234	50
-0.162519	25	0.500775	11
-0.105361	49	0.500775	37
-0.105361	34	0.741937	20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.20799928	Sum Observations	12.0639582
Std Deviation	0.21933665	Variance	0.04810857
Skewness	0.42950198	Kurtosis	-0.0406143
Uncorrected SS	5.25148284	Corrected SS	2.74218824
Coeff Variation	105.450677	Std Error Mean	0.02880031

Basic Statistical Measures

Location		Variability	
Mean	0.20800	Std Deviation	0.21934
Median	0.21100	Variance	0.04811
Mode	-0.10536	Range	1.01693
		Interquartile Range	0.28768

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.222119	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001
Signed Rank	S	645	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8544153
99%	0.8544153
95%	0.5766134
90%	0.4946962
75% Q3	0.3364722
50% Median	0.2109972
25% Q1	0.0487902
10%	-0.1053605
5%	-0.1053605
1%	-0.1625189
0% Min	-0.1625189

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.162519	10	0.506818	6
-0.127833	55	0.536493	38
-0.105361	53	0.576613	11
-0.105361	42	0.625938	8
-0.105361	34	0.854415	20

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.04893403	Sum Observations	2.83817363
Std Deviation	0.12289425	Variance	0.015103
Skewness	0.85907353	Kurtosis	1.33317176
Uncorrected SS	0.99975413	Corrected SS	0.86087086
Coeff Variation	251.14273	Std Error Mean	0.01613681

Basic Statistical Measures

Location		Variability	
Mean	0.048934	Std Deviation	0.12289
Median	0.047956	Variance	0.01510
Mode	0.000000	Range	0.64103
		Interquartile Range	0.13676

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	3.032448	Pr > |t|	0.0036
Sign	M	7.5	Pr >= |M|	0.0534

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	307	Pr >= |S|	0.0054

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.4489502
99%	0.4489502
95%	0.3207429
90%	0.2113091
75% Q3	0.0984401
50% Median	0.0479564
25% Q1	-0.0383189
10%	-0.1053605
5%	-0.1160722
1%	-0.1920777
0% Min	-0.1920777

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.192078	10	0.225011	9
-0.139762	23	0.305382	38
-0.116072	45	0.320743	56
-0.115311	42	0.321584	51
-0.106222	46	0.448950	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.230084	Sum Observations	13.3448718
Std Deviation	0.26206438	Variance	0.06867774
Skewness	-0.2007107	Kurtosis	-0.49425
Uncorrected SS	6.9850725	Corrected SS	3.91463105
Coeff Variation	113.899437	Std Error Mean	0.03441074

Basic Statistical Measures

Location		Variability	
Mean	0.23008	Std Deviation	0.26206
Median	0.22314	Variance	0.06868
Mode	-0.10536	Range	1.07451
		Interquartile Range	0.35667

NOTE: The mode displayed is the smallest of 5 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.686401	Pr > |t|	<.0001
Sign	M	20	Pr >= |M|	<.0001
Signed Rank	S	656.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7178398
99%	0.7178398
95%	0.6259384
90%	0.5933268
75% Q3	0.4054651
50% Median	0.2231436
25% Q1	0.0487902
10%	-0.1053605
5%	-0.2876821
1%	-0.3566749
0% Min	-0.3566749

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.356675	30	0.609766	54
-0.287682	35	0.620576	13
-0.287682	28	0.625938	23
-0.248461	24	0.672944	6
-0.174353	22	0.717840	9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.23505987	Sum Observations	13.6334722
Std Deviation	0.22382265	Variance	0.05009658
Skewness	-0.2920222	Kurtosis	0.32877581
Uncorrected SS	6.06018713	Corrected SS	2.855505
Coeff Variation	95.2194245	Std Error Mean	0.02938935

Basic Statistical Measures

Location		Variability	
Mean	0.235060	Std Deviation	0.22382
Median	0.258503	Variance	0.05010
Mode	0.095310	Range	1.00378
		Interquartile Range	0.27625

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.99813	Pr > |t|	<.0001
Sign	M	21.5	Pr >= |M|	<.0001
Signed Rank	S	709.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6471032
99%	0.6471032
95%	0.6365768
90%	0.5709795
75% Q3	0.3715636
50% Median	0.2585032
25% Q1	0.0953102
10%	-0.0408220
5%	-0.0943107
1%	-0.3566749
0% Min	-0.3566749

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.3566749	35	0.593327	23
-0.3566749	28	0.609766	18
-0.0943107	22	0.636577	25
-0.0833816	14	0.636577	44
-0.0512933	30	0.647103	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.00497587	Sum Observations	0.28860034
Std Deviation	0.12268843	Variance	0.01505245
Skewness	-0.6679641	Kurtosis	2.4381745
Uncorrected SS	0.85942571	Corrected SS	0.85798967
Coeff Variation	2465.66886	Std Error Mean	0.01610978

Basic Statistical Measures

Location		Variability	
Mean	0.004976	Std Deviation	0.12269
Median	0.000000	Variance	0.01505
Mode	0.000000	Range	0.73055
		Interquartile Range	0.14729

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.308873	Pr > |t|	0.7585
Sign	M	1.5	Pr >= |M|	0.7798

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	60	Pr >= |S|	0.5789

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.3053816
99%	0.3053816
95%	0.2006707
90%	0.1541507
75% Q3	0.0800427
50% Median	0.0000000
25% Q1	-0.0672522
10%	-0.1116400
5%	-0.1761296
1%	-0.4251702
0% Min	-0.4251702

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.425170	9	0.154151	41
-0.324587	54	0.177140	16
-0.176130	43	0.200671	33
-0.162519	46	0.238411	24
-0.141775	8	0.305382	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	60	Sum Weights	60
Mean	0.21426614	Sum Observations	12.8559682
Std Deviation	0.2615863	Variance	0.06842739
Skewness	-0.0428789	Kurtosis	-0.7282574
Uncorrected SS	6.79181472	Corrected SS	4.03721606
Coeff Variation	122.084759	Std Error Mean	0.03377065

Basic Statistical Measures

Location		Variability	
Mean	0.214266	Std Deviation	0.26159
Median	0.182322	Variance	0.06843
Mode	0.139762	Range	1.06421
		Interquartile Range	0.40870

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.344745	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	667	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6931472
99%	0.6931472
95%	0.6285198
90%	0.5564219
75% Q3	0.4382549
50% Median	0.1823216
25% Q1	0.0295588
10%	-0.1053605
5%	-0.1451762
1%	-0.3710637
0% Min	-0.3710637

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.371064	14	0.598837	44
-0.356675	24	0.615186	37
-0.162519	28	0.641854	34
-0.127833	53	0.683097	11
-0.127833	52	0.693147	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	60	Sum Weights	60
Mean	0.25953703	Sum Observations	15.5722218
Std Deviation	0.26663713	Variance	0.07109536
Skewness	-0.0357455	Kurtosis	-0.3972515
Uncorrected SS	8.23619443	Corrected SS	4.19462624
Coeff Variation	102.73568	Std Error Mean	0.03442271

Basic Statistical Measures

Location		Variability	
Mean	0.25954	Std Deviation	0.26664
Median	0.26236	Variance	0.07110
Mode	-0.01005	Range	1.22378
		Interquartile Range	0.39588

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.539705	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001
Signed Rank	S	735	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7929925
99%	0.7929925
95%	0.6804883
90%	0.6391875
75% Q3	0.4446653
50% Median	0.2623643
25% Q1	0.0487902
10%	-0.0512933
5%	-0.1392621
1%	-0.4307829
0% Min	-0.4307829

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.4307829	24	0.662688	11
-0.2107210	47	0.667829	37
-0.1392621	14	0.693147	35
-0.1392621	10	0.774727	44
-0.0833816	38	0.792993	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	0.04527089	Sum Observations	2.71625357
Std Deviation	0.12129898	Variance	0.01471344
Skewness	0.52833106	Kurtosis	1.70155589
Uncorrected SS	0.99106031	Corrected SS	0.86809309
Coeff Variation	267.940327	Std Error Mean	0.01565963

Basic Statistical Measures

Location		Variability	
Mean	0.045271	Std Deviation	0.12130
Median	0.041691	Variance	0.01471
Mode	0.000000	Range	0.65549
		Interquartile Range	0.13917

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.89093	Pr > |t|	0.0054
Sign	M	11.5	Pr >= |M|	0.0032

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	355	Pr >= |S|	0.0039

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.4510756
99%	0.4510756
95%	0.2351063
90%	0.1809453
75% Q3	0.1088844
50% Median	0.0416908
25% Q1	-0.0302849
10%	-0.0957735
5%	-0.1687416
1%	-0.2044125
0% Min	-0.2044125

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.204413	49	0.203599	51
-0.203779	46	0.231802	14
-0.199333	18	0.238411	33
-0.138150	47	0.354738	50
-0.133531	26	0.451076	39

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	62	Sum Weights	62
Mean	0.19331779	Sum Observations	11.9857032
Std Deviation	0.27067632	Variance	0.07326567
Skewness	-0.1706638	Kurtosis	0.00672739
Uncorrected SS	6.78625545	Corrected SS	4.46920574
Coeff Variation	140.016245	Std Error Mean	0.03437593

Basic Statistical Measures

Location		Variability	
Mean	0.193318	Std Deviation	0.27068
Median	0.202933	Variance	0.07327
Mode	0.095310	Range	1.30236
		Interquartile Range	0.35863

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.623639	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001
Signed Rank	S	635	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7747272
99%	0.7747272
95%	0.6312718
90%	0.5007753
75% Q3	0.3784364
50% Median	0.2029325
25% Q1	0.0198026
10%	-0.1625189
5%	-0.2231436
1%	-0.5276327
0% Min	-0.5276327

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.527633	56	0.559616	32
-0.356675	31	0.631272	16
-0.287682	21	0.708036	15
-0.223144	62	0.741937	30
-0.210721	40	0.774727	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	62	Sum Weights	62
Mean	0.19872836	Sum Observations	12.3211586
Std Deviation	0.27141215	Variance	0.07366456
Skewness	-0.1127803	Kurtosis	0.5288636
Uncorrected SS	6.94210169	Corrected SS	4.49353801
Coeff Variation	136.574442	Std Error Mean	0.03446938

Basic Statistical Measures

Location		Variability	
Mean	0.198728	Std Deviation	0.27141
Median	0.169734	Variance	0.07366
Mode	0.139762	Range	1.38629
		Interquartile Range	0.32812

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.76536	Pr > |t|	<.0001
Sign	M	19.5	Pr >= |M|	<.0001
Signed Rank	S	644	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8754687
99%	0.8754687
95%	0.5877867
90%	0.5538851
75% Q3	0.3576744
50% Median	0.1697339
25% Q1	0.0295588
10%	-0.1053605
5%	-0.2231436
1%	-0.5108256
0% Min	-0.5108256

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.510826	62	0.576613	59
-0.494296	56	0.587787	16
-0.223144	31	0.625938	15
-0.223144	21	0.792993	10
-0.198451	58	0.875469	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	0.00541057	Sum Observations	0.33545533
Std Deviation	0.09986018	Variance	0.00997205
Skewness	-0.2145385	Kurtosis	1.01705336
Uncorrected SS	0.61011035	Corrected SS	0.60829535
Coeff Variation	1845.64988	Std Error Mean	0.01268226

Basic Statistical Measures

Location		Variability	
Mean	0.005411	Std Deviation	0.09986
Median	0.003322	Variance	0.00997
Mode	0.000000	Range	0.57536
		Interquartile Range	0.13600

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.426625	Pr > |t|	0.6712
Sign	M	4.5	Pr >= |M|	0.2717

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	61.5	Pr >= |S|	0.5910

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.28768207
99%	0.28768207
95%	0.13353139
90%	0.12945807
75% Q3	0.06453852
50% Median	0.00332227
25% Q1	-0.07145896
10%	-0.10536052
5%	-0.15514918
1%	-0.28768207
0% Min	-0.28768207

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.287682	62	0.133531	30
-0.223144	43	0.133531	31
-0.164622	6	0.158824	49
-0.155149	4	0.200671	40
-0.138999	14	0.287682	42

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	56	Sum Weights	56
Mean	0.20486984	Sum Observations	11.4727113
Std Deviation	0.22344566	Variance	0.04992796
Skewness	0.11606539	Kurtosis	-0.3199953
Uncorrected SS	5.09645045	Corrected SS	2.74603786
Coeff Variation	109.067128	Std Error Mean	0.02985918

Basic Statistical Measures

Location		Variability	
Mean	0.204870	Std Deviation	0.22345
Median	0.206981	Variance	0.04993
Mode	0.048790	Range	1.03910
		Interquartile Range	0.32268

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.861201	Pr > |t|	<.0001
Sign	M	19	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	608.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7514161
99%	0.7514161
95%	0.5766134
90%	0.5007753
75% Q3	0.3714684
50% Median	0.2069811
25% Q1	0.0487902
10%	-0.0943107
5%	-0.1625189
1%	-0.2876821
0% Min	-0.2876821

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.287682	41	0.506818	4
-0.186330	14	0.530628	29
-0.162519	34	0.576613	50
-0.162519	19	0.641854	15
-0.105361	20	0.751416	11

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	56	Sum Weights	56
Mean	0.23545818	Sum Observations	13.1856578
Std Deviation	0.22975196	Variance	0.05278596
Skewness	-0.2569131	Kurtosis	1.07070165
Uncorrected SS	6.00789892	Corrected SS	2.90322798
Coeff Variation	97.5765483	Std Error Mean	0.0307019

Basic Statistical Measures

Location		Variability	
Mean	0.235458	Std Deviation	0.22975
Median	0.227128	Variance	0.05279
Mode	0.000000	Range	1.26529
		Interquartile Range	0.28793

NOTE: The mode displayed is the smallest of 5 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.669173	Pr > |t|	<.0001
Sign	M	21.5	Pr >= |M|	<.0001
Signed Rank	S	604.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.879627
99%	0.879627
95%	0.553885
90%	0.488580
75% Q3	0.405465
50% Median	0.227128
25% Q1	0.117536
10%	0.000000
5%	-0.261365
1%	-0.385662
0% Min	-0.385662

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.3856625	45	0.512824	46
-0.3147107	41	0.548121	4
-0.2613648	14	0.553885	10
-0.1053605	20	0.620576	15
-0.0833816	9	0.879627	50

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	0.03058833	Sum Observations	1.71294651
Std Deviation	0.14062625	Variance	0.01977574
Skewness	-0.8057102	Kurtosis	2.91247252
Uncorrected SS	1.14006197	Corrected SS	1.08766579
Coeff Variation	459.738226	Std Error Mean	0.01879197

Basic Statistical Measures

Location		Variability	
Mean	0.030588	Std Deviation	0.14063
Median	0.030454	Variance	0.01978
Mode	0.000000	Range	0.81018
		Interquartile Range	0.12457

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.627734	Pr > |t|	0.1093
Sign	M	6	Pr >= |M|	0.1189

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	238	Pr >= |S|	0.0200

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.3662444
99%	0.3662444
95%	0.2598251
90%	0.1823216
75% Q3	0.0968751
50% Median	0.0304537
25% Q1	-0.0276997
10%	-0.0923733
5%	-0.2295744
1%	-0.4439314
0% Min	-0.4439314

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.443931	11	0.215111	26
-0.395613	45	0.242313	12
-0.229574	37	0.259825	38
-0.160343	36	0.303013	50
-0.138402	39	0.366244	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.2034025	Sum Observations	11.7973453
Std Deviation	0.25638424	Variance	0.06573288
Skewness	0.08279867	Kurtosis	-0.0767283
Uncorrected SS	6.14638375	Corrected SS	3.74677417
Coeff Variation	126.047732	Std Error Mean	0.0336649

Basic Statistical Measures

Location		Variability	
Mean	0.203403	Std Deviation	0.25638
Median	0.227128	Variance	0.06573
Mode	0.246860	Range	1.14967
		Interquartile Range	0.28768

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.041976	Pr > |t|	<.0001
Sign	M	18	Pr >= |M|	<.0001
Signed Rank	S	594	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7929925
99%	0.7929925
95%	0.6523252
90%	0.5877867
75% Q3	0.3364722
50% Median	0.2271276
25% Q1	0.0487902
10%	-0.1625189
5%	-0.2357223
1%	-0.3566749
0% Min	-0.3566749

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.356675	25	0.609766	15
-0.342490	10	0.620576	16
-0.235722	3	0.652325	52
-0.162519	33	0.741937	53
-0.162519	23	0.792993	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.23649287	Sum Observations	13.7165864
Std Deviation	0.25576823	Variance	0.06541739
Skewness	0.15092153	Kurtosis	-0.2741635
Uncorrected SS	6.97266609	Corrected SS	3.7287912
Coeff Variation	108.150505	Std Error Mean	0.03358401

Basic Statistical Measures

Location		Variability	
Mean	0.236493	Std Deviation	0.25577
Median	0.227128	Variance	0.06542
Mode	0.223144	Range	0.99325
		Interquartile Range	0.35282

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.041828	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	682.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7701082
99%	0.7701082
95%	0.7608058
90%	0.5988365
75% Q3	0.3920421
50% Median	0.2271276
25% Q1	0.0392207
10%	-0.1625189
5%	-0.1984509
1%	-0.2231436
0% Min	-0.2231436

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.223144	25	0.625938	14
-0.223144	23	0.746688	15
-0.198451	10	0.760806	16
-0.186330	39	0.765468	31
-0.162519	24	0.770108	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.03309036	Sum Observations	1.91924116
Std Deviation	0.14271015	Variance	0.02036619
Skewness	-0.0428231	Kurtosis	3.2190985
Uncorrected SS	1.22438107	Corrected SS	1.16087268
Coeff Variation	431.274034	Std Error Mean	0.01873876

Basic Statistical Measures

Location		Variability	
Mean	0.033090	Std Deviation	0.14271
Median	0.031819	Variance	0.02037
Mode	0.000000	Range	0.98049
		Interquartile Range	0.17640

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.765878	Pr > |t|	0.0828
Sign	M	6	Pr >= |M|	0.1337

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	232	Pr >= |S|	0.0447

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5270203
99%	0.5270203
95%	0.2264169
90%	0.1776812
75% Q3	0.1265627
50% Median	0.0318190
25% Q1	-0.0498324
10%	-0.1335314
5%	-0.1897565
1%	-0.4534743
0% Min	-0.4534743

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.453474	52	0.179693	56
-0.211309	24	0.200671	29
-0.189757	8	0.226417	1
-0.167054	14	0.287682	11
-0.145852	38	0.527020	35

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	352
Observations Used	352
Observations Not Used	0
Total Observations	352

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.01464	0.001121	13.06	<.0001	0.05	0.01267	0.01711

Fit Statistics

-2 Res Log Likelihood	-428.0
AIC (smaller is better)	-426.0
AICC (smaller is better)	-426.0
BIC (smaller is better)	-422.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.05854	0.02040	341	2.87	0.0044
SEX	Female				0.02302	0.01375	341	1.67	0.0950
SEX	Male				0				.
TRTTYPCD		Diet & Exercise			-0.00124	0.01321	341	-0.09	0.9250
TRTTYPCD		Monotherapy			0				.
TRTCD				Placebo	0.009104	0.02257	341	0.40	0.6869
TRTCD				2.5mg	-0.02337	0.02251	341	-1.04	0.2998
TRTCD				7.5mg	0.01340	0.02233	341	0.60	0.5488
TRTCD				15mg	-0.02860	0.02213	341	-1.29	0.1971
TRTCD				30mg	-0.00380	0.02273	341	-0.17	0.8675
TRTCD				45mg	0				.
REGIONCD			US/Canada		-0.00945	0.01543	341	-0.61	0.5405
REGIONCD			Eastern Europe		-0.00655	0.01625	341	-0.40	0.6872
REGIONCD			Western Europe		0				.
EFLOGBL					-0.1551	0.02825	341	-5.49	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	341	2.80	0.0950
TRTTYPCD	1	341	0.01	0.9250
TRTCD	5	341	1.18	0.3177
REGIONCD	2	341	0.20	0.8180
EFLOGBL	1	341	30.16	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.03248	0.02271	341	-1.43	0.1535	0.05	-0.07714	0.01218
7.5mg vs Pbo	0.004294	0.02238	341	0.19	0.8479	0.05	-0.03972	0.04831
15mg vs Pbo	-0.03771	0.02219	341	-1.70	0.0902	0.05	-0.08136	0.005945
30mg vs Pbo	-0.01290	0.02271	341	-0.57	0.5704	0.05	-0.05758	0.03178
45mg vs Pbo	-0.00910	0.02257	341	-0.40	0.6869	0.05	-0.05349	0.03528

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5028	0.5028	0.5028	0.5028	0.5028
SEX	Male				0.4972	0.4972	0.4972	0.4972	0.4972
TRTTYPCD		Diet & Exercise			0.4063	0.4063	0.4063	0.4063	0.4063
TRTTYPCD		Monotherapy			0.5938	0.5938	0.5938	0.5938	0.5938
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3295	0.3295	0.3295	0.3295	0.3295
REGIONCD			Eastern Europe		0.2699	0.2699	0.2699	0.2699	0.2699
REGIONCD			Western Europe		0.4006	0.4006	0.4006	0.4006	0.4006
EFLOGBL					0.2008	0.2008	0.2008	0.2008	0.2008

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5028
SEX	Male				0.4972
TRTTYPCD		Diet & Exercise			0.4063
TRTTYPCD		Monotherapy			0.5938
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3295
REGIONCD			Eastern Europe		0.2699
REGIONCD			Western Europe		0.4006
EFLOGBL					0.2008

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.04269	0.01598	341	2.67	0.0079	0.05	0.01126	0.07411
TRTCD	2.5mg	WORK.EFF	0.01021	0.01597	341	0.64	0.5233	0.05	-0.02122	0.04163
TRTCD	7.5mg	WORK.EFF	0.04698	0.01564	341	3.00	0.0029	0.05	0.01621	0.07775
TRTCD	15mg	WORK.EFF	0.004976	0.01538	341	0.32	0.7465	0.05	-0.02528	0.03523
TRTCD	30mg	WORK.EFF	0.02978	0.01621	341	1.84	0.0670	0.05	-0.00210	0.06167
TRTCD	45mg	WORK.EFF	0.03358	0.01591	341	2.11	0.0355	0.05	0.002291	0.06487

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.03248	0.02271	341	1.43	0.1535	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	-0.00429	0.02238	341	-0.19	0.8479	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.03771	0.02219	341	1.70	0.0902	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.01290	0.02271	341	0.57	0.5704	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.009104	0.02257	341	0.40	0.6869	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	-0.03677	0.02236	341	-1.64	0.1009	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.005230	0.02216	341	0.24	0.8136	0.05
TRTCD	2.5mg	30mg	WORK.EFF	-0.01958	0.02282	341	-0.86	0.3916	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-0.02337	0.02251	341	-1.04	0.2998	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	0.04200	0.02194	341	1.91	0.0564	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.01720	0.02252	341	0.76	0.4456	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.01340	0.02233	341	0.60	0.5488	0.05
TRTCD	15mg	30mg	WORK.EFF	-0.02481	0.02237	341	-1.11	0.2681	0.05
TRTCD	15mg	45mg	WORK.EFF	-0.02860	0.02213	341	-1.29	0.1971	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.00380	0.02273	341	-0.17	0.8675	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.01218	0.07714
TRTCD	Placebo	7.5mg	-0.04831	0.03972
TRTCD	Placebo	15mg	-0.00595	0.08136
TRTCD	Placebo	30mg	-0.03178	0.05758
TRTCD	Placebo	45mg	-0.03528	0.05349
TRTCD	2.5mg	7.5mg	-0.08075	0.007199
TRTCD	2.5mg	15mg	-0.03836	0.04882
TRTCD	2.5mg	30mg	-0.06447	0.02531
TRTCD	2.5mg	45mg	-0.06765	0.02090
TRTCD	7.5mg	15mg	-0.00115	0.08516

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.02709	0.06148
TRTCD	7.5mg	45mg	-0.03052	0.05731
TRTCD	15mg	30mg	-0.06880	0.01918
TRTCD	15mg	45mg	-0.07214	0.01493
TRTCD	30mg	45mg	-0.04851	0.04092

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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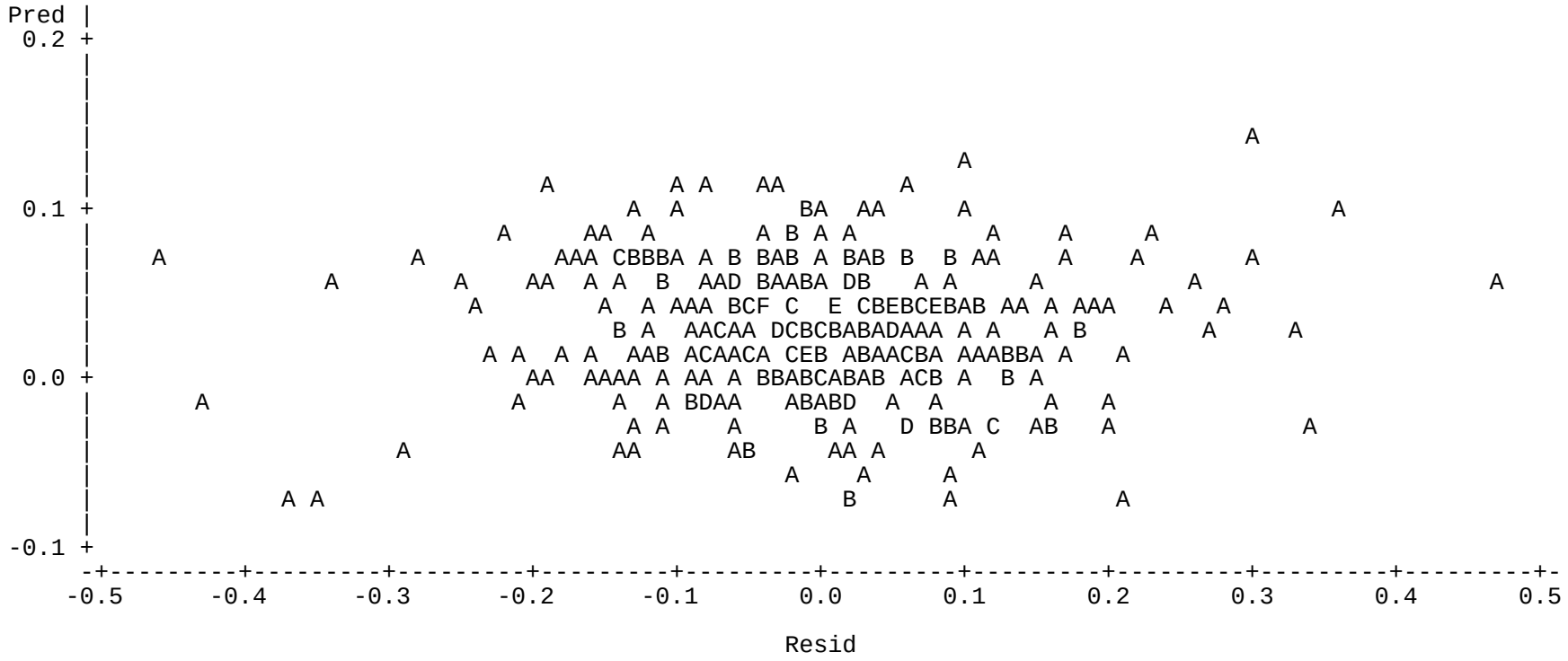
Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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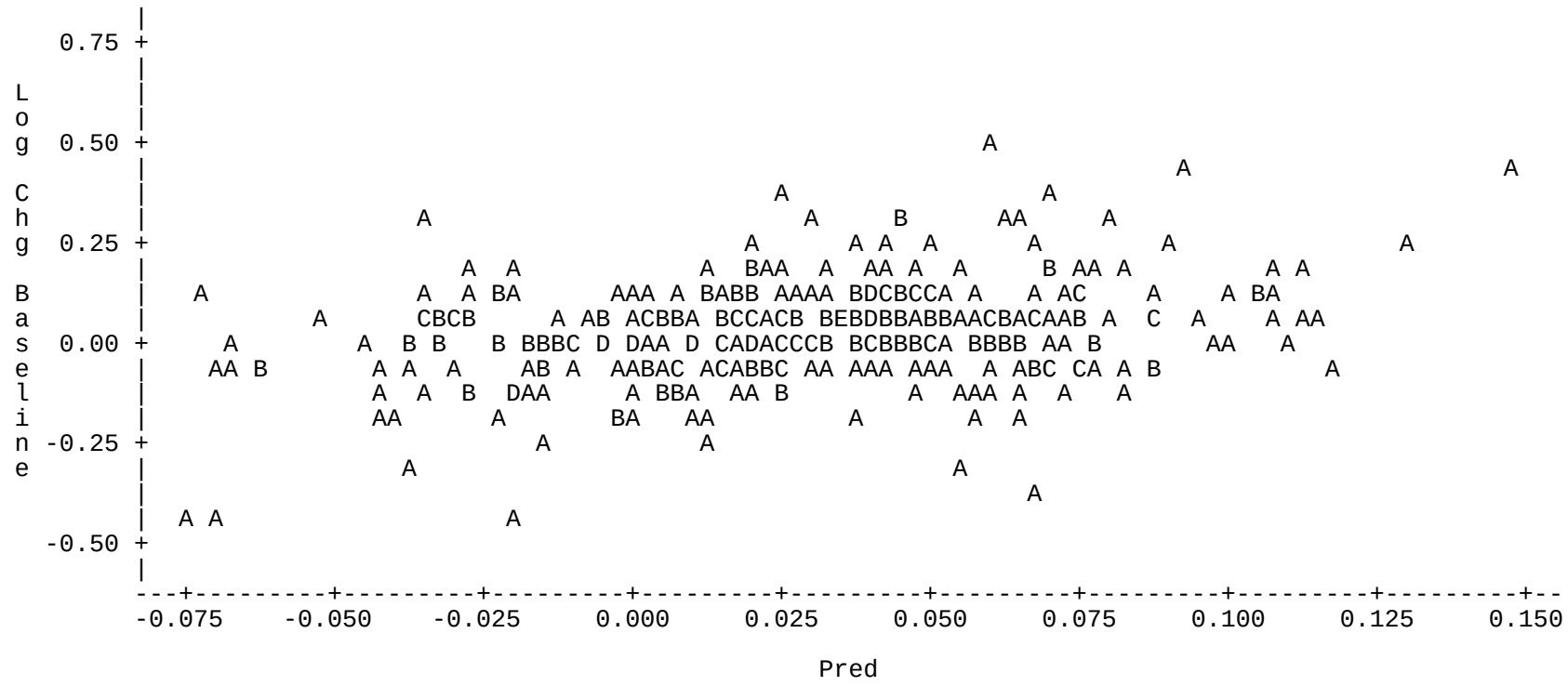
Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	352	Sum Weights	352
Mean	0	Sum Observations	0
Std Deviation	0.11926427	Variance	0.01422397
Skewness	-0.0830457	Kurtosis	1.84238387
Uncorrected SS	4.99261182	Corrected SS	4.99261182
Coeff Variation		Std Error Mean	0.00635681

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.11926
Median	0.00086	Variance	0.01422
Mode	-0.00968	Range	0.93063
		Interquartile Range	0.13587

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	1	Pr >= |M|	0.9575

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	167	Pr >= |S|	0.9305

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.979423	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.047691	Pr > D	0.0494
Cramer-von Mises	W-Sq	0.218322	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.467897	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.466589862
99%	0.328998751
95%	0.194843449
90%	0.135145489
75% Q3	0.068513166
50% Median	0.000857562
25% Q1	-0.067359487

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Quantiles (Definition 5)

Quantile	Estimate
10%	-0.138084188
5%	-0.188693573
1%	-0.348986633
0% Min	-0.464042588

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.464043	287	0.302067	35
-0.432609	299	0.328999	298
-0.374322	73	0.337712	307
-0.348987	52	0.357356	232
-0.341532	352	0.466590	224

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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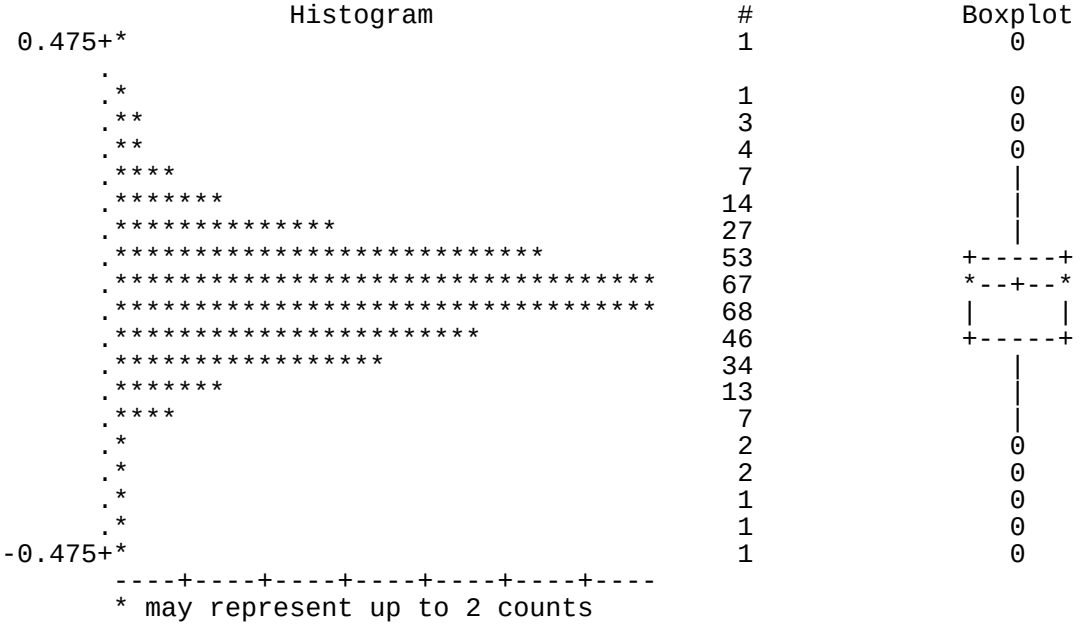
Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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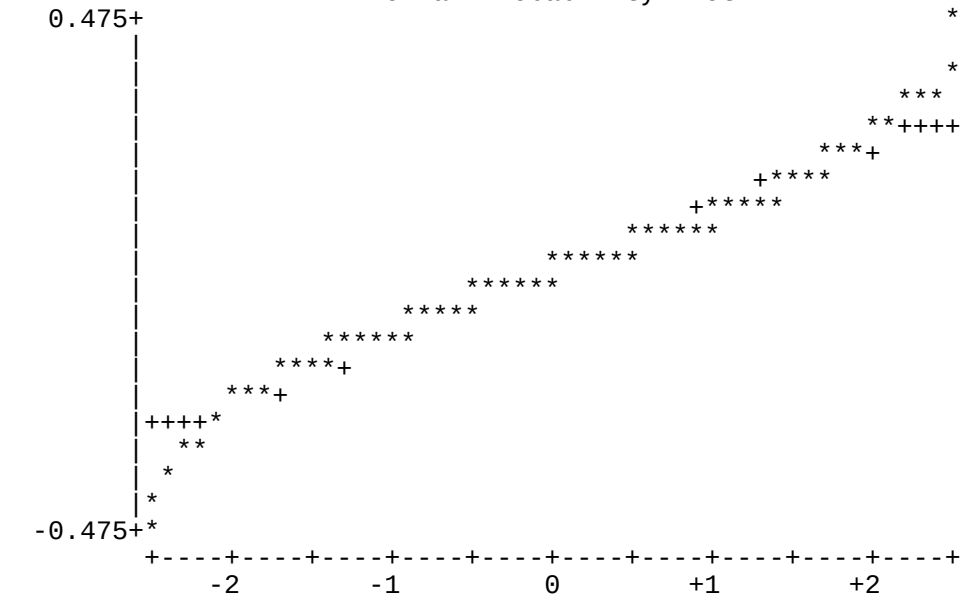
Table 11.48
SAS Statistical Output for Table 11.47
Analysis of Log-Transformed HDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Population: Intent-to-Treat with LOCF

Table 11.49
Summary Statistics of Log-Transformed LDL-c (mmol/L) by Visit

Visit: Week -5

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	55	55	58	55	52
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	2.93	2.99	3.07	2.85	3.18	2.90
	CV (%) [2]	31.512	35.247	29.444	39.162	28.858	32.562
Week -5	Geo Mean	2.81	3.00	3.09	2.82	3.16	2.87
	CV (%) [2]	31.290	33.832	35.959	42.653	33.043	34.299
	Geo Mean - SE[3]	2.70	2.87	2.95	2.68	3.02	2.74
	Geo Mean + SE[3]	2.92	3.14	3.24	2.98	3.30	3.01
	Minimum	1.4	1.0	1.0	0.5	1.2	1.2
	Median	2.99	3.13	3.13	2.95	3.40	3.02
	Maximum	4.8	5.9	5.8	6.3	5.6	5.0
Ratio to Baseline (%) [4]	Geo Mean	-4.14	0.36	0.78	-0.89	-0.85	-0.80
	Geo Mean - SE[3]	-6.96	-2.77	-2.64	-4.40	-4.43	-3.58
	Geo Mean + SE[3]	-1.23	3.58	4.32	2.74	2.86	2.05
	Minimum	-57.7	-51.4	-64.7	-57.4	-58.8	-40.6
	Median	-3.42	-0.97	1.82	2.07	3.20	-2.73
	Maximum	104.3	63.9	78.0	96.5	171.8	93.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.49
Summary Statistics of Log-Transformed LDL-c (mmol/L) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		61	56	56	59	55	56
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	2.93	2.97	3.03	2.85	3.18	2.95
	CV (%) [2]	31.512	35.145	31.191	38.822	28.858	33.015
	Geo Mean - SE[3]	2.82	2.84	2.91	2.72	3.07	2.83
	Geo Mean + SE[3]	3.05	3.11	3.15	3.00	3.31	3.08
	Minimum	1.3	1.3	1.4	0.9	1.6	0.7
	Median	3.09	2.98	3.05	3.04	3.30	2.98
	Maximum	5.1	5.5	5.3	5.9	6.5	5.9

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.49
Summary Statistics of Log-Transformed LDL-c (mmol/L) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		54	54	53	55	53	53
Number (%) of Values Carried Forward		2 (4%)	1 (2%)	4 (8%)	2 (4%)	0	2 (4%)
Baseline	Geo Mean	2.91	2.94	3.03	2.89	3.16	2.96
	CV (%) [2]	31.765	35.030	29.197	35.959	29.210	33.605
Week 4	Geo Mean	2.86	3.02	3.02	2.95	3.08	2.97
	CV (%) [2]	31.195	29.203	34.144	40.314	33.937	35.708
	Geo Mean - SE[3]	2.74	2.90	2.89	2.80	2.94	2.83
	Geo Mean + SE[3]	2.98	3.14	3.16	3.11	3.22	3.12
	Minimum	1.3	1.3	1.2	0.5	1.2	0.9
	Median	2.99	3.09	3.22	3.05	3.28	3.16
	Maximum	4.6	5.5	5.1	6.6	6.4	4.9
Ratio to Baseline (%) [4]	Geo Mean	-1.76	2.61	-0.27	1.85	-2.69	0.54
	Geo Mean - SE[3]	-3.58	0.42	-2.84	-0.82	-5.46	-1.89
	Geo Mean + SE[3]	0.09	4.84	2.37	4.60	0.17	3.03
	Minimum	-26.9	-27.5	-53.8	-53.7	-49.2	-29.7
	Median	-2.56	4.54	1.56	0.00	-0.51	3.01
	Maximum	45.7	43.8	41.3	47.6	102.6	58.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.49
Summary Statistics of Log-Transformed LDL-c (mmol/L) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	55	55	59	55	55
Number (%) of Values Carried Forward		9 (16%)	10 (18%)	7 (13%)	3 (5%)	2 (4%)	8 (15%)
Baseline	Geo Mean	2.92	2.95	3.01	2.85	3.18	2.97
	CV (%) [2]	31.251	34.706	31.005	38.822	28.858	33.171
Week 8	Geo Mean	2.90	3.13	2.99	3.01	3.12	2.98
	CV (%) [2]	29.310	29.335	35.263	43.955	32.558	32.248
	Geo Mean - SE[3]	2.79	3.01	2.85	2.85	2.99	2.86
	Geo Mean + SE[3]	3.01	3.25	3.13	3.18	3.25	3.11
	Minimum	1.3	1.4	1.4	0.5	1.2	1.0
	Median	3.07	3.14	2.91	3.19	3.12	3.08
	Maximum	4.7	5.6	5.4	5.8	6.4	4.9
Ratio to Baseline (%) [4]	Geo Mean	-0.72	6.06	-0.67	5.58	-2.09	0.54
	Geo Mean - SE[3]	-3.41	3.59	-3.71	2.76	-5.21	-2.12
	Geo Mean + SE[3]	2.04	8.58	2.47	8.47	1.14	3.28
	Minimum	-40.6	-21.5	-50.7	-53.7	-61.2	-41.0
	Median	-1.22	3.63	0.00	6.46	2.30	3.26
	Maximum	125.4	86.5	140.1	92.9	82.3	39.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.49
Summary Statistics of Log-Transformed LDL-c (mmol/L) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		58	55	56	59	55	55
Number (%) of Values Carried Forward		12 (21%)	13 (24%)	8 (14%)	6 (10%)	3 (5%)	6 (11%)
Baseline	Geo Mean	2.92	2.95	3.03	2.85	3.18	2.97
	CV (%) [2]	31.251	34.706	31.191	38.822	28.858	33.171
Week 12	Geo Mean	2.89	3.14	3.03	2.85	3.19	2.96
	CV (%) [2]	28.877	27.874	32.958	45.008	29.568	31.447
	Geo Mean - SE[3]	2.79	3.02	2.90	2.69	3.07	2.84
	Geo Mean + SE[3]	3.00	3.25	3.16	3.01	3.32	3.08
	Minimum	1.4	1.8	1.2	0.5	1.6	1.0
	Median	3.00	3.11	3.15	3.06	3.30	3.15
	Maximum	4.9	5.8	5.8	6.2	6.4	4.9
Ratio to Baseline (%) [4]	Geo Mean	-0.80	6.37	0.02	-0.23	0.21	-0.35
	Geo Mean - SE[3]	-3.40	3.21	-2.76	-3.56	-3.12	-4.06
	Geo Mean + SE[3]	1.87	9.61	2.87	3.21	3.66	3.50
	Minimum	-42.0	-45.9	-59.4	-62.3	-61.9	-63.1
	Median	0.57	3.58	2.80	0.85	2.37	0.27
	Maximum	125.4	117.1	51.9	83.3	104.5	142.1

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		58	55	56
Number (%) of Values Carried Forward		12 (21%)	13 (24%)	8 (14%)
Baseline	Geo Mean	2.92	2.95	3.03
	CV (%) [2]	31.251	34.706	31.191
Week 12	Geo Mean	2.89	3.14	3.03
	CV (%) [2]	28.877	27.874	32.958
Ratio to Baseline (% chg) [3]	Geo Mean	-0.80	6.37	0.02
	Geo Mean -SE,+SE	-3.40,1.87	3.21,9.61	-2.76,2.87
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-1.25	6.18	0.44
	Geo Mean -SE,+SE	-4.09,1.68	3.03,9.41	-2.49,3.46
Ratio to Baseline (% diff) [4]	Geo Mean		7.52	1.71
	95% CI		-1.02,16.79	-6.29,10.38
	p-val[5]		0.086	0.684

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		59	55	55
Number (%) of Values Carried Forward		6 (10%)	3 (5%)	6 (11%)
Baseline	Geo Mean	2.85	3.18	2.97
	CV (%) [2]	38.822	28.858	33.171
Week 12	Geo Mean	2.85	3.19	2.96
	CV (%) [2]	45.008	29.568	31.447
Ratio to Baseline (% chg) [3]	Geo Mean	-0.23	0.21	-0.35
	Geo Mean -SE,+SE	-3.56,3.21	-3.12,3.66	-4.06,3.50
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-1.47	1.70	-0.26
	Geo Mean -SE,+SE	-4.28,1.42	-1.31,4.80	-3.20,2.76
Ratio to Baseline (% diff) [4]	Geo Mean	-0.23	2.98	1.00
	95% CI	-7.97,8.17	-5.15,11.82	-6.97,9.64
	p-val[5]	0.956	0.483	0.812

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	1.07035656	Sum Observations	62.0806803
Std Deviation	0.30526013	Variance	0.09318375
Skewness	-0.8523777	Kurtosis	0.50657622
Uncorrected SS	71.7599368	Corrected SS	5.31147359
Coeff Variation	28.5194806	Std Error Mean	0.04008262

Basic Statistical Measures

Location		Variability	
Mean	1.070357	Std Deviation	0.30526
Median	1.116714	Variance	0.09318
Mode	1.220830	Range	1.36475
		Interquartile Range	0.34093

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	26.70376	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.619388
99%	1.619388
95%	1.504077
90%	1.376244
75% Q3	1.280934
50% Median	1.116714
25% Q1	0.940007
10%	0.587787
5%	0.438255
1%	0.254642
0% Min	0.254642

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.254642	36	1.41099	19
0.270027	30	1.42070	7
0.438255	47	1.50408	54
0.463734	31	1.56653	50
0.559616	17	1.61939	26

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	1.06236491	Sum Observations	61.6171649
Std Deviation	0.28300296	Variance	0.08009067
Skewness	-0.6502494	Kurtosis	0.36800128
Uncorrected SS	70.0250823	Corrected SS	4.56516839
Coeff Variation	26.6389593	Std Error Mean	0.03716011

Basic Statistical Measures

Location		Variability	
Mean	1.062365	Std Deviation	0.28300
Median	1.098612	Variance	0.08009
Mode	1.223775	Range	1.28175
		Interquartile Range	0.29824

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	28.58885	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.589235
99%	1.589235
95%	1.549688
90%	1.360977
75% Q3	1.249902
50% Median	1.098612
25% Q1	0.951658
10%	0.667829
5%	0.482426
1%	0.307485
0% Min	0.307485

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.307485	47	1.36098	48
0.385262	30	1.45395	37
0.482426	36	1.54969	51
0.518794	31	1.57277	50
0.565314	44	1.58924	54

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0079916	Sum Observations	-0.4635154
Std Deviation	0.20233397	Variance	0.04093903
Skewness	0.49652776	Kurtosis	4.69379811
Uncorrected SS	2.33722918	Corrected SS	2.33352493
Coeff Variation	-2531.8188	Std Error Mean	0.02656775

Basic Statistical Measures

Location		Variability	
Mean	-0.00799	Std Deviation	0.20233
Median	0.00565	Variance	0.04094
Mode	0.08004	Range	1.35775
		Interquartile Range	0.17813

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.3008	Pr > |t|	0.7647
Sign	M	1.5	Pr >= |M|	0.7914

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-16.5	Pr >= |S|	0.8971

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.81252384
99%	0.81252384
95%	0.23440071
90%	0.21029541
75% Q3	0.08004271
50% Median	0.00565341
25% Q1	-0.09809182
10%	-0.21237145
5%	-0.39580320
1%	-0.54522705
0% Min	-0.54522705

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.545227	24	0.227784	36
-0.520776	26	0.233123	37
-0.395803	10	0.234401	56
-0.321584	38	0.315853	17
-0.255347	16	0.812524	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	55	Sum Weights	55
Mean	1.08094195	Sum Observations	59.4518074
Std Deviation	0.3372411	Variance	0.11373156
Skewness	-0.1074845	Kurtosis	-0.6004999
Uncorrected SS	70.4054571	Corrected SS	6.14150426
Coeff Variation	31.1988169	Std Error Mean	0.04547358

Basic Statistical Measures

Location		Variability	
Mean	1.080942	Std Deviation	0.33724
Median	1.081805	Variance	0.11373
Mode	0.996949	Range	1.43874
		Interquartile Range	0.53377

NOTE: The mode displayed is the smallest of 5 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	23.77077	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	770	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.701105
99%	1.701105
95%	1.654411
90%	1.536867
75% Q3	1.340250
50% Median	1.081805
25% Q1	0.806476
10%	0.636577
5%	0.559616
1%	0.262364
0% Min	0.262364

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.262364	21	1.53687	48
0.500775	29	1.55181	45
0.559616	9	1.65441	43
0.615186	55	1.69562	4
0.625938	23	1.70111	42

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	55	Sum Weights	55
Mean	1.14265096	Sum Observations	62.8458027
Std Deviation	0.2735466	Variance	0.07482774
Skewness	0.02169133	Kurtosis	-0.526439
Uncorrected SS	75.8515147	Corrected SS	4.04069816
Coeff Variation	23.9396467	Std Error Mean	0.03688502

Basic Statistical Measures

Location		Variability	
Mean	1.142651	Std Deviation	0.27355
Median	1.134623	Variance	0.07483
Mode	0.765468	Range	1.15902
		Interquartile Range	0.37010

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	30.97873	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	770	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.757858
99%	1.757858
95%	1.591274
90%	1.543298
75% Q3	1.321756
50% Median	1.134623
25% Q1	0.951658
10%	0.765468
5%	0.688135
1%	0.598837
0% Min	0.598837

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.598837	21	1.57277	42
0.662688	18	1.58924	43
0.688135	3	1.59127	7
0.708036	49	1.62924	47
0.717840	54	1.75786	16

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	0.061709	Sum Observations	3.39399522
Std Deviation	0.22309686	Variance	0.04977221
Skewness	0.66025424	Kurtosis	3.34734852
Uncorrected SS	2.89713925	Corrected SS	2.68769919
Coeff Variation	361.530476	Std Error Mean	0.03008237

Basic Statistical Measures

Location		Variability	
Mean	0.061709	Std Deviation	0.22310
Median	0.035174	Variance	0.04977
Mode		Range	1.38920
		Interquartile Range	0.25361

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.051334	Pr > |t|	0.0451
Sign	M	3.5	Pr >= |M|	0.4188

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	255	Pr >= |S|	0.0313

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7753853
99%	0.7753853
95%	0.3895665
90%	0.2646926
75% Q3	0.1735688
50% Median	0.0351736
25% Q1	-0.0800427
10%	-0.1394195
5%	-0.2188530
1%	-0.6138104
0% Min	-0.6138104

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.613810	4	0.267204	16
-0.242140	48	0.336472	21
-0.218853	44	0.389567	50
-0.190044	32	0.771109	55
-0.180628	45	0.775385	9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	56	Sum Weights	56
Mean	1.10740274	Sum Observations	62.0145533
Std Deviation	0.30469473	Variance	0.09283888
Skewness	-0.315528	Kurtosis	-0.4518309
Uncorrected SS	73.7812245	Corrected SS	5.10613844
Coeff Variation	27.5143562	Std Error Mean	0.04071655

Basic Statistical Measures

Location		Variability	
Mean	1.107403	Std Deviation	0.30469
Median	1.113338	Variance	0.09284
Mode	0.774727	Range	1.34217
		Interquartile Range	0.52995

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	27.19786	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.671473
99%	1.671473
95%	1.515127
90%	1.486140
75% Q3	1.394944
50% Median	1.113338
25% Q1	0.864995
10%	0.741937
5%	0.559616
1%	0.329304
0% Min	0.329304

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.329304	7	1.49065	48
0.457425	10	1.49515	8
0.559616	20	1.51513	42
0.647103	40	1.61343	3
0.717840	27	1.67147	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	56	Sum Weights	56
Mean	1.10755774	Sum Observations	62.0232333
Std Deviation	0.32111655	Variance	0.10311584
Skewness	-0.6475524	Kurtosis	0.48227459
Uncorrected SS	74.3656832	Corrected SS	5.67137118
Coeff Variation	28.993211	Std Error Mean	0.042911

Basic Statistical Measures

Location		Variability	
Mean	1.107558	Std Deviation	0.32112
Median	1.147221	Variance	0.10312
Mode	0.854415	Range	1.60252
		Interquartile Range	0.42545

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	25.81058	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.750937
99%	1.750937
95%	1.553925
90%	1.477049
75% Q3	1.333677
50% Median	1.147221
25% Q1	0.908226
10%	0.708036
5%	0.438255
1%	0.148420
0% Min	0.148420

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.148420	46	1.47705	42
0.405465	33	1.54543	17
0.438255	7	1.55393	3
0.593327	20	1.56444	48
0.636577	44	1.75094	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	0.000155	Sum Observations	0.00868006
Std Deviation	0.21050583	Variance	0.0443127
Skewness	-1.386054	Kurtosis	5.20333081
Uncorrected SS	2.43720001	Corrected SS	2.43719867
Coeff Variation	135809.216	Std Error Mean	0.02813002

Basic Statistical Measures

Location		Variability	
Mean	0.000155	Std Deviation	0.21051
Median	0.027576	Variance	0.04431
Mode	0.000000	Range	1.32045
		Interquartile Range	0.20797

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.00551	Pr > |t|	0.9956
Sign	M	3	Pr >= |M|	0.4966

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	63.5	Pr >= |S|	0.5893

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.4180439
99%	0.4180439
95%	0.3424603
90%	0.2488960
75% Q3	0.1142299
50% Median	0.0275759
25% Q1	-0.0937403
10%	-0.2448711
5%	-0.3317774
1%	-0.9024016
0% Min	-0.9024016

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.902402	46	0.259638	45
-0.418710	33	0.303855	12
-0.331777	24	0.342460	17
-0.304157	18	0.353444	47
-0.268264	31	0.418044	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	59	Sum Weights	59
Mean	1.04848253	Sum Observations	61.8604691
Std Deviation	0.37468083	Variance	0.14038572
Skewness	-1.1860743	Kurtosis	2.34098122
Uncorrected SS	73.001993	Corrected SS	8.14237201
Coeff Variation	35.735534	Std Error Mean	0.04877929

Basic Statistical Measures

Location		Variability	
Mean	1.048483	Std Deviation	0.37468
Median	1.111858	Variance	0.14039
Mode	1.078410	Range	1.92896
		Interquartile Range	0.38583

NOTE: The mode displayed is the smallest of 5 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	21.49442	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001
Signed Rank	S	881	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.766442
99%	1.766442
95%	1.623341
90%	1.410987
75% Q3	1.261298
50% Median	1.111858
25% Q1	0.875469
10%	0.722706
5%	0.076961
1%	-0.162519
0% Min	-0.162519

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.1625189	28	1.55181	8
0.0295588	47	1.57898	22
0.0769610	6	1.62334	10
0.1397619	42	1.64287	29
0.5007753	26	1.76644	27

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	59	Sum Weights	59
Mean	1.04614774	Sum Observations	61.7227169
Std Deviation	0.42948689	Variance	0.18445899
Skewness	-1.4363306	Kurtosis	3.92777263
Uncorrected SS	75.2697025	Corrected SS	10.6986214
Coeff Variation	41.0541334	Std Error Mean	0.05591443

Basic Statistical Measures

Location		Variability	
Mean	1.046148	Std Deviation	0.42949
Median	1.118415	Variance	0.18446
Mode	1.011601	Range	2.50960
		Interquartile Range	0.43242

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	18.7098	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001
Signed Rank	S	875	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.816452
99%	1.816452
95%	1.690096
90%	1.474763
75% Q3	1.324419
50% Median	1.118415
25% Q1	0.891998
10%	0.451076
5%	0.223144
1%	-0.693147
0% Min	-0.693147

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.6931472	6	1.51293	41
0.0295588	42	1.62728	40
0.2231436	28	1.69010	29
0.3364722	48	1.77495	27
0.3506569	18	1.81645	8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	59	Sum Weights	59
Mean	-0.0023348	Sum Observations	-0.1377522
Std Deviation	0.26046242	Variance	0.06784067
Skewness	-1.0098379	Kurtosis	3.52990583
Uncorrected SS	3.93508072	Corrected SS	3.9347591
Coeff Variation	-11155.747	Std Error Mean	0.03390932

Basic Statistical Measures

Location		Variability	
Mean	-0.00233	Std Deviation	0.26046
Median	0.00851	Variance	0.06784
Mode	0.00000	Range	1.58255
		Interquartile Range	0.25579

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.06885	Pr > |t|	0.9453
Sign	M	1.5	Pr >= |M|	0.7914

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	33	Pr >= |S|	0.7958

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.60613580
99%	0.60613580
95%	0.40424336
90%	0.29725152
75% Q3	0.12668986
50% Median	0.00851069
25% Q1	-0.12910465
10%	-0.24205900
5%	-0.47445798
1%	-0.97641813
0% Min	-0.97641813

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.976418	18	0.385662	28
-0.770108	6	0.400566	40
-0.474458	48	0.404243	16
-0.364818	33	0.421517	47
-0.279585	23	0.606136	25

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	55	Sum Weights	55
Mean	1.15837764	Sum Observations	63.71077
Std Deviation	0.28283245	Variance	0.0799942
Skewness	-0.4259363	Kurtosis	0.71900819
Uncorrected SS	78.1208179	Corrected SS	4.31968663
Coeff Variation	24.4162564	Std Error Mean	0.03813712

Basic Statistical Measures

Location		Variability	
Mean	1.158378	Std Deviation	0.28283
Median	1.193922	Variance	0.07999
Mode	0.779325	Range	1.42558
		Interquartile Range	0.35004

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	30.37402	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	770	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.870263
99%	1.870263
95%	1.581038
90%	1.439835
75% Q3	1.350667
50% Median	1.193922
25% Q1	1.000632
10%	0.779325
5%	0.530628
1%	0.444686
0% Min	0.444686

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.444686	37	1.47705	29
0.470004	24	1.55393	10
0.530628	14	1.58104	30
0.708036	31	1.68640	23
0.770108	46	1.87026	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	55	Sum Weights	55
Mean	1.16049388	Sum Observations	63.8271636
Std Deviation	0.28950396	Variance	0.08381254
Skewness	-0.4552243	Kurtosis	0.2726371
Uncorrected SS	78.59691	Corrected SS	4.52587716
Coeff Variation	24.9466162	Std Error Mean	0.03903671

Basic Statistical Measures

Location		Variability	
Mean	1.160494	Std Deviation	0.28950
Median	1.193922	Variance	0.08381
Mode	1.047319	Range	1.41804
		Interquartile Range	0.36546

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	29.72827	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	770	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.856298
99%	1.856298
95%	1.581038
90%	1.451614
75% Q3	1.366092
50% Median	1.193922
25% Q1	1.000632
10%	0.732368
5%	0.570980
1%	0.438255
0% Min	0.438255

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
0.438255	18	1.46326	12
0.512824	14	1.54116	36
0.570980	31	1.58104	10
0.620576	49	1.62924	30
0.693147	24	1.85630	23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	0.00211625	Sum Observations	0.11639353
Std Deviation	0.25096145	Variance	0.06298165
Skewness	-1.0407764	Kurtosis	5.34599095
Uncorrected SS	3.40125537	Corrected SS	3.40100905
Coeff Variation	11858.8034	Std Error Mean	0.03383963

Basic Statistical Measures

Location		Variability	
Mean	0.002116	Std Deviation	0.25096
Median	0.023420	Variance	0.06298
Mode	0.000000	Range	1.68138
		Interquartile Range	0.18038

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.062537	Pr > |t|	0.9504
Sign	M	5.5	Pr >= |M|	0.1690

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	112	Pr >= |S|	0.3261

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7153351
99%	0.7153351
95%	0.2910210
90%	0.2231436
75% Q3	0.1056983
50% Median	0.0234203
25% Q1	-0.0746808
10%	-0.2293957
5%	-0.4603809
1%	-0.9660444
0% Min	-0.9660444

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.966044	41	0.251314	3
-0.740400	18	0.267994	1
-0.460381	48	0.291021	32
-0.297834	25	0.566599	36
-0.283126	29	0.715335	37

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	55	Sum Weights	55
Mean	1.08717141	Sum Observations	59.7944277
Std Deviation	0.32309611	Variance	0.10439109
Skewness	-1.6904784	Kurtosis	6.17447159
Uncorrected SS	70.6439116	Corrected SS	5.63711911
Coeff Variation	29.7189664	Std Error Mean	0.04356627

Basic Statistical Measures

Location		Variability	
Mean	1.087171	Std Deviation	0.32310
Median	1.095273	Variance	0.10439
Mode	1.043804	Range	2.09836
		Interquartile Range	0.31508

NOTE: The mode displayed is the smallest of 5 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	24.95443	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	769	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.769855
99%	1.769855
95%	1.401183
90%	1.383791
75% Q3	1.308333
50% Median	1.095273
25% Q1	0.993252
10%	0.662688
5%	0.576613
1%	-0.328504
0% Min	-0.328504

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.328504	1	1.38879	36
0.343590	15	1.39872	26
0.576613	49	1.40118	50
0.620576	3	1.63900	20
0.636577	13	1.76985	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	55	Sum Weights	55
Mean	1.0836416	Sum Observations	59.600288
Std Deviation	0.30708448	Variance	0.09430088
Skewness	-0.9602363	Kurtosis	1.58664981
Uncorrected SS	69.6775987	Corrected SS	5.09224732
Coeff Variation	28.3381957	Std Error Mean	0.04140726

Basic Statistical Measures

Location		Variability	
Mean	1.083642	Std Deviation	0.30708
Median	1.147402	Variance	0.09430
Mode	0.641854	Range	1.56903
		Interquartile Range	0.40273

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	26.17033	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	770	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.57897870
99%	1.57897870
95%	1.53686722
90%	1.45395301
75% Q3	1.29472717
50% Median	1.14740245
25% Q1	0.89199804
10%	0.66782937
5%	0.55961579
1%	0.00995033
0% Min	0.00995033

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest-------		-----Highest-----	
Value	Obs	Value	Obs
0.00995033	1	1.46094	49
0.40546511	15	1.47247	2
0.55961579	45	1.53687	8
0.64185389	27	1.54330	33
0.64185389	20	1.57898	24

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	-0.0035298	Sum Observations	-0.1941398
Std Deviation	0.28140543	Variance	0.07918901
Skewness	-0.4207815	Kurtosis	3.35378665
Uncorrected SS	4.27689203	Corrected SS	4.27620675
Coeff Variation	-7972.2448	Std Error Mean	0.0379447

Basic Statistical Measures

Location		Variability	
Mean	-0.00353	Std Deviation	0.28141
Median	0.00271	Variance	0.07919
Mode		Range	1.88147
		Interquartile Range	0.29570

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.09303	Pr > |t|	0.9262
Sign	M	1	Pr >= |M|	0.8919

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	17.5	Pr >= |S|	0.8819

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.88432454
99%	0.88432454
95%	0.33845440
90%	0.26178134
75% Q3	0.17332985
50% Median	0.00270636
25% Q1	-0.12237471
10%	-0.28490043
5%	-0.46966297
1%	-0.99714283
0% Min	-0.99714283

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.997143	20	0.283271	4
-0.619039	19	0.315517	3
-0.469663	51	0.338454	1
-0.422857	27	0.499494	33
-0.339507	22	0.884325	49

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	338
Observations Used	338
Observations Not Used	0
Total Observations	338

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.04900	0.003832	12.79	<.0001	0.05	0.04228	0.05747

Fit Statistics

-2 Res Log Likelihood	-13.4
AIC (smaller is better)	-11.4
AICC (smaller is better)	-11.4
BIC (smaller is better)	-7.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.3222	0.05494	327	5.86	<.0001
SEX	Female				0.02206	0.02440	327	0.90	0.3666
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			0.01006	0.02470	327	0.41	0.6841
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	-0.00992	0.04176	327	-0.24	0.8124
TRTCD				2.5mg	0.06255	0.04235	327	1.48	0.1406
TRTCD				7.5mg	0.007009	0.04207	327	0.17	0.8678
TRTCD				15mg	-0.01220	0.04158	327	-0.29	0.7694
TRTCD				30mg	0.01949	0.04239	327	0.46	0.6460
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.07737	0.02852	327	-2.71	0.0070
REGIONCD			Eastern Europe		-0.05187	0.03038	327	-1.71	0.0887
REGIONCD			Western Europe		0			.	
EFLOGBL					-0.2758	0.03799	327	-7.26	<.0001

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	327	0.82	0.3666
TRTTYPCD	1	327	0.17	0.6841
TRTCD	5	327	0.87	0.5037
REGIONCD	2	327	3.88	0.0216
EFLOGBL	1	327	52.71	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	0.07247	0.04207	327	1.72	0.0859	0.05	-0.01029	0.1552
7.5mg vs Pbo	0.01693	0.04161	327	0.41	0.6844	0.05	-0.06493	0.09878
15mg vs Pbo	-0.00228	0.04108	327	-0.06	0.9558	0.05	-0.08310	0.07854
30mg vs Pbo	0.02941	0.04185	327	0.70	0.4827	0.05	-0.05292	0.1117
45mg vs Pbo	0.009917	0.04176	327	0.24	0.8124	0.05	-0.07223	0.09206

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5089	0.5089	0.5089	0.5089	0.5089
SEX	Male				0.4911	0.4911	0.4911	0.4911	0.4911
TRTTYPCD		Diet & Exercise			0.4112	0.4112	0.4112	0.4112	0.4112
TRTTYPCD		Monotherapy			0.5888	0.5888	0.5888	0.5888	0.5888
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3225	0.3225	0.3225	0.3225	0.3225
REGIONCD			Eastern Europe		0.2722	0.2722	0.2722	0.2722	0.2722
REGIONCD			Western Europe		0.4053	0.4053	0.4053	0.4053	0.4053
EFLOGBL					1.0915	1.0915	1.0915	1.0915	1.0915

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5089
SEX	Male				0.4911
TRTTYPCD		Diet & Exercise			0.4112
TRTTYPCD		Monotherapy			0.5888
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3225
REGIONCD			Eastern Europe		0.2722
REGIONCD			Western Europe		0.4053
EFLOGBL					1.0915

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.01254	0.02919	327	-0.43	0.6678	0.05	-0.06997	0.04489
TRTCD	2.5mg	WORK.EFF	0.05993	0.03003	327	2.00	0.0468	0.05	0.000850	0.1190
TRTCD	7.5mg	WORK.EFF	0.004387	0.02960	327	0.15	0.8823	0.05	-0.05384	0.06261
TRTCD	15mg	WORK.EFF	-0.01482	0.02889	327	-0.51	0.6083	0.05	-0.07165	0.04201
TRTCD	30mg	WORK.EFF	0.01687	0.03004	327	0.56	0.5749	0.05	-0.04224	0.07597
TRTCD	45mg	WORK.EFF	-0.00262	0.02987	327	-0.09	0.9301	0.05	-0.06139	0.05615

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-0.07247	0.04207	327	-1.72	0.0859	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	-0.01693	0.04161	327	-0.41	0.6844	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.002280	0.04108	327	0.06	0.9558	0.05
TRTCD	Placebo	30mg	WORK.EFF	-0.02941	0.04185	327	-0.70	0.4827	0.05
TRTCD	Placebo	45mg	WORK.EFF	-0.00992	0.04176	327	-0.24	0.8124	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.05554	0.04213	327	1.32	0.1883	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.07475	0.04161	327	1.80	0.0733	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.04306	0.04265	327	1.01	0.3134	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.06255	0.04235	327	1.48	0.1406	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	0.01921	0.04137	327	0.46	0.6428	0.05
TRTCD	7.5mg	30mg	WORK.EFF	-0.01248	0.04217	327	-0.30	0.7674	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.007009	0.04207	327	0.17	0.8678	0.05
TRTCD	15mg	30mg	WORK.EFF	-0.03169	0.04180	327	-0.76	0.4490	0.05
TRTCD	15mg	45mg	WORK.EFF	-0.01220	0.04158	327	-0.29	0.7694	0.05
TRTCD	30mg	45mg	WORK.EFF	0.01949	0.04239	327	0.46	0.6460	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1552	0.01029
TRTCD	Placebo	7.5mg	-0.09878	0.06493
TRTCD	Placebo	15mg	-0.07854	0.08310
TRTCD	Placebo	30mg	-0.1117	0.05292
TRTCD	Placebo	45mg	-0.09206	0.07223
TRTCD	2.5mg	7.5mg	-0.02734	0.1384
TRTCD	2.5mg	15mg	-0.00711	0.1566
TRTCD	2.5mg	30mg	-0.04085	0.1270
TRTCD	2.5mg	45mg	-0.02076	0.1459
TRTCD	7.5mg	15mg	-0.06218	0.1006

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.09544	0.07048
TRTCD	7.5mg	45mg	-0.07575	0.08976
TRTCD	15mg	30mg	-0.1139	0.05054
TRTCD	15mg	45mg	-0.09399	0.06960
TRTCD	30mg	45mg	-0.06391	0.1029

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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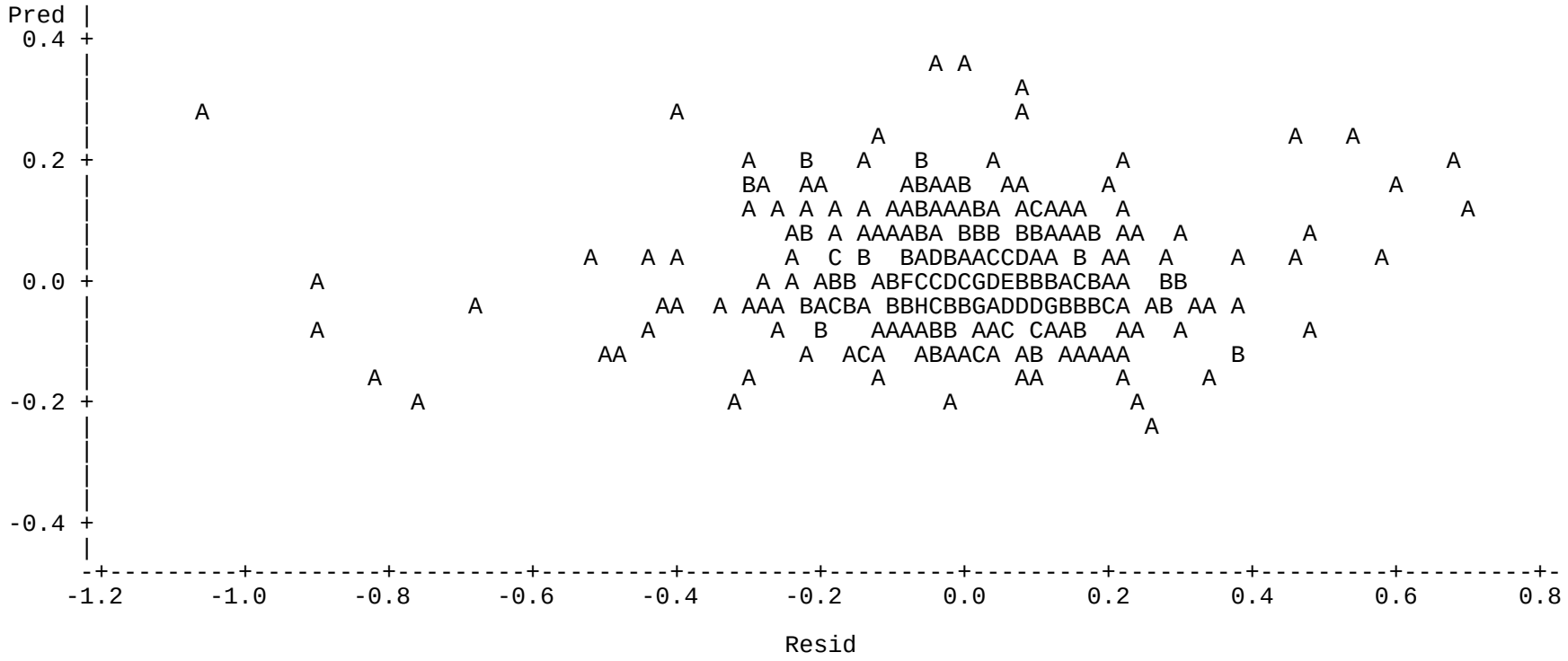
Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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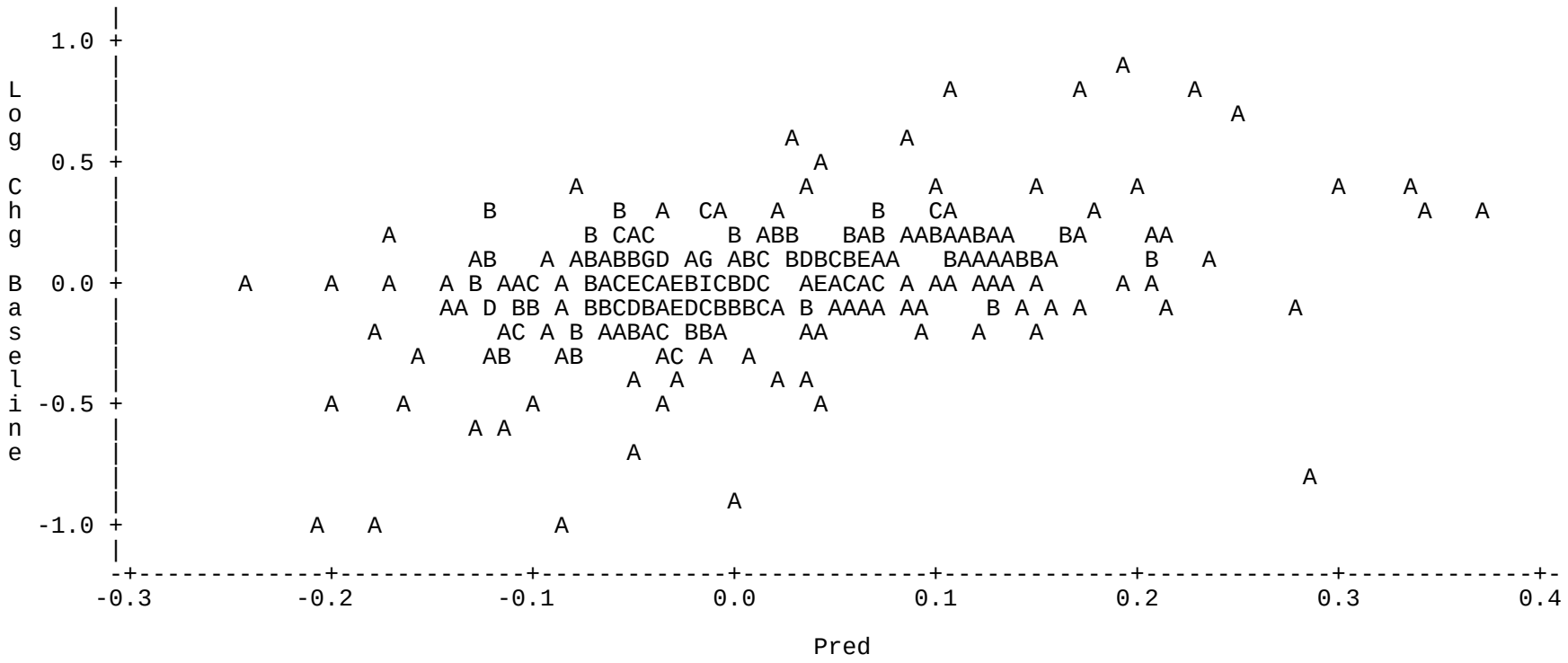
Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	338	Sum Weights	338
Mean	0	Sum Observations	0
Std Deviation	0.21804409	Variance	0.04754323
Skewness	-0.8207432	Kurtosis	4.12922916
Uncorrected SS	16.0220671	Corrected SS	16.0220671
Coeff Variation		Std Error Mean	0.01186004

Basic Statistical Measures

Location		Variability	
Mean	0.000000	Std Deviation	0.21804
Median	0.014449	Variance	0.04754
Mode		Range	1.76247
		Interquartile Range	0.19985

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	13	Pr >= |M|	0.1738
Signed Rank	S	1685.5	Pr >= |S|	0.3492

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.931492	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.096987	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.799821	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.909958	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.7036248
99%	0.5782070
95%	0.3028956
90%	0.2160064
75% Q3	0.1106569
50% Median	0.0144492
25% Q1	-0.0891902
10%	-0.2280836
5%	-0.3190016
1%	-0.8219371
0% Min	-1.0588425

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Table 11.51
SAS Statistical Output for Table 11.50
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.058842	36	0.545040	52
-0.899894	276	0.578207	138
-0.890503	113	0.601346	337
-0.821937	129	0.689101	287
-0.761978	254	0.703625	315

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Table 11.51
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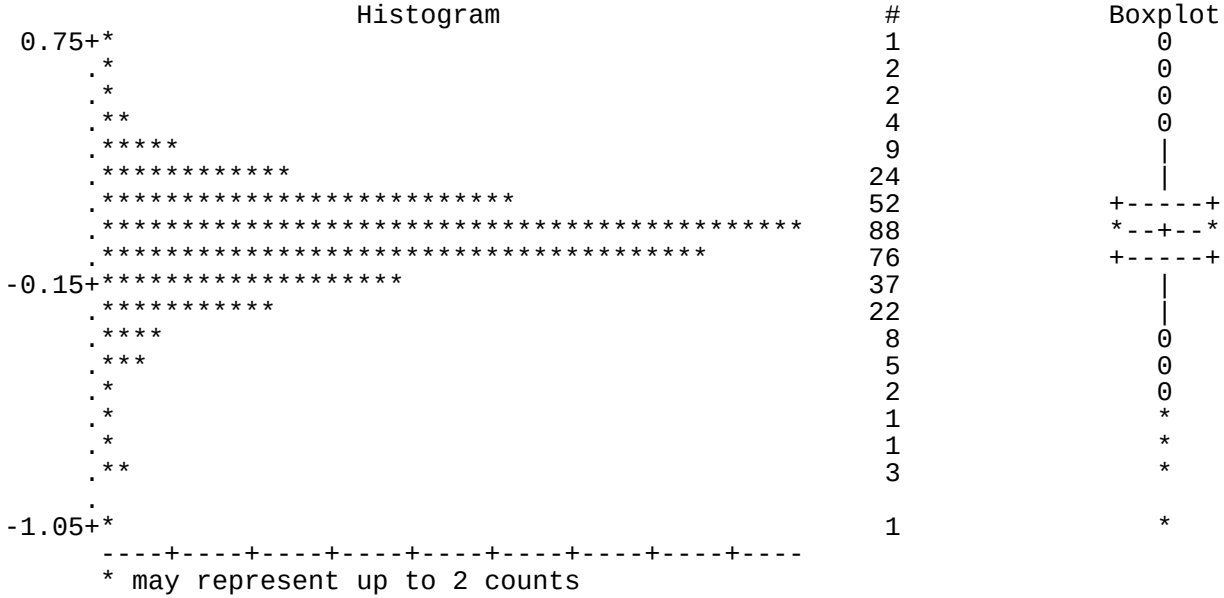
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.51
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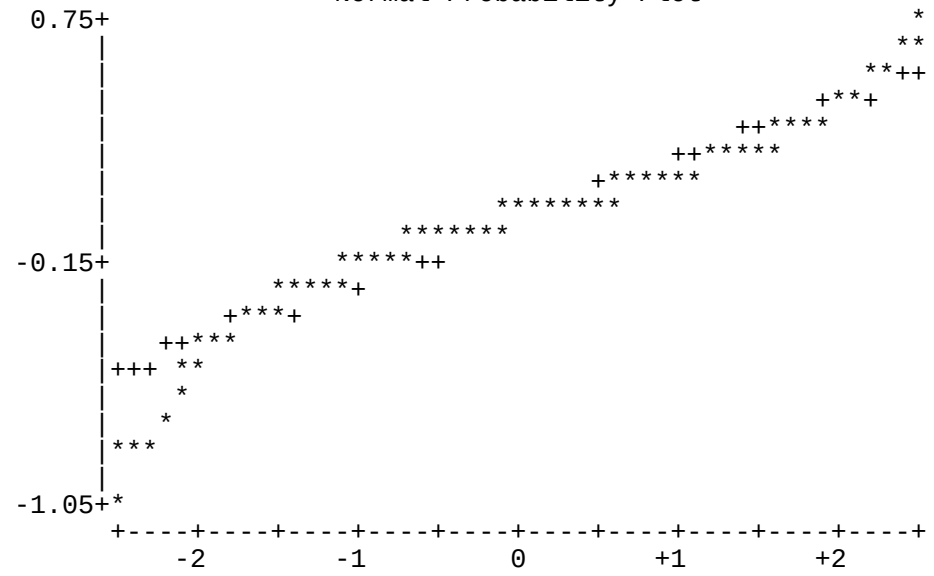
Analysis of Log-Transformed LDL-c (mmol/L) at Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.52
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	51	56	63	52	55
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	57.62	55.95	51.83	53.17	61.39	52.33
	CV (%) [2]	61.709	55.911	60.495	63.949	60.752	65.555
	Geo Mean - SE[3]	53.41	52.01	48.11	49.39	56.80	48.28
	Geo Mean + SE[3]	62.17	60.19	55.85	57.24	66.35	56.72
	Minimum	18.5	22.2	13.4	15.9	22.9	15.7
	Median	51.90	59.20	48.40	55.00	57.50	56.30
	Maximum	218.2	171.3	199.5	204.6	211.3	212.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.52
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		50	46	49	60	45	49
Number (%) of Values Carried Forward		1 (2%)	2 (4%)	3 (6%)	2 (3%)	0	1 (2%)
Baseline	Geo Mean	57.88	57.53	51.58	54.05	61.29	52.22
	CV (%) [2]	59.598	54.131	58.117	64.874	62.668	61.240
Week 4	Geo Mean	54.42	57.06	54.08	53.30	57.07	54.63
	CV (%) [2]	56.732	65.872	66.712	63.379	55.670	64.833
	Geo Mean - SE[3]	50.50	52.22	49.59	49.45	52.82	50.20
	Geo Mean + SE[3]	58.64	62.34	58.98	57.45	61.67	59.46
	Minimum	17.6	18.4	14.2	12.6	18.0	16.2
	Median	56.40	56.20	51.20	52.20	60.10	54.90
	Maximum	167.3	216.6	212.2	159.3	160.0	212.7
Ratio to Baseline (%) [4]	Geo Mean	-5.99	-0.83	4.85	-1.39	-6.89	4.63
	Geo Mean - SE[3]	-11.68	-7.07	-1.52	-7.69	-11.60	-1.05
	Geo Mean + SE[3]	0.07	5.84	11.63	5.35	-1.93	10.63
	Minimum	-84.2	-72.7	-70.3	-79.2	-51.2	-59.1
	Median	-1.76	-0.67	5.81	4.99	-7.82	3.51
	Maximum	98.7	360.9	222.9	343.5	161.9	184.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.52
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		52	48	55	61	51	53
Number (%) of Values Carried Forward		4 (8%)	11 (23%)	10 (18%)	3 (5%)	4 (8%)	9 (17%)
Baseline	Geo Mean	57.43	56.68	51.51	54.04	61.28	53.29
	CV (%) [2]	58.637	54.758	60.887	64.231	61.441	63.844
Week 8	Geo Mean	56.69	59.31	51.23	52.82	55.40	52.99
	CV (%) [2]	57.667	61.457	66.460	63.364	60.094	65.343
	Geo Mean - SE[3]	52.63	54.66	47.22	49.03	51.26	48.82
	Geo Mean + SE[3]	61.06	64.36	55.58	56.90	59.88	57.51
	Minimum	16.4	21.8	14.8	16.7	18.0	16.2
	Median	52.20	57.70	51.20	56.40	55.00	46.70
	Maximum	227.8	208.2	229.3	200.2	193.7	220.5
Ratio to Baseline (%) [4]	Geo Mean	-1.28	4.64	-0.53	-2.27	-9.59	-0.56
	Geo Mean - SE[3]	-6.94	-1.18	-6.97	-8.02	-13.89	-5.65
	Geo Mean + SE[3]	4.72	10.81	6.35	3.85	-5.07	4.82
	Minimum	-69.4	-67.4	-69.0	-77.7	-52.2	-53.4
	Median	-0.70	3.33	-0.42	0.53	-11.44	-2.37
	Maximum	160.5	360.9	365.3	202.6	115.2	112.7

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.52
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	49	55	62	52	53
Number (%) of Values Carried Forward		8 (15%)	14 (29%)	12 (22%)	5 (8%)	4 (8%)	5 (9%)
Baseline	Geo Mean	58.89	56.18	51.51	53.51	61.39	53.29
	CV (%) [2]	61.798	54.555	60.887	64.288	60.752	63.844
Week 12	Geo Mean	57.02	58.91	51.59	51.39	60.07	50.24
	CV (%) [2]	56.468	64.940	69.686	66.381	57.388	68.720
	Geo Mean - SE[3]	53.05	54.13	47.40	47.59	55.79	46.12
	Geo Mean + SE[3]	61.30	64.12	56.16	55.48	64.69	54.72
	Minimum	11.5	19.2	16.4	13.8	18.0	13.0
	Median	57.40	57.60	52.00	50.70	58.10	50.70
	Maximum	174.0	205.5	218.8	214.6	160.0	228.5
Ratio to Baseline (%) [4]	Geo Mean	-3.17	4.86	0.17	-3.96	-2.14	-5.72
	Geo Mean - SE[3]	-8.93	-1.79	-6.20	-10.27	-6.90	-12.00
	Geo Mean + SE[3]	2.95	11.96	6.97	2.79	2.86	1.00
	Minimum	-62.0	-71.3	-58.3	-89.9	-51.6	-82.8
	Median	1.59	-0.96	-2.73	0.72	-1.36	2.39
	Maximum	288.7	360.9	365.3	125.7	199.4	248.5

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.53
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) by Visit

Visit: Baseline

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	51	56	63	52	55
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Geo Mean	37.70	39.08	38.02	37.46	33.97	37.64
	CV (%) [2]	54.433	67.163	58.583	57.662	70.877	65.100
	Geo Mean - SE[3]	35.22	35.88	35.36	35.01	31.09	34.74
	Geo Mean + SE[3]	40.35	42.57	40.88	40.07	37.11	40.78
	Minimum	11.0	8.4	8.5	10.5	5.7	7.8
	Median	37.60	39.60	39.25	37.50	35.20	37.20
	Maximum	123.8	189.7	121.6	112.8	126.6	128.8

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.53
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) by Visit

Visit: Week 4

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		50	46	49	60	45	49
Number (%) of Values Carried Forward		1 (2%)	2 (4%)	3 (6%)	2 (3%)	0	1 (2%)
Baseline	Geo Mean	36.55	38.46	38.14	37.32	33.91	38.65
	CV (%) [2]	51.631	63.718	60.413	59.226	73.963	65.361
Week 4	Geo Mean	37.62	38.45	39.81	41.64	45.09	48.58
	CV (%) [2]	57.295	74.171	66.509	58.829	67.286	66.581
	Geo Mean - SE[3]	34.89	34.87	36.51	38.81	41.16	44.55
	Geo Mean + SE[3]	40.56	42.39	43.41	44.67	49.39	52.97
	Minimum	9.5	8.3	13.4	12.9	12.3	13.8
	Median	39.15	41.10	38.90	40.75	49.00	48.90
	Maximum	122.4	180.9	221.6	137.4	151.8	139.0
Ratio to Baseline (%) [4]	Geo Mean	2.91	-0.03	4.37	11.57	32.95	25.69
	Geo Mean - SE[3]	-1.64	-6.34	-1.32	6.62	27.54	19.55
	Geo Mean + SE[3]	7.66	6.69	10.39	16.75	38.58	32.13
	Minimum	-49.1	-73.6	-70.5	-54.7	-26.6	-42.7
	Median	3.85	-5.04	5.36	11.23	26.70	18.75
	Maximum	257.9	791.1	297.8	352.0	229.6	171.9

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.53
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) by Visit

Visit: Week 8

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		52	48	55	61	51	53
Number (%) of Values Carried Forward		4 (8%)	11 (23%)	10 (18%)	3 (5%)	4 (8%)	9 (17%)
Baseline	Geo Mean	37.43	38.77	38.47	37.31	33.74	37.74
	CV (%) [2]	53.973	62.276	58.304	58.653	71.483	65.475
Week 8	Geo Mean	36.10	36.80	43.22	40.84	44.62	48.14
	CV (%) [2]	65.603	66.517	64.740	60.184	70.234	65.291
	Geo Mean - SE[3]	33.23	33.72	39.91	38.04	40.83	44.35
	Geo Mean + SE[3]	39.23	40.16	46.81	43.86	48.76	52.24
	Minimum	11.0	8.4	8.8	9.1	12.3	9.3
	Median	34.75	41.60	44.20	40.10	49.90	48.70
	Maximum	172.0	91.6	109.9	127.0	151.8	144.9
Ratio to Baseline (%) [4]	Geo Mean	-3.55	-5.07	12.35	9.47	32.25	27.54
	Geo Mean - SE[3]	-8.59	-9.80	6.23	4.91	26.27	21.08
	Geo Mean + SE[3]	1.76	-0.09	18.83	14.22	38.50	34.34
	Minimum	-57.8	-73.6	-70.5	-49.4	-34.6	-43.0
	Median	-6.23	-7.54	10.31	5.56	30.09	26.26
	Maximum	402.9	168.0	215.7	317.8	198.0	275.2

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.53
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) by Visit

Visit: Week 12

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	49	55	62	52	53
Number (%) of Values Carried Forward		8 (15%)	14 (29%)	12 (22%)	5 (8%)	4 (8%)	5 (9%)
Baseline	Geo Mean	36.96	38.35	38.47	37.32	33.97	37.74
	CV (%) [2]	54.406	62.155	58.304	58.097	70.877	65.475
Week 12	Geo Mean	35.06	36.85	42.15	39.46	42.60	47.31
	CV (%) [2]	70.036	74.683	70.448	58.241	79.062	68.323
	Geo Mean - SE[3]	32.15	33.51	38.69	36.84	38.67	43.46
	Geo Mean + SE[3]	38.24	40.53	45.92	42.26	46.92	51.51
	Minimum	5.9	8.4	9.0	14.3	8.3	16.5
	Median	36.70	40.50	42.80	40.10	41.60	45.20
	Maximum	192.1	92.7	184.4	133.1	244.3	160.5
Ratio to Baseline (%) [4]	Geo Mean	-5.13	-3.91	9.57	5.75	25.40	25.36
	Geo Mean - SE[3]	-10.61	-9.34	3.38	0.11	17.42	17.63
	Geo Mean + SE[3]	0.69	1.83	16.14	11.71	33.92	33.59
	Minimum	-72.1	-73.6	-70.5	-77.9	-41.7	-29.0
	Median	1.61	-5.36	8.13	6.48	18.48	16.30
	Maximum	80.7	128.9	427.6	245.7	592.1	843.0

[1]Number of subjects with a value at baseline and at specified visit (after LOCF)
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		53	54	58	58	54	56
Number (%) of Values Carried Forward		9 (17%)	10 (19%)	6 (10%)	1 (2%)	2 (4%)	6 (11%)
Baseline	Mean	7.79	8.00	7.98	7.87	7.78	8.07
	SD	0.666	0.929	0.769	0.624	0.669	0.759
Week 12	Mean	8.06	8.17	7.90	7.88	7.41	7.69
	SD	1.267	1.263	1.140	0.884	0.868	0.977
Chg from Baseline	Mean	0.27	0.17	-0.08	0.01	-0.38	-0.38
	SD	1.073	0.779	0.883	0.729	0.808	0.731
Model-Adj Chg [2]	Mean	0.33	0.16	-0.11	-0.01	-0.37	-0.38
	SE	0.106	0.104	0.101	0.100	0.104	0.102
Diff from Pbo [2]	Mean		-0.17	-0.44	-0.34	-0.70	-0.71
	95% CI		-0.46,0.12	-0.73,-0.16	-0.63,-0.05	-0.99,-0.41	-1.00,-0.42
	p-val [3]		0.251	0.003	0.020	<0.001	<0.001

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	7.79056604	Sum Observations	412.9
Std Deviation	0.66600536	Variance	0.44356313
Skewness	0.09740518	Kurtosis	0.36280874
Uncorrected SS	3239.79	Corrected SS	23.065283
Coeff Variation	8.54886992	Std Error Mean	0.09148287

Basic Statistical Measures

Location		Variability	
Mean	7.790566	Std Deviation	0.66601
Median	7.700000	Variance	0.44356
Mode	7.700000	Range	3.20000
		Interquartile Range	0.80000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	85.15874	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.983393	Pr < W	0.6666
Kolmogorov-Smirnov	D	0.082385	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.048623	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.3154	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.3
99%	9.3
95%	9.2
90%	8.5
75% Q3	8.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.4
10%	6.9
5%	6.6
1%	6.1
0% Min	6.1

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.1	15	8.6	52
6.6	34	8.8	50
6.6	31	9.2	4
6.8	46	9.3	13
6.9	12	9.3	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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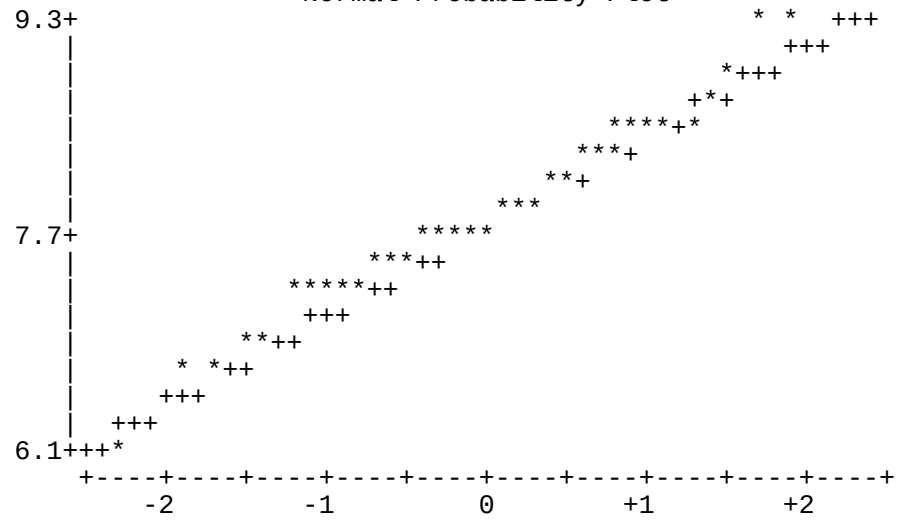
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot
     92 000                      3       |
     90                                  |
     88 0                        1       |
     86 0                        1       |
     84 000000                   6       |
     82 0000                     4    +-----+
     80 0000                     4    |     |
     78 000000                   6    |     |
     76 0000000000              10    *--+--*
     74 000000                   6    +-----+
     72 000000                   6       |
     70                                  |
     68 000                      3       |
     66 00                       2       |
     64                                  |
     62                                  |
     60 0                        1       0
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	8.05849057	Sum Observations	427.1
Std Deviation	1.26680002	Variance	1.60478229
Skewness	0.63300449	Kurtosis	-0.2708812
Uncorrected SS	3525.23	Corrected SS	83.4486792
Coeff Variation	15.7200658	Std Error Mean	0.17400837

Basic Statistical Measures

Location		Variability	
Mean	8.058491	Std Deviation	1.26680
Median	7.800000	Variance	1.60478
Mode	7.600000	Range	5.20000
		Interquartile Range	1.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	46.31094	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.948765	Pr < W	0.0238
Kolmogorov-Smirnov	D	0.128013	Pr > D	0.0289
Cramer-von Mises	W-Sq	0.145718	Pr > W-Sq	0.0260
Anderson-Darling	A-Sq	0.861323	Pr > A-Sq	0.0249

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.4
99%	11.4
95%	10.3
90%	10.0
75% Q3	8.8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.8
25% Q1	7.2
10%	6.4
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	22	10.1	4
6.3	46	10.1	41
6.3	38	10.3	50
6.3	29	10.6	42
6.3	6	11.4	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                 #    Boxplot                    Normal Probability Plot
    11 4                    1       0          11.25+                                  *++
    10 6                    1       |              |                                 *++++
    10 0113                 4       |              |                            ** +*++
     9 5679                 4       |              |                         ****+++
     9 4                    1       |              |                        *+++
     8 678889               6    +-----+        8.75+                    +****
     8 022334               6    |  +  |           |                  ++***
     7 6666678889          10    *-----*           |               +*****
     7 122233444            9    +-----+           |            **+**
     6 78999                5       |              |         ***+*
     6 233334               6       |           6.25+  *   *  +*+*
       ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+
                                                        -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	0.26792453	Sum Observations	14.2
Std Deviation	1.07269854	Variance	1.15068215
Skewness	0.39198828	Kurtosis	-0.1851016
Uncorrected SS	63.64	Corrected SS	59.8354717
Coeff Variation	400.373397	Std Error Mean	0.14734648

Basic Statistical Measures

Location		Variability	
Mean	0.267925	Std Deviation	1.07270
Median	0.100000	Variance	1.15068
Mode	0.100000	Range	4.50000
		Interquartile Range	1.30000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.81833	Pr > |t|	0.0748
Sign	M	5.5	Pr >= |M|	0.1608

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	149.5	Pr >= |S|	0.1631

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.971993	Pr < W	0.2457
Kolmogorov-Smirnov	D	0.110714	Pr > D	0.1013
Cramer-von Mises	W-Sq	0.088652	Pr > W-Sq	0.1589
Anderson-Darling	A-Sq	0.510837	Pr > A-Sq	0.1967

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.8
99%	2.8
95%	2.2
90%	2.0
75% Q3	0.9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.1
25% Q1	-0.4
10%	-1.0
5%	-1.5
1%	-1.7
0% Min	-1.7

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.7	13	2.1	10
-1.7	6	2.1	20
-1.5	38	2.2	42
-1.5	22	2.5	41
-1.0	48	2.8	52

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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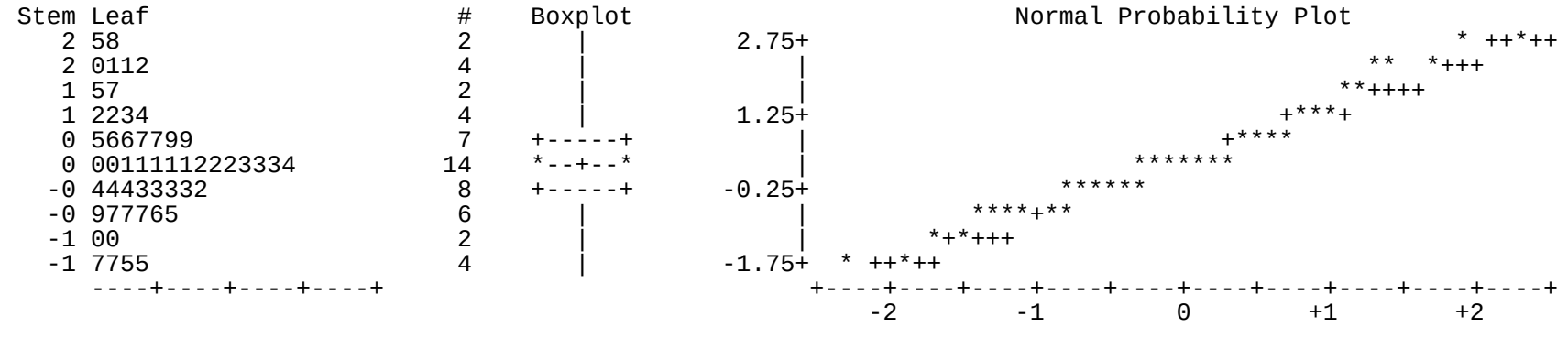
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	8.00185185	Sum Observations	432.1
Std Deviation	0.92888465	Variance	0.86282669
Skewness	0.69877308	Kurtosis	-0.1193155
Uncorrected SS	3503.33	Corrected SS	45.7298148
Coeff Variation	11.608371	Std Error Mean	0.12640519

Basic Statistical Measures

Location		Variability	
Mean	8.001852	Std Deviation	0.92888
Median	7.750000	Variance	0.86283
Mode	7.700000	Range	3.70000
		Interquartile Range	1.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	63.30319	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.936632	Pr < W	0.0068
Kolmogorov-Smirnov	D	0.14157	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.219426	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.276222	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.10
99%	10.10
95%	9.80
90%	9.50
75% Q3	8.40

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.40
10%	7.00
5%	6.80
1%	6.40
0% Min	6.40

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	49	9.7	1
6.4	30	9.8	7
6.8	40	9.8	36
6.8	24	10.1	3
6.9	46	10.1	43

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                     #    Boxplot
   100 00                       2       0
    98 00                       2       |
    96 0                        1       |
    94 00                       2       |
    92 0                        1       |
    90 00                       2       |
    88 0                        1       |
    86                                  |
    84 0000                     4    +-----+
    82 0000                     4    |     |
    80 0000                     4    |  +  |
    78 0000                     4    |     |
    76 00000000                 8    *-----*
    74 0000000                  7    +-----+
    72 0000                     4       |
    70 000                      3       |
    68 000                      3       |
    66                                  |
    64 00                       2       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```

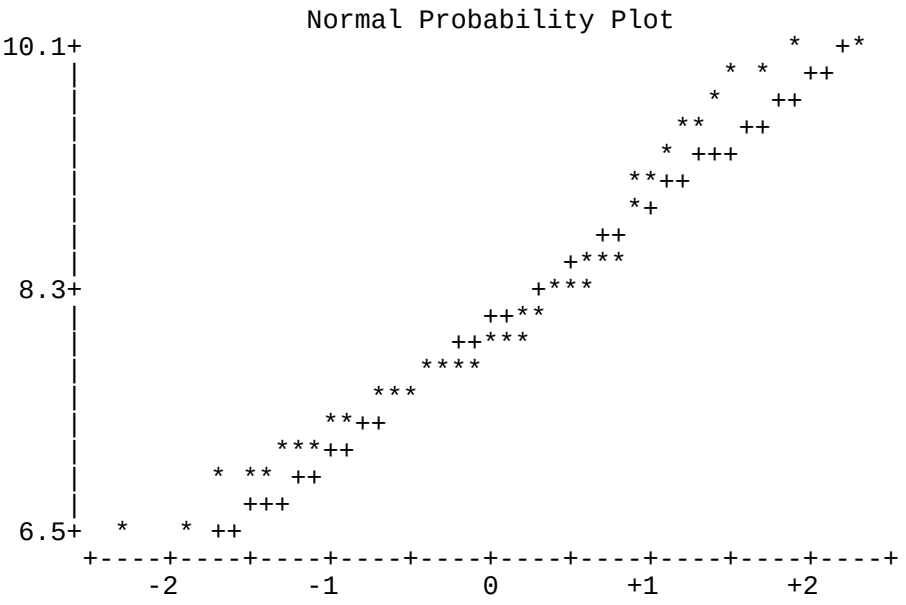

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	8.17407407	Sum Observations	441.4
Std Deviation	1.26329685	Variance	1.59591894
Skewness	0.74901945	Kurtosis	0.13639632
Uncorrected SS	3692.62	Corrected SS	84.5837037
Coeff Variation	15.454923	Std Error Mean	0.17191293

Basic Statistical Measures

Location		Variability	
Mean	8.174074	Std Deviation	1.26330
Median	7.750000	Variance	1.59592
Mode	7.600000	Range	5.50000
		Interquartile Range	1.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	47.54776	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.947552	Pr < W	0.0195
Kolmogorov-Smirnov	D	0.146269	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.153595	Pr > W-Sq	0.0215
Anderson-Darling	A-Sq	0.869124	Pr > A-Sq	0.0242

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.80
99%	11.80
95%	10.60
90%	10.10
75% Q3	9.00

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.75
25% Q1	7.30
10%	6.60
5%	6.50
1%	6.30
0% Min	6.30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.3	30	10.1	7
6.4	37	10.5	9
6.5	51	10.6	2
6.5	50	10.8	48
6.6	41	11.8	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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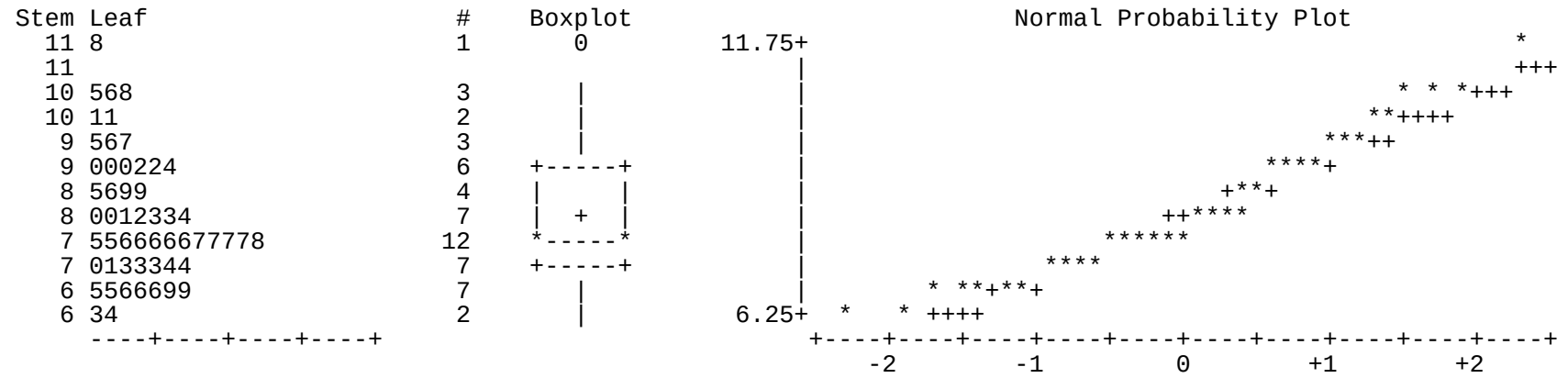
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	0.17222222	Sum Observations	9.3
Std Deviation	0.7793119	Variance	0.60732704
Skewness	-0.0790489	Kurtosis	-0.0951605
Uncorrected SS	33.79	Corrected SS	32.1883333
Coeff Variation	452.503686	Std Error Mean	0.10605092

Basic Statistical Measures

Location		Variability	
Mean	0.17222	Std Deviation	0.77931
Median	0.15000	Variance	0.60733
Mode	-0.50000	Range	3.40000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.623958	Pr > |t|	0.1103
Sign	M	3.5	Pr >= |M|	0.4101
Signed Rank	S	187.5	Pr >= |S|	0.0971

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.98311	Pr < W	0.6417
Kolmogorov-Smirnov	D	0.068274	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.033846	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.264244	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.80
99%	1.80
95%	1.70

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[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	1.10
75% Q3	0.60
50% Median	0.15
25% Q1	-0.30
10%	-0.60
5%	-1.40
1%	-1.60
0% Min	-1.60

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.6	27	1.2	49
-1.4	41	1.3	52
-1.4	14	1.7	3
-1.2	50	1.7	48
-1.0	51	1.8	2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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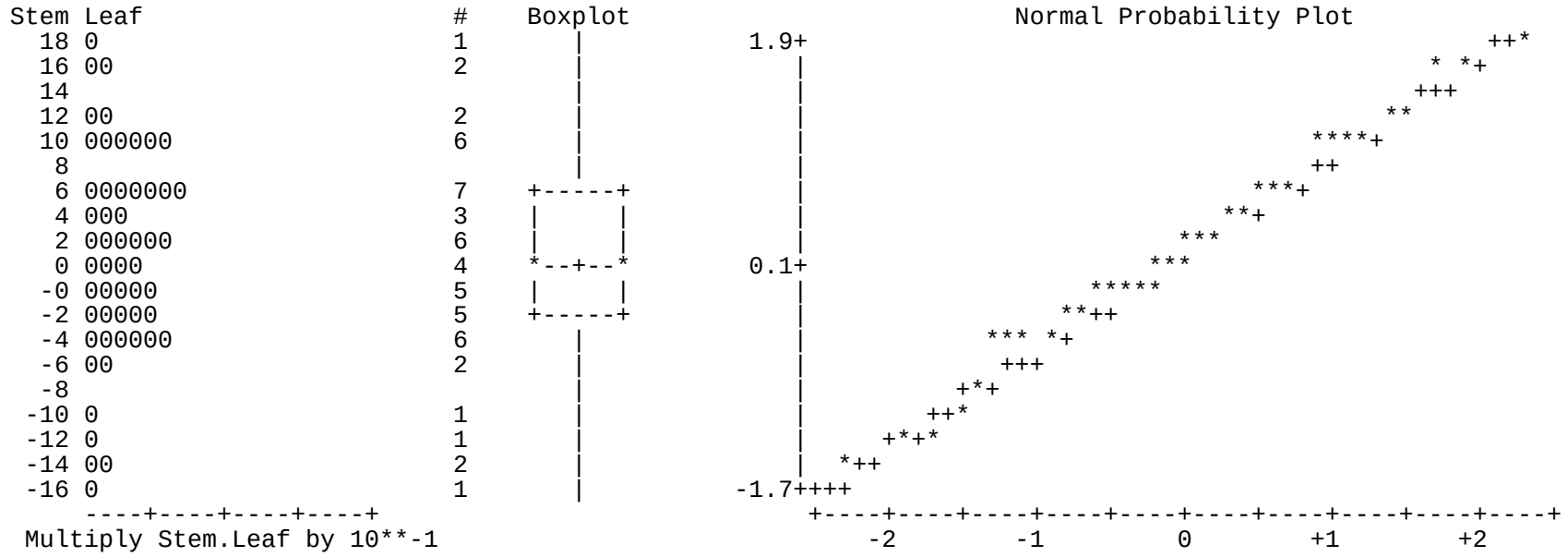
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	7.97931034	Sum Observations	462.8
Std Deviation	0.76863027	Variance	0.5907925
Skewness	0.77678087	Kurtosis	0.07099825
Uncorrected SS	3726.5	Corrected SS	33.6751724
Coeff Variation	9.63279082	Std Error Mean	0.1009261

Basic Statistical Measures

Location		Variability	
Mean	7.979310	Std Deviation	0.76863
Median	7.700000	Variance	0.59079
Mode	7.600000	Range	3.30000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	79.06092	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.932011	Pr < W	0.0029
Kolmogorov-Smirnov	D	0.159084	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.268937	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.557494	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.9
99%	9.9
95%	9.6
90%	9.3
75% Q3	8.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.7
25% Q1	7.4
10%	7.3
5%	6.9
1%	6.6
0% Min	6.6

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.6	29	9.4	27
6.7	23	9.4	45
6.9	41	9.6	31
6.9	10	9.7	30
7.2	22	9.9	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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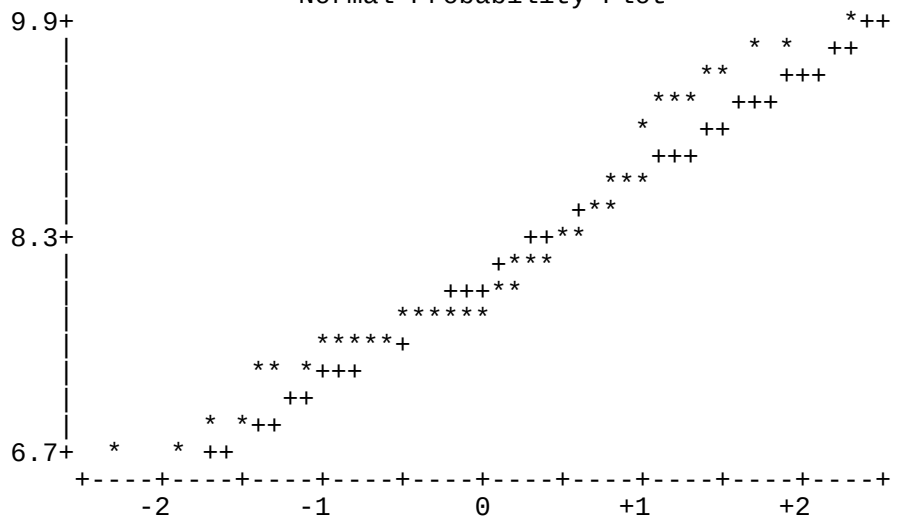
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot
     98 0                        1       0
     96 00                       2       0
     94 00                       2       |
     92 000                      3       |
     90 0                        1       |
     88                                  |
     86 000                      3       |
     84 00                       2       |
     82 0000                     4    +-----+
     80 0000000                  7    |     |
     78 000                      3    |  +  |
     76 000000000000            12    *-----*
     74 000000000                9    +-----+
     72 00000                    5       |
     70                                  |
     68 00                       2       |
     66 00                       2       |
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	7.89827586	Sum Observations	458.1
Std Deviation	1.13978936	Variance	1.29911978
Skewness	0.88196459	Kurtosis	0.34564127
Uncorrected SS	3692.25	Corrected SS	74.0498276
Coeff Variation	14.4308629	Std Error Mean	0.14966167

Basic Statistical Measures

Location		Variability	
Mean	7.898276	Std Deviation	1.13979
Median	7.600000	Variance	1.29912
Mode	7.600000	Range	4.80000
		Interquartile Range	1.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	52.7742	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.935258	Pr < W	0.0040
Kolmogorov-Smirnov	D	0.154945	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.203847	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.180088	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	11.0
99%	11.0
95%	10.4
90%	9.7
75% Q3	8.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.6
25% Q1	7.1
10%	6.6
5%	6.3
1%	6.2
0% Min	6.2

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.2	29	9.8	56
6.2	23	10.2	37
6.3	54	10.4	3
6.4	44	10.7	5
6.6	40	11.0	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                  #    Boxplot                    Normal Probability Plot
     11 0                     1       0          11.25+                                *
     10 7                     1       |              |                                *   +++
     10 24                    2       |              |                             * * ++++
      9 578                   3       |              |                          ***++++
      9 001                   3       |              |                       **+++
      8 667888                6    +-----+        8.75+                   ***+
      8 012244                6    |     |           |                ++***
      7 5555666667899        13    *--+--*           |             +*****
      7 01122233334          11    +-----+           |          ******
      6 66789999              8       |              |       *****+*
      6 2234                  4       |           6.25+  *   * *+*++
        ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+----+
                                                        -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0810345	Sum Observations	-4.7
Std Deviation	0.88346544	Variance	0.78051119
Skewness	0.34797299	Kurtosis	0.86961913
Uncorrected SS	44.87	Corrected SS	44.4891379
Coeff Variation	-1090.234	Std Error Mean	0.1160047

Basic Statistical Measures

Location		Variability	
Mean	-0.08103	Std Deviation	0.88347
Median	-0.20000	Variance	0.78051
Mode	-0.30000	Range	4.40000
		Interquartile Range	0.90000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.69854	Pr > |t|	0.4877
Sign	M	-4.5	Pr >= |M|	0.2717
Signed Rank	S	-135.5	Pr >= |S|	0.2336

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.964408	Pr < W	0.0867
Kolmogorov-Smirnov	D	0.091748	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.118982	Pr > W-Sq	0.0636
Anderson-Darling	A-Sq	0.776953	Pr > A-Sq	0.0427

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.1
99%	2.1
95%	1.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	1.1
75% Q3	0.3
50% Median	-0.2
25% Q1	-0.6
10%	-1.1
5%	-1.7
1%	-2.3
0% Min	-2.3

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.3	49	1.6	37
-1.9	51	1.7	5
-1.7	44	1.7	52
-1.2	54	2.1	3
-1.1	40	2.1	56

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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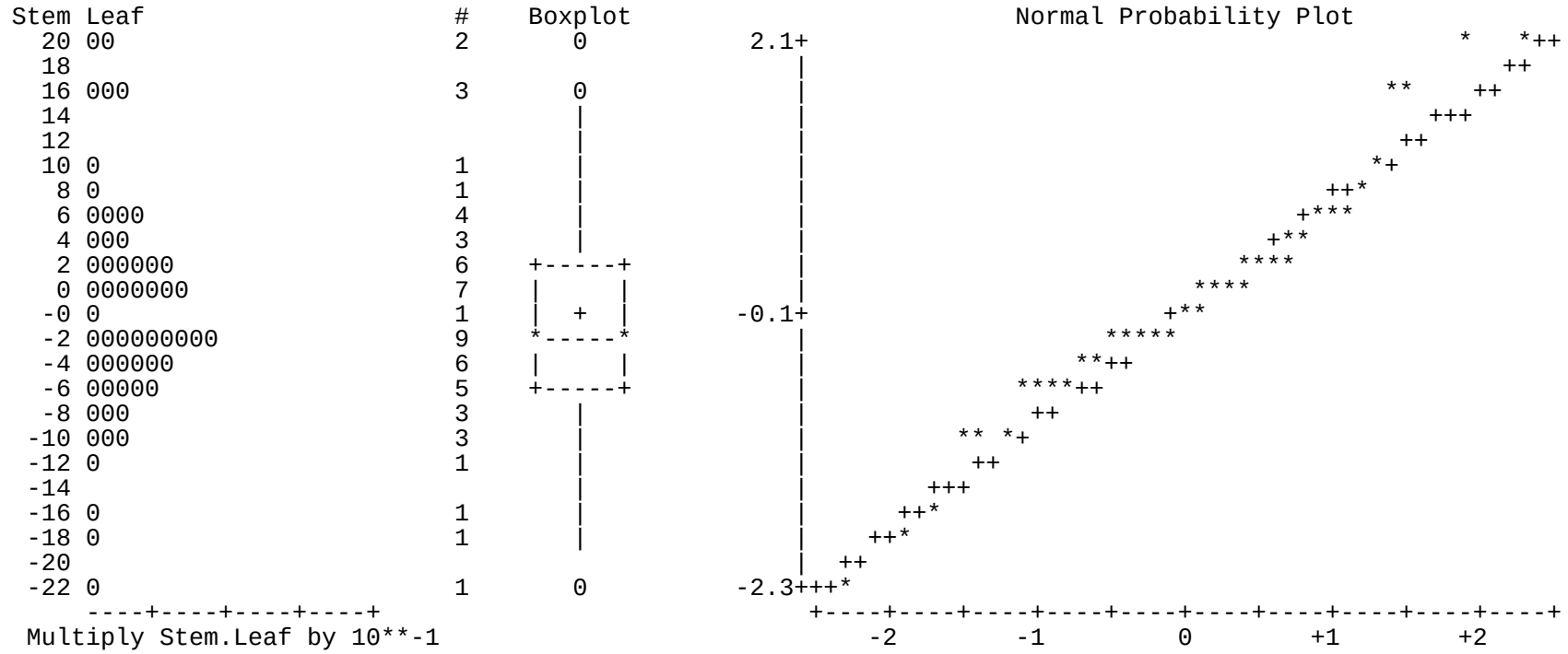
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	58	Sum Weights	58
Mean	7.87241379	Sum Observations	456.6
Std Deviation	0.62430118	Variance	0.38975197
Skewness	-0.0237641	Kurtosis	-0.1594687
Uncorrected SS	3616.76	Corrected SS	22.2158621
Coeff Variation	7.93023841	Std Error Mean	0.08197476

Basic Statistical Measures

Location		Variability	
Mean	7.872414	Std Deviation	0.62430
Median	8.000000	Variance	0.38975
Mode	8.000000	Range	3.00000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	96.0346	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.988792	Pr < W	0.8696
Kolmogorov-Smirnov	D	0.098208	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.058852	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.304301	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.5
99%	9.5
95%	8.9
90%	8.6
75% Q3	8.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	8.0
25% Q1	7.4
10%	7.0
5%	6.8
1%	6.5
0% Min	6.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	25	8.7	54
6.6	6	8.8	28
6.8	3	8.9	21
6.9	45	9.0	30
7.0	16	9.5	23

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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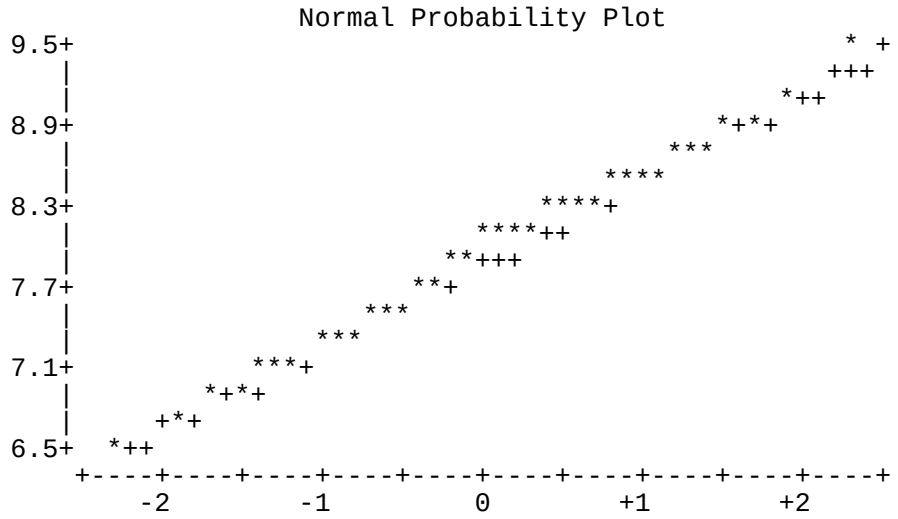
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot
     94 0                        1       |
     92                                  |
     90 0                        1       |
     88 00                       2       |
     86 000                      3       |
     84 000000                   6       |
     82 00000000                 8    +-----+
     80 000000000                9    *-----*
     78 0000                     4    |  +  |
     76 0000                     4    |     |
     74 0000000                  7    +-----+
     72 00000                    5       |
     70 0000                     4       |
     68 00                       2       |
     66 0                        1       |
     64 0                        1       |
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	58	Sum Weights	58
Mean	7.88448276	Sum Observations	457.3
Std Deviation	0.88353392	Variance	0.78063218
Skewness	0.09417181	Kurtosis	-0.432168
Uncorrected SS	3650.07	Corrected SS	44.4960345
Coeff Variation	11.2059845	Std Error Mean	0.11601369

Basic Statistical Measures

Location		Variability	
Mean	7.884483	Std Deviation	0.88353
Median	7.900000	Variance	0.78063
Mode	8.200000	Range	4.00000
		Interquartile Range	1.20000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	67.96166	Pr > |t|	<.0001
Sign	M	29	Pr >= |M|	<.0001
Signed Rank	S	855.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.989929	Pr < W	0.9122
Kolmogorov-Smirnov	D	0.070529	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.034976	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.199951	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	10.0
99%	10.0
95%	9.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	9.1
75% Q3	8.5
50% Median	7.9
25% Q1	7.3
10%	6.7
5%	6.4
1%	6.0
0% Min	6.0

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.0	33	9.2	55
6.4	50	9.3	17
6.4	25	9.5	4
6.5	45	9.5	54
6.5	36	10.0	18

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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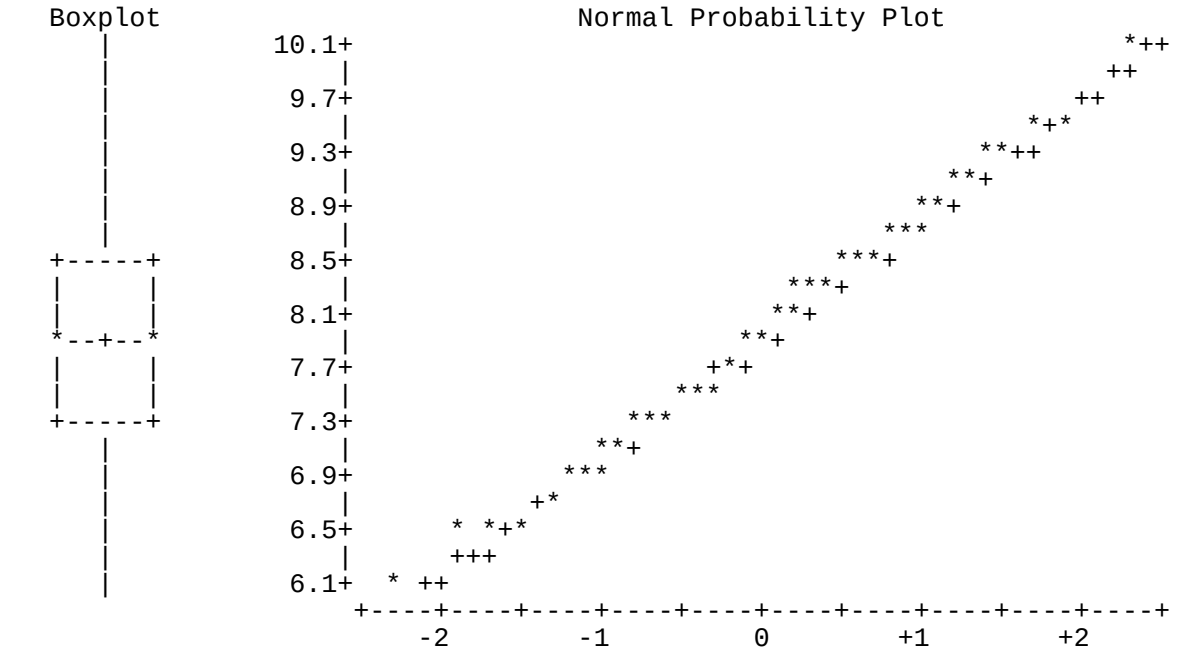
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
   100 0                     1       |
    98                             |
    96                             |
    94 00                     2       |
    92 00                     2       |
    90 00                     2       |
    88 00                     2       |
    86 000                    3       |
    84 0000000                7    +-----+
    82 000000                 6    |     |
    80 00                     2    |     |
    78 0000                   4    *--+--*
    76 0000                   4    |     |
    74 000000                 6    |     |
    72 00000                  5    +-----+
    70 000                    3       |
    68 000                    3       |
    66 0                      1       |
    64 0000                   4       |
    62                             |
    60 0                      1       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	0.01206897	Sum Observations	0.7
Std Deviation	0.72887262	Variance	0.53125529
Skewness	0.22113694	Kurtosis	1.27156141
Uncorrected SS	30.29	Corrected SS	30.2815517
Coeff Variation	6039.23026	Std Error Mean	0.09570566

Basic Statistical Measures

Location		Variability	
Mean	0.012069	Std Deviation	0.72887
Median	0.000000	Variance	0.53126
Mode	0.000000	Range	3.80000
		Interquartile Range	0.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.126105	Pr > |t|	0.9001
Sign	M	2.5	Pr >= |M|	0.5682

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	15.5	Pr >= |S|	0.8792

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.955126	Pr < W	0.0315
Kolmogorov-Smirnov	D	0.139645	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.21791	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.127784	Pr > A-Sq	0.0056

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.0
99%	2.0
95%	1.6
90%	0.8
75% Q3	0.3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-0.3
10%	-1.0
5%	-1.2
1%	-1.8
0% Min	-1.8

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-1.8	23	0.8	54
-1.6	50	1.2	17
-1.2	48	1.6	4
-1.1	40	1.9	6
-1.1	33	2.0	18

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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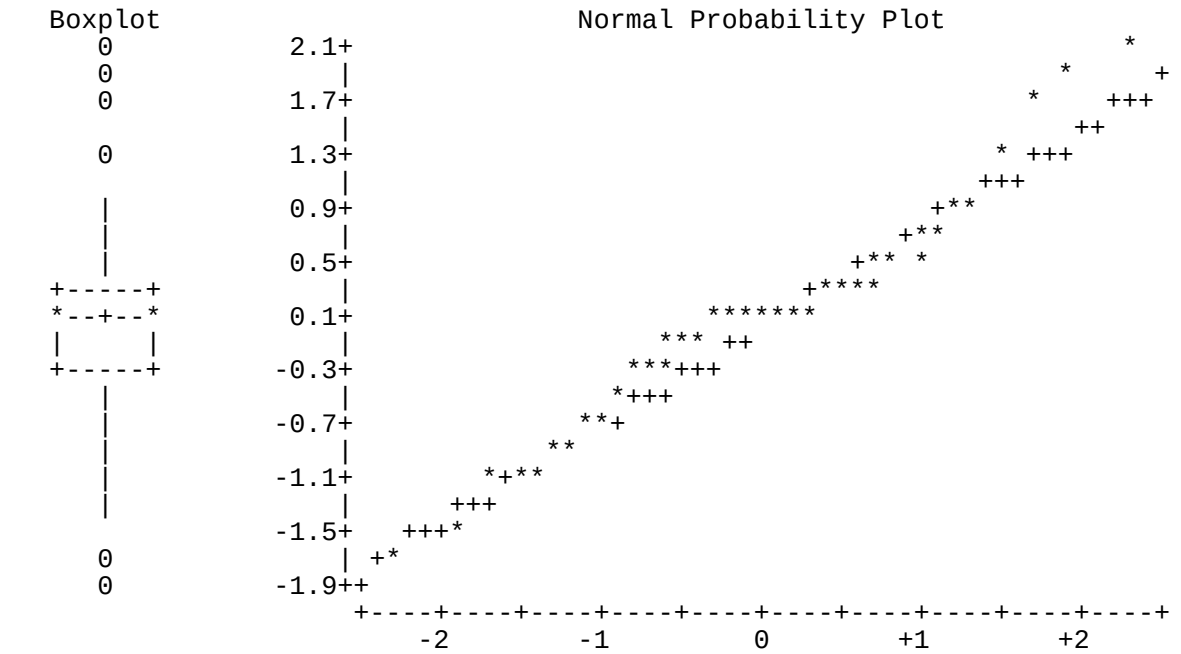
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot
     20 0                        1       0
     18 0                        1       0
     16 0                        1       0
     14                                  |
     12 0                        1       0
     10                                  |
      8 000                      3       |
      6 00                       2       |
      4 00000                    5       |
      2 000000                   6    +-----+
      0 0000000000000000        16    *--+--*
     -0 000                      3    |     |
     -2 00000                    5    +-----+
     -4 000                      3       |
     -6 000                      3       |
     -8 00                       2       |
    -10 000                      3       |
    -12 0                        1       |
    -14                                  |
    -16 0                        1       0
    -18 0                        1       0
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	7.78333333	Sum Observations	420.3
Std Deviation	0.66891915	Variance	0.44745283
Skewness	0.05112634	Kurtosis	-0.3411978
Uncorrected SS	3295.05	Corrected SS	23.715
Coeff Variation	8.59425033	Std Error Mean	0.09102837

Basic Statistical Measures

Location		Variability	
Mean	7.783333	Std Deviation	0.66892
Median	7.800000	Variance	0.44745
Mode	8.400000	Range	3.20000
		Interquartile Range	1.10000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	85.50448	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.970331	Pr < W	0.1994
Kolmogorov-Smirnov	D	0.089986	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.086597	Pr > W-Sq	0.1712
Anderson-Darling	A-Sq	0.571133	Pr > A-Sq	0.1368

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.6
99%	9.6
95%	8.7
90%	8.6
75% Q3	8.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.8
25% Q1	7.3
10%	6.8
5%	6.7
1%	6.4
0% Min	6.4

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.4	39	8.6	26
6.7	21	8.6	44
6.7	14	8.7	24
6.8	52	8.7	47
6.8	51	9.6	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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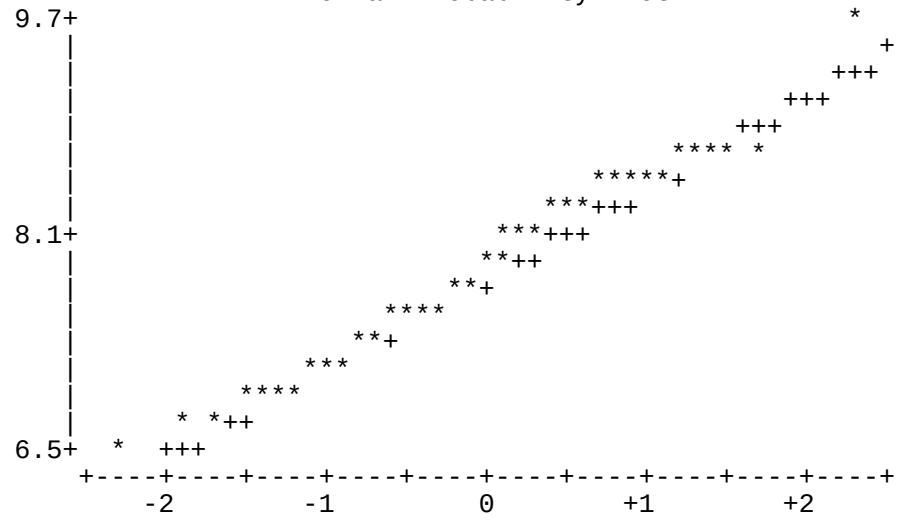
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot
     96 0                        1       |
     94                                  |
     92                                  |
     90                                  |
     88                                  |
     86 000000                   6       |
     84 0000000                  7    +-----+
     82 00000                    5    |     |
     80 000000                   6    |     |
     78 000                      3    *-----*
     76 000                      3    |  +  |
     74 000000000                9    |     |
     72 000                      3    +-----+
     70 0000                     4       |
     68 0000                     4       |
     66 00                       2       |
     64 0                        1       |
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	7.40740741	Sum Observations	400
Std Deviation	0.86827781	Variance	0.75390636
Skewness	0.45215692	Kurtosis	0.22755922
Uncorrected SS	3002.92	Corrected SS	39.957037
Coeff Variation	11.7217505	Std Error Mean	0.11815764

Basic Statistical Measures

Location		Variability	
Mean	7.407407	Std Deviation	0.86828
Median	7.300000	Variance	0.75391
Mode	7.100000	Range	4.20000
		Interquartile Range	1.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	62.69089	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.976072	Pr < W	0.3508
Kolmogorov-Smirnov	D	0.124204	Pr > D	0.0372
Cramer-von Mises	W-Sq	0.095637	Pr > W-Sq	0.1288
Anderson-Darling	A-Sq	0.517005	Pr > A-Sq	0.1900

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.7
99%	9.7
95%	8.9

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[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.6
75% Q3	7.9
50% Median	7.3
25% Q1	6.9
10%	6.3
5%	6.2
1%	5.5
0% Min	5.5

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.5	19	8.8	7
6.1	16	8.9	5
6.2	33	8.9	41
6.2	21	9.4	24
6.2	14	9.7	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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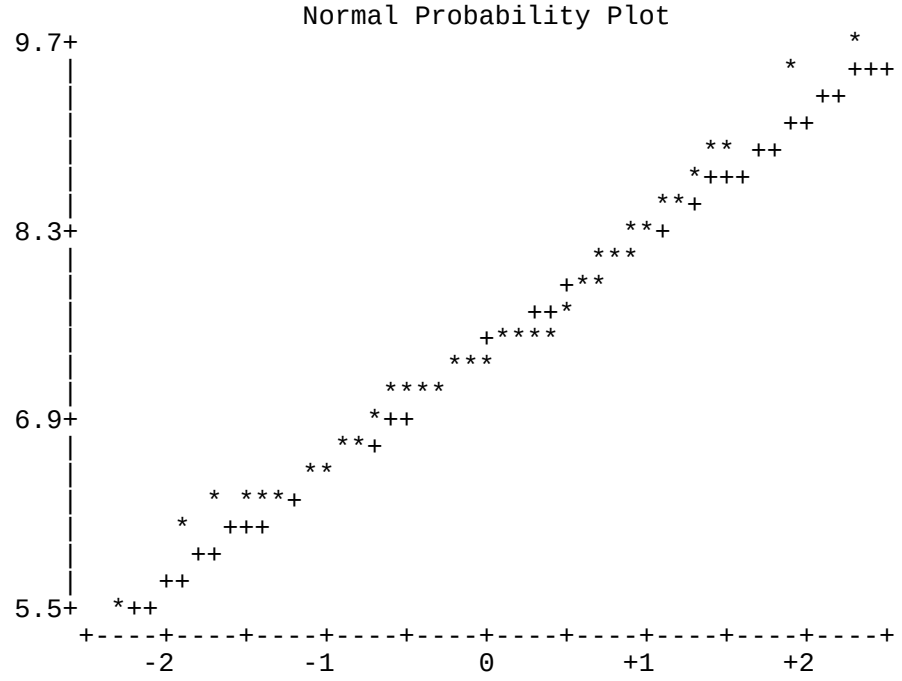
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                 #    Boxplot
    96 0                    1       0
    94 0                    1       |
    92                              |
    90                              |
    88 000                  3       |
    86 0                    1       |
    84 00                   2       |
    82 00                   2       |
    80 000                  3       |
    78 000                  3   +-----+
    76 00                   2   |     |
    74 00000000             8   |  +  |
    72 000000               6   *-----*
    70 00000000             8   |     |
    68 00                   2   +-----+
    66 000                  3       |
    64 00                   2       |
    62 00000                5       |
    60 0                    1       |
    58                              |
    56                              |
    54 0                    1       |
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	-0.3759259	Sum Observations	-20.3
Std Deviation	0.80843085	Variance	0.65356045
Skewness	0.46038092	Kurtosis	2.88244135
Uncorrected SS	42.27	Corrected SS	34.6387037
Coeff Variation	-215.05057	Std Error Mean	0.1100135

Basic Statistical Measures

Location		Variability	
Mean	-0.37593	Std Deviation	0.80843
Median	-0.45000	Variance	0.65356
Mode	-0.50000	Range	5.10000
		Interquartile Range	0.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.41709	Pr > |t|	0.0012
Sign	M	-9	Pr >= |M|	0.0153

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-360.5	Pr >= |S|	0.0002

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.952785	Pr < W	0.0329
Kolmogorov-Smirnov	D	0.108479	Pr > D	0.1118
Cramer-von Mises	W-Sq	0.069707	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.545114	Pr > A-Sq	0.1587

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.60
99%	2.60
95%	0.70
90%	0.40
75% Q3	0.10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.45
25% Q1	-0.80
10%	-1.30
5%	-1.60
1%	-2.50
0% Min	-2.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.5	19	0.6	46
-2.1	16	0.7	39
-1.6	47	0.7	24
-1.5	26	0.9	5
-1.3	48	2.6	53

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.
[redacted]

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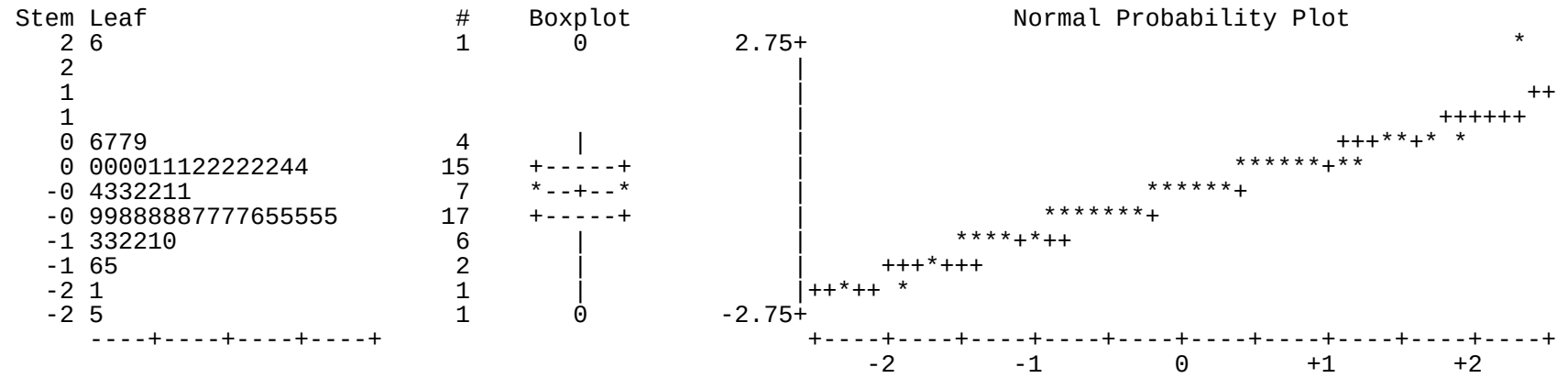
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	8.06607143	Sum Observations	451.7
Std Deviation	0.75877336	Variance	0.57573701
Skewness	-0.00275	Kurtosis	-0.579592
Uncorrected SS	3675.11	Corrected SS	31.6655357
Coeff Variation	9.40697547	Std Error Mean	0.10139536

Basic Statistical Measures

Location		Variability	
Mean	8.066071	Std Deviation	0.75877
Median	8.050000	Variance	0.57574
Mode	7.700000	Range	3.00000
		Interquartile Range	1.05000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	79.5507	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.983354	Pr < W	0.6304
Kolmogorov-Smirnov	D	0.050909	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.020588	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.167922	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.50
99%	9.50
95%	9.50
90%	9.10
75% Q3	8.60

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	8.05
25% Q1	7.55
10%	7.10
5%	6.70
1%	6.50
0% Min	6.50

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
6.5	24	9.2	27
6.7	49	9.3	26
6.7	9	9.5	4
6.8	33	9.5	34
6.9	39	9.5	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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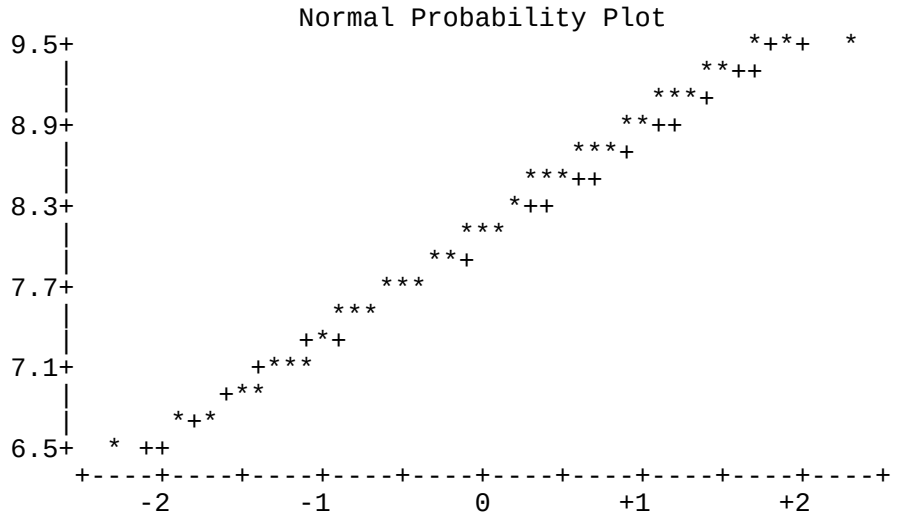
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot
     94 000                      3       |
     92 00                       2       |
     90 000                      3       |
     88 000                      3       |
     86 00000                    5    +-----+
     84 00000                    5    |     |
     82 0000                     4    |     |
     80 00000                    5    *--+--*
     78 000000                   6    |     |
     76 000000                   6    |     |
     74 00000                    5    +-----+
     72 0                        1       |
     70 000                      3       |
     68 00                       2       |
     66 00                       2       |
     64 0                        1       |
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	7.6875	Sum Observations	430.5
Std Deviation	0.97702005	Variance	0.95456818
Skewness	0.25279405	Kurtosis	-0.3605896
Uncorrected SS	3361.97	Corrected SS	52.50125
Coeff Variation	12.7092039	Std Error Mean	0.1305598

Basic Statistical Measures

Location		Variability	
Mean	7.687500	Std Deviation	0.97702
Median	7.650000	Variance	0.95457
Mode	7.300000	Range	4.10000
		Interquartile Range	1.40000

NOTE: The mode displayed is the smallest of 3 modes with a count of 4.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	58.88107	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.983105	Pr < W	0.6183
Kolmogorov-Smirnov	D	0.06816	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.02648	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.212072	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	9.90
99%	9.90
95%	9.70

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	8.90
75% Q3	8.30
50% Median	7.65
25% Q1	6.90
10%	6.50
5%	6.10
1%	5.80
0% Min	5.80

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
5.8	9	9.0	21
6.0	31	9.4	17
6.1	52	9.7	27
6.3	11	9.8	26
6.3	8	9.9	55

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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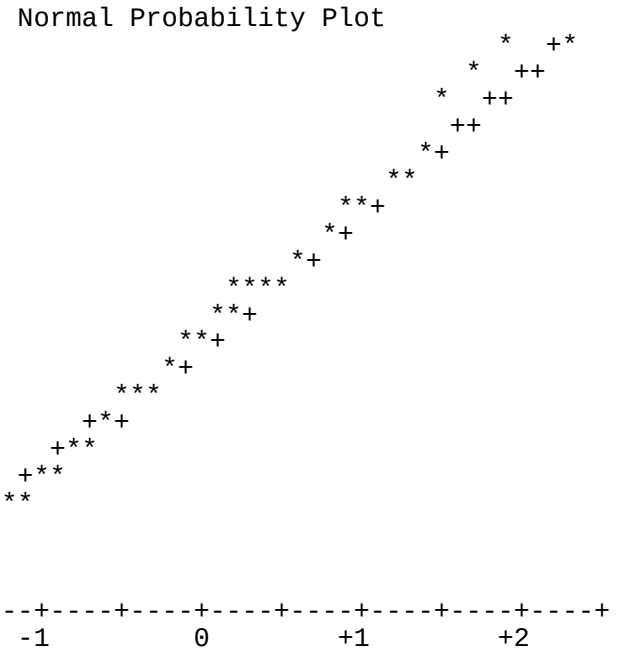
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                     #    Boxplot
     98 00                       2        |
     96 0                        1        |
     94 0                        1        |
     92                                   |
     90 0                        1        |
     88 00                       2        |
     86 0000                     4        |
     84 00                       2        |
     82 000                      3    +-----+
     80 00000000                 8    |     |
     78 00                       2    |     |
     76 0000                     4    *--+--*
     74 0000                     4    |     |
     72 00000                    5    |     |
     70 000                      3    |     |
     68 000                      3    +-----+
     66 000                      3        |
     64 000                      3        |
     62 00                       2        |
     60 00                       2        |
     58 0                        1        |
        ----+----+----+----+
    Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	-0.3785714	Sum Observations	-21.2
Std Deviation	0.7310551	Variance	0.53444156
Skewness	-1.0366192	Kurtosis	1.37042862
Uncorrected SS	37.42	Corrected SS	29.3942857
Coeff Variation	-193.10889	Std Error Mean	0.09769135

Basic Statistical Measures

Location		Variability	
Mean	-0.37857	Std Deviation	0.73106
Median	-0.20000	Variance	0.53444
Mode	0.00000	Range	3.80000
		Interquartile Range	1.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.87518	Pr > |t|	0.0003
Sign	M	-8.5	Pr >= |M|	0.0213

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-341.5	Pr >= |S|	0.0004

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.933119	Pr < W	0.0040
Kolmogorov-Smirnov	D	0.131165	Pr > D	0.0175
Cramer-von Mises	W-Sq	0.212615	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.178936	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.90
99%	0.90
95%	0.50
90%	0.40
75% Q3	0.15

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.20
25% Q1	-0.85
10%	-1.40
5%	-1.80
1%	-2.90
0% Min	-2.90

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-2.9	52	0.4	55
-1.8	19	0.5	26
-1.8	31	0.5	27
-1.6	8	0.7	54
-1.5	51	0.9	21

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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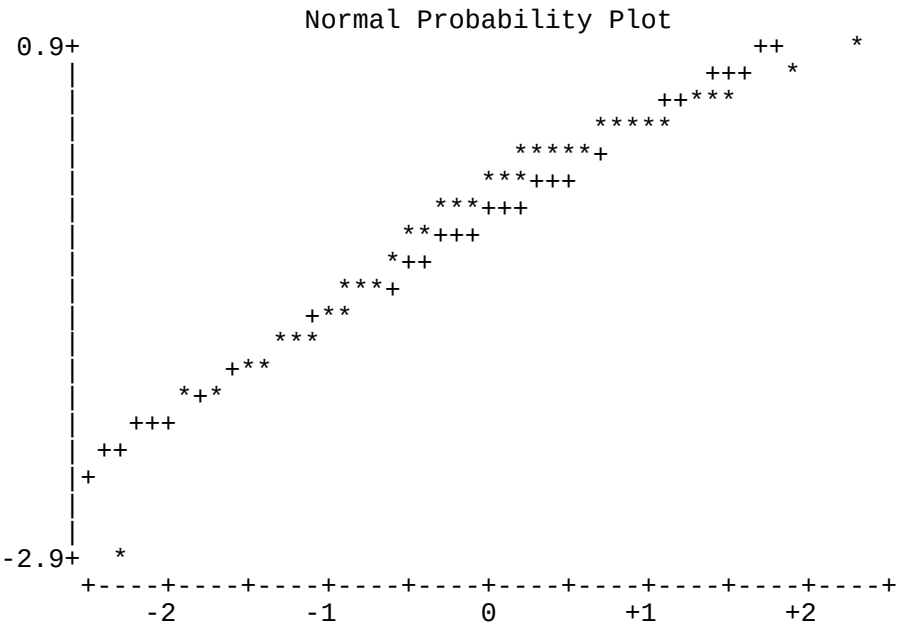
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot
      8 0                        1       |
      6 0                        1       |
      4 0000                     4       |
      2 00000000                 8       |
      0 000000000                9    +-----+
     -0 0000                     4    |     |
     -2 00000                    5    *--+--*
     -4 000000                   6    |     |
     -6 000                      3    |     |
     -8 00000                    5    +-----+
    -10                                 |
    -12 000                     3       |
    -14 000                     3       |
    -16 0                       1       |
    -18 00                      2       |
    -20                                 |
    -22                                 |
    -24                                 |
    -26                                 |
    -28 0                       1       0
        ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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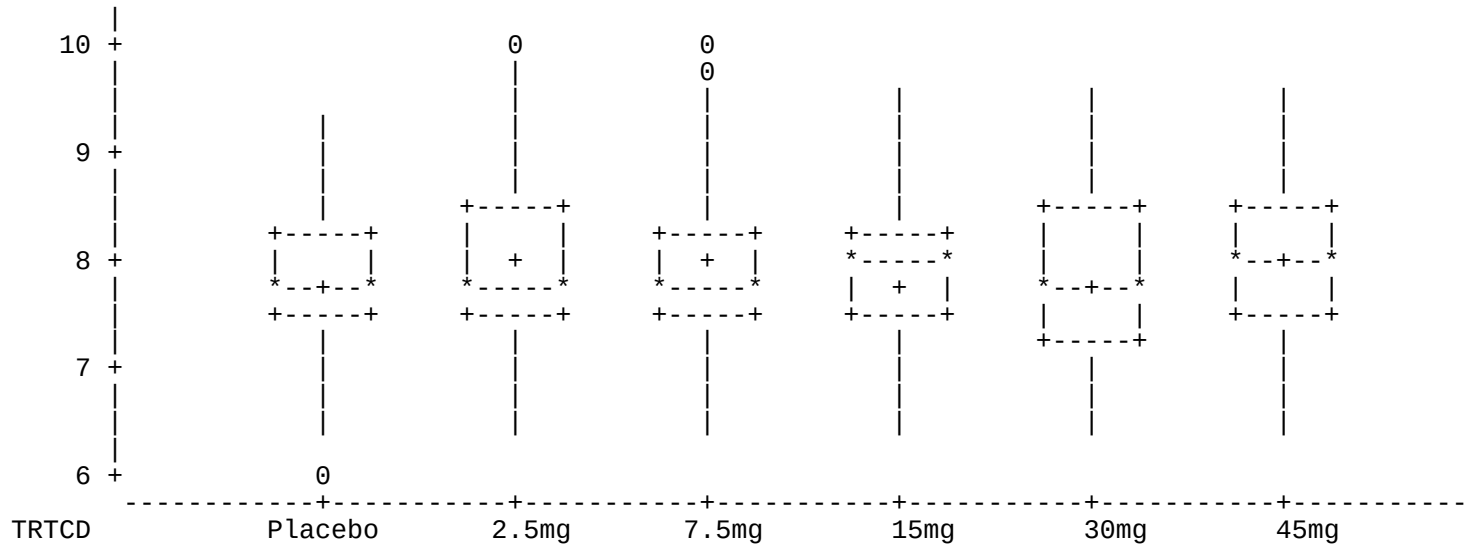
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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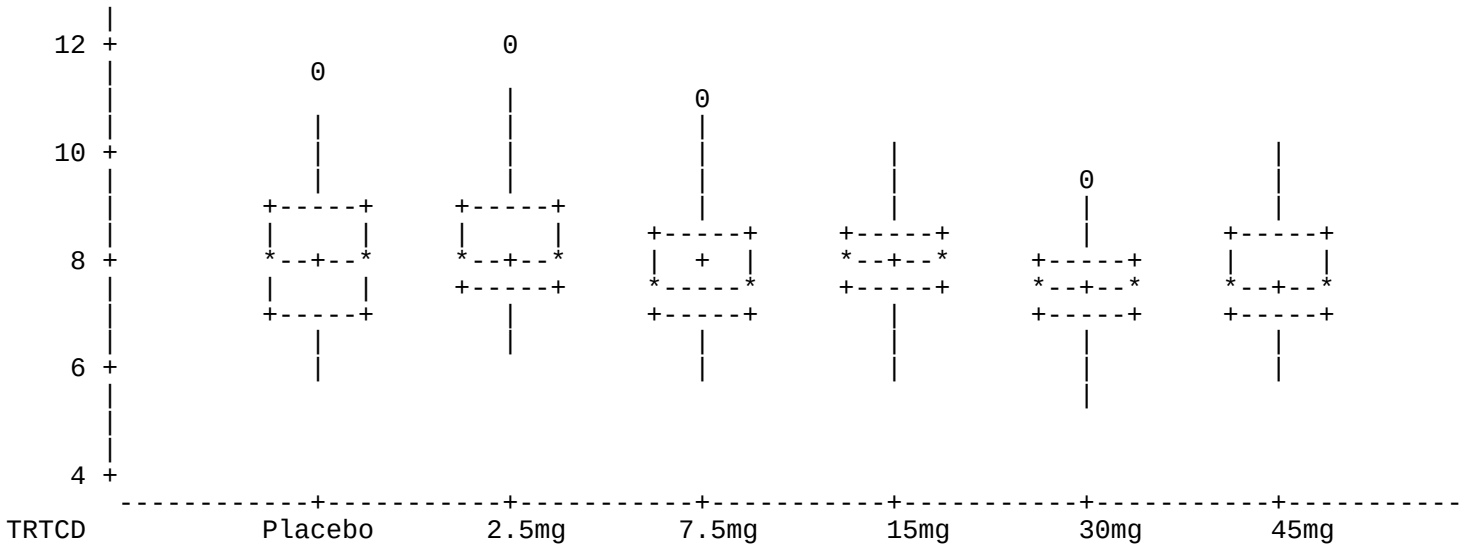
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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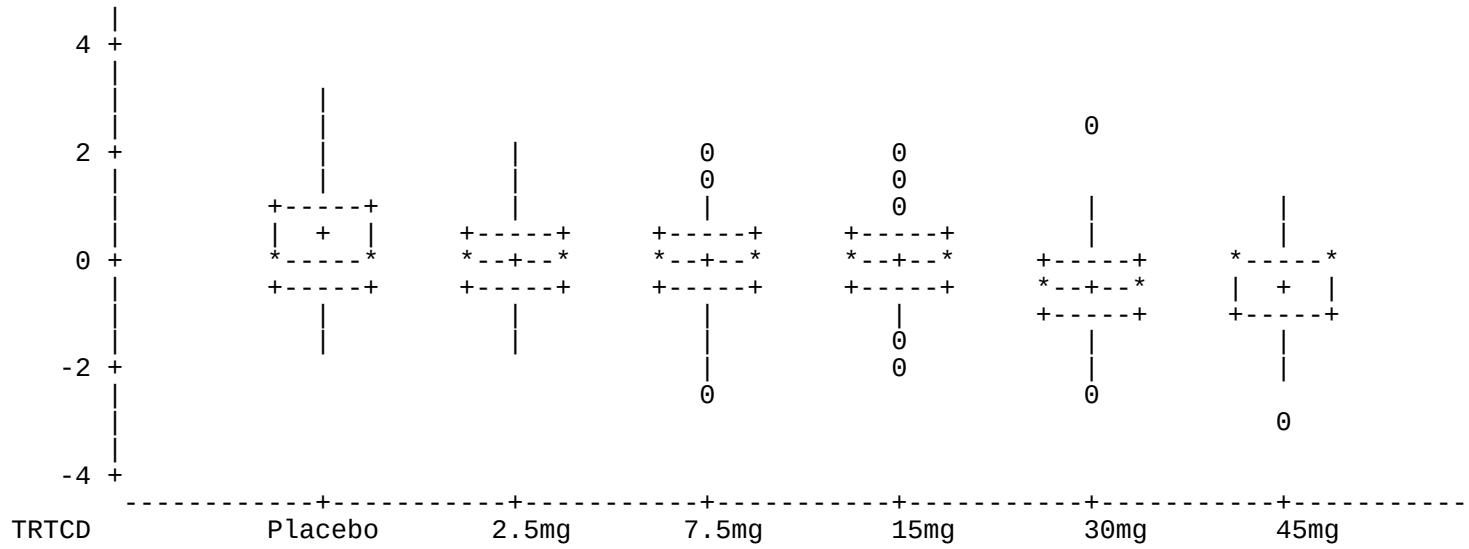
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12
Excluding Subjects from Centre [redacted]
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	333
Observations Used	333
Observations Not Used	0
Total Observations	333

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.5813	0.04581	12.69	<.0001	0.05	0.5010	0.6826

Fit Statistics

-2 Res Log Likelihood	785.4
AIC (smaller is better)	787.4
AICC (smaller is better)	787.4
BIC (smaller is better)	791.2

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.3788	0.4719	322	0.80	0.4227
SEX	Female				-0.04657	0.08469	322	-0.55	0.5828
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			-0.6646	0.08604	322	-7.72	<.0001
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.7102	0.1476	322	4.81	<.0001
TRTCD				2.5mg	0.5389	0.1457	322	3.70	0.0003
TRTCD				7.5mg	0.2657	0.1434	322	1.85	0.0647
TRTCD				15mg	0.3696	0.1434	322	2.58	0.0104
TRTCD				30mg	0.009348	0.1466	322	0.06	0.9492
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-0.3438	0.09950	322	-3.46	0.0006
REGIONCD			Eastern Europe		-0.1041	0.1051	322	-0.99	0.3227
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.03983	0.05724	322	-0.70	0.4871

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	322	0.30	0.5828
TRTTYPCD	1	322	59.67	<.0001
TRTCD	5	322	7.50	<.0001
REGIONCD	2	322	6.19	0.0023
EFSTDBL	1	322	0.48	0.4871

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.1714	0.1491	322	-1.15	0.2513	0.05	-0.4646	0.1219
7.5mg vs Pbo	-0.4445	0.1463	322	-3.04	0.0026	0.05	-0.7323	-0.1567
15mg vs Pbo	-0.3406	0.1456	322	-2.34	0.0199	0.05	-0.6271	-0.05416
30mg vs Pbo	-0.7009	0.1477	322	-4.75	<.0001	0.05	-0.9914	-0.4104
45mg vs Pbo	-0.7102	0.1476	322	-4.81	<.0001	0.05	-1.0005	-0.4200

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5015	0.5015	0.5015	0.5015	0.5015
SEX	Male				0.4985	0.4985	0.4985	0.4985	0.4985
TRTTYPCD		Diet & Exercise			0.4084	0.4084	0.4084	0.4084	0.4084
TRTTYPCD		Monotherapy			0.5916	0.5916	0.5916	0.5916	0.5916
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3423	0.3423	0.3423	0.3423	0.3423
REGIONCD			Eastern Europe		0.2853	0.2853	0.2853	0.2853	0.2853
REGIONCD			Western Europe		0.3724	0.3724	0.3724	0.3724	0.3724
EFSTDBL					7.9171	7.9171	7.9171	7.9171	7.9171

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5015
SEX	Male				0.4985
TRTTYPCD		Diet & Exercise			0.4084
TRTTYPCD		Monotherapy			0.5916
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3423
REGIONCD			Eastern Europe		0.2853
REGIONCD			Western Europe		0.3724
EFSTDBL					7.9171

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	0.3316	0.1056	322	3.14	0.0018	0.05	0.1239	0.5392
TRTCD	2.5mg	WORK.EFF	0.1602	0.1043	322	1.54	0.1255	0.05	-0.04497	0.3654
TRTCD	7.5mg	WORK.EFF	-0.1129	0.1005	322	-1.12	0.2621	0.05	-0.3107	0.08486
TRTCD	15mg	WORK.EFF	-0.00906	0.1002	322	-0.09	0.9280	0.05	-0.2062	0.1881
TRTCD	30mg	WORK.EFF	-0.3693	0.1042	322	-3.54	0.0005	0.05	-0.5744	-0.1643
TRTCD	45mg	WORK.EFF	-0.3787	0.1023	322	-3.70	0.0003	0.05	-0.5800	-0.1773

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.1714	0.1491	322	1.15	0.2513	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.4445	0.1463	322	3.04	0.0026	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.3406	0.1456	322	2.34	0.0199	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.7009	0.1477	322	4.75	<.0001	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.7102	0.1476	322	4.81	<.0001	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.2732	0.1449	322	1.89	0.0603	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.1693	0.1445	322	1.17	0.2424	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.5295	0.1481	322	3.58	0.0004	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.5389	0.1457	322	3.70	0.0003	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.1039	0.1420	322	-0.73	0.4650	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.2564	0.1449	322	1.77	0.0779	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.2657	0.1434	322	1.85	0.0647	0.05
TRTCD	15mg	30mg	WORK.EFF	0.3603	0.1446	322	2.49	0.0132	0.05
TRTCD	15mg	45mg	WORK.EFF	0.3696	0.1434	322	2.58	0.0104	0.05
TRTCD	30mg	45mg	WORK.EFF	0.009348	0.1466	322	0.06	0.9492	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1219	0.4646
TRTCD	Placebo	7.5mg	0.1567	0.7323
TRTCD	Placebo	15mg	0.05416	0.6271
TRTCD	Placebo	30mg	0.4104	0.9914
TRTCD	Placebo	45mg	0.4200	1.0005
TRTCD	2.5mg	7.5mg	-0.01187	0.5582
TRTCD	2.5mg	15mg	-0.1151	0.4536
TRTCD	2.5mg	30mg	0.2382	0.8209
TRTCD	2.5mg	45mg	0.2523	0.8255
TRTCD	7.5mg	15mg	-0.3833	0.1755

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.02877	0.5415
TRTCD	7.5mg	45mg	-0.01634	0.5478
TRTCD	15mg	30mg	0.07576	0.6448
TRTCD	15mg	45mg	0.08756	0.6517
TRTCD	30mg	45mg	-0.2790	0.2977

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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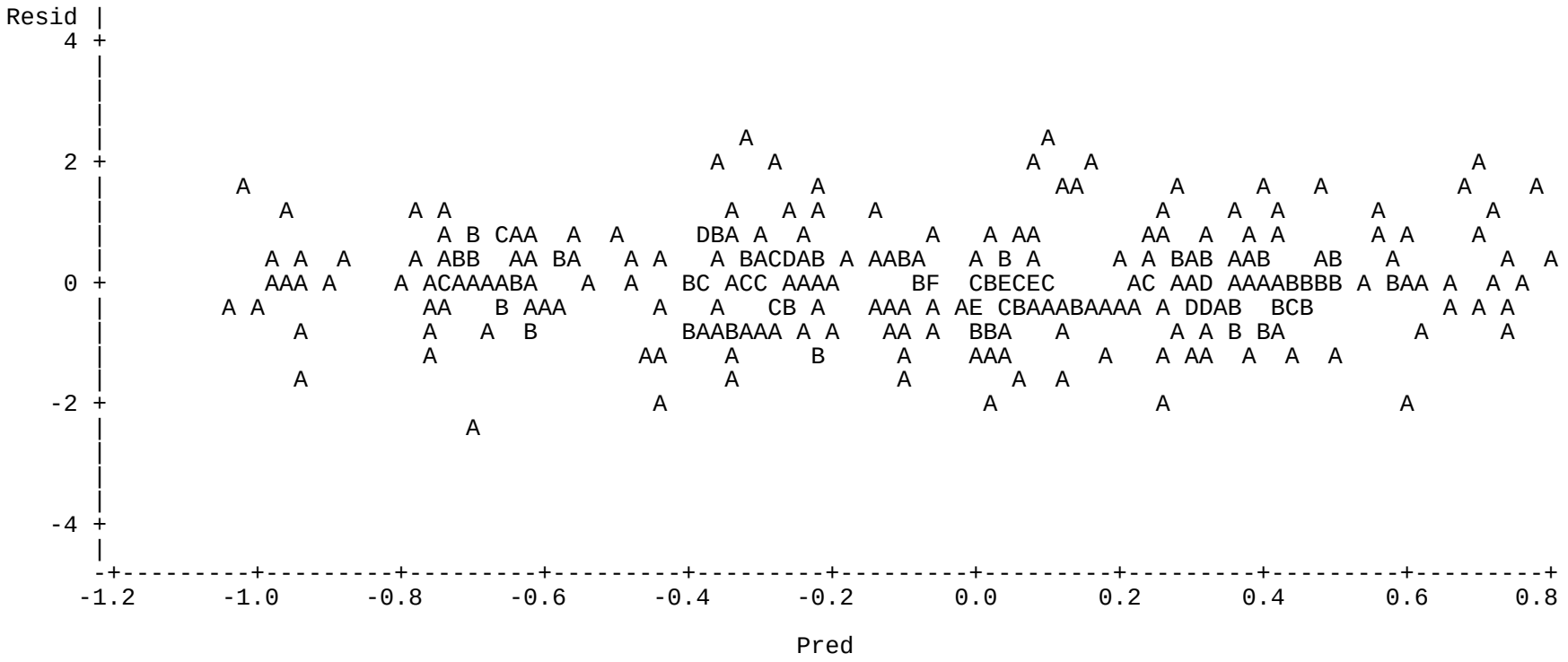
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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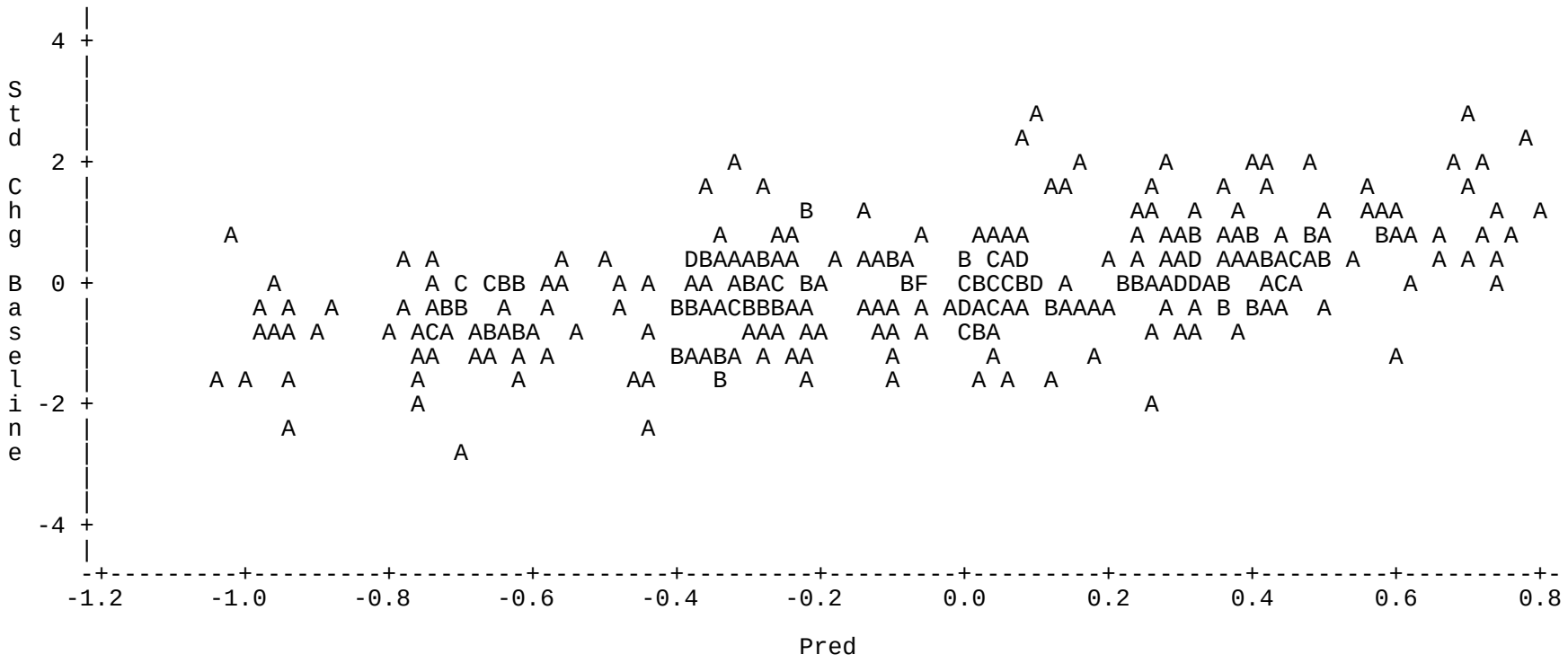
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	333	Sum Weights	333
Mean	0	Sum Observations	0
Std Deviation	0.7508319	Variance	0.56374853
Skewness	0.27269882	Kurtosis	1.03811405
Uncorrected SS	187.164514	Corrected SS	187.164514
Coeff Variation		Std Error Mean	0.04114533

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.75083
Median	-0.02476	Variance	0.56375
Mode	0.11053	Range	4.70379
		Interquartile Range	0.83194

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-9.5	Pr >= |M|	0.3239
Signed Rank	S	-907.5	Pr >= |S|	0.6065

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.981833	Pr < W	0.0003
Kolmogorov-Smirnov	D	0.059296	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.321973	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.91731	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.4946016
99%	2.1000169
95%	1.3833947
90%	0.8770128
75% Q3	0.3901746
50% Median	-0.0247645
25% Q1	-0.4417666
10%	-0.8632508
5%	-1.2429008
1%	-1.8669522
0% Min	-2.2091879

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		-----Highest-----	
Value	Obs	Value	Obs
-2.20919	297	2.06136	311
-2.15547	302	2.10002	320
-1.99910	236	2.11011	234
-1.86695	296	2.42674	325
-1.82627	131	2.49460	316

Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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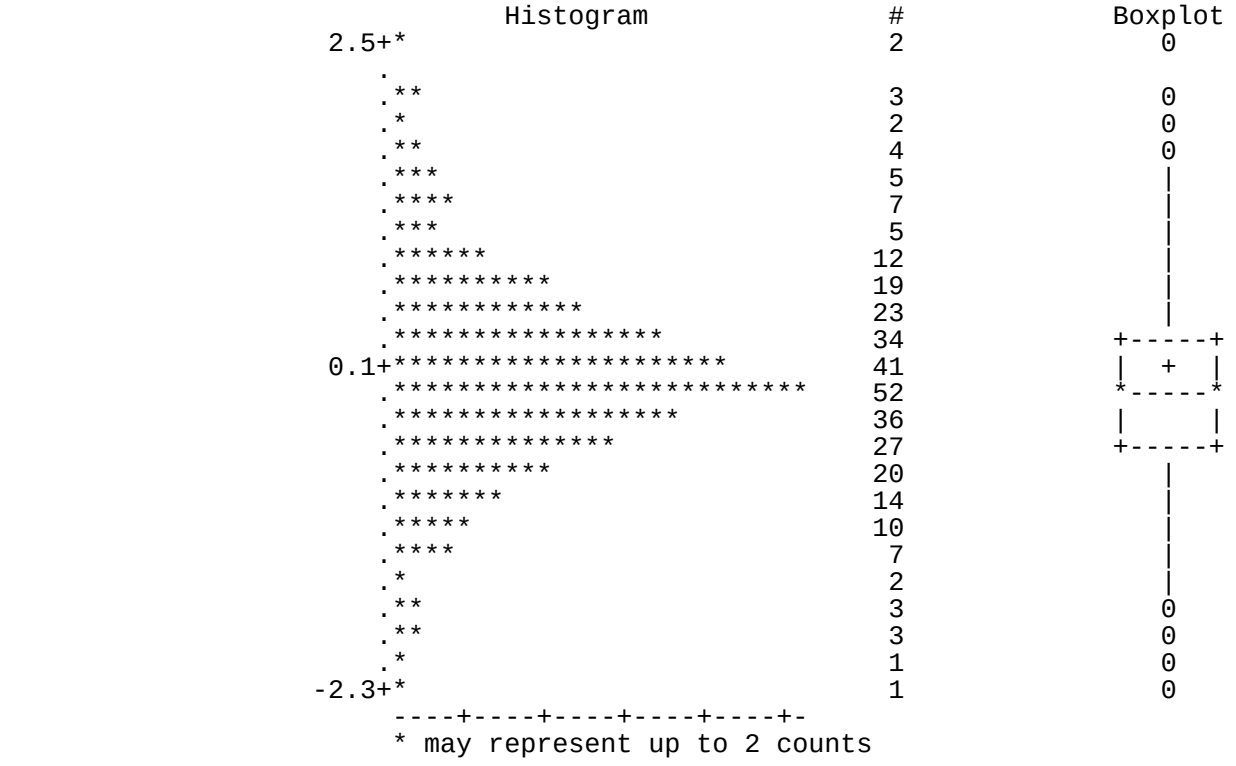
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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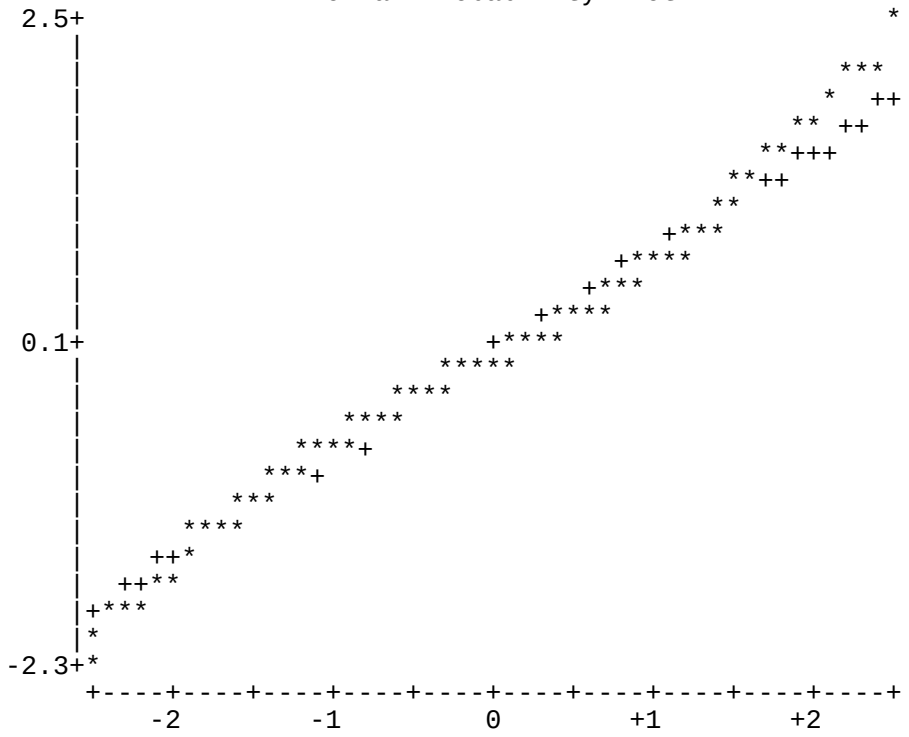
Table 11.55
SAS Statistical Output for Table 11.54
Sensitivity Analysis of Change in HbA1c (%) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Efstdbl is the baseline variable, Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L)
from Baseline to Week 12 Excluding Outliers

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)	15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		56	51	57	61	53	54
Number (%) of Values Carried Forward		10 (18%)	12 (24%)	10 (18%)	3 (5%)	4 (8%)	6 (11%)
Baseline	Mean	87.81	94.80	102.08	105.12	87.47	109.50
	SD	52.405	49.175	62.985	65.497	47.167	73.545
Week 12	Mean	87.92	92.84	104.85	105.14	92.72	118.19
	SD	52.139	56.588	66.650	71.530	54.696	77.105
Chg from Baseline	Mean	0.11	-1.96	2.77	0.02	5.25	8.69
	SD	43.662	44.408	48.700	51.200	34.801	54.605
Model-Adj Chg [2]	Mean	-2.92	-1.85	2.83	2.17	2.21	12.20
	SE	5.982	6.242	5.908	5.719	6.134	6.083
Diff from Pbo [2]	Mean		1.07	5.75	5.09	5.13	15.12
	95% CI		-15.95,18.10	-10.82,22.32	-11.26,21.44	-11.66,21.93	-1.72,31.96
	p-val [3]		0.901	0.495	0.540	0.548	0.078

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Region + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	56	Sum Weights	56
Mean	87.8125	Sum Observations	4917.5
Std Deviation	52.4045247	Variance	2746.2342
Skewness	1.12725714	Kurtosis	1.75917501
Uncorrected SS	582860.85	Corrected SS	151042.881
Coeff Variation	59.6777505	Std Error Mean	7.00284917

Basic Statistical Measures

Location		Variability	
Mean	87.81250	Std Deviation	52.40452
Median	85.30000	Variance	2746
Mode	43.30000	Range	252.60000
		Interquartile Range	66.25000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.53954	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.920084	Pr < W	0.0012
Kolmogorov-Smirnov	D	0.134352	Pr > D	0.0129
Cramer-von Mises	W-Sq	0.150777	Pr > W-Sq	0.0229
Anderson-Darling	A-Sq	1.05634	Pr > A-Sq	0.0085

Quantiles (Definition 5)

Quantile	Estimate
100% Max	267.00
99%	267.00
95%	209.30
90%	144.30
75% Q3	111.90

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	85.30
25% Q1	45.65
10%	28.90
5%	18.00
1%	14.40
0% Min	14.40

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	55	158.8	38
18.0	30	192.0	19
18.0	14	209.3	8
21.7	43	209.3	12
21.7	6	267.0	3

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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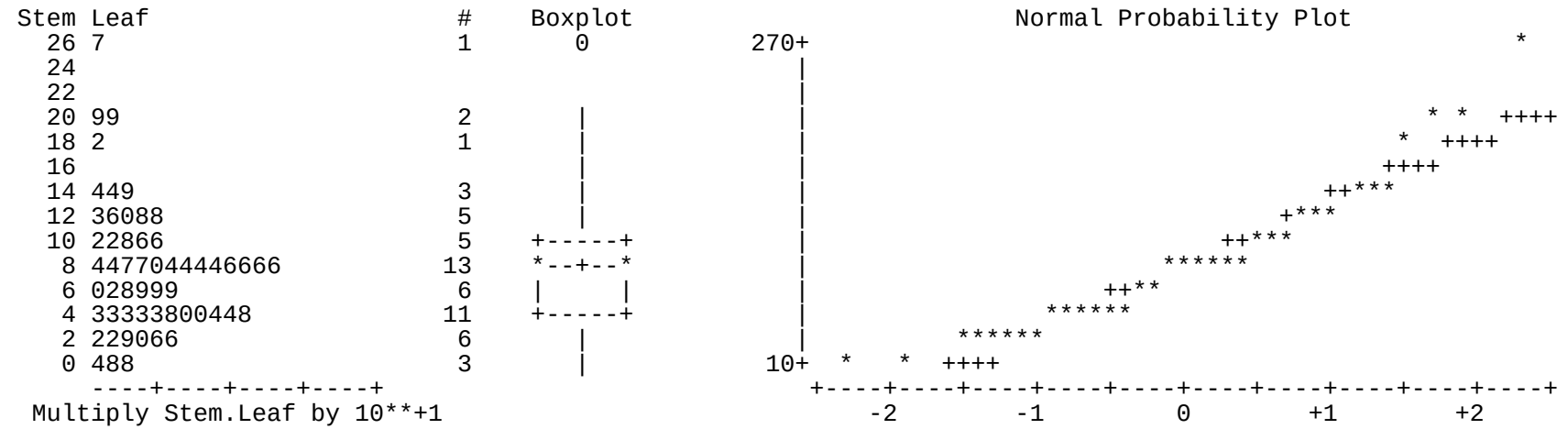
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	56	Sum Weights	56
Mean	87.9196429	Sum Observations	4923.5
Std Deviation	52.1387499	Variance	2718.44924
Skewness	1.80881063	Kurtosis	4.07493773
Uncorrected SS	582387.07	Corrected SS	149514.708
Coeff Variation	59.3027317	Std Error Mean	6.96733353

Basic Statistical Measures

Location		Variability	
Mean	87.91964	Std Deviation	52.13875
Median	79.40000	Variance	2718
Mode	79.40000	Range	252.50000
		Interquartile Range	47.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.61884	Pr > |t|	<.0001
Sign	M	28	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	798	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.834078	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.187226	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.419464	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.528117	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	274.2
99%	274.2
95%	223.7
90%	156.0
75% Q3	101.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	54.1
10%	30.0
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	53	166.0	3
24.0	14	168.0	20
28.9	43	223.7	12
28.9	9	259.8	44
30.0	30	274.2	51

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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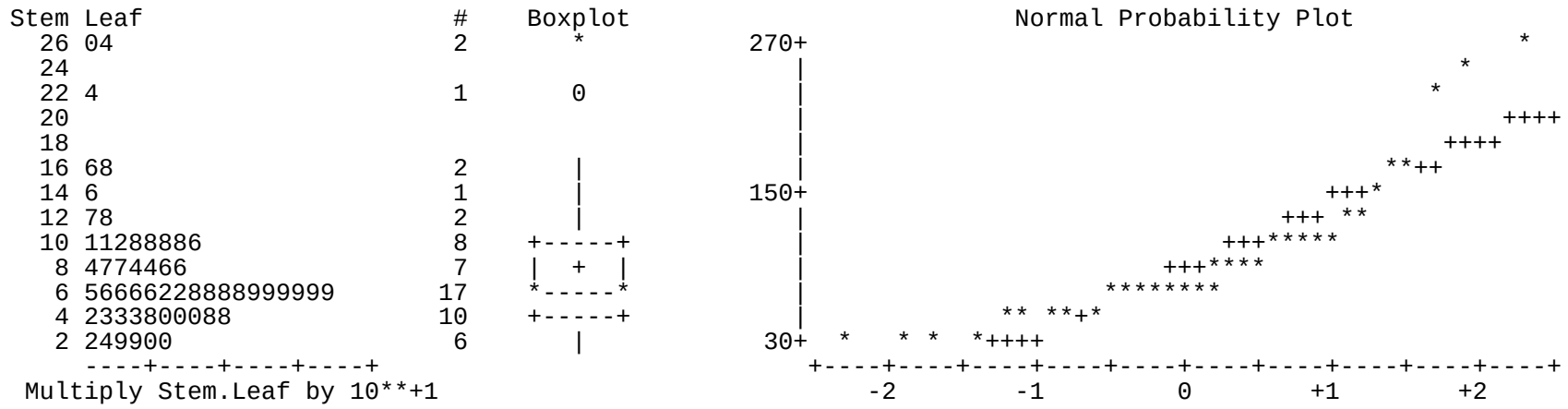
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	56	Sum Weights	56
Mean	0.10714286	Sum Observations	6
Std Deviation	43.6617447	Variance	1906.34795
Skewness	0.04361822	Kurtosis	5.22041797
Uncorrected SS	104849.78	Corrected SS	104849.137
Coeff Variation	40750.9617	Std Error Mean	5.83454605

Basic Statistical Measures

Location		Variability	
Mean	0.107143	Std Deviation	43.66174
Median	0.000000	Variance	1906
Mode	0.000000	Range	303.10000
		Interquartile Range	39.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.018364	Pr > |t|	0.9854
Sign	M	-1.5	Pr >= |M|	0.7798

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-17.5	Pr >= |S|	0.8716

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.878211	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.132049	Pr > D	0.0162
Cramer-von Mises	W-Sq	0.279429	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.889421	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	50.5
90%	42.0
75% Q3	21.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-18.0
10%	-36.1
5%	-50.5
1%	-158.8
0% Min	-158.8

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-158.8	8	43.3	36
-101.0	3	48.0	23
-50.5	38	50.5	37
-43.3	4	129.9	51
-36.1	54	144.3	44

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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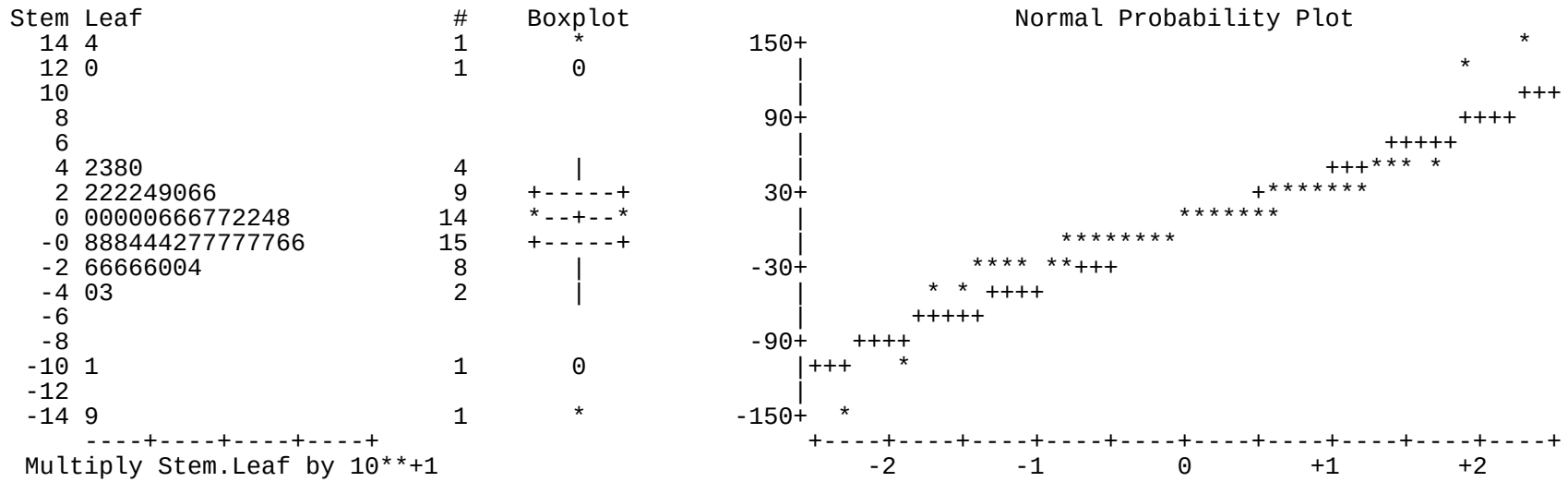
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	51	Sum Weights	51
Mean	94.8019608	Sum Observations	4834.9
Std Deviation	49.1745849	Variance	2418.1398
Skewness	0.76165627	Kurtosis	-0.3168237
Uncorrected SS	579264.99	Corrected SS	120906.99
Coeff Variation	51.8708521	Std Error Mean	6.88581918

Basic Statistical Measures

Location		Variability	
Mean	94.80196	Std Deviation	49.17458
Median	79.40000	Variance	2418
Mode	65.00000	Range	187.10000
		Interquartile Range	68.30000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.76771	Pr > |t|	<.0001
Sign	M	25.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	663	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.926102	Pr < W	0.0035
Kolmogorov-Smirnov	D	0.132743	Pr > D	0.0236
Cramer-von Mises	W-Sq	0.197163	Pr > W-Sq	0.0054
Anderson-Darling	A-Sq	1.2143	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	216.0
99%	216.0
95%	192.0
90%	166.0
75% Q3	126.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	57.7
10%	43.3
5%	30.0
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	17	186.0	27
28.9	4	186.0	34
30.0	35	192.0	51
36.1	41	194.9	19
43.3	44	216.0	30

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

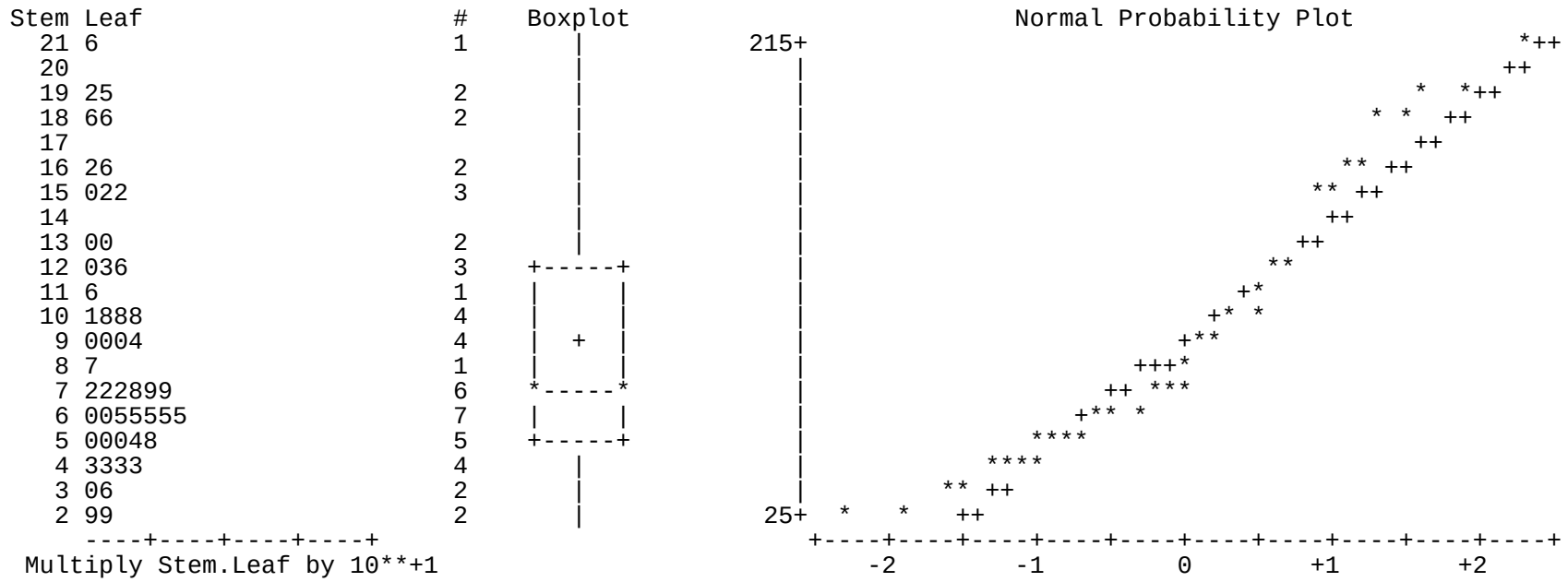

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	51	Sum Weights	51
Mean	92.8411765	Sum Observations	4734.9
Std Deviation	56.5881195	Variance	3202.21527
Skewness	0.90411776	Kurtosis	0.11016146
Uncorrected SS	599704.45	Corrected SS	160110.764
Coeff Variation	60.9515321	Std Error Mean	7.92392168

Basic Statistical Measures

Location		Variability	
Mean	92.84118	Std Deviation	56.58812
Median	84.00000	Variance	3202
Mode	36.10000	Range	231.00000
		Interquartile Range	74.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.71657	Pr > |t|	<.0001
Sign	M	25.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	663	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.91768	Pr < W	0.0017
Kolmogorov-Smirnov	D	0.137455	Pr > D	0.0172
Cramer-von Mises	W-Sq	0.22235	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.371969	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	245.4
99%	245.4
95%	204.0
90%	173.2
75% Q3	122.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	84.0
25% Q1	48.0
10%	36.1
5%	28.9
1%	14.4
0% Min	14.4

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	44	180.0	30
21.7	14	202.1	49
28.9	41	204.0	34
28.9	17	222.0	25
36.1	47	245.4	48

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                  #    Boxplot                    Normal Probability Plot
     24 5                     1       0          250+                                                *
     22 2                     1       |             |                                             *   +++
     20 24                    2       |             |                                          **  ++++
     18 0                     1       |             |                                       *  +++
     16 263                   3       |             |                                    ***+++
     14 99                    2       |             |                                 **+
     12 328                   3    +-----+       130+                              ++**
     10 188888                6    |     |         |                           +****
      8 4447746               7    *--+--*         |                        ++****
      6 622899                6    |     |         |                     ++***
      4 3338000048           10    +-----+         |                  *******
      2 29966666              8       |            |          *  *  *+**
      0 4                     1       |             10+  *      ++++
        ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**+1                          -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	51	Sum Weights	51
Mean	-1.9607843	Sum Observations	-100
Std Deviation	44.4081663	Variance	1972.08523
Skewness	1.05479334	Kurtosis	4.5548261
Uncorrected SS	98800.34	Corrected SS	98604.2616
Coeff Variation	-2264.8165	Std Error Mean	6.21838708

Basic Statistical Measures

Location		Variability	
Mean	-1.96078	Std Deviation	44.40817
Median	-7.20000	Variance	1972
Mode	7.20000	Range	288.70000
		Interquartile Range	46.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.31532	Pr > |t|	0.7538
Sign	M	-3.5	Pr >= |M|	0.3916

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-100.5	Pr >= |S|	0.3223

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.912751	Pr < W	0.0012
Kolmogorov-Smirnov	D	0.124166	Pr > D	0.0478
Cramer-von Mises	W-Sq	0.201001	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.214008	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	173.2
99%	173.2
95%	72.0
90%	43.3
75% Q3	18.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-7.2
25% Q1	-28.9
10%	-36.1
5%	-78.0
1%	-115.5
0% Min	-115.5

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-115.5	47	50.5	12
-79.4	36	54.0	35
-78.0	27	72.0	25
-50.5	39	93.8	49
-43.3	1	173.2	48

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot                          Normal Probability Plot
     16 3                        1       *           170+                                                *
     14                                              |                                                    
     12                                              |                                                    
     10                                              |                                                +++
      8 4                        1       0           |                                             *+++   
      6 2                        1       |           |                                          ++*++     
      4 3304                     4       |           |                                       +*** *       
      2 2249                     4       |            30+                                   +++***         
      0 006777772488            12    +-----+         |                                 ***+***          
     -0 8422777766              10    *--+--*         |                            +****                 
     -2 6660999944222           13    +-----+         |                       ****+****                  
     -4 03                       2       |           |                  * *++++                         
     -6 98                       2       |           |             * +*++                               
     -8                                              |          +++++                                   
    -10 6                        1       0          -110+++*                                            
        ----+----+----+----+                            +----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**+1                            -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	57	Sum Weights	57
Mean	102.080702	Sum Observations	5818.6
Std Deviation	62.9846252	Variance	3967.06301
Skewness	1.79701604	Kurtosis	5.47953759
Uncorrected SS	816122.3	Corrected SS	222155.529
Coeff Variation	61.7008153	Std Error Mean	8.34251741

Basic Statistical Measures

Location		Variability	
Mean	102.0807	Std Deviation	62.98463
Median	93.8000	Variance	3967
Mode	93.8000	Range	357.30000
		Interquartile Range	55.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.2362	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.86457	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.161168	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.299393	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.730336	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	375.3
99%	375.3
95%	223.7
90%	187.6
75% Q3	120.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	93.8
25% Q1	65.0
10%	28.9
5%	24.0
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
18.0	57	202.1	20
18.0	27	209.3	11
24.0	32	223.7	18
24.0	30	245.4	36
28.9	45	375.3	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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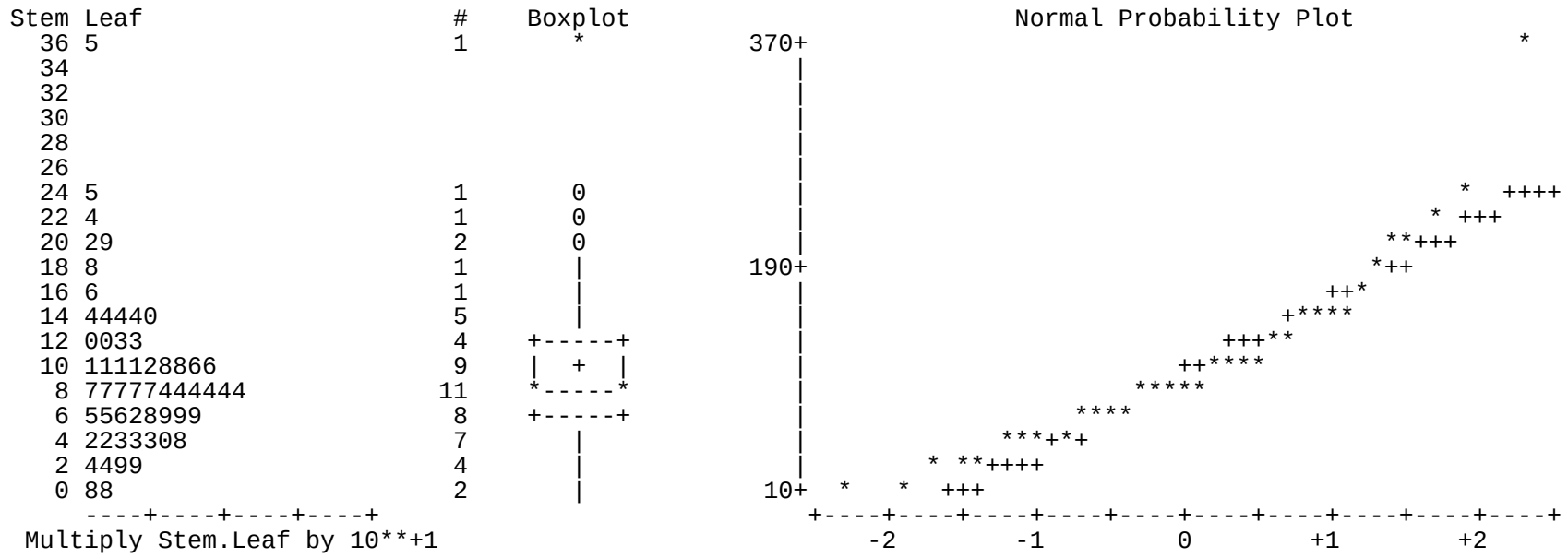
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	57	Sum Weights	57
Mean	104.847368	Sum Observations	5976.3
Std Deviation	66.6504343	Variance	4442.28039
Skewness	1.21332942	Kurtosis	0.96546008
Uncorrected SS	875367.03	Corrected SS	248767.702
Coeff Variation	63.5690102	Std Error Mean	8.82806569

Basic Statistical Measures

Location		Variability	
Mean	104.8474	Std Deviation	66.65043
Median	90.0000	Variance	4442
Mode	108.3000	Range	270.70000
		Interquartile Range	55.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.8766	Pr > |t|	<.0001
Sign	M	28.5	Pr >= |M|	<.0001

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[redacted]

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	826.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.879934	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.216185	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.406248	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.309292	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	288.7
99%	288.7
95%	252.0
90%	230.9
75% Q3	115.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	90.0
25% Q1	60.0
10%	36.1
5%	24.0
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
18.0	32	230.9	10
21.7	45	238.2	35
24.0	34	252.0	26
30.0	27	288.7	18
36.0	30	288.7	19

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                     #    Boxplot
    28 99                       2       *
    26                                  |
    24 2                        1       0
    22 118                      3       0
    20 2                        1       0
    18 00                       2       |
    16 22                       2       |
    14 49                       2       |
    12 3                        1       |
    10 188888886                9    +--+--+
     8 7700044446              10    *-----*
     6 0555622999              10    +-----+
     4 338488                   6       |
     2 2406666                  7       |
     0 8                        1       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```

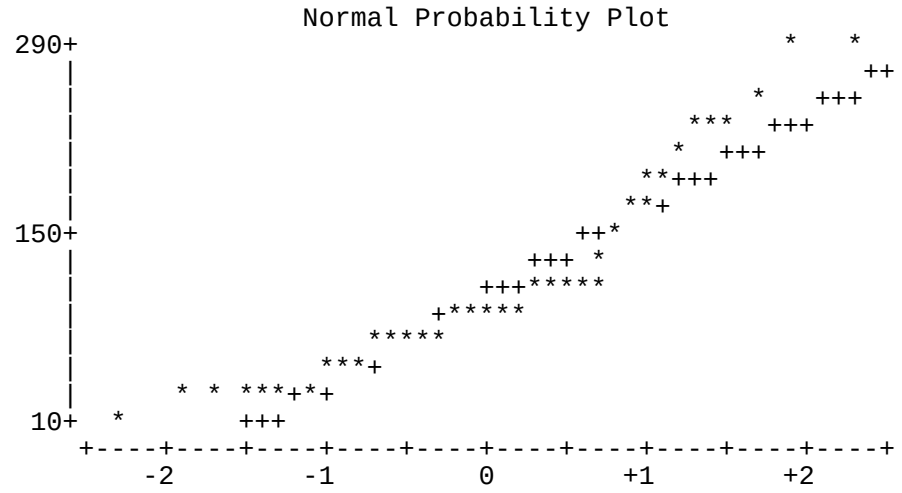

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	57	Sum Weights	57
Mean	2.76666667	Sum Observations	157.7
Std Deviation	48.7002872	Variance	2371.71798
Skewness	-0.6379665	Kurtosis	2.90915779
Uncorrected SS	133252.51	Corrected SS	132816.207
Coeff Variation	1760.25135	Std Error Mean	6.45051062

Basic Statistical Measures

Location		Variability	
Mean	2.76667	Std Deviation	48.70029
Median	7.20000	Variance	2372
Mode	12.00000	Range	295.80000
		Interquartile Range	57.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.428907	Pr > |t|	0.6696
Sign	M	2.5	Pr >= |M|	0.5901

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	92	Pr >= |S|	0.4457

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.951212	Pr < W	0.0223
Kolmogorov-Smirnov	D	0.095029	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.110273	Pr > W-Sq	0.0835
Anderson-Darling	A-Sq	0.667115	Pr > A-Sq	0.0813

Quantiles (Definition 5)

Quantile	Estimate
100% Max	115.4
99%	115.4
95%	93.9
90%	60.0
75% Q3	28.9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.2
25% Q1	-28.8
10%	-50.5
5%	-79.4
1%	-180.4
0% Min	-180.4

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-180.4	36	64.9	10
-86.6	19	65.0	18
-79.4	43	93.9	35
-64.9	6	108.0	26
-57.8	20	115.4	8

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot                          Normal Probability Plot
     10 85                       2       |            110+                                                *+++*+
      8 4                        1       |               |                                              +*++
      6 055                      3       |               |                                          +***
      4 3048                     4       |                50+                                     ++***
      2 22299006                 8    +-----+             |                                  +*****
      0 00772222444448          14    *--+--*             |                             *******
     -0 442777766                9    |     |          -10+                        *****+
     -2 60099992                 8    +-----+             |                   * ***+
     -4 8002                     4       |                |              ****++
     -6 95                       2       |             -70+          *+*++
     -8 7                        1       |                |     ++*++
    -10                                                   |++++
    -12                                               -130+
    -14                                                   |
    -16                                                   |
    -18 0                       1       0             -190+  *
        ----+----+----+----+                                +----+----+----+----+----+----+----+----+----+----+----+
     Multiply Stem.Leaf by 10**+1                             -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	61	Sum Weights	61
Mean	105.118033	Sum Observations	6412.2
Std Deviation	65.4967289	Variance	4289.8215
Skewness	1.18434255	Kurtosis	0.64297661
Uncorrected SS	931427.14	Corrected SS	257389.29
Coeff Variation	62.3077955	Std Error Mean	8.38599682

Basic Statistical Measures

Location		Variability	
Mean	105.1180	Std Deviation	65.49673
Median	84.0000	Variance	4290
Mode	57.7000	Range	281.40000
		Interquartile Range	74.30000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.53495	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001
Signed Rank	S	945.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.872682	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.17831	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.498561	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.819265	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	303.1
99%	303.1
95%	240.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	216.5
75% Q3	132.0
50% Median	84.0
25% Q1	57.7
10%	43.3
5%	36.1
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	54	234.0	35
28.9	50	240.0	24
36.1	58	240.0	31
36.1	15	252.6	57
42.0	30	303.1	48

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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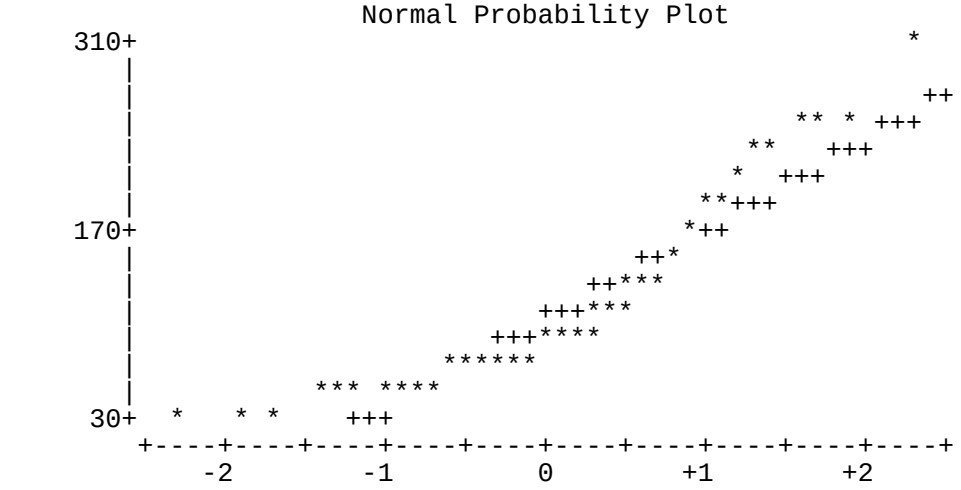
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
    30 3                     1       0
    28                                |
    26                                |
    24 003                   3        0
    22 44                    2        |
    20 26                    2        |
    18 08                    2        |
    16 33                    2        |
    14 42                    2        |
    12 03627                 5    +-----+
    10 2284                  4    |  +  |
     8 44774446              8    *-----*
     6 5555666899999        13    |     |
     4 2233380088888        13    +-----+
     2 2966                  4       |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	61	Sum Weights	61
Mean	105.142623	Sum Observations	6413.7
Std Deviation	71.5304375	Variance	5116.60349
Skewness	1.82479082	Kurtosis	3.61816448
Uncorrected SS	981349.45	Corrected SS	306996.209
Coeff Variation	68.0318176	Std Error Mean	9.15853404

Basic Statistical Measures

Location		Variability	
Mean	105.1426	Std Deviation	71.53044
Median	93.8000	Variance	5117
Mode	43.3000	Range	335.60000
		Interquartile Range	65.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.48029	Pr > |t|	<.0001
Sign	M	30.5	Pr >= |M|	<.0001
Signed Rank	S	945.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.818411	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.187314	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.493274	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.122911	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	353.6
99%	353.6
95%	281.5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	180.0
75% Q3	122.7
50% Median	93.8
25% Q1	57.7
10%	43.3
5%	36.1
1%	18.0
0% Min	18.0

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
18.0	28	194.9	47
21.7	15	281.5	48
30.0	32	310.3	60
36.1	53	330.0	31
43.3	58	353.6	13

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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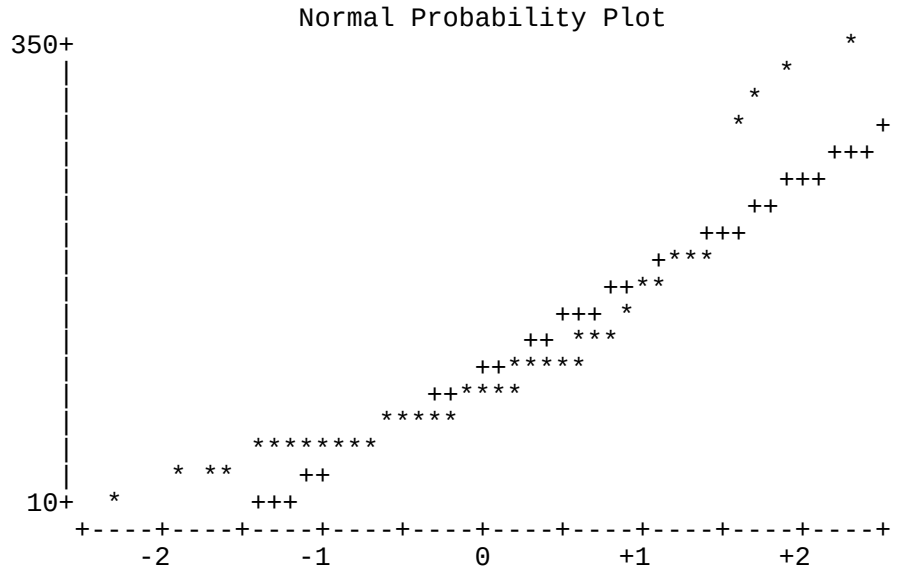
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                     #    Boxplot
     34 4                        1       *
     32 0                        1       *
     30 0                        1       0
     28 2                        1       0
     26                                  |
     24                                  |
     22                                  |
     20                                  |
     18 085                      3       |
     16 633                      3       |
     14 40                       2       |
     12 03678                    5    +-----+
     10 118888884                9    |  +  |
      8 47044446                 8    *-----*
      6 0055622222              10    |     |
      4 3333300004888           13    +-----+
      2 206                      3       |
      0 8                        1       |
        ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	61	Sum Weights	61
Mean	0.02459016	Sum Observations	1.5
Std Deviation	51.2004058	Variance	2621.48155
Skewness	0.24443774	Kurtosis	0.68334078
Uncorrected SS	157288.93	Corrected SS	157288.893
Coeff Variation	208214.984	Std Error Mean	6.55554021

Basic Statistical Measures

Location		Variability	
Mean	0.024590	Std Deviation	51.20041
Median	0.000000	Variance	2621
Mode	0.000000	Range	255.90000
		Interquartile Range	50.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.003751	Pr > |t|	0.9970
Sign	M	0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-21.5	Pr >= |S|	0.8589

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.974792	Pr < W	0.2394
Kolmogorov-Smirnov	D	0.090289	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.099328	Pr > W-Sq	0.1148
Anderson-Darling	A-Sq	0.59458	Pr > A-Sq	0.1205

Quantiles (Definition 5)

Quantile	Estimate
100% Max	129.9
99%	129.9
95%	90.0
90%	54.0
75% Q3	21.7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-28.9
10%	-72.1
5%	-79.4
1%	-126.0
0% Min	-126.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-126.0	24	79.4	19
-93.8	18	90.0	31
-84.0	35	108.3	46
-79.4	57	129.9	60
-79.3	2	129.9	13

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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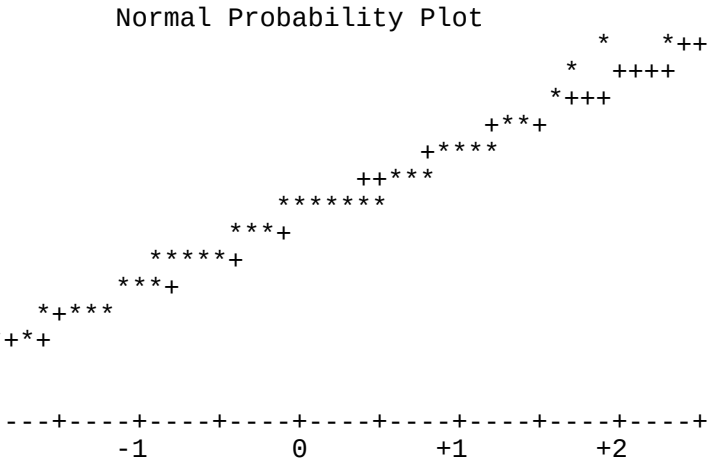
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                  #    Boxplot
    12 00                    2       0
    10 8                     1       0
     8 0                     1       |
     6 29                    2       |
     4 333314                6       |
     2 22490                 5    +-----+
     0 00000077772244488    17    *--+--*
    -0 8442277               7    |     |
    -2 699994222             9    +-----+
    -4 433                   3       |
    -6 99825                 5       |
    -8 44                    2       |
   -10                                |
   -12 6                     1       0
       ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	53	Sum Weights	53
Mean	87.4716981	Sum Observations	4636
Std Deviation	47.1672612	Variance	2224.75053
Skewness	0.8721686	Kurtosis	0.44488262
Uncorrected SS	521205.82	Corrected SS	115687.028
Coeff Variation	53.9228827	Std Error Mean	6.4789216

Basic Statistical Measures

Location		Variability	
Mean	87.47170	Std Deviation	47.16726
Median	79.40000	Variance	2225
Mode	21.70000	Range	202.00000
		Interquartile Range	60.30000

NOTE: The mode displayed is the smallest of 7 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.50097	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.938233	Pr < W	0.0086
Kolmogorov-Smirnov	D	0.096241	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.126238	Pr > W-Sq	0.0484
Anderson-Darling	A-Sq	0.866945	Pr > A-Sq	0.0244

Quantiles (Definition 5)

Quantile	Estimate
100% Max	223.7
99%	223.7
95%	192.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	158.8
75% Q3	108.3
50% Median	79.4
25% Q1	48.0
10%	36.1
5%	21.7
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	51	158.8	45
21.7	38	162.0	31
21.7	16	192.0	28
30.0	29	194.9	48
36.1	43	223.7	7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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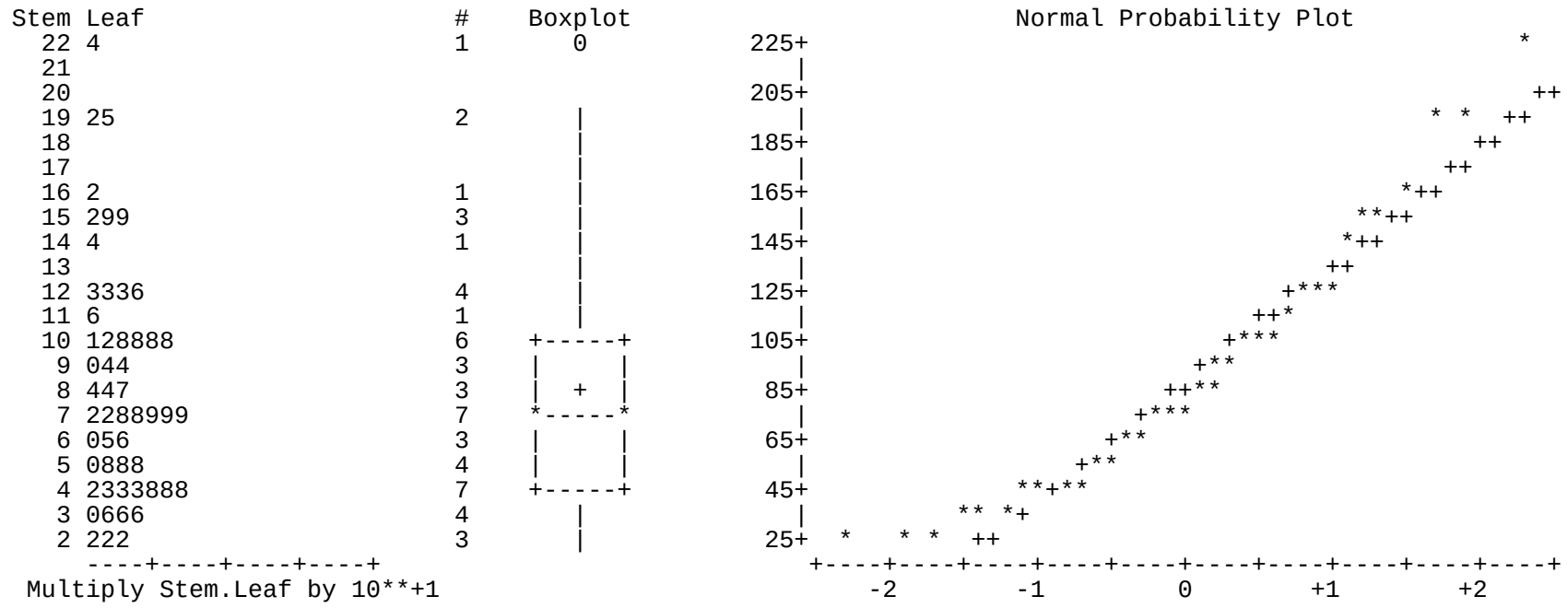
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	53	Sum Weights	53
Mean	92.7169811	Sum Observations	4914
Std Deviation	54.6963356	Variance	2991.68913
Skewness	1.42649568	Kurtosis	2.38074031
Uncorrected SS	611179.08	Corrected SS	155567.835
Coeff Variation	58.9927918	Std Error Mean	7.51311951

Basic Statistical Measures

Location		Variability	
Mean	92.71698	Std Deviation	54.69634
Median	79.40000	Variance	2992
Mode	57.70000	Range	259.80000
		Interquartile Range	66.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.34068	Pr > |t|	<.0001
Sign	M	26.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	715.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.88092	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.133611	Pr > D	0.0190
Cramer-von Mises	W-Sq	0.266053	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.66376	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	288.7
99%	288.7
95%	216.5
90%	158.8
75% Q3	120.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	54.0
10%	36.1
5%	30.0
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	51	173.2	48
28.9	16	187.6	45
30.0	21	216.5	49
36.0	17	223.7	5
36.1	14	288.7	7

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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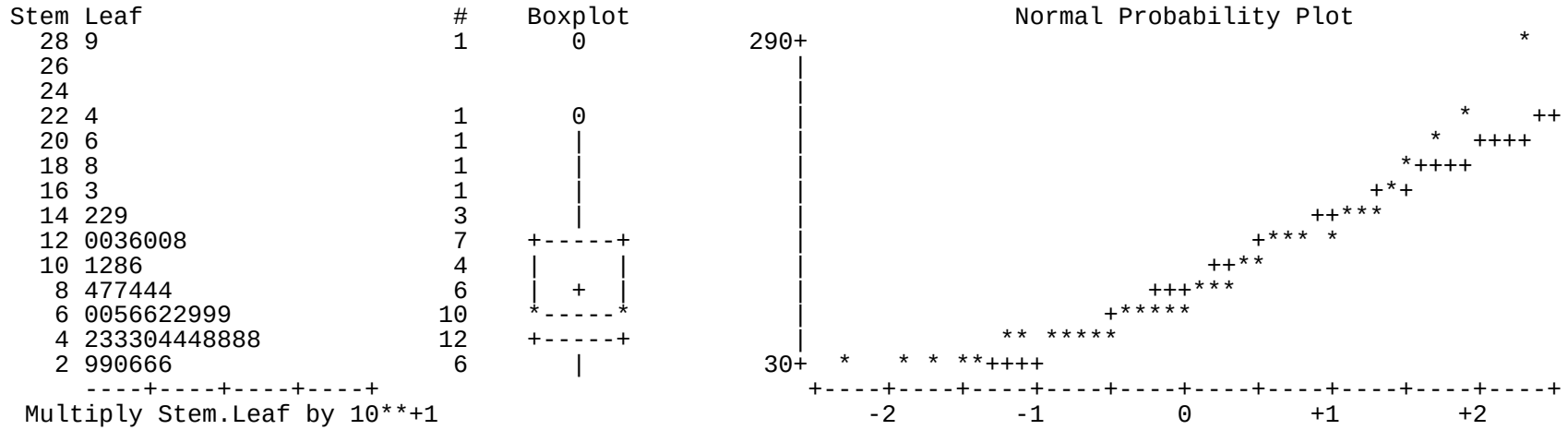
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	53	Sum Weights	53
Mean	5.24528302	Sum Observations	278
Std Deviation	34.8014067	Variance	1211.13791
Skewness	-0.0452468	Kurtosis	2.89070746
Uncorrected SS	64437.36	Corrected SS	62979.1713
Coeff Variation	663.480056	Std Error Mean	4.78034085

Basic Statistical Measures

Location		Variability	
Mean	5.245283	Std Deviation	34.80141
Median	0.000000	Variance	1211
Mode	0.000000	Range	223.40000
		Interquartile Range	27.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.097261	Pr > |t|	0.2776
Sign	M	4	Pr >= |M|	0.2800

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	116.5	Pr >= |S|	0.1471

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.939847	Pr < W	0.0101
Kolmogorov-Smirnov	D	0.136837	Pr > D	0.0145
Cramer-von Mises	W-Sq	0.235252	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.23429	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	115.4
99%	115.4
95%	65.0
90%	43.3
75% Q3	21.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-6.0
10%	-36.1
5%	-54.0
1%	-108.0
0% Min	-108.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-108.0	31	50.5	4
-66.0	28	57.7	35
-54.0	22	65.0	7
-43.3	2	72.2	49
-36.1	15	115.4	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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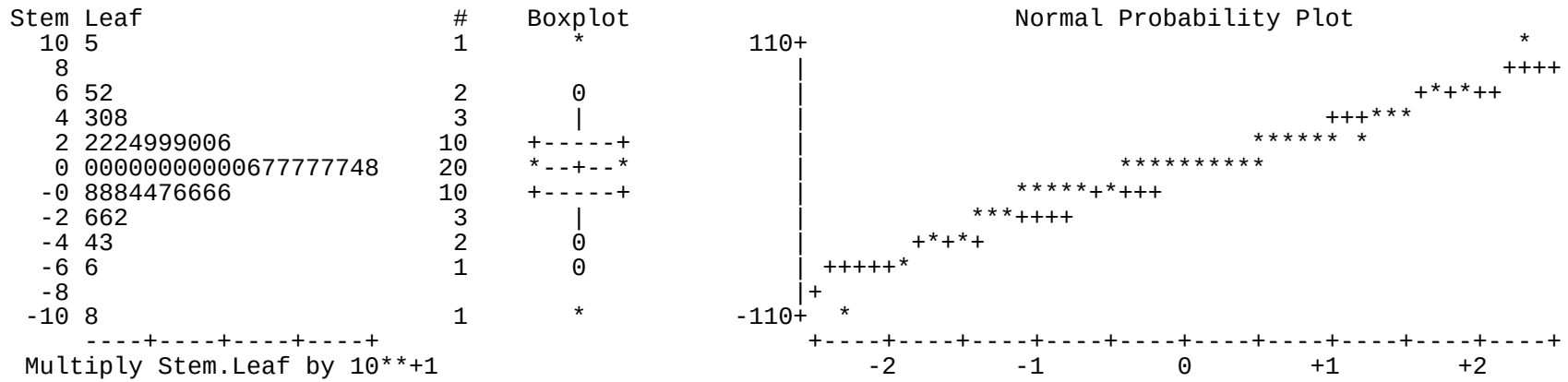
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



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[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	54	Sum Weights	54
Mean	109.503704	Sum Observations	5913.2
Std Deviation	73.5452882	Variance	5408.90942
Skewness	1.78982276	Kurtosis	4.62344705
Uncorrected SS	934189.5	Corrected SS	286672.199
Coeff Variation	67.1623751	Std Error Mean	10.0082461

Basic Statistical Measures

Location		Variability	
Mean	109.5037	Std Deviation	73.54529
Median	85.3000	Variance	5409
Mode	79.4000	Range	392.30000
		Interquartile Range	93.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.94135	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001

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[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.851532	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.160125	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.343273	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.994545	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	414.0
99%	414.0
95%	245.4
90%	180.4
75% Q3	151.6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	85.3
25% Q1	57.7
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	33	209.3	39
24.0	27	234.0	32
28.9	12	245.4	45
36.0	31	288.0	22
36.1	34	414.0	24

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Population: Intent-to-Treat with LOCF

Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

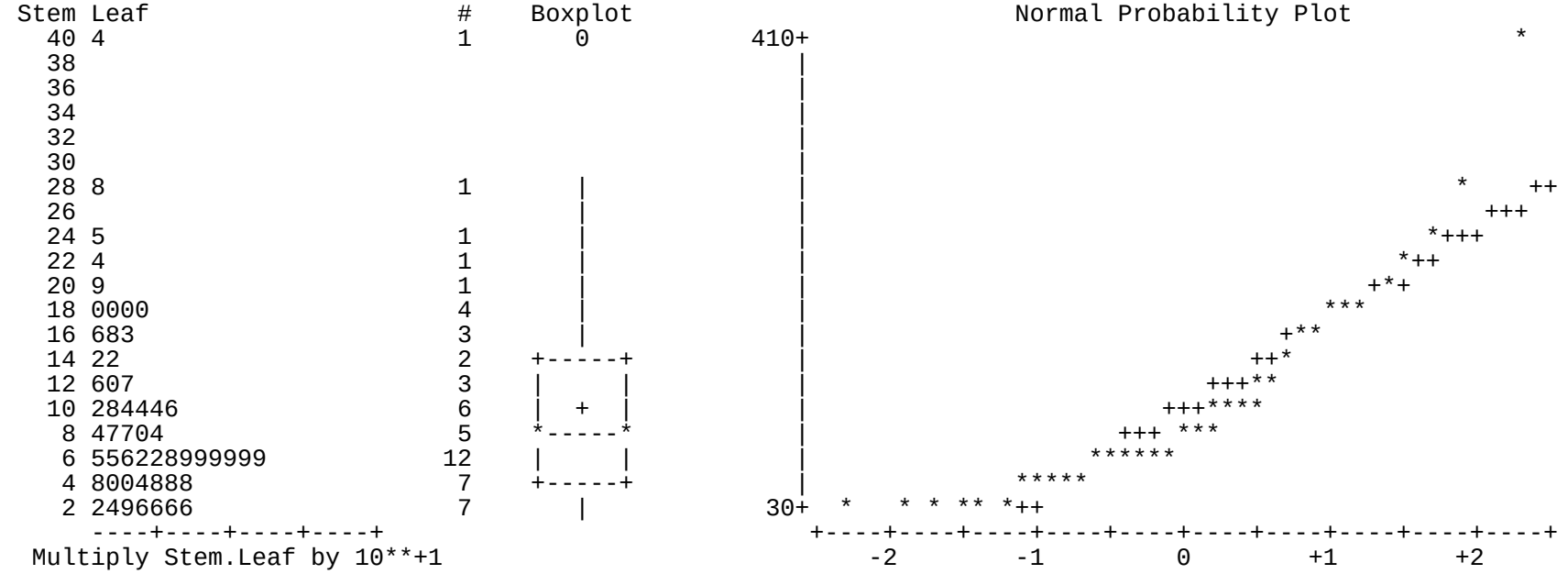

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	54	Sum Weights	54
Mean	118.190741	Sum Observations	6382.3
Std Deviation	77.1053806	Variance	5945.23972
Skewness	1.34865912	Kurtosis	1.85118313
Uncorrected SS	1069426.47	Corrected SS	315097.705
Coeff Variation	65.238089	Std Error Mean	10.4927133

Basic Statistical Measures

Location		Variability	
Mean	118.1907	Std Deviation	77.10538
Median	97.9000	Variance	5945
Mode	65.0000	Range	356.30000
		Interquartile Range	93.80000

NOTE: The mode displayed is the smallest of 4 modes with a count of 3.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.26408	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	742.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.887662	Pr < W	0.0001
Kolmogorov-Smirnov	D	0.162146	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.296117	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.743382	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	378.0
99%	378.0
95%	294.0

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	223.7
75% Q3	158.8
50% Median	97.9
25% Q1	65.0
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	2	234.0	54
28.9	15	245.4	42
28.9	12	294.0	24
36.0	18	317.5	39
36.1	37	378.0	22

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

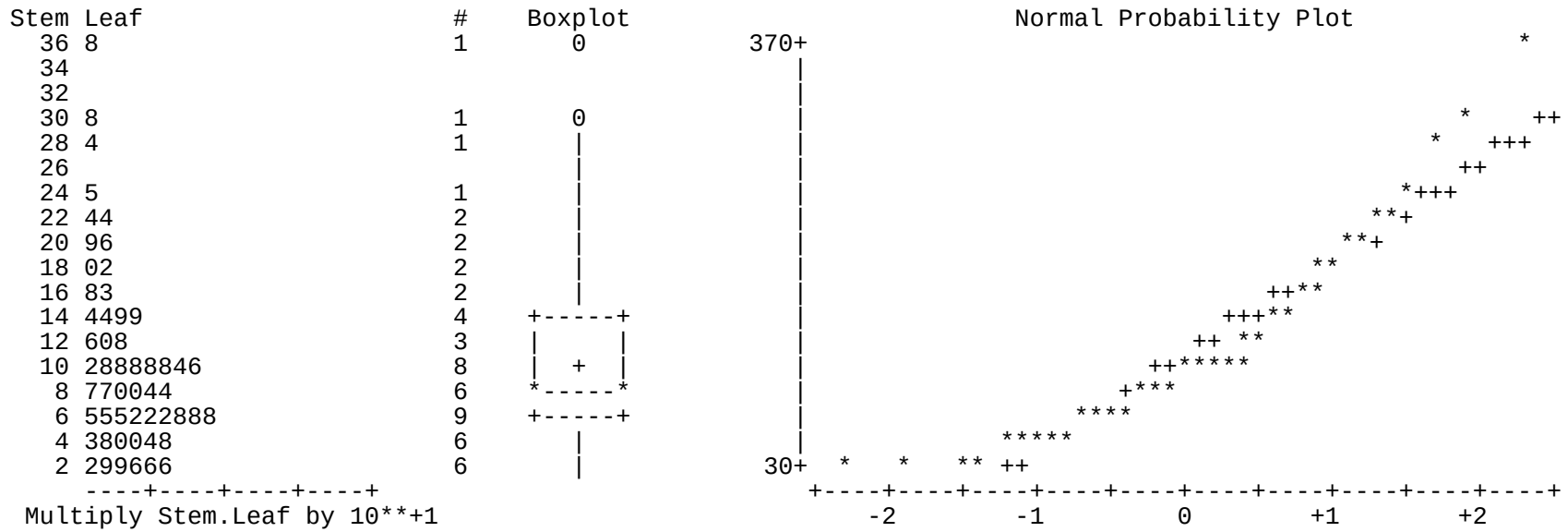

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	54	Sum Weights	54
Mean	8.68703704	Sum Observations	469.1
Std Deviation	54.6047653	Variance	2981.68039
Skewness	0.32787033	Kurtosis	0.4523146
Uncorrected SS	162104.15	Corrected SS	158029.061
Coeff Variation	628.577558	Std Error Mean	7.43076736

Basic Statistical Measures

Location		Variability	
Mean	8.687037	Std Deviation	54.60477
Median	0.000000	Variance	2982
Mode	0.000000	Range	264.30000
		Interquartile Range	57.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.169063	Pr > |t|	0.2476
Sign	M	0.5	Pr >= |M|	1.0000

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	84.5	Pr >= |S|	0.3768

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.967999	Pr < W	0.1572
Kolmogorov-Smirnov	D	0.118756	Pr > D	0.0564
Cramer-von Mises	W-Sq	0.163375	Pr > W-Sq	0.0166
Anderson-Darling	A-Sq	0.833395	Pr > A-Sq	0.0307

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	122.6
90%	86.6
75% Q3	36.0

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-21.6
10%	-65.0
5%	-79.4
1%	-120.0
0% Min	-120.0

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-120.0	24	90.0	22
-96.0	32	108.2	39
-79.4	10	122.6	33
-78.0	18	126.0	54
-66.0	21	144.3	38

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot                          Normal Probability Plot
     14 4                        1       0           150+                                                 * +
     12 36                       2       0              |                                              * * ++++
     10 8                        1       |              |                                           * ++++
      8 70                       2       |              |                                        **++
      6 5558                     4       |              |                                     ****+
      4 201                      3       |              |                                  +***
      2 2006                     4       +-----+        |                               ++***
      0 00000007724488          14       *--+--*         10+                        *******
     -0 444422777                9       |     |         |                     ****+
     -2 66694222                 8       +-----+         |                ******+
     -4                                     |            |                ++++
     -6 9865                     4          |            |          *+***
     -8 6                        1          |            |        *++
    -10                                     |            |   *+++
    -12 0                        1          0         -130+++
        ----+----+----+----+                              +----+----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**+1                              -2        -1         0        +1        +2
```

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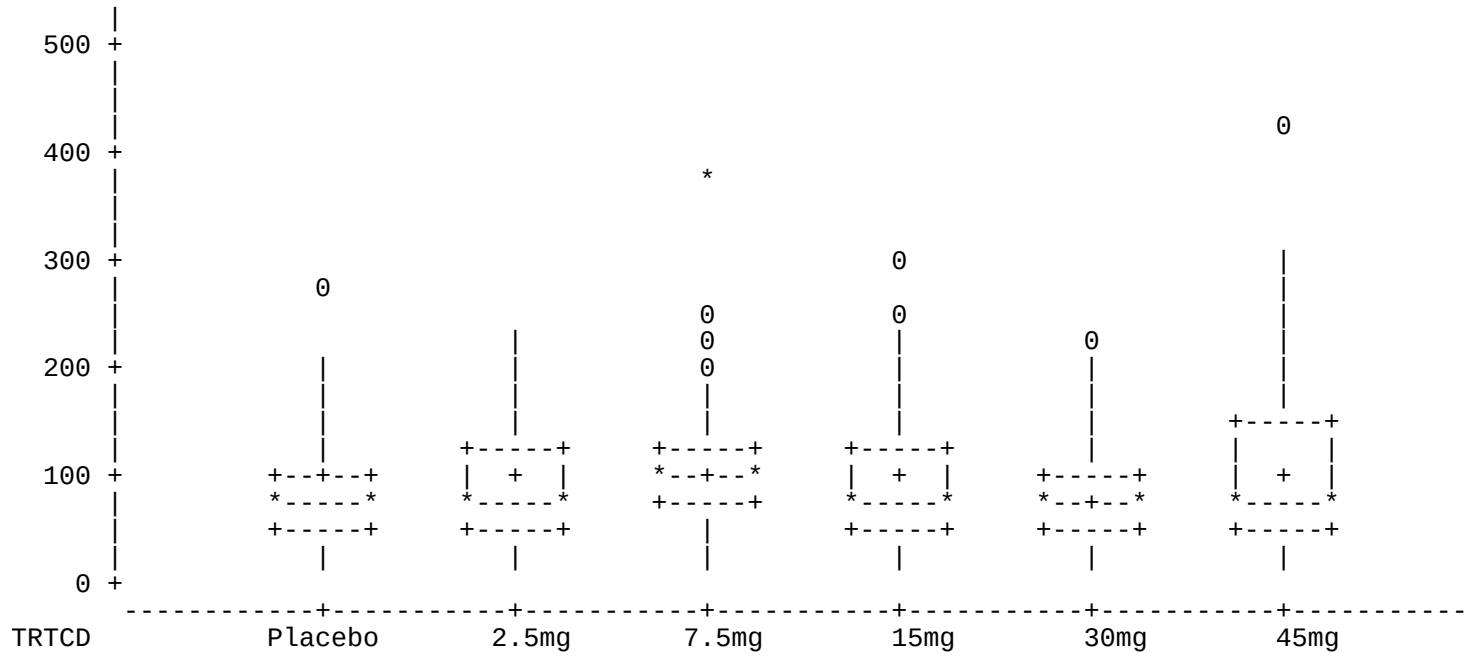
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



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[redacted]

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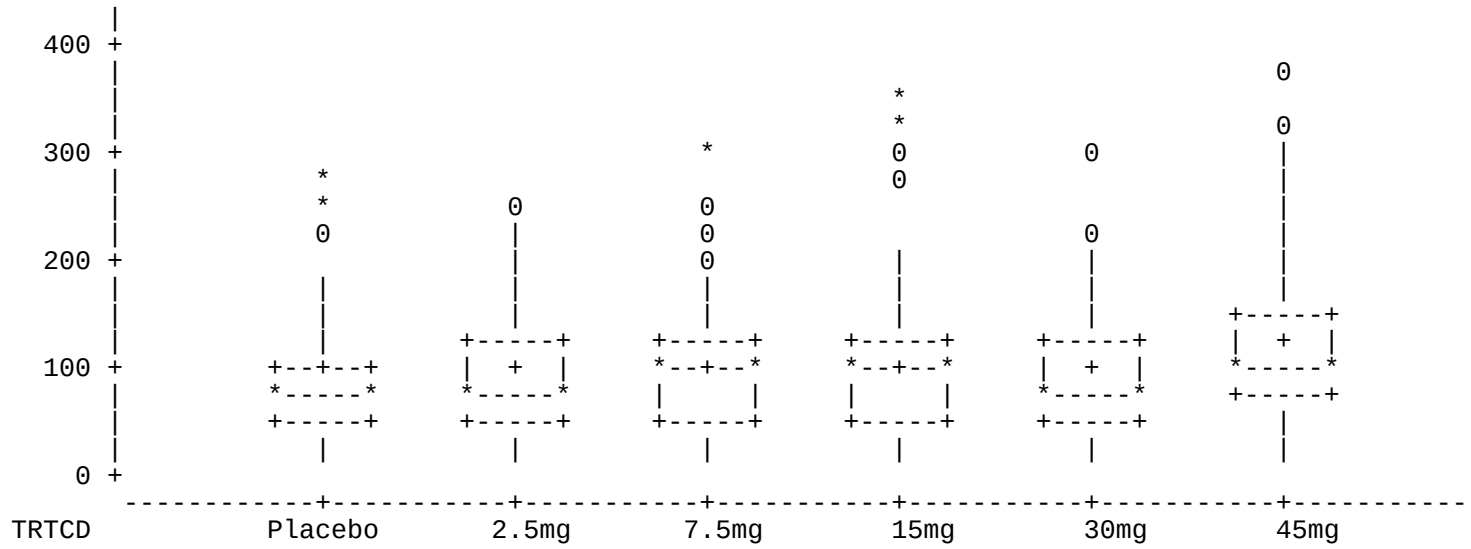
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12
Excluding Outliers
Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots

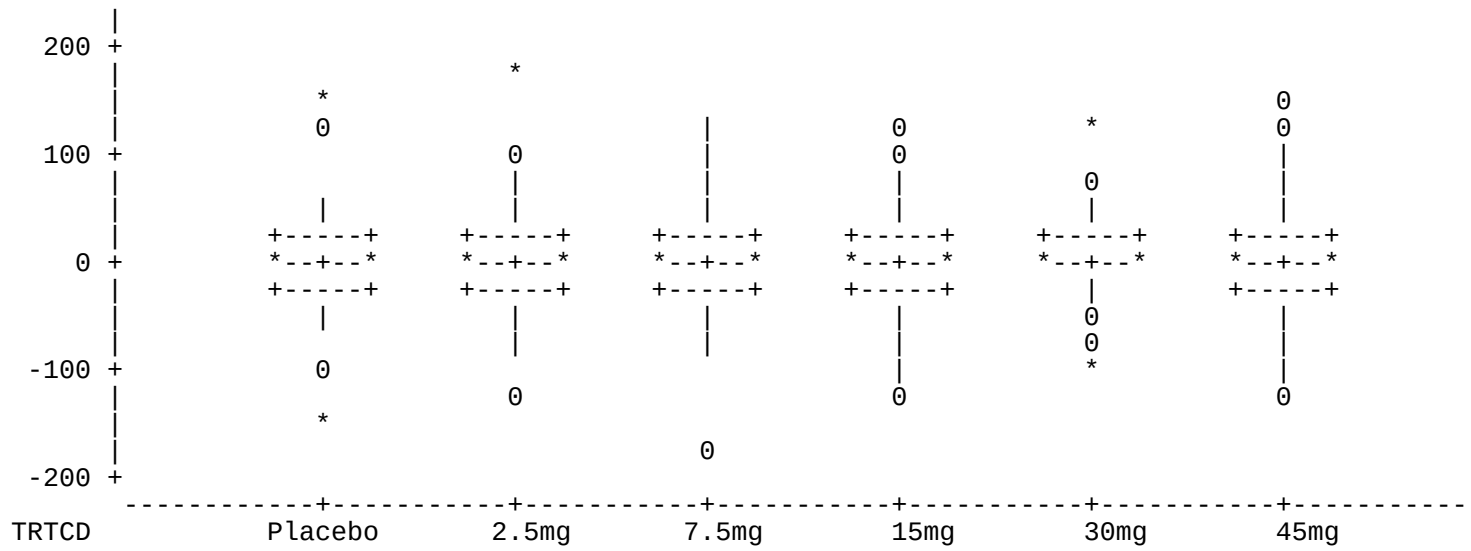

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	332
Observations Used	332
Observations Not Used	0
Total Observations	332

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	1979.51	156.25	12.67	<.0001	0.05	1705.70	2325.34

Fit Statistics

-2 Res Log Likelihood	3402.6
AIC (smaller is better)	3404.6
AICC (smaller is better)	3404.6
BIC (smaller is better)	3408.4

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					36.2192	8.6606	321	4.18	<.0001
SEX	Female				0.4432	4.9622	321	0.09	0.9289
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			11.6112	5.0036	321	2.32	0.0209
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	-15.1228	8.5596	321	-1.77	0.0782
TRTCD				2.5mg	-14.0493	8.7109	321	-1.61	0.1078
TRTCD				7.5mg	-9.3705	8.4825	321	-1.10	0.2701
TRTCD				15mg	-10.0317	8.3335	321	-1.20	0.2296
TRTCD				30mg	-9.9890	8.6714	321	-1.15	0.2502
TRTCD				45mg	0			.	
REGIONCD			US/Canada		-8.4648	5.7837	321	-1.46	0.1443
REGIONCD			Eastern Europe		-10.9218	6.1480	321	-1.78	0.0766
REGIONCD			Western Europe		0			.	
EFSTDBL					-0.2367	0.04184	321	-5.66	<.0001

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	321	0.01	0.9289
TRTTYPCD	1	321	5.38	0.0209
TRTCD	5	321	0.77	0.5728
REGIONCD	2	321	1.86	0.1574
EFSTDBL	1	321	32.00	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	1.0735	8.6534	321	0.12	0.9013	0.05	-15.9510	18.0980
7.5mg vs Pbo	5.7523	8.4216	321	0.68	0.4951	0.05	-10.8162	22.3208
15mg vs Pbo	5.0911	8.3087	321	0.61	0.5405	0.05	-11.2552	21.4374
30mg vs Pbo	5.1338	8.5364	321	0.60	0.5480	0.05	-11.6606	21.9282
45mg vs Pbo	15.1228	8.5596	321	1.77	0.0782	0.05	-1.7173	31.9629

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Table 11.57
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Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.503	0.503	0.503	0.503	0.503
SEX	Male				0.497	0.497	0.497	0.497	0.497
TRTTYPCD		Diet & Exercise			0.4187	0.4187	0.4187	0.4187	0.4187
TRTTYPCD		Monotherapy			0.5813	0.5813	0.5813	0.5813	0.5813
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3404	0.3404	0.3404	0.3404	0.3404
REGIONCD			Eastern Europe		0.2771	0.2771	0.2771	0.2771	0.2771
REGIONCD			Western Europe		0.3825	0.3825	0.3825	0.3825	0.3825
EFSTDBL					97.989	97.989	97.989	97.989	97.989

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.503
SEX	Male				0.497
TRTTYPCD		Diet & Exercise			0.4187
TRTTYPCD		Monotherapy			0.5813
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3404
REGIONCD			Eastern Europe		0.2771
REGIONCD			Western Europe		0.3825
EFSTDBL					97.989

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-2.9205	5.9823	321	-0.49	0.6257	0.05	-14.6900	8.8490
TRTCD	2.5mg	WORK.EFF	-1.8470	6.2422	321	-0.30	0.7675	0.05	-14.1278	10.4338
TRTCD	7.5mg	WORK.EFF	2.8318	5.9081	321	0.48	0.6320	0.05	-8.7917	14.4552
TRTCD	15mg	WORK.EFF	2.1706	5.7187	321	0.38	0.7045	0.05	-9.0802	13.4215
TRTCD	30mg	WORK.EFF	2.2133	6.1344	321	0.36	0.7185	0.05	-9.8553	14.2819
TRTCD	45mg	WORK.EFF	12.2023	6.0833	321	2.01	0.0457	0.05	0.2342	24.1704

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-1.0735	8.6534	321	-0.12	0.9013	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	-5.7523	8.4216	321	-0.68	0.4951	0.05
TRTCD	Placebo	15mg	WORK.EFF	-5.0911	8.3087	321	-0.61	0.5405	0.05
TRTCD	Placebo	30mg	WORK.EFF	-5.1338	8.5364	321	-0.60	0.5480	0.05
TRTCD	Placebo	45mg	WORK.EFF	-15.1228	8.5596	321	-1.77	0.0782	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	-4.6788	8.6043	321	-0.54	0.5870	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-4.0176	8.4654	321	-0.47	0.6354	0.05
TRTCD	2.5mg	30mg	WORK.EFF	-4.0603	8.7564	321	-0.46	0.6432	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-14.0493	8.7109	321	-1.61	0.1078	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	0.6612	8.2166	321	0.08	0.9359	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.6185	8.5197	321	0.07	0.9422	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-9.3705	8.4825	321	-1.10	0.2701	0.05
TRTCD	15mg	30mg	WORK.EFF	-0.04268	8.4095	321	-0.01	0.9960	0.05
TRTCD	15mg	45mg	WORK.EFF	-10.0317	8.3335	321	-1.20	0.2296	0.05
TRTCD	30mg	45mg	WORK.EFF	-9.9890	8.6714	321	-1.15	0.2502	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-18.0980	15.9510
TRTCD	Placebo	7.5mg	-22.3208	10.8162
TRTCD	Placebo	15mg	-21.4374	11.2552
TRTCD	Placebo	30mg	-21.9282	11.6606
TRTCD	Placebo	45mg	-31.9629	1.7173
TRTCD	2.5mg	7.5mg	-21.6067	12.2492
TRTCD	2.5mg	15mg	-20.6722	12.6370
TRTCD	2.5mg	30mg	-21.2875	13.1670
TRTCD	2.5mg	45mg	-31.1869	3.0883
TRTCD	7.5mg	15mg	-15.5040	16.8263

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-16.1431	17.3800
TRTCD	7.5mg	45mg	-26.0588	7.3178
TRTCD	15mg	30mg	-16.5873	16.5020
TRTCD	15mg	45mg	-26.4268	6.3635
TRTCD	30mg	45mg	-27.0489	7.0710

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2005
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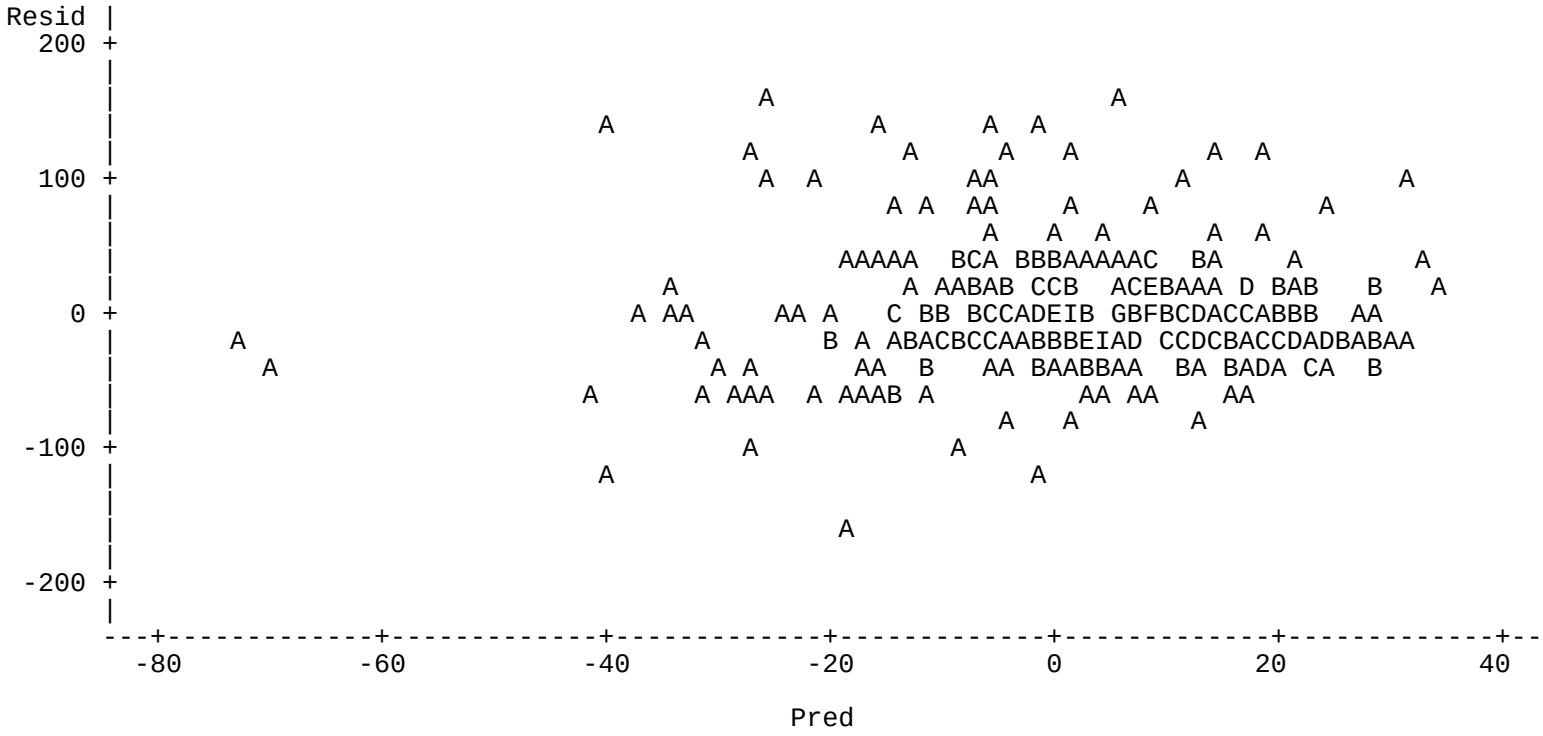
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2006
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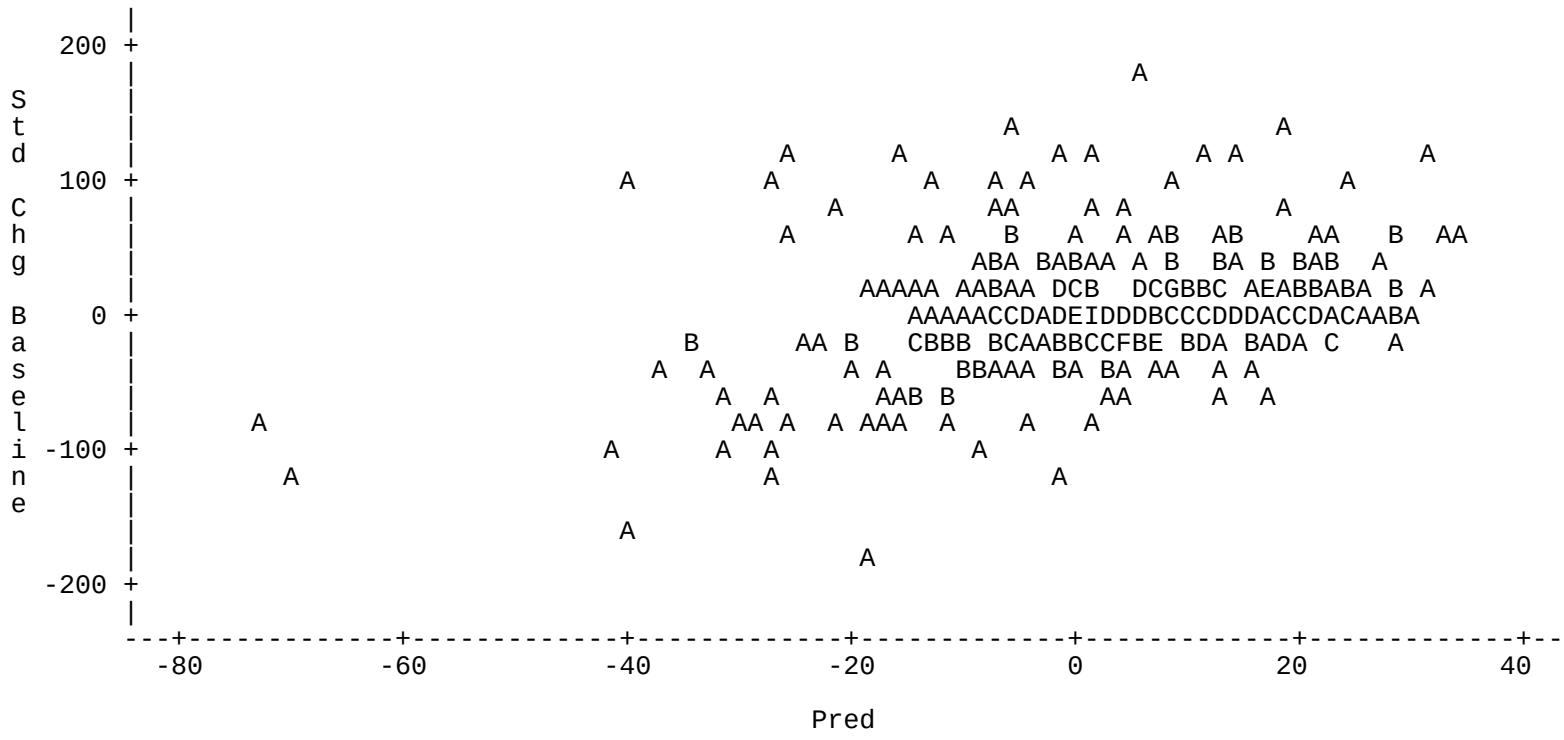
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2007
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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	332	Sum Weights	332
Mean	0	Sum Observations	0
Std Deviation	43.8144001	Variance	1919.70165
Skewness	0.85740414	Kurtosis	2.55973461
Uncorrected SS	635421.247	Corrected SS	635421.247
Coeff Variation		Std Error Mean	2.4046276

Basic Statistical Measures

Location		Variability	
Mean	0.0000	Std Deviation	43.81440
Median	-3.9491	Variance	1920
Mode	-44.1618	Range	328.89442
		Interquartile Range	39.28024

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-21	Pr >= |M|	0.0243
Signed Rank	S	-3286	Pr >= |S|	0.0604

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2008
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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.929679	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.123483	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.191166	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	7.138705	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	167.67628
99%	145.96908
95%	91.51713
90%	47.39573
75% Q3	14.52112
50% Median	-3.94913
25% Q1	-24.75912
10%	-44.55679
5%	-57.94731
1%	-99.47527
0% Min	-161.21814

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2009
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Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-161.2181	216	130.904	311
-119.4342	58	145.969	325
-113.8414	284	149.853	235
-99.4753	195	155.529	60
-98.9704	127	167.676	293

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2010
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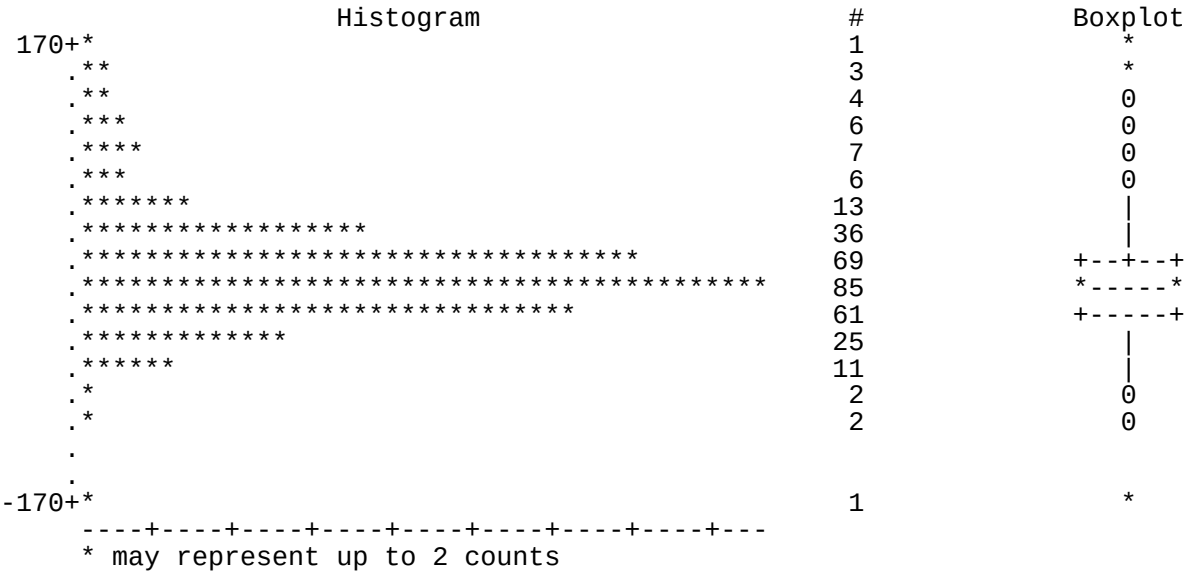
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2011
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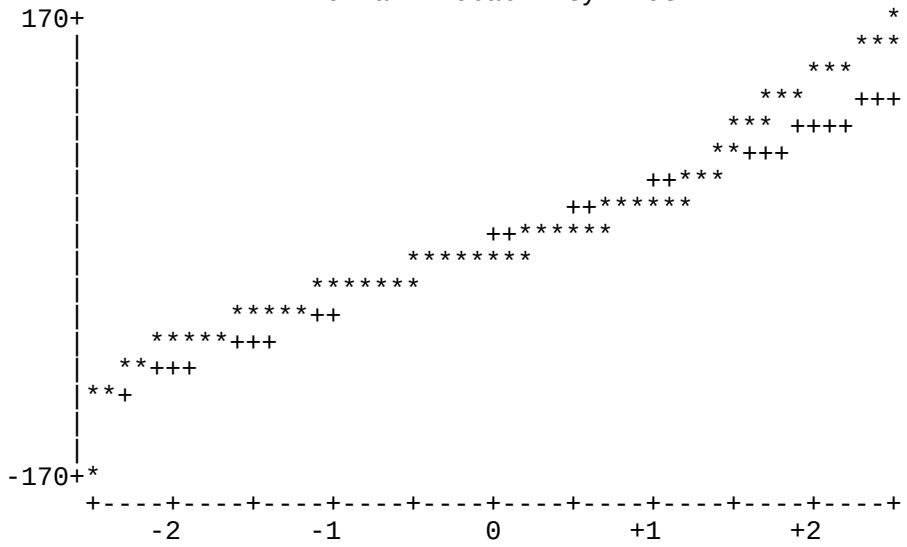
Table 11.57
SAS Statistical Output for Table 11.56
Sensitivity Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2012
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Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

		Placebo (N=62)	2.5mg (N=59)	7.5mg (N=62)
n [1]		58	58	60
Number (%) of Values Carried Forward		9 (16%)	14 (24%)	9 (15%)
Baseline	Geo Mean	2.01	1.90	1.82
	CV (%) [2]	38.362	54.148	55.857
Week 12	Geo Mean	1.96	1.82	1.66
	CV (%) [2]	44.599	48.890	51.163
Ratio to Baseline (% chg) [3]	Geo Mean	-2.33	-4.37	-8.74
	Geo Mean -SE,+SE	-7.46,3.10	-8.83,0.31	-12.35,-4.98
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-1.38	-4.35	-10.53
	Geo Mean -SE,+SE	-5.48,2.90	-8.33,-0.20	-14.18,-6.72
Ratio to Baseline (% diff) [4]	Geo Mean		-3.01	-9.27
	95% CI		-13.86,9.20	-19.31,2.01
	p-val[5]		0.612	0.103

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant trestment difference are for descriptive purposes only.

[redacted]

2013
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Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

		15mg (N=63)	30mg (N=58)	45mg (N=60)
n [1]		62	55	58
Number (%) of Values Carried Forward		4 (6%)	3 (5%)	7 (12%)
Baseline	Geo Mean	1.92	1.92	1.99
	CV (%) [2]	47.607	36.431	54.802
Week 12	Geo Mean	1.87	1.63	1.76
	CV (%) [2]	49.921	33.981	44.378
Ratio to Baseline (% chg) [3]	Geo Mean	-2.37	-15.25	-11.48
	Geo Mean -SE,+SE	-6.54,1.99	-18.36,-12.03	-16.38,-6.30
Model-Adj Ratio to Baseline (% chg) [3,4]	Geo Mean	-2.60	-15.28	-10.28
	Geo Mean -SE,+SE	-6.51,1.47	-18.89,-11.50	-14.00,-6.39
Ratio to Baseline (% diff) [4]	Geo Mean	-1.24	-14.09	-9.02
	95% CI	-12.07,10.92	-23.76,-3.19	-19.15,2.38
	p-val[5]	0.833	0.013	0.116

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]% Change based on log-transformed data: 100 * (exp(mean change on log scale)-1)
[4]Based on ANCOVA: Log(Value)-log(Baseline) = log(Baseline) + Gender + Region + Prior Therapy + Treatment
[5]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95%CIs for treatment differences for doses below the last significant trestment difference are for descriptive purposes only.

[redacted]

2014
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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.69746417	Sum Observations	40.452922
Std Deviation	0.37052937	Variance	0.13729201
Skewness	-0.1289534	Kurtosis	-0.9219668
Uncorrected SS	36.0401085	Corrected SS	7.82564475
Coeff Variation	53.1252189	Std Error Mean	0.04865289

Basic Statistical Measures

Location		Variability	
Mean	0.69746	Std Deviation	0.37053
Median	0.74194	Variance	0.13729
Mode	-0.04082	Range	1.43210
		Interquartile Range	0.62169

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2015
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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	14.33551	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	852.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.3912819
99%	1.3912819
95%	1.2354715
90%	1.1969482
75% Q3	0.9932518
50% Median	0.7419373
25% Q1	0.3715636
10%	0.1988509
5%	0.0953102
1%	-0.0408220
0% Min	-0.0408220

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2016
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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.0408220	46	1.20597	56
-0.0408220	30	1.22378	52
0.0953102	20	1.23547	13
0.1222176	1	1.32442	12
0.1739533	50	1.39128	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2017
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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.67393852	Sum Observations	39.0884339
Std Deviation	0.42592093	Variance	0.18140864
Skewness	-0.0153206	Kurtosis	0.0836027
Uncorrected SS	36.6834936	Corrected SS	10.3402925
Coeff Variation	63.1987817	Std Error Mean	0.05592616

Basic Statistical Measures

Location		Variability	
Mean	0.673939	Std Deviation	0.42592
Median	0.722706	Variance	0.18141
Mode	0.652325	Range	1.95161
		Interquartile Range	0.50948

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

2018
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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.05051	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	831.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.663926
99%	1.663926
95%	1.521699
90%	1.308333
75% Q3	0.908259
50% Median	0.722706
25% Q1	0.398776
10%	0.076961
5%	-0.105361
1%	-0.287682
0% Min	-0.287682

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2876821	38	1.31103	10
-0.1743534	17	1.33763	42
-0.1053605	47	1.52170	49
-0.0725707	11	1.59737	26
0.0392207	30	1.66393	32

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0235257	Sum Observations	-1.3644881
Std Deviation	0.41132744	Variance	0.16919026
Skewness	-0.1288074	Kurtosis	1.44504155
Uncorrected SS	9.67594557	Corrected SS	9.64384509
Coeff Variation	-1748.4206	Std Error Mean	0.05400994

Basic Statistical Measures

Location		Variability	
Mean	-0.02353	Std Deviation	0.41133
Median	0.04272	Variance	0.16919
Mode		Range	2.39097
		Interquartile Range	0.45180

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.43558	Pr > |t|	0.6648
Sign	M	3	Pr >= |M|	0.5118

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-53.5	Pr >= |S|	0.6824

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1100410
99%	1.1100410
95%	0.7820005
90%	0.4476979
75% Q3	0.1803817
50% Median	0.0427168
25% Q1	-0.2714216
10%	-0.4653632
5%	-0.7092333
1%	-1.2809338
0% Min	-1.2809338

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.280934	38	0.459532	46
-0.911769	51	0.710691	1
-0.709233	12	0.782001	26
-0.618184	56	0.798208	10
-0.594707	48	1.110041	32

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.64407911	Sum Observations	37.3565881
Std Deviation	0.50707344	Variance	0.25712348
Skewness	0.36361561	Kurtosis	-0.0631007
Uncorrected SS	38.716636	Corrected SS	14.6560381
Coeff Variation	78.7284416	Std Error Mean	0.066582

Basic Statistical Measures

Location		Variability	
Mean	0.64408	Std Deviation	0.50707
Median	0.59884	Variance	0.25712
Mode	-0.04082	Range	2.26347
		Interquartile Range	0.74639

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

[redacted]

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.673471	Pr > |t|	<.0001
Sign	M	24	Pr >= |M|	<.0001
Signed Rank	S	805.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9487632
99%	1.9487632
95%	1.7509375
90%	1.2809338
75% Q3	0.9932518
50% Median	0.5988365
25% Q1	0.2468601
10%	0.0198026
5%	-0.1053605
1%	-0.3147107
0% Min	-0.3147107

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.314711	23	1.28647	7
-0.248461	49	1.34025	48
-0.105361	18	1.75094	29
-0.040822	37	1.81808	35
-0.040822	6	1.94876	34

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.5994289	Sum Observations	34.766876
Std Deviation	0.46295085	Variance	0.21432349
Skewness	1.12314836	Kurtosis	3.2308218
Uncorrected SS	33.0567091	Corrected SS	12.216439
Coeff Variation	77.2319876	Std Error Mean	0.06078842

Basic Statistical Measures

Location		Variability	
Mean	0.599429	Std Deviation	0.46295
Median	0.601576	Variance	0.21432
Mode	0.482426	Range	2.71344
		Interquartile Range	0.55639

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.860905	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	826.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.4123360
99%	2.4123360
95%	1.5810384
90%	1.0647107
75% Q3	0.8415672
50% Median	0.6015762
25% Q1	0.2851789
10%	0.0953102
5%	-0.0304592
1%	-0.3011051
0% Min	-0.3011051

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3011051	41	1.25846	34
-0.1984509	33	1.28647	26
-0.0304592	22	1.58104	57
-0.0202027	49	1.59331	35
0.0582689	15	2.41234	29

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.0446502	Sum Observations	-2.5897121
Std Deviation	0.36393212	Variance	0.13244659
Skewness	-0.3531351	Kurtosis	0.45556602
Uncorrected SS	7.6650866	Corrected SS	7.54945541
Coeff Variation	-815.07373	Std Error Mean	0.04778663

Basic Statistical Measures

Location		Variability	
Mean	-0.04465	Std Deviation	0.36393
Median	0.02168	Variance	0.13245
Mode		Range	1.82241
		Interquartile Range	0.45636

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.93437	Pr > |t|	0.3541
Sign	M	2	Pr >= |M|	0.6940

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-93.5	Pr >= |S|	0.4739

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6735387
99%	0.6735387
95%	0.6613985
90%	0.3537637
75% Q3	0.2031651
50% Median	0.0216752
25% Q1	-0.2531959
10%	-0.5445367
5%	-0.6273006
1%	-1.1488741
0% Min	-1.1488741

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.148874	22	0.410021	23
-0.690302	34	0.545917	19
-0.627301	48	0.661398	29
-0.626136	16	0.664748	57
-0.597837	56	0.673539	9

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	60	Sum Weights	60
Mean	0.60044853	Sum Observations	36.0269117
Std Deviation	0.5211046	Variance	0.27155
Skewness	1.064056	Kurtosis	1.43487253
Uncorrected SS	37.6537562	Corrected SS	16.0214502
Coeff Variation	86.78589	Std Error Mean	0.06727431

Basic Statistical Measures

Location		Variability	
Mean	0.600449	Std Deviation	0.52110
Median	0.527574	Variance	0.27155
Mode	0.131028	Range	2.36038
		Interquartile Range	0.56671

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.925376	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001
Signed Rank	S	842	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.12465388
99%	2.12465388
95%	1.90905173
90%	1.18922647
75% Q3	0.81727985
50% Median	0.52757396
25% Q1	0.25056943
10%	0.00990131
5%	-0.15680773
1%	-0.23572233
0% Min	-0.23572233

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2357223	50	1.36609	24
-0.1863296	22	1.85942	39
-0.1743534	27	1.95869	53
-0.1392621	41	1.98238	38
-0.0202027	35	2.12465	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	60	Sum Weights	60
Mean	0.50899533	Sum Observations	30.5397197
Std Deviation	0.48219587	Variance	0.23251286
Skewness	0.83305927	Kurtosis	0.59683532
Uncorrected SS	29.2628335	Corrected SS	13.7182588
Coeff Variation	94.7348331	Std Error Mean	0.06225122

Basic Statistical Measures

Location		Variability	
Mean	0.508995	Std Deviation	0.48220
Median	0.418710	Variance	0.23251
Mode	0.418710	Range	2.34607
		Interquartile Range	0.60826

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.176472	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	847	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	2.0175661
99%	2.0175661
95%	1.3871436
90%	1.2294310
75% Q3	0.7649375
50% Median	0.4187103
25% Q1	0.1566749
10%	0.0246807
5%	-0.0833816
1%	-0.3285041
0% Min	-0.3285041

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3285041	29	1.27536	20
-0.3011051	27	1.31103	53
-0.0833816	44	1.46326	10
-0.0833816	6	1.58104	38
-0.0618754	23	2.01757	14

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	60	Sum Weights	60
Mean	-0.0914532	Sum Observations	-5.487192
Std Deviation	0.31245654	Variance	0.09762909
Skewness	-0.3741847	Kurtosis	-0.1117725
Uncorrected SS	6.26193751	Corrected SS	5.76011624
Coeff Variation	-341.65731	Std Error Mean	0.04033797

Basic Statistical Measures

Location		Variability	
Mean	-0.09145	Std Deviation	0.31246
Median	-0.06243	Variance	0.09763
Mode	-0.35341	Range	1.46929
		Interquartile Range	0.40951

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.26717	Pr > |t|	0.0271
Sign	M	-5	Pr >= |M|	0.2451

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-265	Pr >= |S|	0.0502

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5579724
99%	0.5579724
95%	0.3937657
90%	0.3185823
75% Q3	0.1091968
50% Median	-0.0624251
25% Q1	-0.3003119
10%	-0.5226379
5%	-0.6626722
1%	-0.9113197
0% Min	-0.9113197

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.911320	54	0.367982	10
-0.682297	52	0.371564	12
-0.677691	39	0.415968	3
-0.647653	53	0.434573	50
-0.608730	42	0.557972	41

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	62	Sum Weights	62
Mean	0.65217619	Sum Observations	40.4349236
Std Deviation	0.4519763	Variance	0.20428257
Skewness	0.30469255	Kurtosis	-0.7010581
Uncorrected SS	38.8319312	Corrected SS	12.4612369
Coeff Variation	69.3027904	Std Error Mean	0.05740105

Basic Statistical Measures

Location		Variability	
Mean	0.652176	Std Deviation	0.45198
Median	0.587771	Variance	0.20428
Mode	0.113329	Range	1.91054
		Interquartile Range	0.73337

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.36175	Pr > |t|	<.0001
Sign	M	27.5	Pr >= |M|	<.0001
Signed Rank	S	925.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.609438
99%	1.609438
95%	1.401183
90%	1.249902
75% Q3	1.026042
50% Median	0.587771
25% Q1	0.292670
10%	0.122218
5%	0.000000
1%	-0.301105
0% Min	-0.301105

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.3011051	54	1.40118	19
-0.0408220	51	1.40118	42
-0.0100503	16	1.51732	41
0.0000000	25	1.57691	35
0.1133287	59	1.60944	61

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	62	Sum Weights	62
Mean	0.62820009	Sum Observations	38.9484054
Std Deviation	0.47171158	Variance	0.22251182
Skewness	0.40118999	Kurtosis	0.41856206
Uncorrected SS	38.0406126	Corrected SS	13.573221
Coeff Variation	75.0893854	Std Error Mean	0.05990743

Basic Statistical Measures

Location		Variability	
Mean	0.628200	Std Deviation	0.47171
Median	0.612476	Variance	0.22251
Mode	0.165514	Range	2.51373
		Interquartile Range	0.59784

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.48618	Pr > |t|	<.0001
Sign	M	27	Pr >= |M|	<.0001
Signed Rank	S	937.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9516082
99%	1.9516082
95%	1.4586150
90%	1.2470323
75% Q3	0.8754687
50% Median	0.6124756
25% Q1	0.2776317
10%	0.1043600
5%	-0.0304592
1%	-0.5621189
0% Min	-0.5621189

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.5621189	54	1.43031	60
-0.1392621	53	1.45862	61
-0.0618754	52	1.53471	35
-0.0304592	5	1.60944	62
0.0582689	23	1.95161	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	62	Sum Weights	62
Mean	-0.0239761	Sum Observations	-1.4865182
Std Deviation	0.34363691	Variance	0.11808632
Skewness	0.48303777	Kurtosis	3.19147898
Uncorrected SS	7.23890664	Corrected SS	7.20326573
Coeff Variation	-1433.2477	Std Error Mean	0.04364193

Basic Statistical Measures

Location		Variability	
Mean	-0.02398	Std Deviation	0.34364
Median	-0.03483	Variance	0.11809
Mode		Range	2.22123
		Interquartile Range	0.39209

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.54938	Pr > |t|	0.5847
Sign	M	-1.5	Pr >= |M|	0.7982

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-97	Pr >= |S|	0.4905

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.2837788
99%	1.2837788
95%	0.3988426
90%	0.2618408
75% Q3	0.1678809
50% Median	-0.0348339
25% Q1	-0.2242125
10%	-0.3837723
5%	-0.4920056
1%	-0.9374490
0% Min	-0.9374490

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.937449	42	0.332134	46
-0.801950	53	0.398843	43
-0.696155	18	0.546544	44
-0.492006	47	0.725670	62
-0.470004	41	1.283779	6

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	55	Sum Weights	55
Mean	0.6526395	Sum Observations	35.8951724
Std Deviation	0.35302354	Variance	0.12462562
Skewness	-0.2022675	Kurtosis	-0.0382516
Uncorrected SS	30.1563906	Corrected SS	6.72978328
Coeff Variation	54.0916595	Std Error Mean	0.04760168

Basic Statistical Measures

Location		Variability	
Mean	0.652639	Std Deviation	0.35302
Median	0.647103	Variance	0.12463
Mode	0.797507	Range	1.62510
		Interquartile Range	0.55373

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.71043	Pr > |t|	<.0001
Sign	M	24.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	759	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.3506672
99%	1.3506672
95%	1.2809338
90%	1.0851893
75% Q3	0.9321641
50% Median	0.6471032
25% Q1	0.3784364
10%	0.2311117
5%	-0.0202027
1%	-0.2744368
0% Min	-0.2744368

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.2744368	37	1.15057	27
-0.0618754	21	1.23547	5
-0.0202027	45	1.28093	55
0.1570037	48	1.31909	31
0.2151114	28	1.35067	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	55	Sum Weights	55
Mean	0.48715484	Sum Observations	26.7935159
Std Deviation	0.33056554	Variance	0.10927358
Skewness	0.07140384	Kurtosis	0.2165897
Uncorrected SS	18.9533641	Corrected SS	5.90077323
Coeff Variation	67.856361	Std Error Mean	0.04457345

Basic Statistical Measures

Location		Variability	
Mean	0.487155	Std Deviation	0.33057
Median	0.512824	Variance	0.10927
Mode	0.270027	Range	1.65823
		Interquartile Range	0.42312

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.92926	Pr > |t|	<.0001
Sign	M	22.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	744	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.3837912
99%	1.3837912
95%	1.0986123
90%	0.8544153
75% Q3	0.6931472
50% Median	0.5128236
25% Q1	0.2700271
10%	0.1133287
5%	-0.0943107
1%	-0.2744368
0% Min	-0.2744368

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.2744368	21	0.924259	10
-0.0943107	45	0.955511	34
-0.0943107	6	1.098612	31
-0.0833816	7	1.111858	8
-0.0618754	14	1.383791	5

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	55	Sum Weights	55
Mean	-0.1654847	Sum Observations	-9.1016565
Std Deviation	0.27681982	Variance	0.07662921
Skewness	-0.0176148	Kurtosis	0.45053208
Uncorrected SS	5.64416206	Corrected SS	4.13797751
Coeff Variation	-167.27823	Std Error Mean	0.03732638

Basic Statistical Measures

Location		Variability	
Mean	-0.16548	Std Deviation	0.27682
Median	-0.14953	Variance	0.07663
Mode		Range	1.47845
		Interquartile Range	0.36603

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-4.43345	Pr > |t|	<.0001
Sign	M	-14.5	Pr >= |M|	0.0001

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-475	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5444640
99%	0.5444640
95%	0.3155169
90%	0.1483198
75% Q3	-0.0047506
50% Median	-0.1495317
25% Q1	-0.3707796
10%	-0.5016090
5%	-0.5962052
1%	-0.9339903
0% Min	-0.9339903

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.933990	16	0.211970	51
-0.626456	24	0.300105	36
-0.596205	7	0.315517	28
-0.586604	14	0.367725	34
-0.519578	6	0.544464	37

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Moments

N	58	Sum Weights	58
Mean	0.68595465	Sum Observations	39.7853696
Std Deviation	0.5124609	Variance	0.26261617
Skewness	0.33230772	Kurtosis	-0.5566411
Uncorrected SS	42.2600811	Corrected SS	14.9691219
Coeff Variation	74.7076941	Std Error Mean	0.06728941

Basic Statistical Measures

Location		Variability	
Mean	0.685955	Std Deviation	0.51246
Median	0.649714	Variance	0.26262
Mode	0.285179	Range	2.18358
		Interquartile Range	0.80235

NOTE: The mode displayed is the smallest of 6 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.19409	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	830.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.9851309
99%	1.9851309
95%	1.6389967
90%	1.3376292
75% Q3	1.0647107
50% Median	0.6497142
25% Q1	0.2623643
10%	0.0582689
5%	-0.0833816
1%	-0.1984509
0% Min	-0.1984509

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLOGBL (Log of baseline value)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.1984509	45	1.38128	39
-0.1165338	9	1.38629	3
-0.0833816	30	1.63900	43
-0.0304592	52	1.79509	33
0.0198026	15	1.98513	10

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Moments

N	58	Sum Weights	58
Mean	0.56396668	Sum Observations	32.7100673
Std Deviation	0.42399586	Variance	0.17977249
Skewness	0.00189389	Kurtosis	-0.5236126
Uncorrected SS	28.6944197	Corrected SS	10.2470318
Coeff Variation	75.1810124	Std Error Mean	0.05567338

Basic Statistical Measures

Location		Variability	
Mean	0.563967	Std Deviation	0.42400
Median	0.512824	Variance	0.17977
Mode	0.058269	Range	1.83933
		Interquartile Range	0.64589

NOTE: The mode displayed is the smallest of 8 modes with a count of 2.

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.12992	Pr > |t|	<.0001
Sign	M	25	Pr >= |M|	<.0001
Signed Rank	S	804.5	Pr >= |S|	<.0001

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.4085450
99%	1.4085450
95%	1.2178757
90%	1.1216776
75% Q3	0.9082586
50% Median	0.5128236
25% Q1	0.2623643
10%	0.0582689
5%	-0.1743534
1%	-0.4307829
0% Min	-0.4307829

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFLGRESN (Log of analysis numeric result)

Extreme Observations

-------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-0.4307829	1	1.13783	52
-0.3011051	28	1.19996	34
-0.1743534	50	1.21788	23
-0.0100503	9	1.39624	26
0.0582689	42	1.40854	46

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Moments

N	58	Sum Weights	58
Mean	-0.121988	Sum Observations	-7.0753023
Std Deviation	0.43364457	Variance	0.18804761
Skewness	0.34117599	Kurtosis	0.52768489
Uncorrected SS	11.5818155	Corrected SS	10.7187137
Coeff Variation	-355.48141	Std Error Mean	0.05694032

Basic Statistical Measures

Location		Variability	
Mean	-0.12199	Std Deviation	0.43364
Median	-0.17123	Variance	0.18805
Mode		Range	2.18405
		Interquartile Range	0.49756

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.14238	Pr > |t|	0.0364
Sign	M	-6	Pr >= |M|	0.1480

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-291.5	Pr >= |S|	0.0227

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.168292
99%	1.168292
95%	0.589861
90%	0.448025
75% Q3	0.111591
50% Median	-0.171234
25% Q1	-0.385971
10%	-0.652873
5%	-0.886519
1%	-1.015762
0% Min	-1.015762

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Outputs form Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: LOGCHGBL (Log Chg Baseline)

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.015762	33	0.451985	22
-0.955511	1	0.491281	21
-0.886519	10	0.589861	35
-0.793128	43	0.842443	36
-0.723762	39	1.168292	52

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	LOGCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg
REGIONCD	3	US/Canada Eastern Europe Western Europe

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Dimensions

Max Obs Per Subject	351
Observations Used	351
Observations Not Used	0
Total Observations	351

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.1037	0.007952	13.04	<.0001	0.05	0.08971	0.1212

Fit Statistics

-2 Res Log Likelihood	240.3
AIC (smaller is better)	242.3
AICC (smaller is better)	242.3
BIC (smaller is better)	246.1

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept					0.1593	0.05987	340	2.66	0.0082
SEX	Female				-0.05876	0.03470	340	-1.69	0.0913
SEX	Male				0			.	
TRTTYPCD		Diet & Exercise			0.01619	0.03523	340	0.46	0.6462
TRTTYPCD		Monotherapy			0			.	
TRTCD				Placebo	0.09452	0.06000	340	1.58	0.1161
TRTCD				2.5mg	0.06392	0.05989	340	1.07	0.2866
TRTCD				7.5mg	-0.00281	0.05951	340	-0.05	0.9623
TRTCD				15mg	0.08206	0.05892	340	1.39	0.1646
TRTCD				30mg	-0.05733	0.06081	340	-0.94	0.3465
TRTCD				45mg	0			.	
REGIONCD			US/Canada		0.004252	0.04066	340	0.10	0.9168
REGIONCD			Eastern Europe		-0.05161	0.04328	340	-1.19	0.2339
REGIONCD			Western Europe		0			.	
EFLOGBL					-0.3543	0.03789	340	-9.35	<.0001

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	340	2.87	0.0913
TRTTYPCD	1	340	0.21	0.6462
TRTCD	5	340	1.94	0.0868
REGIONCD	2	340	0.94	0.3915
EFLOGBL	1	340	87.43	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.03060	0.06028	340	-0.51	0.6121	0.05	-0.1492	0.08798
7.5mg vs Pbo	-0.09733	0.05959	340	-1.63	0.1033	0.05	-0.2145	0.01988
15mg vs Pbo	-0.01246	0.05905	340	-0.21	0.8330	0.05	-0.1286	0.1037
30mg vs Pbo	-0.1518	0.06073	340	-2.50	0.0129	0.05	-0.2713	-0.03239
45mg vs Pbo	-0.09452	0.06000	340	-1.58	0.1161	0.05	-0.2125	0.02349

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5
Intercept					1	1	1	1	1
SEX	Female				0.5043	0.5043	0.5043	0.5043	0.5043
SEX	Male				0.4957	0.4957	0.4957	0.4957	0.4957
TRTTYPCD		Diet & Exercise			0.4074	0.4074	0.4074	0.4074	0.4074
TRTTYPCD		Monotherapy			0.5926	0.5926	0.5926	0.5926	0.5926
TRTCD				Placebo	1				
TRTCD				2.5mg		1			
TRTCD				7.5mg			1		
TRTCD				15mg				1	
TRTCD				30mg					1
TRTCD				45mg					
REGIONCD			US/Canada		0.3276	0.3276	0.3276	0.3276	0.3276
REGIONCD			Eastern Europe		0.2707	0.2707	0.2707	0.2707	0.2707
REGIONCD			Western Europe		0.4017	0.4017	0.4017	0.4017	0.4017
EFLOGBL					0.6551	0.6551	0.6551	0.6551	0.6551

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Region code	Randomized treatment code	Row6
Intercept					1
SEX	Female				0.5043
SEX	Male				0.4957
TRTTYPCD		Diet & Exercise			0.4074
TRTTYPCD		Monotherapy			0.5926
TRTCD				Placebo	
TRTCD				2.5mg	
TRTCD				7.5mg	
TRTCD				15mg	
TRTCD				30mg	
TRTCD				45mg	1
REGIONCD			US/Canada		0.3276
REGIONCD			Eastern Europe		0.2707
REGIONCD			Western Europe		0.4017
EFLOGBL					0.6551

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.01391	0.04248	340	-0.33	0.7435	0.05	-0.09747	0.06964
TRTCD	2.5mg	WORK.EFF	-0.04451	0.04246	340	-1.05	0.2953	0.05	-0.1280	0.03901
TRTCD	7.5mg	WORK.EFF	-0.1112	0.04167	340	-2.67	0.0080	0.05	-0.1932	-0.02928
TRTCD	15mg	WORK.EFF	-0.02638	0.04094	340	-0.64	0.5198	0.05	-0.1069	0.05415
TRTCD	30mg	WORK.EFF	-0.1658	0.04354	340	-3.81	0.0002	0.05	-0.2514	-0.08012
TRTCD	45mg	WORK.EFF	-0.1084	0.04235	340	-2.56	0.0109	0.05	-0.1917	-0.02513

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.03060	0.06028	340	0.51	0.6121	0.05
TRTCD	Placebo	7.5mg	WORK.EFF	0.09733	0.05959	340	1.63	0.1033	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.01246	0.05905	340	0.21	0.8330	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.1518	0.06073	340	2.50	0.0129	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.09452	0.06000	340	1.58	0.1161	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.06674	0.05950	340	1.12	0.2629	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-0.01814	0.05892	340	-0.31	0.7584	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.1212	0.06099	340	1.99	0.0476	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.06392	0.05989	340	1.07	0.2866	0.05

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	7.5mg	15mg	WORK.EFF	-0.08487	0.05841	340	-1.45	0.1472	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.05451	0.06023	340	0.91	0.3660	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-0.00281	0.05951	340	-0.05	0.9623	0.05
TRTCD	15mg	30mg	WORK.EFF	0.1394	0.05983	340	2.33	0.0204	0.05
TRTCD	15mg	45mg	WORK.EFF	0.08206	0.05892	340	1.39	0.1646	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.05733	0.06081	340	-0.94	0.3465	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.08798	0.1492
TRTCD	Placebo	7.5mg	-0.01988	0.2145
TRTCD	Placebo	15mg	-0.1037	0.1286
TRTCD	Placebo	30mg	0.03239	0.2713
TRTCD	Placebo	45mg	-0.02349	0.2125
TRTCD	2.5mg	7.5mg	-0.05031	0.1838
TRTCD	2.5mg	15mg	-0.1340	0.09777
TRTCD	2.5mg	30mg	0.001279	0.2412
TRTCD	2.5mg	45mg	-0.05388	0.1817
TRTCD	7.5mg	15mg	-0.1998	0.03003

Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Mixed Model Output

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	7.5mg	30mg	-0.06395	0.1730
TRTCD	7.5mg	45mg	-0.1199	0.1142
TRTCD	15mg	30mg	0.02170	0.2571
TRTCD	15mg	45mg	-0.03383	0.1979
TRTCD	30mg	45mg	-0.1769	0.06228

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Model Checking of Residuals

Plot of Pred*Resid. Legend: A = 1 obs, B = 2 obs, etc.

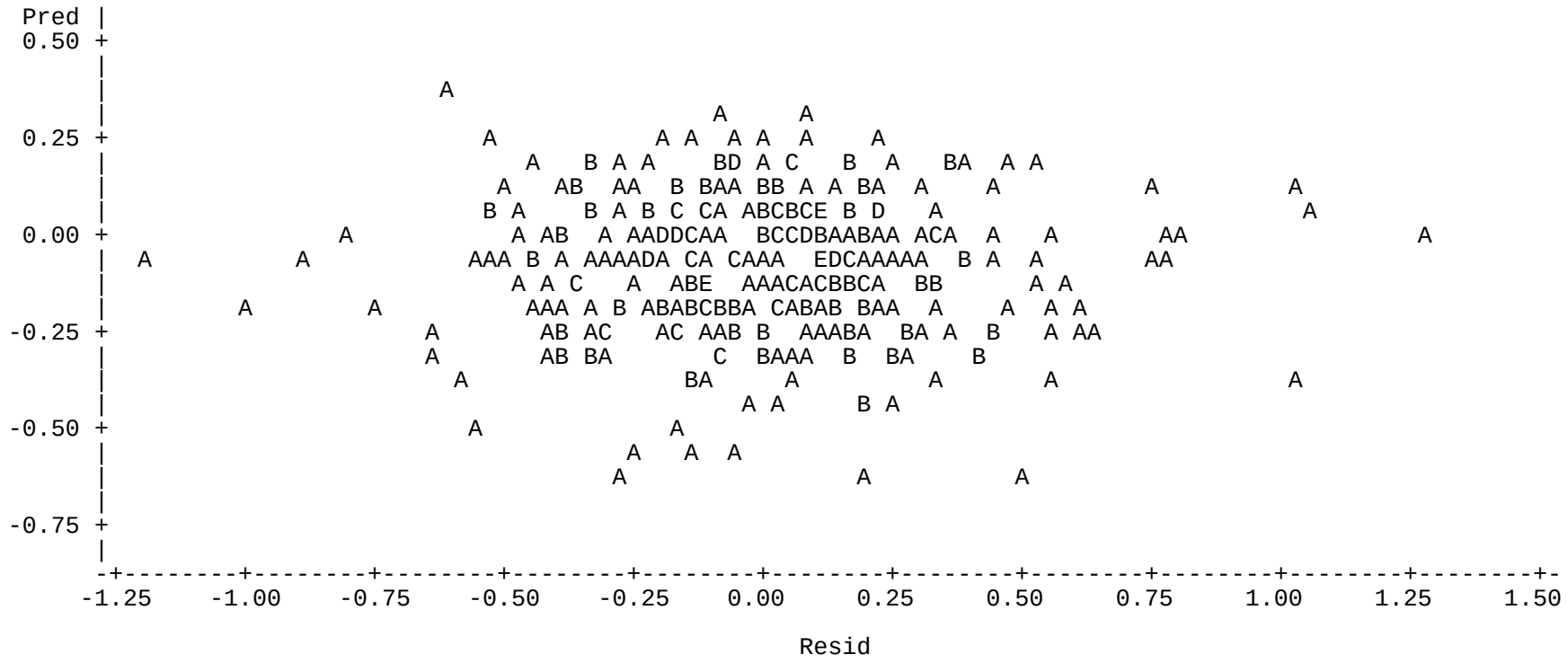

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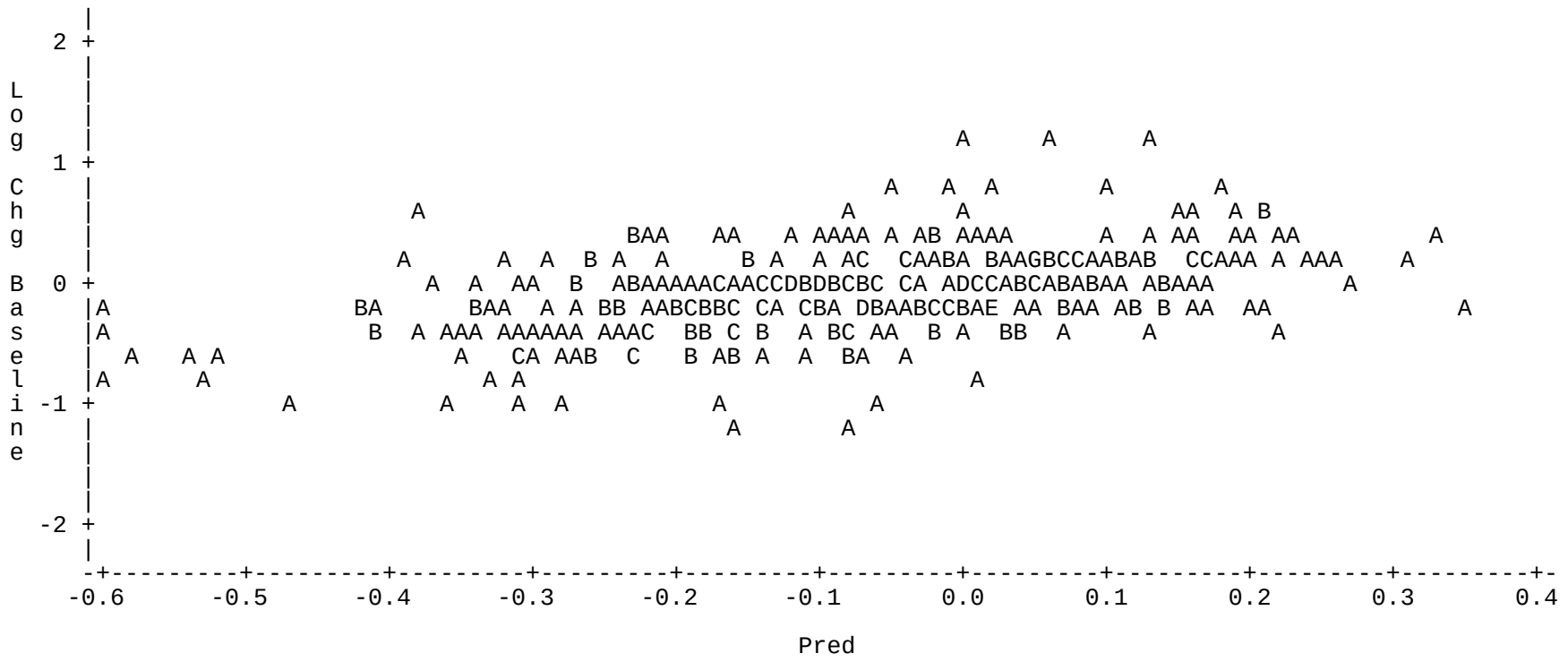
Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Model Checking of Residuals

Plot of LOGCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.59
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Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	351	Sum Weights	351
Mean	0	Sum Observations	0
Std Deviation	0.31737102	Variance	0.10072436
Skewness	0.24830663	Kurtosis	1.7139942
Uncorrected SS	35.2535272	Corrected SS	35.2535272
Coeff Variation		Std Error Mean	0.01694001

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.31737
Median	0.00914	Variance	0.10072
Mode	-0.37880	Range	2.47807
		Interquartile Range	0.36472

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	6.5	Pr >= |M|	0.5219
Signed Rank	S	-556	Pr >= |S|	0.7705

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Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.980123	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.057237	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.198718	Pr > W-Sq	0.0054
Anderson-Darling	A-Sq	1.365151	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.27904330
99%	1.03810965
95%	0.53559744
90%	0.35653859
75% Q3	0.17745484
50% Median	0.00913984
25% Q1	-0.18726266
10%	-0.37879940
5%	-0.48225484
1%	-0.80850718
0% Min	-1.19902285

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Table 11.59
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Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-1.199023	225	0.796633	174
-0.992019	99	1.038110	135
-0.893472	2	1.040774	298
-0.808507	312	1.048220	199
-0.741496	327	1.279043	36

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Table 11.59
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Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

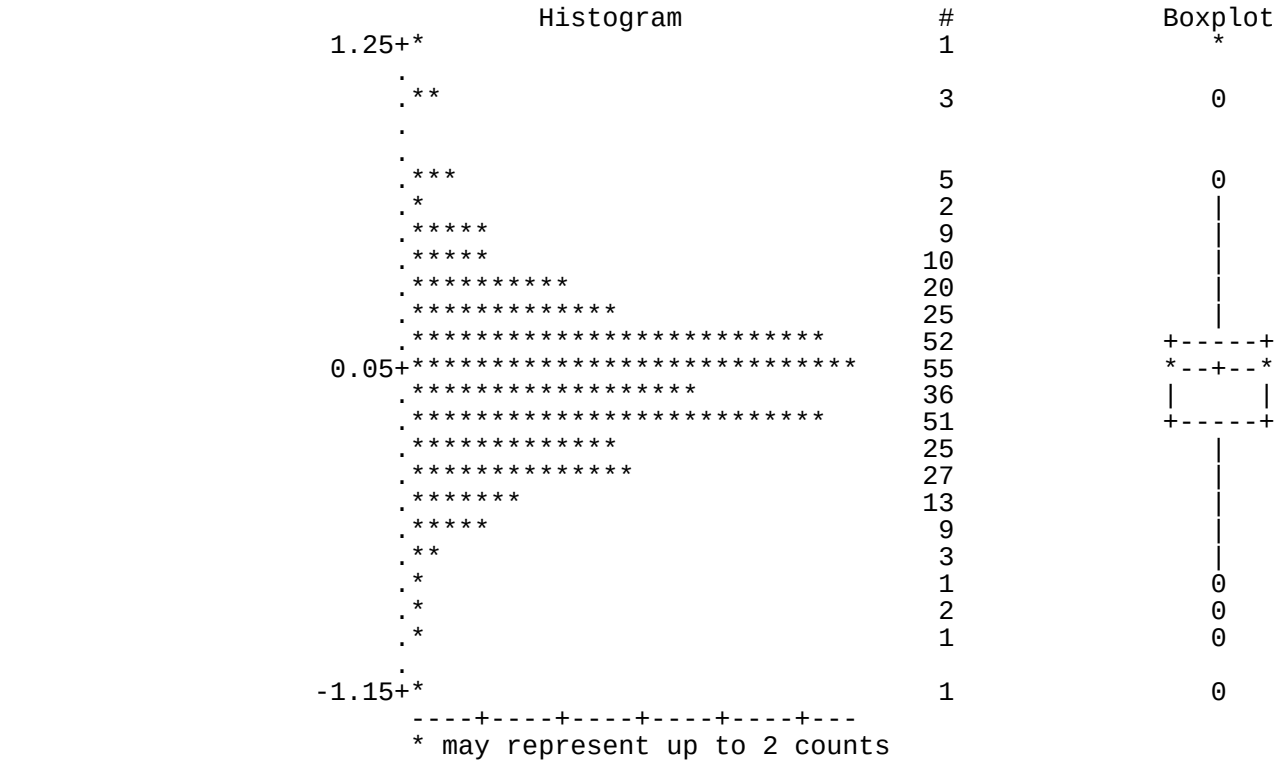

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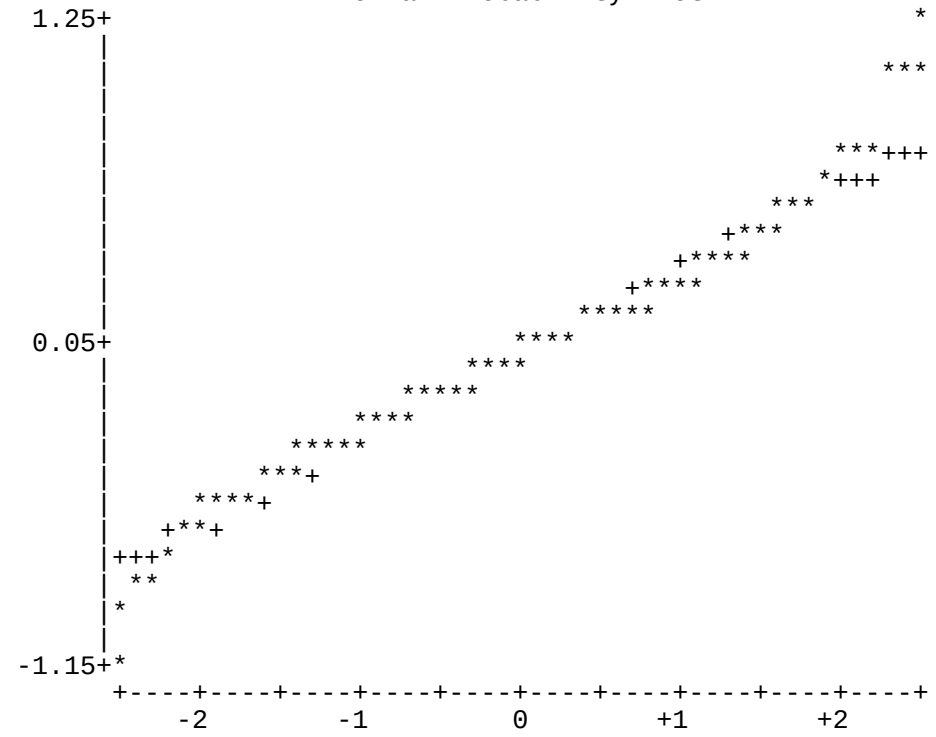
Table 11.59
SAS Statistical Output for Table 11.58
Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Regioncd is the region variable, Eflogbl is the log baseline variable, Efstresn is the log visit value variable and Logchgbl is the log change from baseline variable.

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: Canada

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		10	4	4	10	9	5
n [1]		10	4	4	10	9	5
Number (%) of Values Carried Forward		3 (30%)	1 (25%)	0	0	0	2 (40%)
Baseline	Mean	7.46	7.23	8.25	7.98	7.74	7.94
	SD	0.643	0.403	1.109	0.684	0.637	0.207
	SE	0.203	0.202	0.555	0.216	0.212	0.093
	Minimum	6.6	6.8	7.6	7.1	6.8	7.7
	Median	7.35	7.20	7.75	8.20	8.00	7.90
	Maximum	8.5	7.7	9.9	9.0	8.4	8.2
Week 12	Mean	7.26	6.90	8.58	7.46	7.23	7.50
	SD	0.560	0.529	1.797	0.817	0.784	1.056
	SE	0.177	0.265	0.898	0.258	0.261	0.472
	Minimum	6.3	6.4	6.9	6.0	6.2	6.0
	Median	7.15	6.80	8.20	7.45	7.40	8.10
	Maximum	8.2	7.6	11.0	8.7	8.3	8.5
Change from Baseline	Mean	-0.20	-0.33	0.33	-0.52	-0.51	-0.44
	SD	0.483	0.222	0.834	0.424	0.414	0.907
	SE	0.153	0.111	0.417	0.134	0.138	0.406
	Minimum	-0.9	-0.6	-0.7	-1.1	-0.9	-1.8
	Median	-0.30	-0.30	0.45	-0.50	-0.60	-0.10
	Maximum	0.6	-0.1	1.1	0.0	0.2	0.4

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: Czech Republic/Latvia

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		4	13	11	10	7	11
n [1]		4	12	11	10	7	11
Number (%) of Values Carried Forward		0	0	0	0	0	0
Baseline	Mean	7.15	8.31	7.86	7.95	7.70	8.32
	SD	0.733	1.019	0.671	0.448	0.451	0.675
	SE	0.366	0.294	0.202	0.142	0.170	0.204
	Minimum	6.1	6.8	7.2	6.8	7.0	7.1
	Median	7.40	8.30	7.60	8.00	7.60	8.40
	Maximum	7.7	10.1	9.2	8.4	8.2	9.5
Week 12	Mean	7.00	8.84	8.10	8.61	7.31	8.00
	SD	0.548	1.450	1.274	0.713	0.754	0.735
	SE	0.274	0.419	0.384	0.225	0.285	0.222
	Minimum	6.4	6.6	6.9	7.5	6.1	6.8
	Median	7.00	8.75	7.80	8.45	7.40	8.00
	Maximum	7.6	11.8	10.7	10.0	8.4	9.4
Change from Baseline	Mean	-0.15	0.53	0.24	0.66	-0.39	-0.32
	SD	0.645	0.885	0.972	0.602	0.823	0.525
	SE	0.323	0.255	0.293	0.190	0.311	0.158
	Minimum	-1.0	-1.4	-1.1	-0.1	-2.1	-1.4
	Median	0.00	0.65	0.10	0.60	-0.10	-0.30
	Maximum	0.4	1.8	2.1	2.0	0.4	0.3

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: Germany

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		22	11	23	18	20	14
n [1]		22	10	23	17	19	14
Number (%) of Values Carried Forward		2 (9%)	2 (20%)	1 (4%)	2 (12%)	1 (5%)	2 (14%)
Baseline	Mean	7.76	8.01	7.91	7.90	7.55	8.11
	SD	0.570	0.894	0.671	0.697	0.655	0.697
	SE	0.121	0.283	0.140	0.169	0.150	0.186
	Minimum	6.8	7.0	6.9	6.6	6.4	6.9
	Median	7.75	7.75	7.70	7.80	7.50	7.95
	Maximum	9.0	9.8	9.3	9.6	8.7	9.5
Week 12	Mean	8.84	8.11	7.93	8.22	7.61	7.61
	SD	1.522	1.376	1.150	0.934	0.854	0.777
	SE	0.324	0.435	0.240	0.227	0.196	0.208
	Minimum	6.3	6.5	6.3	6.8	6.5	6.1
	Median	8.70	7.60	7.60	8.30	7.30	7.55
	Maximum	11.8	10.3	10.2	10.4	9.7	8.7
Change from Baseline	Mean	1.08	0.10	0.02	0.32	0.06	-0.49
	SD	1.288	1.332	1.162	0.598	0.957	0.845
	SE	0.275	0.421	0.242	0.145	0.220	0.226
	Minimum	-1.7	-1.9	-2.3	-0.7	-1.6	-2.9
	Median	1.25	0.10	0.00	0.20	0.10	-0.35
	Maximum	2.8	2.5	2.2	1.9	2.6	0.7

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: Romania/Greece

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		8	8	5	7	6	7
n [1]		8	8	4	7	6	7
Number (%) of Values Carried Forward		2 (25%)	3 (38%)	1 (25%)	0	0	0
Baseline	Mean	7.83	8.03	8.40	7.49	8.23	7.44
	SD	0.905	1.197	0.678	0.380	0.776	0.683
	SE	0.320	0.423	0.339	0.144	0.317	0.258
	Minimum	6.8	6.4	7.9	7.0	7.4	6.7
	Median	7.90	7.70	8.15	7.50	8.00	7.50
	Maximum	9.3	10.1	9.4	8.0	9.6	8.6
Week 12	Mean	7.70	8.18	7.90	7.11	7.70	6.70
	SD	1.084	1.251	1.364	0.389	0.751	0.705
	SE	0.383	0.442	0.682	0.147	0.307	0.266
	Minimum	6.3	6.9	6.4	6.4	6.7	5.8
	Median	7.50	7.80	7.75	7.30	7.65	6.50
	Maximum	10.0	10.5	9.7	7.5	8.9	7.7
Change from Baseline	Mean	-0.13	0.15	-0.50	-0.37	-0.53	-0.74
	SD	1.167	0.695	0.849	0.713	0.509	0.594
	SE	0.413	0.246	0.424	0.270	0.208	0.225
	Minimum	-1.7	-0.6	-1.7	-1.6	-1.3	-1.6
	Median	-0.35	0.10	-0.30	0.00	-0.60	-0.90
	Maximum	2.1	1.2	0.3	0.4	0.2	0.0

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: Sweden/Finland

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		2	9	5	8	5	7
n [1]		2	9	5	8	5	7
Number (%) of Values Carried Forward		1 (50%)	2 (22%)	0	0	0	0
Baseline	Mean	8.40	8.24	7.92	7.68	7.74	8.04
	SD	1.131	0.704	0.277	0.607	0.770	0.772
	SE	0.800	0.235	0.124	0.214	0.344	0.292
	Minimum	7.6	7.5	7.6	6.9	6.7	6.8
	Median	8.40	8.30	8.00	7.70	7.50	8.30
	Maximum	9.2	9.5	8.3	8.6	8.6	8.9
Week 12	Mean	8.95	8.71	7.80	7.71	7.30	7.74
	SD	1.626	0.909	0.652	1.016	1.037	0.692
	SE	1.150	0.303	0.292	0.359	0.464	0.262
	Minimum	7.8	7.7	7.2	6.5	6.2	6.8
	Median	8.95	8.50	7.50	7.55	7.50	7.60
	Maximum	10.1	10.8	8.6	9.5	8.6	8.8
Change from Baseline	Mean	0.55	0.47	-0.12	0.04	-0.44	-0.30
	SD	0.495	0.579	0.669	0.812	0.559	0.529
	SE	0.350	0.193	0.299	0.287	0.250	0.200
	Minimum	0.2	-0.5	-1.1	-1.2	-1.2	-1.4
	Median	0.55	0.50	-0.20	0.00	-0.50	-0.10
	Maximum	0.9	1.7	0.6	1.6	0.2	0.2

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: US South Region

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		12	3	9	4	6	8
n [1]		9	3	8	4	5	6
Number (%) of Values Carried Forward		2 (22%)	0	3 (38%)	0	0	1 (17%)
Baseline	Mean	8.07	7.53	8.38	8.38	8.22	8.42
	SD	0.614	0.208	1.108	0.512	0.471	0.875
	SE	0.205	0.120	0.392	0.256	0.211	0.357
	Minimum	7.2	7.3	6.7	7.7	7.4	7.1
	Median	8.10	7.60	8.25	8.45	8.40	8.35
	Maximum	9.3	7.7	9.7	8.9	8.6	9.5
Week 12	Mean	8.11	7.33	8.00	8.45	7.44	8.47
	SD	1.132	0.404	1.102	0.465	0.631	1.297
	SE	0.377	0.233	0.390	0.233	0.282	0.530
	Minimum	6.2	6.9	6.2	7.9	6.9	6.7
	Median	8.30	7.40	8.20	8.45	7.20	8.60
	Maximum	9.7	7.7	9.5	9.0	8.5	9.9
Change from Baseline	Mean	0.04	-0.20	-0.38	0.08	-0.78	0.05
	SD	1.015	0.265	0.306	0.096	0.622	0.787
	SE	0.338	0.153	0.108	0.048	0.278	0.321
	Minimum	-1.5	-0.4	-0.8	0.0	-1.5	-1.3
	Median	0.00	-0.30	-0.40	0.05	-0.80	0.30
	Maximum	2.1	0.1	0.1	0.2	0.1	0.9

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Table 11.60
Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region

Region: US West/Midwest/NE Region

		Placebo	2.5mg	7.5mg	15mg	30mg	45mg
N		4	11	5	6	5	8
n [1]		4	10	4	6	5	8
Number (%) of Values Carried Forward		0	2 (20%)	1 (25%)	0	1 (20%)	1 (13%)
Baseline	Mean	8.00	7.94	7.23	7.92	7.82	8.04
	SD	0.337	1.013	0.435	1.032	0.740	0.944
	SE	0.168	0.320	0.217	0.421	0.331	0.334
	Minimum	7.5	6.4	6.6	6.5	6.7	6.5
	Median	8.15	7.75	7.35	7.80	8.00	8.10
	Maximum	8.2	9.8	7.6	9.5	8.7	9.3
Week 12	Mean	8.83	7.84	6.90	7.52	7.08	7.68
	SD	0.580	1.214	0.523	0.731	1.475	1.137
	SE	0.290	0.384	0.261	0.298	0.660	0.402
	Minimum	8.2	6.3	6.2	6.4	5.5	6.5
	Median	8.75	7.55	7.05	7.65	7.00	7.45
	Maximum	9.6	9.7	7.3	8.5	9.4	9.8
Change from Baseline	Mean	0.83	-0.10	-0.33	-0.40	-0.74	-0.36
	SD	0.591	0.846	0.250	0.707	1.178	0.848
	SE	0.295	0.267	0.125	0.289	0.527	0.300
	Minimum	0.1	-1.6	-0.6	-1.8	-2.5	-1.8
	Median	0.90	-0.10	-0.35	-0.15	-0.50	0.00
	Maximum	1.4	1.1	0.0	0.1	0.7	0.5

[1]Number of subjects with a value at baseline and at Week 12 (after LOCF)

[redacted]

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Population: Intent-to-Treat with LOCF

Table 11.66

Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

		Placebo (N=36)	2.5mg (N=41)	7.5mg (N=44)	15mg (N=43)	30mg (N=38)	45mg (N=39)
n [1]		33	35	42	42	35	34
Number (%) of Values Carried Forward		5 (15%)	8 (23%)	6 (14%)	3 (7%)	4 (11%)	2 (6%)
Baseline	Mean	91.20	98.58	127.84	103.10	88.06	96.80
	SD	59.119	93.023	123.158	67.211	50.055	56.101
Week 12	Mean	91.20	81.87	138.68	105.85	101.66	109.54
	SD	60.528	56.125	196.049	73.676	61.672	71.554
Chg from Baseline	Mean	0.00	-16.71	10.84	2.75	13.60	12.74
	SD	53.366	101.028	95.463	50.351	32.165	50.650
Model-Adj Chg [2]	Mean	-0.41	-17.48	12.05	3.26	12.49	12.95
	SE	12.198	11.850	10.878	10.821	11.858	12.005
Diff from Pbo [2]	Mean		-17.07	12.46	3.67	12.90	13.36
	95% CI		-50.65,16.50	-19.91,44.83	-28.57,35.91	-20.54,46.34	-20.27,47.00
	p-val [3]		0.317	0.449	0.823	0.448	0.434

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	33	Sum Weights	33
Mean	91.1969697	Sum Observations	3009.5
Std Deviation	59.1194685	Variance	3495.11155
Skewness	1.15907099	Kurtosis	1.40020866
Uncorrected SS	386300.85	Corrected SS	111843.57
Coeff Variation	64.8261326	Std Error Mean	10.2913785

Basic Statistical Measures

Location		Variability	
Mean	91.19697	Std Deviation	59.11947
Median	86.60000	Variance	3495
Mode	43.30000	Range	252.60000
		Interquartile Range	72.20000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.861492	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	280.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.906083	Pr < W	0.0077
Kolmogorov-Smirnov	D	0.149107	Pr > D	0.0618
Cramer-von Mises	W-Sq	0.127983	Pr > W-Sq	0.0455
Anderson-Darling	A-Sq	0.887555	Pr > A-Sq	0.0216

Quantiles (Definition 5)

Quantile	Estimate
100% Max	267.0
99%	267.0
95%	209.3
90%	158.8
75% Q3	115.5

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	86.6
25% Q1	43.3
10%	28.9
5%	21.7
1%	14.4
0% Min	14.4

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	32	144.3	28
21.7	21	158.8	16
21.7	6	209.3	8
28.9	30	209.3	12
36.1	17	267.0	3

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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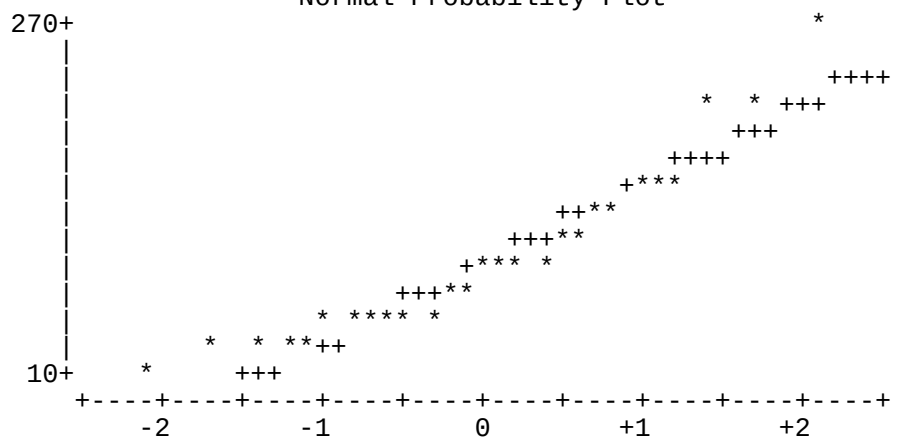
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                  #    Boxplot
     26 7                     1       0
     24
     22
     20 99                    2       |
     18                               |
     16                               |
     14 449                   3       |
     12 30                    2       |
     10 866                   3    +-----+
      8 774444                6    *--+--*
      6 999                   3    |     |
      4 33333008              8    +-----+
      2 2296                  4       |
      0 4                     1       |
        ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	33	Sum Weights	33
Mean	91.1969697	Sum Observations	3009.5
Std Deviation	60.5283481	Variance	3663.68093
Skewness	1.84764136	Kurtosis	3.31146739
Uncorrected SS	391695.07	Corrected SS	117237.79
Coeff Variation	66.3710081	Std Error Mean	10.536633

Basic Statistical Measures

Location		Variability	
Mean	91.19697	Std Deviation	60.52835
Median	79.40000	Variance	3664
Mode	79.40000	Range	252.50000
		Interquartile Range	50.50000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.655229	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	280.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.790949	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.223548	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.40274	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.359618	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	274.2
99%	274.2
95%	259.8
90%	166.0
75% Q3	101.0

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	50.5
10%	43.3
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	30	137.1	11
28.9	21	166.0	3
28.9	9	223.7	12
43.3	32	259.8	22
43.3	10	274.2	28

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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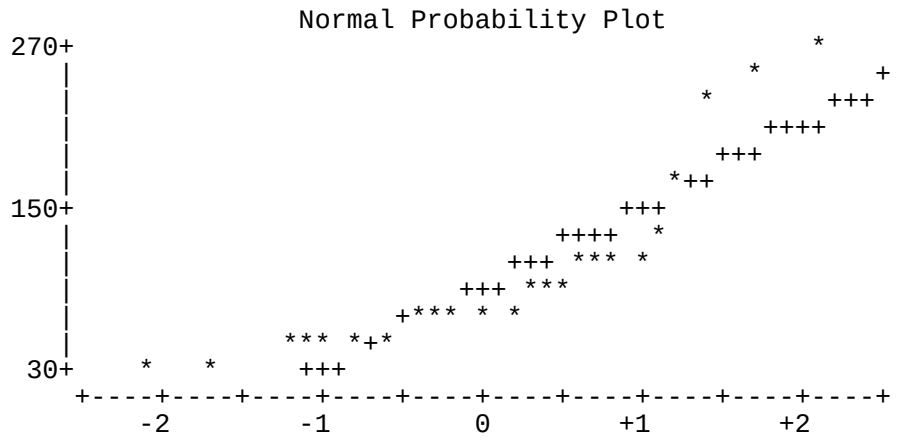
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                     #    Boxplot
     26 04                       2       *
     24                                  |
     22 4                        1       0
     20                                  |
     18                                  |
     16 6                        1       |
     14                                  |
     12 7                        1       |
     10 1186                     4    +-----+
      8 7744                     4    |  +  |
      6 522999999                9    *-----*
      4 33300088                 8    +-----+
      2 299                      3       |
        ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	33	Sum Weights	33
Mean	0	Sum Observations	0
Std Deviation	53.3660063	Variance	2847.93063
Skewness	0.02734827	Kurtosis	3.60839327
Uncorrected SS	91133.78	Corrected SS	91133.78
Coeff Variation		Std Error Mean	9.28982928

Basic Statistical Measures

Location		Variability	
Mean	0	Std Deviation	53.36601
Median	0	Variance	2848
Mode	0	Range	303.10000
		Interquartile Range	36.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-1.5	Pr >= |M|	0.7111

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-6	Pr >= |S|	0.8994

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.883078	Pr < W	0.0020
Kolmogorov-Smirnov	D	0.181523	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.262442	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.534526	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	129.9
90%	43.3
75% Q3	21.6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-14.4
10%	-43.3
5%	-101.0
1%	-158.8
0% Min	-158.8

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-158.8	8	36.1	2
-101.0	3	43.3	14
-50.5	16	50.5	15
-43.3	4	129.9	28
-36.1	31	144.3	22

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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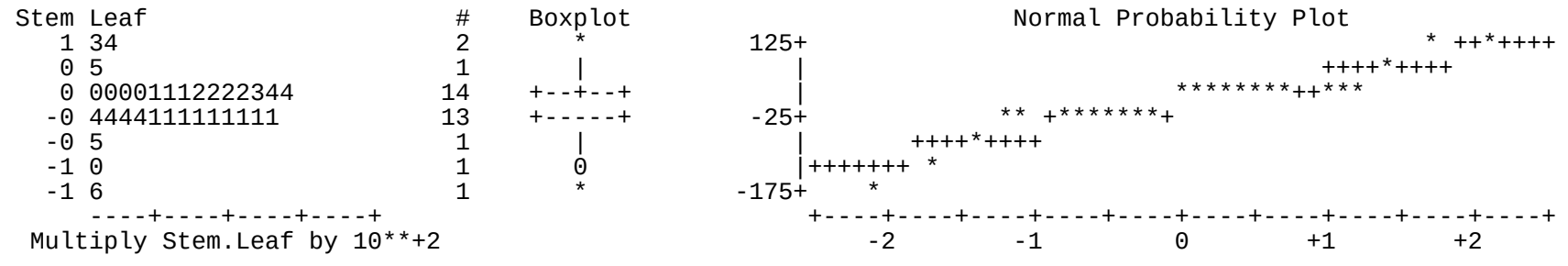
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	35	Sum Weights	35
Mean	98.58	Sum Observations	3450.3
Std Deviation	93.0226373	Variance	8653.21106
Skewness	4.22875163	Kurtosis	21.4691398
Uncorrected SS	634339.75	Corrected SS	294209.176
Coeff Variation	94.3625861	Std Error Mean	15.7236955

Basic Statistical Measures

Location		Variability	
Mean	98.58000	Std Deviation	93.02264
Median	72.20000	Variance	8653
Mode	65.00000	Range	548.50000
		Interquartile Range	65.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.269518	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.557368	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.226909	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.638169	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.850414	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	577.4
99%	577.4
95%	194.9
90%	151.6
75% Q3	115.5

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	72.2
25% Q1	50.5
10%	43.3
5%	28.9
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	18	151.6	14
28.9	5	151.6	33
36.1	28	166.0	23
43.3	31	194.9	20
43.3	19	577.4	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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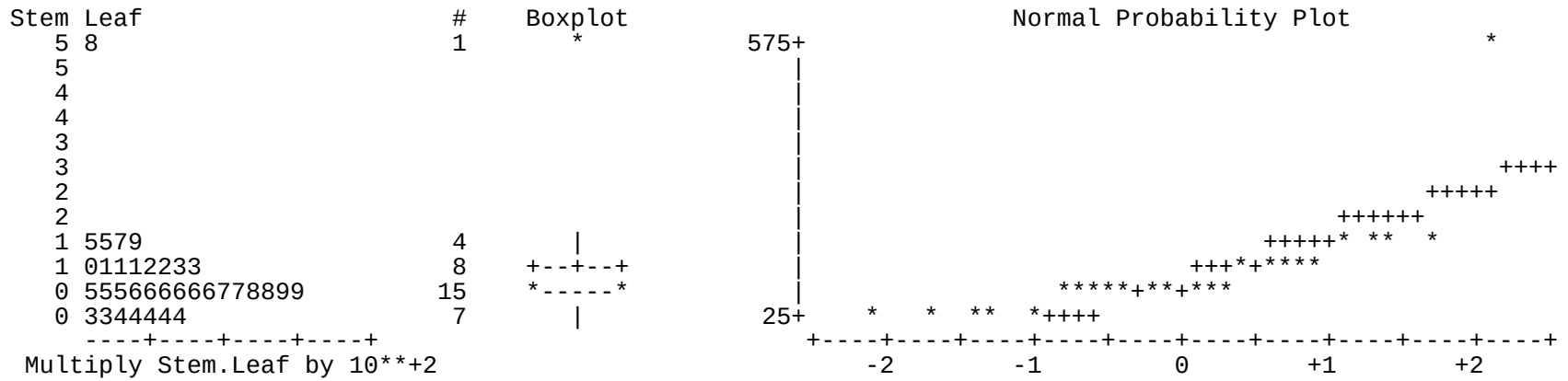
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	35	Sum Weights	35
Mean	81.8685714	Sum Observations	2865.4
Std Deviation	56.1249906	Variance	3150.01457
Skewness	1.21191474	Kurtosis	0.96565464
Uncorrected SS	341686.7	Corrected SS	107100.495
Coeff Variation	68.5549896	Std Error Mean	9.48685492

Basic Statistical Measures

Location		Variability	
Mean	81.86857	Std Deviation	56.12499
Median	57.70000	Variance	3150
Mode	36.10000	Range	231.00000
		Interquartile Range	72.20000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.629685	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.873829	Pr < W	0.0008
Kolmogorov-Smirnov	D	0.197601	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.260977	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.552479	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	245.4
99%	245.4
95%	202.1

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	166.0
75% Q3	108.3
50% Median	57.7
25% Q1	36.1
10%	28.9
5%	21.7
1%	14.4
0% Min	14.4

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
14.4	31	158.8	14
21.7	15	166.0	20
28.9	28	173.2	16
28.9	18	202.1	35
36.1	33	245.4	34

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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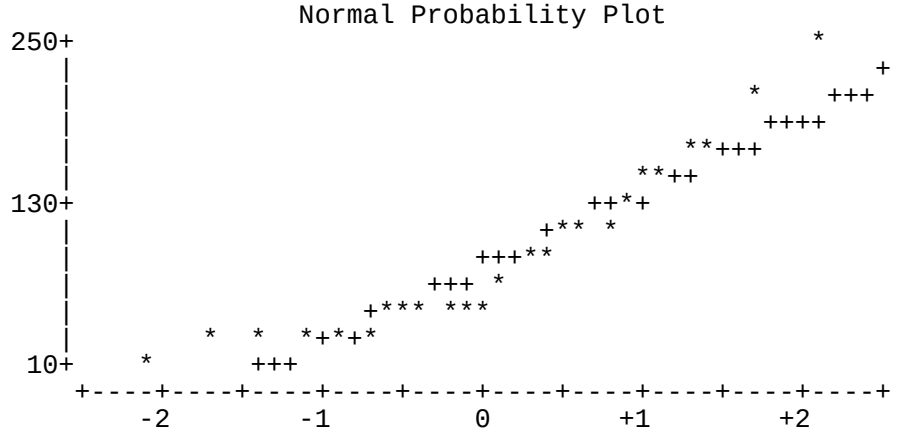
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                  #    Boxplot
     24 5                     1       0
     22                              |
     20 2                     1       |
     18                              |
     16 63                    2       |
     14 99                    2       |
     12 3                     1       |
     10 1888                  4    +-----+
      8 774                   3    |  +  |
      6 299                   3    |     |
      4 333000008             9    *-----*
      2 29966666              8    +-----+
      0 4                     1       |
        ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	35	Sum Weights	35
Mean	-16.711429	Sum Observations	-584.9
Std Deviation	101.028452	Variance	10206.7481
Skewness	-3.7763852	Kurtosis	20.0849854
Uncorrected SS	356803.95	Corrected SS	347029.435
Coeff Variation	-604.54707	Std Error Mean	17.0769252

Basic Statistical Measures

Location		Variability	
Mean	-16.7114	Std Deviation	101.02845
Median	-7.2000	Variance	10207
Mode	7.2000	Range	700.10000
		Interquartile Range	43.30000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.9786	Pr > |t|	0.3347
Sign	M	-2.5	Pr >= |M|	0.4869

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-63.5	Pr >= |S|	0.2625

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.586893	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.283307	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.781974	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.25589	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	173.2
99%	173.2
95%	93.8
90%	43.3
75% Q3	14.4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-7.2
25% Q1	-28.9
10%	-50.5
5%	-115.5
1%	-526.9
0% Min	-526.9

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-526.9	4	43.3	16
-115.5	33	43.3	22
-79.4	23	50.5	13
-50.5	26	93.8	35
-43.3	1	173.2	34

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
   Stem Leaf                     #    Boxplot                        Normal Probability Plot
      1 7                        1       *           175+                                    ++++*
      1                                              |                                  +++++
      0 59                       2       0           |                              +++++  *  *
      0 0011111122344           13    +-----+        |                         ****+*** ** *
     -0 444333322211111         15    *--+--*        |                 **** * ****+*
     -0 85                       2       |           |              **    +++++
     -1 2                        1       0           |           *   +++++
     -1                                              |        +++++
     -2                                              |  +++++
     -2                                              |++
     -3                                              |
     -3                                              |
     -4                                              |
     -4                                              |
     -5 3                        1       *    -525+    *
        ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**+2                          -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	42	Sum Weights	42
Mean	127.840476	Sum Observations	5369.3
Std Deviation	123.158169	Variance	15167.9347
Skewness	4.09683909	Kurtosis	20.4583484
Uncorrected SS	1308299.19	Corrected SS	621885.321
Coeff Variation	96.3373831	Std Error Mean	19.0037181

Basic Statistical Measures

Location		Variability	
Mean	127.8405	Std Deviation	123.15817
Median	93.8000	Variance	15168
Mode	93.8000	Range	757.80000
		Interquartile Range	64.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.72713	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.5685	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.256365	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.917584	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	5.01176	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	786.7
99%	786.7
95%	245.4
90%	209.3
75% Q3	144.3

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	93.8
25% Q1	79.4
10%	43.3
5%	43.3
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	32	209.3	12
28.9	3	223.7	19
43.3	42	245.4	23
43.3	15	375.3	20
43.3	9	786.7	10

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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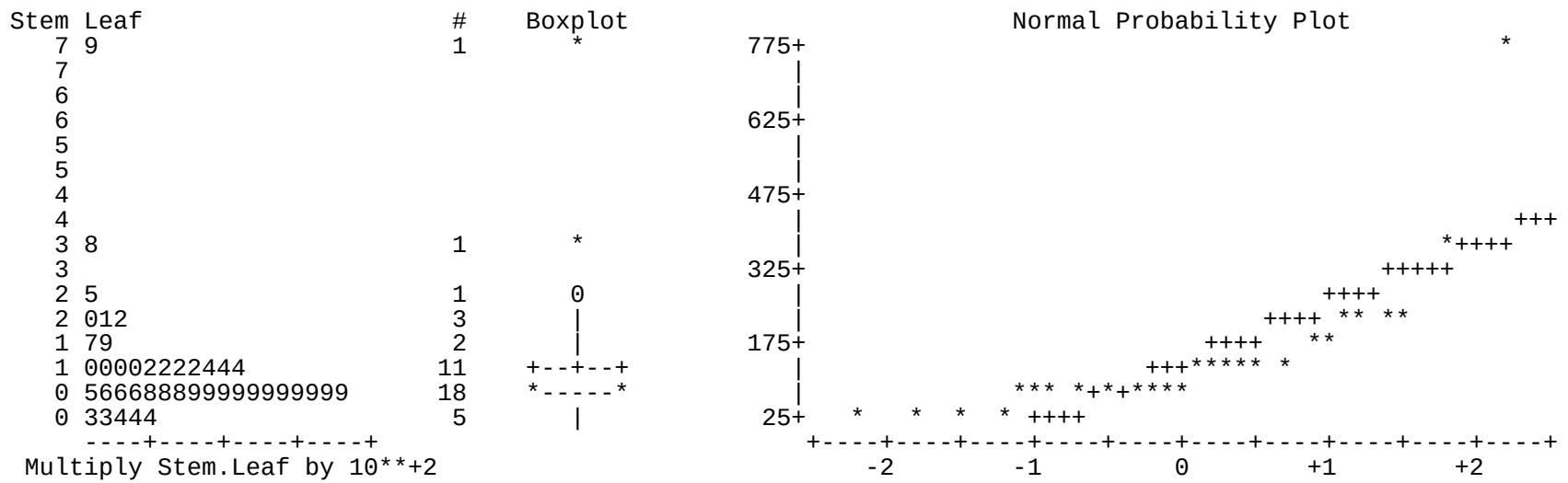
Population: Intent-to-Treat with LOCF

Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	42	Sum Weights	42
Mean	138.680952	Sum Observations	5824.6
Std Deviation	196.049126	Variance	38435.2596
Skewness	5.40573474	Kurtosis	32.3369693
Uncorrected SS	2383606.72	Corrected SS	1575845.64
Coeff Variation	141.367017	Std Error Mean	30.2510368

Basic Statistical Measures

Location		Variability	
Mean	138.6810	Std Deviation	196.04913
Median	93.8000	Variance	38435
Mode	108.3000	Range	1285
		Interquartile Range	57.70000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	4.584337	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.407722	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.294389	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.344175	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	7.251168	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1306.3
99%	1306.3
95%	288.7
90%	230.9
75% Q3	122.7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	93.8
25% Q1	65.0
10%	43.3
5%	36.1
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		-----Highest----	
Value	Obs	Value	Obs
21.7	32	230.9	11
36.1	30	238.2	22
36.1	6	288.7	19
36.1	3	288.7	20
43.3	38	1306.3	10

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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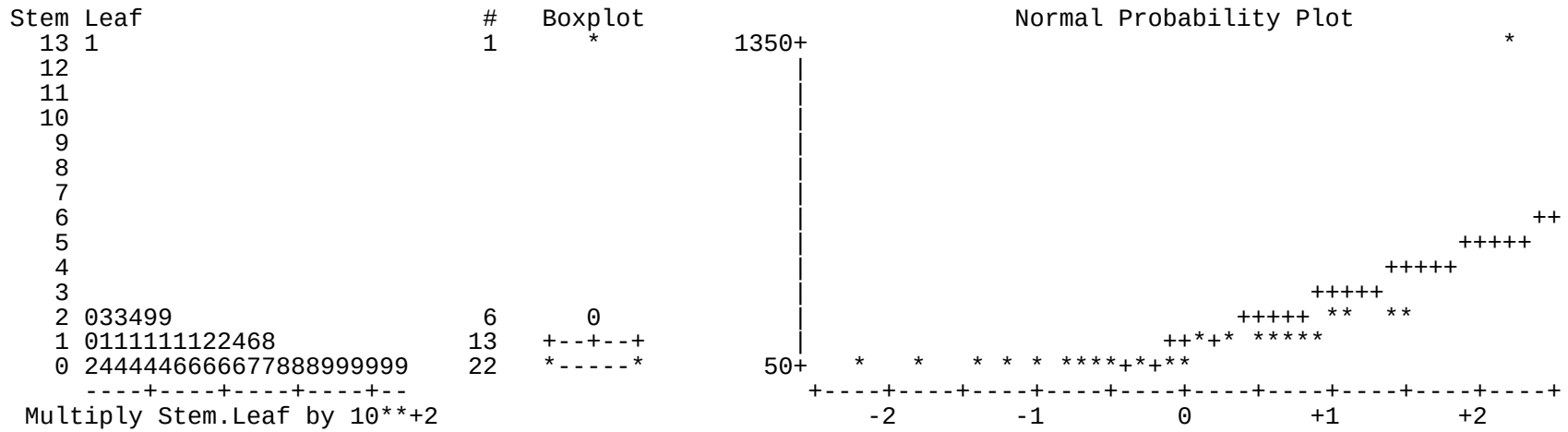
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	42	Sum Weights	42
Mean	10.8404762	Sum Observations	455.3
Std Deviation	95.4630565	Variance	9113.19515
Skewness	3.63937914	Kurtosis	20.1533338
Uncorrected SS	378576.67	Corrected SS	373641.001
Coeff Variation	880.616818	Std Error Mean	14.7302694

Basic Statistical Measures

Location		Variability	
Mean	10.84048	Std Deviation	95.46306
Median	3.60000	Variance	9113
Mode	-7.20000	Range	700.00000
		Interquartile Range	57.70000

NOTE: The mode displayed is the smallest of 3 modes with a count of 3.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.735932	Pr > |t|	0.4660
Sign	M	1	Pr >= |M|	0.8746
Signed Rank	S	26	Pr >= |S|	0.7314

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.647717	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.213815	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.606252	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.565622	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	519.6
99%	519.6
95%	93.9

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	64.9
75% Q3	28.9
50% Median	3.6
25% Q1	-28.8
10%	-57.8
5%	-79.4
1%	-180.4
0% Min	-180.4

Extreme Observations

-----Lowest----		----Highest----	
Value	Obs	Value	Obs
-180.4	23	64.9	11
-86.6	20	65.0	19
-79.4	30	93.9	22
-64.9	6	115.4	8
-57.8	21	519.6	10

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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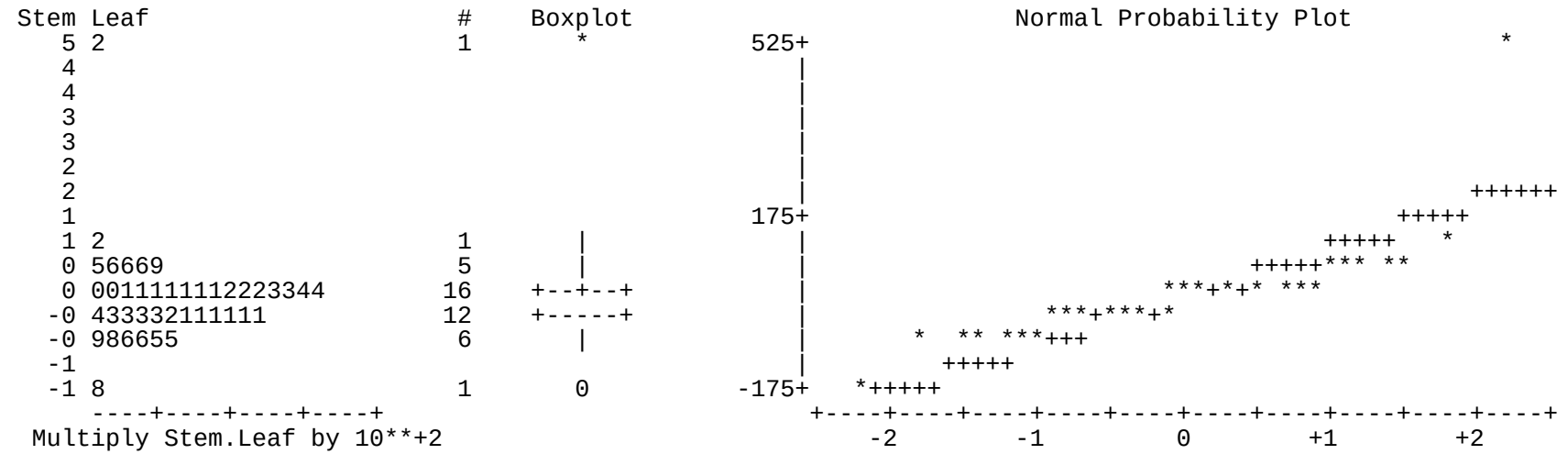
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	42	Sum Weights	42
Mean	103.1	Sum Observations	4330.2
Std Deviation	67.211265	Variance	4517.35415
Skewness	1.20282278	Kurtosis	0.80354056
Uncorrected SS	631655.14	Corrected SS	185211.52
Coeff Variation	65.1903637	Std Error Mean	10.3709233

Basic Statistical Measures

Location		Variability	
Mean	103.1000	Std Deviation	67.21127
Median	79.4000	Variance	4517
Mode	57.7000	Range	281.40000
		Interquartile Range	86.60000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.941256	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.869999	Pr < W	0.0002
Kolmogorov-Smirnov	D	0.221693	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.385091	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.049818	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	303.1
99%	303.1
95%	223.7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	202.1
75% Q3	144.3
50% Median	79.4
25% Q1	57.7
10%	43.3
5%	36.1
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	36	202.1	18
28.9	34	216.5	23
36.1	40	223.7	13
36.1	15	252.6	39
43.3	16	303.1	32

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

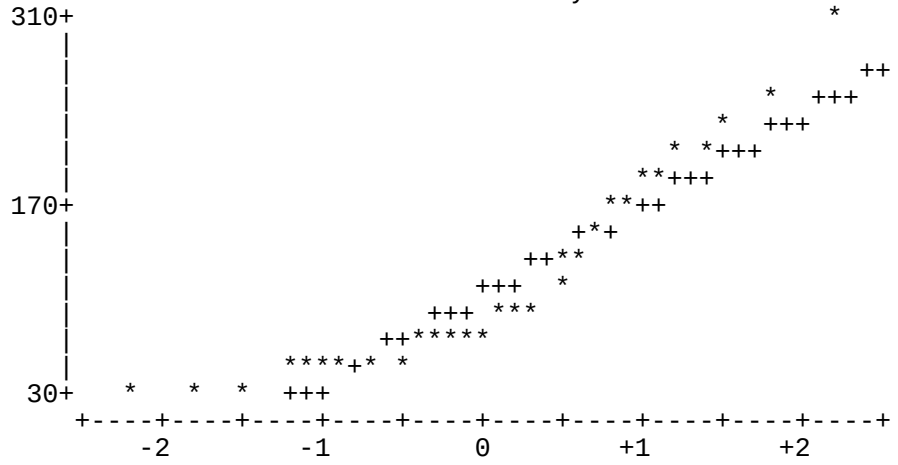
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                  #    Boxplot
    30 3                     1       0
    28                                |
    26                                |
    24 3                     1        |
    22 4                     1        |
    20 26                    2        |
    18 08                    2        |
    16 33                    2        |
    14 42                    2    +-----+
    12 37                    2    |     |
    10 8                     1    |  +  |
     8 77444                 5    |     |
     6 555599999             9    *-----*
     4 3330088888           10    +-----+
     2 2966                  4        |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```

Normal Probability Plot



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	42	Sum Weights	42
Mean	105.85	Sum Observations	4445.7
Std Deviation	73.6763034	Variance	5428.19768
Skewness	1.78713931	Kurtosis	3.32710962
Uncorrected SS	693133.45	Corrected SS	222556.105
Coeff Variation	69.6044435	Std Error Mean	11.3685004

Basic Statistical Measures

Location		Variability	
Mean	105.8500	Std Deviation	73.67630
Median	93.8000	Variance	5428
Mode	43.3000	Range	331.90000
		Interquartile Range	72.20000

NOTE: The mode displayed is the smallest of 2 modes with a count of 5.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.310815	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.812509	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.224831	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.393964	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.401456	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	353.6
99%	353.6
95%	281.5

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	187.6
75% Q3	122.7
50% Median	93.8
25% Q1	50.5
10%	43.3
5%	43.3
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	15	187.6	23
36.1	35	194.9	31
43.3	40	281.5	32
43.3	33	310.3	42
43.3	17	353.6	13

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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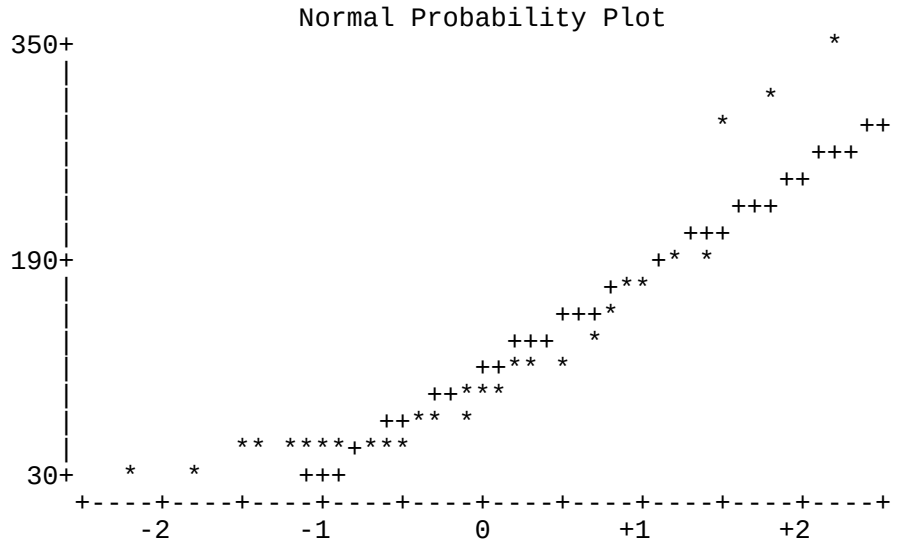
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                     #    Boxplot
     34 4                        1       *
     32
     30 0                        1       0
     28 2                        1       0
     26
     24
     22
     20
     18 85                       2       |
     16 633                      3       |
     14 4                        1       |
     12 37                       2    +-----+
     10 1188888                  7    |  +  |
      8 74444                    5    *-----*
      6 55222                    5    |     |
      4 333330000888            12    +-----+
      2 26                       2       |
        ----+----+----+----+
   Multiply Stem.Leaf by 10**+1
```



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	42	Sum Weights	42
Mean	2.75	Sum Observations	115.5
Std Deviation	50.350795	Variance	2535.20256
Skewness	0.60917638	Kurtosis	0.90828887
Uncorrected SS	104260.93	Corrected SS	103943.305
Coeff Variation	1830.938	Std Error Mean	7.76929635

Basic Statistical Measures

Location		Variability	
Mean	2.750000	Std Deviation	50.35080
Median	0.000000	Variance	2535
Mode	0.000000	Range	223.70000
		Interquartile Range	50.60000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.353957	Pr > |t|	0.7252
Sign	M	0.5	Pr >= |M|	1.0000

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-1	Pr >= |S|	0.9882

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.949352	Pr < W	0.0612
Kolmogorov-Smirnov	D	0.122026	Pr > D	0.1152
Cramer-von Mises	W-Sq	0.10996	Pr > W-Sq	0.0835
Anderson-Darling	A-Sq	0.705847	Pr > A-Sq	0.0635

Quantiles (Definition 5)

Quantile	Estimate
100% Max	129.9
99%	129.9
95%	108.3
90%	50.6
75% Q3	21.7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-28.9
10%	-64.9
5%	-79.3
1%	-93.8
0% Min	-93.8

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
-93.8	18	50.6	38
-79.4	39	79.4	19
-79.3	2	108.3	30
-72.1	26	129.9	42
-64.9	6	129.9	13

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
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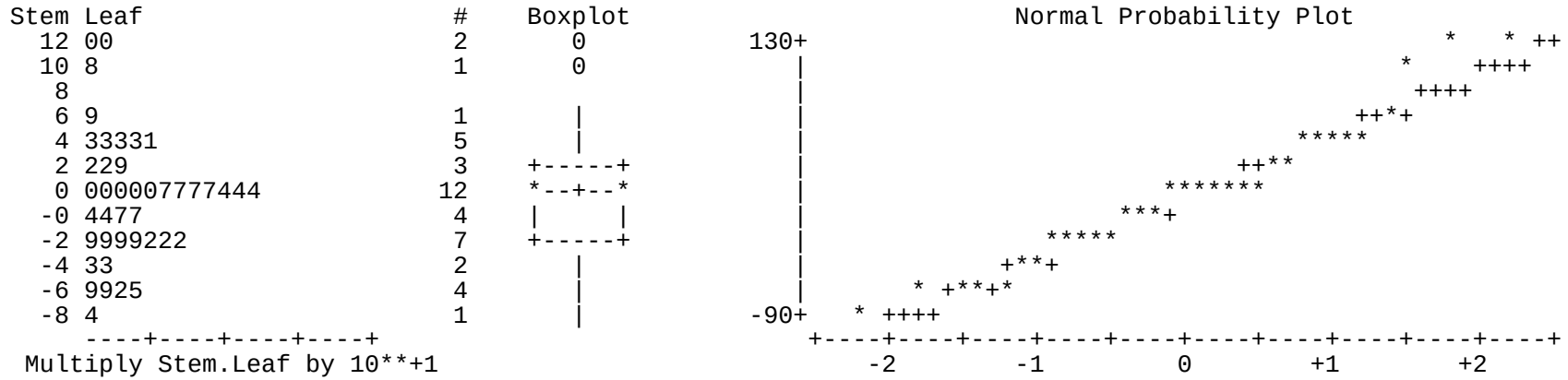
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	35	Sum Weights	35
Mean	88.0571429	Sum Observations	3082
Std Deviation	50.0545895	Variance	2505.46193
Skewness	0.82009696	Kurtosis	0.33587683
Uncorrected SS	356577.82	Corrected SS	85185.7057
Coeff Variation	56.8433041	Std Error Mean	8.46076986

Basic Statistical Measures

Location		Variability	
Mean	88.05714	Std Deviation	50.05459
Median	79.40000	Variance	2505
Mode	21.70000	Range	202.00000
		Interquartile Range	79.40000

NOTE: The mode displayed is the smallest of 6 modes with a count of 3.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.4077	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.939811	Pr < W	0.0552
Kolmogorov-Smirnov	D	0.111513	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.079701	Pr > W-Sq	0.2098
Anderson-Darling	A-Sq	0.558634	Pr > A-Sq	0.1424

Quantiles (Definition 5)

Quantile	Estimate
100% Max	223.7
99%	223.7
95%	194.9

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	158.8
75% Q3	122.7
50% Median	79.4
25% Q1	43.3
10%	36.1
5%	21.7
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	33	151.6	22
21.7	20	158.8	10
21.7	16	158.8	27
36.1	25	194.9	30
36.1	14	223.7	7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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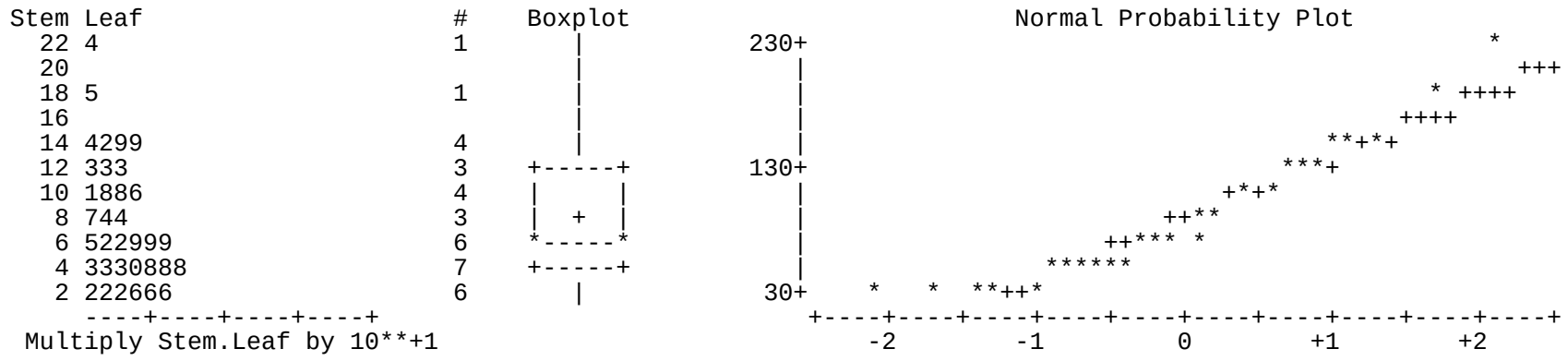
Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	35	Sum Weights	35
Mean	101.657143	Sum Observations	3558
Std Deviation	61.6715603	Variance	3803.38134
Skewness	1.18040851	Kurtosis	1.27027669
Uncorrected SS	491011.08	Corrected SS	129314.966
Coeff Variation	60.6662341	Std Error Mean	10.4243963

Basic Statistical Measures

Location		Variability	
Mean	101.6571	Std Deviation	61.67156
Median	86.6000	Variance	3803
Mode	57.7000	Range	259.80000
		Interquartile Range	72.20000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.751849	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.901199	Pr < W	0.0043
Kolmogorov-Smirnov	D	0.150689	Pr > D	0.0431
Cramer-von Mises	W-Sq	0.15768	Pr > W-Sq	0.0190
Anderson-Darling	A-Sq	0.991819	Pr > A-Sq	0.0119

Quantiles (Definition 5)

Quantile	Estimate
100% Max	288.7
99%	288.7
95%	223.7
90%	187.6
75% Q3	129.9

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	86.6
25% Q1	57.7
10%	36.1
5%	28.9
1%	28.9
0% Min	28.9

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
28.9	33	173.2	30
28.9	16	187.6	27
36.1	14	216.5	31
36.1	2	223.7	5
43.3	20	288.7	7

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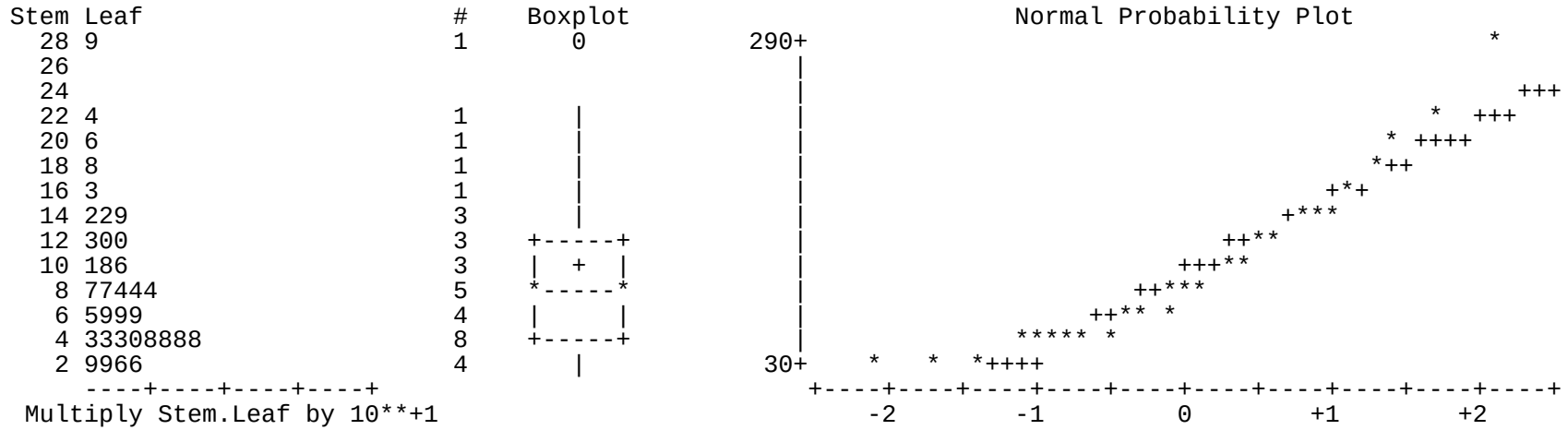
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	35	Sum Weights	35
Mean	13.6	Sum Observations	476
Std Deviation	32.164906	Variance	1034.58118
Skewness	0.96477899	Kurtosis	1.92768242
Uncorrected SS	41649.36	Corrected SS	35175.76
Coeff Variation	236.506662	Std Error Mean	5.43686143

Basic Statistical Measures

Location		Variability	
Mean	13.60000	Std Deviation	32.16491
Median	7.20000	Variance	1035
Mode	0.00000	Range	158.70000
		Interquartile Range	28.80000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	2.501443	Pr > |t|	0.0173
Sign	M	6.5	Pr >= |M|	0.0192

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	94.5	Pr >= |S|	0.0200

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.931739	Pr < W	0.0315
Kolmogorov-Smirnov	D	0.177642	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.170389	Pr > W-Sq	0.0126
Anderson-Darling	A-Sq	0.875822	Pr > A-Sq	0.0229

Quantiles (Definition 5)

Quantile	Estimate
100% Max	115.4
99%	115.4
95%	72.2
90%	57.7
75% Q3	28.8

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	7.2
25% Q1	0.0
10%	-21.7
5%	-36.1
1%	-43.3
0% Min	-43.3

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
-43.3	2	50.5	4
-36.1	15	57.7	17
-36.1	22	65.0	7
-21.7	30	72.2	31
-14.5	12	115.4	5

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

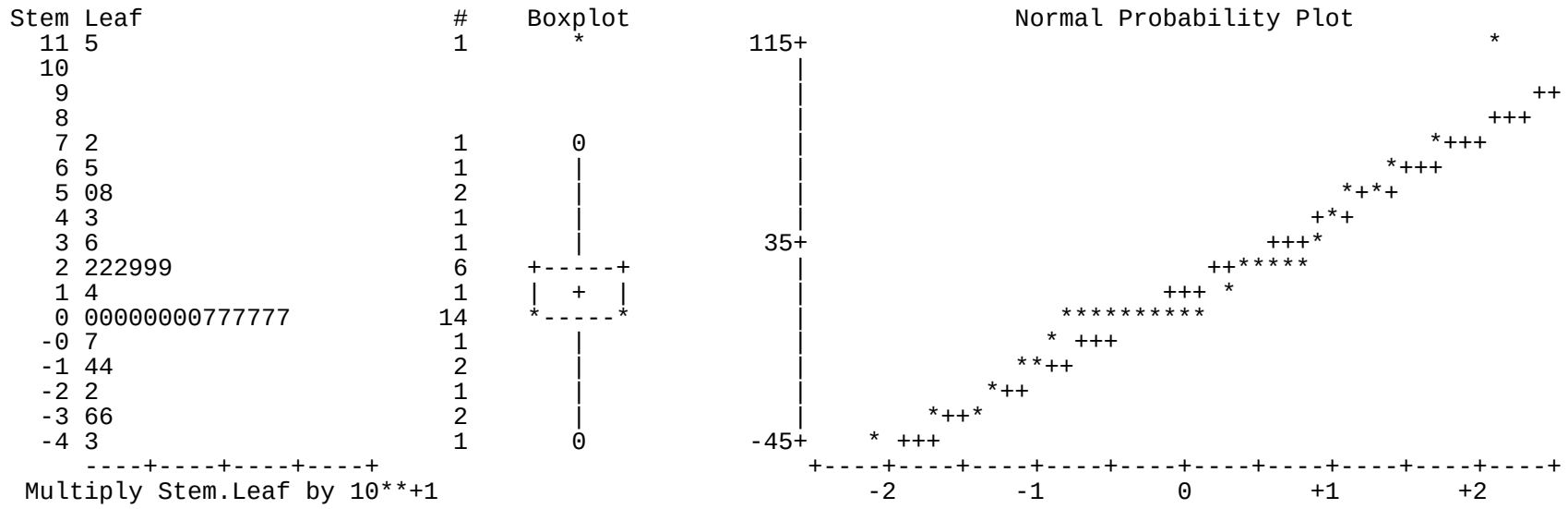

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	34	Sum Weights	34
Mean	96.8	Sum Observations	3291.2
Std Deviation	56.100921	Variance	3147.31333
Skewness	0.94370129	Kurtosis	0.14828157
Uncorrected SS	422449.5	Corrected SS	103861.34
Coeff Variation	57.9554969	Std Error Mean	9.62122857

Basic Statistical Measures

Location		Variability	
Mean	96.80000	Std Deviation	56.10092
Median	79.40000	Variance	3147
Mode	79.40000	Range	223.70000
		Interquartile Range	79.40000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.06109	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.90352	Pr < W	0.0057
Kolmogorov-Smirnov	D	0.219195	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.256331	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.311686	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	245.4
99%	245.4
95%	209.3
90%	180.4
75% Q3	137.1

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	79.4
25% Q1	57.7
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	17	173.2	10
28.9	12	180.4	26
36.1	18	180.4	32
36.1	15	209.3	23
36.1	2	245.4	29

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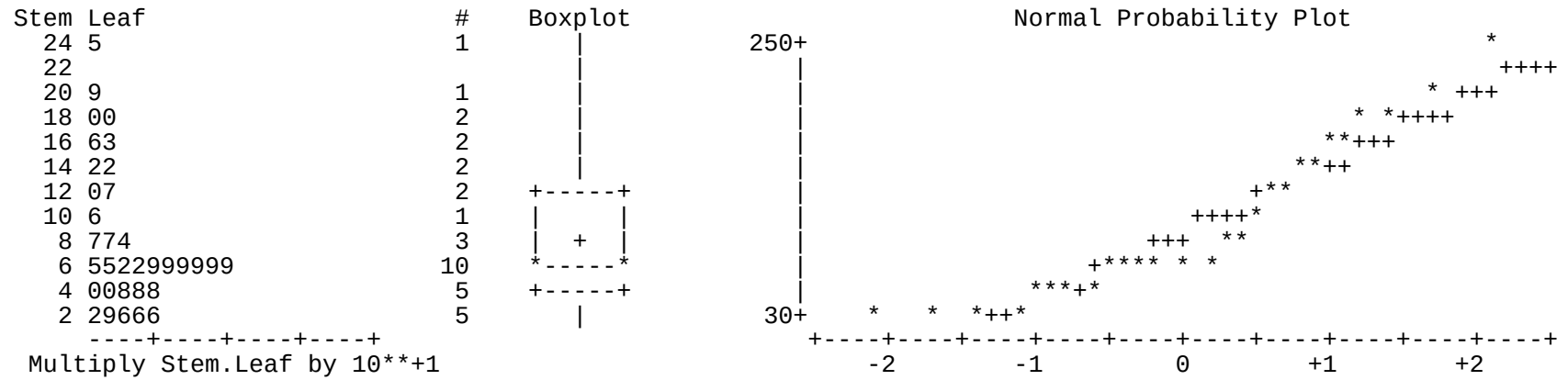
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	34	Sum Weights	34
Mean	109.538235	Sum Observations	3724.3
Std Deviation	71.5535867	Variance	5119.91577
Skewness	1.08070191	Kurtosis	0.77994546
Uncorrected SS	576910.47	Corrected SS	168957.22
Coeff Variation	65.3229317	Std Error Mean	12.2713389

Basic Statistical Measures

Location		Variability	
Mean	109.5382	Std Deviation	71.55359
Median	90.2000	Variance	5120
Mode	65.0000	Range	295.80000
		Interquartile Range	101.10000

NOTE: The mode displayed is the smallest of 3 modes with a count of 3.

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test		-Statistic-		-----p Value------
Student's t	t	8.926348	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test		--Statistic---		-----p Value------
Shapiro-Wilk	W	0.905718	Pr < W	0.0065
Kolmogorov-Smirnov	D	0.153962	Pr > D	0.0401
Cramer-von Mises	W-Sq	0.175943	Pr > W-Sq	0.0099
Anderson-Darling	A-Sq	1.026478	Pr > A-Sq	0.0094

Quantiles (Definition 5)

Quantile	Estimate
100% Max	317.5
99%	317.5
95%	245.4

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	216.5
75% Q3	158.8
50% Median	90.2
25% Q1	57.7
10%	36.1
5%	28.9
1%	21.7
0% Min	21.7

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
21.7	2	209.3	29
28.9	15	216.5	24
28.9	12	223.7	22
36.1	21	245.4	26
36.1	6	317.5	23

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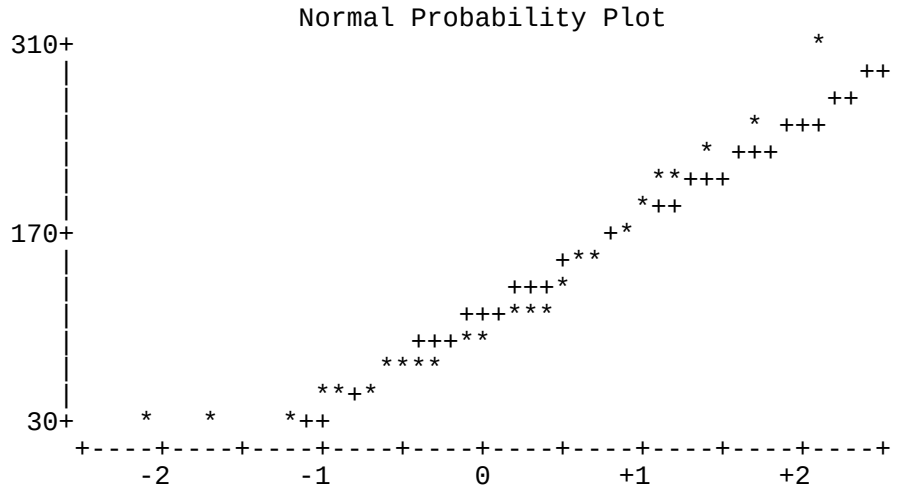
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
  Stem Leaf                  #    Boxplot
    30 8                     1       0
    28                              |
    26                              |
    24 5                     1      |
    22 4                     1      |
    20 96                    2      |
    18 0                     1      |
    16 3                     1      |
    14 499                   3    +-----+
    12 0                     1    |     |
    10 8886                  4    |  +  |
     8 7744                  4    *-----*
     6 555222                6    |     |
     4 3008                  4    +-----+
     2 29966                 5      |
       ----+----+----+----+
  Multiply Stem.Leaf by 10**+1
```



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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	34	Sum Weights	34
Mean	12.7382353	Sum Observations	433.1
Std Deviation	50.6500831	Variance	2565.43092
Skewness	0.89683657	Kurtosis	0.65250286
Uncorrected SS	90176.15	Corrected SS	84659.2203
Coeff Variation	397.622449	Std Error Mean	8.68641759

Basic Statistical Measures

Location		Variability	
Mean	12.73824	Std Deviation	50.65008
Median	0.00000	Variance	2565
Mode	0.00000	Range	223.70000
		Interquartile Range	64.90000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.466454	Pr > |t|	0.1520
Sign	M	-0.5	Pr >= |M|	1.0000

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	36	Pr >= |S|	0.4457

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.917492	Pr < W	0.0137
Kolmogorov-Smirnov	D	0.192796	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.255636	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.282901	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	144.3
99%	144.3
95%	122.6
90%	86.6
75% Q3	50.5

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0
25% Q1	-14.4
10%	-36.1
5%	-65.0
1%	-79.4
0% Min	-79.4

Extreme Observations

----Lowest----		----Highest----	
Value	Obs	Value	Obs
-79.4	10	65.0	9
-65.0	13	86.6	24
-36.1	29	108.2	23
-36.1	5	122.6	17
-28.8	14	144.3	22

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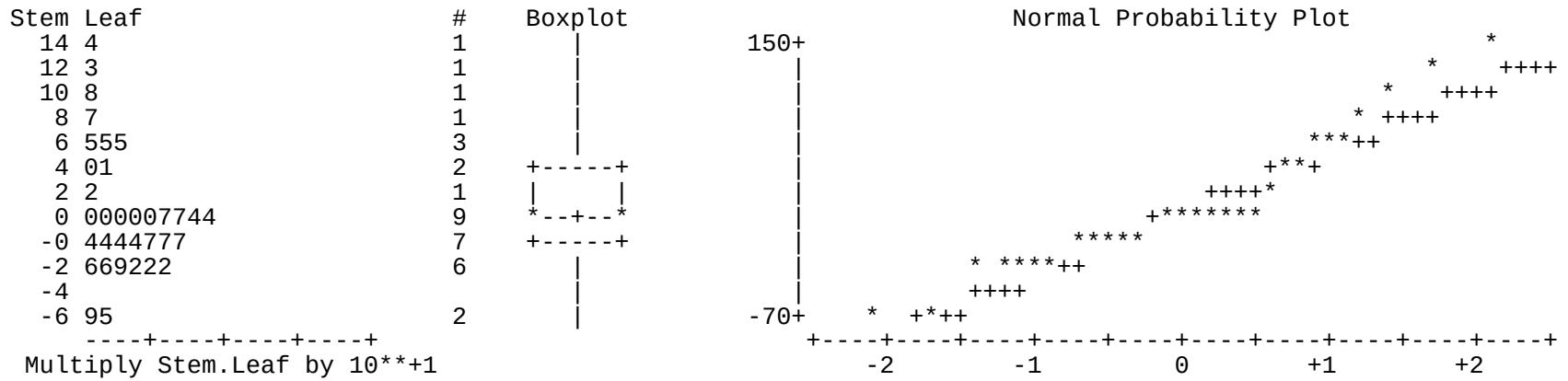
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



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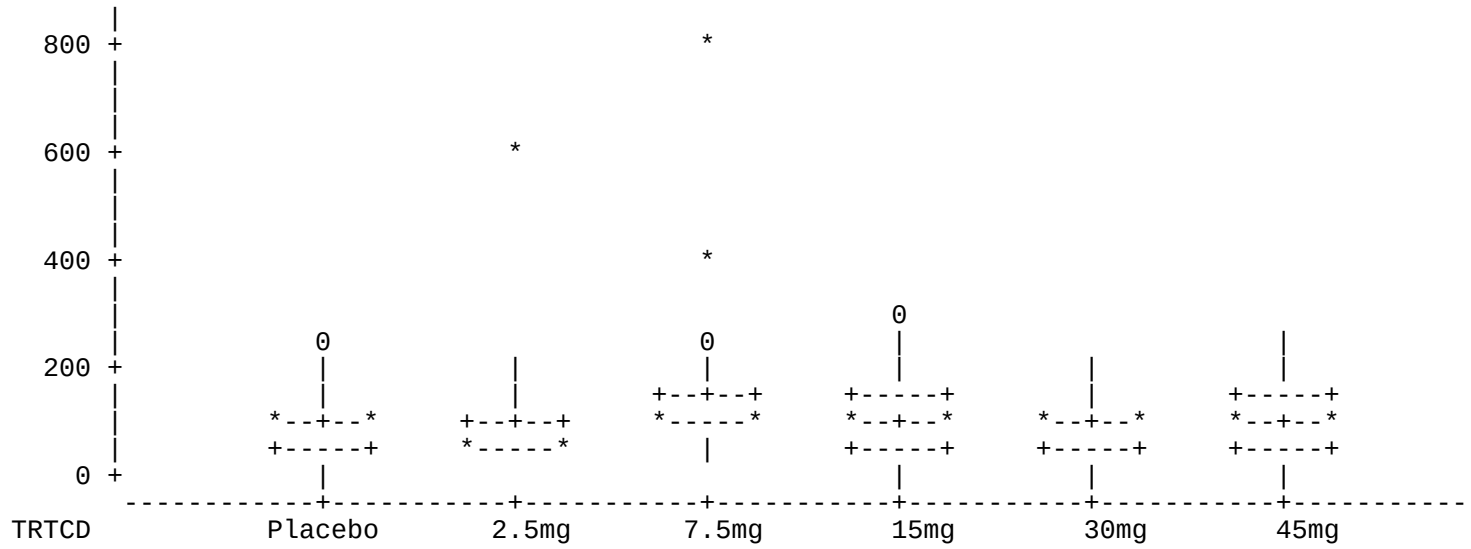
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



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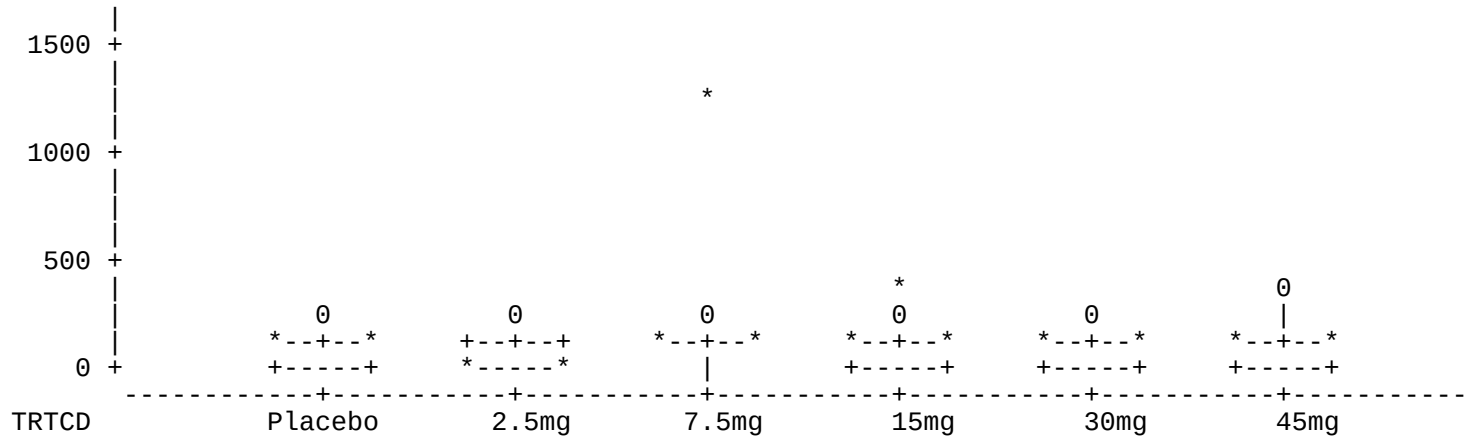
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



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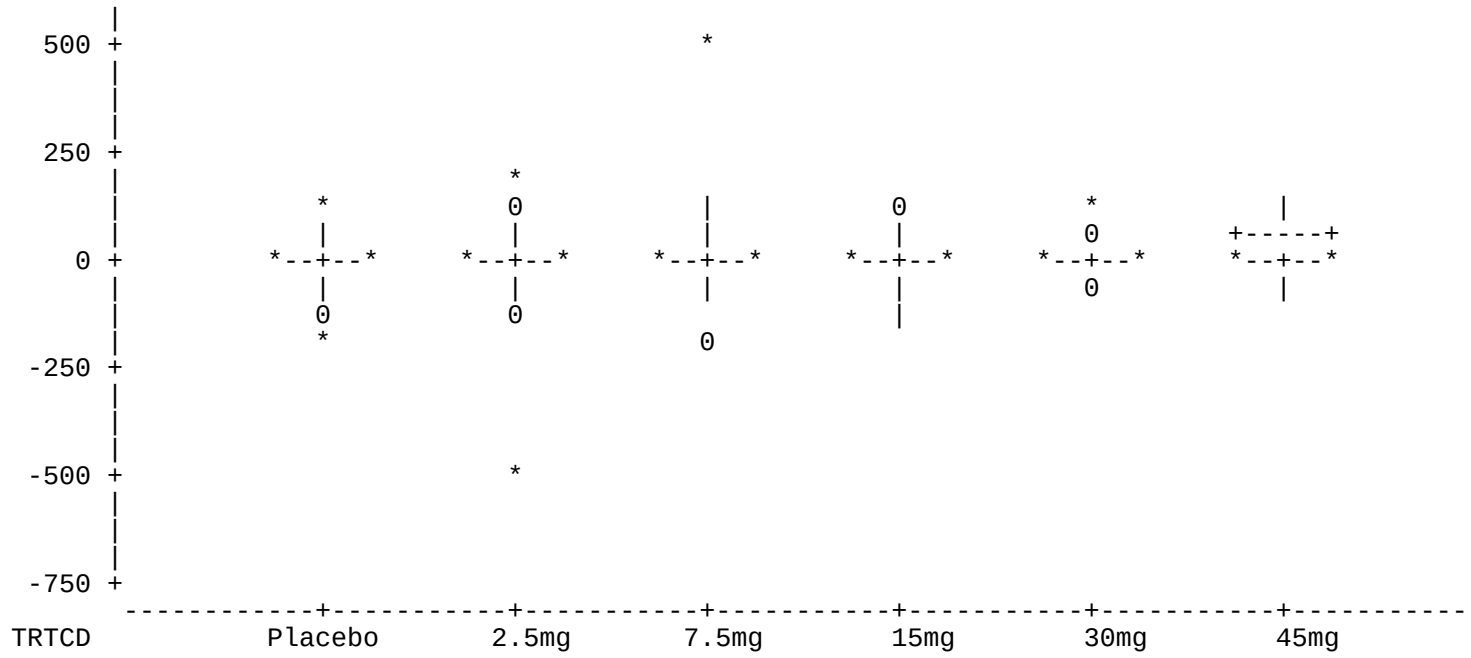
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg

Dimensions

Covariance Parameters	1
Columns in X	12
Columns in Z	0
Subjects	1
Max Obs Per Subject	221
Observations Used	221
Observations Not Used	0
Total Observations	221

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The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	4865.19	472.55	10.30	<.0001	0.05	4057.23	5942.45

Fit Statistics

-2 Res Log Likelihood	2445.2
AIC (smaller is better)	2447.2
AICC (smaller is better)	2447.2
BIC (smaller is better)	2450.5

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept				14.9465	14.5168	212	1.03	0.3044
SEX	Female			5.5258	9.4946	212	0.58	0.5612
SEX	Male			0				.
TRTTYPCD		Diet & Exercise		-1.1795	9.6263	212	-0.12	0.9026
TRTTYPCD		Monotherapy		0				.
TRTCD			Placebo	-13.3639	17.0638	212	-0.78	0.4344
TRTCD			2.5mg	-30.4381	16.9301	212	-1.80	0.0736
TRTCD			7.5mg	-0.9028	16.2334	212	-0.06	0.9557
TRTCD			15mg	-9.6915	16.1616	212	-0.60	0.5494

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
TRTCD			30mg	-0.4665	16.8838	212	-0.03	0.9780
TRTCD			45mg	0				.
EFSTDBL				-0.04190	0.05918	212	-0.71	0.4797

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	212	0.34	0.5612
TRTTYPCD	1	212	0.02	0.9026
TRTCD	5	212	1.01	0.4123
EFSTDBL	1	212	0.50	0.4797

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-17.0741	17.0324	212	-1.00	0.3173	0.05	-50.6487	16.5004
7.5mg vs Pbo	12.4611	16.4231	212	0.76	0.4488	0.05	-19.9125	44.8346
15mg vs Pbo	3.6724	16.3543	212	0.22	0.8225	0.05	-28.5654	35.9102
30mg vs Pbo	12.8974	16.9639	212	0.76	0.4479	0.05	-20.5421	46.3370

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
45mg vs Pbo	13.3639	17.0638	212	0.78	0.4344	0.05	-20.2725	47.0004

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5	Row6
Intercept				1	1	1	1	1	1
SEX	Female			0.5023	0.5023	0.5023	0.5023	0.5023	0.5023
SEX	Male			0.4977	0.4977	0.4977	0.4977	0.4977	0.4977
TRTTYPCD		Diet & Exercise		0.4208	0.4208	0.4208	0.4208	0.4208	0.4208
TRTTYPCD		Monotherapy		0.5792	0.5792	0.5792	0.5792	0.5792	0.5792
TRTCD			Placebo	1					
TRTCD			2.5mg		1				
TRTCD			7.5mg			1			
TRTCD			15mg				1		
TRTCD			30mg					1	
TRTCD			45mg						1
EFSTDBL				101.96	101.96	101.96	101.96	101.96	101.96

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.4108	12.1979	212	-0.03	0.9732	0.05	-24.4556	23.6339
TRTCD	2.5mg	WORK.EFF	-17.4850	11.8504	212	-1.48	0.1416	0.05	-40.8447	5.8748
TRTCD	7.5mg	WORK.EFF	12.0502	10.8782	212	1.11	0.2692	0.05	-9.3931	33.4936
TRTCD	15mg	WORK.EFF	3.2616	10.8214	212	0.30	0.7634	0.05	-18.0697	24.5929
TRTCD	30mg	WORK.EFF	12.4866	11.8577	212	1.05	0.2935	0.05	-10.8875	35.8607
TRTCD	45mg	WORK.EFF	12.9531	12.0052	212	1.08	0.2818	0.05	-10.7118	36.6179

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	17.0741	17.0324	212	1.00	0.3173	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-16.5004	50.6487

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	7.5mg	WORK.EFF	-12.4611	16.4231	212	-0.76	0.4488	0.05
TRTCD	Placebo	15mg	WORK.EFF	-3.6724	16.3543	212	-0.22	0.8225	0.05
TRTCD	Placebo	30mg	WORK.EFF	-12.8974	16.9639	212	-0.76	0.4479	0.05
TRTCD	Placebo	45mg	WORK.EFF	-13.3639	17.0638	212	-0.78	0.4344	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	-29.5352	16.1085	212	-1.83	0.0681	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-20.7465	16.0743	212	-1.29	0.1982	0.05
TRTCD	2.5mg	30mg	WORK.EFF	-29.9716	16.7085	212	-1.79	0.0743	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-30.4381	16.9301	212	-1.80	0.0736	0.05
TRTCD	7.5mg	15mg	WORK.EFF	8.7887	15.3074	212	0.57	0.5665	0.05
TRTCD	7.5mg	30mg	WORK.EFF	-0.4364	16.1891	212	-0.03	0.9785	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-0.9028	16.2334	212	-0.06	0.9557	0.05
TRTCD	15mg	30mg	WORK.EFF	-9.2250	16.1179	212	-0.57	0.5677	0.05
TRTCD	15mg	45mg	WORK.EFF	-9.6915	16.1616	212	-0.60	0.5494	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.4665	16.8838	212	-0.03	0.9780	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	7.5mg	-44.8346	19.9125
TRTCD	Placebo	15mg	-35.9102	28.5654
TRTCD	Placebo	30mg	-46.3370	20.5421
TRTCD	Placebo	45mg	-47.0004	20.2725

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	2.5mg	7.5mg	-61.2886	2.2181
TRTCD	2.5mg	15mg	-52.4325	10.9395
TRTCD	2.5mg	30mg	-62.9077	2.9645
TRTCD	2.5mg	45mg	-63.8109	2.9348
TRTCD	7.5mg	15mg	-21.3856	38.9630
TRTCD	7.5mg	30mg	-32.3485	31.4758
TRTCD	7.5mg	45mg	-32.9025	31.0968
TRTCD	15mg	30mg	-40.9970	22.5469
TRTCD	15mg	45mg	-41.5495	22.1665
TRTCD	30mg	45mg	-33.7481	32.8152

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.

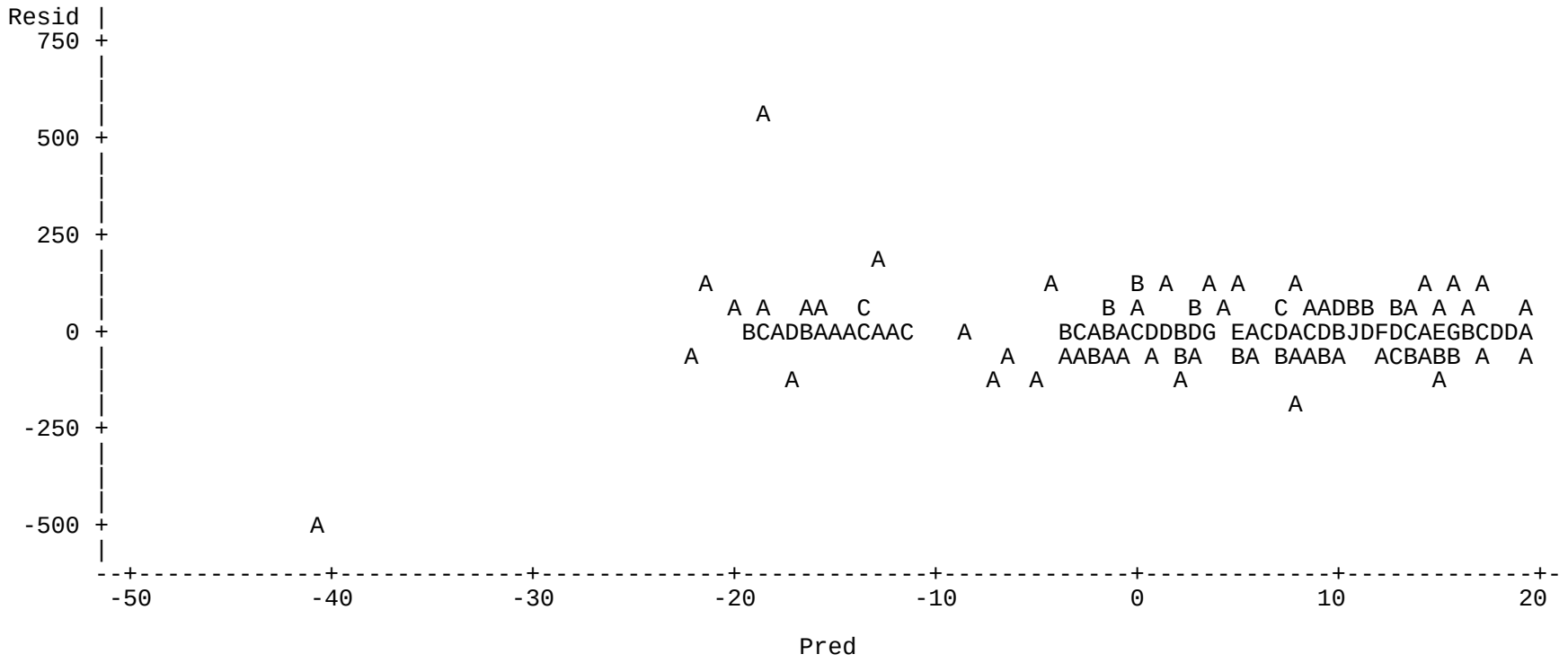

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

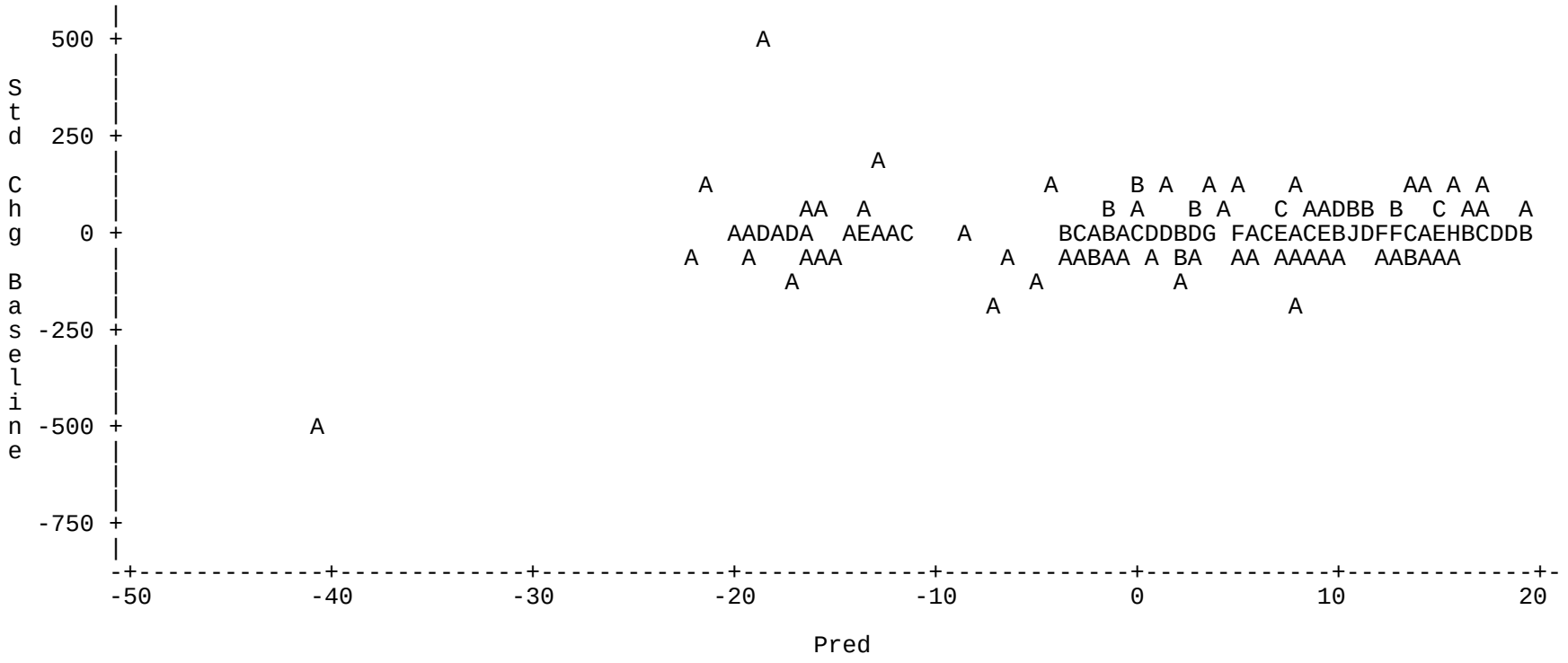

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Table 11.67
SAS Statistical Output for Table 11.66
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	221	Sum Weights	221
Mean	0	Sum Observations	0
Std Deviation	68.4709753	Variance	4688.27445
Skewness	0.72715256	Kurtosis	28.0515335
Uncorrected SS	1031420.38	Corrected SS	1031420.38
Coeff Variation		Std Error Mean	4.60585622

Basic Statistical Measures

Location		Variability	
Mean	0.0000	Std Deviation	68.47098
Median	-4.2940	Variance	4688
Mode	-34.1286	Range	1025
		Interquartile Range	45.80115

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-12.5	Pr >= |M|	0.1062

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-954.5	Pr >= |S|	0.3169

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.724349	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.142369	Pr > D	<0.0100
Cramer-von Mises	W-Sq	1.989936	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	11.14334	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	538.52245
99%	148.73692
95%	103.20362
90%	54.80454
75% Q3	20.85178
50% Median	-4.29396
25% Q1	-24.94937

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Table 11.67
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Quantiles (Definition 5)

Quantile	Estimate
10%	-48.57359
5%	-73.53177
1%	-151.61199
0% Min	-486.03337

Extreme Observations

------Lowest------		-----Highest-----	
Value	Obs	Value	Obs
-486.0334	20	129.673	62
-188.5066	118	130.018	207
-151.6120	60	148.737	137
-98.0020	180	186.191	189
-96.1119	105	538.522	36

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Residual Plots

The UNIVARIATE Procedure
Variable: Resid

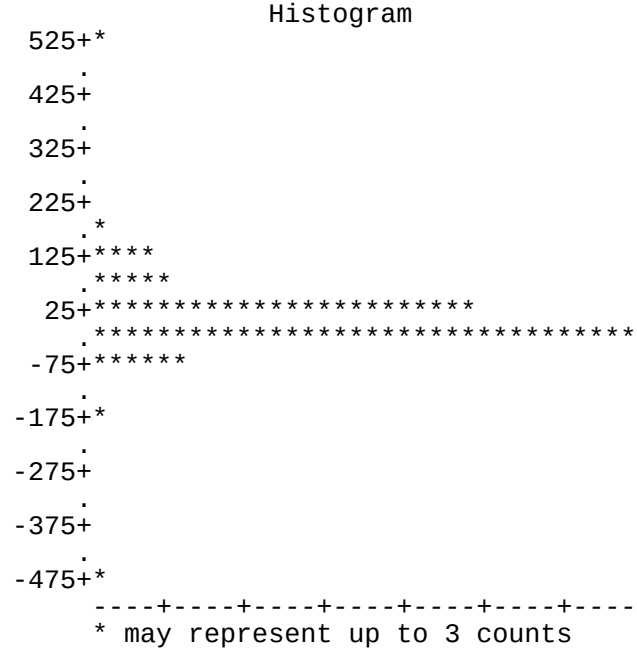

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Table 11.67
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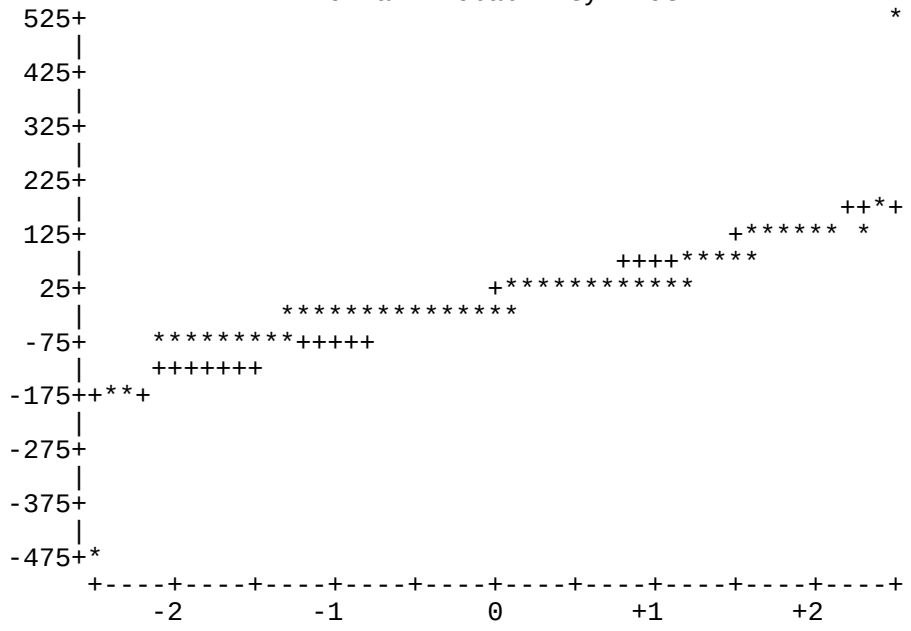
Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Population: Intent-to-Treat with LOCF

Table 11.68

Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

		Placebo (N=26)	2.5mg (N=18)	7.5mg (N=18)	15mg (N=20)	30mg (N=20)	45mg (N=21)
n [1]		23	17	16	20	18	20
Number (%) of Values Carried Forward		5 (22%)	4 (24%)	4 (25%)	0	0	4 (20%)
Baseline	Mean	82.96	115.41	77.25	105.90	86.33	131.10
	SD	41.713	56.942	45.636	63.566	42.333	94.031
Week 12	Mean	83.22	112.94	91.13	115.80	75.33	132.90
	SD	37.788	52.274	65.990	86.184	32.554	85.615
Chg from Baseline	Mean	0.26	-2.47	13.88	9.90	-11.00	1.80
	SD	24.968	34.925	37.930	88.381	34.819	61.500
Model-Adj Chg [2]	Mean	-4.89	-5.29	7.19	14.59	-17.91	17.00
	SE	9.911	11.755	12.025	10.589	11.186	10.946
Diff from Pbo [2]	Mean		-0.39	12.09	19.49	-13.02	21.89
	95% CI		-31.08,30.30	-18.59,42.76	-9.35,48.33	-42.48,16.44	-7.74,51.52
	p-val [3]		0.980	0.436	0.183	0.383	0.146

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	23	Sum Weights	23
Mean	82.9565217	Sum Observations	1908
Std Deviation	41.7127387	Variance	1739.95257
Skewness	0.56788406	Kurtosis	0.78703761
Uncorrected SS	196560	Corrected SS	38278.9565
Coeff Variation	50.2826515	Std Error Mean	8.69770727

Basic Statistical Measures

Location		Variability	
Mean	82.95652	Std Deviation	41.71274
Median	84.00000	Variance	1740
Mode	96.00000	Range	174.00000
		Interquartile Range	48.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.537746	Pr > |t|	<.0001
Sign	M	11.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	138	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.955829	Pr < W	0.3845
Kolmogorov-Smirnov	D	0.150088	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.052138	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.33679	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	192
99%	192
95%	138
90%	138
75% Q3	102

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	84
25% Q1	54
10%	30
5%	18
1%	18
0% Min	18

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
18	17	102	21
18	1	126	13
30	16	138	3
36	15	138	7
48	11	192	6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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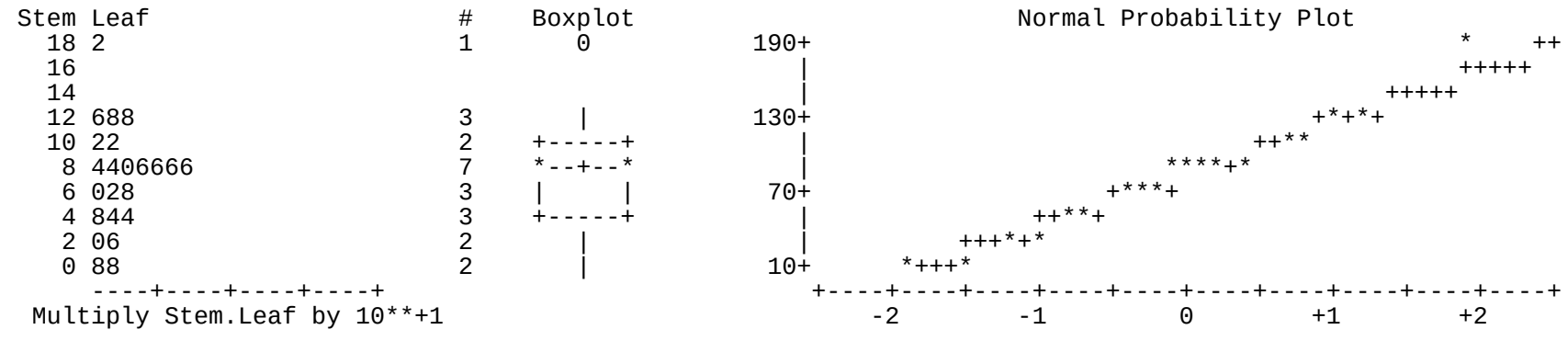
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	23	Sum Weights	23
Mean	83.2173913	Sum Observations	1914
Std Deviation	37.7876321	Variance	1427.90514
Skewness	0.52782705	Kurtosis	0.15156106
Uncorrected SS	190692	Corrected SS	31413.913
Coeff Variation	45.4083353	Std Error Mean	7.87926596

Basic Statistical Measures

Location		Variability	
Mean	83.21739	Std Deviation	37.78763
Median	78.00000	Variance	1428
Mode	66.00000	Range	144.00000
		Interquartile Range	42.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 4.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.56157	Pr > |t|	<.0001
Sign	M	11.5	Pr >= |M|	<.0001
Signed Rank	S	138	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.953595	Pr < W	0.3468
Kolmogorov-Smirnov	D	0.125529	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.05766	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.379715	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	168
99%	168
95%	156

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	138
75% Q3	108
50% Median	78
25% Q1	66
10%	30
5%	30
1%	24
0% Min	24

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
24	1	108	14
30	17	108	22
30	15	138	20
42	12	156	6
48	5	168	7

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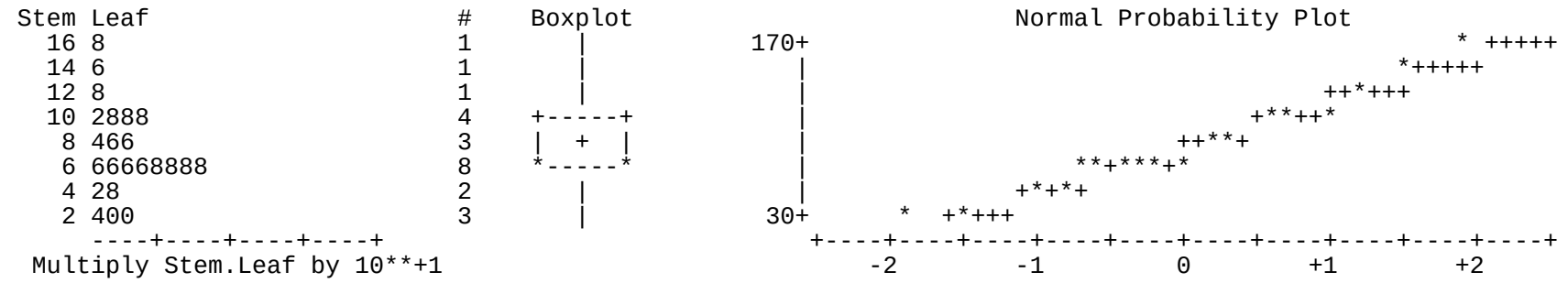
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	23	Sum Weights	23
Mean	0.26086957	Sum Observations	6
Std Deviation	24.967647	Variance	623.383399
Skewness	0.28969436	Kurtosis	-0.8528155
Uncorrected SS	13716	Corrected SS	13714.4348
Coeff Variation	9570.93137	Std Error Mean	5.20611429

Basic Statistical Measures

Location		Variability	
Mean	0.2609	Std Deviation	24.96765
Median	0.0000	Variance	623.38340
Mode	-18.0000	Range	84.00000
		Interquartile Range	36.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 3.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.050108	Pr > |t|	0.9605
Sign	M	0	Pr >= |M|	1.0000
Signed Rank	S	-1.5	Pr >= |S|	0.9624

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.959286	Pr < W	0.4491
Kolmogorov-Smirnov	D	0.115553	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.035279	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.260809	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	48
99%	48
95%	42

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	36
75% Q3	18
50% Median	0
25% Q1	-18
10%	-30
5%	-36
1%	-36
0% Min	-36

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-36	6	24	23
-36	3	30	7
-30	13	36	16
-30	5	42	20
-24	4	48	10

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

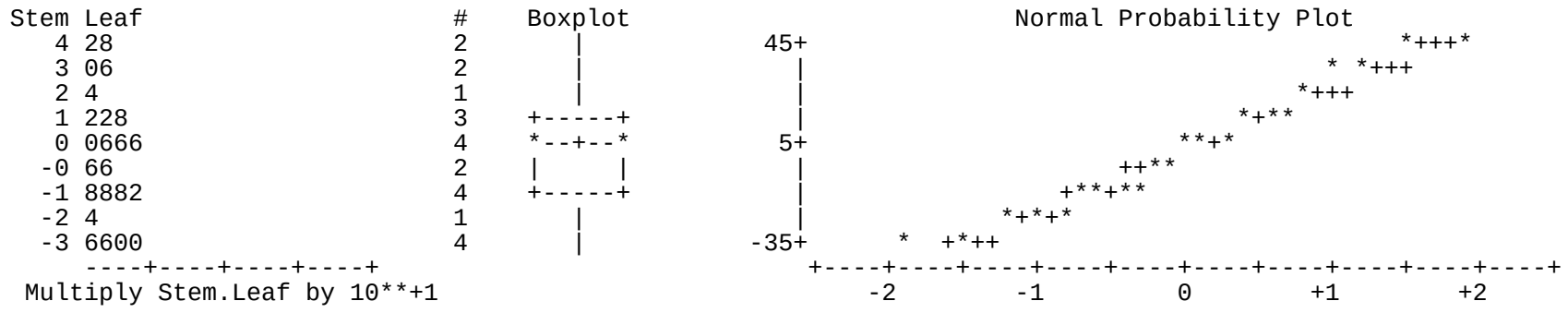

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	17	Sum Weights	17
Mean	115.411765	Sum Observations	1962
Std Deviation	56.9419209	Variance	3242.38235
Skewness	0.35903743	Kurtosis	-1.1826334
Uncorrected SS	278316	Corrected SS	51878.1176
Coeff Variation	49.3380558	Std Error Mean	13.8104444

Basic Statistical Measures

Location		Variability	
Mean	115.4118	Std Deviation	56.94192
Median	90.0000	Variance	3242
Mode	90.0000	Range	186.00000
		Interquartile Range	90.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.356847	Pr > |t|	<.0001
Sign	M	8.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	76.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.932911	Pr < W	0.2434
Kolmogorov-Smirnov	D	0.201713	Pr > D	0.0656
Cramer-von Mises	W-Sq	0.082926	Pr > W-Sq	0.1831
Anderson-Darling	A-Sq	0.488047	Pr > A-Sq	0.2023

Quantiles (Definition 5)

Quantile	Estimate
100% Max	216
99%	216
95%	216
90%	192
75% Q3	162

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	90
25% Q1	72
10%	54
5%	30
1%	30
0% Min	30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
30	14	162	12
54	5	186	6
60	11	186	13
60	3	192	17
72	2	216	9

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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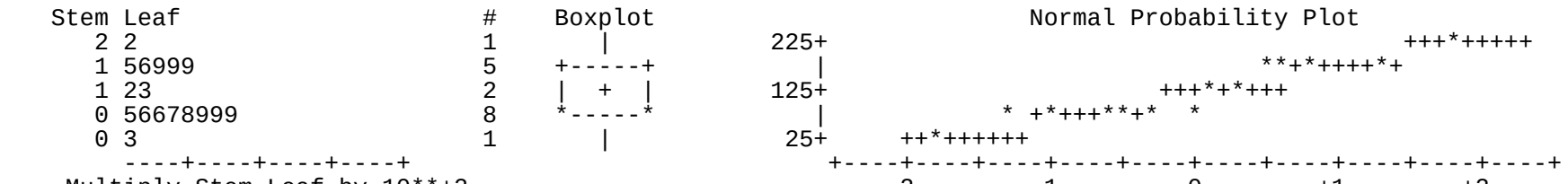
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	17	Sum Weights	17
Mean	112.941176	Sum Observations	1920
Std Deviation	52.2738828	Variance	2732.55882
Skewness	0.8545428	Kurtosis	-0.2670004
Uncorrected SS	260568	Corrected SS	43720.9412
Coeff Variation	46.2841671	Std Error Mean	12.6782788

Basic Statistical Measures

Location		Variability	
Mean	112.9412	Std Deviation	52.27388
Median	96.0000	Variance	2733
Mode	84.0000	Range	174.00000
		Interquartile Range	60.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.908242	Pr > |t|	<.0001
Sign	M	8.5	Pr >= |M|	<.0001

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	76.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.909821	Pr < W	0.0993
Kolmogorov-Smirnov	D	0.184713	Pr > D	0.1241
Cramer-von Mises	W-Sq	0.105882	Pr > W-Sq	0.0886
Anderson-Darling	A-Sq	0.608939	Pr > A-Sq	0.0961

Quantiles (Definition 5)

Quantile	Estimate
100% Max	222
99%	222
95%	222
90%	204
75% Q3	138

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	96
25% Q1	78
10%	54
5%	48
1%	48
0% Min	48

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
48	11	138	12
54	3	162	17
66	15	180	9
72	1	204	13
78	5	222	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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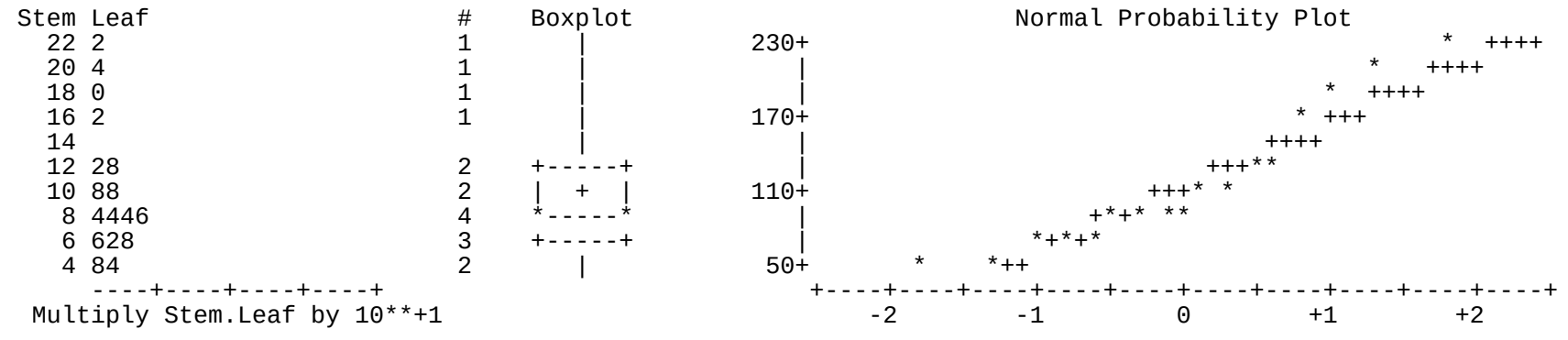
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	17	Sum Weights	17
Mean	-2.4705882	Sum Observations	-42
Std Deviation	34.92513	Variance	1219.76471
Skewness	0.19532855	Kurtosis	1.03795999
Uncorrected SS	19620	Corrected SS	19516.2353
Coeff Variation	-1413.6362	Std Error Mean	8.47058824

Basic Statistical Measures

Location		Variability	
Mean	-2.4706	Std Deviation	34.92513
Median	-6.0000	Variance	1220
Mode	-24.0000	Range	150.00000
		Interquartile Range	42.00000

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.29167	Pr > |t|	0.7743
Sign	M	-1.5	Pr >= |M|	0.6291
Signed Rank	S	-11.5	Pr >= |S|	0.6101

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.965893	Pr < W	0.7433
Kolmogorov-Smirnov	D	0.128482	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.047735	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.321584	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	72
99%	72
95%	72

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	54
75% Q3	18
50% Median	-6
25% Q1	-24
10%	-36
5%	-78
1%	-78
0% Min	-78

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-78	6	18	13
-36	9	18	16
-30	17	24	5
-24	15	54	14
-24	12	72	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

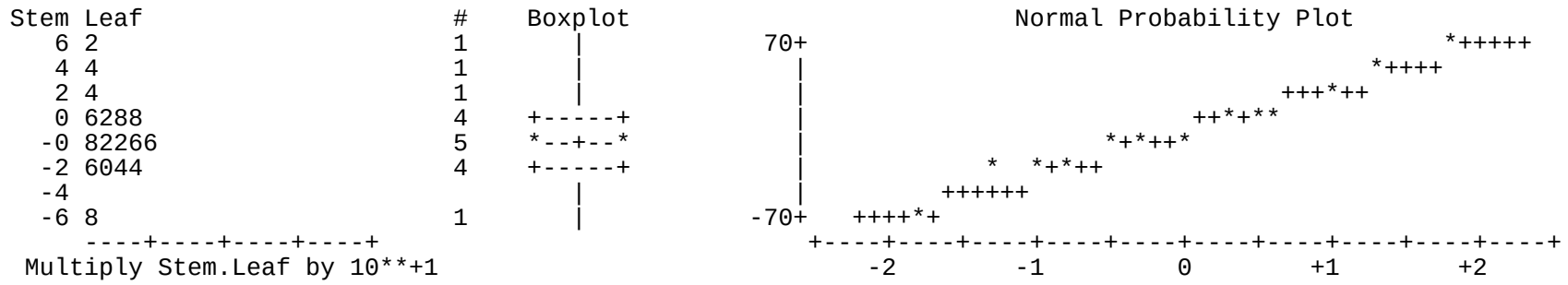

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	16	Sum Weights	16
Mean	77.25	Sum Observations	1236
Std Deviation	45.6355125	Variance	2082.6
Skewness	0.08405798	Kurtosis	-1.399203
Uncorrected SS	126720	Corrected SS	31239
Coeff Variation	59.0750971	Std Error Mean	11.4088781

Basic Statistical Measures

Location		Variability	
Mean	77.25000	Std Deviation	45.63551
Median	75.00000	Variance	2083
Mode	18.00000	Range	132.00000
		Interquartile Range	81.00000

NOTE: The mode displayed is the smallest of 5 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.771043	Pr > |t|	<.0001
Sign	M	8	Pr >= |M|	<.0001
Signed Rank	S	68	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.919264	Pr < W	0.1641
Kolmogorov-Smirnov	D	0.155069	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.065831	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.447531	Pr > A-Sq	0.2473

Quantiles (Definition 5)

Quantile	Estimate
100% Max	150
99%	150
95%	150

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	144
75% Q3	114
50% Median	75
25% Q1	33
10%	18
5%	18
1%	18
0% Min	18

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
18	16	108	9
18	7	120	3
24	12	120	5
24	10	144	6
42	15	150	2

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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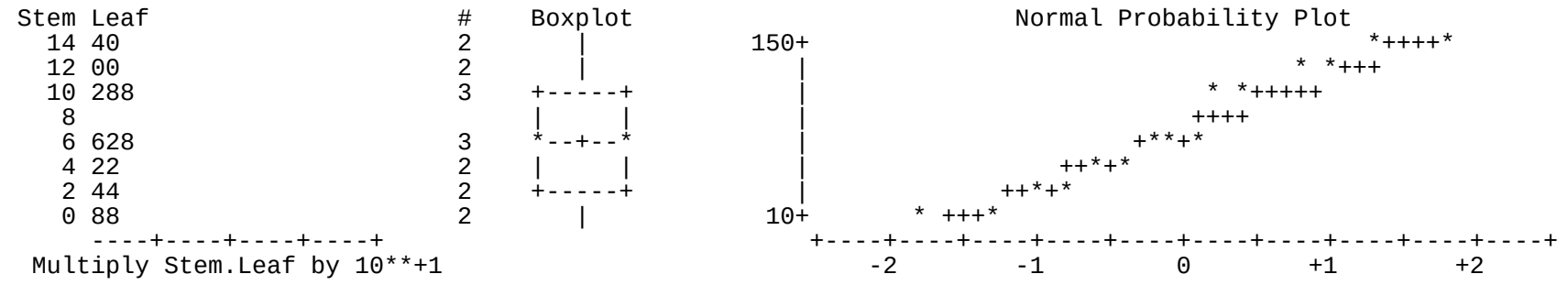
Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	16	Sum Weights	16
Mean	91.125	Sum Observations	1458
Std Deviation	65.9897719	Variance	4354.65
Skewness	1.14300341	Kurtosis	0.81739839
Uncorrected SS	198180	Corrected SS	65319.75
Coeff Variation	72.4167593	Std Error Mean	16.497443

Basic Statistical Measures

Location		Variability	
Mean	91.12500	Std Deviation	65.98977
Median	78.00000	Variance	4355
Mode	90.00000	Range	234.00000
		Interquartile Range	87.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.523583	Pr > |t|	<.0001
Sign	M	8	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	68	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.882926	Pr < W	0.0431
Kolmogorov-Smirnov	D	0.220555	Pr > D	0.0367
Cramer-von Mises	W-Sq	0.126166	Pr > W-Sq	0.0453
Anderson-Darling	A-Sq	0.718684	Pr > A-Sq	0.0486

Quantiles (Definition 5)

Quantile	Estimate
100% Max	252
99%	252
95%	252
90%	180
75% Q3	129

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	78
25% Q1	42
10%	24
5%	18
1%	18
0% Min	18

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
18	12	96	4
24	14	162	8
30	7	162	9
36	10	180	2
48	16	252	6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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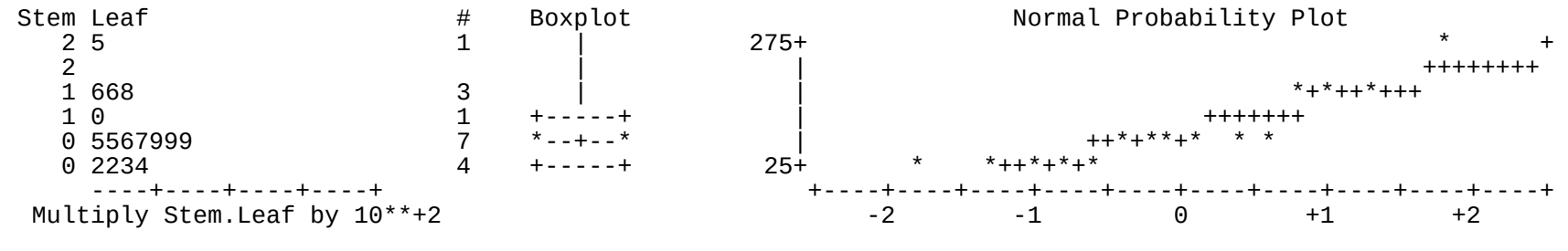
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	16	Sum Weights	16
Mean	13.875	Sum Observations	222
Std Deviation	37.9295399	Variance	1438.65
Skewness	0.87779913	Kurtosis	1.28146403
Uncorrected SS	24660	Corrected SS	21579.75
Coeff Variation	273.366054	Std Error Mean	9.48238498

Basic Statistical Measures

Location		Variability	
Mean	13.87500	Std Deviation	37.92954
Median	12.00000	Variance	1439
Mode	12.00000	Range	150.00000
		Interquartile Range	39.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	1.463239	Pr > |t|	0.1640
Sign	M	2	Pr >= |M|	0.4545

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	26	Pr >= |S|	0.1863

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.939449	Pr < W	0.3423
Kolmogorov-Smirnov	D	0.147871	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.063224	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.385054	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	108
99%	108
95%	108
90%	60
75% Q3	30

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	12
25% Q1	-9
10%	-30
5%	-42
1%	-42
0% Min	-42

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-42	14	30	2
-30	5	30	16
-30	3	54	9
-12	4	60	8
-6	13	108	6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.69
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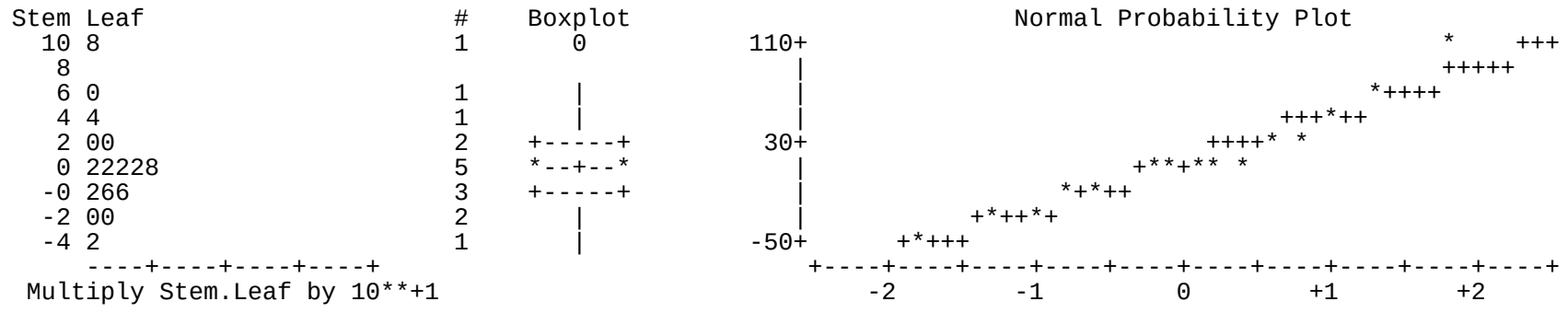
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	20	Sum Weights	20
Mean	105.9	Sum Observations	2118
Std Deviation	63.5658796	Variance	4040.62105
Skewness	1.28924632	Kurtosis	0.85819496
Uncorrected SS	301068	Corrected SS	76771.8
Coeff Variation	60.0244378	Std Error Mean	14.2137628

Basic Statistical Measures

Location		Variability	
Mean	105.9000	Std Deviation	63.56588
Median	90.0000	Variance	4041
Mode	66.0000	Range	204.00000
		Interquartile Range	57.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.450525	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.825214	Pr < W	0.0021
Kolmogorov-Smirnov	D	0.190684	Pr > D	0.0552
Cramer-von Mises	W-Sq	0.185497	Pr > W-Sq	0.0074
Anderson-Darling	A-Sq	1.263133	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	240
99%	240
95%	240
90%	237
75% Q3	123

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SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	90
25% Q1	66
10%	42
5%	39
1%	36
0% Min	36

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
36	20	126	6
42	10	132	19
42	7	234	15
48	16	240	4
66	12	240	11

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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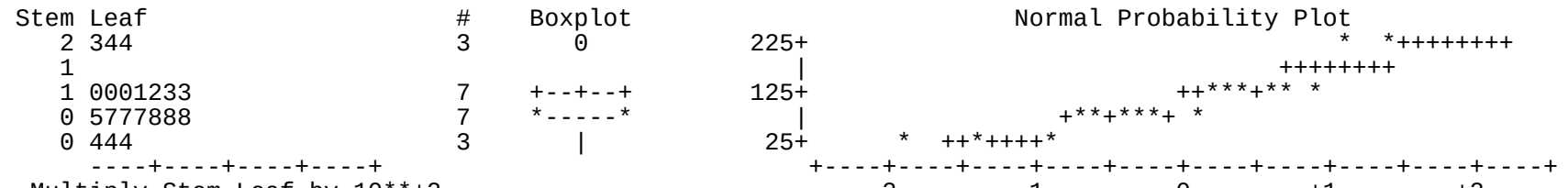
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	20	Sum Weights	20
Mean	115.8	Sum Observations	2316
Std Deviation	86.1843801	Variance	7427.74737
Skewness	1.84205052	Kurtosis	3.30292673
Uncorrected SS	409320	Corrected SS	141127.2
Coeff Variation	74.4251987	Std Error Mean	19.2714132

Basic Statistical Measures

Location		Variability	
Mean	115.8000	Std Deviation	86.18438
Median	93.0000	Variance	7428
Mode	60.0000	Range	330.00000
		Interquartile Range	69.00000

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.0089	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.789654	Pr < W	0.0006
Kolmogorov-Smirnov	D	0.202895	Pr > D	0.0296
Cramer-von Mises	W-Sq	0.235564	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.498005	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	348
99%	348
95%	339

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	255
75% Q3	132
50% Median	93
25% Q1	63
10%	42
5%	24
1%	18
0% Min	18

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
18	8	138	14
30	12	150	15
54	9	180	6
60	13	330	11
60	7	348	20

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

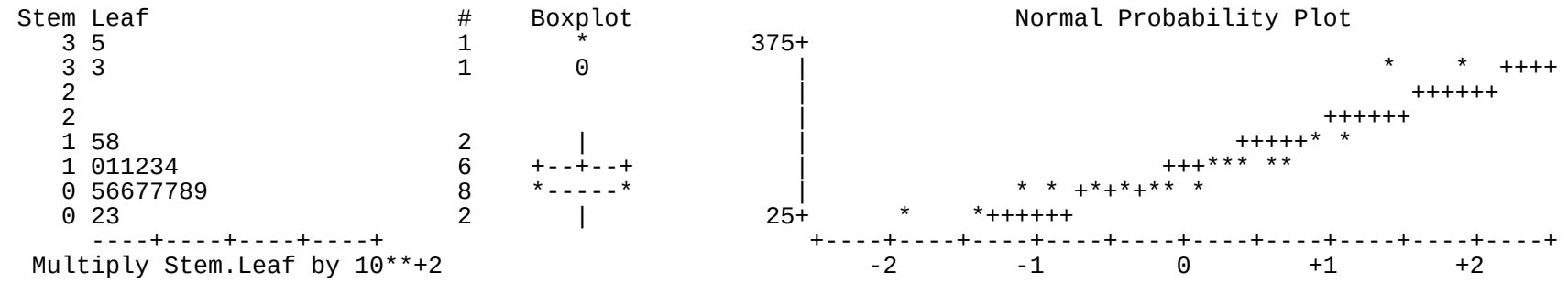

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	20	Sum Weights	20
Mean	9.9	Sum Observations	198
Std Deviation	88.3806957	Variance	7811.14737
Skewness	2.03005108	Kurtosis	6.98787389
Uncorrected SS	150372	Corrected SS	148411.8
Coeff Variation	892.7343	Std Error Mean	19.7625243

Basic Statistical Measures

Location		Variability	
Mean	9.9000	Std Deviation	88.38070
Median	6.0000	Variance	7811
Mode	-12.0000	Range	438.00000
		Interquartile Range	57.00000

NOTE: The mode displayed is the smallest of 3 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.500948	Pr > |t|	0.6222
Sign	M	0.5	Pr >= |M|	1.0000
Signed Rank	S	3	Pr >= |S|	0.9141

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.819207	Pr < W	0.0017
Kolmogorov-Smirnov	D	0.210047	Pr > D	0.0208
Cramer-von Mises	W-Sq	0.166445	Pr > W-Sq	0.0137
Anderson-Darling	A-Sq	1.061509	Pr > A-Sq	0.0071

Quantiles (Definition 5)

Quantile	Estimate
100% Max	312
99%	312
95%	201

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	81
75% Q3	27
50% Median	6
25% Q1	-30
10%	-81
5%	-105
1%	-126
0% Min	-126

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-126	4	30	10
-84	15	54	6
-78	8	72	16
-54	13	90	11
-36	12	312	20

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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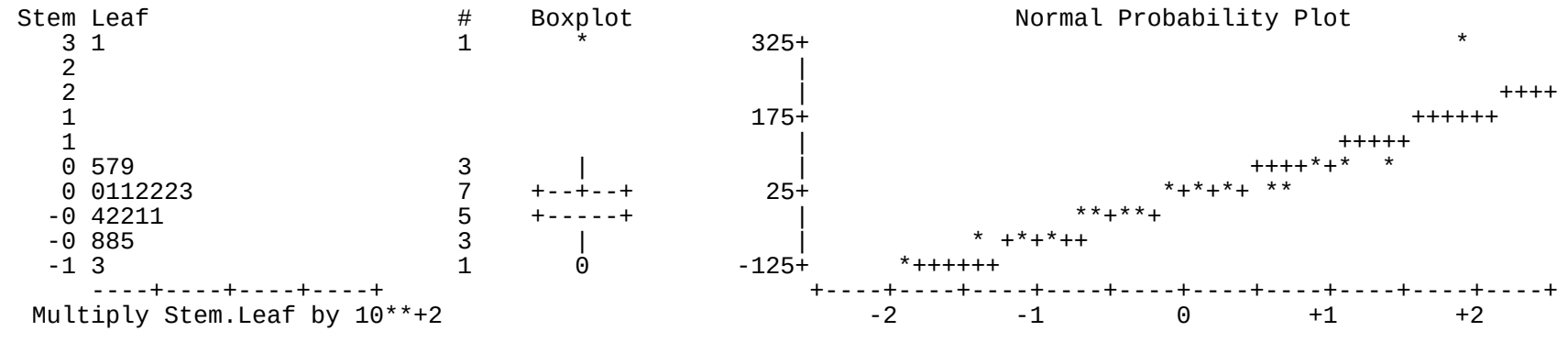
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	18	Sum Weights	18
Mean	86.3333333	Sum Observations	1554
Std Deviation	42.3334105	Variance	1792.11765
Skewness	1.07896098	Kurtosis	1.1245097
Uncorrected SS	164628	Corrected SS	30466
Coeff Variation	49.0348385	Std Error Mean	9.97808055

Basic Statistical Measures

Location		Variability	
Mean	86.33333	Std Deviation	42.33341
Median	81.00000	Variance	1792
Mode	48.00000	Range	162.00000
		Interquartile Range	60.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.652299	Pr > |t|	<.0001
Sign	M	9	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	85.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.917843	Pr < W	0.1184
Kolmogorov-Smirnov	D	0.137725	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.071435	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.502746	Pr > A-Sq	0.1872

Quantiles (Definition 5)

Quantile	Estimate
100% Max	192
99%	192
95%	192
90%	162
75% Q3	108

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	81
25% Q1	48
10%	42
5%	30
1%	30
0% Min	30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
30	13	108	8
42	1	108	9
48	18	126	6
48	16	162	15
48	5	192	12

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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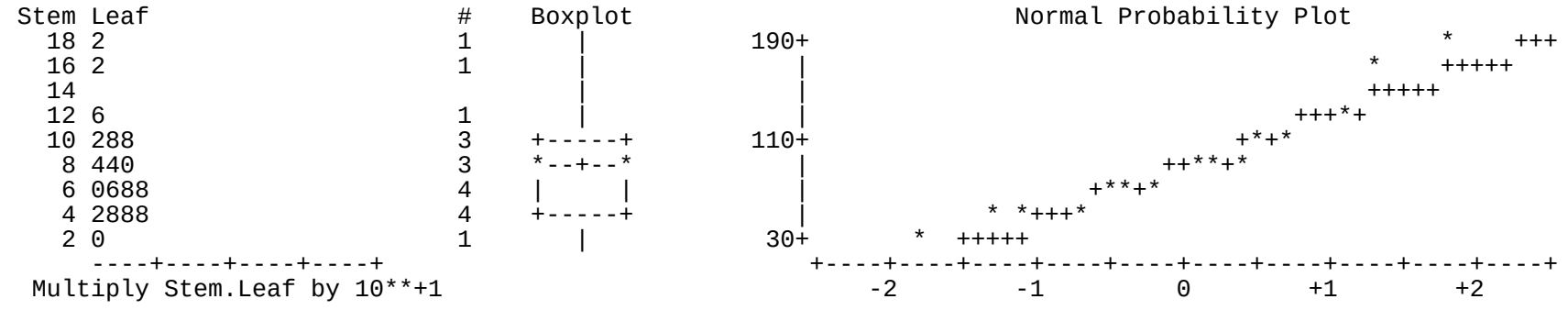
Population: Intent-to-Treat with LOCF

Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	18	Sum Weights	18
Mean	75.3333333	Sum Observations	1356
Std Deviation	32.5540275	Variance	1059.76471
Skewness	0.66161363	Kurtosis	-0.6954744
Uncorrected SS	120168	Corrected SS	18016
Coeff Variation	43.2133108	Std Error Mean	7.67305786

Basic Statistical Measures

Location		Variability	
Mean	75.33333	Std Deviation	32.55403
Median	66.00000	Variance	1060
Mode	54.00000	Range	108.00000
		Interquartile Range	48.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.817902	Pr > |t|	<.0001
Sign	M	9	Pr >= |M|	<.0001

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	85.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.911253	Pr < W	0.0905
Kolmogorov-Smirnov	D	0.207445	Pr > D	0.0398
Cramer-von Mises	W-Sq	0.126341	Pr > W-Sq	0.0456
Anderson-Darling	A-Sq	0.700287	Pr > A-Sq	0.0573

Quantiles (Definition 5)

Quantile	Estimate
100% Max	138
99%	138
95%	138
90%	126
75% Q3	102

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	66
25% Q1	54
10%	36
5%	30
1%	30
0% Min	30

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
30	5	102	8
36	1	120	2
42	18	120	11
54	16	126	12
54	15	138	9

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

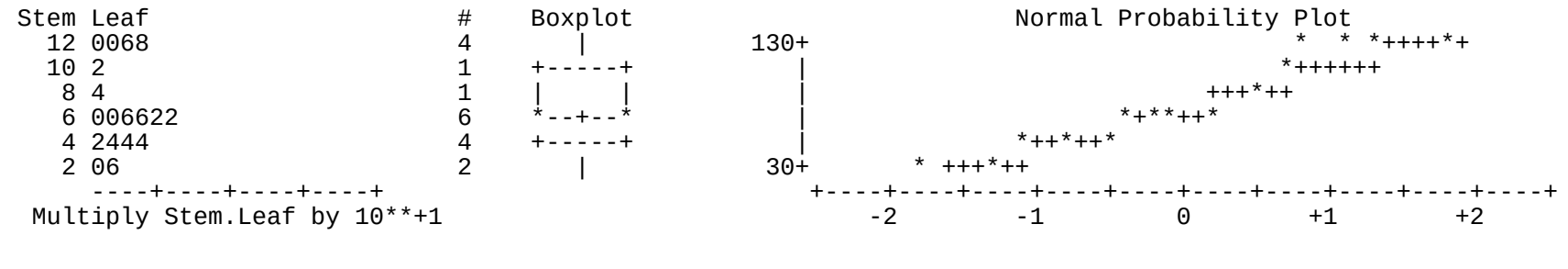

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	18	Sum Weights	18
Mean	-11	Sum Observations	-198
Std Deviation	34.818859	Variance	1212.35294
Skewness	-1.4815793	Kurtosis	2.60926741
Uncorrected SS	22788	Corrected SS	20610
Coeff Variation	-316.53508	Std Error Mean	8.20688377

Basic Statistical Measures

Location		Variability	
Mean	-11.0000	Std Deviation	34.81886
Median	-6.0000	Variance	1212
Mode	-6.0000	Range	138.00000
		Interquartile Range	24.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.34034	Pr > |t|	0.1978
Sign	M	-2.5	Pr >= |M|	0.3018

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-16.5	Pr >= |S|	0.3647

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.85325	Pr < W	0.0095
Kolmogorov-Smirnov	D	0.253667	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.187177	Pr > W-Sq	0.0069
Anderson-Darling	A-Sq	1.005632	Pr > A-Sq	0.0092

Quantiles (Definition 5)

Quantile	Estimate
100% Max	30
99%	30
95%	30
90%	30
75% Q3	6

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-6
25% Q1	-18
10%	-66
5%	-108
1%	-108
0% Min	-108

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-108	15	6	16
-66	12	18	2
-54	6	24	13
-18	10	30	9
-18	5	30	11

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

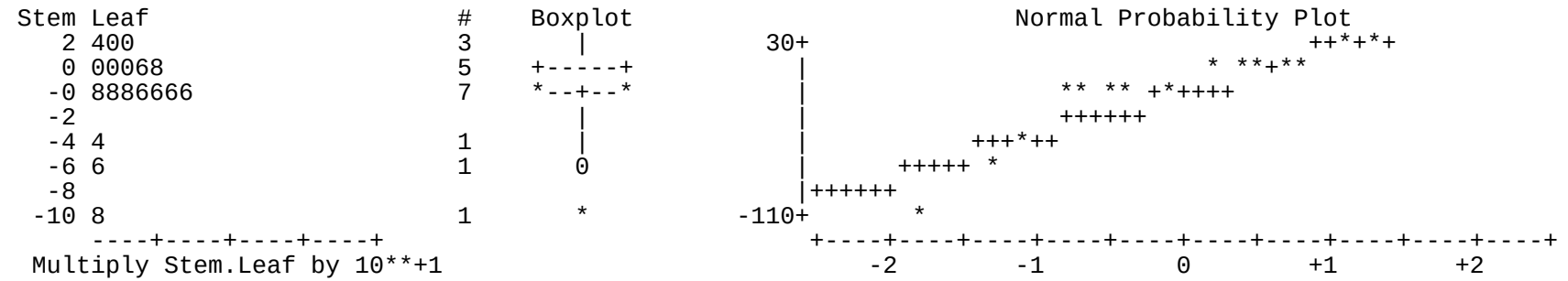

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	20	Sum Weights	20
Mean	131.1	Sum Observations	2622
Std Deviation	94.0312938	Variance	8841.88421
Skewness	1.69548122	Kurtosis	3.36137117
Uncorrected SS	511740	Corrected SS	167995.8
Coeff Variation	71.7248618	Std Error Mean	21.0260365

Basic Statistical Measures

Location		Variability	
Mean	131.1000	Std Deviation	94.03129
Median	111.0000	Variance	8842
Mode	114.0000	Range	390.00000
		Interquartile Range	102.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.235127	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.847395	Pr < W	0.0048
Kolmogorov-Smirnov	D	0.222151	Pr > D	0.0103
Cramer-von Mises	W-Sq	0.173425	Pr > W-Sq	0.0101
Anderson-Darling	A-Sq	1.009701	Pr > A-Sq	0.0093

Quantiles (Definition 5)

Quantile	Estimate
100% Max	414
99%	414
95%	351
90%	261
75% Q3	174

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	111
25% Q1	72
10%	42
5%	30
1%	24
0% Min	24

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
24	11	180	5
36	15	180	19
48	10	234	16
54	4	288	6
66	1	414	8

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

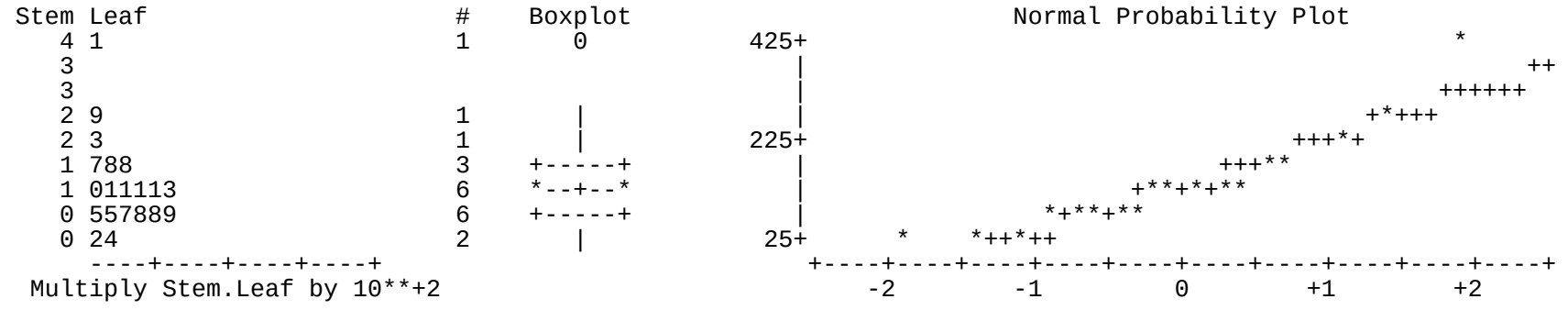

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	20	Sum Weights	20
Mean	132.9	Sum Observations	2658
Std Deviation	85.614743	Variance	7329.88421
Skewness	1.62658788	Kurtosis	2.66642821
Uncorrected SS	492516	Corrected SS	139267.8
Coeff Variation	64.4204236	Std Error Mean	19.1440385

Basic Statistical Measures

Location		Variability	
Mean	132.9000	Std Deviation	85.61474
Median	108.0000	Variance	7330
Mode	78.0000	Range	342.00000
		Interquartile Range	78.00000

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.942109	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.843515	Pr < W	0.0042
Kolmogorov-Smirnov	D	0.198421	Pr > D	0.0383
Cramer-von Mises	W-Sq	0.195417	Pr > W-Sq	0.0052
Anderson-Darling	A-Sq	1.119338	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	378
99%	378
95%	336
90%	264
75% Q3	156

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	108
25% Q1	78
10%	51
5%	42
1%	36
0% Min	36

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
36	2	168	19
48	15	192	9
54	11	234	20
78	18	294	8
78	12	378	6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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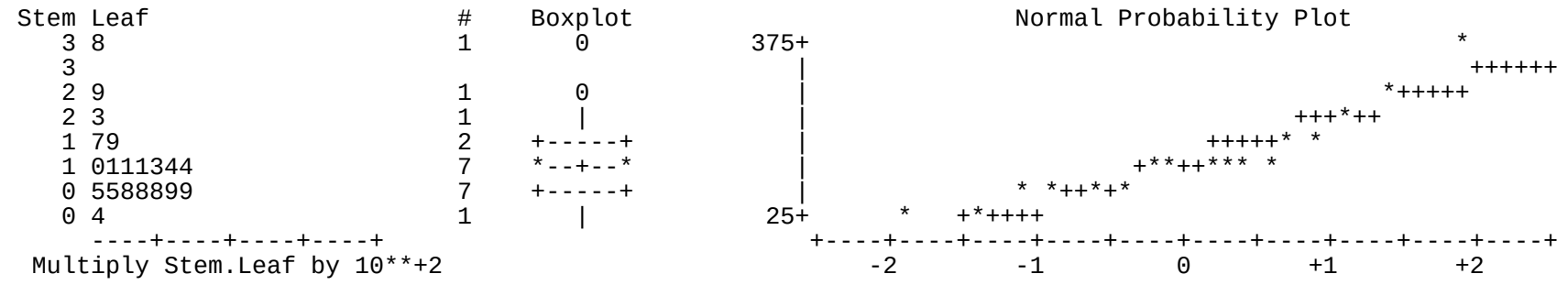
Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	20	Sum Weights	20
Mean	1.8	Sum Observations	36
Std Deviation	61.5001926	Variance	3782.27368
Skewness	-0.1093196	Kurtosis	0.06318924
Uncorrected SS	71928	Corrected SS	71863.2
Coeff Variation	3416.67736	Std Error Mean	13.7518611

Basic Statistical Measures

Location		Variability	
Mean	1.8000	Std Deviation	61.50019
Median	6.0000	Variance	3782
Mode	-12.0000	Range	246.00000
		Interquartile Range	63.00000

NOTE: The mode displayed is the smallest of 4 modes with a count of 2.

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.130891	Pr > |t|	0.8972
Sign	M	1	Pr >= |M|	0.8145
Signed Rank	S	7.5	Pr >= |S|	0.7578

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.979853	Pr < W	0.9322
Kolmogorov-Smirnov	D	0.111227	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.042068	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.238953	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	126
99%	126
95%	108

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
90%	84
75% Q3	33
50% Median	6
25% Q1	-30
10%	-87
5%	-108
1%	-120
0% Min	-120

Extreme Observations

----Lowest----		----Highest---	
Value	Obs	Value	Obs
-120	8	36	4
-96	16	42	1
-78	2	78	9
-66	5	90	6
-36	18	126	20

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

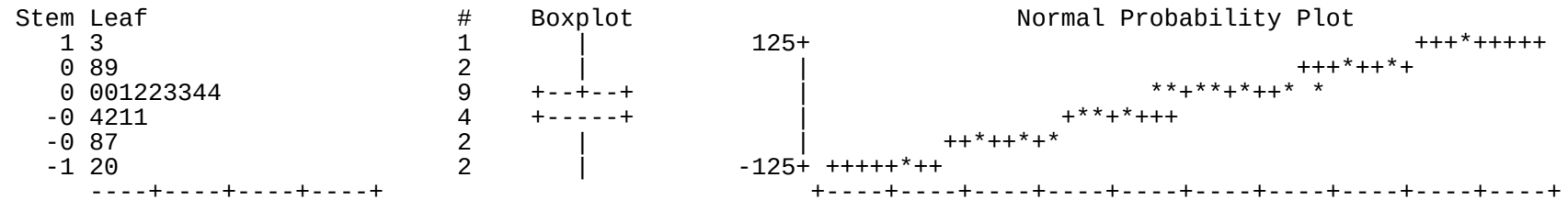

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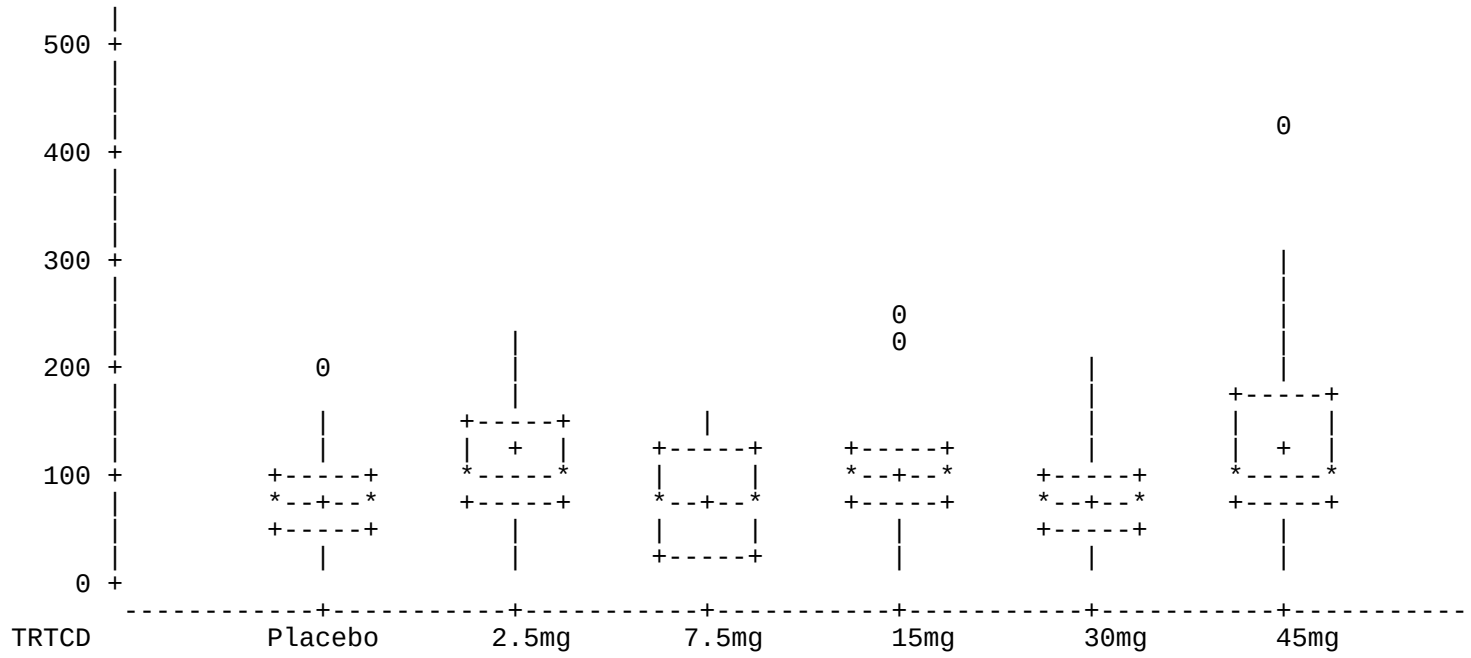
Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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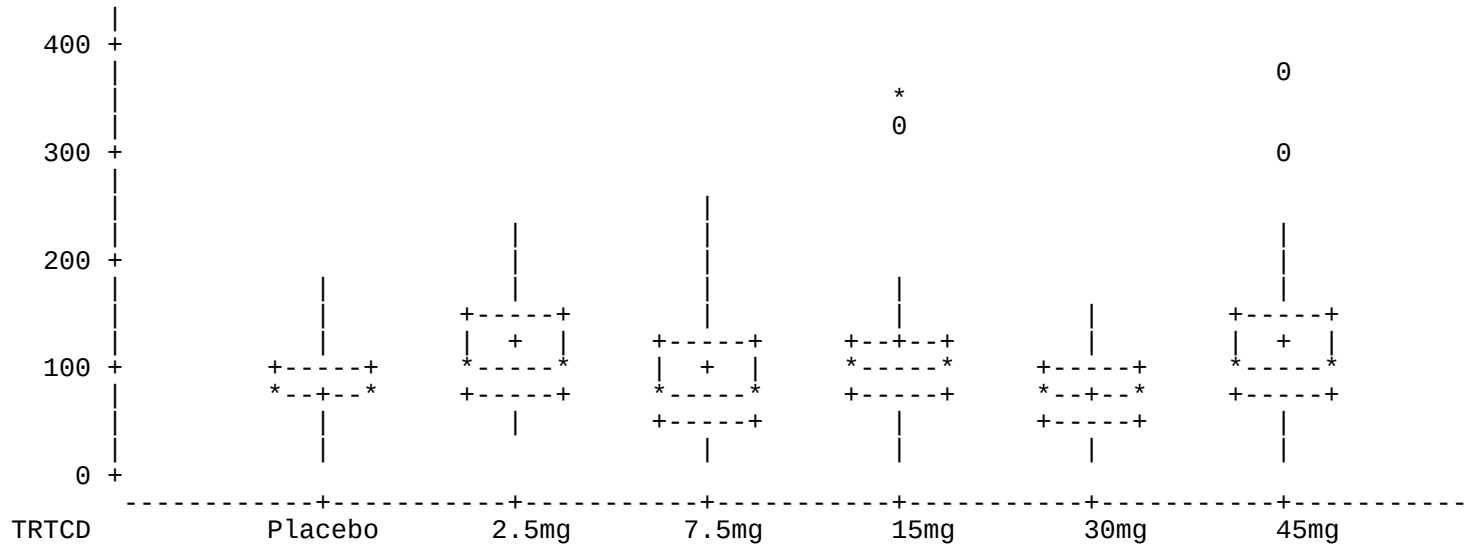
Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots

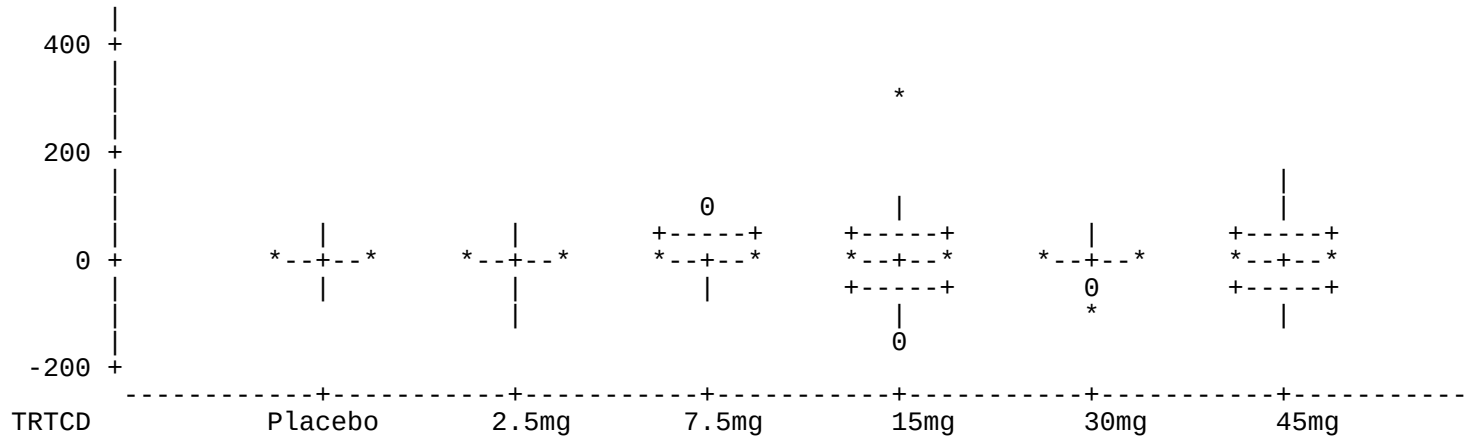

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg

Dimensions

Covariance Parameters	1
Columns in X	12
Columns in Z	0
Subjects	1
Max Obs Per Subject	114
Observations Used	114
Observations Not Used	0
Total Observations	114

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The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	2220.25	306.42	7.25	<.0001	0.05	1723.71	2968.39

Fit Statistics

-2 Res Log Likelihood	1144.1
AIC (smaller is better)	1146.1
AICC (smaller is better)	1146.1
BIC (smaller is better)	1148.7

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept				54.7702	15.6560	105	3.50	0.0007
SEX	Female			-24.6112	9.4308	105	-2.61	0.0104
SEX	Male			0			.	
TRTTYPCD		Diet & Exercise		10.9271	9.3460	105	1.17	0.2450
TRTTYPCD		Monotherapy		0			.	
TRTCD			Placebo	-21.8905	14.9424	105	-1.46	0.1459
TRTCD			2.5mg	-22.2814	16.1268	105	-1.38	0.1700
TRTCD			7.5mg	-9.8021	16.5634	105	-0.59	0.5553
TRTCD			15mg	-2.4016	15.0829	105	-0.16	0.8738

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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
TRTCD			30mg	-34.9089	15.8730	105	-2.20	0.0301
TRTCD			45mg	0			.	
EFSTDBL				-0.3029	0.07513	105	-4.03	0.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	105	6.81	0.0104
TRTTYPCD	1	105	1.37	0.2450
TRTCD	5	105	1.44	0.2149
EFSTDBL	1	105	16.25	0.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	-0.3909	15.4780	105	-0.03	0.9799	0.05	-31.0809	30.2990
7.5mg vs Pbo	12.0884	15.4699	105	0.78	0.4363	0.05	-18.5854	42.7623
15mg vs Pbo	19.4889	14.5436	105	1.34	0.1831	0.05	-9.3485	48.3262
30mg vs Pbo	-13.0184	14.8578	105	-0.88	0.3829	0.05	-42.4786	16.4419

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
45mg vs Pbo	21.8905	14.9424	105	1.46	0.1459	0.05	-7.7375	51.5186

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5	Row6
Intercept				1	1	1	1	1	1
SEX	Female			0.4912	0.4912	0.4912	0.4912	0.4912	0.4912
SEX	Male			0.5088	0.5088	0.5088	0.5088	0.5088	0.5088
TRTTYPCD		Diet & Exercise		0.4211	0.4211	0.4211	0.4211	0.4211	0.4211
TRTTYPCD		Monotherapy		0.5789	0.5789	0.5789	0.5789	0.5789	0.5789
TRTCD			Placebo	1					
TRTCD			2.5mg		1				
TRTCD			7.5mg			1			
TRTCD			15mg				1		
TRTCD			30mg					1	
TRTCD			45mg						1
EFSTDBL				100	100	100	100	100	100

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-4.8950	9.9112	105	-0.49	0.6224	0.05	-24.5471	14.7571
TRTCD	2.5mg	WORK.EFF	-5.2859	11.7553	105	-0.45	0.6539	0.05	-28.5945	18.0227
TRTCD	7.5mg	WORK.EFF	7.1935	12.0247	105	0.60	0.5510	0.05	-16.6493	31.0363
TRTCD	15mg	WORK.EFF	14.5939	10.5894	105	1.38	0.1711	0.05	-6.4030	35.5908
TRTCD	30mg	WORK.EFF	-17.9134	11.1859	105	-1.60	0.1123	0.05	-40.0929	4.2662
TRTCD	45mg	WORK.EFF	16.9956	10.9458	105	1.55	0.1235	0.05	-4.7080	38.6991

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	0.3909	15.4780	105	0.03	0.9799	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-30.2990	31.0809

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	7.5mg	WORK.EFF	-12.0884	15.4699	105	-0.78	0.4363	0.05
TRTCD	Placebo	15mg	WORK.EFF	-19.4889	14.5436	105	-1.34	0.1831	0.05
TRTCD	Placebo	30mg	WORK.EFF	13.0184	14.8578	105	0.88	0.3829	0.05
TRTCD	Placebo	45mg	WORK.EFF	-21.8905	14.9424	105	-1.46	0.1459	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	-12.4793	17.0075	105	-0.73	0.4647	0.05
TRTCD	2.5mg	15mg	WORK.EFF	-19.8798	15.9384	105	-1.25	0.2151	0.05
TRTCD	2.5mg	30mg	WORK.EFF	12.6275	16.1690	105	0.78	0.4366	0.05
TRTCD	2.5mg	45mg	WORK.EFF	-22.2814	16.1268	105	-1.38	0.1700	0.05
TRTCD	7.5mg	15mg	WORK.EFF	-7.4005	16.0203	105	-0.46	0.6451	0.05
TRTCD	7.5mg	30mg	WORK.EFF	25.1068	16.3552	105	1.54	0.1278	0.05
TRTCD	7.5mg	45mg	WORK.EFF	-9.8021	16.5634	105	-0.59	0.5553	0.05
TRTCD	15mg	30mg	WORK.EFF	32.5073	15.4857	105	2.10	0.0382	0.05
TRTCD	15mg	45mg	WORK.EFF	-2.4016	15.0829	105	-0.16	0.8738	0.05
TRTCD	30mg	45mg	WORK.EFF	-34.9089	15.8730	105	-2.20	0.0301	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	7.5mg	-42.7623	18.5854
TRTCD	Placebo	15mg	-48.3262	9.3485
TRTCD	Placebo	30mg	-16.4419	42.4786
TRTCD	Placebo	45mg	-51.5186	7.7375

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	2.5mg	7.5mg	-46.2020	21.2433
TRTCD	2.5mg	15mg	-51.4826	11.7230
TRTCD	2.5mg	30mg	-19.4326	44.6876
TRTCD	2.5mg	45mg	-54.2579	9.6950
TRTCD	7.5mg	15mg	-39.1657	24.3648
TRTCD	7.5mg	30mg	-7.3226	57.5362
TRTCD	7.5mg	45mg	-42.6443	23.0401
TRTCD	15mg	30mg	1.8019	63.2126
TRTCD	15mg	45mg	-32.3082	27.5049
TRTCD	30mg	45mg	-66.3821	-3.4357

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.

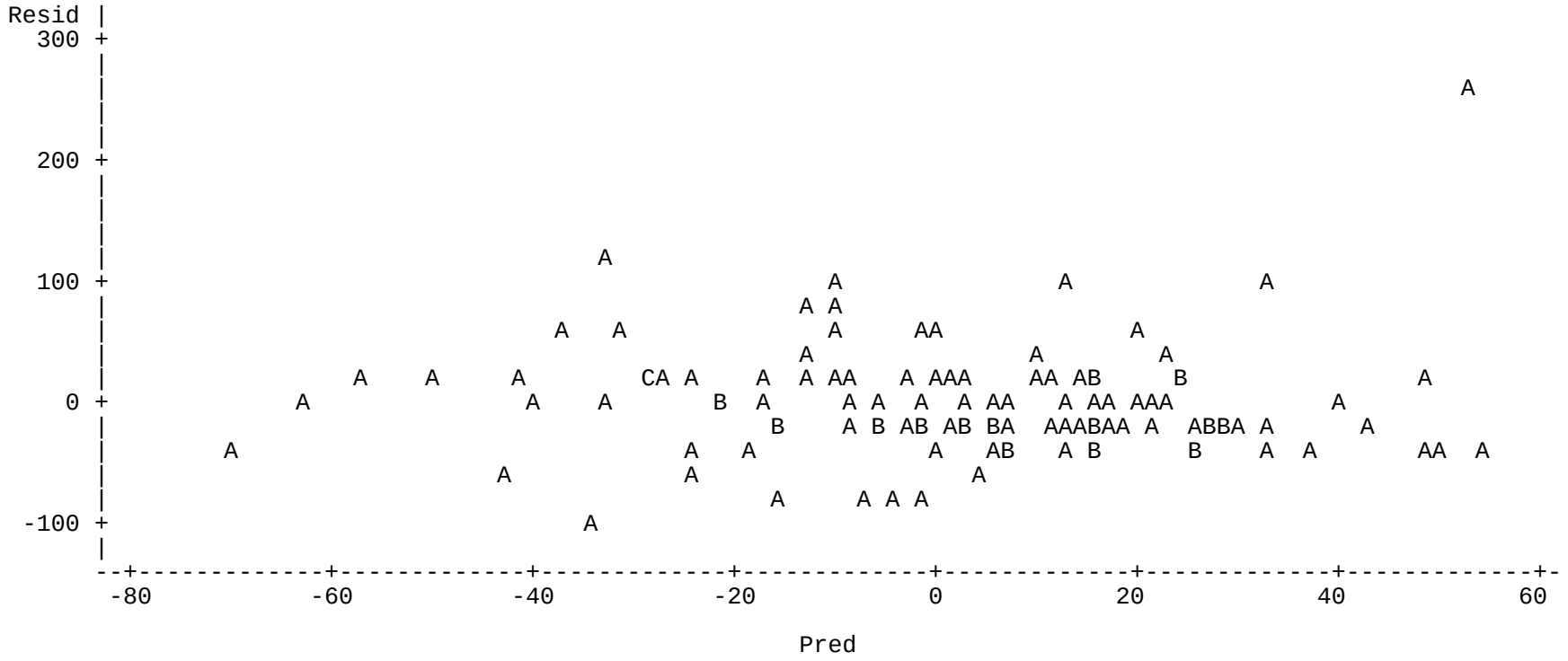

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.

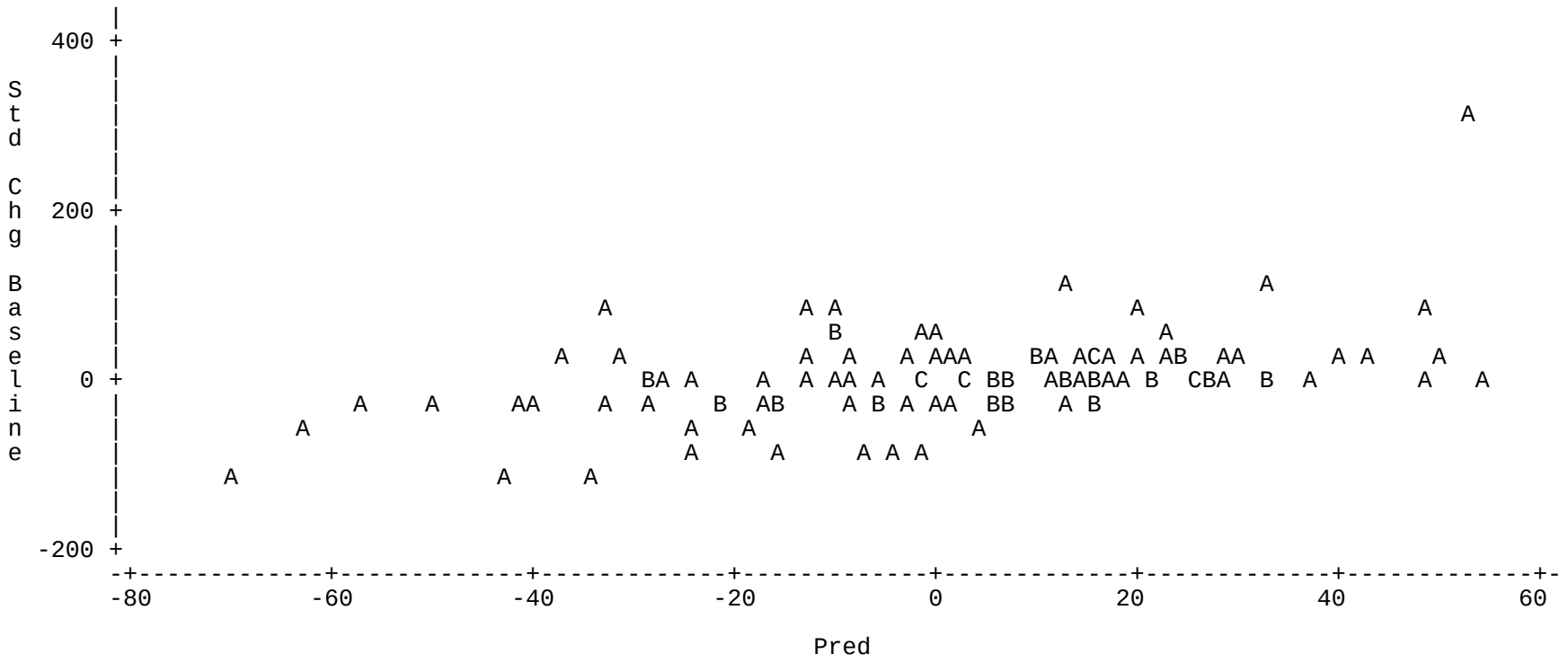

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	114	Sum Weights	114
Mean	0	Sum Observations	0
Std Deviation	45.4210152	Variance	2063.06862
Skewness	1.9287362	Kurtosis	8.92746739
Uncorrected SS	233126.754	Corrected SS	233126.754
Coeff Variation		Std Error Mean	4.25406784

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	45.42102
Median	-8.21594	Variance	2063
Mode		Range	351.60573
		Interquartile Range	41.25376

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-7	Pr >= |M|	0.2232
Signed Rank	S	-403.5	Pr >= |S|	0.2557

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.872433	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.128995	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.455838	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.633921	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	259.60727
99%	122.45297
95%	84.93997
90%	55.42469
75% Q3	17.18544
50% Median	-8.21594
25% Q1	-24.06832
10%	-42.79438
5%	-65.11415
1%	-79.90138
0% Min	-91.99847

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Table 11.69
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Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest-----		------Highest-----	
Value	Obs	Value	Obs
-91.9985	21	93.0114	111
-79.9014	86	95.7164	40
-76.6830	71	99.3904	79
-76.4268	97	122.4530	22
-73.6332	8	259.6073	114

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Table 11.69
SAS Statistical Output for Table 11.68
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Stem	Leaf	#	Boxplot
26	0	1	*
24			
22			
20			
18			
16			
14			
12	2	1	0
10			
8	5369	4	0
6	271	3	|
4	3588	4	|
2	00122237778112	14	|
0	13467788900112234455678	23	+--+--+
-0	7765555544432111111000753322 1	29	*-----*
-2	776664321855432 1000	19	+-----+
-4	8494433220	10	|
-6	7645	4	|
-8	20	2	0

----+----+----+----+----+----

Multiply Stem.Leaf by 10**+1

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.69
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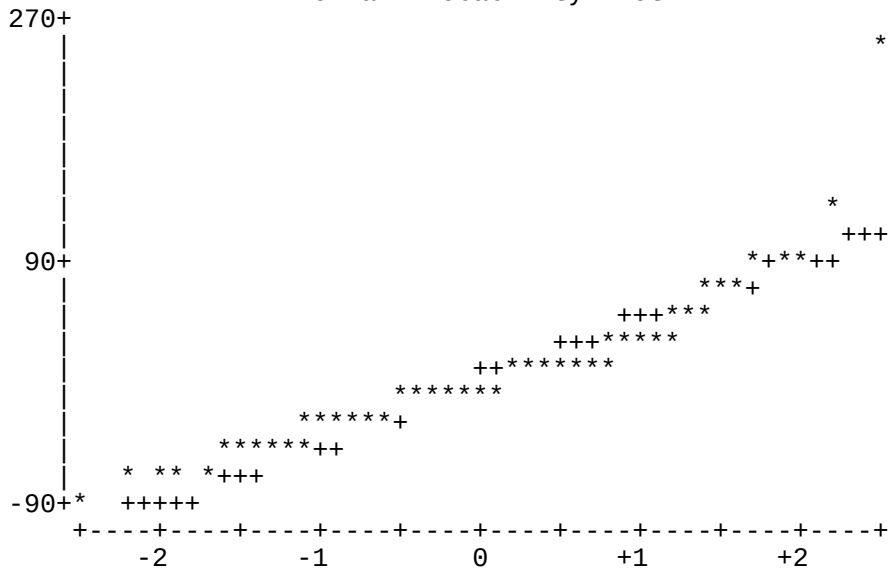
Analysis of Change in Fasting Serum Insulin (pmol/L) from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



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Population: Intent-to-Treat with LOCF

Table 11.70

Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

		Placebo (N=36)	2.5mg (N=41)	7.5mg (N=44)	15mg (N=43)	30mg (N=38)	45mg (N=39)
n [1]		33	35	42	42	34	34
Number (%) of Values Carried Forward		5 (15%)	8 (23%)	6 (14%)	4 (10%)	4 (12%)	2 (6%)
Baseline	Mean	0.40	0.42	0.34	0.36	0.41	0.34
	SD	0.291	0.289	0.204	0.237	0.223	0.157
Week 12	Mean	0.37	0.42	0.30	0.32	0.29	0.28
	SD	0.225	0.290	0.182	0.251	0.130	0.118
Chg from Baseline	Mean	-0.03	-0.01	-0.03	-0.04	-0.12	-0.06
	SD	0.157	0.125	0.113	0.184	0.161	0.105
Model-Adj Chg [2]	Mean	-0.02	0.01	-0.05	-0.05	-0.11	-0.07
	SE	0.022	0.021	0.019	0.019	0.022	0.022
Diff from Pbo [2]	Mean		0.02	-0.03	-0.03	-0.09	-0.05
	95% CI		-0.04,0.09	-0.09,0.03	-0.09,0.03	-0.15,-0.03	-0.11,0.01
	p-val [3]		0.420	0.298	0.268	0.005	0.082

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	33	Sum Weights	33
Mean	0.40247308	Sum Observations	13.2816116
Std Deviation	0.29131906	Variance	0.0848668
Skewness	3.38571724	Kurtosis	15.2995791
Uncorrected SS	8.06122859	Corrected SS	2.71573745
Coeff Variation	72.3822476	Std Error Mean	0.05071214

Basic Statistical Measures

Location		Variability	
Mean	0.402473	Std Deviation	0.29132
Median	0.334873	Variance	0.08487
Mode	0.302267	Range	1.69180
		Interquartile Range	0.22212

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.936425	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001
Signed Rank	S	280.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.67542	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.227445	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.417122	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.550775	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.7697228
99%	1.7697228
95%	0.7638889

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.5505618
75% Q3	0.4986150
50% Median	0.3348730
25% Q1	0.2764977
10%	0.1906412
5%	0.0865801
1%	0.0779221
0% Min	0.0779221

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0779221	13	0.515781	31
0.0865801	22	0.550562	3
0.1386001	28	0.704388	18
0.1906412	5	0.763889	32
0.2132196	19	1.769723	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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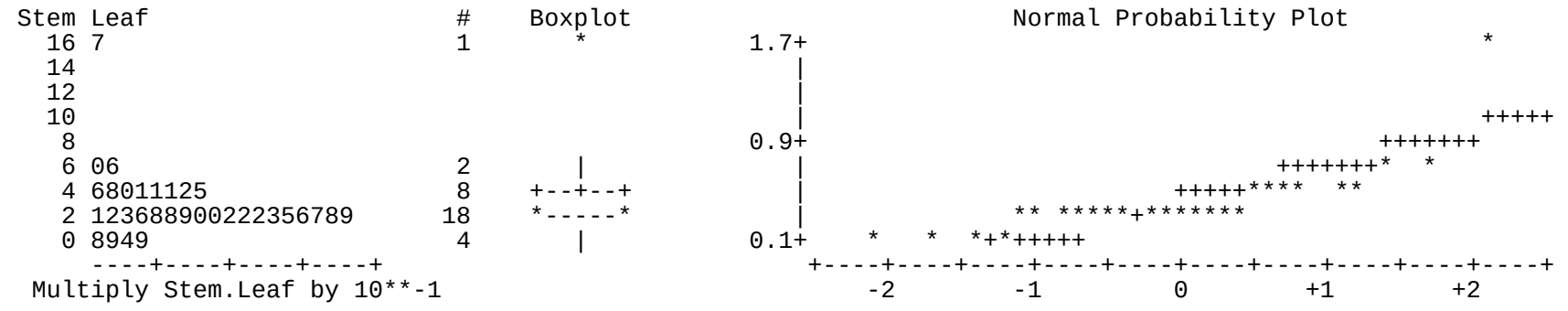
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	33	Sum Weights	33
Mean	0.37276791	Sum Observations	12.301341
Std Deviation	0.2249854	Variance	0.05061843
Skewness	1.47742902	Kurtosis	3.48599234
Uncorrected SS	6.20533495	Corrected SS	1.61978977
Coeff Variation	60.3553563	Std Error Mean	0.03916493

Basic Statistical Measures

Location		Variability	
Mean	0.372768	Std Deviation	0.22499
Median	0.330800	Variance	0.05062
Mode	0.327456	Range	1.07594
		Interquartile Range	0.26281

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.5179	Pr > |t|	<.0001
Sign	M	16.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	280.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.888291	Pr < W	0.0027
Kolmogorov-Smirnov	D	0.131529	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.116692	Pr > W-Sq	0.0671
Anderson-Darling	A-Sq	0.795235	Pr > A-Sq	0.0370

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.1683168
99%	1.1683168
95%	0.7108434
90%	0.6336634
75% Q3	0.4608295

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3308002
25% Q1	0.1980198
10%	0.1276441
5%	0.1000770
1%	0.0923788
0% Min	0.0923788

Extreme Observations

Lowest Value	Lowest Obs	Highest Value	Highest Obs
0.0923788	14	0.628998	31
0.1000770	22	0.633663	8
0.1212121	13	0.658579	26
0.1276441	28	0.710843	3
0.1662050	1	1.168317	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

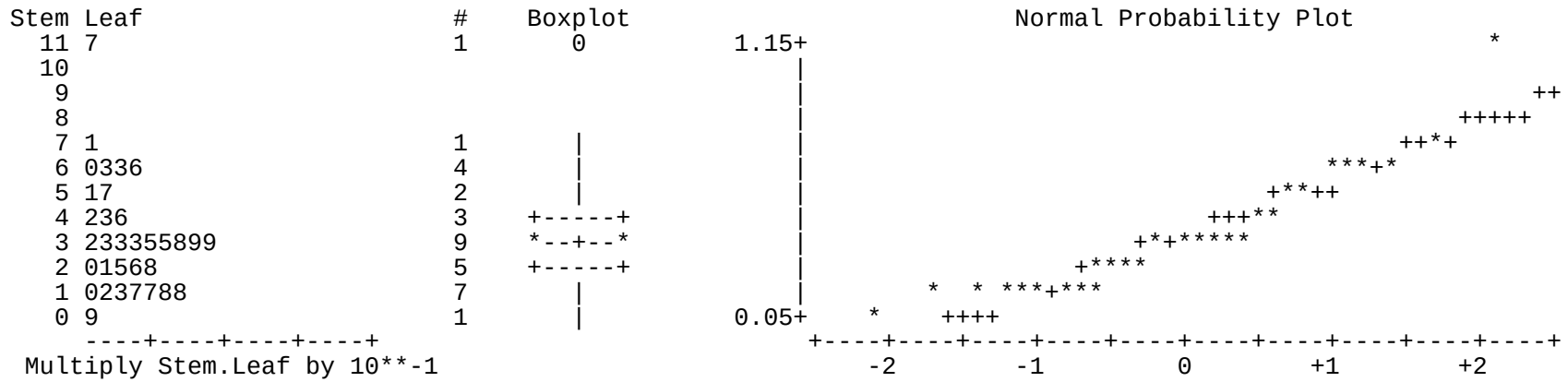

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	33	Sum Weights	33
Mean	-0.0297052	Sum Observations	-0.9802706
Std Deviation	0.15722558	Variance	0.02471988
Skewness	-1.5822832	Kurtosis	5.01361194
Uncorrected SS	0.82015536	Corrected SS	0.79103626
Coeff Variation	-529.28693	Std Error Mean	0.02736946

Basic Statistical Measures

Location		Variability	
Mean	-0.02971	Std Deviation	0.15723
Median	-0.01096	Variance	0.02472
Mode		Range	0.87673
		Interquartile Range	0.14676

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.08534	Pr > |t|	0.2859
Sign	M	-2	Pr >= |M|	0.5966

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-40	Pr >= |S|	0.4633

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.875398	Pr < W	0.0013
Kolmogorov-Smirnov	D	0.181295	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.176605	Pr > W-Sq	0.0097
Anderson-Darling	A-Sq	1.138556	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2753261
99%	0.2753261
95%	0.1602816
90%	0.1249280
75% Q3	0.0550236

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0109561
25% Q1	-0.0917402
10%	-0.1344378
5%	-0.3712792
1%	-0.6014060
0% Min	-0.6014060

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.601406	4	0.113216	31
-0.371279	32	0.124928	33
-0.230947	14	0.146852	26
-0.134438	2	0.160282	3
-0.111023	1	0.275326	8

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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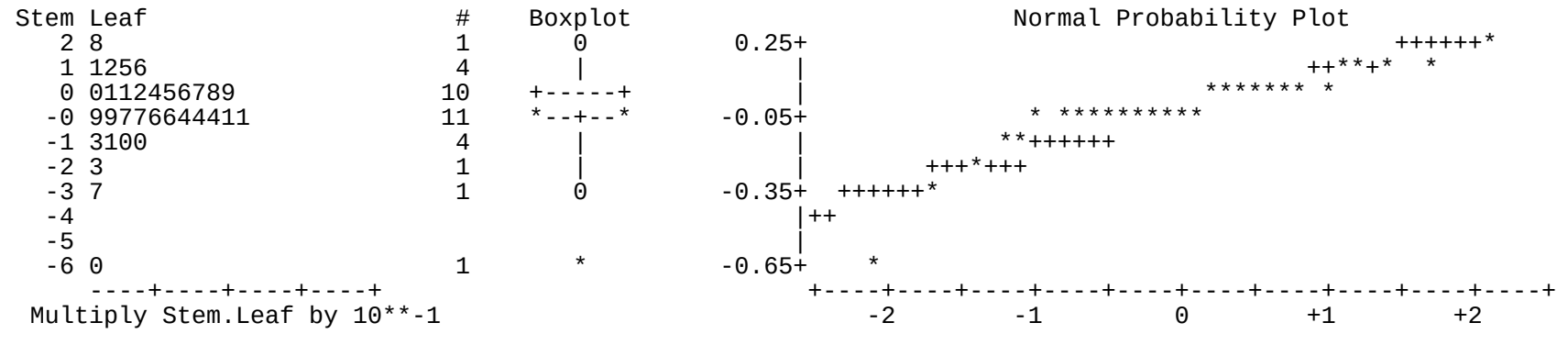
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	35	Sum Weights	35
Mean	0.42396256	Sum Observations	14.8386896
Std Deviation	0.28856583	Variance	0.08327024
Skewness	3.3221737	Kurtosis	15.2822309
Uncorrected SS	9.12223696	Corrected SS	2.83118812
Coeff Variation	68.0639891	Std Error Mean	0.04877653

Basic Statistical Measures

Location		Variability	
Mean	0.423963	Std Deviation	0.28857
Median	0.378578	Variance	0.08327
Mode	0.508083	Range	1.77194
		Interquartile Range	0.22772

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.691938	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.695859	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.213901	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.382513	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.396516	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.8013857
99%	1.8013857
95%	0.7621247
90%	0.6615385
75% Q3	0.4950495

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3785780
25% Q1	0.2673267
10%	0.1980198
5%	0.1616628
1%	0.0294423
0% Min	0.0294423

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0294423	4	0.588235	18
0.1616628	29	0.661538	30
0.1939058	12	0.732673	3
0.1980198	10	0.762125	15
0.2000000	6	1.801386	31

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

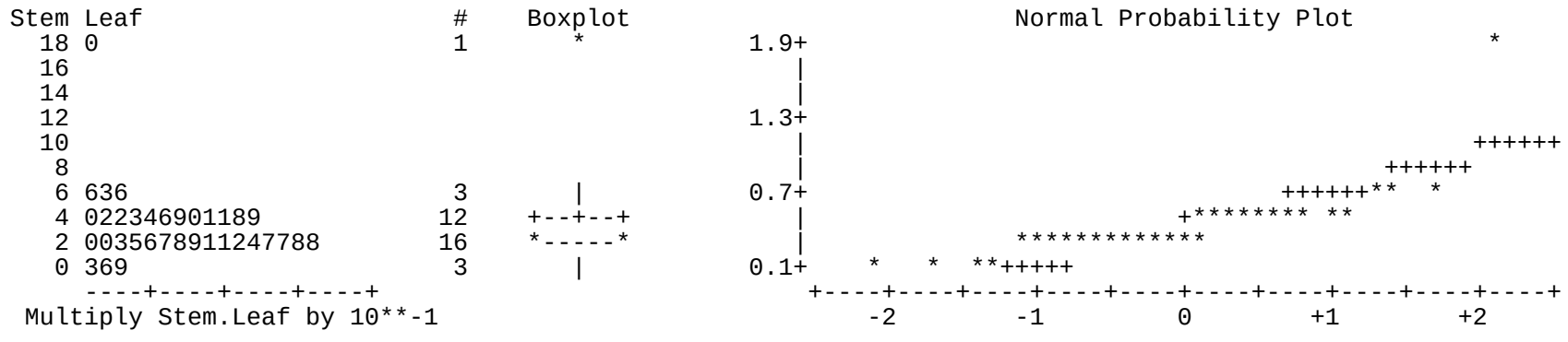

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	35	Sum Weights	35
Mean	0.41520252	Sum Observations	14.5320881
Std Deviation	0.29026856	Variance	0.08425584
Skewness	3.08880571	Kurtosis	12.5822853
Uncorrected SS	8.89845806	Corrected SS	2.86469853
Coeff Variation	69.9101168	Std Error Mean	0.04906434

Basic Statistical Measures

Location		Variability	
Mean	0.415203	Std Deviation	0.29027
Median	0.356436	Variance	0.08426
Mode	0.360111	Range	1.63212
		Interquartile Range	0.24931

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.462409	Pr > |t|	<.0001
Sign	M	17.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	315	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.70134	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.181334	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.421405	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.595488	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.736111
99%	1.736111
95%	1.013825
90%	0.618652
75% Q3	0.498615

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.356436
25% Q1	0.249307
10%	0.196305
5%	0.110803
1%	0.103986
0% Min	0.103986

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.103986	10	0.577367	24
0.110803	33	0.618652	11
0.156971	9	0.633663	30
0.196305	23	1.013825	15
0.220403	13	1.736111	31

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Table 11.71
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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

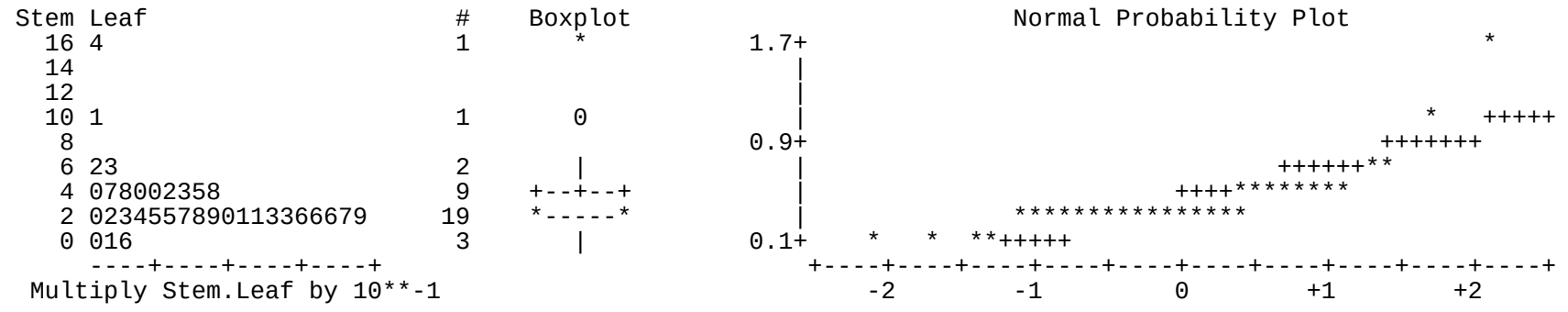

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	35	Sum Weights	35
Mean	-0.00876	Sum Observations	-0.3066016
Std Deviation	0.12512076	Variance	0.01565521
Skewness	0.07548487	Kurtosis	1.49109321
Uncorrected SS	0.53496284	Corrected SS	0.53227699
Coeff Variation	-1428.312	Std Error Mean	0.02114927

Basic Statistical Measures

Location		Variability	
Mean	-0.00876	Std Deviation	0.12512
Median	-0.00947	Variance	0.01566
Mode		Range	0.65814
		Interquartile Range	0.16572

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.4142	Pr > |t|	0.6813
Sign	M	-2.5	Pr >= |M|	0.4996

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-31	Pr >= |S|	0.6187

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.965918	Pr < W	0.3413
Kolmogorov-Smirnov	D	0.127252	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.063387	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.458761	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.32699332
99%	0.32699332
95%	0.25170017
90%	0.10168336
75% Q3	0.07168310

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.00946818
25% Q1	-0.09403367
10%	-0.15817500
5%	-0.23762376
1%	-0.33114918
0% Min	-0.33114918

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.331149	33	0.100231	6
-0.237624	3	0.101683	8
-0.166051	32	0.103691	1
-0.158175	13	0.251700	15
-0.123739	34	0.326993	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                  #    Boxplot                    Normal Probability Plot
     3 3                     1       0          0.325+                                  *   +
     2 5                     1       |             |                                  *   ++++
     2                               |             |                                 ++++
     1                               |             |                             ++++
     1 000                   3       |             |                         ++*+**
     0 5577789               7    +-----+          |                     ******
     0 234                   3    |     |          |                  +***
    -0 32221111              8    *--+--*          |               ******
    -0 9776                  4    +-----+          |            ****
    -1 2210                  4       |             |         ****
    -1 76                    2       |             |       +**+
    -2 4                     1       |             |     ++*+
    -2                               |             |  ++++
    -3 3                     1       |         -0.325+++  *
       ----+----+----+----+                          +----+----+----+----+----+----+----+----+----+----+
   Multiply Stem.Leaf by 10**-1                        -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	42	Sum Weights	42
Mean	0.3358391	Sum Observations	14.1052421
Std Deviation	0.20440944	Variance	0.04178322
Skewness	1.44823857	Kurtosis	1.48485418
Uncorrected SS	6.45020376	Corrected SS	1.71311199
Coeff Variation	60.86529	Std Error Mean	0.03154106

Basic Statistical Measures

Location		Variability	
Mean	0.335839	Std Deviation	0.20441
Median	0.290496	Variance	0.04178
Mode		Range	0.84538
		Interquartile Range	0.20792

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.64768	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	451.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.837317	Pr < W <0.0001
Kolmogorov-Smirnov	D	0.177104	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.395316	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	2.423811	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9209454
99%	0.9209454
95%	0.7625650
90%	0.7462687
75% Q3	0.3861386

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.2904956
25% Q1	0.1782178
10%	0.1625366
5%	0.1386139
1%	0.0755668
0% Min	0.0755668

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0755668	34	0.746269	38
0.1172708	27	0.761246	32
0.1386139	40	0.762565	41
0.1616628	9	0.831234	5
0.1625366	20	0.920945	13

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

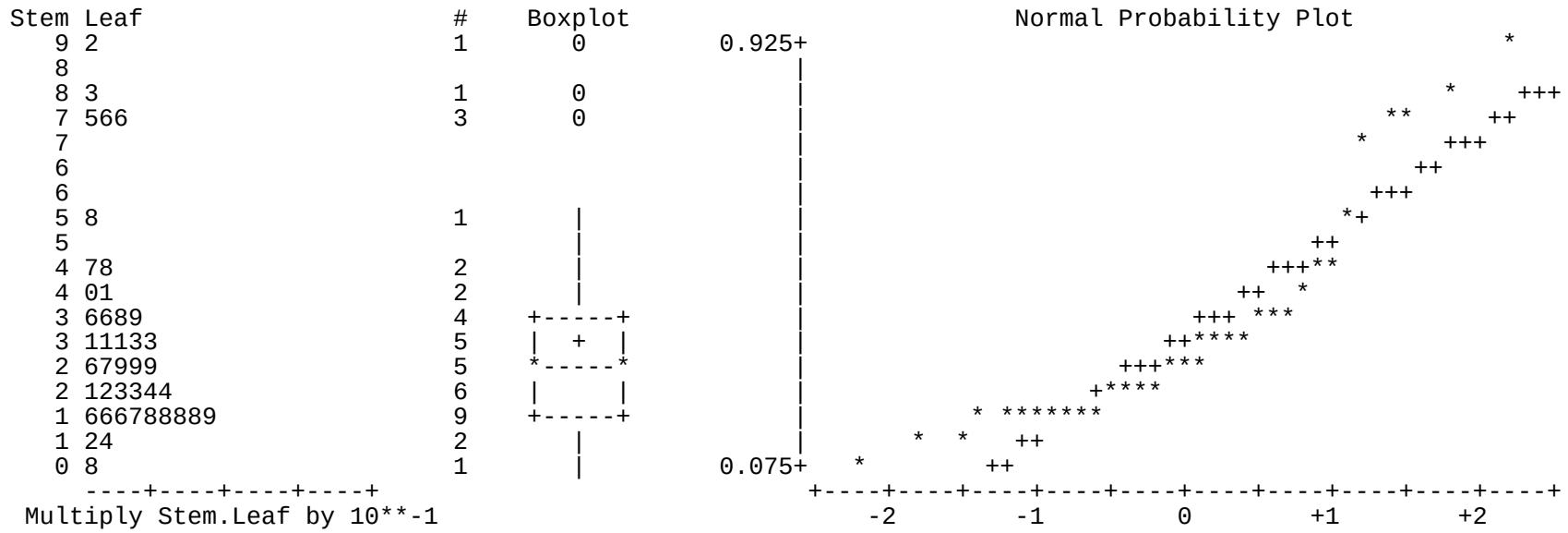

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	42	Sum Weights	42
Mean	0.30154413	Sum Observations	12.6648534
Std Deviation	0.18205667	Variance	0.03314463
Skewness	1.82856692	Kurtosis	3.49830702
Uncorrected SS	5.17794201	Corrected SS	1.35892982
Coeff Variation	60.3748005	Std Error Mean	0.02809195

Basic Statistical Measures

Location		Variability	
Mean	0.301544	Std Deviation	0.18206
Median	0.249307	Variance	0.03314
Mode	0.173310	Range	0.83217
		Interquartile Range	0.12707

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.73418	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.804432	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.239569	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.524744	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.807048	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9068010
99%	0.9068010
95%	0.5990783

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.5540166
75% Q3	0.3117423
50% Median	0.2493075
25% Q1	0.1846722
10%	0.1592284
5%	0.1230769
1%	0.0746269
0% Min	0.0746269

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0746269	40	0.554017	3
0.1076923	27	0.567867	41
0.1230769	23	0.599078	32
0.1523546	9	0.861386	13
0.1592284	10	0.906801	5

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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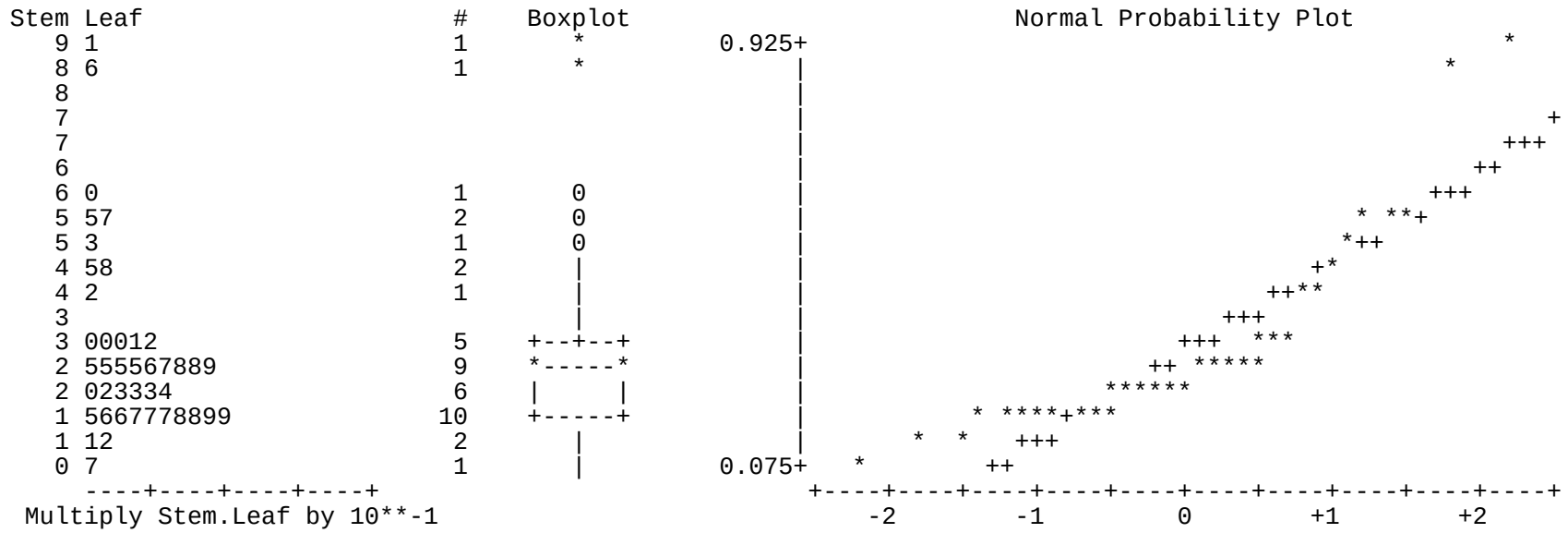
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	42	Sum Weights	42
Mean	-0.034295	Sum Observations	-1.4403887
Std Deviation	0.11252584	Variance	0.01266207
Skewness	0.36512879	Kurtosis	1.53654182
Uncorrected SS	0.56854277	Corrected SS	0.51914468
Coeff Variation	-328.11182	Std Error Mean	0.01736311

Basic Statistical Measures

Location		Variability	
Mean	-0.03429	Std Deviation	0.11253
Median	-0.04391	Variance	0.01266
Mode		Range	0.60363
		Interquartile Range	0.14590

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.97516	Pr > |t|	0.0550
Sign	M	-7	Pr >= |M|	0.0436

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-179.5	Pr >= |S|	0.0229

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.969732	Pr < W	0.3235
Kolmogorov-Smirnov	D	0.084976	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.050326	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.4019	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2985930
99%	0.2985930
95%	0.0991963
90%	0.0865081
75% Q3	0.0418278

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0439067
25% Q1	-0.1040723
10%	-0.1384681
5%	-0.1946980
1%	-0.3050355
0% Min	-0.3050355

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.305035	25	0.0865081	30
-0.261280	38	0.0876233	14
-0.194698	41	0.0991963	24
-0.162167	32	0.2188055	34
-0.138468	18	0.2985930	6

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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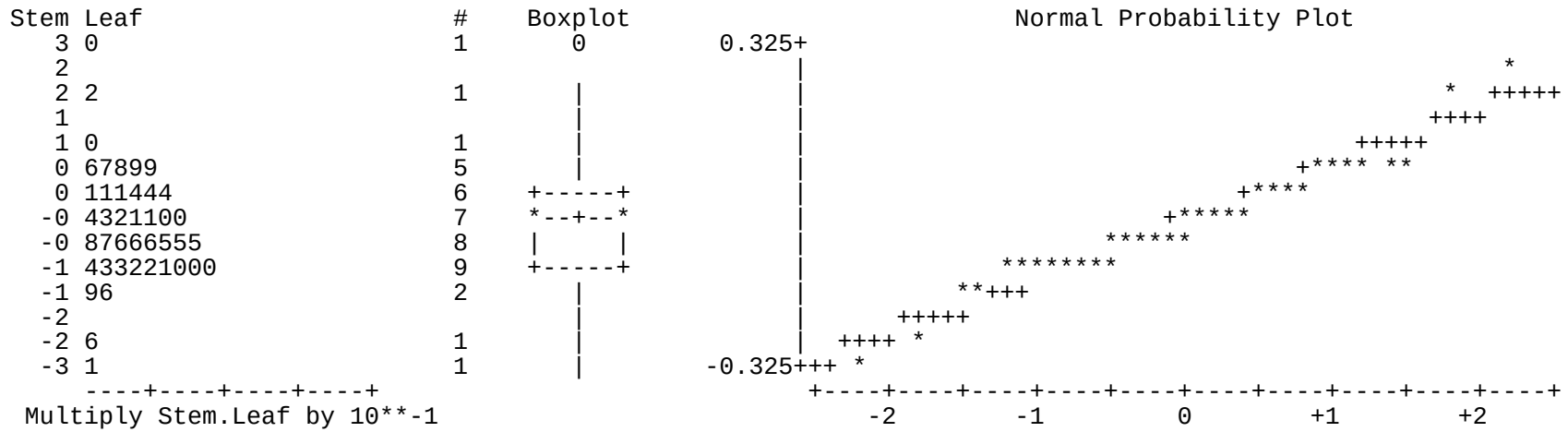
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	42	Sum Weights	42
Mean	0.35923125	Sum Observations	15.0877123
Std Deviation	0.23679871	Variance	0.05607363
Skewness	1.64863685	Kurtosis	2.49412707
Uncorrected SS	7.71899642	Corrected SS	2.29901874
Coeff Variation	65.9181824	Std Error Mean	0.03653883

Basic Statistical Measures

Location		Variability	
Mean	0.359231	Std Deviation	0.23680
Median	0.300954	Variance	0.05607
Mode	0.138539	Range	0.94906
		Interquartile Range	0.26879

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.831492	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.815156	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.188239	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.347747	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.31847	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.059908
99%	1.059908
95%	0.980810

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.554593
75% Q3	0.453401
50% Median	0.300954
25% Q1	0.184615
10%	0.138539
5%	0.138504
1%	0.110847
0% Min	0.110847

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.110847	39	0.554593	38
0.134108	13	0.803324	40
0.138504	24	0.980810	2
0.138539	41	1.009901	17
0.138539	12	1.059908	36

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
   Stem Leaf                     #    Boxplot                        Normal Probability Plot
     10 6                        1       0          1.075+                                  *
     10 1                        1       0               |                                +
      9 8                        1       0               |                              *
      9                                                  |                            ++
      8                                                  |                          ++
      8 0                        1       |               |                        *   ++
      7                                  |               |                      ++
      7                                  |               |                    ++
      6                                  |               |                  ++
      6                                  |               |                ++
      5 55                       2       |               |              ++ *
      5 24                       2       |               |           +++***
      4 567                      3    +-----+            |         ++ **
      4 123                      3    |     |            |       ++ **
      3 5                        1    |  +  |            |     ++
      3 0012334                  7    *-----*            |   ++*****
      2 5699                     4    |     |            | ++***
      2 00244                    5    |     |            +***
      1 566678                   6    +-----+            | ** ***
      1 13444                    5       |          0.125+   *   *  **   ++
        ----+----+----+----+                              +----+----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**-1                            -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	42	Sum Weights	42
Mean	0.31920776	Sum Observations	13.4067261
Std Deviation	0.25060686	Variance	0.0628038
Skewness	3.6497539	Kurtosis	17.5861972
Uncorrected SS	6.85448673	Corrected SS	2.57495566
Coeff Variation	78.5090103	Std Error Mean	0.03866948

Basic Statistical Measures

Location		Variability	
Mean	0.319208	Std Deviation	0.25061
Median	0.276817	Variance	0.06280
Mode	0.167436	Range	1.53104
		Interquartile Range	0.19130

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	8.254773	Pr > |t|	<.0001
Sign	M	21	Pr >= |M|	<.0001
Signed Rank	S	451.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.652422	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.23799	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.538821	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.289927	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.6158818
99%	1.6158818
95%	0.5817175

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.4618938
75% Q3	0.3695150
50% Median	0.2768170
25% Q1	0.1782178
10%	0.1287129
5%	0.0977995
1%	0.0848416
0% Min	0.0848416

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0848416	13	0.461894	40
0.0888099	32	0.514851	26
0.0977995	12	0.581717	4
0.1039261	20	0.808314	17
0.1287129	11	1.615882	2

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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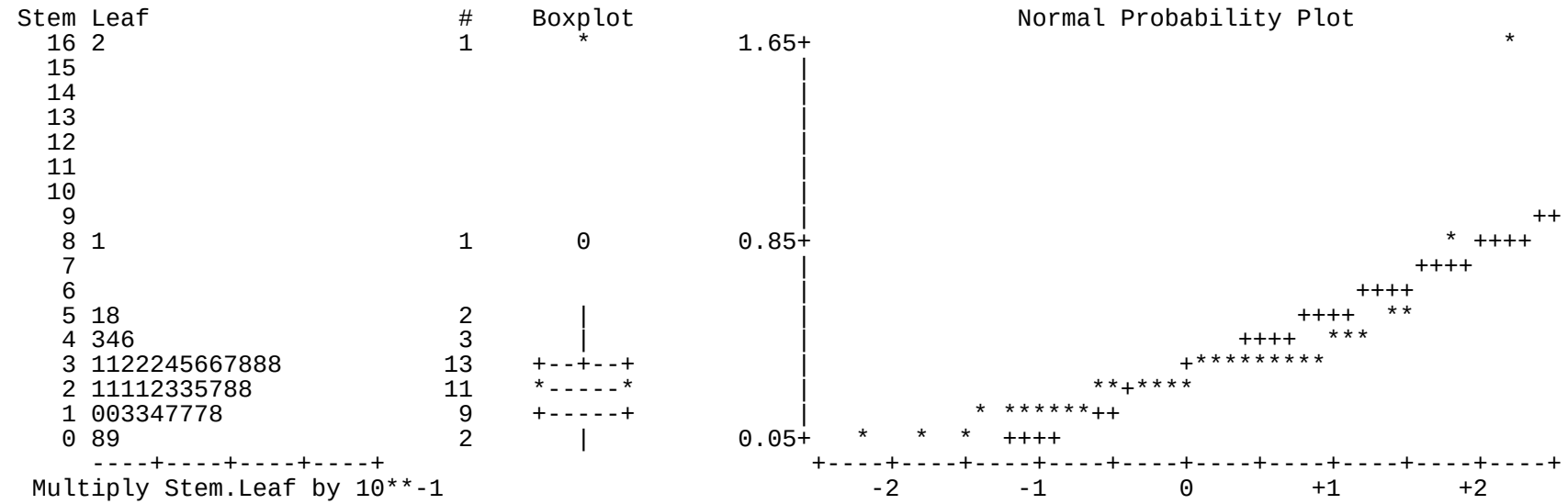
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	42	Sum Weights	42
Mean	-0.0400235	Sum Observations	-1.6809862
Std Deviation	0.18350179	Variance	0.03367291
Skewness	-0.2425618	Kurtosis	8.22129456
Uncorrected SS	1.44786817	Corrected SS	1.38058925
Coeff Variation	-458.48535	Std Error Mean	0.02831494

Basic Statistical Measures

Location		Variability	
Mean	-0.04002	Std Deviation	0.18350
Median	-0.03370	Variance	0.03367
Mode		Range	1.37190
		Interquartile Range	0.13260

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.41351	Pr > |t|	0.1651
Sign	M	-8	Pr >= |M|	0.0195

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-150.5	Pr >= |S|	0.0589

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.815636	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.162687	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.364282	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.203813	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6350716
99%	0.6350716
95%	0.1395224
90%	0.0792079
75% Q3	0.0402256

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0336981
25% Q1	-0.0923788
10%	-0.2015869
5%	-0.2490199
1%	-0.7368309
0% Min	-0.7368309

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.736831	36	0.0792079	37
-0.341430	40	0.1137798	4
-0.249020	34	0.1395224	6
-0.207923	7	0.1549428	18
-0.201587	17	0.6350716	2

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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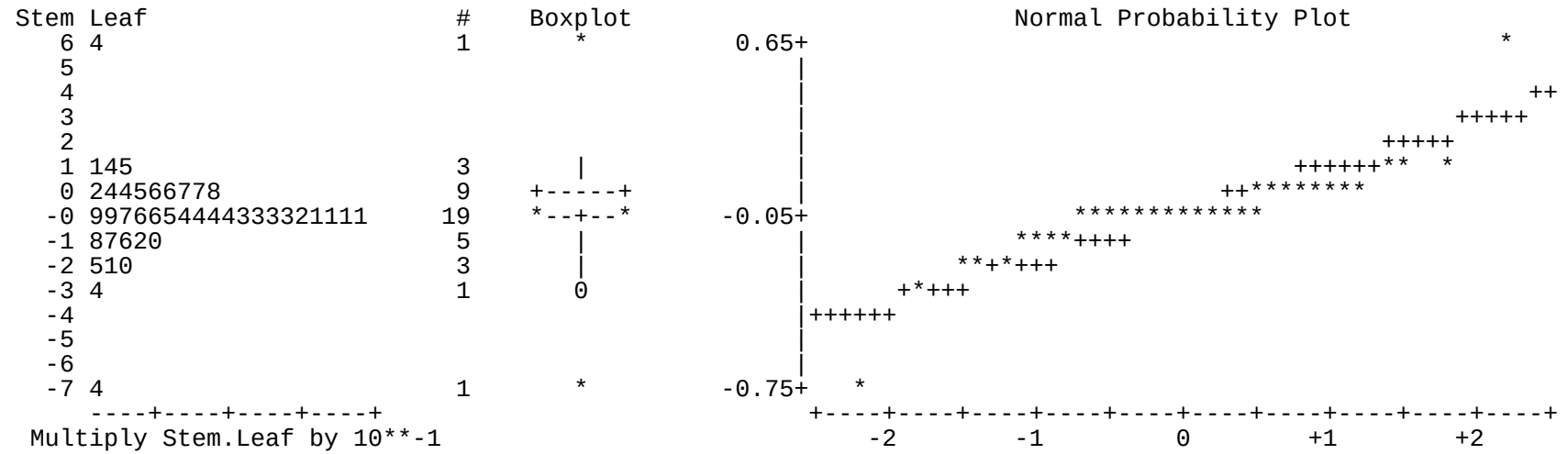
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	34	Sum Weights	34
Mean	0.40633243	Sum Observations	13.8153028
Std Deviation	0.22314109	Variance	0.04979195
Skewness	0.57118696	Kurtosis	-0.3810968
Uncorrected SS	7.25673985	Corrected SS	1.64313426
Coeff Variation	54.9158949	Std Error Mean	0.03826838

Basic Statistical Measures

Location		Variability	
Mean	0.406332	Std Deviation	0.22314
Median	0.366156	Variance	0.04979
Mode	0.691244	Range	0.91312
		Interquartile Range	0.36011

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	10.61797	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.93984	Pr < W	0.0610
Kolmogorov-Smirnov	D	0.15337	Pr > D	0.0416
Cramer-von Mises	W-Sq	0.110218	Pr > W-Sq	0.0822
Anderson-Darling	A-Sq	0.709618	Pr > A-Sq	0.0605

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.9823678
99%	0.9823678
95%	0.7159353
90%	0.6927465
75% Q3	0.5817175

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3661560
25% Q1	0.2216066
10%	0.1538462
5%	0.1303993
1%	0.0692521
0% Min	0.0692521

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0692521	17	0.692695	28
0.1303993	1	0.692747	9
0.1334017	29	0.701754	5
0.1538462	31	0.715935	8
0.1616628	3	0.982368	4

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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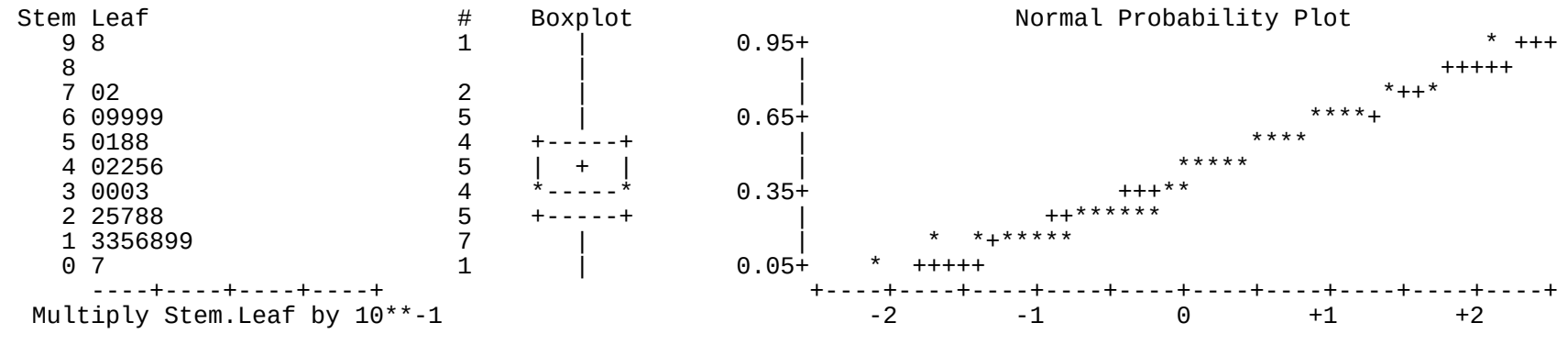
Population: Intent-to-Treat with LOCF

Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	34	Sum Weights	34
Mean	0.28897134	Sum Observations	9.82502571
Std Deviation	0.13002359	Variance	0.01690613
Skewness	0.65016198	Kurtosis	0.1362336
Uncorrected SS	3.39705331	Corrected SS	0.55790243
Coeff Variation	44.9953233	Std Error Mean	0.02229886

Basic Statistical Measures

Location		Variability	
Mean	0.288971	Std Deviation	0.13002
Median	0.285754	Variance	0.01691
Mode	0.242634	Range	0.51963
		Interquartile Range	0.17119

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.95902	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.957942	Pr < W	0.2116
Kolmogorov-Smirnov	D	0.083307	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.046085	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.371443	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6004619
99%	0.6004619
95%	0.5927637

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.4307692
75% Q3	0.3601108
50% Median	0.2857543
25% Q1	0.1889169
10%	0.1385681
5%	0.0977995
1%	0.0808314
0% Min	0.0808314

Extreme Observations

-------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.0808314	31	0.415704	20
0.0977995	1	0.430769	33
0.1316245	7	0.503778	28
0.1385681	3	0.592764	4
0.1492537	6	0.600462	8

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

```
   Stem Leaf                     #    Boxplot                        Normal Probability Plot
      6 0                        1       |          0.625+                                  *  ++
      5 9                        1       |                |                              *   +++
      5 0                        1       |                |                           *  ++++
      4                                  |                |                        ++++
      4 2223                     4       |                |                    ****
      3 668                      3    +-----+             |                 +***
      3 011224                   6    |     |             |              +****
      2 689                      3    *--+--*             |           +***
      2 02244                    5    |     |             |       ++**
      1 567899                   6    +-----+             |    ******
      1 034                      3       |                |  *+**
      0 8                        1       |          0.075+    *  +*++
        ----+----+----+----+                              +----+----+----+----+----+----+----+----+----+----+
    Multiply Stem.Leaf by 10**-1                             -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	34	Sum Weights	34
Mean	-0.1173611	Sum Observations	-3.9902771
Std Deviation	0.16111925	Variance	0.02595941
Skewness	-0.0196012	Kurtosis	-0.2608056
Uncorrected SS	1.32496387	Corrected SS	0.85666061
Coeff Variation	-137.28507	Std Error Mean	0.02763172

Basic Statistical Measures

Location		Variability	
Mean	-0.11736	Std Deviation	0.16112
Median	-0.09572	Variance	0.02596
Mode		Range	0.67527
		Interquartile Range	0.21074

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-4.24733	Pr > |t|	0.0002
Sign	M	-11	Pr >= |M|	0.0002

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-206.5	Pr >= |S|	0.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.981841	Pr < W	0.8288
Kolmogorov-Smirnov	D	0.094839	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.041976	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.25069	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2463753
99%	0.2463753
95%	0.1427278
90%	0.1040548
75% Q3	-0.0230947

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0957215
25% Q1	-0.2338389
10%	-0.3581005
5%	-0.3896041
1%	-0.4288943
0% Min	-0.4288943

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.428894	9	0.0571294	29
-0.389604	4	0.1040548	27
-0.388835	5	0.1171097	34
-0.358101	30	0.1427278	18
-0.287660	16	0.2463753	17

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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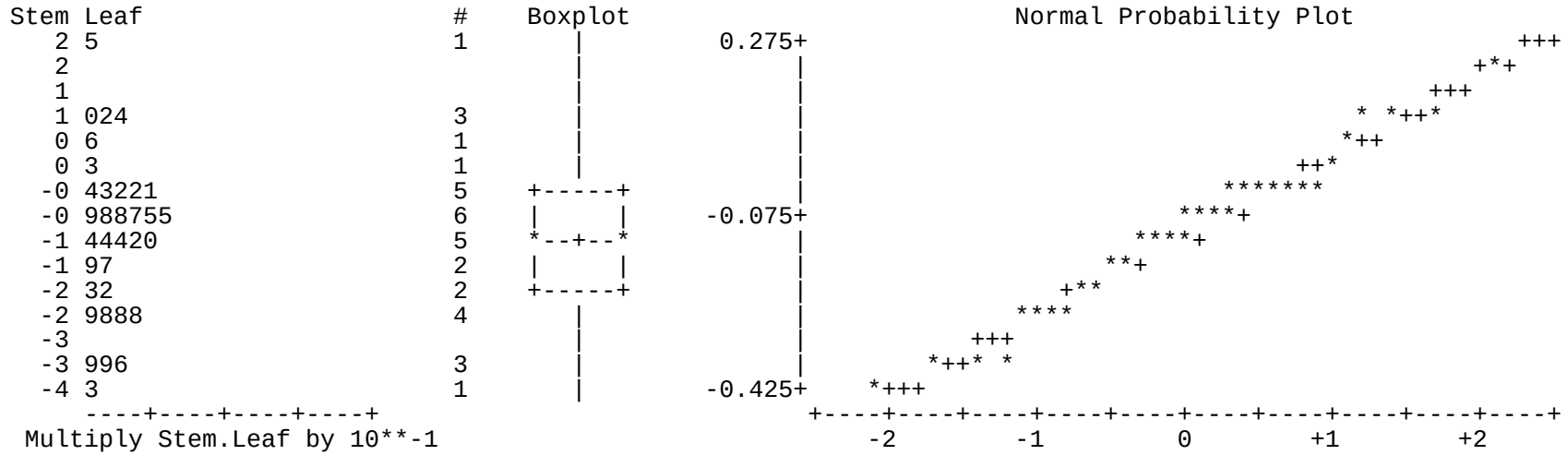
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	34	Sum Weights	34
Mean	0.33909292	Sum Observations	11.5291593
Std Deviation	0.15654473	Variance	0.02450625
Skewness	0.74746916	Kurtosis	-0.0447929
Uncorrected SS	4.71816262	Corrected SS	0.80870633
Coeff Variation	46.1657323	Std Error Mean	0.0268472

Basic Statistical Measures

Location		Variability	
Mean	0.339093	Std Deviation	0.15654
Median	0.318969	Variance	0.02451
Mode		Range	0.57917
		Interquartile Range	0.18843

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.63048	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.937571	Pr < W	0.0522
Kolmogorov-Smirnov	D	0.10609	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.095802	Pr > W-Sq	0.1261
Anderson-Darling	A-Sq	0.639069	Pr > A-Sq	0.0903

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.692521
99%	0.692521
95%	0.687067
90%	0.571924
75% Q3	0.415704

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.318969
25% Q1	0.227273
10%	0.138539
5%	0.123997
1%	0.113350
0% Min	0.113350

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.113350	31	0.562771	3
0.123997	14	0.571924	33
0.138504	2	0.627547	29
0.138539	8	0.687067	10
0.178100	13	0.692521	18

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                     #    Boxplot                    Normal Probability Plot
     6 99                       2       |          0.675+                                  *  +*++
     6 3                        1       |                |                              *  +++
     5 67                       2       |                |                           ** +++
     5 0                        1       |                |                           +++
     4 8                        1       |                |                        +**
     4 22                       2    +-----+             |                     +++**
     3 67889                    5    |     |             |                  ++****
     3 01234                    5    *--+--*             |               +****
     2 5668                     4    |     |             |            +***
     2 112334                   6    +-----+             |         ******
     1 8                        1       |                |      +*++
     1 1244                     4       |          0.125+    *   * +*+*
       ----+----+----+----+               +----+----+----+----+----+----+----+----+----+----+
  Multiply Stem.Leaf by 10**-1                            -2        -1         0        +1        +2
```

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	34	Sum Weights	34
Mean	0.27865115	Sum Observations	9.47413914
Std Deviation	0.11751748	Variance	0.01381036
Skewness	0.51551636	Kurtosis	-0.6976665
Uncorrected SS	3.0957216	Corrected SS	0.45574182
Coeff Variation	42.1736929	Std Error Mean	0.02015408

Basic Statistical Measures

Location		Variability	
Mean	0.278651	Std Deviation	0.11752
Median	0.276966	Variance	0.01381
Mode		Range	0.41328
		Interquartile Range	0.18642

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	13.82604	Pr > |t|	<.0001
Sign	M	17	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	297.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.941615	Pr < W	0.0689
Kolmogorov-Smirnov	D	0.145658	Pr > D	0.0670
Cramer-von Mises	W-Sq	0.094375	Pr > W-Sq	0.1317
Anderson-Darling	A-Sq	0.62244	Pr > A-Sq	0.0974

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.514851
99%	0.514851
95%	0.510823
90%	0.463450
75% Q3	0.369344

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.276966
25% Q1	0.182927
10%	0.144342
5%	0.123077
1%	0.101570
0% Min	0.101570

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.101570	14	0.429363	4
0.123077	8	0.463450	29
0.134108	22	0.495050	5
0.144342	32	0.510823	3
0.151134	9	0.514851	7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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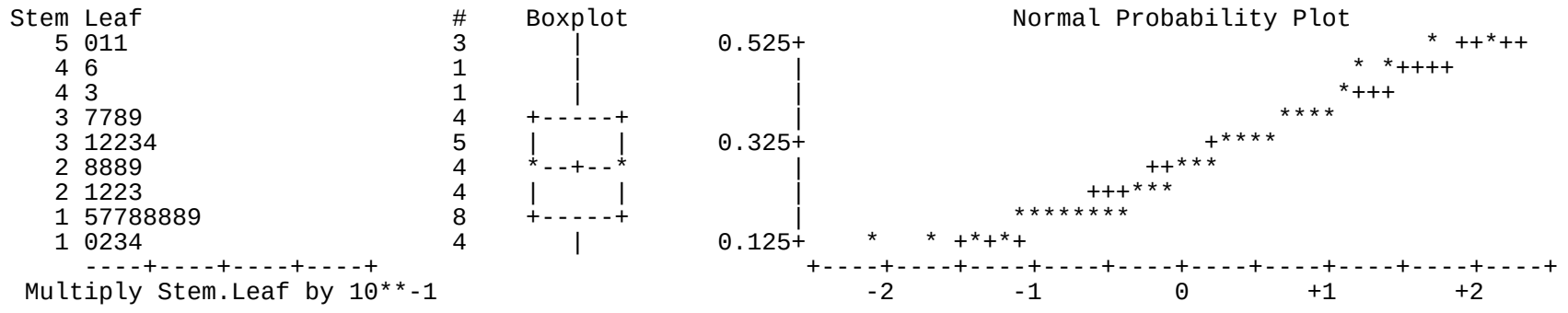
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	34	Sum Weights	34
Mean	-0.0604418	Sum Observations	-2.0550201
Std Deviation	0.10503512	Variance	0.01103238
Skewness	-0.8556585	Kurtosis	2.30026469
Uncorrected SS	0.48827749	Corrected SS	0.36406844
Coeff Variation	-173.77903	Std Error Mean	0.01801337

Basic Statistical Measures

Location		Variability	
Mean	-0.06044	Std Deviation	0.10504
Median	-0.05042	Variance	0.01103
Mode		Range	0.55327
		Interquartile Range	0.09098

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-3.35538	Pr > |t|	0.0020
Sign	M	-8.5	Pr >= |M|	0.0046

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-187.5	Pr >= |S|	0.0003

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.925299	Pr < W	0.0229
Kolmogorov-Smirnov	D	0.154496	Pr > D	0.0388
Cramer-von Mises	W-Sq	0.177924	Pr > W-Sq	0.0094
Anderson-Darling	A-Sq	1.007301	Pr > A-Sq	0.0103

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.1840765
99%	0.1840765
95%	0.0793451
90%	0.0369515
75% Q3	0.0000000

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0504213
25% Q1	-0.0909809
10%	-0.2025793
5%	-0.3139326
1%	-0.3691951
0% Min	-0.3691951

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.369195	18	0.0198020	7
-0.313933	10	0.0369515	24
-0.205942	22	0.0712653	31
-0.202579	33	0.0793451	5
-0.164097	29	0.1840765	2

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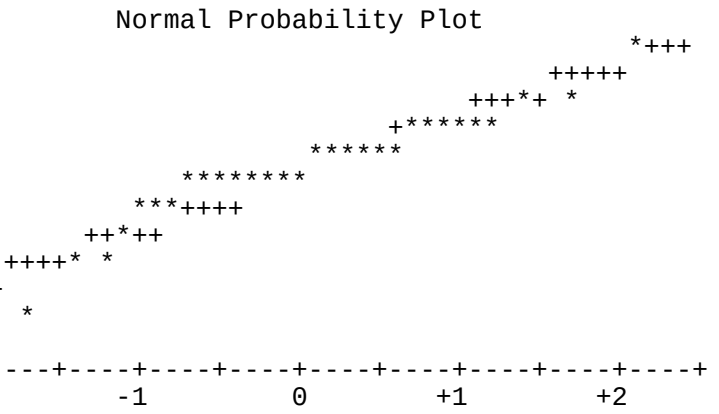
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

```
  Stem Leaf                     #    Boxplot
     1 8                        1       0
     1                                  |
     0 78                       2       |
     0 011124                   6    +-----+
    -0 43220                    5    |     |
    -0 998866655555            12    *--+--*
    -1 410                      3       |
    -1 6                        1       |
    -2 10                       2       |
    -2                                  |
    -3 1                        1       0
    -3 7                        1       *
       ----+----+----+----+
   Multiply Stem.Leaf by 10**-1
```



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[redacted]

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots

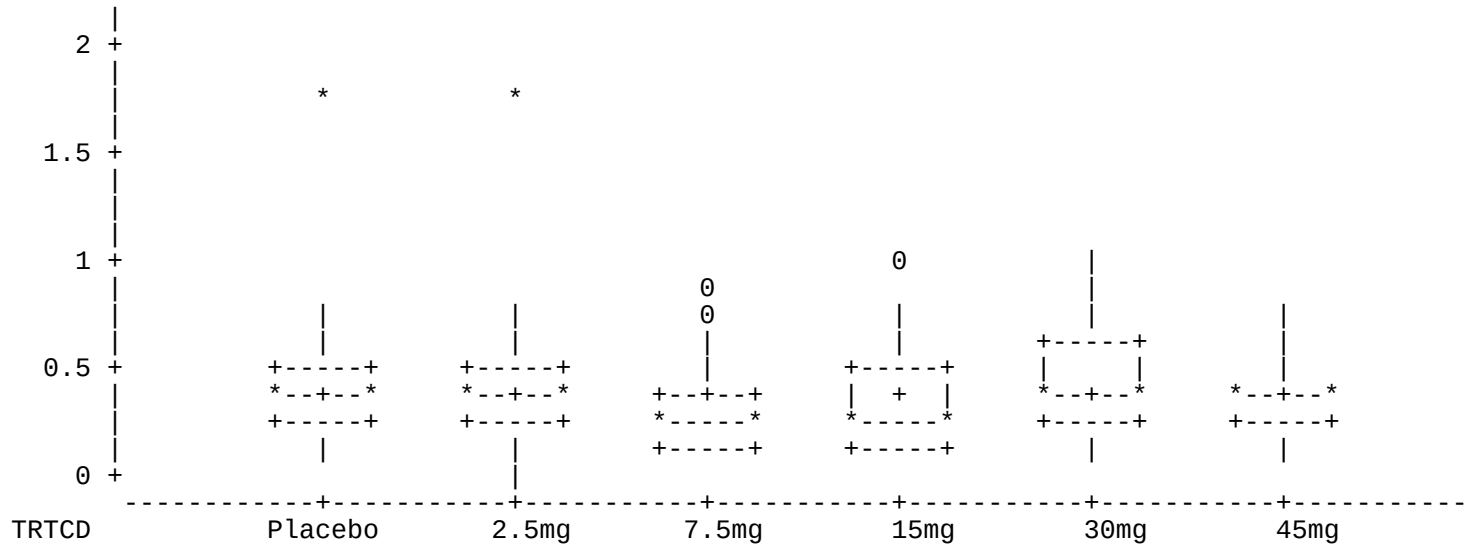

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Table 11.71
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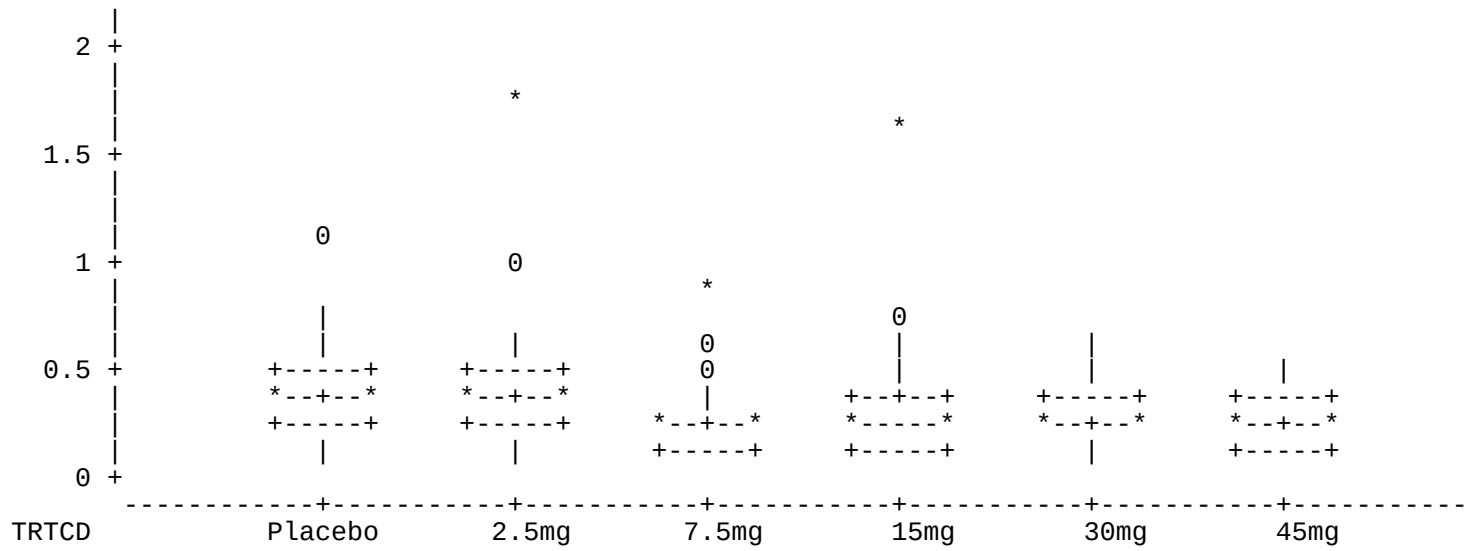
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



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[redacted]

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Table 11.71
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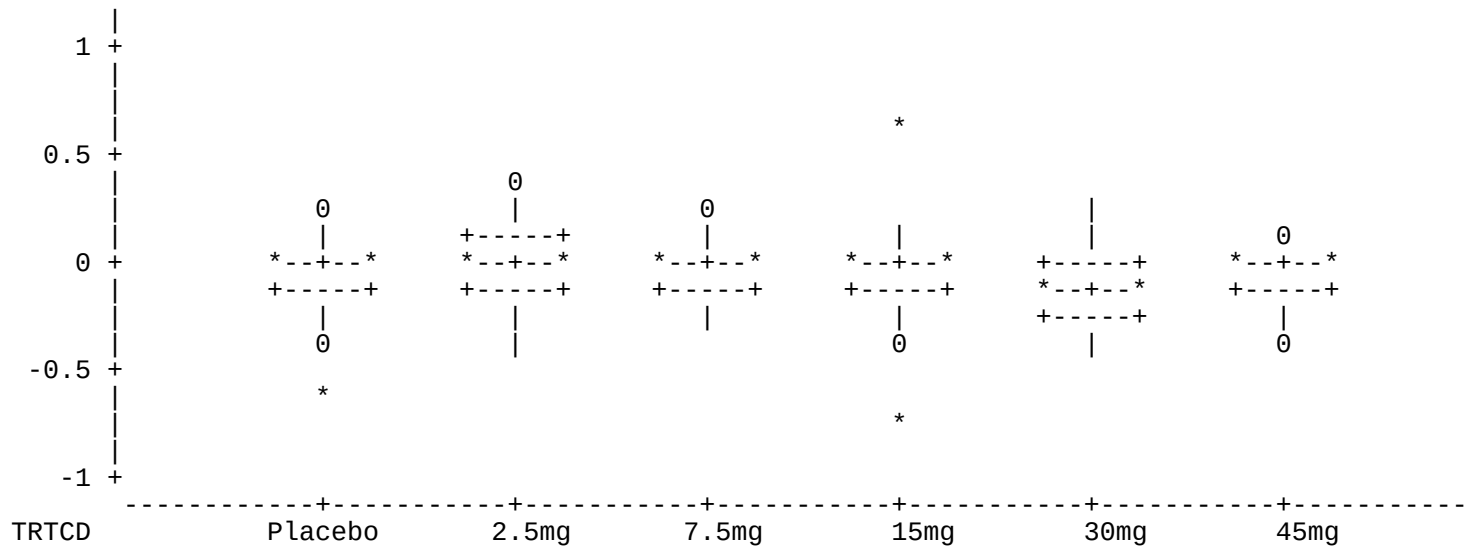
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



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Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg

Dimensions

Covariance Parameters	1
Columns in X	12
Columns in Z	0
Subjects	1
Max Obs Per Subject	220
Observations Used	220
Observations Not Used	0
Total Observations	220

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.01574	0.001532	10.27	<.0001	0.05	0.01312	0.01923

Fit Statistics

-2 Res Log Likelihood	-245.3
AIC (smaller is better)	-243.3
AICC (smaller is better)	-243.3
BIC (smaller is better)	-240.0

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept				0.07791	0.02937	211	2.65	0.0086
SEX	Female			-0.03067	0.01748	211	-1.75	0.0808
SEX	Male			0			.	
TRTTYPCD		Diet & Exercise		-0.03294	0.01770	211	-1.86	0.0641
TRTTYPCD		Monotherapy		0			.	
TRTCD			Placebo	0.05376	0.03080	211	1.75	0.0824
TRTCD			2.5mg	0.07849	0.03061	211	2.56	0.0110
TRTCD			7.5mg	0.02304	0.02899	211	0.79	0.4276
TRTCD			15mg	0.02103	0.02905	211	0.72	0.4699

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
TRTCD			30mg	-0.03383	0.03069	211	-1.10	0.2715
TRTCD			45mg	0			.	
EFSTDBL				-0.3195	0.03781	211	-8.45	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	211	3.08	0.0808
TRTTYPCD	1	211	3.46	0.0641
TRTCD	5	211	3.38	0.0059
EFSTDBL	1	211	71.41	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	0.02474	0.03062	211	0.81	0.4200	0.05	-0.03562	0.08509
7.5mg vs Pbo	-0.03071	0.02941	211	-1.04	0.2976	0.05	-0.08869	0.02727
15mg vs Pbo	-0.03273	0.02949	211	-1.11	0.2684	0.05	-0.09086	0.02540
30mg vs Pbo	-0.08759	0.03073	211	-2.85	0.0048	0.05	-0.1482	-0.02701

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Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
45mg vs Pbo	-0.05376	0.03080	211	-1.75	0.0824	0.05	-0.1145	0.006961

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5	Row6
Intercept				1	1	1	1	1	1
SEX	Female			0.5	0.5	0.5	0.5	0.5	0.5
SEX	Male			0.5	0.5	0.5	0.5	0.5	0.5
TRTTYPCD		Diet & Exercise		0.4182	0.4182	0.4182	0.4182	0.4182	0.4182
TRTTYPCD		Monotherapy		0.5818	0.5818	0.5818	0.5818	0.5818	0.5818
TRTCD			Placebo	1					
TRTCD			2.5mg		1				
TRTCD			7.5mg			1			
TRTCD			15mg				1		
TRTCD			30mg					1	
TRTCD			45mg						1
EFSTDBL				0.3757	0.3757	0.3757	0.3757	0.3757	0.3757

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.01750	0.02195	211	-0.80	0.4263	0.05	-0.06076	0.02577
TRTCD	2.5mg	WORK.EFF	0.007241	0.02140	211	0.34	0.7354	0.05	-0.03493	0.04942
TRTCD	7.5mg	WORK.EFF	-0.04821	0.01943	211	-2.48	0.0139	0.05	-0.08651	-0.00991
TRTCD	15mg	WORK.EFF	-0.05022	0.01949	211	-2.58	0.0107	0.05	-0.08865	-0.01180
TRTCD	30mg	WORK.EFF	-0.1051	0.02161	211	-4.86	<.0001	0.05	-0.1477	-0.06248
TRTCD	45mg	WORK.EFF	-0.07125	0.02162	211	-3.30	0.0012	0.05	-0.1139	-0.02863

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-0.02474	0.03062	211	-0.81	0.4200	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.08509	0.03562

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	7.5mg	WORK.EFF	0.03071	0.02941	211	1.04	0.2976	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.03273	0.02949	211	1.11	0.2684	0.05
TRTCD	Placebo	30mg	WORK.EFF	0.08759	0.03073	211	2.85	0.0048	0.05
TRTCD	Placebo	45mg	WORK.EFF	0.05376	0.03080	211	1.75	0.0824	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.05545	0.02902	211	1.91	0.0574	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.05746	0.02907	211	1.98	0.0494	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.1123	0.03023	211	3.72	0.0003	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.07849	0.03061	211	2.56	0.0110	0.05
TRTCD	7.5mg	15mg	WORK.EFF	0.002013	0.02742	211	0.07	0.9415	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.05687	0.02917	211	1.95	0.0525	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.02304	0.02899	211	0.79	0.4276	0.05
TRTCD	15mg	30mg	WORK.EFF	0.05486	0.02925	211	1.88	0.0621	0.05
TRTCD	15mg	45mg	WORK.EFF	0.02103	0.02905	211	0.72	0.4699	0.05
TRTCD	30mg	45mg	WORK.EFF	-0.03383	0.03069	211	-1.10	0.2715	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	7.5mg	-0.02727	0.08869
TRTCD	Placebo	15mg	-0.02540	0.09086
TRTCD	Placebo	30mg	0.02701	0.1482
TRTCD	Placebo	45mg	-0.00696	0.1145

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The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	2.5mg	7.5mg	-0.00176	0.1127
TRTCD	2.5mg	15mg	0.000160	0.1148
TRTCD	2.5mg	30mg	0.05273	0.1719
TRTCD	2.5mg	45mg	0.01815	0.1388
TRTCD	7.5mg	15mg	-0.05203	0.05606
TRTCD	7.5mg	30mg	-0.00062	0.1144
TRTCD	7.5mg	45mg	-0.03411	0.08020
TRTCD	15mg	30mg	-0.00279	0.1125
TRTCD	15mg	45mg	-0.03624	0.07830
TRTCD	30mg	45mg	-0.09432	0.02666

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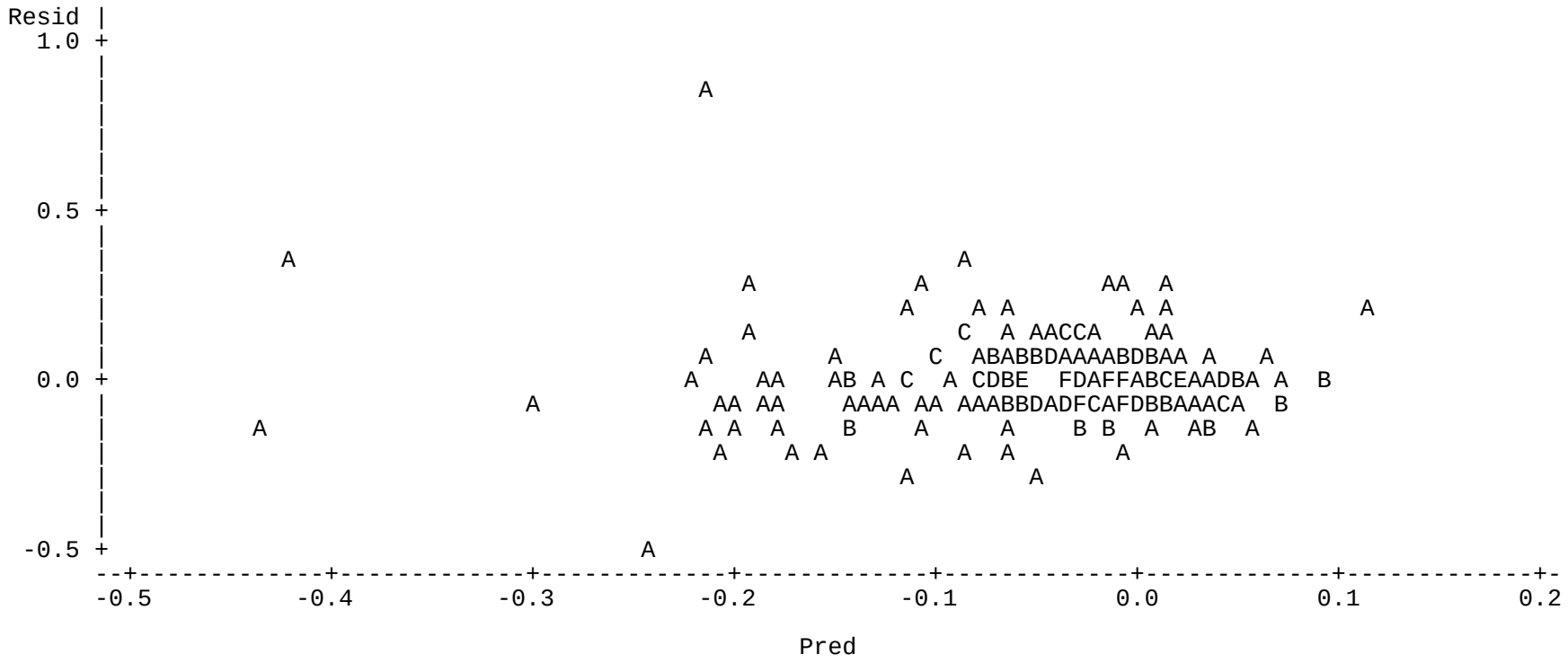
Table 11.71
SAS Statistical Output for Table 11.70
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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[redacted]

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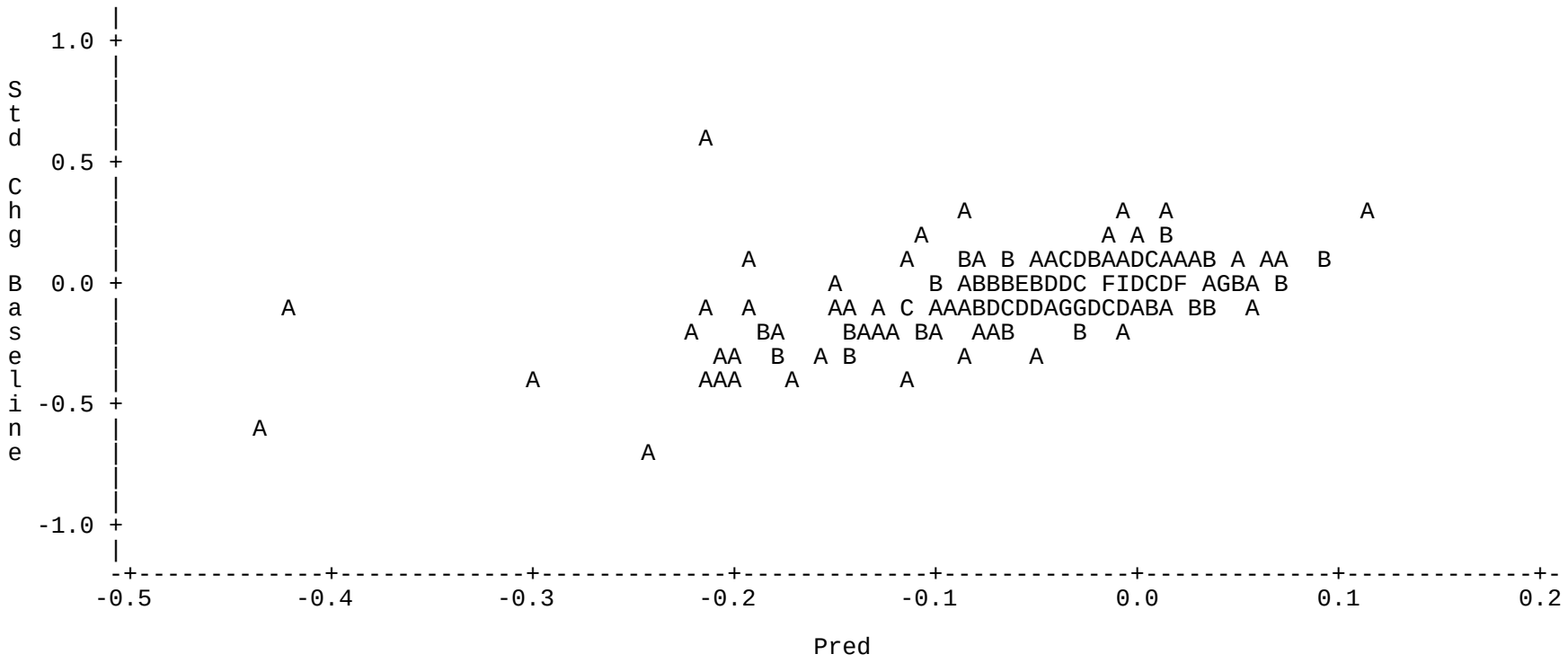
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	220	Sum Weights	220
Mean	0	Sum Observations	0
Std Deviation	0.12312713	Variance	0.01516029
Skewness	1.53738275	Kurtosis	11.0192187
Uncorrected SS	3.3201034	Corrected SS	3.3201034
Coeff Variation		Std Error Mean	0.00830123

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.12313
Median	-0.01289	Variance	0.01516
Mode		Range	1.34663
		Interquartile Range	0.10459

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-15	Pr >= |M|	0.0503
Signed Rank	S	-1191	Pr >= |S|	0.2084

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[redacted]

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Table 11.71
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.881266	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.117679	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.886678	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	4.832422	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8495290
99%	0.3388169
95%	0.2111526
90%	0.1322228
75% Q3	0.0472960
50% Median	-0.0128945
25% Q1	-0.0572946
10%	-0.1223590
5%	-0.1707324
1%	-0.2588607
0% Min	-0.4970994

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.497099	194	0.270886	21
-0.282725	179	0.303346	22
-0.258861	216	0.338817	85
-0.226359	112	0.353917	170
-0.222472	127	0.849529	8

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for Europe Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

```
                Histogram                #             Boxplot
 0.85+*                                  1                *
      .
      .
      .
      .
      .*                                3                0
      .***                              9                0
      .*******                         21                |
      .**********                      61           +--+--+
      .**********                      98           *-----*
      .*******                         21                |
      .**                               5                0
      .
-0.45+*                                 1                *
      ----+----+----+----+----+----+---
      * may represent up to 3 counts
```

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Table 11.71
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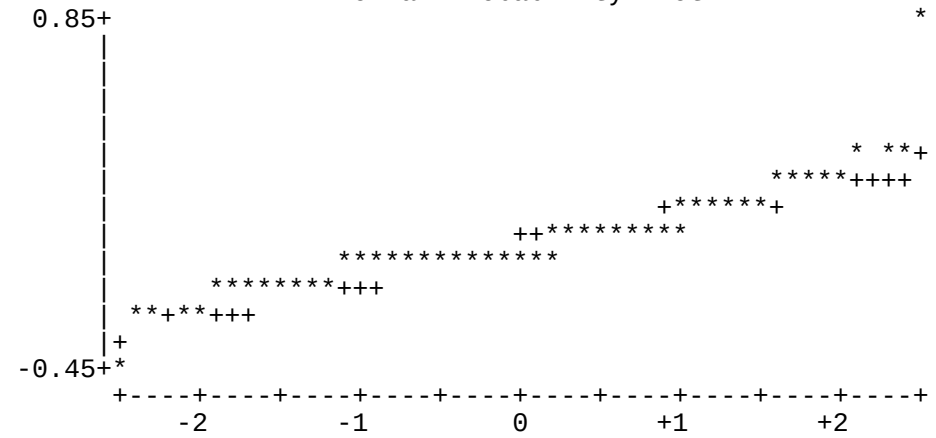
Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Normal Probability Plot



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Population: Intent-to-Treat with LOCF

Table 11.72

Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

		Placebo (N=26)	2.5mg (N=18)	7.5mg (N=18)	15mg (N=20)	30mg (N=20)	45mg (N=21)
n [1]		23	17	16	20	18	20
Number (%) of Values Carried Forward		5 (22%)	4 (24%)	5 (31%)	0	0	4 (20%)
Baseline	Mean	0.27	0.43	0.39	0.42	0.42	0.40
	SD	0.108	0.295	0.212	0.286	0.231	0.196
Week 12	Mean	0.28	0.42	0.36	0.33	0.36	0.35
	SD	0.110	0.184	0.246	0.199	0.163	0.173
Chg from Baseline	Mean	0.01	-0.01	-0.03	-0.09	-0.06	-0.05
	SD	0.105	0.231	0.213	0.282	0.108	0.113
Model-Adj Chg [2]	Mean	-0.05	0.02	-0.02	-0.07	-0.04	-0.04
	SE	0.031	0.036	0.037	0.033	0.034	0.033
Diff from Pbo [2]	Mean		0.06	0.02	-0.03	0.01	0.00
	95% CI		-0.03,0.16	-0.07,0.12	-0.12,0.06	-0.08,0.10	-0.09,0.10
	p-val [3]		0.181	0.637	0.557	0.826	0.917

[1]Number of subjects with a value at baseline and at specified visit
[2]Based on ANCOVA: Change = Baseline + Gender + Prior Therapy + Treatment
[3]A closed test procedure will be used. Tests will be performed in an hierarchical manner, that is, tests will be applied sequentially where testing does not proceed to the next step unless the previous test is found to be significant. P-values and 95% CIs for treatment differences for doses below the last significant treatment difference are for descriptive purposes only.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	23	Sum Weights	23
Mean	0.26943239	Sum Observations	6.19694488
Std Deviation	0.10821766	Variance	0.01171106
Skewness	0.59822704	Kurtosis	-0.185066
Uncorrected SS	1.92730099	Corrected SS	0.25764335
Coeff Variation	40.1650515	Std Error Mean	0.02256494

Basic Statistical Measures

Location		Variability	
Mean	0.269432	Std Deviation	0.10822
Median	0.250000	Variance	0.01171
Mode	0.166667	Range	0.39583
		Interquartile Range	0.14444

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	11.94031	Pr > |t|	<.0001
Sign	M	11.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	138	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.949218	Pr < W	0.2819
Kolmogorov-Smirnov	D	0.152173	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.070385	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.429913	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.500000
99%	0.500000
95%	0.462963
90%	0.450000
75% Q3	0.333333

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.250000
25% Q1	0.188889
10%	0.166667
5%	0.104167
1%	0.104167
0% Min	0.104167

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.104167	11	0.369792	6
0.104167	8	0.388889	1
0.166667	22	0.450000	10
0.166667	19	0.462963	23
0.166667	15	0.500000	17

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

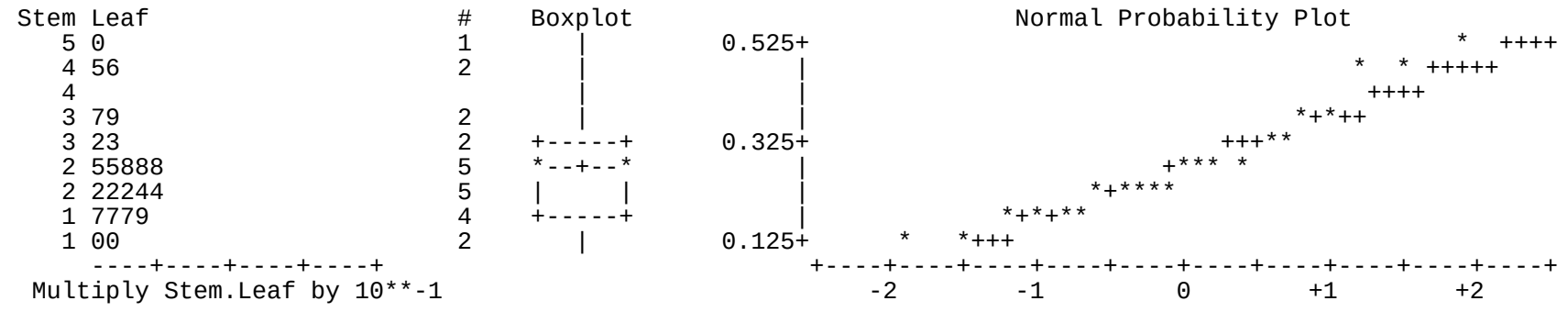

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	23	Sum Weights	23
Mean	0.28146704	Sum Observations	6.47374184
Std Deviation	0.11030436	Variance	0.01216705
Skewness	1.24969752	Kurtosis	1.91350963
Uncorrected SS	2.08982008	Corrected SS	0.26767515
Coeff Variation	39.1890874	Std Error Mean	0.02300005

Basic Statistical Measures

Location		Variability	
Mean	0.281467	Std Deviation	0.11030
Median	0.245098	Variance	0.01217
Mode		Range	0.47179
		Interquartile Range	0.15079

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	12.23767	Pr > |t|	<.0001
Sign	M	11.5	Pr >= |M|	<.0001

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	138	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.911164	Pr < W	0.0432
Kolmogorov-Smirnov	D	0.150931	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.089545	Pr > W-Sq	0.1481
Anderson-Darling	A-Sq	0.611773	Pr > A-Sq	0.0986

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.600000
99%	0.600000
95%	0.479167
90%	0.404762
75% Q3	0.345238

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.245098
25% Q1	0.194444
10%	0.179487
5%	0.166667
1%	0.128205
0% Min	0.128205

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.128205	8	0.354167	13
0.166667	15	0.371795	23
0.179487	18	0.404762	7
0.181818	16	0.479167	9
0.188406	20	0.600000	17

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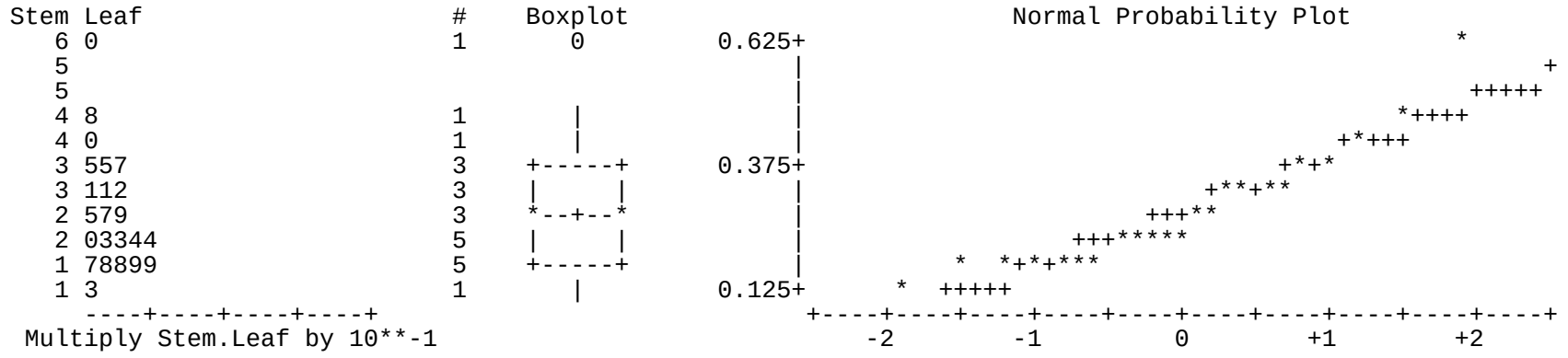
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	23	Sum Weights	23
Mean	0.01203465	Sum Observations	0.27679695
Std Deviation	0.10497581	Variance	0.01101992
Skewness	0.26021141	Kurtosis	-0.6179576
Uncorrected SS	0.24576942	Corrected SS	0.24243827
Coeff Variation	872.279715	Std Error Mean	0.02188897

Basic Statistical Measures

Location		Variability	
Mean	0.012035	Std Deviation	0.10498
Median	0.013617	Variance	0.01102
Mode		Range	0.38068
		Interquartile Range	0.18415

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0.549804	Pr > |t|	0.5880
Sign	M	3	Pr >= |M|	0.2863

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	16.5	Pr >= |S|	0.6038

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.962394	Pr < W	0.5134
Kolmogorov-Smirnov	D	0.141571	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.049601	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.319501	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2291667
99%	0.2291667
95%	0.1873706
90%	0.1410256
75% Q3	0.0928030

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0136166
25% Q1	-0.0913462
10%	-0.1259259
5%	-0.1326122
1%	-0.1515152
0% Min	-0.1515152

Extreme Observations

Lowest Value	Lowest Obs	Highest Value	Highest Obs
-0.1515152	16	0.100000	17
-0.1326122	6	0.129552	21
-0.1259259	10	0.141026	19
-0.0972222	1	0.187371	7
-0.0928442	20	0.229167	9

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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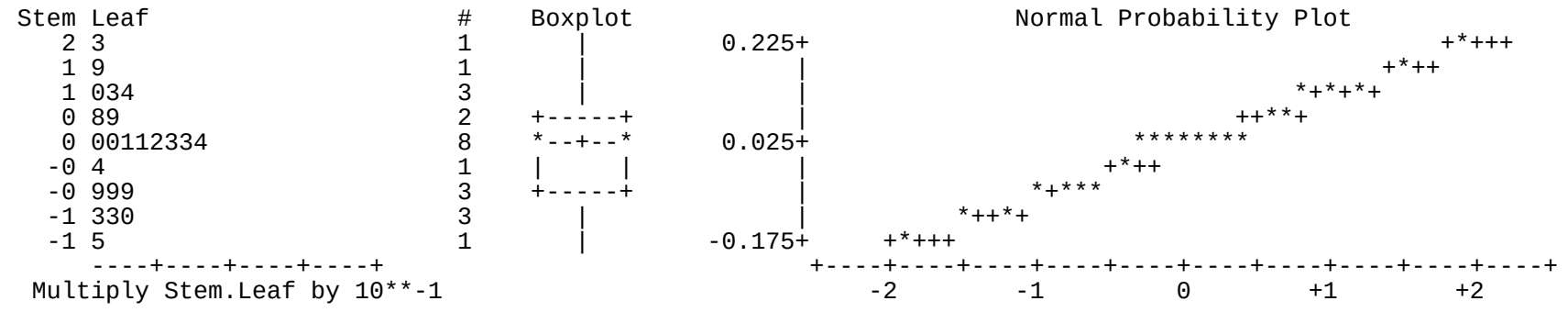
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=Placebo ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



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Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

[redacted]

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	17	Sum Weights	17
Mean	0.43270365	Sum Observations	7.35596207
Std Deviation	0.29514494	Variance	0.08711054
Skewness	2.05319725	Kurtosis	4.01397224
Uncorrected SS	4.57672025	Corrected SS	1.39376861
Coeff Variation	68.2094878	Std Error Mean	0.07158316

Basic Statistical Measures

Location		Variability	
Mean	0.432704	Std Deviation	0.29514
Median	0.366667	Variance	0.08711
Mode		Range	1.11111
		Interquartile Range	0.16336

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.044768	Pr > |t|	<.0001
Sign	M	8.5	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	76.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.744304	Pr < W 0.0004
Kolmogorov-Smirnov	D	0.259564	Pr > D <0.0100
Cramer-von Mises	W-Sq	0.288165	Pr > W-Sq <0.0050
Anderson-Darling	A-Sq	1.661776	Pr > A-Sq <0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.266667
99%	1.266667
95%	1.266667
90%	1.044444
75% Q3	0.436508

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.366667
25% Q1	0.273148
10%	0.183333
5%	0.155556
1%	0.155556
0% Min	0.155556

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.155556	1	0.436508	10
0.183333	3	0.494624	13
0.198925	6	0.553333	4
0.266667	15	1.044444	8
0.273148	9	1.266667	14

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

```
  Stem Leaf                     #    Boxplot                          Normal Probability Plot
    12 7                        1       *           1.3+                                    *
    10 4                        1       *              |                                 *      ++++++
     8                                                 |                                 +++++++
     6                                                 |                              +++++++
     4 01495                    5    +--+--+           |                        ++++*+** * *
     2 07789478                 8    *-----*           |                  *+***+*+***
     0 68                       2       |              |           *   +*++*++
       ----+----+----+----+                            +----+----+----+----+----+----+----+----+----+----+
   Multiply Stem.Leaf by 10**-1                             -2        -1         0        +1        +2
```

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	17	Sum Weights	17
Mean	0.42185771	Sum Observations	7.17158109
Std Deviation	0.18372111	Variance	0.03375345
Skewness	0.62865143	Kurtosis	-0.0535794
Uncorrected SS	3.56544191	Corrected SS	0.54005513
Coeff Variation	43.5504917	Std Error Mean	0.04455891

Basic Statistical Measures

Location		Variability	
Mean	0.421858	Std Deviation	0.18372
Median	0.407407	Variance	0.03375
Mode		Range	0.65476
		Interquartile Range	0.26894

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.467415	Pr > |t|	<.0001
Sign	M	8.5	Pr >= |M|	<.0001

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Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	76.5	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.954754	Pr < W 0.5359
Kolmogorov-Smirnov	D	0.094535	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.029607	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq	0.249981	Pr > A-Sq >0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.821429
99%	0.821429
95%	0.821429
90%	0.727273
75% Q3	0.541667

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.407407
25% Q1	0.272727
10%	0.205556
5%	0.166667
1%	0.166667
0% Min	0.166667

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.166667	1	0.541667	11
0.205556	9	0.567568	4
0.222222	3	0.568627	13
0.239583	16	0.727273	10
0.272727	15	0.821429	8

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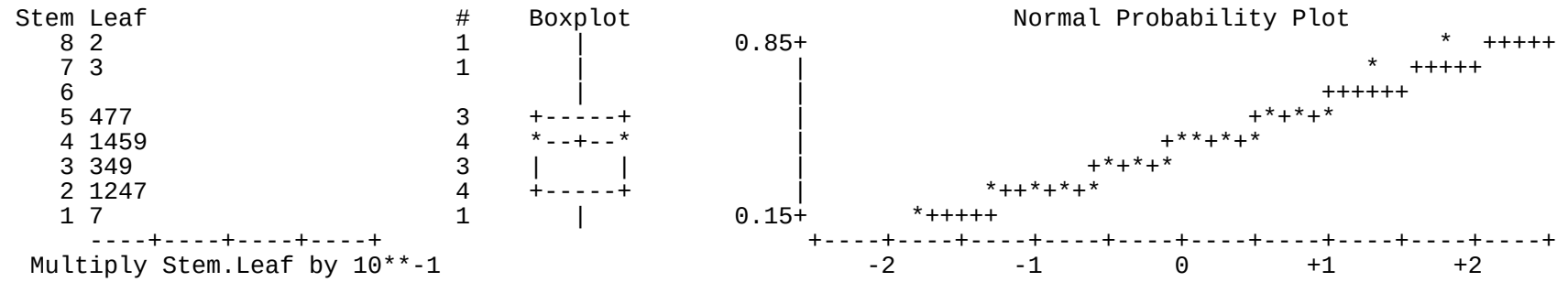
Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	17	Sum Weights	17
Mean	-0.0108459	Sum Observations	-0.184381
Std Deviation	0.23067594	Variance	0.05321139
Skewness	-2.4032016	Kurtosis	7.95688091
Uncorrected SS	0.85338201	Corrected SS	0.85138223
Coeff Variation	-2126.8414	Std Error Mean	0.05594713

Basic Statistical Measures

Location		Variability	
Mean	-0.01085	Std Deviation	0.23068
Median	0.01423	Variance	0.05321
Mode		Range	1.06934
		Interquartile Range	0.12929

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.19386	Pr > |t|	0.8487
Sign	M	2.5	Pr >= |M|	0.3323

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	15.5	Pr >= |S|	0.4874

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.757186	Pr < W	0.0006
Kolmogorov-Smirnov	D	0.252195	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.234029	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.380396	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.2907648
99%	0.2907648
95%	0.2907648
90%	0.1899642
75% Q3	0.0740038

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.0142342
25% Q1	-0.0552885
10%	-0.2230159
5%	-0.7785714
1%	-0.7785714
0% Min	-0.7785714

Extreme Observations

Lowest Value	Lowest Obs	Highest Value	Highest Obs
-0.7785714	14	0.0740038	13
-0.2230159	8	0.1581197	5
-0.0874933	12	0.1583333	11
-0.0675926	9	0.1899642	6
-0.0552885	16	0.2907648	10

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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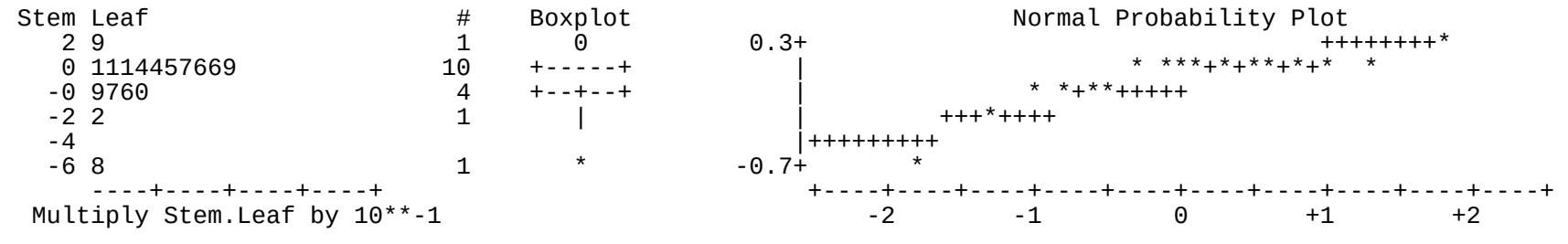
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=2.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	16	Sum Weights	16
Mean	0.38670682	Sum Observations	6.18730909
Std Deviation	0.21180188	Variance	0.04486004
Skewness	0.89880347	Kurtosis	0.089543
Uncorrected SS	3.06557516	Corrected SS	0.67290055
Coeff Variation	54.770661	Std Error Mean	0.05295047

Basic Statistical Measures

Location		Variability	
Mean	0.386707	Std Deviation	0.21180
Median	0.320000	Variance	0.04486
Mode	0.500000	Range	0.70370
		Interquartile Range	0.27880

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.30318	Pr > |t|	<.0001
Sign	M	8	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	68	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.901913	Pr < W 0.0862
Kolmogorov-Smirnov	D	0.161978	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.085124	Pr > W-Sq 0.1689
Anderson-Darling	A-Sq	0.573719	Pr > A-Sq 0.1181

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.833333
99%	0.833333
95%	0.833333
90%	0.785714
75% Q3	0.503472

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.320000
25% Q1	0.224673
10%	0.166667
5%	0.129630
1%	0.129630
0% Min	0.129630

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.129630	4	0.500000	16
0.166667	10	0.506944	6
0.190476	1	0.545455	14
0.194444	13	0.785714	15
0.254902	8	0.833333	7

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Population: Intent-to-Treat with LOCF

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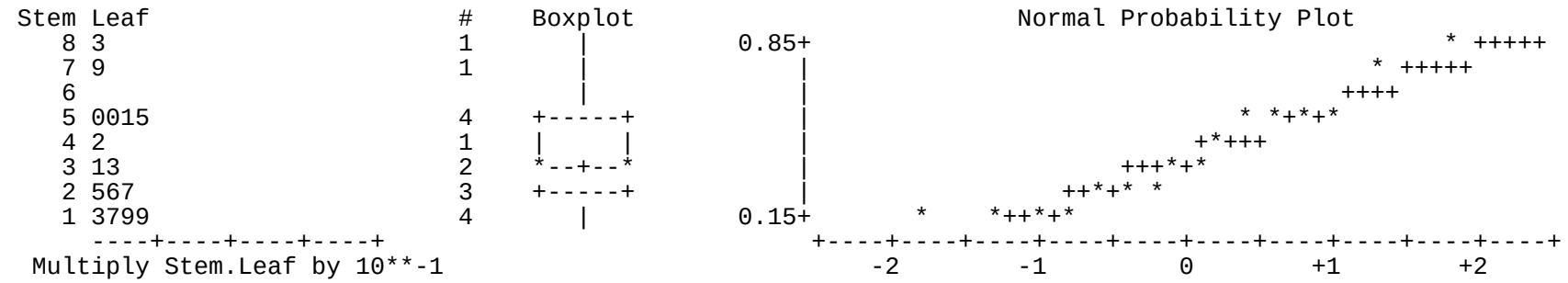
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	16	Sum Weights	16
Mean	0.35741458	Sum Observations	5.71863335
Std Deviation	0.2460887	Variance	0.06055965
Skewness	2.17757555	Kurtosis	6.07065687
Uncorrected SS	2.95231772	Corrected SS	0.90839476
Coeff Variation	68.8524519	Std Error Mean	0.06152218

Basic Statistical Measures

Location		Variability	
Mean	0.357415	Std Deviation	0.24609
Median	0.266667	Variance	0.06056
Mode	0.250000	Range	1.01389
		Interquartile Range	0.19033

NOTE: The mode displayed is the smallest of 2 modes with a count of 2.

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	5.809524	Pr > |t|	<.0001
Sign	M	8	Pr >= |M|	<.0001
Signed Rank	S	68	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.78212	Pr < W	0.0016
Kolmogorov-Smirnov	D	0.206347	Pr > D	0.0683
Cramer-von Mises	W-Sq	0.171329	Pr > W-Sq	0.0107
Anderson-Darling	A-Sq	1.097042	Pr > A-Sq	0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.125000
99%	1.125000
95%	1.125000

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
90%	0.566667
75% Q3	0.428968
50% Median	0.266667
25% Q1	0.238636
10%	0.129630
5%	0.111111
1%	0.111111
0% Min	0.111111

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.111111	10	0.424603	6
0.129630	1	0.433333	15
0.141975	8	0.555556	12
0.227273	13	0.566667	7
0.250000	16	1.125000	14

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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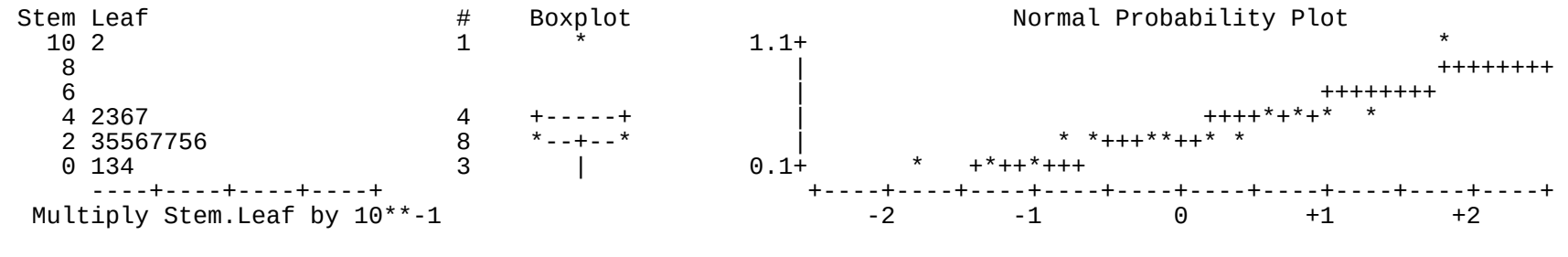
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	16	Sum Weights	16
Mean	-0.0292922	Sum Observations	-0.4686757
Std Deviation	0.21323074	Variance	0.04546735
Skewness	1.38411084	Kurtosis	3.79860989
Uncorrected SS	0.69573882	Corrected SS	0.68201026
Coeff Variation	-727.94292	Std Error Mean	0.05330769

Basic Statistical Measures

Location		Variability	
Mean	-0.02929	Std Deviation	0.21323
Median	-0.05820	Variance	0.04547
Mode		Range	0.93193
		Interquartile Range	0.20012

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-0.54949	Pr > |t|	0.5908
Sign	M	-2.5	Pr >= |M|	0.3018

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-18	Pr >= |S|	0.3303

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.88977	Pr < W	0.0552
Kolmogorov-Smirnov	D	0.152635	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.086594	Pr > W-Sq	0.1600
Anderson-Darling	A-Sq	0.58993	Pr > A-Sq	0.1059

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.5795455
99%	0.5795455
95%	0.5795455
90%	0.1388889
75% Q3	0.0695816

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0582011
25% Q1	-0.1305374
10%	-0.2666667
5%	-0.3523810
1%	-0.3523810
0% Min	-0.3523810

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.352381	15	0.0328283	13
-0.266667	7	0.1063348	11
-0.250000	16	0.1203704	4
-0.148148	9	0.1388889	12
-0.112927	8	0.5795455	14

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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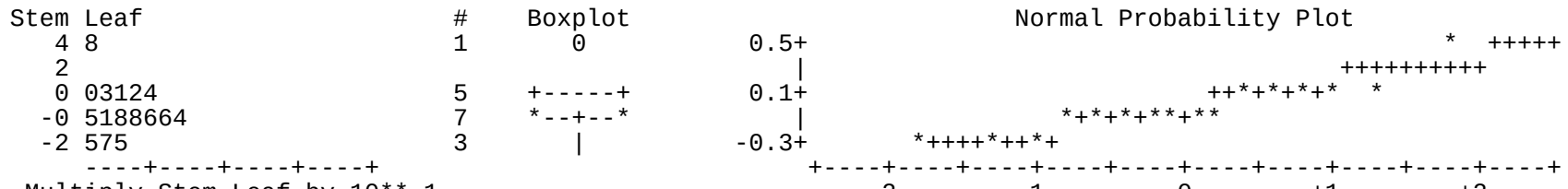
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=7.5mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	20	Sum Weights	20
Mean	0.41793937	Sum Observations	8.35878746
Std Deviation	0.28649088	Variance	0.08207702
Skewness	1.34225037	Kurtosis	1.23615297
Uncorrected SS	5.05292984	Corrected SS	1.55946345
Coeff Variation	68.5484302	Std Error Mean	0.06406131

Basic Statistical Measures

Location		Variability	
Mean	0.417939	Std Deviation	0.28649
Median	0.312675	Variance	0.08208
Mode		Range	1.04545
		Interquartile Range	0.34754

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	6.524053	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.851842	Pr < W	0.0057
Kolmogorov-Smirnov	D	0.232407	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.203651	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.122467	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	1.166667
99%	1.166667
95%	1.061404
90%	0.853070
75% Q3	0.581169

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.312675
25% Q1	0.233631
10%	0.140649
5%	0.124332
1%	0.121212
0% Min	0.121212

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.121212	12	0.590909	9
0.127451	17	0.709402	15
0.153846	5	0.750000	16
0.206349	6	0.956140	13
0.229167	4	1.166667	20

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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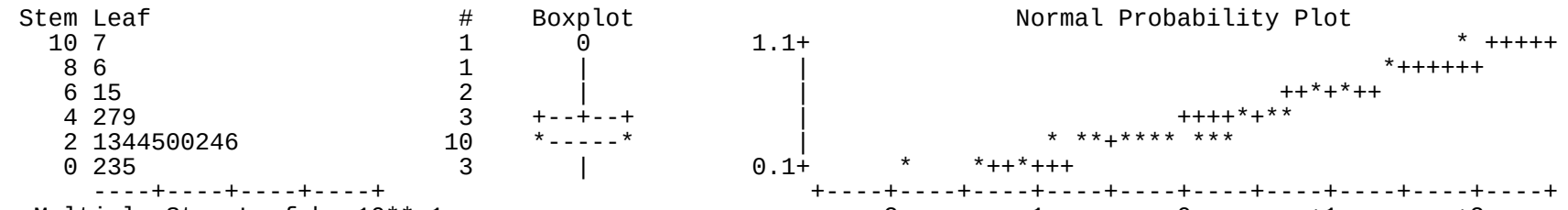
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	20	Sum Weights	20
Mean	0.32572196	Sum Observations	6.51443921
Std Deviation	0.19900769	Variance	0.03960406
Skewness	1.60738227	Kurtosis	2.17944721
Uncorrected SS	2.87437308	Corrected SS	0.75247717
Coeff Variation	61.0974133	Std Error Mean	0.04449947

Basic Statistical Measures

Location		Variability	
Mean	0.325722	Std Deviation	0.19901
Median	0.250209	Variance	0.03960
Mode		Range	0.74603
		Interquartile Range	0.22513

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.319681	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.801292	Pr < W	0.0009
Kolmogorov-Smirnov	D	0.263114	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.288434	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.5409	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.888889
99%	0.888889
95%	0.777778
90%	0.625000
75% Q3	0.420833

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.250209
25% Q1	0.195707
10%	0.163496
5%	0.144345
1%	0.142857
0% Min	0.142857

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.142857	17	0.466667	15
0.145833	18	0.508333	16
0.181159	14	0.583333	13
0.183333	7	0.666667	9
0.194444	10	0.888889	8

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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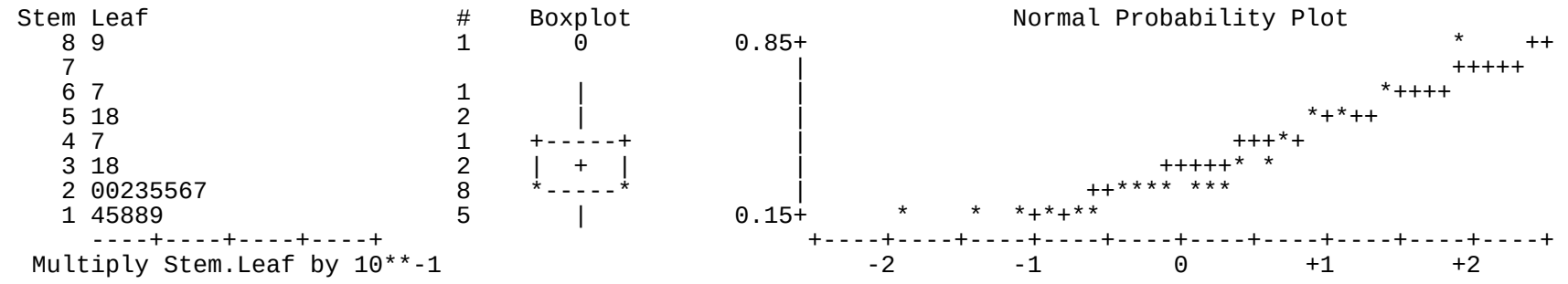
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	20	Sum Weights	20
Mean	-0.0922174	Sum Observations	-1.8443483
Std Deviation	0.28190886	Variance	0.07947261
Skewness	-0.2361952	Kurtosis	3.89416758
Uncorrected SS	1.68006056	Corrected SS	1.50997954
Coeff Variation	-305.70025	Std Error Mean	0.06303674

Basic Statistical Measures

Location		Variability	
Mean	-0.09222	Std Deviation	0.28191
Median	-0.05920	Variance	0.07947
Mode		Range	1.49808
		Interquartile Range	0.27387

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.46292	Pr > |t|	0.1598
Sign	M	-2	Pr >= |M|	0.5034

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-46	Pr >= |S|	0.0897

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.887628	Pr < W	0.0243
Kolmogorov-Smirnov	D	0.195756	Pr > D	0.0435
Cramer-von Mises	W-Sq	0.135203	Pr > W-Sq	0.0357
Anderson-Darling	A-Sq	0.881633	Pr > A-Sq	0.0207

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6388889
99%	0.6388889
95%	0.3702991
90%	0.0902486
75% Q3	0.0393954

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0591985
25% Q1	-0.2344697
10%	-0.3748956
5%	-0.6180898
1%	-0.8591954
0% Min	-0.8591954

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.859195	20	0.0535714	2
-0.376984	10	0.0757576	9
-0.372807	13	0.0787879	12
-0.242735	15	0.1017094	5
-0.241667	16	0.6388889	8

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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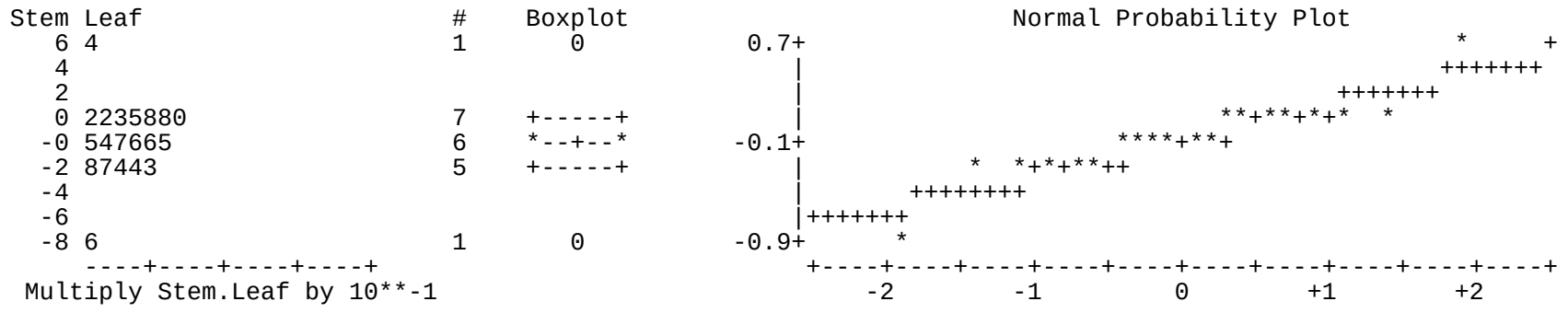
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=15mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	18	Sum Weights	18
Mean	0.41678298	Sum Observations	7.50209369
Std Deviation	0.23104444	Variance	0.05338153
Skewness	0.95009379	Kurtosis	-0.3926263
Uncorrected SS	4.03423103	Corrected SS	0.90748604
Coeff Variation	55.4351896	Std Error Mean	0.0544577

Basic Statistical Measures

Location		Variability	
Mean	0.416783	Std Deviation	0.23104
Median	0.333606	Variance	0.05338
Mode	0.277778	Range	0.73810
		Interquartile Range	0.40509

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	7.653335	Pr > |t|	<.0001
Sign	M	9	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	85.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.864396	Pr < W	0.0144
Kolmogorov-Smirnov	D	0.231193	Pr > D	0.0119
Cramer-von Mises	W-Sq	0.187599	Pr > W-Sq	0.0068
Anderson-Darling	A-Sq	1.013658	Pr > A-Sq	0.0089

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.904762
99%	0.904762
95%	0.904762
90%	0.812500
75% Q3	0.645833

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.333606
25% Q1	0.240741
10%	0.178571
5%	0.166667
1%	0.166667
0% Min	0.166667

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.166667	18	0.645833	5
0.178571	7	0.655556	11
0.213542	12	0.733333	17
0.227273	4	0.812500	16
0.240741	15	0.904762	1

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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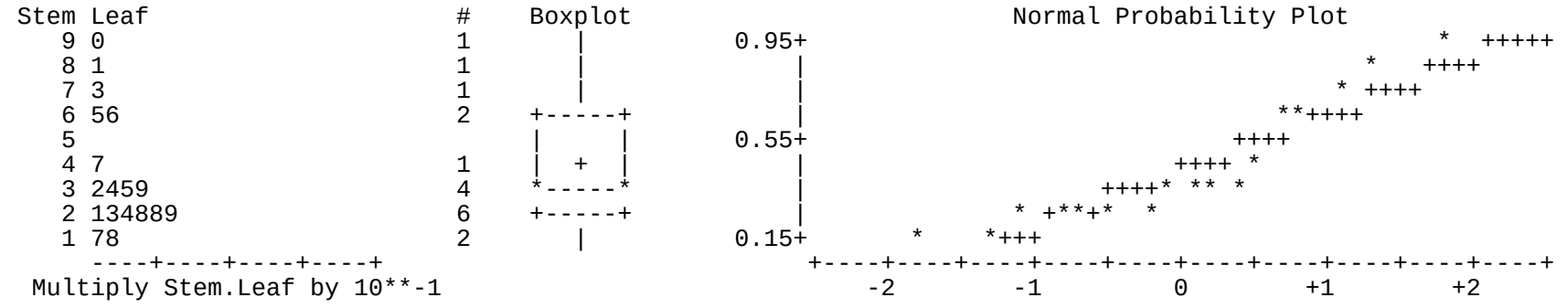
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	18	Sum Weights	18
Mean	0.36156802	Sum Observations	6.5082244
Std Deviation	0.16317119	Variance	0.02662484
Skewness	1.21594679	Kurtosis	2.04915169
Uncorrected SS	2.80578804	Corrected SS	0.45262221
Coeff Variation	45.1287659	Std Error Mean	0.03845982

Basic Statistical Measures

Location		Variability	
Mean	0.361568	Std Deviation	0.16317
Median	0.309127	Variance	0.02662
Mode		Range	0.69444
		Interquartile Range	0.16061

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.401189	Pr > |t|	<.0001
Sign	M	9	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	85.5	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.912763	Pr < W	0.0963
Kolmogorov-Smirnov	D	0.1798	Pr > D	0.1249
Cramer-von Mises	W-Sq	0.112128	Pr > W-Sq	0.0744
Anderson-Darling	A-Sq	0.628135	Pr > A-Sq	0.0886

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.805556
99%	0.805556
95%	0.805556
90%	0.583333
75% Q3	0.433333

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.309127
25% Q1	0.272727
10%	0.190476
5%	0.111111
1%	0.111111
0% Min	0.111111

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.111111	6	0.433333	5
0.190476	7	0.483333	11
0.227273	4	0.537037	16
0.264706	8	0.583333	17
0.272727	3	0.805556	1

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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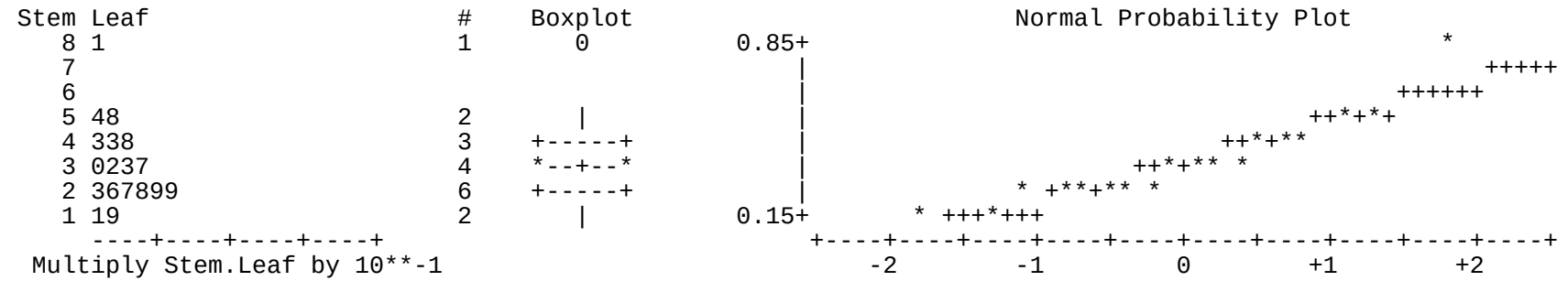
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	18	Sum Weights	18
Mean	-0.055215	Sum Observations	-0.9938693
Std Deviation	0.10760959	Variance	0.01157982
Skewness	-0.4428614	Kurtosis	-0.5395021
Uncorrected SS	0.25173344	Corrected SS	0.19685699
Coeff Variation	-194.89208	Std Error Mean	0.02536382

Basic Statistical Measures

Location		Variability	
Mean	-0.05521	Std Deviation	0.10761
Median	-0.01977	Variance	0.01158
Mode		Range	0.39451
		Interquartile Range	0.16190

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-2.17692	Pr > |t|	0.0439
Sign	M	-2.5	Pr >= |M|	0.3323

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-39.5	Pr >= |S|	0.0638

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.954451	Pr < W	0.4990
Kolmogorov-Smirnov	D	0.16461	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.08487	Pr > W-Sq	0.1722
Anderson-Darling	A-Sq	0.426493	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.1190476
99%	0.1190476
95%	0.1190476
90%	0.0880456
75% Q3	0.0119048

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0197712
25% Q1	-0.1500000
10%	-0.2125000
5%	-0.2754630
1%	-0.2754630
0% Min	-0.2754630

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.275463	16	0.0119048	7
-0.212500	5	0.0205128	10
-0.172222	11	0.0370370	15
-0.166667	6	0.0880456	12
-0.150000	17	0.1190476	18

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
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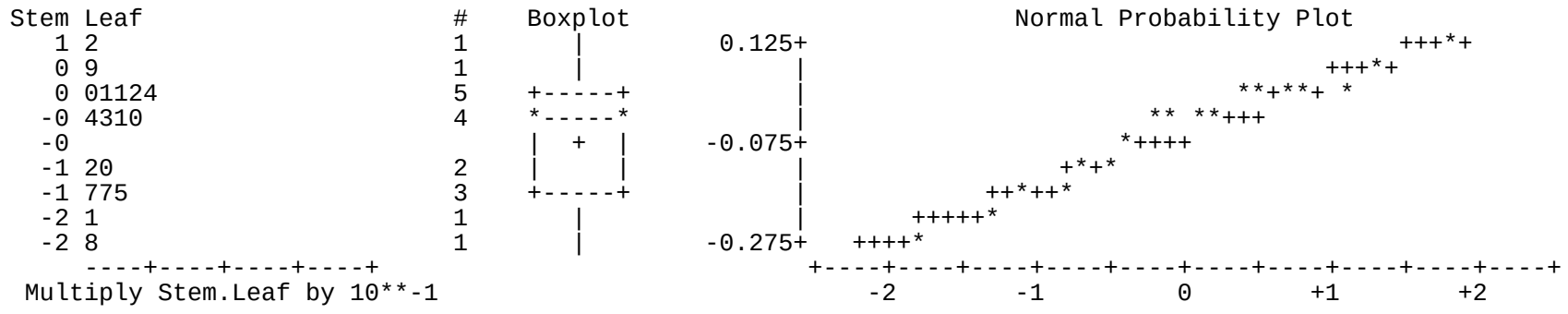
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=30mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



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Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Moments

N	20	Sum Weights	20
Mean	0.40308951	Sum Observations	8.06179019
Std Deviation	0.19602037	Variance	0.03842398
Skewness	0.18880995	Kurtosis	-0.1848643
Uncorrected SS	3.97967875	Corrected SS	0.73005569
Coeff Variation	48.6294883	Std Error Mean	0.04383149

Basic Statistical Measures

Location		Variability	
Mean	0.403090	Std Deviation	0.19602
Median	0.405556	Variance	0.03842
Mode		Range	0.75155
		Interquartile Range	0.22395

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.196346	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	105	Pr >= |S|	<.0001

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.98488	Pr < W	0.9808
Kolmogorov-Smirnov	D	0.077977	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.019435	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.137722	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.8095238
99%	0.8095238
95%	0.7589286
90%	0.6825980
75% Q3	0.5049858

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.4055556
25% Q1	0.2810391
10%	0.1388889
5%	0.0845411
1%	0.0579710
0% Min	0.0579710

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
0.057971	8	0.518519	4
0.111111	17	0.561404	9
0.166667	15	0.656863	14
0.184524	7	0.708333	11
0.254386	2	0.809524	3

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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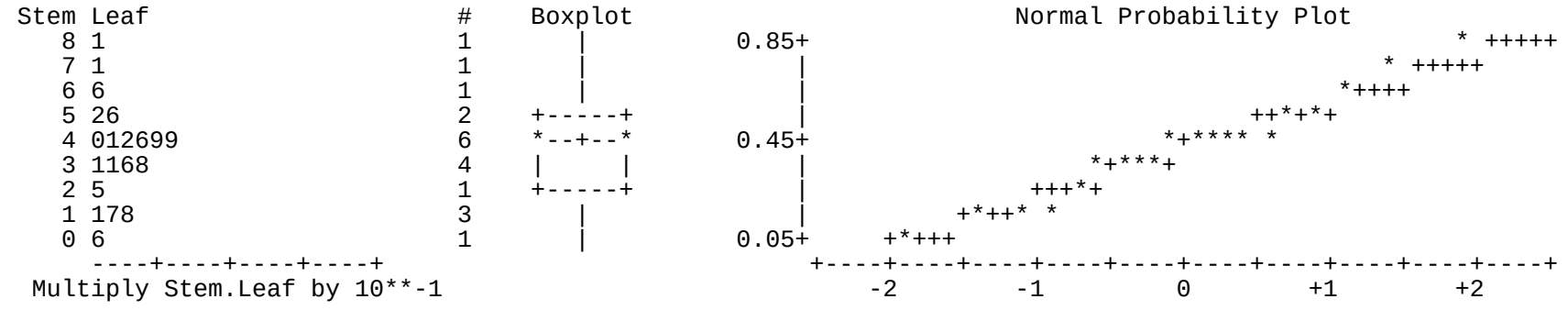
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Moments

N	20	Sum Weights	20
Mean	0.35306656	Sum Observations	7.06133111
Std Deviation	0.17297073	Variance	0.02991887
Skewness	-0.073163	Kurtosis	-0.9250948
Uncorrected SS	3.06157841	Corrected SS	0.56845856
Coeff Variation	48.9909686	Std Error Mean	0.03867743

Basic Statistical Measures

Location		Variability	
Mean	0.353067	Std Deviation	0.17297
Median	0.351852	Variance	0.02992
Mode		Range	0.56703
		Interquartile Range	0.28086

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	9.128491	Pr > |t|	<.0001
Sign	M	10	Pr >= |M|	<.0001

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------
Signed Rank	S	105	Pr >= |S| <.0001

Tests for Normality

Test	--Statistic---		-----p Value------
Shapiro-Wilk	W	0.959825	Pr < W 0.5404
Kolmogorov-Smirnov	D	0.090994	Pr > D >0.1500
Cramer-von Mises	W-Sq	0.024832	Pr > W-Sq >0.2500
Anderson-Darling	A-Sq	0.219105	Pr > A-Sq >0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6078431
99%	0.6078431
95%	0.6046462
90%	0.5975996
75% Q3	0.4923977

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	0.3518519
25% Q1	0.2115385
10%	0.1230159
5%	0.0600907
1%	0.0408163
0% Min	0.0408163

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.0408163	8	0.511111	14
0.0793651	17	0.566138	6
0.1666667	15	0.593750	9
0.1875000	7	0.601449	16
0.1923077	12	0.607843	3

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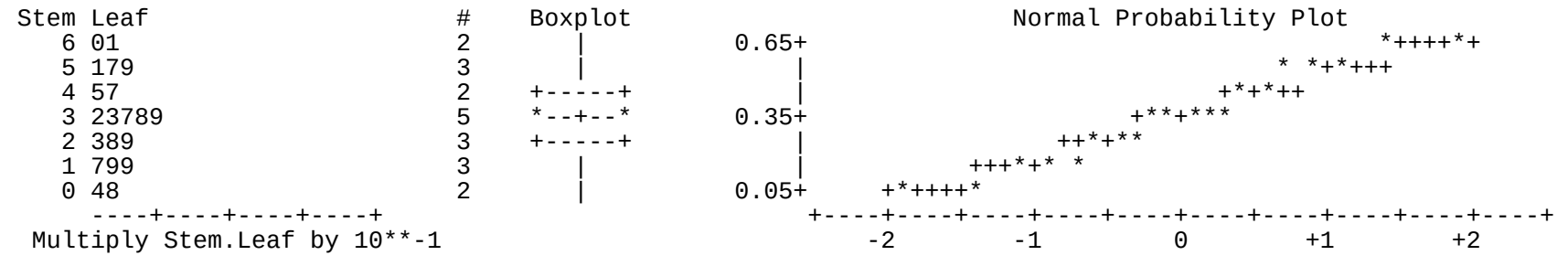
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Moments

N	20	Sum Weights	20
Mean	-0.050023	Sum Observations	-1.0004591
Std Deviation	0.11266562	Variance	0.01269354
Skewness	-0.7698621	Kurtosis	0.66118189
Uncorrected SS	0.29122323	Corrected SS	0.24117731
Coeff Variation	-225.22785	Std Error Mean	0.0251928

Basic Statistical Measures

Location		Variability	
Mean	-0.05002	Std Deviation	0.11267
Median	-0.02445	Variance	0.01269
Mode		Range	0.44796
		Interquartile Range	0.15712

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	-1.98561	Pr > |t|	0.0617
Sign	M	-1.5	Pr >= |M|	0.6476

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Table 11.73
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Signed Rank	S	-42	Pr >= |S|	0.0955

Tests for Normality

Test	--Statistic---		-----p Value------	
Shapiro-Wilk	W	0.947667	Pr < W	0.3331
Kolmogorov-Smirnov	D	0.126291	Pr > D	>0.1500
Cramer-von Mises	W-Sq	0.054553	Pr > W-Sq	>0.2500
Anderson-Darling	A-Sq	0.349091	Pr > A-Sq	>0.2500

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.1099963
99%	0.1099963
95%	0.1089003
90%	0.0851887
75% Q3	0.0278692

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Quantiles (Definition 5)

Quantile	Estimate
50% Median	-0.0244504
25% Q1	-0.1292548
10%	-0.1795440
5%	-0.2698218
1%	-0.3379630
0% Min	-0.3379630

Extreme Observations

------Lowest------		------Highest------	
Value	Obs	Value	Obs
-0.337963	11	0.0323465	9
-0.201681	3	0.0523810	19
-0.157407	20	0.0625731	5
-0.145752	14	0.1078042	6
-0.129630	4	0.1099963	16

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Population: Intent-to-Treat with LOCF

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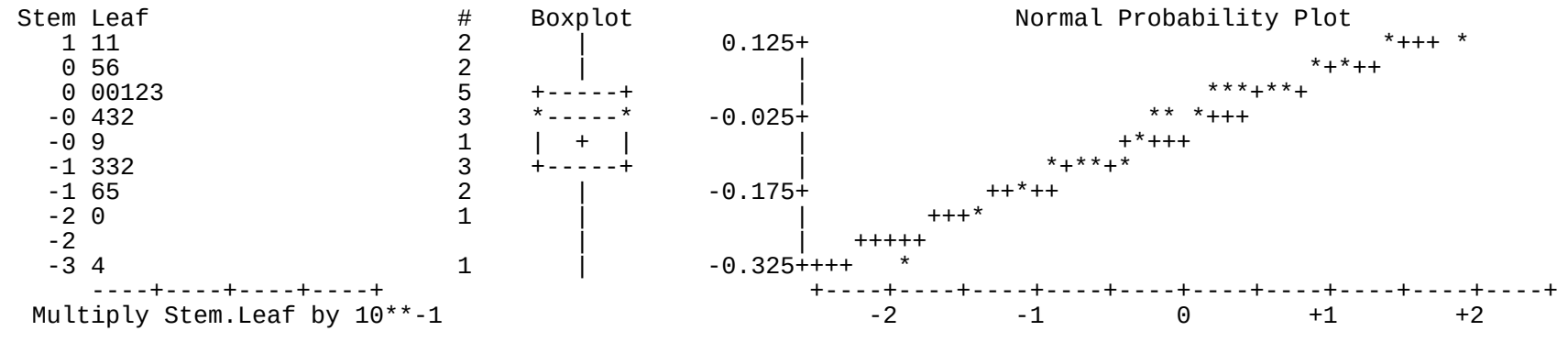
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

---------- Randomized treatment code=45mg ----------

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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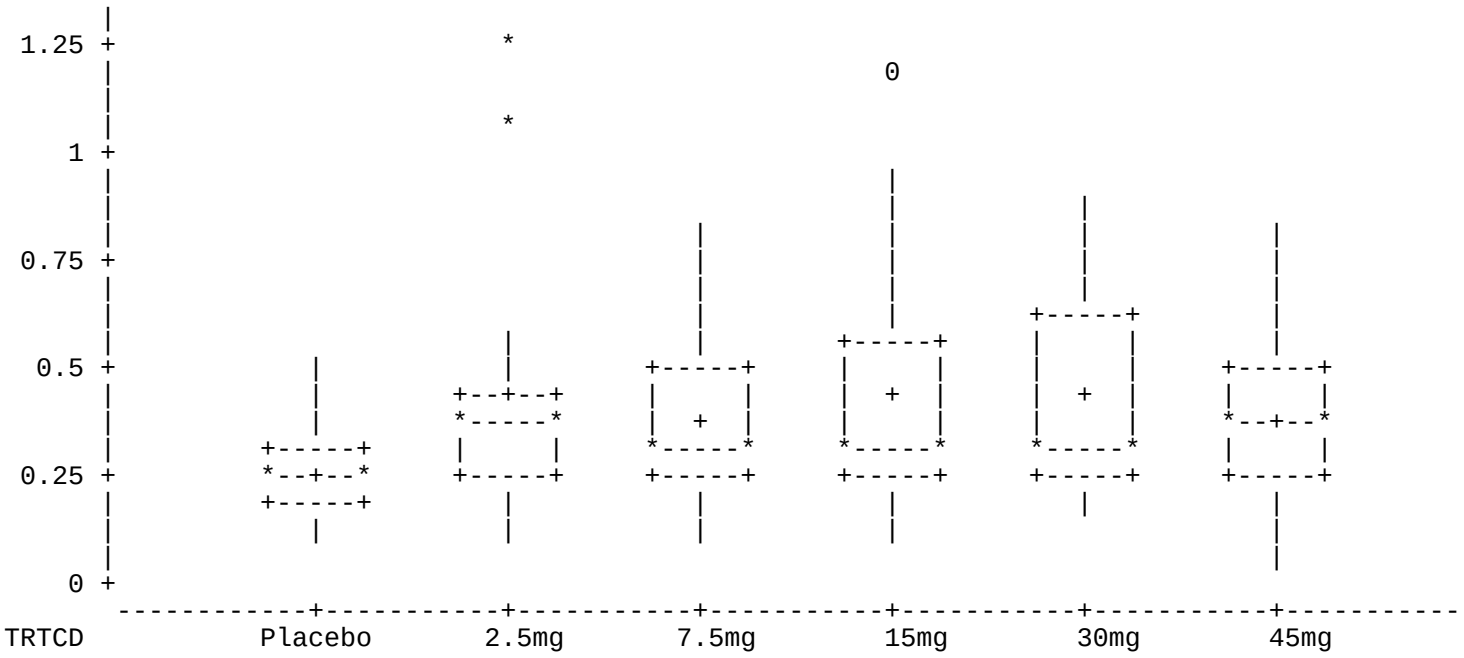
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTDBL (Baseline value in standard units)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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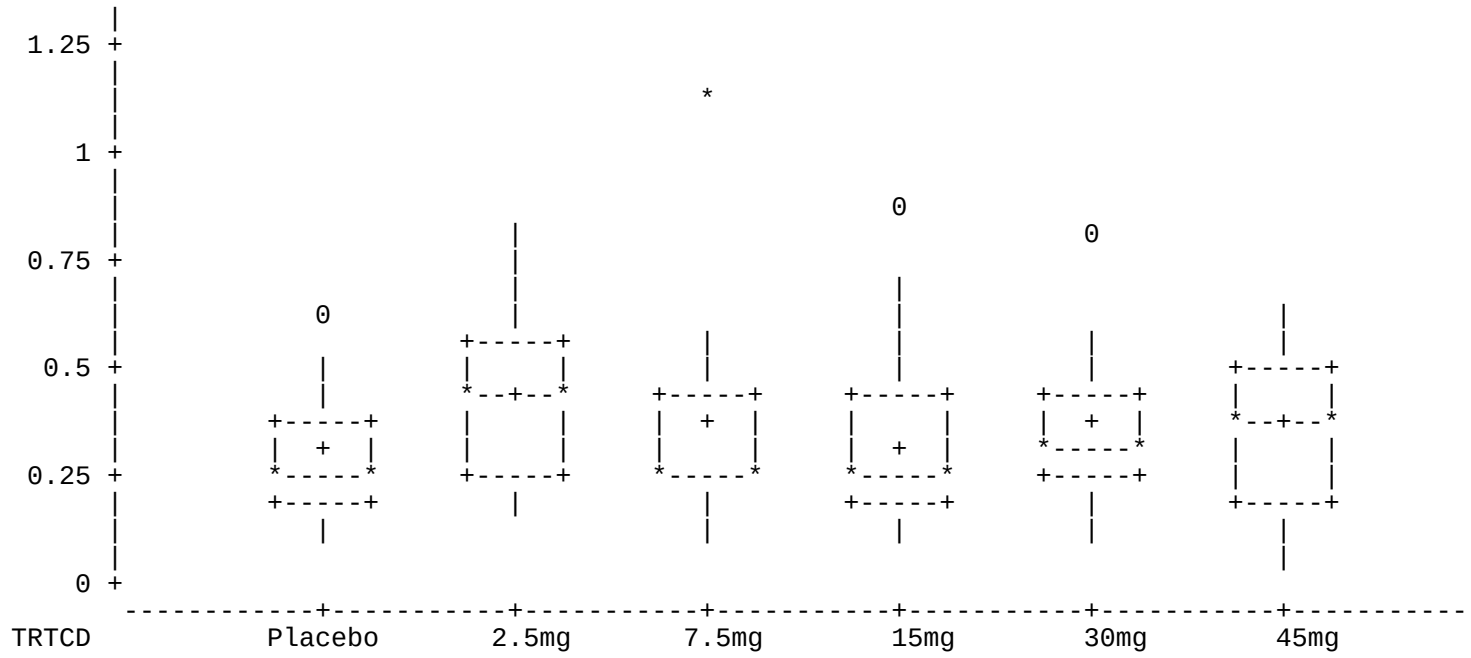
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: EFSTRESN (SI numeric result)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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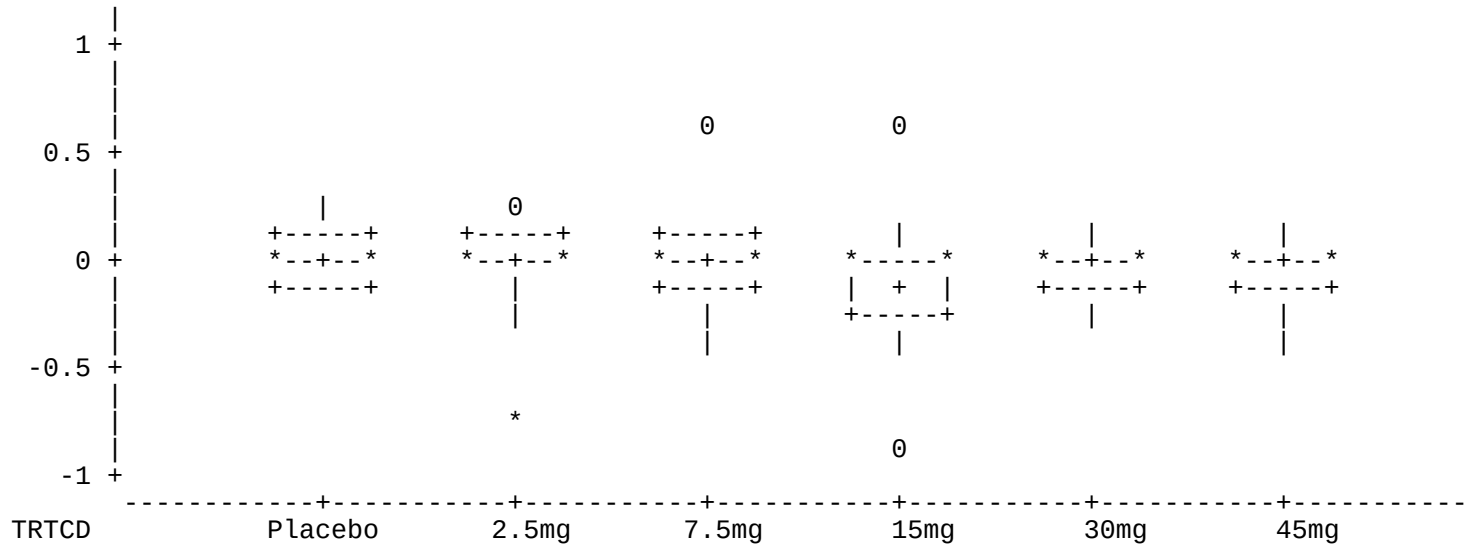
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Outputs for Baseline, Endpoint and Change from Baseline

The UNIVARIATE Procedure
Variable: STDCHGBL (Std Chg Baseline)

Schematic Plots



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	Female Male
TRTTYPCD	2	Diet & Exercise Monotherapy
TRTCD	6	Placebo 2.5mg 7.5mg 15mg 30mg 45mg

Dimensions

Covariance Parameters	1
Columns in X	12
Columns in Z	0
Subjects	1
Max Obs Per Subject	114
Observations Used	114
Observations Not Used	0
Total Observations	114

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Alpha	Lower	Upper
Residual	0.02109	0.002911	7.25	<.0001	0.05	0.01638	0.02820

Fit Statistics

-2 Res Log Likelihood	-81.4
AIC (smaller is better)	-79.4
AICC (smaller is better)	-79.4
BIC (smaller is better)	-76.7

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept				0.1642	0.04855	105	3.38	0.0010
SEX	Female			-0.00017	0.02947	105	-0.01	0.9955
SEX	Male			0			.	
TRTTYPCD		Diet & Exercise		-0.01869	0.02880	105	-0.65	0.5178
TRTTYPCD		Monotherapy		0			.	
TRTCD			Placebo	-0.00479	0.04574	105	-0.10	0.9168
TRTCD			2.5mg	0.05972	0.04963	105	1.20	0.2316
TRTCD			7.5mg	0.01804	0.04953	105	0.36	0.7164
TRTCD			15mg	-0.03168	0.04613	105	-0.69	0.4937

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Solution for Fixed Effects

Effect	Sex	Pre-study treatment code	Randomized treatment code	Estimate	Standard Error	DF	t Value	Pr > |t|
TRTCD			30mg	0.005514	0.04793	105	0.12	0.9086
TRTCD			45mg	0			.	
EFSTDBL				-0.5197	0.06296	105	-8.25	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	105	0.00	0.9955
TRTTYPCD	1	105	0.42	0.5178
TRTCD	5	105	0.75	0.5870
EFSTDBL	1	105	68.13	<.0001

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
2.5mg vs Pbo	0.06451	0.04787	105	1.35	0.1807	0.05	-0.03040	0.1594
7.5mg vs Pbo	0.02283	0.04830	105	0.47	0.6374	0.05	-0.07293	0.1186
15mg vs Pbo	-0.02689	0.04566	105	-0.59	0.5572	0.05	-0.1174	0.06365
30mg vs Pbo	0.01030	0.04662	105	0.22	0.8255	0.05	-0.08213	0.1027

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
45mg vs Pbo	0.004790	0.04574	105	0.10	0.9168	0.05	-0.08590	0.09548

Coefficients for TRTCD Least Squares Means Using WORK.EFF Margins

Effect	Sex	Pre-study treatment code	Randomized treatment code	Row1	Row2	Row3	Row4	Row5	Row6
Intercept				1	1	1	1	1	1
SEX	Female			0.4912	0.4912	0.4912	0.4912	0.4912	0.4912
SEX	Male			0.5088	0.5088	0.5088	0.5088	0.5088	0.5088
TRTTYPCD		Diet & Exercise		0.4211	0.4211	0.4211	0.4211	0.4211	0.4211
TRTTYPCD		Monotherapy		0.5789	0.5789	0.5789	0.5789	0.5789	0.5789
TRTCD			Placebo	1					
TRTCD			2.5mg		1				
TRTCD			7.5mg			1			
TRTCD			15mg				1		
TRTCD			30mg					1	
TRTCD			45mg						1
EFSTDBL				0.383	0.383	0.383	0.383	0.383	0.383

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Least Squares Means

Effect	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
TRTCD	Placebo	WORK.EFF	-0.04755	0.03115	105	-1.53	0.1299	0.05	-0.1093	0.01422
TRTCD	2.5mg	WORK.EFF	0.01696	0.03603	105	0.47	0.6388	0.05	-0.05449	0.08841
TRTCD	7.5mg	WORK.EFF	-0.02471	0.03665	105	-0.67	0.5016	0.05	-0.09738	0.04795
TRTCD	15mg	WORK.EFF	-0.07444	0.03274	105	-2.27	0.0250	0.05	-0.1394	-0.00952
TRTCD	30mg	WORK.EFF	-0.03724	0.03439	105	-1.08	0.2813	0.05	-0.1054	0.03095
TRTCD	45mg	WORK.EFF	-0.04276	0.03309	105	-1.29	0.1991	0.05	-0.1084	0.02285

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	2.5mg	WORK.EFF	-0.06451	0.04787	105	-1.35	0.1807	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	2.5mg	-0.1594	0.03040

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Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha
TRTCD	Placebo	7.5mg	WORK.EFF	-0.02283	0.04830	105	-0.47	0.6374	0.05
TRTCD	Placebo	15mg	WORK.EFF	0.02689	0.04566	105	0.59	0.5572	0.05
TRTCD	Placebo	30mg	WORK.EFF	-0.01030	0.04662	105	-0.22	0.8255	0.05
TRTCD	Placebo	45mg	WORK.EFF	-0.00479	0.04574	105	-0.10	0.9168	0.05
TRTCD	2.5mg	7.5mg	WORK.EFF	0.04168	0.05152	105	0.81	0.4204	0.05
TRTCD	2.5mg	15mg	WORK.EFF	0.09140	0.04904	105	1.86	0.0652	0.05
TRTCD	2.5mg	30mg	WORK.EFF	0.05420	0.04933	105	1.10	0.2744	0.05
TRTCD	2.5mg	45mg	WORK.EFF	0.05972	0.04963	105	1.20	0.2316	0.05
TRTCD	7.5mg	15mg	WORK.EFF	0.04972	0.04897	105	1.02	0.3123	0.05
TRTCD	7.5mg	30mg	WORK.EFF	0.01253	0.05035	105	0.25	0.8040	0.05
TRTCD	7.5mg	45mg	WORK.EFF	0.01804	0.04953	105	0.36	0.7164	0.05
TRTCD	15mg	30mg	WORK.EFF	-0.03720	0.04758	105	-0.78	0.4361	0.05
TRTCD	15mg	45mg	WORK.EFF	-0.03168	0.04613	105	-0.69	0.4937	0.05
TRTCD	30mg	45mg	WORK.EFF	0.005514	0.04793	105	0.12	0.9086	0.05

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	Placebo	7.5mg	-0.1186	0.07293
TRTCD	Placebo	15mg	-0.06365	0.1174
TRTCD	Placebo	30mg	-0.1027	0.08213
TRTCD	Placebo	45mg	-0.09548	0.08590

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

The Mixed Procedure

Differences of Least Squares Means

Effect	Randomized treatment code	Randomized treatment code	Lower	Upper
TRTCD	2.5mg	7.5mg	-0.06048	0.1438
TRTCD	2.5mg	15mg	-0.00584	0.1886
TRTCD	2.5mg	30mg	-0.04361	0.1520
TRTCD	2.5mg	45mg	-0.03869	0.1581
TRTCD	7.5mg	15mg	-0.04738	0.1468
TRTCD	7.5mg	30mg	-0.08731	0.1124
TRTCD	7.5mg	45mg	-0.08016	0.1162
TRTCD	15mg	30mg	-0.1315	0.05714
TRTCD	15mg	45mg	-0.1231	0.05978
TRTCD	30mg	45mg	-0.08952	0.1005

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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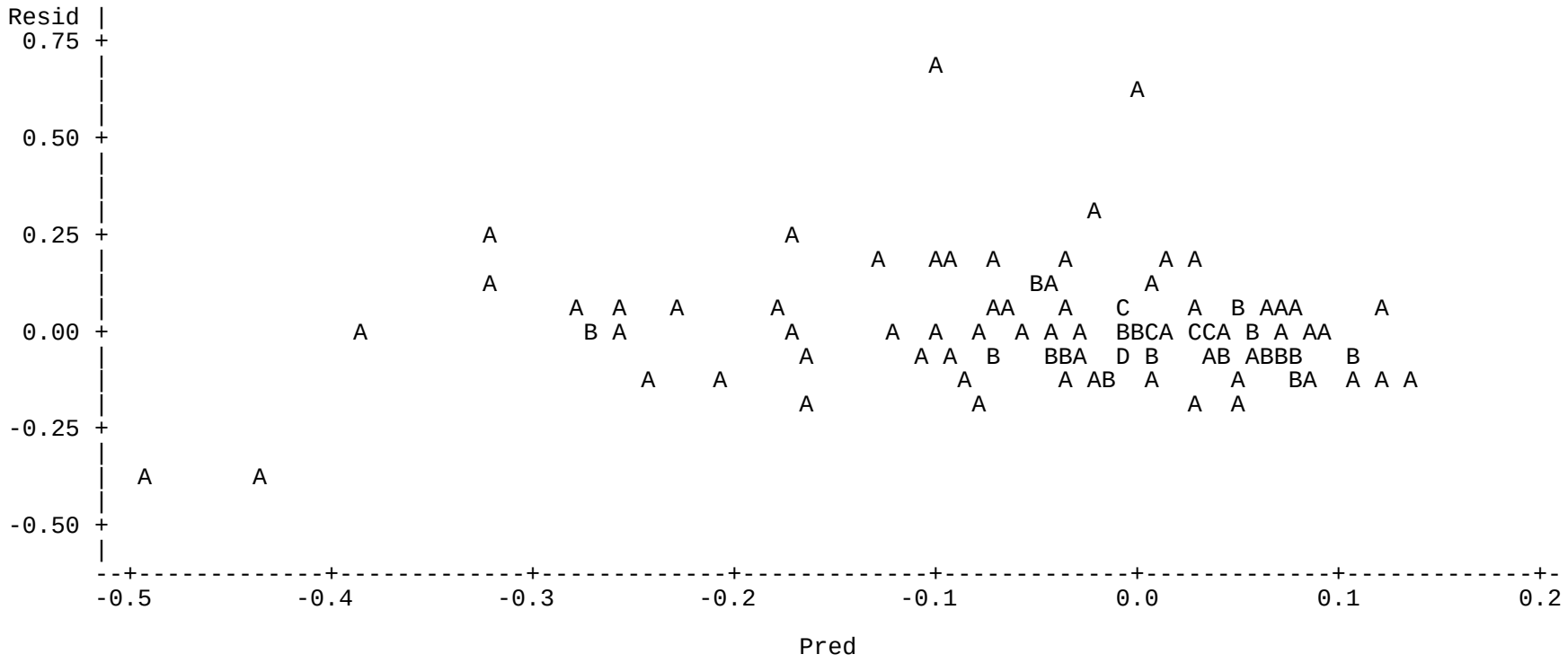
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Model Checking of Residuals

Plot of Resid*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
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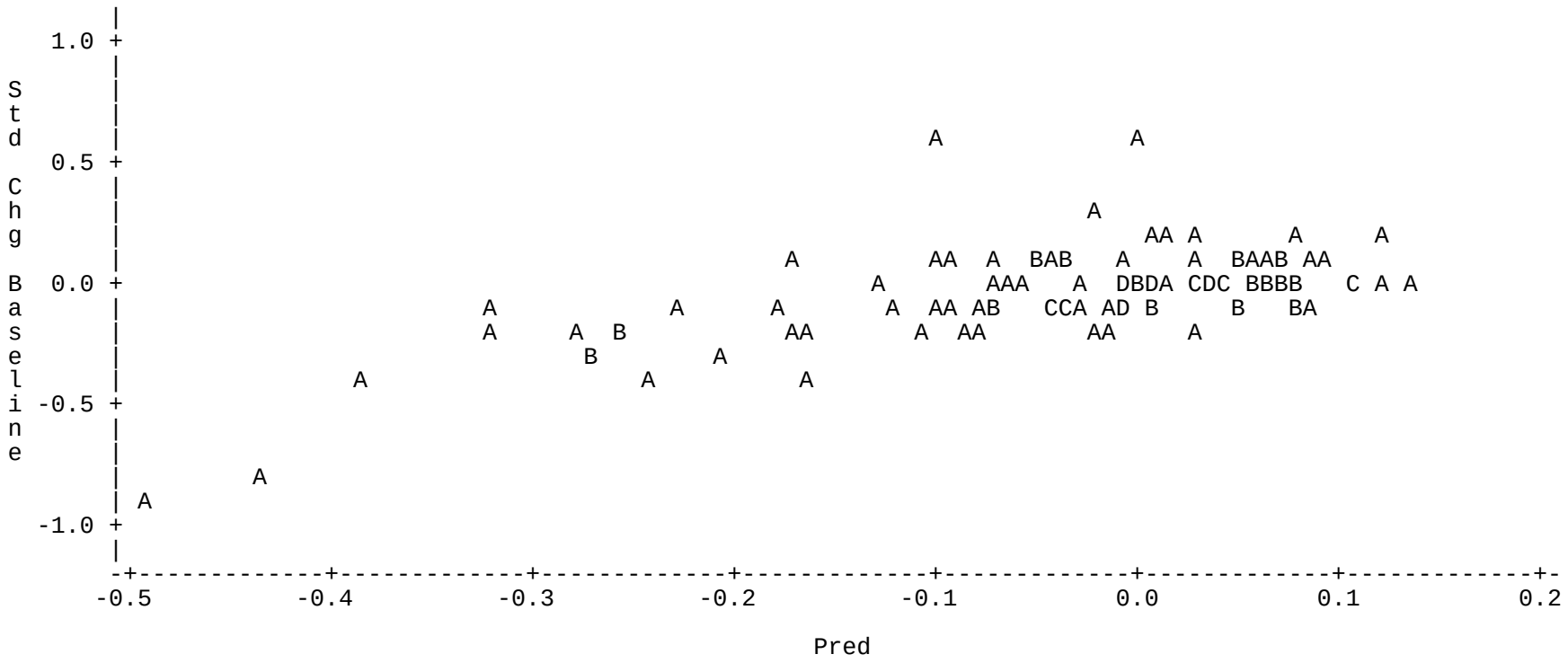
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Model Checking of Residuals

Plot of STDCHGBL*Pred. Legend: A = 1 obs, B = 2 obs, etc.



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Moments

N	114	Sum Weights	114
Mean	0	Sum Observations	0
Std Deviation	0.13999667	Variance	0.01959907
Skewness	1.75453318	Kurtosis	7.77787637
Uncorrected SS	2.21469465	Corrected SS	2.21469465
Coeff Variation		Std Error Mean	0.01311189

Basic Statistical Measures

Location		Variability	
Mean	0.00000	Std Deviation	0.14000
Median	-0.00925	Variance	0.01960
Mode		Range	1.04766
		Interquartile Range	0.12476

Tests for Location: Mu0=0

Test	-Statistic-		-----p Value------	
Student's t	t	0	Pr > |t|	1.0000
Sign	M	-5	Pr >= |M|	0.3994
Signed Rank	S	-386.5	Pr >= |S|	0.2764

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Tests for Normality

Test		--Statistic---	-----p Value------	
Shapiro-Wilk	W	0.860808	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.136724	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.526234	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.180536	Pr > A-Sq	<0.0050

Quantiles (Definition 5)

Quantile	Estimate
100% Max	0.6808987
99%	0.6364231
95%	0.2183276
90%	0.1595852
75% Q3	0.0536513
50% Median	-0.0092487
25% Q1	-0.0711050
10%	-0.1377338
5%	-0.1625693
1%	-0.3442597
0% Min	-0.3667641

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid

Extreme Observations

------Lowest------		------Highest-----	
Value	Obs	Value	Obs
-0.366764	114	0.219920	1
-0.344260	96	0.250457	72
-0.212408	74	0.312342	59
-0.192061	36	0.636423	71
-0.172437	109	0.680899	78

Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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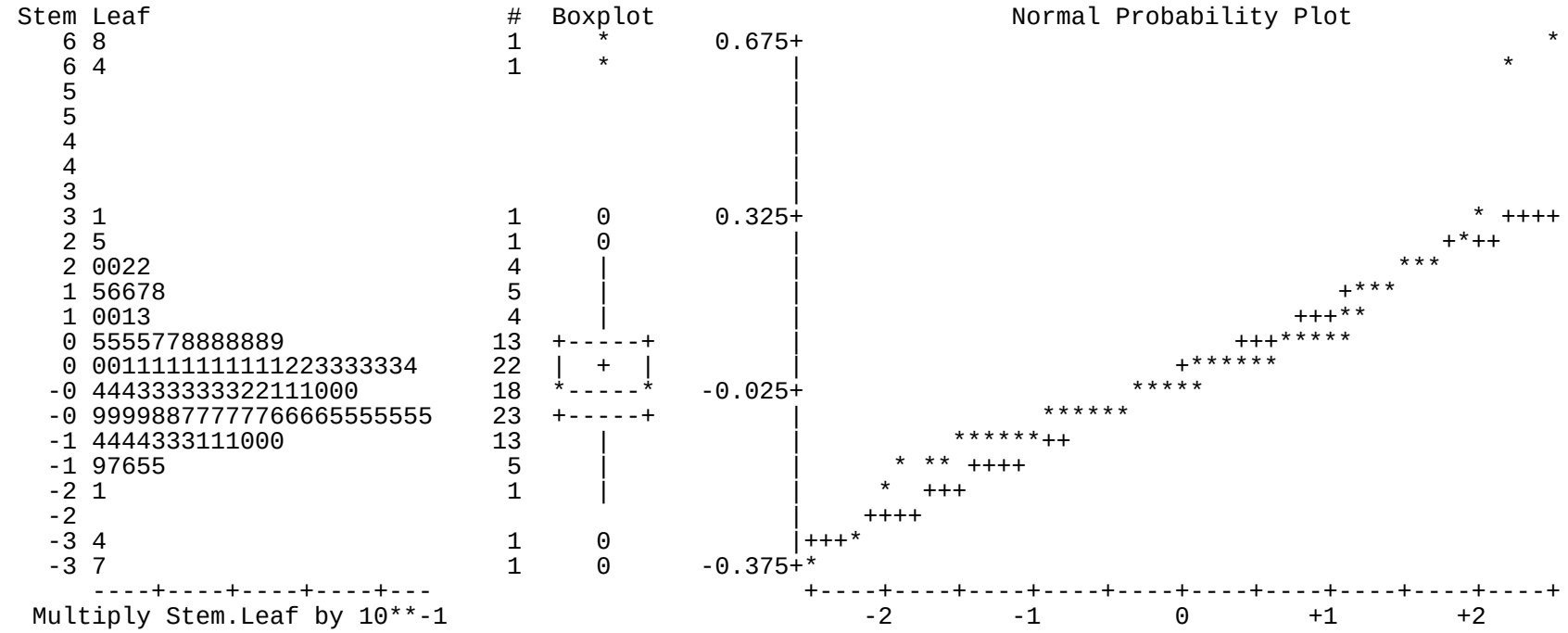
Table 11.73
SAS Statistical Output for Table 11.72
Analysis of Change in Pro-Insulin:Insulin Ratio from Baseline to Week 12 for US/Canada Region

Residual Plots

The UNIVARIATE Procedure
Variable: Resid



Trttypcd is the prior therapy variable, Efstdbl is the baseline variable,
Efstresn is the visit value variable and Stdchgbl is the change from baseline variable.

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Table 11.74
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) at Week 12 by Region

Region: Europe

		Pbo to 2.5mg	2.5mg	7.5mg	15mg	30mg	45mg
N		36	41	44	43	38	39
n [1]		32	33	41	42	35	34
Number (%) of Values Carried Forward		4 (13%)	10 (30%)	8 (20%)	4 (10%)	4 (11%)	2 (6%)
Baseline	Geo Mean	60.18	59.99	47.96	54.69	61.56	57.12
	CV (%) [2]	71.200	50.701	56.231	66.800	65.560	62.364
Week	Geo Mean	57.80	65.02	49.68	53.02	55.38	54.04
	CV (%) [2]	64.621	70.682	65.228	67.106	61.526	72.532
	Geo Mean - SE[3]	52.07	58.20	45.27	48.26	50.32	48.34
	Geo Mean + SE[3]	64.16	72.64	54.52	58.25	60.94	60.41
	Minimum	11.5	19.2	16.4	14.3	18.0	16.2
	Median	57.15	61.50	51.20	50.45	55.30	52.55
	Maximum	174.0	205.5	218.8	214.6	160.0	228.5
Ratio to Baseline (%) [4]	Geo Mean	-3.96	8.38	3.57	-3.05	-10.04	-5.40
	Geo Mean - SE[3]	-12.01	-0.53	-4.24	-9.70	-14.70	-13.34
	Geo Mean + SE[3]	4.82	18.10	12.02	4.08	-5.12	3.28
	Minimum	-62.0	-71.3	-58.3	-66.4	-51.6	-82.8
	Median	1.39	-1.09	-2.07	0.72	-11.84	3.01
	Maximum	288.7	360.9	365.3	125.7	122.9	93.4

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.74
Summary Statistics of Log-Transformed HOMA Insulin Sensitivity (%) at Week 12 by Region

Region: US/Canada

		Pbo to 2.5mg	2.5mg	7.5mg	15mg	30mg	45mg
N		26	18	18	20	20	21
n [1]		21	16	14	20	17	19
Number (%) of Values Carried Forward		4 (19%)	4 (25%)	4 (29%)	1 (5%)	0	3 (16%)
Baseline	Geo Mean	56.98	49.08	63.46	51.10	61.04	47.06
	CV (%) [2]	47.503	61.043	70.301	60.415	52.263	65.821
Week	Geo Mean	55.87	48.07	57.64	48.11	71.03	44.09
	CV (%) [2]	44.138	46.536	84.177	66.169	44.536	60.781
	Geo Mean - SE[3]	50.96	43.03	47.40	42.05	64.07	38.77
	Geo Mean + SE[3]	61.26	53.70	70.10	55.05	78.75	50.14
	Minimum	30.1	22.2	16.6	13.8	34.9	13.0
	Median	57.50	47.90	53.00	51.70	71.40	43.00
	Maximum	168.0	105.5	200.0	155.9	153.5	143.6
Ratio to Baseline (%) [4]	Geo Mean	-1.95	-2.06	-9.16	-5.84	16.36	-6.30
	Geo Mean - SE[3]	-9.58	-11.00	-19.32	-19.11	5.82	-16.40
	Geo Mean + SE[3]	6.31	7.79	2.28	9.60	27.96	5.01
	Minimum	-57.5	-64.3	-47.8	-89.9	-45.6	-52.1
	Median	3.20	12.90	-16.08	-1.15	10.78	-16.16
	Maximum	73.8	81.8	179.7	119.9	199.4	248.5

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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Table 11.75
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) at Week 12 by Region

Region: Europe

		Pbo to 2.5mg	2.5mg	7.5mg	15mg	30mg	45mg
N		36	41	44	43	38	39
n [1]		32	33	41	42	35	34
Number (%) of Values Carried Forward		4 (13%)	10 (30%)	8 (20%)	4 (10%)	4 (11%)	2 (6%)
Baseline	Geo Mean	36.40	33.32	39.34	36.52	33.49	38.55
	CV (%) [2]	55.175	66.781	64.536	61.715	81.144	65.002
Week	Geo Mean	33.68	31.56	45.28	37.77	44.95	47.96
	CV (%) [2]	74.722	76.841	71.103	60.278	92.706	80.407
	Geo Mean - SE[3]	29.94	28.03	40.97	34.66	39.35	42.49
	Geo Mean + SE[3]	37.89	35.53	50.04	41.16	51.36	54.13
	Minimum	5.9	8.4	9.0	14.3	8.3	16.5
	Median	30.15	30.40	47.90	39.95	45.70	42.55
	Maximum	92.2	92.7	184.4	133.1	244.3	160.5
Ratio to Baseline (%) [4]	Geo Mean	-7.46	-5.30	15.11	3.43	34.24	24.41
	Geo Mean - SE[3]	-14.97	-12.17	7.24	-2.63	23.42	13.96
	Geo Mean + SE[3]	0.71	2.11	23.55	9.86	46.01	35.80
	Minimum	-72.1	-73.6	-70.5	-67.9	-37.4	-29.0
	Median	2.48	-5.36	12.40	4.59	20.57	14.74
	Maximum	80.7	128.9	427.6	245.7	592.1	843.0

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

[redacted]

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Table 11.75
Summary Statistics of Log-Transformed HOMA Beta Cell Function (%) at Week 12 by Region

Region: US/Canada

		Pbo to 2.5mg	2.5mg	7.5mg	15mg	30mg	45mg
N		26	18	18	20	20	21
n [1]		21	16	14	20	17	19
Number (%) of Values Carried Forward		4 (19%)	4 (25%)	4 (29%)	1 (5%)	0	3 (16%)
Baseline	Geo Mean	37.84	51.24	36.04	39.04	34.98	36.34
	CV (%) [2]	54.638	36.575	38.467	51.360	49.742	68.222
Week	Geo Mean	37.29	50.74	34.18	43.26	38.12	46.18
	CV (%) [2]	64.023	55.256	64.898	53.988	48.364	45.940
	Geo Mean - SE[3]	32.81	44.60	29.17	38.63	34.11	41.77
	Geo Mean + SE[3]	42.38	57.73	40.05	48.44	42.60	51.05
	Minimum	11.2	18.4	9.0	20.6	15.7	19.3
	Median	40.90	54.10	39.90	42.75	38.10	48.10
	Maximum	192.1	92.6	86.3	106.3	73.8	103.1
Ratio to Baseline (%) [4]	Geo Mean	-1.46	-0.98	-5.15	10.81	8.99	27.08
	Geo Mean - SE[3]	-8.94	-9.46	-13.28	-1.23	-1.07	16.63
	Geo Mean + SE[3]	6.63	8.29	3.73	24.31	20.08	38.45
	Minimum	-50.1	-54.8	-55.0	-77.9	-41.7	-26.3
	Median	-3.66	-6.56	0.35	13.94	5.59	19.65
	Maximum	63.4	81.7	62.3	133.2	120.4	147.4

[1]Number of subjects with a value at baseline and at specified visit
[2]CV (Coefficient of Variation) = 100 * sqrt(exp((SD on log scale)^2)-1)
[3]SE in log scale added or subtracted, then entire quantity exponentiated
[4]% Change based on log-transformed data: 100*(exp(mean change on log scale)-1)

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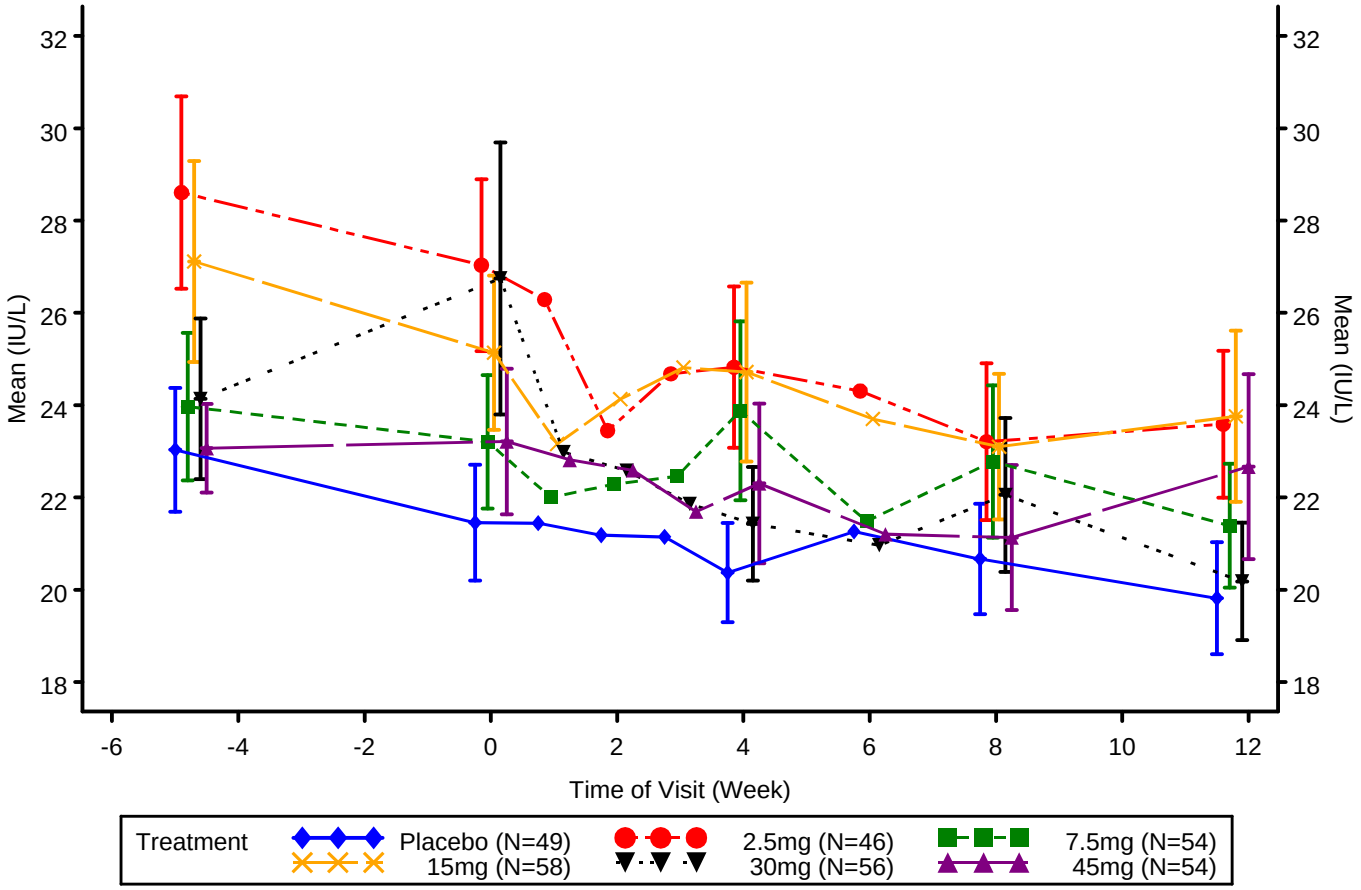
Figure 12.1
Line Graph of Mean (+-SE) for Alanine Amino Transferase (IU/L) by Visit



Note: N are number of subjects at Week 12. Week 0 shows all Baseline values.

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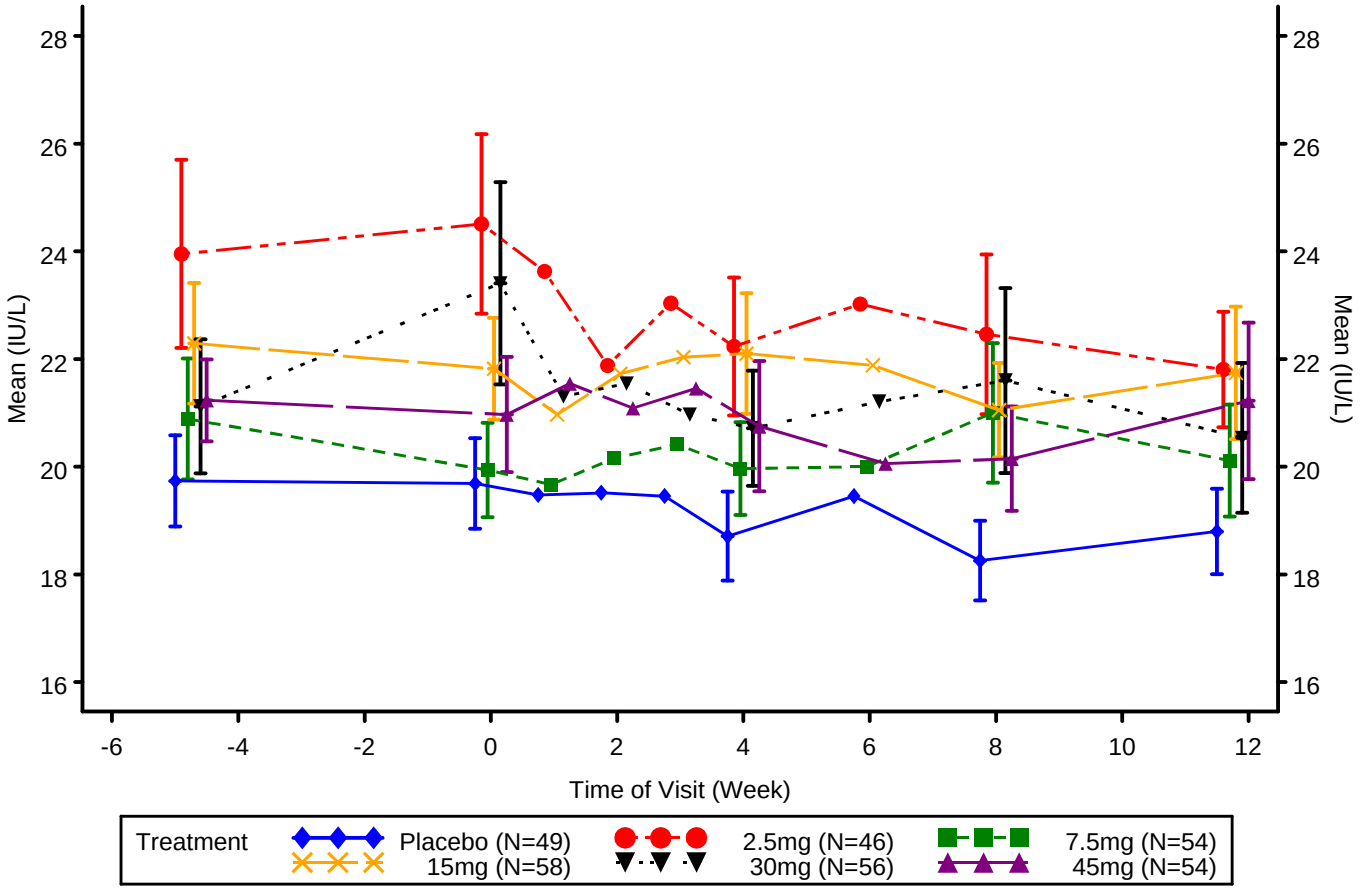
Figure 12.2
Line Graph of Mean (+-SE) for Aspartate Amino Transferase (IU/L) by Visit



Note: N are number of subjects at Week 12. Week 0 shows all Baseline values.

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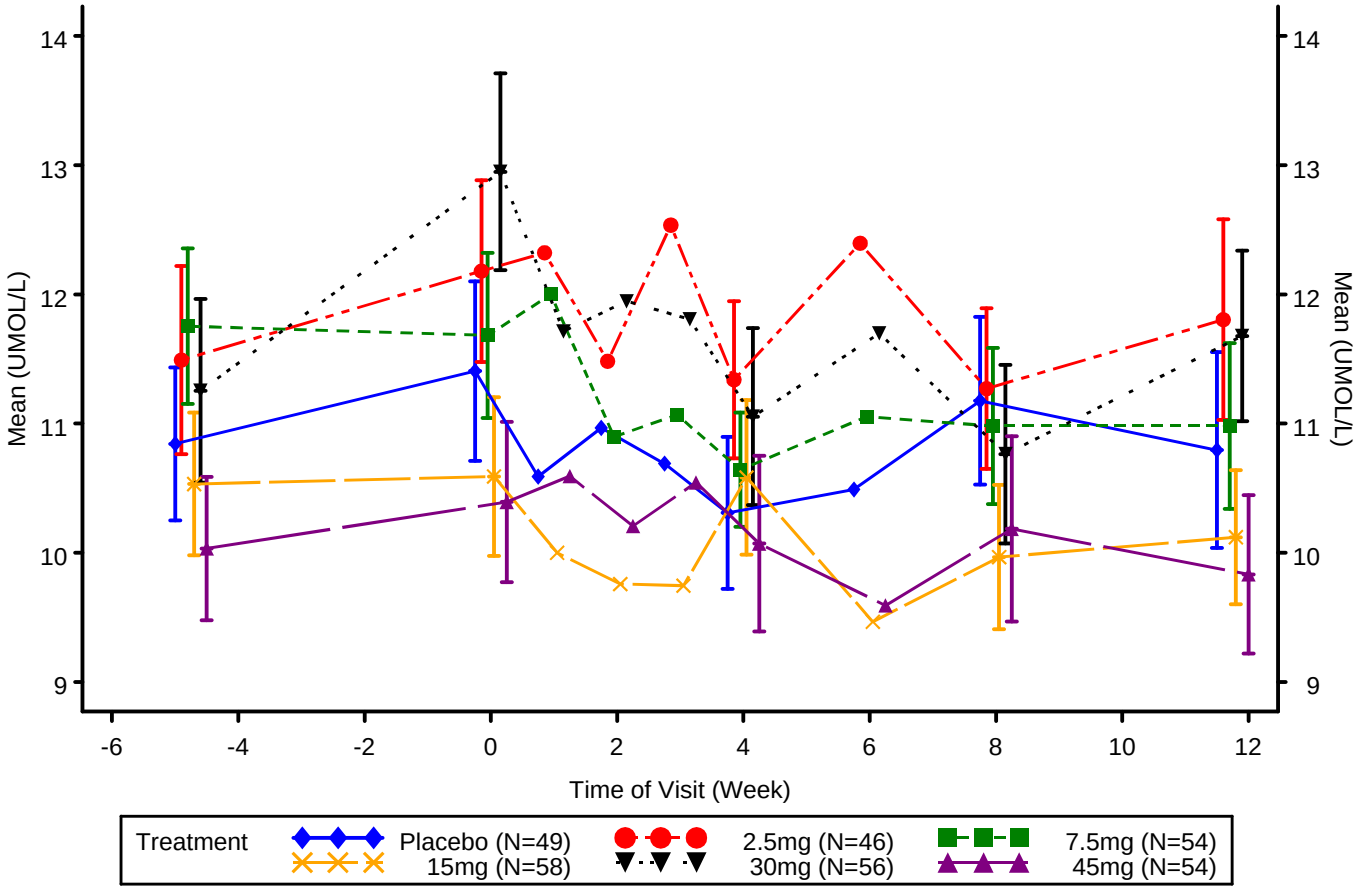
Figure 12.3
Line Graph of Mean (+-SE) for Total Bilirubin (UMOL/L) by Visit



Note: N are number of subjects at Week 12. Week 0 shows all Baseline values.

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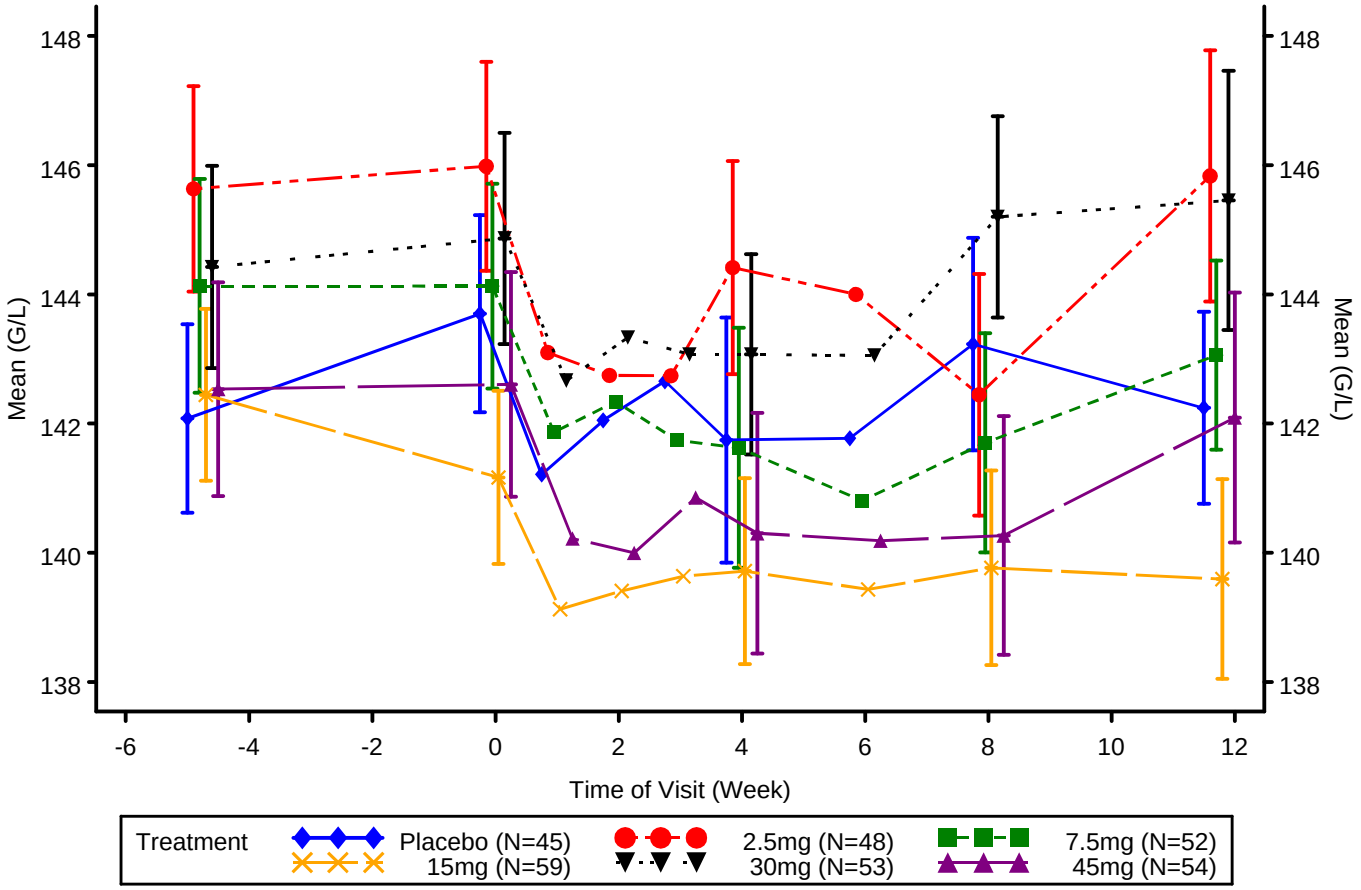
Figure 12.4
Line Graph of Mean (+-SE) for Hemoglobin (G/L) by Visit



Note: N are number of subjects at Week 12. Week 0 shows all Baseline values.

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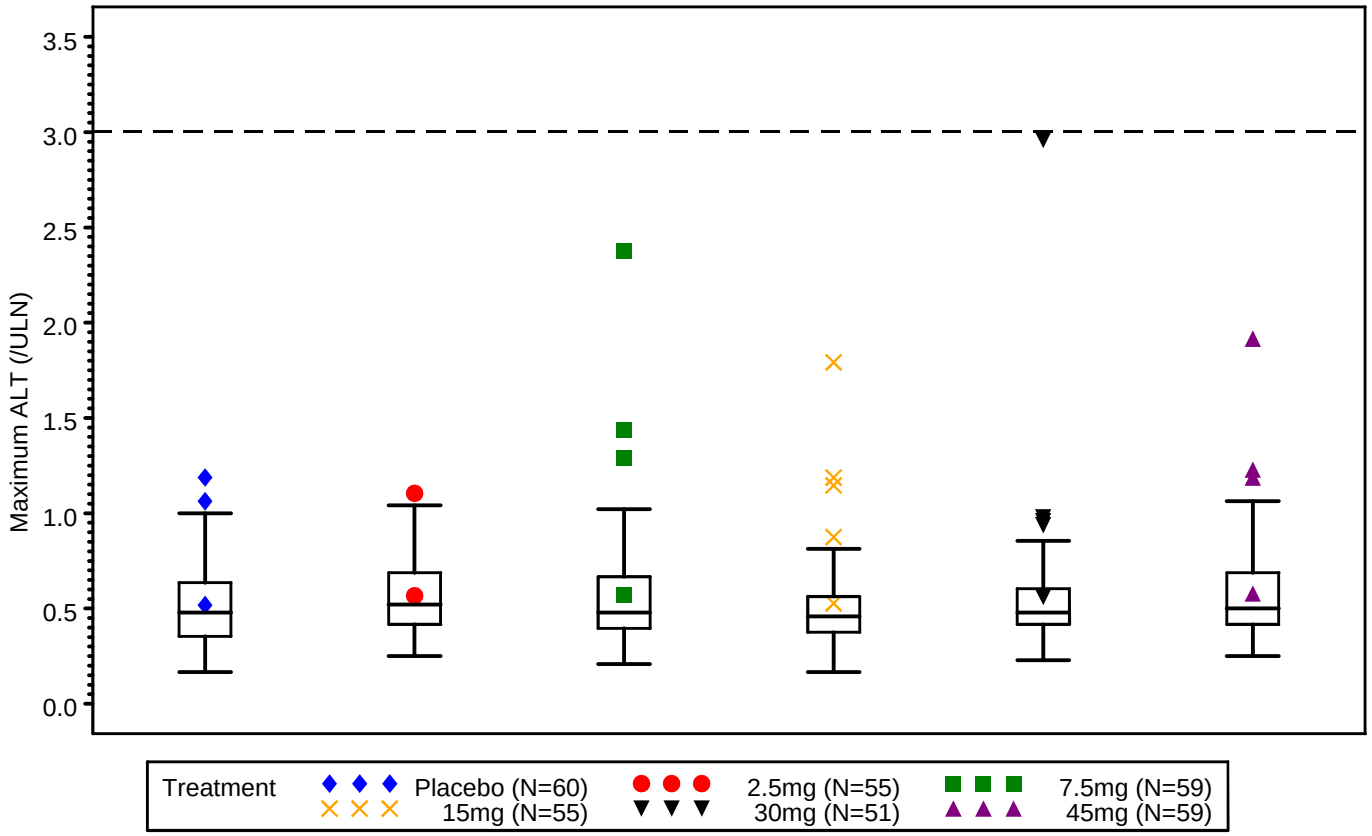
Figure 12.5
Boxplot of Maximum Post-Baseline Alanine Amino Transferase (IU/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline. The dotted line indicates the clinical concern level.

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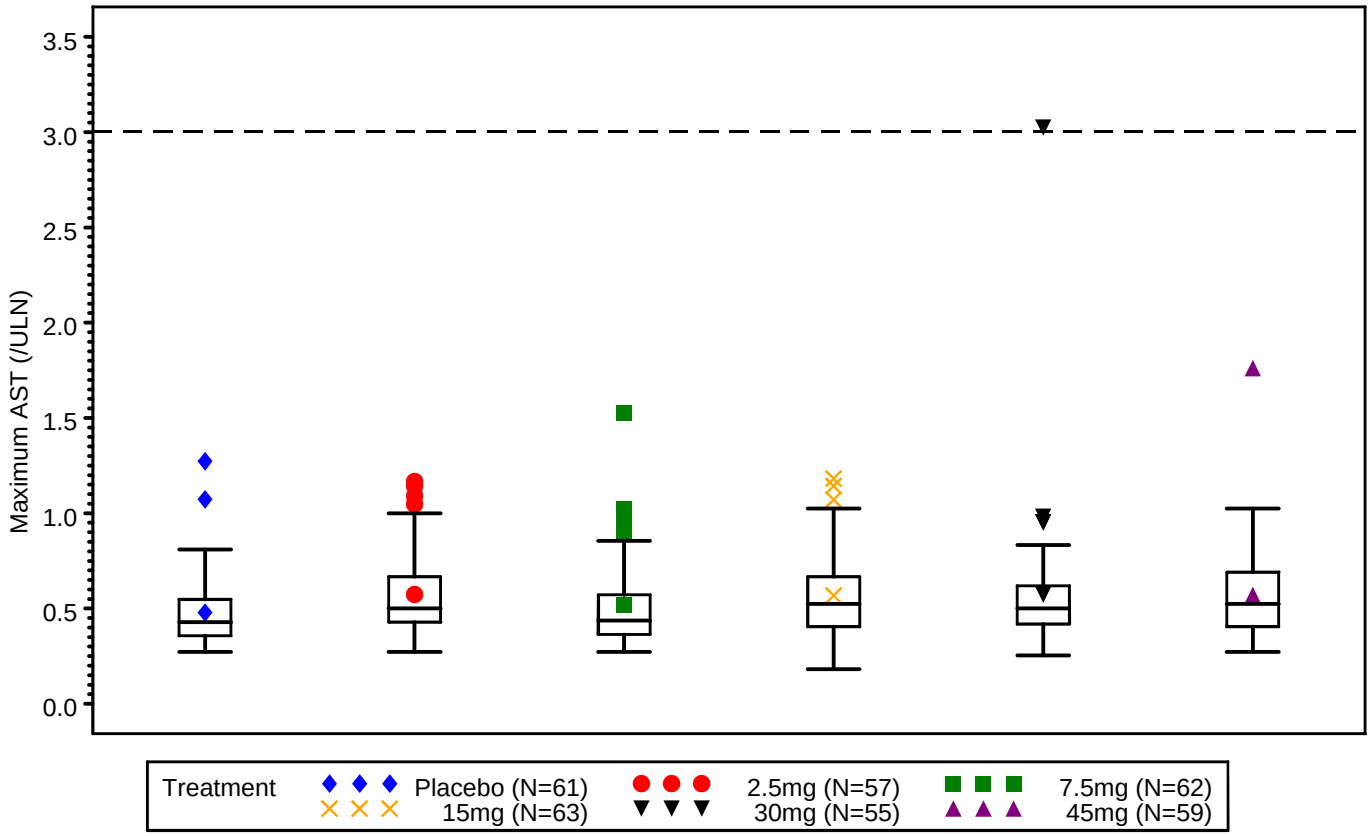
Figure 12.6
Boxplot of Maximum Post-Baseline Aspartate Amino Transferase (IU/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline. The dotted line indicates the clinical concern level.

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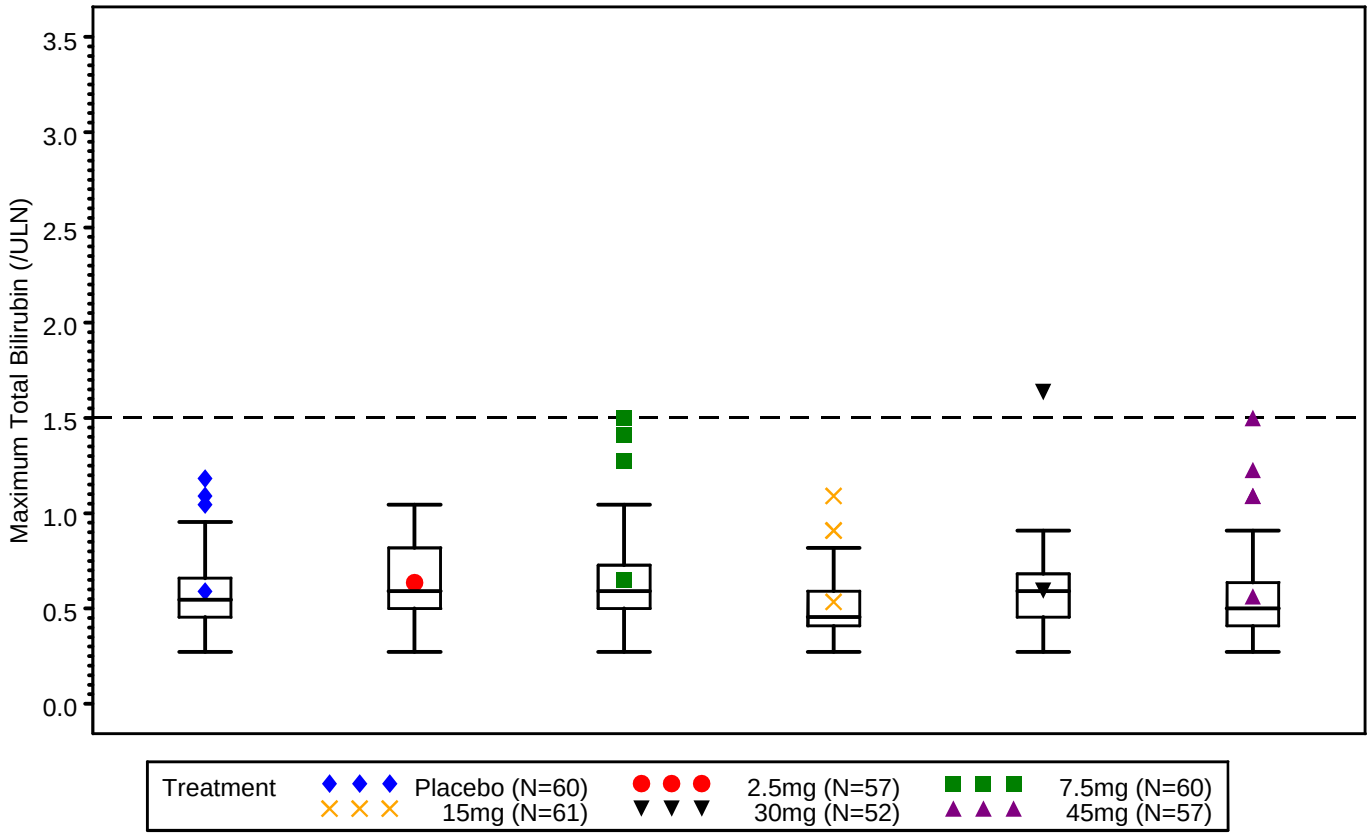
Figure 12.7
Boxplot of Maximum Post-Baseline Total Bilirubin (UMOL/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline. The dotted line indicates the clinical concern level.

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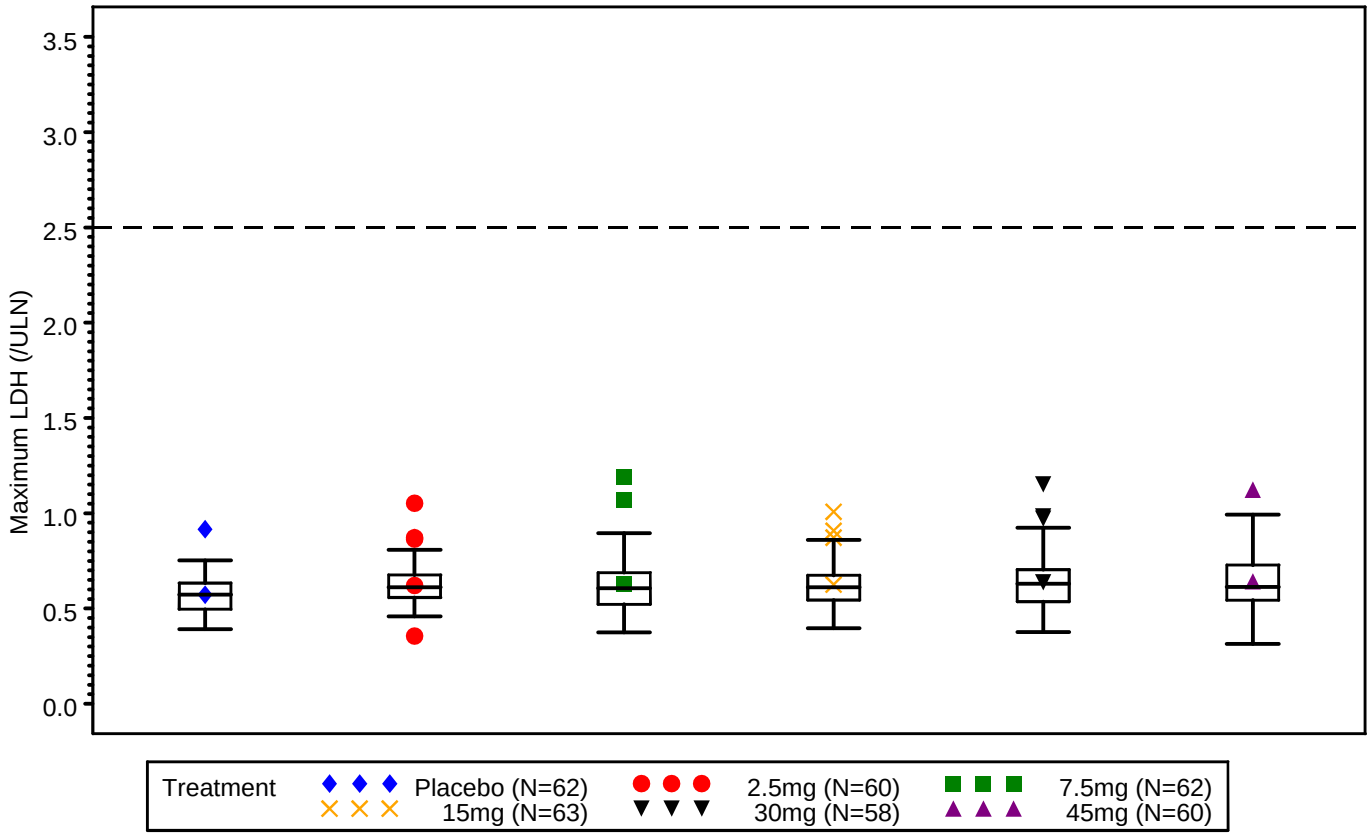
Figure 12.8
Boxplot of Maximum Post-Baseline Lactate Dehydrogenase (IU/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline. The dotted line indicates the clinical concern level.

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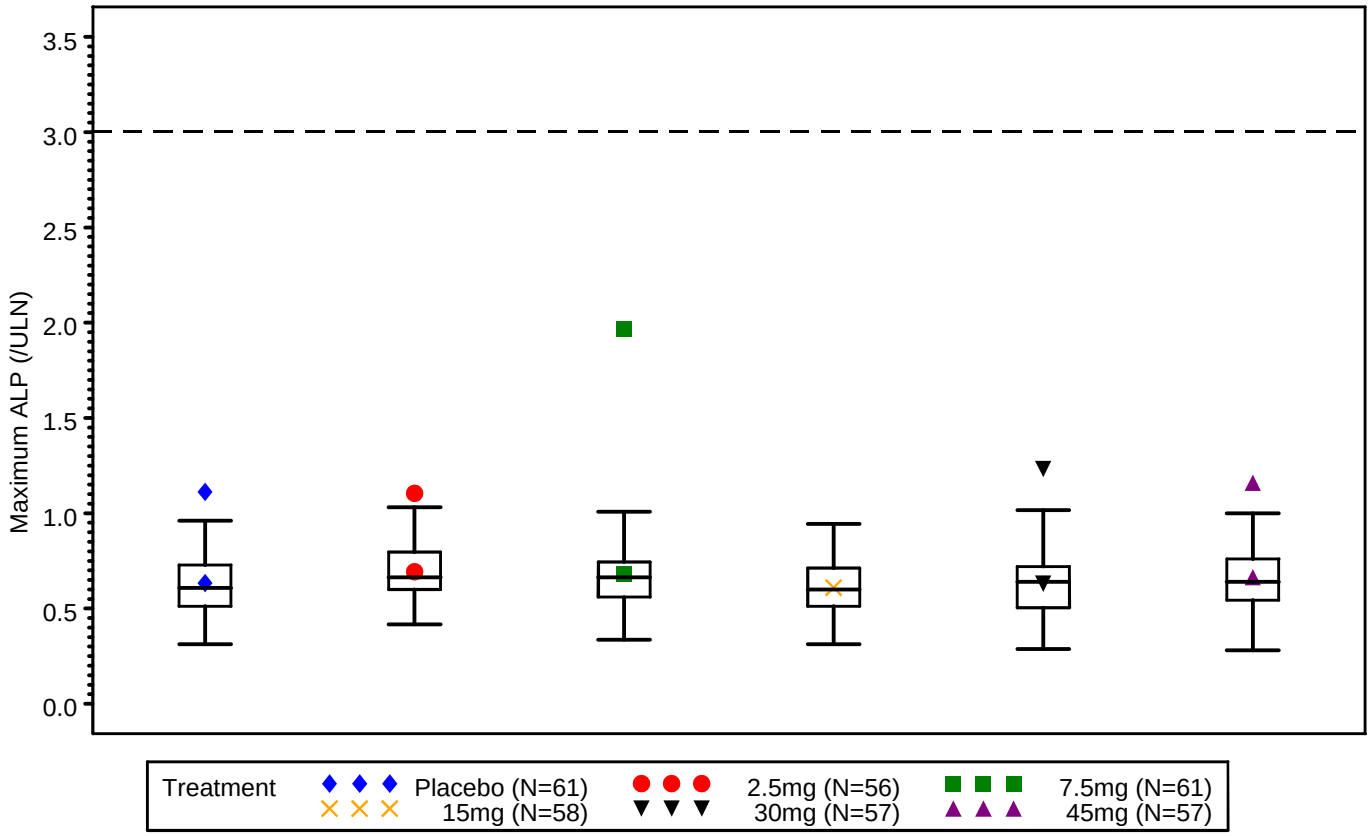
Figure 12.9
Boxplot of Maximum Post-Baseline Alkaline Phosphatase (IU/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline. The dotted line indicates the clinical concern level.

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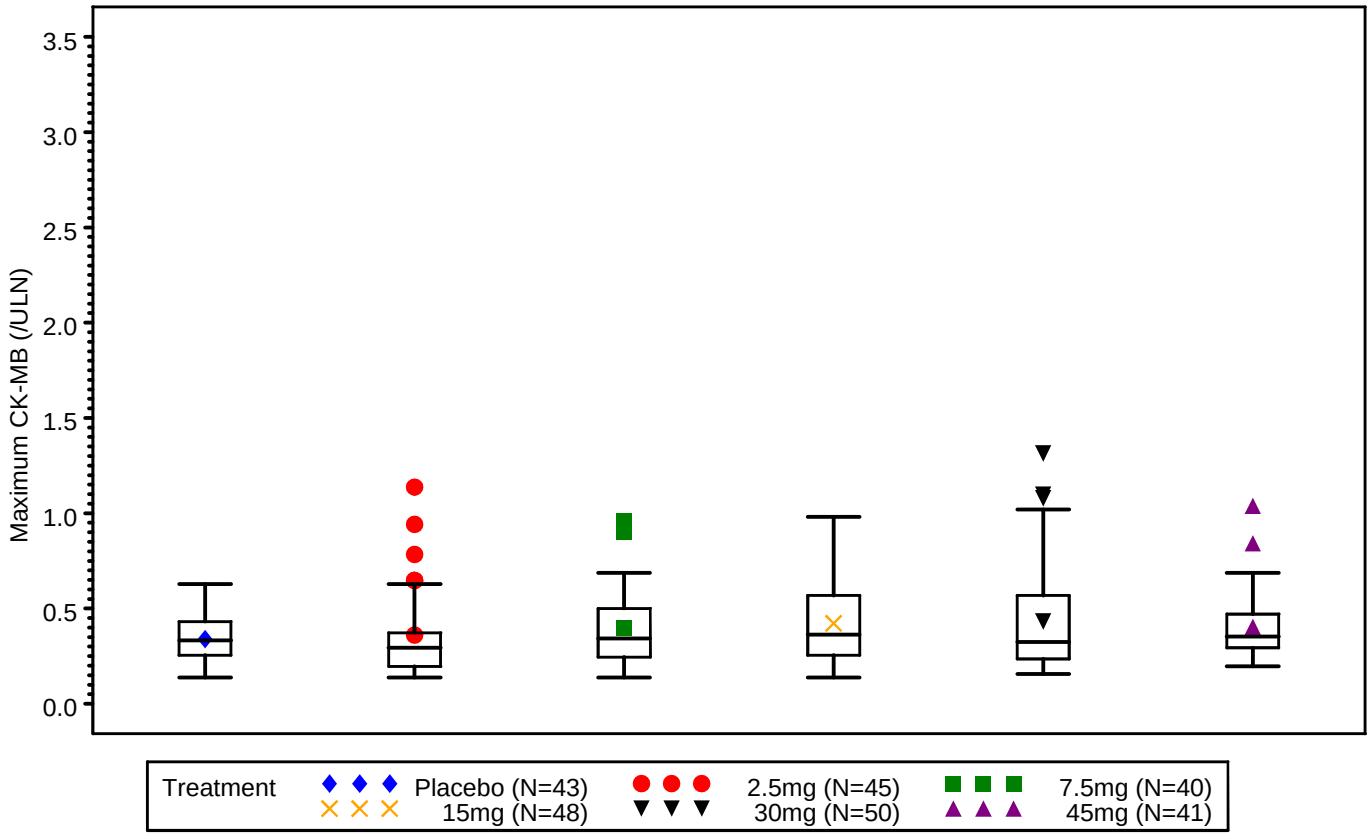
Figure 12.10
Boxplot of Maximum Post-Baseline Creatine Kinase MB (MCG/L) Values Relative to Upper Limit of Normal



Note: Graph only includes subjects who were below ULN at baseline.

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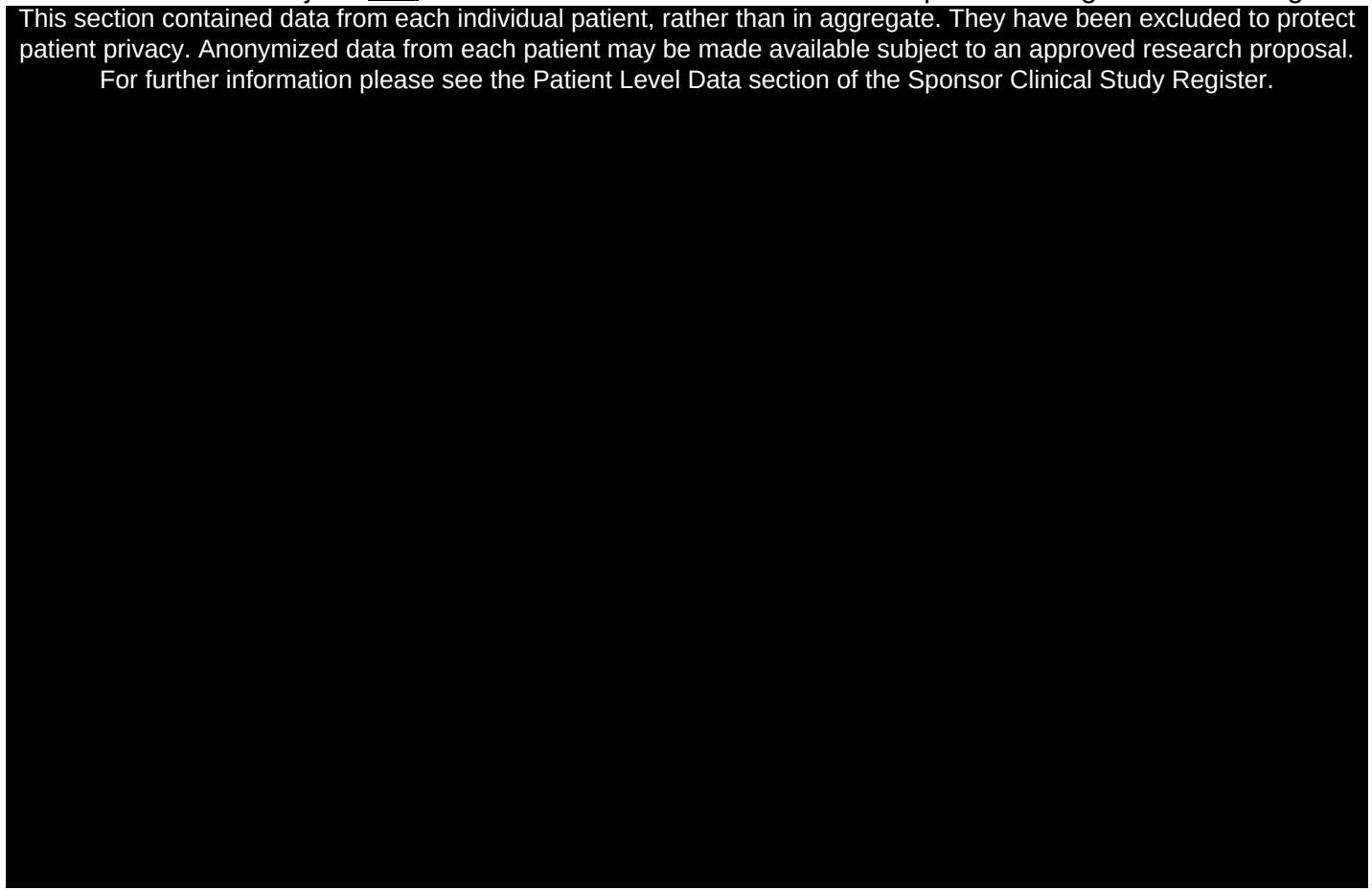
Figure 12.11
Patient Profiles for Selected Laboratory Parameter Post-Baseline Data of Potential Clinical Concern
Treatment=Placebo Subject=[redacted] Race=White - White/Caucasian/European Heritage Sex=Male Age=64

This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the Sponsor Clinical Study Register.



Note: Clinical Concern Levels: ALT, AST, Alk. Phos.: 3xULN, Total Bili.: 1.5xULN

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Figure 12.12
Dotplot and Relative Risk for Common (>=5% total incidence) Adverse Events
15mg vs Placebo

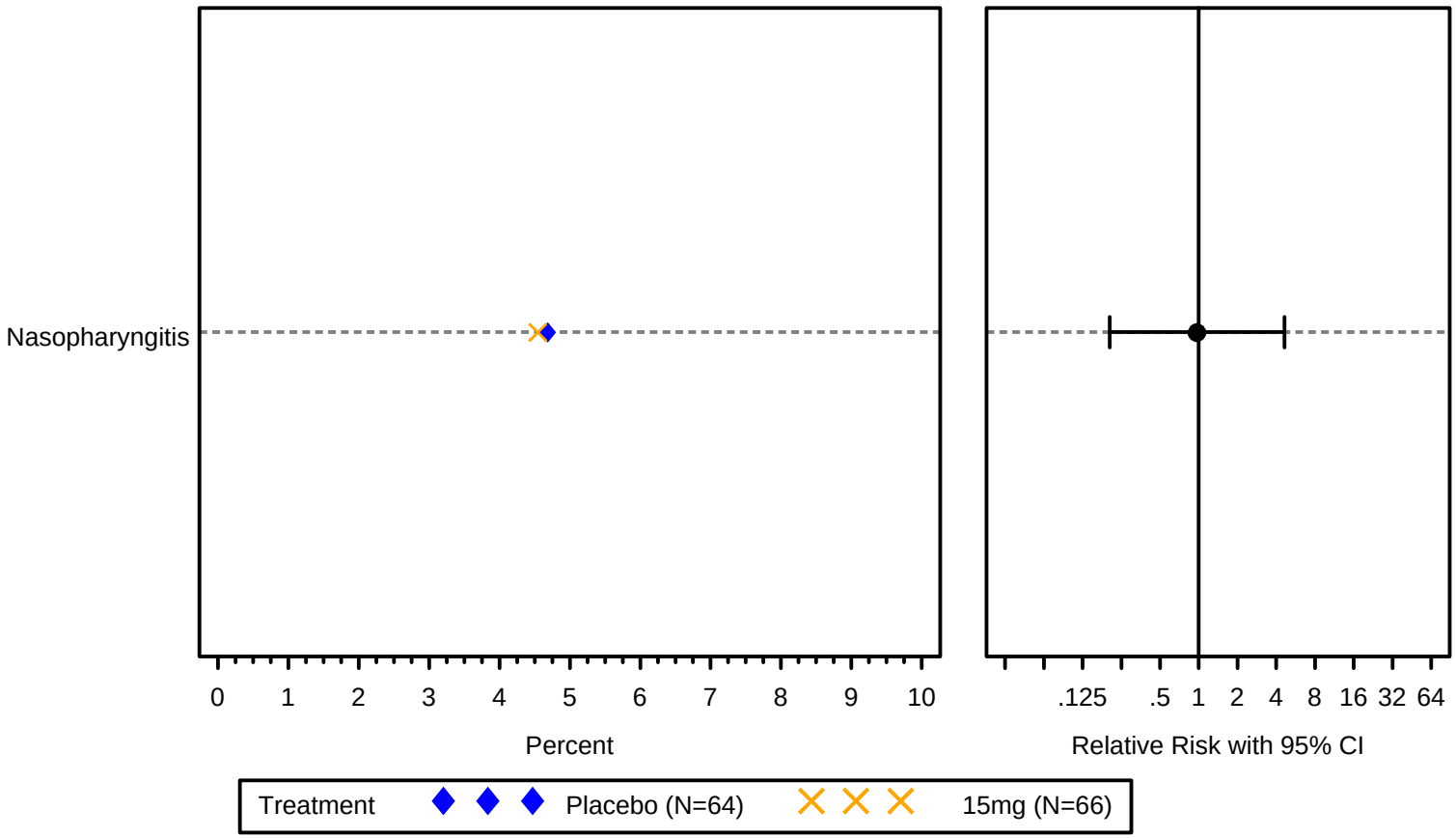

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Figure 12.13
Dotplot and Relative Risk for Common (>=5% total incidence) Adverse Events
30mg vs Placebo

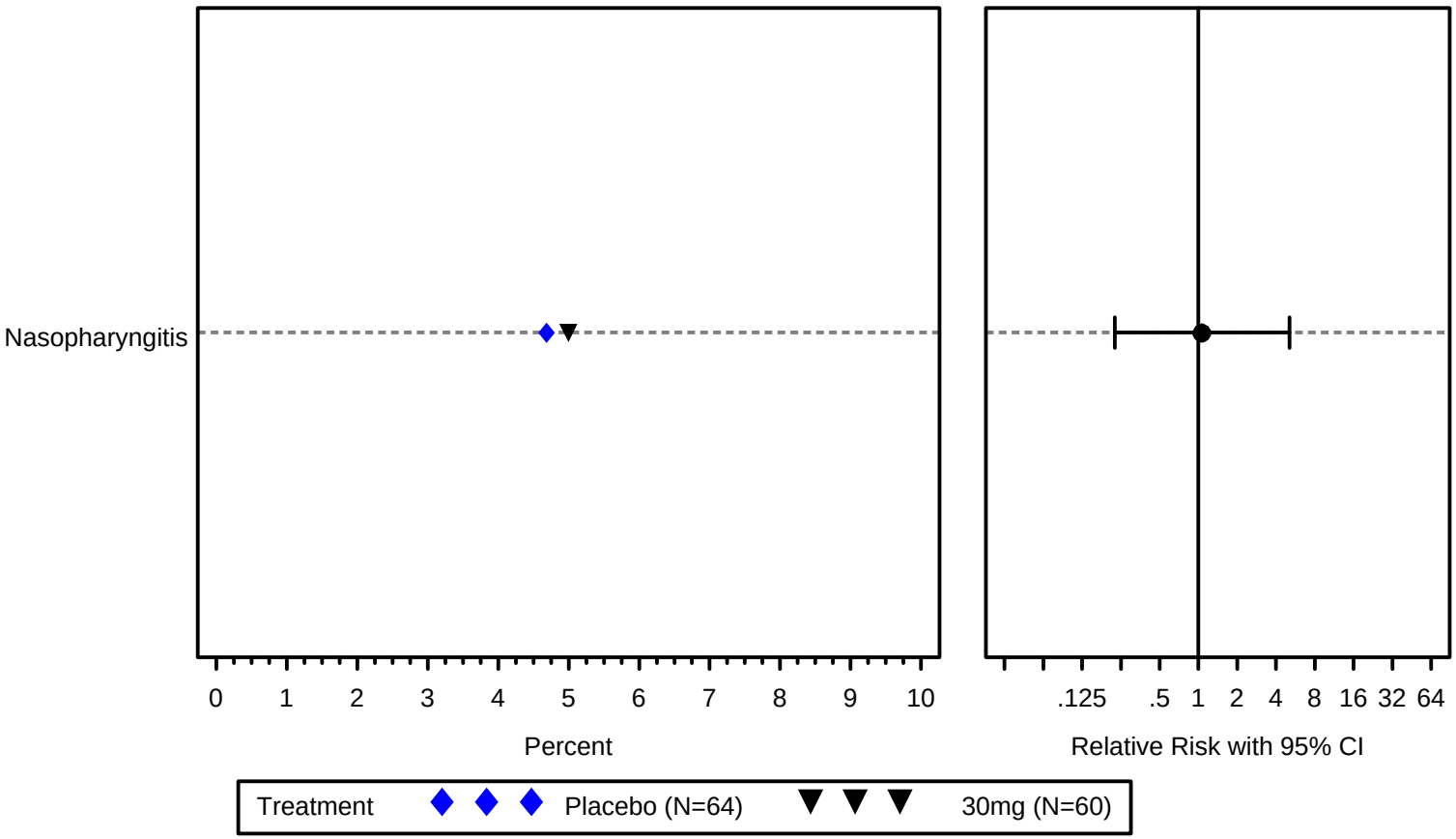

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Figure 12.14
Dotplot and Relative Risk for Common (>=5% total incidence) Adverse Events
45mg vs Placebo

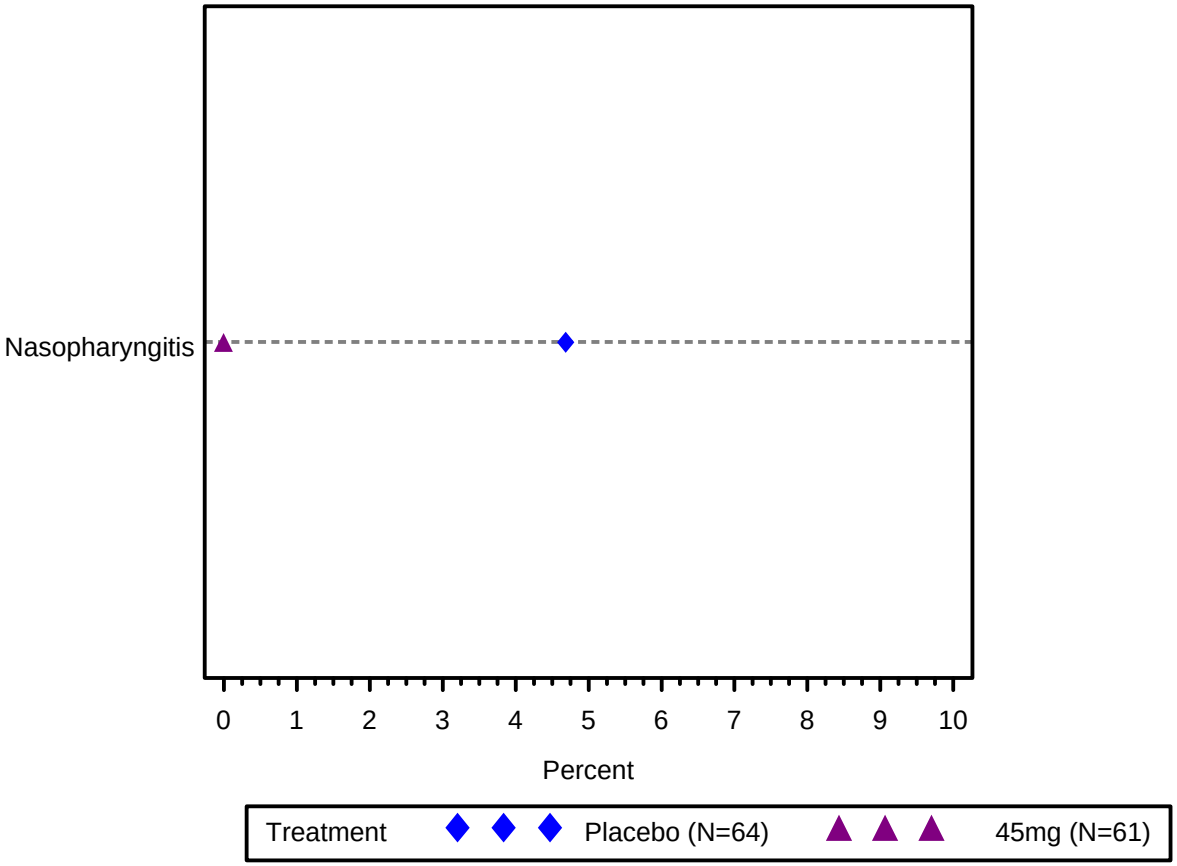

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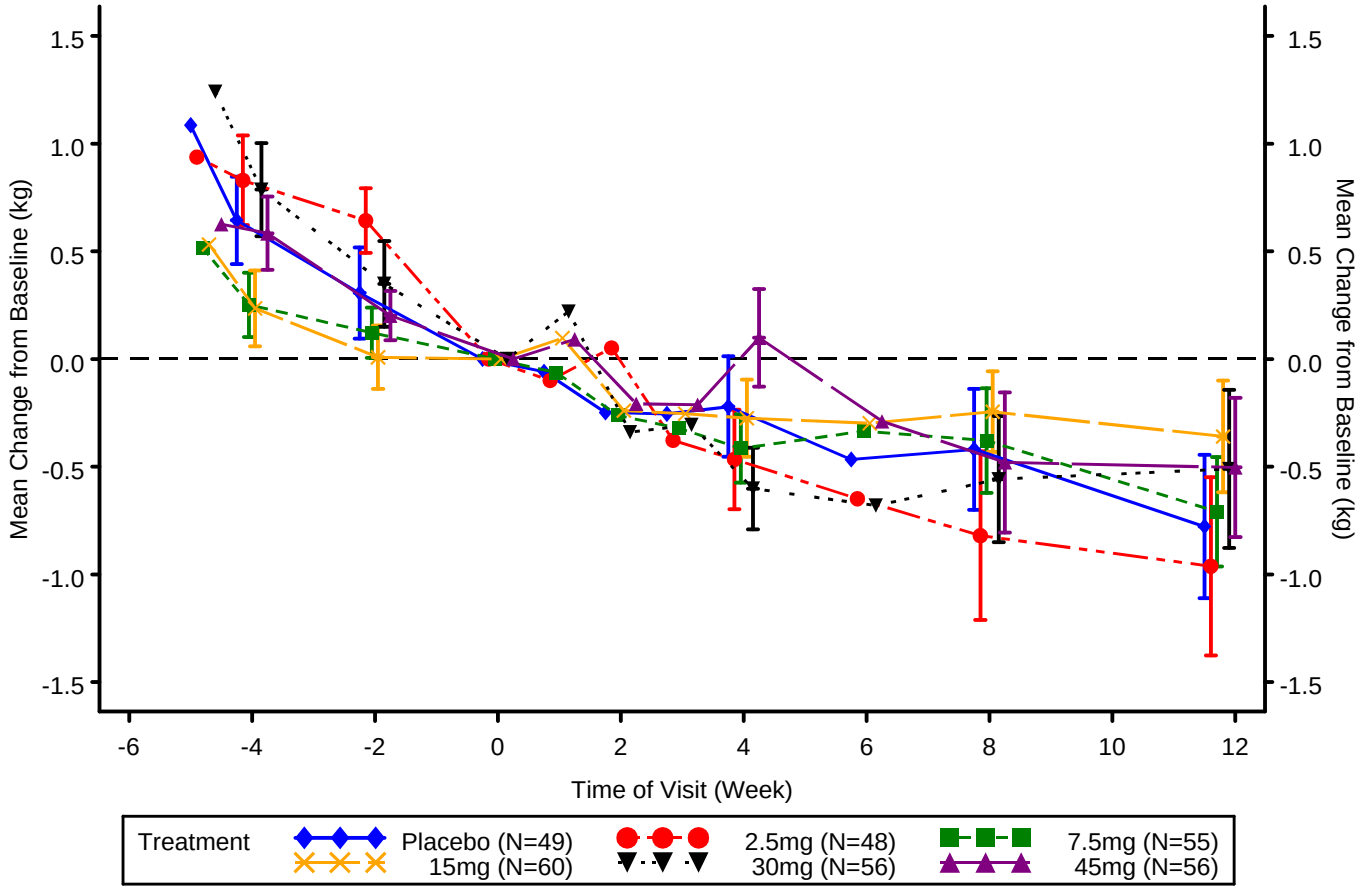
Figure 12.15
Line Graph of Mean Change from Baseline (+/-SE) for Weight (kg) by Visit



Note: N is the number of subjects at Week 12

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Table 12.1
Summary of Exposure to Main-Phase Study Medication

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Subject Exposure (days)							
n	64	61	63	66	60	61	311
<=14	6 (9%)	2 (3%)	3 (5%)	4 (6%)	2 (3%)	0	11 (4%)
15-28	2 (3%)	3 (5%)	1 (2%)	1 (2%)	0	3 (5%)	8 (3%)
29-56	9 (14%)	8 (13%)	3 (5%)	4 (6%)	2 (3%)	4 (7%)	21 (7%)
57-84	32 (50%)	28 (46%)	32 (51%)	38 (58%)	36 (60%)	32 (52%)	166 (53%)
>84	15 (23%)	20 (33%)	24 (38%)	19 (29%)	20 (33%)	22 (36%)	105 (34%)
Mean	69.6	72.4	78.2	76.7	79.5	78.2	77.0
SD	25.04	24.11	20.65	21.61	16.68	17.45	20.34
Median	84.0	84.0	84.0	84.0	84.0	84.0	84.0
Min.	5	1	8	5	7	18	1
Max.	94	92	105	94	91	95	105
Total Exposure in Subject Years	12.19	12.10	13.49	13.87	13.06	13.06	65.58

Note: When the exact extent of exposure was unknown, an approximation based on last known visit was used where possible.

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Table 12.2
Summary of All Pre-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	12 (19%)	15 (25%)	11 (17%)	17 (26%)	4 (7%)	11 (18%)	58 (19%)
Infections and infestations							
Any event	3 (5%)	6 (10%)	4 (6%)	4 (6%)	1 (2%)	3 (5%)	18 (6%)
Nasopharyngitis	0	3 (5%)	1 (2%)	2 (3%)	1 (2%)	1 (2%)	8 (3%)
Cystitis	0	0	1 (2%)	1 (2%)	0	0	2 (<1%)
Acute tonsillitis	0	0	1 (2%)	0	0	0	1 (<1%)
Bacteriuria	0	1 (2%)	0	0	0	0	1 (<1%)
Bronchitis	0	0	1 (2%)	0	0	0	1 (<1%)
Fungal infection	0	0	0	0	0	1 (2%)	1 (<1%)
Gastroenteritis	1 (2%)	0	0	0	0	0	0
Herpes zoster	0	1 (2%)	0	0	0	0	1 (<1%)
Infected sebaceous cyst	1 (2%)	0	0	0	0	0	0
Tonsillitis	0	1 (2%)	0	0	0	0	1 (<1%)
Tooth infection	0	0	0	0	0	1 (2%)	1 (<1%)
Tracheobronchitis	0	1 (2%)	0	0	0	0	1 (<1%)
Upper respiratory tract infection	1 (2%)	0	0	0	0	0	0
Urinary tract infection	0	0	0	1 (2%)	0	0	1 (<1%)
Vulvovaginal mycotic infection	1 (2%)	0	0	0	0	0	0
Nervous system disorders							
Any event	3 (5%)	6 (10%)	2 (3%)	1 (2%)	1 (2%)	3 (5%)	13 (4%)
Headache	0	1 (2%)	1 (2%)	0	1 (2%)	1 (2%)	4 (1%)
Cervicobrachial syndrome	1 (2%)	0	0	1 (2%)	0	0	1 (<1%)
Dizziness	1 (2%)	0	1 (2%)	0	0	0	1 (<1%)
Hypoaesthesia	0	2 (3%)	0	0	0	0	2 (<1%)
Paraesthesia	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Burning sensation	0	1 (2%)	0	0	0	0	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.2
Summary of All Pre-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Lethargy	0	0	0	0	0	1 (2%)	1 (<1%)
Memory impairment	0	1 (2%)	0	0	0	0	1 (<1%)
Polyneuropathy	0	0	0	0	0	1 (2%)	1 (<1%)
Gastrointestinal disorders							
Any event	3 (5%)	2 (3%)	0	5 (8%)	2 (3%)	2 (3%)	11 (4%)
Nausea	2 (3%)	0	0	0	0	1 (2%)	1 (<1%)
Abdominal pain	1 (2%)	0	0	0	1 (2%)	0	1 (<1%)
Abdominal pain upper	0	0	0	2 (3%)	0	0	2 (<1%)
Stomach discomfort	1 (2%)	0	0	0	1 (2%)	0	1 (<1%)
Toothache	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Constipation	0	0	0	1 (2%)	0	0	1 (<1%)
Diarrhoea	1 (2%)	0	0	0	0	0	0
Flatulence	1 (2%)	0	0	0	0	0	0
Food poisoning	0	0	0	1 (2%)	0	0	1 (<1%)
Haemorrhoids	0	1 (2%)	0	0	0	0	1 (<1%)
Oesophagitis	0	0	0	0	1 (2%)	0	1 (<1%)
Vomiting	0	1 (2%)	0	0	0	0	1 (<1%)
Musculoskeletal and connective tissue disorders							
Any event	2 (3%)	2 (3%)	1 (2%)	3 (5%)	1 (2%)	1 (2%)	8 (3%)
Arthralgia	1 (2%)	0	0	0	0	1 (2%)	1 (<1%)
Back pain	0	1 (2%)	1 (2%)	0	0	0	2 (<1%)
Myalgia	0	1 (2%)	0	0	0	1 (2%)	2 (<1%)
Shoulder pain	0	0	0	2 (3%)	0	0	2 (<1%)
Bursitis	0	0	0	1 (2%)	0	0	1 (<1%)
Musculoskeletal discomfort	0	0	0	0	1 (2%)	0	1 (<1%)
Pain in extremity	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.2
Summary of All Pre-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
General disorders and administration site conditions							
Any event	1 (2%)	0	1 (2%)	3 (5%)	1 (2%)	2 (3%)	7 (2%)
Chest pain	0	0	1 (2%)	2 (3%)	0	0	3 (<1%)
Fatigue	1 (2%)	0	0	0	0	2 (3%)	2 (<1%)
Chest discomfort	0	0	0	0	1 (2%)	0	1 (<1%)
Oedema peripheral	0	0	0	1 (2%)	0	0	1 (<1%)
Skin and subcutaneous tissue disorders							
Any event	3 (5%)	0	0	2 (3%)	0	2 (3%)	4 (1%)
Dry skin	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Acne	0	0	0	0	0	1 (2%)	1 (<1%)
Eczema	1 (2%)	0	0	0	0	0	0
Hyperhidrosis	1 (2%)	0	0	0	0	0	0
Pruritus generalised	1 (2%)	0	0	0	0	0	0
Psoriasis	0	0	0	1 (2%)	0	0	1 (<1%)
Respiratory, thoracic and mediastinal disorders							
Any event	1 (2%)	0	3 (5%)	1 (2%)	0	1 (2%)	5 (2%)
Pharyngolaryngeal pain	1 (2%)	0	0	0	0	1 (2%)	1 (<1%)
Cough	0	0	0	1 (2%)	0	0	1 (<1%)
Dysphonia	0	0	1 (2%)	0	0	0	1 (<1%)
Nasal congestion	0	0	1 (2%)	0	0	0	1 (<1%)
Rhinitis allergic	0	0	1 (2%)	0	0	0	1 (<1%)
Injury, poisoning and procedural complications							
Any event	1 (2%)	0	1 (2%)	3 (5%)	0	0	4 (1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.2
Summary of All Pre-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Back injury	1 (2%)	0	0	0	0	0	0
Fall	0	0	0	1 (2%)	0	0	1 (<1%)
Head injury	0	0	0	1 (2%)	0	0	1 (<1%)
Muscle injury	0	0	0	1 (2%)	0	0	1 (<1%)
Muscle strain	0	0	1 (2%)	0	0	0	1 (<1%)
Tendon injury	0	0	0	1 (2%)	0	0	1 (<1%)
Eye disorders							
Any event	0	0	1 (2%)	0	0	2 (3%)	3 (<1%)
Conjunctivitis allergic	0	0	0	0	0	1 (2%)	1 (<1%)
Dry eye	0	0	0	0	0	1 (2%)	1 (<1%)
Eye haemorrhage	0	0	1 (2%)	0	0	0	1 (<1%)
Eye pruritus	0	0	0	0	0	1 (2%)	1 (<1%)
Vision blurred	0	0	0	0	0	1 (2%)	1 (<1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Any event	1 (2%)	0	0	1 (2%)	0	0	1 (<1%)
Bladder neoplasm	1 (2%)	0	0	0	0	0	0
Pyogenic granuloma	0	0	0	1 (2%)	0	0	1 (<1%)
Ear and labyrinth disorders							
Any event	1 (2%)	0	0	0	0	0	0
Tinnitus	1 (2%)	0	0	0	0	0	0
Metabolism and nutrition disorders							
Any event	0	0	0	0	0	1 (2%)	1 (<1%)
Dyslipidaemia	0	0	0	0	0	1 (2%)	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.2
Summary of All Pre-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Psychiatric disorders							
Any event	0	0	0	0	1 (2%)	0	1 (<1%)
Anxiety	0	0	0	0	1 (2%)	0	1 (<1%)
Renal and urinary disorders							
Any event	1 (2%)	0	0	0	0	0	0
Haematuria	1 (2%)	0	0	0	0	0	0
Reproductive system and breast disorders							
Any event	0	0	0	0	1 (2%)	0	1 (<1%)
Vulvovaginal discomfort	0	0	0	0	1 (2%)	0	1 (<1%)
Surgical and medical procedures							
Any event	0	0	0	0	0	1 (2%)	1 (<1%)
Tooth extraction	0	0	0	0	0	1 (2%)	1 (<1%)
Vascular disorders							
Any event	0	0	0	1 (2%)	0	0	1 (<1%)
Hot flush	0	0	0	1 (2%)	0	0	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	24 (38%)	22 (36%)	20 (32%)	28 (42%)	19 (32%)	23 (38%)	112 (36%)
Infections and infestations							
Any event	7 (11%)	7 (11%)	10 (16%)	9 (14%)	6 (10%)	9 (15%)	41 (13%)
Nasopharyngitis	3 (5%)	3 (5%)	7 (11%)	3 (5%)	3 (5%)	0	16 (5%)
Upper respiratory tract infection	1 (2%)	2 (3%)	1 (2%)	1 (2%)	0	2 (3%)	6 (2%)
Laryngitis	1 (2%)	1 (2%)	0	1 (2%)	0	0	2 (<1%)
Sinusitis	0	0	1 (2%)	0	1 (2%)	1 (2%)	3 (<1%)
Acute sinusitis	0	0	0	0	0	2 (3%)	2 (<1%)
Influenza	0	0	0	2 (3%)	0	0	2 (<1%)
Pharyngitis	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
Respiratory tract infection viral	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Tooth abscess	1 (2%)	0	0	0	0	1 (2%)	1 (<1%)
Tooth infection	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Bronchitis	0	0	0	0	1 (2%)	0	1 (<1%)
Bronchitis acute	0	0	0	0	0	1 (2%)	1 (<1%)
Carbuncle	0	0	0	0	0	1 (2%)	1 (<1%)
Cellulitis	0	0	0	0	1 (2%)	0	1 (<1%)
Cystitis	0	0	1 (2%)	0	0	0	1 (<1%)
Furuncle	0	0	0	1 (2%)	0	0	1 (<1%)
Gastroenteritis	1 (2%)	0	0	0	0	0	0
Otitis media	0	0	0	0	0	1 (2%)	1 (<1%)
Tracheobronchitis	0	0	0	0	0	1 (2%)	1 (<1%)
Urinary tract infection	0	0	0	0	1 (2%)	0	1 (<1%)
Viral upper respiratory tract infection	0	1 (2%)	0	0	0	0	1 (<1%)
Gastrointestinal disorders							

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Any event	7 (11%)	5 (8%)	2 (3%)	7 (11%)	7 (12%)	6 (10%)	27 (9%)
Nausea	1 (2%)	2 (3%)	2 (3%)	4 (6%)	1 (2%)	0	9 (3%)
Constipation	3 (5%)	0	0	2 (3%)	1 (2%)	1 (2%)	4 (1%)
Diarrhoea	1 (2%)	1 (2%)	0	1 (2%)	3 (5%)	1 (2%)	6 (2%)
Haemorrhoids	0	0	0	1 (2%)	1 (2%)	1 (2%)	3 (<1%)
Abdominal pain	2 (3%)	0	0	0	0	0	0
Dyspepsia	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Vomiting	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Abdominal distension	0	0	0	0	0	1 (2%)	1 (<1%)
Abdominal pain lower	0	1 (2%)	0	0	0	0	1 (<1%)
Abdominal pain upper	0	0	1 (2%)	0	0	0	1 (<1%)
Abdominal strangulated hernia	0	0	0	0	1 (2%)	0	1 (<1%)
Abdominal tenderness	0	0	0	0	1 (2%)	0	1 (<1%)
Aphthous stomatitis	1 (2%)	0	0	0	0	0	0
Faeces hard	0	0	0	1 (2%)	0	0	1 (<1%)
Gastritis	0	0	0	1 (2%)	0	0	1 (<1%)
Glossodynia	1 (2%)	0	0	0	0	0	0
Inguinal hernia	1 (2%)	0	0	0	0	0	0
Intestinal polyp	0	0	0	0	0	1 (2%)	1 (<1%)
Pruritus ani	1 (2%)	0	0	0	0	0	0
Swollen tongue	1 (2%)	0	0	0	0	0	0
Tooth disorder	0	1 (2%)	0	0	0	0	1 (<1%)
Musculoskeletal and connective tissue disorders							
Any event	3 (5%)	4 (7%)	1 (2%)	8 (12%)	3 (5%)	9 (15%)	25 (8%)
Back pain	1 (2%)	0	0	4 (6%)	0	2 (3%)	6 (2%)
Arthralgia	0	2 (3%)	0	1 (2%)	0	1 (2%)	4 (1%)
Pain in extremity	0	1 (2%)	0	0	1 (2%)	1 (2%)	3 (<1%)
Shoulder pain	0	0	1 (2%)	0	1 (2%)	1 (2%)	3 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Bursitis	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Muscle spasms	0	0	0	0	0	2 (3%)	2 (<1%)
Myalgia	1 (2%)	0	0	0	0	1 (2%)	1 (<1%)
Exostosis	0	0	0	0	0	1 (2%)	1 (<1%)
Gouty arthritis	0	0	0	1 (2%)	0	0	1 (<1%)
Limb discomfort	0	0	0	0	1 (2%)	0	1 (<1%)
Musculoskeletal chest pain	1 (2%)	0	0	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	1 (2%)	1 (<1%)
Tendonitis	0	1 (2%)	0	0	0	0	1 (<1%)
Torticollis	0	0	0	1 (2%)	0	0	1 (<1%)
Nervous system disorders							
Any event	4 (6%)	4 (7%)	3 (5%)	6 (9%)	4 (7%)	5 (8%)	22 (7%)
Headache	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0	2 (3%)	8 (3%)
Dizziness	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)	2 (3%)	6 (2%)
Sinus headache	0	0	0	1 (2%)	1 (2%)	0	2 (<1%)
Cerebrovascular accident	0	0	0	0	1 (2%)	0	1 (<1%)
Dizziness postural	1 (2%)	0	0	0	0	0	0
Hemiparesis	0	0	0	0	1 (2%)	0	1 (<1%)
Hypoaesthesia	0	1 (2%)	0	0	0	0	1 (<1%)
Ischaemic stroke	0	0	0	0	1 (2%)	0	1 (<1%)
Memory impairment	0	1 (2%)	0	0	0	0	1 (<1%)
Migraine	1 (2%)	0	0	0	0	0	0
Sciatica	0	0	0	1 (2%)	0	0	1 (<1%)
Sensory loss	0	0	0	1 (2%)	0	0	1 (<1%)
Tension headache	0	0	0	0	0	1 (2%)	1 (<1%)
Injury, poisoning and procedural complications							
Any event	2 (3%)	1 (2%)	2 (3%)	4 (6%)	3 (5%)	2 (3%)	12 (4%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Back injury	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
Excoriation	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
Fall	1 (2%)	0	0	0	0	1 (2%)	1 (<1%)
Chest injury	0	0	0	0	1 (2%)	0	1 (<1%)
Epicondylitis	0	0	0	0	0	1 (2%)	1 (<1%)
Foot fracture	0	0	0	1 (2%)	0	0	1 (<1%)
Hand fracture	0	0	0	0	1 (2%)	0	1 (<1%)
Joint injury	0	0	0	1 (2%)	0	0	1 (<1%)
Joint sprain	0	0	0	1 (2%)	0	0	1 (<1%)
Limb injury	0	0	0	1 (2%)	0	0	1 (<1%)
Muscle injury	1 (2%)	0	0	0	0	0	0
Skin laceration	0	0	1 (2%)	0	0	0	1 (<1%)
Thermal burn	0	0	1 (2%)	0	0	0	1 (<1%)
Whiplash injury	0	0	0	0	1 (2%)	0	1 (<1%)
Respiratory, thoracic and mediastinal disorders							
Any event	5 (8%)	1 (2%)	3 (5%)	2 (3%)	0	3 (5%)	9 (3%)
Pharyngolaryngeal pain	1 (2%)	1 (2%)	1 (2%)	0	0	1 (2%)	3 (<1%)
Cough	2 (3%)	0	0	1 (2%)	0	0	1 (<1%)
Epistaxis	1 (2%)	0	0	1 (2%)	0	0	1 (<1%)
Interstitial lung disease	0	0	0	0	0	1 (2%)	1 (<1%)
Nasal congestion	0	0	0	0	0	1 (2%)	1 (<1%)
Rhinitis allergic	0	0	1 (2%)	0	0	0	1 (<1%)
Sinus congestion	1 (2%)	0	0	0	0	0	0
Throat tightness	0	0	1 (2%)	0	0	0	1 (<1%)
Skin and subcutaneous tissue disorders							
Any event	3 (5%)	2 (3%)	1 (2%)	2 (3%)	2 (3%)	2 (3%)	9 (3%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Eczema	0	1 (2%)	0	1 (2%)	0	0	2 (<1%)
Hyperhidrosis	0	0	0	0	1 (2%)	1 (2%)	2 (<1%)
Dermal cyst	0	0	1 (2%)	0	0	0	1 (<1%)
Dermatitis	0	0	0	1 (2%)	0	0	1 (<1%)
Dermatitis contact	0	0	0	0	1 (2%)	0	1 (<1%)
Purpura	1 (2%)	0	0	0	0	0	0
Rash	0	0	0	0	0	1 (2%)	1 (<1%)
Rash papular	1 (2%)	0	0	0	0	0	0
Rosacea	0	1 (2%)	0	0	0	0	1 (<1%)
Skin lesion	1 (2%)	0	0	0	0	0	0
General disorders and administration site conditions							
Any event	1 (2%)	2 (3%)	1 (2%)	2 (3%)	2 (3%)	2 (3%)	9 (3%)
Fatigue	0	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
Chest pain	0	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Asthenia	0	0	0	0	1 (2%)	0	1 (<1%)
Chest discomfort	0	0	1 (2%)	0	0	0	1 (<1%)
Feeling cold	0	1 (2%)	0	0	0	0	1 (<1%)
Malaise	1 (2%)	0	0	0	0	0	0
Pyrexia	0	0	0	0	1 (2%)	0	1 (<1%)
Metabolism and nutrition disorders							
Any event	0	5 (8%)	0	2 (3%)	0	3 (5%)	10 (3%)
Hyperglycaemia	0	3 (5%)	0	0	0	0	3 (<1%)
Diabetes mellitus	0	0	0	1 (2%)	0	0	1 (<1%)
Dyslipidaemia	0	1 (2%)	0	0	0	0	1 (<1%)
Fluid retention	0	0	0	0	0	1 (2%)	1 (<1%)
Gout	0	1 (2%)	0	0	0	0	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Hyperkalaemia	0	0	0	0	0	1 (2%)	1 (<1%)
Hyperlipidaemia	0	0	0	1 (2%)	0	0	1 (<1%)
Hypertriglyceridaemia	0	1 (2%)	0	0	0	0	1 (<1%)
Iron deficiency	0	0	0	0	0	1 (2%)	1 (<1%)
Eye disorders							
Any event	1 (2%)	1 (2%)	2 (3%)	0	2 (3%)	1 (2%)	6 (2%)
Vision blurred	0	0	2 (3%)	0	0	0	2 (<1%)
Abnormal sensation in eye	0	0	0	0	1 (2%)	0	1 (<1%)
Eye disorder	1 (2%)	0	0	0	0	0	0
Glaucoma	0	0	0	0	1 (2%)	0	1 (<1%)
Ocular hyperaemia	0	1 (2%)	0	0	0	0	1 (<1%)
Uveitis	0	0	0	0	0	1 (2%)	1 (<1%)
Investigations							
Any event	2 (3%)	3 (5%)	0	0	0	0	3 (<1%)
Neutrophil count decreased	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Blood pressure increased	0	1 (2%)	0	0	0	0	1 (<1%)
Blood triglycerides increased	1 (2%)	0	0	0	0	0	0
Haemoglobin decreased	0	1 (2%)	0	0	0	0	1 (<1%)
Low density lipoprotein increased	1 (2%)	0	0	0	0	0	0
Reproductive system and breast disorders							
Any event	1 (2%)	1 (2%)	0	1 (2%)	2 (3%)	0	4 (1%)
Menorrhagia	0	1 (2%)	0	0	1 (2%)	0	2 (<1%)
Breast pain	0	0	0	1 (2%)	0	0	1 (<1%)
Breast tenderness	0	0	0	0	1 (2%)	0	1 (<1%)
Rectocele	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Vascular disorders							
Any event	1 (2%)	0	3 (5%)	0	0	1 (2%)	4 (1%)
Hypertension	1 (2%)	0	2 (3%)	0	0	1 (2%)	3 (<1%)
Intermittent claudication	0	0	1 (2%)	0	0	0	1 (<1%)
Psychiatric disorders							
Any event	0	1 (2%)	0	0	0	2 (3%)	3 (<1%)
Dependent personality disorder	0	0	0	0	0	1 (2%)	1 (<1%)
Depression	0	1 (2%)	0	0	0	0	1 (<1%)
Insomnia	0	0	0	0	0	1 (2%)	1 (<1%)
Restlessness	0	0	0	0	0	1 (2%)	1 (<1%)
Renal and urinary disorders							
Any event	1 (2%)	0	0	1 (2%)	0	1 (2%)	2 (<1%)
Calculus bladder	1 (2%)	0	0	0	0	0	0
Dysuria	1 (2%)	0	0	0	0	0	0
Glycosuria	0	0	0	1 (2%)	0	0	1 (<1%)
Micturition urgency	1 (2%)	0	0	0	0	0	0
Renal colic	0	0	0	0	0	1 (2%)	1 (<1%)
Urinary incontinence	1 (2%)	0	0	0	0	0	0
Surgical and medical procedures							
Any event	1 (2%)	1 (2%)	0	0	0	1 (2%)	2 (<1%)
Haemorrhoid operation	0	1 (2%)	0	0	0	0	1 (<1%)
Tooth repair	0	0	0	0	0	1 (2%)	1 (<1%)
Transurethral prostatectomy	1 (2%)	0	0	0	0	0	0
Cardiac disorders							

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.3
Summary of All On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Any event	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Palpitations	0	1 (2%)	0	0	0	0	1 (<1%)
Ventricular extrasystoles	1 (2%)	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Any event	1 (2%)	0	0	1 (2%)	0	0	1 (<1%)
Bladder neoplasm	1 (2%)	0	0	0	0	0	0
Skin papilloma	0	0	0	1 (2%)	0	0	1 (<1%)
Blood and lymphatic system disorders							
Any event	0	0	1 (2%)	0	0	0	1 (<1%)
Anaemia	0	0	1 (2%)	0	0	0	1 (<1%)
Ear and labyrinth disorders							
Any event	1 (2%)	0	0	0	0	0	0
Cerumen impaction	1 (2%)	0	0	0	0	0	0
Hepatobiliary disorders							
Any event	0	1 (2%)	0	0	0	0	1 (<1%)
Gallbladder disorder	0	1 (2%)	0	0	0	0	1 (<1%)
Immune system disorders							
Any event	1 (2%)	0	0	0	0	0	0
Hypersensitivity	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.4
Summary of All Post-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	2 (3%)	0	0	0	0	0	0
Infections and infestations							
Any event	2 (3%)	0	0	0	0	0	0
Influenza	1 (2%)	0	0	0	0	0	0
Pneumonia	1 (2%)	0	0	0	0	0	0
Gastrointestinal disorders							
Any event	1 (2%)	0	0	0	0	0	0
Abdominal pain upper	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)			
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild		
ANY EVENT	0	13 (20%)	11 (17%)	0	0	6 (10%)		
Infections and infestations								
Any Event	0	5 (8%)	2 (3%)	0	0	5 (8%)		
Nasopharyngitis	0	3 (5%)	0	0	0	3 (5%)		
Upper respiratory tract infection	0	1 (2%)	0	0	0	1 (2%)		
Laryngitis	0	1 (2%)	0	0	0	0		
Sinusitis	0	0	0	0	0	0		
Acute sinusitis	0	0	0	0	0	0		
Influenza	0	0	0	0	0	0		
Pharyngitis	0	0	0	0	0	0		
Respiratory tract infection viral	0	0	1 (2%)	0	0	1 (2%)		
Tooth abscess	0	1 (2%)	0	0	0	0		
Tooth infection	0	0	0	0	0	0		
Bronchitis	0	0	0	0	0	0		
Bronchitis acute	0	0	0	0	0	0		
Carbuncle	0	0	0	0	0	0		
Cellulitis	0	0	0	0	0	0		
Cystitis	0	0	0	0	0	0		
Furuncle	0	0	0	0	0	0		
Gastroenteritis	0	0	1 (2%)	0	0	0		
Otitis media	0	0	0	0	0	0		
Tracheobronchitis	0	0	0	0	0	0		
Urinary tract infection	0	0	0	0	0	0		
Viral upper respiratory tract infection	0	0	0	0	0	1 (2%)		
Gastrointestinal disorders								
Any Event	0	2 (3%)	5 (8%)	0	0	3 (5%)		
Nausea	0	1 (2%)	0	0	0	2 (3%)		

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
ANY EVENT	13 (21%)	3 (5%)	0	17 (27%)	3 (5%)	0
Infections and infestations						
Any Event	2 (3%)	0	0	10 (16%)	0	0
Nasopharyngitis	0	0	0	7 (11%)	0	0
Upper respiratory tract infection	1 (2%)	0	0	1 (2%)	0	0
Laryngitis	1 (2%)	0	0	0	0	0
Sinusitis	0	0	0	1 (2%)	0	0
Acute sinusitis	0	0	0	0	0	0
Influenza	0	0	0	0	0	0
Pharyngitis	0	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0	0
Tooth abscess	0	0	0	0	0	0
Tooth infection	0	0	0	0	0	0
Bronchitis	0	0	0	0	0	0
Bronchitis acute	0	0	0	0	0	0
Carbuncle	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0
Cystitis	0	0	0	1 (2%)	0	0
Furuncle	0	0	0	0	0	0
Gastroenteritis	0	0	0	0	0	0
Otitis media	0	0	0	0	0	0
Tracheobronchitis	0	0	0	0	0	0
Urinary tract infection	0	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0	0
Gastrointestinal disorders						
Any Event	1 (2%)	1 (2%)	0	1 (2%)	1 (2%)	0
Nausea	0	0	0	1 (2%)	1 (2%)	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
ANY EVENT	0	13 (20%)	14 (21%)	1 (2%)	0	8 (13%)
Infections and infestations						
Any Event	0	4 (6%)	5 (8%)	0	0	1 (2%)
Nasopharyngitis	0	3 (5%)	0	0	0	1 (2%)
Upper respiratory tract infection	0	1 (2%)	0	0	0	0
Laryngitis	0	0	1 (2%)	0	0	0
Sinusitis	0	0	0	0	0	0
Acute sinusitis	0	0	0	0	0	0
Influenza	0	0	2 (3%)	0	0	0
Pharyngitis	0	0	0	0	0	0
Respiratory tract infection viral	0	0	0	0	0	0
Tooth abscess	0	0	0	0	0	0
Tooth infection	0	0	1 (2%)	0	0	0
Bronchitis	0	0	0	0	0	0
Bronchitis acute	0	0	0	0	0	0
Carbuncle	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0
Cystitis	0	0	0	0	0	0
Furuncle	0	0	1 (2%)	0	0	0
Gastroenteritis	0	0	0	0	0	0
Otitis media	0	0	0	0	0	0
Tracheobronchitis	0	0	0	0	0	0
Urinary tract infection	0	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0	0
Gastrointestinal disorders						
Any Event	0	3 (5%)	3 (5%)	1 (2%)	0	6 (10%)
Nausea	0	2 (3%)	1 (2%)	1 (2%)	0	1 (2%)

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)			
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
ANY EVENT	10 (17%)	1 (2%)	0	12 (20%)	8 (13%)	3 (5%)
Infections and infestations						
Any Event	5 (8%)	0	0	7 (11%)	2 (3%)	0
Nasopharyngitis	2 (3%)	0	0	0	0	0
Upper respiratory tract infection	0	0	0	2 (3%)	0	0
Laryngitis	0	0	0	0	0	0
Sinusitis	1 (2%)	0	0	1 (2%)	0	0
Acute sinusitis	0	0	0	1 (2%)	1 (2%)	0
Influenza	0	0	0	0	0	0
Pharyngitis	1 (2%)	0	0	0	1 (2%)	0
Respiratory tract infection viral	0	0	0	0	0	0
Tooth abscess	0	0	0	1 (2%)	0	0
Tooth infection	0	0	0	1 (2%)	0	0
Bronchitis	1 (2%)	0	0	0	0	0
Bronchitis acute	0	0	0	0	1 (2%)	0
Carbuncle	0	0	0	1 (2%)	0	0
Cellulitis	1 (2%)	0	0	0	0	0
Cystitis	0	0	0	0	0	0
Furuncle	0	0	0	0	0	0
Gastroenteritis	0	0	0	0	0	0
Otitis media	0	0	0	1 (2%)	0	0
Tracheobronchitis	0	0	0	1 (2%)	0	0
Urinary tract infection	1 (2%)	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0	0
Gastrointestinal disorders						
Any Event	1 (2%)	0	0	3 (5%)	2 (3%)	1 (2%)
Nausea	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
ANY EVENT	0	56 (18%)	48 (15%)	8 (3%)
Infections and infestations				
Any Event	0	27 (9%)	14 (5%)	0
Nasopharyngitis	0	14 (5%)	2 (<1%)	0
Upper respiratory tract infection	0	5 (2%)	1 (<1%)	0
Laryngitis	0	0	2 (<1%)	0
Sinusitis	0	2 (<1%)	1 (<1%)	0
Acute sinusitis	0	1 (<1%)	1 (<1%)	0
Influenza	0	0	2 (<1%)	0
Pharyngitis	0	0	2 (<1%)	0
Respiratory tract infection viral	0	1 (<1%)	0	0
Tooth abscess	0	1 (<1%)	0	0
Tooth infection	0	1 (<1%)	1 (<1%)	0
Bronchitis	0	0	1 (<1%)	0
Bronchitis acute	0	0	1 (<1%)	0
Carbuncle	0	1 (<1%)	0	0
Cellulitis	0	0	1 (<1%)	0
Cystitis	0	1 (<1%)	0	0
Furuncle	0	0	1 (<1%)	0
Gastroenteritis	0	0	0	0
Otitis media	0	1 (<1%)	0	0
Tracheobronchitis	0	1 (<1%)	0	0
Urinary tract infection	0	0	1 (<1%)	0
Viral upper respiratory tract infection	0	1 (<1%)	0	0
Gastrointestinal disorders				
Any Event	0	16 (5%)	8 (3%)	3 (<1%)
Nausea	0	6 (2%)	2 (<1%)	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)			
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild		
Constipation	0	1	(2%)	2 (3%)	0	0		
Diarrhoea	0	0		1 (2%)	0	0	1	(2%)
Haemorrhoids	0	0		0	0	0		
Abdominal pain	0	2	(3%)	0	0	0		
Dyspepsia	0	1	(2%)	0	0	0		
Vomiting	0	0		0	0	0		
Abdominal distension	0	0		0	0	0		
Abdominal pain lower	0	0		0	0	1	(2%)	
Abdominal pain upper	0	0		0	0	0		
Abdominal strangulated hernia	0	0		0	0	0		
Abdominal tenderness	0	0		0	0	0		
Aphthous stomatitis	0	0		1 (2%)	0	0		
Faeces hard	0	0		0	0	0		
Gastritis	0	0		0	0	0		
Glossodynia	0	1	(2%)	0	0	0		
Inguinal hernia	0	0		1 (2%)	0	0		
Intestinal polyp	0	0		0	0	0		
Pruritus ani	0	0		1 (2%)	0	0		
Swollen tongue	0	1	(2%)	0	0	0		
Tooth disorder	0	0		0	0	0		
Musculoskeletal and connective tissue disorders								
Any Event	0	3	(5%)	0	0	4	(7%)	
Back pain	0	1	(2%)	0	0	0		
Arthralgia	0	0		0	0	2	(3%)	
Pain in extremity	0	0		0	0	1	(2%)	
Shoulder pain	0	0		0	0	0		
Bursitis	0	0		0	0	0		
Muscle spasms	0	0		0	0	0		

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Constipation	0	0	0	0	0	0
Diarrhoea	0	0	0	0	0	0
Haemorrhoids	0	0	0	0	0	0
Abdominal pain	0	0	0	0	0	0
Dyspepsia	0	1 (2%)	0	0	0	0
Vomiting	0	0	0	0	0	0
Abdominal distension	0	0	0	0	0	0
Abdominal pain lower	0	0	0	0	0	0
Abdominal pain upper	0	0	0	0	1 (2%)	0
Abdominal strangulated hernia	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	0
Aphthous stomatitis	0	0	0	0	0	0
Faeces hard	0	0	0	0	0	0
Gastritis	0	0	0	0	0	0
Glossodynia	0	0	0	0	0	0
Inguinal hernia	0	0	0	0	0	0
Intestinal polyp	0	0	0	0	0	0
Pruritus ani	0	0	0	0	0	0
Swollen tongue	0	0	0	0	0	0
Tooth disorder	1 (2%)	0	0	0	0	0
Musculoskeletal and connective tissue disorders						
Any Event	0	0	0	1 (2%)	0	0
Back pain	0	0	0	0	0	0
Arthralgia	0	0	0	0	0	0
Pain in extremity	0	0	0	0	0	0
Shoulder pain	0	0	0	1 (2%)	0	0
Bursitis	0	0	0	0	0	0
Muscle spasms	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Constipation	0	1 (2%)	1 (2%)	0	0	1 (2%)
Diarrhoea	0	0	1 (2%)	0	0	3 (5%)
Haemorrhoids	0	0	1 (2%)	0	0	1 (2%)
Abdominal pain	0	0	0	0	0	0
Dyspepsia	0	0	0	0	0	0
Vomiting	0	0	1 (2%)	0	0	0
Abdominal distension	0	0	0	0	0	0
Abdominal pain lower	0	0	0	0	0	0
Abdominal pain upper	0	0	0	0	0	0
Abdominal strangulated hernia	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	1 (2%)
Aphthous stomatitis	0	0	0	0	0	0
Faeces hard	0	1 (2%)	0	0	0	0
Gastritis	0	0	1 (2%)	0	0	0
Glossodynia	0	0	0	0	0	0
Inguinal hernia	0	0	0	0	0	0
Intestinal polyp	0	0	0	0	0	0
Pruritus ani	0	0	0	0	0	0
Swollen tongue	0	0	0	0	0	0
Tooth disorder	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders						
Any Event	0	4 (6%)	4 (6%)	0	0	2 (3%)
Back pain	0	2 (3%)	2 (3%)	0	0	0
Arthralgia	0	0	1 (2%)	0	0	0
Pain in extremity	0	0	0	0	0	1 (2%)
Shoulder pain	0	0	0	0	0	0
Bursitis	0	0	1 (2%)	0	0	0
Muscle spasms	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)			
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Constipation	0	0	0	0	1 (2%)	0
Diarrhoea	0	0	0	1 (2%)	0	0
Haemorrhoids	0	0	0	1 (2%)	0	0
Abdominal pain	0	0	0	0	0	0
Dyspepsia	0	0	0	0	0	0
Vomiting	0	0	0	0	1 (2%)	0
Abdominal distension	0	0	0	1 (2%)	0	0
Abdominal pain lower	0	0	0	0	0	0
Abdominal pain upper	0	0	0	0	0	0
Abdominal strangulated hernia	1 (2%)	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	0
Aphthous stomatitis	0	0	0	0	0	0
Faeces hard	0	0	0	0	0	0
Gastritis	0	0	0	0	0	0
Glossodynia	0	0	0	0	0	0
Inguinal hernia	0	0	0	0	0	0
Intestinal polyp	0	0	0	0	0	1 (2%)
Pruritus ani	0	0	0	0	0	0
Swollen tongue	0	0	0	0	0	0
Tooth disorder	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders						
Any Event	1 (2%)	0	0	3 (5%)	6 (10%)	0
Back pain	0	0	0	0	2 (3%)	0
Arthralgia	0	0	0	0	1 (2%)	0
Pain in extremity	0	0	0	0	1 (2%)	0
Shoulder pain	1 (2%)	0	0	1 (2%)	0	0
Bursitis	0	0	0	0	1 (2%)	0
Muscle spasms	0	0	0	1 (2%)	1 (2%)	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Constipation	0	2 (<1%)	2 (<1%)	0
Diarrhoea	0	5 (2%)	1 (<1%)	0
Haemorrhoids	0	2 (<1%)	1 (<1%)	0
Abdominal pain	0	0	0	0
Dyspepsia	0	0	0	1 (<1%)
Vomiting	0	0	2 (<1%)	0
Abdominal distension	0	1 (<1%)	0	0
Abdominal pain lower	0	1 (<1%)	0	0
Abdominal pain upper	0	0	1 (<1%)	0
Abdominal strangulated hernia	0	0	1 (<1%)	0
Abdominal tenderness	0	1 (<1%)	0	0
Aphthous stomatitis	0	0	0	0
Faeces hard	0	1 (<1%)	0	0
Gastritis	0	0	1 (<1%)	0
Glossodynia	0	0	0	0
Inguinal hernia	0	0	0	0
Intestinal polyp	0	0	0	1 (<1%)
Pruritus ani	0	0	0	0
Swollen tongue	0	0	0	0
Tooth disorder	0	0	1 (<1%)	0
Musculoskeletal and connective tissue disorders				
Any Event	0	14 (5%)	11 (4%)	0
Back pain	0	2 (<1%)	4 (1%)	0
Arthralgia	0	2 (<1%)	2 (<1%)	0
Pain in extremity	0	2 (<1%)	1 (<1%)	0
Shoulder pain	0	2 (<1%)	1 (<1%)	0
Bursitis	0	0	2 (<1%)	0
Muscle spasms	0	1 (<1%)	1 (<1%)	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64) Not Applicable	Mild	Moderate	Severe	2.5mg (N=61) Not Applicable	Mild
Myalgia	0	1 (2%)	0	0	0	0
Exostosis	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Limb discomfort	0	0	0	0	0	0
Musculoskeletal chest pain	0	1 (2%)	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	1 (2%)
Torticollis	0	0	0	0	0	0
Nervous system disorders						
Any Event	0	1 (2%)	3 (5%)	0	0	3 (5%)
Headache	0	0	1 (2%)	0	0	2 (3%)
Dizziness	0	0	1 (2%)	0	0	1 (2%)
Sinus headache	0	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	0
Dizziness postural	0	1 (2%)	0	0	0	0
Hemiparesis	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	1 (2%)
Ischaemic stroke	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0
Migraine	0	0	1 (2%)	0	0	0
Sciatica	0	0	0	0	0	0
Sensory loss	0	0	0	0	0	0
Tension headache	0	0	0	0	0	0
Injury, poisoning and procedural complications						
Any Event	0	2 (3%)	0	0	0	0
Back injury	0	0	0	0	0	0
Excoriation	0	0	0	0	0	1 (2%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Myalgia	0	0	0	0	0	0
Exostosis	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Limb discomfort	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Torticollis	0	0	0	0	0	0
Nervous system disorders						
Any Event	1 (2%)	0	0	3 (5%)	0	0
Headache	0	0	0	1 (2%)	0	0
Dizziness	0	0	0	2 (3%)	0	0
Sinus headache	0	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	0
Dizziness postural	0	0	0	0	0	0
Hemiparesis	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	0
Ischaemic stroke	0	0	0	0	0	0
Memory impairment	1 (2%)	0	0	0	0	0
Migraine	0	0	0	0	0	0
Sciatica	0	0	0	0	0	0
Sensory loss	0	0	0	0	0	0
Tension headache	0	0	0	0	0	0
Injury, poisoning and procedural complications						
Any Event	1 (2%)	0	0	1 (2%)	1 (2%)	0
Back injury	1 (2%)	0	0	0	0	0
Excoriation	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Myalgia	0	0	0	0	0	0
Exostosis	0	0	0	0	0	0
Gouty arthritis	0	1 (2%)	0	0	0	0
Limb discomfort	0	0	0	0	0	1 (2%)
Musculoskeletal chest pain	0	0	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Torticollis	0	1 (2%)	0	0	0	0
Nervous system disorders						
Any Event	0	3 (5%)	3 (5%)	0	0	2 (3%)
Headache	0	1 (2%)	2 (3%)	0	0	0
Dizziness	0	0	0	0	0	1 (2%)
Sinus headache	0	1 (2%)	0	0	0	1 (2%)
Cerebrovascular accident	0	0	0	0	0	0
Dizziness postural	0	0	0	0	0	0
Hemiparesis	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	0
Ischaemic stroke	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0
Migraine	0	0	0	0	0	0
Sciatica	0	0	1 (2%)	0	0	0
Sensory loss	0	1 (2%)	0	0	0	0
Tension headache	0	0	0	0	0	0
Injury, poisoning and procedural complications						
Any Event	0	0	4 (6%)	0	0	2 (3%)
Back injury	0	0	0	0	0	1 (2%)
Excoriation	0	0	0	0	0	1 (2%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)			45mg (N=61)				
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe		
Myalgia	0	0	0	0	1 (2%)	0		
Exostosis	0	0	0	1 (2%)	0	0		
Gouty arthritis	0	0	0	0	0	0		
Limb discomfort	0	0	0	0	0	0		
Musculoskeletal chest pain	0	0	0	0	0	0		
Rotator cuff syndrome	0	0	0	0	1 (2%)	0		
Tendonitis	0	0	0	0	0	0		
Torticollis	0	0	0	0	0	0		
Nervous system disorders								
Any Event	1 (2%)	1 (2%)	0	3 (5%)	1 (2%)	1 (2%)		
Headache	0	0	0	1 (2%)	1 (2%)	0		
Dizziness	0	0	0	2 (3%)	0	0		
Sinus headache	0	0	0	0	0	0		
Cerebrovascular accident	0	1 (2%)	0	0	0	0		
Dizziness postural	0	0	0	0	0	0		
Hemiparesis	1 (2%)	0	0	0	0	0		
Hypoaesthesia	0	0	0	0	0	0		
Ischaemic stroke	1 (2%)	0	0	0	0	0		
Memory impairment	0	0	0	0	0	0		
Migraine	0	0	0	0	0	0		
Sciatica	0	0	0	0	0	0		
Sensory loss	0	0	0	0	0	0		
Tension headache	0	0	0	0	0	1 (2%)		
Injury, poisoning and procedural complications								
Any Event	1 (2%)	0	0	0	2 (3%)	0		
Back injury	0	0	0	0	0	0		
Excoriation	0	0	0	0	0	0		

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Myalgia	0	0	1 (<1%)	0
Exostosis	0	1 (<1%)	0	0
Gouty arthritis	0	1 (<1%)	0	0
Limb discomfort	0	1 (<1%)	0	0
Musculoskeletal chest pain	0	0	0	0
Rotator cuff syndrome	0	0	1 (<1%)	0
Tendonitis	0	1 (<1%)	0	0
Torticollis	0	1 (<1%)	0	0
Nervous system disorders				
Any Event	0	14 (5%)	6 (2%)	2 (<1%)
Headache	0	5 (2%)	3 (<1%)	0
Dizziness	0	6 (2%)	0	0
Sinus headache	0	2 (<1%)	0	0
Cerebrovascular accident	0	0	0	1 (<1%)
Dizziness postural	0	0	0	0
Hemiparesis	0	0	1 (<1%)	0
Hypoaesthesia	0	1 (<1%)	0	0
Ischaemic stroke	0	0	1 (<1%)	0
Memory impairment	0	0	1 (<1%)	0
Migraine	0	0	0	0
Sciatica	0	0	1 (<1%)	0
Sensory loss	0	1 (<1%)	0	0
Tension headache	0	0	0	1 (<1%)
Injury, poisoning and procedural complications				
Any Event	0	3 (<1%)	9 (3%)	0
Back injury	0	1 (<1%)	1 (<1%)	0
Excoriation	0	2 (<1%)	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64) Not Applicable	Mild	Moderate	Severe	2.5mg (N=61) Not Applicable	Mild
Fall	0	1 (2%)	0	0	0	0
Chest injury	0	0	0	0	0	0
Epicondylitis	0	0	0	0	0	0
Foot fracture	0	0	0	0	0	0
Hand fracture	0	0	0	0	0	0
Joint injury	0	0	0	0	0	0
Joint sprain	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Muscle injury	0	1 (2%)	0	0	0	0
Skin laceration	0	0	0	0	0	0
Thermal burn	0	0	0	0	0	0
Whiplash injury	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders						
Any Event	0	5 (8%)	0	0	0	0
Pharyngolaryngeal pain	0	1 (2%)	0	0	0	0
Cough	0	2 (3%)	0	0	0	0
Epistaxis	0	1 (2%)	0	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Nasal congestion	0	0	0	0	0	0
Rhinitis allergic	0	0	0	0	0	0
Sinus congestion	0	1 (2%)	0	0	0	0
Throat tightness	0	0	0	0	0	0
Skin and subcutaneous tissue disorders						
Any Event	0	3 (5%)	0	0	0	2 (3%)
Eczema	0	0	0	0	0	1 (2%)
Hyperhidrosis	0	0	0	0	0	0
Dermal cyst	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Fall	0	0	0	0	0	0
Chest injury	0	0	0	0	0	0
Epicondylitis	0	0	0	0	0	0
Foot fracture	0	0	0	0	0	0
Hand fracture	0	0	0	0	0	0
Joint injury	0	0	0	0	0	0
Joint sprain	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Muscle injury	0	0	0	0	0	0
Skin laceration	0	0	0	0	1 (2%)	0
Thermal burn	0	0	0	1 (2%)	0	0
Whiplash injury	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders						
Any Event	1 (2%)	0	0	3 (5%)	0	0
Pharyngolaryngeal pain	1 (2%)	0	0	1 (2%)	0	0
Cough	0	0	0	0	0	0
Epistaxis	0	0	0	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Nasal congestion	0	0	0	0	0	0
Rhinitis allergic	0	0	0	1 (2%)	0	0
Sinus congestion	0	0	0	0	0	0
Throat tightness	0	0	0	1 (2%)	0	0
Skin and subcutaneous tissue disorders						
Any Event	0	0	0	1 (2%)	0	0
Eczema	0	0	0	0	0	0
Hyperhidrosis	0	0	0	0	0	0
Dermal cyst	0	0	0	1 (2%)	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Fall	0	0	0	0	0	0
Chest injury	0	0	0	0	0	0
Epicondylitis	0	0	0	0	0	0
Foot fracture	0	0	1 (2%)	0	0	0
Hand fracture	0	0	0	0	0	0
Joint injury	0	0	1 (2%)	0	0	0
Joint sprain	0	0	1 (2%)	0	0	0
Limb injury	0	0	1 (2%)	0	0	0
Muscle injury	0	0	0	0	0	0
Skin laceration	0	0	0	0	0	0
Thermal burn	0	0	0	0	0	0
Whiplash injury	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders						
Any Event	0	2 (3%)	0	0	0	0
Pharyngolaryngeal pain	0	0	0	0	0	0
Cough	0	1 (2%)	0	0	0	0
Epistaxis	0	1 (2%)	0	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Nasal congestion	0	0	0	0	0	0
Rhinitis allergic	0	0	0	0	0	0
Sinus congestion	0	0	0	0	0	0
Throat tightness	0	0	0	0	0	0
Skin and subcutaneous tissue disorders						
Any Event	0	2 (3%)	0	0	0	2 (3%)
Eczema	0	1 (2%)	0	0	0	0
Hyperhidrosis	0	0	0	0	0	1 (2%)
Dermal cyst	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)			
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Fall	0	0	0	0	1 (2%)	0
Chest injury	1 (2%)	0	0	0	0	0
Epicondylitis	0	0	0	0	1 (2%)	0
Foot fracture	0	0	0	0	0	0
Hand fracture	1 (2%)	0	0	0	0	0
Joint injury	0	0	0	0	0	0
Joint sprain	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Muscle injury	0	0	0	0	0	0
Skin laceration	0	0	0	0	0	0
Thermal burn	0	0	0	0	0	0
Whiplash injury	1 (2%)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders						
Any Event	0	0	0	1 (2%)	2 (3%)	0
Pharyngolaryngeal pain	0	0	0	1 (2%)	0	0
Cough	0	0	0	0	0	0
Epistaxis	0	0	0	0	0	0
Interstitial lung disease	0	0	0	0	1 (2%)	0
Nasal congestion	0	0	0	0	1 (2%)	0
Rhinitis allergic	0	0	0	0	0	0
Sinus congestion	0	0	0	0	0	0
Throat tightness	0	0	0	0	0	0
Skin and subcutaneous tissue disorders						
Any Event	0	0	0	1 (2%)	1 (2%)	0
Eczema	0	0	0	0	0	0
Hyperhidrosis	0	0	0	1 (2%)	0	0
Dermal cyst	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Fall	0	0	1 (<1%)	0
Chest injury	0	0	1 (<1%)	0
Epicondylitis	0	0	1 (<1%)	0
Foot fracture	0	0	1 (<1%)	0
Hand fracture	0	0	1 (<1%)	0
Joint injury	0	0	1 (<1%)	0
Joint sprain	0	0	1 (<1%)	0
Limb injury	0	0	1 (<1%)	0
Muscle injury	0	0	0	0
Skin laceration	0	0	1 (<1%)	0
Thermal burn	0	1 (<1%)	0	0
Whiplash injury	0	0	1 (<1%)	0
Respiratory, thoracic and mediastinal disorders				
Any Event	0	6 (2%)	3 (<1%)	0
Pharyngolaryngeal pain	0	2 (<1%)	1 (<1%)	0
Cough	0	1 (<1%)	0	0
Epistaxis	0	1 (<1%)	0	0
Interstitial lung disease	0	0	1 (<1%)	0
Nasal congestion	0	0	1 (<1%)	0
Rhinitis allergic	0	1 (<1%)	0	0
Sinus congestion	0	0	0	0
Throat tightness	0	1 (<1%)	0	0
Skin and subcutaneous tissue disorders				
Any Event	0	8 (3%)	1 (<1%)	0
Eczema	0	2 (<1%)	0	0
Hyperhidrosis	0	2 (<1%)	0	0
Dermal cyst	0	1 (<1%)	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)			
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild		
Dermatitis	0	0	0	0	0	0		
Dermatitis contact	0	0	0	0	0	0		
Purpura	0	1 (2%)	0	0	0	0		
Rash	0	0	0	0	0	0		
Rash papular	0	1 (2%)	0	0	0	0		
Rosacea	0	0	0	0	0	1	(2%)	
Skin lesion	0	1 (2%)	0	0	0	0		
General disorders and administration site conditions								
Any Event	0	0	1 (2%)	0	0	1	(2%)	
Fatigue	0	0	0	0	0	0		
Chest pain	0	0	0	0	0	0		
Asthenia	0	0	0	0	0	0		
Chest discomfort	0	0	0	0	0	0		
Feeling cold	0	0	0	0	0	1	(2%)	
Malaise	0	0	1 (2%)	0	0	0		
Pyrexia	0	0	0	0	0	0		
Metabolism and nutrition disorders								
Any Event	0	0	0	0	0	1	(2%)	
Hyperglycaemia	0	0	0	0	0	0		
Diabetes mellitus	0	0	0	0	0	0		
Dyslipidaemia	0	0	0	0	0	1	(2%)	
Fluid retention	0	0	0	0	0	0		
Gout	0	0	0	0	0	0		
Hyperkalaemia	0	0	0	0	0	0		
Hyperlipidaemia	0	0	0	0	0	0		
Hypertriglyceridaemia	0	0	0	0	0	1	(2%)	
Iron deficiency	0	0	0	0	0	0		

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Dermatitis	0	0	0	0	0	0
Dermatitis contact	0	0	0	0	0	0
Purpura	0	0	0	0	0	0
Rash	0	0	0	0	0	0
Rash papular	0	0	0	0	0	0
Rosacea	0	0	0	0	0	0
Skin lesion	0	0	0	0	0	0
General disorders and administration site conditions						
Any Event	1 (2%)	0	0	1 (2%)	0	0
Fatigue	1 (2%)	0	0	0	0	0
Chest pain	0	0	0	0	0	0
Asthenia	0	0	0	0	0	0
Chest discomfort	0	0	0	1 (2%)	0	0
Feeling cold	0	0	0	0	0	0
Malaise	0	0	0	0	0	0
Pyrexia	0	0	0	0	0	0
Metabolism and nutrition disorders						
Any Event	2 (3%)	2 (3%)	0	0	0	0
Hyperglycaemia	2 (3%)	1 (2%)	0	0	0	0
Diabetes mellitus	0	0	0	0	0	0
Dyslipidaemia	0	0	0	0	0	0
Fluid retention	0	0	0	0	0	0
Gout	0	1 (2%)	0	0	0	0
Hyperkalaemia	0	0	0	0	0	0
Hyperlipidaemia	0	0	0	0	0	0
Hypertriglyceridaemia	0	0	0	0	0	0
Iron deficiency	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Dermatitis	0	1 (2%)	0	0	0	0
Dermatitis contact	0	0	0	0	0	1 (2%)
Purpura	0	0	0	0	0	0
Rash	0	0	0	0	0	0
Rash papular	0	0	0	0	0	0
Rosacea	0	0	0	0	0	0
Skin lesion	0	0	0	0	0	0
General disorders and administration site conditions						
Any Event	0	1 (2%)	1 (2%)	0	0	2 (3%)
Fatigue	0	1 (2%)	0	0	0	0
Chest pain	0	0	1 (2%)	0	0	0
Asthenia	0	0	0	0	0	1 (2%)
Chest discomfort	0	0	0	0	0	0
Feeling cold	0	0	0	0	0	0
Malaise	0	0	0	0	0	0
Pyrexia	0	0	0	0	0	1 (2%)
Metabolism and nutrition disorders						
Any Event	0	2 (3%)	0	0	0	0
Hyperglycaemia	0	0	0	0	0	0
Diabetes mellitus	0	1 (2%)	0	0	0	0
Dyslipidaemia	0	0	0	0	0	0
Fluid retention	0	0	0	0	0	0
Gout	0	0	0	0	0	0
Hyperkalaemia	0	0	0	0	0	0
Hyperlipidaemia	0	1 (2%)	0	0	0	0
Hypertriglyceridaemia	0	0	0	0	0	0
Iron deficiency	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)				
	Moderate	Severe	Not Applicable	Mild	Moderate		Severe
Dermatitis	0	0	0	0	0		0
Dermatitis contact	0	0	0	0	0		0
Purpura	0	0	0	0	0		0
Rash	0	0	0	0	1	(2%)	0
Rash papular	0	0	0	0	0		0
Rosacea	0	0	0	0	0		0
Skin lesion	0	0	0	0	0		0
General disorders and administration site conditions							
Any Event	0	0	0	2 (3%)	0		0
Fatigue	0	0	0	1 (2%)	0		0
Chest pain	0	0	0	1 (2%)	0		0
Asthenia	0	0	0	0	0		0
Chest discomfort	0	0	0	0	0		0
Feeling cold	0	0	0	0	0		0
Malaise	0	0	0	0	0		0
Pyrexia	0	0	0	0	0		0
Metabolism and nutrition disorders							
Any Event	0	0	0	2 (3%)	1	(2%)	0
Hyperglycaemia	0	0	0	0	0		0
Diabetes mellitus	0	0	0	0	0		0
Dyslipidaemia	0	0	0	0	0		0
Fluid retention	0	0	0	1 (2%)	0		0
Gout	0	0	0	0	0		0
Hyperkalaemia	0	0	0	1 (2%)	0		0
Hyperlipidaemia	0	0	0	0	0		0
Hypertriglyceridaemia	0	0	0	0	0		0
Iron deficiency	0	0	0	0	1	(2%)	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Dermatitis	0	1 (<1%)	0	0
Dermatitis contact	0	1 (<1%)	0	0
Purpura	0	0	0	0
Rash	0	0	1 (<1%)	0
Rash papular	0	0	0	0
Rosacea	0	1 (<1%)	0	0
Skin lesion	0	0	0	0
General disorders and administration site conditions				
Any Event	0	7 (2%)	2 (<1%)	0
Fatigue	0	2 (<1%)	1 (<1%)	0
Chest pain	0	1 (<1%)	1 (<1%)	0
Asthenia	0	1 (<1%)	0	0
Chest discomfort	0	1 (<1%)	0	0
Feeling cold	0	1 (<1%)	0	0
Malaise	0	0	0	0
Pyrexia	0	1 (<1%)	0	0
Metabolism and nutrition disorders				
Any Event	0	5 (2%)	3 (<1%)	2 (<1%)
Hyperglycaemia	0	0	2 (<1%)	1 (<1%)
Diabetes mellitus	0	1 (<1%)	0	0
Dyslipidaemia	0	1 (<1%)	0	0
Fluid retention	0	1 (<1%)	0	0
Gout	0	0	0	1 (<1%)
Hyperkalaemia	0	1 (<1%)	0	0
Hyperlipidaemia	0	1 (<1%)	0	0
Hypertriglyceridaemia	0	1 (<1%)	0	0
Iron deficiency	0	0	1 (<1%)	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)			
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Eye disorders								
Any Event	0	0	1 (2%)	0	0	1 (2%)	0	0
Vision blurred	0	0	0	0	0	0	0	0
Abnormal sensation in eye	0	0	0	0	0	0	0	0
Eye disorder	0	0	1 (2%)	0	0	0	0	0
Glaucoma	0	0	0	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	1 (2%)	0	0
Uveitis	0	0	0	0	0	0	0	0
Investigations								
Any Event	0	0	2 (3%)	0	0	2 (3%)	0	0
Neutrophil count decreased	0	0	1 (2%)	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	1 (2%)	0	0
Blood triglycerides increased	0	0	1 (2%)	0	0	0	0	0
Haemoglobin decreased	0	0	0	0	0	1 (2%)	0	0
Low density lipoprotein increased	0	0	1 (2%)	0	0	0	0	0
Reproductive system and breast disorders								
Any Event	0	1 (2%)	0	0	0	0	0	0
Menorrhagia	0	0	0	0	0	0	0	0
Breast pain	0	0	0	0	0	0	0	0
Breast tenderness	0	0	0	0	0	0	0	0
Rectocele	0	1 (2%)	0	0	0	0	0	0
Vascular disorders								
Any Event	0	1 (2%)	0	0	0	0	0	0
Hypertension	0	1 (2%)	0	0	0	0	0	0
Intermittent claudication	0	0	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)			
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe	
Eye disorders							
Any Event	0	0	0	2 (3%)	0	0	
Vision blurred	0	0	0	2 (3%)	0	0	
Abnormal sensation in eye	0	0	0	0	0	0	
Eye disorder	0	0	0	0	0	0	
Glaucoma	0	0	0	0	0	0	
Ocular hyperaemia	0	0	0	0	0	0	
Uveitis	0	0	0	0	0	0	
Investigations							
Any Event	1 (2%)	0	0	0	0	0	
Neutrophil count decreased	1 (2%)	0	0	0	0	0	
Blood pressure increased	0	0	0	0	0	0	
Blood triglycerides increased	0	0	0	0	0	0	
Haemoglobin decreased	0	0	0	0	0	0	
Low density lipoprotein increased	0	0	0	0	0	0	
Reproductive system and breast disorders							
Any Event	1 (2%)	0	0	0	0	0	
Menorrhagia	1 (2%)	0	0	0	0	0	
Breast pain	0	0	0	0	0	0	
Breast tenderness	0	0	0	0	0	0	
Rectocele	0	0	0	0	0	0	
Vascular disorders							
Any Event	0	0	0	2 (3%)	1 (2%)	0	
Hypertension	0	0	0	2 (3%)	0	0	
Intermittent claudication	0	0	0	0	1 (2%)	0	

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Eye disorders						
Any Event	0	0	0	0	0	1 (2%)
Vision blurred	0	0	0	0	0	0
Abnormal sensation in eye	0	0	0	0	0	1 (2%)
Eye disorder	0	0	0	0	0	0
Glaucoma	0	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	0
Uveitis	0	0	0	0	0	0
Investigations						
Any Event	0	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0
Blood triglycerides increased	0	0	0	0	0	0
Haemoglobin decreased	0	0	0	0	0	0
Low density lipoprotein increased	0	0	0	0	0	0
Reproductive system and breast disorders						
Any Event	0	1 (2%)	0	0	0	1 (2%)
Menorrhagia	0	0	0	0	0	0
Breast pain	0	1 (2%)	0	0	0	0
Breast tenderness	0	0	0	0	0	1 (2%)
Rectocele	0	0	0	0	0	0
Vascular disorders						
Any Event	0	0	0	0	0	0
Hypertension	0	0	0	0	0	0
Intermittent claudication	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)			45mg (N=61)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Eye disorders						
Any Event	1 (2%)	0	0	1 (2%)	0	0
Vision blurred	0	0	0	0	0	0
Abnormal sensation in eye	0	0	0	0	0	0
Eye disorder	0	0	0	0	0	0
Glaucoma	1 (2%)	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	0
Uveitis	0	0	0	1 (2%)	0	0
Investigations						
Any Event	0	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0
Blood triglycerides increased	0	0	0	0	0	0
Haemoglobin decreased	0	0	0	0	0	0
Low density lipoprotein increased	0	0	0	0	0	0
Reproductive system and breast disorders						
Any Event	1 (2%)	0	0	0	0	0
Menorrhagia	1 (2%)	0	0	0	0	0
Breast pain	0	0	0	0	0	0
Breast tenderness	0	0	0	0	0	0
Rectocele	0	0	0	0	0	0
Vascular disorders						
Any Event	0	0	0	1 (2%)	0	0
Hypertension	0	0	0	1 (2%)	0	0
Intermittent claudication	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Eye disorders				
Any Event	0	5 (2%)	1 (<1%)	0
Vision blurred	0	2 (<1%)	0	0
Abnormal sensation in eye	0	1 (<1%)	0	0
Eye disorder	0	0	0	0
Glaucoma	0	0	1 (<1%)	0
Ocular hyperaemia	0	1 (<1%)	0	0
Uveitis	0	1 (<1%)	0	0
Investigations				
Any Event	0	2 (<1%)	1 (<1%)	0
Neutrophil count decreased	0	0	1 (<1%)	0
Blood pressure increased	0	1 (<1%)	0	0
Blood triglycerides increased	0	0	0	0
Haemoglobin decreased	0	1 (<1%)	0	0
Low density lipoprotein increased	0	0	0	0
Reproductive system and breast disorders				
Any Event	0	2 (<1%)	2 (<1%)	0
Menorrhagia	0	0	2 (<1%)	0
Breast pain	0	1 (<1%)	0	0
Breast tenderness	0	1 (<1%)	0	0
Rectocele	0	0	0	0
Vascular disorders				
Any Event	0	3 (<1%)	1 (<1%)	0
Hypertension	0	3 (<1%)	0	0
Intermittent claudication	0	0	1 (<1%)	0

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)			
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Psychiatric disorders								
Any Event	0	0	0	0	0	0	0	0
Dependent personality disorder	0	0	0	0	0	0	0	0
Depression	0	0	0	0	0	0	0	0
Insomnia	0	0	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0	0	0
Renal and urinary disorders								
Any Event	0	0	1 (2%)	0	0	0	0	0
Calculus bladder	1 (2%)	0	0	0	0	0	0	0
Dysuria	0	0	1 (2%)	0	0	0	0	0
Glycosuria	0	0	0	0	0	0	0	0
Micturition urgency	0	0	1 (2%)	0	0	0	0	0
Renal colic	0	0	0	0	0	0	0	0
Urinary incontinence	0	1 (2%)	0	0	0	0	0	0
Surgical and medical procedures								
Any Event	1 (2%)	0	0	0	0	0	0	0
Haemorrhoid operation	0	0	0	0	0	0	0	0
Tooth repair	0	0	0	0	0	0	0	0
Transurethral prostatectomy	1 (2%)	0	0	0	0	0	0	0
Cardiac disorders								
Any Event	0	1 (2%)	0	0	0	1 (2%)	0	0
Palpitations	0	0	0	0	0	1 (2%)	0	0
Ventricular extrasystoles	0	1 (2%)	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Psychiatric disorders						
Any Event	1 (2%)	0	0	0	0	0
Dependent personality disorder	0	0	0	0	0	0
Depression	1 (2%)	0	0	0	0	0
Insomnia	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0
Renal and urinary disorders						
Any Event	0	0	0	0	0	0
Calculus bladder	0	0	0	0	0	0
Dysuria	0	0	0	0	0	0
Glycosuria	0	0	0	0	0	0
Micturition urgency	0	0	0	0	0	0
Renal colic	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Surgical and medical procedures						
Any Event	1 (2%)	0	0	0	0	0
Haemorrhoid operation	1 (2%)	0	0	0	0	0
Tooth repair	0	0	0	0	0	0
Transurethral prostatectomy	0	0	0	0	0	0
Cardiac disorders						
Any Event	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Ventricular extrasystoles	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66)				30mg (N=60)	
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild
Psychiatric disorders						
Any Event	0	0	0	0	0	0
Dependent personality disorder	0	0	0	0	0	0
Depression	0	0	0	0	0	0
Insomnia	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0
Renal and urinary disorders						
Any Event	0	1 (2%)	0	0	0	0
Calculus bladder	0	0	0	0	0	0
Dysuria	0	0	0	0	0	0
Glycosuria	0	1 (2%)	0	0	0	0
Micturition urgency	0	0	0	0	0	0
Renal colic	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Surgical and medical procedures						
Any Event	0	0	0	0	0	0
Haemorrhoid operation	0	0	0	0	0	0
Tooth repair	0	0	0	0	0	0
Transurethral prostatectomy	0	0	0	0	0	0
Cardiac disorders						
Any Event	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Ventricular extrasystoles	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)				
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe	
Psychiatric disorders							
Any Event	0	0	0	2 (3%)	0	0	
Dependent personality disorder	0	0	0	1 (2%)	0	0	
Depression	0	0	0	0	0	0	
Insomnia	0	0	0	1 (2%)	0	0	
Restlessness	0	0	0	1 (2%)	0	0	
Renal and urinary disorders							
Any Event	0	0	0	0	0	1	(2%)
Calculus bladder	0	0	0	0	0	0	
Dysuria	0	0	0	0	0	0	
Glycosuria	0	0	0	0	0	0	
Micturition urgency	0	0	0	0	0	0	
Renal colic	0	0	0	0	0	1	(2%)
Urinary incontinence	0	0	0	0	0	0	
Surgical and medical procedures							
Any Event	0	0	0	1 (2%)	0	0	
Haemorrhoid operation	0	0	0	0	0	0	
Tooth repair	0	0	0	1 (2%)	0	0	
Transurethral prostatectomy	0	0	0	0	0	0	
Cardiac disorders							
Any Event	0	0	0	0	0	0	
Palpitations	0	0	0	0	0	0	
Ventricular extrasystoles	0	0	0	0	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Psychiatric disorders				
Any Event	0	2 (<1%)	1 (<1%)	0
Dependent personality disorder	0	1 (<1%)	0	0
Depression	0	0	1 (<1%)	0
Insomnia	0	1 (<1%)	0	0
Restlessness	0	1 (<1%)	0	0
Renal and urinary disorders				
Any Event	0	1 (<1%)	0	1 (<1%)
Calculus bladder	0	0	0	0
Dysuria	0	0	0	0
Glycosuria	0	1 (<1%)	0	0
Micturition urgency	0	0	0	0
Renal colic	0	0	0	1 (<1%)
Urinary incontinence	0	0	0	0
Surgical and medical procedures				
Any Event	0	1 (<1%)	1 (<1%)	0
Haemorrhoid operation	0	0	1 (<1%)	0
Tooth repair	0	1 (<1%)	0	0
Transurethral prostatectomy	0	0	0	0
Cardiac disorders				
Any Event	0	1 (<1%)	0	0
Palpitations	0	1 (<1%)	0	0
Ventricular extrasystoles	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	Placebo (N=64)				2.5mg (N=61)	
	Not Applicable	Mild	Moderate	Severe	Not Applicable	Mild
Any Event	1 (2%)	0	0	0	0	0
Bladder neoplasm	1 (2%)	0	0	0	0	0
Skin papilloma	0	0	0	0	0	0
Blood and lymphatic system disorders						
Any Event	0	0	0	0	0	0
Anaemia	0	0	0	0	0	0
Ear and labyrinth disorders						
Any Event	0	1 (2%)	0	0	0	0
Cerumen impaction	0	1 (2%)	0	0	0	0
Hepatobiliary disorders						
Any Event	0	0	0	0	0	0
Gallbladder disorder	0	0	0	0	0	0
Immune system disorders						
Any Event	0	1 (2%)	0	0	0	0
Hypersensitivity	0	1 (2%)	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	2.5mg (N=61)			7.5mg (N=63)		
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Any Event	0	0	0	0	0	0
Bladder neoplasm	0	0	0	0	0	0
Skin papilloma	0	0	0	0	0	0
Blood and lymphatic system disorders						
Any Event	0	0	0	1 (2%)	0	0
Anaemia	0	0	0	1 (2%)	0	0
Ear and labyrinth disorders						
Any Event	0	0	0	0	0	0
Cerumen impaction	0	0	0	0	0	0
Hepatobiliary disorders						
Any Event	1 (2%)	0	0	0	0	0
Gallbladder disorder	1 (2%)	0	0	0	0	0
Immune system disorders						
Any Event	0	0	0	0	0	0
Hypersensitivity	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	15mg (N=66) Not Applicable	Mild	Moderate	Severe	30mg (N=60) Not Applicable	Mild
Any Event	0	0	1 (2%)	0	0	0
Bladder neoplasm	0	0	0	0	0	0
Skin papilloma	0	0	1 (2%)	0	0	0
Blood and lymphatic system disorders						
Any Event	0	0	0	0	0	0
Anaemia	0	0	0	0	0	0
Ear and labyrinth disorders						
Any Event	0	0	0	0	0	0
Cerumen impaction	0	0	0	0	0	0
Hepatobiliary disorders						
Any Event	0	0	0	0	0	0
Gallbladder disorder	0	0	0	0	0	0
Immune system disorders						
Any Event	0	0	0	0	0	0
Hypersensitivity	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	30mg (N=60)		45mg (N=61)			
	Moderate	Severe	Not Applicable	Mild	Moderate	Severe
Any Event	0	0	0	0	0	0
Bladder neoplasm	0	0	0	0	0	0
Skin papilloma	0	0	0	0	0	0
Blood and lymphatic system disorders						
Any Event	0	0	0	0	0	0
Anaemia	0	0	0	0	0	0
Ear and labyrinth disorders						
Any Event	0	0	0	0	0	0
Cerumen impaction	0	0	0	0	0	0
Hepatobiliary disorders						
Any Event	0	0	0	0	0	0
Gallbladder disorder	0	0	0	0	0	0
Immune system disorders						
Any Event	0	0	0	0	0	0
Hypersensitivity	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.5
Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity

System Organ Class Preferred Term	093 Sub-total (N=311) Not Applicable	Mild	Moderate	Severe
Any Event	0	0	1 (<1%)	0
Bladder neoplasm	0	0	0	0
Skin papilloma	0	0	1 (<1%)	0
Blood and lymphatic system disorders				
Any Event	0	1 (<1%)	0	0
Anaemia	0	1 (<1%)	0	0
Ear and labyrinth disorders				
Any Event	0	0	0	0
Cerumen impaction	0	0	0	0
Hepatobiliary disorders				
Any Event	0	0	1 (<1%)	0
Gallbladder disorder	0	0	1 (<1%)	0
Immune system disorders				
Any Event	0	0	0	0
Hypersensitivity	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.6
Summary of Related On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	6 (9%)	5 (8%)	1 (2%)	2 (3%)	0	4 (7%)	12 (4%)
Gastrointestinal disorders							
Any event	2 (3%)	1 (2%)	0	1 (2%)	0	2 (3%)	4 (1%)
Constipation	2 (3%)	0	0	1 (2%)	0	0	1 (<1%)
Abdominal distension	0	0	0	0	0	1 (2%)	1 (<1%)
Abdominal pain lower	0	1 (2%)	0	0	0	0	1 (<1%)
Nausea	0	1 (2%)	0	0	0	0	1 (<1%)
Vomiting	0	0	0	0	0	1 (2%)	1 (<1%)
Nervous system disorders							
Any event	2 (3%)	1 (2%)	0	1 (2%)	0	1 (2%)	3 (<1%)
Headache	1 (2%)	1 (2%)	0	1 (2%)	0	0	2 (<1%)
Dizziness	0	0	0	0	0	1 (2%)	1 (<1%)
Migraine	1 (2%)	0	0	0	0	0	0
Metabolism and nutrition disorders							
Any event	0	4 (7%)	0	0	0	0	4 (1%)
Hyperglycaemia	0	3 (5%)	0	0	0	0	3 (<1%)
Hypertriglyceridaemia	0	1 (2%)	0	0	0	0	1 (<1%)
Infections and infestations							
Any event	2 (3%)	0	0	0	0	0	0
Gastroenteritis	1 (2%)	0	0	0	0	0	0
Nasopharyngitis	1 (2%)	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders							
Any event	0	0	0	0	0	2 (3%)	2 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.6
Summary of Related On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Arthralgia	0	0	0	0	0	1 (2%)	1 (<1%)
Muscle spasms	0	0	0	0	0	1 (2%)	1 (<1%)
Myalgia	0	0	0	0	0	1 (2%)	1 (<1%)
Eye disorders							
Any event	1 (2%)	0	0	0	0	0	0
Eye disorder	1 (2%)	0	0	0	0	0	0
Investigations							
Any event	1 (2%)	0	0	0	0	0	0
Blood triglycerides increased	1 (2%)	0	0	0	0	0	0
Low density lipoprotein increased	1 (2%)	0	0	0	0	0	0
Psychiatric disorders							
Any event	0	0	0	0	0	1 (2%)	1 (<1%)
Dependent personality disorder	0	0	0	0	0	1 (2%)	1 (<1%)
Restlessness	0	0	0	0	0	1 (2%)	1 (<1%)
Respiratory, thoracic and mediastinal disorders							
Any event	1 (2%)	0	0	0	0	0	0
Epistaxis	1 (2%)	0	0	0	0	0	0
Skin and subcutaneous tissue disorders							
Any event	0	0	0	0	0	1 (2%)	1 (<1%)
Hyperhidrosis	0	0	0	0	0	1 (2%)	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.6
Summary of Related On-Therapy Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Vascular disorders							
Any event	0	0	1 (2%)	0	0	0	1 (<1%)
Hypertension	0	0	1 (2%)	0	0	0	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.7
Summary of Common On-Therapy Adverse Events (>=5% Incidence in any Treatment Group) by Treatment

Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	24 (38%)	22 (36%)	20 (32%)	28 (42%)	19 (32%)	23 (38%)	112 (36%)
Nasopharyngitis	3 (5%)	3 (5%)	7 (11%)	3 (5%)	3 (5%)	0	16 (5%)
Nausea	1 (2%)	2 (3%)	2 (3%)	4 (6%)	1 (2%)	0	9 (3%)
Headache	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0	2 (3%)	8 (3%)
Back pain	1 (2%)	0	0	4 (6%)	0	2 (3%)	6 (2%)
Constipation	3 (5%)	0	0	2 (3%)	1 (2%)	1 (2%)	4 (1%)
Diarrhoea	1 (2%)	1 (2%)	0	1 (2%)	3 (5%)	1 (2%)	6 (2%)
Hyperglycaemia	0	3 (5%)	0	0	0	0	3 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.8
Summary of Related Common On-Therapy Adverse Events (>=5% Incidence in any Treatment Group)
by Treatment

Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	6 (9%)	5 (8%)	1 (2%)	2 (3%)	0	4 (7%)	12 (4%)
Hyperglycaemia	0	3 (5%)	0	0	0	0	3 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.9
Summary of All Pre-Therapy Serious Adverse Events

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	1 (2%)	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Any event	1 (2%)	0	0	0	0	0	0
Bladder neoplasm	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.10
Summary of All On-Therapy Serious Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	1 (2%)	1 (2%)	0	0	2 (3%)	1 (2%)	4 (1%)
Infections and infestations							
Any event	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Gastroenteritis	1 (2%)	0	0	0	0	0	0
Laryngitis	0	1 (2%)	0	0	0	0	1 (<1%)
Nervous system disorders							
Any event	0	0	0	0	2 (3%)	0	2 (<1%)
Cerebrovascular accident	0	0	0	0	1 (2%)	0	1 (<1%)
Hemiparesis	0	0	0	0	1 (2%)	0	1 (<1%)
Ischaemic stroke	0	0	0	0	1 (2%)	0	1 (<1%)
Gastrointestinal disorders							
Any event	0	0	0	0	0	1 (2%)	1 (<1%)
Intestinal polyp	0	0	0	0	0	1 (2%)	1 (<1%)

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.
The adverse event term 'Intestinal polyp' has been clarified and is now known to be an event of 'Diverticular perforation'

[redacted]

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Table 12.11
Summary of All Post-Therapy Serious Adverse Events by Treatment

No data to report

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.12
Summary of Related On-Therapy Serious Adverse Events by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	1 (2%)	0	0	0	0	0	0
Infections and infestations							
Any event	1 (2%)	0	0	0	0	0	0
Gastroenteritis	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

[redacted]

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Table 12.13
Summary of Pre-Therapy Adverse Events Leading to Main Phase Withdrawal by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	2 (3%)	1 (2%)	0	0	0	0	1 (<1%)
Nervous system disorders							
Any event	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Hypoaesthesia	0	1 (2%)	0	0	0	0	1 (<1%)
Paraesthesia	1 (2%)	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Any event	1 (2%)	0	0	0	0	0	0
Bladder neoplasm	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.14
Summary of On-Therapy Adverse Events Leading to Main Phase Withdrawal by Treatment

System Organ Class Preferred Term	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
ANY EVENT	3 (5%)	3 (5%)	0	0	1 (2%)	0	4 (1%)
Infections and infestations							
Any event	1 (2%)	1 (2%)	0	0	0	0	1 (<1%)
Gastroenteritis	1 (2%)	0	0	0	0	0	0
Laryngitis	0	1 (2%)	0	0	0	0	1 (<1%)
Metabolism and nutrition disorders							
Any event	0	2 (3%)	0	0	0	0	2 (<1%)
Hyperglycaemia	0	2 (3%)	0	0	0	0	2 (<1%)
Nervous system disorders							
Any event	1 (2%)	0	0	0	1 (2%)	0	1 (<1%)
Cerebrovascular accident	0	0	0	0	1 (2%)	0	1 (<1%)
Headache	1 (2%)	0	0	0	0	0	0
Cardiac disorders							
Any event	1 (2%)	0	0	0	0	0	0
Ventricular extrasystoles	1 (2%)	0	0	0	0	0	0

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Blood and lymphatic system disorders	Anaemia	Anemia
Cardiac disorders	Palpitations	Palpitation
	Ventricular extrasystoles	premature ventricular contractions
Ear and labyrinth disorders	Cerumen impaction	cerumen bilaterally
	Tinnitus	tinnitus
Eye disorders	Abnormal sensation in eye	feeling of tightness of left eye
	Conjunctivitis allergic	allergic conjuntivitis
	Dry eye	Dry Eyes
	Eye disorder	Ophtalmic symptoms
	Eye haemorrhage	eye hemorrhage
	Eye pruritus	Itchy Eyes
	Glaucoma	Glaucoma
	Ocular hyperaemia	Red eye
	Uveitis	uveitis oc.l.utriq.
	Vision blurred	Blurred Vision
		blurred vision
		cloudy vision intermitent from left eye
Gastrointestinal disorders	Abdominal distension	bloating
	Abdominal pain	Abdomen-pain, right side.
		Abdominal Cramps
		Abdominal pain
	Abdominal pain lower	Lower abdominal pain
	Abdominal pain upper	Epigastralgie
		Stomac pain
		stomach pain(familary stress)
		stomack ache

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Gastrointestinal disorders	Abdominal strangulated hernia	Strangulated hernia
	Abdominal tenderness	Right upper quadrant tenderness
	Aphthous stomatitis	Aphtous gum ulcer(inferior right side)
	Constipation	Accentuation of constipation
		Constipation
		constipation
		worsening of occasionnal constipation
	Diarrhoea	Diarrea
		Diarrhea
		Diarrhoe
		diarrhea
		diarrhoea
	Dyspepsia	Dispepsia
		Stomach burning
	Faeces hard	Harder stool
	Flatulence	flatulence
	Food poisoning	food poisoning
	Gastritis	Gastritis
	Glossodynia	Sore tongue
	Haemorrhoids	Hemoroid
		Hemorrhoid
		Hemorrhoids
		Hemorroid
	Inguinal hernia	Right inguinal hernia
	Intestinal polyp	polyp
	Nausea	Nausea
		intermittent nausea
		nausea
	Oesophagitis	Oesophagitis
	Pruritus ani	Rectal itchiness
	Stomach discomfort	nervous stomach

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Gastrointestinal disorders	Stomach discomfort	stomach discomfort
	Swollen tongue	swelling of the tongue
	Tooth disorder	Toothinflammation
	Toothache	Tooth Ache
		toothache
	Vomiting	Vomiting
		vomitting
General disorders and administration site conditions	Asthenia	weakness
	Chest discomfort	Tightness in chest
		chest heaviness (non cardiac)
	Chest pain	Chest pain
		Chestpain
		chest pain
		chest pains
		unspecific intermittent pain localized in the chest region
	Fatigue	Fatigue
		Tired
		Tiredness
		fatigue
		increased fatigue
		tired
	Feeling cold	Feeling Cold
	Malaise	Feeling of sickness
	Oedema peripheral	Feet swelling
	Pyrexia	Fever
Hepatobiliary disorders	Gallbladder disorder	Gall Bladder Attack

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Immune system disorders	Hypersensitivity	Allergic reaction to opsite plaster
Infections and infestations	Acute sinusitis	Acute Sinusitis
		Acute Sinusitus
	Acute tonsillitis	Angina tonsillaris
	Bacteriuria	bacterieuriae
		bacteriuria
	Bronchitis	bronchitis
	Bronchitis acute	Acute bronchitis
	Carbuncle	Left axilla carbuncle
	Cellulitis	Cellulitis right toes and forefoot
	Cystitis	Cystitis
		cystitis
	Fungal infection	Yeast Infection
	Furuncle	Boil on Buttocks
	Gastroenteritis	GASTRENTERITIS
		Gastro enteritis
	Herpes zoster	Herpes Zoster
	Infected sebaceous cyst	Infected sebaceous cyst right groin
	Influenza	Flu
		flu
		influenza,
	Laryngitis	Laringitis
		laryngitis
	Nasopharyngitis	Cold
		Cold Symptoms
		Common Cold
		Common Cold, nasal congestion
		Common cold
		Head Cold
		Head cold, mild Headache

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Infections and infestations	Nasopharyngitis	Rinopharingitis
		cold
		cold Symptoms of sore throat and stuffy nose
		cold symptoms
		common cold
	Otitis media	Otitis Media
	Pharyngitis	Pharyngitis
		pharyngitis
	Pneumonia	Pneumonia
	Respiratory tract infection viral	Respiratory virosis
		Viral Upper Respiratory Infection
	Sinusitis	Sinusitis
		sinus infection
		sinusitis
	Tonsillitis	tonsilits
	Tooth abscess	Dental abces
		absessed tooth
	Tooth infection	Left Lower Molar Infection
		tooth infection
		tooth pain, dental infection
	Tracheobronchitis	tracheobronchitis
	Upper respiratory tract infection	Infection of upper respiratory tract
		UPPER RESPIRATORY TRACT INFECTION
		URI
		URTI (Upper Respiratory Tract Infection)
		Upper Respiratory Infection
		Upper respiratory infection
		Upper respiratory tract infection
	Urinary tract infection	Urinary tract infection

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Infections and infestations	Urinary tract infection	urinary tract infection
	Viral upper respiratory tract infection	viral upper respiratory illness
	Vulvovaginal mycotic infection	Vaginal Yeast Infection
Injury, poisoning and procedural complications	Back injury	Low back strain
		lumbar sprain
		strained back
	Chest injury	chest wall injury
	Epicondylitis	left epicondylitis
	Excoriation	Excoriations of the skin
		Multiple abrasions on lower arms
	Fall	Fall
		fall from the ladder
		fall over the staircase
	Foot fracture	middle foot fracture
	Hand fracture	Fracture right 5th metacarpal
	Head injury	injury to the head
	Joint injury	trauma right shoulder
	Joint sprain	sprained ankle
	Limb injury	Trauma (Left toes: Large and 2nd largest)
	Muscle injury	Injury of muscles at lower level of right leg
		Traumatic injury of trapezius muscle
	Muscle strain	pulled muscle in back
	Skin laceration	laceration of 2nd and 4th finger - right hand
	Tendon injury	Injury of tendons at lower level of right leg
	Thermal burn	burn-right index finger
	Whiplash injury	Whiplash Neck
Investigations	Blood pressure increased	increased blood pressure

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Investigations	Blood triglycerides increased	Worsening of elevated triglyceride level
		worsening of elevated triglyceride level
	Haemoglobin decreased	Decreased Hemoglobin
	Low density lipoprotein increased	Elevated LDL level
	Neutrophil count decreased	Clinically Low Neutrophils on labs
		Clinically significant low neutrophil count
Metabolism and nutrition disorders	Diabetes mellitus	worsening of diabetes
	Dyslipidaemia	dyslipidemia
		worsening dysilipidemia because of HX
	Fluid retention	Chronic fluid retention
	Gout	goutte pain
	Hyperglycaemia	HIPERGLIKEMIA
		hyperglucemia
	Hyperkalaemia	hyperkalemia
	Hyperlipidaemia	hyperlipedemia
	Hypertriglyceridaemia	hypertriglyceridemia
	Iron deficiency	sideropenia
Musculoskeletal and connective tissue disorders	Arthralgia	Acute pain associated with arthritis
		Ankle Pain
		Intermittent generalized joint paint
		Pain in elbows and knees
		Pain in right arm joints
		generalized joint pain
	Back pain	Back Pain, Intermittent
		Lower Back Pain
		Lumbago

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Musculoskeletal and connective tissue disorders	Back pain	Lumbalgia
		Worsening of low back pain
		back pain
		lumbalgia
	Bursitis	Bursitis right shoulder
		Left shoulder bursitis
		bursitis, left elbow
	Exostosis	Neck Bone Spur
	Gouty arthritis	Arthritis uratica
	Limb discomfort	right lower leg discomfort
	Muscle spasms	Leg Cramps
		muscle spasms in back.
	Musculoskeletal chest pain	Dull ache in sternum
	Musculoskeletal discomfort	right knee discomfort
	Myalgia	Low back muscle pain
		Myalgia of trapezius muscle
		generalized muscle pain
		intermittent generalized muscle pain
	Pain in extremity	Bilateral foot pain
		Left Foot Pain
		R great toe pain
		Throbbing in lower extremities
	Rotator cuff syndrome	L Rotator Cuff Tear
	Shoulder pain	Pain below right schoulder
		Pain in left shoulder.
		Shoulder pain
		right shoulder sore
		worsening left shoulder pain
	Tendonitis	Right achilles enthesitis
	Torticollis	Torticollis

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder neoplasm	bladder tumor
		transurethral resection of bladder tumor
	Pyogenic granuloma	Pyogenic Granuloma
	Skin papilloma	Right index finger wart
Nervous system disorders	Burning sensation	Burning Feet
	Cerebrovascular accident	stroke
	Cervicobrachial syndrome	cervical syndrome
		hand-shoulder syndrome
	Dizziness	Dizziness
		Dizzyness
		dizziness
		dzziness
	Dizziness postural	Dizziness upon rising
		Lightheaded upon rising
	Headache	Cefaleea
		Headache
		Headaches
		Increase frequency of intermittent light headaches
		Minor headaches
		cephaleea
		chronic headache
		headache
	Hemiparesis	Left side hemiparesis
	Hypoaesthesia	Numbness in feet.
		Sensation of numbness both legs before he falls aslee. Stop when he get out of bed.
		numbnes in her right toes

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Nervous system disorders	Ischaemic stroke	Acute ischemic stroke in right ACM pool
	Lethargy	lethargy
	Memory impairment	Memory impairment
		forgetfulness
	Migraine	Migraine
	Paraesthesia	Paresthesia in ankles.
		Paresthesia in feet.
		Tingling in right and left fingertips
	Polyneuropathy	polyneropathia
	Sciatica	Worsening or sciatalgia
	Sensory loss	low vibratory sensation
	Sinus headache	Sinus headache
		sinus headache
	Tension headache	Tension Headache
Psychiatric disorders	Anxiety	anxiety
	Dependent personality disorder	Passivity
	Depression	depression
	Insomnia	insomnia
	Restlessness	Feeling of restless
Renal and urinary disorders	Calculus bladder	bladder stones
	Dysuria	painful urination
	Glycosuria	Glucosuria
	Haematuria	hematuria
	Micturition urgency	urinary urgency
	Renal colic	renal colic
	Urinary incontinence	urinary incontinence
Reproductive system and breast disorders	Breast pain	Left breast pain

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Reproductive system and breast disorders	Breast tenderness	breast tenderness
	Menorrhagia	Menorrhagia
	Rectocele	Rectocele accentuated
	Vulvovaginal discomfort	vaginal irritation
Respiratory, thoracic and mediastinal disorders	Cough	Cough
		cough
	Dysphonia	hoarseness
	Epistaxis	nose bleeds
		nosebleed
	Interstitial lung disease	Interstitial pneumonia
	Nasal congestion	Nasal Congestion
		Nasal congestion
	Pharyngolaryngeal pain	Sore Throat
		Sore throat
		Sore throat.
		soare throat
		sore throat
		sored throat
	Rhinitis allergic	Allergic Rhinitis
		allergic rhinitis
	Sinus congestion	sinus congestion
	Throat tightness	Tightness in Throat
Skin and subcutaneous tissue disorders	Acne	akne vulgaris
	Dermal cyst	sebacceous cyst/right neck
	Dermatitis	Anterior chest dermatitis
	Dermatitis contact	Contact Dermatitis Lower Right Leg

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.15
Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms and Verbatim Text

System Organ Class	Preferred Term	Verbatim Text
Skin and subcutaneous tissue disorders	Dry skin	Dry Skin
		Worsening of skin xerosis forehead
	Eczema	Eczema
		Right ear canal eczema
		eczema of penis
	Hyperhidrosis	Excessive Sweating
		Felt sweaty.
		perspiration
	Pruritus generalised	Generalized itchiness
	Psoriasis	psoriasis increasing activity right leg
	Purpura	purpura of crus
	Rash	skin rash
	Rash papular	small red bumps on right wrist and back of neck.
	Rosacea	Roscea
	Skin lesion	lesion on scalp
Surgical and medical procedures	Haemorrhoid operation	Operation of haemorrhoids
	Tooth extraction	tooth extraction
	Tooth repair	tooth filling
	Transurethral prostatectomy	transuretheral recestion of prostate
Vascular disorders	Hot flush	Hot Flashes
	Hypertension	Exacerbation of Hyppertension
		Worsening of the arterial hypertension
		hypertension
		hypertension worsening
	Intermittent claudication	Claudication

Note: Hypoglycaemic events that are not SAEs are captured on the hypoglycaemic log page and reported separately.

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Table 12.16
Summary of Pre-Therapy Hypoglycaemic Events by
Intensity, SAE Status, Relationship to Investigational Product and Withdrawal Status

No data to report

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Table 12.17
Summary of On-Therapy Hypoglycaemic Events by
Intensity, SAE Status, Relationship to Investigational Product and Withdrawal Status

	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)	
	No. (%) of Subjects	No. of Events	No. (%) of Subjects	No. of Events	No. (%) of Subjects	No. of Events	No. (%) of Subjects	No. of Events
Total	1 (2%)	1	0	0	0	0	2 (3%)	2
Intensity								
Mild	1 (2%)	1	0	0	0	0	2 (3%)	2
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Serious Adverse Event								
Yes	0	0	0	0	0	0	0	0
Related to Investigational Product								
Yes	0	0	0	0	0	0	2 (3%)	2
Withdrawn Due to Hypoglycaemic Event								
Yes	0	0	0	0	0	0	0	0

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Table 12.17
Summary of On-Therapy Hypoglycaemic Events by
Intensity, SAE Status, Relationship to Investigational Product and Withdrawal Status

	30mg (N=60)		45mg (N=61)		093 Sub-total (N=311)	
	No. (%) of Subjects	No. of Events	No. (%) of Subjects	No. of Events	No. (%) of Subjects	No. of Events
Total	0	0	0	0	2 (<1%)	2
Intensity						
Mild	0	0	0	0	2 (<1%)	2
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Serious Adverse Event						
Yes	0	0	0	0	0	0
Related to Investigational Product						
Yes	0	0	0	0	2 (<1%)	2
Withdrawn Due to Hypoglycaemic Event						
Yes	0	0	0	0	0	0

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Table 12.18
Summary of Subjects with On-Therapy Hypoglycaemic Events by Number of Events

	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)	093 Sub-total (N=311)
Number of Subjects with Hypoglycaemic Events	1 (2%)	0	0	2 (3%)	0	0	2 (<1%)
Number of Events							
1 event	1 (2%)	0	0	2 (3%)	0	0	2 (<1%)
2-5 events	0	0	0	0	0	0	0
6-10 events	0	0	0	0	0	0	0
>10 events	0	0	0	0	0	0	0

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	Placebo	64	Week -5	64	23.0	10.74	19.5	10	51
			Baseline	64	21.5	10.05	18.0	7	63
			Week 1	61	21.4	9.94	19.0	7	57
			Week 2	60	21.2	9.61	18.0	6	51
			Week 3	55	21.1	9.91	19.0	8	60
			Week 4	54	20.4	7.91	19.0	8	42
			Week 6	53	21.3	10.26	18.0	8	57
			Week 8	51	20.7	8.56	19.0	7	40
			Week 12	49	19.8	8.49	18.0	8	48
	2.5mg	61	Week -5	61	28.6	16.28	24.0	8	102
			Baseline	61	27.0	14.55	22.0	10	77
			Week 1	59	26.3	13.88	23.0	10	87
			Week 2	58	23.4	11.67	20.5	4	80
			Week 3	56	24.7	13.14	21.0	8	86
			Week 4	56	24.8	13.08	20.5	11	81
			Week 6	49	24.3	12.09	21.0	9	57
			Week 8	48	23.2	11.77	19.0	11	56
			Week 12	46	23.6	10.79	21.0	9	56
	7.5mg	63	Week -5	61	24.0	12.47	20.0	4	62
			Baseline	63	23.2	11.47	20.0	9	62
			Week 1	60	22.0	9.62	21.0	8	49
			Week 2	59	22.3	11.85	19.0	7	69
			Week 3	59	22.5	10.62	19.0	7	57
			Week 4	57	23.9	14.65	20.0	10	114
			Week 6	56	21.5	9.93	18.5	8	54
			Week 8	54	22.8	12.15	19.5	9	62
			Week 12	54	21.4	9.85	19.0	8	56
	15mg	66	Week -5	62	27.1	17.13	21.0	8	83

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	15mg	66	Baseline	66	25.1	13.58	21.0	9	60
			Week 1	63	23.2	12.04	20.0	5	56
			Week 2	62	24.1	14.40	20.0	6	89
			Week 3	59	24.8	13.50	20.0	7	58
			Week 4	60	24.7	15.03	19.5	8	73
			Week 6	60	23.7	15.14	18.5	6	75
			Week 8	60	23.1	12.24	18.5	6	59
			Week 12	58	23.8	14.13	19.5	5	86
	30mg	60	Week -5	59	24.1	13.37	21.0	5	68
			Baseline	59	26.7	22.62	20.0	5	166
			Week 1	56	23.0	11.05	20.0	7	51
			Week 2	57	22.6	18.47	19.0	8	142
			Week 3	57	21.9	10.44	20.0	9	54
			Week 4	56	21.4	9.21	20.0	8	53
			Week 6	53	21.0	9.97	18.0	8	59
			Week 8	55	22.1	12.35	19.0	7	83
			Week 12	56	20.2	9.52	18.5	7	56
	45mg	61	Week -5	60	23.1	7.45	22.0	11	48
			Baseline	61	23.2	12.33	19.0	8	95
			Week 1	59	22.8	14.85	18.0	9	114
			Week 2	58	22.6	15.22	18.0	10	96
			Week 3	55	21.7	12.47	19.0	8	100
			Week 4	56	22.3	12.94	19.5	11	94
			Week 6	54	21.2	13.26	20.0	5	103
			Week 8	54	21.1	11.54	19.0	8	85
			Week 12	54	22.7	14.75	18.5	10	108
Albumin (G/L)	Placebo	64	Week -5	64	43.1	2.73	43.0	36	48

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Albumin (G/L)	Placebo	64	Baseline	64	43.3	2.89	43.0	38	52
			Week 1	61	42.9	2.84	43.0	36	48
			Week 2	60	43.5	3.30	44.0	35	52
			Week 3	55	43.2	3.26	44.0	38	50
			Week 4	55	43.4	2.93	44.0	35	50
			Week 6	53	43.1	3.12	44.0	34	51
			Week 8	51	44.2	3.06	44.0	34	50
			Week 12	49	43.8	3.05	44.0	35	49
	2.5mg	61	Week -5	61	43.4	2.81	43.0	38	50
			Baseline	61	43.4	2.56	43.0	39	51
			Week 1	59	43.6	2.86	43.0	37	50
			Week 2	58	43.4	3.10	44.0	37	50
			Week 3	56	43.3	2.73	43.0	37	50
			Week 4	56	43.6	3.19	44.0	33	52
			Week 6	49	43.6	2.72	43.0	39	49
			Week 8	48	43.8	2.97	43.5	37	50
			Week 12	46	43.9	2.64	44.0	39	50
	7.5mg	63	Week -5	61	43.9	2.89	44.0	38	52
			Baseline	63	43.3	2.46	43.0	38	49
			Week 1	60	43.0	2.92	43.0	36	49
			Week 2	59	43.4	2.59	43.0	37	50
			Week 3	59	42.9	2.75	43.0	36	48
			Week 4	57	43.7	2.63	44.0	38	49
			Week 6	56	43.2	2.83	43.0	35	50
			Week 8	54	43.4	2.42	44.0	38	48
			Week 12	54	43.9	2.46	44.0	39	49
	15mg	66	Week -5	62	43.2	2.93	43.0	38	51
			Baseline	66	43.0	2.53	43.0	38	48
			Week 1	63	42.4	2.84	42.0	36	48

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Albumin (G/L)	15mg	66	Week 2	62	42.5	3.12	43.0	33	48
			Week 3	59	42.7	2.40	43.0	38	48
			Week 4	60	43.2	2.71	43.0	36	51
			Week 6	60	42.6	2.37	42.5	38	48
			Week 8	60	43.0	2.75	43.0	36	49
			Week 12	58	43.1	2.76	43.0	38	50
	30mg	60	Week -5	59	42.9	3.22	43.0	35	52
			Baseline	59	42.9	3.20	43.0	35	49
			Week 1	56	42.7	2.89	43.0	35	48
			Week 2	57	42.7	2.78	43.0	36	49
			Week 3	57	43.1	2.55	43.0	38	48
			Week 4	56	43.1	2.50	43.0	36	47
			Week 6	53	43.0	2.77	43.0	37	49
			Week 8	55	43.1	2.35	43.0	38	47
			Week 12	56	42.8	2.79	43.0	35	51
	45mg	61	Week -5	60	44.1	2.63	44.0	40	51
			Baseline	61	43.8	2.46	44.0	39	50
			Week 1	59	44.0	2.81	44.0	38	50
			Week 2	58	43.6	3.06	44.0	38	52
			Week 3	55	44.2	2.56	44.0	39	50
			Week 4	56	43.9	3.52	44.0	38	59
			Week 6	54	43.5	2.79	44.0	33	50
			Week 8	54	44.1	2.86	44.0	38	49
			Week 12	54	44.0	3.04	44.0	36	49
Alkaline Phosphatase (IU/L)	Placebo	64	Week -5	64	71.0	20.89	66.5	28	162
			Baseline	64	71.4	18.59	67.5	36	147
			Week 1	61	70.4	18.91	69.0	34	151
			Week 2	60	70.3	18.81	69.5	27	129

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	Placebo	64	Week 3	55	73.4	19.39	70.0	35	139
			Week 4	55	72.3	19.83	70.0	37	144
			Week 6	53	72.7	20.41	71.0	39	126
			Week 8	51	74.2	20.58	71.0	39	128
			Week 12	49	74.1	24.03	70.0	33	155
	2.5mg	61	Week -5	61	81.2	20.47	77.0	46	134
			Baseline	61	81.2	22.53	77.0	46	144
			Week 1	59	81.0	21.01	77.0	43	139
			Week 2	58	80.9	21.85	77.5	45	142
			Week 3	56	79.7	18.93	78.0	48	135
			Week 4	56	82.6	19.97	78.0	50	134
			Week 6	49	82.6	22.05	79.0	41	145
			Week 8	48	79.1	23.93	75.0	37	143
			Week 12	46	82.6	20.81	78.5	43	135
	7.5mg	63	Week -5	61	77.8	19.52	77.0	37	140
			Baseline	63	76.3	22.61	72.0	35	178
			Week 1	60	77.0	23.01	74.5	35	184
			Week 2	59	75.3	21.06	74.0	38	167
			Week 3	59	77.0	23.79	73.0	40	182
			Week 4	57	79.2	32.29	74.0	40	246
			Week 6	56	76.2	21.65	74.0	40	177
			Week 8	54	77.0	23.72	72.5	41	189
			Week 12	54	75.6	23.02	71.5	39	180
	15mg	66	Week -5	62	73.3	25.00	67.0	36	163
			Baseline	66	76.9	28.72	69.0	30	168
			Week 1	63	75.2	28.36	70.0	35	180
			Week 2	62	77.0	30.43	71.5	35	204
			Week 3	59	74.1	29.72	65.0	38	194
			Week 4	60	73.3	27.22	68.5	39	197

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	15mg	66	Week 6	60	72.2	26.47	67.5	37	181
			Week 8	60	72.4	24.61	66.5	36	157
			Week 12	58	70.9	24.02	65.5	31	157
	30mg	60	Week -5	59	72.9	19.96	75.0	41	130
			Baseline	59	70.9	17.91	69.0	37	126
			Week 1	56	70.4	18.43	66.5	36	124
			Week 2	57	69.2	17.10	69.0	30	119
			Week 3	57	69.2	18.68	68.0	36	127
			Week 4	56	71.1	21.63	71.0	33	154
			Week 6	53	69.7	18.55	68.0	34	118
			Week 8	55	70.1	20.31	69.0	31	124
			Week 12	56	69.9	21.46	67.0	32	127
	45mg	61	Week -5	60	79.7	30.09	79.0	33	207
			Baseline	61	76.0	26.49	73.0	33	189
			Week 1	59	76.9	28.21	71.0	33	207
			Week 2	58	76.8	24.67	71.0	30	177
			Week 3	55	76.0	29.02	70.0	22	216
			Week 4	56	76.3	28.67	68.0	31	202
			Week 6	54	75.1	24.91	70.5	35	179
			Week 8	54	74.2	25.84	67.0	32	169
			Week 12	54	73.8	22.88	69.5	32	158
Aspartate Amino Transferase (IU/L)	Placebo	64	Week -5	64	19.7	6.79	18.0	9	41
			Baseline	64	19.7	6.73	18.0	9	43
			Week 1	61	19.5	7.95	17.0	11	59
			Week 2	60	19.5	7.12	18.0	10	48
			Week 3	55	19.5	7.04	17.0	11	46
			Week 4	55	18.7	6.13	17.0	10	35

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	Placebo	64	Week 6	53	19.5	9.11	17.0	11	70
			Week 8	51	18.3	5.29	17.0	10	32
			Week 12	49	18.8	5.55	17.0	9	35
	2.5mg	61	Week -5	61	24.0	13.65	21.0	12	83
			Baseline	61	24.5	13.02	21.0	11	84
			Week 1	59	23.6	11.02	19.0	11	77
			Week 2	58	21.9	11.02	19.0	10	88
			Week 3	56	23.0	12.12	19.0	10	75
			Week 4	56	22.2	9.60	19.0	12	66
			Week 6	48	23.0	9.98	21.0	10	60
			Week 8	48	22.5	10.26	19.0	11	68
			Week 12	46	21.8	7.27	20.0	12	43
	7.5mg	63	Week -5	61	20.9	8.77	19.0	9	54
			Baseline	63	19.9	6.96	18.0	10	40
			Week 1	60	19.7	6.48	18.0	10	39
			Week 2	59	20.2	7.81	18.0	10	56
			Week 3	58	20.4	7.99	17.0	9	47
			Week 4	56	20.0	6.45	18.0	11	37
			Week 6	56	20.0	6.77	17.5	11	38
			Week 8	54	21.0	9.51	17.5	10	64
			Week 12	54	20.1	7.65	18.0	12	45
	15mg	66	Week -5	62	22.3	8.81	19.5	7	50
			Baseline	66	21.8	7.67	20.0	9	43
			Week 1	63	21.0	6.73	20.0	8	42
			Week 2	62	21.7	8.57	20.0	7	48
			Week 3	59	22.0	8.09	20.0	10	45
			Week 4	60	22.1	8.67	20.0	9	46
			Week 6	60	21.9	8.47	19.5	9	60

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	15mg	66	Week 8	60	21.1	6.80	20.0	10	43
			Week 12	58	21.7	9.38	19.0	9	65
	30mg	60	Week -5	59	21.1	9.57	19.0	6	57
			Baseline	59	23.4	14.41	20.0	9	94
			Week 1	56	21.3	9.20	18.5	12	62
			Week 2	57	21.5	15.71	19.0	10	127
			Week 3	56	21.0	8.00	19.5	11	54
			Week 4	56	20.7	8.02	19.5	11	63
			Week 6	53	21.2	7.32	20.0	9	50
			Week 8	55	21.6	12.73	19.0	11	96
			Week 12	56	20.5	10.39	18.5	9	78
	45mg	61	Week -5	60	21.2	5.89	20.0	13	41
			Baseline	61	21.0	8.36	19.0	11	69
			Week 1	59	21.5	9.94	19.0	13	79
			Week 2	57	21.1	9.94	19.0	10	74
			Week 3	55	21.5	8.27	20.0	11	61
			Week 4	56	20.8	9.06	19.0	10	74
			Week 6	54	20.1	8.73	18.0	4	64
			Week 8	54	20.1	7.13	18.0	11	59
			Week 12	54	21.2	10.67	19.0	10	80
Basophils (GI/L)	Placebo	64	Week -5	63	0.019	0.0113	0.020	0.00	0.05
			Baseline	64	0.020	0.0107	0.020	0.00	0.05
			Week 1	56	0.021	0.0117	0.020	0.00	0.06
			Week 2	60	0.021	0.0147	0.020	0.00	0.08
			Week 3	55	0.017	0.0115	0.020	0.00	0.06
			Week 4	55	0.021	0.0128	0.020	0.00	0.05
			Week 6	53	0.019	0.0125	0.020	0.00	0.06

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Basophils (GI/L)	Placebo	64	Week 8	52	0.020	0.0120	0.020	0.00	0.06
			Week 12	44	0.020	0.0134	0.020	0.00	0.07
	2.5mg	61	Week -5	60	0.023	0.0109	0.020	0.00	0.05
			Baseline	61	0.022	0.0084	0.020	0.01	0.04
			Week 1	60	0.022	0.0135	0.020	0.00	0.08
			Week 2	59	0.020	0.0098	0.020	0.00	0.05
			Week 3	58	0.022	0.0110	0.020	0.01	0.06
			Week 4	53	0.021	0.0106	0.020	0.00	0.05
			Week 6	51	0.021	0.0127	0.020	0.00	0.06
			Week 8	47	0.022	0.0154	0.020	0.00	0.07
			Week 12	48	0.021	0.0100	0.020	0.00	0.05
	7.5mg	63	Week -5	61	0.021	0.0127	0.020	0.00	0.05
			Baseline	63	0.023	0.0135	0.020	0.00	0.08
			Week 1	60	0.020	0.0118	0.020	0.00	0.05
			Week 2	59	0.022	0.0157	0.020	0.00	0.11
			Week 3	58	0.021	0.0137	0.020	0.00	0.07
			Week 4	56	0.022	0.0137	0.020	0.00	0.07
			Week 6	57	0.021	0.0144	0.020	0.00	0.06
			Week 8	53	0.023	0.0228	0.020	0.00	0.16
			Week 12	52	0.018	0.0100	0.020	0.00	0.06
	15mg	66	Week -5	62	0.021	0.0119	0.020	0.00	0.05
			Baseline	66	0.020	0.0095	0.020	0.00	0.04
			Week 1	63	0.020	0.0116	0.020	0.00	0.04
			Week 2	61	0.018	0.0082	0.020	0.00	0.04
			Week 3	58	0.024	0.0126	0.020	0.00	0.06
			Week 4	60	0.020	0.0124	0.020	0.00	0.05
			Week 6	60	0.019	0.0111	0.020	0.00	0.05
			Week 8	60	0.017	0.0121	0.020	0.00	0.06
			Week 12	59	0.017	0.0098	0.020	0.00	0.04

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Basophils (GI/L)	30mg	60	Week -5	59	0.024	0.0116	0.020	0.00	0.05
			Baseline	60	0.023	0.0122	0.020	0.00	0.05
			Week 1	57	0.021	0.0099	0.020	0.00	0.05
			Week 2	54	0.020	0.0131	0.020	0.00	0.06
			Week 3	57	0.022	0.0129	0.020	0.00	0.07
			Week 4	57	0.021	0.0101	0.020	0.00	0.05
			Week 6	56	0.022	0.0131	0.020	0.00	0.05
			Week 8	54	0.019	0.0143	0.020	0.00	0.06
			Week 12	53	0.021	0.0124	0.020	0.00	0.05
	45mg	61	Week -5	59	0.025	0.0134	0.020	0.00	0.07
			Baseline	60	0.022	0.0120	0.020	0.00	0.06
			Week 1	59	0.022	0.0130	0.020	0.00	0.06
			Week 2	60	0.022	0.0114	0.020	0.01	0.05
			Week 3	55	0.025	0.0126	0.020	0.01	0.07
			Week 4	56	0.023	0.0113	0.020	0.01	0.06
			Week 6	53	0.023	0.0123	0.020	0.00	0.06
			Week 8	56	0.024	0.0131	0.020	0.00	0.07
			Week 12	54	0.023	0.0140	0.020	0.00	0.06
C-Peptide (NMOL/L)	Placebo	64	Week -5	63	1.137	0.5209	1.100	0.41	2.28
			Baseline	63	1.141	0.5182	1.100	0.41	2.28
	2.5mg	61	Week -5	57	1.246	0.4439	1.250	0.38	2.00
			Baseline	57	1.236	0.4354	1.250	0.38	2.00
	7.5mg	63	Week -5	60	1.174	0.6567	1.060	0.33	4.96
			Baseline	62	1.149	0.6612	1.040	0.25	4.96
	15mg	66	Week -5	62	1.154	0.4154	1.110	0.45	2.53
			Baseline	65	1.125	0.4290	1.040	0.27	2.53

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
C-Peptide (NMOL/L)	30mg	60	Week -5	57	1.158	0.4675	1.080	0.47	2.27
			Baseline	58	1.165	0.4665	1.080	0.47	2.27
	45mg	61	Week -5	57	1.161	0.5546	1.030	0.31	2.93
			Baseline	58	1.158	0.5500	1.030	0.31	2.93
Calcium (MMOL/L)	Placebo	64	Week -5	64	2.349	0.0984	2.345	2.08	2.75
			Baseline	64	2.344	0.1222	2.345	1.99	2.64
			Week 1	61	2.313	0.1110	2.310	2.08	2.62
			Week 2	60	2.308	0.1612	2.320	1.53	2.68
			Week 3	55	2.277	0.1774	2.300	1.44	2.60
			Week 4	55	2.325	0.1397	2.320	1.96	2.73
			Week 6	53	2.302	0.1470	2.300	1.78	2.64
			Week 8	51	2.335	0.1250	2.340	2.02	2.64
			Week 12	49	2.327	0.1250	2.340	1.85	2.73
	2.5mg	61	Week -5	61	2.310	0.1671	2.340	1.34	2.63
			Baseline	61	2.292	0.1402	2.310	1.79	2.57
			Week 1	59	2.319	0.1261	2.320	1.83	2.64
			Week 2	58	2.293	0.1434	2.300	1.67	2.52
			Week 3	56	2.284	0.1467	2.310	1.81	2.62
			Week 4	56	2.308	0.1184	2.315	2.02	2.66
			Week 6	48	2.305	0.1234	2.320	1.84	2.57
			Week 8	48	2.313	0.1277	2.320	1.80	2.57
			Week 12	46	2.311	0.1027	2.320	2.01	2.50
	7.5mg	63	Week -5	60	2.347	0.0882	2.340	2.16	2.60
			Baseline	62	2.304	0.1254	2.315	1.58	2.50
			Week 1	60	2.272	0.1682	2.310	1.45	2.56
			Week 2	59	2.289	0.1466	2.300	1.84	2.52
			Week 3	57	2.313	0.1199	2.320	1.81	2.55

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Calcium (MMOL/L)	7.5mg	63	Week 4	56	2.297	0.1505	2.290	1.61	2.54
			Week 6	56	2.269	0.1565	2.310	1.71	2.58
			Week 8	54	2.291	0.1156	2.310	1.81	2.48
			Week 12	54	2.319	0.0992	2.320	2.03	2.56
	15mg	66	Week -5	62	2.342	0.1050	2.335	2.14	2.66
			Baseline	66	2.315	0.1135	2.310	1.96	2.64
			Week 1	63	2.303	0.1046	2.300	2.08	2.63
			Week 2	62	2.286	0.1439	2.300	1.69	2.72
			Week 3	59	2.296	0.1457	2.300	1.66	2.63
			Week 4	60	2.317	0.1089	2.320	2.00	2.72
			Week 6	60	2.306	0.1310	2.300	1.91	2.69
			Week 8	60	2.298	0.1062	2.290	2.05	2.70
			Week 12	58	2.315	0.0945	2.310	2.14	2.62
	30mg	60	Week -5	59	2.330	0.0772	2.320	2.19	2.54
			Baseline	59	2.320	0.1141	2.320	1.93	2.56
			Week 1	56	2.316	0.1135	2.315	2.04	2.62
			Week 2	57	2.316	0.1176	2.340	2.01	2.54
			Week 3	56	2.329	0.0911	2.320	2.14	2.54
			Week 4	56	2.328	0.0899	2.300	2.14	2.54
			Week 6	53	2.309	0.1066	2.320	1.91	2.56
			Week 8	55	2.309	0.1042	2.320	2.08	2.52
			Week 12	56	2.283	0.1345	2.300	1.72	2.54
	45mg	61	Week -5	61	2.346	0.1091	2.340	2.10	2.54
			Baseline	61	2.336	0.1098	2.350	1.90	2.60
			Week 1	59	2.331	0.1341	2.340	1.68	2.66
			Week 2	57	2.305	0.1797	2.340	1.50	2.55
			Week 3	55	2.333	0.1389	2.340	1.62	2.60
			Week 4	56	2.336	0.1371	2.335	1.64	2.65
			Week 6	54	2.264	0.1918	2.320	1.55	2.64

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Calcium (MMOL/L)	45mg	61	Week 8	54	2.333	0.1146	2.360	2.05	2.70
			Week 12	54	2.322	0.1206	2.320	2.03	2.70
Carbon Dioxide content / Bicarbonate (MMOL/L)	Placebo	64	Week -5	64	22.6	2.78	23.0	15	28
			Baseline	64	22.6	2.34	23.0	17	30
			Week 1	61	23.1	2.46	23.0	17	29
			Week 2	60	22.6	2.60	23.0	17	27
			Week 3	55	23.2	2.58	23.0	16	28
			Week 4	55	22.4	3.01	22.0	16	28
			Week 6	53	23.2	2.20	23.0	18	27
			Week 8	51	22.6	2.78	23.0	16	28
			Week 12	49	22.3	2.43	23.0	17	28
	2.5mg	61	Week -5	61	23.0	2.82	23.0	15	29
			Baseline	61	22.9	2.42	23.0	17	30
			Week 1	59	22.9	3.06	23.0	13	28
			Week 2	58	22.4	2.91	23.0	13	28
			Week 3	56	22.6	2.88	23.0	16	28
			Week 4	56	22.2	3.09	22.5	16	28
			Week 6	48	23.5	2.58	24.0	18	27
			Week 8	48	22.2	2.70	23.0	16	27
			Week 12	46	22.8	2.38	23.0	18	28
	7.5mg	63	Week -5	60	23.0	2.46	23.0	16	28
			Baseline	63	22.4	2.68	22.0	16	28
			Week 1	60	22.7	3.10	23.0	15	29
			Week 2	59	22.6	2.93	23.0	15	30
			Week 3	57	22.8	2.94	23.0	14	28
			Week 4	56	22.4	2.56	23.0	14	27
			Week 6	56	22.7	2.73	23.0	15	28

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Carbon Dioxide content / Bicarbonate (MMOL/L)	7.5mg	63	Week 8	54	22.4	3.12	23.0	13	29
			Week 12	54	22.0	2.62	22.0	16	28
	15mg	66	Week -5	62	22.2	3.07	23.0	12	32
			Baseline	66	22.3	2.56	22.0	17	29
			Week 1	63	22.7	2.88	23.0	16	29
			Week 2	62	22.2	2.75	22.0	16	27
			Week 3	59	22.2	2.51	23.0	16	27
			Week 4	60	22.2	2.56	22.5	15	28
			Week 6	60	22.6	2.66	22.5	16	28
			Week 8	60	22.0	2.83	22.0	16	27
			Week 12	58	22.2	2.62	23.0	14	28
	30mg	60	Week -5	59	23.0	2.83	23.0	14	30
			Baseline	59	21.9	3.11	22.0	13	29
			Week 1	56	23.2	3.12	23.0	17	32
			Week 2	57	22.6	2.69	22.0	18	30
			Week 3	56	23.3	2.88	23.0	18	30
			Week 4	56	22.0	2.91	22.0	16	29
			Week 6	53	23.3	2.74	23.0	19	30
			Week 8	55	22.3	3.11	22.0	16	29
			Week 12	56	22.7	2.47	23.0	18	29
	45mg	61	Week -5	61	21.8	2.89	22.0	13	30
			Baseline	61	22.1	2.76	22.0	14	30
			Week 1	59	22.5	2.12	22.0	18	28
			Week 2	57	22.3	2.77	22.0	15	28
			Week 3	55	22.3	2.73	22.0	15	29
			Week 4	56	21.6	3.02	22.0	14	27
			Week 6	54	22.4	2.97	22.0	15	27
			Week 8	54	21.5	2.70	22.0	16	27

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Carbon Dioxide content / Bicarbonate (MMOL/L)	45mg	61	Week 12	54	21.6	3.06	21.5	16	31
Chloride (MMOL/L)	Placebo	64	Week -5	64	103.1	3.19	103.0	93	112
			Baseline	64	102.9	2.87	103.5	94	108
			Week 1	61	103.7	2.78	104.0	94	108
			Week 2	60	103.1	2.80	103.0	95	111
			Week 3	55	103.5	2.99	104.0	92	109
			Week 4	55	103.5	3.09	103.0	98	111
			Week 6	53	103.4	2.98	103.0	94	110
			Week 8	51	102.8	3.16	103.0	90	108
			Week 12	49	102.8	3.38	103.0	91	109
	2.5mg	61	Week -5	61	103.1	2.61	103.0	97	111
			Baseline	61	103.5	3.07	103.0	95	115
			Week 1	59	103.3	3.07	104.0	97	112
			Week 2	58	103.1	2.94	103.0	96	111
			Week 3	56	103.6	2.87	104.5	98	109
			Week 4	56	102.7	2.89	103.0	97	110
			Week 6	49	103.3	3.16	103.0	96	112
			Week 8	48	103.6	3.23	104.0	97	112
			Week 12	46	103.2	3.00	103.0	97	110
	7.5mg	63	Week -5	61	103.1	2.82	103.0	94	109
			Baseline	63	103.4	2.37	103.0	96	110
			Week 1	60	104.0	2.26	104.0	97	110
			Week 2	59	104.0	2.41	104.0	98	110
			Week 3	59	103.8	2.63	104.0	96	109
			Week 4	57	103.3	2.47	103.0	96	111
			Week 6	56	103.7	2.52	104.0	97	110
			Week 8	54	103.3	2.89	104.0	95	109

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Chloride (MMOL/L)	7.5mg	63	Week 12	54	103.6	2.54	104.0	96	109
	15mg	66	Week -5	62	103.4	2.63	103.0	96	109
			Baseline	66	103.4	2.58	104.0	98	110
			Week 1	63	103.8	2.45	104.0	96	109
			Week 2	62	104.1	2.54	104.0	99	112
			Week 3	59	103.9	2.78	104.0	99	111
			Week 4	60	103.5	2.52	103.0	97	109
			Week 6	60	103.9	2.54	104.0	96	109
			Week 8	60	104.1	2.70	104.0	99	112
			Week 12	58	103.8	2.30	104.0	98	109
	30mg	60	Week -5	58	102.4	3.28	103.0	93	108
			Baseline	59	102.5	3.33	103.0	93	110
			Week 1	56	103.3	3.26	104.0	91	110
			Week 2	57	103.1	3.25	104.0	94	109
			Week 3	57	103.0	3.45	104.0	91	111
			Week 4	56	103.2	3.41	103.0	93	110
			Week 6	53	103.5	3.34	104.0	92	111
			Week 8	55	103.6	2.78	104.0	95	109
			Week 12	56	102.9	2.99	103.0	93	108
	45mg	61	Week -5	61	103.3	2.60	103.0	97	109
			Baseline	61	103.4	3.11	103.0	93	110
			Week 1	59	103.8	2.78	104.0	95	109
			Week 2	58	104.1	2.69	104.5	94	108
			Week 3	55	103.9	3.29	104.0	95	109
			Week 4	56	103.8	2.63	104.0	96	109
			Week 6	54	103.5	3.75	104.0	87	109
			Week 8	54	103.9	3.51	104.0	90	110
			Week 12	54	104.1	3.17	105.0	93	109

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatinine (UMOL/L)	Placebo	64	Week -5	64	81.4	18.86	80.0	53	144
			Baseline	64	81.0	17.29	80.0	49	132
			Week 1	61	82.9	18.98	80.0	53	135
			Week 2	60	82.7	16.84	81.5	53	129
			Week 3	55	81.4	18.63	79.0	53	158
			Week 4	55	81.2	16.14	81.0	52	133
			Week 6	53	80.9	18.38	80.0	53	150
			Week 8	51	81.9	18.51	80.0	53	156
			Week 12	49	82.1	20.31	80.0	44	149
	2.5mg	61	Week -5	61	80.0	16.77	78.0	44	124
			Baseline	61	80.4	17.84	76.0	42	133
			Week 1	59	82.7	18.96	79.0	43	150
			Week 2	58	82.5	19.39	79.5	50	150
			Week 3	56	81.7	17.98	78.0	41	133
			Week 4	56	81.5	17.85	78.0	45	141
			Week 6	49	82.4	16.96	80.0	46	124
			Week 8	48	81.1	17.53	79.5	41	115
			Week 12	46	80.8	20.07	77.0	41	159
	7.5mg	63	Week -5	60	79.5	16.48	78.0	44	115
			Baseline	63	80.8	16.27	80.0	53	115
			Week 1	60	81.5	15.84	80.0	48	115
			Week 2	59	81.8	16.59	80.0	53	124
			Week 3	59	82.7	16.31	81.0	48	124
			Week 4	56	81.1	15.28	80.0	52	115
			Week 6	56	82.5	15.96	81.0	57	124
			Week 8	54	81.6	16.34	80.0	53	115
			Week 12	54	82.1	16.41	79.5	53	117
	15mg	66	Week -5	62	83.1	17.84	80.0	54	166
			Baseline	66	83.3	19.40	81.0	51	190

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatinine (UMOL/L)	15mg	66	Week 1	63	83.0	19.82	82.0	44	188
			Week 2	62	84.0	20.30	80.0	53	200
			Week 3	59	84.5	19.53	81.0	54	184
			Week 4	60	84.4	20.02	84.0	52	186
			Week 6	60	84.0	19.48	82.0	55	188
			Week 8	60	84.3	20.37	82.5	52	199
			Week 12	58	86.1	20.21	85.5	59	190
	30mg	60	Week -5	59	77.2	14.67	73.0	46	108
			Baseline	59	78.0	15.23	75.0	47	116
			Week 1	56	78.2	14.38	75.0	47	111
			Week 2	57	80.5	14.45	80.0	43	118
			Week 3	57	80.4	14.70	80.0	47	115
			Week 4	56	78.9	15.54	76.5	45	113
			Week 6	53	77.7	16.97	76.0	31	124
			Week 8	55	79.6	16.23	76.0	48	119
			Week 12	56	79.0	15.95	78.5	44	113
	45mg	61	Week -5	60	80.1	16.93	76.5	48	152
			Baseline	61	80.8	18.04	80.0	49	152
			Week 1	59	81.1	17.74	76.0	50	133
			Week 2	58	82.1	17.13	80.0	51	130
			Week 3	55	82.7	19.96	80.0	53	171
			Week 4	56	78.9	13.93	79.5	52	111
			Week 6	54	81.9	20.29	79.0	51	147
			Week 8	54	79.9	16.49	80.0	53	123
			Week 12	54	81.0	15.35	80.0	53	124
Direct Bilirubin (UMOL/L)	Placebo	64	Week -5	64	2.3	1.62	2.0	0	9
			Baseline	64	2.3	1.39	2.0	0	8
			Week 1	61	2.3	1.52	2.0	0	8

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	Placebo	64	Week 2	60	2.2	1.18	2.0	0	6
			Week 3	55	2.3	1.13	2.0	1	6
			Week 4	55	2.1	1.10	2.0	0	6
			Week 6	53	2.2	1.09	2.0	1	6
			Week 8	51	2.3	1.22	2.0	1	6
			Week 12	49	2.2	1.24	2.0	0	6
	2.5mg	61	Week -5	61	2.3	1.17	2.0	1	6
			Baseline	61	2.5	1.21	2.0	1	8
			Week 1	59	2.4	1.34	2.0	1	8
			Week 2	58	2.2	1.24	2.0	0	6
			Week 3	56	2.6	1.16	2.0	1	6
			Week 4	56	2.3	1.08	2.0	1	5
			Week 6	49	2.3	1.07	2.0	1	5
			Week 8	48	2.2	0.91	2.0	1	4
			Week 12	45	2.3	1.10	2.0	0	5
	7.5mg	63	Week -5	61	2.3	1.08	2.0	1	5
			Baseline	63	2.3	0.98	2.0	1	5
			Week 1	60	2.2	1.17	2.0	0	6
			Week 2	59	2.1	1.04	2.0	0	6
			Week 3	59	2.2	0.93	2.0	0	4
			Week 4	56	2.1	0.83	2.0	1	4
			Week 6	56	2.2	1.27	2.0	0	6
			Week 8	54	2.0	1.12	2.0	0	6
			Week 12	54	2.1	0.99	2.0	1	5
	15mg	66	Week -5	62	2.0	0.90	2.0	0	4
			Baseline	66	2.1	1.00	2.0	0	5
			Week 1	63	1.9	0.86	2.0	0	4
			Week 2	62	1.9	0.90	2.0	0	4
			Week 3	59	1.8	0.71	2.0	0	4

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	15mg	66	Week 4	60	2.0	1.03	2.0	0	6
			Week 6	60	1.8	0.77	2.0	0	4
			Week 8	60	2.0	0.92	2.0	0	4
			Week 12	58	1.9	1.08	2.0	0	4
	30mg	60	Week -5	59	2.3	1.43	2.0	0	6
			Baseline	59	2.5	1.55	2.0	0	6
			Week 1	56	2.4	1.18	2.0	0	6
			Week 2	57	2.5	1.26	2.0	0	6
			Week 3	57	2.4	1.45	2.0	0	8
			Week 4	56	2.1	1.23	2.0	0	6
			Week 6	53	2.5	1.67	2.0	0	8
			Week 8	55	2.1	1.24	2.0	0	6
			Week 12	56	2.4	1.26	2.0	0	6
	45mg	61	Week -5	60	2.0	1.03	2.0	0	6
			Baseline	61	2.0	1.27	2.0	0	6
			Week 1	59	2.1	1.16	2.0	0	6
			Week 2	58	2.0	1.40	2.0	0	8
			Week 3	55	2.1	1.28	2.0	0	6
			Week 4	56	1.9	0.97	2.0	0	6
			Week 6	54	1.9	0.97	2.0	0	5
			Week 8	54	1.9	1.19	2.0	0	6
			Week 12	54	1.9	1.05	2.0	0	5
Eosinophils (GI/L)	Placebo	64	Week -5	63	0.182	0.1167	0.160	0.00	0.48
			Baseline	64	0.170	0.1088	0.150	0.01	0.62
			Week 1	56	0.179	0.1271	0.160	0.02	0.88
			Week 2	60	0.184	0.1285	0.150	0.01	0.67
			Week 3	55	0.163	0.1014	0.150	0.00	0.43
			Week 4	55	0.167	0.1101	0.140	0.00	0.50

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Eosinophils (GI/L)	Placebo	64	Week 6	53	0.166	0.1085	0.150	0.00	0.52
			Week 8	52	0.160	0.1083	0.140	0.01	0.49
			Week 12	44	0.177	0.1022	0.165	0.00	0.47
	2.5mg	61	Week -5	60	0.176	0.0918	0.150	0.05	0.46
			Baseline	61	0.190	0.1418	0.150	0.03	0.96
			Week 1	60	0.194	0.1668	0.140	0.00	0.89
			Week 2	59	0.205	0.1515	0.160	0.02	0.79
			Week 3	58	0.192	0.1360	0.150	0.04	0.89
			Week 4	53	0.174	0.1158	0.140	0.04	0.72
			Week 6	51	0.179	0.1209	0.140	0.05	0.66
			Week 8	47	0.188	0.1227	0.160	0.03	0.56
			Week 12	48	0.178	0.1021	0.150	0.02	0.43
	7.5mg	63	Week -5	61	0.191	0.1346	0.170	0.00	0.87
			Baseline	63	0.206	0.1499	0.160	0.01	0.80
			Week 1	60	0.208	0.1730	0.165	0.00	0.84
			Week 2	59	0.194	0.1443	0.160	0.00	0.64
			Week 3	58	0.194	0.1412	0.165	0.01	0.79
			Week 4	56	0.212	0.1451	0.180	0.01	0.70
			Week 6	57	0.205	0.1547	0.160	0.02	0.88
			Week 8	53	0.182	0.1283	0.150	0.01	0.57
			Week 12	52	0.185	0.1325	0.160	0.02	0.69
	15mg	66	Week -5	62	0.189	0.1408	0.180	0.00	1.01
			Baseline	66	0.164	0.0778	0.155	0.03	0.43
			Week 1	63	0.201	0.1038	0.180	0.03	0.47
			Week 2	61	0.166	0.0771	0.170	0.01	0.34
			Week 3	58	0.183	0.0848	0.175	0.02	0.45
			Week 4	60	0.163	0.0801	0.150	0.01	0.43
			Week 6	60	0.179	0.0831	0.165	0.02	0.44
			Week 8	60	0.166	0.1947	0.150	0.03	1.58

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Eosinophils (GI/L)	15mg	66	Week 12	59	0.168	0.0809	0.160	0.03	0.48
	30mg	60	Week -5	59	0.207	0.1467	0.180	0.01	0.84
			Baseline	60	0.196	0.1288	0.160	0.04	0.67
			Week 1	57	0.181	0.1270	0.150	0.03	0.71
			Week 2	54	0.179	0.1140	0.160	0.01	0.61
			Week 3	57	0.196	0.1265	0.160	0.02	0.57
			Week 4	57	0.185	0.1251	0.150	0.00	0.57
			Week 6	56	0.206	0.1552	0.170	0.02	0.83
			Week 8	54	0.169	0.1121	0.155	0.00	0.55
			Week 12	53	0.183	0.1224	0.170	0.00	0.66
	45mg	61	Week -5	59	0.191	0.0900	0.180	0.06	0.41
			Baseline	60	0.176	0.0800	0.165	0.03	0.46
			Week 1	59	0.179	0.1103	0.160	0.01	0.76
			Week 2	60	0.189	0.1010	0.170	0.01	0.48
			Week 3	55	0.168	0.0821	0.160	0.00	0.43
			Week 4	56	0.189	0.0998	0.160	0.05	0.49
			Week 6	53	0.171	0.0835	0.170	0.00	0.36
			Week 8	56	0.177	0.1031	0.160	0.00	0.53
			Week 12	54	0.185	0.1097	0.160	0.00	0.49
Glucose (MMOL/L)	Placebo	64	Week -6	64	9.52	1.584	9.50	5.7	13.2
			Week -5	63	9.52	1.652	9.20	6.7	15.8
			Week -4	64	9.73	1.904	9.30	6.7	15.9
			Week -2	61	9.56	1.640	9.20	6.6	13.6
			Baseline	64	9.63	1.969	9.35	5.5	15.8
			Week 1	61	10.00	2.357	9.40	4.1	15.8
			Week 2	60	9.97	2.154	9.55	6.4	17.2
			Week 3	55	10.02	2.264	9.60	4.9	17.4
			Week 4	56	9.77	1.942	9.50	5.7	14.8

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Glucose (MMOL/L)	Placebo	64	Week 6	53	9.80	2.187	9.40	5.5	15.7
			Week 8	53	9.89	2.371	9.40	5.4	15.5
			Week 12	49	10.07	2.947	9.50	5.2	17.7
	2.5mg	61	Week -6	60	9.35	1.848	9.45	5.4	15.0
			Week -5	61	9.59	1.676	9.40	6.4	13.2
			Week -4	61	9.81	1.964	9.60	6.6	15.9
			Week -2	58	9.95	2.178	9.60	6.5	17.3
			Baseline	59	9.60	2.418	9.20	5.7	16.7
			Week 1	60	9.80	2.328	9.40	4.8	15.7
			Week 2	59	9.87	2.468	9.60	5.8	15.3
			Week 3	58	9.77	2.341	9.85	5.8	16.8
			Week 4	53	9.87	2.516	10.00	4.7	15.8
			Week 6	51	9.70	2.448	9.50	5.0	16.3
			Week 8	47	9.44	2.185	9.50	5.0	14.8
			Week 12	48	9.52	2.478	8.95	5.2	16.1
	7.5mg	63	Week -6	61	9.38	1.966	9.10	6.4	14.3
			Week -5	62	9.22	1.645	9.20	5.7	13.3
			Week -4	62	9.52	1.820	9.55	6.2	14.4
			Week -2	61	9.97	2.332	9.60	4.7	17.0
			Baseline	63	9.90	2.011	9.90	5.5	15.6
			Week 1	62	9.44	2.110	9.25	4.3	16.1
			Week 2	60	9.43	2.019	9.55	4.7	15.5
			Week 3	59	9.00	2.011	9.10	4.8	12.8
			Week 4	57	9.16	2.271	9.00	3.1	14.5
			Week 6	57	9.05	2.323	8.90	4.7	16.1
			Week 8	56	9.07	2.395	8.85	5.1	16.6
			Week 12	53	9.46	2.968	8.90	4.1	19.0
	15mg	66	Week -6	62	9.71	2.007	9.50	6.6	17.5
			Week -5	63	9.44	1.685	9.20	6.8	14.8

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Glucose (MMOL/L)	15mg	66	Week -4	62	9.83	1.444	9.65	6.9	13.9
			Week -2	66	9.93	1.699	9.80	6.8	15.7
			Baseline	66	9.96	1.597	9.90	6.8	15.0
			Week 1	63	9.82	1.871	9.70	6.3	15.2
			Week 2	63	9.68	1.793	9.30	6.3	14.1
			Week 3	60	9.67	1.988	9.40	6.6	14.2
			Week 4	60	9.53	2.013	9.10	5.9	14.6
			Week 6	60	9.69	1.901	9.45	6.3	15.5
			Week 8	60	9.64	2.121	9.30	6.1	14.4
			Week 12	59	9.94	2.149	9.20	6.2	15.8
	30mg	60	Week -6	60	9.55	1.936	9.25	6.0	14.5
			Week -5	58	9.54	1.827	9.20	6.1	14.2
			Week -4	60	9.55	1.467	9.50	6.1	12.0
			Week -2	58	9.78	1.953	9.50	5.8	14.2
			Baseline	60	9.92	2.289	9.65	5.9	18.7
			Week 1	58	9.17	2.057	9.20	5.7	17.0
			Week 2	57	9.29	2.045	9.10	5.7	16.5
			Week 3	56	9.13	2.112	8.65	6.3	15.5
			Week 4	57	8.76	1.820	8.40	5.0	12.5
			Week 6	57	8.90	1.963	8.70	5.2	13.6
			Week 8	56	9.11	2.081	8.85	5.8	14.1
			Week 12	56	8.86	2.183	8.35	4.2	15.8
	45mg	61	Week -6	58	9.56	1.654	9.25	6.3	14.9
			Week -5	60	9.75	1.664	9.45	7.2	14.9
			Week -4	60	9.87	1.271	9.80	6.6	12.8
			Week -2	61	10.04	2.021	9.80	4.6	15.2
			Baseline	60	10.05	1.659	9.95	5.5	13.5
			Week 1	60	9.36	1.837	9.30	5.7	15.2
			Week 2	60	9.36	2.173	9.20	2.3	15.3
			Week 3	56	9.03	2.085	8.60	5.9	16.0

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Glucose (MMOL/L)	45mg	61	Week 4	57	8.62	1.875	8.50	4.9	13.2
			Week 6	55	9.15	2.191	9.00	4.6	14.2
			Week 8	56	8.77	1.914	8.40	5.3	14.4
			Week 12	55	9.10	2.170	9.00	5.5	15.1
Hematocrit (1)	Placebo	64	Week -5	63	0.423	0.0350	0.429	0.35	0.50
			Baseline	64	0.428	0.0365	0.427	0.36	0.53
			Week 1	56	0.420	0.0333	0.415	0.35	0.50
			Week 2	60	0.423	0.0353	0.422	0.35	0.52
			Week 3	55	0.423	0.0341	0.430	0.35	0.50
			Week 4	55	0.421	0.0428	0.429	0.27	0.53
			Week 6	53	0.419	0.0351	0.426	0.34	0.50
			Week 8	52	0.423	0.0341	0.429	0.34	0.49
			Week 12	45	0.420	0.0292	0.422	0.36	0.48
	2.5mg	61	Week -5	60	0.434	0.0364	0.428	0.36	0.52
			Baseline	61	0.432	0.0363	0.428	0.35	0.57
			Week 1	60	0.424	0.0381	0.418	0.34	0.51
			Week 2	59	0.421	0.0328	0.418	0.33	0.48
			Week 3	58	0.423	0.0316	0.419	0.35	0.49
			Week 4	53	0.427	0.0346	0.427	0.35	0.51
			Week 6	51	0.427	0.0357	0.431	0.35	0.51
			Week 8	47	0.424	0.0368	0.426	0.34	0.48
			Week 12	48	0.430	0.0382	0.423	0.32	0.51
	7.5mg	63	Week -5	61	0.432	0.0387	0.431	0.34	0.52
			Baseline	63	0.428	0.0362	0.425	0.34	0.51
			Week 1	60	0.421	0.0381	0.420	0.33	0.50
			Week 2	59	0.422	0.0357	0.423	0.32	0.50
			Week 3	58	0.420	0.0418	0.418	0.31	0.52
			Week 4	56	0.422	0.0440	0.416	0.31	0.59

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematocrit (1)	7.5mg	63	Week 6	57	0.419	0.0362	0.418	0.31	0.49
			Week 8	54	0.418	0.0366	0.421	0.31	0.48
			Week 12	52	0.422	0.0327	0.422	0.34	0.50
	15mg	66	Week -5	63	0.424	0.0310	0.417	0.36	0.50
			Baseline	66	0.419	0.0309	0.420	0.35	0.49
			Week 1	63	0.413	0.0324	0.410	0.34	0.50
			Week 2	61	0.413	0.0305	0.412	0.32	0.48
			Week 3	58	0.414	0.0288	0.415	0.34	0.48
			Week 4	60	0.416	0.0302	0.416	0.34	0.49
			Week 6	60	0.414	0.0278	0.416	0.32	0.48
			Week 8	60	0.415	0.0325	0.411	0.33	0.49
			Week 12	59	0.413	0.0336	0.413	0.33	0.50
	30mg	60	Week -5	59	0.429	0.0336	0.425	0.34	0.51
			Baseline	60	0.429	0.0373	0.436	0.32	0.51
			Week 1	57	0.423	0.0326	0.419	0.34	0.48
			Week 2	54	0.424	0.0320	0.425	0.33	0.49
			Week 3	57	0.424	0.0328	0.426	0.35	0.50
			Week 4	57	0.425	0.0347	0.425	0.34	0.51
			Week 6	56	0.424	0.0313	0.425	0.35	0.50
			Week 8	55	0.428	0.0324	0.429	0.33	0.51
			Week 12	53	0.431	0.0437	0.433	0.34	0.63
	45mg	61	Week -5	60	0.424	0.0379	0.425	0.31	0.50
			Baseline	61	0.423	0.0376	0.413	0.35	0.52
			Week 1	59	0.418	0.0400	0.410	0.31	0.51
			Week 2	60	0.415	0.0357	0.408	0.33	0.49
			Week 3	55	0.419	0.0441	0.412	0.33	0.52
			Week 4	56	0.417	0.0429	0.413	0.31	0.52
			Week 6	53	0.417	0.0391	0.410	0.33	0.51
			Week 8	56	0.415	0.0398	0.412	0.33	0.50

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematocrit (1)	45mg	61	Week 12	54	0.420	0.0413	0.419	0.35	0.55
Hemoglobin (G/L)	Placebo	64	Week -5	63	142.1	11.59	144.0	121	169
			Baseline	64	143.7	12.21	143.5	120	175
			Week 1	56	141.2	10.73	141.0	123	168
			Week 2	60	142.1	11.22	143.0	121	171
			Week 3	55	142.7	10.86	144.0	122	161
			Week 4	55	141.7	14.07	144.0	92	176
			Week 6	53	141.8	11.68	144.0	118	164
			Week 8	52	143.2	11.86	145.5	112	168
			Week 12	45	142.2	9.97	144.0	119	164
	2.5mg	61	Week -5	60	145.6	12.34	144.0	121	171
			Baseline	61	146.0	12.62	147.0	116	186
			Week 1	60	143.1	12.99	141.5	111	170
			Week 2	59	142.7	12.22	144.0	109	166
			Week 3	58	142.7	11.33	141.0	113	166
			Week 4	53	144.4	12.02	144.0	112	166
			Week 6	51	144.0	11.96	144.0	111	169
			Week 8	47	142.4	12.82	144.0	106	163
			Week 12	48	145.8	13.46	144.5	102	173
	7.5mg	63	Week -5	61	144.1	12.92	144.0	115	177
			Baseline	63	144.1	12.58	142.0	111	173
			Week 1	60	141.9	12.76	142.0	108	169
			Week 2	59	142.3	12.25	143.0	105	168
			Week 3	58	141.7	13.92	143.0	103	172
			Week 4	56	141.6	13.91	141.5	100	188
			Week 6	57	140.8	12.10	142.0	98	164
			Week 8	54	141.7	12.48	141.0	99	163
			Week 12	52	143.1	10.55	142.5	116	166

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hemoglobin (G/L)	15mg	66	Week -5	63	142.4	10.56	141.0	115	166
			Baseline	66	141.2	10.89	141.0	111	166
			Week 1	63	139.1	11.20	140.0	109	166
			Week 2	61	139.4	11.13	139.0	102	164
			Week 3	58	139.6	10.27	139.5	107	166
			Week 4	60	139.7	11.16	139.0	108	169
			Week 6	60	139.4	10.19	139.0	102	161
			Week 8	60	139.8	11.67	138.0	104	163
			Week 12	59	139.6	11.87	139.0	104	166
	30mg	60	Week -5	59	144.4	12.03	144.0	115	169
			Baseline	60	144.9	12.67	148.0	109	169
			Week 1	57	142.7	11.66	143.0	112	163
			Week 2	54	143.3	11.92	145.0	109	163
			Week 3	57	143.1	12.09	144.0	114	166
			Week 4	57	143.1	11.70	145.0	112	170
			Week 6	56	143.1	10.59	143.5	118	165
			Week 8	55	145.2	11.55	146.0	114	174
			Week 12	53	145.5	14.60	146.0	113	204
	45mg	61	Week -5	60	142.5	12.83	143.5	107	171
			Baseline	61	142.6	13.59	140.0	114	181
			Week 1	59	140.2	13.73	139.0	106	169
			Week 2	60	140.0	12.69	138.5	111	168
			Week 3	55	140.9	14.87	139.0	114	177
			Week 4	56	140.3	13.94	138.5	111	170
			Week 6	53	140.2	14.07	138.0	111	173
			Week 8	56	140.3	13.83	138.0	113	170
			Week 12	54	142.1	14.22	142.5	115	184
Indirect Bilirubin (UMOL/L)	Placebo	64	Week -5	64	8.6	3.86	8.0	3	26

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	Placebo	64	Baseline	64	9.2	4.57	8.0	3	30
			Week 1	61	8.3	3.75	7.0	3	22
			Week 2	60	8.7	4.26	8.0	4	22
			Week 3	55	8.4	3.70	8.0	4	24
			Week 4	55	8.2	3.56	8.0	4	22
			Week 6	53	8.3	3.28	8.0	4	20
			Week 8	51	8.9	3.74	8.0	4	24
			Week 12	49	8.6	4.39	8.0	2	31
	2.5mg	61	Week -5	61	9.2	4.76	8.0	4	24
			Baseline	61	9.7	4.55	9.0	4	28
			Week 1	59	9.9	4.41	9.0	4	26
			Week 2	58	9.3	4.08	8.5	3	25
			Week 3	56	9.9	4.26	9.0	4	24
			Week 4	56	9.1	3.80	8.0	3	26
			Week 6	48	10.1	4.44	9.0	4	27
			Week 8	48	9.1	3.80	8.0	4	20
			Week 12	45	9.5	4.53	8.0	4	25
	7.5mg	63	Week -5	61	9.4	3.91	9.0	4	26
			Baseline	63	9.4	4.38	9.0	2	32
			Week 1	60	9.8	4.49	9.0	4	27
			Week 2	59	8.8	3.36	8.0	4	22
			Week 3	59	8.9	3.84	8.0	4	27
			Week 4	55	8.5	2.94	8.0	4	19
			Week 6	56	8.9	3.72	8.0	4	23
			Week 8	54	8.9	3.59	8.0	3	22
			Week 12	54	8.9	3.99	8.0	3	23
	15mg	66	Week -5	62	8.5	3.75	8.0	4	22
			Baseline	66	8.5	4.22	8.0	4	30
			Week 1	63	8.1	3.22	8.0	4	19

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	15mg	66	Week 2	62	7.9	3.06	7.5	4	19
			Week 3	59	7.9	3.26	7.0	2	21
			Week 4	60	8.6	3.84	8.0	4	21
			Week 6	60	7.7	2.83	7.0	4	18
			Week 8	60	8.0	3.72	7.0	4	24
			Week 12	58	8.3	3.35	8.0	4	20
	30mg	60	Week -5	59	8.9	4.43	8.0	3	28
			Baseline	59	10.4	4.74	10.0	4	26
			Week 1	56	9.3	3.74	9.0	4	24
			Week 2	57	9.5	4.31	9.0	4	30
			Week 3	57	9.4	4.79	8.0	4	28
			Week 4	56	9.0	4.15	8.0	4	24
			Week 6	53	9.2	4.06	8.0	4	24
			Week 8	55	8.7	4.20	8.0	3	24
			Week 12	56	9.3	4.02	9.0	4	24
	45mg	61	Week -5	59	8.1	3.53	8.0	3	22
			Baseline	61	8.4	3.85	8.0	4	23
			Week 1	59	8.5	4.04	8.0	2	22
			Week 2	58	8.2	4.60	7.0	3	31
			Week 3	55	8.5	3.84	7.0	4	22
			Week 4	56	8.1	4.31	7.0	4	29
			Week 6	54	7.7	3.45	7.0	3	20
			Week 8	54	8.3	4.46	7.5	3	29
			Week 12	54	7.9	3.73	7.0	3	24
Lactate Dehydrogenase (IU/L)	Placebo	64	Week -5	64	131.2	22.64	127.0	79	194
			Baseline	64	132.4	24.25	131.0	73	189
			Week 1	61	132.4	20.63	133.0	93	190
			Week 2	60	135.2	25.25	136.0	81	229

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lactate Dehydrogenase (IU/L)	Placebo	64	Week 3	55	132.5	22.00	133.0	87	199
			Week 4	55	130.7	22.12	130.0	87	209
			Week 6	53	133.7	23.79	131.0	91	229
			Week 8	51	135.0	23.71	137.0	74	193
			Week 12	48	133.0	22.39	130.0	88	188
	2.5mg	61	Week -5	61	138.0	30.25	137.0	70	222
			Baseline	61	144.7	29.06	145.0	73	237
			Week 1	59	144.4	26.20	139.0	79	213
			Week 2	58	143.2	26.39	141.0	88	218
			Week 3	56	139.7	26.25	140.5	71	206
			Week 4	56	141.1	25.91	138.5	78	231
			Week 6	48	144.7	26.92	145.0	85	209
			Week 8	48	143.2	31.95	140.0	76	284
			Week 12	46	141.9	23.06	143.0	91	195
	7.5mg	63	Week -5	61	134.4	29.44	131.0	72	221
			Baseline	63	139.7	26.01	135.0	86	217
			Week 1	60	139.5	24.12	137.0	92	208
			Week 2	59	142.4	33.43	137.0	91	236
			Week 3	58	139.9	29.53	134.0	88	241
			Week 4	56	142.1	25.35	139.5	89	222
			Week 6	56	142.7	29.43	139.5	93	246
			Week 8	54	145.7	36.68	143.5	87	298
			Week 12	54	145.4	27.60	141.5	96	224
	15mg	66	Week -5	62	136.0	21.97	136.0	95	187
			Baseline	66	139.7	26.47	138.5	87	221
			Week 1	63	143.8	28.00	143.0	91	252
			Week 2	62	138.8	21.45	138.5	89	197
			Week 3	59	141.8	26.45	138.0	68	215
			Week 4	60	143.4	26.34	138.5	75	202

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lactate Dehydrogenase (IU/L)	15mg	66	Week 6	60	145.2	26.02	140.5	95	227
			Week 8	58	140.6	23.34	139.5	90	218
			Week 12	58	141.9	23.35	138.0	99	206
	30mg	60	Week -5	59	139.7	33.74	136.0	58	217
			Baseline	59	149.1	32.21	141.0	74	214
			Week 1	56	142.3	28.89	137.5	82	211
			Week 2	57	144.9	35.88	142.0	74	288
			Week 3	56	146.9	30.65	143.0	78	230
			Week 4	56	145.6	27.83	144.0	75	201
			Week 6	53	147.0	32.44	142.0	81	243
			Week 8	55	144.8	29.18	144.0	80	217
			Week 12	56	143.3	30.68	138.0	81	246
	45mg	61	Week -5	61	137.2	27.86	134.0	58	226
			Baseline	61	136.6	29.47	132.0	57	212
			Week 1	59	138.2	28.63	130.0	60	208
			Week 2	57	140.2	30.90	139.0	64	248
			Week 3	55	141.0	28.05	134.0	84	214
			Week 4	56	139.3	29.89	138.5	64	224
			Week 6	54	141.1	37.27	136.0	55	281
			Week 8	54	141.0	30.21	137.5	60	240
			Week 12	54	139.1	30.35	132.5	64	212
Lymphocytes (GI/L)	Placebo	64	Week -5	63	2.105	0.6559	2.070	1.01	4.15
			Baseline	64	2.086	0.6599	2.060	1.01	4.41
			Week 1	56	2.018	0.6004	2.030	1.07	3.58
			Week 2	60	2.125	0.6089	2.110	0.97	3.60
			Week 3	55	2.055	0.5768	1.960	0.94	3.56
			Week 4	55	1.989	0.5121	1.940	1.05	3.28
			Week 6	53	2.076	0.5979	2.010	1.10	3.75

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lymphocytes (GI/L)	Placebo	64	Week 8	52	2.142	0.6181	2.085	1.05	3.87
			Week 12	44	2.070	0.5655	2.000	0.93	3.74
	2.5mg	61	Week -5	60	2.132	0.6337	2.060	1.10	4.42
			Baseline	61	2.020	0.5383	1.980	0.97	3.48
			Week 1	60	2.142	0.6860	2.000	0.94	4.52
			Week 2	59	2.095	0.6575	2.050	1.09	3.72
			Week 3	58	2.145	0.6959	2.000	0.87	4.16
			Week 4	53	2.097	0.7319	1.920	0.98	4.16
			Week 6	51	2.179	0.7339	2.160	1.07	4.38
			Week 8	47	2.092	0.6238	2.110	1.04	3.62
			Week 12	48	1.999	0.6675	1.875	0.89	3.62
	7.5mg	63	Week -5	61	2.146	0.5567	2.170	0.97	3.34
			Baseline	63	2.178	0.6272	2.160	1.00	4.74
			Week 1	60	2.146	0.5884	2.175	0.90	3.74
			Week 2	59	2.102	0.6651	1.980	0.69	3.89
			Week 3	58	2.156	0.6146	2.055	1.08	3.67
			Week 4	56	2.131	0.5376	2.060	1.03	3.23
			Week 6	57	2.179	0.6058	2.110	1.11	3.32
			Week 8	53	2.100	0.5060	2.000	1.17	3.75
			Week 12	52	2.084	0.4996	2.050	0.91	3.12
	15mg	66	Week -5	62	2.056	0.4907	2.035	1.04	3.11
			Baseline	66	2.021	0.4641	2.015	1.14	3.06
			Week 1	63	2.080	0.5219	2.020	1.03	3.49
			Week 2	61	2.064	0.4618	2.010	0.97	3.44
			Week 3	58	2.057	0.5189	2.015	0.92	3.37
			Week 4	60	1.966	0.4827	1.840	1.16	3.04
			Week 6	60	2.095	0.5542	2.140	0.75	3.44
			Week 8	60	1.957	0.5249	1.870	0.96	3.40
			Week 12	59	1.937	0.5026	1.800	0.94	3.25

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lymphocytes (GI/L)	30mg	60	Week -5	59	2.039	0.6325	2.000	0.74	3.44
			Baseline	60	2.083	0.7228	2.035	0.69	3.94
			Week 1	57	2.129	0.6487	2.070	1.01	3.45
			Week 2	54	2.121	0.6944	2.110	0.85	3.86
			Week 3	57	2.017	0.6805	1.970	0.53	3.52
			Week 4	57	1.987	0.6401	1.870	0.88	3.41
			Week 6	56	2.081	0.7056	1.980	0.74	3.98
			Week 8	54	1.991	0.6461	2.050	0.86	3.44
			Week 12	53	2.019	0.6819	1.970	0.71	3.68
	45mg	61	Week -5	59	2.286	0.6491	2.160	0.81	4.13
			Baseline	60	2.235	0.6943	2.110	1.08	4.34
			Week 1	59	2.183	0.6477	2.120	0.98	3.82
			Week 2	60	2.174	0.6446	2.035	1.03	4.11
			Week 3	55	2.173	0.6482	2.090	1.08	4.44
			Week 4	56	2.174	0.7032	2.105	0.97	4.11
			Week 6	53	2.201	0.8390	2.080	1.05	5.95
			Week 8	56	2.126	0.6372	2.000	1.03	3.94
			Week 12	54	2.174	0.6812	2.125	0.90	3.68
Monocytes (GI/L)	Placebo	64	Week -5	63	0.370	0.1633	0.340	0.09	0.82
			Baseline	64	0.340	0.1376	0.315	0.11	0.72
			Week 1	56	0.328	0.1429	0.300	0.01	0.65
			Week 2	60	0.336	0.1262	0.315	0.08	0.68
			Week 3	55	0.351	0.1437	0.340	0.08	0.84
			Week 4	55	0.332	0.1389	0.320	0.09	0.76
			Week 6	53	0.349	0.1580	0.330	0.06	0.72
			Week 8	52	0.363	0.1746	0.345	0.01	0.90
			Week 12	44	0.374	0.1944	0.315	0.00	1.14
	2.5mg	61	Week -5	60	0.353	0.1345	0.335	0.10	0.70

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Monocytes (GI/L)	2.5mg	61	Baseline	61	0.347	0.1401	0.330	0.01	0.74
			Week 1	60	0.385	0.1743	0.345	0.16	1.12
			Week 2	59	0.364	0.1643	0.330	0.13	0.79
			Week 3	58	0.379	0.1509	0.340	0.14	0.77
			Week 4	53	0.392	0.1765	0.360	0.14	0.97
			Week 6	51	0.408	0.1636	0.400	0.18	0.97
			Week 8	47	0.341	0.1196	0.330	0.00	0.56
			Week 12	48	0.390	0.1742	0.355	0.14	0.96
	7.5mg	63	Week -5	61	0.351	0.1244	0.360	0.05	0.61
			Baseline	63	0.365	0.1319	0.350	0.13	0.85
			Week 1	60	0.402	0.2226	0.380	0.00	1.49
			Week 2	59	0.393	0.1768	0.370	0.10	0.96
			Week 3	58	0.408	0.1600	0.405	0.10	0.90
			Week 4	56	0.368	0.1676	0.350	0.10	0.74
			Week 6	57	0.413	0.2040	0.370	0.10	1.24
			Week 8	53	0.402	0.1671	0.370	0.08	0.83
			Week 12	52	0.396	0.1543	0.380	0.11	0.75
	15mg	66	Week -5	62	0.376	0.1358	0.350	0.16	0.83
			Baseline	66	0.357	0.1121	0.340	0.09	0.63
			Week 1	63	0.401	0.1464	0.400	0.08	0.78
			Week 2	61	0.364	0.1420	0.370	0.02	0.63
			Week 3	58	0.424	0.1596	0.420	0.01	0.88
			Week 4	60	0.394	0.1570	0.375	0.09	0.87
			Week 6	60	0.420	0.1391	0.415	0.15	0.82
			Week 8	60	0.397	0.1369	0.380	0.13	0.77
			Week 12	59	0.388	0.1437	0.370	0.07	0.72
	30mg	60	Week -5	59	0.394	0.1425	0.390	0.04	0.76
			Baseline	60	0.382	0.1359	0.375	0.13	0.69
			Week 1	57	0.401	0.1493	0.410	0.01	0.75

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Monocytes (GI/L)	30mg	60	Week 2	54	0.438	0.1548	0.425	0.02	0.85
			Week 3	57	0.422	0.1599	0.410	0.12	0.82
			Week 4	57	0.410	0.1490	0.410	0.18	0.80
			Week 6	56	0.438	0.1341	0.445	0.18	0.72
			Week 8	54	0.454	0.1558	0.405	0.21	0.82
			Week 12	53	0.413	0.1677	0.390	0.10	0.86
	45mg	61	Week -5	59	0.368	0.1372	0.350	0.13	0.94
			Baseline	60	0.351	0.1535	0.325	0.09	0.81
			Week 1	59	0.388	0.1687	0.350	0.05	0.81
			Week 2	60	0.414	0.1558	0.380	0.16	0.93
			Week 3	55	0.413	0.1859	0.370	0.01	1.12
			Week 4	56	0.392	0.1394	0.365	0.07	0.68
			Week 6	53	0.378	0.1677	0.370	0.09	0.83
			Week 8	56	0.410	0.1451	0.400	0.16	0.85
			Week 12	54	0.392	0.1898	0.350	0.00	0.94
Phosphorus, Inorganic (MMOL/L)	Placebo	64	Week -5	64	1.132	0.1665	1.150	0.69	1.50
			Baseline	64	1.116	0.1782	1.125	0.72	1.49
			Week 1	61	1.082	0.1693	1.070	0.72	1.55
			Week 2	60	1.112	0.1659	1.100	0.70	1.50
			Week 3	55	1.087	0.1487	1.100	0.72	1.35
			Week 4	55	1.084	0.1683	1.110	0.65	1.43
			Week 6	53	1.104	0.1701	1.090	0.81	1.60
			Week 8	51	1.090	0.1702	1.090	0.75	1.50
			Week 12	49	1.071	0.1354	1.050	0.83	1.35
	2.5mg	61	Week -5	61	1.082	0.1511	1.080	0.78	1.50
			Baseline	61	1.082	0.1128	1.060	0.90	1.35
			Week 1	59	1.105	0.1245	1.100	0.86	1.37

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Phosphorus, Inorganic (MMOL/L)	2.5mg	61	Week 2	58	1.102	0.1362	1.095	0.80	1.42
			Week 3	56	1.089	0.1300	1.055	0.82	1.47
			Week 4	56	1.094	0.1401	1.100	0.77	1.54
			Week 6	49	1.077	0.1394	1.100	0.80	1.40
			Week 8	48	1.085	0.1408	1.055	0.82	1.45
			Week 12	46	1.072	0.1646	1.045	0.73	1.45
	7.5mg	63	Week -5	61	1.118	0.1695	1.150	0.66	1.45
			Baseline	63	1.077	0.1686	1.100	0.70	1.49
			Week 1	60	1.070	0.1462	1.060	0.71	1.35
			Week 2	59	1.080	0.1827	1.080	0.75	1.58
			Week 3	59	1.114	0.2432	1.060	0.74	2.51
			Week 4	57	1.084	0.1635	1.090	0.68	1.50
			Week 6	56	1.074	0.1719	1.055	0.68	1.48
			Week 8	54	1.080	0.1510	1.050	0.79	1.41
			Week 12	54	1.077	0.1930	1.055	0.78	1.85
	15mg	66	Week -5	62	1.087	0.1769	1.095	0.68	1.45
			Baseline	66	1.067	0.1548	1.050	0.83	1.50
			Week 1	63	1.079	0.1763	1.050	0.69	1.55
			Week 2	62	1.079	0.1746	1.060	0.77	1.53
			Week 3	59	1.069	0.1590	1.060	0.75	1.40
			Week 4	60	1.052	0.1651	1.050	0.75	1.55
			Week 6	60	1.088	0.1553	1.070	0.78	1.60
			Week 8	58	1.044	0.1516	1.035	0.78	1.40
			Week 12	58	1.047	0.1524	1.050	0.74	1.41
	30mg	60	Week -5	59	1.115	0.1407	1.120	0.82	1.50
			Baseline	59	1.104	0.1320	1.100	0.82	1.40
			Week 1	56	1.134	0.1465	1.145	0.85	1.50
			Week 2	57	1.107	0.1552	1.140	0.70	1.45

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Phosphorus, Inorganic (MMOL/L)	30mg	60	Week 3	57	1.094	0.1521	1.080	0.75	1.45
			Week 4	56	1.098	0.1446	1.100	0.64	1.35
			Week 6	53	1.100	0.1460	1.130	0.83	1.37
			Week 8	55	1.094	0.1506	1.080	0.75	1.50
			Week 12	56	1.102	0.1521	1.115	0.76	1.45
	45mg	61	Week -5	61	1.120	0.1772	1.110	0.80	1.53
			Baseline	61	1.122	0.1690	1.120	0.77	1.55
			Week 1	59	1.112	0.1440	1.110	0.82	1.45
			Week 2	58	1.115	0.1555	1.100	0.81	1.50
			Week 3	55	1.115	0.1521	1.110	0.83	1.59
			Week 4	56	1.109	0.1663	1.120	0.77	1.55
			Week 6	54	1.102	0.1749	1.110	0.59	1.45
			Week 8	54	1.109	0.1621	1.150	0.78	1.50
			Week 12	54	1.093	0.1796	1.105	0.78	1.50
Platelet count (GI/L)	Placebo	64	Week -5	63	233.4	60.25	229.0	130	474
			Baseline	64	241.8	61.31	238.0	137	465
			Week 1	56	234.0	49.42	227.0	143	366
			Week 2	60	232.2	51.86	225.5	145	379
			Week 3	55	231.5	58.65	223.0	130	376
			Week 4	54	233.1	52.01	230.0	139	354
			Week 6	53	234.8	51.88	236.0	141	391
			Week 8	52	230.4	53.04	226.0	143	371
			Week 12	44	222.9	61.78	220.5	102	361
	2.5mg	61	Week -5	60	240.9	62.96	229.0	138	412
			Baseline	61	234.6	59.21	229.0	140	411
			Week 1	60	238.6	61.85	228.0	139	440
			Week 2	59	243.1	64.82	231.0	127	429

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Platelet count (GI/L)	2.5mg	61	Week 3	58	235.4	62.81	214.0	129	421
			Week 4	53	231.1	57.39	219.0	132	407
			Week 6	51	238.4	67.88	220.0	127	416
			Week 8	47	239.0	67.53	219.0	134	425
			Week 12	48	232.5	62.30	212.5	128	402
	7.5mg	63	Week -5	61	252.4	49.98	246.0	134	361
			Baseline	63	250.7	56.82	242.0	126	430
			Week 1	59	260.2	58.84	245.0	142	376
			Week 2	59	261.0	52.62	254.0	156	382
			Week 3	58	252.2	56.39	243.0	124	380
			Week 4	55	260.8	53.94	254.0	149	422
			Week 6	57	255.7	57.41	246.0	161	411
			Week 8	54	257.9	52.95	248.0	137	400
			Week 12	52	255.1	53.04	248.0	169	390
	15mg	66	Week -5	63	250.4	56.58	241.0	151	419
			Baseline	66	246.9	54.65	243.5	152	371
			Week 1	63	250.8	58.19	247.0	145	418
			Week 2	61	252.6	56.74	237.0	161	390
			Week 3	58	249.1	52.12	236.0	162	364
			Week 4	60	248.8	57.50	240.0	147	415
			Week 6	60	255.4	60.74	246.5	143	410
			Week 8	60	245.4	58.15	231.0	150	393
			Week 12	59	247.6	59.41	231.0	135	454
	30mg	60	Week -5	59	250.3	53.86	254.0	100	394
			Baseline	59	251.2	64.89	246.0	77	444
			Week 1	57	255.2	63.72	249.0	73	498
			Week 2	54	255.8	53.00	252.5	117	367
			Week 3	56	256.7	59.94	248.0	107	383
			Week 4	57	257.8	62.20	251.0	104	394

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Platelet count (GI/L)	30mg	60	Week 6	56	257.4	62.47	246.5	102	434
			Week 8	54	249.8	60.37	244.0	81	384
			Week 12	52	255.5	56.12	257.0	155	389
	45mg	61	Week -5	58	249.5	67.07	246.5	131	423
			Baseline	61	251.5	63.85	253.0	125	456
			Week 1	57	250.6	60.49	244.0	148	418
			Week 2	60	259.4	65.59	259.5	128	419
			Week 3	55	251.2	60.58	252.0	132	420
			Week 4	56	253.2	64.06	245.0	114	406
			Week 6	53	253.2	73.65	242.0	124	448
			Week 8	56	253.4	69.39	241.5	141	449
			Week 12	54	246.9	67.35	240.0	96	372
Potassium (MMOL/L)	Placebo	64	Week -5	64	4.34	0.619	4.20	3.4	7.3
			Baseline	64	4.37	0.538	4.20	3.6	6.4
			Week 1	61	4.50	0.583	4.40	3.4	5.9
			Week 2	59	4.51	0.732	4.50	3.4	8.9
			Week 3	55	4.66	0.807	4.50	3.6	8.5
			Week 4	55	4.44	0.626	4.30	3.6	7.2
			Week 6	53	4.47	0.643	4.30	3.5	6.6
			Week 8	51	4.53	0.624	4.30	3.7	6.2
			Week 12	48	4.35	0.627	4.20	3.6	6.9
	2.5mg	61	Week -5	61	4.35	0.501	4.20	3.1	6.7
			Baseline	61	4.56	0.722	4.40	3.4	7.2
			Week 1	59	4.46	0.486	4.40	3.5	6.1
			Week 2	58	4.48	0.622	4.30	3.3	6.4
			Week 3	55	4.40	0.493	4.30	3.5	5.7
			Week 4	56	4.42	0.579	4.30	3.3	7.1
			Week 6	48	4.55	0.722	4.35	3.4	7.6

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Potassium (MMOL/L)	2.5mg	61	Week 8	48	4.42	0.751	4.20	3.4	8.5
			Week 12	46	4.31	0.468	4.20	3.2	5.9
	7.5mg	63	Week -5	60	4.28	0.368	4.30	3.7	5.5
			Baseline	62	4.44	0.694	4.20	3.6	7.5
			Week 1	60	4.52	0.659	4.40	3.6	7.4
			Week 2	59	4.57	0.714	4.50	3.4	6.7
			Week 3	58	4.61	0.897	4.30	3.5	8.5
			Week 4	56	4.39	0.452	4.35	3.4	5.9
			Week 6	56	4.46	0.562	4.35	3.5	6.4
			Week 8	54	4.39	0.484	4.30	3.4	5.5
			Week 12	54	4.48	0.563	4.50	3.5	6.2
	15mg	66	Week -5	62	4.31	0.345	4.30	3.5	5.3
			Baseline	66	4.38	0.441	4.35	3.6	6.1
			Week 1	63	4.49	0.541	4.30	3.5	6.4
			Week 2	62	4.54	0.608	4.35	3.5	6.7
			Week 3	59	4.47	0.615	4.30	3.7	7.3
			Week 4	60	4.37	0.469	4.25	3.5	5.6
			Week 6	60	4.53	0.584	4.35	3.7	6.2
			Week 8	60	4.50	0.521	4.40	3.4	6.0
			Week 12	58	4.39	0.540	4.40	3.4	6.3
	30mg	60	Week -5	59	4.34	0.478	4.30	3.6	6.1
			Baseline	59	4.45	0.789	4.20	3.4	7.3
			Week 1	56	4.48	0.577	4.30	3.7	6.9
			Week 2	57	4.53	0.698	4.30	3.6	7.2
			Week 3	56	4.42	0.466	4.40	3.5	5.9
			Week 4	56	4.30	0.406	4.20	3.6	5.7
			Week 6	53	4.35	0.560	4.20	3.6	6.9
			Week 8	55	4.55	0.933	4.30	3.6	8.0
			Week 12	55	4.36	0.590	4.20	3.6	6.6

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Potassium (MMOL/L)	45mg	61	Week -5	61	4.41	0.470	4.40	3.6	6.6
			Baseline	61	4.47	0.579	4.30	3.7	6.6
			Week 1	59	4.45	0.562	4.40	3.7	6.4
			Week 2	57	4.63	0.666	4.50	3.3	7.0
			Week 3	55	4.45	0.528	4.30	3.7	6.5
			Week 4	56	4.36	0.477	4.25	3.6	6.4
			Week 6	54	4.71	0.937	4.40	3.5	8.9
			Week 8	54	4.51	0.594	4.40	3.7	6.9
			Week 12	54	4.57	0.676	4.40	3.6	7.5
Red Blood Cell Count (TI/L)	Placebo	64	Week -5	63	4.71	0.403	4.70	4.0	5.6
			Baseline	64	4.77	0.391	4.70	4.1	5.8
			Week 1	56	4.67	0.371	4.65	4.0	5.5
			Week 2	60	4.72	0.382	4.70	4.0	5.5
			Week 3	55	4.72	0.369	4.80	4.0	5.4
			Week 4	55	4.72	0.453	4.80	3.0	5.7
			Week 6	53	4.69	0.382	4.70	3.9	5.5
			Week 8	52	4.74	0.397	4.75	3.8	5.5
			Week 12	45	4.75	0.324	4.70	4.1	5.4
	2.5mg	61	Week -5	60	4.79	0.346	4.80	3.9	5.6
			Baseline	61	4.79	0.348	4.80	4.2	5.7
			Week 1	60	4.70	0.352	4.70	4.0	5.7
			Week 2	59	4.69	0.302	4.70	4.1	5.6
			Week 3	58	4.71	0.331	4.70	4.0	5.7
			Week 4	53	4.75	0.369	4.70	4.1	5.8
			Week 6	51	4.74	0.352	4.70	3.8	5.8
			Week 8	47	4.73	0.372	4.70	4.0	5.7
			Week 12	48	4.82	0.370	4.80	4.0	6.0
	7.5mg	63	Week -5	61	4.74	0.424	4.80	3.6	5.6

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Red Blood Cell Count (TI/L)	7.5mg	63	Baseline	63	4.72	0.399	4.70	3.6	5.5
			Week 1	60	4.65	0.400	4.70	3.6	5.6
			Week 2	59	4.66	0.397	4.80	3.6	5.6
			Week 3	58	4.65	0.437	4.70	3.6	5.6
			Week 4	56	4.66	0.465	4.65	3.6	6.0
			Week 6	57	4.62	0.407	4.60	3.7	5.5
			Week 8	54	4.65	0.406	4.70	3.5	5.3
			Week 12	52	4.71	0.390	4.70	3.7	5.6
	15mg	66	Week -5	63	4.70	0.390	4.70	4.1	5.4
			Baseline	66	4.65	0.392	4.70	3.8	5.4
			Week 1	63	4.59	0.390	4.60	3.8	5.2
			Week 2	61	4.59	0.364	4.60	3.7	5.4
			Week 3	58	4.62	0.376	4.65	3.8	5.4
			Week 4	60	4.61	0.386	4.60	3.8	5.4
			Week 6	60	4.61	0.374	4.60	3.8	5.5
			Week 8	60	4.64	0.389	4.60	3.8	5.4
			Week 12	59	4.65	0.398	4.60	3.7	5.6
	30mg	60	Week -5	59	4.74	0.414	4.70	3.6	5.6
			Baseline	60	4.76	0.401	4.70	3.8	5.5
			Week 1	57	4.71	0.363	4.70	3.7	5.5
			Week 2	54	4.72	0.394	4.70	3.7	5.6
			Week 3	57	4.71	0.402	4.60	3.8	5.5
			Week 4	57	4.74	0.387	4.80	3.9	5.6
			Week 6	56	4.74	0.370	4.70	3.8	5.5
			Week 8	55	4.77	0.359	4.80	3.7	5.5
			Week 12	53	4.82	0.455	4.70	3.7	6.5
	45mg	61	Week -5	60	4.69	0.405	4.70	3.5	5.4
			Baseline	61	4.69	0.399	4.60	3.8	5.6
			Week 1	59	4.61	0.415	4.50	3.5	5.4

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Red Blood Cell Count (TI/L)	45mg	61	Week 2	60	4.61	0.369	4.60	3.7	5.4
			Week 3	55	4.64	0.447	4.60	3.8	5.6
			Week 4	56	4.61	0.425	4.60	3.5	5.5
			Week 6	53	4.63	0.421	4.60	3.7	5.5
			Week 8	56	4.64	0.406	4.60	3.8	5.4
			Week 12	54	4.70	0.452	4.70	3.9	5.8
Sodium (MMOL/L)	Placebo	64	Week -5	64	139.7	2.79	139.5	135	155
			Baseline	64	139.5	2.20	139.5	133	144
			Week 1	61	139.9	2.55	140.0	131	146
			Week 2	60	139.4	2.38	139.5	134	145
			Week 3	55	140.0	2.89	140.0	132	147
			Week 4	55	139.4	2.42	139.0	134	143
			Week 6	53	139.8	2.22	140.0	136	144
			Week 8	51	139.3	2.31	139.0	135	144
			Week 12	49	139.1	2.71	139.0	132	144
	2.5mg	61	Week -5	61	139.7	2.08	139.0	135	146
			Baseline	61	140.0	2.42	140.0	136	146
			Week 1	59	139.5	2.34	140.0	131	146
			Week 2	58	139.1	2.10	139.0	135	145
			Week 3	56	139.4	1.95	139.0	135	144
			Week 4	56	139.3	2.42	139.0	134	145
			Week 6	49	139.4	2.04	139.0	135	144
			Week 8	48	139.6	1.93	140.0	134	144
			Week 12	46	139.5	2.39	139.0	135	144
	7.5mg	63	Week -5	61	139.9	2.35	140.0	133	145
			Baseline	63	139.9	2.50	140.0	133	148
			Week 1	60	140.2	2.32	140.0	135	147
			Week 2	59	140.1	2.62	140.0	134	150

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Sodium (MMOL/L)	7.5mg	63	Week 3	59	140.1	2.32	140.0	135	148
			Week 4	57	140.0	1.79	140.0	136	145
			Week 6	56	139.8	2.26	140.0	134	145
			Week 8	54	139.9	2.52	140.0	134	145
			Week 12	54	139.6	2.61	140.0	134	147
	15mg	66	Week -5	62	139.7	2.40	140.0	135	146
			Baseline	66	139.4	2.35	139.0	133	147
			Week 1	63	139.1	2.30	140.0	130	143
			Week 2	62	140.0	2.88	140.0	135	149
			Week 3	59	139.6	2.53	140.0	133	147
			Week 4	60	139.4	2.27	139.0	132	145
			Week 6	60	139.6	2.19	139.0	134	144
			Week 8	60	140.0	3.18	140.0	133	154
			Week 12	58	139.9	2.06	140.0	135	145
	30mg	60	Week -5	59	139.3	3.35	139.0	130	155
			Baseline	59	138.9	2.38	139.0	130	145
			Week 1	56	139.1	2.28	139.0	131	145
			Week 2	57	139.4	2.43	139.0	132	146
			Week 3	57	139.3	2.82	140.0	129	147
			Week 4	56	139.3	2.35	139.0	131	144
			Week 6	53	139.4	2.24	139.0	136	146
			Week 8	55	139.5	2.51	140.0	135	150
			Week 12	56	139.7	2.04	140.0	137	145
	45mg	61	Week -5	61	139.1	2.27	140.0	134	144
			Baseline	61	139.2	2.27	140.0	134	147
			Week 1	59	139.3	2.15	140.0	133	143
			Week 2	58	139.7	2.25	140.0	135	146
			Week 3	55	139.3	2.28	139.0	135	145
			Week 4	56	139.5	2.01	139.0	136	145

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Sodium (MMOL/L)	45mg	61	Week 6	54	138.9	4.30	139.0	111	144
			Week 8	54	139.3	2.75	140.0	126	144
			Week 12	54	139.8	2.25	140.0	133	144
Thyroid Stimulating Hormone (MU/L)	Placebo	64	Week -5	63	1.87	1.140	1.50	0.4	6.3
			Baseline	63	1.85	1.046	1.50	0.4	5.5
	2.5mg	61	Week -5	60	1.72	1.396	1.30	0.1	7.2
			Baseline	60	1.70	1.240	1.30	0.4	6.7
	7.5mg	63	Week -5	60	2.00	2.000	1.70	0.3	15.4
			Baseline	61	1.77	0.963	1.70	0.3	5.0
	15mg	66	Week -5	61	1.59	0.926	1.40	0.3	3.9
			Baseline	64	1.57	0.914	1.35	0.3	3.9
	30mg	60	Week -5	59	1.57	1.062	1.20	0.2	5.8
			Baseline	60	1.49	0.899	1.20	0.2	4.9
	45mg	61	Week -5	59	1.92	1.092	1.90	0.3	6.9
			Baseline	60	1.92	1.083	1.90	0.3	6.9
Total Bilirubin (UMOL/L)	Placebo	64	Week -5	64	10.8	4.73	10.0	4	31
			Baseline	64	11.4	5.55	10.0	4	36
			Week 1	61	10.6	4.86	10.0	4	30
			Week 2	60	11.0	5.17	10.0	5	28
			Week 3	55	10.7	4.59	10.0	6	29
			Week 4	55	10.3	4.37	9.0	4	27
			Week 6	53	10.5	4.01	10.0	5	24

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Bilirubin (UMOL/L)	Placebo	64	Week 8	51	11.2	4.64	10.0	5	30
			Week 12	49	10.8	5.30	10.0	4	37
	2.5mg	61	Week -5	61	11.5	5.69	10.0	6	30
			Baseline	61	12.2	5.49	11.0	6	36
			Week 1	59	12.3	5.25	12.0	5	32
			Week 2	58	11.5	5.01	10.0	4	30
			Week 3	56	12.5	5.09	12.0	6	29
			Week 4	56	11.3	4.54	10.0	4	30
			Week 6	48	12.4	5.18	11.0	5	31
			Week 8	48	11.3	4.31	10.0	6	23
			Week 12	46	11.8	5.27	10.0	6	29
	7.5mg	63	Week -5	61	11.8	4.70	11.0	5	31
			Baseline	63	11.7	5.07	11.0	4	37
			Week 1	60	12.0	5.23	11.0	6	33
			Week 2	59	10.9	4.12	11.0	4	26
			Week 3	59	11.1	4.41	10.0	6	31
			Week 4	56	10.6	3.31	10.0	5	22
			Week 6	56	11.1	4.59	10.0	4	28
			Week 8	54	11.0	4.44	10.0	5	26
			Week 12	54	11.0	4.72	10.0	4	28
	15mg	66	Week -5	62	10.5	4.35	10.0	4	26
			Baseline	66	10.6	4.99	9.5	6	35
			Week 1	63	10.0	3.80	9.0	4	22
			Week 2	62	9.8	3.63	9.0	6	23
			Week 3	59	9.7	3.63	9.0	4	25
			Week 4	60	10.6	4.64	9.0	6	25
			Week 6	60	9.5	3.30	9.0	4	21
			Week 8	60	10.0	4.32	9.0	4	28
			Week 12	58	10.1	3.96	10.0	6	24

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Bilirubin (UMOL/L)	30mg	60	Week -5	59	11.3	5.46	10.0	4	34
			Baseline	59	12.9	5.84	12.0	6	32
			Week 1	56	11.7	4.56	11.0	6	30
			Week 2	57	11.9	5.19	12.0	6	36
			Week 3	57	11.8	6.01	10.0	4	36
			Week 4	56	11.1	5.13	9.5	4	30
			Week 6	53	11.7	5.30	10.0	6	32
			Week 8	55	10.8	5.13	10.0	4	30
			Week 12	56	11.7	4.94	11.0	6	30
	45mg	61	Week -5	60	10.0	4.30	9.0	5	28
			Baseline	61	10.4	4.85	9.0	4	29
			Week 1	59	10.6	4.90	9.0	4	26
			Week 2	58	10.2	5.75	9.0	4	39
			Week 3	55	10.5	4.81	9.0	5	28
			Week 4	56	10.1	5.09	9.0	5	35
			Week 6	54	9.6	4.17	8.0	4	24
			Week 8	54	10.2	5.26	9.0	4	33
			Week 12	54	9.8	4.51	8.0	4	29
Total Neutrophils (GI/L)	Placebo	64	Week -5	63	3.842	1.4224	3.730	0.91	8.36
			Baseline	64	3.633	1.1184	3.535	1.15	6.06
			Week 1	56	3.664	1.1378	3.575	1.51	7.38
			Week 2	60	3.781	1.3418	3.665	1.48	7.45
			Week 3	55	3.868	1.5865	3.510	1.75	11.17
			Week 4	55	3.747	1.3625	3.700	1.07	9.36
			Week 6	53	3.571	1.0596	3.550	1.62	5.99
			Week 8	52	3.741	1.2032	3.625	1.42	7.23
			Week 12	44	3.783	1.1737	3.575	2.08	7.11
	2.5mg	61	Week -5	60	4.110	1.4229	4.015	1.93	7.55

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Neutrophils (GI/L)	2.5mg	61	Baseline	61	3.768	1.3364	3.600	1.47	7.11
			Week 1	60	3.894	1.6412	3.550	1.69	10.20
			Week 2	59	3.878	1.5090	3.450	1.59	9.64
			Week 3	58	3.808	1.3503	3.505	1.76	7.32
			Week 4	53	3.852	1.7909	3.430	1.30	9.79
			Week 6	51	4.130	1.6694	3.840	1.58	9.51
			Week 8	47	3.999	1.5771	3.740	1.47	8.34
			Week 12	48	4.050	1.4029	3.820	1.84	8.07
	7.5mg	63	Week -5	61	4.077	1.2009	3.990	1.58	7.04
			Baseline	63	3.960	1.2028	4.000	1.48	6.98
			Week 1	60	3.885	1.0903	3.895	1.63	6.83
			Week 2	59	4.255	1.5776	4.020	1.90	10.56
			Week 3	58	4.191	1.2501	4.050	1.91	7.09
			Week 4	56	4.128	1.1296	4.055	1.68	7.59
			Week 6	57	4.409	1.6786	4.220	1.79	9.18
			Week 8	53	4.218	1.3678	4.310	1.87	7.71
			Week 12	52	4.114	1.2561	4.040	1.31	7.24
	15mg	66	Week -5	62	4.182	1.3913	3.915	1.79	8.90
			Baseline	66	3.797	1.3517	3.500	1.32	8.38
			Week 1	63	3.992	1.4113	3.890	1.62	7.62
			Week 2	61	4.171	1.5031	3.930	2.04	8.25
			Week 3	58	4.166	1.3564	4.005	2.01	7.64
			Week 4	60	4.098	1.5642	3.930	1.28	9.31
			Week 6	60	4.193	1.6181	3.990	1.53	8.56
			Week 8	60	4.089	1.4669	3.755	1.18	7.54
			Week 12	59	4.101	1.4318	3.720	1.58	7.03
	30mg	60	Week -5	59	4.327	1.3968	4.280	2.24	9.19
			Baseline	60	4.073	1.2688	4.095	1.80	8.70
			Week 1	57	4.205	1.3741	4.040	1.92	8.79

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Neutrophils (GI/L)	30mg	60	Week 2	54	4.324	1.3895	4.170	1.98	7.41
			Week 3	57	4.237	1.3968	4.020	1.94	7.85
			Week 4	57	4.134	1.2370	4.030	1.67	7.06
			Week 6	56	4.213	1.4363	3.890	1.97	8.59
			Week 8	54	4.573	1.6671	4.245	1.85	9.36
			Week 12	53	4.578	1.9957	4.090	1.87	11.95
	45mg	61	Week -5	59	3.759	1.1187	3.540	1.38	6.98
			Baseline	60	3.820	1.5137	3.625	1.59	11.18
			Week 1	59	4.115	1.2688	4.120	1.54	7.11
			Week 2	60	4.163	1.4805	3.980	1.47	9.69
			Week 3	55	3.984	1.3320	3.900	1.60	9.66
			Week 4	56	4.075	1.7655	3.785	1.69	12.39
			Week 6	53	4.071	1.3414	3.890	1.45	8.89
			Week 8	56	4.091	1.2490	3.910	1.75	8.06
			Week 12	54	4.067	1.1809	4.195	1.80	6.47
Total Protein (G/L)	Placebo	64	Week -5	64	70.3	4.23	70.0	62	79
			Baseline	64	70.5	4.22	70.0	62	81
			Week 1	61	69.0	4.07	68.0	60	81
			Week 2	60	69.9	3.48	70.0	61	79
			Week 3	55	69.8	4.27	70.0	62	81
			Week 4	55	70.0	3.82	70.0	62	78
			Week 6	53	69.5	3.67	69.0	63	81
			Week 8	51	70.6	3.21	71.0	64	80
			Week 12	49	70.3	4.00	70.0	63	80
	2.5mg	61	Week -5	61	71.6	4.28	71.0	61	83
			Baseline	61	71.3	4.84	70.0	62	86
			Week 1	59	70.8	4.32	71.0	62	86
			Week 2	58	70.4	4.87	70.0	63	89

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Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Protein (G/L)	2.5mg	61	Week 3	56	70.1	4.44	70.0	60	82
			Week 4	56	71.1	4.78	71.0	58	82
			Week 6	49	70.9	4.78	71.0	61	81
			Week 8	48	71.3	4.85	71.0	64	84
			Week 12	46	71.8	5.02	71.0	62	85
	7.5mg	63	Week -5	61	72.3	4.64	73.0	63	86
			Baseline	63	71.2	3.97	71.0	62	84
			Week 1	60	70.6	3.90	71.0	61	79
			Week 2	59	71.2	3.72	71.0	63	78
			Week 3	59	70.8	4.08	71.0	62	79
			Week 4	57	71.5	4.22	71.0	62	82
			Week 6	56	70.7	3.84	71.0	61	79
			Week 8	54	71.6	3.90	72.0	63	81
			Week 12	54	71.9	4.37	72.0	63	84
	15mg	66	Week -5	62	71.2	4.33	71.0	62	82
			Baseline	66	70.9	4.41	70.5	61	81
			Week 1	63	69.6	4.20	69.0	61	79
			Week 2	62	70.2	3.88	70.0	61	78
			Week 3	59	69.7	3.81	70.0	60	79
			Week 4	60	70.6	3.63	70.5	61	79
			Week 6	60	70.0	4.25	69.0	61	79
			Week 8	60	70.2	4.62	70.0	59	82
			Week 12	58	70.2	3.66	71.0	61	77
	30mg	60	Week -5	59	71.6	4.14	72.0	64	79
			Baseline	59	71.3	4.58	71.0	61	82
			Week 1	56	70.7	4.16	70.5	62	81
			Week 2	57	70.9	4.08	71.0	61	82
			Week 3	57	70.9	4.03	71.0	62	80
			Week 4	56	71.3	4.39	70.5	64	85

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Protein (G/L)	30mg	60	Week 6	53	70.9	4.59	70.0	62	83
			Week 8	55	71.3	4.33	71.0	62	80
			Week 12	56	70.8	4.20	71.0	61	82
	45mg	61	Week -5	61	72.2	3.95	72.0	65	83
			Baseline	61	71.2	3.95	70.0	63	86
			Week 1	59	70.7	3.79	70.0	62	85
			Week 2	58	70.8	4.10	71.0	61	82
			Week 3	55	71.4	3.95	71.0	65	84
			Week 4	56	71.4	5.00	71.0	61	88
			Week 6	54	70.8	4.52	70.0	53	85
			Week 8	54	71.4	4.16	71.0	65	87
			Week 12	54	71.7	4.58	71.5	62	84
Urea (MMOL/L)	Placebo	64	Week -5	64	5.58	1.543	5.50	3.0	9.5
			Baseline	64	5.68	1.500	5.50	3.0	9.7
			Week 1	61	5.86	1.598	5.50	2.8	10.3
			Week 2	60	5.72	1.465	5.50	3.0	9.5
			Week 3	55	5.80	1.479	5.50	3.3	10.4
			Week 4	55	5.90	1.527	5.70	2.7	9.8
			Week 6	53	5.80	1.698	5.80	3.3	9.8
			Week 8	51	5.99	1.769	5.70	2.5	12.1
			Week 12	49	5.79	1.723	5.60	2.5	12.0
	2.5mg	61	Week -5	61	5.81	1.586	5.50	3.5	11.1
			Baseline	61	5.95	1.836	5.50	2.1	12.0
			Week 1	59	5.96	1.648	5.70	2.0	10.0
			Week 2	58	5.93	1.911	5.70	3.0	11.5
			Week 3	56	6.12	1.674	5.65	4.0	11.0
			Week 4	56	5.99	1.667	5.50	2.8	13.0
			Week 6	49	5.96	1.784	5.90	2.1	10.1

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urea (MMOL/L)	2.5mg	61	Week 8	48	6.15	1.701	5.85	3.0	12.2
			Week 12	46	5.90	1.728	5.80	2.5	10.5
	7.5mg	63	Week -5	61	5.50	1.376	5.50	2.2	9.9
			Baseline	63	5.59	1.318	5.70	3.0	8.8
			Week 1	60	5.44	1.269	5.50	2.4	8.6
			Week 2	59	5.46	1.306	5.40	3.0	8.7
			Week 3	59	5.36	1.352	5.30	2.7	9.3
			Week 4	57	5.54	1.236	5.50	2.5	8.9
			Week 6	56	5.59	1.281	5.50	3.1	9.1
			Week 8	54	5.52	1.330	5.40	3.0	8.1
			Week 12	54	5.54	1.246	5.50	3.0	8.9
	15mg	66	Week -5	62	5.95	1.561	5.50	3.0	11.1
			Baseline	66	5.76	1.815	5.45	3.0	12.1
			Week 1	63	5.78	1.633	5.50	3.0	12.9
			Week 2	62	5.70	1.770	5.55	2.5	13.8
			Week 3	59	5.84	1.710	5.70	2.5	11.0
			Week 4	60	5.70	1.569	5.55	3.0	12.4
			Week 6	60	5.96	1.756	5.90	3.0	13.6
			Week 8	60	5.80	1.637	5.50	3.0	11.8
			Week 12	58	5.82	1.565	5.75	3.5	11.5
	30mg	60	Week -5	59	5.29	1.388	5.10	2.5	9.7
			Baseline	59	5.55	1.470	5.30	3.0	10.2
			Week 1	56	5.29	1.320	5.10	2.9	10.1
			Week 2	57	5.38	1.464	5.30	3.0	11.0
			Week 3	57	5.16	1.434	4.80	2.5	9.8
			Week 4	56	5.74	1.487	5.50	3.0	10.1
			Week 6	53	5.42	1.409	5.20	1.9	10.4
			Week 8	55	5.58	1.451	5.40	3.0	10.2
			Week 12	56	5.61	1.637	5.10	3.2	10.7

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urea (MMOL/L)	45mg	61	Week -5	60	5.51	1.770	5.35	2.6	14.0
			Baseline	61	5.69	1.920	5.40	3.1	14.0
			Week 1	59	5.40	1.720	4.90	3.0	11.1
			Week 2	58	5.47	1.741	5.10	2.5	10.6
			Week 3	55	5.65	1.736	5.50	2.8	11.8
			Week 4	56	5.19	1.339	4.90	2.8	8.4
			Week 6	54	5.34	1.812	5.10	2.4	11.3
			Week 8	54	5.35	1.736	4.90	2.5	10.8
			Week 12	54	5.65	1.657	5.50	2.8	10.7
Uric Acid (UMOL/L)	Placebo	64	Week -5	64	333.8	85.72	320.5	195	710
			Baseline	64	322.1	79.77	310.0	204	652
			Week 1	61	324.2	90.35	300.0	174	600
			Week 2	60	320.9	73.86	320.0	180	482
			Week 3	55	319.3	87.62	301.0	186	609
			Week 4	55	316.5	79.74	312.0	180	503
			Week 6	53	310.4	74.93	310.0	164	502
			Week 8	51	311.4	81.03	296.0	174	596
			Week 12	49	310.8	81.68	292.0	180	544
	2.5mg	61	Week -5	61	335.4	85.76	319.0	197	560
			Baseline	61	321.7	92.67	311.0	151	610
			Week 1	59	323.2	93.86	320.0	166	590
			Week 2	58	312.8	100.87	296.0	160	640
			Week 3	56	314.2	91.99	293.5	180	620
			Week 4	56	317.9	85.14	295.5	198	550
			Week 6	49	318.3	84.35	310.0	177	570
			Week 8	48	303.7	77.84	298.5	157	490
			Week 12	46	302.7	80.33	287.5	152	570
	7.5mg	63	Week -5	61	323.2	84.59	338.0	151	582

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Uric Acid (UMOL/L)	7.5mg	63	Baseline	63	311.3	78.18	302.0	193	616
			Week 1	60	322.8	95.35	318.0	180	658
			Week 2	59	324.0	91.09	307.0	180	619
			Week 3	59	325.9	88.06	301.0	180	588
			Week 4	56	320.5	90.99	294.5	157	619
			Week 6	56	314.6	95.47	299.0	150	632
			Week 8	54	316.6	89.64	293.5	180	621
			Week 12	54	316.8	89.16	294.0	184	632
	15mg	66	Week -5	62	337.8	78.44	336.5	163	585
			Baseline	66	325.7	90.76	319.0	168	600
			Week 1	63	320.2	82.73	314.0	131	557
			Week 2	62	322.4	80.29	319.0	149	572
			Week 3	59	320.2	86.44	315.0	126	570
			Week 4	60	318.9	84.95	320.0	120	544
			Week 6	60	325.9	79.12	317.0	140	604
			Week 8	60	322.4	86.28	321.5	100	561
			Week 12	58	315.3	73.90	320.0	158	481
	30mg	60	Week -5	59	331.8	81.05	330.0	195	536
			Baseline	59	330.2	76.19	325.0	160	521
			Week 1	56	323.7	84.28	320.0	143	548
			Week 2	57	336.2	96.48	330.0	137	611
			Week 3	57	326.2	87.28	310.0	146	578
			Week 4	56	319.7	77.14	320.0	141	542
			Week 6	53	332.6	73.29	320.0	193	516
			Week 8	55	318.0	77.38	310.0	170	535
			Week 12	56	311.7	75.26	309.0	161	502
	45mg	61	Week -5	60	339.5	76.27	334.0	170	556
			Baseline	61	317.6	80.12	329.0	110	460
			Week 1	59	316.3	67.08	329.0	120	430

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Uric Acid (UMOL/L)	45mg	61	Week 2	58	323.9	89.88	332.5	120	613
			Week 3	55	315.3	77.81	323.0	120	468
			Week 4	56	309.5	76.37	312.5	140	421
			Week 6	54	312.7	70.96	322.0	140	428
			Week 8	54	311.4	68.86	300.0	160	450
			Week 12	54	321.6	72.60	313.5	208	482
White Blood Cell Count (GI/L)	Placebo	64	Week -5	63	6.52	1.743	6.20	2.9	12.3
			Baseline	64	6.25	1.422	6.15	2.7	9.3
			Week 1	56	6.21	1.375	6.10	3.2	9.9
			Week 2	60	6.45	1.725	6.25	3.2	11.7
			Week 3	55	6.45	1.759	6.00	3.7	14.0
			Week 4	55	6.26	1.489	6.30	3.7	11.8
			Week 6	53	6.18	1.477	5.90	3.3	10.4
			Week 8	52	6.42	1.456	6.35	3.2	10.6
			Week 12	44	6.42	1.409	6.10	4.2	10.2
	2.5mg	61	Week -5	60	6.79	1.778	6.50	3.6	10.7
			Baseline	61	6.35	1.568	6.10	3.8	10.5
			Week 1	60	6.64	2.041	6.10	3.8	13.2
			Week 2	59	6.56	1.924	6.10	3.8	13.2
			Week 3	58	6.55	1.803	6.25	3.7	11.2
			Week 4	53	6.53	2.275	5.80	3.0	13.5
			Week 6	51	6.92	2.117	6.60	3.6	13.3
			Week 8	47	6.64	1.794	6.50	3.9	10.8
			Week 12	48	6.64	1.746	6.70	4.1	12.4
	7.5mg	63	Week -5	61	6.79	1.453	6.80	3.8	9.7
			Baseline	63	6.73	1.472	6.60	3.6	9.9
			Week 1	60	6.66	1.546	6.60	3.6	9.6

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
White Blood Cell Count (GI/L)	7.5mg	63	Week 2	59	6.97	2.010	6.60	4.0	14.1
			Week 3	58	6.97	1.593	6.80	4.0	10.4
			Week 4	56	6.86	1.404	6.90	3.8	10.5
			Week 6	57	7.23	2.042	6.90	4.4	12.8
			Week 8	54	6.90	1.638	6.85	4.0	10.8
			Week 12	52	6.80	1.544	6.75	3.9	9.9
	15mg	66	Week -5	62	6.82	1.701	6.75	3.4	11.8
			Baseline	66	6.36	1.512	6.40	3.6	11.1
			Week 1	63	6.69	1.697	6.50	3.7	10.4
			Week 2	61	6.78	1.726	6.50	3.4	11.1
			Week 3	58	6.86	1.670	6.60	3.3	10.9
			Week 4	60	6.64	1.849	6.60	3.8	13.2
			Week 6	60	6.91	1.939	6.75	3.8	11.8
			Week 8	60	6.63	1.777	6.50	3.4	10.4
			Week 12	59	6.61	1.651	6.40	3.9	10.3
	30mg	60	Week -5	59	6.99	1.810	6.80	4.4	12.5
			Baseline	60	6.76	1.798	6.70	3.2	12.7
			Week 1	57	6.94	1.855	6.40	3.9	12.7
			Week 2	54	7.08	1.865	6.85	4.1	12.1
			Week 3	57	6.89	1.806	6.50	4.2	11.7
			Week 4	57	6.74	1.649	6.60	3.7	10.3
			Week 6	56	6.96	1.854	6.80	4.1	11.8
			Week 8	55	7.20	2.030	6.70	4.0	13.5
			Week 12	53	7.21	2.482	6.70	3.8	16.0
	45mg	61	Week -5	60	6.62	1.490	6.50	3.8	11.1
			Baseline	61	6.58	1.800	6.30	3.7	13.9
			Week 1	59	6.89	1.653	6.90	3.3	11.5
			Week 2	60	6.96	1.880	6.70	3.1	12.5

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Table 12.19
Summary Statistics of Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
White Blood Cell Count (GI/L)	45mg	61	Week 3	55	6.76	1.745	6.80	3.6	13.6
			Week 4	56	6.85	2.152	6.40	3.2	15.9
			Week 6	53	6.84	1.724	6.80	3.4	11.3
			Week 8	56	6.83	1.628	6.50	3.6	11.5
			Week 12	54	6.84	1.586	6.75	3.2	9.5

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	Placebo	64	Week -5	63	1.6	7.57	1.0	-22	22
			Week 1	61	-0.1	6.15	0.0	-15	33
			Week 2	60	-0.5	4.58	-1.0	-12	15
			Week 3	55	0.1	5.63	-1.0	-9	27
			Week 4	54	-1.4	5.27	-1.0	-21	11
			Week 6	53	-0.3	5.04	-1.0	-13	12
			Week 8	51	-0.7	6.86	-1.0	-23	15
			Week 12	49	-1.6	6.67	-2.0	-27	17
	2.5mg	61	Week -5	60	1.6	8.79	2.0	-35	28
			Week 1	59	-0.4	5.45	-1.0	-18	17
			Week 2	58	-2.7	9.00	-1.5	-51	11
			Week 3	56	-1.4	6.23	-1.0	-20	11
			Week 4	56	-1.9	8.41	-1.0	-40	28
			Week 6	49	-3.0	8.20	-1.0	-34	13
			Week 8	48	-4.5	8.67	-3.0	-39	15
			Week 12	46	-3.7	10.56	-0.5	-45	12
	7.5mg	63	Week -5	60	0.4	6.67	0.0	-13	23
			Week 1	60	-1.5	4.12	-2.0	-14	8
			Week 2	59	-1.0	7.57	-2.0	-15	45
			Week 3	59	-0.9	6.68	-1.0	-22	21
			Week 4	57	0.3	14.69	0.0	-31	92
			Week 6	56	-2.4	7.65	-1.0	-29	23
			Week 8	54	-0.9	11.19	-2.0	-31	47
			Week 12	54	-2.4	6.93	-2.0	-30	12
	15mg	66	Week -5	61	1.9	8.72	1.0	-17	47
			Week 1	63	-2.2	5.92	-1.0	-29	13
			Week 2	62	-1.3	7.67	-1.0	-29	34
			Week 3	59	-1.0	7.81	-2.0	-32	30

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	15mg	66	Week 4	60	-0.1	8.12	-1.0	-22	30
			Week 6	60	-1.1	9.33	-1.0	-24	39
			Week 8	60	-1.7	7.15	-1.0	-22	23
			Week 12	58	-1.2	9.01	-1.0	-20	50
	30mg	60	Week -5	59	-2.6	20.51	0.0	-145	25
			Week 1	55	-3.8	18.89	0.0	-133	13
			Week 2	56	-3.6	25.21	-1.5	-147	105
			Week 3	56	-4.4	21.54	-1.5	-149	17
			Week 4	55	-4.8	21.99	-1.0	-151	22
			Week 6	53	-2.8	10.23	0.0	-44	25
			Week 8	55	-4.2	22.25	-1.0	-151	26
			Week 12	55	-5.5	21.66	-2.0	-148	19
	45mg	61	Week -5	58	1.1	6.66	1.0	-29	18
			Week 1	59	-0.4	5.72	-1.0	-12	19
			Week 2	58	-0.4	10.79	-1.5	-15	72
			Week 3	55	-1.5	5.29	-2.0	-14	10
			Week 4	56	-1.2	8.78	-2.0	-19	41
			Week 6	54	-1.8	6.23	-2.0	-16	18
			Week 8	54	-2.0	7.18	-1.5	-20	27
			Week 12	54	-0.5	10.97	-1.0	-21	49
Albumin (G/L)	Placebo	64	Week -5	63	-0.2	2.51	0.0	-6	6
			Week 1	61	-0.5	2.31	0.0	-6	5
			Week 2	60	0.1	2.17	0.0	-4	8
			Week 3	55	-0.2	2.36	-1.0	-6	5
			Week 4	55	0.0	2.09	0.0	-6	4
			Week 6	53	-0.4	2.14	0.0	-7	3
			Week 8	51	0.7	2.35	1.0	-4	7

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Albumin (G/L)	Placebo	64	Week 12	49	0.3	2.59	0.0	-6	6
	2.5mg	61	Week -5	60	0.0	2.78	0.0	-7	7
			Week 1	59	0.2	2.44	0.0	-6	6
			Week 2	58	0.0	2.40	0.0	-7	5
			Week 3	56	-0.1	2.11	0.0	-5	4
			Week 4	56	0.3	2.50	0.0	-10	5
			Week 6	49	0.1	2.44	0.0	-6	5
			Week 8	48	0.3	2.25	0.0	-4	5
			Week 12	46	0.5	2.47	0.0	-5	7
	7.5mg	63	Week -5	60	0.7	2.46	1.0	-5	8
			Week 1	60	-0.3	2.47	0.0	-6	7
			Week 2	59	0.1	2.24	0.0	-6	5
			Week 3	59	-0.3	2.32	0.0	-7	5
			Week 4	57	0.4	2.23	0.0	-4	6
			Week 6	56	-0.3	2.68	0.0	-7	5
			Week 8	54	0.0	2.45	0.0	-6	6
			Week 12	54	0.4	2.35	1.0	-8	5
	15mg	66	Week -5	61	0.2	2.16	0.0	-4	5
			Week 1	63	-0.7	1.90	0.0	-5	3
			Week 2	62	-0.6	2.45	-1.0	-12	4
			Week 3	59	-0.5	2.39	0.0	-6	4
			Week 4	60	0.2	2.19	0.0	-4	5
			Week 6	60	-0.4	2.20	0.0	-6	6
			Week 8	60	-0.1	2.28	0.0	-5	5
			Week 12	58	-0.0	2.29	0.0	-6	6
	30mg	60	Week -5	59	0.1	3.02	0.0	-7	10
			Week 1	55	-0.3	2.49	0.0	-7	6
			Week 2	56	-0.3	1.94	0.0	-5	4

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Albumin (G/L)	30mg	60	Week 3	56	0.1	2.52	0.0	-5	5
			Week 4	55	0.0	2.67	0.0	-6	6
			Week 6	53	0.1	2.44	0.0	-6	5
			Week 8	55	0.3	2.20	0.0	-5	6
			Week 12	55	-0.0	2.50	0.0	-5	5
	45mg	61	Week -5	58	0.3	2.37	0.0	-5	9
			Week 1	59	0.2	2.11	0.0	-3	6
			Week 2	58	-0.1	2.29	-1.0	-6	5
			Week 3	55	0.4	2.02	0.0	-4	6
			Week 4	56	0.1	2.78	0.0	-6	10
			Week 6	54	-0.3	2.44	0.0	-11	5
			Week 8	54	0.2	2.29	0.0	-5	5
			Week 12	54	0.3	2.17	0.0	-5	5
Alkaline Phosphatase (IU/L)	Placebo	64	Week -5	63	-0.4	12.30	-1.0	-35	57
			Week 1	61	-1.4	6.69	-2.0	-23	14
			Week 2	60	-1.4	7.53	-2.0	-18	24
			Week 3	55	1.3	9.09	0.0	-12	33
			Week 4	55	-0.7	9.90	-2.0	-29	30
			Week 6	53	-0.2	9.33	-1.0	-26	25
			Week 8	51	0.8	10.57	0.0	-22	34
			Week 12	49	1.1	10.71	-1.0	-13	33
	2.5mg	61	Week -5	60	0.1	11.59	1.5	-29	29
			Week 1	59	-0.8	11.05	-1.0	-27	44
			Week 2	58	-0.0	11.33	0.0	-36	36
			Week 3	56	-0.5	10.10	1.0	-39	22
			Week 4	56	1.8	9.87	2.0	-20	36
			Week 6	49	0.5	13.14	1.0	-25	63
			Week 8	48	-2.3	12.35	1.0	-47	24

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	2.5mg	61	Week 12	46	-0.9	11.88	-1.5	-29	27
	7.5mg	63	Week -5	60	1.9	10.87	3.0	-38	37
			Week 1	60	-0.2	6.92	-0.5	-23	17
			Week 2	59	-1.6	9.91	-2.0	-46	14
			Week 3	59	0.2	10.63	0.0	-18	44
			Week 4	57	2.0	26.93	1.0	-27	186
			Week 6	56	0.1	9.80	0.0	-22	40
			Week 8	54	1.2	12.42	-0.5	-24	44
			Week 12	54	-0.1	12.05	-1.0	-26	30
	15mg	66	Week -5	61	-3.1	10.25	-3.0	-33	16
			Week 1	63	-1.0	9.98	0.0	-21	45
			Week 2	62	0.6	13.43	-1.0	-26	74
			Week 3	59	-1.6	10.76	-2.0	-35	34
			Week 4	60	-1.6	8.74	-2.0	-17	37
			Week 6	60	-2.7	8.42	-2.5	-22	21
			Week 8	60	-2.5	8.98	-3.0	-25	26
			Week 12	58	-3.9	8.73	-3.0	-34	22
	30mg	60	Week -5	59	1.9	12.38	0.0	-34	52
			Week 1	55	-0.0	7.56	-1.0	-28	23
			Week 2	56	-1.0	8.51	0.0	-30	22
			Week 3	56	-1.0	9.57	0.0	-29	33
			Week 4	55	0.1	14.90	1.0	-32	85
			Week 6	53	-1.4	9.70	-2.0	-25	19
			Week 8	55	0.1	11.40	-2.0	-33	33
			Week 12	55	-0.8	11.65	-2.0	-31	25
	45mg	61	Week -5	58	3.8	18.58	-1.0	-20	112
			Week 1	59	0.5	9.66	0.0	-21	33
			Week 2	58	0.7	12.94	-1.5	-24	47

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Alkaline Phosphatase (IU/L)	45mg	61	Week 3	55	-0.2	11.94	-1.0	-33	31
			Week 4	56	-0.1	12.88	-1.5	-37	40
			Week 6	54	-1.3	15.42	-3.5	-37	51
			Week 8	54	-1.3	15.29	-3.0	-22	79
			Week 12	54	-1.0	12.39	-1.0	-31	41
Aspartate Amino Transferase (IU/L)	Placebo	64	Week -5	62	0.0	5.50	0.0	-17	16
			Week 1	61	-0.4	6.63	-1.0	-9	43
			Week 2	60	-0.4	4.11	-1.0	-14	11
			Week 3	55	-0.1	5.40	-1.0	-12	30
			Week 4	55	-0.9	4.04	-1.0	-14	9
			Week 6	53	-0.1	5.61	-1.0	-10	33
			Week 8	51	-1.5	4.95	-1.0	-18	8
			Week 12	49	-0.7	4.28	-1.0	-15	12
	2.5mg	61	Week -5	59	-0.6	10.51	-1.0	-44	44
			Week 1	59	-0.6	8.67	0.0	-41	27
			Week 2	58	-1.6	9.05	-1.0	-37	29
			Week 3	56	-1.1	6.32	-1.0	-21	12
			Week 4	56	-2.5	9.23	-1.0	-40	24
			Week 6	48	-2.6	8.26	-1.5	-27	11
			Week 8	48	-3.2	7.56	-1.0	-28	12
			Week 12	46	-2.6	8.90	-0.5	-28	13
	7.5mg	63	Week -5	60	0.8	5.11	0.5	-9	17
			Week 1	60	-0.4	3.16	0.0	-11	9
			Week 2	59	0.2	5.67	0.0	-12	35
			Week 3	58	0.3	4.80	-0.5	-14	15
			Week 4	56	-0.4	5.02	0.0	-15	17
			Week 6	56	-0.4	5.43	-0.5	-15	19

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	7.5mg	63	Week 8	54	0.6	8.41	-0.5	-14	43
			Week 12	54	-0.3	5.62	0.0	-17	20
	15mg	66	Week -5	61	0.3	4.96	0.0	-13	16
			Week 1	63	-1.0	3.87	-1.0	-11	8
			Week 2	62	-0.4	4.15	0.0	-9	13
			Week 3	59	-0.4	4.91	1.0	-18	9
			Week 4	60	0.5	4.53	0.0	-9	11
			Week 6	60	0.3	5.82	0.0	-13	24
			Week 8	60	-0.6	4.92	0.0	-13	12
			Week 12	58	0.0	5.52	0.0	-11	29
	30mg	60	Week -5	59	-2.3	11.84	0.0	-68	21
			Week 1	55	-2.3	10.36	0.0	-70	8
			Week 2	56	-1.7	17.09	-2.0	-68	95
			Week 3	55	-2.5	10.69	-1.0	-67	13
			Week 4	55	-2.3	10.86	-1.0	-72	13
			Week 6	53	-1.0	7.29	0.0	-32	15
			Week 8	55	-1.7	11.29	-1.0	-71	20
			Week 12	55	-2.2	10.02	-1.0	-64	16
	45mg	61	Week -5	58	1.1	5.50	1.0	-13	22
			Week 1	59	0.5	5.12	0.0	-16	17
			Week 2	57	0.3	8.69	-1.0	-18	55
			Week 3	55	0.5	5.77	0.0	-11	19
			Week 4	56	-0.2	4.63	0.0	-10	15
			Week 6	54	-0.7	5.95	-1.0	-16	21
			Week 8	54	-0.8	4.89	0.0	-15	12
			Week 12	54	0.5	6.97	-1.0	-9	30

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Basophils (GI/L)	Placebo	64	Week -5	62	-0.001	0.0140	0.000	-0.03	0.03
			Week 1	56	0.002	0.0128	0.000	-0.03	0.03
			Week 2	60	0.002	0.0174	0.000	-0.03	0.08
			Week 3	55	-0.002	0.0138	0.000	-0.04	0.04
			Week 4	55	0.002	0.0116	0.000	-0.02	0.02
			Week 6	53	0.000	0.0149	0.000	-0.03	0.05
			Week 8	52	0.001	0.0125	0.000	-0.02	0.04
			Week 12	44	0.000	0.0164	0.000	-0.04	0.05
	2.5mg	61	Week -5	58	0.001	0.0126	0.000	-0.03	0.02
			Week 1	60	0.001	0.0151	0.000	-0.03	0.07
			Week 2	59	-0.002	0.0118	0.000	-0.02	0.03
			Week 3	58	0.001	0.0114	0.000	-0.02	0.03
			Week 4	53	-0.001	0.0125	0.000	-0.03	0.03
			Week 6	51	-0.001	0.0139	0.000	-0.03	0.04
			Week 8	47	-0.000	0.0145	0.000	-0.03	0.05
			Week 12	48	-0.001	0.0112	0.000	-0.02	0.02
	7.5mg	63	Week -5	59	-0.002	0.0156	0.000	-0.06	0.02
			Week 1	60	-0.003	0.0155	0.000	-0.06	0.03
			Week 2	59	0.000	0.0144	0.000	-0.04	0.03
			Week 3	58	-0.001	0.0162	0.000	-0.06	0.05
			Week 4	56	0.000	0.0163	0.000	-0.05	0.04
			Week 6	57	-0.001	0.0175	0.000	-0.04	0.04
			Week 8	53	0.003	0.0233	0.000	-0.03	0.14
			Week 12	52	-0.004	0.0152	0.000	-0.06	0.03
	15mg	66	Week -5	61	0.001	0.0135	0.000	-0.03	0.03
			Week 1	63	-0.001	0.0128	0.000	-0.03	0.03
			Week 2	61	-0.003	0.0106	0.000	-0.02	0.03
			Week 3	58	0.004	0.0136	0.000	-0.02	0.05
			Week 4	60	-0.000	0.0131	0.000	-0.03	0.04

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Basophils (GI/L)	15mg	66	Week 6	60	-0.001	0.0120	0.000	-0.03	0.04
			Week 8	60	-0.003	0.0129	-0.005	-0.02	0.03
			Week 12	59	-0.003	0.0111	0.000	-0.02	0.03
	30mg	60	Week -5	58	0.002	0.0127	0.000	-0.03	0.03
			Week 1	57	-0.002	0.0152	0.000	-0.04	0.04
			Week 2	54	-0.003	0.0150	0.000	-0.04	0.03
			Week 3	57	-0.000	0.0163	0.000	-0.04	0.05
			Week 4	57	-0.001	0.0131	0.000	-0.03	0.03
			Week 6	56	-0.001	0.0141	0.000	-0.03	0.03
			Week 8	54	-0.003	0.0148	0.000	-0.04	0.04
			Week 12	53	-0.002	0.0145	0.000	-0.04	0.03
	45mg	61	Week -5	58	0.003	0.0147	0.000	-0.04	0.05
			Week 1	58	0.000	0.0144	0.000	-0.03	0.04
			Week 2	59	-0.000	0.0144	0.000	-0.04	0.04
			Week 3	54	0.003	0.0141	0.000	-0.02	0.04
			Week 4	55	0.001	0.0149	0.000	-0.03	0.05
			Week 6	52	0.001	0.0167	0.000	-0.04	0.04
			Week 8	55	0.001	0.0135	0.000	-0.03	0.03
			Week 12	53	0.001	0.0175	0.000	-0.05	0.03
Calcium (MMOL/L)	Placebo	64	Week -5	62	0.005	0.1477	0.005	-0.26	0.76
			Week 1	61	-0.040	0.1064	-0.040	-0.27	0.16
			Week 2	60	-0.045	0.1551	-0.030	-0.72	0.24
			Week 3	55	-0.085	0.1874	-0.060	-0.81	0.20
			Week 4	55	-0.031	0.1259	-0.030	-0.38	0.22
			Week 6	53	-0.059	0.1653	-0.030	-0.83	0.20
			Week 8	51	-0.033	0.1187	-0.020	-0.39	0.24
			Week 12	49	-0.042	0.1245	-0.030	-0.42	0.27

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Calcium (MMOL/L)	2.5mg	61	Week -5	59	0.019	0.2035	0.000	-0.81	0.84
			Week 1	59	0.023	0.1552	0.000	-0.49	0.65
			Week 2	58	-0.005	0.1624	0.000	-0.63	0.65
			Week 3	56	-0.022	0.1498	-0.010	-0.49	0.39
			Week 4	56	0.013	0.1684	0.005	-0.38	0.87
			Week 6	48	0.011	0.1521	0.005	-0.52	0.45
			Week 8	48	0.023	0.2039	0.020	-0.65	0.78
			Week 12	46	0.021	0.1337	0.020	-0.33	0.52
	7.5mg	63	Week -5	58	0.045	0.1293	0.025	-0.16	0.76
			Week 1	59	-0.030	0.1849	0.000	-0.57	0.74
			Week 2	58	-0.012	0.1477	0.000	-0.54	0.26
			Week 3	56	-0.001	0.1175	0.005	-0.44	0.43
			Week 4	55	0.001	0.1855	-0.020	-0.68	0.64
			Week 6	55	-0.020	0.1324	0.000	-0.51	0.36
			Week 8	53	-0.005	0.1668	-0.020	-0.48	0.74
			Week 12	53	0.020	0.1498	0.000	-0.26	0.76
	15mg	66	Week -5	61	0.029	0.1111	0.010	-0.24	0.41
			Week 1	63	-0.012	0.1020	-0.010	-0.31	0.24
			Week 2	62	-0.026	0.1126	-0.015	-0.32	0.20
			Week 3	59	-0.017	0.1607	-0.020	-0.73	0.32
			Week 4	60	-0.001	0.0998	0.000	-0.17	0.29
			Week 6	60	-0.012	0.1313	-0.015	-0.49	0.24
			Week 8	60	-0.019	0.1173	-0.020	-0.36	0.28
			Week 12	58	-0.001	0.1060	-0.015	-0.20	0.32
	30mg	60	Week -5	59	0.010	0.0898	0.000	-0.16	0.29
			Week 1	55	-0.006	0.1230	-0.010	-0.50	0.33
			Week 2	56	0.000	0.1139	0.000	-0.31	0.29
			Week 3	55	0.001	0.1088	0.020	-0.22	0.28
			Week 4	55	0.003	0.1029	0.000	-0.24	0.32

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Calcium (MMOL/L)	30mg	60	Week 6	53	-0.007	0.1020	0.000	-0.30	0.23
			Week 8	55	-0.008	0.0941	-0.010	-0.23	0.17
			Week 12	55	-0.036	0.1571	-0.010	-0.66	0.22
	45mg	61	Week -5	59	0.010	0.1160	0.000	-0.21	0.44
			Week 1	59	-0.003	0.1394	-0.010	-0.63	0.50
			Week 2	57	-0.035	0.1881	-0.010	-0.90	0.37
			Week 3	55	0.003	0.1211	-0.020	-0.46	0.44
			Week 4	56	0.003	0.1415	0.000	-0.57	0.41
			Week 6	54	-0.069	0.1728	-0.020	-0.76	0.19
			Week 8	54	-0.003	0.1069	0.010	-0.35	0.22
			Week 12	54	-0.012	0.1191	-0.020	-0.32	0.32
Carbon Dioxide content / Bicarbonate (MMOL/L)	Placebo	64	Week -5	62	0.0	2.83	0.0	-8	7
			Week 1	61	0.5	2.61	1.0	-5	7
			Week 2	60	0.1	2.77	0.0	-8	8
			Week 3	55	0.6	2.86	1.0	-8	6
			Week 4	55	-0.2	3.56	0.0	-12	6
			Week 6	53	0.5	2.74	1.0	-9	6
			Week 8	51	0.2	3.06	1.0	-7	4
			Week 12	49	-0.2	2.62	0.0	-9	6
	2.5mg	61	Week -5	59	0.0	3.05	0.0	-8	7
			Week 1	59	-0.0	3.24	0.0	-8	7
			Week 2	58	-0.6	2.88	-0.5	-8	6
			Week 3	56	-0.3	3.44	0.0	-8	5
			Week 4	56	-0.6	3.17	0.0	-9	6
			Week 6	48	0.6	2.77	1.0	-5	6
			Week 8	48	-0.5	3.21	-1.0	-8	7
			Week 12	46	0.0	3.03	-1.0	-7	5

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Carbon Dioxide content / Bicarbonate (MMOL/L)	7.5mg	63	Week -5	59	0.5	2.91	0.0	-7	6
			Week 1	60	0.3	3.73	0.0	-8	8
			Week 2	59	0.1	2.91	1.0	-9	7
			Week 3	57	0.3	3.02	1.0	-6	5
			Week 4	56	0.0	2.74	0.0	-7	6
			Week 6	56	0.3	2.86	0.0	-9	7
			Week 8	54	0.1	3.16	0.0	-8	7
			Week 12	54	-0.3	2.92	0.0	-10	5
	15mg	66	Week -5	61	0.0	3.19	1.0	-8	10
			Week 1	63	0.5	3.25	1.0	-7	6
			Week 2	62	0.0	2.79	0.0	-7	6
			Week 3	59	-0.0	3.04	0.0	-7	7
			Week 4	60	-0.1	2.67	0.0	-7	7
			Week 6	60	0.2	2.36	1.0	-8	4
			Week 8	60	-0.3	2.80	0.0	-11	6
			Week 12	58	-0.1	2.75	0.0	-7	5
	30mg	60	Week -5	59	1.1	3.35	1.0	-7	7
			Week 1	55	1.3	3.12	2.0	-7	7
			Week 2	56	0.7	2.78	1.0	-4	11
			Week 3	55	1.4	3.49	1.0	-6	10
			Week 4	55	-0.0	3.89	0.0	-9	9
			Week 6	53	1.3	3.74	1.0	-8	10
			Week 8	55	0.3	3.22	1.0	-8	8
			Week 12	55	0.8	3.29	1.0	-6	10
	45mg	61	Week -5	59	-0.3	3.25	0.0	-8	6
			Week 1	59	0.3	2.84	0.0	-6	8
			Week 2	57	0.2	3.07	0.0	-9	7
			Week 3	55	0.1	3.21	0.0	-9	7

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Carbon Dioxide content / Bicarbonate (MMOL/L)	45mg	61	Week 4	56	-0.6	3.35	-0.5	-10	5
			Week 6	54	0.2	3.08	0.0	-8	6
			Week 8	54	-0.7	2.90	-0.5	-7	5
			Week 12	54	-0.6	3.53	-1.0	-7	8
Chloride (MMOL/L)	Placebo	64	Week -5	63	0.2	2.96	0.0	-5	12
			Week 1	61	0.7	2.40	1.0	-5	12
			Week 2	60	0.2	2.28	0.0	-4	8
			Week 3	55	0.7	2.54	1.0	-5	10
			Week 4	55	0.5	2.45	0.0	-3	7
			Week 6	53	0.6	2.66	0.0	-4	10
			Week 8	51	-0.0	3.01	0.0	-6	10
			Week 12	49	0.0	3.51	0.0	-8	12
	2.5mg	61	Week -5	60	-0.4	2.57	0.0	-9	5
			Week 1	59	-0.2	2.53	0.0	-5	7
			Week 2	58	-0.4	2.13	-0.5	-6	4
			Week 3	56	0.0	2.63	0.5	-6	5
			Week 4	56	-0.7	2.28	-1.0	-5	5
			Week 6	49	-0.1	2.69	0.0	-8	7
			Week 8	48	-0.2	2.33	0.0	-5	6
			Week 12	46	-0.5	2.65	-1.0	-7	6
	7.5mg	63	Week -5	60	-0.3	2.93	0.0	-11	6
			Week 1	60	0.6	2.38	0.5	-4	8
			Week 2	59	0.5	2.28	0.0	-4	8
			Week 3	59	0.4	2.47	1.0	-5	5
			Week 4	57	-0.1	2.26	0.0	-7	4
			Week 6	56	0.3	2.11	0.0	-6	5
			Week 8	54	-0.1	2.77	0.0	-10	4

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Chloride (MMOL/L)	7.5mg	63	Week 12	54	0.2	2.41	0.0	-8	5
	15mg	66	Week -5	61	-0.0	2.87	0.0	-6	5
			Week 1	63	0.4	2.34	1.0	-7	5
			Week 2	62	0.7	2.50	1.0	-4	6
			Week 3	59	0.7	2.43	1.0	-6	7
			Week 4	60	0.0	2.24	0.0	-7	5
			Week 6	60	0.4	2.17	0.0	-6	5
			Week 8	60	0.7	2.47	1.0	-3	11
			Week 12	58	0.3	2.35	0.0	-5	5
	30mg	60	Week -5	58	-0.1	3.12	0.0	-11	6
			Week 1	55	0.9	2.23	1.0	-6	6
			Week 2	56	0.7	2.63	1.0	-11	6
			Week 3	56	0.6	2.18	0.0	-4	5
			Week 4	55	0.9	2.73	0.0	-7	8
			Week 6	53	0.8	2.64	1.0	-7	9
			Week 8	55	0.9	2.10	1.0	-3	6
			Week 12	55	0.1	2.68	0.0	-6	6
	45mg	61	Week -5	59	-0.1	2.86	0.0	-8	8
			Week 1	59	0.5	2.65	0.0	-6	8
			Week 2	58	0.7	2.82	1.0	-6	9
			Week 3	55	0.7	3.53	1.0	-7	9
			Week 4	56	0.7	2.61	0.5	-6	6
			Week 6	54	0.4	3.75	1.0	-18	7
			Week 8	54	0.7	3.24	1.0	-14	7
			Week 12	54	0.9	2.73	1.0	-6	7
Creatinine (UMOL/L)	Placebo	64	Week -5	63	0.4	8.35	0.0	-17	26
			Week 1	61	1.2	9.20	0.0	-17	44

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatinine (UMOL/L)	Placebo	64	Week 2	60	0.6	8.42	0.0	-27	27
			Week 3	55	-0.1	10.18	0.0	-26	29
			Week 4	55	-0.4	6.89	0.0	-17	20
			Week 6	53	-1.2	8.62	0.0	-27	18
			Week 8	51	1.4	8.82	0.0	-15	27
			Week 12	49	0.1	13.66	0.0	-43	62
	2.5mg	61	Week -5	60	-0.4	9.49	0.0	-18	41
			Week 1	59	2.1	8.40	0.0	-11	35
			Week 2	58	1.6	7.35	0.0	-11	21
			Week 3	56	1.1	6.76	0.0	-19	19
			Week 4	56	1.7	7.16	0.0	-10	26
			Week 6	49	1.8	7.33	1.0	-17	20
			Week 8	48	0.9	9.21	0.0	-18	27
			Week 12	46	0.7	9.42	0.0	-19	26
	7.5mg	63	Week -5	59	-2.1	10.85	-1.0	-38	25
			Week 1	60	0.3	8.67	0.0	-20	28
			Week 2	59	1.0	10.64	0.0	-20	43
			Week 3	59	1.5	7.87	0.0	-18	26
			Week 4	56	0.3	8.19	0.0	-33	23
			Week 6	56	1.1	8.10	1.5	-20	20
			Week 8	54	1.3	9.64	0.0	-18	34
			Week 12	54	1.2	7.08	0.0	-17	19
	15mg	66	Week -5	61	-0.5	7.03	0.0	-24	13
			Week 1	63	-0.5	8.49	0.0	-34	21
			Week 2	62	0.8	8.31	0.0	-37	19
			Week 3	59	-0.2	7.90	0.0	-24	16
			Week 4	60	0.6	6.62	0.0	-15	22
			Week 6	60	0.3	7.36	0.0	-24	18
			Week 8	60	0.6	7.34	0.0	-27	18

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatinine (UMOL/L)	15mg	66	Week 12	58	1.4	7.95	0.0	-23	27
	30mg	60	Week -5	59	-0.8	7.78	0.0	-26	18
			Week 1	55	0.9	5.91	0.0	-18	17
			Week 2	56	3.3	6.80	3.0	-11	28
			Week 3	56	3.4	7.65	2.0	-15	27
			Week 4	55	1.3	6.46	0.0	-9	25
			Week 6	53	1.1	11.47	0.0	-53	27
			Week 8	55	1.9	8.24	2.0	-18	22
			Week 12	55	1.4	8.15	0.0	-13	25
	45mg	61	Week -5	58	-0.9	11.27	0.0	-48	26
			Week 1	59	0.9	8.63	0.0	-25	27
			Week 2	58	1.2	10.65	1.5	-28	23
			Week 3	55	3.1	11.13	2.0	-39	47
			Week 4	56	-0.6	10.58	1.0	-51	18
			Week 6	54	0.9	15.13	0.0	-70	53
			Week 8	54	-0.7	11.02	0.0	-39	27
			Week 12	54	-0.5	10.08	0.0	-31	27
Direct Bilirubin (UMOL/L)	Placebo	64	Week -5	63	0.0	1.38	0.0	-2	8
			Week 1	61	0.1	1.12	0.0	-2	4
			Week 2	60	-0.0	1.01	0.0	-2	3
			Week 3	55	0.0	0.99	0.0	-2	2
			Week 4	55	-0.1	1.08	0.0	-2	2
			Week 6	53	0.0	1.02	0.0	-2	3
			Week 8	51	0.1	1.10	0.0	-2	3
			Week 12	49	-0.0	1.03	0.0	-2	2
	2.5mg	61	Week -5	60	-0.2	0.99	0.0	-2	3
			Week 1	59	-0.1	0.95	0.0	-2	4

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	2.5mg	61	Week 2	58	-0.3	0.95	0.0	-2	2
			Week 3	56	0.1	0.97	0.0	-2	2
			Week 4	56	-0.2	1.11	0.0	-2	3
			Week 6	49	-0.2	1.07	0.0	-2	3
			Week 8	48	-0.3	0.94	0.0	-2	2
			Week 12	45	-0.2	0.90	0.0	-2	2
	7.5mg	63	Week -5	60	0.0	0.90	0.0	-2	2
			Week 1	60	-0.1	1.02	0.0	-2	4
			Week 2	59	-0.2	0.97	0.0	-2	2
			Week 3	59	-0.1	0.97	0.0	-2	2
			Week 4	56	-0.2	0.80	0.0	-2	2
			Week 6	56	0.0	1.10	0.0	-2	4
			Week 8	54	-0.1	0.98	0.0	-2	2
			Week 12	54	0.0	0.66	0.0	-2	1
	15mg	66	Week -5	61	-0.1	0.94	0.0	-2	2
			Week 1	63	-0.2	0.89	0.0	-2	2
			Week 2	62	-0.1	0.80	0.0	-2	2
			Week 3	59	-0.2	1.03	0.0	-3	2
			Week 4	60	-0.1	0.85	0.0	-2	2
			Week 6	60	-0.2	0.85	0.0	-2	1
			Week 8	60	-0.1	0.84	0.0	-2	2
			Week 12	58	-0.2	1.01	0.0	-2	2
	30mg	60	Week -5	59	-0.2	1.18	0.0	-4	2
			Week 1	55	-0.2	1.09	0.0	-4	2
			Week 2	56	-0.1	1.04	0.0	-2	2
			Week 3	56	-0.2	1.17	0.0	-4	2
			Week 4	55	-0.4	1.24	0.0	-4	2
			Week 6	53	-0.1	1.31	0.0	-4	4
			Week 8	55	-0.5	1.12	0.0	-4	2

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	30mg	60	Week 12	55	-0.1	1.29	0.0	-3	2
	45mg	61	Week -5	58	0.0	1.20	0.0	-5	2
			Week 1	59	0.1	1.11	0.0	-2	3
			Week 2	58	0.1	1.19	0.0	-3	3
			Week 3	55	0.1	1.01	0.0	-2	2
			Week 4	56	0.0	1.06	0.0	-4	2
			Week 6	54	-0.1	1.20	0.0	-4	3
			Week 8	54	-0.1	1.39	0.0	-4	3
			Week 12	54	-0.1	1.12	0.0	-4	3
Eosinophils (GI/L)	Placebo	64	Week -5	62	0.010	0.1174	0.000	-0.53	0.45
			Week 1	56	0.016	0.0993	0.010	-0.16	0.61
			Week 2	60	0.020	0.1214	0.010	-0.37	0.56
			Week 3	55	-0.007	0.1120	0.000	-0.57	0.31
			Week 4	55	-0.001	0.1180	-0.010	-0.51	0.36
			Week 6	53	-0.008	0.1226	0.010	-0.51	0.49
			Week 8	52	-0.003	0.1088	-0.005	-0.31	0.33
			Week 12	44	0.013	0.1196	0.005	-0.33	0.33
	2.5mg	61	Week -5	58	-0.016	0.1109	0.000	-0.63	0.16
			Week 1	60	0.003	0.1271	0.000	-0.26	0.69
			Week 2	59	0.012	0.0967	0.000	-0.23	0.35
			Week 3	58	-0.000	0.0774	0.005	-0.22	0.18
			Week 4	53	-0.027	0.0799	-0.030	-0.24	0.18
			Week 6	51	-0.018	0.0841	-0.010	-0.30	0.17
			Week 8	47	-0.016	0.0970	0.000	-0.42	0.23
			Week 12	48	-0.022	0.1164	0.000	-0.53	0.17
	7.5mg	63	Week -5	59	-0.010	0.1200	0.000	-0.38	0.35
			Week 1	60	0.001	0.1104	0.010	-0.30	0.38

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Eosinophils (GI/L)	7.5mg	63	Week 2	59	-0.008	0.1082	0.000	-0.23	0.45
			Week 3	58	-0.014	0.1000	-0.010	-0.35	0.29
			Week 4	56	0.014	0.1329	0.005	-0.40	0.46
			Week 6	57	0.012	0.1434	0.010	-0.41	0.63
			Week 8	53	-0.004	0.0958	-0.010	-0.32	0.35
			Week 12	52	-0.013	0.1203	-0.010	-0.34	0.42
	15mg	66	Week -5	61	0.025	0.1180	0.010	-0.22	0.76
			Week 1	63	0.036	0.0814	0.020	-0.13	0.21
			Week 2	61	0.002	0.0616	0.000	-0.21	0.15
			Week 3	58	0.024	0.0804	0.015	-0.17	0.35
			Week 4	60	-0.001	0.0766	0.000	-0.29	0.24
			Week 6	60	0.016	0.0875	0.015	-0.19	0.34
			Week 8	60	0.003	0.1946	-0.010	-0.26	1.38
			Week 12	59	0.006	0.0904	0.010	-0.29	0.26
	30mg	60	Week -5	58	0.009	0.1102	-0.005	-0.26	0.36
			Week 1	57	-0.014	0.1026	-0.010	-0.41	0.39
			Week 2	54	-0.015	0.0926	-0.010	-0.39	0.11
			Week 3	57	0.007	0.1013	0.000	-0.27	0.29
			Week 4	57	-0.011	0.0970	-0.020	-0.40	0.22
			Week 6	56	0.006	0.1248	0.010	-0.37	0.57
			Week 8	54	-0.025	0.1146	-0.005	-0.40	0.31
			Week 12	53	-0.023	0.1464	-0.010	-0.49	0.40
	45mg	61	Week -5	58	0.014	0.0750	0.020	-0.22	0.19
			Week 1	58	0.003	0.0649	0.000	-0.20	0.30
			Week 2	59	0.015	0.0571	0.010	-0.16	0.18
			Week 3	54	0.001	0.0622	0.010	-0.20	0.16
			Week 4	55	0.015	0.0592	0.010	-0.12	0.22
			Week 6	52	-0.002	0.0574	-0.005	-0.15	0.17
			Week 8	55	-0.004	0.0697	0.000	-0.20	0.16

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Eosinophils (GI/L)	45mg	61	Week 12	53	0.008	0.0819	0.010	-0.23	0.18
Glucose (MMOL/L)	Placebo	64	Week -6	64	-0.12	2.440	0.05	-6.2	4.9
			Week -5	63	-0.17	2.093	0.00	-6.7	6.4
			Week -4	64	0.10	2.167	0.15	-5.6	8.2
			Week -2	61	-0.02	1.663	0.10	-5.7	5.7
			Week 1	61	0.33	1.247	0.40	-2.9	3.1
			Week 2	60	0.34	1.388	0.05	-2.7	4.6
			Week 3	55	0.33	1.491	0.20	-4.2	4.6
			Week 4	56	0.11	1.636	0.10	-4.1	5.0
			Week 6	53	0.08	1.563	0.00	-3.5	4.5
			Week 8	53	0.26	1.787	0.00	-2.6	5.4
			Week 12	49	0.43	2.158	0.00	-3.9	5.1
	2.5mg	61	Week -6	58	-0.27	2.438	-0.20	-5.8	5.8
			Week -5	59	-0.00	2.245	0.30	-7.1	3.2
			Week -4	59	0.19	2.058	0.20	-3.6	6.7
			Week -2	56	0.33	1.678	0.20	-3.7	6.8
			Week 1	58	0.18	2.178	0.15	-9.2	6.6
			Week 2	58	0.23	2.113	0.10	-7.5	5.7
			Week 3	57	0.16	1.983	0.30	-7.4	6.7
			Week 4	52	0.26	1.992	0.00	-5.5	6.7
			Week 6	50	0.19	2.210	0.00	-7.1	7.3
			Week 8	46	0.21	2.029	0.00	-5.6	5.0
			Week 12	47	0.16	2.276	0.00	-4.8	6.8
	7.5mg	63	Week -6	61	-0.48	2.220	-0.40	-5.3	4.4
			Week -5	62	-0.66	2.130	-0.20	-6.4	4.6
			Week -4	62	-0.37	2.209	-0.10	-5.2	5.0
			Week -2	61	0.06	1.668	0.00	-4.3	3.7
			Week 1	62	-0.45	1.462	-0.40	-6.5	2.6

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Glucose (MMOL/L)	7.5mg	63	Week 2	60	-0.36	1.567	-0.20	-6.1	3.7
			Week 3	59	-0.75	1.801	-0.50	-8.1	2.8
			Week 4	57	-0.62	2.287	-0.30	-8.0	7.0
			Week 6	57	-0.69	2.182	-0.60	-7.6	6.5
			Week 8	56	-0.70	2.099	-0.50	-7.1	5.6
			Week 12	53	-0.38	2.679	-0.10	-8.6	8.0
	15mg	66	Week -6	62	-0.25	2.505	-0.70	-5.5	8.6
			Week -5	63	-0.49	2.066	-0.90	-4.3	5.1
			Week -4	62	-0.13	1.481	-0.15	-3.7	4.2
			Week -2	66	-0.02	1.261	0.05	-2.8	3.9
			Week 1	63	-0.11	1.782	-0.50	-4.6	5.2
			Week 2	63	-0.25	1.460	-0.40	-2.8	4.0
			Week 3	60	-0.25	1.638	-0.15	-4.9	4.0
			Week 4	60	-0.40	1.528	-0.45	-5.4	4.2
			Week 6	60	-0.24	1.387	-0.35	-3.4	3.7
			Week 8	60	-0.29	1.574	-0.50	-3.6	3.9
			Week 12	59	-0.01	1.950	-0.20	-3.0	6.9
	30mg	60	Week -6	60	-0.36	2.268	-0.20	-7.3	4.8
			Week -5	58	-0.38	2.098	-0.30	-7.9	4.7
			Week -4	60	-0.37	1.863	0.00	-8.2	3.3
			Week -2	58	-0.18	1.786	0.00	-6.0	4.6
			Week 1	58	-0.72	1.080	-0.60	-3.7	1.9
			Week 2	57	-0.66	1.514	-0.50	-5.0	3.0
			Week 3	56	-0.77	1.585	-0.60	-6.8	4.1
			Week 4	57	-1.21	1.527	-0.90	-6.6	1.1
			Week 6	57	-0.98	1.644	-0.70	-5.6	2.0
			Week 8	56	-0.75	1.801	-0.55	-6.3	4.8
			Week 12	56	-0.99	2.185	-0.65	-7.8	4.4
	45mg	61	Week -6	58	-0.45	1.957	-0.55	-4.4	4.7

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Glucose (MMOL/L)	45mg	61	Week -5	59	-0.31	2.030	-0.70	-4.4	4.3
			Week -4	59	-0.17	1.756	-0.20	-4.1	4.3
			Week -2	60	-0.02	1.914	0.10	-8.9	4.5
			Week 1	59	-0.72	1.617	-0.50	-6.5	3.8
			Week 2	59	-0.69	2.059	-0.50	-11.2	2.8
			Week 3	55	-0.93	1.833	-1.00	-5.5	4.7
			Week 4	56	-1.44	1.732	-1.15	-8.4	2.5
			Week 6	54	-0.84	1.900	-0.85	-6.2	3.5
			Week 8	55	-1.19	1.808	-1.10	-8.2	3.7
			Week 12	54	-0.83	2.097	-0.70	-6.9	4.4
Hematocrit (1)	Placebo	64	Week -5	62	-0.005	0.0310	-0.001	-0.14	0.07
			Week 1	56	-0.010	0.0267	-0.006	-0.14	0.03
			Week 2	60	-0.006	0.0262	-0.002	-0.14	0.04
			Week 3	55	-0.008	0.0298	-0.005	-0.15	0.05
			Week 4	55	-0.010	0.0332	-0.006	-0.14	0.07
			Week 6	53	-0.013	0.0320	-0.013	-0.16	0.05
			Week 8	52	-0.006	0.0361	-0.001	-0.19	0.04
			Week 12	45	-0.006	0.0225	-0.005	-0.07	0.03
	2.5mg	61	Week -5	58	0.002	0.0333	0.008	-0.17	0.06
			Week 1	60	-0.007	0.0321	-0.008	-0.19	0.05
			Week 2	59	-0.009	0.0309	-0.005	-0.18	0.05
			Week 3	58	-0.007	0.0290	-0.004	-0.19	0.04
			Week 4	53	-0.004	0.0302	0.000	-0.18	0.03
			Week 6	51	-0.003	0.0336	-0.001	-0.16	0.09
			Week 8	47	-0.007	0.0304	-0.003	-0.18	0.04
			Week 12	48	-0.003	0.0366	-0.002	-0.19	0.05
	7.5mg	63	Week -5	59	0.003	0.0264	0.004	-0.12	0.05
			Week 1	60	-0.007	0.0200	-0.005	-0.10	0.04

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematocrit (1)	7.5mg	63	Week 2	59	-0.005	0.0191	-0.005	-0.08	0.04
			Week 3	58	-0.007	0.0245	-0.007	-0.07	0.08
			Week 4	56	-0.003	0.0366	-0.003	-0.11	0.20
			Week 6	57	-0.009	0.0234	-0.008	-0.08	0.04
			Week 8	54	-0.007	0.0243	-0.011	-0.08	0.05
			Week 12	52	-0.004	0.0231	-0.001	-0.09	0.04
	15mg	66	Week -5	62	0.004	0.0197	0.005	-0.05	0.04
			Week 1	63	-0.008	0.0173	-0.011	-0.06	0.03
			Week 2	61	-0.009	0.0173	-0.009	-0.06	0.05
			Week 3	58	-0.007	0.0185	-0.009	-0.06	0.04
			Week 4	60	-0.004	0.0197	-0.002	-0.07	0.04
			Week 6	60	-0.006	0.0177	-0.008	-0.04	0.04
			Week 8	60	-0.005	0.0213	-0.008	-0.06	0.05
			Week 12	59	-0.006	0.0212	-0.007	-0.07	0.04
	30mg	60	Week -5	58	-0.000	0.0281	0.002	-0.09	0.13
			Week 1	57	-0.006	0.0242	-0.004	-0.08	0.10
			Week 2	54	-0.005	0.0257	-0.009	-0.07	0.09
			Week 3	57	-0.005	0.0272	-0.006	-0.12	0.10
			Week 4	57	-0.004	0.0230	-0.008	-0.05	0.11
			Week 6	56	-0.004	0.0237	-0.003	-0.05	0.09
			Week 8	55	-0.001	0.0258	-0.005	-0.07	0.13
			Week 12	53	-0.001	0.0363	-0.002	-0.06	0.14
	45mg	61	Week -5	59	0.001	0.0183	-0.002	-0.04	0.04
			Week 1	59	-0.004	0.0276	-0.003	-0.10	0.12
			Week 2	60	-0.007	0.0181	-0.006	-0.07	0.03
			Week 3	55	-0.004	0.0180	-0.006	-0.03	0.04
			Week 4	56	-0.006	0.0208	-0.006	-0.06	0.08
			Week 6	53	-0.005	0.0204	-0.007	-0.07	0.04
			Week 8	56	-0.007	0.0247	-0.009	-0.07	0.07

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematocrit (1)	45mg	61	Week 12	54	-0.003	0.0253	-0.004	-0.09	0.08
Hemoglobin (G/L)	Placebo	64	Week -5	62	-1.7	9.98	-0.5	-48	20
			Week 1	56	-3.3	8.24	-2.5	-47	10
			Week 2	60	-2.2	7.68	-2.0	-43	9
			Week 3	55	-2.2	9.33	-1.0	-48	14
			Week 4	55	-2.9	9.99	-1.0	-45	19
			Week 6	53	-3.2	10.43	-2.0	-51	15
			Week 8	52	-1.3	11.41	-0.5	-60	15
			Week 12	45	-0.9	7.48	-1.0	-27	11
	2.5mg	61	Week -5	58	-0.4	9.75	0.5	-53	17
			Week 1	60	-2.8	9.59	-2.0	-56	16
			Week 2	59	-2.9	9.31	-2.0	-52	16
			Week 3	58	-2.8	8.78	-2.0	-54	14
			Week 4	53	-1.9	8.81	-1.0	-51	9
			Week 6	51	-1.8	10.54	0.0	-49	24
			Week 8	47	-3.3	9.48	-3.0	-53	13
			Week 12	48	-0.8	10.71	0.5	-52	16
	7.5mg	63	Week -5	59	-0.4	8.14	0.0	-40	15
			Week 1	60	-2.4	6.53	-2.5	-30	15
			Week 2	59	-1.5	6.10	-1.0	-30	9
			Week 3	58	-1.9	8.12	-2.0	-19	32
			Week 4	56	-1.4	11.37	-1.0	-39	56
			Week 6	57	-3.1	7.71	-1.0	-28	13
			Week 8	54	-1.7	7.75	-1.5	-23	16
			Week 12	52	-0.3	7.59	1.0	-26	13
	15mg	66	Week -5	62	0.9	5.80	0.5	-16	16
			Week 1	63	-2.5	4.83	-2.0	-19	8

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hemoglobin (G/L)	15mg	66	Week 2	61	-2.3	4.97	-3.0	-18	12
			Week 3	58	-1.9	5.56	-1.0	-14	10
			Week 4	60	-1.4	5.83	-1.0	-21	11
			Week 6	60	-1.7	5.13	-2.0	-10	12
			Week 8	60	-1.4	6.02	-1.0	-19	14
			Week 12	59	-1.5	5.87	-1.0	-15	11
	30mg	60	Week -5	58	-0.2	8.53	0.0	-26	38
			Week 1	57	-1.9	7.31	-2.0	-22	32
			Week 2	54	-1.3	8.48	-1.5	-32	28
			Week 3	57	-1.4	8.69	-1.0	-35	34
			Week 4	57	-1.2	7.56	-2.0	-15	34
			Week 6	56	-1.4	7.76	-1.5	-18	30
			Week 8	55	0.9	8.20	0.0	-22	42
			Week 12	53	0.0	10.53	0.0	-21	42
	45mg	61	Week -5	59	-0.2	6.02	-1.0	-14	14
			Week 1	59	-2.0	9.14	-2.0	-33	40
			Week 2	60	-2.3	5.83	-3.0	-18	10
			Week 3	55	-1.8	5.50	-2.0	-16	15
			Week 4	56	-2.3	6.23	-3.0	-15	24
			Week 6	53	-2.3	6.50	-3.0	-23	14
			Week 8	56	-2.1	8.15	-3.0	-27	29
			Week 12	54	-0.6	7.38	0.5	-21	25
Indirect Bilirubin (UMOL/L)	Placebo	64	Week -5	63	-0.6	3.46	0.0	-12	6
			Week 1	61	-0.7	2.79	0.0	-8	6
			Week 2	60	-0.3	3.24	0.0	-8	14
			Week 3	55	-0.5	2.97	0.0	-11	6
			Week 4	55	-0.6	2.78	0.0	-8	6
			Week 6	53	-0.3	2.75	0.0	-10	4

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	Placebo	64	Week 8	51	-0.2	3.31	0.0	-14	11
			Week 12	49	-0.2	3.05	0.0	-9	6
	2.5mg	61	Week -5	59	-0.6	3.34	-1.0	-7	12
			Week 1	59	0.1	2.91	0.0	-6	9
			Week 2	58	-0.6	3.01	0.0	-8	6
			Week 3	56	-0.1	3.02	0.0	-8	8
			Week 4	56	-0.6	3.21	-1.0	-5	10
			Week 6	48	0.1	3.22	0.0	-6	7
			Week 8	48	-0.5	2.95	-0.5	-6	9
			Week 12	45	-0.2	3.13	0.0	-6	8
	7.5mg	63	Week -5	60	-0.1	2.76	-0.5	-8	7
			Week 1	60	0.2	4.08	0.5	-11	14
			Week 2	59	-0.2	3.05	0.0	-10	8
			Week 3	59	-0.1	3.71	0.0	-8	14
			Week 4	55	-0.6	2.85	0.0	-7	6
			Week 6	56	-0.2	3.66	-0.5	-6	17
			Week 8	54	-0.1	2.90	0.0	-8	6
			Week 12	54	-0.1	2.47	0.0	-7	7
	15mg	66	Week -5	61	0.2	2.58	0.0	-9	7
			Week 1	63	-0.2	2.90	0.0	-13	7
			Week 2	62	-0.4	2.99	0.0	-16	7
			Week 3	59	-0.5	2.95	0.0	-13	7
			Week 4	60	0.4	2.66	0.0	-11	9
			Week 6	60	-0.5	2.68	0.0	-13	4
			Week 8	60	-0.2	2.55	0.0	-6	6
			Week 12	58	-0.0	2.87	0.0	-10	8
	30mg	60	Week -5	59	-1.5	3.79	-1.0	-9	16
			Week 1	55	-1.3	3.47	-1.0	-14	12

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	30mg	60	Week 2	56	-1.1	4.27	0.0	-14	18
			Week 3	56	-1.2	3.20	-1.0	-9	12
			Week 4	55	-1.5	2.44	-1.0	-7	2
			Week 6	53	-1.3	3.73	-1.0	-14	12
			Week 8	55	-1.8	3.81	-1.0	-11	12
			Week 12	55	-1.1	4.09	-1.0	-14	12
	45mg	61	Week -5	57	-0.3	3.73	0.0	-16	8
			Week 1	59	0.1	3.32	0.0	-10	11
			Week 2	58	-0.3	3.41	0.0	-11	12
			Week 3	55	-0.2	2.57	0.0	-9	5
			Week 4	56	-0.2	3.05	0.0	-14	9
			Week 6	54	-0.8	3.72	-0.5	-15	14
			Week 8	54	-0.3	3.88	0.0	-16	16
			Week 12	54	-0.7	2.94	0.0	-10	9
Lactate Dehydrogenase (IU/L)	Placebo	64	Week -5	62	-1.2	17.85	2.5	-56	31
			Week 1	61	0.1	16.84	0.0	-46	56
			Week 2	60	2.9	16.33	4.0	-55	44
			Week 3	55	-0.5	19.25	0.0	-77	33
			Week 4	55	-1.0	16.40	-1.0	-47	31
			Week 6	53	1.5	18.54	4.0	-57	42
			Week 8	51	1.4	19.12	2.0	-66	39
			Week 12	48	1.3	14.70	-0.5	-35	45
	2.5mg	61	Week -5	59	-6.9	17.70	-6.0	-58	29
			Week 1	59	0.6	17.05	0.0	-50	40
			Week 2	58	0.4	17.67	2.5	-52	44
			Week 3	56	-3.4	19.20	-2.0	-58	46
			Week 4	56	-2.9	19.13	-2.0	-49	38
			Week 6	48	-1.4	18.18	-1.0	-52	26

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lactate Dehydrogenase (IU/L)	2.5mg	61	Week 8	48	-1.4	23.27	2.5	-54	71
			Week 12	46	-2.6	19.52	-3.0	-49	43
	7.5mg	63	Week -5	60	-5.8	21.64	-5.5	-78	53
			Week 1	60	0.2	16.24	0.5	-34	36
			Week 2	59	2.1	25.21	0.0	-38	96
			Week 3	58	-0.7	19.32	0.0	-57	56
			Week 4	56	1.4	19.81	1.0	-49	77
			Week 6	56	2.0	21.99	2.0	-55	76
			Week 8	54	4.5	29.30	1.0	-35	148
			Week 12	54	4.5	19.47	6.0	-32	43
	15mg	66	Week -5	61	-3.7	18.79	-1.0	-85	28
			Week 1	63	3.9	22.05	2.0	-60	124
			Week 2	62	-1.2	17.13	1.5	-82	30
			Week 3	59	2.3	19.41	0.0	-57	68
			Week 4	60	4.0	16.56	4.5	-72	43
			Week 6	60	5.8	21.54	1.0	-45	77
			Week 8	58	1.5	18.89	3.0	-92	38
			Week 12	58	3.7	14.75	4.0	-26	47
	30mg	60	Week -5	59	-9.5	25.37	-9.0	-86	42
			Week 1	55	-7.1	17.88	-3.0	-52	32
			Week 2	56	-5.8	28.58	-5.5	-82	103
			Week 3	55	-2.7	21.13	-1.0	-45	59
			Week 4	55	-3.5	18.26	-3.0	-54	39
			Week 6	53	-1.9	19.88	-1.0	-51	32
			Week 8	55	-3.9	19.81	-4.0	-55	56
			Week 12	55	-4.9	24.83	-2.0	-80	68
	45mg	61	Week -5	59	0.7	19.75	-3.0	-39	57
			Week 1	59	1.4	20.81	0.0	-70	76

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lactate Dehydrogenase (IU/L)	45mg	61	Week 2	57	3.1	23.61	3.0	-39	122
			Week 3	55	5.5	21.44	2.0	-55	82
			Week 4	56	3.4	21.01	3.0	-62	80
			Week 6	54	4.8	23.49	1.5	-47	88
			Week 8	54	5.7	23.64	4.0	-86	82
			Week 12	54	3.5	24.97	0.5	-65	83
Lymphocytes (GI/L)	Placebo	64	Week -5	62	0.047	0.4818	0.105	-1.35	1.98
			Week 1	56	-0.049	0.5315	0.045	-2.71	0.84
			Week 2	60	0.017	0.3826	0.045	-1.58	1.11
			Week 3	55	-0.037	0.4769	0.060	-2.42	0.75
			Week 4	55	-0.120	0.5140	-0.020	-2.14	0.69
			Week 6	53	0.010	0.4009	0.040	-1.50	0.65
			Week 8	52	0.046	0.3722	0.095	-1.26	0.89
			Week 12	44	-0.032	0.4090	-0.020	-1.35	0.74
	2.5mg	61	Week -5	58	0.097	0.4971	0.085	-1.00	1.84
			Week 1	60	0.120	0.5412	0.035	-1.06	2.71
			Week 2	59	0.082	0.4808	0.080	-1.16	1.91
			Week 3	58	0.121	0.5911	0.030	-1.30	2.19
			Week 4	53	0.091	0.5355	0.020	-0.99	2.10
			Week 6	51	0.168	0.5646	0.100	-0.90	2.13
			Week 8	47	0.119	0.4369	0.080	-0.88	1.59
			Week 12	48	0.021	0.4926	-0.040	-1.06	1.59
	7.5mg	63	Week -5	59	-0.042	0.4944	0.030	-2.19	0.84
			Week 1	60	-0.028	0.4562	0.000	-1.73	1.07
			Week 2	59	-0.041	0.5712	0.040	-2.02	1.31
			Week 3	58	0.009	0.4530	-0.015	-2.08	1.15
			Week 4	56	-0.025	0.5180	-0.010	-1.99	1.97
			Week 6	57	0.012	0.4842	0.040	-1.53	1.22

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Lymphocytes (GI/L)	7.5mg	63	Week 8	53	-0.039	0.4616	0.000	-2.39	0.76
			Week 12	52	-0.075	0.4344	-0.030	-1.75	0.68
	15mg	66	Week -5	61	0.021	0.4146	-0.010	-1.52	0.89
			Week 1	63	0.044	0.3505	0.040	-0.77	0.92
			Week 2	61	0.039	0.2874	0.060	-1.13	0.65
			Week 3	58	0.043	0.3158	0.020	-0.87	0.85
			Week 4	60	-0.068	0.3550	-0.080	-0.78	1.38
			Week 6	60	0.062	0.3674	0.010	-0.62	0.99
			Week 8	60	-0.077	0.4020	-0.140	-0.91	1.11
			Week 12	59	-0.096	0.3838	-0.110	-1.34	1.01
	30mg	60	Week -5	58	-0.056	0.4494	-0.040	-1.39	0.88
			Week 1	57	0.002	0.3232	0.040	-0.76	0.58
			Week 2	54	0.024	0.4392	0.055	-0.82	1.22
			Week 3	57	-0.078	0.4713	-0.010	-2.43	0.47
			Week 4	57	-0.115	0.4258	-0.070	-1.49	0.73
			Week 6	56	-0.010	0.4750	0.040	-1.61	1.21
			Week 8	54	-0.113	0.5130	-0.070	-1.62	1.19
			Week 12	53	-0.106	0.3710	-0.070	-0.90	0.64
	45mg	61	Week -5	58	0.040	0.3706	0.000	-0.98	1.54
			Week 1	58	-0.026	0.3086	0.020	-0.75	0.62
			Week 2	59	-0.080	0.4245	-0.160	-1.13	1.02
			Week 3	54	-0.038	0.3949	-0.025	-1.11	1.41
			Week 4	55	-0.071	0.4099	-0.120	-1.16	1.08
			Week 6	52	-0.018	0.6872	-0.055	-1.29	4.07
			Week 8	55	-0.119	0.3257	-0.120	-0.95	0.66
			Week 12	53	-0.085	0.3777	-0.090	-0.90	1.12
Monocytes (GI/L)	Placebo	64	Week -5	62	0.033	0.1096	0.015	-0.27	0.35

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Monocytes (GI/L)	Placebo	64	Week 1	56	-0.006	0.1058	0.005	-0.34	0.23
			Week 2	60	-0.003	0.1034	-0.010	-0.40	0.22
			Week 3	55	0.011	0.1166	0.000	-0.25	0.31
			Week 4	55	-0.008	0.1246	-0.010	-0.23	0.51
			Week 6	53	0.009	0.1169	0.010	-0.32	0.32
			Week 8	52	0.018	0.1420	0.020	-0.38	0.27
			Week 12	44	0.040	0.1474	0.020	-0.25	0.62
	2.5mg	61	Week -5	58	0.003	0.1138	0.000	-0.31	0.22
			Week 1	60	0.039	0.1126	0.025	-0.22	0.54
			Week 2	59	0.015	0.1180	0.010	-0.40	0.28
			Week 3	58	0.029	0.1088	0.020	-0.30	0.34
			Week 4	53	0.029	0.1159	0.010	-0.21	0.39
			Week 6	51	0.057	0.1118	0.040	-0.19	0.44
			Week 8	47	-0.006	0.1234	0.000	-0.52	0.27
			Week 12	48	0.041	0.1528	0.025	-0.40	0.50
	7.5mg	63	Week -5	59	-0.016	0.1095	-0.020	-0.40	0.27
			Week 1	60	0.042	0.1988	0.025	-0.44	1.18
			Week 2	59	0.032	0.1526	0.020	-0.62	0.47
			Week 3	58	0.053	0.1203	0.020	-0.10	0.48
			Week 4	56	0.003	0.1313	0.010	-0.32	0.29
			Week 6	57	0.049	0.1944	0.050	-0.64	0.93
			Week 8	53	0.041	0.1450	0.030	-0.64	0.47
			Week 12	52	0.039	0.1335	0.010	-0.23	0.41
	15mg	66	Week -5	61	0.016	0.1292	0.010	-0.26	0.54
			Week 1	63	0.039	0.1122	0.040	-0.26	0.32
			Week 2	61	-0.001	0.1246	0.030	-0.39	0.17
			Week 3	58	0.060	0.1475	0.065	-0.40	0.48
			Week 4	60	0.030	0.1303	0.020	-0.24	0.53
			Week 6	60	0.056	0.1095	0.050	-0.20	0.43

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Monocytes (GI/L)	15mg	66	Week 8	60	0.034	0.1201	0.030	-0.31	0.34
			Week 12	59	0.022	0.1360	0.010	-0.38	0.50
	30mg	60	Week -5	58	0.010	0.1363	0.020	-0.39	0.30
			Week 1	57	0.017	0.1169	0.040	-0.44	0.23
			Week 2	54	0.054	0.1221	0.045	-0.42	0.37
			Week 3	57	0.041	0.1091	0.040	-0.30	0.36
			Week 4	57	0.026	0.1313	0.010	-0.26	0.41
			Week 6	56	0.048	0.1069	0.040	-0.32	0.31
			Week 8	54	0.061	0.1472	0.045	-0.44	0.54
			Week 12	53	0.030	0.1297	0.040	-0.36	0.38
	45mg	61	Week -5	58	0.016	0.1090	0.015	-0.30	0.26
			Week 1	58	0.044	0.0972	0.045	-0.30	0.28
			Week 2	59	0.066	0.1275	0.070	-0.33	0.34
			Week 3	54	0.069	0.1728	0.075	-0.62	0.55
			Week 4	55	0.040	0.1115	0.040	-0.36	0.33
			Week 6	52	0.017	0.1508	0.030	-0.72	0.26
			Week 8	55	0.055	0.1290	0.080	-0.31	0.33
			Week 12	53	0.037	0.1631	0.040	-0.42	0.46
Phosphorus, Inorganic (MMOL/L)	Placebo	64	Week -5	63	0.016	0.1584	0.000	-0.60	0.35
			Week 1	61	-0.032	0.1352	0.000	-0.35	0.31
			Week 2	60	-0.006	0.1256	0.000	-0.35	0.31
			Week 3	55	-0.037	0.1509	0.000	-0.40	0.30
			Week 4	55	-0.040	0.1491	-0.040	-0.41	0.34
			Week 6	53	-0.021	0.1701	-0.040	-0.54	0.34
			Week 8	51	-0.033	0.1640	0.000	-0.42	0.25
			Week 12	49	-0.053	0.1579	-0.050	-0.45	0.25

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Phosphorus, Inorganic (MMOL/L)	2.5mg	61	Week -5	60	0.000	0.1463	0.000	-0.33	0.40
			Week 1	59	0.022	0.1115	0.020	-0.23	0.31
			Week 2	58	0.023	0.1089	0.030	-0.25	0.27
			Week 3	56	0.007	0.1148	0.005	-0.33	0.23
			Week 4	56	0.015	0.1288	0.010	-0.31	0.29
			Week 6	49	-0.003	0.1308	0.000	-0.34	0.23
			Week 8	48	-0.001	0.1151	0.000	-0.30	0.27
			Week 12	46	-0.003	0.1298	-0.035	-0.22	0.33
	7.5mg	63	Week -5	60	0.042	0.1493	0.050	-0.19	0.43
			Week 1	60	-0.004	0.1298	0.000	-0.30	0.26
			Week 2	59	0.000	0.1552	0.000	-0.41	0.38
			Week 3	59	0.037	0.2417	0.000	-0.21	1.65
			Week 4	57	0.010	0.1684	0.030	-0.66	0.31
			Week 6	56	-0.003	0.1636	0.000	-0.44	0.39
			Week 8	54	0.004	0.1418	0.000	-0.34	0.32
			Week 12	54	0.010	0.1345	0.000	-0.30	0.36
	15mg	66	Week -5	61	0.022	0.1302	0.030	-0.25	0.35
			Week 1	63	0.016	0.1392	0.000	-0.35	0.40
			Week 2	62	0.019	0.1338	0.015	-0.35	0.40
			Week 3	59	0.020	0.1471	0.000	-0.22	0.55
			Week 4	60	-0.014	0.1239	-0.005	-0.25	0.31
			Week 6	60	0.021	0.1258	0.040	-0.35	0.32
			Week 8	58	-0.023	0.1154	-0.035	-0.30	0.31
			Week 12	58	-0.011	0.1335	-0.020	-0.35	0.39
	30mg	60	Week -5	59	0.011	0.1209	0.000	-0.30	0.25
			Week 1	55	0.028	0.0934	0.020	-0.14	0.24
			Week 2	56	0.007	0.1164	0.015	-0.29	0.30
			Week 3	56	-0.002	0.1245	-0.020	-0.25	0.38

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Phosphorus, Inorganic (MMOL/L)	30mg	60	Week 4	55	-0.005	0.1136	0.000	-0.32	0.23
			Week 6	53	0.005	0.1494	0.000	-0.40	0.30
			Week 8	55	-0.000	0.1374	0.010	-0.35	0.31
			Week 12	55	0.004	0.1348	0.000	-0.25	0.35
	45mg	61	Week -5	59	-0.002	0.1968	0.000	-0.50	0.41
			Week 1	59	-0.006	0.1683	0.000	-0.51	0.32
			Week 2	58	0.002	0.1392	0.000	-0.44	0.29
			Week 3	55	0.007	0.1625	0.020	-0.44	0.33
			Week 4	56	-0.009	0.1690	0.025	-0.43	0.30
			Week 6	54	-0.005	0.1717	0.005	-0.40	0.41
			Week 8	54	-0.002	0.1555	0.005	-0.55	0.25
			Week 12	54	-0.019	0.1714	0.000	-0.53	0.25
Platelet count (GI/L)	Placebo	64	Week -5	62	-6.7	33.41	-4.5	-162	108
			Week 1	56	-0.8	27.02	-4.0	-87	108
			Week 2	60	-4.1	35.72	-1.5	-137	145
			Week 3	55	-4.3	35.18	-2.0	-161	63
			Week 4	54	-4.8	37.65	0.5	-163	70
			Week 6	53	0.4	26.89	4.0	-100	68
			Week 8	52	-3.2	41.22	-2.0	-136	123
			Week 12	44	-14.8	55.45	-1.5	-229	72
	2.5mg	61	Week -5	58	5.8	24.91	7.0	-48	80
			Week 1	60	4.6	33.12	3.0	-133	118
			Week 2	59	9.8	23.46	9.0	-47	78
			Week 3	58	2.6	22.69	4.5	-75	45
			Week 4	53	5.2	30.08	3.0	-41	143
			Week 6	51	6.8	28.63	3.0	-84	75
			Week 8	47	5.5	33.30	7.0	-61	147

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Platelet count (GI/L)	2.5mg	61	Week 12	48	0.3	27.95	-2.5	-72	66
	7.5mg	63	Week -5	59	2.6	35.46	4.0	-90	114
			Week 1	59	7.4	30.41	7.0	-92	96
			Week 2	59	5.6	32.99	4.0	-98	76
			Week 3	58	-0.2	31.78	0.0	-96	54
			Week 4	55	9.7	31.95	6.0	-92	98
			Week 6	57	4.3	40.08	4.0	-88	164
			Week 8	54	8.9	29.39	7.0	-56	98
			Week 12	52	4.5	33.33	3.0	-79	73
	15mg	66	Week -5	62	3.2	28.31	5.5	-117	58
			Week 1	63	3.5	21.88	2.0	-40	60
			Week 2	61	3.6	29.49	4.0	-77	66
			Week 3	58	4.6	32.76	7.5	-107	62
			Week 4	60	3.0	22.12	1.0	-53	50
			Week 6	60	9.6	25.68	9.5	-46	79
			Week 8	60	-0.4	26.09	0.5	-75	59
			Week 12	59	1.2	27.71	2.0	-69	83
	30mg	60	Week -5	58	-0.9	33.84	1.0	-106	101
			Week 1	56	3.9	36.00	1.0	-99	153
			Week 2	53	7.9	35.05	7.0	-46	116
			Week 3	55	3.3	39.11	5.0	-126	133
			Week 4	57	5.2	37.80	3.0	-94	127
			Week 6	55	7.3	35.06	-5.0	-58	129
			Week 8	54	-2.4	36.61	-5.5	-64	153
			Week 12	51	-2.4	43.12	-3.0	-177	108
	45mg	61	Week -5	56	1.2	32.21	4.0	-156	91
			Week 1	57	1.0	33.62	3.0	-150	80
			Week 2	60	7.2	30.31	3.0	-96	87

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Platelet count (GI/L)	45mg	61	Week 3	55	4.7	22.64	3.0	-42	51
			Week 4	56	2.7	33.81	1.5	-75	109
			Week 6	53	5.9	35.20	4.0	-125	125
			Week 8	56	4.3	39.95	2.0	-112	122
			Week 12	54	-1.9	24.47	1.0	-88	54
Potassium (MMOL/L)	Placebo	64	Week -5	62	-0.03	0.631	0.00	-1.9	2.2
			Week 1	61	0.15	0.643	0.10	-2.0	2.0
			Week 2	59	0.13	0.726	0.10	-1.5	3.5
			Week 3	55	0.34	0.860	0.10	-1.7	4.6
			Week 4	55	0.12	0.594	0.10	-1.1	1.9
			Week 6	53	0.14	0.594	0.00	-1.6	2.4
			Week 8	51	0.19	0.576	0.00	-0.7	2.3
			Week 12	48	0.02	0.736	0.00	-1.9	3.3
	2.5mg	61	Week -5	59	-0.22	0.759	-0.10	-3.0	2.2
			Week 1	59	-0.08	0.701	0.00	-2.8	1.8
			Week 2	58	-0.06	0.748	0.00	-2.8	1.3
			Week 3	55	-0.08	0.663	0.00	-3.0	1.3
			Week 4	56	-0.14	0.751	-0.05	-2.8	1.9
			Week 6	48	-0.04	0.848	0.00	-2.8	2.5
			Week 8	48	-0.18	0.884	-0.10	-2.9	3.4
			Week 12	46	-0.28	0.640	-0.20	-2.7	0.7
	7.5mg	63	Week -5	58	-0.15	0.692	0.00	-3.5	0.7
			Week 1	59	0.12	0.765	0.10	-3.2	1.8
			Week 2	58	0.14	0.787	0.05	-3.2	2.0
			Week 3	57	0.19	0.954	0.10	-3.2	4.1
			Week 4	55	-0.03	0.701	0.00	-2.4	1.5
			Week 6	55	0.01	0.470	0.10	-1.2	1.3
			Week 8	53	-0.05	0.760	0.00	-3.2	1.6

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Potassium (MMOL/L)	7.5mg	63	Week 12	53	0.02	0.729	0.00	-2.9	1.5
	15mg	66	Week -5	61	-0.06	0.479	0.00	-1.8	1.2
			Week 1	63	0.14	0.515	0.10	-1.2	1.8
			Week 2	62	0.18	0.691	0.10	-1.5	3.0
			Week 3	59	0.11	0.629	0.10	-1.4	2.8
			Week 4	60	-0.01	0.492	0.00	-1.5	1.9
			Week 6	60	0.15	0.628	0.05	-1.5	2.1
			Week 8	60	0.13	0.624	0.15	-1.9	2.2
			Week 12	58	0.02	0.403	0.00	-1.4	1.0
	30mg	60	Week -5	59	-0.11	0.651	0.00	-3.1	1.1
			Week 1	55	0.10	0.636	0.10	-3.0	2.1
			Week 2	56	0.05	0.590	0.10	-1.9	1.5
			Week 3	55	-0.00	0.719	0.10	-3.1	1.0
			Week 4	55	-0.18	0.625	0.00	-2.6	0.9
			Week 6	53	-0.14	0.712	0.00	-3.1	1.3
			Week 8	55	0.08	0.629	0.10	-1.3	3.6
			Week 12	54	-0.09	0.839	-0.10	-3.0	2.1
	45mg	61	Week -5	59	-0.06	0.569	0.00	-1.9	1.4
			Week 1	59	0.00	0.689	0.00	-1.7	2.1
			Week 2	57	0.19	0.715	0.10	-1.5	2.5
			Week 3	55	0.01	0.515	0.00	-1.5	1.3
			Week 4	56	-0.05	0.598	0.00	-1.7	2.2
			Week 6	54	0.25	0.667	0.10	-1.0	2.3
			Week 8	54	0.05	0.614	0.00	-1.5	2.6
			Week 12	54	0.11	0.490	0.10	-1.3	1.5
Red Blood Cell Count (TI/L)	Placebo	64	Week -5	62	-0.06	0.344	-0.10	-1.5	0.8
			Week 1	56	-0.09	0.280	-0.10	-1.5	0.4

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Red Blood Cell Count (TI/L)	Placebo	64	Week 2	60	-0.06	0.302	-0.10	-1.4	1.0
			Week 3	55	-0.08	0.349	-0.10	-1.5	0.5
			Week 4	55	-0.08	0.351	0.00	-1.4	0.7
			Week 6	53	-0.12	0.348	-0.10	-1.6	0.6
			Week 8	52	-0.04	0.418	0.00	-1.9	1.0
			Week 12	45	-0.01	0.242	0.00	-0.7	0.5
	2.5mg	61	Week -5	58	-0.01	0.306	0.00	-1.5	0.5
			Week 1	60	-0.09	0.286	-0.10	-1.6	0.4
			Week 2	59	-0.09	0.280	-0.10	-1.5	0.6
			Week 3	58	-0.07	0.271	-0.05	-1.6	0.4
			Week 4	53	-0.05	0.278	0.00	-1.5	0.3
			Week 6	51	-0.05	0.330	0.00	-1.4	0.9
			Week 8	47	-0.07	0.270	0.00	-1.5	0.2
			Week 12	48	0.02	0.333	0.00	-1.6	0.7
	7.5mg	63	Week -5	59	0.02	0.206	0.00	-0.5	0.5
			Week 1	60	-0.07	0.184	-0.10	-0.8	0.4
			Week 2	59	-0.05	0.206	-0.10	-1.0	0.3
			Week 3	58	-0.06	0.218	0.00	-0.6	0.5
			Week 4	56	-0.04	0.400	-0.05	-1.4	1.9
			Week 6	57	-0.10	0.271	0.00	-0.9	0.5
			Week 8	54	-0.06	0.278	-0.10	-0.9	0.6
			Week 12	52	0.00	0.253	0.00	-0.7	0.4
	15mg	66	Week -5	62	0.03	0.193	0.00	-0.6	0.4
			Week 1	63	-0.07	0.166	-0.10	-0.5	0.3
			Week 2	61	-0.08	0.172	-0.10	-0.5	0.5
			Week 3	58	-0.06	0.193	-0.10	-0.5	0.4
			Week 4	60	-0.04	0.223	0.00	-0.7	0.5
			Week 6	60	-0.05	0.198	-0.10	-0.4	0.5
			Week 8	60	-0.02	0.219	-0.05	-0.6	0.5

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Red Blood Cell Count (TI/L)	15mg	66	Week 12	59	-0.01	0.239	0.00	-0.6	0.5
	30mg	60	Week -5	58	-0.01	0.298	0.00	-1.1	1.4
			Week 1	57	-0.05	0.249	0.00	-0.7	1.2
			Week 2	54	-0.05	0.275	-0.10	-0.8	1.1
			Week 3	57	-0.04	0.304	0.00	-1.3	1.3
			Week 4	57	-0.01	0.267	0.00	-0.4	1.3
			Week 6	56	-0.02	0.278	0.00	-0.9	1.1
			Week 8	55	0.03	0.284	0.00	-0.5	1.6
			Week 12	53	0.02	0.392	0.00	-0.7	1.7
	45mg	61	Week -5	59	0.01	0.207	0.00	-0.5	0.6
			Week 1	59	-0.06	0.360	-0.10	-1.9	1.3
			Week 2	60	-0.07	0.209	0.00	-0.9	0.4
			Week 3	55	-0.05	0.183	0.00	-0.7	0.3
			Week 4	56	-0.07	0.214	-0.10	-0.7	0.8
			Week 6	53	-0.06	0.307	-0.10	-1.5	1.0
			Week 8	56	-0.03	0.250	-0.10	-0.5	1.0
			Week 12	54	0.02	0.293	0.05	-1.2	0.9
Sodium (MMOL/L)	Placebo	64	Week -5	63	0.2	2.98	0.0	-6	14
			Week 1	61	0.4	2.66	0.0	-8	9
			Week 2	60	-0.0	2.17	0.0	-4	5
			Week 3	55	0.6	2.82	1.0	-8	10
			Week 4	55	-0.1	2.66	0.0	-6	8
			Week 6	53	0.3	2.52	0.0	-6	8
			Week 8	51	-0.0	2.52	0.0	-5	8
			Week 12	49	-0.2	2.96	0.0	-8	6
	2.5mg	61	Week -5	60	-0.3	2.55	0.0	-6	6
			Week 1	59	-0.5	2.71	-1.0	-8	8

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Sodium (MMOL/L)	2.5mg	61	Week 2	58	-0.8	2.23	-1.0	-7	5
			Week 3	56	-0.5	2.70	-0.5	-7	5
			Week 4	56	-0.6	2.41	-1.0	-8	6
			Week 6	49	-0.6	2.73	0.0	-7	5
			Week 8	48	-0.5	2.81	-1.0	-10	5
			Week 12	46	-0.5	2.75	0.0	-9	4
	7.5mg	63	Week -5	60	0.2	2.51	0.0	-8	7
			Week 1	60	0.5	2.84	0.5	-5	10
			Week 2	59	0.2	2.70	0.0	-7	8
			Week 3	59	0.3	2.50	0.0	-4	7
			Week 4	57	0.2	2.20	0.0	-4	7
			Week 6	56	-0.1	2.38	0.0	-6	5
			Week 8	54	0.1	2.66	0.0	-7	5
			Week 12	54	-0.1	2.76	0.0	-8	8
	15mg	66	Week -5	61	0.3	2.35	0.0	-6	5
			Week 1	63	-0.3	2.55	0.0	-8	5
			Week 2	62	0.5	2.95	1.0	-8	7
			Week 3	59	0.3	2.41	1.0	-5	6
			Week 4	60	-0.1	2.89	0.0	-12	6
			Week 6	60	0.2	2.52	0.0	-7	7
			Week 8	60	0.5	3.27	0.0	-5	16
			Week 12	58	0.3	1.94	0.0	-4	5
	30mg	60	Week -5	59	0.4	3.61	0.0	-11	18
			Week 1	55	0.2	2.14	0.0	-4	5
			Week 2	56	0.3	2.51	1.0	-9	7
			Week 3	56	0.4	2.19	0.0	-4	6
			Week 4	55	0.4	2.36	0.0	-8	5
			Week 6	53	0.3	2.27	0.0	-8	4
			Week 8	55	0.4	2.12	0.0	-5	6

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Sodium (MMOL/L)	30mg	60	Week 12	55	0.5	2.03	0.0	-4	6
	45mg	61	Week -5	59	-0.0	2.46	0.0	-5	6
			Week 1	59	0.3	2.65	1.0	-5	5
			Week 2	58	0.6	2.88	0.0	-6	8
			Week 3	55	0.2	2.59	0.0	-5	5
			Week 4	56	0.5	2.48	0.0	-8	7
			Week 6	54	-0.0	4.60	0.0	-29	5
			Week 8	54	0.2	3.04	0.5	-15	5
			Week 12	54	0.8	2.61	0.0	-5	7
Total Bilirubin (UMOL/L)	Placebo	64	Week -5	63	-0.6	3.61	0.0	-12	7
			Week 1	61	-0.6	3.30	0.0	-9	6
			Week 2	60	-0.3	3.73	0.0	-10	16
			Week 3	55	-0.5	3.48	0.0	-12	6
			Week 4	55	-0.7	3.31	0.0	-10	7
			Week 6	53	-0.3	3.31	0.0	-12	6
			Week 8	51	-0.1	3.98	0.0	-16	14
			Week 12	49	-0.2	3.55	0.0	-10	8
	2.5mg	61	Week -5	59	-0.7	3.97	-1.0	-8	14
			Week 1	59	0.0	3.31	-1.0	-6	10
			Week 2	58	-0.9	3.46	-0.5	-10	8
			Week 3	56	-0.0	3.79	0.0	-10	10
			Week 4	56	-0.8	3.85	-1.0	-7	13
			Week 6	48	-0.0	4.01	0.0	-8	10
			Week 8	48	-0.8	3.56	-1.0	-7	11
			Week 12	46	-0.4	3.54	-1.5	-6	8
	7.5mg	63	Week -5	60	-0.1	3.17	-0.5	-10	8
			Week 1	60	0.1	4.67	0.0	-12	18

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Bilirubin (UMOL/L)	7.5mg	63	Week 2	59	-0.4	3.62	0.0	-12	8
			Week 3	59	-0.1	4.32	0.0	-10	16
			Week 4	56	-0.8	3.25	0.0	-8	7
			Week 6	56	-0.2	4.47	-1.0	-8	21
			Week 8	54	-0.2	3.37	0.0	-10	8
			Week 12	54	-0.1	2.83	0.0	-9	8
	15mg	66	Week -5	61	0.1	3.02	0.0	-10	8
			Week 1	63	-0.4	3.32	0.0	-15	8
			Week 2	62	-0.5	3.39	0.0	-18	9
			Week 3	59	-0.7	3.49	0.0	-16	9
			Week 4	60	0.4	3.05	0.0	-12	11
			Week 6	60	-0.8	3.14	-0.5	-15	5
			Week 8	60	-0.3	3.06	0.0	-8	7
			Week 12	58	-0.2	3.32	0.0	-11	10
	30mg	60	Week -5	59	-1.7	4.17	-1.0	-10	16
			Week 1	55	-1.5	3.88	0.0	-16	12
			Week 2	56	-1.2	4.66	0.0	-14	18
			Week 3	56	-1.4	3.68	-1.0	-10	12
			Week 4	55	-2.0	3.03	-2.0	-10	2
			Week 6	53	-1.4	4.33	-1.0	-14	14
			Week 8	55	-2.3	4.27	-2.0	-12	12
			Week 12	55	-1.2	4.83	-1.0	-16	12
	45mg	61	Week -5	58	-0.3	4.51	0.0	-21	8
			Week 1	59	0.2	4.05	0.0	-12	14
			Week 2	58	-0.3	4.17	0.0	-14	15
			Week 3	55	-0.1	2.98	0.0	-11	6
			Week 4	56	-0.2	3.70	0.0	-17	11
			Week 6	54	-0.8	4.55	0.0	-18	17
			Week 8	54	-0.4	4.70	0.0	-19	18

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Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Bilirubin (UMOL/L)	45mg	61	Week 12	54	-0.8	3.66	0.0	-12	12
Total Neutrophils (GI/L)	Placebo	64	Week -5	62	0.207	1.3677	0.050	-3.13	5.82
			Week 1	56	0.050	0.7679	0.090	-1.68	4.09
			Week 2	60	0.187	0.9426	0.045	-1.53	4.16
			Week 3	55	0.256	1.0605	0.130	-1.18	5.42
			Week 4	55	0.114	0.9276	0.090	-1.96	3.49
			Week 6	53	-0.059	0.7587	0.080	-3.17	1.46
			Week 8	52	0.149	0.8529	0.160	-1.58	3.93
			Week 12	44	0.198	0.9334	0.115	-1.57	2.67
	2.5mg	61	Week -5	58	0.337	1.0157	0.335	-2.47	3.20
			Week 1	60	0.129	1.1662	0.030	-3.74	5.66
			Week 2	59	0.123	0.7846	0.030	-1.90	2.84
			Week 3	58	0.050	0.8409	0.030	-1.85	3.27
			Week 4	53	0.098	1.0364	0.000	-2.51	5.25
			Week 6	51	0.289	1.2525	0.240	-2.72	3.49
			Week 8	47	0.099	1.1407	0.190	-2.92	3.31
			Week 12	48	0.150	0.9655	0.105	-2.01	2.38
	7.5mg	63	Week -5	59	0.080	1.0045	-0.040	-2.70	2.49
			Week 1	60	-0.096	1.0643	0.045	-2.83	2.40
			Week 2	59	0.291	1.5013	0.220	-2.72	7.19
			Week 3	58	0.279	1.0741	0.145	-2.26	2.95
			Week 4	56	0.203	0.9898	0.215	-2.48	2.93
			Week 6	57	0.485	1.4795	0.450	-2.54	5.04
			Week 8	53	0.256	1.0817	0.280	-2.75	3.30
			Week 12	52	0.210	1.0838	-0.005	-2.45	2.90
	15mg	66	Week -5	61	0.339	0.9264	0.430	-1.93	2.47
			Week 1	63	0.169	0.7555	0.050	-1.52	2.11

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Neutrophils (GI/L)	15mg	66	Week 2	61	0.319	0.8890	0.330	-1.66	3.01
			Week 3	58	0.349	0.9785	0.310	-2.79	3.14
			Week 4	60	0.288	1.2336	0.135	-1.95	5.91
			Week 6	60	0.383	1.0440	0.245	-1.74	4.12
			Week 8	60	0.279	0.9251	0.465	-2.23	1.92
			Week 12	59	0.310	1.0227	0.450	-2.34	2.89
	30mg	60	Week -5	58	0.262	1.1385	0.135	-2.17	4.75
			Week 1	57	0.176	0.9003	0.190	-2.66	2.04
			Week 2	54	0.264	1.2949	0.020	-2.84	3.82
			Week 3	57	0.210	1.0892	0.110	-2.19	3.62
			Week 4	57	0.092	1.0415	0.260	-2.55	2.52
			Week 6	56	0.186	1.1946	0.205	-2.97	2.28
			Week 8	54	0.577	1.2241	0.435	-1.85	3.83
			Week 12	53	0.470	1.4104	0.240	-2.50	5.64
	45mg	61	Week -5	58	-0.050	1.3501	0.035	-6.89	4.63
			Week 1	58	0.280	1.4668	0.410	-8.71	2.06
			Week 2	59	0.233	1.2927	0.240	-7.47	2.52
			Week 3	54	0.201	1.4213	0.415	-7.28	3.99
			Week 4	55	0.055	1.2709	0.010	-5.65	3.95
			Week 6	52	0.227	1.4805	0.300	-7.92	3.22
			Week 8	55	0.233	1.1858	0.400	-5.03	3.17
			Week 12	53	0.183	1.5787	0.390	-8.65	2.36
Total Protein (G/L)	Placebo	64	Week -5	63	-0.1	4.13	0.0	-11	10
			Week 1	61	-1.5	3.73	-2.0	-10	11
			Week 2	60	-0.6	3.15	-1.0	-8	7
			Week 3	55	-0.7	3.92	-1.0	-15	7
			Week 4	55	-0.5	3.68	-1.0	-9	10
			Week 6	53	-1.2	3.00	-1.0	-10	6

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Protein (G/L)	Placebo	64	Week 8	51	-0.2	3.39	-1.0	-6	7
			Week 12	49	-0.5	3.42	-1.0	-7	6
	2.5mg	61	Week -5	60	0.3	4.24	1.0	-10	12
			Week 1	59	-0.6	3.66	0.0	-8	7
			Week 2	58	-0.9	3.28	0.0	-11	7
			Week 3	56	-1.2	2.88	-1.5	-8	6
			Week 4	56	-0.2	3.99	0.0	-12	8
			Week 6	49	-0.5	4.09	0.0	-11	9
			Week 8	48	-0.1	3.06	0.0	-8	6
			Week 12	46	0.5	3.72	1.0	-7	7
	7.5mg	63	Week -5	60	1.1	3.62	2.0	-9	8
			Week 1	60	-0.8	3.46	-1.0	-11	10
			Week 2	59	0.1	3.12	0.0	-7	8
			Week 3	59	-0.3	3.50	0.0	-8	6
			Week 4	57	0.2	3.48	0.0	-8	7
			Week 6	56	-0.6	3.56	-1.0	-10	10
			Week 8	54	0.2	3.32	0.0	-7	9
			Week 12	54	0.6	3.99	1.0	-9	9
	15mg	66	Week -5	61	0.4	3.16	1.0	-7	6
			Week 1	63	-1.2	2.76	-1.0	-9	5
			Week 2	62	-0.6	3.20	-1.0	-8	7
			Week 3	59	-1.0	3.37	-1.0	-9	7
			Week 4	60	0.0	3.41	-0.5	-9	7
			Week 6	60	-0.7	2.85	-0.5	-8	6
			Week 8	60	-0.4	3.56	-1.0	-7	9
			Week 12	58	-0.4	3.03	-0.5	-6	7
	30mg	60	Week -5	59	0.3	3.24	0.0	-5	10
			Week 1	55	-0.7	2.89	-1.0	-8	7

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Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Total Protein (G/L)	30mg	60	Week 2	56	-0.4	2.98	-1.0	-6	8
			Week 3	56	-0.5	3.12	-1.0	-7	6
			Week 4	55	-0.3	3.01	-1.0	-6	7
			Week 6	53	-0.2	3.07	0.0	-6	7
			Week 8	55	0.1	3.16	0.0	-8	8
			Week 12	55	-0.5	3.64	-1.0	-8	11
	45mg	61	Week -5	59	1.0	3.44	1.0	-8	13
			Week 1	59	-0.7	2.91	-1.0	-9	5
			Week 2	58	-0.4	2.92	0.0	-6	6
			Week 3	55	0.3	3.83	0.0	-8	12
			Week 4	56	0.1	3.94	-0.5	-7	17
			Week 6	54	-0.4	3.48	0.0	-13	6
			Week 8	54	0.2	3.42	1.0	-9	12
			Week 12	54	0.6	3.58	0.5	-5	11
Urea (MMOL/L)	Placebo	64	Week -5	63	-0.10	1.363	0.00	-2.5	4.0
			Week 1	61	0.10	1.356	0.10	-2.5	3.9
			Week 2	60	0.00	1.166	0.00	-2.5	3.5
			Week 3	55	0.03	1.122	0.00	-2.0	2.4
			Week 4	55	0.14	1.368	0.00	-2.5	3.5
			Week 6	53	0.09	1.324	0.00	-2.6	3.6
			Week 8	51	0.22	1.436	0.00	-2.5	4.0
			Week 12	49	0.01	1.483	0.00	-3.6	3.1
	2.5mg	61	Week -5	60	-0.14	1.263	-0.05	-4.1	2.5
			Week 1	59	-0.02	1.146	0.00	-3.8	2.4
			Week 2	58	-0.09	1.294	-0.35	-3.0	3.0
			Week 3	56	0.08	1.103	0.00	-3.7	3.4
			Week 4	56	-0.05	1.464	0.00	-4.0	5.5
			Week 6	49	-0.16	1.394	-0.20	-4.3	3.2

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urea (MMOL/L)	2.5mg	61	Week 8	48	0.05	1.589	0.00	-4.0	3.6
			Week 12	46	-0.22	1.322	-0.05	-4.1	2.5
	7.5mg	63	Week -5	60	-0.12	1.262	-0.20	-3.0	3.3
			Week 1	60	-0.19	1.068	0.00	-3.5	1.5
			Week 2	59	-0.11	1.102	0.00	-2.9	2.2
			Week 3	59	-0.26	1.102	-0.20	-2.5	2.5
			Week 4	57	-0.06	1.017	0.00	-2.5	2.9
			Week 6	56	0.04	1.377	0.00	-3.0	4.1
			Week 8	54	0.02	1.358	0.00	-3.6	3.5
			Week 12	54	0.00	1.134	0.00	-3.4	2.8
	15mg	66	Week -5	61	0.23	1.198	0.00	-3.9	3.5
			Week 1	63	0.06	1.504	0.00	-5.1	5.0
			Week 2	62	-0.02	1.539	0.00	-4.6	3.5
			Week 3	59	0.13	1.311	0.00	-3.4	4.4
			Week 4	60	-0.00	1.182	0.00	-3.5	3.5
			Week 6	60	0.26	1.617	0.50	-4.8	6.0
			Week 8	60	0.10	1.146	0.20	-2.9	2.8
			Week 12	58	0.08	1.466	0.00	-4.1	3.5
	30mg	60	Week -5	59	-0.26	1.120	-0.40	-2.5	1.9
			Week 1	55	-0.15	1.163	0.00	-3.5	1.5
			Week 2	56	-0.11	1.470	-0.45	-3.5	3.5
			Week 3	56	-0.35	1.277	-0.30	-4.5	2.0
			Week 4	55	0.15	1.418	0.00	-3.5	4.0
			Week 6	53	-0.12	1.373	0.00	-4.2	2.9
			Week 8	55	-0.09	1.191	0.00	-2.3	2.5
			Week 12	55	-0.00	1.494	0.00	-2.7	4.1
	45mg	61	Week -5	58	-0.21	1.324	0.00	-4.0	2.5
			Week 1	59	-0.22	1.093	-0.20	-3.5	2.7

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urea (MMOL/L)	45mg	61	Week 2	58	-0.25	1.457	-0.40	-3.4	5.2
			Week 3	55	0.23	1.366	0.00	-4.2	3.2
			Week 4	56	-0.34	1.342	0.00	-3.7	2.5
			Week 6	54	-0.29	1.569	-0.20	-4.0	4.4
			Week 8	54	-0.20	1.380	0.00	-4.2	3.5
			Week 12	54	-0.06	1.476	0.00	-4.1	3.2
Uric Acid (UMOL/L)	Placebo	64	Week -5	63	11.9	59.72	11.0	-111	246
			Week 1	61	3.2	55.51	0.0	-76	220
			Week 2	60	-4.1	42.66	-5.5	-170	156
			Week 3	55	-2.1	49.80	-7.0	-88	198
			Week 4	55	-7.4	51.22	-9.0	-149	190
			Week 6	53	-14.6	42.83	-11.0	-150	174
			Week 8	51	-12.1	53.33	-20.0	-99	185
			Week 12	49	-17.1	66.41	-24.0	-108	247
	2.5mg	61	Week -5	60	13.9	52.23	14.0	-120	146
			Week 1	59	3.1	40.36	3.0	-78	109
			Week 2	58	-4.9	46.19	-1.0	-97	120
			Week 3	56	-4.4	42.29	-3.0	-137	90
			Week 4	56	-1.8	50.75	2.5	-157	132
			Week 6	49	-10.3	53.59	-10.0	-172	194
			Week 8	48	-22.3	53.80	-24.0	-174	84
			Week 12	46	-15.2	39.18	-13.5	-100	111
	7.5mg	63	Week -5	60	10.7	58.66	8.5	-177	203
			Week 1	60	9.6	41.47	6.5	-143	131
			Week 2	59	10.8	47.73	3.0	-80	193
			Week 3	59	9.8	47.42	3.0	-90	147
			Week 4	56	3.3	51.43	5.0	-171	207
			Week 6	56	-0.3	55.95	0.0	-129	142

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Uric Acid (UMOL/L)	7.5mg	63	Week 8	54	3.3	38.15	0.5	-60	85
			Week 12	54	2.5	38.42	-4.5	-87	100
	15mg	66	Week -5	61	11.1	48.83	19.0	-146	130
			Week 1	63	-5.7	42.56	-2.0	-127	69
			Week 2	62	-5.8	43.48	-6.0	-136	107
			Week 3	59	-6.7	43.94	-14.0	-131	101
			Week 4	60	-8.2	46.31	-10.0	-139	80
			Week 6	60	-1.1	53.19	0.0	-141	100
			Week 8	60	-4.7	46.37	0.0	-117	74
			Week 12	58	-12.4	63.51	-9.5	-343	80
	30mg	60	Week -5	59	1.5	60.72	0.0	-168	236
			Week 1	55	-3.1	39.95	0.0	-154	69
			Week 2	56	10.1	63.67	10.0	-225	295
			Week 3	56	-0.3	52.95	-1.5	-75	257
			Week 4	55	-6.5	41.67	0.0	-97	90
			Week 6	53	0.3	46.87	-1.0	-194	90
			Week 8	55	-12.1	44.29	-13.0	-190	91
			Week 12	55	-15.0	48.22	-16.0	-180	101
	45mg	61	Week -5	58	23.3	64.36	30.0	-130	140
			Week 1	59	-0.9	37.06	0.0	-83	90
			Week 2	58	8.6	60.91	9.0	-110	234
			Week 3	55	-2.7	39.72	0.0	-149	95
			Week 4	56	-8.0	41.87	-2.0	-138	90
			Week 6	54	-11.2	45.37	-11.5	-133	72
			Week 8	54	-7.1	52.31	-10.0	-123	184
			Week 12	54	-4.8	59.84	-4.0	-140	177

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
White Blood Cell Count (GI/L)	Placebo	64	Week -5	62	0.30	1.251	0.15	-1.9	4.7
			Week 1	56	0.01	0.761	0.05	-2.7	1.5
			Week 2	60	0.22	1.058	0.25	-2.4	4.2
			Week 3	55	0.22	1.166	0.10	-2.1	5.1
			Week 4	55	-0.01	0.957	-0.10	-2.0	3.7
			Week 6	53	-0.05	0.863	0.00	-2.4	1.8
			Week 8	52	0.21	0.891	0.15	-2.3	4.0
			Week 12	44	0.22	1.001	0.15	-2.2	2.6
	2.5mg	61	Week -5	58	0.42	1.207	0.45	-2.8	3.4
			Week 1	60	0.29	1.265	0.10	-3.1	5.8
			Week 2	59	0.23	0.860	0.10	-1.4	3.3
			Week 3	58	0.20	1.151	0.10	-2.7	4.9
			Week 4	53	0.19	1.368	-0.10	-2.3	6.1
			Week 6	51	0.49	1.564	0.30	-2.6	5.9
			Week 8	47	0.20	1.313	0.30	-3.3	3.4
			Week 12	48	0.19	1.170	0.20	-2.4	4.1
	7.5mg	63	Week -5	59	0.01	1.233	-0.10	-2.8	2.8
			Week 1	60	-0.08	1.277	0.00	-4.3	3.2
			Week 2	59	0.27	1.667	0.30	-3.1	6.8
			Week 3	58	0.33	1.219	0.30	-2.7	3.5
			Week 4	56	0.19	1.106	0.25	-2.3	3.4
			Week 6	57	0.56	1.661	0.40	-2.9	5.9
			Week 8	54	0.24	1.275	0.30	-3.6	3.7
			Week 12	52	0.16	1.073	0.05	-2.3	2.5
	15mg	66	Week -5	61	0.40	1.096	0.40	-2.1	3.1
			Week 1	63	0.29	0.861	0.10	-1.6	2.5
			Week 2	61	0.36	0.880	0.40	-1.6	3.2
			Week 3	58	0.48	1.058	0.40	-2.4	3.5

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Table 12.20
Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
White Blood Cell Count (GI/L)	15mg	66	Week 4	60	0.25	1.321	0.15	-2.4	6.4
			Week 6	60	0.51	1.149	0.40	-1.5	4.2
			Week 8	60	0.24	0.995	0.45	-2.3	2.5
			Week 12	59	0.24	0.968	0.20	-2.1	3.1
	30mg	60	Week -5	58	0.23	1.427	0.30	-3.1	4.5
			Week 1	57	0.18	1.075	0.30	-2.7	2.7
			Week 2	54	0.33	1.505	0.25	-3.5	5.2
			Week 3	57	0.18	1.352	0.10	-2.7	3.7
			Week 4	57	-0.01	1.303	0.00	-3.3	2.8
			Week 6	56	0.23	1.495	0.30	-4.9	3.2
			Week 8	55	0.44	1.412	0.50	-3.1	3.8
			Week 12	53	0.37	1.578	0.20	-3.6	6.0
	45mg	61	Week -5	59	0.04	1.450	0.20	-7.2	4.7
			Week 1	59	0.28	1.473	0.50	-8.0	2.5
			Week 2	60	0.35	1.633	0.25	-7.5	7.0
			Week 3	55	0.24	1.544	0.40	-7.8	5.0
			Week 4	56	0.23	1.921	0.10	-5.0	10.4
			Week 6	53	0.26	1.258	0.30	-4.6	2.7
			Week 8	56	0.18	1.248	0.25	-5.5	2.5
			Week 12	54	0.19	1.664	0.25	-9.3	2.7

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Alanine Amino Transferase

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		59		60	
	> ref. range high	5	(8%)	5	(8%)	4	(7%)	9	(15%)	5	(8%)	0	
Baseline	n	64		61		63		66		59		61	
	> ref. range high	2	(3%)	5	(8%)	3	(5%)	8	(12%)	7	(12%)	1	(2%)
Week 1	n	61		59		60		63		56		59	
	> ref. range high	2	(3%)	4	(7%)	2	(3%)	4	(6%)	2	(4%)	2	(3%)
Week 2	n	60		58		59		62		57		58	
	> ref. range high	1	(2%)	1	(2%)	2	(3%)	3	(5%)	2	(4%)	2	(3%)
Week 3	n	55		56		59		59		57		55	
	> ref. range high	1	(2%)	4	(7%)	1	(2%)	7	(12%)	1	(2%)	1	(2%)
Week 4	n	54		56		57		60		56		56	
	> ref. range high	0		4	(7%)	1	(2%)	8	(13%)	1	(2%)	2	(4%)
Week 6	n	53		49		56		60		53		54	
	> ref. range high	2	(4%)	4	(8%)	1	(2%)	4	(7%)	1	(2%)	1	(2%)
Week 8	n	51		48		54		60		55		54	
	> ref. range high	0		3	(6%)	4	(7%)	4	(7%)	2	(4%)	2	(4%)
Week 12	n	49		46		54		58		56		54	
	> ref. range high	0		2	(4%)	2	(4%)	4	(7%)	2	(4%)	2	(4%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	3	(5%)	7	(11%)	7	(11%)	10	(15%)	4	(7%)	6	(10%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Albumin

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	60
	> ref. range high	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)
	< ref. range low	0	0	0	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	2 (3%)	1 (2%)	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 2	n	60	58	59	62	57	58
	> ref. range high	1 (2%)	0	0	0	0	1 (2%)
	< ref. range low	0	0	0	0	0	0
Week 3	n	55	56	59	59	57	55
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 4	n	55	56	57	60	56	56
	> ref. range high	0	2 (4%)	0	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	0	0	0
Week 6	n	53	49	56	60	53	54
	> ref. range high	1 (2%)	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Albumin

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 12	n	49	46	54	58	56	54
	> ref. range high	0	0	0	0	1 (2%)	0
	< ref. range low	0	0	0	0	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	1 (2%)	2 (3%)	0	1 (2%)	1 (2%)	2 (3%)
	< ref. range low	0	0	0	0	0	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Alkaline Phosphatase

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		59		60	
	> ref. range high	1	(2%)	3	(5%)	1	(2%)	3	(5%)	1	(2%)	4	(7%)
	< ref. range low	0		0		0		0		0		0	
Baseline	n	64		61		63		66		59		61	
	> ref. range high	1	(2%)	4	(7%)	1	(2%)	5	(8%)	1	(2%)	3	(5%)
	< ref. range low	0		0		0		0		0		0	
Week 1	n	61		59		60		63		56		59	
	> ref. range high	1	(2%)	3	(5%)	1	(2%)	4	(6%)	0		3	(5%)
	< ref. range low	0		0		0		0		0		0	
Week 2	n	60		58		59		62		57		58	
	> ref. range high	1	(2%)	3	(5%)	1	(2%)	3	(5%)	0		3	(5%)
	< ref. range low	0		0		0		0		0		0	
Week 3	n	55		56		59		59		57		55	
	> ref. range high	1	(2%)	2	(4%)	1	(2%)	3	(5%)	1	(2%)	2	(4%)
	< ref. range low	0		0		0		0		0		0	
Week 4	n	55		56		57		60		56		56	
	> ref. range high	1	(2%)	3	(5%)	3	(5%)	2	(3%)	1	(2%)	4	(7%)
	< ref. range low	0		0		0		0		0		0	
Week 6	n	53		49		56		60		53		54	
	> ref. range high	1	(2%)	2	(4%)	1	(2%)	3	(5%)	0		2	(4%)
	< ref. range low	0		0		0		0		0		0	

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Alkaline Phosphatase

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	51		48		54		60		55		54	
	> ref. range high	1	(2%)	4	(8%)	2	(4%)	2	(3%)	0		2	(4%)
	< ref. range low	0		0		0		0		0		0	
Week 12	n	49		46		54		58		56		54	
	> ref. range high	2	(4%)	3	(7%)	1	(2%)	2	(3%)	1	(2%)	2	(4%)
	< ref. range low	0		0		0		0		0		0	
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	2	(3%)	5	(8%)	3	(5%)	4	(6%)	3	(5%)	4	(7%)
	< ref. range low	0		0		0		0		0		0	

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Aspartate Amino Transferase

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	60
	> ref. range high	0	3 (5%)	1 (2%)	1 (2%)	3 (5%)	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	1 (2%)	3 (5%)	0	0	3 (5%)	1 (2%)
Week 1	n	61	59	60	63	56	59
	> ref. range high	1 (2%)	3 (5%)	0	0	1 (2%)	2 (3%)
Week 2	n	60	58	59	62	57	57
	> ref. range high	0	2 (3%)	1 (2%)	2 (3%)	2 (4%)	2 (4%)
Week 3	n	55	56	58	59	56	55
	> ref. range high	0	3 (5%)	0	0	1 (2%)	1 (2%)
Week 4	n	55	56	56	60	56	56
	> ref. range high	0	2 (4%)	0	1 (2%)	1 (2%)	1 (2%)
Week 6	n	53	48	56	60	53	54
	> ref. range high	1 (2%)	2 (4%)	0	1 (2%)	1 (2%)	1 (2%)
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	2 (4%)	2 (4%)	0	1 (2%)	1 (2%)
Week 12	n	49	46	54	58	56	54
	> ref. range high	0	1 (2%)	0	1 (2%)	2 (4%)	1 (2%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	2 (3%)	7 (11%)	2 (3%)	4 (6%)	2 (3%)	3 (5%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Basophils

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Any visit	n	64	61	63	66	60	61
	> ref. range high	0	0	0	0	0	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: C-Peptide

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	63	57	60	62	57	57
	> ref. range high	11 (17%)	11 (19%)	7 (12%)	6 (10%)	10 (18%)	9 (16%)
	< ref. range low	0	0	1 (2%)	0	0	1 (2%)
Baseline	n	63	57	62	65	58	58
	> ref. range high	11 (17%)	10 (18%)	7 (11%)	6 (9%)	10 (17%)	9 (16%)
	< ref. range low	0	0	2 (3%)	1 (2%)	0	1 (2%)
Any visit post-baseline	n	0	1	0	1	0	0
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Calcium

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	60	62	59	61
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	3 (5%)	0	0
	< ref. range low	1 (2%)	4 (7%)	0	0	0	1 (2%)
Baseline	n	64	61	63	66	59	61
	> ref. range high	5 (8%)	1 (2%)	0	2 (3%)	0	1 (2%)
	< ref. range low	2 (3%)	5 (8%)	3 (5%)	3 (5%)	2 (3%)	2 (3%)
Week 1	n	61	59	60	63	56	59
	> ref. range high	1 (2%)	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)
	< ref. range low	2 (3%)	2 (3%)	5 (8%)	2 (3%)	2 (4%)	1 (2%)
Week 2	n	60	58	59	62	57	57
	> ref. range high	1 (2%)	0	0	1 (2%)	0	0
	< ref. range low	4 (7%)	3 (5%)	6 (10%)	5 (8%)	2 (4%)	4 (7%)
Week 3	n	55	56	58	59	56	55
	> ref. range high	1 (2%)	1 (2%)	0	2 (3%)	0	2 (4%)
	< ref. range low	6 (11%)	7 (13%)	4 (7%)	4 (7%)	0	2 (4%)
Week 4	n	55	56	56	60	56	56
	> ref. range high	1 (2%)	1 (2%)	0	2 (3%)	0	2 (4%)
	< ref. range low	3 (5%)	3 (5%)	3 (5%)	1 (2%)	0	1 (2%)
Week 6	n	53	48	56	60	53	54
	> ref. range high	2 (4%)	1 (2%)	1 (2%)	2 (3%)	0	1 (2%)
	< ref. range low	5 (9%)	3 (6%)	5 (9%)	3 (5%)	2 (4%)	8 (15%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Calcium

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	51		48		54		60		55		54	
	> ref. range high	1	(2%)	1	(2%)	0		1	(2%)	0		2	(4%)
	< ref. range low	2	(4%)	3	(6%)	2	(4%)	2	(3%)	3	(5%)	2	(4%)
Week 12	n	49		46		54		58		56		54	
	> ref. range high	1	(2%)	0		0		2	(3%)	0		2	(4%)
	< ref. range low	2	(4%)	2	(4%)	1	(2%)	0		4	(7%)	1	(2%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	3	(5%)	4	(7%)	1	(2%)	2	(3%)	1	(2%)	5	(8%)
	< ref. range low	16	(25%)	16	(26%)	16	(25%)	12	(18%)	9	(15%)	13	(22%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Carbon Dioxide content / Bicarbonate

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	60	62	59	61
	> ref. range high	0	0	0	0	0	0
	< ref. range low	8 (13%)	6 (10%)	4 (7%)	13 (21%)	6 (10%)	11 (18%)
Baseline	n	64	61	63	66	59	61
	> ref. range high	0	0	0	0	0	0
	< ref. range low	4 (6%)	4 (7%)	7 (11%)	10 (15%)	16 (27%)	10 (16%)
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	0	0	0	0	0
	< ref. range low	6 (10%)	7 (12%)	12 (20%)	8 (13%)	7 (13%)	1 (2%)
Week 2	n	60	58	59	62	57	57
	> ref. range high	0	0	0	0	0	0
	< ref. range low	9 (15%)	12 (21%)	8 (14%)	11 (18%)	4 (7%)	10 (18%)
Week 3	n	55	56	57	59	56	55
	> ref. range high	0	0	0	0	0	0
	< ref. range low	4 (7%)	8 (14%)	8 (14%)	9 (15%)	6 (11%)	8 (15%)
Week 4	n	55	56	56	60	56	56
	> ref. range high	0	0	0	0	0	0
	< ref. range low	11 (20%)	12 (21%)	5 (9%)	9 (15%)	10 (18%)	14 (25%)
Week 6	n	53	48	56	60	53	54
	> ref. range high	0	0	0	0	0	0
	< ref. range low	4 (8%)	5 (10%)	7 (13%)	9 (15%)	5 (9%)	7 (13%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Carbon Dioxide content / Bicarbonate

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	51		48		54		60		55		54	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	6	(12%)	10	(21%)	8	(15%)	11	(18%)	11	(20%)	12	(22%)
Week 12	n	49		46		54		58		56		54	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	7	(14%)	4	(9%)	8	(15%)	9	(16%)	4	(7%)	14	(26%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	29	(46%)	33	(54%)	31	(49%)	32	(49%)	29	(49%)	33	(55%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Chloride

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		58		61	
	> ref. range high	2	(3%)	1	(2%)	2	(3%)	1	(2%)	0		2	(3%)
	< ref. range low	1	(2%)	0		1	(2%)	0		2	(3%)	0	
Baseline	n	64		61		63		66		59		61	
	> ref. range high	0		3	(5%)	1	(2%)	2	(3%)	2	(3%)	3	(5%)
	< ref. range low	1	(2%)	0		0		0		3	(5%)	1	(2%)
Week 1	n	61		59		60		63		56		59	
	> ref. range high	0		2	(3%)	2	(3%)	1	(2%)	2	(4%)	2	(3%)
	< ref. range low	1	(2%)	0		0		0		1	(2%)	0	
Week 2	n	60		58		59		62		57		58	
	> ref. range high	2	(3%)	1	(2%)	2	(3%)	2	(3%)	1	(2%)	0	
	< ref. range low	0		0		0		0		1	(2%)	1	(2%)
Week 3	n	55		56		59		59		57		55	
	> ref. range high	1	(2%)	1	(2%)	2	(3%)	1	(2%)	2	(4%)	6	(11%)
	< ref. range low	1	(2%)	0		0		0		2	(4%)	0	
Week 4	n	55		56		57		60		56		56	
	> ref. range high	4	(7%)	1	(2%)	1	(2%)	1	(2%)	2	(4%)	2	(4%)
	< ref. range low	0		0		0		0		1	(2%)	0	
Week 6	n	53		49		56		60		53		54	
	> ref. range high	2	(4%)	2	(4%)	2	(4%)	2	(3%)	3	(6%)	2	(4%)
	< ref. range low	1	(2%)	0		0		0		1	(2%)	2	(4%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Chloride

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	2 (4%)	1 (2%)	3 (5%)	2 (4%)	2 (4%)
	< ref. range low	1 (2%)	0	0	0	0	1 (2%)
Week 12	n	49	46	54	58	56	54
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	2 (3%)	0	3 (6%)
	< ref. range low	1 (2%)	0	0	0	1 (2%)	1 (2%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	7 (11%)	4 (7%)	4 (6%)	8 (12%)	8 (14%)	13 (22%)
	< ref. range low	1 (2%)	0	0	0	3 (5%)	4 (7%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Creatine Kinase MB

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	63	58	60	62	58	57
	> ref. range high	1 (2%)	2 (3%)	3 (5%)	2 (3%)	4 (7%)	0
Baseline	n	63	59	63	66	60	59
	> ref. range high	0	1 (2%)	2 (3%)	1 (2%)	3 (5%)	1 (2%)
Week 4	n	52	54	56	59	54	53
	> ref. range high	0	1 (2%)	1 (2%)	1 (2%)	4 (7%)	1 (2%)
Week 12	n	48	43	51	59	52	51
	> ref. range high	0	0	1 (2%)	0	5 (10%)	2 (4%)
Any visit post-baseline	n	61	60	62	64	59	57
	> ref. range high	0	1 (2%)	2 (3%)	1 (2%)	7 (12%)	2 (4%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Creatinine

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		60		62		59		60	
	> ref. range high	4	(6%)	0		0		1	(2%)	0		1	(2%)
	< ref. range low	0		0		0		0		0		0	
Baseline	n	64		61		63		66		59		61	
	> ref. range high	2	(3%)	2	(3%)	0		1	(2%)	0		1	(2%)
	< ref. range low	0		1	(2%)	0		0		0		0	
Week 1	n	61		59		60		63		56		59	
	> ref. range high	3	(5%)	2	(3%)	0		1	(2%)	0		2	(3%)
	< ref. range low	0		1	(2%)	0		0		0		0	
Week 2	n	60		58		59		62		57		58	
	> ref. range high	2	(3%)	2	(3%)	0		1	(2%)	0		2	(3%)
	< ref. range low	0		0		0		0		1	(2%)	0	
Week 3	n	55		56		59		59		57		55	
	> ref. range high	2	(4%)	1	(2%)	0		1	(2%)	0		1	(2%)
	< ref. range low	0		1	(2%)	0		0		0		0	
Week 4	n	55		56		56		60		56		56	
	> ref. range high	1	(2%)	2	(4%)	0		1	(2%)	0		0	
	< ref. range low	0		0		0		0		0		0	
Week 6	n	53		49		56		60		53		54	
	> ref. range high	2	(4%)	0		0		1	(2%)	0		3	(6%)
	< ref. range low	0		0		0		0		1	(2%)	0	

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Creatinine

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	2 (4%)	0	0	1 (2%)	0	0
	< ref. range low	0	1 (2%)	0	0	0	0
Week 12	n	49	46	54	58	56	54
	> ref. range high	3 (6%)	2 (4%)	0	2 (3%)	0	0
	< ref. range low	0	1 (2%)	0	0	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	4 (6%)	4 (7%)	0	2 (3%)	0	4 (7%)
	< ref. range low	0	1 (2%)	0	0	2 (3%)	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Direct Bilirubin

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	60
	> ref. range high	1 (2%)	0	0	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	1 (2%)	1 (2%)	0	0	0	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	1 (2%)	1 (2%)	0	0	0	0
Week 2	n	60	58	59	62	57	58
	> ref. range high	0	0	0	0	0	1 (2%)
Week 3	n	55	56	59	59	57	55
	> ref. range high	0	0	0	0	1 (2%)	0
Week 4	n	55	56	56	60	56	56
	> ref. range high	0	0	0	0	0	0
Week 6	n	53	49	56	60	53	54
	> ref. range high	0	0	0	0	1 (2%)	0
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	0	0	0	0	0
Week 12	n	49	45	54	58	56	54
	> ref. range high	0	0	0	0	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	0	2 (3%)	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Eosinophils

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	63	60	61	62	59	59
	> ref. range high	0	0	1 (2%)	1 (2%)	1 (2%)	0
	< ref. range low	6 (10%)	0	4 (7%)	4 (6%)	6 (10%)	0
Baseline	n	64	61	63	66	60	60
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)	0
	< ref. range low	6 (9%)	2 (3%)	4 (6%)	1 (2%)	1 (2%)	2 (3%)
Week 1	n	56	60	60	63	57	59
	> ref. range high	1 (2%)	2 (3%)	4 (7%)	0	2 (4%)	1 (2%)
	< ref. range low	5 (9%)	3 (5%)	5 (8%)	1 (2%)	2 (4%)	2 (3%)
Week 2	n	60	59	59	61	54	60
	> ref. range high	2 (3%)	1 (2%)	3 (5%)	0	1 (2%)	0
	< ref. range low	4 (7%)	3 (5%)	3 (5%)	3 (5%)	3 (6%)	3 (5%)
Week 3	n	55	58	58	58	57	55
	> ref. range high	0	1 (2%)	2 (3%)	0	2 (4%)	0
	< ref. range low	6 (11%)	2 (3%)	3 (5%)	2 (3%)	2 (4%)	3 (5%)
Week 4	n	55	53	56	60	57	56
	> ref. range high	0	1 (2%)	3 (5%)	0	1 (2%)	0
	< ref. range low	2 (4%)	2 (4%)	3 (5%)	3 (5%)	5 (9%)	0
Week 6	n	53	51	57	60	56	53
	> ref. range high	0	1 (2%)	2 (4%)	0	2 (4%)	0
	< ref. range low	5 (9%)	0	3 (5%)	1 (2%)	6 (11%)	2 (4%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Eosinophils

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	53	60	54	56
	> ref. range high	0	1 (2%)	1 (2%)	1 (2%)	0	0
	< ref. range low	8 (15%)	1 (2%)	3 (6%)	1 (2%)	8 (15%)	2 (4%)
Week 12	n	44	48	52	59	53	54
	> ref. range high	0	0	2 (4%)	0	1 (2%)	0
	< ref. range low	4 (9%)	1 (2%)	1 (2%)	2 (3%)	3 (6%)	2 (4%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	3 (5%)	3 (5%)	9 (14%)	1 (2%)	4 (7%)	1 (2%)
	< ref. range low	9 (14%)	9 (15%)	10 (16%)	8 (12%)	14 (24%)	6 (10%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Glucose

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -6	n	64	60	61	62	60	59
	> ref. range high	64 (100%)	59 (98%)	61 (100%)	62 (100%)	60 (100%)	58 (98%)
	< ref. range low	0	0	0	0	0	1 (2%)
Week -5	n	63	61	62	63	58	60
	> ref. range high	63 (100%)	61 (100%)	62 (100%)	63 (100%)	58 (100%)	60 (100%)
	< ref. range low	0	0	0	0	0	0
Week -4	n	64	61	62	62	60	60
	> ref. range high	64 (100%)	61 (100%)	62 (100%)	62 (100%)	60 (100%)	60 (100%)
	< ref. range low	0	0	0	0	0	0
Week -2	n	61	58	61	66	59	61
	> ref. range high	61 (100%)	58 (100%)	60 (98%)	66 (100%)	58 (98%)	60 (98%)
	< ref. range low	0	0	0	0	1 (2%)	0
Baseline	n	64	59	63	66	60	60
	> ref. range high	63 (98%)	59 (100%)	61 (97%)	66 (100%)	60 (100%)	59 (98%)
	< ref. range low	0	0	0	0	0	0
Week 1	n	61	60	62	63	58	60
	> ref. range high	60 (98%)	59 (98%)	60 (97%)	63 (100%)	58 (100%)	60 (100%)
	< ref. range low	0	0	0	0	0	0
Week 2	n	60	59	60	63	57	60
	> ref. range high	60 (100%)	59 (100%)	57 (95%)	63 (100%)	57 (100%)	59 (98%)
	< ref. range low	0	0	0	0	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Glucose

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 3	n	55	58	59	60	56	56
	> ref. range high	54 (98%)	58 (100%)	55 (93%)	60 (100%)	56 (100%)	56 (100%)
	< ref. range low	0	0	0	0	0	0
Week 4	n	56	53	57	60	57	57
	> ref. range high	56 (100%)	52 (98%)	54 (95%)	60 (100%)	56 (98%)	54 (95%)
	< ref. range low	0	0	1 (2%)	0	0	0
Week 6	n	53	51	57	60	57	55
	> ref. range high	52 (98%)	50 (98%)	54 (95%)	60 (100%)	56 (98%)	53 (96%)
	< ref. range low	0	0	0	0	0	0
Week 8	n	53	47	56	60	56	56
	> ref. range high	52 (98%)	45 (96%)	54 (96%)	60 (100%)	56 (100%)	54 (96%)
	< ref. range low	0	0	0	0	0	0
Week 12	n	49	48	54	59	56	55
	> ref. range high	48 (98%)	47 (98%)	49 (91%)	59 (100%)	54 (96%)	54 (98%)
	< ref. range low	0	0	1 (2%)	0	0	0
Any visit post-baseline	n	63	61	63	66	59	60
	> ref. range high	63 (100%)	61 (100%)	62 (98%)	66 (100%)	59 (100%)	60 (100%)
	< ref. range low	0	0	2 (3%)	0	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Hematocrit

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		63		59		60	
	> ref. range high	2	(3%)	5	(8%)	6	(10%)	3	(5%)	3	(5%)	2	(3%)
	< ref. range low	1	(2%)	3	(5%)	2	(3%)	2	(3%)	1	(2%)	1	(2%)
Baseline	n	64		61		63		66		60		61	
	> ref. range high	4	(6%)	5	(8%)	6	(10%)	1	(2%)	2	(3%)	1	(2%)
	< ref. range low	1	(2%)	5	(8%)	1	(2%)	3	(5%)	3	(5%)	5	(8%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	4	(7%)	4	(7%)	5	(8%)	1	(2%)	1	(2%)	2	(3%)
	< ref. range low	4	(7%)	8	(13%)	2	(3%)	6	(10%)	3	(5%)	5	(8%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	3	(5%)	1	(2%)	1	(2%)	0		2	(4%)	1	(2%)
	< ref. range low	1	(2%)	7	(12%)	2	(3%)	4	(7%)	2	(4%)	6	(10%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	1	(2%)	1	(2%)	4	(7%)	0		1	(2%)	6	(11%)
	< ref. range low	0		2	(3%)	5	(9%)	5	(9%)	0		3	(5%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	3	(5%)	2	(4%)	3	(5%)	0		4	(7%)	2	(4%)
	< ref. range low	4	(7%)	3	(6%)	3	(5%)	5	(8%)	1	(2%)	3	(5%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	0		2	(4%)	2	(4%)	0		1	(2%)	3	(6%)
	< ref. range low	3	(6%)	3	(6%)	3	(5%)	4	(7%)	2	(4%)	5	(9%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Hematocrit

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	54	60	55	56
	> ref. range high	1 (2%)	0	3 (6%)	0	3 (5%)	1 (2%)
	< ref. range low	3 (6%)	3 (6%)	3 (6%)	4 (7%)	0	7 (13%)
Week 12	n	45	48	52	59	53	54
	> ref. range high	1 (2%)	4 (8%)	3 (6%)	0	2 (4%)	1 (2%)
	< ref. range low	1 (2%)	2 (4%)	4 (8%)	4 (7%)	3 (6%)	4 (7%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	10 (16%)	7 (11%)	8 (13%)	1 (2%)	4 (7%)	9 (15%)
	< ref. range low	9 (14%)	10 (16%)	6 (10%)	10 (15%)	6 (10%)	11 (18%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Hemoglobin

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		63		59		60	
	> ref. range high	1	(2%)	2	(3%)	3	(5%)	0		4	(7%)	0	
	< ref. range low	1	(2%)	2	(3%)	2	(3%)	4	(6%)	2	(3%)	3	(5%)
Baseline	n	64		61		63		66		60		61	
	> ref. range high	3	(5%)	3	(5%)	4	(6%)	0		3	(5%)	1	(2%)
	< ref. range low	1	(2%)	6	(10%)	2	(3%)	3	(5%)	3	(5%)	2	(3%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	0		1	(2%)	1	(2%)	0		0		0	
	< ref. range low	1	(2%)	7	(12%)	1	(2%)	2	(3%)	3	(5%)	7	(12%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	1	(2%)	1	(2%)	1	(2%)	0		1	(2%)	0	
	< ref. range low	1	(2%)	6	(10%)	1	(2%)	5	(8%)	2	(4%)	4	(7%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	0		1	(2%)	3	(5%)	0		2	(4%)	1	(2%)
	< ref. range low	1	(2%)	3	(5%)	3	(5%)	6	(10%)	2	(4%)	3	(5%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	2	(4%)	1	(2%)	2	(4%)	0		2	(4%)	0	
	< ref. range low	3	(5%)	4	(8%)	2	(4%)	3	(5%)	4	(7%)	2	(4%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	0		1	(2%)	2	(4%)	0		1	(2%)	1	(2%)
	< ref. range low	3	(6%)	5	(10%)	2	(4%)	3	(5%)	3	(5%)	4	(8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Hemoglobin

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	52		47		54		60		55		56	
	> ref. range high	0		0		2	(4%)	0		2	(4%)	0	
	< ref. range low	2	(4%)	3	(6%)	2	(4%)	3	(5%)	1	(2%)	4	(7%)
Week 12	n	45		48		52		59		53		54	
	> ref. range high	1	(2%)	2	(4%)	1	(2%)	0		3	(6%)	1	(2%)
	< ref. range low	1	(2%)	3	(6%)	2	(4%)	2	(3%)	3	(6%)	2	(4%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	4	(6%)	2	(3%)	7	(11%)	0		4	(7%)	2	(3%)
	< ref. range low	5	(8%)	10	(16%)	5	(8%)	9	(14%)	6	(10%)	10	(17%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Indirect Bilirubin

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		59		59	
	> ref. range high	3	(5%)	4	(7%)	2	(3%)	2	(3%)	4	(7%)	3	(5%)
Baseline	n	64		61		63		66		59		61	
	> ref. range high	3	(5%)	3	(5%)	3	(5%)	3	(5%)	7	(12%)	3	(5%)
Week 1	n	61		59		60		63		56		59	
	> ref. range high	2	(3%)	4	(7%)	5	(8%)	2	(3%)	2	(4%)	3	(5%)
Week 2	n	60		58		59		62		57		58	
	> ref. range high	5	(8%)	3	(5%)	1	(2%)	2	(3%)	2	(4%)	2	(3%)
Week 3	n	55		56		59		59		57		55	
	> ref. range high	2	(4%)	4	(7%)	2	(3%)	2	(3%)	4	(7%)	2	(4%)
Week 4	n	55		56		55		60		56		56	
	> ref. range high	1	(2%)	3	(5%)	1	(2%)	3	(5%)	2	(4%)	2	(4%)
Week 6	n	53		48		56		60		53		54	
	> ref. range high	1	(2%)	4	(8%)	1	(2%)	2	(3%)	2	(4%)	2	(4%)
Week 8	n	51		48		54		60		55		54	
	> ref. range high	2	(4%)	3	(6%)	3	(6%)	2	(3%)	2	(4%)	2	(4%)
Week 12	n	49		45		54		58		56		54	
	> ref. range high	1	(2%)	5	(11%)	3	(6%)	2	(3%)	3	(5%)	1	(2%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	7	(11%)	9	(15%)	7	(11%)	3	(5%)	5	(8%)	5	(8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Lactate Dehydrogenase

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	61
	> ref. range high	0	0	0	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	0	0	0	0	0	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	0	0	1 (2%)	0	0
Week 2	n	60	58	59	62	57	57
	> ref. range high	0	0	0	0	1 (2%)	0
Week 3	n	55	56	58	59	56	55
	> ref. range high	0	0	0	0	0	0
Week 4	n	55	56	56	60	56	56
	> ref. range high	0	0	0	0	0	0
Week 6	n	53	48	56	60	53	54
	> ref. range high	0	0	0	0	0	1 (2%)
Week 8	n	51	48	54	58	55	54
	> ref. range high	0	1 (2%)	2 (4%)	0	0	0
Week 12	n	48	46	54	58	56	54
	> ref. range high	0	0	0	0	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	0	1 (2%)	2 (3%)	1 (2%)	1 (2%)	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Lymphocytes

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	63	60	61	62	59	59
	> ref. range high	1 (2%)	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	0	0	0	1 (2%)	1 (2%)
Baseline	n	64	61	63	66	60	60
	> ref. range high	1 (2%)	0	1 (2%)	0	0	1 (2%)
	< ref. range low	0	0	0	0	1 (2%)	0
Week 1	n	56	60	60	63	57	59
	> ref. range high	0	1 (2%)	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 2	n	60	59	59	61	54	60
	> ref. range high	0	0	0	0	0	1 (2%)
	< ref. range low	0	0	1 (2%)	0	0	0
Week 3	n	55	58	58	58	57	55
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	0	0	0	2 (4%)	0
Week 4	n	55	53	56	60	57	56
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	0	0	0	0	0
Week 6	n	53	51	57	60	56	53
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	0	0	1 (2%)	1 (2%)	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Lymphocytes

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	53	60	54	56
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 12	n	44	48	52	59	53	54
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	1 (2%)	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	0	4 (7%)	0	0	0	4 (7%)
	< ref. range low	1 (2%)	0	1 (2%)	1 (2%)	2 (3%)	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Monocytes

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		62		59		59	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	8	(13%)	4	(7%)	6	(10%)	3	(5%)	4	(7%)	3	(5%)
Baseline	n	64		61		63		66		60		60	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	9	(14%)	8	(13%)	6	(10%)	3	(5%)	5	(8%)	8	(13%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	0		1	(2%)	1	(2%)	0		0		0	
	< ref. range low	9	(16%)	5	(8%)	8	(13%)	4	(6%)	3	(5%)	6	(10%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	8	(13%)	5	(8%)	6	(10%)	8	(13%)	2	(4%)	2	(3%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	0		0		0		0		0		1	(2%)
	< ref. range low	5	(9%)	4	(7%)	4	(7%)	3	(5%)	4	(7%)	3	(5%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	0		0		0		0		0		0	
	< ref. range low	6	(11%)	3	(6%)	9	(16%)	2	(3%)	6	(11%)	3	(5%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	0		0		1	(2%)	0		0		0	
	< ref. range low	7	(13%)	5	(10%)	6	(11%)	2	(3%)	1	(2%)	8	(15%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Monocytes

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	53	60	54	56
	> ref. range high	0	0	0	0	0	0
	< ref. range low	10 (19%)	4 (9%)	4 (8%)	3 (5%)	0	4 (7%)
Week 12	n	44	48	52	59	53	54
	> ref. range high	1 (2%)	0	0	0	0	0
	< ref. range low	3 (7%)	4 (8%)	3 (6%)	5 (8%)	5 (9%)	5 (9%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	1 (2%)	1 (2%)	2 (3%)	0	0	1 (2%)
	< ref. range low	22 (35%)	16 (26%)	17 (27%)	17 (26%)	17 (29%)	15 (25%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Phosphorus, Inorganic

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	61
	> ref. range high	1 (2%)	1 (2%)	0	0	1 (2%)	3 (5%)
	< ref. range low	1 (2%)	0	2 (3%)	3 (5%)	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	3 (5%)	0	2 (3%)	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	0	0	2 (3%)
Week 1	n	61	59	60	63	56	59
	> ref. range high	1 (2%)	0	0	1 (2%)	2 (4%)	0
	< ref. range low	1 (2%)	0	0	2 (3%)	0	0
Week 2	n	60	58	59	62	57	58
	> ref. range high	1 (2%)	0	2 (3%)	3 (5%)	0	2 (3%)
	< ref. range low	0	0	1 (2%)	3 (5%)	0	0
Week 3	n	55	56	59	59	57	55
	> ref. range high	0	1 (2%)	2 (3%)	0	0	2 (4%)
	< ref. range low	0	0	0	1 (2%)	1 (2%)	0
Week 4	n	55	56	57	60	56	56
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)
	< ref. range low	1 (2%)	1 (2%)	2 (4%)	4 (7%)	1 (2%)	1 (2%)
Week 6	n	53	49	56	60	53	54
	> ref. range high	1 (2%)	0	1 (2%)	1 (2%)	0	2 (4%)
	< ref. range low	0	0	2 (4%)	0	0	2 (4%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Phosphorus, Inorganic

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	58	55	54
	> ref. range high	1 (2%)	0	0	0	2 (4%)	1 (2%)
	< ref. range low	1 (2%)	0	1 (2%)	1 (2%)	0	2 (4%)
Week 12	n	49	46	54	58	56	54
	> ref. range high	0	0	1 (2%)	0	0	2 (4%)
	< ref. range low	0	1 (2%)	2 (4%)	2 (3%)	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	4 (6%)	2 (3%)	8 (13%)	4 (6%)	4 (7%)	5 (8%)
	< ref. range low	3 (5%)	2 (3%)	6 (10%)	6 (9%)	2 (3%)	5 (8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Platelet count

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	63	60	61	63	59	58
	> ref. range high	1 (2%)	2 (3%)	0	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	0	1 (2%)	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)	1 (2%)
	< ref. range low	0	0	1 (2%)	0	2 (3%)	1 (2%)
Week 1	n	56	60	59	63	57	57
	> ref. range high	0	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)
	< ref. range low	0	0	0	0	1 (2%)	0
Week 2	n	60	59	59	61	54	60
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	1 (2%)	0	0	1 (2%)	1 (2%)
Week 3	n	55	58	58	58	56	55
	> ref. range high	0	2 (3%)	0	0	0	1 (2%)
	< ref. range low	0	1 (2%)	1 (2%)	0	1 (2%)	0
Week 4	n	54	53	55	60	57	56
	> ref. range high	0	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	0	2 (4%)	1 (2%)
Week 6	n	53	51	57	60	56	53
	> ref. range high	0	3 (6%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)
	< ref. range low	0	1 (2%)	0	0	1 (2%)	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Platelet count

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	54	60	54	56
	> ref. range high	0	2 (4%)	0	0	0	3 (5%)
	< ref. range low	0	0	0	0	1 (2%)	0
Week 12	n	44	48	52	59	52	54
	> ref. range high	0	1 (2%)	0	1 (2%)	0	0
	< ref. range low	1 (2%)	1 (2%)	0	0	0	3 (6%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	1 (2%)	4 (7%)	2 (3%)	1 (2%)	1 (2%)	4 (7%)
	< ref. range low	1 (2%)	1 (2%)	1 (2%)	0	2 (3%)	3 (5%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Potassium

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	60	62	59	61
	> ref. range high	4 (6%)	3 (5%)	1 (2%)	0	3 (5%)	1 (2%)
	< ref. range low	1 (2%)	1 (2%)	0	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	5 (8%)	8 (13%)	8 (13%)	2 (3%)	7 (12%)	6 (10%)
	< ref. range low	0	1 (2%)	0	0	1 (2%)	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	6 (10%)	5 (8%)	5 (8%)	3 (5%)	6 (11%)	4 (7%)
	< ref. range low	1 (2%)	0	0	0	0	0
Week 2	n	60	58	59	62	57	57
	> ref. range high	4 (7%)	6 (10%)	9 (15%)	6 (10%)	8 (14%)	9 (16%)
	< ref. range low	1 (2%)	1 (2%)	2 (3%)	0	0	1 (2%)
Week 3	n	55	56	58	59	56	55
	> ref. range high	7 (13%)	5 (9%)	8 (14%)	5 (8%)	1 (2%)	3 (5%)
	< ref. range low	0	0	0	0	0	0
Week 4	n	55	56	56	60	56	56
	> ref. range high	4 (7%)	2 (4%)	2 (4%)	3 (5%)	1 (2%)	3 (5%)
	< ref. range low	0	1 (2%)	1 (2%)	0	0	0
Week 6	n	53	48	56	60	53	54
	> ref. range high	3 (6%)	6 (13%)	4 (7%)	6 (10%)	2 (4%)	9 (17%)
	< ref. range low	0	1 (2%)	0	0	0	0

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Potassium

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	6 (12%)	3 (6%)	3 (6%)	5 (8%)	5 (9%)	4 (7%)
	< ref. range low	0	1 (2%)	1 (2%)	1 (2%)	0	0
Week 12	n	49	46	54	58	56	54
	> ref. range high	4 (8%)	2 (4%)	5 (9%)	3 (5%)	4 (7%)	3 (6%)
	< ref. range low	0	1 (2%)	0	2 (3%)	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	18 (29%)	16 (26%)	21 (33%)	16 (25%)	14 (24%)	17 (28%)
	< ref. range low	2 (3%)	1 (2%)	3 (5%)	2 (3%)	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Red Blood Cell Count

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		63		59		60	
	> ref. range high	2	(3%)	1	(2%)	3	(5%)	1	(2%)	2	(3%)	2	(3%)
	< ref. range low	1	(2%)	3	(5%)	1	(2%)	2	(3%)	2	(3%)	3	(5%)
Baseline	n	64		61		63		66		60		61	
	> ref. range high	5	(8%)	1	(2%)	1	(2%)	0		2	(3%)	1	(2%)
	< ref. range low	1	(2%)	1	(2%)	1	(2%)	3	(5%)	1	(2%)	1	(2%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	1	(2%)	0		0		0		2	(4%)	0	
	< ref. range low	0		3	(5%)	1	(2%)	4	(6%)	1	(2%)	2	(3%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	3	(5%)	0		0		0		2	(4%)	0	
	< ref. range low	0		2	(3%)	1	(2%)	3	(5%)	2	(4%)	2	(3%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	2	(4%)	0		1	(2%)	0		3	(5%)	0	
	< ref. range low	0		1	(2%)	0		4	(7%)	2	(4%)	2	(4%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	2	(4%)	0		1	(2%)	0		3	(5%)	0	
	< ref. range low	2	(4%)	1	(2%)	0		3	(5%)	2	(4%)	2	(4%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	1	(2%)	0		1	(2%)	0		2	(4%)	1	(2%)
	< ref. range low	0		2	(4%)	1	(2%)	3	(5%)	1	(2%)	2	(4%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Red Blood Cell Count

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	52		47		54		60		55		56	
	> ref. range high	3	(6%)	0		1	(2%)	0		2	(4%)	0	
	< ref. range low	1	(2%)	2	(4%)	2	(4%)	2	(3%)	2	(4%)	1	(2%)
Week 12	n	45		48		52		59		53		54	
	> ref. range high	2	(4%)	1	(2%)	2	(4%)	0		3	(6%)	0	
	< ref. range low	0		1	(2%)	2	(4%)	3	(5%)	1	(2%)	1	(2%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	5	(8%)	1	(2%)	6	(10%)	0		5	(8%)	1	(2%)
	< ref. range low	3	(5%)	5	(8%)	3	(5%)	6	(9%)	5	(8%)	5	(8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Sodium

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	61
	> ref. range high	1 (2%)	0	0	0	1 (2%)	0
	< ref. range low	0	0	1 (2%)	0	3 (5%)	1 (2%)
Baseline	n	64	61	63	66	59	61
	> ref. range high	0	0	1 (2%)	1 (2%)	0	1 (2%)
	< ref. range low	1 (2%)	0	2 (3%)	1 (2%)	2 (3%)	2 (3%)
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	0	1 (2%)	0	0	0
	< ref. range low	1 (2%)	1 (2%)	0	1 (2%)	2 (4%)	3 (5%)
Week 2	n	60	58	59	62	57	58
	> ref. range high	0	0	1 (2%)	1 (2%)	0	0
	< ref. range low	2 (3%)	0	1 (2%)	0	3 (5%)	0
Week 3	n	55	56	59	59	57	55
	> ref. range high	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	0
	< ref. range low	1 (2%)	0	0	3 (5%)	3 (5%)	0
Week 4	n	55	56	57	60	56	56
	> ref. range high	0	0	0	0	0	0
	< ref. range low	2 (4%)	1 (2%)	0	2 (3%)	1 (2%)	0
Week 6	n	53	49	56	60	53	54
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	1 (2%)	1 (2%)	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Sodium

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	0	0	2 (3%)	1 (2%)	0
	< ref. range low	0	1 (2%)	3 (6%)	1 (2%)	0	2 (4%)
Week 12	n	49	46	54	58	56	54
	> ref. range high	0	0	1 (2%)	0	0	0
	< ref. range low	2 (4%)	0	3 (6%)	0	0	1 (2%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	1 (2%)	0	3 (5%)	4 (6%)	2 (3%)	0
	< ref. range low	7 (11%)	4 (7%)	7 (11%)	7 (11%)	5 (8%)	5 (8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Thyroid Stimulating Hormone

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	60	61	59	60
	> ref. range high	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	1 (2%)
	< ref. range low	1 (2%)	3 (5%)	2 (3%)	2 (3%)	1 (2%)	2 (3%)
Baseline	n	64	61	61	64	60	61
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	1 (2%)	1 (2%)	2 (3%)	2 (3%)	1 (2%)	2 (3%)
Any visit post-baseline	n	2	2	0	0	0	1
	> ref. range high	0	0	0	0	0	0
	< ref. range low	1 (50%)	1 (50%)	0	0	0	1 (100%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Total Bilirubin

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		59		60	
	> ref. range high	1	(2%)	4	(7%)	2	(3%)	2	(3%)	2	(3%)	1	(2%)
Baseline	n	64		61		63		66		59		61	
	> ref. range high	2	(3%)	3	(5%)	1	(2%)	2	(3%)	4	(7%)	3	(5%)
Week 1	n	61		59		60		63		56		59	
	> ref. range high	2	(3%)	3	(5%)	4	(7%)	0		2	(4%)	3	(5%)
Week 2	n	60		58		59		62		57		58	
	> ref. range high	5	(8%)	2	(3%)	1	(2%)	1	(2%)	1	(2%)	2	(3%)
Week 3	n	55		56		59		59		57		55	
	> ref. range high	1	(2%)	4	(7%)	1	(2%)	1	(2%)	2	(4%)	1	(2%)
Week 4	n	55		56		56		60		56		56	
	> ref. range high	1	(2%)	1	(2%)	0		3	(5%)	2	(4%)	1	(2%)
Week 6	n	53		48		56		60		53		54	
	> ref. range high	1	(2%)	2	(4%)	1	(2%)	0		2	(4%)	1	(2%)
Week 8	n	51		48		54		60		55		54	
	> ref. range high	1	(2%)	2	(4%)	3	(6%)	1	(2%)	2	(4%)	2	(4%)
Week 12	n	49		46		54		58		56		54	
	> ref. range high	1	(2%)	4	(9%)	3	(6%)	1	(2%)	3	(5%)	1	(2%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	5	(8%)	5	(8%)	7	(11%)	3	(5%)	4	(7%)	5	(8%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Total Neutrophils

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		62		59		59	
	> ref. range high	1	(2%)	0		0		1	(2%)	2	(3%)	0	
	< ref. range low	3	(5%)	0		1	(2%)	1	(2%)	0		2	(3%)
Baseline	n	64		61		63		66		60		60	
	> ref. range high	0		0		0		1	(2%)	1	(2%)	1	(2%)
	< ref. range low	1	(2%)	1	(2%)	2	(3%)	1	(2%)	0		2	(3%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	0		2	(3%)	0		0		1	(2%)	0	
	< ref. range low	1	(2%)	1	(2%)	1	(2%)	3	(5%)	0		1	(2%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	0		1	(2%)	2	(3%)	2	(3%)	0		1	(2%)
	< ref. range low	1	(2%)	1	(2%)	0		0		0		3	(5%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	1	(2%)	0		0		0		0		1	(2%)
	< ref. range low	2	(4%)	1	(2%)	0		0		0		1	(2%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	1	(2%)	2	(4%)	0		1	(2%)	0		3	(5%)
	< ref. range low	2	(4%)	3	(6%)	1	(2%)	1	(2%)	1	(2%)	2	(4%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	0		2	(4%)	3	(5%)	3	(5%)	1	(2%)	1	(2%)
	< ref. range low	1	(2%)	2	(4%)	1	(2%)	2	(3%)	0		1	(2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Total Neutrophils

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	53	60	54	56
	> ref. range high	0	1 (2%)	0	0	3 (6%)	1 (2%)
	< ref. range low	2 (4%)	2 (4%)	0	2 (3%)	0	1 (2%)
Week 12	n	44	48	52	59	53	54
	> ref. range high	0	1 (2%)	0	0	3 (6%)	0
	< ref. range low	0	0	1 (2%)	1 (2%)	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	2 (3%)	5 (8%)	5 (8%)	5 (8%)	6 (10%)	6 (10%)
	< ref. range low	5 (8%)	6 (10%)	4 (6%)	5 (8%)	1 (2%)	4 (7%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Total Protein

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	61
	> ref. range high	0	0	2 (3%)	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	0	1 (2%)	0	0	0	1 (2%)
	< ref. range low	0	0	0	0	0	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	1 (2%)	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 2	n	60	58	59	62	57	58
	> ref. range high	0	1 (2%)	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 3	n	55	56	59	59	57	55
	> ref. range high	0	0	0	0	0	0
	< ref. range low	0	0	0	0	0	0
Week 4	n	55	56	57	60	56	56
	> ref. range high	0	0	1 (2%)	0	1 (2%)	2 (4%)
	< ref. range low	0	1 (2%)	0	0	0	0
Week 6	n	53	49	56	60	53	54
	> ref. range high	0	0	0	0	1 (2%)	0
	< ref. range low	0	0	0	0	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Total Protein

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	51	48	54	60	55	54
	> ref. range high	0	0	0	1 (2%)	0	1 (2%)
	< ref. range low	0	0	0	1 (2%)	0	0
Week 12	n	49	46	54	58	56	54
	> ref. range high	0	0	2 (4%)	0	0	0
	< ref. range low	0	0	0	0	0	0
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	0	1 (2%)	2 (3%)	1 (2%)	2 (3%)	2 (3%)
	< ref. range low	0	1 (2%)	0	1 (2%)	0	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Urea

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	64	61	61	62	59	60
	> ref. range high	0	1 (2%)	0	2 (3%)	0	2 (3%)
	< ref. range low	0	0	1 (2%)	0	0	0
Baseline	n	64	61	63	66	59	61
	> ref. range high	0	3 (5%)	0	1 (2%)	0	2 (3%)
	< ref. range low	0	1 (2%)	0	0	0	0
Week 1	n	61	59	60	63	56	59
	> ref. range high	0	2 (3%)	0	2 (3%)	0	2 (3%)
	< ref. range low	0	1 (2%)	1 (2%)	0	0	0
Week 2	n	60	58	59	62	57	58
	> ref. range high	0	3 (5%)	0	2 (3%)	1 (2%)	2 (3%)
	< ref. range low	0	0	0	0	0	0
Week 3	n	55	56	59	59	57	55
	> ref. range high	0	3 (5%)	0	2 (3%)	0	3 (5%)
	< ref. range low	0	0	0	0	0	0
Week 4	n	55	56	57	60	56	56
	> ref. range high	2 (4%)	1 (2%)	0	3 (5%)	0	0
	< ref. range low	0	0	0	0	0	0
Week 6	n	53	49	56	60	53	54
	> ref. range high	1 (2%)	1 (2%)	0	2 (3%)	0	2 (4%)
	< ref. range low	0	1 (2%)	0	0	1 (2%)	1 (2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Urea

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	51		48		54		60		55		54	
	> ref. range high	2	(4%)	2	(4%)	0		1	(2%)	0		2	(4%)
	< ref. range low	0		0		0		0		0		0	
Week 12	n	49		46		54		58		56		54	
	> ref. range high	1	(2%)	2	(4%)	0		1	(2%)	2	(4%)	2	(4%)
	< ref. range low	0		0		0		0		0		0	
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	5	(8%)	5	(8%)	0		5	(8%)	3	(5%)	5	(8%)
	< ref. range low	0		1	(2%)	1	(2%)	0		1	(2%)	1	(2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Uric Acid

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	64		61		61		62		59		60	
	> ref. range high	3	(5%)	5	(8%)	1	(2%)	2	(3%)	3	(5%)	2	(3%)
	< ref. range low	3	(5%)	2	(3%)	5	(8%)	4	(6%)	2	(3%)	3	(5%)
Baseline	n	64		61		63		66		59		61	
	> ref. range high	1	(2%)	3	(5%)	1	(2%)	3	(5%)	3	(5%)	1	(2%)
	< ref. range low	5	(8%)	5	(8%)	5	(8%)	5	(8%)	3	(5%)	6	(10%)
Week 1	n	61		59		60		63		56		59	
	> ref. range high	3	(5%)	4	(7%)	4	(7%)	2	(3%)	4	(7%)	0	
	< ref. range low	3	(5%)	6	(10%)	5	(8%)	5	(8%)	4	(7%)	6	(10%)
Week 2	n	60		58		59		62		57		58	
	> ref. range high	2	(3%)	5	(9%)	4	(7%)	3	(5%)	5	(9%)	3	(5%)
	< ref. range low	3	(5%)	8	(14%)	3	(5%)	2	(3%)	3	(5%)	7	(12%)
Week 3	n	55		56		59		59		57		55	
	> ref. range high	1	(2%)	3	(5%)	4	(7%)	2	(3%)	4	(7%)	0	
	< ref. range low	5	(9%)	5	(9%)	2	(3%)	3	(5%)	2	(4%)	4	(7%)
Week 4	n	55		56		56		60		56		56	
	> ref. range high	0		3	(5%)	3	(5%)	2	(3%)	3	(5%)	0	
	< ref. range low	5	(9%)	2	(4%)	3	(5%)	5	(8%)	3	(5%)	5	(9%)
Week 6	n	53		49		56		60		53		54	
	> ref. range high	0		3	(6%)	4	(7%)	3	(5%)	2	(4%)	0	
	< ref. range low	5	(9%)	3	(6%)	4	(7%)	5	(8%)	2	(4%)	4	(7%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: Uric Acid

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week 8	n	51		48		54		60		55		54	
	> ref. range high	1	(2%)	1	(2%)	2	(4%)	3	(5%)	4	(7%)	0	
	< ref. range low	3	(6%)	5	(10%)	3	(6%)	5	(8%)	2	(4%)	3	(6%)
Week 12	n	49		46		54		58		56		54	
	> ref. range high	2	(4%)	1	(2%)	4	(7%)	1	(2%)	1	(2%)	2	(4%)
	< ref. range low	3	(6%)	3	(7%)	3	(6%)	5	(9%)	4	(7%)	4	(7%)
Any visit post-baseline	n	63		61		63		65		59		60	
	> ref. range high	6	(10%)	7	(11%)	8	(13%)	4	(6%)	8	(14%)	5	(8%)
	< ref. range low	9	(14%)	10	(16%)	7	(11%)	8	(12%)	8	(14%)	8	(13%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: White Blood Cell Count

Planned Relative Time	Normal Range Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Week -5	n	63		60		61		62		59		60	
	> ref. range high	1	(2%)	0		0		1	(2%)	2	(3%)	1	(2%)
	< ref. range low	2	(3%)	1	(2%)	0		2	(3%)	0		0	
Baseline	n	64		61		63		66		60		61	
	> ref. range high	0		0		0		1	(2%)	1	(2%)	1	(2%)
	< ref. range low	1	(2%)	0		1	(2%)	2	(3%)	1	(2%)	1	(2%)
Week 1	n	56		60		60		63		57		59	
	> ref. range high	0		3	(5%)	0		0		3	(5%)	1	(2%)
	< ref. range low	1	(2%)	0		2	(3%)	1	(2%)	0		1	(2%)
Week 2	n	60		59		59		61		54		60	
	> ref. range high	1	(2%)	2	(3%)	2	(3%)	1	(2%)	1	(2%)	2	(3%)
	< ref. range low	2	(3%)	0		0		1	(2%)	0		1	(2%)
Week 3	n	55		58		58		58		57		55	
	> ref. range high	1	(2%)	3	(5%)	0		1	(2%)	4	(7%)	1	(2%)
	< ref. range low	1	(2%)	1	(2%)	0		1	(2%)	0		1	(2%)
Week 4	n	55		53		56		60		57		56	
	> ref. range high	1	(2%)	3	(6%)	0		2	(3%)	0		2	(4%)
	< ref. range low	1	(2%)	1	(2%)	0		0		1	(2%)	1	(2%)
Week 6	n	53		51		57		60		56		53	
	> ref. range high	0		4	(8%)	5	(9%)	4	(7%)	2	(4%)	2	(4%)
	< ref. range low	1	(2%)	2	(4%)	0		0		0		1	(2%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.21
Summary of Laboratory Evaluations Outside the Normal Reference Range by Treatment

Lab Test: White Blood Cell Count

Planned Relative Time	Normal Range Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week 8	n	52	47	54	60	55	56
	> ref. range high	0	0	0	0	4 (7%)	1 (2%)
	< ref. range low	1 (2%)	0	0	2 (3%)	0	2 (4%)
Week 12	n	44	48	52	59	53	54
	> ref. range high	0	1 (2%)	0	0	6 (11%)	0
	< ref. range low	0	0	0	0	0	1 (2%)
Any visit post-baseline	n	63	61	63	65	59	60
	> ref. range high	3 (5%)	6 (10%)	8 (13%)	5 (8%)	10 (17%)	7 (12%)
	< ref. range low	3 (5%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	2 (3%)

Note: Post-baseline includes Follow-up for Early Withdrawal visits

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Table 12.22
Summary of Laboratory Evaluations of Potential Clinical Concern at Any Time On-Therapy

Lab Test	Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Alanine Amino Transferase (IU/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
Albumin (G/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		1	(2%)
	Low	0		0		0		0		0		0	
Alkaline Phosphatase (IU/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
Aspartate Amino Transferase (IU/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		1	(2%)	0	
Calcium (MMOL/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
	Low	3	(5%)	2	(3%)	5	(8%)	2	(3%)	1	(2%)	7	(12%)
Carbon Dioxide content / Bicarbonate (MMOL/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
	Low	0		3	(5%)	6	(10%)	2	(3%)	0		5	(8%)
Chloride (MMOL/L)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
Creatinine (UMOL/L)	n	62		60		62		63		59		60	
	High	0		0		0		1	(2%)	0		1	(2%)

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Table 12.22
Summary of Laboratory Evaluations of Potential Clinical Concern at Any Time On-Therapy

Lab Test	Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Glucose (MMOL/L)	n	62	60	62	63	59	60
	High	0	0	0	0	0	0
	Low	0	0	1 (2%)	0	0	1 (2%)
Hematocrit (1)	n	62	60	62	63	59	60
	High	2 (3%)	0	2 (3%)	0	2 (3%)	1 (2%)
	Low	1 (2%)	3 (5%)	0	1 (2%)	0	0
Hemoglobin (G/L)	n	62	60	62	63	59	60
	High	2 (3%)	1 (2%)	3 (5%)	0	1 (2%)	1 (2%)
	Low	1 (2%)	2 (3%)	1 (2%)	0	1 (2%)	0
Lactate Dehydrogenase (IU/L)	n	62	60	62	63	59	60
	High	0	0	0	0	0	0
Lymphocytes (GI/L)	n	62	60	62	63	59	60
	Low	0	0	0	0	0	0
Phosphorus, Inorganic (MMOL/L)	n	62	60	62	63	59	60
	High	0	0	2 (3%)	0	0	0
	Low	0	0	0	0	0	0
Platelet count (GI/L)	n	62	60	62	63	59	60
	High	0	0	0	0	0	0
	Low	0	0	0	0	1 (2%)	0
Potassium (MMOL/L)	n	62	60	62	63	59	60
	High	6 (10%)	3 (5%)	6 (10%)	4 (6%)	7 (12%)	8 (13%)
	Low	0	0	0	0	0	0

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Table 12.22
Summary of Laboratory Evaluations of Potential Clinical Concern at Any Time On-Therapy

Lab Test	Category	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Sodium (MMOL/L)	n	62	60	62	63	59	60
	High	0	0	0	1 (2%)	0	0
	Low	0	0	0	0	1 (2%)	2 (3%)
Total Bilirubin (UMOL/L)	n	62	60	62	63	59	60
	High	1 (2%)	0	1 (2%)	0	2 (3%)	1 (2%)
Total Neutrophils (GI/L)	n	62	60	62	63	59	60
	Low	0	0	0	0	0	0
Total Protein (G/L)	n	62	60	62	63	59	60
	High	0	0	0	0	0	0
	Low	0	0	0	0	0	0
Urea (MMOL/L)	n	62	60	62	63	59	60
	High	0	0	0	0	0	0
Uric Acid (UMOL/L)	n	62	60	62	63	59	60
	High	0	0	1 (2%)	0	0	0
White Blood Cell Count (GI/L)	n	62	60	62	63	59	60
	High	0	0	0	0	1 (2%)	1 (2%)
	Low	0	0	0	0	0	0

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	Placebo	64	Week -5	64	133.4	14.13	135.0	88	168
			Week -4	64	133.2	14.31	130.5	105	183
			Week -2	63	131.8	14.85	130.0	103	176
			Baseline	64	133.2	16.39	135.0	90	185
			Week 1	61	134.0	17.88	133.0	100	187
			Week 2	60	133.5	15.07	135.0	100	186
			Week 3	56	130.7	13.68	130.0	101	171
			Week 4	57	132.8	14.83	135.0	100	161
			Week 6	54	134.0	21.39	130.0	98	202
			Week 8	52	131.5	14.85	130.0	107	166
			Week 12	49	134.4	16.54	133.0	100	174
	2.5mg	61	Week -5	61	133.4	13.78	138.0	99	155
			Week -4	61	132.4	15.38	130.0	100	191
			Week -2	61	133.6	15.07	135.0	100	181
			Baseline	61	131.8	15.82	130.0	97	175
			Week 1	59	132.0	12.63	130.0	105	167
			Week 2	58	130.9	11.47	130.0	107	162
			Week 3	58	132.2	14.72	135.0	103	165
			Week 4	56	131.8	15.95	133.0	89	165
			Week 6	51	131.6	13.68	134.0	100	160
			Week 8	49	133.0	14.64	135.0	99	165
			Week 12	48	135.6	15.44	138.0	95	181
	7.5mg	63	Week -5	62	131.8	15.17	134.5	95	175
			Week -4	62	132.6	14.74	136.5	90	156
			Week -2	60	130.5	14.82	130.0	99	170
			Baseline	63	131.4	13.49	132.0	99	155
			Week 1	62	130.3	13.79	130.0	100	165
			Week 2	60	132.2	13.87	130.5	103	165
			Week 3	58	130.1	14.27	131.0	95	166
			Week 4	58	130.6	13.93	132.0	95	160
			Week 6	57	131.5	13.33	133.0	103	166

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	7.5mg	63	Week 8	56	132.2	16.73	130.5	95	178
			Week 12	55	130.1	15.80	130.0	100	174
	15mg	66	Week -5	63	132.0	12.33	130.0	108	160
			Week -4	63	131.5	11.86	130.0	110	167
			Week -2	63	130.9	12.61	130.0	99	172
			Baseline	66	129.6	11.57	130.0	108	157
			Week 1	63	131.7	14.42	130.0	100	170
			Week 2	63	130.5	13.48	130.0	110	160
			Week 3	61	129.4	13.86	127.0	105	170
			Week 4	60	127.3	11.07	127.0	99	150
			Week 6	60	128.0	12.19	130.0	102	154
			Week 8	60	127.2	12.21	128.0	100	161
			Week 12	60	129.1	12.18	130.0	107	171
	30mg	60	Week -5	60	133.3	11.90	134.0	110	158
			Week -4	60	131.0	12.90	131.5	109	165
			Week -2	59	131.9	12.26	134.0	101	160
			Baseline	60	131.5	14.28	130.0	103	164
			Week 1	58	131.2	14.16	130.5	103	165
			Week 2	57	130.6	12.52	130.0	105	159
			Week 3	57	131.0	13.51	133.0	100	169
			Week 4	58	130.2	14.09	132.5	99	168
			Week 6	57	133.2	15.05	132.0	98	175
			Week 8	57	132.6	15.01	132.0	105	180
			Week 12	56	133.2	15.99	130.0	103	173
	45mg	61	Week -5	61	132.9	11.08	135.0	100	155
			Week -4	61	133.0	10.91	133.0	110	165
			Week -2	61	130.2	10.81	130.0	104	152
			Baseline	61	129.5	11.33	130.0	104	160
			Week 1	60	130.2	11.67	130.0	105	163
			Week 2	60	131.3	12.35	130.0	104	166

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	45mg	61	Week 3	57	132.6	14.39	130.0	109	192
			Week 4	58	130.9	12.51	130.0	110	156
			Week 6	55	132.4	12.97	134.0	100	156
			Week 8	56	131.8	13.18	131.5	100	169
			Week 12	56	131.4	12.69	130.5	98	163
Diastolic BP (mmHg)	Placebo	64	Week -5	64	78.9	9.04	80.0	53	100
			Week -4	64	78.6	8.07	80.0	55	90
			Week -2	63	80.0	9.07	80.0	54	99
			Baseline	64	80.0	9.31	80.0	57	99
			Week 1	61	79.3	10.46	80.0	50	102
			Week 2	60	80.1	8.79	80.0	54	104
			Week 3	56	78.4	8.74	80.0	52	95
			Week 4	57	79.2	9.52	80.0	51	98
			Week 6	54	78.3	10.52	80.0	53	108
			Week 8	52	79.0	9.79	80.0	51	108
			Week 12	49	79.7	9.24	80.0	53	102
	2.5mg	61	Week -5	61	81.2	7.38	80.0	64	97
			Week -4	61	79.5	7.08	80.0	60	94
			Week -2	61	80.6	7.29	80.0	66	100
			Baseline	61	80.1	8.85	80.0	60	110
			Week 1	59	80.3	7.24	80.0	64	110
			Week 2	58	80.1	7.07	80.0	58	95
			Week 3	58	78.9	8.97	80.0	40	92
			Week 4	56	80.6	7.92	80.0	54	100
			Week 6	51	79.6	7.66	80.0	59	95
			Week 8	49	79.7	8.67	80.0	56	98
			Week 12	48	81.5	8.06	80.0	65	102
	7.5mg	63	Week -5	62	78.5	9.43	80.0	59	97
			Week -4	62	79.4	8.14	80.0	60	96

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Diastolic BP (mmHg)	7.5mg	63	Week -2	60	78.8	8.39	80.0	61	97
			Baseline	63	79.4	7.86	80.0	60	95
			Week 1	62	79.0	8.79	80.0	59	104
			Week 2	60	78.6	7.43	80.0	58	92
			Week 3	58	78.3	8.17	80.0	60	95
			Week 4	58	77.8	8.08	80.0	53	92
			Week 6	57	78.3	7.46	80.0	60	92
			Week 8	56	78.9	8.54	80.0	60	104
			Week 12	55	78.7	9.62	80.0	56	100
	15mg	66	Week -5	63	78.3	7.80	80.0	60	94
			Week -4	63	78.3	7.07	78.0	65	93
			Week -2	63	78.0	7.12	80.0	60	93
			Baseline	66	77.5	6.39	80.0	60	91
			Week 1	63	77.4	7.76	79.0	61	100
			Week 2	63	77.0	7.36	78.0	60	90
			Week 3	61	76.8	8.68	78.0	60	103
			Week 4	60	76.9	7.65	77.5	60	93
			Week 6	60	76.7	7.50	80.0	60	90
			Week 8	60	76.1	8.13	77.5	60	92
			Week 12	60	76.4	7.83	78.0	60	97
	30mg	60	Week -5	60	82.0	8.18	80.0	66	100
			Week -4	60	79.0	8.82	79.5	59	100
			Week -2	59	79.4	7.92	80.0	60	98
			Baseline	60	79.5	8.48	80.0	60	100
			Week 1	58	80.1	8.23	80.0	61	94
			Week 2	57	80.9	7.27	80.0	66	97
			Week 3	57	80.2	7.26	80.0	65	101
			Week 4	58	79.0	8.54	80.0	59	99
			Week 6	57	79.3	8.97	80.0	62	100
			Week 8	57	79.8	8.93	80.0	57	100
			Week 12	56	80.6	9.54	80.0	55	105

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Diastolic BP (mmHg)	45mg	61	Week -5	61	79.6	7.53	80.0	60	92
			Week -4	61	79.5	6.55	80.0	65	100
			Week -2	61	79.0	7.68	80.0	58	91
			Baseline	61	79.0	6.53	80.0	59	92
			Week 1	60	78.0	6.85	80.0	61	95
			Week 2	60	78.4	6.89	80.0	60	90
			Week 3	57	78.8	6.15	80.0	64	90
			Week 4	58	78.3	7.79	80.0	60	95
			Week 6	55	80.0	8.49	80.0	60	105
			Week 8	56	78.8	6.73	80.0	57	90
			Week 12	56	79.2	7.07	80.0	61	94
Heart Rate (bpm)	Placebo	64	Week -5	64	72.0	8.73	72.0	53	92
			Week -4	64	71.6	8.88	72.0	49	100
			Week -2	63	71.7	9.08	72.0	50	102
			Baseline	64	70.8	9.02	69.0	53	103
			Week 1	61	71.1	9.13	70.0	50	100
			Week 2	60	71.4	8.40	70.5	52	100
			Week 3	56	70.2	9.28	69.5	50	99
			Week 4	57	69.9	9.64	70.0	45	96
			Week 6	54	71.1	9.17	72.0	48	99
			Week 8	52	69.6	7.74	69.0	51	89
			Week 12	49	72.3	9.31	72.0	54	97
	2.5mg	61	Week -5	61	70.8	8.03	72.0	50	84
			Week -4	61	70.4	7.23	70.0	52	88
			Week -2	61	71.1	7.17	70.0	55	86
			Baseline	61	68.6	7.81	69.0	54	86
			Week 1	59	70.5	6.91	70.0	58	88
			Week 2	58	70.2	7.24	70.0	57	87
			Week 3	58	70.1	6.99	70.0	52	87
			Week 4	56	69.1	8.81	70.0	52	86

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	2.5mg	61	Week 6	51	69.8	8.82	71.0	53	106
			Week 8	49	70.7	7.97	72.0	55	90
			Week 12	48	71.3	9.32	73.0	51	88
	7.5mg	63	Week -5	62	72.0	10.99	73.0	40	104
			Week -4	62	71.5	10.31	72.5	45	96
			Week -2	60	70.2	10.27	70.0	40	92
			Baseline	63	70.1	10.91	71.0	48	95
			Week 1	62	70.4	8.91	71.0	47	92
			Week 2	60	71.0	9.49	71.0	50	96
			Week 3	58	71.8	9.62	71.0	51	95
			Week 4	58	69.6	8.43	71.0	51	86
			Week 6	57	70.8	9.71	72.0	44	103
			Week 8	56	70.6	9.33	70.5	52	90
			Week 12	55	70.2	10.77	70.0	48	98
	15mg	66	Week -5	63	71.6	7.26	72.0	60	93
			Week -4	63	71.6	8.56	71.0	52	94
			Week -2	63	70.8	7.44	70.0	56	90
			Baseline	66	70.5	8.11	70.0	56	86
			Week 1	63	70.9	8.39	70.0	55	101
			Week 2	63	70.9	7.88	71.0	54	93
			Week 3	61	70.3	8.12	70.0	52	98
			Week 4	60	69.8	8.02	70.5	46	88
			Week 6	60	70.4	7.12	70.0	53	87
			Week 8	60	70.4	7.12	70.0	52	86
			Week 12	60	70.4	8.60	70.5	52	92
	30mg	60	Week -5	60	74.0	6.88	74.0	62	93
			Week -4	60	72.3	7.10	72.0	50	86
			Week -2	59	72.3	7.02	72.0	57	87
			Baseline	60	71.5	9.01	72.0	52	97
			Week 1	58	70.7	6.56	70.0	55	93

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Table 12.23
Summary Statistics of Vital Signs by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	30mg	60	Week 2	57	71.7	7.49	71.0	54	98
			Week 3	57	71.7	7.99	72.0	52	88
			Week 4	58	71.8	8.22	72.0	50	98
			Week 6	57	72.7	8.37	72.0	57	100
			Week 8	57	72.3	6.91	72.0	55	86
			Week 12	56	73.2	8.79	72.5	52	104
	45mg	61	Week -5	61	69.5	8.35	68.0	50	82
			Week -4	61	69.3	7.73	69.0	49	92
			Week -2	61	68.0	7.46	68.0	54	90
			Baseline	61	69.5	8.32	70.0	50	93
			Week 1	60	68.8	7.70	70.0	46	90
			Week 2	60	68.7	8.06	67.5	49	93
			Week 3	57	69.8	8.82	71.0	50	91
			Week 4	58	67.5	8.67	67.5	49	92
			Week 6	55	69.5	8.33	68.0	51	88
			Week 8	55	68.3	7.60	68.0	53	88
			Week 12	55	68.9	9.37	67.0	50	90

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	Placebo	64	Week -5	64	0.2	11.23	0.0	-29	28
			Week -4	64	-0.0	12.50	0.0	-28	40
			Week -2	63	-1.2	12.39	0.0	-35	31
			Week 1	61	0.9	11.87	0.0	-20	35
			Week 2	60	-0.4	11.10	1.0	-32	20
			Week 3	56	-3.3	11.18	-1.5	-34	20
			Week 4	57	-1.1	12.23	0.0	-32	27
			Week 6	54	0.1	13.36	-2.0	-23	39
			Week 8	52	-3.5	12.46	-3.5	-29	24
			Week 12	49	-0.6	14.81	-1.0	-40	30
	2.5mg	61	Week -5	61	1.7	12.60	0.0	-28	41
			Week -4	61	0.6	11.14	0.0	-30	35
			Week -2	61	1.8	11.87	-1.0	-28	37
			Week 1	59	0.1	10.69	0.0	-30	24
			Week 2	58	-1.9	11.33	0.0	-35	19
			Week 3	58	-0.3	10.41	-0.5	-30	25
			Week 4	56	-1.3	14.40	-2.5	-28	50
			Week 6	51	-0.8	11.32	-1.0	-31	40
			Week 8	49	0.3	12.64	0.0	-31	30
			Week 12	48	2.7	15.74	0.0	-28	63
	7.5mg	63	Week -5	62	0.3	11.81	0.0	-20	30
			Week -4	62	1.2	10.43	0.0	-20	30
			Week -2	60	-1.0	9.73	-0.5	-20	30
			Week 1	62	-1.2	9.03	0.0	-20	20
			Week 2	60	0.7	8.75	0.0	-18	29
			Week 3	58	-2.1	11.25	-2.5	-24	30
			Week 4	58	-1.0	10.28	-3.0	-20	20
			Week 6	57	0.0	11.58	-2.0	-25	30
			Week 8	56	0.9	11.54	0.0	-24	30
			Week 12	55	-1.2	10.84	0.0	-21	26

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	15mg	66	Week -5	63	2.1	10.80	2.0	-23	26
			Week -4	63	1.6	10.07	0.0	-27	29
			Week -2	63	1.0	9.66	0.0	-21	20
			Week 1	63	1.7	12.51	0.0	-34	33
			Week 2	63	0.6	11.63	0.0	-37	25
			Week 3	61	-0.8	11.50	0.0	-27	30
			Week 4	60	-2.8	12.28	-3.0	-30	36
			Week 6	60	-2.2	11.07	0.0	-28	22
			Week 8	60	-2.9	12.59	-4.0	-35	28
			Week 12	60	-1.0	10.69	0.0	-27	26
	30mg	60	Week -5	60	1.8	10.70	0.5	-23	29
			Week -4	60	-0.5	10.56	0.0	-26	24
			Week -2	59	0.6	9.64	0.0	-23	22
			Week 1	58	-0.7	8.35	0.0	-23	25
			Week 2	57	-1.6	12.45	0.0	-34	23
			Week 3	57	-1.2	11.01	0.0	-30	25
			Week 4	58	-1.8	13.11	0.0	-32	26
			Week 6	57	0.9	11.64	0.0	-25	40
			Week 8	57	0.3	11.56	0.0	-32	30
			Week 12	56	1.4	11.38	0.0	-20	41
	45mg	61	Week -5	61	3.4	10.83	2.0	-25	30
			Week -4	61	3.5	9.90	3.0	-19	24
			Week -2	61	0.7	11.35	1.0	-36	30
			Week 1	60	0.8	10.44	-0.5	-18	38
			Week 2	60	1.9	10.35	0.0	-20	28
			Week 3	57	3.4	12.58	1.0	-24	67
			Week 4	58	1.9	11.91	0.0	-27	33
			Week 6	55	3.1	12.92	0.0	-37	30
			Week 8	56	2.4	11.09	3.0	-20	32
			Week 12	56	2.0	12.58	0.0	-30	32

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Diastolic BP (mmHg)	Placebo	64	Week -5	64	-1.0	7.94	0.0	-24	30
			Week -4	64	-1.4	8.10	0.0	-19	20
			Week -2	63	0.1	8.01	0.0	-22	23
			Week 1	61	-0.8	8.44	0.0	-30	22
			Week 2	60	0.1	7.43	0.0	-20	23
			Week 3	56	-1.4	8.88	0.0	-22	23
			Week 4	57	-0.7	8.55	0.0	-20	33
			Week 6	54	-1.7	8.32	-1.5	-20	23
			Week 8	52	-1.2	8.37	-2.0	-20	23
			Week 12	49	-0.2	7.19	0.0	-15	23
	2.5mg	61	Week -5	61	1.1	7.70	0.0	-20	23
			Week -4	61	-0.6	7.23	0.0	-24	14
			Week -2	61	0.5	6.14	0.0	-12	24
			Week 1	59	0.1	5.92	0.0	-18	14
			Week 2	58	-0.1	6.56	0.0	-20	20
			Week 3	58	-1.3	7.30	0.0	-35	10
			Week 4	56	0.4	7.67	0.0	-22	30
			Week 6	51	-0.3	6.34	0.0	-21	16
			Week 8	49	-0.3	7.90	0.0	-18	17
			Week 12	48	1.2	7.19	0.0	-13	20
	7.5mg	63	Week -5	62	-0.7	7.98	0.0	-22	16
			Week -4	62	0.2	7.24	0.0	-18	20
			Week -2	60	-0.2	5.87	0.0	-14	14
			Week 1	62	-0.2	7.08	0.0	-19	22
			Week 2	60	-0.7	6.39	0.0	-15	20
			Week 3	58	-1.2	6.49	0.0	-15	13
			Week 4	58	-1.6	6.61	0.0	-20	12
			Week 6	57	-1.0	6.64	0.0	-20	20
			Week 8	56	-0.4	6.95	0.0	-12	20
			Week 12	55	-0.4	7.52	0.0	-15	20

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Diastolic BP (mmHg)	15mg	66	Week -5	63	0.9	8.12	0.0	-19	20
			Week -4	63	0.9	5.61	1.0	-11	17
			Week -2	63	0.6	5.96	1.0	-18	10
			Week 1	63	0.0	7.09	0.0	-18	20
			Week 2	63	-0.4	5.97	0.0	-14	11
			Week 3	61	-0.7	7.86	0.0	-22	30
			Week 4	60	-0.6	7.28	0.0	-20	12
			Week 6	60	-0.7	7.23	0.0	-21	11
			Week 8	60	-1.4	8.30	0.0	-22	13
			Week 12	60	-1.1	7.72	0.0	-18	14
	30mg	60	Week -5	60	2.5	6.83	2.0	-12	19
			Week -4	60	-0.5	6.26	0.0	-12	14
			Week -2	59	-0.1	5.29	0.0	-11	14
			Week 1	58	0.4	6.67	0.0	-18	24
			Week 2	57	1.1	7.38	0.0	-16	17
			Week 3	57	0.4	5.95	0.0	-11	13
			Week 4	58	-0.7	7.10	0.0	-17	13
			Week 6	57	-0.4	5.81	0.0	-12	20
			Week 8	57	0.1	7.09	0.0	-16	20
			Week 12	56	0.9	7.67	0.0	-20	22
	45mg	61	Week -5	61	0.6	6.15	0.0	-16	16
			Week -4	61	0.5	6.02	0.0	-18	22
			Week -2	61	-0.0	6.25	0.0	-20	12
			Week 1	60	-1.0	5.86	0.0	-22	10
			Week 2	60	-0.6	6.25	0.0	-17	14
			Week 3	57	-0.2	6.66	0.0	-14	26
			Week 4	58	-0.6	7.43	0.0	-25	28
			Week 6	55	1.0	7.27	0.0	-16	20
			Week 8	56	-0.4	5.91	0.0	-16	12
			Week 12	56	0.0	5.95	0.0	-17	13

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	Placebo	64	Week -5	64	1.2	7.48	0.0	-17	17
			Week -4	64	0.9	6.98	0.0	-16	17
			Week -2	63	0.9	7.20	0.0	-18	18
			Week 1	61	0.2	6.98	0.0	-18	26
			Week 2	60	0.7	6.78	1.0	-16	16
			Week 3	56	-0.8	7.74	0.0	-20	18
			Week 4	57	-0.9	8.64	-2.0	-17	32
			Week 6	54	-0.2	6.78	0.0	-21	13
			Week 8	52	-1.5	7.57	-2.0	-19	15
			Week 12	49	0.4	9.00	1.0	-21	22
	2.5mg	61	Week -5	61	2.2	6.64	3.0	-10	18
			Week -4	61	1.8	7.87	2.0	-15	21
			Week -2	61	2.5	7.42	4.0	-13	18
			Week 1	59	1.8	7.13	2.0	-15	22
			Week 2	58	1.5	6.63	1.0	-15	18
			Week 3	58	1.4	6.23	1.0	-17	20
			Week 4	56	0.4	6.12	0.0	-16	17
			Week 6	51	0.7	8.15	0.0	-19	30
			Week 8	49	1.5	8.21	2.0	-20	21
			Week 12	48	1.9	6.96	2.0	-16	22
	7.5mg	63	Week -5	62	1.7	9.08	2.0	-24	26
			Week -4	62	1.2	9.61	0.0	-23	34
			Week -2	60	0.1	7.39	0.0	-20	18
			Week 1	62	0.1	8.72	0.0	-18	31
			Week 2	60	0.3	8.40	-0.5	-17	26
			Week 3	58	1.2	8.53	1.5	-18	20
			Week 4	58	-1.0	8.02	-0.5	-26	19
			Week 6	57	0.5	9.23	0.0	-22	26
			Week 8	56	0.4	7.85	1.0	-22	20
			Week 12	55	0.3	8.38	0.0	-19	30

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Table 12.24
Summary Statistics of Change from Baseline in Vital Signs by Treatment

Vital signs test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	15mg	66	Week -5	63	1.4	8.14	1.0	-20	20
			Week -4	63	1.4	7.06	2.0	-13	24
			Week -2	63	0.6	7.57	0.0	-15	19
			Week 1	63	0.7	7.17	0.0	-16	27
			Week 2	63	0.7	6.48	0.0	-14	15
			Week 3	61	0.5	7.41	0.0	-14	23
			Week 4	60	-0.3	6.36	0.0	-20	13
			Week 6	60	0.3	7.08	0.0	-18	17
			Week 8	60	0.3	5.75	0.0	-12	16
			Week 12	60	0.3	8.12	0.5	-22	21
	30mg	60	Week -5	60	2.5	8.46	3.5	-19	23
			Week -4	60	0.8	7.10	2.0	-21	15
			Week -2	59	0.8	6.99	2.0	-20	14
			Week 1	58	-0.9	5.18	-0.5	-14	12
			Week 2	57	0.2	5.60	0.0	-14	13
			Week 3	57	0.2	6.74	0.0	-14	20
			Week 4	58	0.3	6.42	0.0	-17	16
			Week 6	57	1.1	6.97	2.0	-18	22
			Week 8	57	0.6	7.90	0.0	-21	23
			Week 12	56	1.6	8.07	2.0	-17	33
	45mg	61	Week -5	61	-0.0	7.74	0.0	-22	15
			Week -4	61	-0.1	7.73	0.0	-22	16
			Week -2	61	-1.5	6.84	-2.0	-24	18
			Week 1	60	-0.8	6.49	-0.5	-28	15
			Week 2	60	-0.9	5.94	0.0	-18	14
			Week 3	57	0.5	6.26	0.0	-14	18
			Week 4	58	-2.1	7.50	-2.0	-26	21
			Week 6	55	-0.1	7.94	0.0	-25	23
			Week 8	55	-1.2	7.82	-1.0	-28	18
			Week 12	55	-0.5	6.94	-1.0	-20	14

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Table 12.25
Summary of Vital Signs of Potential Clinical Concern at Any Time On-Therapy

Vital signs test	Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Systolic BP (mmHg)	n	62		60		62		63		59		60	
	High	5	(8%)	1	(2%)	3	(5%)	1	(2%)	2	(3%)	1	(2%)
	Low	1	(2%)	3	(5%)	2	(3%)	1	(2%)	1	(2%)	1	(2%)
Diastolic BP (mmHg)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
	Low	0		1	(2%)	0		0		0		0	
Heart Rate (bpm)	n	62		60		62		63		59		60	
	High	0		0		0		0		0		0	
	Low	1	(2%)	0		3	(5%)	1	(2%)	0		3	(5%)

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Table 12.26
Summary of Changes from Baseline in Vital Signs of Potential Clinical Concern at Any Time On-therapy

Vital signs test	Category	Placebo (N=64)		2.5mg (N=61)		7.5mg (N=63)		15mg (N=66)		30mg (N=60)		45mg (N=61)	
Systolic BP (mmHg)	n	62		60		62		63		59		60	
	High	2	(3%)	4	(7%)	0		3	(5%)	3	(5%)	3	(5%)
	Low	4	(6%)	3	(5%)	0		2	(3%)	3	(5%)	1	(2%)
Diastolic BP (mmHg)	n	62		60		62		63		59		60	
	High	3	(5%)	1	(2%)	1	(2%)	1	(2%)	2	(3%)	2	(3%)
	Low	3	(5%)	3	(5%)	0		3	(5%)	0		2	(3%)
Heart Rate (bpm)	n	62		60		62		63		59		60	
	High	1	(2%)	0		1	(2%)	0		1	(2%)	0	
	Low	0		0		0		0		0		0	

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week -5

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	63 (98%)	61 (100%)	58 (92%)	62 (94%)	59 (98%)	59 (97%)
Urine Glucose (dipstick)	NEGATIVE	47 (73%)	48 (79%)	44 (70%)	52 (79%)	43 (72%)	41 (67%)
	TRACE OR 1/10 G/DL (%)	7 (11%)	3 (5%)	6 (10%)	4 (6%)	3 (5%)	9 (15%)
	1+ OR 1/4 G/DL (%)	3 (5%)	6 (10%)	4 (6%)	3 (5%)	5 (8%)	2 (3%)
	2+ OR 1/2 G/DL (%)	1 (2%)	1 (2%)	1 (2%)	2 (3%)	4 (7%)	4 (7%)
	3+ OR 1 G/DL (%)	5 (8%)	3 (5%)	3 (5%)	1 (2%)	4 (7%)	3 (5%)
Urine Ketones (dipstick)	NEGATIVE	59 (92%)	58 (95%)	54 (86%)	61 (92%)	58 (97%)	57 (93%)
	TRACE	3 (5%)	2 (3%)	3 (5%)	1 (2%)	1 (2%)	2 (3%)
	1+	1 (2%)	1 (2%)	1 (2%)	0	0	0
Urine Protein (dipstick)	NEGATIVE	48 (75%)	50 (82%)	42 (67%)	51 (77%)	47 (78%)	54 (89%)
	TRACE	8 (13%)	4 (7%)	9 (14%)	5 (8%)	5 (8%)	3 (5%)
	1+	6 (9%)	6 (10%)	5 (8%)	5 (8%)	4 (7%)	2 (3%)
	2+	0	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0
	3+	1 (2%)	0	0	0	0	0

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Summary of Urinalysis Dipstick Results

Planned Relative Time: Week -5

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	41 (64%)	38 (62%)	45 (71%)	42 (64%)	43 (72%)	39 (64%)
	0-1	3 (5%)	1 (2%)	2 (3%)	0	2 (3%)	2 (3%)
	1-3	3 (5%)	4 (7%)	1 (2%)	2 (3%)	2 (3%)	1 (2%)
	3-5	1 (2%)	1 (2%)	1 (2%)	0	0	0
	5-10	2 (3%)	3 (5%)	0	0	2 (3%)	1 (2%)
	10-15	0	0	0	0	1 (2%)	0
	15-25	0	0	0	0	0	1 (2%)
	25-50	1 (2%)	0	0	0	0	0
	50-100	0	0	0	1 (2%)	0	0
	INNUMERABLE	1 (2%)	0	1 (2%)	0	0	0
Urine microscopy - White Blood Cells	NONE SEEN	27 (42%)	32 (52%)	36 (57%)	30 (45%)	30 (50%)	34 (56%)
	0-1	7 (11%)	4 (7%)	3 (5%)	1 (2%)	3 (5%)	1 (2%)
	1-3	2 (3%)	1 (2%)	4 (6%)	3 (5%)	3 (5%)	2 (3%)
	3-5	2 (3%)	2 (3%)	1 (2%)	0	3 (5%)	2 (3%)
	5-10	3 (5%)	3 (5%)	1 (2%)	3 (5%)	1 (2%)	2 (3%)
	10-15	0	0	0	0	0	0
	15-25	4 (6%)	2 (3%)	1 (2%)	5 (8%)	2 (3%)	1 (2%)
	25-50	2 (3%)	1 (2%)	1 (2%)	2 (3%)	4 (7%)	1 (2%)
	50-100	1 (2%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	0
	INNUMERABLE	4 (6%)	1 (2%)	1 (2%)	0	1 (2%)	1 (2%)

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 0

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	62 (97%)	58 (95%)	60 (95%)	64 (97%)	60 (100%)	55 (90%)
Urine Glucose (dipstick)	NEGATIVE	41 (64%)	39 (64%)	42 (67%)	44 (67%)	48 (80%)	36 (59%)
	TRACE OR 1/10 G/DL (%)	10 (16%)	5 (8%)	3 (5%)	5 (8%)	6 (10%)	6 (10%)
	1+ OR 1/4 G/DL (%)	3 (5%)	5 (8%)	7 (11%)	7 (11%)	2 (3%)	5 (8%)
	2+ OR 1/2 G/DL (%)	5 (8%)	3 (5%)	3 (5%)	4 (6%)	2 (3%)	0
	3+ OR 1 G/DL (%)	3 (5%)	6 (10%)	5 (8%)	4 (6%)	2 (3%)	8 (13%)
Urine Ketones (dipstick)	NEGATIVE	60 (94%)	56 (92%)	57 (90%)	63 (95%)	58 (97%)	52 (85%)
	TRACE	2 (3%)	2 (3%)	3 (5%)	1 (2%)	2 (3%)	3 (5%)
	1+	0	0	0	0	0	0
Urine Protein (dipstick)	NEGATIVE	44 (69%)	44 (72%)	49 (78%)	48 (73%)	50 (83%)	47 (77%)
	TRACE	9 (14%)	10 (16%)	5 (8%)	9 (14%)	3 (5%)	6 (10%)
	1+	8 (13%)	2 (3%)	4 (6%)	4 (6%)	5 (8%)	2 (3%)
	2+	1 (2%)	1 (2%)	2 (3%)	3 (5%)	2 (3%)	0
	3+	0	1 (2%)	0	0	0	0

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Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 0

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	44 (69%)	38 (62%)	46 (73%)	45 (68%)	38 (63%)	41 (67%)
	0-1	3 (5%)	0	3 (5%)	1 (2%)	0	0
	1-3	1 (2%)	3 (5%)	0	2 (3%)	3 (5%)	2 (3%)
	3-5	3 (5%)	4 (7%)	0	0	1 (2%)	1 (2%)
	5-10	0	0	0	3 (5%)	2 (3%)	0
	10-15	0	0	0	0	0	0
	15-25	0	0	0	0	1 (2%)	0
	25-50	1 (2%)	0	2 (3%)	0	1 (2%)	0
	50-100	0	0	0	1 (2%)	1 (2%)	0
	INNUMERABLE	1 (2%)	0	0	1 (2%)	0	1 (2%)
Urine microscopy - White Blood Cells	NONE SEEN	30 (47%)	22 (36%)	32 (51%)	32 (48%)	26 (43%)	34 (56%)
	0-1	6 (9%)	2 (3%)	4 (6%)	3 (5%)	2 (3%)	2 (3%)
	1-3	3 (5%)	4 (7%)	3 (5%)	6 (9%)	3 (5%)	1 (2%)
	3-5	4 (6%)	4 (7%)	0	1 (2%)	2 (3%)	0
	5-10	5 (8%)	4 (7%)	0	4 (6%)	7 (12%)	3 (5%)
	10-15	0	0	0	0	0	0
	15-25	2 (3%)	2 (3%)	4 (6%)	2 (3%)	2 (3%)	3 (5%)
	25-50	0	4 (7%)	5 (8%)	2 (3%)	4 (7%)	1 (2%)
	50-100	0	2 (3%)	3 (5%)	2 (3%)	1 (2%)	1 (2%)
	INNUMERABLE	3 (5%)	1 (2%)	0	1 (2%)	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 1

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	57 (89%)	57 (93%)	59 (94%)	60 (91%)	57 (95%)	57 (93%)
Urine Glucose (dipstick)	NEGATIVE	35 (55%)	38 (62%)	40 (63%)	46 (70%)	50 (83%)	43 (70%)
	TRACE OR 1/10 G/DL (%)	7 (11%)	4 (7%)	9 (14%)	8 (12%)	4 (7%)	4 (7%)
	1+ OR 1/4 G/DL (%)	5 (8%)	7 (11%)	3 (5%)	3 (5%)	2 (3%)	4 (7%)
	2+ OR 1/2 G/DL (%)	4 (6%)	1 (2%)	2 (3%)	2 (3%)	0	1 (2%)
	3+ OR 1 G/DL (%)	6 (9%)	7 (11%)	5 (8%)	1 (2%)	1 (2%)	5 (8%)
Urine Ketones (dipstick)	NEGATIVE	54 (84%)	56 (92%)	56 (89%)	60 (91%)	56 (93%)	54 (89%)
	TRACE	2 (3%)	1 (2%)	3 (5%)	0	1 (2%)	3 (5%)
	1+	1 (2%)	0	0	0	0	0
Urine Protein (dipstick)	NEGATIVE	43 (67%)	44 (72%)	49 (78%)	52 (79%)	47 (78%)	53 (87%)
	TRACE	7 (11%)	7 (11%)	6 (10%)	4 (6%)	7 (12%)	4 (7%)
	1+	7 (11%)	6 (10%)	2 (3%)	3 (5%)	2 (3%)	0
	2+	0	0	1 (2%)	1 (2%)	1 (2%)	0
	3+	0	0	1 (2%)	0	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 1

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	35 (55%)	32 (52%)	40 (63%)	39 (59%)	39 (65%)	39 (64%)
	0-1	2 (3%)	1 (2%)	2 (3%)	2 (3%)	0	1 (2%)
	1-3	2 (3%)	6 (10%)	5 (8%)	1 (2%)	1 (2%)	1 (2%)
	3-5	2 (3%)	1 (2%)	0	2 (3%)	0	1 (2%)
	5-10	1 (2%)	0	0	2 (3%)	0	0
	10-15	0	0	0	0	0	0
	15-25	0	0	0	0	0	0
	25-50	2 (3%)	1 (2%)	2 (3%)	0	0	0
	50-100	1 (2%)	0	1 (2%)	0	1 (2%)	1 (2%)
	INNUMERABLE	0	0	0	1 (2%)	0	0
Urine microscopy - White Blood Cells	NONE SEEN	24 (38%)	26 (43%)	27 (43%)	30 (45%)	24 (40%)	32 (52%)
	0-1	3 (5%)	1 (2%)	3 (5%)	3 (5%)	0	4 (7%)
	1-3	6 (9%)	6 (10%)	6 (10%)	5 (8%)	2 (3%)	0
	3-5	0	1 (2%)	2 (3%)	4 (6%)	5 (8%)	1 (2%)
	5-10	4 (6%)	2 (3%)	3 (5%)	2 (3%)	1 (2%)	1 (2%)
	10-15	0	0	0	0	0	0
	15-25	3 (5%)	0	3 (5%)	1 (2%)	1 (2%)	2 (3%)
	25-50	1 (2%)	3 (5%)	2 (3%)	1 (2%)	2 (3%)	1 (2%)
	50-100	3 (5%)	1 (2%)	4 (6%)	1 (2%)	4 (7%)	2 (3%)
	INNUMERABLE	1 (2%)	1 (2%)	0	0	2 (3%)	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 2

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	60 (94%)	57 (93%)	59 (94%)	62 (94%)	54 (90%)	58 (95%)
Urine Glucose (dipstick)	NEGATIVE	45 (70%)	36 (59%)	41 (65%)	50 (76%)	46 (77%)	45 (74%)
	TRACE OR 1/10 G/DL (%)	4 (6%)	6 (10%)	9 (14%)	5 (8%)	1 (2%)	4 (7%)
	1+ OR 1/4 G/DL (%)	1 (2%)	3 (5%)	2 (3%)	1 (2%)	7 (12%)	5 (8%)
	2+ OR 1/2 G/DL (%)	3 (5%)	4 (7%)	1 (2%)	3 (5%)	0	1 (2%)
	3+ OR 1 G/DL (%)	7 (11%)	8 (13%)	6 (10%)	3 (5%)	0	3 (5%)
Urine Ketones (dipstick)	NEGATIVE	56 (88%)	54 (89%)	58 (92%)	61 (92%)	53 (88%)	58 (95%)
	TRACE	3 (5%)	3 (5%)	0	1 (2%)	1 (2%)	0
	1+	1 (2%)	0	1 (2%)	0	0	0
Urine Protein (dipstick)	NEGATIVE	49 (77%)	49 (80%)	51 (81%)	52 (79%)	44 (73%)	54 (89%)
	TRACE	4 (6%)	5 (8%)	6 (10%)	6 (9%)	5 (8%)	4 (7%)
	1+	6 (9%)	3 (5%)	1 (2%)	3 (5%)	4 (7%)	0
	2+	0	0	1 (2%)	1 (2%)	1 (2%)	0
	3+	1 (2%)	0	0	0	0	0

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Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 2

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	32 (50%)	39 (64%)	46 (73%)	40 (61%)	35 (58%)	34 (56%)
	0-1	3 (5%)	0	0	4 (6%)	1 (2%)	3 (5%)
	1-3	3 (5%)	3 (5%)	0	1 (2%)	4 (7%)	2 (3%)
	3-5	0	2 (3%)	1 (2%)	1 (2%)	1 (2%)	2 (3%)
	5-10	1 (2%)	0	0	0	0	3 (5%)
	10-15	0	0	0	0	0	0
	15-25	1 (2%)	0	0	0	0	0
	25-50	3 (5%)	1 (2%)	1 (2%)	3 (5%)	0	0
	50-100	2 (3%)	0	0	0	0	0
	INNUMERABLE	0	0	0	0	0	0
Urine microscopy - White Blood Cells	NONE SEEN	23 (36%)	32 (52%)	35 (56%)	34 (52%)	19 (32%)	28 (46%)
	0-1	3 (5%)	1 (2%)	2 (3%)	0	3 (5%)	6 (10%)
	1-3	6 (9%)	3 (5%)	2 (3%)	2 (3%)	3 (5%)	0
	3-5	1 (2%)	3 (5%)	2 (3%)	3 (5%)	1 (2%)	3 (5%)
	5-10	4 (6%)	2 (3%)	0	2 (3%)	1 (2%)	2 (3%)
	10-15	0	0	0	1 (2%)	0	0
	15-25	2 (3%)	0	1 (2%)	4 (6%)	1 (2%)	1 (2%)
	25-50	3 (5%)	3 (5%)	4 (6%)	2 (3%)	9 (15%)	2 (3%)
	50-100	3 (5%)	1 (2%)	1 (2%)	1 (2%)	2 (3%)	2 (3%)
	INNUMERABLE	0	0	1 (2%)	0	2 (3%)	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 3

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	55 (86%)	56 (92%)	57 (90%)	60 (91%)	56 (93%)	54 (89%)
Urine Glucose (dipstick)	NEGATIVE	39 (61%)	37 (61%)	41 (65%)	45 (68%)	50 (83%)	42 (69%)
	TRACE OR 1/10 G/DL (%)	4 (6%)	5 (8%)	11 (17%)	6 (9%)	1 (2%)	5 (8%)
	1+ OR 1/4 G/DL (%)	3 (5%)	7 (11%)	2 (3%)	2 (3%)	2 (3%)	2 (3%)
	2+ OR 1/2 G/DL (%)	1 (2%)	0	1 (2%)	4 (6%)	1 (2%)	1 (2%)
	3+ OR 1 G/DL (%)	8 (13%)	7 (11%)	2 (3%)	3 (5%)	2 (3%)	4 (7%)
Urine Ketones (dipstick)	NEGATIVE	55 (86%)	55 (90%)	55 (87%)	59 (89%)	54 (90%)	52 (85%)
	TRACE	0	1 (2%)	2 (3%)	1 (2%)	2 (3%)	2 (3%)
	1+	0	0	0	0	0	0
Urine Protein (dipstick)	NEGATIVE	44 (69%)	47 (77%)	48 (76%)	52 (79%)	49 (82%)	49 (80%)
	TRACE	7 (11%)	5 (8%)	5 (8%)	2 (3%)	4 (7%)	2 (3%)
	1+	2 (3%)	4 (7%)	3 (5%)	5 (8%)	1 (2%)	3 (5%)
	2+	2 (3%)	0	0	1 (2%)	2 (3%)	0
	3+	0	0	1 (2%)	0	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 3

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	37 (58%)	38 (62%)	42 (67%)	42 (64%)	37 (62%)	42 (69%)
	0-1	3 (5%)	0	1 (2%)	0	1 (2%)	1 (2%)
	1-3	1 (2%)	4 (7%)	2 (3%)	1 (2%)	1 (2%)	0
	3-5	0	0	0	0	0	0
	5-10	3 (5%)	0	0	1 (2%)	0	0
	10-15	0	0	0	0	0	0
	15-25	0	1 (2%)	0	0	0	0
	25-50	4 (6%)	0	0	2 (3%)	1 (2%)	0
	50-100	0	1 (2%)	0	1 (2%)	0	0
	INNUMERABLE	0	0	0	0	1 (2%)	0
Urine microscopy - White Blood Cells	NONE SEEN	30 (47%)	28 (46%)	31 (49%)	36 (55%)	25 (42%)	27 (44%)
	0-1	1 (2%)	2 (3%)	3 (5%)	0	1 (2%)	4 (7%)
	1-3	4 (6%)	1 (2%)	2 (3%)	1 (2%)	1 (2%)	3 (5%)
	3-5	3 (5%)	2 (3%)	2 (3%)	3 (5%)	0	2 (3%)
	5-10	4 (6%)	4 (7%)	2 (3%)	3 (5%)	1 (2%)	2 (3%)
	10-15	0	0	0	0	0	0
	15-25	2 (3%)	3 (5%)	1 (2%)	0	2 (3%)	1 (2%)
	25-50	2 (3%)	1 (2%)	1 (2%)	2 (3%)	3 (5%)	2 (3%)
	50-100	2 (3%)	0	2 (3%)	1 (2%)	8 (13%)	2 (3%)
	INNUMERABLE	0	3 (5%)	1 (2%)	1 (2%)	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 4

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	55 (86%)	56 (92%)	56 (89%)	60 (91%)	57 (95%)	57 (93%)
Urine Glucose (dipstick)	NEGATIVE	41 (64%)	35 (57%)	43 (68%)	45 (68%)	47 (78%)	47 (77%)
	TRACE OR 1/10 G/DL (%)	3 (5%)	8 (13%)	5 (8%)	7 (11%)	3 (5%)	4 (7%)
	1+ OR 1/4 G/DL (%)	2 (3%)	5 (8%)	0	6 (9%)	4 (7%)	2 (3%)
	2+ OR 1/2 G/DL (%)	1 (2%)	5 (8%)	3 (5%)	1 (2%)	2 (3%)	4 (7%)
	3+ OR 1 G/DL (%)	8 (13%)	3 (5%)	5 (8%)	1 (2%)	1 (2%)	0
Urine Ketones (dipstick)	NEGATIVE	54 (84%)	55 (90%)	55 (87%)	59 (89%)	56 (93%)	56 (92%)
	TRACE	1 (2%)	1 (2%)	1 (2%)	1 (2%)	0	0
	1+	0	0	0	0	1 (2%)	1 (2%)
Urine Protein (dipstick)	NEGATIVE	43 (67%)	46 (75%)	51 (81%)	49 (74%)	48 (80%)	56 (92%)
	TRACE	7 (11%)	7 (11%)	3 (5%)	6 (9%)	4 (7%)	1 (2%)
	1+	3 (5%)	3 (5%)	1 (2%)	4 (6%)	4 (7%)	0
	2+	2 (3%)	0	1 (2%)	1 (2%)	1 (2%)	0
	3+	0	0	0	0	0	0

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Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 4

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	36 (56%)	40 (66%)	42 (67%)	38 (58%)	41 (68%)	37 (61%)
	0-1	1 (2%)	0	0	0	4 (7%)	1 (2%)
	1-3	3 (5%)	3 (5%)	0	3 (5%)	2 (3%)	4 (7%)
	3-5	1 (2%)	0	0	1 (2%)	1 (2%)	0
	5-10	1 (2%)	3 (5%)	0	0	0	0
	10-15	0	0	0	0	0	0
	15-25	0	0	0	2 (3%)	1 (2%)	0
	25-50	0	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)
	50-100	0	0	0	0	0	0
	INNUMERABLE	1 (2%)	0	0	0	0	0
Urine microscopy - White Blood Cells	NONE SEEN	23 (36%)	28 (46%)	33 (52%)	30 (45%)	26 (43%)	31 (51%)
	0-1	5 (8%)	1 (2%)	2 (3%)	1 (2%)	3 (5%)	2 (3%)
	1-3	5 (8%)	2 (3%)	1 (2%)	4 (6%)	4 (7%)	1 (2%)
	3-5	1 (2%)	5 (8%)	1 (2%)	0	1 (2%)	1 (2%)
	5-10	2 (3%)	1 (2%)	0	2 (3%)	4 (7%)	3 (5%)
	10-15	1 (2%)	0	0	0	0	1 (2%)
	15-25	0	3 (5%)	3 (5%)	3 (5%)	4 (7%)	2 (3%)
	25-50	3 (5%)	4 (7%)	2 (3%)	3 (5%)	5 (8%)	1 (2%)
	50-100	2 (3%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
	INNUMERABLE	1 (2%)	1 (2%)	0	1 (2%)	2 (3%)	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 6

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	54 (84%)	50 (82%)	57 (90%)	59 (89%)	57 (95%)	53 (87%)
Urine Glucose (dipstick)	NEGATIVE	36 (56%)	31 (51%)	41 (65%)	46 (70%)	47 (78%)	43 (70%)
	TRACE OR 1/10 G/DL (%)	6 (9%)	7 (11%)	5 (8%)	9 (14%)	6 (10%)	3 (5%)
	1+ OR 1/4 G/DL (%)	2 (3%)	4 (7%)	6 (10%)	1 (2%)	2 (3%)	3 (5%)
	2+ OR 1/2 G/DL (%)	4 (6%)	5 (8%)	2 (3%)	1 (2%)	1 (2%)	1 (2%)
	3+ OR 1 G/DL (%)	6 (9%)	3 (5%)	3 (5%)	2 (3%)	1 (2%)	3 (5%)
Urine Ketones (dipstick)	NEGATIVE	52 (81%)	48 (79%)	55 (87%)	58 (88%)	57 (95%)	51 (84%)
	TRACE	2 (3%)	1 (2%)	2 (3%)	1 (2%)	0	2 (3%)
	1+	0	1 (2%)	0	0	0	0
Urine Protein (dipstick)	NEGATIVE	41 (64%)	38 (62%)	49 (78%)	46 (70%)	50 (83%)	48 (79%)
	TRACE	8 (13%)	8 (13%)	5 (8%)	6 (9%)	2 (3%)	4 (7%)
	1+	4 (6%)	3 (5%)	3 (5%)	5 (8%)	3 (5%)	1 (2%)
	2+	1 (2%)	1 (2%)	0	2 (3%)	2 (3%)	0
	3+	0	0	0	0	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 6

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	36 (56%)	34 (56%)	43 (68%)	39 (59%)	35 (58%)	36 (59%)
	0-1	1 (2%)	1 (2%)	1 (2%)	2 (3%)	2 (3%)	1 (2%)
	1-3	1 (2%)	4 (7%)	1 (2%)	2 (3%)	2 (3%)	2 (3%)
	3-5	0	1 (2%)	0	1 (2%)	1 (2%)	0
	5-10	0	1 (2%)	0	1 (2%)	1 (2%)	0
	10-15	0	0	0	0	0	0
	15-25	1 (2%)	0	1 (2%)	0	1 (2%)	1 (2%)
	25-50	2 (3%)	0	0	1 (2%)	1 (2%)	1 (2%)
	50-100	1 (2%)	0	0	0	0	0
	INNUMERABLE	0	0	0	0	0	0
Urine microscopy - White Blood Cells	NONE SEEN	22 (34%)	23 (38%)	31 (49%)	31 (47%)	23 (38%)	28 (46%)
	0-1	2 (3%)	2 (3%)	2 (3%)	2 (3%)	3 (5%)	2 (3%)
	1-3	4 (6%)	5 (8%)	6 (10%)	4 (6%)	3 (5%)	1 (2%)
	3-5	2 (3%)	2 (3%)	0	1 (2%)	0	2 (3%)
	5-10	0	2 (3%)	0	2 (3%)	1 (2%)	1 (2%)
	10-15	0	0	0	0	0	0
	15-25	2 (3%)	1 (2%)	2 (3%)	1 (2%)	4 (7%)	2 (3%)
	25-50	5 (8%)	3 (5%)	4 (6%)	3 (5%)	6 (10%)	4 (7%)
	50-100	2 (3%)	2 (3%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
	INNUMERABLE	3 (5%)	1 (2%)	0	1 (2%)	2 (3%)	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 8

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	52 (81%)	47 (77%)	56 (89%)	60 (91%)	56 (93%)	55 (90%)
Urine Glucose (dipstick)	NEGATIVE	35 (55%)	33 (54%)	39 (62%)	43 (65%)	49 (82%)	45 (74%)
	TRACE OR 1/10 G/DL (%)	6 (9%)	5 (8%)	5 (8%)	7 (11%)	3 (5%)	5 (8%)
	1+ OR 1/4 G/DL (%)	1 (2%)	3 (5%)	5 (8%)	3 (5%)	2 (3%)	2 (3%)
	2+ OR 1/2 G/DL (%)	2 (3%)	2 (3%)	2 (3%)	5 (8%)	2 (3%)	3 (5%)
	3+ OR 1 G/DL (%)	8 (13%)	4 (7%)	5 (8%)	2 (3%)	0	0
Urine Ketones (dipstick)	NEGATIVE	51 (80%)	46 (75%)	55 (87%)	60 (91%)	53 (88%)	54 (89%)
	TRACE	1 (2%)	1 (2%)	0	0	3 (5%)	1 (2%)
	1+	0	0	1 (2%)	0	0	0
Urine Protein (dipstick)	NEGATIVE	45 (70%)	38 (62%)	47 (75%)	49 (74%)	48 (80%)	52 (85%)
	TRACE	2 (3%)	5 (8%)	5 (8%)	8 (12%)	3 (5%)	1 (2%)
	1+	4 (6%)	4 (7%)	4 (6%)	2 (3%)	5 (8%)	2 (3%)
	2+	1 (2%)	0	0	0	0	0
	3+	0	0	0	1 (2%)	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 8

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	34 (53%)	28 (46%)	44 (70%)	39 (59%)	37 (62%)	40 (66%)
	0-1	1 (2%)	0	0	1 (2%)	1 (2%)	1 (2%)
	1-3	1 (2%)	5 (8%)	1 (2%)	2 (3%)	2 (3%)	1 (2%)
	3-5	1 (2%)	0	0	1 (2%)	1 (2%)	0
	5-10	0	1 (2%)	0	1 (2%)	0	0
	10-15	1 (2%)	0	0	0	1 (2%)	0
	15-25	2 (3%)	1 (2%)	0	0	1 (2%)	0
	25-50	0	1 (2%)	0	1 (2%)	0	0
	50-100	1 (2%)	0	0	1 (2%)	0	0
	INNUMERABLE	0	0	0	0	1 (2%)	0
Urine microscopy - White Blood Cells	NONE SEEN	22 (34%)	28 (46%)	33 (52%)	31 (47%)	18 (30%)	32 (52%)
	0-1	5 (8%)	1 (2%)	2 (3%)	0	3 (5%)	2 (3%)
	1-3	5 (8%)	0	1 (2%)	4 (6%)	6 (10%)	3 (5%)
	3-5	0	1 (2%)	2 (3%)	3 (5%)	3 (5%)	0
	5-10	3 (5%)	3 (5%)	1 (2%)	2 (3%)	1 (2%)	0
	10-15	0	0	0	0	0	1 (2%)
	15-25	0	2 (3%)	2 (3%)	2 (3%)	5 (8%)	1 (2%)
	25-50	1 (2%)	0	2 (3%)	4 (6%)	3 (5%)	1 (2%)
	50-100	3 (5%)	1 (2%)	2 (3%)	0	3 (5%)	1 (2%)
	INNUMERABLE	2 (3%)	0	0	0	2 (3%)	1 (2%)

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 12

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine Bilirubin (dipstick)	NEGATIVE	48 (75%)	46 (75%)	54 (86%)	57 (86%)	55 (92%)	52 (85%)
Urine Glucose (dipstick)	NEGATIVE	32 (50%)	27 (44%)	37 (59%)	44 (67%)	51 (85%)	41 (67%)
	TRACE OR 1/10 G/DL (%)	6 (9%)	7 (11%)	7 (11%)	5 (8%)	2 (3%)	3 (5%)
	1+ OR 1/4 G/DL (%)	1 (2%)	6 (10%)	2 (3%)	2 (3%)	1 (2%)	6 (10%)
	2+ OR 1/2 G/DL (%)	3 (5%)	1 (2%)	1 (2%)	4 (6%)	0	2 (3%)
	3+ OR 1 G/DL (%)	6 (9%)	6 (10%)	7 (11%)	2 (3%)	1 (2%)	0
Urine Ketones (dipstick)	NEGATIVE	47 (73%)	42 (69%)	54 (86%)	57 (86%)	55 (92%)	51 (84%)
	TRACE	1 (2%)	4 (7%)	0	0	0	1 (2%)
	1+	0	1 (2%)	0	0	0	0
Urine Protein (dipstick)	NEGATIVE	39 (61%)	36 (59%)	46 (73%)	46 (70%)	46 (77%)	48 (79%)
	TRACE	7 (11%)	6 (10%)	5 (8%)	6 (9%)	4 (7%)	4 (7%)
	1+	1 (2%)	5 (8%)	3 (5%)	4 (6%)	4 (7%)	0
	2+	1 (2%)	0	0	0	1 (2%)	0
	3+	0	0	0	1 (2%)	0	0

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Table 12.27
Summary of Urinalysis Dipstick Results

Planned Relative Time: Week 12

		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Urine microscopy - Red Blood Cells	NONE SEEN	33 (52%)	36 (59%)	38 (60%)	40 (61%)	35 (58%)	38 (62%)
	0-1	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)	0
	1-3	1 (2%)	2 (3%)	5 (8%)	2 (3%)	3 (5%)	1 (2%)
	3-5	0	0	0	0	0	1 (2%)
	5-10	1 (2%)	1 (2%)	1 (2%)	1 (2%)	0	0
	10-15	0	0	0	0	0	0
	15-25	2 (3%)	0	0	1 (2%)	1 (2%)	0
	25-50	0	0	1 (2%)	1 (2%)	0	0
	50-100	2 (3%)	0	0	0	1 (2%)	0
	INNUMERABLE	0	0	0	0	0	0
Urine microscopy - White Blood Cells	NONE SEEN	18 (28%)	27 (44%)	31 (49%)	32 (48%)	25 (42%)	29 (48%)
	0-1	2 (3%)	3 (5%)	4 (6%)	3 (5%)	3 (5%)	1 (2%)
	1-3	6 (9%)	2 (3%)	2 (3%)	0	3 (5%)	4 (7%)
	3-5	2 (3%)	0	1 (2%)	1 (2%)	0	1 (2%)
	5-10	2 (3%)	1 (2%)	2 (3%)	3 (5%)	1 (2%)	0
	10-15	0	0	0	1 (2%)	0	0
	15-25	2 (3%)	2 (3%)	2 (3%)	0	2 (3%)	1 (2%)
	25-50	3 (5%)	5 (8%)	2 (3%)	1 (2%)	2 (3%)	3 (5%)
	50-100	4 (6%)	0	1 (2%)	3 (5%)	4 (7%)	0
	INNUMERABLE	1 (2%)	0	1 (2%)	1 (2%)	1 (2%)	1 (2%)

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	Placebo	64	Week -5	64	87.96	15.940	84.75	57.3	143.0
			Week -4	64	87.52	15.818	84.80	58.5	142.1
			Week -2	63	87.23	15.925	83.00	58.0	142.6
			Baseline	64	86.87	15.723	83.05	59.0	143.0
			Week 1	61	87.34	15.948	84.00	58.0	142.0
			Week 2	60	86.85	15.755	83.30	57.4	140.7
			Week 3	55	86.91	15.870	84.00	57.8	141.0
			Week 4	57	87.22	15.916	84.60	57.7	141.0
			Week 6	54	87.37	16.122	84.40	58.2	140.3
			Week 8	52	86.85	16.220	84.00	58.0	141.0
			Week 12	49	87.03	16.424	85.00	55.4	140.3
	2.5mg	61	Week -5	61	90.19	17.353	87.00	53.4	131.5
			Week -4	61	90.08	17.244	86.60	53.9	131.5
			Week -2	61	89.90	17.138	87.50	52.9	131.9
			Baseline	61	89.25	16.907	85.00	52.9	130.6
			Week 1	60	89.25	17.022	85.20	52.4	130.1
			Week 2	58	89.26	17.268	86.55	52.4	130.9
			Week 3	58	88.66	17.091	85.10	52.7	131.4
			Week 4	56	88.31	17.369	84.40	52.8	130.9
			Week 6	51	88.68	18.009	84.00	53.6	130.0
			Week 8	49	89.13	18.324	86.40	53.1	130.6
			Week 12	48	88.59	18.601	85.70	52.6	133.3
	7.5mg	63	Week -5	62	88.74	16.017	88.55	60.0	134.0
			Week -4	62	88.47	16.046	87.70	60.0	133.0
			Week -2	59	88.09	16.182	86.70	60.0	134.0
			Baseline	63	87.71	16.312	86.20	56.1	135.0
			Week 1	62	88.16	15.977	86.90	60.0	134.5
			Week 2	60	88.00	16.198	86.25	60.0	136.2
			Week 3	59	88.20	16.043	87.20	59.5	134.7

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	7.5mg	63	Week 4	58	88.35	16.122	87.25	60.0	135.2
			Week 6	57	88.41	16.331	87.00	60.0	135.8
			Week 8	56	88.22	16.300	86.60	60.0	136.0
			Week 12	55	88.07	16.484	87.40	59.0	135.5
	15mg	66	Week -5	63	87.89	14.181	89.80	57.0	115.0
			Week -4	63	87.60	14.160	90.00	57.3	115.0
			Week -2	63	87.37	14.051	88.50	56.4	114.5
			Baseline	66	86.66	14.271	86.90	53.0	113.0
			Week 1	63	87.46	13.926	88.30	57.4	113.5
			Week 2	63	87.12	14.060	86.60	57.7	114.0
			Week 3	61	87.21	14.246	86.70	57.3	115.0
			Week 4	60	87.14	14.202	87.20	57.0	116.5
			Week 6	60	87.11	14.298	87.95	57.4	114.5
			Week 8	60	87.17	14.094	87.55	57.3	116.0
			Week 12	60	87.05	14.165	87.40	57.1	117.5
	30mg	60	Week -5	60	91.60	18.825	88.75	58.2	149.5
			Week -4	60	91.15	18.171	88.65	57.8	141.0
			Week -2	59	90.51	18.449	88.00	58.3	139.3
			Baseline	60	90.36	18.267	87.50	57.8	143.0
			Week 1	58	90.53	19.073	87.80	57.7	145.5
			Week 2	57	89.63	18.585	87.00	58.3	141.7
			Week 3	57	89.66	18.638	87.00	57.4	139.7
			Week 4	58	89.30	18.204	86.20	56.3	140.7
			Week 6	57	89.58	18.012	86.80	56.7	140.5
			Week 8	57	89.71	18.559	86.80	57.0	146.0
			Week 12	56	89.47	18.573	86.10	56.7	145.8
	45mg	61	Week -5	61	90.83	15.246	86.80	63.5	123.2
			Week -4	61	90.78	14.873	86.70	63.5	122.0

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	45mg	61	Week -2	61	90.40	14.757	86.10	62.5	119.6
			Baseline	61	90.20	14.752	85.80	62.5	122.0
			Week 1	60	89.94	14.913	86.25	61.7	124.5
			Week 2	60	89.64	14.926	85.55	62.6	125.0
			Week 3	57	89.56	14.689	86.30	62.6	123.0
			Week 4	58	90.36	14.617	87.25	62.1	122.0
			Week 6	55	89.58	14.657	86.00	62.1	121.0
			Week 8	56	89.27	14.545	86.60	61.7	120.0
			Week 12	56	89.24	14.638	86.15	61.2	120.0
Hip Circumference (cm)	Placebo	64	Week -5	63	108.3	11.18	107.0	86	134
			Baseline	64	108.5	11.44	106.0	90	137
			Week 12	48	108.2	10.07	107.0	90	131
	2.5mg	61	Week -5	61	110.2	9.53	110.0	90	137
			Baseline	61	110.2	9.32	111.0	94	136
			Week 12	48	110.1	8.81	110.0	94	135
	7.5mg	63	Week -5	61	108.8	10.03	108.0	82	139
			Baseline	63	108.9	11.05	108.0	80	136
			Week 12	53	109.3	10.93	109.0	80	137
	15mg	66	Week -5	63	107.8	10.51	107.0	91	137
			Baseline	66	108.1	9.70	108.0	90	135
			Week 12	58	109.2	10.16	108.0	84	134
	30mg	60	Week -5	60	111.0	10.56	109.5	93	140
			Baseline	60	110.4	10.80	108.0	88	137
			Week 12	53	109.9	10.85	108.0	94	137

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hip Circumference (cm)	45mg	61	Week -5	60	111.5	9.51	109.5	94	136
			Baseline	61	111.6	9.98	109.0	91	135
			Week 12	56	109.1	10.11	107.5	92	136
Waist Circumference (cm)	Placebo	64	Week -5	63	104.2	12.43	102.0	82	140
			Baseline	64	103.5	12.53	101.0	82	139
			Week 12	48	103.0	12.81	101.0	81	135
	2.5mg	61	Week -5	61	107.2	11.13	108.0	82	134
			Baseline	61	104.7	11.15	105.0	74	131
			Week 12	48	104.0	11.17	103.5	76	129
	7.5mg	63	Week -5	62	105.0	11.58	106.0	84	134
			Baseline	63	103.8	11.55	103.0	82	132
			Week 12	53	103.3	11.15	103.0	82	127
	15mg	66	Week -5	63	103.3	10.72	103.0	84	125
			Baseline	66	102.2	9.70	100.5	84	121
			Week 12	58	102.3	9.51	101.5	84	122
	30mg	60	Week -5	60	104.7	12.69	104.0	83	149
			Baseline	60	106.1	12.48	104.0	82	147
			Week 12	53	105.0	12.99	103.0	80	148
	45mg	61	Week -5	60	106.0	11.09	105.0	75	138
			Baseline	61	104.6	11.04	104.0	72	138
			Week 12	56	105.7	11.00	103.5	75	138
Waist:Hip Ratio	Placebo	64	Week -5	63	0.96	0.089	0.95	0.8	1.3

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Waist:Hip Ratio	Placebo	64	Baseline	64	0.96	0.078	0.95	0.8	1.1
			Week 12	48	0.95	0.078	0.96	0.8	1.1
	2.5mg	61	Week -5	61	0.97	0.081	0.97	0.8	1.2
			Baseline	61	0.95	0.086	0.96	0.7	1.2
			Week 12	48	0.95	0.072	0.96	0.8	1.1
	7.5mg	63	Week -5	61	0.97	0.090	0.96	0.8	1.2
			Baseline	63	0.96	0.081	0.95	0.8	1.2
			Week 12	53	0.95	0.085	0.95	0.8	1.1
	15mg	66	Week -5	63	0.96	0.075	0.95	0.8	1.2
			Baseline	66	0.95	0.060	0.95	0.8	1.1
			Week 12	58	0.94	0.061	0.93	0.8	1.1
	30mg	60	Week -5	60	0.94	0.067	0.93	0.8	1.1
			Baseline	60	0.96	0.076	0.96	0.8	1.2
			Week 12	53	0.96	0.072	0.94	0.8	1.1
	45mg	61	Week -5	60	0.95	0.095	0.95	0.7	1.3
			Baseline	61	0.94	0.091	0.94	0.7	1.1
			Week 12	56	0.97	0.108	0.97	0.7	1.3
BMI (kg/m^2)	Placebo	64	Week -5	64	30.922	4.8625	29.756	23.79	40.15
			Week -4	64	30.781	4.9104	29.851	23.52	40.31
			Week -2	63	30.707	4.8878	29.586	23.39	40.12
			Baseline	64	30.548	4.8391	29.617	23.22	39.61
			Week 1	61	30.632	4.9396	29.586	22.92	39.92
			Week 2	60	30.513	4.7661	29.539	23.46	39.88
			Week 3	55	30.506	4.8543	29.414	22.74	39.26

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	Placebo	64	Week 4	57	30.604	4.8708	29.586	22.63	39.61
			Week 6	54	30.568	4.9389	29.444	22.73	39.49
			Week 8	52	30.654	4.8578	29.853	23.02	39.92
			Week 12	49	30.684	4.9328	30.195	22.88	39.90
	2.5mg	61	Week -5	61	31.839	4.6933	31.329	20.86	40.59
			Week -4	61	31.800	4.6431	31.194	21.05	40.59
			Week -2	61	31.739	4.6484	31.142	20.66	40.71
			Baseline	61	31.447	4.6785	30.860	20.66	40.76
			Week 1	60	31.398	4.7100	30.948	20.47	40.60
			Week 2	58	31.382	4.7053	30.819	20.47	40.73
			Week 3	58	31.144	4.6874	30.559	20.59	40.48
			Week 4	56	31.012	4.6584	30.484	20.62	40.76
			Week 6	51	31.148	4.7158	30.570	20.94	40.30
			Week 8	49	31.220	4.7980	30.222	20.74	40.76
			Week 12	48	31.105	4.9352	30.734	20.55	41.60
	7.5mg	63	Week -5	62	31.041	4.7285	30.569	22.96	40.53
			Week -4	62	30.956	4.7912	30.526	22.81	41.27
			Week -2	59	30.800	4.8128	30.223	22.71	40.56
			Baseline	63	30.764	4.7727	30.378	22.77	41.18
			Week 1	62	30.834	4.7645	30.443	22.67	41.18
			Week 2	60	30.837	4.8773	30.290	22.78	42.12
			Week 3	59	30.855	4.8429	30.475	22.98	41.03
			Week 4	58	30.894	4.8937	30.796	22.68	41.29
			Week 6	57	30.888	4.9264	30.814	22.41	41.25
			Week 8	56	30.989	4.8768	31.213	22.31	41.10
			Week 12	55	30.872	4.9377	31.107	22.31	40.35
	15mg	66	Week -5	63	30.915	4.0792	30.471	24.49	39.63
			Week -4	63	30.810	4.0804	30.471	24.49	40.26

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	15mg	66	Week -2	63	30.723	3.9680	30.387	24.27	40.09
			Baseline	66	30.574	4.0807	30.429	20.20	39.56
			Week 1	63	30.740	3.9304	30.469	24.14	39.74
			Week 2	63	30.617	3.9597	30.207	23.41	39.91
			Week 3	61	30.619	3.9896	30.405	23.25	40.26
			Week 4	60	30.710	4.1327	30.446	23.25	40.79
			Week 6	60	30.697	4.1240	30.590	23.41	40.09
			Week 8	60	30.724	4.1110	30.550	23.41	40.61
			Week 12	60	30.677	4.0710	30.454	23.61	41.14
	30mg	60	Week -5	60	32.045	4.8771	30.934	22.86	40.16
			Week -4	60	31.900	4.7559	31.031	22.79	40.46
			Week -2	59	31.685	4.7856	30.930	22.68	40.52
			Baseline	60	31.507	4.6239	30.958	22.59	39.81
			Week 1	58	31.661	4.7176	31.058	22.59	41.23
			Week 2	57	31.400	4.5932	30.930	22.77	39.75
			Week 3	57	31.417	4.6851	30.955	22.41	40.22
			Week 4	58	31.227	4.5754	30.913	22.59	40.52
			Week 6	57	31.150	4.5334	30.718	22.30	40.88
			Week 8	57	31.182	4.6721	30.659	22.52	40.52
			Week 12	56	31.140	4.6721	30.375	22.59	40.12
	45mg	61	Week -5	61	31.691	4.3721	31.239	23.63	39.74
			Week -4	61	31.680	4.2618	31.531	24.80	40.01
			Week -2	61	31.542	4.1889	31.476	24.62	39.63
			Baseline	61	31.452	4.1705	31.137	24.30	40.09
			Week 1	60	31.413	4.2792	30.922	24.09	40.09
			Week 2	60	31.307	4.2695	30.912	23.99	40.09
			Week 3	57	31.301	4.2818	30.695	23.83	40.70
			Week 4	58	31.536	4.1786	31.435	23.99	40.81
			Week 6	55	31.355	4.1927	31.153	23.67	40.23

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Table 12.28
Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	45mg	61	Week 8	56	31.237	4.1549	31.158	23.83	41.02
			Week 12	56	31.230	4.2088	30.795	23.36	40.23

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	Placebo	64	Week -5	64	1.09	2.138	0.60	-1.7	11.0
			Week -4	64	0.64	1.624	0.40	-1.3	11.0
			Week -2	63	0.31	1.680	0.00	-4.0	11.0
			Week 1	61	-0.06	1.547	0.00	-2.5	9.5
			Week 2	60	-0.25	1.687	-0.30	-3.3	9.5
			Week 3	55	-0.25	1.724	-0.50	-2.6	9.0
			Week 4	57	-0.22	1.761	-0.30	-3.0	9.6
			Week 6	54	-0.47	1.394	-0.50	-3.0	2.8
			Week 8	52	-0.42	2.023	-0.95	-4.6	9.0
			Week 12	49	-0.78	2.332	-0.40	-6.5	5.4
	2.5mg	61	Week -5	61	0.94	1.923	0.70	-2.0	8.0
			Week -4	61	0.83	1.625	0.50	-1.7	9.0
			Week -2	61	0.64	1.175	0.50	-2.0	5.0
			Week 1	60	-0.10	0.927	0.00	-3.6	1.8
			Week 2	58	0.05	1.935	-0.05	-4.2	11.0
			Week 3	58	-0.38	1.458	-0.15	-4.0	2.8
			Week 4	56	-0.47	1.730	-0.15	-5.3	3.4
			Week 6	51	-0.65	2.413	-0.40	-6.0	9.0
			Week 8	49	-0.82	2.743	-0.70	-7.9	8.4
			Week 12	48	-0.96	2.869	-0.65	-8.9	6.3
	7.5mg	63	Week -5	62	0.52	1.321	0.50	-2.0	3.7
			Week -4	62	0.25	1.178	0.00	-3.0	3.0
			Week -2	59	0.12	0.895	0.00	-1.7	2.0
			Week 1	62	-0.06	0.928	0.00	-2.0	3.7
			Week 2	60	-0.26	1.085	0.00	-3.2	2.5
			Week 3	59	-0.32	1.135	0.00	-3.0	3.0
			Week 4	58	-0.42	1.210	-0.20	-3.5	3.0
			Week 6	57	-0.34	1.413	0.00	-5.0	3.0
			Week 8	56	-0.38	1.817	-0.40	-6.0	4.5

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	7.5mg	63	Week 12	55	-0.71	1.885	-0.50	-7.0	3.6
	15mg	66	Week -5	63	0.53	1.740	0.20	-3.2	7.2
			Week -4	63	0.23	1.396	0.00	-3.8	4.5
			Week -2	63	0.01	1.167	0.00	-3.1	3.0
			Week 1	63	0.10	0.818	0.00	-1.5	3.0
			Week 2	63	-0.24	1.060	-0.20	-2.7	3.0
			Week 3	61	-0.25	1.266	-0.10	-3.0	3.0
			Week 4	60	-0.28	1.386	-0.30	-4.2	4.1
			Week 6	60	-0.30	1.601	0.00	-4.7	4.0
			Week 8	60	-0.25	1.450	0.00	-4.0	3.0
			Week 12	60	-0.36	2.009	-0.25	-5.5	4.5
	30mg	60	Week -5	60	1.24	1.922	0.90	-1.7	6.5
			Week -4	60	0.79	1.676	0.65	-4.3	6.2
			Week -2	59	0.35	1.529	0.20	-4.0	5.5
			Week 1	58	0.22	1.396	0.00	-2.7	6.8
			Week 2	57	-0.34	2.253	0.00	-14.0	5.4
			Week 3	57	-0.31	1.364	-0.20	-3.3	4.9
			Week 4	58	-0.60	1.448	-0.35	-5.7	3.0
			Week 6	57	-0.68	2.070	-0.50	-7.1	4.0
			Week 8	57	-0.56	2.213	-0.50	-5.9	4.9
			Week 12	56	-0.51	2.745	-0.15	-8.9	7.0
	45mg	61	Week -5	61	0.63	1.808	0.30	-5.4	5.0
			Week -4	61	0.58	1.329	0.20	-3.0	5.0
			Week -2	61	0.20	0.894	0.00	-2.4	2.0
			Week 1	60	0.09	1.023	0.00	-2.0	4.0
			Week 2	60	-0.21	1.264	0.00	-5.0	3.0
			Week 3	57	-0.21	1.625	0.00	-7.7	1.9
			Week 4	58	0.10	1.722	0.00	-5.6	3.5

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	45mg	61	Week 6	55	-0.29	2.285	0.00	-8.6	6.3
			Week 8	56	-0.48	2.435	0.00	-10.6	5.0
			Week 12	56	-0.50	2.422	-0.15	-9.9	3.8
Weight (%)	Placebo	64	Week -5	64	1.25	2.505	0.78	-2.9	13.6
			Week -4	64	0.74	1.966	0.46	-2.1	13.6
			Week -2	63	0.35	2.053	0.00	-4.8	13.6
			Week 1	61	-0.07	1.884	0.00	-2.7	11.7
			Week 2	60	-0.28	2.036	-0.39	-4.3	11.7
			Week 3	55	-0.24	2.076	-0.56	-3.6	11.1
			Week 4	57	-0.22	2.126	-0.48	-3.6	11.9
			Week 6	54	-0.49	1.560	-0.55	-3.6	3.0
			Week 8	52	-0.45	2.341	-1.07	-4.2	11.1
			Week 12	49	-0.84	2.696	-0.51	-6.5	6.7
	2.5mg	61	Week -5	61	1.02	2.121	0.83	-2.4	9.4
			Week -4	61	0.91	1.862	0.69	-2.0	10.6
			Week -2	61	0.71	1.348	0.67	-1.9	5.9
			Week 1	60	-0.11	0.983	0.00	-3.3	1.9
			Week 2	58	0.08	2.199	-0.06	-3.9	12.9
			Week 3	58	-0.40	1.575	-0.16	-4.8	2.5
			Week 4	56	-0.51	1.841	-0.18	-5.9	3.6
			Week 6	51	-0.69	2.457	-0.56	-7.1	8.9
			Week 8	49	-0.90	2.913	-0.91	-8.2	8.3
			Week 12	48	-1.12	3.021	-0.69	-9.4	6.2
	7.5mg	63	Week -5	62	0.59	1.553	0.48	-2.6	4.5
			Week -4	62	0.27	1.345	0.00	-3.9	3.9
			Week -2	59	0.15	1.007	0.00	-1.9	2.0
			Week 1	62	-0.08	1.071	0.00	-3.0	4.3

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (%)	7.5mg	63	Week 2	60	-0.31	1.264	0.00	-4.1	2.4
			Week 3	59	-0.35	1.273	0.00	-3.9	2.7
			Week 4	58	-0.47	1.412	-0.19	-5.4	2.7
			Week 6	57	-0.39	1.597	0.00	-5.0	3.8
			Week 8	56	-0.41	2.170	-0.39	-7.0	6.1
			Week 12	55	-0.81	2.176	-0.54	-7.0	4.9
	15mg	66	Week -5	63	0.59	1.985	0.26	-3.2	8.4
			Week -4	63	0.24	1.612	0.00	-3.9	5.2
			Week -2	63	-0.01	1.436	0.00	-5.2	4.1
			Week 1	63	0.12	0.968	0.00	-2.0	4.1
			Week 2	63	-0.29	1.241	-0.20	-3.0	4.1
			Week 3	61	-0.31	1.473	-0.10	-3.7	4.1
			Week 4	60	-0.35	1.551	-0.40	-4.5	4.5
			Week 6	60	-0.38	1.805	0.00	-6.3	3.6
			Week 8	60	-0.29	1.613	0.00	-3.7	2.7
			Week 12	60	-0.41	2.218	-0.28	-6.4	4.0
	30mg	60	Week -5	60	1.35	2.021	0.94	-1.5	8.7
			Week -4	60	0.93	1.797	0.80	-3.2	8.3
			Week -2	59	0.40	1.584	0.19	-3.7	5.7
			Week 1	58	0.17	1.235	0.00	-2.0	5.1
			Week 2	57	-0.35	2.299	0.00	-14.6	4.0
			Week 3	57	-0.36	1.372	-0.19	-2.5	4.0
			Week 4	58	-0.65	1.484	-0.36	-4.4	2.7
			Week 6	57	-0.69	2.126	-0.56	-5.9	5.0
			Week 8	57	-0.64	2.326	-0.57	-6.3	4.0
			Week 12	56	-0.57	2.976	-0.22	-8.3	9.2
	45mg	61	Week -5	61	0.65	2.084	0.30	-7.5	5.3
			Week -4	61	0.65	1.407	0.21	-2.5	4.3

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (%)	45mg	61	Week -2	61	0.23	0.945	0.00	-2.0	1.9
			Week 1	60	0.06	1.082	0.00	-2.9	3.4
			Week 2	60	-0.28	1.342	0.00	-4.8	2.5
			Week 3	57	-0.21	1.641	0.00	-6.5	2.3
			Week 4	58	0.12	1.858	0.00	-5.3	3.7
			Week 6	55	-0.30	2.596	0.00	-8.0	8.7
			Week 8	56	-0.51	2.584	0.00	-8.9	5.3
			Week 12	56	-0.56	2.704	-0.17	-10.0	5.3
Hip Circumference (cm)	Placebo	64	Week -5	63	-0.1	5.55	0.0	-23	12
			Week 12	48	-0.4	4.73	0.0	-20	13
	2.5mg	61	Week -5	60	0.0	4.49	0.0	-15	10
			Week 12	48	-0.5	4.36	-1.0	-12	20
	7.5mg	63	Week -5	61	-0.5	4.05	0.0	-21	8
			Week 12	53	-0.2	3.25	0.0	-15	7
	15mg	66	Week -5	63	-0.3	3.92	0.0	-15	11
			Week 12	58	0.6	3.82	0.0	-8	19
	30mg	60	Week -5	60	0.6	5.31	0.0	-20	15
			Week 12	53	-0.1	4.77	0.0	-12	15
	45mg	61	Week -5	60	-0.2	4.61	0.0	-28	9
			Week 12	56	-2.6	6.25	-0.5	-27	5
Waist Circumference (cm)	Placebo	64	Week -5	63	1.0	4.49	0.0	-9	24
			Week 12	48	-1.1	4.90	-1.0	-21	10

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Waist Circumference (cm)	2.5mg	61	Week -5	60	2.6	4.19	1.0	-4	19
			Week 12	48	-0.5	4.47	0.0	-17	8
	7.5mg	63	Week -5	62	0.9	4.46	0.0	-11	27
			Week 12	53	-1.0	3.26	0.0	-18	3
	15mg	66	Week -5	63	0.9	5.16	0.0	-8	24
			Week 12	58	-0.4	3.39	0.0	-9	13
	30mg	60	Week -5	60	-1.4	4.97	0.0	-21	6
			Week 12	53	-0.1	4.78	0.0	-13	13
	45mg	61	Week -5	60	1.3	6.08	0.0	-9	29
			Week 12	56	1.2	7.60	0.0	-16	29
Waist:Hip Ratio	Placebo	64	Week -5	63	0.01	0.086	0.00	-0.2	0.5
			Week 12	48	-0.01	0.054	-0.00	-0.2	0.2
	2.5mg	61	Week -5	60	0.02	0.063	0.01	-0.1	0.3
			Week 12	48	-0.00	0.070	0.00	-0.4	0.1
	7.5mg	63	Week -5	61	0.01	0.063	0.00	-0.1	0.4
			Week 12	53	-0.01	0.037	0.00	-0.2	0.1
	15mg	66	Week -5	63	0.01	0.067	0.00	-0.1	0.3
			Week 12	58	-0.01	0.047	-0.01	-0.1	0.1
	30mg	60	Week -5	60	-0.02	0.060	-0.00	-0.3	0.1
			Week 12	53	-0.00	0.067	0.00	-0.3	0.2

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Waist:Hip Ratio	45mg	61	Week -5	60	0.01	0.086	0.00	-0.2	0.5
			Week 12	56	0.03	0.109	0.00	-0.1	0.5
BMI (kg/m^2)	Placebo	64	Week -5	64	0.374	0.7989	0.222	-0.75	3.94
			Week -4	64	0.233	0.6648	0.142	-0.94	3.94
			Week -2	63	0.108	0.6859	0.000	-1.58	3.94
			Week 1	61	-0.025	0.5418	0.000	-0.83	3.41
			Week 2	60	-0.091	0.5994	-0.110	-1.34	3.41
			Week 3	55	-0.090	0.6028	-0.200	-0.91	3.23
			Week 4	57	-0.076	0.6281	-0.120	-1.19	3.44
			Week 6	54	-0.165	0.4784	-0.191	-1.19	0.89
			Week 8	52	-0.158	0.7015	-0.312	-1.61	3.23
			Week 12	49	-0.282	0.8331	-0.147	-2.28	1.94
	2.5mg	61	Week -5	61	0.392	0.7566	0.239	-0.97	2.77
			Week -4	61	0.353	0.7561	0.222	-0.90	3.11
			Week -2	61	0.292	0.6340	0.188	-0.63	3.10
			Week 1	60	-0.037	0.3218	0.000	-1.25	0.60
			Week 2	58	0.015	0.6716	-0.016	-1.45	3.81
			Week 3	58	-0.131	0.4948	-0.049	-1.38	0.91
			Week 4	56	-0.169	0.5870	-0.053	-1.83	0.99
			Week 6	51	-0.237	0.8112	-0.161	-2.08	2.94
			Week 8	49	-0.303	0.9424	-0.239	-2.73	2.74
			Week 12	48	-0.356	0.9912	-0.257	-3.08	2.06
	7.5mg	63	Week -5	62	0.183	0.6269	0.124	-1.60	1.90
			Week -4	62	0.098	0.5932	0.000	-1.75	1.90
			Week -2	59	0.029	0.4579	0.000	-1.60	1.40
			Week 1	62	-0.025	0.3264	0.000	-0.82	1.15
			Week 2	60	-0.089	0.3943	0.000	-1.27	0.94

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	7.5mg	63	Week 3	59	-0.111	0.3975	0.000	-1.06	1.05
			Week 4	58	-0.140	0.4301	-0.068	-1.30	1.05
			Week 6	57	-0.118	0.5153	0.000	-1.84	1.30
			Week 8	56	-0.128	0.6772	-0.134	-2.20	1.87
			Week 12	55	-0.247	0.6796	-0.173	-2.57	1.50
	15mg	66	Week -5	63	0.207	0.6319	0.106	-1.20	2.74
			Week -4	63	0.102	0.5311	0.000	-1.90	1.71
			Week -2	63	0.015	0.4473	0.000	-1.90	1.01
			Week 1	63	0.032	0.2852	0.000	-0.64	1.01
			Week 2	63	-0.091	0.3694	-0.062	-1.02	1.01
			Week 3	61	-0.095	0.4416	-0.037	-1.03	1.01
			Week 4	60	-0.094	0.4858	-0.107	-1.23	1.54
			Week 6	60	-0.107	0.5504	0.000	-2.01	1.17
			Week 8	60	-0.080	0.4984	0.000	-1.15	1.05
			Week 12	60	-0.127	0.7081	-0.092	-2.10	1.58
	30mg	60	Week -5	60	0.538	0.8620	0.318	-0.44	3.85
			Week -4	60	0.393	0.8380	0.242	-1.26	4.07
			Week -2	59	0.231	0.8162	0.059	-1.03	4.00
			Week 1	58	0.057	0.4327	0.000	-0.79	1.79
			Week 2	57	-0.130	0.7748	0.000	-4.96	1.38
			Week 3	57	-0.112	0.4597	-0.059	-0.85	1.56
			Week 4	58	-0.218	0.5059	-0.110	-1.67	1.08
			Week 6	57	-0.243	0.7277	-0.173	-2.27	1.54
			Week 8	57	-0.211	0.7819	-0.195	-2.39	1.56
			Week 12	56	-0.195	0.9608	-0.059	-3.12	2.51
	45mg	61	Week -5	61	0.239	0.7085	0.181	-1.91	2.12
			Week -4	61	0.228	0.5114	0.071	-0.96	1.46
			Week -2	61	0.090	0.3338	0.000	-0.77	0.71

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Table 12.29
Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist:Hip Ratio and Body Mass Index by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
BMI (kg/m^2)	45mg	61	Week 1	60	0.030	0.3405	0.000	-0.71	1.17
			Week 2	60	-0.077	0.4441	0.000	-1.77	0.96
			Week 3	57	-0.069	0.5451	0.000	-2.32	0.66
			Week 4	58	0.035	0.6149	0.000	-1.78	1.17
			Week 6	55	-0.103	0.8156	0.000	-2.67	2.23
			Week 8	56	-0.173	0.8603	0.000	-3.20	1.95
			Week 12	56	-0.179	0.8777	-0.049	-3.33	1.35

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	Placebo	64	Week -5	60	69.3	10.43	69.0	50	104
			Baseline	64	67.8	9.88	67.0	49	94
			Week 4	55	67.8	11.57	66.0	45	103
			Week 12	45	69.0	8.86	69.0	54	90
	2.5mg	61	Week -5	60	70.0	9.47	71.0	50	91
			Baseline	61	67.7	7.80	67.0	53	85
			Week 4	55	66.8	10.31	66.0	47	93
			Week 12	45	70.0	11.42	69.0	47	97
	7.5mg	63	Week -5	60	67.9	11.54	67.0	48	108
			Baseline	63	67.9	11.53	67.0	43	98
			Week 4	55	66.4	9.07	65.0	48	86
			Week 12	51	68.1	10.96	68.0	47	99
	15mg	66	Week -5	60	70.1	9.23	69.5	54	94
			Baseline	65	69.1	8.66	69.0	50	86
			Week 4	58	68.4	10.16	67.0	43	97
			Week 12	59	69.6	8.92	69.0	47	89
	30mg	60	Week -5	59	71.7	9.94	70.0	51	101
			Baseline	60	69.8	10.27	68.0	51	100
			Week 4	54	70.8	10.22	68.5	46	102
			Week 12	53	71.3	10.60	69.0	52	108
	45mg	61	Week -5	60	65.9	9.98	66.0	48	92
			Baseline	61	67.1	12.00	66.0	47	119
			Week 4	55	65.1	8.89	65.0	48	91
			Week 12	52	66.5	10.57	65.0	49	92
PR Interval(msec)	Placebo	64	Week -5	59	169.1	25.65	170.0	115	248
			Baseline	63	170.0	28.31	168.0	123	251

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
PR Interval(msec)	Placebo	64	Week 4	54	173.1	29.96	168.0	97	255
			Week 12	45	169.1	25.64	167.0	123	264
	2.5mg	61	Week -5	60	171.1	20.36	170.0	126	224
			Baseline	61	170.2	22.86	171.0	127	264
			Week 4	55	170.0	25.33	166.0	125	245
			Week 12	45	169.6	29.35	169.0	127	259
	7.5mg	63	Week -5	59	172.7	27.53	170.0	122	254
			Baseline	62	172.6	25.96	174.0	129	240
			Week 4	55	172.2	23.53	173.0	119	241
			Week 12	51	171.5	23.22	170.0	129	238
	15mg	66	Week -5	60	166.0	21.77	167.0	123	247
			Baseline	65	166.8	22.20	168.0	128	248
			Week 4	58	167.0	21.35	167.0	121	233
			Week 12	59	168.4	22.87	166.0	123	260
	30mg	60	Week -5	59	167.3	25.43	164.0	128	234
			Baseline	60	169.2	27.36	166.0	122	229
			Week 4	54	170.0	27.52	168.5	123	241
			Week 12	53	170.2	24.48	169.0	131	229
	45mg	61	Week -5	60	175.4	28.38	171.0	131	285
			Baseline	61	175.2	27.74	169.0	125	285
			Week 4	55	171.5	22.14	167.0	133	235
			Week 12	52	172.6	24.53	169.0	131	258
QRS Duration (msec)	Placebo	64	Week -5	60	93.8	14.71	90.5	75	152
			Baseline	64	94.0	14.34	90.5	72	165
			Week 4	55	91.7	11.88	91.0	73	139
			Week 12	45	91.7	11.58	91.0	72	132

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QRS Duration (msec)	2.5mg	61	Week -5	60	90.8	14.77	87.5	71	145
			Baseline	61	92.1	15.70	88.0	71	153
			Week 4	55	92.0	13.98	89.0	73	145
			Week 12	45	90.8	14.40	88.0	73	143
	7.5mg	63	Week -5	60	93.2	15.74	89.0	77	160
			Baseline	63	90.9	13.88	87.0	75	146
			Week 4	55	91.3	13.24	89.0	72	152
			Week 12	51	93.3	17.56	91.0	73	162
	15mg	66	Week -5	60	92.2	10.32	91.0	75	136
			Baseline	65	90.8	9.10	90.0	78	128
			Week 4	58	91.8	12.04	91.0	65	139
			Week 12	59	91.1	13.66	90.0	72	147
	30mg	60	Week -5	59	90.2	11.56	91.0	72	138
			Baseline	60	90.6	11.25	90.0	75	143
			Week 4	54	89.1	9.77	88.0	75	138
			Week 12	53	91.0	11.71	89.0	76	144
	45mg	61	Week -5	60	92.1	11.50	91.5	73	137
			Baseline	61	90.6	12.61	89.0	64	138
			Week 4	55	92.4	11.53	91.0	79	154
			Week 12	52	92.3	11.52	91.0	73	146
QT Interval (msec)	Placebo	64	Week -5	60	396.1	31.42	396.0	296	457
			Baseline	64	402.1	30.49	397.5	341	474
			Week 4	55	397.6	29.82	395.0	340	459
			Week 12	45	393.0	21.91	394.0	342	433
	2.5mg	61	Week -5	60	393.7	24.38	391.5	337	447
			Baseline	61	400.7	26.43	399.0	331	471

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QT Interval (msec)	2.5mg	61	Week 4	55	399.4	30.78	391.0	331	466
			Week 12	45	393.3	26.33	392.0	329	445
	7.5mg	63	Week -5	60	398.4	34.67	394.0	323	493
			Baseline	63	398.6	34.60	397.0	316	493
			Week 4	55	399.9	26.79	398.0	339	471
			Week 12	51	397.3	31.50	394.0	322	474
	15mg	66	Week -5	60	392.6	21.85	390.0	342	437
			Baseline	65	398.2	22.89	400.0	346	460
			Week 4	58	398.7	28.72	397.5	323	477
			Week 12	59	394.4	21.02	394.0	333	437
	30mg	60	Week -5	59	387.4	23.50	389.0	333	446
			Baseline	60	393.5	26.29	388.5	339	473
			Week 4	54	393.2	26.88	393.5	320	491
			Week 12	53	389.5	25.02	388.0	320	459
	45mg	61	Week -5	60	402.6	26.34	403.0	345	473
			Baseline	61	401.1	27.43	399.0	324	463
			Week 4	55	411.1	29.55	404.0	357	500
			Week 12	52	403.9	32.89	404.0	349	493
QTc(Bazett) (msec)	Placebo	64	Week -5	60	422.7	21.89	425.5	369	466
			Baseline	64	424.6	24.90	428.0	355	490
			Week 4	55	419.2	25.25	418.0	355	481
			Week 12	45	419.5	22.74	419.0	351	459
	2.5mg	61	Week -5	60	422.7	21.27	423.0	374	464
			Baseline	61	423.8	20.41	423.0	371	481
			Week 4	55	418.2	19.36	418.0	370	477
			Week 12	45	421.7	21.48	419.0	380	482

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QTc(Bazett) (msec)	7.5mg	63	Week -5	60	420.2	24.40	419.0	379	521
			Baseline	63	419.9	25.82	416.0	367	487
			Week 4	55	418.8	23.19	420.0	372	475
			Week 12	51	420.0	22.99	421.0	370	490
	15mg	66	Week -5	60	422.1	16.28	423.0	384	453
			Baseline	65	425.4	20.04	423.0	373	484
			Week 4	58	422.9	19.71	421.0	373	488
			Week 12	59	422.8	19.09	426.0	365	472
	30mg	60	Week -5	59	421.4	21.30	424.0	369	460
			Baseline	60	421.9	23.87	420.0	382	480
			Week 4	54	424.2	21.61	421.5	384	478
			Week 12	53	422.0	18.67	423.0	384	462
	45mg	61	Week -5	60	419.7	26.75	419.5	362	497
			Baseline	61	421.1	29.16	418.0	372	534
			Week 4	55	425.8	24.47	427.0	377	505
			Week 12	52	421.9	25.57	419.0	368	500
QTc(Fridericia) (msec)	Placebo	64	Week -5	60	413.4	21.39	417.0	343	454
			Baseline	64	416.7	22.91	417.0	352	471
			Week 4	55	411.5	21.63	414.0	366	465
			Week 12	45	410.3	18.90	411.0	355	444
	2.5mg	61	Week -5	60	412.5	17.84	412.5	370	452
			Baseline	61	415.8	19.76	414.0	364	462
			Week 4	55	411.5	18.83	411.0	373	459
			Week 12	45	411.8	17.24	411.0	369	447
	7.5mg	63	Week -5	60	412.4	23.72	409.0	362	512
			Baseline	63	412.3	23.88	413.0	355	480

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QTc(Fridericia) (msec)	7.5mg	63	Week 4	55	412.2	20.63	410.0	370	464
			Week 12	51	412.0	21.26	411.0	369	475
	15mg	66	Week -5	60	411.9	13.63	413.0	383	438
			Baseline	65	415.9	17.05	414.0	376	456
			Week 4	58	414.4	18.31	413.5	379	459
			Week 12	59	412.9	15.44	414.0	376	452
	30mg	60	Week -5	59	409.6	18.00	413.0	368	450
			Baseline	60	411.9	20.46	407.5	379	474
			Week 4	54	413.5	19.06	412.5	366	469
			Week 12	53	410.6	16.40	408.0	367	445
	45mg	61	Week -5	60	413.7	22.41	411.0	363	489
			Baseline	61	414.0	23.42	413.0	370	509
			Week 4	55	420.6	22.51	419.0	379	503
			Week 12	52	415.5	23.70	412.5	368	497
RR Interval(msec)	Placebo	64	Week -5	60	885.0	131.31	869.5	579	1193
			Baseline	64	904.4	134.52	896.5	637	1221
			Week 4	55	910.5	152.07	903.0	583	1329
			Week 12	45	884.9	114.14	865.0	667	1112
	2.5mg	61	Week -5	60	875.0	126.12	847.0	660	1209
			Baseline	61	898.7	105.56	897.0	710	1145
			Week 4	55	919.3	140.02	914.0	647	1278
			Week 12	45	879.9	145.00	877.0	621	1280
	7.5mg	63	Week -5	60	907.8	147.24	900.0	557	1252
			Baseline	63	911.0	160.84	893.0	615	1410
			Week 4	55	919.1	126.55	919.0	698	1243
			Week 12	51	903.5	149.13	877.0	608	1286

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Table 12.30
Summary Statistics of ECG Values by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
RR Interval(msec)	15mg	66	Week -5	60	870.6	112.65	864.0	636	1110
			Baseline	65	882.6	114.39	865.0	701	1202
			Week 4	58	896.3	136.49	897.0	619	1395
			Week 12	59	876.8	117.44	865.0	676	1283
	30mg	60	Week -5	59	852.8	114.32	857.0	596	1176
			Baseline	60	877.9	124.25	882.0	599	1186
			Week 4	54	866.1	123.01	878.5	591	1309
			Week 12	53	858.0	116.93	864.0	556	1148
	45mg	61	Week -5	60	932.5	143.90	913.5	650	1339
			Baseline	61	920.2	150.30	909.0	505	1278
			Week 4	55	939.3	130.44	917.0	661	1257
			Week 12	52	925.6	146.50	918.0	655	1236

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Heart Rate (bpm)	Placebo	64	Week -5	57	1.9	7.37	2.0	-12	25
			Week 4	55	-0.4	8.93	1.0	-25	36
			Week 12	45	-0.6	8.32	-1.0	-23	12
	2.5mg	61	Week -5	56	2.3	8.01	2.0	-22	24
			Week 4	55	-1.3	7.29	-1.0	-26	15
			Week 12	45	1.4	9.31	0.0	-20	19
	7.5mg	63	Week -5	57	0.2	7.47	-1.0	-14	22
			Week 4	55	-1.2	7.43	-1.0	-25	15
			Week 12	51	0.2	7.13	1.0	-16	22
	15mg	66	Week -5	57	1.0	5.83	1.0	-12	18
			Week 4	57	-0.7	7.06	-1.0	-23	21
			Week 12	58	0.4	8.63	0.0	-36	20
	30mg	60	Week -5	58	1.8	8.77	1.0	-23	23
			Week 4	54	1.4	8.62	2.0	-29	23
			Week 12	53	1.5	8.47	3.0	-17	18
	45mg	61	Week -5	58	-1.1	8.36	0.5	-28	15
			Week 4	55	-2.4	8.82	-1.0	-28	16
			Week 12	52	0.1	7.98	0.0	-19	23
PR Interval(msec)	Placebo	64	Week -5	56	-1.5	13.52	-1.5	-52	30
			Week 4	54	1.4	13.56	1.5	-32	48
			Week 12	45	-0.2	14.14	-2.0	-39	26
	2.5mg	61	Week -5	56	1.0	11.38	1.5	-40	35
			Week 4	55	0.3	13.03	-1.0	-32	27
			Week 12	45	-0.4	17.29	-1.0	-39	58

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
PR Interval(msec)	7.5mg	63	Week -5	56	0.2	13.71	-2.0	-25	42
			Week 4	55	-1.1	17.22	0.0	-38	57
			Week 12	51	-1.4	14.67	-2.0	-37	45
	15mg	66	Week -5	57	-0.1	13.16	0.0	-34	38
			Week 4	57	-0.3	14.17	0.0	-43	41
			Week 12	58	1.9	13.62	2.0	-29	43
	30mg	60	Week -5	58	-1.3	13.42	-2.0	-29	37
			Week 4	54	0.5	14.18	1.0	-34	47
			Week 12	53	1.1	14.19	0.0	-34	35
	45mg	61	Week -5	57	0.4	14.42	1.0	-42	27
			Week 4	55	-3.5	22.94	-1.0	-125	34
			Week 12	52	-4.1	23.38	-1.0	-137	21
QRS Duration(msec)	Placebo	64	Week -5	57	-0.4	8.22	-1.0	-22	16
			Week 4	55	-2.0	7.87	-1.0	-26	14
			Week 12	45	-1.5	7.06	-2.0	-13	21
	2.5mg	61	Week -5	56	-1.4	7.36	-0.5	-17	16
			Week 4	55	-0.1	7.84	0.0	-20	14
			Week 12	45	-0.2	6.85	0.0	-16	13
	7.5mg	63	Week -5	57	2.1	8.25	2.0	-20	32
			Week 4	55	-0.5	8.49	1.0	-39	15
			Week 12	51	2.2	8.65	1.0	-15	32
	15mg	66	Week -5	57	1.0	10.92	0.0	-20	55
			Week 4	57	0.7	10.44	-1.0	-17	58
			Week 12	58	-0.0	12.21	-0.5	-19	66

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QRS Duration(msec)	30mg	60	Week -5	58	-0.6	7.80	-1.0	-15	26
			Week 4	54	-0.6	7.40	0.0	-18	15
			Week 12	53	0.1	7.29	1.0	-22	15
	45mg	61	Week -5	58	1.5	8.63	0.0	-22	22
			Week 4	55	0.8	8.36	0.0	-16	18
			Week 12	52	0.9	8.97	1.0	-21	22
QT Interval(msec)	Placebo	64	Week -5	57	-7.2	20.58	-4.0	-57	30
			Week 4	55	-4.7	22.21	-5.0	-59	57
			Week 12	45	-5.4	20.76	-3.0	-53	44
	2.5mg	61	Week -5	56	-6.6	21.32	-5.5	-50	61
			Week 4	55	-0.9	18.52	-3.0	-38	75
			Week 12	45	-6.7	21.53	-4.0	-44	45
	7.5mg	63	Week -5	57	-2.1	20.28	-1.0	-51	43
			Week 4	55	0.4	20.89	2.0	-44	54
			Week 12	51	-2.1	19.20	-3.0	-51	38
	15mg	66	Week -5	57	-5.7	16.47	-4.0	-48	37
			Week 4	57	0.4	18.44	1.0	-46	51
			Week 12	58	-3.2	18.37	-1.0	-52	52
	30mg	60	Week -5	58	-6.2	20.34	-4.0	-50	25
			Week 4	54	-0.6	21.32	0.5	-62	50
			Week 12	53	-3.1	17.18	-2.0	-60	39
	45mg	61	Week -5	58	1.6	19.43	1.0	-39	47
			Week 4	55	9.0	18.34	8.0	-32	40
			Week 12	52	0.2	20.74	0.5	-47	49

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QTc(Bazett) (msec)	Placebo	64	Week -5	57	-1.9	20.79	-1.0	-74	54
			Week 4	55	-6.8	19.85	-8.0	-64	37
			Week 12	45	-7.3	22.54	-7.0	-53	47
	2.5mg	61	Week -5	56	-0.8	17.21	0.5	-35	54
			Week 4	55	-6.5	15.93	-8.0	-52	30
			Week 12	45	-4.2	22.27	-8.0	-52	51
	7.5mg	63	Week -5	57	-1.2	18.52	-3.0	-50	46
			Week 4	55	-1.1	20.65	0.0	-74	35
			Week 12	51	-1.2	18.28	0.0	-55	41
	15mg	66	Week -5	57	-3.6	14.95	-4.0	-37	37
			Week 4	57	-2.9	15.22	-2.0	-32	48
			Week 12	58	-2.3	17.82	-2.0	-59	29
	30mg	60	Week -5	58	-0.7	18.37	1.5	-42	34
			Week 4	54	3.4	17.15	1.0	-35	36
			Week 12	53	1.5	17.86	0.0	-34	37
	45mg	61	Week -5	58	-1.1	19.49	-4.0	-37	58
			Week 4	55	2.7	17.44	3.0	-29	41
			Week 12	52	0.0	18.96	1.0	-37	41
QTc(Fridericia) (msec)	Placebo	64	Week -5	57	-3.8	18.10	-4.0	-68	29
			Week 4	55	-6.1	17.19	-7.0	-55	30
			Week 12	45	-6.6	18.93	-6.0	-46	34
	2.5mg	61	Week -5	56	-3.0	14.83	-3.5	-31	40
			Week 4	55	-4.6	13.17	-7.0	-26	39
			Week 12	45	-5.1	18.06	-5.0	-46	33

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
QTc(Fridericia) (msec)	7.5mg	63	Week -5	57	-1.6	15.98	-3.0	-40	38
			Week 4	55	-0.5	17.66	0.0	-47	41
			Week 12	51	-1.5	15.42	-1.0	-37	33
	15mg	66	Week -5	57	-4.4	13.03	-3.0	-36	23
			Week 4	57	-1.9	13.17	-1.0	-28	32
			Week 12	58	-2.7	13.27	-1.0	-39	21
	30mg	60	Week -5	58	-2.5	15.28	-0.5	-40	29
			Week 4	54	2.1	15.11	2.0	-38	35
			Week 12	53	-0.1	13.35	0.0	-31	26
	45mg	61	Week -5	58	-0.1	15.97	0.0	-29	41
			Week 4	55	5.0	13.05	3.0	-20	36
			Week 12	52	0.1	15.58	-1.0	-32	44
RR Interval(msec)	Placebo	64	Week -5	57	-25.5	91.91	-32.0	-298	156
			Week 4	55	10.8	106.59	-5.0	-314	357
			Week 12	45	6.4	102.69	14.0	-164	218
	2.5mg	61	Week -5	56	-22.7	107.49	-28.5	-278	350
			Week 4	55	26.0	99.73	3.0	-142	366
			Week 12	45	-5.6	117.39	4.0	-253	341
	7.5mg	63	Week -5	57	-6.0	101.05	6.0	-290	183
			Week 4	55	4.7	104.53	12.0	-382	300
			Week 12	51	-4.6	102.36	-7.0	-305	280
	15mg	66	Week -5	57	-9.7	75.09	-7.0	-260	158
			Week 4	57	15.2	88.86	14.0	-184	270
			Week 12	58	-4.1	118.91	-8.0	-269	558

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Table 12.31
Summary Statistics of ECG Change from Baseline by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
RR Interval(msec)	30mg	60	Week -5	58	-25.0	101.94	-17.0	-264	271
			Week 4	54	-17.5	97.17	-16.5	-248	249
			Week 12	53	-21.4	103.46	-43.0	-241	242
	45mg	61	Week -5	58	10.7	102.88	-7.0	-259	304
			Week 4	55	23.1	105.94	12.0	-230	304
			Week 12	52	-2.2	104.03	7.5	-334	263

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Table 12.32
Summary of Abnormal ECG Findings by Treatment

	Placebo (N=64)		2.5 mg (N=61)		7.5 mg (N=63)		15 mg (N=66)		30 mg (N=60)		45 mg (N=61)	
Week -5												
n	60		60		60		60		59		60	
Normal	37	(62%)	44	(73%)	42	(70%)	42	(70%)	44	(75%)	41	(68%)
Abnormal	23	(38%)	16	(27%)	18	(30%)	18	(30%)	15	(25%)	19	(32%)
n[1]	60		60		60		60		59		59	
Normal to Abnormal	0		2	(3%)	2	(3%)	1	(2%)	2	(3%)	2	(3%)
Abnormal to Normal	2	(3%)	0		1	(2%)	3	(5%)	2	(3%)	4	(7%)
No Change	58	(97%)	58	(97%)	57	(95%)	56	(93%)	55	(93%)	53	(90%)
Baseline												
n	64		61		63		65		60		60	
Normal	37	(58%)	47	(77%)	45	(71%)	44	(68%)	44	(73%)	39	(65%)
Abnormal	27	(42%)	14	(23%)	18	(29%)	21	(32%)	16	(27%)	21	(35%)
Week 4												
n	55		55		55		58		54		55	
Normal	37	(67%)	40	(73%)	39	(71%)	36	(62%)	42	(78%)	38	(69%)
Abnormal	18	(33%)	15	(27%)	16	(29%)	22	(38%)	12	(22%)	17	(31%)
n[1]	55		55		55		57		54		55	
Normal to Abnormal	2	(4%)	3	(5%)	3	(5%)	3	(5%)	1	(2%)	2	(4%)
Abnormal to Normal	7	(13%)	1	(2%)	2	(4%)	0		3	(6%)	5	(9%)
No Change	46	(84%)	51	(93%)	50	(91%)	54	(95%)	50	(93%)	48	(87%)
Week 12												
n	45		45		51		59		53		52	
Normal	27	(60%)	34	(76%)	35	(69%)	39	(66%)	39	(74%)	34	(65%)
Abnormal	18	(40%)	11	(24%)	16	(31%)	20	(34%)	14	(26%)	18	(35%)
n[1]	45		45		51		58		53		52	
Normal to Abnormal	5	(11%)	1	(2%)	3	(6%)	2	(3%)	3	(6%)	1	(2%)
Abnormal to Normal	4	(9%)	0		1	(2%)	1	(2%)	3	(6%)	2	(4%)
No Change	36	(80%)	44	(98%)	47	(92%)	55	(95%)	47	(89%)	49	(94%)

[1] Change from Baseline

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Table 12.32
Summary of Abnormal ECG Findings by Treatment

	Placebo (N=64)		2.5 mg (N=61)		7.5 mg (N=63)		15 mg (N=66)		30 mg (N=60)		45 mg (N=61)	
Any Time Post-Baseline												
n	61		59		59		60		58		57	
Normal	34	(56%)	41	(69%)	40	(68%)	36	(60%)	42	(72%)	35	(61%)
Abnormal	27	(44%)	18	(31%)	19	(32%)	24	(40%)	16	(28%)	22	(39%)
n[1]	61		59		59		59		58		57	
Normal to Abnormal	6	(10%)	4	(7%)	4	(7%)	4	(7%)	3	(5%)	2	(4%)
Abnormal to Normal	5	(8%)	0		1	(2%)	0		3	(5%)	1	(2%)
No Change	50	(82%)	55	(93%)	54	(92%)	55	(93%)	52	(90%)	54	(95%)

[1] Change from Baseline

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Table 12.33
Summary of ECG Values of Potential Clinical Concern at any Time On-therapy

ECG Test	Category	Placebo (N=64)	2.5 mg (N=61)	7.5 mg (N=63)	15 mg (N=66)	30 mg (N=60)	45 mg (N=61)
Heart Rate (bpm)	n	61	59	59	60	58	57
	<50bpm	3 (5%)	1 (2%)	3 (5%)	3 (5%)	1 (2%)	2 (4%)
	>120bpm	0	0	0	0	0	0
PR Interval (msec)	n	61	59	59	60	58	57
	>300msec	0	0	0	0	0	0
QRS Duration (msec)	n	61	59	59	60	58	57
	>200msec	0	0	0	0	0	0
QTc(Bazett) (msec)	n	61	59	59	60	58	57
	>500msec	0	0	0	0	0	1 (2%)
QTc(Fridericia) (msec)	n	61	59	59	60	58	57
	>500msec	0	0	0	0	0	1 (2%)

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Table 12.34
Summary of Changes from Baseline in ECG Values of Potential Clinical Concern at any Time On-therapy

ECG Test	Category	Placebo (N=64)	2.5 mg (N=61)	7.5 mg (N=63)	15 mg (N=66)	30 mg (N=60)	45 mg (N=61)
PR Interval (msec)	n	61	59	59	60	58	57
	Increase of >25% when baseline >200msec	0	0	0	0	0	0
	Increase of >50% when baseline <=200msec	0	0	0	0	0	0
QRS Duration (msec)	n	61	59	59	60	58	57
	Increase of >25% when baseline >100msec	0	0	0	0	0	0
	Increase of >50% when baseline <=100msec	0	0	0	1 (2%)	0	0
QTc(Bazett) (msec)	n	61	59	59	60	58	57
	Increase of >10% when baseline >440msec	0	0	0	0	0	0
	Increase of >20% when baseline <=440msec	0	0	0	0	0	0
QTc(Fridericia) (msec)	n	61	59	59	60	58	57
	Increase of >10% when baseline >440msec	0	0	0	0	0	0

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Table 12.34
Summary of Changes from Baseline in ECG Values of Potential Clinical Concern at any Time On-therapy

ECG Test	Category	Placebo (N=64)	2.5 mg (N=61)	7.5 mg (N=63)	15 mg (N=66)	30 mg (N=60)	45 mg (N=61)
QTc(Fridericia) (msec)	Increase of >20% when baseline <=440msec	0	0	0	0	0	0

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Table 12.35
Summary Statistics of Exploratory Biomarker CK-MB

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatine Kinase MB (MCG/L)	Placebo	64	Week -5	49	1.60	0.772	1.40	0.7	5.1
			Baseline	49	1.57	0.859	1.40	0.7	4.8
			Week 4	39	1.49	0.552	1.40	0.7	2.7
			Week 12	36	1.66	0.566	1.60	0.7	3.2
	2.5mg	61	Week -5	49	1.75	1.124	1.40	0.7	6.9
			Baseline	51	1.65	0.876	1.40	0.7	5.4
			Week 4	40	1.81	1.183	1.35	0.8	5.8
			Week 12	34	1.66	0.783	1.45	0.7	4.0
	7.5mg	63	Week -5	50	2.12	2.100	1.55	0.7	13.1
			Baseline	43	2.16	2.596	1.40	0.7	16.1
			Week 4	40	1.82	1.133	1.40	0.8	7.0
			Week 12	39	1.98	1.406	1.60	0.7	7.8
	15mg	66	Week -5	54	2.02	1.212	1.65	0.7	7.6
			Baseline	53	1.88	0.990	1.70	0.7	6.0
			Week 4	47	2.02	1.201	1.80	0.7	7.7
			Week 12	50	1.86	1.014	1.40	0.7	4.2
	30mg	60	Week -5	50	2.05	1.385	1.55	0.7	6.2
			Baseline	55	2.07	1.505	1.50	0.7	7.9
			Week 4	47	2.32	1.786	1.60	0.7	9.1
			Week 12	45	2.30	2.431	1.60	0.7	14.8
	45mg	61	Week -5	46	1.75	0.837	1.60	0.7	4.5
			Baseline	48	1.71	0.965	1.45	0.7	5.6
			Week 4	42	1.84	0.883	1.65	0.7	5.4
			Week 12	41	1.86	1.264	1.60	0.7	7.2

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Table 12.36
Summary Statistics of Exploratory Biomarker CK-MB Change from Baseline

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Creatine Kinase MB (MCG/L)	Placebo	64	Week -5	42	0.02	0.903	0.00	-3.4	2.4
			Week 4	36	-0.08	0.608	0.00	-2.7	0.7
			Week 12	34	-0.01	0.837	0.10	-3.0	1.2
	2.5mg	61	Week -5	44	0.12	0.945	-0.05	-0.6	5.5
			Week 4	38	0.04	0.659	0.00	-1.1	2.3
			Week 12	31	0.15	0.650	0.10	-1.1	2.4
	7.5mg	63	Week -5	39	0.10	0.894	0.00	-3.0	2.7
			Week 4	33	0.03	0.936	0.10	-2.3	2.5
			Week 12	33	0.13	0.799	0.00	-1.8	1.9
	15mg	66	Week -5	47	0.19	1.086	0.10	-1.8	5.9
			Week 4	45	0.13	0.890	0.00	-1.3	4.1
			Week 12	46	0.01	0.880	0.00	-2.9	2.2
	30mg	60	Week -5	49	-0.08	1.026	-0.10	-3.7	2.8
			Week 4	44	0.19	1.026	0.00	-1.5	3.7
			Week 12	43	0.32	1.471	0.00	-1.4	8.1
	45mg	61	Week -5	42	0.02	0.733	0.00	-3.0	1.4
			Week 4	38	0.08	0.688	0.15	-2.4	1.5
			Week 12	37	0.13	1.004	0.10	-2.8	3.5

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Table 12.37
Exploratory Summary of Troponin I by Defined Categories

Planned Relative Time	Troponin I (mcg/L)	Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Week -5	n	62	58	60	62	58	57
	<0.2	62 (100%)	58 (100%)	60 (100%)	62 (100%)	58 (100%)	57 (100%)
	0.2 - 0.35	0	0	0	0	0	0
	>0.35 - 1.5	0	0	0	0	0	0
	>1.5	0	0	0	0	0	0
Baseline	n	63	59	63	66	60	59
	<0.2	63 (100%)	57 (97%)	63 (100%)	65 (98%)	57 (95%)	59 (100%)
	0.2 - 0.35	0	0	0	1 (2%)	0	0
	>0.35 - 1.5	0	2 (3%)	0	0	3 (5%)	0
	>1.5	0	0	0	0	0	0
Week 4	n	52	54	56	59	54	53
	<0.2	52 (100%)	54 (100%)	56 (100%)	59 (100%)	54 (100%)	53 (100%)
	0.2 - 0.35	0	0	0	0	0	0
	>0.35 - 1.5	0	0	0	0	0	0
	>1.5	0	0	0	0	0	0
Week 12	n	47	42	51	59	52	51
	<0.2	47 (100%)	41 (98%)	51 (100%)	59 (100%)	52 (100%)	50 (98%)
	0.2 - 0.35	0	0	0	0	0	1 (2%)
	>0.35 - 1.5	0	1 (2%)	0	0	0	0
	>1.5	0	0	0	0	0	0
Any Time Post-Baseline	n	61	60	62	64	59	57
	<0.2	61 (100%)	59 (98%)	62 (100%)	64 (100%)	59 (100%)	56 (98%)
	0.2 - 0.35	0	0	0	0	0	1 (2%)
	>0.35 - 1.5	0	1 (2%)	0	0	0	0
	>1.5	0	0	0	0	0	0

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Table 12.38
Additional Summary of Change from Baseline in Weight (kg) by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Weight (kg)	Placebo	64	Week -5	64	1.09	0.267	0.60	-1.7	11.0
			Week -4	64	0.64	0.203	0.40	-1.3	11.0
			Week -2	63	0.31	0.212	0.00	-4.0	11.0
			Week 1	61	-0.06	0.198	0.00	-2.5	9.5
			Week 2	60	-0.25	0.218	-0.30	-3.3	9.5
			Week 3	55	-0.25	0.232	-0.50	-2.6	9.0
			Week 4	57	-0.22	0.233	-0.30	-3.0	9.6
			Week 6	54	-0.47	0.190	-0.50	-3.0	2.8
			Week 8	52	-0.42	0.281	-0.95	-4.6	9.0
			Week 12	49	-0.78	0.333	-0.40	-6.5	5.4
	2.5mg	61	Week -5	61	0.94	0.246	0.70	-2.0	8.0
			Week -4	61	0.83	0.208	0.50	-1.7	9.0
			Week -2	61	0.64	0.150	0.50	-2.0	5.0
			Week 1	60	-0.10	0.120	0.00	-3.6	1.8
			Week 2	58	0.05	0.254	-0.05	-4.2	11.0
			Week 3	58	-0.38	0.191	-0.15	-4.0	2.8
			Week 4	56	-0.47	0.231	-0.15	-5.3	3.4
			Week 6	51	-0.65	0.338	-0.40	-6.0	9.0
			Week 8	49	-0.82	0.392	-0.70	-7.9	8.4
			Week 12	48	-0.96	0.414	-0.65	-8.9	6.3
	7.5mg	63	Week -5	62	0.52	0.168	0.50	-2.0	3.7
			Week -4	62	0.25	0.150	0.00	-3.0	3.0
			Week -2	59	0.12	0.117	0.00	-1.7	2.0
			Week 1	62	-0.06	0.118	0.00	-2.0	3.7
			Week 2	60	-0.26	0.140	0.00	-3.2	2.5
			Week 3	59	-0.32	0.148	0.00	-3.0	3.0
			Week 4	58	-0.42	0.159	-0.20	-3.5	3.0
			Week 6	57	-0.34	0.187	0.00	-5.0	3.0
			Week 8	56	-0.38	0.243	-0.40	-6.0	4.5
			Week 12	55	-0.71	0.254	-0.50	-7.0	3.6

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Table 12.38
Additional Summary of Change from Baseline in Weight (kg) by Treatment

	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Weight (kg)	15mg	66	Week -5	63	0.53	0.219	0.20	-3.2	7.2
			Week -4	63	0.23	0.176	0.00	-3.8	4.5
			Week -2	63	0.01	0.147	0.00	-3.1	3.0
			Week 1	63	0.10	0.103	0.00	-1.5	3.0
			Week 2	63	-0.24	0.134	-0.20	-2.7	3.0
			Week 3	61	-0.25	0.162	-0.10	-3.0	3.0
			Week 4	60	-0.28	0.179	-0.30	-4.2	4.1
			Week 6	60	-0.30	0.207	0.00	-4.7	4.0
			Week 8	60	-0.25	0.187	0.00	-4.0	3.0
			Week 12	60	-0.36	0.259	-0.25	-5.5	4.5
	30mg	60	Week -5	60	1.24	0.248	0.90	-1.7	6.5
			Week -4	60	0.79	0.216	0.65	-4.3	6.2
			Week -2	59	0.35	0.199	0.20	-4.0	5.5
			Week 1	58	0.22	0.183	0.00	-2.7	6.8
			Week 2	57	-0.34	0.298	0.00	-14.0	5.4
			Week 3	57	-0.31	0.181	-0.20	-3.3	4.9
			Week 4	58	-0.60	0.190	-0.35	-5.7	3.0
			Week 6	57	-0.68	0.274	-0.50	-7.1	4.0
			Week 8	57	-0.56	0.293	-0.50	-5.9	4.9
			Week 12	56	-0.51	0.367	-0.15	-8.9	7.0
	45mg	61	Week -5	61	0.63	0.231	0.30	-5.4	5.0
			Week -4	61	0.58	0.170	0.20	-3.0	5.0
			Week -2	61	0.20	0.114	0.00	-2.4	2.0
			Week 1	60	0.09	0.132	0.00	-2.0	4.0
			Week 2	60	-0.21	0.163	0.00	-5.0	3.0
			Week 3	57	-0.21	0.215	0.00	-7.7	1.9
			Week 4	58	0.10	0.226	0.00	-5.6	3.5
			Week 6	55	-0.29	0.308	0.00	-8.6	6.3
			Week 8	56	-0.48	0.325	0.00	-10.6	5.0
			Week 12	56	-0.50	0.324	-0.15	-9.9	3.8

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	Placebo	64	Week -5	64	23.0	1.34	19.5	10	51
			Baseline	64	21.5	1.26	18.0	7	63
			Week 1	61	21.4	1.27	19.0	7	57
			Week 2	60	21.2	1.24	18.0	6	51
			Week 3	55	21.1	1.34	19.0	8	60
			Week 4	54	20.4	1.08	19.0	8	42
			Week 6	53	21.3	1.41	18.0	8	57
			Week 8	51	20.7	1.20	19.0	7	40
			Week 12	49	19.8	1.21	18.0	8	48
	2.5mg	61	Week -5	61	28.6	2.08	24.0	8	102
			Baseline	61	27.0	1.86	22.0	10	77
			Week 1	59	26.3	1.81	23.0	10	87
			Week 2	58	23.4	1.53	20.5	4	80
			Week 3	56	24.7	1.76	21.0	8	86
			Week 4	56	24.8	1.75	20.5	11	81
			Week 6	49	24.3	1.73	21.0	9	57
			Week 8	48	23.2	1.70	19.0	11	56
			Week 12	46	23.6	1.59	21.0	9	56
	7.5mg	63	Week -5	61	24.0	1.60	20.0	4	62
			Baseline	63	23.2	1.45	20.0	9	62
			Week 1	60	22.0	1.24	21.0	8	49
			Week 2	59	22.3	1.54	19.0	7	69
			Week 3	59	22.5	1.38	19.0	7	57
			Week 4	57	23.9	1.94	20.0	10	114
			Week 6	56	21.5	1.33	18.5	8	54
			Week 8	54	22.8	1.65	19.5	9	62
			Week 12	54	21.4	1.34	19.0	8	56
	15mg	66	Week -5	62	27.1	2.18	21.0	8	83
			Baseline	66	25.1	1.67	21.0	9	60
			Week 1	63	23.2	1.52	20.0	5	56

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	15mg	66	Week 2	62	24.1	1.83	20.0	6	89
			Week 3	59	24.8	1.76	20.0	7	58
			Week 4	60	24.7	1.94	19.5	8	73
			Week 6	60	23.7	1.96	18.5	6	75
			Week 8	60	23.1	1.58	18.5	6	59
			Week 12	58	23.8	1.86	19.5	5	86
	30mg	60	Week -5	59	24.1	1.74	21.0	5	68
			Baseline	59	26.7	2.95	20.0	5	166
			Week 1	56	23.0	1.48	20.0	7	51
			Week 2	57	22.6	2.45	19.0	8	142
			Week 3	57	21.9	1.38	20.0	9	54
			Week 4	56	21.4	1.23	20.0	8	53
			Week 6	53	21.0	1.37	18.0	8	59
			Week 8	55	22.1	1.67	19.0	7	83
			Week 12	56	20.2	1.27	18.5	7	56
	45mg	61	Week -5	60	23.1	0.96	22.0	11	48
			Baseline	61	23.2	1.58	19.0	8	95
			Week 1	59	22.8	1.93	18.0	9	114
			Week 2	58	22.6	2.00	18.0	10	96
			Week 3	55	21.7	1.68	19.0	8	100
			Week 4	56	22.3	1.73	19.5	11	94
			Week 6	54	21.2	1.80	20.0	5	103
			Week 8	54	21.1	1.57	19.0	8	85
			Week 12	54	22.7	2.01	18.5	10	108
Aspartate Amino Transferase (IU/L)	Placebo	64	Week -5	64	19.7	0.85	18.0	9	41
			Baseline	64	19.7	0.84	18.0	9	43
			Week 1	61	19.5	1.02	17.0	11	59
			Week 2	60	19.5	0.92	18.0	10	48
			Week 3	55	19.5	0.95	17.0	11	46

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	Placebo	64	Week 4	55	18.7	0.83	17.0	10	35
			Week 6	53	19.5	1.25	17.0	11	70
			Week 8	51	18.3	0.74	17.0	10	32
			Week 12	49	18.8	0.79	17.0	9	35
	2.5mg	61	Week -5	61	24.0	1.75	21.0	12	83
			Baseline	61	24.5	1.67	21.0	11	84
			Week 1	59	23.6	1.43	19.0	11	77
			Week 2	58	21.9	1.45	19.0	10	88
			Week 3	56	23.0	1.62	19.0	10	75
			Week 4	56	22.2	1.28	19.0	12	66
			Week 6	48	23.0	1.44	21.0	10	60
			Week 8	48	22.5	1.48	19.0	11	68
			Week 12	46	21.8	1.07	20.0	12	43
	7.5mg	63	Week -5	61	20.9	1.12	19.0	9	54
			Baseline	63	19.9	0.88	18.0	10	40
			Week 1	60	19.7	0.84	18.0	10	39
			Week 2	59	20.2	1.02	18.0	10	56
			Week 3	58	20.4	1.05	17.0	9	47
			Week 4	56	20.0	0.86	18.0	11	37
			Week 6	56	20.0	0.90	17.5	11	38
			Week 8	54	21.0	1.29	17.5	10	64
			Week 12	54	20.1	1.04	18.0	12	45
	15mg	66	Week -5	62	22.3	1.12	19.5	7	50
			Baseline	66	21.8	0.94	20.0	9	43
			Week 1	63	21.0	0.85	20.0	8	42
			Week 2	62	21.7	1.09	20.0	7	48
			Week 3	59	22.0	1.05	20.0	10	45
			Week 4	60	22.1	1.12	20.0	9	46
			Week 6	60	21.9	1.09	19.5	9	60
			Week 8	60	21.1	0.88	20.0	10	43

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	15mg	66	Week 12	58	21.7	1.23	19.0	9	65
	30mg	60	Week -5	59	21.1	1.25	19.0	6	57
			Baseline	59	23.4	1.88	20.0	9	94
			Week 1	56	21.3	1.23	18.5	12	62
			Week 2	57	21.5	2.08	19.0	10	127
			Week 3	56	21.0	1.07	19.5	11	54
			Week 4	56	20.7	1.07	19.5	11	63
			Week 6	53	21.2	1.01	20.0	9	50
			Week 8	55	21.6	1.72	19.0	11	96
			Week 12	56	20.5	1.39	18.5	9	78
	45mg	61	Week -5	60	21.2	0.76	20.0	13	41
			Baseline	61	21.0	1.07	19.0	11	69
			Week 1	59	21.5	1.29	19.0	13	79
			Week 2	57	21.1	1.32	19.0	10	74
			Week 3	55	21.5	1.12	20.0	11	61
			Week 4	56	20.8	1.21	19.0	10	74
			Week 6	54	20.1	1.19	18.0	4	64
			Week 8	54	20.1	0.97	18.0	11	59
			Week 12	54	21.2	1.45	19.0	10	80
Direct Bilirubin (UMOL/L)	Placebo	64	Week -5	64	2.3	0.20	2.0	0	9
			Baseline	64	2.3	0.17	2.0	0	8
			Week 1	61	2.3	0.20	2.0	0	8
			Week 2	60	2.2	0.15	2.0	0	6
			Week 3	55	2.3	0.15	2.0	1	6
			Week 4	55	2.1	0.15	2.0	0	6
			Week 6	53	2.2	0.15	2.0	1	6
			Week 8	51	2.3	0.17	2.0	1	6
			Week 12	49	2.2	0.18	2.0	0	6

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	2.5mg	61	Week -5	61	2.3	0.15	2.0	1	6
			Baseline	61	2.5	0.15	2.0	1	8
			Week 1	59	2.4	0.17	2.0	1	8
			Week 2	58	2.2	0.16	2.0	0	6
			Week 3	56	2.6	0.15	2.0	1	6
			Week 4	56	2.3	0.14	2.0	1	5
			Week 6	49	2.3	0.15	2.0	1	5
			Week 8	48	2.2	0.13	2.0	1	4
			Week 12	45	2.3	0.16	2.0	0	5
	7.5mg	63	Week -5	61	2.3	0.14	2.0	1	5
			Baseline	63	2.3	0.12	2.0	1	5
			Week 1	60	2.2	0.15	2.0	0	6
			Week 2	59	2.1	0.14	2.0	0	6
			Week 3	59	2.2	0.12	2.0	0	4
			Week 4	56	2.1	0.11	2.0	1	4
			Week 6	56	2.2	0.17	2.0	0	6
			Week 8	54	2.0	0.15	2.0	0	6
			Week 12	54	2.1	0.13	2.0	1	5
	15mg	66	Week -5	62	2.0	0.11	2.0	0	4
			Baseline	66	2.1	0.12	2.0	0	5
			Week 1	63	1.9	0.11	2.0	0	4
			Week 2	62	1.9	0.11	2.0	0	4
			Week 3	59	1.8	0.09	2.0	0	4
			Week 4	60	2.0	0.13	2.0	0	6
			Week 6	60	1.8	0.10	2.0	0	4
			Week 8	60	2.0	0.12	2.0	0	4
			Week 12	58	1.9	0.14	2.0	0	4
	30mg	60	Week -5	59	2.3	0.19	2.0	0	6
			Baseline	59	2.5	0.20	2.0	0	6
			Week 1	56	2.4	0.16	2.0	0	6

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Direct Bilirubin (UMOL/L)	30mg	60	Week 2	57	2.5	0.17	2.0	0	6
			Week 3	57	2.4	0.19	2.0	0	8
			Week 4	56	2.1	0.16	2.0	0	6
			Week 6	53	2.5	0.23	2.0	0	8
			Week 8	55	2.1	0.17	2.0	0	6
			Week 12	56	2.4	0.17	2.0	0	6
	45mg	61	Week -5	60	2.0	0.13	2.0	0	6
			Baseline	61	2.0	0.16	2.0	0	6
			Week 1	59	2.1	0.15	2.0	0	6
			Week 2	58	2.0	0.18	2.0	0	8
			Week 3	55	2.1	0.17	2.0	0	6
			Week 4	56	1.9	0.13	2.0	0	6
			Week 6	54	1.9	0.13	2.0	0	5
			Week 8	54	1.9	0.16	2.0	0	6
			Week 12	54	1.9	0.14	2.0	0	5
Indirect Bilirubin (UMOL/L)	Placebo	64	Week -5	64	8.6	0.48	8.0	3	26
			Baseline	64	9.2	0.57	8.0	3	30
			Week 1	61	8.3	0.48	7.0	3	22
			Week 2	60	8.7	0.55	8.0	4	22
			Week 3	55	8.4	0.50	8.0	4	24
			Week 4	55	8.2	0.48	8.0	4	22
			Week 6	53	8.3	0.45	8.0	4	20
			Week 8	51	8.9	0.52	8.0	4	24
			Week 12	49	8.6	0.63	8.0	2	31
	2.5mg	61	Week -5	61	9.2	0.61	8.0	4	24
			Baseline	61	9.7	0.58	9.0	4	28
			Week 1	59	9.9	0.57	9.0	4	26
			Week 2	58	9.3	0.54	8.5	3	25
			Week 3	56	9.9	0.57	9.0	4	24

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	2.5mg	61	Week 4	56	9.1	0.51	8.0	3	26
			Week 6	48	10.1	0.64	9.0	4	27
			Week 8	48	9.1	0.55	8.0	4	20
			Week 12	45	9.5	0.67	8.0	4	25
	7.5mg	63	Week -5	61	9.4	0.50	9.0	4	26
			Baseline	63	9.4	0.55	9.0	2	32
			Week 1	60	9.8	0.58	9.0	4	27
			Week 2	59	8.8	0.44	8.0	4	22
			Week 3	59	8.9	0.50	8.0	4	27
			Week 4	55	8.5	0.40	8.0	4	19
			Week 6	56	8.9	0.50	8.0	4	23
			Week 8	54	8.9	0.49	8.0	3	22
			Week 12	54	8.9	0.54	8.0	3	23
	15mg	66	Week -5	62	8.5	0.48	8.0	4	22
			Baseline	66	8.5	0.52	8.0	4	30
			Week 1	63	8.1	0.41	8.0	4	19
			Week 2	62	7.9	0.39	7.5	4	19
			Week 3	59	7.9	0.42	7.0	2	21
			Week 4	60	8.6	0.50	8.0	4	21
			Week 6	60	7.7	0.37	7.0	4	18
			Week 8	60	8.0	0.48	7.0	4	24
			Week 12	58	8.3	0.44	8.0	4	20
	30mg	60	Week -5	59	8.9	0.58	8.0	3	28
			Baseline	59	10.4	0.62	10.0	4	26
			Week 1	56	9.3	0.50	9.0	4	24
			Week 2	57	9.5	0.57	9.0	4	30
			Week 3	57	9.4	0.63	8.0	4	28
			Week 4	56	9.0	0.55	8.0	4	24
			Week 6	53	9.2	0.56	8.0	4	24
			Week 8	55	8.7	0.57	8.0	3	24

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Indirect Bilirubin (UMOL/L)	30mg	60	Week 12	56	9.3	0.54	9.0	4	24
	45mg	61	Week -5	59	8.1	0.46	8.0	3	22
			Baseline	61	8.4	0.49	8.0	4	23
			Week 1	59	8.5	0.53	8.0	2	22
			Week 2	58	8.2	0.60	7.0	3	31
			Week 3	55	8.5	0.52	7.0	4	22
			Week 4	56	8.1	0.58	7.0	4	29
			Week 6	54	7.7	0.47	7.0	3	20
			Week 8	54	8.3	0.61	7.5	3	29
			Week 12	54	7.9	0.51	7.0	3	24
Total Bilirubin (UMOL/L)	Placebo	64	Week -5	64	10.8	0.59	10.0	4	31
			Baseline	64	11.4	0.69	10.0	4	36
			Week 1	61	10.6	0.62	10.0	4	30
			Week 2	60	11.0	0.67	10.0	5	28
			Week 3	55	10.7	0.62	10.0	6	29
			Week 4	55	10.3	0.59	9.0	4	27
			Week 6	53	10.5	0.55	10.0	5	24
			Week 8	51	11.2	0.65	10.0	5	30
			Week 12	49	10.8	0.76	10.0	4	37
	2.5mg	61	Week -5	61	11.5	0.73	10.0	6	30
			Baseline	61	12.2	0.70	11.0	6	36
			Week 1	59	12.3	0.68	12.0	5	32
			Week 2	58	11.5	0.66	10.0	4	30
			Week 3	56	12.5	0.68	12.0	6	29
			Week 4	56	11.3	0.61	10.0	4	30
			Week 6	48	12.4	0.75	11.0	5	31
			Week 8	48	11.3	0.62	10.0	6	23
			Week 12	46	11.8	0.78	10.0	6	29

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Total Bilirubin (UMOL/L)	7.5mg	63	Week -5	61	11.8	0.60	11.0	5	31
			Baseline	63	11.7	0.64	11.0	4	37
			Week 1	60	12.0	0.67	11.0	6	33
			Week 2	59	10.9	0.54	11.0	4	26
			Week 3	59	11.1	0.57	10.0	6	31
			Week 4	56	10.6	0.44	10.0	5	22
			Week 6	56	11.1	0.61	10.0	4	28
			Week 8	54	11.0	0.60	10.0	5	26
			Week 12	54	11.0	0.64	10.0	4	28
	15mg	66	Week -5	62	10.5	0.55	10.0	4	26
			Baseline	66	10.6	0.61	9.5	6	35
			Week 1	63	10.0	0.48	9.0	4	22
			Week 2	62	9.8	0.46	9.0	6	23
			Week 3	59	9.7	0.47	9.0	4	25
			Week 4	60	10.6	0.60	9.0	6	25
			Week 6	60	9.5	0.43	9.0	4	21
			Week 8	60	10.0	0.56	9.0	4	28
			Week 12	58	10.1	0.52	10.0	6	24
	30mg	60	Week -5	59	11.3	0.71	10.0	4	34
			Baseline	59	12.9	0.76	12.0	6	32
			Week 1	56	11.7	0.61	11.0	6	30
			Week 2	57	11.9	0.69	12.0	6	36
			Week 3	57	11.8	0.80	10.0	4	36
			Week 4	56	11.1	0.68	9.5	4	30
			Week 6	53	11.7	0.73	10.0	6	32
			Week 8	55	10.8	0.69	10.0	4	30
			Week 12	56	11.7	0.66	11.0	6	30
	45mg	61	Week -5	60	10.0	0.56	9.0	5	28
			Baseline	61	10.4	0.62	9.0	4	29
			Week 1	59	10.6	0.64	9.0	4	26

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Table 12.39
Additional Summary of Selected Laboratory Parameters by Treatment

Lab Test	Treatment	N	Planned Relative Time	n	Mean	SE	Median	Min.	Max.
Total Bilirubin (UMOL/L)	45mg	61	Week 2	58	10.2	0.75	9.0	4	39
			Week 3	55	10.5	0.65	9.0	5	28
			Week 4	56	10.1	0.68	9.0	5	35
			Week 6	54	9.6	0.57	8.0	4	24
			Week 8	54	10.2	0.72	9.0	4	33
			Week 12	54	9.8	0.61	8.0	4	29

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Table 12.40
Summary of Relative Risks for Common On-therapy Adverse Events (>=5% Total Incidence)
by Treatment

Preferred Term		Placebo (N=64)	2.5mg (N=61)	7.5mg (N=63)	15mg (N=66)	30mg (N=60)	45mg (N=61)
Any event		24 (38%)	22 (36%)	20 (32%)	28 (42%)	19 (32%)	23 (38%)
Nasopharyngitis	N (%)	3 (5%)	3 (5%)	7 (11%)	3 (5%)	3 (5%)	0
	Relative Risk		1.0	2.4	1.0	1.1	
	95% CI		0.2, 5.0	0.6, 8.8	0.2, 4.6	0.2, 5.1	

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Table 12.41
Summary Statistics of Maximum Post-Baseline Laboratory Results
Relative to Upper Limit of Normal

Lab Test	Treatment	N	n	Mean	SD	Median	Min.	Max.
Alanine Amino Transferase (IU/L)	Placebo	64	61	0.53	0.228	0.48	0.2	1.2
	2.5mg	61	56	0.57	0.195	0.52	0.3	1.1
	7.5mg	63	60	0.57	0.332	0.48	0.2	2.4
	15mg	66	57	0.53	0.261	0.46	0.2	1.8
	30mg	60	51	0.56	0.386	0.48	0.2	3.0
	45mg	61	59	0.58	0.283	0.50	0.3	1.9
Alkaline Phosphatase (IU/L)	Placebo	64	62	0.63	0.157	0.61	0.3	1.1
	2.5mg	61	57	0.69	0.155	0.66	0.4	1.1
	7.5mg	63	62	0.68	0.220	0.66	0.3	2.0
	15mg	66	60	0.61	0.154	0.60	0.3	0.9
	30mg	60	57	0.63	0.169	0.64	0.3	1.2
	45mg	61	57	0.66	0.172	0.64	0.3	1.2

Note: Includes Follow-up for Early Withdrawal visits

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Table 12.41
Summary Statistics of Maximum Post-Baseline Laboratory Results
Relative to Upper Limit of Normal

Lab Test	Treatment	N	n	Mean	SD	Median	Min.	Max.
Aspartate Amino Transferase (IU/L)	Placebo	64	62	0.49	0.202	0.43	0.3	1.3
	2.5mg	61	58	0.57	0.208	0.50	0.3	1.2
	7.5mg	63	63	0.52	0.228	0.44	0.3	1.5
	15mg	66	65	0.56	0.217	0.51	0.2	1.2
	30mg	60	55	0.57	0.372	0.50	0.3	3.0
	45mg	61	59	0.57	0.244	0.52	0.3	1.8
Creatine Kinase MB (MCG/L)	Placebo	64	49	0.33	0.110	0.31	0.1	0.6
	2.5mg	61	51	0.34	0.212	0.27	0.1	1.1
	7.5mg	63	51	0.37	0.188	0.31	0.1	1.0
	15mg	66	55	0.40	0.201	0.35	0.1	1.0
	30mg	60	54	0.41	0.273	0.30	0.2	1.3
	45mg	61	47	0.38	0.178	0.33	0.1	1.0

Note: Includes Follow-up for Early Withdrawal visits

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Table 12.41
Summary Statistics of Maximum Post-Baseline Laboratory Results
Relative to Upper Limit of Normal

Lab Test	Treatment	N	n	Mean	SD	Median	Min.	Max.
Lactate Dehydrogenase (IU/L)	Placebo	64	63	0.57	0.101	0.57	0.4	0.9
	2.5mg	61	61	0.62	0.111	0.61	0.4	1.1
	7.5mg	63	63	0.62	0.149	0.60	0.4	1.2
	15mg	66	65	0.62	0.117	0.61	0.4	1.0
	30mg	60	58	0.64	0.147	0.63	0.4	1.2
	45mg	61	60	0.64	0.151	0.61	0.3	1.1
Total Bilirubin (UMOL/L)	Placebo	64	61	0.59	0.193	0.55	0.3	1.2
	2.5mg	61	58	0.64	0.200	0.61	0.3	1.0
	7.5mg	63	62	0.65	0.257	0.59	0.3	1.5
	15mg	66	63	0.54	0.178	0.45	0.3	1.1
	30mg	60	54	0.61	0.231	0.59	0.3	1.6
	45mg	61	57	0.56	0.239	0.50	0.3	1.5

Note: Includes Follow-up for Early Withdrawal visits

[redacted]

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DPB100925

This section contained patient narratives which are textual descriptions of medical history, treatment and outcome for individual patients who experienced a clinically important adverse event including serious adverse events during the trial. They have been excluded to protect patient privacy. This data may be made available subject to an approved research proposal and a determination of the ability to provide information from the specific narratives whilst protecting the patient's privacy. For further information please see the Patient Level Data section of the ***GSK Clinical Study Register****.*

Division: Worldwide Development
Retention Category: GRS019
Information Type: Protocol Amendment

Title:	A 12-Week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects With Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Compound Number: GW823093

Effective Date: 5-Apr-2006

Protocol Amendment Number: 2

Description: A 12-week, parallel-group, double-blind, randomized, placebo-controlled, multicenter, dose-ranging study to evaluate the efficacy, safety and tolerability of 5 doses of GW823093 administered orally, once a daily as monotherapy in subjects with type 2 diabetes mellitus followed by a 12-week active treatment extension. This study will provide dose response for this compound

Subject: GW823093, Phase IIb, DPPIV Inhibition, Type 2 Diabetes Mellitus, Dose-Ranging, Pharmacokinetics, Pharmacodynamics, Safety, Efficacy, Tolerability

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Revision Chronology:

ZM2004/00083/00	2004-DEC-16	Original

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ZM2004/00083/01	2005-MAR-10	Amendment No.01: Inclusion of population cardiac biomarkers, additional ECG measurement at V2 and central ECG reading process for all ECGs. Clarify FPG inclusion criteria, address administrative revisions and clarify hypoglycemia reporting procedures, correct typographical errors
ZM2004/00083/02	2006-APR-5	Amendment 2: Outline cardiac troponin I withdrawal criteria and follow-up. Update contact information.

CONFIDENTIAL ZM2004/00083/02
DPB100925

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EurdraCT Number: 2004-004193-91

INVESTIGATOR AGREEMENT PAGE

I confirm agreement to conduct the study in compliance with the protocol, as amended by this protocol amendment.

Investigator Name: _____

_____ _____
Investigator Signature Date

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ABBREVIATIONS

ACE	Angiotensin converting enzyme
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine transaminase
ABPM	Ambulatory Blood Pressure Monitoring
Apo-B	Apolipoprotein-B
AR	Adrenergic receptor
AST	Aspartate transaminase
ATP	Adenosine triphosphate
AUC	Area under the curve
BMI	Body mass index
BP	Blood pressure
bpm	Beats per minute
BQL	Below quantitation limit
°C	Degrees Celsius
CI	Confidence interval
CIB	Clinical Investigator's Brochure
CK-MB	Creatine Kinase MB
CL	Clearance
COPD	Chronic obstructive pulmonary disease
CLcr	Creatinine clearance
CTM	Clinical trial medication
dL	deciliter
DNA	Deoxyribonucleic acid
DPP-IV	Dipeptidyl Peptidase-IV
ECG	Electrocardiogram
eCRF	Electronic case report form
EDTA	Ethylenediamine tetra-acetic acid
EISR	Expedited investigator safety report
FCBG	Fasting Capillary Blood Glucose
FFA	Free fatty acids
FPG	Fasting plasma glucose
GCP	Good clinical practice
GCSP	Global Clinical Safety & Pharmacovigilance
GLP-1	Post prandial glucagon Like Peptide-1
GSK	GlaxoSmithKline
hr	Hour
HbA1c	Glycosylated hemoglobin
HCG	Human chorionic gondadotropin
HDL-c	High density lipoprotein cholesterol
HIV	Human immunodeficiency virus
HLA	Human leukocyte antigen
HR	Heart rate
HSL	Hormone sensitive lipase

IB	Investigator's Brochure
IBW	Ideal bodyweight
IEC	Independent ethics committee
IND	Investigational new drug
IRB	Independent review committee
ISA	Insulin sensitizing agent
ITT	Intent-to-treat
IVRS	Interactive voice response system
kg	Kilogram(s)
LDH	Lactate dehydrogenase
LDL-c	Low density lipoprotein cholesterol
LloQ	Lower limit of quantitation
LOCF	Last observation carried forward
MedDRA	Medical dictionary for regulatory activities
mg	Milligram(s)
mL	Milliliter(s)
msec	Millisecond(s)
MSDS	Material safety data sheet
NYHA	New York Heart Association
OGTT	Oral glucose tolerance test
OTC	Over the counter non-prescription medication
PD	Pharmacodynamics
PGx	Pharmacogenetics
PK	Pharmacokinetics
PPAR	Peroxisome proliferator activated receptor
PPG	Post Prandial Glucose
PTCA	Percutaneous transluminal coronary angioplasty
QC	Quality control
qd	Once daily
RAP	Reporting analysis plan
RDM	Remote data management
SAE	Serious adverse event
SNP	Single nucleotide polymorphism
SOP	Standard operating procedures
SUs	Sulphonylureas
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
T_{max}	Time to maximum observed plasma drug concentrations
cTnI	Troponin-I
TSH	Thyroid stimulating hormone
TZD	Thiazolidinedione
UCP	Uncoupling protein
ULRR	Upper limit of the reference range
US	United States
V	Volume of distribution

PROTOCOL SUMMARY

Rationale

Dipeptidyl-peptidase (DPP-IV), also known as the T-cell antigen CD26, is a serine aminopeptidase. DPP-IV rapidly (t1/2 < 5 min) inactivates the incretins, glucagon-like peptide 1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), by cleaving off a dipeptide at the penultimate alanine near the amino-terminus of GLP-1 (7-36) amide. Improving the stability and action of GLP-1 and GIP, which are responsible for at least 50% of nutrient stimulated insulin secretion, has been shown to improve glycemic control in subjects with type 2 diabetes mellitus (T2DM). GW823093 is a selective DPP-IV inhibitor being investigated for the treatment of T2DM. In addition to GW823093, several oral DPP-IV inhibitors have progressed to clinical studies in healthy individuals and subjects with T2DM. Studies up to 52-weeks in duration with another DPP-IV inhibitor compound (LAF-237-Novartis) have demonstrated improvements in glycemic control with an acceptable tolerability/safety profile [Ahrén, 2004a; Ahrén, 2004b; and Pratley, 2004].

A single-dose study with GW823093 has been completed. GW823093 was well tolerated after single oral doses of 2.5, 5, 10, 15, 25, and 50mg in healthy male subjects. There were no severe AEs, serious AEs or drug-related AEs leading to discontinuation. Headache, nausea and dizziness were the most frequently reported events with episodes occurring more frequently with GW823093C than placebo. There did not appear to be any investigational product- or dose-related trend in the frequency of clinical chemistry, hematology or urinalysis shifts from pre-dose. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities.

Two multiple-dose studies have been completed. GW823093 was administered, at doses of 5, 15 and 30mg for 13-days to healthy lean and obese subjects (DPB10002) and for 7-days to subjects with T2DM (DPB10003). In both studies, GW823093 was well tolerated and no serious or significant adverse events or clinically significant findings were observed. There was no apparent dose-related trend in the frequency of clinical chemistry, haematology or urinalysis shifts from baseline. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities. Substantial DPP-IV inhibition ($\geq$70% at 24 hours at the 15 and 30mg doses) was observed in both studies. Data from both studies indicated a dose-related reduction in fasting and post-prandial glucose. An apparent increase in post-prandial insulin was seen after a single dose and after 7-days of dosing in subjects with T2DM (DPB10003).

The highest proposed dose (45mg) has recently been assessed in a 10-day repeat dose study in healthy subjects (DPB102875). This study was the first to evaluate the safety, tolerability and pharmacokinetics of multiple doses (10 days) of a 45 mg dose of GW823093. Twenty-nine healthy volunteers were enrolled and preliminary listings of reported blinded adverse events are available for analysis. Adverse events were reported by 18/27 (67%) subjects. Headache, lightheadedness and diarrhea were the most commonly reported adverse events. One individual was discontinued from the study due

to left flank pain and dysuria. The symptoms resolved in one day and the subject refused additional diagnostic tests required for analysis of nephrolithiasis. Another individual developed severe nausea and emesis but was able to complete the study. Full evaluation of unblinded safety will be completed in ensuing weeks, but based upon review of blinded data; no events are expected to preclude inclusion of 45mg doses in larger Phase 2/3 trials.

This Phase IIb dose-ranging study will evaluate the dose response, efficacy, safety and tolerability of a range of doses of GW823093, compared to placebo, over a 12-week Main Phase in subjects with T2DM. A 12-week Extension Phase will follow the Main Phase and will evaluate the safety and tolerability and time course for glycemic effects after an additional 12 weeks of dosing. During the Extension Phase subjects who were randomized to placebo during the first 12 weeks in the Main Phase will be placed on a 2.5mg dose of GW823093 for the remaining 12 weeks. Subjects who were randomized to GW823093 in the Main Phase will remain at their randomized dose during the course of the extension phase.

The dose range for this study was determined by examining the preliminary results of multiple dose studies that are currently being analysed in healthy volunteers and in subjects with T2DM. The planned doses of 2.5, 7.5, 15, 30 and 45mg target a range of DPP-IV inhibition profiles and exposures to GW823093. The dose range is designed to determine both minimally effective and maximum effective safe and tolerable doses. The lowest dose is anticipated to be below the therapeutic threshold. Based on glucose and other pharmacodynamic data from DPB10003 the therapeutic dose range is expected to be between 5 mg and 30 mg/day. The highest dose (45mg) is at the higher end of the allowable clinical dose range based on current safety assessment data. Active medication will be provided as capsules (2.5mg and 15mg strengths) with matching placebo. Each subject will receive the same number of capsules per dose.

An external Independent Data Monitoring Committee (IDMC) will be utilized during the study. The committee will be composed of members external to GSK. The objective of the committee is to monitor on an on-going basis safety data (e.g., clinical chemistry, adverse events). The approved IDMC charter will be on file and available for inspection as requested.

Objective(s)

Main Phase

Primary Objective

- To evaluate the dose response and efficacy of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), versus placebo on the change in HbA1c after 12 weeks of dosing in subjects with T2DM.

Secondary objectives

- To investigate the safety and tolerability of a range of doses of GW823093 versus placebo during 12 weeks of dosing in subjects with T2DM.
- To evaluate the effect of a range of doses of GW823093, versus placebo, on glycemic parameters (e.g., HbA1c, fasting plasma glucose (FPG), fasting fructosamine), fasting insulin and serum lipid profile during 12 weeks of dosing in subjects with T2DM.
- To characterize the pharmacokinetics of GW823093 in type 2 diabetic subjects after chronic administration using a combined sparse and serial sampling scheme, and to investigate pharmacokinetic (PK)/pharmacodynamic (PD) relationships (e.g. safety and efficacy endpoints).
- To evaluate the effect of a range of doses of GW823093 on DPP-IV inhibition as part of population PK assessment.

Extension Phase

Objectives:

- To evaluate the effect of a range of doses of GW823093 on safety and tolerability (including incidence and severity of hypoglycaemia), glycemic parameters (e.g., HbA1c, FPG, fasting fructosamine), serum lipid profile, fasting insulin level, pharmacokinetics and additional biomarkers during the additional 12 weeks of dosing in subjects with type 2 diabetes. No statistical comparisons are planned for the extension phase data.

Exploratory Objectives (Main and Extension Phase)

- To evaluate plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- To evaluate the correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.
- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.
- To evaluate exploratory endpoints described in the Informed Consent including pharmacogenetics, lipomics and/or proteomics. Pharmacogenetics data will be collected to investigate the potential influence of genetic variation on glycemic control after GW823093 treatment. Samples will be taken and frozen for future analysis as described in the Informed Consent Document.

Endpoint(s)

Main Phase

Primary efficacy

- Change from baseline (Week 0) in HbA1c at Week 12.

Secondary efficacy

- Change from baseline (Week 0) in HbA1c at Weeks 4 and 8.
- Change from baseline (Week 0) in FPG at Weeks 1, 2, 3, 4, 6, 8 and 12
- Proportion of subjects who achieve various HbA1c ($\leq 6.5\%$, $< 7\%$ and $\leq 8\%$) and FPG (< 126mg/dL [7.0mmol/L] and < 140mg/dL [7.8mmol/L]) targets, and/or achieve a clinically meaningful decrease in HbA1c ($\geq 0.7\%$) and FPG (≥ 30mg/dL [1.7mmol/L]).
- Change from baseline (week 0) in fructosamine (total and corrected for protein), fasting serum insulin, pro-insulin and pro-insulin:insulin ratio at Weeks 4, 8 and 12.
- Population PK parameters of GW823093 including clearance (CL) and volume of distribution (Vd) with assessment of demographic covariates influencing GW823093 pharmacokinetic profile. Dependent on the final compartmental model describing GW823093 disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK

Other Metabolic Endpoints

- Percent change from baseline (Week 0) in fasting lipids (triglycerides, free fatty acids (FFAs), TC, LDL-c, HDL-c) based on log-transformed data at Weeks 4, 8, and 12.

Safety

- Safety and tolerability, assessed by the incidence and severity of adverse events over the course of the Main Phase.
- Hematology, clinical chemistry, urinalysis laboratory parameters at each visit.
- Incidence and severity of hypoglycemia over the course of the Main Phase.
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic BP and radial HR at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V2, V5, V9 and V12 in main phase.

- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist:hip ratio at Week 12.

Extension Phase

Secondary Endpoints

- Safety and tolerability, assessed by the incidence and severity of adverse events over the course of the Extension Phase.
- Hematology, urinalysis and chemistry laboratory parameters at each visit.
- Change from baseline (Week 0) in HbA1c at Weeks 16, 20 and 24.
- Change from baseline (Week 0) in FPG at Weeks 13, 14, 15, 16, 20 and 24, and fructosamine (total and corrected for protein) at Weeks 16, 20 and 24, fasting serum insulin and pro-insulin at Weeks 16, 20 and 24.
- Incidence and severity of hypoglycemia over the course of the Extension Phase.
- Population PK parameters of GW823093 including clearance (CL) and volume of distribution (Vd) with assessment of demographic covariates influencing GW823093 pharmacokinetic profile. Dependent on the final compartmental model describing GW823093 disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic BP and radial HR at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 24. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V16 and V18.
- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist:hip ratio at Week 24.

Other Metabolic Endpoints

- Percent change from baseline (Week 0) in fasting lipids (triglycerides, FFAs, TC, LDL-c, HDL-c) based on log-transformed data at Weeks 16, 20, and 24.

Exploratory Endpoints (Main and Extension Phase)

- Descriptive statistics of plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- Correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.

- Descriptive statistics of the population cardiac biomarkers, CK-MB and cTnI at each collection time point in the main and extension phases.
- Exploratory endpoints may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples.

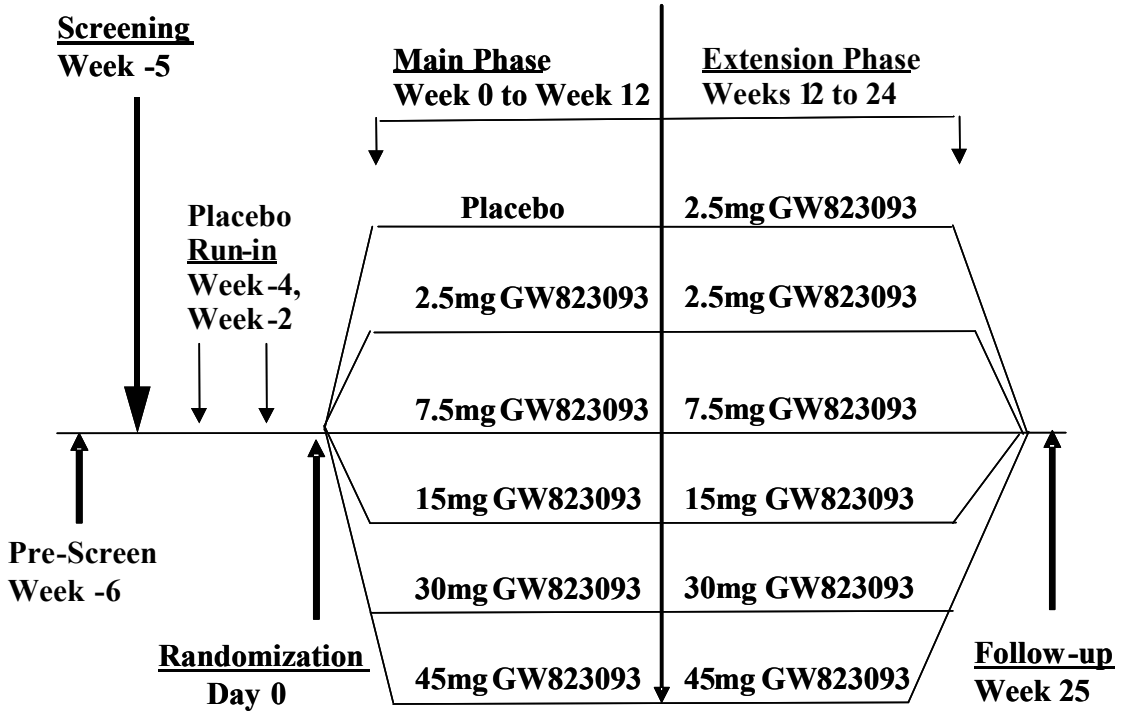
Study Design

This study will be a multi-center, randomized, double-blind, placebo-controlled, parallel-group dose-ranging study with five treatment arms plus a placebo arm conducted in two phases: the Main Phase (first 12-weeks of treatment) and an Extension Phase (second 12-weeks of treatment). Subjects with T2DM who are drug-naïve, treated with diet and exercise or on prior oral anti-diabetic monotherapy will be recruited.

The study will be comprised of six study periods: Pre-Screen, Screen, Run-In, Main Phase, Extension Phase and Post-treatment Follow-up. The Time and Events Schedule details the procedures to be performed at each study Visit (See Section 15.1, Appendix 1). The schematic below represents the overall study design.

An external Independent Data Monitoring Committee (IDMC) will be utilized during the study. The committee will be composed of external members. The objective of the committee is to monitor on an on-going basis safety data (e.g., clinical chemistry, adverse events). The approved IDMC charter will be on file and available for inspection as requested.

Study Design



N=61 Subjects/arm

Pre-Screening Period

This visit (Week -6) will be conducted within one week (prior to) of the Screening Visit. Potential subjects who are thought to meet the eligibility criteria for the study will be informed of the requirements of the study, will give their written informed consent to participate, and will undergo a pre-screening assessment, including a brief medical history and a review of inclusion and exclusion criteria. Subjects will have HbA1c analysis and a fasting plasma glucose (FPG) done during this visit as an initial assessment of eligibility. Those subjects who meet the initial criteria will undergo the remainder of the screening assessments at the next visit (Screening Visit). Initial HbA1c criteria at the pre-screening visit are as follows:

- HbA1c level ≥ 7.0% to ≤ 8.5% for subjects on oral anti-diabetic monotherapy
- HbA1c level ≥ 7.5% to ≤ 10.0% for subjects on diet and exercise alone

Screen (V2)

Approximately one-week after providing informed consent and completing the pre-screen visit, eligible subjects will undergo a Screening visit (**Week -5**) to determine eligibility to proceed in the study. The Screen visit must include a formal review of medical history, concurrent medications, and a review of all eligibility requirements for the study. The Screening Visit will include review of the inclusion/exclusion criteria, electrocardiogram (ECG), a physical exam including blood pressure and heart rate, a complete medical history, height, weight, waist circumference and hip measurements, blood samples, β-HCG (women), and urinalysis.

At the Screen visit patients will be taken off their anti-diabetic medications and prohibited concomitant medications for the duration of the trial (Section 15.3, Appendix 3). Since not all Screen eligibility information will be immediately available during the Screen visit, the Investigator must also review laboratory and other Screening information as it becomes available to ensure patients' continued eligibility for the Run-in period of the study. For those patients taking prior medications requiring wash-out, the duration of wash-out must be observed as detailed in Section 15.3, Appendix 3. Patients will be provided a glucose meter at the screening visit and instructed on its operation and frequency of use. Subjects will be asked to return in approximately one week for the start of Run-in visit. The central laboratory values from the Screen Visit for each subject must be reviewed upon receipt and a judgement made regarding the eligibility of the subject. Subjects should be called back-in for a re-test if any lab values return that indicate ineligibility. The Investigator must exercise their medical judgement during this process to ensure ethical treatment of the patient.

Run-In

Standard diabetic dietary and exercise advice will be provided at the beginning of the Run-in and reinforced at every visit thereafter. Approximately one week after the Screening Visit, eligible subjects will return to the clinic to start a 4-week run-in period. During this period, subjects will be seen twice (every 2 weeks) to assess continued

eligibility. At Visits 3 and 4 the inclusion/exclusion criteria should be reviewed and blood pressure and heart rate measured.

At the Run-in visit (week -4) subjects will be dispensed three (3) bottles of single-blind placebo run-in medication and instructed to take 1 capsule daily in the morning at breakfast from each bottle.

Fasting glucose level during run-in: FPG will be tested on **Weeks -4 (Visit 3)** and **-2 (Visit 4)** by central laboratory and on **Week 0 (Visit 5)** by fasting capillary blood glucose (FCBG) and central laboratory:

1. If Fasting Plasma Glucose (FPG) > 240mg/dL (13.3mmol/L) at Visit 3 or 4, reschedule and repeat test one time by central laboratory. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.
2. Fasting Capillary Blood Glucose (FCBG) should be the first assessment performed in the clinic at Week 0 (Visit 5). If FCBG in the clinic is > 240 mg/dL (13.3mmol/L) (after repeated FCBG), a blood sample to assess FPG should be drawn (no other Visit 5 assessments conducted at that time). The patient should be re-dispensed their remaining run-in medication and sent home to await the FPG results. Subjects should be reassured that this is acceptable and to call if there are any questions or concerns. Randomization and completion of all visit 5 assessments should be delayed until measurement is confirmed by central laboratory measurement of FPG. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.

Main Treatment Phase

Upon successful completion of the run-in phase, each subject will be randomly assigned to one dose group of GW823093 or placebo. Eligible subjects will be stratified by gender and prior therapy (no therapy or diet and exercise alone; monotherapy). To achieve balance between treatment groups, after completing the placebo run-in, subjects will be randomized in a 1:1:1:1:1:1 ratio to receive placebo, or each of 5 doses of GW823093 qd for 12-weeks within each stratum.

The duration of the Main Phase is 12 weeks from the time of randomization. Study visits will occur at **Weeks 0 (Visit 5), 1 (Visit 6), 2 (Visit 7), 3 (Visit 8), 4 (Visit 9), 6 (Visit 10), 8 (Visit 11), and 12 (Visit 12).** Permitted visit windows are plus or minus 3 days when visit intervals are 1 week and plus or minus 7 days when visit intervals are 2 or 4 weeks but every effort should be made to keep subjects on or close to the protocol-defined visit schedule. Standard diabetic dietary and exercise advice will be provided at **Week 0** and reinforced at each clinic visit. Subjects who have a FPG > 270 mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, or 11 will be asked to return to the clinic as soon as possible for a retest. If the FPG remains >270 mg/dL (15.0mmol/L) upon retest, the subject must be withdrawn from the study. Subjects with an FPG >270 mg/dL

(15.0mmol/L) (confirmed with re-test) at Visit 12 (week 12) will not be permitted to enter the Extension phase.

Extension Phase

Study visits in the extension will occur at **Weeks 13 (Visit 13), 14 (Visit 14), 15 (Visit 15), 16 (Visit 16), 20 (Visit 17)** and **24 (Visit 18)**.

All subjects will be on active treatment (GW823093) during the Extension Phase. Subjects randomized to placebo in the Main Phase will be placed on a 2.5 mg dose of GW823093 at the Week 12 visit. This will limit the duration during which those subjects randomized to placebo will not receive active treatment for their type 2 diabetes. Subjects randomized to GW823093 in the Main Phase remain at their randomized dose and dosing regimen in the extension phase in blinded fashion. Subjects who demonstrate insufficient therapeutic effect (FPG> 270mg/dL (15.0mmol/L) confirmed by retest) after 12 weeks of treatment, will not continue into the Extension Phase, and will be referred to their physician for follow-up care. Subjects who have a FPG > 270 mg/dL (15.0mmol/L) at Visits 13, 14, 15, 16, or 17 will be asked to return to the clinic as soon as possible for a retest. If the FPG remains >270 mg/dL (15.0mmol/L) upon retest, the subject must be withdrawn from the study.

Post-Treatment Follow-up

Upon completion of the Main Phase and the Extension Phase, each subject will be asked to return one week (plus or minus 3 days) later **Week 25 (Visit 19)** to complete a series of safety assessments that will include vital signs and collection of blood samples for clinical laboratory evaluations.

Study Population

This study will be conducted in approximately 100 centers worldwide. Each study center is projected to screen approximately 7 subjects and randomize approximately 4 subjects.

Based on a 52% screen failure rate, approximately 763 subjects will be screened, with a target to randomize 366 subjects into the double-blind treatment phase to generate data from at least 348 evaluable subjects.

A minimum target of 40% of the all randomized population should be drug naïve at screening with a corresponding maximum of 60% of the all randomized population having been on oral anti-diabetic medications at screening. Subjects on fixed-dose combination oral anti-diabetic therapy of any kind are not eligible for the study.

Study Assessments

The following measurements and evaluations will be conducted during the trial. The study assessments and procedures are outlined in the Times and Events Table (see Section 15.1, Appendix 1).

Demographic and baseline assessments

- Demographic data will include date of birth, race, sex, height, reproductive status (for women), body weight, waist and hip circumference, and body mass index (BMI). Baseline characteristics will include a comprehensive physical examination, vital signs, medical conditions and medical history including concomitant medications, alcohol and tobacco use.

Safety Assessments

- Pregnancy test (in all females)
- TSH
- Standard panels for safety (see Section 15.7, Appendix 7 for details):
  - Hematology
  - Clinical chemistry
  - Urinalysis
  - Immunochemical fecal occult blood analysis for subjects experiencing reductions in hemoglobin of ≥ 2 g/dL from baseline over the course of the study
- Incidence and severity of hypoglycemic events
- ECG read centrally and locally at V2, V5, V9, V12, V16, V18
- Blood pressure and heart rate measurements
- Body weight, waist and hip circumference and BMI

Efficacy Assessments

Glycemic

- HbA1c, FPG and fructosamine

Other Pharmacodynamic/Metabolic

- DPP-IV inhibition, fasting insulin, pro-insulin, pro-insulin:insulin ratio, fasting lipids (triglycerides, FFAs, TC, LDL-c, HDL-c)

Exploratory Assessments

- Plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- Correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.

- Population cardiac biomarkers; creatine kinase MB(CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.
- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples. Samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

Pharmacokinetics and Pharmacodynamics

- Accurate recording of dosing and sample collection times is critical. The date and time of all doses administered in the clinic will be recorded. On days when pre-dose PK samples are collected, the date and time of the most recent dose of study medication prior to sample collection will be recorded. The actual sample collection times must be recorded accurately in the eCRF. This study has both sparse PK and serial PK components. Those subjects participating in the serial PK regimen do not participate in the sparse PK sampling and the sparse PK subjects do not participate in the serial PK testing. Post meal challenge pharmacodynamic testing will be done in conjunction with the serial PK assessments and those subjects participating in the post meal pharmacodynamic testing is limited to the serial PK population. Refer to (Section 15.6, Appendix 6) for details on pharmacokinetic sampling.

1. INTRODUCTION

1.1. Background

Type 2 diabetes mellitus (T2DM) accounts for more than 85% of the total number of diabetes cases. The primary manifestation of this disease is chronic hyperglycemia, resulting from resistance to insulin action at a cellular and molecular level and inadequate secretion of endogenous insulin. The incidence and prevalence of T2DM is considered to be at epidemic levels in North America and Europe and is increasing worldwide, with a projected estimate that approximately 221 million people will have the condition by the year 2010 [Amos, 1997]. T2DM is a major health care issue due to increased patient morbidity and mortality resulting from complications arising from the disease, especially cardiovascular, renal, and neurological, as well as the costs associated with the management of its complications.

The medical management of patients with T2DM consists of diet, exercise, and weight reduction, together with oral anti-diabetic medications or insulin therapy, as appropriate. Current pharmacological treatments for T2DM include drugs that increase insulin secretion (sulfonylureas [SU] and meglitinides), increase glucose utilization (glitazones), reduce hepatic glucose production (metformin), and delay glucose absorption (α-glucosidase inhibitors). Side effects of these medications include hypoglycemia and GI disturbances. Two peroxisome proliferator activated receptor gamma (PPARγ) agonists have been approved for use (rosiglitazone, pioglitazone). These insulin sensitizing agents (ISAs) increase the insulin sensitivity of adipose and skeletal muscle tissue. Although ISAs do not lead to hypoglycemic events when used as monotherapy or in combination with metformin, side effects can include weight gain and fluid retention in certain patients.

T2DM treatment is evolving. In order to achieve glycemic targets, multiple agents and complementary mechanisms are frequently required. Consequently, new agents with mechanisms that are different, yet complementary, to existing classes are required.

GW823093 is a selective inhibitor of the dipeptidyl peptidase IV enzyme (DPP-IV) and is being investigated for the treatment of T2DM. DPP-IV rapidly inactivates the incretin hormones Glucagon Like Peptide-1 (GLP-1) and Glucose Dependent Insulinotrophic Polypeptide-1 (GIP-1) secreted by cells in the gut in response to meal ingestion. Inhibiting the natural action of DPP-IV through use of a DPP-IV inhibitor improves the stability of GLP-1 and potentiates the physiologic actions of GLP-1 such as glucose dependent insulin secretion and inhibition of glucagon production. GLP-1 is a new therapeutic target of an emerging class of compounds called gliptins.

1.2. Rationale

Dipeptidyl-peptidase (DPP-IV), also known as the T-cell antigen CD26, is a serine aminopeptidase. DPP-IV rapidly ($t1/2 < 5$ min) inactivates the incretins, glucagon-like peptide 1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), by cleaving off a dipeptide at the penultimate alanine near the amino-terminus of GLP-1 (7-36)

amide. Improving the stability and action of GLP-1 and GIP, which are responsible for at least 50% of nutrient stimulated insulin secretion, has been shown to improve glycemic control in subjects with type 2 diabetes mellitus (T2DM). GW823093 is a selective DPP-IV inhibitor being investigated for the treatment of T2DM. In addition to GW823093, several oral DPP-IV inhibitors have progressed to clinical studies in healthy individuals and subjects with T2DM. Studies up to 52-weeks in duration with another DPP-IV inhibitor compound (LAF-237-Novartis) have demonstrated improvements in glycemic control with an acceptable tolerability/safety profile [Ahrén, 2004a; Ahrén, 2004b; Pratley, 2004].

A single-dose study with GW823093 has been completed. GW823093 was well tolerated after single oral doses of 2.5, 5, 10, 15, 25, and 50mg in healthy male subjects. There were no severe AEs, serious AEs or drug-related AEs leading to discontinuation. Headache, nausea and dizziness were the most frequently reported events with episodes occurring more frequently with GW823093 than placebo. There did not appear to be any investigational product- or dose-related trend in the frequency of clinical chemistry, hematology or urinalysis shifts from pre-dose. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities.

Two multiple-dose studies have been completed. GW823093 was administered, at doses of 5, 15 and 30mg for 13-days to healthy lean and obese subjects (DPB10002) and for 7-days to subjects with T2DM (DPB10003). In both studies, GW823093 was well tolerated and no serious or significant adverse events or clinically significant findings were observed. There was no apparent dose-related trend in the frequency of clinical chemistry, haematology or urinalysis shifts from baseline. There were no notable dose-related changes from pre-dose in vital signs. There were no drug-related, clinically significant ECG abnormalities. Substantial DPP-IV inhibition ($\geq$70% at 24 hours at the 15 and 30mg doses) was observed in both studies. Data from both studies indicated a dose-related reduction in fasting and post-prandial glucose. An apparent increase in post-prandial insulin was seen after a single dose and after 7-days of dosing in subjects with T2DM (DPB10003).

The highest proposed dose (45mg) has recently been assessed in a 10-day repeat dose study in healthy subjects (DPB102875). This study was the first to evaluate the safety, tolerability and pharmacokinetics of multiple doses (10 days) of a 45 mg dose of GW823093. Twenty-nine healthy volunteers were enrolled and preliminary listings of reported blinded adverse events are available for analysis. Adverse events were reported by 18/27 (67%) subjects. Headache, lightheadedness and diarrhea were the most commonly reported adverse events. One individual was discontinued from the study due to left flank pain and dysuria. The symptoms resolved in one day and the subject refused additional diagnostic tests required for analysis of nephrolithiasis. Another individual developed severe nausea and emesis but was able to complete the study. Full evaluation of unblinded safety will be completed in ensuing weeks, but based upon review of blinded data, no events are expected to preclude inclusion of 45mg doses in larger Phase 2/3 trials.

This Phase IIb dose-ranging study will evaluate the dose-response, efficacy, safety and tolerability of a range of doses of GW823093, compared to placebo, over a 12-week Main Phase in subjects with T2DM. A 12-week Extension Phase will follow the Main Phase and will evaluate the safety and tolerability and time course for glycemic effects after an additional 12 weeks of dosing. During the Extension Phase subjects who were randomized to placebo during the first 12 weeks will be placed on a 2.5 mg dose of GW823093 for the remaining 12 weeks. Subjects who had been randomized to GW823093 in the Main Phase will remain at their respective dose in blinded fashion throughout the extension phase. The dose range for this study was determined by examining the preliminary results of multiple dose studies that are currently being analysed in healthy volunteers and in subjects with T2DM. The planned doses of 2.5, 7.5, 15, 30 and 45mg target a range of DPP-IV inhibition profiles and exposures to GW823093. The dose range is designed to determine both minimally effective and maximum effective safe and tolerable doses. The lowest dose (2.5mg) is anticipated to be below the therapeutic threshold. Based on glucose data from DPB10003 the therapeutic dose range is expected to be between 5 mg and 30 mg/day. The highest dose (45mg) is at the higher end of the allowable clinical dose range based on current safety assessment data. Active medication will be provided as capsules (2.5mg and 15mg strengths) with matching placebo. Each subject will receive the same number of capsules per dose.

An Independent Data Monitoring Committee (IDMC) will be utilized during the study. The committee will be composed of members external to GSK. The objective of the committee is to monitor safety data (e.g., clinical chemistry, adverse events) on an on-going basis to ensure maximal safety for recruited subjects and maintain integrity of the data. The approved IDMC charter will be on file and available for inspection as requested.

2. OBJECTIVE(S)

2.1. Main Phase

2.1.1. Primary

- To evaluate the dose response and efficacy of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), versus placebo on the change in HbA1c after 12 weeks of dosing in subjects with T2DM.

2.1.2. Secondary

- To investigate the safety and tolerability of a range of doses of GW823093 versus placebo over 12 weeks of dosing in subjects with T2DM.
- To evaluate the effect of a range of doses of GW823093, versus placebo, on glycemic parameters (HbA1c, fasting plasma glucose (FPG), fasting fructosamine), fasting insulin and serum lipid profile during 12 weeks of dosing in subjects with T2DM.

- To characterize the pharmacokinetics of GW823093 in type 2 diabetic subjects after chronic administration using a combined sparse and serial sampling scheme, and to investigate pharmacokinetic/pharmacodynamic relationships (e.g. safety and efficacy endpoints).
- To evaluate the effect of a range of doses of GW823093 on DPP-IV inhibition as part of population PK assessment

2.2. Extension Phase-Objectives

- To evaluate the effect of a range of doses of GW823093 on safety and tolerability (including incidence and severity of hypoglycaemia), glycemic parameters (HbA1c, FPG, fasting fructosamine), serum lipid profile, fasting insulin level, pharmacokinetics and additional biomarkers during the additional 12 weeks of dosing in subjects with type 2 diabetes No statistical comparisons are planned for the extension phase data.

2.3. Exploratory Objectives

- To evaluate plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- To evaluate the correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.
- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.
- To evaluate exploratory endpoints described in the Informed Consent including pharmacogenetics, lipomics and/or proteomics. Pharmacogenetics data will be collected to investigate the potential influence of genetic variation on glycemic control after GW823093 treatment. Samples will be taken and frozen for future analysis as described in the Informed Consent Document.

3. ENDPOINT(S)

3.1. Main Phase

3.1.1. Primary-Main Phase

- Change from baseline (Week 0) in HbA1c at Week 12.

3.1.2. Secondary-Main Phase

- Change from baseline (Week 0) in HbA1c at Weeks 4 and 8.
- Change from baseline (Week 0) in FPG at Weeks 1, 2, 3, 4, 6, 8 and 12

- Proportion of subjects who achieve various HbA1c (≤6.5%, < 7% and ≤ 8%) and FPG (< 126mg/dL [7.0mmol/L] and < 140mg/dL [7.8mmol/L]) targets, and/or achieve a clinically meaningful decrease in HbA1c (≥ 0.7%) and FPG (≥ 30mg/dL [1.7mmol/L]).
- Change from baseline (week 0) in fructosamine (total and corrected for protein), fasting serum insulin, pro-insulin and pro-insulin:insulin ratio at Weeks 4, 8 and 12
- Population PK parameters of GW823093 including clearance (CL) and volume of distribution (V) with assessment of demographic covariates influencing GW823093 PK. Dependent on the final compartmental model describing GW823093 disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK

3.1.3. Other Metabolic Endpoints-Main Phase

- Percent change from baseline (Week 0) in fasting lipids (triglycerides, FFAs, TC, LDL-c, HDL-c) based on log-transformed data at Weeks 4, 8, and 12.

3.1.4. Safety-Main Phase

- Safety and tolerability, assessed by the incidence and severity of adverse events over the course of the Main Phase.
- Hematology, urinalysis and clinical chemistry laboratory parameters at each visit.
- Incidence and severity of hypoglycemia over the course of the Main Phase.
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic BP and radial HR at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V2, V5, V9 and V12.
- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist:hip ratio at Week 12.

3.2. Extension Phase

3.2.1. Secondary Endpoints-Extension Phase

- Safety and tolerability, assessed by the incidence and severity of adverse events over the course of the Extension Phase.
- Hematology, urinalysis and chemistry laboratory parameters at each visit.
- Change from baseline (Week 0) in HbA1c at Weeks 16, 20 and 24.

- Change from baseline (Week 0) in FPG at Weeks 13, 14, 15, 16, 20 and 24, and fructosamine (total and corrected for protein) at Weeks 16, 20 and 24, fasting serum insulin and pro-insulin at Weeks 16, 20 and 24.
- Incidence and severity of hypoglycemia over the course of the Extension Phase.
- Population PK parameters of GW823093 including clearance (CL) and volume of distribution (Vd) with assessment of demographic covariates influencing GW823093 PK. Dependent on the final compartmental model describing GW823093 disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic BP and radial HR at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 16, 24. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V16 and V18.
- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist:hip ratio at Week 24.

3.2.2. Other Metabolic Endpoints – Extension Phase

- Percent change from baseline (Week 0) in fasting lipids (triglycerides, FFAs, TC, LDL-c, HDL-c) based on log-transformed data at Weeks 16, 20, and 24.

3.3. Exploratory Endpoints-Main and Extension Phase

- Descriptive statistics of plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- Correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.
- Descriptive statistics of population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.
- Plasma and serum samples will be stored to evaluate exploratory endpoints. Examples may include pharmacogenetics, lipomics and/or proteomics and DPP-IV Inhibition.

4. STUDY DESIGN

This study will be a multi-center, randomized, double-blind, placebo-controlled, parallel-group dose-ranging study with five treatment arms conducted in two phases: the Main Phase (first 12-weeks of treatment) and an Extension Phase (second 12-weeks of treatment). Subjects with T2DM who are drug-naïve, treated with diet and exercise or on prior oral anti-diabetic monotherapy will be recruited.

The study will be comprised of six study periods: Pre-Screen, Screen, Run-In, Main Phase, Extension Phase and Post-treatment Follow-up. The Time and Events Schedule details the procedures to be performed at each study Visit (See Section 15.1, Appendix 1).

5. STUDY POPULATION

5.1. Number of Subjects

This study will be conducted in approximately 100 centres in Europe and North America. Each study center is projected to screen approximately 7 subjects and randomize approximately 4 subjects.

Based on a 52% screening failure rate, approximately 763 subjects will be screened, with a target to randomize 366 subjects into the double-blind treatment phase to generate data from at least 348 evaluable subjects.

Target recruitment will be by prior therapy with a minimum of 40% of the all randomized population being drug naïve at screening and a corresponding maximum of 60% of the all randomized population having been on oral anti-diabetic medications (OAD) at screening. Subjects on fixed-dose combination OAD therapy of any kind are not eligible for the study.

5.2. Eligibility Criteria

5.2.1. Inclusion Criteria

A subject will be eligible for inclusion in this study only if all of the following criteria apply:

1. Subjects with T2DM as defined by the criteria of the American Diabetes Association and recognized by WHO, Expert Committee on the Diagnosis and Classification of Diabetes Mellitus [American Diabetes Association, 2004a] at least 3 months preceding screening (see Section 15.8, Appendix 8, "Diagnosis and Classification of Diabetes Mellitus"). Eligible subjects must demonstrate endogenous insulin production as manifested by a fasting C-peptide level of $\geq$ 0.8 ng/mL at screening.
2. Concurrent T2DM therapy:
   - Must be diet and exercise treated

   OR

   - Not taking more than 1 oral anti-diabetic agent, and willing to stop treatment at **Screening (Visit 2)**
   - Previous diabetes monotherapy will be limited to: sulfonylureas, glitinides, biguanides, or α-glucosidase inhibitors such as acarbose. A

thiazolidinedione (TZD) is only acceptable if stopped 3 or more months prior to screening. Monotherapy with a fixed-dose combination drug is not allowed. Subjects must not have been taking any oral anti-diabetic combination therapy (including with a fixed dose combination drug) for at least 3 months prior to the screen visit.

3. Glycemic parameters:
   - HbA1c level at **Pre-screening (Visit 1)**
     - For subjects treated with oral monotherapy: ≥ 7.0% and ≤ 8.5%;
     - For subjects treated with diet and exercise only: ≥ 7.5% and ≤ 10.0%
   - Fasting glucose level at the **Screening Visit (Visit 2)**:
     - For subjects treated with oral monotherapy: FPG ≥ 140mg/dL(7.8 mmol/L) and ≤ 240mg/dL (13.3mmol/L) (Note: Subjects must have discontinued any OAD combination therapy at least 3 months prior to screening)
     - For subjects treated with diet and exercise or no therapy: FPG ≥ 140mg/dL (7.8mmol/L) and ≤ 240mg/dL (13.3mmol/L)
   - Fasting Capillary Blood Glucose (FCBG) should be the first assessment performed in the clinic at Week 0 (Visit 5). If FCBG in the clinic is > 240 mg/dL (13.3mmol/L) (after repeated), a blood sample to assess FPG should be drawn (no other Visit 5 assessments conducted at that time). The patient should be re-dispensed their remaining run-in medication and sent home to await the FPG results. Randomization and completion of all Visit 5 assessments should be delayed until measurement is confirmed by central laboratory measurement of FPG. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.
4. Men and women who are 18 to 75 years of age inclusive at the time of **Screening (Visit 2)**.
5. Body Mass Index (BMI) ≥ 24 (kg/m^2) and ≤ 40 (kg/m^2).
6. If subject is a smoker, must be able to abstain while in clinic at each visit.
7. If female, is eligible to enter and participate in this study:
   - If of non-childbearing potential (i.e., physiologically incapable of becoming pregnant (tubal ligation), including any female who is post-menopausal [> 1 year without menstrual period]); **or,**
   - If of child-bearing potential, has a negative pregnancy test at **Screening (Visit 2)** (serum) and at **Week 0 (Visit 5)** (urine and serum) and:
   - Has a male partner who is sterile prior to the female subject's entry into the study and is the sole sexual partner for that female subject, **or**

- Uses double-barrier methods of contraception; condoms (with spermicide) and IUDs are acceptable, **or**
- Uses hormonal contraceptives (oral, depots, patches etc) with double-barrier methods of contraception as outlined above, **or**
- Abstains from sexual intercourse, **or**
- Is with a same-sex partner and does not participate in bisexual activities where there is any risk of pregnancy.

8. Informed Consent: a signed and dated written consent obtained from the subject before any study related procedures are performed.

5.2.2. Exclusion Criteria

A subject will not be eligible for inclusion in this study if any of the following criteria apply:

1. Metabolic Disease including but not limited to:
   - Diagnosis of Type 1 diabetes mellitus
   - Uncorrected thyroid dysfunction. (NOTE: subjects with hypothyroidism on a stable dose of thyroid replacement therapy for at least 3 months prior to **Screening (Visit 2)**, and who have a screening thyroid stimulating hormone (TSH) within the limits of normal may participate).
   - Significant weight gain or loss (as defined as > 5% of total body weight) within the past 3 months prior to **Screening (Visit 2)**.

2 Previous use of insulin:
   - Within 3 months of screening;
   - For > 2 weeks when used for acute illness in the last 12 months prior to **Screening (Visit 2)**;
   - Used for more than 1 year when associated with gestational DM.

3. History of clinically significant cardiovascular disease including:
   - Documented myocardial infarction in the past year
   - Coronary revascularization including percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) surgery in the previous year.
   - Unstable angina
   - Clinically significant arrhythmia or valvular heart disease
   - Congestive heart failure (CHF) classified as New York Heart Association (NYHA) Class II, III or IV heart failure (see Section 15.9, Appendix 9), New York Heart Association Functional Classification)]

- Blood pressure > 150/100mmHg or HR > 100 beats/minute. Subjects using antihypertensives must be on stable doses during the 3 months prior to Screening and during the trial.
- A QTc interval ≥ 440msec in males and ≥ 450msec in females at **Screening (Visit 2).**
- Other clinically significant ECG abnormalities which, in the opinion of the Investigator, may affect the interpretation of safety and/or efficacy data, or which otherwise, contraindicates participation in a clinical trial with a new chemical entity.

4. Fasting serum triglycerides ≥400mg/dL (4.5mmol/L) at Screening (Visit 2). If a subject is receiving lipid-lowering therapy, then they must have been on the same dose of therapy for the past 3 months.
5. Is currently lactating, pregnant or actively trying to become pregnant.
6. Has a significant renal impairment as defined by serum creatinine > 2mg/dL (>176umol/L).
7. History of significant co-morbid diseases active within the last 6 months (e.g., gastrointestinal disease, etc.).
8. History of pancreatitis
9. Has a documented history of chronic or advanced hepato-biliary disease including a history of, or positive laboratory results for hepatitis at Screening (Visit 2), and/or clinically significant hepatic enzyme elevation including:
    - Any one of the following enzymes greater than 2.5 times the upper limit of the reference range (ULRR) value at **Screening (Visit 2)**
        - alanine transaminase (ALT)
        - aspartate transaminase (AST)
        - alkaline phosphatase (ALP)
        - Has a total bilirubin level that is > 1.5 times the ULRR at **Screening (Visit 2)**.
10. Has a history of alcohol or substance abuse within the past year, as determined by the Investigator or a positive urine drug screen (UDS) at Screening (Visit 2) or during treatment:
    - Unwilling to refrain from the use of excessive alcohol or illicit drugs and adhere to other protocol-stated restrictions while participating in the study.
    - History of alcohol abuse defined as an average weekly intake of greater than 21 units or an average daily intake of greater than 3 units (males) or defined as an average weekly intake of greater than 14 units or an average daily intake of greater than 2 units (females). One unit is equivalent to a half-pint of beer or 1 measure of spirits or 1 glass of wine.
    - The Investigator should exercise their medical judgement to determine if a UDS is indicated.

11. Is currently taking prohibited concomitant medications, listed in Section 15.3, Appendix 3.
12. Known allergy to any of the capsule excipients, or history of drug or other allergy, which, in the opinion of the responsible study physician, contradicts participation.
13. Received treatment with an investigational drug or participated in any other clinical trial during the previous 3 months.
14. Clinically significant anemia (i.e., hemoglobin < 12.0g/dL or < 120.0g/L for males and < 11.0g/dL or < 110.0g/L for females) or any other abnormal hematological profile that is considered by the investigator to be clinically significant.
15. In the opinion of the Investigator has a risk of non-compliance with study procedures, or cannot read, understand, or complete study-related materials, particularly the informed consent.
16. Has any concurrent condition or any clinically significant abnormality identified on the screening physical examination, laboratory tests, electrocardiogram (ECG), including pulmonary, neurological or inflammatory diseases, which, in the opinion of the Investigator, may affect the interpretation of efficacy and safety data, or which otherwise, contraindicates participation in a clinical trial with a new chemical entity.

5.2.3. Other Eligibility Criteria Considerations

To assess any potential impact on subject eligibility with regard to safety, the investigator must refer to the available document(s) for detailed information regarding warnings, precautions, contraindications, adverse events, and other significant data pertaining to the investigational product(s) being used in this study. Such documents may include but are not limited to the Clinical Investigator's Brochure (CIB) or equivalent as provided by GlaxoSmithKline (GSK).

6. STUDY ASSESSMENTS AND PROCEDURES

The following measurements and evaluations will be conducted during the trial. The study assessments and procedures are outlined in the Times and Events Table (Section 15.1, Appendix 1).

6.1. Demographic and Baseline Assessments

Demographic data will include date of birth, race, sex, height, reproductive status (for women), body weight, waist and hip circumference, and body mass index (BMI). Baseline characteristics will include a comprehensive physical examination, medical conditions and medical history including concomitant medications, alcohol and tobacco use.

A routine physical examination performed by a qualified and licensed medical professional (i.e., physician, physician's assistant or certified nurse practitioner). A complete physical exam, including a thorough review of all body systems, should be done at Visits 2, 5, 10, 12, and 18 (or early withdrawal).

6.2. Safety

Safety Assessments

- Pregnancy test (in all females)
- TSH
- Standard panels for safety (see Section 15.7, Appendix 7 for details):
  - Hematology
  - Clinical chemistry
  - Urinalysis
  - Immunochemical fecal occult blood analysis for subjects experiencing reductions in hemoglobin of ≥ 2 g/dL over the course of the study
- Incidence and severity of hypoglycemic events
- ECG read centrally and locally at V2, V5, V9, V12, V16, V18
- Blood pressure and heart rate measurements
- Body weight, waist and hip circumference and BMI

6.2.1. Hypoglycemia

All medications that lower blood glucose are capable of producing hypoglycemia or symptoms of hypoglycemia. This manifestation of hypoglycemia is variable among diabetic subjects. In addition to the symptoms that may occur in association with a low blood glucose levels, some diabetics may experience symptoms with a rapid lowering or improvement in their blood glucose control. In contrast, some diabetics with a very low glucose level may be unaware or asymptomatic.

Subjects will be provided with a Hypoglycemic Symptoms Log at each visit and will be asked to record symptoms of hypoglycemia and wherever possible, corresponding fingerstick glucose readings for each event. Subjects will also receive a Glucose Log for routine recording of glucometer readings as directed by the Investigator.

Using the Hypoglycemic Symptoms Log, the investigator is responsible for assessment and documentation of events/symptoms that are diagnostic or indicative of hypoglycemia. A separate page(s) in the eCRF is provided to capture events of hypoglycemia. These data include recording whether there were symptoms; associated blood glucose values if available; interventions, and whether there was external assistance in addition to questions to assess the events similar to those recorded for adverse events as in section 11. Information recorded by the subject but judged by the Investigator not to be hypoglycemia should be noted in the 'site comments' section of the log and recorded as an adverse experience where appropriate.

6.2.2. Pregnancy

6.2.2.1. Time period for collecting pregnancy information

Serum pregnancy testing will be conducted at the screening visit (Visit 2), randomization visit (Visit 5), week 4 (Visit 9), week 8 (Visit 11) and week 12 (Visit 12), week 16 (Visit 16), week 20, (Visit 17) and week 24 (Visit 18) or early withdrawal visit for women of childbearing potential. A urine pregnancy test will be conducted at week 0 (Visit 5) to confirm eligibility and at the follow-up **Visit 19 (Week 25)** or early withdrawal visit.

6.2.2.2. Action to be taken if pregnancy occurs

If at anytime a subject becomes pregnant while enrolled in the study she should be instructed to immediately stop taking the study medication and be discontinued from the study and scheduled for an early withdrawal visit.

The investigator will collect pregnancy information on any female subject, who becomes pregnant while participating in this study. The investigator will record pregnancy information on the appropriate form and submit it to GSK within 2 weeks of learning of a subject's pregnancy. The subject will also be followed to determine the outcome of the pregnancy. Information on the status of the mother and child will be forwarded to GSK. Generally, follow-up will be no longer than 6 to 8 weeks following the estimated delivery date. Any premature termination of the pregnancy will be reported.

While pregnancy itself is not considered to be an AE or SAE, any pregnancy complication or elective termination of a pregnancy for medical reasons will be recorded as an AE or SAE (see section 11 of the protocol and the SRM for definitions and a description of follow-up).

A spontaneous abortion is always considered to be an SAE and will be reported as such. Furthermore, any SAE occurring as a result of a post-study pregnancy and is considered reasonably related to the investigational product by the investigator, will be reported to GSK as described in section entitled, "Post-study AEs and SAEs" of the SRM. While the investigator is not obligated to actively seek this information in former study participants, he or she may learn of an SAE through spontaneous reporting.

6.2.2.3. Action to be taken if pregnancy occurs in a female partner of a male study subject

The investigator will attempt to collect pregnancy information on any female partner of a male study subject who becomes pregnant while participating in this study. The investigator will record pregnancy information on the appropriate form and submit it to GSK within 2 weeks of learning of the partner’s pregnancy. The partner will also be followed to determine the outcome of the pregnancy. Information on the status of the mother and child will be forwarded to GSK. Generally, follow-up will be no longer than 6 to 8 weeks following the estimated delivery date. Any premature termination of the pregnancy will be reported.

6.3. Efficacy

Glycemic Assessments

- HbA1c, FPG and fructosamine

Other Pharmacodynamic/Metabolic Assessments

- DPP-IV inhibition, fasting insulin, pro-insulin, pro-insulin:insulin ratio, fasting lipids (triglycerides, FFAs, TC LDL-c, HDL-c)

Exploratory Assessments

- Plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the main phase.
- Correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the main phase.
- Population cardiac biomarkers; CK-MB and cTnI at each collection time point in the main and extension phases.
- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples. Samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

6.4. Pharmacokinetics

Accurate recording of dosing and sample collection times is critical. The date and time of all doses administered in the clinic will be recorded. On days when pre-dose PK samples are collected, the date and time of the most recent dose of study medication prior to sample collection will be recorded. The actual sample collection times must be recorded accurately in the eCRF. This study has both sparse PK and serial PK components. Those subjects participating in the serial PK regimen do not participate in the sparse PK sampling and the sparse PK subjects do not participate in the serial PK testing. Only those subjects participating in the serial PK component will participate in the meal challenge assessment and associated pharmacodynamic testing. The Time and Events Schedule details the PK procedures to be performed at each study Visit (See Section 15.6, Appendix 6).

Sparse Sampling Population:

In the sparse sampling population a total of 6 blood samples, 2mL each will be obtained over the course of the study for determination of GW823093 plasma concentrations and DPP-IV inhibition. For each PK sampling visit a sampling interval has been defined. PK samples may be collected at any time during the defined sampling intervals. An effort

should be made to ensure that samples are not consistently collected at the same time point within a defined collection interval.

This study provides flexible options for scheduling of most sparse PK samples. This flexibility is incorporated to improve subject convenience for sampling at later time points.

Sparse PK and DPP-IV inhibition samples will be obtained at the following times:

- A pre-dose sample will be collected on EACH of weeks 0, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.
- A single PK sample will be collected in the time interval of 0.5 to 1.5 hours post dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20.
- A single PK sample will be collected in the time interval of 2 to 4 hours post dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20.
- A single PK sample will be collected in the time interval of 6 to 10 hours post-dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20
- The options for scheduling of PK samples should be discussed with subjects at the beginning of the study to select PK sampling visits that are most convenient for each subject.

Serial PK Sampling Population (at selected sites in North America):

Serial PK assessments will be done during the main phase of the study at Week 0 (Visit 5), Week 6 (Visit 10) and Week 12 (Visit 12). Subjects must remain in the center for the duration and refrain from eating or drinking anything except for the standard meals provided by study personnel. Approximately sixty subjects at selected centers in North America will provide a total of 30 blood samples each (2mL per sample) for serial PK and PD sampling. Samples will be obtained for determination of GW823093 plasma concentrations, DPP-IV inhibition, active/intact GLP-1 and post prandial glucagon profiles in the serial sampling population. Samples must be collected as close to the specified times as possible.

- On Week 0 (Visit 5), Week 6 (Visit 10) and Week 12 (Visit 12) subjects will be dosed in the clinic and PK and DPP-IV activity samples will be collected at the following time points:
- Pre-dose and 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, and 8 hours post-dose.
- Subjects in the serial PK group will undergo a standard meal challenge with pharmacodynamic testing being done at specific time intervals as described in the pharmacodynamic section 6.5

- Samples for glucose, glucagon and active/intact GLP-1 will be collected prior to clinic provided meal and at 0.25, 0.5, 1, 1.5, 2, and 3 hr post each meal.
- Subjects identified for the serial PK do not take part in the population (sparse) PK sampling regimen.

6.5. Pharmacodynamics/Meal Challenge

- Subjects in the serial PK group will undergo a standard meal challenge with pharmacodynamic testing being done at specified time intervals that coincide with the serial PK samples.
- Subjects must remain in the center for the duration of the visit and refrain from eating or drinking anything except for the meals provided by study personnel.
- Serial PK visits and meal challenge assessment must begin in the morning of the scheduled visit.
- A commercially available breakfast meal will be provided and subjects instructed to begin consumption just after their pre-dose blood sample is taken. Subjects will take their dose of study medication with their morning meal. The exact time of the dosing and meal must be accurately recorded.
- Samples for glucose, insulin, glucagon and active/intact GLP-1 will be collected prior to clinic provided meal and at 0.25, 0.5, 1 ,1.5, 2, and 3 hr post each meal.

6.6. Biomarker(s)

Blood samples will be taken for the exploratory population cardiac biomarkers; CK-MB and cTnI. Additional samples will be stored for exploratory analyses of biomarkers. Any analyses will be dependent on what biomarkers are assayed. The decision to evaluate additional biomarkers will be done after the study.

6.7. Pharmacogenetics

A blood sample for PGx research will be collected from all subjects who provide informed consent. PGx activities will build on any information produced from studies DPB10002 and DPB10003 and will further explore the influence of genetic variation on glycemic control or other PD parameters after GW823093. The analysis undertaken will be limited to PGx analysis of GW823093 glycemic response or other PD response, and may include the evaluation of specific candidate genes, the conduct of a whole genome single nucleotide polymorphism (SNP) scan or other marker scan.

In addition to any blood samples taken for the clinical study, a sample of whole blood (~10mL) will be collected for the PGx research using a tube containing ethylenediamine tetraacetic acid (EDTA). The PGx sample is labeled (or "coded") with a study specific number that can be traced or linked back to the subject by the Investigator or site staff. Coded samples do not carry personal identifiers such as name or social security number. The blood sample will be taken on a single occasion unless a duplicate sample is required due to inability to utilize the original sample. It is recommended that the blood sample be

taken at the first available opportunity, but may be taken at any time while the subject is participating in the clinical study.

Instructions for the collection, labeling and storage of samples will be provided by the central laboratory.

Information regarding pharmacogenetic research is detailed in (Section 15.4, Appendix 4)

7. LIFESTYLE AND/OR DIETARY RESTRICTIONS

Beginning at the screening stage a qualified provider should counsel each subject on proper diet and exercise management for type 2 diabetic mellitus (such as the American Diabetes Association [American Diabetes Association, 2004a] current recommendations). There are no special requirements or materials covering diet or exercise related to the conduct of this study except for those subjects enrolled in the serial PK sampling population. As detailed in section 6.4 and in (section 15.6) subjects participating in the serial PK assessment must remain in the clinic for the duration of their visit and refrain from eating or drinking anything but study provided meals during their PK visits.

8. INVESTIGATIONAL PRODUCT(S)

8.1. Description of Investigational Product

GW823093 capsules are white, opaque capsules with no identifying markings, containing white to off-white beads. Capsules will be prepared to contain each dose of study medication (i.e., 2.5mg, 15mg, or placebo). The capsules are comprised of hypromellose. The capsules contain sugar spheres and hypromellose.

8.2. Dosage and Administration

Dosing cards will be provided to each study subject. Dosing directions will be reviewed with the subject at every visit beginning at Visit 3 (Run-in). Subjects will be instructed to take their dose of study medication in the morning at breakfast but no longer than 30 minutes before breakfast.

8.2.1. Run-In

At Visit 3 (Week -4) subjects will begin the run-in phase of the study and will be provided 3 bottles (Bottle A, Bottle B and Bottle C) of single-blind placebo and instructed to take 1 capsule daily from each bottle in the morning no more than 30 minutes prior to breakfast. The run-in period lasts for 4 weeks. If the subject is unable to take a dose, or forgets to take a dose, they should continue to take the drug at their next meal and should not take a “catch-up” dose. On mornings when the subjects come in to the clinic for a fasted visit (Visit 4 Week -2), they should take their medication with them to the clinic and take their medication when instructed by study personnel. They should

refrain from eating or drinking anything but water until instructed to do so by study personnel in the clinic.

8.2.2. Treatment

Subjects who remain eligible and successfully complete the run-in phase will proceed into the randomized double-blind treatment phase of the study. At the baseline Visit 5 (Week 0) subjects will de dispensed 3 bottles (Bottle A, Bottle B and Bottle C) of double-blind study medication and instructed to take 1 capsule daily from each bottle in the morning no more than 30 minutes prior to breakfast. If the subject is unable to take a dose, or forgets to take a dose, they should continue to take the drug at their next meal and should not take a "catch-up" dose. On mornings when the subjects come in to the clinic for a fasted visit (Visit 4 Week -2), they should bring their medication to the clinic but NOT take their medication and should refrain from eating until instructed to do so by study personnel in the clinic.

Subjects will be randomized, with stratification for gender and prior therapy (drug naïve or oral monotherapy) in a 1:1:1:1:1:1 ratio to receive double-blinded placebo or one of the five doses of GW823093 once daily for the duration of the treatment period.

8.3. Dose Rationale

The dose range for this study was determined by examining the preliminary results of multiple dose studies that have been completed and are currently being analysed from healthy volunteers and subjects with T2DM. The planned doses of 2.5, 7.5, 15, 30 and 45mg target a range of DPP-IV inhibition profiles and exposures to GW823093. The dose range is designed to determine both minimally effective and maximum effective safe and tolerable doses. The lowest dose is anticipated to be below the therapeutic threshold. Based on glucose and other pharmacodynamic data from DPB10003 the therapeutic dose range is expected to be between 5 mg and 30 mg/day.

The highest proposed dose (45mg) has recently been assessed in a 10-day repeat dose study in healthy subjects (DPB102875). This study was the first to evaluate the safety, tolerability and pharmacokinetics of multiple doses (10 days) of a 45 mg dose of GW823093. Twenty-nine healthy volunteers were enrolled and preliminary listings of reported blinded adverse events are available for analysis. Adverse events were reported by 18 (67%) subjects. Headache, lightheadedness and diarrhea were the most commonly reported adverse events. One individual was discontinued from the study due to left flank pain and dysuria. The symptoms resolved in one day and the subject refused additional diagnostic tests required for analysis of nephrolithiasis. Another individual developed severe nausea and emesis but was able to complete the study. Full evaluation of unblinded safety will be completed in ensuing weeks, but based upon review of blinded data, no events are expected to preclude inclusion of 45mg doses in larger Phase 2/3 trials.

The PK profiles in health subjects and subjects with type 2 diabetes appear similar. Thus, the GW823093 exposures from the current study are expected to be similar to those obtained previously in multiple-dose studies in healthy subjects. In Study DPB10001

subjects received single oral doses of GW823093 ranging from 2.5mg to 50mg. Exposures increased greater-than-dose-proportionately across this dose range. A single dose of 50mg administered to fasted healthy subjects resulted in a geometric mean AUC (0-24h) and Cmax of 7422ng.h/mL and 653ng/mL, respectively. In study DPB10002 GW823093 was administered to healthy volunteers as single daily doses of 5mg, 15mg, or 30mg GW823093 for 13 days. At steady-state, geometric mean AUC (0-24h) and Cmax following a 30 mg dose were approximately 5181ng.h/mL and 406ng/mL, respectively. In healthy subjects over 13 days of dosing GW823093 accumulated relative to Day 1. By day 13 AUC (0-24h) and Cmax had increased by ~30 and ~19%, respectively. In T2DM subjects minimal accumulation was observed (~11%) following 7 days of dosing.

The NOAEL exposure limit has been set by non-clinical toxicology findings in a 14-day mouse study. At the NOAEL dose in this study, AUC(0-24h) and Cmax were 13,381 ng.h/mL and 11,223 ng/mL, respectively. In addition, 6-month non-clinical toxicology studies have been completed in the rat and dog. The rat was the most sensitive of these two species with AUC(0-24) and Cmax of 25,502 ng.h/mL and 6,879 ng/mL

Preliminary PK data at steady-state from study DPB102875 (45 mg QD) were used to simulate the AUC(0-24h) and Cmax distributions in a large population (4000 subjects simulated). Simulations were performed based on mean exposures and variability observed in DPB102875 (log-normal distribution assumed). For AUC(0-24h), ~0.3% of subjects are predicted to exceed NOAEL limits in the 14-day mouse study. The maximum AUC(0-24h) observed in these simulations was 14,522ng.h/mL (~9% above the NOAEL AUC(0-24h)). No subjects are predicted to exceed the NOAEL Cmax limit following a 45 mg dose. The maximum Cmax observed in these simulations was 1,548 ng/mL (~7.3 –fold below the NOAEL Cmax).

Predicted Steady-State Exposures and Cover Relative to NOAEL[1]

Dose (mg)	Predicted Median AUC(0-τ)	Fold-Cover Relative to Median Predicted AUC(0-τ)	Predicted Maximum AUC(0-τ)	Fold-Cover Relative to Maximum predicted AUC(0-τ)
		AUC(0-τ) (ng.h/mL)		
2.5	244	55	431	31
5	488	27	862	16
7.5	732	18	1,293	10
15	2,187	6	5,079	3
30	5,134	3	10,609	1.3
45[2]	8,379	2	14,522	0.9[†]
		Cmax (ng/mL)		
Dose (mg)	Predicted Median Cmax	Fold-Cover Relative to Median Predicted Cmax	Predicted Maximum Cmax	Fold-Cover Relative to Maximum Predicted Cmax
2.5	39	289	126	89
5	77	146	266	42
7.5	117	96	377	30
15	261	43	937	12
30	551	20	1,579	7.1
45	841	13	1,548	7.3

1. NOAEL AUC(0-τ) = 13,381 ng.h/mL; NOAEL Cmax = 11,223 ng/mL
2. Approximately 0.3% of subjects are predicted to exceed NOAEL AUC(0-τ) at the 45mg dose level

8.4. Blinding

Only in the case of an emergency, when knowledge of the investigational product is essential for the clinical management or welfare of the subject, the investigator may unblind a subject's treatment assignment. The investigator will, whenever possible, discuss options with the Medical Monitor, on-call physician, or appropriate GSK study personnel before unblinding. If the blind is broken for any reason and the investigator is unable to contact GSK prior to unblinding, the investigator must notify GSK **as soon as possible following** the unblinding incident **without revealing the subject's study treatment assignment,** unless the information is important to the safety of subjects remaining in the study. In addition, the investigator will record the date and reason for revealing the blinded treatment assignment for that subject in the appropriate data collection tool.

If a serious adverse event (SAE; as defined in Section 11.2, "Definition of an SAE") is reported to GSK, Global Clinical Safety and Pharmacovigilance (GCSP) staff may unblind the treatment assignment for the individual subject. If an expedited regulatory report to one or more regulatory agencies is required, the report will identify the subject's

treatment assignment. When applicable, a copy of the regulatory report may be sent to investigators in accordance with relevant regulations, GSK policy, or both.

8.5. Treatment Assignment

Subjects will be assigned to study treatment in accordance with the randomization schedule. The randomisation code will be generated using the GSK randomisation system RandAll. Subjects will be allocated to the 6 treatment groups in a 1:1:1:1:1:1 ratio. The randomisation will be stratified based on gender and prior therapy (drug naïve or oral monotherapy). A fixed block size will be used, but will remain confidential. Central randomization will be used (i.e. blocks will be applied globally from one central list).

At Visit 5, each subject will be randomized by the GSK Randomization and Medication Ordering System (RAMOS). GSK RAMOS is a telephone based interactive voice response system which will randomise the subject and direct the investigator to assign the appropriate subject kit to each subject. Detailed instructions for the use of RAMOS will be provided to each site in the Study Reference Manual. The general process for registering, randomising and ordering medication is as follows:

At Visit 1 (Pre-screening), the investigator or designate will telephone RAMOS to Register the patient. Eligible subjects will be dispensed 3 bottles of single-blind Placebo run-in medication at the run-in visit 3 (WK-4).

At every subject visit thereafter center personnel must call RAMOS to inform GSK of subject progression in the study. Calls into RAMOS at the dispensing **Visits 9, 11, 12, 16 and 20** will be used to dispense appropriate container numbers to the subjects and will serve the dual purpose of informing GSK of subject progress and generating dispensing information for study medication according to the randomization scheme.

At Visit 5, Investigator or designee will call RAMOS to randomise the subject. RAMOS will assign the randomisation number and appropriate medication container numbers verbally. This will be confirmed by fax. The appropriate container number(s) can then be assigned to the subject and medication bottle(s) dispensed.

If a patient withdraws at any time after they have been registered in RAMOS at Visit 1, the investigator or designee will call RAMOS to notify GSK of the withdrawal.

8.6. Packaging and Labeling

CTM will be packaged and labeled in accordance with all applicable regulatory requirements. Study medication will be provided in 45cc HDPE bottles with child resistant caps containing a 35 capsule fill count (equivalent to 4 weeks of treatment plus a 7 capsule overage per bottle) of either placebo for GW823093, GW823093 2.5mg, or GW823093 15mg. Each bottle of study medication will be labeled and packed with a desiccant. All labels will contain the name of the sponsor, the sponsor's address, the protocol number, storage conditions and the dosage directions, "Take ONE capsule daily." In addition, each double-blind bottle will be labeled with a unique 6-digit container number.

During the run-in period, subjects will receive 3 bottles, all containing placebo (which will match GW823093 capsules). At the baseline visit and all subsequent dispensing visits (including those occurring during the extension phase), subjects will receive 3 bottles of study medication, such that taking one capsule from each bottle daily will provide the appropriate dose to the subject (i.e., placebo, 2.5mg, 7.5mg, 15mg, 30mg, or 45mg).

8.7. Handling and Storage

Investigational product must be dispensed or administered according to procedures described herein. Only subjects enrolled in the study may receive investigational product, in accordance with all applicable regulatory requirements. Only authorized site staff may supply or administer investigational product. All investigational products must be stored in a secure area with access limited to the investigator and authorized site staff and under physical conditions that are consistent with investigational product-specific requirements. GW823093 capsules must be stored at controlled room temperature (up to 30 °C).

8.8. Product Accountability

The investigator, institution, or the head of the medical institution (where applicable) is responsible for investigational product accountability, reconciliation, and record maintenance. In accordance with all applicable regulatory requirements, the investigator or the head of the medical institution (where applicable), or designated site staff (e.g., storage manager, where applicable) must maintain investigational product accountability records throughout the course of the study. The responsible person(s) will document the amount of investigational product received from and returned to GSK (when applicable), the amount supplied and/or administered to and returned by subjects, if applicable.

8.9. Assessment of Compliance

Subject compliance with study medication will be assessed at every visit except for Visit 1, Visit 2 and Visit 3. Compliance is calculated based on the number of capsules dispensed and the number returned and the days between the date dispensed and the date returned. Calculated percent compliance will be entered into the designated section of the eCRF at each visit where it is assessed. If the subject is calculated to be less than 80% compliant with study medication the subject should be counseled by appropriate study personnel. If the subject remains less than 80% compliant for two consecutive visits the subject should be discontinued and the early withdrawal procedures followed.

8.10. Treatment of Investigational Product Overdose

There is no specific antidote for an overdosage of GW823093. In the event of an actual or suspected overdose individuals should be referred to an appropriate facility and managed with supportive therapy as determined necessary by the treating physician. The GSK Medical Monitor should be contacted immediately. Overdosage should be recorded

as an Adverse Event and the individual followed appropriately until full resolution is documented. Adverse Events that occur as a result of the overdose must be recorded.

8.11. Occupational Safety

Investigational product is not expected to pose significant occupational safety risk to site staff under normal conditions of use and administration. A Material Safety Data Sheet (MSDS)/equivalent document describing occupational hazards and recommended handling precautions either will be provided to the investigator, where this is required by local laws, or is available upon request from GSK.

9. CONCOMITANT MEDICATIONS AND NON-DRUG THERAPIES

9.1. Permitted Medications

All concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 3 months prior to screening and throughout their participation in the study unless a dose adjustment is medically necessary to manage the subject during the trial.

9.2. Medications Requiring Wash-out/Prohibited Medications

Subjects must not use any of the following medications during the course of the study; however, if they are taking them at the time of Screening, they should be discontinued and washed off of them during the 4-week run-in period:

- Oral anti-diabetic agents: Subjects who have received a thiazolidinedione (TZD) within the 3 months prior to Screening (**Visit 2**).
- Insulin (Per exclusion criteria)
- Subjects on warfarin or digoxin will not be allowed to participate in this study. Subjects must not be washed off of these medications for the purposes of meeting eligibility criteria.
- Oral anticoagulants (other than aspirin and non-steroidal anti-inflammatory drugs).
- Oral or injectable corticosteroids (other than inhaled and intranasal).
- Monoamine oxidase inhibitors and tri-cyclic amines
- Antiretroviral drugs
- Prescription and over-the-counter weight loss drugs

A full listing of prohibited concomitant medications is listed in Section 15.3, Appendix 3. All concomitant medications must be fully recorded in the appropriate section of the eCRF.

9.3. Non-Drug Therapies

The Principal Investigator should exercise their medical judgment to decide if non-prescription (OTC) medications or preparations have the potential to affect the subjects' response with respect to the endpoints of or their participation in the study. If OTC compounds have such potential then they should be discontinued and recorded in the concomitant medication section of the eCRF.

10. SUBJECT COMPLETION AND WITHDRAWAL

10.1. Subject Completion

All subjects will be considered to have completed the study if they have taken at least 24 weeks of therapy and completed the assessments for Visit 18. The follow-up visit at week 25 (Visit 19) is required in the study but is not a pre-requisite for designation in the completers population. Subjects completing only the Main phase of the study will also be summarized.

10.2. Subject Withdrawal

10.2.1. Subject Withdrawal from Study

Any subject, who enters the study, (i.e., gives written informed consent) but does not, **for any reason,** complete the study according to the definition given above, will be considered as a withdrawal, irrespective of whether they have received any study medication.

Enrolment will continue until approximately 366 subjects have been randomized into the study. At this time, recruitment will cease. Each subject participating in the study will be assigned a unique CRF/subject number.

Every effort should be made to follow up subjects who withdraw or are withdrawn from the study prematurely. For subjects who withdraw **prior to randomization** (i.e., during the Run-in), complete the Baseline Conclusion page in the CRF. If the withdrawal occurs at a scheduled visit, complete that visit. If a subject withdraws at any other time following randomization, complete the assessments for the Week 24 / Early Withdrawal Visit. At the subject's final visit, collect any unused study medication and record the date of the last dose taken. Study medication provided to the withdrawn subjects will not be reused. Safety assessments may be performed at the discretion of the Investigator.

Subjects who terminate their participation in the study due to adverse experiences should be followed up as appropriate in order to determine the final outcome.

10.2.2. Subject Withdrawal from Investigational Product

Every effort should be made to keep subjects in the study. However, a subject may be discontinued prior to completion of the study for the following reasons:

- Subjects who have a FPG > 270 mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, or 18 will be asked to return to the clinic as soon as possible for a retest. If the FPG remains >270 mg/dL (15.0mmol/L) upon retest, the subject must be withdrawn from the study. -Subjects with an FPG >270 mg/dL (15.0mmol/L) (confirmed with re-test) at Visit 12 (week 12) will not be permitted to enter the Extension phase.
- Subjects who have cTnI values >0.35 ng/mL should be contacted as soon as possible for withdrawal from study and further evaluation. Additional evaluation should include central cTnI and ECG as well a local sample to be assayed for cTnI. Concomitant to this assessment, all subjects should be evaluated by a local cardiologist; this evaluation is particularly urgent if local cTnI is elevated. At a minimum, evaluation of the left ventricular function should be undertaken in all subjects and depending on locally available modalities, this could include an echocardiogram or a radionuclide ventriculography. Other diagnostic modalities could be used if necessary. Approximately 3 months after withdrawal, subjects should have a follow-up evaluation with a brief physical examination, ECG and redraw of cTnI.
- Introduction of any oral anti-diabetic medication other than study medication
- ALT or AST levels ≥ 3 times the upper limit of the reference range (ULRR) and a concurrent total bilirubin level that is ≥ 2.0x ULRR (predominantly direct), or an isolated ALT or AST ≥ 5x ULRR, all which are confirmed on repeated testing after Baseline (Visit 3)
- Adverse event which in the opinion of the investigator requires withdrawal
- Severe or repeated occurrences of hypoglycaemia which in the opinion of the investigator requires withdrawal
- Consent withdrawn
- Lost to follow-up
- Protocol violation
- Termination of study by sponsor
- Other: Document reason in CRF

For subjects who withdraw or are withdrawn from the study **after randomization**, all of the Visit 18 assessments and procedures should be completed.

CRFs of **all** subjects entered into the study must be completed and the reasons for withdrawal will be noted on the Study Conclusion page for all randomized subjects who do not complete the study. In addition, the date of last dose of study medication must be recorded on the Study Conclusion page for all subjects withdrawn from the study.

Subjects who terminate their participation in the study due to adverse experiences should be followed up as appropriate in order to determine the final outcome.

10.3. Treatment After the End of the Study

Following completion of the study and cessation of study medication subjects will be asked to return to the center for a follow-up visit Week 25 (Visit 19). All subjects should be advised (referred as necessary) to follow-up with their primary care physician for proper management of T2DM.

10.4. Screen and Baseline Failures

Subjects who are considered pre-screen, screen and baseline failures due to ineligibility should be referred to their primary care physician for proper management of their T2DM.

11. ADVERSE EVENTS (AE) AND SERIOUS ADVERSE EVENTS (SAE)

The investigator is responsible for the detection and documentation of events meeting the criteria and definition of an AE or SAE, as provided in this protocol. During the study when there is a safety evaluation, the investigator or site staff will be responsible for detecting, documenting and reporting AEs and SAEs, as detailed in this protocol.

11.1. Definition of an AE

Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Note: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse.

11.1.1. Events of Hypoglycemia

Events of hypoglycemia per se will not be reported as an AE, but are to be reported as Serious Adverse Events if they fulfil the definition. All hypoglycemia events are recorded on the “Hypoglycemia Event Page

11.2. Definition of a SAE

A serious adverse event is any untoward medical occurrence that, at any dose:

a) Results in death

b) Is life-threatening

NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death, if it were more severe.

c) Requires hospitalization or prolongation of existing hospitalization

NOTE: In general, hospitalization signifies that the subject has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out-patient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious.

Hospitalization for elective treatment of a pre-existing condition that did not worsen from baseline is not considered an AE.

d) Results in disability/incapacity, or

NOTE: The term disability means a substantial disruption of a person's ability to conduct normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (e.g. sprained ankle) which may interfere or prevent everyday life functions but do not constitute a substantial disruption.

e) Is a congenital anomaly/birth defect

f) Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the subject or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also be considered serious. Examples of such events are invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse.

11.2.1. Clinical Laboratory Abnormalities and Other Abnormal Assessments as AEs and SAEs

Abnormal laboratory findings (e.g., clinical chemistry, hematology, and urinalysis) or other abnormal assessments that are judged by the investigator as **clinically significant** will be recorded as AEs or SAEs if they meet the definition of an AE or SAE. Clinically significant abnormal laboratory findings or other abnormal assessments that are detected during the study or are present at baseline and significantly worsen following the start of the study will be reported as AEs or SAEs. However, clinically significant abnormal laboratory findings or other abnormal assessments that are associated with the disease being studied, unless judged by the investigator as more severe than expected for the subject's condition, or that are present or detected at the start of the study and do not worsen, will **not** be reported as AEs or SAEs.

The investigator will exercise his or her medical and scientific judgment in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

11.3. Time Period, and Frequency of Detecting AEs and SAEs

From the time a subject consents to participate in the study until he or she has completed the study (including any follow-up period), all SAEs assessed as related to study participation (e.g., protocol-mandated procedures, invasive tests, or change in existing therapy) or related to a GSK concomitant medication, will be reported promptly to GSK.

11.4. Prompt Reporting of SAEs to GSK

SAEs will be reported promptly to GSK as described in the following table once the investigator determines that the event meets the protocol definition of an SAE.

11.4.1. Timeframes for Submitting SAE Reports to GSK

	Initial SAE Reports		Follow-up Information on a Previously Reported SAE	
Type of SAE	Time Frame	Documents	Time Frame	Documents
ALL SAE's	24 hours	Designated SAE eCRF pages	24 hours	Updated SAE eCRF pages
All SAEs	24 hrs	"SAE" data collection tool	24 hrs	Updated "SAE" data collection tool

11.5. AE and SAE Documentation and Follow-up Procedures

The investigator will review and adhere to the following procedures, which are outlined in detail in the AE/SAE section of the SRM:

- Method of Detecting AEs and SAEs
- Recording of AEs and SAEs
- Evaluating of AEs and SAEs
- Completion and Transmission of SAE Reports to GSK
- Follow-up of AEs and SAEs
- Post-study AEs and SAEs
- Regulatory Reporting Requirements for SAEs

12. DATA ANALYSIS AND STATISTICAL CONSIDERATIONS

12.1. Hypotheses

This study is designed to show that at least one of the GW823093 groups is superior to placebo. The null hypothesis for the primary endpoint analysis is that there is no difference in terms of change from baseline to Week 12 (Visit 12) in HbA1c in any active group compared to placebo. The alternative hypothesis is that there is a difference. Significance tests will be two-sided.

12.2. Study Design Considerations

12.2.1. Sample Size Assumptions

The sample size of 58 evaluable subjects per treatment group (61 allowing for 5% unevaluable for primary endpoint assessment) is based on a LOCF analysis of the difference between GW823093 and placebo with regards to change from baseline in HbA1c at Week 12. It is calculated to achieve a precision in estimating the treatment effect of 0.8% for the 95% confidence interval, assuming a standard deviation of 1.1%. The calculated sample size provides 93% power to detect a clinically relevant treatment difference of 0.7%. All statistical tests will be performed using two-sided tests of significance and at the 5% level.

Subjects will be centrally randomized to treatment. This randomization will be stratified by gender and prior therapy (drug naive/monotherapy subjects).

12.2.2. Sample Size Sensitivity

The effects of changes in the assumed of standard deviation on the precision in estimating the treatment effect (measured by the width of the 95% confidence interval), the treatment difference that can be detected with 90% power and the power to detect a clinically relevant difference of 0.7%, based on a sample size of 58 per treatment arm, are all summarized in the Table 1 below.

Table 1 The effects of changes in the assumption of standard deviation

STANDARD DEVIATION (%)	PRECISION IN ESTIMATING TREATMENT EFFECT (WIDTH OF 95% CONFIDENCE INTERVAL) (%)	TREATMENT DIFFERENCE THAT CAN BE DETECTED WITH 90% POWER (%)	POWER TO DETECT CLINICALLY RELEVANT DIFFERENCE OF 0.7% WITH 58 SUBJECTS PER ARM (%)
0.9	**0.66**	**0.54**	**99**
1.0	**0.73**	**0.60**	**96**
1.1	0.80	0.66	93
1.2	**0.87**	**0.72**	**88**
1.3	**0.95**	**0.78**	**83**
1.4	**1.02**	**0.84**	**77**

12.2.3. Sample Size Re-estimation

No sample size re-estimation is planned for this study.

Enrollment may be extended to ensure that at least 40% of subjects are drug naïve.

12.3. Data Analysis Considerations

12.3.1. Analysis Populations

The following populations will be assessed.

Safety Population. This population consists of all randomized subjects who received at least one dose of study medication. This population will be used for assessing safety.

Intent-to-Treat Population (ITT). This population will consist of all randomized subjects who received at least one dose of study medication, have a baseline assessment and have at least one corresponding on-therapy efficacy assessment. This will be the primary population for assessing efficacy.

Per Protocol Population (PP). This population will consist of any ITT subjects who are compliant with protocol-specific criteria (see RAP for more details of exclusion criteria). The Per Protocol population will be used for a supporting analysis of the primary endpoint comparison only. The Per Protocol population will not be analyzed if this population comprises of more than 95% of the ITT population.

Serial PK Population (SPK). This population will consist of those subjects undergoing serial PK testing and meal challenge testing who have at least one post-baseline assessment. This population will be restricted to North American centers (US & Canada) and is expected to involve approximately sixty (60) subjects at twenty (20) centers in North America.

Sparse PK Population (PPK). This population will consist of those subjects assigned to the sparse (population PK) group. All consenting subjects will be eligible for inclusion in the sparse PK population except for those subjects participating in the serial PK assessment. The target number of subjects in the sparse population is approximately 300 (three-hundred) subjects in North America and Europe.

12.3.2. Analysis Data Sets

Two datasets for the statistical analysis for efficacy will be formed based on the Intent-to-treat (ITT) population. The primary set will use the ITT population with last observation carried forward (LOCF) for withdrawn subjects or missing values, while the secondary dataset will use the ITT population without LOCF where missing on-therapy values will remain missing.

12.3.3. Treatment Comparisons

12.3.3.1. Primary Comparisons of Interest

The primary objective of the study will be assessed through tests of hypotheses. The primary endpoint is change from baseline to Week 12 in HbA1c which will be compared between each GW823093 group and placebo.

The primary analysis will be performed on the Intent-to-Treat Population with LOCF (see Section 12.3.1 & Section 12.3.2 for definition of this population and the data to be used).

To address the issue of multiplicity, inferences from the study will be based on a closed testing procedure. The highest dose, GW823093 45mg, will be assessed first, in comparison to placebo. This will be tested at 5% significance level. If this comparison is significant, then the comparison of the GW823093 30mg dose to placebo will also be interpreted at 5% level, this process will continue, going down through all the doses until the first non-significant test is reached. With this approach, no adjustment to the significance level at each step is needed.

12.3.3.2. Other Comparisons of Interest

The primary comparison described above will also be performed using ITT population where missing values remain missing (See Section 12.3.2) and a further comparison where repeated measures is used may also be considered. Detail for all other formal comparisons of interest are given in Section 12.3.5.1.

12.3.4. Interim Analysis

No interim analysis is planned for this study.

An external independent Statistician will produce the summaries required for the IDMC. Details of the procedures and summaries to be produced will be specified in the Charter for the Safety Review Committee (SRC) for this protocol.

12.3.5. Key Elements of Analysis Plan

Results from the main double-blind study (initial 12 weeks) and the extension phase (subsequent 12 weeks) will be described in separate clinical study reports.

The extension will be ongoing at the time the main study results are reported but its conduct will not depend on these results. Treatment assignment details for individual subjects will not be made available to participating sites until the extension is complete. However, it will be necessary for GSK personnel involved in reporting the main study to have access to this information and as such, there will be a degree of unblinding for the extension. This does not compromise the primary analyses of efficacy and safety data which will all be performed within the main study.

The analyses planned in this protocol for the main and extension study will be expanded in the Reporting and Analysis Plan. This will be completed prior to unblinding the study.

Any deviations from the analyses described in the protocol will be described in the Reporting and Analysis Plan and final Study Report as appropriate.

Definition of country/geographical region will be included in the Reporting and Analysis Plan. This is included as a factor in the primary analysis model.

12.3.5.1. Subgroup Analyses

Subgroup summaries/analyses by previous treatment (drug naive/monotherapy subjects) and gender will be produced for the primary and some secondary endpoints. As the subgroup analysis is considered exploratory, no adjustment for multiplicity will be made.

12.3.5.2. Missing data

Analysis of the Intent-to-treat and if necessary the Per protocol population will be performed using a LOCF approach, carrying forward the last non-missing post-baseline assessment for subjects prematurely discontinued from the study and for subjects with ad-hoc missing data.

For some endpoints, an additional analysis will be performed to check the sensitivity of the results. In this approach, missing values at post-baseline assessments are not replicated and are regarded as missing.

For some endpoints, an additional repeated measures analysis may be performed to check the sensitivity of the results. This approach is a model based method over time.

12.3.5.3. Derived and Transformed data

The body mass index for each subject will be defined as the weight (kg), at screening, divided by the height (m) squared.

The waist:hip ratio will be defined as the waist circumference (cm) divided by the hip circumference (cm).

Endpoints will be log-transformed prior to analysis where this will improve the assumptions underlying the analysis of covariance.

12.3.5.4. Assessment windows

The Reporting and Analysis Plan will include details of assessment windows and the visit slotting algorithm.

12.3.5.5. Efficacy Analyses

12.3.5.5.1. Primary Analysis

The primary objective of comparing the change in HbA1c from baseline at Week 12 between each of the five GW0823093 treatment groups and the placebo group will be performed by using a (5% two-sided) hypothesis test. This test will be based on an analysis of covariance model with terms for gender, prior therapy (drug naïve/monotherapy), treatment, country/region and baseline measurement (continuous covariate). The point estimates and corresponding 95% confidence intervals for treatment differences from placebo will be calculated. To address the issue of multiplicity, a closed testing procedure will be used (see Section 12.3.3.1). The treatment-by-baseline, treatment-by-country/region, treatment-by-prior-therapy and treatment-by-gender interactions will be investigated at a significance level of 0.10 but interactions will not be included in the main model where treatment effects are tested and compared.

Although the study conclusion regarding the primary comparison of interest will be based on analysis in the ITT with LOCF population, the primary efficacy analysis will also be performed on the ITT without LOCF population, the PP population with LOCF and potentially the ITT population without LOCF using repeated measures.

An investigation into the dose-response curve will also be conducted. Tests for linear, quadratic and cubic trends will be made using orthogonal contrasts. Full details will be provided in the Reporting and Analysis Plan.

12.3.5.5.2. Secondary Analysis

Main Study (Initial 12 Weeks)

For all secondary efficacy parameters, the comparisons of interest will be between GW823093 treatment groups and the placebo group.

To assess the difference between treatment groups with regard to change from baseline to Week 12 in FPG, fructosamine (total and corrected for protein), fasting insulin and pro-insulin, an analysis of covariance with terms for gender, prior therapy, treatment, country/region and baseline will be performed. The point estimates and corresponding 95% confidence intervals for treatment differences will be calculated.

HbA1c, FPG, fructosamine (total and corrected for protein), fasting insulin and pro-insulin will also be summarized at each treatment week where data is collected.

Responder Analysis

Differences between treatment groups in the proportion of subjects who achieve various HbA1c (≤6.5%, <7%, and ≤ 8%) and FPG (<126mg/dL [7.0mmol/L] and <140mg/dL [7.8mmol/L]) targets, and/or achieve a clinically meaningful decrease in HbA1c (≥ 0.7%) and FPG (≥ 30mg/dL [1.7mmol/L]) at Week 12 will be assessed based on a logistic regression model with terms for treatment, gender, prior therapy, and baseline measurement.

Summary statistics will be provided at each visit where data is collected by treatment group.

12.3.5.5.3. Other Efficacy Analysis

For all lipid parameters (triglycerides, FFAs, TC, LDL-c, HDL-c) the percentage change from baseline (based on log transformed data) will be summarized at each treatment week where data is collected. Formal statistical analysis will be performed at Week 12, using an analysis of covariance with terms for gender, prior therapy, treatment, country/region and log-transformed baseline. The point estimates and corresponding 95% confidence intervals for treatment ratios will be calculated. Data from the other pharmacodynamic assessments and biomarkers will be summarized as appropriate. Details of all summaries to be provided will be specified in the Reporting and Analysis Plan.

Extension Study (subsequent 12 weeks)

Once subjects have completed the main study they will continue into the double-blind extension. During the extension efficacy and safety data will be collected, (see Appendix 1, Section 15.1 'Time and Events Schedule'). Extension data will be summarized by initial randomized treatment group, namely:

- Placebo → GW823093 2.5mg
- GW823093 2.5mg → GW823093 2.5mg
- GW823093 7.5mg → GW823093 7.5mg
- GW823093 15mg → GW823093 15mg
- GW823093 30mg → GW823093 30mg
- GW823093 45mg → GW823093 45mg

No statistical analysis will be performed on the extension data. Summaries will be performed for the extension as described for the main phase in Section 12.3.5.5.2 Secondary Efficacy Analysis and Section 12.3.5.5.3 Other Efficacy Analysis. Baseline is defined as the baseline of the main study (Week 0).

An investigation into the dose-response curve for HbA1c will also be conducted on the extension data as described for the main phase in Section 12.3.5.5.1 Primary Efficacy Analysis.

12.3.5.6. Safety Analyses

All Safety analyses will be performed on the Safety population.

Safety endpoints include reported adverse events, clinical laboratory tests, hypoglycemic episodes, weight, waist and hip circumference, waist:hip ratio, BMI, cuff systolic, diastolic BP, radial HR and ECGs.

Summaries to be performed on the safety data from the main phase (initial 12 weeks) study are detailed below. As subjects will be continuing directly into the extension, any post-treatment data from the main study relates to subjects who have prematurely discontinued during that initial 12-week period.

Safety data collected during the extension phase will also be summarized as detailed below. Extension data will be summarized by initial randomized treatment group as described in Section 12.3.5.5.3 Other Efficacy Analysis.

12.3.5.6.1. Extent of Exposure

The number of days exposure to study medication will be summarized by treatment group. Subject exposure will also be categorized and the number and percentage of subjects in each category presented for each treatment group.

12.3.5.6.2. Adverse Events

AE summaries will be performed using the preferred terms and system organ class assigned by the Medical Dictionary for Regulatory Activities (MedDRA).

The proportion of subjects reporting each type of adverse event will be tabulated for each treatment group. The following summaries of adverse events will be provided:

- all adverse events
- treatment-related adverse events
- adverse events leading to withdrawal from study medication
- serious adverse events

Full details for all adverse events will be listed.

For reporting of hypoglycemic events see Section 12.3.5.6.4.

12.3.5.6.3. Clinical Laboratory Evaluations

Details of how laboratory measurements will be summarized will be given in the Reporting and Analysis Plan.

12.3.5.6.4. Other Safety Measures

Hypoglycemia

Hypoglycemic events merit special attention in the development and study of drugs for the treatment of type 2 diabetes since they are often related to the efficacy of a compound. In order to accomplish this, hypoglycemic events have been collected separately and are reported separately from adverse events, including supplemental data which is not collected for adverse events. However, any hypoglycemic event which meets the criteria for a serious adverse event will be included in the serious adverse event summaries.

The number of subjects in each group that experience a hypoglycemic event will be summarized by frequency of the events.

Details of all summaries to be provided for hypoglycemic adverse events will be specified in the reporting and analysis plan.

Vital signs

All Vital signs data will be summarized by visit and treatment group. Change from baseline will also be derived and summarized.

Electrocardiograms

All ECG data will be summarized by visit and treatment group. Change from baseline will be calculated for interval/duration data and summarized by visit and treatment group.

All ECGs will be read locally by the Investigator or his/her designate and will be forwarded electronically for central interpretation. If clinically significant, findings from locally read ECGs will be recorded by the Investigator as a medical condition (if identified at V2) or as an adverse event in the eCRF (if identified at a visit other than V2). The Investigator will also be sent a report of the central interpretation of the ECG which should be kept with the source documentation. The findings from the central report do not routinely need to be entered into the eCRF. If the central reading indicates a clinically significant ECG abnormality, this should be recorded in the medical conditions (if identified at V2) or adverse events section of the eCRF (if identified at a visit other than V2) and the subject should be appropriately managed. Centrally read ECG data will be transferred electronically to the sponsor's data management department and IDMC.

Weight, Hip and Waist Circumference, Waist:Hip Ratio, BMI

Weight (kg), hip circumference (cm), waist circumference (cm), waist:hip ratio and BMI (kg/m^2) will be summarized at each time point recorded by treatment group. Percentage change from baseline may also be derived and summarized.

12.3.5.7. Pharmacogenetic Analyses (PGx)

If at any time it appears that there is a potential unexpected or unexplained variation in drug handling or response (e.g., PK, efficacy and/or safety) that may be attributable to genetic variation, then PGx analysis may be conducted. In these circumstances the analysis undertaken will be limited to PGx analysis of response to or handling of GW823093.

Generally GSK will utilize two approaches to explore genetic variation in drug handling or response.

1. Hypothesis driven approach: A specific hypothesis is generated about sections of DNA (or individual single nucleotide polymorphisms (SNPs) or other genetic markers) that may be associated with differential drug handling or response. Specific sections of DNA may be selected from areas of the genome (e.g., candidate genes) known to encode the drug target, drug metabolizing enzymes, areas associated with mechanisms underlying adverse events, and those linked to study disease and, thus, linked to drug response.
2. Genome-wide approach utilizing polymorphic markers (e.g., SNPs): By evaluating large numbers of polymorphic markers throughout the genome, sets of markers may be identified that correspond to differential drug response or handling.

Analysis of genetic markers (e.g., whether within candidate genes or SNPs studied in a genome-wide analysis) will include the following considerations. The genotypic frequencies of each polymorphism will be evaluated for conformity to those expected under normal conditions by employing Hardy-Weinberg Equilibrium testing. Any departure from expectation will be taken into account, possibly signaling a data error or alternatively a connection between the polymorphism and T2DM.

For pairs of polymorphisms, the degree to which alleles from the two sites are correlated (linkage disequilibrium) may also be evaluated. If the genotypes at two polymorphic sites within a gene are shown to be statistically associated with a response to investigational product, the degree of linkage disequilibrium will aid interpretation in that it will indicate the extent to which the two sites are exerting independent effects.

A decision regarding the construction and analysis of marker haplotypes -- combinations of alleles from different polymorphic sites that are inherited from one parent -- may be guided by the assessment of linkage disequilibrium. For example, if there is no linkage disequilibrium between polymorphic sites, then haplotype construction will be uninformative.

Differences in baseline clinical characteristics and potential contributing covariates may be summarized and compared among genotype (or haplotype) subgroups.

Analyses may be carried out to evaluate the degree of association between subject genotype (or haplotype) and selected parameters (e.g., PK, efficacy and safety). Where such genotypic tests are inappropriate (for example, where the number of marker genotypes is too large and/or the frequency of individual genotypes too small), allelic tests may be conducted. Allelic tests evaluate whether the frequency of each marker allele is the same in responders and non-responders.

In addition to evaluating the main effects of the genotypes (haplotypes or alleles) on the selected parameters, the possibility of a treatment group by genotype (haplotype or allele) interaction may also be explored. If appropriate, the joint effects of multiple markers (gene-gene interactions) may also be evaluated.

Sample Size Considerations

The ability to detect differential drug response or handling among genotypes at a polymorphic site depends on the total number of subjects genotyped and the frequency distribution of the different genotypes. Consequently, genotyping analyses are plausible for those polymorphic sites where the number of subjects comprising the genotypic groups is sufficiently large; however, these frequencies will not be known until sufficient samples have been collected and genotyping is complete.

Estimates of sample sizes required to demonstrate genotype effects vary considerably, depending on the assumptions made about allele frequency, genetic effect size, and mechanism of inheritance [Cardon, 2000]. In the work by Palmer and Cookson [Palmer, 2001], which assumed a genotype relative risk of 1.5, it was estimated that more than 300 cases and 600 controls would be needed to conduct a genetic association analysis. In contrast, McCarthy and Hilfiker [McCarthy, 2000] showed that with a genotype relative risk of 2.16 and a relatively commonly occurring genotype, only 30 cases and 30 controls would be needed to demonstrate an association. Consequently, it is quite possible that effects with relatively large genotype relative risks may be detectable in individual Phase I or Phase II studies. A range of examples exist to demonstrate robust and clinically relevant PGx data may be generated from PGx studies with sample sizes far less than the sizes proposed by Palmer and Cookson.

Published PGx examples include abacavir hypersensitivity reaction [Hetherington, 2002 and Mallal, 2002] and tranilast induced hyperbilirubinemia [Roses, 2002] where genetic markers have been found to significantly associate with hypersensitivity reaction (abacavir) and hyperbilirubinemia (tranilast). These examples show that small sample sizes typically encountered in Phase I and Phase II studies may be sufficient to identify clinically relevant genetic associations.

12.3.5.8. Pharmacokinetic Analyses

The PK population includes all subjects for which GW823093 concentration data are available.

For the current study, plasma concentrations of GW823093 for each subject will be listed based on the dose level, time, and day at which each sample was collected relative to the first dose.

Relevant data from the current study and from studies DPB10001, DPB10002, and DPB10003 will be combined and analyzed using a nonlinear mixed effects modeling approach (population PK). Population PK parameters including CL and V will be estimated. Dependent on the final structural PK model additional PK parameters also may be estimated.

Sources of variability in PK parameters will be investigated during population modeling. Demographic parameters including, but not limited to, age, sex, and body weight will be evaluated as potential predictors of inter- and intra-subject variability for PK parameters. Population modeling will be performed using the non-linear mixed effects modeling software NONMEM (Globomax LLC; Hanover, MD).

Further details of population PK analyses will be described under a separate Reporting and Analysis Plan (RAP). Results of the population PK analysis will be included in a dedicated report separate from the clinical study report.

12.3.5.9. Pharmacokinetics/Pharmacodynamics Analyses

Changes in relevant primary and secondary pharmacodynamic and safety endpoints will be plotted against plasma concentrations of GW823093. The relationship between the change in pharmacodynamic/safety endpoints and GW823093 concentration will be examined visually. If a relationship is found, the appropriate linear or nonlinear regression analysis will be performed.

Any PK/PD correlations found from the current study may be investigated further as part of a population PK/PD analysis.

Further details of population PK analyses will be described under a separate Reporting and Analysis Plan (RAP). Results of the population PK analyses will be included in a dedicated report separate from the clinical study report.

12.3.5.10. Biomarker(s) Analyses

Descriptive statistics will be provided for population cardiac biomarkers; CK-MB and cTnI at each collection time point in the main and extension phases. In addition, blood samples will be taken and serum and plasma frozen for future biomarker analyses as deemed appropriate and as provided by the Informed Consent Document.

13. STUDY ADMINISTRATION

13.1. Regulatory and Ethical Considerations, Including the Informed Consent Process

GSK will obtain favorable opinion/approval to conduct the study from the appropriate regulatory agency in accordance with any applicable country-specific regulatory requirements prior to a site initiating the study in that country.

The study will be conducted in accordance with all applicable regulatory requirements, including conduct under U.S. IND, 67,873.

The study will also be conducted in accordance with "good clinical practice" (GCP), all applicable subject privacy requirements, and, the guiding principles of the Declaration of Helsinki. This includes, but is not limited to, the following:

- IRB/IEC review and favorable opinion/approval to conduct the study and of any subsequent relevant amended documents
- Subject informed consent
- Investigator reporting requirements

GSK will provide full details of the above either verbally, in writing or both.

Written informed consent will be obtained for each subject before he or she can participate in the study.

13.2. Quality Control (Study Monitoring)

In accordance with applicable regulations, GCP, and GSK procedures, GSK monitors will contact the site prior to the start of the study to review with the site staff the protocol, study requirements, and their responsibilities to satisfy regulatory, ethical, and GSK requirements. When reviewing data collection procedures, the discussion will also include identification, agreement and documentation of data items for which the eCRF will serve as the source document.

GSK will monitor the study consistent with the demands of the study and site activity to verify that the:

- Data are authentic, accurate, and complete.
- Safety and rights of subjects are being protected.
- Study is conducted in accordance with the currently approved protocol and any other study agreements, GCP, and all applicable regulatory requirements.

The investigator and the head of the medical institution (where applicable) agrees to allow the monitor direct access to all relevant documents

13.3. Quality Assurance

To ensure compliance with GCP and all applicable regulatory requirements, GSK may conduct a quality assurance audit. Regulatory agencies may also conduct a regulatory inspection of this study. Such audits/inspections can occur at any time during or after completion of the study. If an audit or inspection occurs, the investigator and institution agree to allow the auditor/inspector direct access to all relevant documents and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any relevant issues.

13.4. Study and Site Closure

Upon completion or premature discontinuation of the study, the monitor will conduct site closure activities with the investigator or site staff, as appropriate, in accordance with applicable regulations, GCP, and GSK procedures.

In addition, GSK reserves the right to temporarily suspend or prematurely discontinue this study at any time for reasons including, but not limited to, safety or ethical issues or severe non-compliance. For multicenter studies, this can occur at one or more or at all sites. If GSK determines such action is needed, GSK will discuss this with the investigator or the head of the medical institution (where applicable), including the reasons for taking such action, at that time. When feasible, GSK will provide advance notification to the investigator or the head of the medical institution, where applicable, of the impending action prior to it taking effect.

GSK will promptly inform all other investigators or the head of the medical institution (where applicable), and/or institutions conducting the study if the study is suspended or terminated for safety reasons. GSK will also promptly inform the regulatory authorities of the suspension or termination of the study and the reason(s) for the action. If required by applicable regulations, the investigator or the head of the medical institution (where applicable) must inform the IEC/IRB promptly and provide the reason for the suspension or termination.

13.5. Records Retention

Following closure of the study, the investigator or the head of the medical institution (where applicable) must maintain all site study records, except for those required by local regulations to be maintained by someone else, in a safe and secure location. The records must be maintained to allow easy and timely retrieval, when needed (e.g., audit or inspection), and, whenever feasible, to allow any subsequent review of data in conjunction with assessment of the facility, supporting systems, and staff. Where permitted by local laws/regulations or institutional policy, some or all of these records can be maintained in a format other than hard copy (e.g., microfiche, scanned, electronic); however, caution needs to be exercised before such action is taken. The investigator must assure that all reproductions are legible and are a true and accurate copy of the original, and meet accessibility and retrieval standards, including re-generating a hard copy, if required. Furthermore, the investigator must ensure there is an acceptable

back-up of these reproductions and that an acceptable quality control process exists for making these reproductions.

GSK will inform the investigator of the time period for retaining these records to comply with all applicable regulatory requirements. The minimum retention time will meet the strictest standard applicable to that site for the study, as dictated by any institutional requirements or local laws or regulations, or GSK standards/procedures; otherwise, the retention period will default to 15 years.

The investigator must notify GSK of any changes in the archival arrangements, including, but not limited to, the following: archival at an off-site facility, transfer of ownership of the records in the event the investigator leaves the site.

13.6. Provision of Study Results and Information to Investigators

When required by applicable regulations, the investigator signatory for the clinical study report will be determined at the time the report is written. When the clinical study report is completed, GSK will provide the investigator with a full summary of the study results. The investigator is encouraged to share the summary results with the subjects, as appropriate. In addition, the investigator will be given reasonable access to review the relevant statistical tables, figures, and reports and will be able to review the results for the entire study at a GSK site or other mutually agreeable location.

GSK will provide the investigator with the randomization codes for their site after the statistical analysis for the entire study has been completed.

13.7. Data Management

The data collection tool for this study will be GSK-defined electronic case report forms (eCRFs). In all cases, subject initials will not be collected nor transmitted to GSK. Subject data necessary for analysis and reporting will be entered/transmitted into a validated database or data system. Clinical data management will be performed in accordance with applicable GSK standards and data cleaning procedures. Original eCRFs will be retained by GSK, while the investigator will retain a copy.

13.8. PGx Data Management

Data from the case report panel on the eCRF and PGx research using the coded sample will be stored electronically. International regulations for information on computers and relevant laws on processing personal information will be followed.

13.9. Confidentiality of PGx Data

GSK advises that participation in this PGx research, withdrawal from this research, sample destruction, and/or PGx results should not be documented in the subject's medical records. Storage of information regarding the PGx research with source documents for the study is permissible if stored in the investigator study files.

Coded PGx samples and results will be associated with the subject's study specific number in computer databases. Coded PGx research results may be submitted to regulatory agencies as part of an investigational product submission and/or included in a research publication.

Individual genotype results will only be shared with a subject through the Investigator if the subject requests to see their results and it is a requirement of a governmental agency or other legal authority that GSK make these results available. GSK will not release individual PGx results to anyone else (e.g., family members, primary care physicians, insurers, or employers) under any circumstance, unless required by law.

13.10. Independent Data Monitoring Committee (IDMC)

An IDMC will be utilized during the conduct of this study. A copy of the IDMC charter is available from GSK upon request.

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15. APPENDICES

15.1. Appendix 1: Time and Events Schedule - Main Phase

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline /Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Informed Consent, Medical History, Demographics[1]	√	√										
Inclusion/Exclusion Criteria		√	√	√	√							
Concomitant Medications	√	√	√	√	√	√	√	√	√	√	√	√
Physical Exam		√			√					√		√
Blood Pressure and Heart Rate[2]		√	√	√	√	√	√	√	√	√	√	√
ECG (locally and centrally read)		√			√				√			√
Blood Samples for Safety: Haematology, UA and chemistry[3]		√			√	√	√	√	√	√	√	√
Efficacy: HbA1c	√			√	√				√		√	√
Efficacy: Fasting plasma glucose	√	√	√	√	√	√	√	√	√	√	√	√
Fasting Capillary Blood Glucose (FCBG) (fingerstick)					√							
Efficacy: Fructosamine[4]		√		√	√				√		√	√
Lipids (TC, LDL-c, HDL-c, trigs, FFA)		√			√				√		√	√
Insulin, pro-insulin					√				√		√	√
PK /PD– sparse sampling					√				√			√
PK/PD – serial sampling					√					√		√
Blood Sample for PGx[5]					√							
Blood Sample Population Cardiac Biomarkers: CK-MB, cTnI		√			√				√			√
Blood sample: exploratory endpoints					√				√			√
Weight, height[6]		√	√	√	√	√	√	√	√	√	√	√
Waist and hip measurements		√			√							√

15.1 Time and Events Schedule- Main Phase (Continued)

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline/ Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Pregnancy Test[7]		√			√				√		√	√
Discontinue prior anti-diabetic medication		√										
Issue investigational product[8]			√	√	√				√		√	√
Diet and Exercise Advice		√	√	√	√	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events		√	√	√	√	√	√	√	√	√	√	√
Compliance				√	√				√		√	√

1. At the pre-screening visit, informed consent and brief medical history only
2. Blood pressure and HR (in duplicate) will be taken pre-dose, on Week -5 (Visit 2), **Week 0 (Visit 5), Week 4 (Visit 9), Week 12 (Visit 12)**.
3. TSH at **Screening (Visit 2** only; Perform fecal occult blood assessment if reduction in hemoglobin ≥ 2 g/dL from baseline during the course of the study
4. Fructosamine: Total and corrected for protein
5. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
6. Height at **Screening (Visit 2**) and confirmed at **Baseline (Visit 5**).
7. Serum pregnancy at **Screening (Visit 2)** and pre-dose on **Week 0 (Visit 5**), **Weeks 4 (Visit 9), 8 (Visit 11), and 12 (Visit 12)**. Urine pregnancy pre-dose on **Week 0 (Visit 5)**.
8. Single-blind medication issued at **Week -4 (Visit 3)** and **Week -2 (Visit 4**).
9. Early withdrawals during the Main Phase should use the Week 24, Early Withdrawal Form for the subject's last visit. These subjects will not be allowed to enter the extension phase.

15.1 Time and Events Schedule-Extension Phase

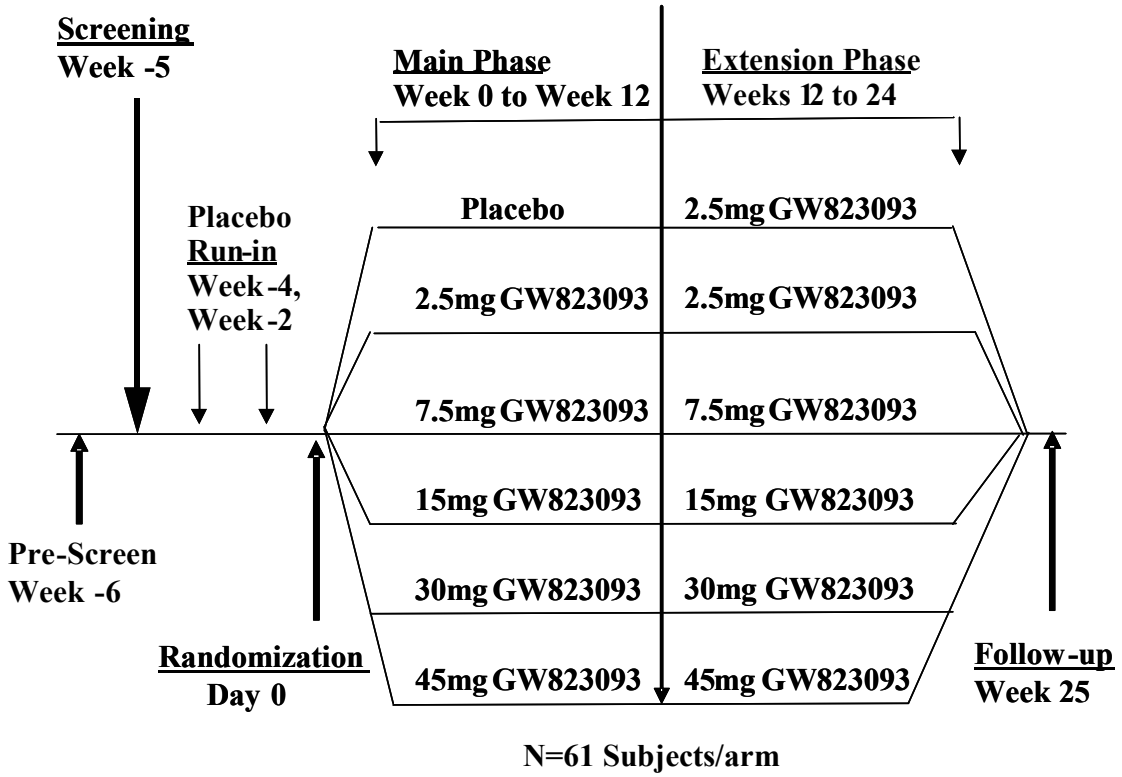
Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Concomitant Medications	√	√	√	√	√	√	√
Physical Exam						√	
Blood Pressure and Heart Rate[1]	√	√	√	√	√	√	√
ECG (centrally and locally read)				√		√	
Blood Samples for Safety: Hematology, urinalysis and chemistry[2]	√	√	√	√	√	√	√
Efficacy: HbA1c				√	√	√	√
Efficacy: Fasting Plasma Glucose	√	√	√	√	√	√	√
Efficacy: Fructosamine[3]				√	√	√	
Lipids (TC, LDL-c, HDL-c, triglycerides, FFA)				√	√	√	√
Efficacy: Insulin, Pro-insulin				√	√	√	
PK/PD: sparse sampling*				√	√		
Blood Sample for PGx[4]	√						
Blood Sample Population Cardiac Biomarkers: CK-MB, cTnI				√		√	
Blood sample: exploratory endpoints						√	
Weight	√	√	√	√	√	√	√
Waist and hip measurements						√	
Pregnancy Test[5]				√	√	√	√
Issue investigational product				√	√		
Diet and Exercise Advice	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events	√	√	√	√	√	√	√

15.1 Time and Events Schedule-Extension Phase *(continued)*

Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Compliance				√	√	√	

1. Blood pressure and HR (in duplicate) will be taken pre-dose at all visits.
2. TSH at **Week 24 (Visit 18)** only; Perform fecal occult blood assessment if reduction in hemoglobin ≥ 2 g/dL seen during the course of the study
3. Fructosamine: Total and corrected for protein
4. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
5. Serum pregnancy pre-dose on **Weeks 16 (Visit 16), 20 (Visit 17), and 24 (Visit 18)**.
6. Early withdrawals during the Extension Phase should use the Week 24, Early Withdrawal Form for the subject's last visit.

15.2. Appendix 2: Study Schematic Figure



15.3. Appendix 3: Prohibited Concomitant Medication

All prescription concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 3 months prior to screening and throughout their participation in the study unless a dose adjustment is medically necessary to manage the subject during the trial.

Subjects must not use any of the following medications during the course of the study; however, if they are taking them at the time of Screening, they should be discontinued and washed off of them during the 4-week run-in period:

- Oral anti-diabetic agents: Subjects who have received a thiazolidinedione (TZD) within the 3 months prior to Screening (**Visit 2**).
- Insulin (Per exclusion criteria)
- Subjects on warfarin or digoxin will not be allowed to participate in this study. Subjects must not be washed off of these medications for the purposes of meeting eligibility criteria.
- Oral anticoagulants (other than aspirin and non-steroidal anti-inflammatory drugs).
- Oral or injectable corticosteroids (other than inhaled and intranasal).
- Monoamine oxidase inhibitors and tri-cyclic amines
- Antiretroviral drugs
- Prescription and over-the-counter weight loss drugs

All concomitant medications must be fully recorded in the appropriate section of the eCRF.

15.4. Appendix 4: Pharmacogenetic Research [PGx]

Pharmacogenetic Research

Pharmacogenetics – Background

Pharmacogenetics (PGx) is the study of variability in drug response due to hereditary factors in different populations. There is increasing evidence that an individual's genetic composition (i.e., genotype) may impact the pharmacokinetics (absorption, distribution, metabolism, and elimination), pharmacodynamics (relationship between concentrations and pharmacologic effects or the time course of pharmacologic effects) and/or clinical outcome (in terms of efficacy and/or safety and tolerability). Some reported examples of PGx analysis include:

Drug	Disease	Gene	Outcome
Abacavir	HIV [Hetherington, 2002 and Mallal, 2002]	HLA (human leukocyte antigen)	Caucasian males with HLA B57 variant were at increased risk for experiencing hypersensitivity to abacavir
Tranilast	Restenosis prevention following coronary bypass [Roses, 2002]	UGT1A1	Drug induced hyperbilirubinemia explained by high proportion of affected patients having 7/7 TA repeat genotype, consistent with clinically benign Gilbert's Syndrome
ABT-761	Asthma [Drazen, 1999]	ALOX5	ALOX5 Sp1 promoter genotype (x,x) associated with reduced response to 5-lipoxygenase inhibitor ABT-761

Pharmacogenetic Research Objectives

If at any time it appears there is potential variability in response in this clinical study or in a series of clinical studies with GW823093 that may be attributable to genetic variations of subjects, the following objectives may be investigated:

- Relationship between genetic variants and the pharmacokinetics of investigational product
- Relationship between genetic variants and safety and/or tolerability of investigational product

Study Population

Any subject who has given informed consent to participate in the clinical study, has met all the entry criteria for the clinical study, and receives investigational product may take

part in the PGx research. Any subject who has received an allogeneic bone marrow transplant must be excluded from the PGx research.

Subject participation in the PGx research is voluntary and refusal to participate will not indicate withdrawal from the clinical study. Refusal to participate will involve no penalty or loss of benefits to which the subject would otherwise be entitled.

Study Assessments and Procedures

In addition to any blood samples take for the clinical study, a whole blood sample (~10ml) will be collected for the PGx research using a tube containing EDTA. The PGx sample is labelled (or "coded") with a study specific number that can be traced or linked back to the subject by the investigator or site staff. Coded samples do not carry personal identifiers (such as name or social security number). The blood sample will be taken on a single occasion unless a duplicate sample is required due to inability to utilize the original sample. It is recommended that the blood sample be taken at the first opportunity after a subject has been randomized and provided informed consent for PGx research, but may be taken at any time while the subject is participating in the clinical study.

If deoxyribonucleic acid (DNA) is extracted from the blood sample, the DNA may be subjected to sample quality control analysis. This analysis will involve the genotyping of several genetic markers to confirm the integrity of individual samples. If inconsistencies are noted in the analysis, then those samples may be destroyed.

Subject Withdrawal from Study

If a subject who has consented to participate in PGx research withdraws from the clinical study for any reason other than lost to follow-up, the subject will be given the following options concerning the PGx sample, if already collected:

- PGx research continues per the subject's consent; or,
- Any remaining sample is destroyed

If a subject withdraws consent from the PGx research or requests sample destruction, the investigator must complete the appropriate documentation to request sample destruction within the timeframe specified by GSK and maintain the documentation in the site study records. In either case, GSK will only keep study information collected/generated up to that point.

Screen and Baseline Failures

If a blood sample for PGx research has been collected and it is determined that the subject does not meet the entry criteria for participation in the clinical study, then the investigator must complete the appropriate documentation to request sample destruction within the timeframe specified by GSK and maintain the documentation in the site study records.

Pharmacogenetics Analyses

The need to conduct PGx analysis may be identified after a study (or set of studies) of GW823093 has been completed and the study data reviewed. For this reason, samples may be kept for up to 15 years after the last subject completes the study or GSK may destroy the samples sooner. In special cases, the samples may not be studied. This might happen if there are not enough subjects, if the study is stopped for other reasons, or if no questions are raised about how people respond to GW823093

Generally GSK will utilize two approaches to explore genetic variation in drug response.

g) Specific sections of DNA may be selected from areas of the genome (e.g., candidate genes) known to encode the drug target, drug metabolizing enzymes, areas associated with mechanisms underlying adverse events, and those linked to study disease and, thus, linked to drug response.

In addition, continuing research may identify other enzymes, transporters, proteins, or receptors that may be involved in response to GW823093. The genes that may code for these proteins may also be studied.

By evaluating large numbers of polymorphic markers (e.g., single nucleotide polymorphisms or SNPs) throughout the genome, sets of markers may be identified that correspond to differential drug response.

Hardy-Weinberg Equilibrium Testing

The genotypic frequencies of each polymorphism will be evaluated for conformity to those expected under normal conditions by employing Hardy-Weinberg Equilibrium testing.

Comparison of Demographic and Baseline Characteristics by Genotype

Differences in baseline clinical characteristics and potential contributing covariates may be summarized and compared among genotype (or haplotype) subgroups.

Evaluation of Genotypic Effects

Analyses may be carried out to evaluate the degree of association between subject genotype (or haplotype) and selected parameters (e.g., pharmacokinetics, efficacy and safety). Where such genotypic tests are inappropriate (for example, where the number of marker genotypes is too large and/or the frequency of individual genotypes too small), allelic tests may be conducted. Allelic tests evaluate whether the frequency of each marker allele is the same in responders and non-responders.

Evaluation of Treatment by Genotype and Gene-Gene Interaction

In addition to evaluating the main effects of the genotypes (haplotypes or alleles) on the selected parameters, the possibility of a treatment group by genotype (haplotype or allele) interaction will also be explored. If appropriate, the joint effects of multiple markers (gene-gene interactions) may also be evaluated.

Linkage Disequilibrium

For pairs of polymorphisms, the degree to which alleles from the two sites are correlated (linkage disequilibrium) may also be evaluated. If the genotypes at two polymorphic sites within a gene are shown to be statistically associated with a response to investigational product, the degree of linkage disequilibrium will aid interpretation in that it will indicate the extent to which the two sites are exerting independent effects.

Multiple Comparisons and Multiplicity

To the extent that multiple markers are evaluated (especially in the case of a genome scan for association), an adjustment to observed p-values may be made to limit erroneous conclusions due to multiple tests.

Power and Sample Size Considerations

The ability to detect differential drug response among genotypes at a polymorphic site depends on the total number of subjects genotyped and the frequency distribution of the different genotypes. Consequently, genotyping analyses are plausible for those polymorphic sites where the number of subjects comprising the genotypic groups is sufficiently large; however, these frequencies will not be known until sufficient samples have been collected and genotyping is complete.

Estimates of sample sizes required to demonstrate genotype effects vary considerably, depending on the assumptions made about allele frequency, genetic effect size, and mechanism of inheritance [Cardon, 2000]. In the work by Palmer and Cookson [Palmer, 2001], which assumed a genotype relative risk of 1.5, it was estimated that more than 300 cases and 600 controls would be needed to conduct a genetic association analysis. In contrast, McCarthy and Hilfiker [McCarthy, 2000] showed that with a genotype relative risk of 2.16 and a relatively commonly occurring genotype, only 30 cases and 30 controls would be needed to demonstrate an association.

Published PGx examples include abacavir hypersensitivity reaction [Hetherington, 2002 and Mallal, 2002] and tranilast induced hyperbilirubinemia [Roses, 2002] where genetic markers have been found to significantly associate with hypersensitivity reaction (abacavir) and hyperbilirubinemia (tranilast). These examples show that small sample sizes typically encountered in Phase I and Phase II studies may be sufficient to identify clinically relevant genetic associations.

Informed Consent

Subjects who do not wish to participate in the PGx research may still participate in the clinical study. PGx informed consent must be obtained prior to any blood being taken for PGx research.

References

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15.5. Appendix 5: Country Specific Requirements

No country-specific requirements exist

15.6. Appendix 6: Pharmacokinetic Sampling

Sparse Sampling

The table below summarizes the sparse pharmacokinetic sampling plan:

PK / PD Assessment: Sparse Sampling Population											
	Main and Extension Treatment Periods (Week)										
	0	1	2	4	6	8	12		16	20	24
PREDOSE (3 samples)	X						X			X	
0.5 to 1.5 hours (choose any one)				X or			X or		X or	X or	
2 to 4 hours (choose any one)				X or			X or		X or	X or	
6 – 10 hour (choose any one)				X or			X or		X or	X or	

- In the sparse sampling population a total of 6 blood samples, 2mL each will be obtained over the course of the study for determination of GW823093 plasma concentrations and DPP-IV inhibition. For each PK sampling visit a sampling interval has been defined. PK samples may be collected at any time during the defined sampling intervals. An effort should be made to ensure that samples are not consistently collected at the same time point within a defined collection interval.
- This study provides flexible options for scheduling of most PK samples. This flexibility is incorporated to improve subject convenience for sampling at later timepoints:

Sparse PK and DPP-IV inhibition samples will be obtained at the following times:

- A predose sample will be collected on EACH of weeks 0, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.
- A single PK sample will be collected in the time interval of 0.5 to 1.5 hours post dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20.
- A single PK sample will be collected in the time interval of 2 to 4 hours post dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20.
- A single PK sample will be collected in the time interval of 6 to 10 hours post-dose (to be dosed in clinic). This sample must be collected on any ONE of the following weeks: 4, 12, 16, or 20

- The options for scheduling of PK samples should be discussed with subjects at the beginning of the study to select PK sampling visits that are most convenient for each subject.

Serial (Intensive) PK Sampling (Sub-Population)

The table below summarizes the serial pharmacokinetic sampling plan:

PK / PD Assessment: Serial Sampling Population (at dedicated sites)			
Timepoints (hours)	Treatment Periods (Week)		
Week Visit	0 (Baseline) Visit 5	Week 6 Visit 10	Week 12 Visit 12
PREDOSE	X	X	X
0.25	X	X	X
0.5	X	X	X
1	X	X	X
1.5	X	X	X
2	X	X	X
3	X	X	X
4	X	X	X
6	X	X	X
8	X	X	X

Approximately sixty subjects will provide a total of 30 blood samples each (2mL per sample) for serial PK and PD sampling. Samples will be obtained during the main phase of the study for determination of GW823093 plasma concentrations, DPP-IV inhibition, active/intact GLP-1 and post prandial glucagon profiles in the serial sampling population. Samples must be collected as close to the specified times as possible.

- On Week 0 (Visit 5), Week 6 (Visit 10) and Week 12 (Visit 12) subjects will be dosed in the clinic and PK and DPP-IV activity samples will be collected at the following timepoints:
- Pre-dose and 0.25, 0.5, 1, 1.5, 2, 3, 4, 6 and 8 hours post-dose.
- Subjects in the serial PK group will undergo a standard meal challenge with pharmacodynamic testing being done at specific time intervals TBD
- Samples for glucose, post prandial glucagon and active (intact) GLP-1 will be collected prior to each meal and at 0.25, 0.5, 1, 1.5, 2, and 3 hr post each meal.
- Subjects identified for the serial PK do not take part in the population (sparse) PK sampling regimen.

15.7. Appendix 7: Clinical Laboratory Testing

HEMATOLOGY	**SERUM CHEMISTRY**	**URINALYSIS**
	Sodium	Glucose
RBC count	Potassium	Bilirubin
Hemoglobin	Chloride	Protein
Hematocrit	Bicarbonate	Ketones
Platelet Count	LDH (>2x ULRR collect	RBCs/HPF and
Total White Cell Count	LDH isoenzymes)	WBCs/HPF
	Total Protein	
At **Screening** only:	Albumin	
Differential:	Blood Urea Nitrogen	**STOOL SAMPLE**
Neutrophils	Creatinine	
Lymphocytes	Total and direct bilirubin	Fecal occult blood
Monocytes	Alkaline Phosphatase	assessment on 3
Eosinophils	Aspartate transaminase	consecutive stools only for
Basophils	(AST)	subjects with reduction in
RBC morphology	Alanine transaminase	haemoglobin ≥ 2g/dL over
	(ALT)	the course of the study
	Calcium	
	Phosphorus (inorganic)	
	Uric Acid	
GLYCEMIA FACTORS AND BLOOD LIPIDS	**THYROID STATUS**	**PREGNANCY TEST**
HbA_{1c}	TSH (at **Screening** only)	β-HCG (serum and urine)
Glucose		
Fructosamine (total and corrected for plasma proteins)	**POPULATION CARDIAC BIOMARKERS**	
Insulin	Creatine kinase MB (CK-MB)	
Pro-insulin	Troponin I (cTnI)	
C-peptide		
Total Cholesterol		
Triglycerides		
HDL-cholesterol		
LDL-cholesterol		
FFA		

15.8. Appendix 8: Diagnosis Criteria for Diabetes Mellitus

Diagnosis Criteria for Diabetes

An FPG value ≥126mg/dL (7.0mmol/L) (confirmed by testing on two different occasions) is diagnostic for diabetes. The diagnostic cutpoint (FPG ≥126mg/dL) is based on the observation that this degree of hyperglycemia usually reflects a serious metabolic abnormality that has been shown to be associated with serious complications. The criteria are for diagnosis and are not treatment criteria or goals. The HbA1c is not recommended for diagnosis at this time. Please refer to the ADA Clinical Practice Recommendations (ADA, 2004).

Criteria for the Diagnosis of Diabetes

Fasting Plasma Glucose (FPG) (preferred)[1]	**Casual[2] Plasma Glucose**	**Oral Glucose Tolerance Test (OGTT)[3]**
FPG ≥126mg/dL (7.0mmol/L)	Casual plasma glucose 200mg/dL (11.1mmol/L) plus symptoms[4]	Two-hour plasma glucose (2h PG) ≥200mg/dL
Impaired Fasting Glucose (IFG) FPG ≥110mg/dL (6.1mmol/L) and <126mg/dL (7.0mmol/L)		Impaired Glucose Tolerance (IGT) 2h PG ≥140mg/dL (7.8mmol/L) and <200mg/dL (11.1mmol/L)
FPG <110mg/dL (6.1mmol/L)		2hPG <140mg/dL (7.8mol/L)
The FPG is the preferred test for diagnosis, but any one of the three listed is acceptable. Fasting is defined as no caloric intake for at least 8 hours.		
Casual is defined as any time of day without regard to time since last meal. Symptoms are the classic ones of polyuria, polydipsia, and unexplained weight loss.		
OGTT should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. The OGTT is not recommended for routine clinical use.		
If casual plasma glucose ≥160mg/dL (8.9mmol/L), patient requires diagnostic evaluation for diabetes.		

Source: [American Diabetes Association, 2004b]

15.9. Appendix 9: New York Heart Association (NYHA) Functional Classification

Grade	Description
I	Subjects with cardiac disease, but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, dyspnea, or anginal pain.
II	Subjects with cardiac disease resulting in slight limitations of physical activity. Ordinary physical activity results in fatigue, palpitations, dyspnea, or anginal pain.
III	Subjects with cardiac disease resulting in marked limitations of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitations, dyspnea, or anginal pain.
IV	Subjects with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

15.10. Appendix 10: Protocol Changes

Amendment 2 – All Countries

This amendment applies to all countries participating in this study.

Rationale: Cardiac troponin withdrawal criteria have been added to provide additional assurance of patient safety in the trial and to provide for consistency of subject evaluation in the event of a significant elevation in cTnI. The level of cTnI for withdrawal of subjects from the trial is based on consideration of levels which may be indicative of cardiac injury (levels that exceed the 99th percentile of those values collected in a normal healthy population) and the characteristics of the assay used by the designated central laboratory where values of >0.35 ng/mL are associated with coefficient of variation ≤ 10%.

Section in protocol: Sponsor Information Page, Sponsor Contact Information

Changed from:

[redacted] MD

Telephone number: [redacted]

Changed to:

[redacted] MD

Telephone number: [redacted]

Section in protocol: 10.2.2 Subject withdrawal from Investigational Product

Added:

Subjects who have cTnI values >0.35 ng/mL should be contacted as soon as possible for withdrawal from study and further evaluation. Additional evaluation should include central cTnI and ECG as well a local sample to be assayed for cTnI. Concomitant to this assessment, all subjects should be evaluated by a local cardiologist; this evaluation is particularly urgent if local cTnI is elevated. At a minimum, evaluation of the left ventricular function should be undertaken in all subjects and depending on locally available modalities, this could include an echocardiogram or a radionuclide ventriculography. Other diagnostic modalities could be used if necessary. Approximately 3 months after withdrawal, subjects should have a follow-up evaluation with a brief physical examination, ECG and redraw of cTnI.

Amendment 1 – All Countries

Section in protocol: Sponsor Information Page, Sponsor Contact Information

Added:

[redacted] MD

GlaxoSmithKline
891-995 Greenford Road
Greenford, Middlesex
UB6 0HE
United Kingdom
Telephone number: [redacted]

Section in protocol: Sponsor Information Page, Regulatory Agency Identifying Number(s)

Added:

EurdraCT Number: 2004-004193-91

Section in protocol: Abbreviations

Removed:

FBG: Fasting Blood Glucose

Added:

CK-MB: Creatine kinase MB

FCBG: Fasting Capillary Blood Glucose

cTnI: Troponin I

Section in protocol: Protocol Summary, Exploratory Objectives (Main and Extension Phase)

Added:

- To evaluate the population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.

Section in protocol: Protocol Summary, Endpoints, Main Phase, Safety

Changed from:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration.

Changed to:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V2, V5, V9 and V12 in main phase.

Section in protocol: Protocol Summary, Endpoints, Extension Phase, Secondary Endpoints

Changed from:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 24. Measures include PR, QT and QTc intervals and QRS duration.

Changed to:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 24. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V16 and V18.

Section in protocol: Protocol Summary, Endpoints Exploratory Endpoints (Main and Extension Phase)

Added:

- Descriptive statistics of the population cardiac biomarkers, CK-MB and cTnI at each collection time point in the main and extension phases.

Changed from:

- Exploratory endpoints may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma samples.

Changed to:

- Exploratory endpoints may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples.

Section in protocol: Protocol Summary, Study Design, Screen

Added:

V2 to header descriptor

Section in protocol: Protocol Summary, Study Design, Run-In

Changed from:

Fasting glucose level during run-in: FPG will be tested on **Weeks -4 (Visit 3)** and **-2 (Visit 4)** by central laboratory and on **Week 0 (Visit 5)** by finger-stick (FBG) and central laboratory:

1. If Fasting Plasma Glucose (FPG) > 240mg/dL (13.3mmol/L), reschedule and repeat test one time by central laboratory. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.
2. If Fasting Blood Glucose (Capillary Glucose-FBG) in the clinic is > 240 mg/dL (13.3mmol/L) (after repeated FBG) at Week 0 (Visit 5) randomization should be delayed until measurement is confirmed by central laboratory measurement of FPG. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.

Changed to:

Fasting glucose level during run-in: FPG will be tested on **Weeks -4 (Visit 3)** and **-2 (Visit 4)** by central laboratory and on **Week 0 (Visit 5)** by fasting capillary blood glucose (FCBG) and central laboratory:

1. If Fasting Plasma Glucose (FPG) > 240mg/dL (13.3mmol/L) at Visit 3 or 4, reschedule and repeat test one time by central laboratory. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.
2. Fasting Capillary Blood Glucose (FCBG) should be the first assessment performed in the clinic at Week 0 (Visit 5). If FCBG in the clinic is > 240 mg/dL (13.3mmol/L) (after repeated FCBG), a blood sample to assess FPG should be drawn (no other Visit 5 assessments conducted at that time). The patient should be re-dispensed their remaining run-in medication and sent home to await the FPG results. Subjects should be reassured that this is acceptable and to call if there are any questions or concerns. Randomization and completion of all visit 5 assessments should be delayed until measurement is confirmed by central laboratory measurement of FPG. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.

Section in protocol: Protocol Summary, Main Treatment Phase

Changed from:

The duration of the Main Phase is 12 weeks from the time of randomization. Study visits will occur at **Weeks 0 (Visit 5), 1 (Visit 6), 2 (Visit 7), 3 (Visit 8), 4 (Visit 9), 6 (Visit 10), 8 (Visit 11), and 12 (Visit 12).** Standard diabetic dietary and exercise advice will be provided at **Week 0** and reinforced at each clinic visit. Subjects who have a FPG > 270 mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, or 11 will be asked to return to the clinic as soon as possible for a retest. If the FPG remains >270 mg/dL (15.0mmol/L) upon retest, the subject must be withdrawn from the study. Subjects with an FPG >270 mg/dL (15.0mmol/L) (confirmed with re-test) at Visit 12 (week 12) will not be permitted to enter the Extension phase.

Changed to:

The duration of the Main Phase is 12 weeks from the time of randomization. Study visits will occur at **Weeks 0 (Visit 5), 1 (Visit 6), 2 (Visit 7), 3 (Visit 8), 4 (Visit 9), 6 (Visit 10), 8 (Visit 11), and 12 (Visit 12).** Permitted visit windows are plus or minus 3 days when visit intervals are 1 week and plus or minus 7 days when visit intervals are 2 or 4 weeks but every effort should be made to keep subjects on the protocol-defined visit schedule. Standard diabetic dietary and exercise advice will be provided at **Week 0** and reinforced at each clinic visit. Subjects who have a FPG > 270 mg/dL (15.0mmol/L) at Visits 6, 7, 8, 9, 10, or 11 will be asked to return to the clinic as soon as possible for a retest. If the FPG remains >270 mg/dL (15.0mmol/L) upon retest, the subject must be withdrawn from the study. Subjects with an FPG >270 mg/dL (15.0mmol/L) (confirmed with re-test) at Visit 12 (week 12) will not be permitted to enter the Extension phase.

Section in protocol: Protocol Summary, Safety Assessments

Changed from:

- Immunochemical fecal occult blood analysis for subjects experiencing reductions in hemoglobin of ≥ 2 g/dL over the course of the study

Changed to:

- Immunochemical fecal occult blood analysis for subjects experiencing reductions in hemoglobin of ≥ 2 g/dL from baseline over the course of the study

Changed from:

- ECGs

Changed to:

- ECG read centrally and locally at V2, V5, V9, V12, V16, V18

Section in protocol: Protocol Summary, Exploratory Assessments

Added:

- Population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.

Changed from:

- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma samples. Plasma samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

Changed to:

- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples. Samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

Section in protocol: 3.1.4 Safety – Main Phase

Changed from:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration.

Changed to:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 4, 12. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V2, V5, V9 and V12.

Section in protocol: 3.2.1 Secondary Endpoints – Extension Phase

Changed from:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 16, 24. Measures include PR, QT and QTc intervals and QRS duration.

Changed to:

- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Week 16, 24. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V16 and V18.

Section in protocol: 3.3 Exploratory Endpoints – Main and Extension Phase

Added:

- Descriptive statistics of population cardiac biomarkers; creatine kinase MB (CK-MB) and troponin I (cTnI) at each collection time point in the main and extension phases.

Changed from:

- Plasma samples will be stored to evaluate exploratory endpoints. Examples may include pharmacogenetics, lipomics and/or proteomics and DPP-IV Inhibition.

Changed to:

- Plasma and serum samples will be stored to evaluate exploratory endpoints. Examples may include pharmacogenetics, lipomics and/or proteomics and DPP-IV Inhibition.

Section in protocol: 5.2.1 Inclusion Criteria – 3. Glycemic Parameters

Changed from:

- For subjects treated with diet and exercise or no therapy: ≥ 140mg/dL (7.8mmol/L) and ≤ 240mg/dL (13.3mmol/L)

Changed to:

- For subjects treated with diet and exercise or no therapy: FPG ≥ 140mg/dL (7.8mmol/L) and ≤ 240mg/dL (13.3mmol/L)

- Fasting Capillary Blood Glucose (FCBG) should be the first assessment performed in the clinic at Week 0 (Visit 5). If FCBG in the clinic is > 240 mg/dL (13.3mmol/L) (after repeated FCBG), a blood sample to assess FPG should be drawn (no other Visit 5 assessments conducted at that time). The patient should be re-dispensed their remaining run-in medication and sent home to await the FPG results. Randomization and completion of all Visit 5 assessments should be delayed until measurement is confirmed by central laboratory measurement of FPG. If FPG > 240mg/dL (13.3mmol/L) after confirming by central laboratory measure, subject is not eligible to be randomized and should be withdrawn from the study and referred for follow-up.

Section in protocol: 5.2.1 Inclusion Criteria

Changed from:

5. Body Mass Index (BMI) ≥ 24 ($kg/m^{2)}$ and ≤ 40 (kg/m^2).

Changed to:

5. Body Mass Index (BMI) ≥ 24 (kg/m^2) and ≤ 40 (kg/m^2).

Section in protocol: 5.2.2 Exclusion Criteria

Changed from:

10. Has a history of alcohol or substance abuse within the past year, as determined by the Investigator or a positive urine drug screen (UDS) at Screening (Visit 2) or during treatment:

    - Unwilling to refrain from the use of excessive alcohol or illicit drugs and adhere to other protocol-stated restrictions while participating in the study.
    - History of alcohol abuse defined as an average weekly intake of greater than 21 units or an average daily intake of greater than 3 units (males) or defined as an average weekly intake of greater than 14 units or an average daily intake of greater than 2 units (females). One unit is equivalent to a half-pint of beer or 1 measure of spirits or 1 glass of wine.

Changed to:

10. Has a history of alcohol or substance abuse within the past year, as determined by the Investigator or a positive urine drug screen (UDS) at Screening (Visit 2) or during treatment:

    - Unwilling to refrain from the use of excessive alcohol or illicit drugs and adhere to other protocol-stated restrictions while participating in the study.
    - History of alcohol abuse defined as an average weekly intake of greater than 21 units or an average daily intake of greater than 3 units (males) or defined as an average weekly intake of greater than 14 units or an average daily intake of greater than 2 units (females). One unit is equivalent to a half-pint of beer or 1 measure of spirits or 1 glass of wine.
    - The Investigator should exercise their medical judgement to determine if a UDS is indicated.

Section in protocol: 6.1 Demographic and Baseline Assessments

Changed from:

A routine physical examination performed by a qualified and licensed medical professional (i.e., physician, physician's assistant or certified nurse practitioner). A complete physical exam, including a thorough review of all body systems, should be done at Visits 2, 5, 12, and 18 (or early withdrawal)

Changed to:

A routine physical examination performed by a qualified and licensed medical professional (i.e., physician, physician's assistant or certified nurse practitioner). A complete physical exam, including a thorough review of all body systems, should be done at Visits 2, 5, 10, 12, and 18 (or early withdrawal).

Section in protocol: 6.2 Safety

Changed from:

- ECGs

Changed to:

- ECG read centrally and locally at V2, V5, V9, V12, V16, V18

Section in protocol: 6.2.1 Hypoglycemia

Changed from:

All medications that lower blood glucose are capable of producing hypoglycemia or symptoms of hypoglycemia. This manifestation of hypoglycemia is variable among diabetic subjects. In addition to the symptoms that may occur in association with a low blood glucose levels, some diabetics may experience symptoms with a rapid lowering or improvement in their blood glucose control. In contrast, some diabetics with a very low glucose level may be unaware or asymptomatic.

The investigator is responsible for the detection and documentation of events/symptoms that are diagnostic or indicative of hypoglycemia. A separate page(s) in the eCRF is provided to capture events of hypoglycemia. These data include recording whether there were symptoms; associated blood glucose values if available; interventions, and whether there was external assistance in addition to questions to assess the events similar to those recorded for adverse events as in section 11.

Changed to:

All medications that lower blood glucose are capable of producing hypoglycemia or symptoms of hypoglycemia. This manifestation of hypoglycemia is variable among diabetic subjects. In addition to the symptoms that may occur in association with a low blood glucose levels, some diabetics may experience symptoms with a rapid lowering or improvement in their blood glucose control. In contrast, some diabetics with a very low glucose level may be unaware or asymptomatic.

Subjects will be provided with a Hypoglycemic Symptoms Log at each visit and will be asked to record symptoms of hypoglycemia and wherever possible, corresponding fingerstick glucose readings for each event. Subjects will also receive a Glucose Log for routine recording of glucometer readings as directed by the Investigator.

Using the Hypoglycemic Symptoms Log, the investigator is responsible for assessment and documentation of events/symptoms that are diagnostic or indicative of hypoglycemia. A separate page(s) in the eCRF is provided to capture events of hypoglycemia. These data include recording whether there were symptoms; associated blood glucose values if available; interventions, and whether there was external assistance in addition to questions to assess the events similar to those recorded for adverse events as in section 11. Information recorded by the subject but judged by the Investigator not to be hypoglycemia should be noted in the ‘site comments’ section of the log and recorded as an adverse experience where appropriate.

Section in protocol: 6.3 Efficacy, Exploratory Assessments

Added:

- Population cardiac biomarkers; CK-MB and cTnI at each collection time point in the main and extension phases.

Changed from:

- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma samples. Plasma samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

Changed to:

- Exploratory assessments may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples. Samples will be stored frozen for potential future measurement of exploratory or other assessments as provided for in the Informed Consent Document(s).

Section in protocol: 6.4 Pharmacokinetics, Sparse Sampling Population

Changed from:

- A pre-dose sample will be collected on EACH of weeks 1, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.

Changed to:

- A pre-dose sample will be collected on EACH of weeks 0, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.

Section in protocol: 6.4 Pharmacokinetics, Serial PK Sampling Population (at selected sites in North America

Changed from:

- Samples for glucose, glucagon and active/intact GLP-1 will be collected prior to each meal and at 0.25, 0.5, 1, 1.5, 2, and 3 hr post each meal.

Changed to:

- Samples for glucose, glucagon and active/intact GLP-1 will be collected prior to clinic provided meal and at 0.25, 0.5, 1, 1.5, 2, and 3 hr post each meal.

Section in protocol: 6.5 Pharmacodynamics/Meal Challenge

Changed from:

- Samples for glucose, insulin, glucagon and active/intact GLP-1 will be collected prior to each meal and at 0.25, 0.5, 1 ,1.5, 2, and 3 hr post each meal.

Changed to:

- Samples for glucose, insulin, glucagon and active/intact GLP-1 will be collected prior to clinic provided meal and at 0.25, 0.5, 1 ,1.5, 2, and 3 hr post each meal.

Section in protocol: 6.6 Biomarker(s)

Changed from:

Blood samples will stored for exploratory analyses of biomarkers. Any analyses will be dependent on what biomarkers are assayed. The decision to evaluate biomarkers will be done after the study.

Changed to:

Blood samples will be taken for the exploratory population cardiac biomarkers; CK-MB and cTnI. Additional samples will be stored for exploratory analyses of biomarkers. Any analyses will be dependent on what biomarkers are assayed. The decision to evaluate additional biomarkers will be done after the study.

Section in protocol: 8.5 Treatment Assignment

Changed from:

At Visit 2 (Screening), the investigator or designate will telephone RAMOS to Register the patient and the subjects will be dispensed 3 bottles of single-blind Placebo run-in capsules.

Changed to:

At Visit 1(Pre-screening), the investigator or designate will telephone RAMOS to Register the patient. Eligible subjects will be dispensed 3 bottles of single-blind Placebo run-in medication at the run-in visit 3 (WK-4).

Section in protocol: 9.1 Permitted Medications

Changed from:

All concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 1 month prior to screening and throughout their participation in the study.

Changed to:

All concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 3 months prior to screening and throughout their participation in the study unless a dose adjustment is medically indicated to manage the subject during the trial.

Section in protocol: 12.3.5.6.4 Other Safety Measures, Electrocardiograms

Changed from:

All ECG data will be summarized by visit and treatment group. Change from baseline will be calculated for interval/duration data and summarized by visit and treatment group.

Changed to:

All ECG data will be summarized by visit and treatment group. Change from baseline will be calculated for interval/duration data and summarized by visit and treatment group.

All ECGs will be read locally by the Investigator or his/her designate and will be forwarded electronically for central interpretation. If clinically significant, findings from locally read ECGs will be recorded by the Investigator as a medical condition (if identified at V2) or as an adverse event in the eCRF (if identified at a visit other than V2). The Investigator will also be sent a report of the central interpretation of the ECG which should be kept with the source documentation. The findings from the central report do not routinely need to be entered into the eCRF. If the central reading indicates a clinically significant ECG abnormality, this should be recorded in the medical conditions (if identified at V2) or adverse events section of the eCRF (if identified at a visit other than V2) and the subject should be appropriately managed. Centrally read ECG data will be transferred electronically to the sponsor's data management department and IDMC.

Section in protocol: 12.3.5.10 Biomarker(s) Analyses

Changed from:

Samples will be taken and plasma frozen for future biomarker analyses as deemed appropriate and as provided by the Informed Consent Document.

Changed to:

Descriptive statistics will be provided for population cardiac biomarkers; CK-MB and cTnI at each collection time point in the main and extension phases. In addition, blood samples will be taken and serum and plasma frozen for future biomarker analyses as deemed appropriate and as provided by the Informed Consent Document.

Section in protocol: 15.1 Appendix 1 Time and Events Table

Changed from:

15.1 Appendix 1: Time and Events Table-Main Phase

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline/ Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Informed Consent, Medical History, Demographics[1]	√	√										
Inclusion/Exclusion Criteria		√	√	√	√							
Concomitant Medications		√	√	√	√	√	√	√	√	√	√	√
Physical Exam		√			√					√		√
Blood Pressure and Heart Rate[2]		√	√	√	√	√	√	√	√	√	√	√
ECG					√				√			√
Blood Samples for Safety: Haematology, UA and chemistry[3]		√			√	√	√	√	√	√	√	√
Efficacy: HbA1c	√			√	√				√		√	√
Efficacy: Fasting plasma glucose	√	√	√	√	√	√	√	√	√	√	√	√
Fasting Blood Glucose (FBG by fingerstick)					√							
Efficacy: Fructosamine[4]		√		√	√				√		√	√
Lipids (TC, LDL-c, HDL-c, trigs, FFA)		√			√				√		√	√
Insulin, pro-insulin					√				√		√	√
PK /PD– sparse sampling*					√	√			√		√	√
PK/PD – serial sampling					√					√		√
Blood Sample for PGx[5]					√							
Blood sample: exploratory endpoints					√				√			√
Weight, height[6]		√	√	√	√	√	√	√	√	√	√	√
Waist and hip measurements		√			√							√

15.1 Time and Events Schedule- Main Phase (Continued)

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline /Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Pregnancy Test[7]		√			√				√		√	√
Issue investigational product[8]			√	√	√				√		√	√
Diet and Exercise Advice		√	√	√	√	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events		√	√	√	√	√	√	√	√	√	√	√
Compliance				√	√				√		√	√

1. At the pre-screening visit, informed consent and brief medical history only
2. Blood pressure and HR (in duplicate) will be taken at pre-dose, 2 and 4 hours post-dose on **Week 0 (Visit 5)** and **Week 12 (Visit 12)**, and pre-dose on the other days.
3. TSH at **Screening (Visit 2)** and **Week 12 (Visit 12)** only; Perform fecal occult blood assessment if reduction in hemoglobin $\geq$ 2 g/dL seen during the course of the study
4. Fructosamine: Total and corrected for protein
5. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
6. Height at **Screening (Visit 2**) and confirmed at **Baseline (Visit 5**).
7. Serum pregnancy at **Screening (Visit 2)** and pre-dose on **Week 0 (Visit 5)**, **Weeks 4 (Visit 9), 8 (Visit 11), and 12 (Visit 12)**. Urine pregnancy pre-dose on **Week 0 (Visit 5)**.
8. Single-blind medication issued at **Week -4 (Visit 3)** and **Week -2 (Visit 4)**.
9. Early withdrawals during the Main Phase should use the Week 24, Early Withdrawal Form for the subject's last visit. These subjects will not be allowed to enter the extension phase.

15.1 Time and Events Schedule-Extension Phase

Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Concomitant Medications	√	√	√	√	√	√	√
Physical Exam						√	
Blood Pressure and Heart Rate[1]	√	√	√	√	√	√	√
ECG				√		√	
Blood Samples for Safety: Hematology, urinalysis and chemistry[2]	√	√	√	√	√	√	√
Efficacy: HbA1c				√	√	√	√
Efficacy: Fasting Plasma Glucose	√	√	√	√	√	√	√
Efficacy: Fructosamine[3]				√	√	√	
Lipids (TC, LDL-c, HDL-c, triglycerides, FFA)				√	√	√	√
Efficacy: Insulin, Pro-insulin				√	√	√	
PK/PD: sparse sampling*				√	√	√	
Blood Sample for PGx[4]	√						
Blood sample: exploratory endpoints						√	
Weight	√	√	√	√	√	√	√
Waist and hip measurements						√	
Pregnancy Test[5]				√	√	√	√
Issue investigational product				√	√		
Diet and Exercise Advice	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events	√	√	√	√	√	√	√

15.1 Time and Events Schedule-Extension Phase (continued)

Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Compliance				√	√	√	

1. Blood pressure and HR (in duplicate) will be taken pre-dose at all visits.
2. TSH at **Week 24 (Visit 18)** only; Perform fecal occult blood assessment if reduction in hemoglobin ≥ 2 g/dL seen during the course of the study
3. Fructosamine: Total and corrected for protein
4. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
5. Serum pregnancy pre-dose on **Weeks 16 (Visit 16), 20 (Visit 17), and 24 (Visit 18)**.
6. Early withdrawals during the Extension Phase should use the Week 24, Early Withdrawal Form for the subject's last visit.

Changed to:

15.1 Appendix 1: Time and Events Schedule - Main Phase

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline /Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Informed Consent, Medical History, Demographics[1]	√	√										
Inclusion/Exclusion Criteria		√	√	√	√							
Concomitant Medications	?	√	√	√	√	√	√	√	√	√	√	√
Physical Exam		√			√					√		√
Blood Pressure and Heart Rate[2]		√	√	√	√	√	√	√	√	√	√	√
ECG (locally and centrally read)		√			√				√			√
Blood Samples for Safety: Haematology, UA and chemistry[3]		√			√	√	√	√	√	√	√	√
Efficacy: HbA1c	√			√	√				√		√	√
Efficacy: Fasting plasma glucose	√	√	√	√	√	√	√	√	√	√	√	√
Fasting Capillary Blood Glucose (FCBG by fingerstick)					√							
Efficacy: Fructosamine[4]		√		√	√				√		√	√
Lipids (TC, LDL-c, HDL-c, trigs, FFA)		√			√				√		√	√
Insulin, pro-insulin					√				√		√	√
PK /PD– sparse sampling					√				√			√
PK/PD – serial sampling					√					√		√
Blood Sample for PGx[5]					√							
Blood Sample Population Cardiac Biomarkers: CK-MB, cTnI		√			√				√			√
Blood sample: exploratory endpoints					√				√			√
Weight, height[6]		√	√	√	√	√	√	√	√	√	√	√
Waist and hip measurements		√			√							√

15.1 Time and Events Schedule- Main Phase (Continued)

Study Procedure	Pre-Screen Visit	Screening Visit	Single-blind placebo run-in		Main Phase							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12[9]
	Pre-Screen Week -6	Screening Week -5	Week -4	Week -2	Baseline/ Week 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12
Pregnancy Test[7]		√			√				√		√	√
Discontinue Prior Anti-Diabetic Medication		√										
Issue investigational product[8]			√	√	√				√		√	√
Diet and Exercise Advice		√	√	√	√	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events		√	√	√	√	√	√	√	√	√	√	√
Compliance				√	√				√		√	√

1. At the pre-screening visit, informed consent and brief medical history only
2. Blood pressure and HR (in duplicate) will be taken pre-dose, on Week -5 (Visit 2), **Week 0 (Visit 5), Week 4 (Visit 9), Week 12 (Visit 12)**.
3. TSH at **Screening (Visit 2** only; Perform fecal occult blood assessment if reduction in hemoglobin ≥ 2 g/dL from baseline during the course of the study
4. Fructosamine: Total and corrected for protein
5. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
6. Height at **Screening (Visit 2**) and confirmed at **Baseline (Visit 5**).
7. Serum pregnancy at **Screening (Visit 2)** and pre-dose on **Week 0 (Visit 5)**, **Weeks 4 (Visit 9), 8 (Visit 11), and 12 (Visit 12)**. Urine pregnancy pre-dose on **Week 0 (Visit 5)**.
8. Single-blind medication issued at **Week -4 (Visit 3)** and **Week -2 (Visit 4)**.
9. Early withdrawals during the Main Phase should use the Week 24, Early Withdrawal Form for the subject's last visit. These subjects will not be allowed to enter the extension phase.

15.1 Time and Events Schedule-Extension Phase

Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Concomitant Medications	√	√	√	√	√	√	√
Physical Exam						√	
Blood Pressure and Heart Rate[1]	√	√	√	√	√	√	√
ECG (centrally and locally read)				√		√	
Blood Samples for Safety: Hematology, urinalysis and chemistry[2]	√	√	√	√	√	√	√
Efficacy: HbA1c				√	√	√	√
Efficacy: Fasting Plasma Glucose	√	√	√	√	√	√	√
Efficacy: Fructosamine[3]				√	√	√	
Lipids (TC, LDL-c, HDL-c, triglycerides, FFA)				√	√	√	√
Efficacy: Insulin, Pro-insulin				√	√	√	
PK/PD: sparse sampling*				√	√		
Blood Sample for PGx[4]	√						
Blood Sample Population Cardiac Biomarkers: CK-MB, cTnI				√		√	
Blood sample: exploratory endpoints						√	
Weight	√	√	√	√	√	√	√
Waist and hip measurements						√	
Pregnancy Test[5]				√	√	√	√
Issue investigational product				√	√		
Diet and Exercise Advice	√	√	√	√	√	√	√
Adverse and Hypoglycemic Events	√	√	√	√	√	√	√

15.1 Time and Events Schedule-Extension Phase (continued)

Study Procedure	Extension Phase						Post-treatment Follow-up
	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19[6]
	Week 13	Week 14	Week 15	Week 16	Week 20	Week 24 (or early withdrawal)	Week 25
Compliance				√	√	√	

1. Blood pressure and HR (in duplicate) will be taken pre-dose at all visits.
2. TSH at **Week 24 (Visit 18)** only; Perform fecal occult blood assessment if reduction in hemoglobin ≥ 2 g/dL seen during the course of the study
3. Fructosamine: Total and corrected for protein
4. PGx sample may be taken at any time during the study after the PGx Informed Consent has been obtained.
5. Serum pregnancy pre-dose on **Weeks 16 (Visit 16), 20 (Visit 17), and 24 (Visit 18)**.
6. Early withdrawals during the Extension Phase should use the Week 24, Early Withdrawal Form for the subject's last visit.

Section in protocol: 15.3 Appendix 3: Prohibited Concomitant Medication

Changed from:

All prescription concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 1 month prior to screening and throughout their participation in the study.

Changed to:

All prescription concomitant medications taken during the study will be recorded in the CRF. The minimum requirement is that drug name and the dates of administration are recorded. Oral anti-hypertensives and statins are permitted concomitant medications provided subjects are on the same drug on a stable dose for 3 months prior to screening and throughout their participation in the study unless a dose adjustment is medically necessary to manage the subject during the trial.

Section in protocol: 15.6.1 Sparse Sampling

Changed from:

The table below summarizes the sparse pharmacokinetic sampling plan:

PK / PD Assessment: Sparse Sampling Population											
	Main and Extension Treatment Periods (Week)										
	0	1	2	4	6	8	12		16	20	24
PREDOSE (3 samples)		X					X			X	
0.5 to 1.5 hours (choose any one)				X or			X or		X or	X or	
2 to 4 hours (choose any one)				X or			X or		X or	X or	
6 – 10 hour (choose any one)				X or			X or		X or	X or	

Changed to:

The table below summarizes the sparse pharmacokinetic sampling plan:

PK / PD Assessment: Sparse Sampling Population											
	Main and Extension Treatment Periods (Week)										
	0	1	2	4	6	8	12		16	20	24
PREDOSE (3 samples)	X						X			X	
0.5 to 1.5 hours (choose any one)				X or			X or		X or	X or	
2 to 4 hours (choose any one)				X or			X or		X or	X or	
6 – 10 hour (choose any one)				X or			X or		X or	X or	

Changed from:

Sparse PK and DPP-IV inhibition samples will be obtained at the following times:

- A predose sample will be collected on EACH of weeks 1, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.

Changed to:

Sparse PK and DPP-IV inhibition samples will be obtained at the following times:

- A predose sample will be collected on EACH of weeks 0, 12, and 20 (3 samples total over the course of the study). The date and timing of the most recent dose of study medication should be documented.

Section in protocol: 15.6.2 Serial (Intensive) PK Sampling (Sub-Population)

Changed from:

- Pre-dose and 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, 9, and 12 hours post-dose.

Changed to:

- Pre-dose and 0.25, 0.5, 1, 1.5, 2, 3, 4, 6 and 8 hours post-dose.

Section in protocol: 15.7 Appendix 7: Clinhical Laboratory Testing

Changed from:

HEMATOLOGY	**SERUM CHEMISTRY**	**URINALYSIS**
	Sodium	Glucose
RBC count	Potassium	Bilirubin
Hemoglobin	Chloride	Protein
Hematocrit	Bicarbonate	Ketones
Platelet Count	LDH (>2x ULRR collect	RBCs/HPF and
Total White Cell Count	LDH isoenzymes)	WBCs/HPF
	Total Protein	
At **Screening** only:	Albumin	
Differential:	Blood Urea Nitrogen	**STOOL SAMPLE**
Neutrophils	Creatinine	
Lymphocytes	Total and direct bilirubin	Fecal occult blood
Monocytes	Alkaline Phosphatase	assessment on 3
Eosinophils	Aspartate transaminase	consecutive stools only for
Basophils	(AST)	subjects with reduction in
RBC morphology	Alanine transaminase	haemoglobin ≥ 2g/dL over
	(ALT)	the course of the study
	Calcium	
	Phosphorus (inorganic)	
	Uric Acid	
GLYCEMIA FACTORS AND BLOOD LIPIDS	**THYROID STATUS**	**PREGNANCY TEST**
HbA_{1c}	TSH, T3, T4 (at **Screening**	β-HCG (serum and urine)
Glucose	only)	
Fructosamine (total and corrected for plasma proteins)		
Insulin		
Pro-insulin		
C-peptide		
Total Cholesterol		
Triglycerides		
HDL-cholesterol		
LDL-cholesterol		
FFA		

Changed to:

HEMATOLOGY	**SERUM CHEMISTRY**	**URINALYSIS**
	Sodium	Glucose
RBC count	Potassium	Bilirubin
Hemoglobin	Chloride	Protein
Hematocrit	Bicarbonate	Ketones
Platelet Count	LDH (>2x ULRR collect	RBCs/HPF and
Total White Cell Count	LDH isoenzymes)	WBCs/HPF
	Total Protein	
At **Screening** only:	Albumin	
Differential:	Blood Urea Nitrogen	**STOOL SAMPLE**
Neutrophils	Creatinine	
Lymphocytes	Total and direct bilirubin	Fecal occult blood
Monocytes	Alkaline Phosphatase	assessment on 3
Eosinophils	Aspartate transaminase	consecutive stools only for
Basophils	(AST)	subjects with reduction in
RBC morphology	Alanine transaminase	haemoglobin ≥ 2g/dL over
	(ALT)	the course of the study
	Calcium	
	Phosphorus (inorganic)	
	Uric Acid	
GLYCEMIA FACTORS AND BLOOD LIPIDS	**THYROID STATUS**	**PREGNANCY TEST**
HbA_{1c}	TSH, T3, T4 (at **Screening**	β-HCG (serum and urine)
Glucose	only)	
Fructosamine (total and		
corrected for plasma	**POPULATION**	
proteins)	**CARDIAC**	
	BIOMARKERS	
Insulin		
Pro-insulin	Creatine kinase MB (CK-	
C-peptide	MB)	
Total Cholesterol	Troponin I (cTnI)	
Triglycerides		
HDL-cholesterol		
LDL-cholesterol		
FFA		

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Information Type: Reporting and Analysis Plan

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Compound Number: GW823093

Effective Date: 15-MAY-2006

Description: This document outlines the amended efficacy and safety analyses planned for the main phase of the protocol for study DPB100925.

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Author's Name, Title and Functional Area:

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GM2005/00087/02	15-MAY-2006	Amendment No. 2: Addition of Protocol Deviation criteria relating to inclusion criteria. Addition of sensitivity tables. Amendment to region definition. Inclusion of PK outputs.

Approved by:

[redacted] 18 May 2006
Director Clinical Development **Date**
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ABBREVIATIONS

AE	Adverse event
ALT	Alanine transaminase
ANCOVA	Analysis of Covariance
AST	Aspartate transaminase
BCF	Beta-cell Function
BMI	Body mass index
BP	Blood pressure
bpm	Beats per minute
BUN	Blood Urea Nitrogen
CI	Confidence interval
CK-MB	Creatine Kinase MB
CL	Clearance
cTnl	Troponin-I
CV	Cardiovascular
dL	decilitre
DNA	Deoxyribonucleic acid
DPP-IV	Dipeptidyl Peptidase-IV
DS	Data standard
ECG	Electrocardiogram
eCRF	Electronic case report form
FCBG	Fasting Capillary Blood Glucose
FFA	Free fatty acids
FPG	Fasting plasma glucose
GLP-1	Post prandial glucagon Like Peptide-1
GSK	GlaxoSmithKline
HbA1c	Glycosylated haemoglobin
HDL-c	High density lipoprotein cholesterol
HR	Heart rate
IDMC	Independent Data Monitoring Committee
IR	Insulin resistance
IS	Insulin Sensitivity
ITT	Intent-to-treat
kg	Kilogram(s)
LDL-c	Low density lipoprotein cholesterol
LLN	Lower limit of normal
LOCF	Last observation carried forward
MedDRA	Medical dictionary for regulatory activities
mg	Milligram(s)
mL	Millilitre(s)
msec	Millisecond(s)
PD	Pharmacodynamics
PGx	Pharmacogenetics
PK	Pharmacokinetics
PP	Per Protocol
qd	Once daily
RAP	Reporting analysis plan
RBC	Red blood cells
SAE	Serious adverse event

Continued…

ABBREVIATIONS (Cont/d.)

SNP	Single nucleotide polymorphism
SOP	Standard operating procedures
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
ULN	Upper limit of normal
US	United States
V or Vd	Volume of distribution
WBC	White blood cells

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1. INTRODUCTION

This Reporting and Analysis Plan (RAP) outlines efficacy and safety analyses planned for the Main Phase of the protocol for study DPB100925. The safety and efficacy analyses planned for the Extension Phase of this study will be detailed in a separate RAP.

In this RAP, reference is made to the protocol for study DPB100925, protocol amendment 1 (10th March 2005) and amendment 2 (5th April 2006).

The structure of this RAP follows closely to that of GSK RAP SOP- and DS-WWD-4000 V02 (August 2004). Appropriate guidelines and data display specifications in the Diabetes Generic RAP (version 1.1, November 2004) have been applied. Appropriate guidelines for safety analyses from the Rolling Safety Summary have also been applied (SOP-WWD-3010 v01; November 04).

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. Study Objectives

The objectives stated below are defined for the Main Phase of the study; refer to the Extension Phase RAP for the Extension Phase objectives.

2.1.1. Primary Objective

The primary objective of the study is to evaluate the dose response and efficacy of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), versus placebo on the change in HbA1c after 12 weeks of dosing in subjects with T2DM.

2.1.2. Secondary Objectives

The secondary objectives of the study are:

- To investigate the safety and tolerability of a range of doses of GW823093 versus placebo during 12 weeks of dosing in subjects with T2DM.
- To evaluate the effect of a range of doses of GW823093, versus placebo, on glycaemic parameters (e.g., HbA1c, fasting plasma glucose (FPG), fasting fructosamine), fasting insulin and serum lipid profile during 12 weeks of dosing in subjects with T2DM.
- To characterise the pharmacokinetics of GW823093 in type 2 diabetic subjects after chronic administration using a combined sparse and serial sampling scheme, and to investigate pharmacokinetic (PK)/pharmacodynamic (PD) relationships (e.g. safety and efficacy endpoints).
- To evaluate the effect of a range of doses of GW823093 on DPP-IV inhibition as part of population PK assessment.

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2.1.3. Exploratory Objectives

The exploratory objectives of the study are:

- To evaluate plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the Main Phase.
- To evaluate the correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the Main Phase.
- To evaluate the population cardiac biomarkers; creatine kinase (CK-MB) and troponin I (cTnI) at each collection time point in the Main Phase.
- To evaluate exploratory endpoints described in the Informed Consent including pharmacogenetics, lipomics and/or proteomics. Pharmacogenetics data will be collected to investigate the potential influence of genetic variation on glycaemic control after GW823093 treatment. Samples will be taken and frozen for future analysis as described in the Informed Consent Document.

2.2. Study Endpoints

2.2.1. Primary Efficacy

- Change from baseline (Week 0) in HbA1c at Week 12.

2.2.2. Secondary Efficacy

- Change from baseline (Week 0) in HbA1c at Weeks 4 and 8.
- Change from baseline (Week 0) in FPG at Weeks 1, 2, 3, 4, 6, 8 and 12.
- Proportion of subjects who achieve various HbA1c ($\leq$ 6.5%, < 7% and $\leq$ 8%) and FPG (< 126mg/dL [7.0mmol/L] and < 140mg/dL [7.8mmol/L]) targets, and/or achieve a clinically meaningful decrease in HbA1c ($\geq$ 0.7%) and FPG ($\geq$ 30mg/dL [1.7mmol/L]).
- Change from baseline (Week 0) in fructosamine (total and corrected for protein), fasting serum insulin, pro-insulin and pro-insulin: insulin ratio at Weeks 4, 8 and 12.
- Population PK parameters of GW823093 including clearance (CL) and volume of distribution (Vd) with assessment of demographic covariates influencing GW823093 pharmacokinetic profile. Dependent on the final compartmental model describing GW823093 disposition, additional PK parameters also may be estimated.
- Descriptive statistics of DPP-IV inhibition performed as part of the population PK.

2.2.3. Other Metabolic Endpoints

- Percent change from baseline (Week 0) in fasting lipids (triglycerides, free fatty acids (FFAs), TC, LDL-c, HDL-c) based on log-transformed data at Weeks 4, 8, and 12.

2.2.4. Safety

- Safety and tolerability, assessed by the incidence and severity of adverse events over the course of the Main Phase.
- Haematology, clinical chemistry and urinalysis laboratory parameters at each visit.
- Incidence and severity of hypoglycaemia over the course of the Main Phase.
- Change from baseline (Week 0) in vital signs: cuff systolic and diastolic BP and radial HR at each visit.
- Change from baseline (Week 0) in 12-lead electrocardiogram (ECG) at Weeks 4, 12. Measures include PR, QT and QTc intervals and QRS duration. ECG will be taken and read locally and centrally at V2, V5, V9 and V12 in the Main Phase.
- Change from baseline (Week 0) in BMI and body weight at each visit and change from baseline (Week 0) in waist circumference, hip circumference and waist: hip ratio at Week 12.

2.2.5. Exploratory Endpoints

- Descriptive statistics of plasma GW823093 concentrations, glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition at each collection time point in the serial PK sampling performed during the Main Phase.
- Correlation between the serial PK of GW823093 and glucose, insulin, glucagon, active (intact) GLP-1, and DPP-IV inhibition during the Main Phase.
- Descriptive statistics of the population cardiac biomarkers, CK-MB and cTnI at each collection time point in the Main Phase.
- Exploratory endpoints may include pharmacogenetics, lipomics and/or proteomics using stored frozen plasma and serum samples.

2.3. Statistical Hypotheses

This study is designed to show that at least one of the GW823093 groups is superior to placebo. The null hypothesis for the primary endpoint analysis is that there is no difference in terms of change from baseline to Week 12 (Visit 12) in HbA1c in any active group compared to placebo. The alternative hypothesis is that there is a difference. Significance tests will be two-sided.

3. STUDY DESIGN

This study is a multi-centre, randomised, double-blind, placebo-controlled, parallel group dose-ranging study with five treatment arms conducted in two phases: the Main Phase (first 12-weeks of treatment) and an Extension Phase (second 12-weeks of treatment). Subjects with T2DM who are drug-naïve, treated with diet and exercise or on prior oral anti-diabetic monotherapy will be recruited.

The study will be comprised of six study periods: Pre-Screen, Screen, Run-In, Main Phase, Extension Phase and Post-treatment Follow-up. The schematic below represents the overall study design.

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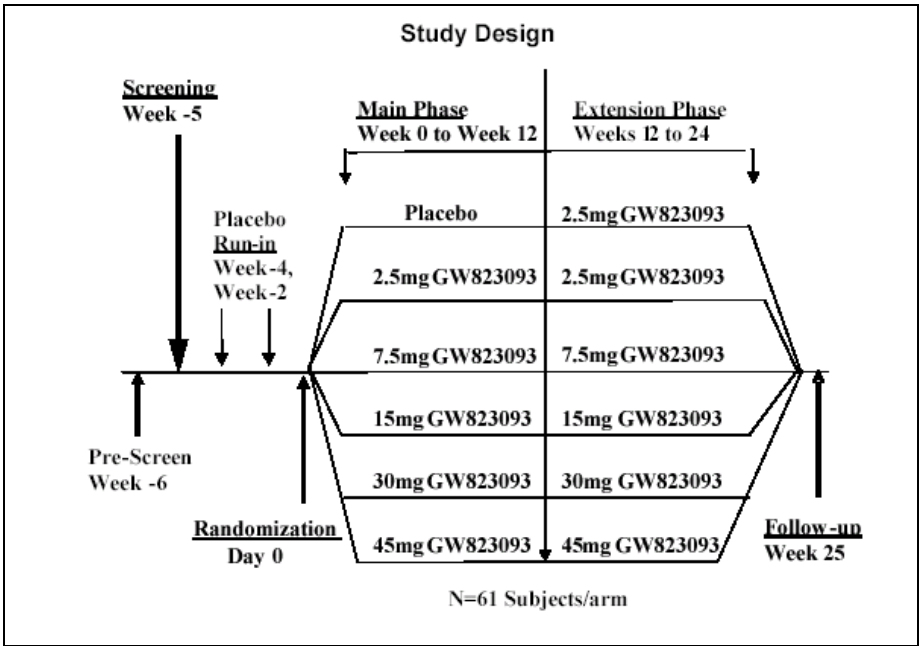
If subjects pass the initial screening criteria (Pre-Screening) then at the Screening visit subjects will be taken off their anti-diabetic medications and prohibited concomitant medications for the duration of the trial. Standard diabetic dietary and exercise advice will be provided at the beginning of the run-in, when subjects begin the single-blind placebo run-in medication and reinforced at every visit thereafter.

Subjects will be assigned to study treatment in accordance with the randomisation schedule. The randomisation code was generated using the GSK randomisation system RandAll. Upon successful completion of the run-in phase, each subject will be randomly assigned to one dose group of GW823093 or placebo. Eligible subjects will be stratified by gender and prior therapy (diet & exercise or monotherapy). To achieve balance between treatment groups, after completing the placebo run-in, subjects will be randomised in a 1:1:1:1:1:1 ratio to receive placebo, or one of the 5 doses (2.5, 7.5, 15, 30 or 45mg) of GW823093 qd for 12-weeks within each stratum. A fixed block size will be used, but will remain confidential. Central randomisation will be used (i.e. blocks will be applied globally from one central list).

All subjects will be on active treatment (GW823093) during the Extension Phase. Subjects randomised to placebo in the Main Phase will be placed on a 2.5 mg dose of GW823093 at the Week 12 visit. Subjects randomised to GW823093 in the Main Phase remain at their randomised dose and dosing regimen in the Extension Phase in a blinded fashion.

Upon completion of the Main Phase and the Extension Phase, subjects will be asked to return one week later to complete a series of safety assessments.

Refer to the study protocol for a more detailed explanation of each phase of the study.



An external Independent Data Monitoring Committee (IDMC) will be utilised during the study. The committee will be composed of external members. The objective of the

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committee is to monitor safety data (e.g. clinical chemistry, adverse events) on an on-going basis. The approved IDMC charter will be on file and available for inspection as requested.

4. PLANNED ANALYSES

Statistical programming will commence after data have been collected and are available in the database. A data look will be planned and will be performed using dummy treatment codes from RandAll to maintain the treatment blind.

All planned analyses for the Main Phase of the study will be performed once the eCRF freeze has taken place on the Main Phase data and the Main Phase treatment codes have been unblinded in RandAll. In this study there will be two eCRF freezes, one when all the Main Phase data are completed and one when all the Extension Phase data are completed. The processes during eCRF freeze will follow that outlined in the Guidance Document - Subject Freeze, Final Data Resolution, DBR and DBF (eDM-0009 v02; September 2004).

PK and PK/PD analyses will be performed by the Clinical Pharmacokinetics/Modelling & Simulation group. A separate RAP will be developed by this group for PK/PD analyses and will be finalised before unblinding the Main phase treatment codes.

Results from the main double-blind period *(initial 12 weeks)* and the results from the main and extension double-blind periods combined (*initial 12 weeks plus subsequent 12 weeks*), will be reported separately. The extension is designed to evaluate the safety and tolerability and time course for glycaemic effects after an additional 12 weeks of dosing. The extension will be ongoing at the time the main study results are reported but its conduct will not depend on these results. Treatment assignment details for individual subjects will not be made available to participating sites until the extension is complete. However, it will be necessary for GSK personnel involved in reporting the main study to have access to this information and as such, there will be a degree of unblinding for the extension. This will not compromise the primary analyses of efficacy and safety data which will all be performed within the Main Phase of the study.

A second RAP will be produced to expand on the data summaries planned for the Extension Phase of the study. This RAP will be produced according to the timelines specified in the RAP SOP (SOP-WWD-4000 V02) and before the Main Phase treatment codes are unblinded.

4.1. Interim Analyses

No interim analysis is planned for this study.

An external independent Statistician will produce the summaries required for the IDMC. No adjustment to the type I error will be made whilst the IDMC receive this data because there is no potential for stopping this study for efficacy. Details of the procedures and summaries produced are specified in the IDMC Charter and the IDMC RAP for this study.

4.2. Final Analysis

Analysis of covariance, adjusting for gender, prior therapy (diet & exercise/Monotherapy), region and baseline measurement will be carried out for the primary endpoint of change from baseline in HbA1c at Week 12, and for secondary endpoints (change from baseline to Week 12 in FPG, fructosamine, fasting serum insulin, pro-insulin and pro-insulin: insulin ratio). Responder analyses for HbA1c and FPG will also be performed. For details of full analyses refer to Section 11.

5. SAMPLE SIZE CONSIDERATIONS

The sample size of 58 evaluable subjects per treatment group (61 allowing for 5% unevaluable for primary endpoint assessment) is based on a last observation carried forward (LOCF) analysis of the difference between GW823093 and placebo with regards to change from baseline in HbA1c at Week 12. It is calculated to achieve a precision in estimating the treatment effect of 0.8% for the 95% confidence interval, assuming a standard deviation of 1.1%. The calculated sample size provides 93% power to detect a clinically relevant treatment difference of 0.7%. All statistical tests will be performed using two-sided tests of significance. The significance level for each individual hypothesis is 5% and the overall significance level is also 5%. No adjustment for the significance level is needed because the stepwise test is closed (refer to Section 7.1.1).

5.1. Sample Size Sensitivity

The effects of changes in the assumed standard deviation on the precision in estimating the treatment effect (measured by the width of the 95% confidence interval), the treatment difference that can be detected with 90% power and the power to detect a clinically relevant difference of 0.7%, based on a sample size of 58 per treatment arm, are all summarised in Table 1.

Table 1 The effects of changes in the assumption of standard deviation

Standard deviation (%)	Precision in estimating treatment effect (width of 95% confidence interval) (%)	Treatment difference that can be detected with 90% power (%)	Power to detect clinically relevant difference of 0.7% with 58 subjects per arm (%)
0.9	0.66	0.54	99
1.0	0.73	0.60	96
1.1	0.80	0.66	93
1.2	0.87	0.72	88
1.3	0.95	0.78	83
1.4	1.02	0.84	77

6. ANALYSIS POPULATIONS

The following populations will be assessed:

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Safety Population[1]. This population consists of all subjects who received at least one dose of study medication and will be used for assessing safety. Any subjects erroneously taking double-blind study medication during the run-in period will be included in this population.

Intent-to-Treat Population (ITT). This population will consist of all randomised subjects who received at least one dose of randomised study medication, have a baseline assessment and have at least one corresponding on-therapy (scheduled or unscheduled) efficacy assessment. This will be the primary population for assessing efficacy.

Per Protocol Population (PP). This population will consist of any ITT subjects who are compliant with protocol-specific criteria (refer to Section 10.2 for details of protocol deviations). Subjects with specified protocol deviations and non-completers of the Main Phase will be excluded from the Per Protocol population. Completers for this purpose will be subjects who have an HbA1c value at the Week 12 visit. The Per Protocol population will be used for a supporting analysis of the primary endpoint comparison only. The Per Protocol population will not be analysed if this population comprises of more than 95% or less than 50% of the ITT population.

Refer to the PK RAP for definitions of the Serial PK population and the Sparse PK population.

The Main Phase treatment codes will not be unblinded until all subjects' disposition with respect to these study populations has been finalised.

If any subject does not take treatment according to the randomisation schedule, the assignment of treatment for summary and analysis will follow the principles outlined below:

- If a subject takes the non-randomised treatment for only part of the Main Phase, the subject will be analysed based on randomised treatment assignment for both safety and efficacy. The deviation will be discussed within the text of the study report.
- If a subject takes the non-randomised treatment for the whole of the Main Phase, the subject will be analysed based on the treatment actually taken for safety analyses. However, the subject will still be analysed according to randomised treatment for efficacy as per the intent-to-treat principle. These subjects will be highlighted by a footnote in the study disposition table (this table details the number of subjects in each population).
- Any subject taking the incorrect treatment, for either all or part of the Main Phase of the study will be excluded from the Per Protocol population.

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[1] The definition of this population is more inclusive than that stated in the protocol to allow inclusion of subjects who received study medication during the run-in period.

7. TREATMENT COMPARISONS

7.1. Primary Comparisons of Interest

The primary objective of the study will be assessed through tests of hypotheses. The primary endpoint is the change from baseline to Week 12 in HbA1c which will be compared between each GW823093 group and placebo.

The primary analysis will be performed on the ITT Population with LOCF (refer to Section 6 for definition of this population and Section 9.1 for the approach to be used).

To address the issue of multiplicity, inferences from the study will be based on a closed testing procedure [Marcus, 1976]. The highest dose, GW823093 45mg, will be assessed first, in comparison to placebo. This will be tested at 5% significance level. If this comparison is significant, then the comparison of the GW823093 30mg dose to placebo will also be interpreted at 5% level, this process will continue, going down through all the doses until the first non-significant test is reached. With this approach, no adjustment to the significance level at each step is needed.

7.1.1. Other Comparisons of Interest

The primary comparison described above will also be performed using the ITT population where missing values are not imputed (refer to Section 9.1) and a further comparison where repeated measures analyses are used. Details for all other formal comparisons of interest are given in Section 11.

7.2. Data Display Treatment and Other Sub-group Descriptors

Refer to Section 17.7 (in a separate attachment) for an example showing how treatment groups will be displayed in the study report data displays.

8. GENERAL CONSIDERATIONS FOR DATA ANALYSES

8.1. Multicentre Studies

This study will be conducted in approximately 100 centres across North America (US and Canada; 52) and Europe (45).

For the US, geographical region will first be classified as follows (based on the US Census Bureau):

- Northeast: [redacted]
- Midwest: [redacted]
- South: [redacted]

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- West: [redacted]
- For the purposes of analysis, region will be classified as:
- US/Canada: Northeast, Midwest, South and West US, and Canada.
- Eastern Europe: Latvia, Romania, Czech Republic and Greece.
- Western Europe: Finland, Germany and Sweden.

Refer to the attachment in Section 17.1 for details of the number of centres and subjects.

Geographical region will be included as a factor for the primary analysis model, that is, analysis of the primary efficacy endpoint (and secondary endpoints where specified) will be adjusted for region.

For the primary efficacy endpoint only, treatment-by-region interaction will be assessed using a 10% significance level. In the presence of a significant treatment-by-region interaction, the method of Gail and Simon [Gail, 1985] will be used to test for qualitative interaction using a 10% significance level.

8.2. Other Strata and Covariates

The effects of baseline measurement and the stratification variables, gender and prior therapy, will be controlled for in all efficacy measures that will be analysed using analysis of covariance [Fleiss, 1986]. Gender and prior therapy will be taken as recorded in the eCRF (i.e. actual gender and prior therapy). The stratification variables as recorded in RAMOS will not be used (in the event that subjects are randomised into the incorrect strata).

Refer to Section 11.1 for details of assessments to be carried out for treatment by covariate interactions.

8.3. Examination of Subgroups

Subgroup summaries will be produced for the primary endpoint by the following:

- Previous treatment (diet & exercise, monotherapy)
- Gender
- Baseline HbA1c (<7.5%, 7.5-8.5% and > 8.5%)
- Baseline BMI (< 27kg/m2, 27 – 30 kg/m2 and > 30kg/m2)
- Region

Subgroup summaries will only be produced if there are at least 15 subjects per group. Refer to Section 11.1 for further details on subgroup investigations.

In addition, a supplementary summary table by detailed region will also be included. Detailed region is defined as follows: Sweden/Finland, Czech Republic/Latvia,

Romania/Greece, Germany, Canada, US Northeast/Midwest/West Region and US South Region.

8.4. Multiple Comparisons and Multiplicity

To address the issue of multiplicity, inferences from the study will be based on a closed testing procedure (refer to Section 7.1.1 for details).

8.5. Changes from Analyses Planned in the Protocol

Reproductive status will no longer be collected on the eCRF and therefore will not be summarised as part of subject demographics.

Indirect bilirubin will be calculated in-house and summarised in the appropriate laboratory tables (refer to Section 9.2.6 for calculation details).

The HOMA parameters of insulin resistance (IR), beta-cell function (BCF) and insulin sensitivity (IS) will be summarised and or/listed (refer to Section 9.2.7 for details).

The HbA1c target of ≤ 8% will no longer be formally analysed at Week 12 as this historical target is no longer deemed necessary; HbA1c targets of ≤ 6.5% and < 7% will still be analysed at Week 12.

Fructosamine was stated in the protocol as fructosamine (total and corrected for protein). It is no longer possible to measure fructosamine corrected for protein so only one fructosamine variable will be reported for this study.

The variable blood urea nitrogen (BUN) will be replaced by the variable serum urea. BUN is the American terminology for serum urea. In order to follow the GSK principle of using British English to standardise spelling and terminology, it was agreed that BUN should not be used since it is synonymous with serum urea.

References to drug naïve have been changed to diet & exercise as it is believed this is a better reflection of the population referred to as drug naïve (a subject is considered as diet & exercise (drug naïve) if they have not taken any anti-diabetic medication within the three months prior to the pre-screen visit date).

9. DATA HANDLING CONVENTIONS

9.1. Premature Withdrawal and Missing Data

Analysis of the ITT population will be performed using the LOCF approach. For subjects who withdraw from the study, the last valid observation recorded on-treatment (scheduled or unscheduled) will be carried forward to all remaining Main Phase visits. Also, for subjects who had missing observations prior to the last Main Phase treatment visit, the closest previous non-missing on-treatment observation will be carried forward to missing visits. If a subject has missing observation(s)

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immediately after baseline, the baseline observation will not be carried forward and the visit(s) will be left as missing.

For the primary efficacy endpoint, two additional sensitivity analyses will be performed. In the first approach, values will not be imputed for post-baseline assessments which are missing. In the second approach, a repeated measures analysis will be performed, this approach is a model based method over time.

9.2. Derived and Transformed Data

9.2.1. Baseline

Baseline is defined as the period immediately preceding treatment with double-blind study medication. Change from baseline will be computed as (visit value – baseline value). All Baseline assessments that are made on treatment will be re-assigned to the first on-treatment visit.

For efficacy parameters:

- The data to be used for the Baseline value will be the last scheduled or unscheduled value recorded for that parameter that is taken between 7 days prior to Main Phase treatment start date and Main Phase treatment start date.

For safety parameters:

- The data to be used for the Baseline value will be the last scheduled or unscheduled value recorded for that parameter that is taken between Screening (Week -5) and the Main Phase treatment start date.

- If subjects erroneously received double-blind study medication during the run-in period, their baseline assessment will be taken as the last time point prior to receiving double blind medication (expected to be the Screening visit).

9.2.2. Age

Age will be calculated from the Baseline visit. Age in years will be calculated by taking the number of years between the Baseline visit date and the subject's date of birth. An adjustment will be made if the months are the same as age is not increased until the birthday has occurred.

9.2.3. BMI

The body mass index for each subject will be defined as weight (kg) divided by the height (m) squared (height measured at baseline).

9.2.4. Waist: Hip Ratio

The waist: hip ratio will be defined as the waist circumference (cm) divided by the hip circumference (cm).

9.2.5. Duration of Diabetes

Duration of diabetes will be calculated from the Baseline visit.

9.2.6. Indirect Bilirubin

Indirect bilirubin will be calculated as total bilirubin minus direct bilirubin.

9.2.7. HOMA (Homeostasis Model Assessment) Measures

HOMA2 is a computer-generated model consisting of non-linear empirical equations solved numerically to predict glucose, insulin and c-peptide concentrations in the fasting state for any combination of beta-cell function (BCF) and insulin sensitivity (IS) [Matthews, 2004]. This software will be employed to yield an estimate of IS and BCF from fasting plasma insulin and fasting plasma glucose levels using the HOMA model (C-peptide will not be employed in this model as this endpoint was only collected at Screening).

Insulin resistance is the inverse of insulin sensitivity (1/IS).

As HOMA is a steady state model, only clinically realistic values that would be seen in a fasting subject should be used. These are:

- Plasma glucose 3.5 to 25.0 mmol/L (63 - 450mg/dL; note subjects will be withdrawn from this study if their FPG measurement is > 270mg/dL)
- Plasma insulin 20 to 400 pmol/L

Any values out of these ranges will be omitted from the HOMA model.

9.2.8. Exposure

Each subject's exposure in days to study medication will be calculated as follows:

- (double blind study medication stop date – double blind study medication start date) + 1.

Total exposure in subject years will be calculated for each treatment group by totalling all subjects' exposure within that treatment group and then dividing by 365.25.

9.3. Assessment Windows

In this study it is assumed that subjects will take their last dose of Main Phase study medication on the day before their Week 12 visit. At their Week 12 visit, subjects will arrive in clinic in a fasting state, and after all required measurements have been taken, they will be given the first dose of their Extension Phase study medication.

9.3.1. Main Phase Therapy Periods

For classifying adverse events (AEs) and hypoglycaemic events the following periods of the Main Phase will be defined in this study:

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Pre-Therapy: The onset date is before the start date of double-blind Main Phase study medication. If the onset date is on the start date of double-blind Main Phase medication, then the event will be considered as on therapy, as this is the conservative approach.

For subjects who do not withdraw during the Main Phase -

On-Therapy: Main Phase treatment start date ≤ onset date < double-blind Extension Phase treatment start date.

For subjects who withdraw during the Main Phase -

On-Therapy: Main Phase treatment start date ≤ onset date ≤ Main Phase treatment stop date + **2** days.

Post-Therapy: onset date ≥ Main Phase treatment stop date + **3** days

Note: Any event occurring on or after the start date of Extension Phase medication will be reported in the Extension Phase. If for some reason a subject does not take their first dose of Extension Phase study medication in clinic at their Week 12 visit (i.e. there is a gap in treatment between the Main and the Extension Phase) then any AEs or hypoglycaemic events occurring between the date of last dose of Main Phase medication and before the first dose of Extension Phase medication will be reviewed on an case-by-case basis prior to unblinding the Main Phase treatment codes (to ensure this data is assigned to Main Phase).

AEs, hypoglycaemic events and concomitant medications will be collected on a separate eCRF page for the Main Phase and for the Extension Phase.

9.3.2. Visit Slotting Algorithm

For safety and efficacy endpoints to be summarised or analysed by visit, data records should be slotted to one of the protocol specified visits using the following algorithm:

a. Determine relative day and last dose day:

- relative day = date of assessment - date of first dose +1, if date of assessment ≥ first dose date
- relative day = date of assessment - date of first dose, if date of assessment < first dose date.
- last dose day = date of last dose - date of first dose +1.

  Note that the date of first dose is day 1 and the day before the date of first dose is Day -1 (There is no longer a day 0).

b. For records that are not early withdrawal, if a nominal visit number for a **scheduled** visit (that is, a visit that is not a repeat visit) was assigned, then use it to slot the record and check to make sure that visit numbers match with therapy phases as defined in Section 9.3.1.

   If the record does not match the therapy phase, then this record will not be reported for that nominal scheduled visit number but will appear in subject listings. For example, if the nominal scheduled visit number is for Week 8 but

this subject withdrew from the study, and consequently this Week 8 record falls into the post-therapy phase. This data will not be reported in the tables but will be flagged in subject listings.

c. Any early withdrawal record (regardless of the visit number assigned), any unscheduled visit record at any time, any repeat visit record, or any record for which the visit number is missing or where the visit number does **not** correspond to a scheduled visit should be slotted or re-slotted to a visit as follows:

- If the parameter is scheduled to be measured at every protocol specified visit then use this window to slot a record:
- Visit 1 (Pre-Screen; Week -6) = days ≤ -39
- Visit 2 (Screening; Week -5) = -38 ≤ days ≤ -32
- Visit 3 (Week -4) = -31 ≤ days ≤ -22
- Visit 4 (Week -2) = -21 ≤ days ≤ -8
- Visit 5 (Week 0) = -7 ≤ days ≤ 1
- Visit 6 (Week 1) = days 2 – 11
- Visit 7 (Week 2) = days 12 – 18
- Visit 8 (Week 3) = days 19 – 25
- Visit 9 (Week 4) = days 26 – 35
- Visit 10 (Week 6) = days 36 – 49
- Visit 11 (Week 8) = days 50 – 70
- Visit 12 (Week 12) = days 71 - 87
- Follow-up for Early Withdrawals = days > last dose day + 2

- When performing visit slotting, the dates will be checked to ensure an unscheduled/early withdrawal record does not get slotted to an earlier visit where there exists (for a later visit) a nominal scheduled visit record with an earlier date. If this is the case then the scheduled/early withdrawal record will be slotted using the actual visit date as well as relative days to ensure chronological order of visits. The same applies if an unscheduled/early withdrawal record gets slotted to a later visit where there exists (for an earlier visit) a nominal scheduled visit record with a later date.

  For example, say a nominal scheduled visit record for Visit 2 is recorded on 21-Jun-05, the actual Visit 2 visit date is also 21-Jun-05, and two unscheduled records are taken on 24-Jun-05 (relative day = -39) and 28-Jun-05 (relative day = -35). Based on the relative days using c) above, the 24-Jun-05 record will get slotted to Visit 1 and the 28-Jun-05 will get slotted to Visit 2. Since the 24-Jun-05 record is slotted to Visit 1, yet the nominal scheduled Visit 2 record was taken on 21-Jun-05, we need to re-slot the 24-Jun-05 record. Since the actual Visit 2 visit date is 21-Jun-05, the 24-Jun-05 record will get re-slotted to Visit 2 to ensure records are in chronological order.

- If any subject withdraws in the period after their last dose of Main Phase treatment and before their Week 12 visit and there is no Extension Phase treatment start date and their early withdrawal record is greater than 87 days then

this will be handled on a case-by-case basis prior to unblinding the Main Phase treatment codes (to ensure their records are slotted to Main Phase).

- For parameters which were not scheduled to be collected at all visits, the all-inclusive visit intervals defined for all visits (i.e. the window defined above) will still be used to slot records. However, if a value is slotted to a visit unscheduled for a parameter, it will not be summarised but will be included in data listings.
- An exception to the above will be if a value is slotted to a visit unscheduled for that parameter and that is the last on-therapy (Main Phase) value recorded for that parameter for that subject. If this is the case then this unscheduled visit value will be carried forward to all remaining on-therapy scheduled visits in LOCF summaries and analyses. Similarly, if an early withdrawal record is slotted to a visit where a nominal visit already exists, then this early withdrawal visit value will be carried forward to all remaining on-therapy scheduled visits in LOCF summaries and analyses (since this will be the last on-therapy (Main Phase) value recorded for this subject).

d. If after all records have been slotted or re-slotted, either by visit number for a scheduled visit or by relative day, there are multiple valid records within a visit, the following hierarchy should be used to determine the appropriate record to use (in decreasing order):

    - the record with an original nominal visit number for a scheduled visit
    - the record closest to the target visit day (e.g., for visit 9 (week 4), target day is 4 x 7 = 28 days)
    - the record which will be the earliest in time

In this instance, the multiple record (i.e. the record which is not the appropriate record as stated above) will not be included in summaries and analyses but will appear in the appropriate listing.

Example

A subject is randomised on 01/06/2005, receives their last dose of treatment on 24/08/2005, has HbA1c measured at Week 4 (Visit 9) on 01/07/2005 (which is a scheduled visit for this parameter) and has an unscheduled HbA1c measurement taken on 05/07/2005. This subject did not withdraw during the Main Phase. Using the algorithm:

a. relative day = date of assessment – date of first dose + 1 = 01/07/2005 - 01/06/2005 + 1 = 31
last dose day = date of last dose – date of first dose + 1 = 24/08/2005 – 01/06/2005 + 1 = 85

b. This subject is not an early withdrawal so the nominal visit number for the scheduled visit of Week 4 (Visit 9) will be used to place this record at the Week 4 (Visit 9) visit. This is an on-therapy visit, as the visit is after the date of first dose and not more than the last date of Main Phase study medication.

c. Since this record has a nominal visit number for a scheduled visit, no further action is required.

Now, it is necessary to look at the unscheduled measurement, using the algorithm:

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a. relative day = date of assessment – date of first dose + 1 = 05/07/2005 - 01/06/2005 + 1 = 35
last dose day = date of last dose – date of first dose + 1 = 24/08/2005 – 01/06/2005 + 1 = 85

b. This subject is not an early withdrawal but this record does not have a nominal visit number for a scheduled visit (note – the record is unscheduled), so move onto c).

c. Since this record is for an unscheduled visit, this record needs to be slotted. The relative day is 35 days which lies within the Week 4 (Visit 9) window of days 26-35. This HbA1c measurement will be slotted to the Week 4 (Visit 9) visit.

d. For Week 4 (Visit 9), there are now multiple valid records of HbA1c for this subject. Using the hierarchy stated above:

   Eg1) First consider if there is a record with an original nominal visit number for a scheduled visit. This is the HbA1c measurement taken on 01/07/2005 and so this reading will be the appropriate record to use for Week 4 (Visit 9).

   Eg2) If neither of the two HbA1c measurements were originally recorded at Week 4 (Visit 9) then the second in the hierarchy will be looked at. That is, the record closest to the target visit day (4×7 = 28 days). This is again the HbA1c measurement taken on 01/07/2005 and so this reading will be the appropriate record to use for Week 4 (Visit 9).

   Eg3) If neither of the two HbA1c measurements were originally recorded at Week 4 (Visit 9) and both were equidistance from the target visit day (i.e. one was recorded at 26 days and one at 30 days with the target visit day of 28 days), then the third in the hierarchy will be looked at. The record which is the earliest in time will be used as the appropriate record (in this hypothetical example, this will be the recording at 26 days).

9.3.3. Invalid Laboratory Values

The following laboratory endpoints are required to be fasting:

- FPG
- All lipids
- Insulin and Pro-Insulin
- Fructosamine
- C-peptide

If these endpoints are recorded on the database in a non-fasting manner, then these values will be excluded from all summaries and statistical analyses but will be flagged in subject listings.

9.4. Laboratory Assessments

The default convention for reporting of laboratory units will be standard international (SI) units.

9.5. Values of Clinical Concern

Refer to the attachments in Section 17.2, Section 17.3 and Section 17.4 which respectively detail the laboratory values, vital signs values and ECG values of potential clinical concern.

10. STUDY POPULATION

10.1. Disposition of Subjects

The number of subjects who entered the run-in phase, the number of subjects who were randomised into the study, the number of subjects within each population (Safety, Intent-to-Treat and Per Protocol), and the number of subjects who completed the Main Phase of the study will be summarised for each treatment group and overall. The number of subjects in the above populations within each stratum (gender and prior therapy) will be summarised by treatment group.

The number of subjects in each centre who were included in the Safety population, the ITT population and who completed the study will be summarised for each treatment group and overall.

Reasons for discontinuation pre-therapy (during screening or run-in) will be summarised. Reasons for discontinuation on-therapy will be summarised for each treatment group and overall. A by-subject listing of data on subject reasons for discontinuation for both pre- and on-therapy will be produced.

10.2. Protocol Deviations

10.2.1. Inclusion – Exclusion Criteria

The number and percentage of subjects who were randomised into the study, but deviated from the inclusion or exclusion criteria will be summarised for each treatment group and overall. A by-subject listing will also be produced.

10.2.2. Per Protocol Population

The following criteria define **major** protocol deviations, which will lead to the exclusion of a subject from the Per Protocol population (refer to Section 6 for population definitions):

- Prohibited concomitant medications:
  - Oral anti-diabetic agents
  - Insulin (Per exclusion criteria)
  - Subjects on warfarin or digoxin will not be allowed to participate in this study. Subjects must not be washed off of these medications for the purposes of meeting eligibility criteria.
  - Oral anticoagulants (other than aspirin and non-steroidal anti-inflammatory drugs).

  - Oral or injectable corticosteroids (other than inhaled and intranasal).
  - Monoamine oxidase inhibitors and tri-cyclic amines
  - Antiretroviral drugs
  - Prescription and over-the-counter weight loss drugs
- Non-compliance with study medication (refer to Section 10.4 for definition).
- Treatment was not taken according to randomisation.
- Subject took double-blind study medication during the Run-In Phase
- Subject randomised into the incorrect strata (gender and prior therapy). This includes subjects in the Diet & Exercise (drug naïve) strata, who from reviewing their prior anti-diabetic medications have taken prior medications for any length of time in the three months prior to their pre-screen visit date and subjects in the Monotherapy strata, who from reviewing their prior anti-diabetic medications have not taken prior medications for any length of time in the three months prior to their pre-screen visit date (these will be reviewed on a case-by-case basis)).
- Subjects in the Monotherapy strata who have a washout period (number of days between Screening Visit (Visit 2, Week -5) and Baseline Visit (Visit 5, Week 0)) that is less than 28 days.
- Subjects treated by Investigator [redacted] (Centre [redacted] Due to a systematic violation of the planned visit schedule resulting in completion of the study in approximately 12 weeks rather than 24 weeks and potentially starting Extension Phase study medication during the Main Phase.
- Subjects who violate the HbA1c and/or FPG inclusion criteria as follows will be reviewed on a case-by-case basis to determine whether the subject is a protocol violator:
  - HbA1c at Pre-Screen (Visit 1): Diet & Exercise Subjects <7.5% or >10%; Monotherapy subjects: <7% or >8.5%.
  - FPG at Screening (Visit 2) < 7.8mmol/l.
  - FPG at Baseline >13.3mmol/l.

Any unforeseen circumstance occurring during the Main Phase study period will be reviewed on an individual basis (prior to unblinding the Main Phase) to determine whether it constitutes a protocol deviation.

A summary of major protocol deviations leading to exclusion from the Per Protocol population will be provided. Subjects who do not complete the Main Phase of the study will also be excluded from the Per Protocol population, but these subjects will not be included in the above table as they are not protocol violators per se. A by-subject listing of this data will be produced.

A listing of concomitant medications will be produced and a clinical review will highlight all prohibited medications and the timings relative to study medication when their use is prohibited. This process will be completed prior to unblinding the Main Phase treatment codes.

10.3. Demographic and Baseline Characteristics

10.3.1. Demography and Baseline Data

Demographic data will include age, ethnicity, sex, height, body weight and waist and hip circumference. Body mass index (BMI) and waist: hip ratio will be calculated in-house based on the formulas in Section 9.2. Furthermore, BMI and age will also be categorised as: BMI ($< 27 kg/m^2$, $\geq 27 kg/m^2$; after the Data Look, if deemed more appropriate the $\geq 27 kg/m^2$ category may be extended to $27 – 30 kg/m^2$ and $> 30 kg/m^2$) and age (<65, ≥65 years). All the above demographic data will be summarised by treatment group and overall. The following demographic data will be summarised by strata (gender & prior therapy): BMI and duration of diabetes. Summaries on race categories will also be generated.

A by-subject listing of data of demographic and baseline characteristics, including C-peptide (taken at screening) and fasting capillary blood glucose (FCBG; taken at baseline) will be produced. A by-subject listing of data on race will also be produced.

Summaries of disease history (prior therapy & duration of diabetes) will be generated and a by-subject listing of data of disease history will be produced.

Summary of substance use (alcohol and tobacco) will be generated and a by-subject listing of data on substance use will be provided.

10.3.2. Medical History

The number and percentage of subjects with each past and current condition will be reported for each treatment group and overall. Past conditions are those reported as ‘past’ and current conditions are those reported as ‘current’ at screening. Past and current conditions will be reported separately. A by-subject listing of data of past and current medical conditions will be produced.

10.3.3. Concomitant Medications

The GSK drug dictionary will be used to code drug names. The number and percentage of subjects receiving prior anti-diabetic medications, prior medications and concomitant medications will be summarised separately by treatment group and overall. A summary of prior SU and prior Metformin medications will also be produced. Prior medications are those started before randomisation, concomitant medications are those taken at any time after randomisation (i.e. on or after the first date of study medication dosing) and up to (but not including) the start date of Extension Phase study medication (including those started prior to randomisation which were continued during the Main Phase study period).

A by-subject listing of prior anti-diabetic medications and of prior and concomitant medications will be produced.

10.4. Treatment Compliance

The number and percentage of subjects in the following categories for overall compliance will be presented for each treatment group and overall by visit: 0%, > 0 -

< 80%, 80% -120%, >120% compliant; the reason for non-compliance will also be summarised. Summary of overall compliance will also be generated. A by-subject listing of data of study medication compliance will be produced.

Compliance (for double-blind treatment) will be measured at Weeks 4, 8 and 12 (and early withdrawal visit, if applicable). Overall study (Main Phase) non-compliance is defined as not being compliant for two or more out of the three compliance visits (i.e. not being in the '80 – 120%' category for two or three of the three visits or simply, being in the '80 – 120%' category for only one of the three visits). If subjects are only in the study (Main-Phase) for one or two of these compliance visits (i.e. the subject withdraws from the study), then the following rules for compliance will apply:

- One visit – the subject must be in '80 – 120%' category for that visit to be study compliant.
- Two visits - the subject must be in '80 – 120%' category for both visits to be study compliant.

For this study, the subject number, start date of Main Phase study medication and end date of Main Phase study medication will be listed for the subject(s) with the earliest date for the first dose of Main Phase study medication and the subject(s) with the latest date of the last dose of Main Phase study medication.

11. EFFICACY ANALYSES

Analysis of covariance (ANCOVA) will be the statistical method used to assess changes from baseline for the endpoints in this study. One of the assumptions underlying this method is that the response variable is normally distributed. The distributions of the efficacy endpoints in this study will be examined along with the influence of any extreme outlying observations. In the event of any extreme outliers, a sensitivity analysis may be provided.

11.1. Primary Efficacy Analysis

The primary objective of comparing the change in HbA1c from baseline at Week 12 between each of the five treatment groups and the placebo group will be performed by using a (5% two-sided) hypothesis test. This test will be based on an analysis of covariance model with terms for gender, prior therapy (diet & exercise/monotherapy), treatment, region and baseline measurement (continuous covariate). The point estimates and corresponding 95% confidence intervals for treatment differences from placebo will be calculated. To address the issue of multiplicity, a closed testing procedure will be used (see Section 7.1.1). With this approach, confidence intervals for treatment differences below the last statistically significant treatment difference (i.e. treatment comparisons for doses below the last significant dose) will be identified as 'for descriptive purposes only'.

The treatment-by-baseline, treatment-by-region, treatment-by-prior-therapy and treatment-by-gender interactions will be investigated at a significance level of 10% but interactions will not be included in the main model where treatment effects are tested and compared. If the treatment-by-baseline interaction is statistically significant, each active dose to placebo slope coefficient will be examined to see if they are all in a common direction. If the treatment-by-region, treatment-by-prior-

therapy or treatment-by-gender interactions are statistically significant, the likelihood ratio test for qualitative significance proposed by Gail and Simon [Gail, 1985] will be performed. In order to quantify the treatment effect relative to placebo in the prior therapy and gender subgroups, a formal (exploratory) analysis may be conducted (if required). Shapiro-Wilk test for normality of the efficacy variables performed using PROC UNIVARIATE will be included in the SAS statistical output in support of the efficacy analysis.

Tables displaying summary statistics and tables associated with the analysis of the primary endpoint will be produced. Appropriate figures will also be provided.

11.1.1. Sensitivity Analyses

The primary efficacy analysis will be based on an analysis of the ITT with LOCF population, however a sensitivity analysis will also be performed on the ITT without LOCF population, the Per Protocol population (if applicable; refer to Section 6) and the ITT population without LOCF using repeated measures.

An additional sensitivity analysis will be conducted for the primary endpoint on the ITT with LOCF population. Subjects treated by Investigator [redacted] (Centre [redacted] will be excluded due to a systematic violation of the planned visit schedule resulting in completion of the study in approximately 12 weeks rather than 24 weeks and potentially starting Extension Phase study medication during the Main Phase.

Tables displaying summary statistics and tables associated with the sensitivity analysis of the primary endpoint for the populations stated above will be produced.

11.1.1.1. Repeated Measures

For the assessment of differences between the treatment groups with regard to repeated measures over time, a multivariate linear model analysis incorporating on-therapy values at all time points will be employed (PROC MIXED in SAS). The estimated method will be Restricted Maximum Likelihood and the Kenward-Rogers adjustment to the denominator degrees of freedom for the F-test will be applied [Kenward, 1997]. The model will use saturated means and an unstructured covariance matrix. The dependent variable will be change in HbA1c from baseline; effects in the model will be gender, prior therapy (diet & exercise/monotherapy), treatment, region, baseline measurement, time, and treatment-by-time interaction. Time will be treated as the repeated variable within a subject. Subject, treatment, region, gender, prior therapy and time will be treated as class variables.

11.1.2. Dose-Response

An investigation into the dose-response curve will be conducted. An ANCOVA model will be fitted with response of change from baseline at Week 12 with model terms for gender, prior therapy (diet&exercise/monotherapy), treatment, region and baseline HbA1c. Firstly, orthogonal contrasts to test for linear, quadratic and cubic trends [Robson, 1959] will be carried out using the CONTRAST statement within PROC MIXED in SAS. Based on the outcome from these tests, the least-square means (model-adjusted) from the ANCOVA model will be used as data in a weighted regression to estimate the predicted dose response curve.

A figure showing the least-square means (model-adjusted) across each of the 6 doses (Placebo (Dose 0), 2.5, 7.5, 15, 30 and 45mg) with 95% CI and the predicted dose response curve with 95% CI will be produced. This figure will include the p-values for the linear, quadratic and cubic trends.

Further exploratory work may be carried out examining dose on the log-scale. The output obtained from all the dose-response work will be included in the Statistical Appendix of the clinical study report.

11.2. Secondary Efficacy Analyses

For all secondary efficacy parameters, the comparisons of interest will be between treatment groups and the placebo group.

To assess the difference between treatment groups with regards to change from baseline to Week 12 in FPG, fructosamine, fasting serum insulin, pro-insulin and pro-insulin: insulin ratio, an analysis of covariance with terms for gender, prior therapy, treatment, region and baseline measurement will be performed. The point estimates and corresponding 95% confidence intervals for treatment differences will be calculated.

Tables associated with the analysis of the secondary endpoints will be produced. Secondary endpoints will also be summarised at appropriate visits by treatment group. Appropriate figures and a by-subject listing of glycaemic endpoints will also be provided.

11.2.1. Responder Analysis

Differences between treatment groups in the proportion of subjects who achieve the HbA1c targets of ≤ 6.5% and < 7% and the FPG target of < 126mg/dL [7.0mmol/L] at Week 12 will be assessed based on a logistic regression model with terms included for treatment, gender, prior therapy, and baseline measurement.

Differences between treatment groups in the proportion of subjects who achieve a clinically meaningful decrease from baseline in HbA1c (≥ 0.7%) and FPG (≥ 30mg/dL [1.7mmol/L]) will be assessed in the same manner.

Tables associated with the analysis of HbA1c and FPG responders at Week 12 will be produced. A by-subject listing of responders will also be provided.

11.3. Other Efficacy Analyses

11.3.1. Lipids

For all lipid parameters (triglycerides, FFAs, TC, LDL-c, HDL-c) the percentage change from baseline will be summarised at each visit where data are collected (the proposed method of analysis involves a log-transformation; refer to Section 11.2.3 of the Diabetes Generic RAP for statistical methods on calculation and treatment comparison of geometric means). Formal statistical analysis will be performed at Week 12, using an analysis of covariance with terms for gender, prior therapy,

treatment, region and log-transformed baseline measurement. The point estimates and corresponding 95% confidence intervals for treatment ratios will be calculated.

Tables associated with the analysis of lipids will be produced. Lipid endpoints will also be summarised at appropriate visits by treatment group. Appropriate figures and a by-subject listing of lipids will also be provided.

11.3.2. HOMA Measures

HOMA measures (IS and BCF) will be logarithmically transformed and summarised at each visit by treatment group (refer to Section 9.2.7). IS, BCF and IR will be listed.

11.3.3. Pharmacodynamic Assessments and Biomarkers

Refer to Section 14 for the assessment of Biomarkers.

12. SAFETY ANALYSES

Refer to Section 6 for the definition of the Safety population.

12.1. Extent of Exposure

The number of days of exposure to study medication will be summarised for each treatment group and overall. Subject exposure will also be categorised and the number and percentage of subjects in each category presented for each treatment group and overall. A by-subject listing of data on subject exposure to study drug will also be produced.

12.2. Adverse Events

Adverse events will be summarised by their occurrence in regard to therapeutic phase, i.e. pre-therapy, on-therapy and post-therapy as defined Section 9.3.1.

AE summaries will be performed using the preferred terms and body system assigned by the Medical Dictionary for Regulatory Activities (MedDRA).

The proportion of subjects reporting each type of adverse event will be tabulated for each treatment group. The following summaries of adverse events will be provided:

- all adverse events
- treatment-related adverse events
- common adverse events (≥ 5% incidence)

If a relationship to drug is missing or unknown it will be assumed, for the purpose of analyses, to be drug-related. In the case of an adverse event occurring more than once within a time period (pre-therapy, on-therapy or post-therapy), only one event in that period will be used in the summary. When summarising by Intensity, maximum intensity in that period will be used if an AE occurs with different intensities within the same period.

Full details for all adverse events will be listed. Any subjects who have an AE that began in the Main Phase and is ongoing when the Main Phase data are reported will be listed in a separate listing.

Dotplots (with relative risks and confidence intervals) for common AEs will be produced for the doses of 15, 30 and 45mg versus Placebo.

12.3. Deaths and Serious Adverse Events

Serious adverse events will be summarised by their occurrence in regard to therapeutic phase, i.e. pre-therapy, on-therapy and post-therapy as defined in Section 9.3.1.

A summary of the number and percentage of subjects with all serious adverse events will be provided.

12.3.1. Deaths

A by subject listing of fatal adverse events will be displayed.

12.3.2. Serious Non-Fatal Adverse Events

A by subject listing of non-fatal serious adverse events will be displayed.

12.4. Adverse Events Leading to Discontinuation of Investigational Product and/or Withdrawal from the Study and Other Significant Adverse Events

A summary of the number and percentage of subjects with pre-therapy and with on-therapy adverse events leading to permanent discontinuation of study drug (subjects who discontinued and re-started study medication will not be considered as withdrawals/withdrawal) from the Main Phase of the study will be displayed separately. A by subject listing of all adverse events leading to permanent discontinuation of study drug/withdrawal from the study will be produced.

12.5. Pregnancies

Pregnancies will not be reported as adverse events. Case narratives of all subjects who became pregnant will be provided in the main text of the study report.

12.6. Clinical Laboratory Evaluations

Laboratory data (clinical chemistry and haematology) will be summarised, for each treatment group, at every assessed time point. Parameter values and change from baseline will be summarised separately. An additional table of selected laboratory parameters at each time point which includes SE will also be produced.

Each laboratory test will be summarised, for each treatment group, at every assessed time point using classification by reference ranges as "> reference range high" (i.e. >ULN), "< reference range low" (i.e. <LLN).

The number of subjects with abnormal values at any time on-therapy will be summarised, for each treatment group and overall. The display will categorise the data according to whether the values meet predefined criteria of potential clinical concern (refer to Section 17.2).

Figures over time for the following selected laboratory data will be produced: ALT, AST, Bilirubin and Haemoglobin. Box plots of maximum post-baseline value relative to ULN will be produced for LDH, ALT, AST, Bilirubin, Alkaline Phosphatase and the exploratory biomarker, CK-MB. Patient profiles for post-baseline values > 1.5*ULN for ALT, AST, Bilirubin and Alkaline Phosphatase will also be produced.

A listing of laboratory data for subjects with laboratory abnormalities of potential clinical concern will be provided. An all-subject listing of laboratory data will also be produced.

12.7. Other Safety Measures

12.7.1. Hypoglycaemic Events

Hypoglycaemic events merit special attention in the development and study of drugs for the treatment of type 2 diabetes since they are often related to the efficacy of a compound. In order to accomplish this, hypoglycaemic events will be collected separately and will be reported separately from adverse events, including supplemental data which is not collected for adverse events. However, any hypoglycaemic event which meets the criteria for a serious adverse event will be included in the serious adverse event summaries.

The number of subjects in each treatment group that experience a hypoglycaemic event will be summarised by frequency of the events.

12.7.2. Vital Signs

All Vital signs data (systolic BP, diastolic BP and heart rate) will be summarised at every assessed time point by treatment group. Change from baseline will also be derived and summarised.

A summary of vital signs of potential clinical concern (refer to Section 17.4) at any time on-therapy will be presented.

A by subject listing of vital sign values at each time point will be produced.

12.7.3. Urinalysis

Urinalysis dipstick results (Glucose, Bilirubin, Protein, Ketones, RBCs/HPF and WBCs/HPF) will be summarised at each assessed time point by treatment group. A by-subject listing will also be produced.

12.7.4. Weight, Hip and Waist Circumference, Waist: Hip Ratio and BMI

Weight (kg), hip circumference (cm), waist circumference (cm), waist: hip ratio and BMI, will be summarised at each time point by treatment group. Summary statistics for change from baseline at each visit will also be produced. Percentage change from baseline will also be summarised for weight. An additional table of change from baseline in weight which includes SE will also be produced. A figure of change from baseline over time for weight will also be included.

A by subject listing of weight, hip and waist circumference, waist: hip ratio and BMI at each time point will be produced.

12.7.5. Electrocardiograms

All ECGs will be read locally by the Investigator or his/her designate and will be forwarded electronically for central interpretation.

Twelve-lead electrocardiogram measurements will be taken at visits 2, 5, 9 and 12. Ventricular Rate (bpm), RR Interval (msec), PR Interval (msec), QRS Duration (msec), QT Interval (msec), QTcB Interval (msec) and QTcF Interval (msec) will be summarised by treatment group and visit. Parameter values and change from baseline will be summarised separately.

A summary of the number and percentage of subjects who had abnormal and/or clinically significant ECG findings will be displayed by treatment group and overall.

The number and percentage of subjects with ECGs of potential clinical concern (refer to Section 17.3) occurring at any time on-therapy will be presented separately.

Listings of ECG values, ECG changes from baseline and on-therapy abnormal and/or clinically significant ECG findings will be produced.

13. CLINICAL PHARMACOLOGY DATA ANALYSES

13.1. Pharmacokinetic Analyses

The PK population includes all subjects for which GW823093 concentration data are available.

For the current study, plasma concentrations of GW823093 for each subject will be listed based on the dose level, time, and day at which each sample was collected relative to the first dose.

Relevant data from the current study and from study DPB10003 will be combined and analysed using a nonlinear mixed effects modelling approach (population PK). Population PK parameters including CL and V will be estimated. Dependent on the final structural PK model additional PK parameters also may be estimated.

Sources of variability in PK parameters will be investigated during population modelling. Demographic parameters including, but not limited to, age, sex, and body

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weight will be evaluated as potential predictors of inter- and intra-subject variability for PK parameters. Population modelling will be performed using the non-linear mixed effects modelling software NONMEM (Globomax LLC; Hanover, MD).

Further details of population PK analyses will be described under a separate RAP (which will be finalised prior to unblinding the Main Phase treatment codes). Results of the population PK analysis will be included in a dedicated report separate from the clinical study report.

13.2. Pharmacokinetic/Pharmacodynamic Analyses

Changes in relevant primary and secondary pharmacodynamic and safety endpoints will be plotted against plasma concentrations of GW823093. The relationship between the change in pharmacodynamic/safety endpoints and GW823093 concentration will be examined visually. If a relationship is found, the appropriate linear or nonlinear regression analysis will be performed.

Any PK/PD correlations found from the current study may be investigated further as part of a population PK/PD analysis.

Further details of population PK analyses will be described under a separate RAP (which will be finalised prior to unblinding the Main Phase treatment codes). Results of the population PK analyses will be included in a dedicated report separate from the clinical study report.

Summary statistics tables and line graphs over time for Serial Sampling PK subjects in the ITT population will be produced for the following data: glucose, insulin, glucagon, GLP-1 and DPPIV inhibition. A listing of this data will also be provided.

Listings, summary statistics, and plots of GW823093 concentrations will be included in the Population PK RAP. Relevant correlations between GW823093 concentrations/exposures and glucose, insulin, glucagon, GLP-1 and DPPIV inhibition will also be included in the Population PK RAP.

14. BIOMARKER DATA ANALYSIS

Descriptive statistics will be provided for the population cardiac biomarker, CK-MB at each collection time point in the Main Phase. A summary will be produced for specific ranges of the population biomarker cTnI at each visit, the ranges of interest are: <0.2, $\geq 0.2 - 0.35$, $>0.35 - 1.5$ and > 1.5 mcg/l. This summary will be considered as exploratory for this study. A listing of these population biomarkers will also be provided.

In addition, blood samples will be taken and serum and plasma frozen for future biomarker analyses as deemed appropriate and as provided by the Informed Consent Document.

15. PHARMACOGENETIC DATA ANALYSES

Refer to the protocol for information on Pharmacogenetic analyses.

16. REFERENCES

Fleiss JL. The Design and Analysis of Clinical Experiments. Wiley 1986:186-207.

Gail M, Simon R. Testing for Qualitative Interactions between Treatment Effects and Patient Subsets. Biometrics 1985; 41: 361-372.

Kenward, M.G. and Roger, J.H. Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood. Biometrics, 1997; 53, 983 -997.

Marcus R, Peritz E and Gabriel K. On Closed Testing Procedures with Special Reference to Ordered Analysis of Variance. Biometrika 1976; 63: 655-60.

Matthews D, Wallace T and Levy J. Use and Abuse of HOMA Modelling. Diabetes Care 2004; 27: 1487-95.

Robson DS. A Simple Method for Constructing Orthogonal Polynomials when the Independent Variable is Unequally Spaced. Biometrics 1959; 15: 187-191.

17. ATTACHMENTS

17.1. Geographical Regions

Regions	Target No. of Centres	Target No. of Subjects	Actual[1] No. of Centres	Actual No. of Subjects
US Northeast Region	7	116	34 (across US regions)	59
US Midwest Region	5			
US South Region (+Puerto Rico)	17			
US West Region	11			
Canada	12	30	12	29
Czech Republic	5	31	8	24
Finland	5	30	3	3
Germany	10	35	28	46
Greece	8	36	3	5
Latvia	5	28	7	8
Romania	3	23	3	10
Sweden	1	23	1	24

1. Actual is from the data taken on the date the RAP Amendment 1 was signed off.

17.2. Laboratory Values of Potential Clinical Concern

Laboratory Parameter	Reporting Units (SI)	Values of Potential Clinical Concern (F3)
Haematology		
Haemoglobin		
Males & females (18+ years)	g/L	> 20g/L below LLRR or > 10g/L above ULRR
Haematocrit		
Males & females (18+ years)	1	> 0.05 below LLRR or > 0.04 above ULRR
White Blood Cell Count	GI/L	> 1GI/L below LLRR or > 5 GI/L above ULRR
Total Neutrophils	GI/L	<0.5 x LLRR
Lymphocytes	GI/L	<0.5 x LLRR
Platelets	GI/L	<80 or >500
Biochemistry		
Total Bilirubin	μmol/L	>1.5 x ULRR
Total Protein	g/L	> 15 g/L above or below RR
Albumin	g/L	> 5 g/L above or below RR
AST (SGOT)	U/L	>3 x ULRR
ALT (SGPT)	U/L	>3 x ULRR
Alkaline Phosphatase	U/L	>3 x ULRR
Chloride	mmol/L	> 5 x ULRR
Creatinine	μmol/L	>159
Serum Urea	mmol/L	>2 x ULRR
Uric Acid	μmol/L	>654
Sodium	mmol/L	> 5 mmol/L above or below RR
Potassium	mmol/L	> 0.5 mmol/L below LLRR or > 1 mmol/L above ULRR
Bicarbonate	mmol/L	<16 or >40
Calcium	mmol/L	<1.8 or >3.0
Phosphorus	mmol/L	> 0.323 mmol/L above or below RR
Lactate Dehydrogenase	U/L	>2.5 x ULRR
Other Tests		
Glucose	mmol/L	<3 or >22

1. LLRR = lower limit of the reference range; ULRR = upper limit of the reference range.
2. Red Blood Cells, Monocytes, Eosinophils, Basophils, Direct & Indirect Billirubin and Cholesterol do not have any values of potential clinical concern. Triglycerides values of potential clinical concern will not be assessed.

17.3. Vital Signs Considered to be of Potential Clinical Concern

Parameter	Units	Change from Baseline of Potential Clinical Concern (F2)	Potential Clinical Concern Value (F3)
Heart rate	bpm	increase or decrease >30 bpm	<50 or > 120 bpm
Systolic Blood Pressure	mmHg	increase or decrease >30 mmHg in same posture	>170 mmHg or <100 mmHg
Diastolic Blood Pressure	mmHg	increase or decrease >20 mmHg in same posture	>110 mmHg or <50 mmHg

17.4. ECG Values Considered to be of Potential Clinical Concern

Parameter	Units	Change from Baseline of Potential Clinical Concern (F2)	Potential Clinical Concern Value (F3)
PR interval	msec	Increase of > 25% when baseline PR >200 msec Increase of > 50% when baseline PR ≤200 msec	>300 msec
QRS interval	msec	Increase of > 25% when baseline QRS >100 msec Increase of > 50% when baseline QRS ≤100 msec	>200 msec
QTc interval	msec	Increase of > 10% when baseline QTc >440 msec Increase of > 20% when baseline QTc ≤440 msec	>500 msec
Ventricular rate	bpm		Supine: < 50 or > 120

17.5. Visit Scheduling

Visit 1 Pre-Screen (Week -6)	Visit 2 Screening (Week -5)	Visit 3 Week -4	Visit 4 Week -2	Visit 5 Baseline	Visit 6 Week 1	Visit 7 Week 2	Visit 8 Week 3	Visit 9 Week 4	Visit 10 Week 6	Visit 11 Week 8	Visit 12 Week 12

17.6. Table of Contents for Data Display Specifications

17.6.1. Table of Contents for Study Population Tables

Output ID	Title (including study population)	Parameters /Comments	Generic RAP ID	TST/ IDSL ID
Table 10.1	Summary of Subject Disposition, All Subjects	Include Per Protocol population, if required.	T10.1.2	MetTST
Table 10.2	Summary of Subject Disposition by Gender and Prior Therapy, All Randomised Subjects			
Table 10.3	Summary of Subject Disposition by Country, Safety Population		T10.1.3	MetTST
Table 10.4 Table 10.5	Summary of Screen and Run-In Failures, All Subjects Summary of Study Conclusion, Safety Population		T10.1.1 T10.1.1	IDSL ES1 IDSL ES1
Table 10.6	Summary of Inclusion/Exclusion Criteria Deviations, Safety Population	Inclusion/Exclusion criteria as detailed in Protocol Amendment 1.	T10.2.1	IDSL IE1
Table 10.7	Summary of Major Protocol Deviations Leading to Exclusion from the Per Protocol Population, ITT Population		N/A	IDSL SA2

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Output ID	Title (including study population)	Parameters /Comments	Generic RAP ID	TST/ IDSL ID
Table 10.8	Summary of Demographic Characteristics, Safety Population	To be included in the order stated below • *Age (Year) + categories* • *Gender* • *Ethnicity* • *Baseline weight (kg)* • *Baseline BMI (kg/m²) + categories* • *Baseline Hba1c (%)* • *Baseline height (cm)* • *Baseline waist circumference* • *Baseline hip circumference* • *Baseline waist/hip ratio*	T10.3.1.1	IDSL DM1
Table 10.9	Summary of Type II Diabetes Mellitus History, Safety Population		T10.3.2	MetTST 2.1
Table 10.10	Summary of Selected Demographic Characteristics by Gender and Prior Therapy, Safety Population	• *Baseline BMI (kg/m²)* • *Duration of Diabetes (yrs)*		
Table 10.11	Summary of Baseline HbA1c (%) by Prior Therapy, Safety Population	HbA1c categories: < 7.5 ≥ 7.5 to < 8 ≥ 8 to < 8.5 ≥ 8.5		
Table 10.12 Table 10.13	Summary of Race and Racial Combinations, Safety Population Summary of Race and Racial Combination Details, Safety Population	Concatenation of high level race terms not required if not present in data. Need to display mixed race categories, even if not present in data.	T10.3.1.2 T10.3.1.3	IDSL DM5 IDSL DM6
Table 10.14	Summary of Substance Use, Safety Population	• *Smoking History* • *Drink Alcohol* • *Alcohol Units/Week*	T10.3.3	IDSL SU1

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Output ID	Title (including study population)	Parameters /Comments	Generic RAP ID	TST/ IDSL ID
Table 10.15	Summary of Past Medical Conditions, Safety Population		N/A	IDSL MH1
Table 10.16	Summary of Current Medical Conditions, Safety Population		N/A	IDSL MH1
Table 10.17	Summary of Past Diabetes Medical Conditions, Safety Population		T10.4.2	MetTST 1.2
Table 10.18	Summary of Current Diabetes Medical Conditions, Safety Population		T10.4.2	MetTST 1.2
Table 10.19	Summary of Past Cardiovascular Medical Conditions, Safety Population		T10.4.2	MetTST 1.2
Table 10.20	Summary of Current Cardiovascular Medical Conditions, Safety Population		T10.4.2	MetTST 1.2
Table 10.21	Summary of Prior Anti-Diabetic Medications, Safety Population		T10.5.1	IDSL CM1
Table 10.22	Summary of Prior Medications, Safety Population	Summary of Medications with Combination Products Listed as Combinations.	N/A	New layout, HARP macro exists
Table 10.23	Summary of Prior SU and Metformin Medications, Safety Population		N/A	New layout, HARP macro exists
Table 10.24	Summary of Concomitant Medications, Safety Population	Summary of Medications with Combination Products Listed as Combinations.	N/A	
Table 10.25	Summary of Study Medication Compliance, Safety Population		T10.6.1	MetTST 4.1
Table 10.26	Summary of Overall Compliance, Safety Population		T10.6.2	MetTST 4.2

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17.6.2. Table of Contents for Efficacy Tables

Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Primary Analyses of HbA1c				
Table 11.1	Summary Statistics for HbA1c (%) by Visit, ITT with LOCF	At Visits: 1,4,5,9,11,12	T11.1.1	Metabolic 6.1
Table 11.2	Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT with LOCF		T11.1.2.1	Metabolic 8.1
Table 11.3	SAS Statistical Output for Table 11.2 Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT with LOCF		T11.1.2.2	Metabolic 8.2
Table 11.4	Summary Statistics for HbA1c (%) by Visit, ITT without LOCF		T11.1.1	Metabolic 6.1
Table 11.5	Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT without LOCF		T11.1.2.1	Metabolic 8.1
Table 11.6	SAS Statistical Output for Table 11.5 Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT without LOCF		T11.1.2.2	Metabolic 8.2
Table 11.7	Summary Statistics for HbA1c (%) by Visit, PP		T11.1.1	Metabolic 6.1
Table 11.8	Analysis of Change in HbA1c (%) From Baseline to Week 12, PP		T11.1.2.1	Metabolic 8.1
Table 11.9	SAS Statistical Output for Table 11.8 Analysis of Change in HbA1c (%) From Baseline to Week 12, PP		T11.1.2.2	Metabolic 8.2
Table 11.10	Summary Statistics for HbA1c (%) at Week 12 by Region, ITT with LOCF	Regions are as listed in Section 8.1.		

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Table 11.11	Summary Statistics for HbA1c (%) at Week 12 by Gender, ITT with LOCF	Gender: Male & Female		
Table 11.12	Summary Statistics for HbA1c (%) at Week 12 by Prior Therapy, ITT with LOCF	Prior Therapy: Diet & exercise & Monotherapy		
Table 11.13	Summary Statistics for HbA1c (%) at Week 12 by Baseline HbA1c, ITT with LOCF	Baseline HbA1c: (<7.5%, 7.5-8.5% and > 8.5%)		
Table 11.14	Summary Statistics for HbA1c (%) at Week 12 by Baseline BMI, ITT with LOCF	Baseline BMI: (< 27kg/m^2, 27 – 30 kg/m^2 and > 30kg/m^2)		
Table 11.15	Repeated Measures Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT Population without LOCF		T11.5.1.1	Metabolic 17.1
Table 11.16	SAS Statistical Output for Table 11.15 Repeated Measures Analysis of Change in HbA1c (%) From Baseline to Week 12, ITT Population without LOCF		T11.5.1.2	Metabolic 17.2
Secondary Analyses – Glycaemic Endpoints				
Tables 11.17, 11.21, 11.24, 11.27, 11.30	Summary Statistics for *Endpoint (unit)* by Visit, ITT with LOCF	• *FPG (mmol/L)* • *Fructosamine (mmol/L)* • *Fasting Serum Insulin (pmol/L)* • *Pro-Insulin (pmol/l)* • *Pro-Insulin:Insulin Ratio* • *FPG - All Visits* • *Fructosamine by Visit 2,4,5, 9,11,12* • *Insulins by Visit 5,9,11,12*	T11.1.1	Metabolic 6.1
Table 11.18	Summary Statistics for FPG (mmol/l) at Week 12 by Prior Therapy, ITT with LOCF	Prior Therapy: Diet & exercise & Monotherapy		

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Secondary Analyses – Glycaemic Endpoints				
Tables 11.19, 11.22, 11.25, 11.28, 11.31	Analysis of Change in *Endpoint (unit)* From Baseline to Week 12, ITT with LOCF	• FPG (mmol/L) • Fructosamine (mmol/L) • Fasting Serum Insulin (pmol/L) • Pro-Insulin (pmol/l) • Pro-Insulin:Insulin Ratio	T11.1.2.1	Metabolic 8.1
Tables 11.20, 11.23, 11.26, 11.29, 11.32	SAS Statistical Output for Tables 11.18-11.30 Analysis of Change in *Endpoint (unit)* From Baseline to Week 12, ITT with LOCF		T11.1.2.2	Metabolic 8.2
Secondary Analyses – Responder Analyses				
Table 11.33	Analysis of the Proportion of HbA1c Responders at Week 12, ITT with LOCF	Test for 1. HbA1c Reduction≥ 0.7% 2. HbA1c Target ≤ 6.5% 3. HbA1c Target < 7.0%	T11.3.2	Metabolic 11.2
Table 11.34	SAS Statistical Output for Table 11.32 Analysis of the Proportion of HbA1c Responders at Week 12, ITT with LOCF			
Table 11.35 Table 11.36	Analysis of the Proportion of Fasting Plasma Glucose Responders at Week 12, ITT with LOCF SAS Statistical Output for Table 11.34 Analysis of the Proportion of Fasting Plasma Glucose Responders at Week 12, ITT with LOCF	Test for FPG Reduction ≥ 1.7 mmol/L FPG Target < 7 mmol/L	T11.3.4	Metabolic 11.4

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Secondary Analyses – Lipids				
Tables 11.37, 11.40, 11.43, 11.46, 11.49	Summary Statistics of Log-Transformed *Endpoint (Units)* by Visit, ITT with LOCF	• *Triglycerides (mmol/L)* • *FFA (mmol/L)* • *TC (mmol/L)* • *HDL-c (mmol/l)* • *LDL-c (mmol/l)* At Visits: 2, 5, 9,11,12	T11.2.1	Metabolic 7.1
Tables 11.38, 11.41, 11.44, 11.47, 11.50	Analysis of Log-Transformed *Endpoint (units)* at Week 12, ITT with LOCF	• *Triglycerides (mmol/L)* • *FFA (mmol/L)* • *TC (mmol/L)* • *HDL-c (mmol/l)* • *LDL-c (mmol/l)*	T11.2.2.1	Metabolic 9.1
Tables 11.39, 11.42, 11.45, 11.48, 11.51	SAS Statistical Output for Tables 11.37-11.49 Analysis of Log-Transformed *Endpoint (units)* at Week 12, ITT with LOCF		T11.2.2.1	Metabolic 9.2
HOMA				
Tables 11.52, 11.53	Summary Statistics of Log-Transformed HOMA *Endpoint (Units)* by Visit, ITT with LOCF	At visits: 5, 9, 11, 12. • Insulin Sensitivity • Beta-Cell Function	T11.2.1	Metabolic 7.1
Supplementary/Sensitivity Outputs				
Table 11.54	Sensitivity Analysis of Change in HbA1c (%) From Baseline to Week 12 Excluding Subjects from Centre [redacted] ITT with LOCF		T11.1.2.1	
Table 11.55	SAS Statistical Output for Table 11.54 Sensitivity Analysis of Change in HbA1c (%) From Baseline to Week 12 Excluding Subjects from Centre [redacted] ITT with LOCF		T11.1.2.2	

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Table 11.56	Sensitivity Analysis of Change in Insulin (pmol/L) from Baseline to Week 12 Excluding Outliers, ITT with LOCF		T11.1.2.1	T11.1.2.1
Table 11.57	SAS Statistical Output for Table 11.56 Sensitivity Analysis of Change in Insulin (pmol/L) from Baseline to Week 12 Excluding Outliers, ITT with LOCF		T11.1.2.2	T11.1.2.2
Table 11.58	Sensitivity Analysis of Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier, ITT with LOCF		T11.1.2.1	T11.1.2.1
Table 11.59	SAS Statistical Output for Table 11.58 Sensitivity Analysis Log-Transformed Triglycerides (mmol/L) at Week 12 Excluding an Outlier, ITT with LOCF		T11.1.2.2	T11.1.2.2
Table 11.60	Supplementary Summary Statistics for HbA1c (%) at Week 12 by Detailed Region, ITT with LOCF	Detailed region as defined in Section 8.1.		
PK Outputs				
Table 11.61	Summary Statistics for Serial PK Glucose (mmol/l) by Visit, ITT Population		T11.1.1	Metabolic 6.1
Table 11.62	Summary Statistics for Serial PK Insulin (pmol/l) by Visit, ITT Population		T11.1.1	Metabolic 6.1
Table 11.63	Summary Statistics for Serial PK Glucagon (pg/ml) by Visit, ITT Population		T11.1.1	Metabolic 6.1
Table 11.64	Summary Statistics for Serial PK GLP-1 (pm/l) by Visit, ITT Population		T11.1.1	Metabolic 6.1
Table 11.65	Summary Statistics for Serial PK DPPIV Inhibition (nmol/min/mL) by Visit, ITT Population		T11.1.1	Metabolic 6.1

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17.6.3. Table of Contents for Safety Tables

Output ID	Title (including analysis population)	Parameters /Comments	Generic RAP ID	TST/IDSL ID
Table 12.1	Summary of Exposure to Main-Phase Study Medication, Safety Population		T12.1.1	MetTST 15.1
AE by Treatment				
Table 12.2	Summary of All Pre-Therapy Adverse Events, Safety Population	This is by treatment.	T12.2.1	IDSL AE1
Table 12.3	Summary of All On-Therapy Adverse Events by Treatment, Safety Population		T12.2.1	IDSL AE1
Table 12.4	Summary of All Post-Therapy Adverse Events by Treatment, Safety Population		T12.2.1	IDSL AE1
AE by Intensity				
Table 12.5	Summary of On-Therapy Adverse Events by Treatment and Maximum Intensity, Safety Population		T12.2.3	IDSL AE5
Related AE by Treatment				
Table 12.6	Summary of Related On-Therapy Adverse Events by Treatment, Safety Population		T12.2.2	IDSL AE1
Common AE by Treatment				
Table 12.7	Summary of Common On-Therapy Adverse Events (≥ 5% total incidence) by Treatment, Safety Population	Required for ISO.	T12.2.4	IDSL AE3
Table 12.8	Summary of Related Common On-Therapy Adverse Events (≥ 5% total incidence) by Treatment, Safety Population	Required for ISO.	T12.2.4	IDSL AE3

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Output ID	Title (including analysis population)	Parameters /Comments	Generic RAP ID	TST/IDSL ID
Serious AE by Treatment				
Table 12.9	Summary of All Pre-Therapy Serious Adverse Events by Treatment, Safety Population		T12.3.1	IDSL AE1
Table 12.10	Summary of All On-Therapy Serious Adverse Events by Treatment, Safety Population		T12.3.1	IDSL AE1
Table 12.11	Summary of All Post-Therapy Serious Adverse Events by Treatment, Safety Population		T12.3.1	IDSL AE1
Table 12.12	Summary of Related On-Therapy Serious Adverse Events by Treatment, Safety Population		T12.3.2	IDSL AE1
Other AE				
Table 12.13	Summary of Pre-Therapy Adverse Events Leading to Main Phase Withdrawal by Treatment, Safety Population		T12.5.1	
Table 12.14	Summary of On-Therapy Adverse Events Leading to Main Phase Withdrawal by Treatment, Safety Population		T12.5.1	IDSL AE1
Table 12.15	Summary of Relationship between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text		T12.2.17	IDSL AE2
Hypoglycaemic Events				
Table 12.16	Summary of Pre-Therapy Hypoglycaemic Events by Intensity, SAE Status, Relationship, and Withdrawn, Safety Population		T12.2.5	MetTST 13.1
Table 12.17	Summary of On-Therapy Hypoglycaemic Events by Intensity, SAE Status, Relationship and Withdrawn Safety Population		T12.2.5	MetTST 13.1
Table 12.18	Summary of On-Therapy Hypoglycaemic Events by Number of Events, Safety Population	On-therapy data.	T12.2.7	MetTST 13.7

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Output ID	Title (including analysis population)	Parameters /Comments	Generic RAP ID	TST/IDSL ID
Clinical Laboratory Evaluations				
Table 12.19	Summary Statistics of Laboratory Evaluations by Treatment, Safety Population	At Visits 2,5,6,7,8,9,10,11 & 12: RBC count, Haemoglobin, Haematocrit, Platelet Count, Total White Cell Count, Sodium, Potassium, Chloride, Bicarbonate, LDH, Total Protein, Albumin, Serum Urea Creatinine, Total, direct & indirect bilirubin, Alkaline Phosphatase, Aspartate transaminase (AST), Alanine transaminase (ALT), Calcium, Phosphorus (inorganic), Uric Acid. At Visit 2 only following are recorded: Differential:Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, RBC morphology	T12.7.1	IDSL LB1
Table 12.20	Summary Statistics of Change from Baseline in Laboratory Evaluations by Treatment, Safety Population		T12.7.2	IDSL LB1
Table 12.21	Summary of Laboratory Evaluations Outside the Reference Range by Treatment, Safety Population		T12.7.3	IDSL LB2
Table 12.22	Summary of Laboratory Evaluations of Potential Clinical Concern at Any Time On-Therapy, Safety Population	Lab endpoints as listed in Attachment 17.2.	T12.7.4.2	IDSL LB2
Vital Signs				
Table 12.23	Summary Statistics of Vital Signs by Treatment, Safety Population	• *SBP (mmHg)* • *DBP (mmHg)* • *Heart rate (bpm)* At Visits: All except Visit 1.	T12.8.1.1	IDSL VS1

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Output ID	Title (including analysis population)	Parameters /Comments	Generic RAP ID	TST/IDSL ID
Table 12.24	Summary Statistics of Change from Baseline in Vital Signs by Treatment, Safety Population	• *SBP (mmHg)* • *DBP (mmHg)* • *Heart rate (bpm)*	T12.8.1.2	IDSL VS1
Table 12.25	Summary of Vital Signs of Potential Clinical Concern at Any Time On-Therapy, Safety Population	• *SBP (mmHg)* • *DBP (mmHg)* • *Heart rate (bpm)* Replace high/low by values in Attachment 17.3	T12.8.2.2	IDSL LB2
Table 12.26	Summary of Changes from Baseline in Vital Signs of Potential Clinical Concern at any Time On-therapy	• *SBP (mmHg)* • *DBP (mmHg)* • *Heart rate (bpm)* Replace high/low by values in Attachment 17.3	T12.8.2.3	IDSL LB2
Urinalysis				
Table 12.27	Summary of Urinalysis Dipstick Results	At Visits: 2,5,6,7,8,9,10,11 & 12	T12.8.4	IDSL UR3
Weight, Hip and Waist Circumference, Waist: Hip Ratio and BMI				
Table 12.28	Summary Statistics of Weight, Hip Circumference, Waist Circumference, Waist: Hip Ratio and Body Mass Index, Safety Population	Weight & BMI at All Visits except Visit 1. Hip, Waist and Waist: Hip Ratio at Visits: 2,5,12.	T12.8.5.1	IDSL VS1
Table 12.29	Summary Statistics of Change from Baseline in Weight, Hip Circumference, Waist Circumference, Waist: Hip Ratio and Body Mass Index, Safety Population	Include % change from baseline for weight.	T12.8.5.2	IDSL VS1

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Output ID	Title (including analysis population)	Parameters /Comments	Generic RAP ID	TST/IDSL ID
		ECG		
Table 12.30	Summary Statistics of ECG Values by Treatment, Safety Population	At Visits: 2, 5, 9 12 Ventricular (heart) rate, PR, QRS, QT, QTcB, QTcF, RR	T12.8.8	IDSL EG2
Table 12.31	Summary Statistics of ECG Change from Baseline by Treatment, Safety Population		T12.8.9	IDSL EG3
Table 12.32	Summary of Abnormal ECG Findings by Treatment, Safety Population		T12.8.7	IDSL EG1
Table 12.33	Summary of ECG Values of Potential Clinical Concern at any Time On-therapy, Safety Population	ECG endpoints as listed in Attachment 17.4. Replace high/low by values in the attachment.	T12.8.2.2	IDSL LB2
Table 12.34	Summary of Changes from Baseline in ECG Values of Potential Clinical Concern at any Time On-therapy, Safety Population	ECG endpoints as listed in Attachment 17.4 Replace high/low by values in the attachment.	T12.8.2.3	IDSL LB2
		Biomarkers		
Table 12.35	Summary Statistics of Exploratory Biomarker CK-MB, Safety Population	At Visits: 2, 5, 9, 12 CK-MB		
Table 12.36	Summary Statistics of Exploratory Biomarker CK-MB Change from Baseline, Safety Population	At Visits: 2, 5, 9, 12 CK-MB		
Table 12.37	Exploratory Summary of Troponin I by Defined Categories, Safety Population	At Visits: 2, 5, 9, 12		

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Supplementary Outputs				
Table 12.38	Additional Summary of Change from Baseline in Weight (kg) by Treatment, Safety Population	Include SE in the summary	T12.8.5.2	
Table 12.39	Additional Summary of Selected Laboratory Parameters by Treatment, Safety Population	Replace SD with SE, for ALT, AST, Bili & Haemaglobin only.	T12.7.2	
Table 12.40	Summary of Relative Risks for Common On-therapy Adverse Events (≥ 5% Total Incidence) by Treatment, Safety Population	Table corresponds to information in Figures 12.12,12.13, 12.14.		
Table 12.41	Summary Statistics of Maximum Post-Baseline Laboratory Results Relative to Upper Limit of Normal, Safety Population			

17.6.4. Table of Contents for Efficacy Figures

Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figure 11.1	Line Graph of Mean (±SE) for HbA1c (%) by Visit, ITT with LOCF	At Visits: 1,4,5,9,11,12	F11.1.1	Metabolic 6.2
Figure 11.2	Line Graph of Mean Change from Baseline (±SE) for HbA1c (%) by Visit, ITT with LOCF	Include screening visit on this figure.	F11.1.2	Metabolic 6.3
Figure 11.3	Line Graph of Mean (±SE) for HbA1c (%) by Visit for Diet & Exercise Strata, ITT with LOCF	At Visits: 1,4,5,9,11,12	F11.1.1	Metabolic 6.2
Figure 11.4	Line Graph of Mean (±SE) for HbA1c (%) by Visit for Monotherapy Strata, ITT with LOCF	At Visits: 1,4,5,9,11,12	F11.1.1	Metabolic 6.2

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figure 11.5	Line Graph of Mean Change from Baseline (±SE) for HbA1c (%) by Visit for Diet & Exercise Strata, ITT with LOCF	Include screening visit on this figure.	F11.1.2	Metabolic 6.3
Figure 11.6	Line Graph of Mean Change from Baseline (±SE) for HbA1c (%) by Visit for Monotherapy Strata, ITT with LOCF	Include screening visit on this figure.	F11.1.2	Metabolic 6.3
Figure 11.7	Figure of Treatment Difference in HbA1c (%) Change From Baseline to Week 12, ITT with LOCF	Include baseline HbA1c for each treatment group at the bottom of this figure.	F11.1.3	Metabolic 8.3
Figure 11.8	Distribution of Baseline HbA1c (%) by Treatment and Prior Therapy, ITT with LOCF	Using HbA1c categories: < 7.5 ≥ 7.5 to < 8 ≥ 8 to < 8.5 ≥ 8.5		
Figure 11.9	Distribution of Change from Baseline to Week 12 in HbA1c (%) by Treatment, ITT with LOCF			
Figure 11.10	Boxplot of Change from Baseline at Week 12 by Treatment, ITT with LOCF			
Figure 11.11	Cumulative Distribution Curve of Change from Baseline at Week 12 in HbA1c (%), ITT with LOCF			
Figure 11.12	Line Graph of Mean Change from Baseline (±SE) for HbA1c (%) by Visit, ITT without LOCF	At Visits: 1,4,5,9,11,12.	F11.1.2	Metabolic 6.3
Figure 11.13	Line Graph of Mean Change from Baseline (±SE) for HbA1c (%) by Visit, Per Protocol Population	At Visits: 1,4,5,9,11,12.	F11.1.2	Metabolic 6.3

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figure 11.14	Figure of Predicted Dose Response Curve for Change from Baseline for HbA1c (%) at Week 12, ITT with LOCF			
Figure 11.15	Line Graph of Repeated Measures Model-Adjusted Mean Change from Baseline (±SE) for HbA1c (%) by Visit, ITT without LOCF		F11.5.1	Metabolic 17.3
Figures 11.16, 11.23, 11.26, 11.29, 11.32	Line Graph of Mean (±SE) for *Endpoint (units)* by Visit, ITT with LOCF	• FPG (mmol/L) • Fructosamine (mmol/L) • Fasting Serum Insulin (pmol/L) • Pro-Insulin (pmol/l) • Pro-Insulin:Insulin Ratio 1. FPG - All Visits 2. Fructosamine by Visit 2,4,5, 9,11,12 3. Insulins by Visit 5,9,11,12	F11.1.1	Metabolic 6.2
Figures 11.17, 11.24, 11.27, 11.30, 11.33	Line Graph of Mean Change from Baseline (±SE) for *Endpoint (units)* by Visit, ITT with LOCF	• *FPG (mmol/L)* • *Fructosamine (mmol/L)* • *Fasting Serum Insulin (pmol/L)* • *Pro-Insulin (pmol/l)* • *Pro-Insulin:Insulin Ratio* 1. FPG - All Visits 2. Fructosamine by Visit 2,4,5, 9,11,12 3. Insulins by Visit 5,9,11,12	F11.1.2	Metabolic 6.3
Figure 11.18	Line Graph of Mean (±SE) for FPG (mmol/l) by Visit for Diet & Exercise Strata, ITT with LOCF	• At Visits: 1,4,5,9,11,12	F11.1.1	Metabolic 6.2
Figure 11.19	Line Graph of Mean (±SE) for FPG (mmol/l) by Visit for Monotherapy Strata, ITT with LOCF	• At Visits: 1,4,5,9,11,12	F11.1.1	Metabolic 6.2

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figure 11.20	Line Graph of Mean Change from Baseline (±SE) for FPG (mmol/l) by Visit for Diet & Exercise Strata, ITT with LOCF	• Include screening visit on this figure.	F11.1.2	Metabolic 6.3
Figure 11.21	Line Graph of Mean Change from Baseline (±SE) for FPG (mmol/l) by Visit for Monotherapy Strata, ITT with LOCF	• Include screening visit on this figure.	F11.1.2	Metabolic 6.3
Figures 11.22, 11.25, 11.28, 11.31, 11.34	Figure of Treatment Difference in *Endpoint (units)* Change From Baseline to Week 12, ITT with LOCF	• *FPG (mmol/L)* • *Fructosamine (mmol/L)* • *Fasting Serum Insulin (pmol/L)* • *Pro-Insulin (pmol/l)* • *Pro-Insulin:Insulin Ratio*	F11.1.3	Metabolic 8.3
Figure 11.35 Figure 11.36	Figure of Percentage of Subjects with HbA1c Reduction from Baseline >=0.7% at Week 12, ITT with LOCF Figure of Percentage of Subjects with HbA1c ≤ 6.5% at Week 12, ITT with LOCF		F11.3.1 F11.3.1	Metabolic 11.8 Metabolic 11.8
Figure 11.37	Figure of Percentage of Subjects with HbA1c <7% at Week 12, ITT with LOCF		F11.3.1	Metabolic 11.8
Figure 11.38 Figure 11.39	Figure of Percentage of Subjects with FPG Reduction from Baseline >=1.7mmol/L at Week 12, ITT with LOCF Figure of Percentage of Subjects with FPG <7mmol/L at Week 12, ITT with LOCF		F11.3.1 F11.3.1	Metabolic 11.8 Metabolic 11.8

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figures 11.40, 11.43, 11.46, 11.49, 11.52	Line Graph of Geometric Mean (+-SE) for *Endpoint (Units)* by Visit, ITT with LOCF	• *Triglycerides (mmol/L)* • *FFA (mmol/L)* • *TC (mmol/L)* • *HDL-c (mmol/l)* • *LDL-c (mmol/l)* At Visits: 2, 5, 9,11,12	F11.2.1	Metabolic 7.2
Figures 11.41, 11.44, 11.47, 11.50, 11.53	Line Graph of Ratio to Baseline (+-SE) Expressed as Percent Change from Baseline for *Endpoint (Units)* by Visit, ITT with LOCF	• *Triglycerides (mmol/L)* • *FFA (mmol/L)* • *TC (mmol/L)* • *HDL-c (mmol/l)* • *LDL-c (mmol/l)*	F11.2.2	Metabolic 7.3
Figures 11.42, 11.45, 11.48, 11.51, 11.54	Figure of Treatment Ratio to Placebo Expressed as % Difference in *Endpoint (Units)* at Week 12, ITT with LOCF	• *Triglycerides (mmol/L)* • *FFA (mmol/L)* • *TC (mmol/L)* • *HDL-c (mmol/l)* • *LDL-c (mmol/l)*	F11.2.3	Metabolic 9.3
		PK Outputs		
Figure 11.55	Line Graph of Mean (±SE) for Serial PK Glucose (mmol/l) by Visit, ITT Population	Dependent on distribution, alternative summary statistics (i.e. median, interquartile range) may be more appropriate. This applies to all PK figures.	F11.1.1	Metabolic 6.2
Figure 11.56	Line Graph of Mean (±SE) for Serial PK Insulin (pmol/l) by Visit, ITT Population		F11.1.1	Metabolic 6.2
Figure 11.57	Line Graph of Mean (±SE) for Serial PK Glucagon (pg/ml) Visit, ITT Population		F11.1.1	Metabolic 6.2
Figure 11.58	Line Graph of Mean (±SE) for Serial PK GLP-1 (pm/l) Visit, ITT Population		F11.1.1	Metabolic 6.2

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Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figure 11.59	Line Graph of Mean (±SE) for Serial PK DPPIV Inhibition (nmol/min/mL) by Visit, ITT Population		F11.1.1	Metabolic 6.2

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17.6.5. Table of Contents for Safety Figures

Output ID	Title (including analysis population)	Parameters/Comments	Generic RAP ID	TST/ IDSL ID
Figures 12.1, 12.2, 12.3 , 12.4	Line Graph of Mean (±SE) for parameter (units) by Visit, Safety Population	ALT (U/L), AST (U/L), Bilirubin (µmol/L) and Haemoglobin (g/L) At Visits: 2,5,6,7,8,9,10,11,12	F11.1.1	Metabolic 6.2
Figures 12.5, 12.6, 12.7 , 12.8, 12.9, 12.10	Boxplot of Maximum Post-Baseline *parameter(units)* Values Relative to Upper Limit of Normal, Safety Population	Parameters: ALT (U/L), AST (U/L), Bilirubin (µmol/L), LDH (U/L), Alkaline Phosptase (U/L) and CK-MB (MCG/L)		
Figure 12.11	Patient Profiles for Post-Baseline LFT Values > 1.5 x ULN, Safety Population	Parameters to be included are: ALT (U/L), AST (U/L), Bilirubin (µmol/L) and Alkaline Phosptase (U/L)		
Figures 12.12, 12.13, 12.14	Dotplot and Relative Risk for Common (≥ 5% total incidence) Adverse Events - Placebo vs *dose mg*, Safety Population	Doses are: 15mg, 30mg & 45mg		
Figure 12.15	Line Graph of Mean Change from Baseline (±SE) for Weight (kg) by Visit, Safety Population			

17.6.6. Table of Contents for Data Listings

ICH Listings

Output ID	Title (including study population)	Parameters/Comments	Generic RAP ID	TST/IDSL ID
Listing 1	Listing of Study Conclusion, Safety Population		L10.1.1	IDSL ES2
Listing 2	Listing of Subject Disposition, All Subjects			

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Output ID	Title (including study population)	Parameters/Comments	Generic RAP ID	TST/IDSL ID
Listing 3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations, Safety Population		L10.2.1	IDSL IE3
Listing 4	Listing of Subjects Excluded from the Per Protocol Population, ITT Population		N/A	IDSL SA3a
Listing 5 Listing 6	Listing of Demographic Characteristics, Safety Population Listing of Race, Safety Population	Include baseline FCBG and screening C-Peptide measurements.	L10.3.1.1 L10.3.1.2	IDSL DM2 IDSL DM9
Listing 7	Listing of Type II Diabetes Mellitus History, Safety Population		L10.3.2	MetTST 2.2
Listing 8	Listing of Substance Use, Safety Population		L10.3.3	IDSL SU2
Listing 9	Listing of Past and Current Medical Conditions, Safety Population		L10.4.1	MetTST 1.3
Listing 10	Listing of Past and Current Diabetes/Cardiovascular Medical History, Safety Population		L10.4.1	MetTST 1.3
Listing 11	Listing of Prior Anti-Diabetic Medications, Safety Population		L10.5.2	IDSL CM3
Listing 12	Listing of Prior and Concomitant Medications, Safety Population		L10.5.2	IDSL CM3
Listing 13	Listing of Study Medication Compliance, Safety Population		L10.6.1	MetTST 4.3
Listing 14	Listing of Glycaemic Efficacy Variables, ITT Population	HbA1c (%), FPG (mmol/L), Fructosamine, Fasting Serum Insulin, Pro-insulin and Pro-insulin: insulin ratio. Note: include a flag for non-fasting data, refer to Section 9.3.3 for details.	L11.1.1	Metabolic 12.1
Listing 15	Listing of HbA1c Responders by Study Visit, ITT Population		L11.3.1	Metabolic 11.5
Listing 16	Listing of FPG Responders by Study Visit, ITT Population		L11.3.1	Metabolic 11.5

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Output ID	Title (including study population)	Parameters/Comments	Generic RAP ID	TST/IDSL ID
Listing 17	Listing of Lipid Efficacy Variables, ITT Population	Triglycerides, FFA, TC, LDL-c, HDL-c. Note: include a flag for non-fasting data, refer to Section 9.3.3 for details.	L11.1.1	Metabolic 12.1
Listing 18	Listing of HOMA Parameters, ITT Population	IR, IS and BCF	L11.1.1	Metabolic 12.1
Listing 19	Listing of Exposure Data, Safety Population		L12.1.1	MetTST 15.4
Listing 20	Listing of Subject Numbers for Individual Adverse Events, Safety Population		L12.2.1	IDSL AE7
Listing 21, 22, 23	Listing of All *Therapeutic Phase* Adverse Events, Safety Population	Pre-therapy, on-therapy and post-therapy	L12.2.2	IDSL AE8
Listing 24	Listing of Related On-Therapy Adverse Events, Safety Population			
Listing 25	Listing of Fatal Adverse Events, Safety Population		L12.3.1	IDSL AE8
Listing 26	Listing of Serious Non-fatal Adverse Events, Safety Population		L12.3.2	IDSL AE8
Listing 27	Listing of Adverse Events Leading to Withdrawal, Safety Population		L12.5.1	IDSL AE8
Listing 28	Listing of On-going Main Phase Adverse Events, Safety Population			
Listing 29	Listing of Laboratory Evaluations, Safety Population		L12.7.2	IDSL LB5
Listing 30	Listing of Laboratory Evaluations for Subjects with Abnormalities of Potential Clinical Concern		L12.7.1	IDSL LB5

Non-ICH Listings

Output ID	Title (including study population)	Parameters/Comments	Generic RAP ID	TST/IDSL ID
Listing 1	Start and End date of Investigational Product		L10.7.1	MetTST x.x

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Output ID	Title (including study population)	Parameters/Comments	Generic RAP ID	TST/IDSL ID
Listing 2	Listing of Hypoglycaemic Events for All Subjects, Safety Population		L12.2.3	MetTST 13.13
Listing 3	Listing of Vital Signs, Safety Population		L12.8.1.1	IDSL VS4
Listing 4 Listing 5	Listing of Weight, Hip Circumference, Waist Circumference, Waist: Hip Ratio and BMI, Safety Population Listing of ECG Values, Safety Population		L12.8.2 L12.8.3	IDSL VS4 IDSL EG3
Listing 6	Listing of ECG Change from Baseline, Safety Population		L12.8.3	IDSL EG3
Listing 7	Listing of ECG Findings, Safety Population		L12.8.4	IDSL EG5
Listing 8	Listing of Exploratory Biomarkers, Safety Population	CK-MB & cTnI	L11.1.1	Metabolic 12.1
Listing 9	Listing of Urinalysis Data, Safety Population		UR1	
Listing 10	Listing of Subjects for Whom the Main-Phase Treatment Blind was Broken During the Study, Safety Population		BL1	IDSL BL1
Listing 11 Listing 12	Listing of Subject Randomisation, Safety Population Listing of Serial PK Data, ITT Population	Include glucose, insulin, GLP-1, glucagon, DPPIV inhibition.	L11.1.1	MetTST Metabolic 12.1

17.7. Data Display Specifications

Stored in a separate document.

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17.8. RAP Changes

Section 1: Introduction

Changed From:

In this RAP, reference is made to the protocol for study DPB100925 and protocol amendment 1 (10th March 2005).

Changed To:

In this RAP, reference is made to the protocol for study DPB100925, protocol amendment 1 (10th March 2005) and amendment 2 (5th April 2006).

Section 8.1: Multicentre Studies

Changed From:

For the purposes of analysis, geographical region will be classified using the following regions for the US (based on the US Census Bureau):

- Northeast Region: [redacted]
- Midwest Region: [redacted]
- South Region: [redacted]
- West Region: [redacted]

Country will serve as region in the rest of the world; Canada, Czech Republic, Finland, Germany, Greece, Latvia, Romania and Sweden.

Refer to the attachment in Section 17.1 for details of the number of centres and subjects per region and, the process to follow for the grouping of regions if there are an insufficient number of subjects within a region.

Changed To:

For the US, geographical region will first be classified as follows (based on the US Census Bureau):

- Northeast: [redacted]
- Midwest: [redacted]

- South: [redacted]
- West: [redacted]

For the purposes of analysis, region will be classified as:

- US/Canada: Northeast, Midwest, South and West US, and Canada.
- Eastern Europe: Latvia, Romania, Czech Republic and Greece.
- Western Europe: Finland, Germany and Sweden.

Refer to the attachment in Section 17.1 for details of the number of centres and subjects.

Section 8.2: Other Strata and Covariates

Added:

Gender and prior therapy will be taken as recorded in the eCRF (i.e. actual gender and prior therapy). The stratification variables as recorded in RAMOS will not be used (in the event that subjects are randomised into the incorrect strata).

Section 8.3: Examination of Subgroups

Added:

In addition, a supplementary summary table by detailed region will also be included. Detailed region is defined as follows: Sweden/Finland, Czech Republic/Latvia, Romania/Greece, Germany, Canada, US Northeast/Midwest/West Region and US South Region.

Section 10.2.2: Per-Protocol Population

Changed From:

- Subject randomised into the incorrect strata (gender and prior therapy) and subjects randomised to the diet & exercise (drug naïve) strata, who from reviewing their prior anti-diabetic medications have taken prior medications for any length of time in the three months prior to their pre-screen visit date, and are therefore more representative of a subject randomised to the Monotherapy strata (these will be reviewed on a case-by-case basis).
- Subject who was randomised to the Monotherapy strata and has a washout period (number of days between Screening Visit (Visit 2, Week -5) and Baseline Visit (Visit 5, Week 0)) that is less than 28 days.

Changed To:

- Subject randomised into the incorrect strata (gender and prior therapy). This includes subjects in the Diet & Exercise (drug naïve) strata, who from reviewing their prior anti-diabetic medications have taken prior medications for any length of time in the three months prior to their pre-screen visit date and subjects in the Monotherapy strata, who from reviewing their prior anti-diabetic medications have not taken prior medications for any length of time in the three months prior to their pre-screen visit date (these will be reviewed on a case-by-case basis)).
- Subjects in the Monotherapy strata who have a washout period (number of days between Screening Visit (Visit 2, Week -5) and Baseline Visit (Visit 5, Week 0)) that is less than 28 days.

Added:

- Subjects who violate the HbA1c and/or FPG inclusion criteria as follows will be reviewed on a case-by-case basis to determine whether the subject is a protocol violator:
  - HbA1c at Pre-Screen (Visit 1): Diet & Exercise Subjects <7.5% or >10%; Monotherapy subjects: <7% or >8.5%.
  - FPG at Screening (Visit 2) < 7.8mmol/l.
  - FPG at Baseline >13.3mmol/l.

Section 10.4: Treatment Compliance

Changed From:

Compliance (for double-blind treatment) will be measured at Weeks 4, 8 and 12. Overall study (Main Phase) non-compliance is defined as not being compliant for two or more out of the three compliance visits (i.e. not being in the '80 – 120%' category for two or three of the three visits or simply, being in the '80 – 120%' category for only one of the three visits).

Changed To:

Compliance (for double-blind treatment) will be measured at Weeks 4, 8 and 12 (and early withdrawal visit, if applicable). Overall study (Main Phase) non-compliance is defined as not being compliant for two or more out of the three compliance visits (i.e. not being in the '80 – 120%' category for two or three of the three visits or simply, being in the '80 – 120%' category for only one of the three visits). If subjects are only in the study (Main-Phase) for one or two of these compliance visits (i.e. the subject withdraws from the study), then the following rules for compliance will apply:

- One visit – the subject must be in '80 – 120%' category for that visit to be study compliant.
- Two visits - the subject must be in '80 – 120%' category for both visits to be study compliant.

Section 11: Efficacy Analyses

Added:

Analysis of covariance (ANCOVA) will be the statistical method used to assess changes from baseline for the endpoints in this study. One of the assumptions underlying this method is that the response variable is normally distributed. The distributions of the endpoints in this study will be examined along with any extreme outlying observations. In the event of any extreme outliers, a sensitivity analysis may be provided.

Section 11.1: Primary Efficacy Analyses

Added:

In order to quantify the treatment effect relative to placebo in the prior therapy and gender subgroups, a formal (exploratory) analysis may be conducted (if required).

Section 12.7.4: Weight, Hip and Waist Circumference, Waist: Hip Ratio and BMI

Added:

A figure of change from baseline over time for weight will also be included.

Section 13.1: Pharmacokinetic Analyses

Changed From:

Relevant data from the current study and from studies DPB10001, DPB10002, and DPB10003 will be combined and analyzed using a nonlinear mixed effects modelling approach (population PK). Population PK parameters including CL and V will be estimated. Dependent on the final structural PK model additional PK parameters also may be estimated.

Changed To:

Relevant data from the current study and from study DPB10003 will be combined and analysed using a nonlinear mixed effects modelling approach (population PK). Population PK parameters including CL and V will be estimated. Dependent on the final structural PK model additional PK parameters also may be estimated

Section 13.2: Pharmacokinetic/Pharmacodynamic Analyses

Added:

Summary statistics tables and line graphs over time for Serial Sampling PK subjects in the ITT population will be produced for the following data: glucose, insulin, glucagon, GLP-1 and DPPIV inhibition. A listing of this data will also be provided.

Listings, summary statistics, and plots of GW823093 concentrations will be included in the Population PK RAP. Relevant correlations between GW823093 concentrations/exposures and glucose, insulin, glucagon, GLP-1 and DPPIV inhibition will also be included in the Population PK RAP.

[Unspecified]

Annotated Design For Trial 'dpb925prd'

Protocol: DPB100925

Generated By InForm Architect®

March 15, 2006 8:30AM

[redacted]

FORM: INFORM SCREENING (SCREEN) TRIAL: dpb925prd

INFORM SCREENING		
1.*	Subject initials *[hidden]*	A3 (MAPPINGS3:t_SCREEN.txtScrSINIT) (MAPPINGS1:t_SCREEN.txtScrSINIT) (MAPPINGS2:t_SCREEN.txtScrSINIT)
2.	Date of birth	Req / Req / Req (1900-2005) (MAPPINGS3:t_SCREEN.BIRTHDT) (MAPPINGS1:t_SCREEN.BIRTHDT) (MAPPINGS2:t_SCREEN.BIRTHDT)
3.	What is the **primary method** that prompted the subject's interest in the study?	(MAPPINGS3:t_SCREEN.chkSCREENMethod1) (MAPPINGS1:t_SCREEN.chkSCREENMethod1) (MAPPINGS2:t_SCREEN.chkSCREENMethod1) *[1]* ☐ Clinic patient (site actively reviews patient charts and/or databases and initiates contact with patient). (MAPPINGS3:t_SCREEN.chkSCREENMethod2) (MAPPINGS1:t_SCREEN.chkSCREENMethod2) (MAPPINGS2:t_SCREEN.chkSCREENMethod2) *[2]* ☐ Physician referral (e.g., lunch-n-learn, letter to colleagues, etc.) (MAPPINGS3:t_SCREEN.chkSCREENMethod3) (MAPPINGS1:t_SCREEN.chkSCREENMethod3) (MAPPINGS2:t_SCREEN.chkSCREENMethod3) *[3]* ☐ Referred by family member (MAPPINGS3:t_SCREEN.chkSCREENMethod4) (MAPPINGS1:t_SCREEN.chkSCREENMethod4) (MAPPINGS2:t_SCREEN.chkSCREENMethod4) *[4]* ☐ Referred by study participant (MAPPINGS3:t_SCREEN.chkSCREENMethod5) (MAPPINGS1:t_SCREEN.chkSCREENMethod5) (MAPPINGS2:t_SCREEN.chkSCREENMethod5) *[5]* ☐ Subject-initiated internet search (e.g. discovered findclinicalstudy.com) (MAPPINGS3:t_SCREEN.chkSCREENMethod6) (MAPPINGS1:t_SCREEN.chkSCREENMethod6) (MAPPINGS2:t_SCREEN.chkSCREENMethod6) **[6]** ☐ Other internet provider paid by GSK (e.g., harrisinteractive.com), *specify* (MAPPINGS3:t_SCREEN.txtSCREENMethe) (MAPPINGS1:t_SCREEN.txtSCREENMethe) (MAPPINGS2:t_SCREEN.txtSCREENMethe) A200 (MAPPINGS3:t_SCREEN.chkSCREENMethod7) (MAPPINGS1:t_SCREEN.chkSCREENMethod7) (MAPPINGS2:t_SCREEN.chkSCREENMethod7) *[7]* ☐ Information in clinic (e.g., posters, brochurs, etc.) (MAPPINGS3:t_SCREEN.chkSCREENMethod8) (MAPPINGS1:t_SCREEN.chkSCREENMethod8) (MAPPINGS2:t_SCREEN.chkSCREENMethod8) *[8]* ☐ Community outreach (e.g., healthfair, advocacy groups, support groups, etc.) (MAPPINGS3:t_SCREEN.chkSCREENMethod9) (MAPPINGS1:t_SCREEN.chkSCREENMethod9) (MAPPINGS2:t_SCREEN.chkSCREENMethod9) *[9]* ☐ Local newspaper advertisement (MAPPINGS3:t_SCREEN.chkSCREENMethod10) (MAPPINGS1:t_SCREEN.chkSCREENMethod10) (MAPPINGS2:t_SCREEN.chkSCREENMethod10) *[10]* ☐ Local radio advertisement (MAPPINGS3:t_SCREEN.chkSCREENMethod11) (MAPPINGS1:t_SCREEN.chkSCREENMethod11) (MAPPINGS2:t_SCREEN.chkSCREENMethod11) *[11]* ☐ Other local paid advertisement (e.g., local television, local direct mail, etc.) (MAPPINGS3:t_SCREEN.chkSCREENMethod12) (MAPPINGS1:t_SCREEN.chkSCREENMethod12) (MAPPINGS2:t_SCREEN.chkSCREENMethod12) *[12]* ☐ Information at daycare (MAPPINGS3:t_SCREEN.chkSCREENMethod13) (MAPPINGS1:t_SCREEN.chkSCREENMethod13) (MAPPINGS2:t_SCREEN.chkSCREENMethod13) *[13]* ☐ National radio campaign (MAPPINGS3:t_SCREEN.chkSCREENMethod14) (MAPPINGS1:t_SCREEN.chkSCREENMethod14) (MAPPINGS2:t_SCREEN.chkSCREENMethod14) *[14]* ☐ National television campaign (MAPPINGS3:t_SCREEN.chkSCREENMethod15) (MAPPINGS1:t_SCREEN.chkSCREENMethod15) (MAPPINGS2:t_SCREEN.chkSCREENMethod15) *[15]* ☐ Other national campaign (e.g., national magazine, national direct mail, etc.) (MAPPINGS3:t_SCREEN.chkSCREENMethod16) (MAPPINGS1:t_SCREEN.chkSCREENMethod16) (MAPPINGS2:t_SCREEN.chkSCREENMethod16) *[16]* ☐ Call center

* Item is not required

Form Design Note:
Trial designers must use this form as specified here. Allowed changes are mentioned in the particular item level notes.

Item Design Notes:	
Item No.	**Design Note**
1.	This item is hidden to all users and will be autopopulated by the system as "---"
2.	Will be automatically mapped to demography form
3.	This item is optional. Select only choices that are applicable to the study. Study-specific criteria may be added as needed. More than one study-specific criterion may be added if needed, however it must be a unique reason not already listed.

CDD: MAPPINGS1 Table: t_SCREEN Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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chkSCREENMethod5	STRING(255)	
chkSCREENMethod6	STRING(255)	
txtSCREENMethe	STRING(200) - A200	
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chkSCREENMethod10	STRING(255)	
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chkSCREENMethod12	STRING(255)	
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CDD_MAPPING53 Table: t_SCREEN Key Type: PATIENTVISIT		
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chkSCREENMethod15	STRING(255)	
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FORM: INFORM ENROLMENT (ENROL) TRIAL: dpb925prd

SUBJECT NUMBER		
1.	Subject number	A6 (MAPPINGS3.t_ENROL.mtxtSubjectNumber) (MAPPINGS1.t_ENROL.mtxtSubjectNumber) (MAPPINGS2.t_ENROL.mtxtSubjectNumber)

CDD: MAPPINGS1 Table: t_ENROL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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CDD: MAPPINGS2 Table: t_ENROL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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CDD: MAPPINGS3 Table: t_ENROL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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FORM: DATE OF VISIT/ASSESSMENT (DOV) TRIAL: dpb925prd

DATE OF VISIT/ASSESSMENT		
1.	Date of visit/assessment	Req / Req / Req [2005-2007] (MAPPINGS1:t_DOV.DOV) (MAPPINGS2:t_DOV.DOV) (MAPPINGS3:t_DOV.DOV)
2.*	SDV Performed at this Visit [GSK usage only] *[hidden]*	(MAPPINGS1:t_DOV.chkSDVYes) (MAPPINGS2:t_DOV.chkSDVYes) (MAPPINGS3:t_DOV.chkSDVYes) [?] ☐ Yes
* Item is not required		

CDD: MAPPINGS1 Table: t_DOV Key Type: PATIENTVISIT		
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CDD: MAPPINGS2 Table: t_DOV Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DOV	DATE - DDMONYYYY	
chkSDVYes	STRING(255)	

CDD: MAPPINGS3 Table: t_DOV Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DOV	DATE - DDMONYYYY	
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[redacted]

FORM: DEMOGRAPHY (DEMOG) TRIAL: dpb925prd

DEMOGRAPHY		
1.	Date of birth	Req / Req / Req (1900-2066) (MAPPINGS3:t_DEMO.BIRTHDT) (MAPPINGS1:t_DEMO.BIRTHDT) (MAPPINGS2:t_DEMO.BIRTHDT)
2.	Sex	(MAPPINGS3:t_DEMO.SEX1) (MAPPINGS1:t_DEMO.SEX1) (MAPPINGS2:t_DEMO.SEX1) [M] ○ Male [F] ○ Female
3.	Ethnicity	(MAPPINGS3:t_DEMO.ETHNICCD) (MAPPINGS1:t_DEMO.ETHNICCD) (MAPPINGS2:t_DEMO.ETHNICCD) [1] ○ Hispanic or Latino [2] ○ Not Hispanic or Latino
4.	Race	Check all that apply (MAPPINGS3:t_DEMO.RACECCD11) (MAPPINGS1:t_DEMO.RACECCD11) (MAPPINGS2:t_DEMO.RACECCD11) [11] ☐ African American/African Heritage (MAPPINGS3:t_DEMO.RACECCD12) (MAPPINGS1:t_DEMO.RACECCD12) (MAPPINGS2:t_DEMO.RACECCD12) [12] ☐ American Indian or Alaskan Native (MAPPINGS3:t_DEMO.RACECCD13) (MAPPINGS1:t_DEMO.RACECCD13) (MAPPINGS2:t_DEMO.RACECCD13) [13] ☐ Asian - Central/South Asian Heritage (MAPPINGS2:t_DEMO.RACECCD14) (MAPPINGS3:t_DEMO.RACECCD14) (MAPPINGS1:t_DEMO.RACECCD14) [14] ☐ Asian - East Asian Heritage (MAPPINGS3:t_DEMO.RACECCD15) (MAPPINGS3:t_DEMO.RACECCD15) (MAPPINGS1:t_DEMO.RACECCD15) [15] ☐ Asian - Japanese Heritage (MAPPINGS2:t_DEMO.RACECCD16) (MAPPINGS3:t_DEMO.RACECCD16) (MAPPINGS1:t_DEMO.RACECCD16) [16] ☐ Asian - South East Asian Heritage (MAPPINGS2:t_DEMO.RACECCD17) (MAPPINGS3:t_DEMO.RACECCD17) (MAPPINGS1:t_DEMO.RACECCD17) [17] ☐ Native Hawaiian or Other Pacific Islander (MAPPINGS2:t_DEMO.RACECCD18) (MAPPINGS3:t_DEMO.RACECCD18) (MAPPINGS1:t_DEMO.RACECCD18) [18] ☐ White - Arabic/North African Heritage (MAPPINGS2:t_DEMO.RACECCD19) (MAPPINGS3:t_DEMO.RACECCD19) (MAPPINGS1:t_DEMO.RACECCD19) [19] ☐ White - White/Caucasian/European Heritage

Form Design Note:
IDSL Version 01.00A - 01 DEC 04

Item Design Notes:	
Item No.	**Design Note**
1.	Will be automatically mapped to demography form
2.	This item is conditional; Use it if you DO NOT need to collect childbearing potential information; Remove the other Sex item

CDD: MAPPINGS1 Table: t_DEMO Key Type: PATIENTVISIT		
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ETHNICCD	STRING(1)	
RACECCD11	STRING(255)	
RACECCD12	STRING(255)	
RACECCD13	STRING(255)	
RACECCD14	STRING(255)	
RACECCD15	STRING(255)	
RACECCD16	STRING(255)	
RACECCD17	STRING(255)	
RACECCD18	STRING(255)	
RACECCD19	STRING(255)	

CDD: MAPPINGS2 Table: t_DEMO Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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ETHNICCD	STRING(1)	
RACECCD11	STRING(255)	
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RACECCD14	STRING(255)	
RACECCD15	STRING(255)	
RACECCD16	STRING(255)	
RACECCD17	STRING(255)	
RACECCD18	STRING(255)	
RACECCD19	STRING(255)	

CDD: MAPPINGS3 Table: t_DEMO Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
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ETHNICCD	STRING(1)	
RACECCD11	STRING(255)	
RACECCD12	STRING(255)	
RACECCD13	STRING(255)	
RACECCD14	STRING(255)	

[redacted]

RACECCD15	STRING(255)	
RACECCD16	STRING(255)	
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RACECCD18	STRING(255)	
RACECCD19	STRING(255)	

FORM: SUBJECT IDENTIFICATION (SUB ID) TRIAL: dpb925prd

SUBJECT IDENTIFICATION		
If Subject number was entered incorrectly, please correct and submit; otherwise disregard		
1.	Subject number	A6 (MAPPINGS2:t_SUBID.mtxtSubjectNumber) (MAPPINGS1:t_SUBID.mtxtSubjectNumber) (MAPPINGS1:t_SUBID.mtxtSubjectNumber)

Item Design Notes:	
Item No.	**Design Note**
1.	This item will be mapped from the InForm enrollment form so that the number can be changed if needed

CDD: MAPPINGS1 Table: t_SUBID Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
mtxtSubjectNumber	STRING(6) - A6	

CDD: MAPPINGS2 Table: t_SUBID Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
mtxtSubjectNumber	STRING(6) - A6	

CDD: MAPPINGS3 Table: t_SUBID Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
mtxtSubjectNumber	STRING(6) - A6	

FORM: DISEASE HISTORY (DHIST) TRIAL: dpb925prd

DISEASE HISTORY		
1.	Year of Diagnosis of Type II Diabetes	[xxxx] e.g. 1975 (MAPPINGS2:t_DHIST.DIAGYR) (MAPPINGS3:t_DHIST.DIAGYR) (MAPPINGS1:t_DHIST.DIAGYR)
2.	Month of Diagnosis	(MAPPINGS2:t_DHIST.DIAMTHCD) (MAPPINGS3:t_DHIST.DIAMTHCD) (MAPPINGS1:t_DHIST.DIAMTHCD) [JAN] ○ January [FEB] ○ February [MAR] ○ March [APR] ○ April [MAY] ○ May [JUN] ○ June [JUL] ○ July [AUG] ○ August [SEP] ○ September [OCT] ○ October [NOV] ○ November [DEC] ○ December [UnkElement] ○ Unknown
3.	What is the pre-study treatment?	(MAPPINGS2:t_DHIST.TRTTYPCD) (MAPPINGS3:t_DHIST.TRTTYPCD) (MAPPINGS1:t_DHIST.TRTTYPCD) [1] ○ Diet and exercise regimen alone [2] ○ Oral anti-diabetic monotherapy [3] ○ Oral anti-diabetic dual therapy *(Subject should be withdrawn at this point)* [4] ○ Oral anti-diabetic triple therapy *(Subject should be withdrawn at this point)* [5] ○ Insulin monotherapy *(Subject should be withdrawn at this point)* [6] ○ Insulin and Oral anti-diabetic *(Subject should be withdrawn at this point)*

CDD: MAPPINGS1 Table: t_DHIST Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DIAGYR	NUMERIC - N4	
DIAMTHCD	STRING(10)	
TRTTYPCD	STRING(1)	

CDD: MAPPINGS2 Table: t_DHIST Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DIAGYR	NUMERIC - N4	
DIAMTHCD	STRING(10)	
TRTTYPCD	STRING(1)	

CDD: MAPPINGS3 Table: t_DHIST Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DIAGYR	NUMERIC - N4	
DIAMTHCD	STRING(10)	
TRTTYPCD	STRING(1)	

FORM: ELECTRONICALLY TRANSFERRED LAB DATA (LAB) TRIAL: dpb925prd

ELECTRONICALLY TRANSFERRED LAB DATA		
1.	Date blood sample taken for central laboratory	(MAPPINGS3:t_LABLINK_A1.rdcLABDTTM) (MAPPINGS2:t_LABLINK_A1.rdcLABDTTM) [-99] Date Req / Req / Req (2005-2007) (MAPPINGS3:t_LABLINK_A1.LABDTTM1) (MAPPINGS2:t_LABLINK_A1.LABDTTM1) [ND] Not Done
	Blood Lab type code [*hidden*]	(MAPPINGS3:t_LABLINK_A1.LBTYPCD1) (MAPPINGS2:t_LABLINK_A1.LBTYPCD1)

Form Design Note:
This form is optional. Add an item for each labtype to be collected.

Section Design Notes:	
Title	**Design Note**
ELECTRONICALLY TRANSFERRED LAB DATA	If only one sample date and time is needed for all lab tests performed remove the last two items and modify the text of the first item
sctLBTYPCD1	This section is required and should be the last section on this form. Add or remove items as required by the trial

Item Design Notes:	
Item No.	**Design Note**
1.	Time is optional. Use this item as the first item on this form. For additional tests, use the second item.
itmLBTYPCD1	This item will be calculated by InForm

CDD: MAPPINGS2 Table: t_LABLINK_A1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcLABDTTM	STRING(3)	
LABDTTM1	DATE - DDMONYYYY	
LBTYPCD1	STRING(255)	

CDD: MAPPINGS3 Table: t_LABLINK_A1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcLABDTTM	STRING(3)	
LABDTTM1	DATE - DDMONYYYY	
LBTYPCD1	STRING(255)	

[redacted]

FORM: ELIGIBILITY QUESTION (ELIG) TRIAL: dpb925prd

ELIGIBILITY QUESTION		
1.	Did the subject meet all the entry criteria?	(MAPPINGS1:t_ELIG.IEELIG) (MAPPINGS2:t_ELIG.IEELIG) (MAPPINGS3:t_ELIG.IEELIG) [Y] ○ Yes [N] ○ No, please select all boxes corresponding to violations of any inclusion/exclusion criteria **Inclusion Criteria** (MAPPINGS1:t_ELIG.IECRTNUMI01) (MAPPINGS2:t_ELIG.IECRTNUMI01) (MAPPINGS3:t_ELIG.IECRTNUMI01) [I01] ☐ Inclusion Criteria 1 (MAPPINGS1:t_ELIG.IECRTNUMI02) (MAPPINGS2:t_ELIG.IECRTNUMI02) (MAPPINGS3:t_ELIG.IECRTNUMI02) [I02] ☐ Inclusion Criteria 2 (MAPPINGS3:t_ELIG.IECRTNUMI03) (MAPPINGS1:t_ELIG.IECRTNUMI03) (MAPPINGS2:t_ELIG.IECRTNUMI03) [I03] ☐ Inclusion Criteria 3 (MAPPINGS3:t_ELIG.IECRTNUMI04) (MAPPINGS1:t_ELIG.IECRTNUMI04) (MAPPINGS2:t_ELIG.IECRTNUMI04) [I04] ☐ Inclusion Criteria 4 (MAPPINGS3:t_ELIG.IECRTNUMI05) (MAPPINGS1:t_ELIG.IECRTNUMI05) (MAPPINGS2:t_ELIG.IECRTNUMI05) [I05] ☐ Inclusion Criteria 5 (MAPPINGS3:t_ELIG.IECRTNUMI06) (MAPPINGS1:t_ELIG.IECRTNUMI06) (MAPPINGS2:t_ELIG.IECRTNUMI06) [I06] ☐ Inclusion Criteria 6 (MAPPINGS3:t_ELIG.IECRTNUMI07) (MAPPINGS1:t_ELIG.IECRTNUMI07) (MAPPINGS2:t_ELIG.IECRTNUMI07) [I07] ☐ Inclusion Criteria 7 (MAPPINGS3:t_ELIG.IECRTNUMI08) (MAPPINGS1:t_ELIG.IECRTNUMI08) (MAPPINGS2:t_ELIG.IECRTNUMI08) [I08] ☐ Inclusion Criteria 8 **Exclusion Criteria** (MAPPINGS3:t_ELIG.IECRTNUME01) (MAPPINGS1:t_ELIG.IECRTNUME01) (MAPPINGS2:t_ELIG.IECRTNUME01) [E01] ☐ Exclusion Criteria 1 (MAPPINGS3:t_ELIG.IECRTNUME02) (MAPPINGS1:t_ELIG.IECRTNUME02) (MAPPINGS2:t_ELIG.IECRTNUME02) [E02] ☐ Exclusion Criteria 2 (MAPPINGS3:t_ELIG.IECRTNUME03) (MAPPINGS1:t_ELIG.IECRTNUME03) (MAPPINGS2:t_ELIG.IECRTNUME03) [E03] ☐ Exclusion Criteria 3 (MAPPINGS3:t_ELIG.IECRTNUME04) (MAPPINGS1:t_ELIG.IECRTNUME04) (MAPPINGS2:t_ELIG.IECRTNUME04) [E04] ☐ Exclusion Criteria 4 (MAPPINGS3:t_ELIG.IECRTNUME05) (MAPPINGS1:t_ELIG.IECRTNUME05) (MAPPINGS2:t_ELIG.IECRTNUME05) [E05] ☐ Exclusion Criteria 5 (MAPPINGS3:t_ELIG.IECRTNUME06) (MAPPINGS1:t_ELIG.IECRTNUME06) (MAPPINGS2:t_ELIG.IECRTNUME06) [E06] ☐ Exclusion Criteria 6 (MAPPINGS3:t_ELIG.IECRTNUME07) (MAPPINGS1:t_ELIG.IECRTNUME07) (MAPPINGS2:t_ELIG.IECRTNUME07) [E07] ☐ Exclusion Criteria 7 (MAPPINGS3:t_ELIG.IECRTNUME08) (MAPPINGS1:t_ELIG.IECRTNUME08) (MAPPINGS2:t_ELIG.IECRTNUME08) [E08] ☐ Exclusion Criteria 8 (MAPPINGS3:t_ELIG.IECRTNUME09) (MAPPINGS1:t_ELIG.IECRTNUME09) (MAPPINGS2:t_ELIG.IECRTNUME09) [E09] ☐ Exclusion Criteria 9 (MAPPINGS3:t_ELIG.IECRTNUME10) (MAPPINGS1:t_ELIG.IECRTNUME10) (MAPPINGS2:t_ELIG.IECRTNUME10) [E10] ☐ Exclusion Criteria 10 (MAPPINGS3:t_ELIG.IECRTNUME11) (MAPPINGS1:t_ELIG.IECRTNUME11) (MAPPINGS2:t_ELIG.IECRTNUME11) [E11] ☐ Exclusion Criteria 11 (MAPPINGS3:t_ELIG.IECRTNUME12) (MAPPINGS1:t_ELIG.IECRTNUME12) (MAPPINGS2:t_ELIG.IECRTNUME12) [E12] ☐ Exclusion Criteria 12 (MAPPINGS3:t_ELIG.IECRTNUME13) (MAPPINGS1:t_ELIG.IECRTNUME13) (MAPPINGS2:t_ELIG.IECRTNUME13) [E13] ☐ Exclusion Criteria 13 (MAPPINGS3:t_ELIG.IECRTNUME14) (MAPPINGS1:t_ELIG.IECRTNUME14) (MAPPINGS2:t_ELIG.IECRTNUME14) [E14] ☐ Exclusion Criteria 14 (MAPPINGS3:t_ELIG.IECRTNUME15) (MAPPINGS1:t_ELIG.IECRTNUME15) (MAPPINGS2:t_ELIG.IECRTNUME15) [E15] ☐ Exclusion Criteria 15 (MAPPINGS3:t_ELIG.IECRTNUME16) (MAPPINGS1:t_ELIG.IECRTNUME16) (MAPPINGS2:t_ELIG.IECRTNUME16) [E16] ☐ Exclusion Criteria 16 Do not admit the subject into this study if any Inclusion / Exclusion criteria is checked unless an exception has been granted by the GSK Medical Monitor and subject is continuing in the study. Please clarify the exemption(s) below A200 (MAPPINGS3:t_ELIG.txtEligExempt) (MAPPINGS1:t_ELIG.txtEligExempt) (MAPPINGS2:t_ELIG.txtEligExempt)

CDD: MAPPINGS1 Table: t_ELIG Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
IEELIG	STRING(1)	
IECRTNUMI01	STRING(255)	
IECRTNUMI02	STRING(255)	
IECRTNUMI03	STRING(255)	
IECRTNUMI04	STRING(255)	
IECRTNUMI05	STRING(255)	
IECRTNUMI06	STRING(255)	
IECRTNUMI07	STRING(255)	
IECRTNUMI08	STRING(255)	
IECRTNUME01	STRING(255)	

[redacted]

IECRTNUME02	STRING(255)	
IECRTNUME03	STRING(255)	
IECRTNUME04	STRING(255)	
IECRTNUME05	STRING(255)	
IECRTNUME06	STRING(255)	
IECRTNUME07	STRING(255)	
IECRTNUME08	STRING(255)	
IECRTNUME09	STRING(255)	
IECRTNUME10	STRING(255)	
IECRTNUME11	STRING(255)	
IECRTNUME12	STRING(255)	
IECRTNUME13	STRING(255)	
IECRTNUME14	STRING(255)	
IECRTNUME15	STRING(255)	
IECRTNUME16	STRING(255)	
txtEligExempt	STRING(200) - A200	

CDD: MAPPINGS2	Table: t_ELIG	Key Type: PATIENTVISIT
Column Name	**Column Data Type**	**Design Note**
IEELIG	STRING(1)	
IECRTNUMI01	STRING(255)	
IECRTNUMI02	STRING(255)	
IECRTNUMI03	STRING(255)	
IECRTNUMI04	STRING(255)	
IECRTNUMI05	STRING(255)	
IECRTNUMI06	STRING(255)	
IECRTNUMI07	STRING(255)	
IECRTNUMI08	STRING(255)	
IECRTNUME01	STRING(255)	
IECRTNUME02	STRING(255)	
IECRTNUME03	STRING(255)	
IECRTNUME04	STRING(255)	
IECRTNUME05	STRING(255)	
IECRTNUME06	STRING(255)	
IECRTNUME07	STRING(255)	
IECRTNUME08	STRING(255)	
IECRTNUME09	STRING(255)	
IECRTNUME10	STRING(255)	
IECRTNUME11	STRING(255)	
IECRTNUME12	STRING(255)	
IECRTNUME13	STRING(255)	
IECRTNUME14	STRING(255)	
IECRTNUME15	STRING(255)	
IECRTNUME16	STRING(255)	
txtEligExempt	STRING(200) - A200	

CDD: MAPPINGS3	Table: t_ELIG	Key Type: PATIENTVISIT
Column Name	**Column Data Type**	**Design Note**
IEELIG	STRING(1)	
IECRTNUMI01	STRING(255)	
IECRTNUMI02	STRING(255)	
IECRTNUMI03	STRING(255)	
IECRTNUMI04	STRING(255)	
IECRTNUMI05	STRING(255)	
IECRTNUMI06	STRING(255)	
IECRTNUMI07	STRING(255)	
IECRTNUMI08	STRING(255)	
IECRTNUME01	STRING(255)	
IECRTNUME02	STRING(255)	
IECRTNUME03	STRING(255)	
IECRTNUME04	STRING(255)	
IECRTNUME05	STRING(255)	
IECRTNUME06	STRING(255)	
IECRTNUME07	STRING(255)	
IECRTNUME08	STRING(255)	
IECRTNUME09	STRING(255)	
IECRTNUME10	STRING(255)	
IECRTNUME11	STRING(255)	
IECRTNUME12	STRING(255)	
IECRTNUME13	STRING(255)	
IECRTNUME14	STRING(255)	
IECRTNUME15	STRING(255)	
IECRTNUME16	STRING(255)	
txtEligExempt	STRING(200) - A200	

FORM: ANTI-DIABETIC MEDICATIONS (DMEDS) TRIAL: dpb925prd

New

#		Sequence Number	Drug Name (Trade Name preferred)	Unit Dose	Units	Frequency	Route	Start Date	Taken Prior to Study?	Ongoing?
1										

ANTI-DIABETIC PRIOR MEDICATIONS
Record all anti-diabetic medications taken in the previous 12 months.

	Sequence Number	(MAPPINGS1t_CONMEDS_1.CMSEQ) (MAPPINGS11_CONMEDS_1.CMSEQ) (MAPPINGS21_CONMEDS_1.CMSEQ)
1.	Drug Name (Trade Name preferred)	A100 (MAPPINGS3:t_CONMEDS_1.CMTERM) (MAPPINGS11_CONMEDS_1.CMTERM) (MAPPINGS21_CONMEDS_1.CMTERM)
2.*	Modified reported term *[hidden]*	A100 (MAPPINGS3:t_CONMEDS_1.CMMODIFY) (MAPPINGS11_CONMEDS_1.CMMODIFY) (CM_CODE1:0.VISIT2.CONMEDS_1.actCM_1.0.itmCMDRGCOL.CMDRGCOL) (CM_SYNONYM1.0.VISIT2.CONMEDS_1.actCM_1.0.itmCMDRGSYN.CMDRGSYN) (CM_FAILED1:0.VISIT2.CONMEDS_1.actCM_1.0.itmCM_FAILED.calCM_FAILED) (MAPPINGS21_CONMEDS_1.CMMODIFY)
	GSK Drug synonym *[hidden]*	(MAPPINGS3:t_CONMEDS_1.CMDRGSYN) (MAPPINGS11_CONMEDS_1.CMDRGSYN) (MAPPINGS21_CONMEDS_1.CMDRGSYN)
	GSK Drug Collection code *[hidden]*	(MAPPINGS3:t_CONMEDS_1.CMDRGCOL) (MAPPINGS11_CONMEDS_1.CMDRGCOL) (MAPPINGS21_CONMEDS_1.CMDRGCOL)
	Failed coding *[hidden]*	(MAPPINGS3:t_CONMEDS_1.calCM_FAILED) (MAPPINGS11_CONMEDS_1.calCM_FAILED) (MAPPINGS21_CONMEDS_1.calCM_FAILED)
3.	Unit Dose	A10 (MAPPINGS3:t_CONMEDS_1.CMUDOS) (MAPPINGS11_CONMEDS_1.CMUDOS) (MAPPINGS21_CONMEDS_1.CMUDOS)
4.	Units	Pulldown List 1 (MAPPINGS3:t_CONMEDS_1.CMUNIT) (MAPPINGS11_CONMEDS_1.CMUNIT) (MAPPINGS21_CONMEDS_1.CMUNIT)
5.	Frequency	Pulldown List 2 (MAPPINGS3:t_CONMEDS_1.CMFREQ) (MAPPINGS11_CONMEDS_1.CMFREQ) (MAPPINGS21_CONMEDS_1.CMFREQ)
6.	Route	Pulldown List 3 (MAPPINGS3:t_CONMEDS_1.CMROUTCD) (MAPPINGS11_CONMEDS_1.CMROUTCD) (MAPPINGS21_CONMEDS_1.CMROUTCD)
7.	Start Date	Req/Unk / Req/Unk / Req/Unk (1900-2006) (MAPPINGS3:t_CONMEDS_1.CMSTDT) (MAPPINGS11_CONMEDS_1.CMSTDT) (MAPPINGS21_CONMEDS_1.CMSTDT)
8.	Taken Prior to Study?	(MAPPINGS3:t_CONMEDS_1.CMPRIOR) (MAPPINGS11_CONMEDS_1.CMPRIOR) (MAPPINGS21_CONMEDS_1.CMPRIOR) *[Y]* ○ Yes *[N]* ○ No
9.	Ongoing?	(MAPPINGS3:t_CONMEDS_1.CMONGO) (MAPPINGS11_CONMEDS_1.CMONGO) (MAPPINGS21_CONMEDS_1.CMONGO) *[Y]* ○ Yes **[N]** ○ No, specify End Date Req/Unk / Req/Unk / Req/Unk (2004-2006) (MAPPINGS3:t_CONMEDS_1.CMENDDT) (MAPPINGS11_CONMEDS_1.CMENDDT) (MAPPINGS21_CONMEDS_1.CMENDDT)
	Medication Type *[hidden]*	(MAPPINGS3:t_CONMEDS_1.CMTYPCD) (MAPPINGS11_CONMEDS_1.CMTYPCD) (MAPPINGS21_CONMEDS_1.CMTYPCD)

* Item is not required

Form Design Note:
This form can be used for disease specific conmeds or as a generic conmed form. If both are required in the trial, copy this form and adjust the form title and section titles

Section Design Notes:	
Title	**Design Note**
setCMTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	**Design Note**
3.	This item is conditional
4.	This item is conditional
5.	This item is conditional
6.	This item is optional
7.	Time is optional
8.	This item is optional
9.	Time is optional
itmCMTYPCD	This item will be calculated by InForm

Pulldown List 1:			
RefName	**Display Text**	**Value**	**Design Note**
mestrUnitACTU	Actuation	ACTU	
mestrUnitAMP	Ampoule	AMP	
mestrUnitAPP	Application	APP	
mestrUnitBOT	Bottle	BOT	
mestrUnitCAP	Capsule	CAP	
mestrUnitCC	Cubic centimeter	CC	
mestrUnitGTT	Drops	GTT	
mestrUnitGM	Gram	G	
mestrUnitIU	International units	IU	
mestrUnitIUKG	International units per kilogram	IU/KG	
mestrUnitIUML	International units per millilitre	IU/ML	
mestrUnitL	Litre	L	
mestrUnitLPM	Litre per minute	L/MIN	
mestrUnitLOZ	Lozenge	LOZ	
mestrUnitMU	Megaunits (million units)	MU	
mestrUnitMCG	Microgram (MCG)	MCG	
mestrUnitUG	Microgram (UG)	UG	
mestrUnitMCGKG	Microgram/kilogram	MCG/KG	
mestrUnitMCGKGMIN	Microgram/kilogram/minute	MCG/KG/MIN	
mestrUnitMCGMIN	Micrograms/minute	MCG/MIN	

mestrUnitMCL	Microlitre	MCL	
mestrUnitMEQ	Milliequivalent	MEQ	
mestrUnitMEQ24HR	Milliequivalent/24 hours	MEQ/24HR	
mestrUnitMG	Milligram	MG	
mestrUnitMGPER	Milligrams percent	MG%	
mestrUnitMGHR	Milligram/hour	MG/HR	
mestrUnitMGKG	Milligram/kilogram	MG/KG	
mestrUnitMGKGHR	Milligram/kilogram/hour	MG/KG/HR	
mestrUnitMGKGMIN	Milligram/kilogram/minute	MG/KG/MIN	
mestrUnitMGM2	Milligram/metre squared	MG/M2	
mestrUnitMGML	Milligram/millilitre	MG/ML	
mestrUnitML	Millilitre	ML	
mestrUnitMLHR	Millilitre/hour	ML/HR	
mestrUnitMLMIN	Millilitre/minute	ML/MIN	
mestrUnitMMOL	Millimole	MMOL	
mestrUnitMIU	Million international units	MIU	
mestrUnitMAC	Minimum alveolar concentration	MAC	
mestrUnitNEB	Nebula	NEB	
mestrUnitPATCH	Patch	PATCH	
mestrUnitPer	Percent	%	
mestrUnitPUFF	Puff	PUFF	
mestrUnitSACH	Sachet	SACH	
mestrUnitSP	Spray	SPR	
mestrUnitSUPP	Suppository	SUPP	
mestrUnitTBSP	Tablespoon	TBLSP	
mestrUnitTAB	Tablet	TAB	
mestrUnitTSP	Teaspoon	TSP	
mestrUnitUNIT	Units	U	
mestrUnitUNK	Unknown	UNK	
mestrUnitVIAL	Vial	VIAL	

Pulldown List 2:			
RefName	**Display Text**	**Value**	**Design Note**
mestrFreq2XWK	2 times per week	2XWK	
mestrFreq3XWK	3 times per week	3XWK	
mestrFreq4XWK	4 times per week	4XWK	
mestrFreq5XD	5 times per day	5XD	
mestrFreq5XWK	5 times per week	5XWK	
mestrFreqAC	AC	AC	
mestrFreqBID	BID	BID	
mestrFreqCINF	Continuous infusion	CINF	
mestrFreqQ2WK	Every 2 weeks	Q2WK	
mestrFreqQ3WK	Every 3 weeks	Q3WK	
mestrFreqQ3M	Every 3 months	Q3M	
mestrFreqQOD	Every other day	QOD	
mestrFreqHS	HS	HS	
mestrFreqQM	Once a month	QM	
mestrFreqQWK	Once a week	QWK	
mestrFreqQD	Once daily	QD	
mestrFreqONE	Once only	ONE	
mestrFreqPC	PC	PC	
mestrFreqPRN	PRN	PRN	
mestrFreqQ2H	Q2H	Q2H	
mestrFreqQ3D	Q3D	Q3D	
mestrFreqQ4D	Q4D	Q4D	
mestrFreqQ4H	Q4H	Q4H	
mestrFreqQ6H	Q6H	Q6H	
mestrFreqQ8H	Q8H	Q8H	
mestrFreqQ12H	Q12H	Q12H	
mestrFreqQAM	QAM	QAM	
mestrFreqQH	QH	QH	
mestrFreqQID	QID	QID	
mestrFreqQPM	QPM	QPM	
mestrFreqTID	TID	TID	
mestrFreqUNK	Unknown	UNK	

Pulldown List 3:			
RefName	**Display Text**	**Value**	**Design Note**
mestrRouteOU	Both eyes	OU	
mestrRouteEP	Epidural	EP	
mestrRouteGTT	Gastrostomy tube	GTT	
mestrRouteIH	Inhalation	IH	
mestrRouteINJ	Injection	INJ	
mestrRouteIA	Intra-arterial	IA	
mestrRouteIB	Intra-bursa	IB	
mestrRouteIM	Intramuscular	IM	
mestrRouteIN	Intranasal	IN	
mestrRouteIO	Intraocular	IO	
mestrRouteIOS	Intraosteal	IOS	
mestrRouteIT	Intrathecal	IT	
mestrRouteIU	Intrauterine	IU	
mestrRouteIV	Intravenous	IV	
mestrRouteNS	Nasal	NS	
mestrRoutePO	Oral	PO	

[redacted]

mestrRoutePR	Rectal	PR	
mestrRouteSC	Subcutaneous	SC	
mestrRouteSL	Sublingual	SL	
mestrRouteTP	Topical	TP	
mestrRouteTD	Transdermal	TD	
mestrRouteUNK	Unknown	UNK	
mestrRouteVG	Vaginal	VG	

CDD: MAPPINGS1 Table: t_CONMEDS_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(1)	
CMENDDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_CONMEDS_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(1)	
CMENDDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_CONMEDS_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(1)	
CMENDDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

FORM: MEDICAL CONDITIONS (MEDHX) TRIAL: dpb925prd

MEDICAL CONDITIONS		
Check only one response for each MedDRA System Organ Class		
1.	Blood and lymphatic system disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC0) (MAPPINGS1:t_MEDHIST_C.MHSTATC0) (MAPPINGS2:t_MEDHIST_C.MHSTATC0) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
2.	Cardiac disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC1) (MAPPINGS1:t_MEDHIST_C.MHSTATC1) (MAPPINGS2:t_MEDHIST_C.MHSTATC1) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
3.	Ear and labyrinth disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC2) (MAPPINGS1:t_MEDHIST_C.MHSTATC2) (MAPPINGS2:t_MEDHIST_C.MHSTATC2) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
4.	Endocrine disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC3) (MAPPINGS1:t_MEDHIST_C.MHSTATC3) (MAPPINGS2:t_MEDHIST_C.MHSTATC3) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
5.	Eye disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC4) (MAPPINGS1:t_MEDHIST_C.MHSTATC4) (MAPPINGS2:t_MEDHIST_C.MHSTATC4) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
6.	Gastrointestinal disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC5) (MAPPINGS1:t_MEDHIST_C.MHSTATC5) (MAPPINGS2:t_MEDHIST_C.MHSTATC5) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
7.	Hepatobiliary disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC6) (MAPPINGS1:t_MEDHIST_C.MHSTATC6) (MAPPINGS2:t_MEDHIST_C.MHSTATC6) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
8.	Immune system disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC7) (MAPPINGS1:t_MEDHIST_C.MHSTATC7) (MAPPINGS2:t_MEDHIST_C.MHSTATC7) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
9.	Metabolism and nutrition disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC8) (MAPPINGS1:t_MEDHIST_C.MHSTATC8) (MAPPINGS2:t_MEDHIST_C.MHSTATC8) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
10.	Musculoskeletal and connective tissue disorders	(MAPPINGS3:t_MEDHIST_C.MHSTATC9) (MAPPINGS1:t_MEDHIST_C.MHSTATC9) (MAPPINGS2:t_MEDHIST_C.MHSTATC9) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
11.	Neoplasms benign, malignant and unspecified (including cysts and polyps)	(MAPPINGS3:t_MEDHIST_C.MHSTAT10) (MAPPINGS1:t_MEDHIST_C.MHSTAT10) (MAPPINGS2:t_MEDHIST_C.MHSTAT10) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
12.	Nervous system disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT11) (MAPPINGS1:t_MEDHIST_C.MHSTAT11) (MAPPINGS2:t_MEDHIST_C.MHSTAT11) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
13.	Psychiatric disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT12) (MAPPINGS1:t_MEDHIST_C.MHSTAT12) (MAPPINGS2:t_MEDHIST_C.MHSTAT12) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
14.	Renal and urinary disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT13) (MAPPINGS1:t_MEDHIST_C.MHSTAT13) (MAPPINGS2:t_MEDHIST_C.MHSTAT13) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
15.	Reproductive system and breast disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT14) (MAPPINGS1:t_MEDHIST_C.MHSTAT14) (MAPPINGS2:t_MEDHIST_C.MHSTAT14) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
16.	Respiratory, thoracic and mediastinal disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT15) (MAPPINGS1:t_MEDHIST_C.MHSTAT15) (MAPPINGS2:t_MEDHIST_C.MHSTAT15) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
17.	Skin and subcutaneous tissue disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT16) (MAPPINGS1:t_MEDHIST_C.MHSTAT16) (MAPPINGS2:t_MEDHIST_C.MHSTAT16) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
18.	Vascular disorders	(MAPPINGS3:t_MEDHIST_C.MHSTAT17) (MAPPINGS1:t_MEDHIST_C.MHSTAT17) (MAPPINGS2:t_MEDHIST_C.MHSTAT17) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
19.	Infections and infestations	(MAPPINGS3:t_MEDHIST_C.MHSTAT18) (MAPPINGS1:t_MEDHIST_C.MHSTAT18) (MAPPINGS2:t_MEDHIST_C.MHSTAT18) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
20.	Congenital, familial and genetic disorders	(MAPPINGS2:t_MEDHIST_C.MHSTAT19) (MAPPINGS3:t_MEDHIST_C.MHSTAT19) (MAPPINGS1:t_MEDHIST_C.MHSTAT19) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
21.	General disorders and administration site conditions	(MAPPINGS2:t_MEDHIST_C.MHSTAT20) (MAPPINGS3:t_MEDHIST_C.MHSTAT20)

		(MAPPINGS1:t_MEDHIST_C.MHSTAT20) [1] ○ Current [2] ○ Past [8] ○ No Medical Condition
22.	Injury, poisoning and procedural complications	(MAPPINGS2:t_MEDHIST_C.MHSTAT21) (MAPPINGS3:t_MEDHIST_C.MHSTAT21) (MAPPINGS1:t_MEDHIST_C.MHSTAT21) [1] ○ Current [2] ○ Past [8] ○ No Medical Condition

Form Design Note:
This form is optional

Section Design Notes:	
Title	**Design Note**
MEDICAL CONDITIONS	The following combinations are acceptable: 1. Current+No Medical Condition;2. Current+Past+No Medical Condition;3. Past+No Medical History. Not Assessed is optional for all combinations. Combinations must be consistent for all terms specified.

CDD: MAPPINGS1 **Table: t_MEDHIST_C** **Key Type: PATIENTVISIT**		
Column Name	**Column Data Type**	**Design Note**
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	
MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	
MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	

CDD: MAPPINGS2 **Table: t_MEDHIST_C** **Key Type: PATIENTVISIT**		
Column Name	**Column Data Type**	**Design Note**
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	
MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	
MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	

CDD: MAPPINGS3 **Table: t_MEDHIST_C** **Key Type: PATIENTVISIT**		
Column Name	**Column Data Type**	**Design Note**
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	
MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	

MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	

[redacted]

FORM: MEDICAL CONDITIONS, CV (MEDHX CV) TRIAL: dpb925prd

CARDIOVASCULAR MEDICAL CONDITIONS		
1.	Myocardial infarction	(MAPPINGS2:t_MEDHIST_CV.MHSTATCD) (MAPPINGS3:t_MEDHIST_CV.MHSTATCD) (MAPPINGS1:t_MEDHIST_CV.MHSTATCD) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
2.	Ischaemic heart disease without cardiomyopathy	(MAPPINGS2:t_MEDHIST_CV.MHSTATC1) (MAPPINGS3:t_MEDHIST_CV.MHSTATC1) (MAPPINGS1:t_MEDHIST_CV.MHSTATC1) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
3.	Ischaemic heart disease	(MAPPINGS2:t_MEDHIST_CV.MHSTATC2) (MAPPINGS3:t_MEDHIST_CV.MHSTATC2) (MAPPINGS1:t_MEDHIST_CV.MHSTATC2) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
4.	Stable angina pectoris	(MAPPINGS2:t_MEDHIST_CV.MHSTATC3) (MAPPINGS3:t_MEDHIST_CV.MHSTATC3) (MAPPINGS1:t_MEDHIST_CV.MHSTATC3) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
5.	Unstable angina	(MAPPINGS2:t_MEDHIST_CV.MHSTATC4) (MAPPINGS3:t_MEDHIST_CV.MHSTATC4) (MAPPINGS1:t_MEDHIST_CV.MHSTATC4) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
6.	Atherosclerosis	(MAPPINGS2:t_MEDHIST_CV.MHSTATC5) (MAPPINGS3:t_MEDHIST_CV.MHSTATC5) (MAPPINGS1:t_MEDHIST_CV.MHSTATC5) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
7.	Cardiac valve disease	(MAPPINGS2:t_MEDHIST_CV.MHSTATC6) (MAPPINGS3:t_MEDHIST_CV.MHSTATC6) (MAPPINGS1:t_MEDHIST_CV.MHSTATC6) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
8.	Peripheral vascular disease	(MAPPINGS2:t_MEDHIST_CV.MHSTATC7) (MAPPINGS3:t_MEDHIST_CV.MHSTATC7) (MAPPINGS1:t_MEDHIST_CV.MHSTATC7) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
9.	Cerebrovascular disorder	(MAPPINGS2:t_MEDHIST_CV.MHSTATC8) (MAPPINGS3:t_MEDHIST_CV.MHSTATC8) (MAPPINGS1:t_MEDHIST_CV.MHSTATC8) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
10.	Transient ischaemic attack	(MAPPINGS2:t_MEDHIST_CV.MHSTATC9) (MAPPINGS3:t_MEDHIST_CV.MHSTATC9) (MAPPINGS1:t_MEDHIST_CV.MHSTATC9) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
11.	Stroke	(MAPPINGS2:t_MEDHIST_CV.MHSTAT10) (MAPPINGS3:t_MEDHIST_CV.MHSTAT10) (MAPPINGS1:t_MEDHIST_CV.MHSTAT10) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
12.	Cardiac arrest	(MAPPINGS2:t_MEDHIST_CV.MHSTAT11) (MAPPINGS3:t_MEDHIST_CV.MHSTAT11) (MAPPINGS1:t_MEDHIST_CV.MHSTAT11) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
13.	Coronary artery disease	(MAPPINGS2:t_MEDHIST_CV.MHSTAT12) (MAPPINGS3:t_MEDHIST_CV.MHSTAT12) (MAPPINGS1:t_MEDHIST_CV.MHSTAT12) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
14.	Heart failure	(MAPPINGS2:t_MEDHIST_CV.MHSTAT13) (MAPPINGS3:t_MEDHIST_CV.MHSTAT13) (MAPPINGS1:t_MEDHIST_CV.MHSTAT13) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
15.	Arrhythmia	(MAPPINGS2:t_MEDHIST_CV.MHSTAT14) (MAPPINGS3:t_MEDHIST_CV.MHSTAT14) (MAPPINGS1:t_MEDHIST_CV.MHSTAT14) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
16.	Left ventricular dysfunction	(MAPPINGS2:t_MEDHIST_CV.MHSTAT15) (MAPPINGS3:t_MEDHIST_CV.MHSTAT15) (MAPPINGS1:t_MEDHIST_CV.MHSTAT15) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
17.	Pulmonary oedema	(MAPPINGS2:t_MEDHIST_CV.MHSTAT16) (MAPPINGS3:t_MEDHIST_CV.MHSTAT16) (MAPPINGS1:t_MEDHIST_CV.MHSTAT16) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
18.	Hypertension	(MAPPINGS2:t_MEDHIST_CV.MHSTAT17) (MAPPINGS3:t_MEDHIST_CV.MHSTAT17) (MAPPINGS1:t_MEDHIST_CV.MHSTAT17) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
19.	Oedema	(MAPPINGS2:t_MEDHIST_CV.MHSTAT18) (MAPPINGS3:t_MEDHIST_CV.MHSTAT18) (MAPPINGS1:t_MEDHIST_CV.MHSTAT18) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
20.	Left ventricular hypertrophy	(MAPPINGS2:t_MEDHIST_CV.MHSTAT19) (MAPPINGS3:t_MEDHIST_CV.MHSTAT19) (MAPPINGS1:t_MEDHIST_CV.MHSTAT19) [2] ○ Past [1] ○ Current [5] ○ No Medical Condition
21.	Cardiomegaly	(MAPPINGS1:t_MEDHIST_CV.MHSTAT20) (MAPPINGS2:t_MEDHIST_CV.MHSTAT20) (MAPPINGS3:t_MEDHIST_CV.MHSTAT20) [2] ○ Past

		[1] ○ Current [8] ○ No Medical Condition
22.	Cardiomyopathy	(MAPPINGS1:t_MEDHIST_CV.MHSTAT21) (MAPPINGS2:t_MEDHIST_CV.MHSTAT21) (MAPPINGS3:t_MEDHIST_CV.MHSTAT21) [2] ○ Past [1] ○ Current [8] ○ No Medical Condition
23.	Diastolic dysfunction	(MAPPINGS1:t_MEDHIST_CV.MHSTAT22) (MAPPINGS2:t_MEDHIST_CV.MHSTAT22) (MAPPINGS3:t_MEDHIST_CV.MHSTAT22) [2] ○ Past [1] ○ Current [8] ○ No Medical Condition

Form Design Note:
This form is optional

Section Design Notes:	
Title	**Design Note**
CARDIOVASCULAR MEDICAL CONDITIONS	The following combinations are acceptable: 1. Current+No Medical Condition;2. Current+Past+No Medical Condition;3. Past+No Medical History. Not Assessed is optional for all combinations. Combinations must be consistent for all terms specified

CDD: MAPPINGS1 Table: t_MEDHIST_CV Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	
MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	
MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	
MHSTAT22	STRING(1)	

CDD: MAPPINGS2 Table: t_MEDHIST_CV Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	
MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	
MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	
MHSTAT22	STRING(1)	

CDD: MAPPINGS3 Table: t_MEDHIST_CV Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	

[redacted]

MHSTAT10	STRING(1)	
MHSTAT11	STRING(1)	
MHSTAT12	STRING(1)	
MHSTAT13	STRING(1)	
MHSTAT14	STRING(1)	
MHSTAT15	STRING(1)	
MHSTAT16	STRING(1)	
MHSTAT17	STRING(1)	
MHSTAT18	STRING(1)	
MHSTAT19	STRING(1)	
MHSTAT20	STRING(1)	
MHSTAT21	STRING(1)	
MHSTAT22	STRING(1)	

FORM: MEDICAL CONDITIONS, DIABETES (MEDHX DIA) TRIAL: dpb925prd

DIABETES MEDICAL CONDITIONS		
1.	Diabetic retinopathy	(MAPPINGS1:t_MEDHIST_DIAB.MHSTATCD) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATCD) (MAPPINGS3:t_MEDHIST_DIAB.MHSTATCD) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
2.	Autonomic neuropathy	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC1) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC1) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC1) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
3.	Neuropathy peripheral	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC2) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC2) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC2) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
4.	Dyslipidaemia	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC3) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC3) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC3) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
5.	Diabetic foot ulcer	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC4) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC4) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC4) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
6.	Proteinuria	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC5) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC5) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC5) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
7.	Nephropathy	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC6) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC6) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC6) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
8.	Microalbuminuria	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC7) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC7) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC7) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
9.	Chronic renal insufficiency	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC8) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC8) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC8) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition
10.	Chronic renal failure	(MAPPINGS3:t_MEDHIST_DIAB.MHSTATC9) (MAPPINGS1:t_MEDHIST_DIAB.MHSTATC9) (MAPPINGS2:t_MEDHIST_DIAB.MHSTATC9) [1] ○ Current [2] ○ Past [5] ○ No Medical Condition

Form Design Note:
IDSL Version 01.00A - 01 DEC 04 This form is optional.

Section Design Notes:	
Title	Design Note
DIABETES MEDICAL CONDITIONS	The following combinations are acceptable: 1. Current+No Medical Condition;2. Current+Past+No Medical Condition;3. Past+No Medical History. Not Assessed is optional for all combinations. Combinations must be consistent for all terms specified

CDD: MAPPINGS1 Table: t_MEDHIST_DIAB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	

CDD: MAPPINGS2 Table: t_MEDHIST_DIAB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	
MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	

CDD: MAPPINGS3 Table: t_MEDHIST_DIAB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MHSTATCD	STRING(1)	
MHSTATC1	STRING(1)	

[redacted]

MHSTATC2	STRING(1)	
MHSTATC3	STRING(1)	
MHSTATC4	STRING(1)	
MHSTATC5	STRING(1)	
MHSTATC6	STRING(1)	
MHSTATC7	STRING(1)	
MHSTATC8	STRING(1)	
MHSTATC9	STRING(1)	

FORM: ALCOHOL INTAKE (ALCOHOL) TRIAL: dpb925prd

ALCOHOL INTAKE	
1. Does the subject consume alcohol?	{MAPPINGS2:t_SUBUSE_AL.SUAL} {MAPPINGS3:t_SUBUSE_AL.SUAL} {MAPPINGS1:t_SUBUSE_AL.SUAL} *[0]* ○ No *[1]* ○ Yes, record the average number of units of alcohol consumed per week {MAPPINGS2:t_SUBUSE_AL.SUALUNWK} {MAPPINGS3:t_SUBUSE_AL.SUALUNWK} {MAPPINGS1:t_SUBUSE_AL.SUALUNWK} xxxxx.
Substance Use Type [*hidden*]	{MAPPINGS2:t_SUBUSE_AL.SUTYPCD} {MAPPINGS3:t_SUBUSE_AL.SUTYPCD} {MAPPINGS1:t_SUBUSE_AL.SUTYPCD}

Form Design Note:
This form is optional

Section Design Notes:	
Title	Design Note
sctSUTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	Design Note
itmSUTYPCD	This item will be calculated by InForm.

CDD: MAPPINGS1 Table: t_SUBUSE_AL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUAL	STRING(1)	
SUALUNWK	FLOAT - F6.0	
SUTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_SUBUSE_AL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUAL	STRING(1)	
SUALUNWK	FLOAT - F6.0	
SUTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_SUBUSE_AL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUAL	STRING(1)	
SUALUNWK	FLOAT - F6.0	
SUTYPCD	STRING(255)	

FORM: HISTORY OF TOBACCO USE (TOB HIST) TRIAL: dpb925prd

HISTORY OF TOBACCO USE	
1. What is the subject's history of tobacco use (includes all tobacco products)	(MAPPINGS2:t_SUBUSE_SMHS.SUSMHSCD) (MAPPINGS3:t_SUBUSE_SMHS.SUSMHSCD) (MAPPINGS1:t_SUBUSE_SMHS.SUSMHSCD) [1] ○ Never smoked [2] ○ Current smoker [3] ○ Former smoker, when did the subject last smoke/use tobacco? Req/Unk / Req/Unk / Req/Unk (1900-2007) (MAPPINGS2:t_SUBUSE_SMHS.SUSMLSDT) (MAPPINGS3:t_SUBUSE_SMHS.SUSMLSDT) (MAPPINGS1:t_SUBUSE_SMHS.SUSMLSDT)
Substance Use Type *[hidden]*	(MAPPINGS2:t_SUBUSE_SMHS.SUTYPCD) (MAPPINGS3:t_SUBUSE_SMHS.SUTYPCD) (MAPPINGS1:t_SUBUSE_SMHS.SUTYPCD)

Form Design Note:
This form is optional

Section Design Notes:	
Title	**Design Note**
setSUTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	**Design Note**
itmSUTYPCD	This item will be calculated by InForm.

CDD: MAPPINGS1 Table: t_SUBUSE_SMHS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUSMHSCD	STRING(1)	
SUSMLSDT	DATE - DDMONYYYY	
SUTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_SUBUSE_SMHS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUSMHSCD	STRING(1)	
SUSMLSDT	DATE - DDMONYYYY	
SUTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_SUBUSE_SMHS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUSMHSCD	STRING(1)	
SUSMLSDT	DATE - DDMONYYYY	
SUTYPCD	STRING(255)	

FORM: ELECTRONICALLY TRANSFERRED LAB DATA (LAB) TRIAL: dpb925prd

ELECTRONICALLY TRANSFERRED LAB DATA		
1.	Date blood sample taken for central laboratory	(MAPPINGS3:t_LABLINK_A.rdcLABDTTM) (MAPPINGS1:t_LABLINK_A.rdcLABDTTM) (MAPPINGS2:t_LABLINK_A.rdcLABDTTM) [-99] ○ Date Req / Req / Req (2005-2007) (MAPPINGS3:t_LABLINK_A.LABDTTM1) (MAPPINGS1:t_LABLINK_A.LABDTTM1) (MAPPINGS2:t_LABLINK_A.LABDTTM1) [ND] ○ Not Done
2.	Date urine sample taken for central laboratory	(MAPPINGS3:t_LABLINK_A.rdcLABDTTM1) (MAPPINGS1:t_LABLINK_A.rdcLABDTTM1) (MAPPINGS2:t_LABLINK_A.rdcLABDTTM1) [-98] ○ Same as the previous sample [-99] ○ Date Req / Req / Req (2005-2007) (MAPPINGS3:t_LABLINK_A.LABDTTM2) (MAPPINGS1:t_LABLINK_A.LABDTTM2) (MAPPINGS2:t_LABLINK_A.LABDTTM2) [ND] ○ Not Done
	Blood Lab type code [*hidden*]	(MAPPINGS3:t_LABLINK_A.LBTYPCD1) (MAPPINGS1:t_LABLINK_A.LBTYPCD1) (MAPPINGS2:t_LABLINK_A.LBTYPCD1)
	Urine Lab type code [*hidden*]	(MAPPINGS3:t_LABLINK_A.LBTYPCD2) (MAPPINGS1:t_LABLINK_A.LBTYPCD2) (MAPPINGS2:t_LABLINK_A.LBTYPCD2)

Form Design Note:
This form is optional. Add an item for each labtype to be collected.

Section Design Notes:	
Title	Design Note
ELECTRONICALLY TRANSFERRED LAB DATA	If only one sample date and time is needed for all lab tests performed remove the last two items and modify the text of the first item
sctLBTYPCD	This section is required and should be the last section on this form. Add or remove items as required by the trial

Item Design Notes:	
Item No.	Design Note
1.	Time is optional. Use this item as the first item on this form. For additional tests, use the second item.
2.	Time is optional. Use this item for all other samples on the form
itmLBTYPCD1	This item will be calculated by InForm
itmLBTYPCD2	This item will be calculated by InForm

CDD: MAPPINGS1 Table: t_LABLINK_A Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcLABDTTM	STRING(3)	
LABDTTM1	DATE - DDMONYYYY	
rdcLABDTTM1	STRING(3)	
LABDTTM2	DATE - DDMONYYYY	
LBTYPCD1	STRING(255)	
LBTYPCD2	STRING(255)	

CDD: MAPPINGS2 Table: t_LABLINK_A Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcLABDTTM	STRING(3)	
LABDTTM1	DATE - DDMONYYYY	
rdcLABDTTM1	STRING(3)	
LABDTTM2	DATE - DDMONYYYY	
LBTYPCD1	STRING(255)	
LBTYPCD2	STRING(255)	

CDD: MAPPINGS3 Table: t_LABLINK_A Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcLABDTTM	STRING(3)	
LABDTTM1	DATE - DDMONYYYY	
rdcLABDTTM1	STRING(3)	
LABDTTM2	DATE - DDMONYYYY	
LBTYPCD1	STRING(255)	
LBTYPCD2	STRING(255)	

[redacted]

FORM: VITAL SIGNS (VS) TRIAL: dpb925prd

VITAL SIGNS		
1.	Height	xxx cm (MAPPINGS21_VITALS.HEIGHT) (MAPPINGS31_VITALS.HEIGHT) (MAPPINGS11_VITALS.HEIGHT)
2.	Weight *(to 1 decimal place, e.g. 65.0)*	xxx.x kg (MAPPINGS21_VITALS.WEIGHT) (MAPPINGS31_VITALS.WEIGHT) (MAPPINGS11_VITALS.WEIGHT)
	Body mass index	(MAPPINGS21_VITALS.VSBMI) (MAPPINGS31_VITALS.VSBMI) (MAPPINGS11_VITALS.VSBMI)
3.	Hip circumference *(standing)*	xxx cm (MAPPINGS21_VITALS.VSHIPCIR) (MAPPINGS31_VITALS.VSHIPCIR) (MAPPINGS11_VITALS.VSHIPCIR)
4.	Waist circumference *(standing)*	xxx cm (MAPPINGS21_VITALS.VSWSTCIR) (MAPPINGS31_VITALS.VSWSTCIR) (MAPPINGS11_VITALS.VSWSTCIR)
5.	Blood pressure *(Average of 2 readings taken 5 minutes apart)*	xxx / (MAPPINGS21_VITALS.SYSBP) (MAPPINGS31_VITALS.SYSBP) (MAPPINGS11_VITALS.SYSBP) xxx mmHg (MAPPINGS21_VITALS.DIABP) (MAPPINGS31_VITALS.DIABP) (MAPPINGS11_VITALS.DIABP) (systolic/diastolic)
6.	Heart rate *(Average of 2 readings taken 5 minutes apart)*	xxx beats/min (MAPPINGS21_VITALS.HEART) (MAPPINGS31_VITALS.HEART) (MAPPINGS11_VITALS.HEART)
	Calculated Subject position [hidden]	(MAPPINGS21_VITALS.VSPOSCD1) (MAPPINGS31_VITALS.VSPOSCD1) (MAPPINGS11_VITALS.VSPOSCD1)

Form Design Note:
This form is optional. This form is to be used when one Vitals is taken at a visit.

Section Design Notes:	
Title	**Design Note**
VITAL SIGNS	All items are optional
setVSPOS_CAL	This section should be the last section on the form and is required when position of BP is consistent throughout the study.

Item Design Notes:	
Item No.	**Design Note**
itmVSBMI	Item to be calculated as: Weight in kilograms divided by the square of height in meters
3.	Delete text standing or supine as appropriate for study
4.	Delete text standing or supine as appropriate for study
itmVSPOS_CAL	This item should be used if only one position is stipulated for the trial. Remove the other Position item and adjust the calculation rule accordingly.

CDD: MAPPINGS1 Table: t_VITALS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HEIGHT	NUMERIC - N3	
WEIGHT	FLOAT - F5.1	
VSBMI	STRING(255)	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS2 Table: t_VITALS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HEIGHT	NUMERIC - N3	
WEIGHT	FLOAT - F5.1	
VSBMI	STRING(255)	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS3 Table: t_VITALS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HEIGHT	NUMERIC - N3	
WEIGHT	FLOAT - F5.1	
VSBMI	STRING(255)	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

FORM: 12-LEAD ECG (ECG) TRIAL: dpb925prd

12-LEAD ECG		
1.	Date and Time of ECG Hr:Min (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS1:t_ECG_NOABN_1:EGDTTM) (MAPPINGS2:t_ECG_NOABN_1:EGDTTM) (MAPPINGS3:t_ECG_NOABN_1:EGDTTM) Req : Req

Form Design Note:
IDSL Version 01.00A - 01 DEC 04 This form is optional and should be used when abnormalities are not collected, or when abnormalities are collected on a separate form. Trial designer to modify the form and section title per protocol.

Item Design Notes:	
Item No.	**Design Note**
1.	Time is optional.

CDD: MAPPINGS1 Table: t_ECG_NOABN_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EGDTTM	DATE - DDMONYYYY HHMM	

CDD: MAPPINGS2 Table: t_ECG_NOABN_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EGDTTM	DATE - DDMONYYYY HHMM	

CDD: MAPPINGS3 Table: t_ECG_NOABN_1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EGDTTM	DATE - DDMONYYYY HHMM	

FORM: ECG_Confirmation (ECG_Conf) TRIAL: dpb925prd

ECG Confirmation		
1.	Based on the local or centralised ECG interpretation were there any ECG abnormalities which in the opinion of the Investigator should preclude the subject's continued participation in this clinical trial?	(MAPPINGS1:t_ECG_CONFIRMATION.rdcECGConf) (MAPPINGS2:t_ECG_CONFIRMATION.rdcECGConf) (MAPPINGS3:t_ECG_CONFIRMATION.rdcECGConf) [Y] ○ Yes, Complete the "MEDHX CV" tab, select relevant violation criteria on "ELIG" tab & withdraw subject selecting reason as "Did not fulfill eligibility criteria" on "CONC" tab in the logs. [N] ○ No, Continue in Study

CDD: MAPPINGS1 Table: t_ECG_CONFIRMATION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcECGConf	STRING(1)	

CDD: MAPPINGS2 Table: t_ECG_CONFIRMATION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcECGConf	STRING(1)	

CDD: MAPPINGS3 Table: t_ECG_CONFIRMATION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcECGConf	STRING(1)	

FORM: ELIGIBILITY CONFIRMATION (ELIG_CONF) TRIAL: dpb925prd

ELIGIBILITY CONFIRMATION		
1.	Did the subject meet all the protocol defined study criteria?	{MAPPINGS3:t_ELIG_CONF.grpECONF} {MAPPINGS1:t_ELIG_CONF.grpECONF} {MAPPINGS2:t_ELIG_CONF.grpECONF} *[1]* ○ Yes *[0]* ○ No. Please go to Visit 1 ELIG tab and select all boxes corresponding to violations of any inclusion/exclusion criteria

CDD: MAPPINGS1 Table: t_ELIG_CONF Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpECONF	STRING(1)	

CDD: MAPPINGS2 Table: t_ELIG_CONF Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpECONF	STRING(1)	

CDD: MAPPINGS3 Table: t_ELIG_CONF Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpECONF	STRING(1)	

FORM: VITAL SIGNS (VS) TRIAL: dpb925prd

VITAL SIGNS		
1.	Weight *(to 1 decimal place, e.g. 65.0)*	xxx.x kg (MAPPINGS2:t_VITALS_1.WEIGHT) (MAPPINGS3:t_VITALS_1.WEIGHT) (MAPPINGS1:t_VITALS_1.WEIGHT)
2.	Blood pressure *(Average of 2 readings taken 5 minutes apart)*	xxx / (MAPPINGS2:t_VITALS_1.SYSBP) (MAPPINGS3:t_VITALS_1.SYSBP) (MAPPINGS1:t_VITALS_1.SYSBP) xxx mmHg (MAPPINGS2:t_VITALS_1.DIABP) (MAPPINGS3:t_VITALS_1.DIABP) (MAPPINGS1:t_VITALS_1.DIABP) (systolic/diastolic)
3.	Heart rate *(Average of 2 readings taken 5 minutes apart)*	xxx beats/min (MAPPINGS2:t_VITALS_1.HEART) (MAPPINGS3:t_VITALS_1.HEART) (MAPPINGS1:t_VITALS_1.HEART)
	Calculated Subject position *[hidden]*	(MAPPINGS1:t_VITALS_1.VSPOSCD1) (MAPPINGS2:t_VITALS_1.VSPOSCD1) (MAPPINGS3:t_VITALS_1.VSPOSCD1)

Form Design Note:
This form is optional. This form is to be used when one Vitals is taken at a visit.

Section Design Notes:	
Title	Design Note
VITAL SIGNS	All items are optional
setVSPOS_CAL	This section should be the last section on the form and is required when position of BP is consistent throughout the study.

Item Design Notes:	
Item No.	Design Note
itmVSPOS_CAL	This item should be used if only one position is stipulated for the trial. Remove the other Position item and adjust the calculation rule accordingly.

CDD: MAPPINGS1 Table: t_VITALS_1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
WEIGHT	FLOAT - F5.1	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS2 Table: t_VITALS_1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
WEIGHT	FLOAT - F5.1	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS3 Table: t_VITALS_1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
WEIGHT	FLOAT - F5.1	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

FORM: FPG REMINDER (FPG) TRIAL: dpb925prd

FPG REMINDER		
1.	Does subject have an FPG (by central laboratory) <= 240 mg/dl (13.3 mmol) ? If No after confirmation the subject should be withdrawn and referred for appropriate follow-up treatment.	(MAPPINGS3:t_FPG.grpFPG) (MAPPINGS1:t_FPG.grpFPG) (MAPPINGS2:t_FPG.grpFPG) [Y] ○ Yes [N] ○ No

CDD: MAPPINGS1 Table: t_FPG Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpFPG	STRING(1)	

CDD: MAPPINGS2 Table: t_FPG Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpFPG	STRING(1)	

CDD: MAPPINGS3 Table: t_FPG Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpFPG	STRING(1)	

FORM: GLUCOSE (GLUC) TRIAL: dpb925prd

GLUCOSE		
1.	Result of Capillary Blood Glucose (fingerstick) *(to one decimal place)*	XXX.X (MAPPINGS2.t_GLUCOSE.CBGRES) (MAPPINGS3.t_GLUCOSE.CBGRES) (MAPPINGS1.t_GLUCOSE.CBGRES) (MAPPINGS2.t_GLUCOSE.CBGRESUN) (MAPPINGS3.t_GLUCOSE.CBGRESUN) (MAPPINGS1.t_GLUCOSE.CBGRESUN) Unit *[MG/DL]* ○ Milligrams per decilitre (MG/DL) *[MMOL/L]* ○ Millimoles per litre (MMOL/L)

CDD: MAPPINGS1 Table: t_GLUCOSE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CBGRES	FLOAT - F5.1	
CBGRESUN	STRING(6)	

CDD: MAPPINGS2 Table: t_GLUCOSE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CBGRES	FLOAT - F5.1	
CBGRESUN	STRING(6)	

CDD: MAPPINGS3 Table: t_GLUCOSE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CBGRES	FLOAT - F5.1	
CBGRESUN	STRING(6)	

FORM: COMPLIANCE (COMP) TRIAL: dpb925prd

COMPLIANCE		
1.	Compliance (%) since the last visit	(MAPPINGS2:t_COMP.CMPPCTCD) (MAPPINGS3:t_COMP.CMPPCTCD) (MAPPINGS1:t_COMP.CMPPCTCD) [1] ○ 0% compliant (subject did not take any doses) [2] ○ > 0% and <80% compliant (subject missed a number of doses) [3] ○ >= 80% and <=120% (number of doses taken was within compliance range) [4] ○ > 120% compliant (number of doses taken exceeds compliance levels)
2.*	Reason for non-compliance	(MAPPINGS2:t_COMP.NOCMPAE1) (MAPPINGS3:t_COMP.NOCMPAE1) (MAPPINGS1:t_COMP.NOCMPAE1) [1] ☐ Adverse Event (MAPPINGS2:t_COMP.NOCMPDE1) (MAPPINGS3:t_COMP.NOCMPDE1) (MAPPINGS1:t_COMP.NOCMPDE1) [2] ☐ Dispensing error (MAPPINGS2:t_COMP.NOCMPMED1) (MAPPINGS3:t_COMP.NOCMPMED1) (MAPPINGS1:t_COMP.NOCMPMED1) [3] ☐ Subject did not take medication according to protocol (MAPPINGS2:t_COMP.NOCMPOTH2) (MAPPINGS3:t_COMP.NOCMPOTH2) (MAPPINGS1:t_COMP.NOCMPOTH2) [Y] ☐ Other, specify (MAPPINGS2:t_COMP.NOCMPOSP1) (MAPPINGS3:t_COMP.NOCMPOSP1) (MAPPINGS1:t_COMP.NOCMPOSP1) A200
* Item is not required		

CDD: MAPPINGS1 Table: t_COMP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMPPCTCD	STRING(1)	
NOCMPAE1	STRING(255)	
NOCMPDE1	STRING(255)	
NOCMPMED1	STRING(255)	
NOCMPOTH2	STRING(255)	
NOCMPOSP1	STRING(200) - A200	

CDD: MAPPINGS2 Table: t_COMP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMPPCTCD	STRING(1)	
NOCMPAE1	STRING(255)	
NOCMPDE1	STRING(255)	
NOCMPMED1	STRING(255)	
NOCMPOTH2	STRING(255)	
NOCMPOSP1	STRING(200) - A200	

CDD: MAPPINGS3 Table: t_COMP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMPPCTCD	STRING(1)	
NOCMPAE1	STRING(255)	
NOCMPDE1	STRING(255)	
NOCMPMED1	STRING(255)	
NOCMPOTH2	STRING(255)	
NOCMPOSP1	STRING(200) - A200	

FORM: RANDOMISATION NUMBER (RAND) TRIAL: dpb925prd

RANDOMISATION NUMBER		
1.	Was the subject able to be randomised?	(MAPPINGS3:t_RAND.rdcRandYN) (MAPPINGS1:t_RAND.rdcRandYN) (MAPPINGS2:t_RAND.rdcRandYN) [N] ○ No [Y] ○ Yes, provide: Randomisation number (MAPPINGS3:t_RAND.RANDNUM) (MAPPINGS1:t_RAND.RANDNUM) (MAPPINGS2:t_RAND.RANDNUM) XXXXXX

CDD: MAPPINGS1 Table: t_RAND Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcRandYN	STRING(1)	
RANDNUM	NUMERIC - N6	

CDD: MAPPINGS2 Table: t_RAND Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcRandYN	STRING(1)	
RANDNUM	NUMERIC - N6	

CDD: MAPPINGS3 Table: t_RAND Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcRandYN	STRING(1)	
RANDNUM	NUMERIC - N6	

FORM: INVESTIGATIONAL PRODUCT CONTAINER NUMBER (PACK) TRIAL: dpb925prd

INVESTIGATIONAL PRODUCT CONTAINER NUMBER		
Record the identifying number from the investigational product container dispensed at this visit		
1.	Investigational product container number (Bottle A)	A6 (MAPPINGS3:t_EXPOSURE_CONTAINER.EXINVNUM01) (MAPPINGS1:t_EXPOSURE_CONTAINER.EXINVNUM01) (MAPPINGS2:t_EXPOSURE_CONTAINER.EXINVNUM01)
2.	Investigational product container number (Bottle B)	A6 (MAPPINGS3:t_EXPOSURE_CONTAINER.EXINVNUM02) (MAPPINGS1:t_EXPOSURE_CONTAINER.EXINVNUM02) (MAPPINGS2:t_EXPOSURE_CONTAINER.EXINVNUM02)
3.	Investigational product container number (Bottle C)	A6 (MAPPINGS3:t_EXPOSURE_CONTAINER.EXINVNUM03) (MAPPINGS1:t_EXPOSURE_CONTAINER.EXINVNUM03) (MAPPINGS2:t_EXPOSURE_CONTAINER.EXINVNUM03)

Form Design Note:
This form is conditional on RAMOS being used in the trial. If additional container numbers are needed, copy the first item as needed, or change the repeating property on this form to True

CDD: MAPPINGS1 Table: t_EXPOSURE_CONTAINER Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVNUM01	STRING(6) - A6	
EXINVNUM02	STRING(6) - A6	
EXINVNUM03	STRING(6) - A6	

CDD: MAPPINGS2 Table: t_EXPOSURE_CONTAINER Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVNUM01	STRING(6) - A6	
EXINVNUM02	STRING(6) - A6	
EXINVNUM03	STRING(6) - A6	

CDD: MAPPINGS3 Table: t_EXPOSURE_CONTAINER Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVNUM01	STRING(6) - A6	
EXINVNUM02	STRING(6) - A6	
EXINVNUM03	STRING(6) - A6	

FORM: Pharmacokinetic Population (PKPOP) TRIAL: dpb925prd

Pharmacokinetic Population		
1.	What type of Pharmacokinetic Sampling will be performed?	{MAPPINGS3.t_PKPOP.PKPOP} {MAPPINGS1.t_PKPOP.PKPOP} {MAPPINGS2.t_PKPOP.PKPOP} [1] ○ Sparse Sampling [2] ○ Serial Sampling

CDD: MAPPINGS1 Table: t_PKPOP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKPOP	STRING(1)	

CDD: MAPPINGS2 Table: t_PKPOP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKPOP	STRING(1)	

CDD: MAPPINGS3 Table: t_PKPOP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKPOP	STRING(1)	

FORM: MEAL (MEAL) TRIAL: dpb925prd

Meal		
1.	End time of clinic provided meal	NReq : NReq {MAPPINGS1.t_MEAL.MEALDTTM} {MAPPINGS1.t_MEAL.MEALDTTM} {MAPPINGS2.t_MEAL.MEALDTTM}

CDD: MAPPINGS1 Table: t_MEAL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
MEALDTTM	DATE - HHMM	

CDD: MAPPINGS2 Table: t_MEAL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
MEALDTTM	DATE - HHMM	

CDD: MAPPINGS3 Table: t_MEAL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
MEALDTTM	DATE - HHMM	

FORM: INVESTIGATIONAL PRODUCT (IP) TRIAL: dpb925prd

INVESTIGATIONAL PRODUCT		
1.	Date and Time of Dose Hr:Min (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS3:t_EXPOSURE_IP.EXSTDTTM) (MAPPINGS1:t_EXPOSURE_IP.EXSTDTTM) (MAPPINGS2:t_EXPOSURE_IP.EXSTDTTM) Req : Req

Form Design Note:
This form is required when IP is administered. If Planned Timepoint is not used, but repeats are needed, make this form repeating. Use this form for: Multiple assessments (per visit) running log (per study))

Item Design Notes:	
Item No.	**Design Note**
1.	This item is conditionally required for single dose studies

CDD: MAPPINGS1 Table: t_EXPOSURE_IP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXSTDTTM	DATE - DDMONYYYY HHMM	

CDD: MAPPINGS2 Table: t_EXPOSURE_IP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXSTDTTM	DATE - DDMONYYYY HHMM	

CDD: MAPPINGS3 Table: t_EXPOSURE_IP Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXSTDTTM	DATE - DDMONYYYY HHMM	

FORM: PHARMACOKINETICS/PHARMACODYNAMICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTTM) (MAPPINGS1:t_PK_LTDAY.PKSTTM) (MAPPINGS2:t_PK_LTDAY.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMPID) (MAPPINGS1:t_PK_LTDAY.PKSMPID) (MAPPINGS2:t_PK_LTDAY.PKSMPID) [N] No
0.25 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA1) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT1) (MAPPINGS1:t_PK_LTDAY.PKSTT1) (MAPPINGS2:t_PK_LTDAY.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP1) (MAPPINGS1:t_PK_LTDAY.PKSMP1) (MAPPINGS2:t_PK_LTDAY.PKSMP1) [N] No
0.5 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA2) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA2) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA2) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT2) (MAPPINGS1:t_PK_LTDAY.PKSTT2) (MAPPINGS2:t_PK_LTDAY.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP2) (MAPPINGS1:t_PK_LTDAY.PKSMP2) (MAPPINGS2:t_PK_LTDAY.PKSMP2) [N] No
1 HOUR POSTDOSE	
4. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA3) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA3) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA3) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT3) (MAPPINGS1:t_PK_LTDAY.PKSTT3) (MAPPINGS2:t_PK_LTDAY.PKSTT3) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP3) (MAPPINGS1:t_PK_LTDAY.PKSMP3) (MAPPINGS2:t_PK_LTDAY.PKSMP3) [N] No
1.5 HOURS POSTDOSE	
5. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA4) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA4) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA4) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT4) (MAPPINGS1:t_PK_LTDAY.PKSTT4) (MAPPINGS2:t_PK_LTDAY.PKSTT4) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP4) (MAPPINGS1:t_PK_LTDAY.PKSMP4) (MAPPINGS2:t_PK_LTDAY.PKSMP4) [N] No
2 HOURS POSTDOSE	
6. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA5) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA5) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA5) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT5) (MAPPINGS1:t_PK_LTDAY.PKSTT5) (MAPPINGS2:t_PK_LTDAY.PKSTT5) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP5) (MAPPINGS1:t_PK_LTDAY.PKSMP5) (MAPPINGS2:t_PK_LTDAY.PKSMP5) [N] No
3 HOURS POSTDOSE	
7. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA6) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA6) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA6) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT6) (MAPPINGS1:t_PK_LTDAY.PKSTT6) (MAPPINGS2:t_PK_LTDAY.PKSTT6) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP6) (MAPPINGS1:t_PK_LTDAY.PKSMP6) (MAPPINGS2:t_PK_LTDAY.PKSMP6) [N] No
4 HOURS POSTDOSE	
8. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA7) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA7) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA7) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT7) (MAPPINGS1:t_PK_LTDAY.PKSTT7) (MAPPINGS2:t_PK_LTDAY.PKSTT7) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP7) (MAPPINGS1:t_PK_LTDAY.PKSMP7) (MAPPINGS2:t_PK_LTDAY.PKSMP7) [N] No
6 HOURS POSTDOSE	
9. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY.rdcPKLTDA8) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA8) (MAPPINGS2:t_PK_LTDAY.rdcPKLTDA8) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY.PKSTT8) (MAPPINGS1:t_PK_LTDAY.PKSTT8) (MAPPINGS2:t_PK_LTDAY.PKSTT8) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY.PKSMP8) (MAPPINGS1:t_PK_LTDAY.PKSMP8) (MAPPINGS2:t_PK_LTDAY.PKSMP8) [N] No
8 HOURS POSTDOSE	
10. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY.rdcPKLTDA9) (MAPPINGS3:t_PK_LTDAY.rdcPKLTDA9) (MAPPINGS1:t_PK_LTDAY.rdcPKLTDA9) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY.PKSTT9) (MAPPINGS3:t_PK_LTDAY.PKSTT9) (MAPPINGS1:t_PK_LTDAY.PKSTT9) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY.PKSMP9) (MAPPINGS3:t_PK_LTDAY.PKSMP9) (MAPPINGS1:t_PK_LTDAY.PKSMP9) [N] No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY.PKTYPCD) (MAPPINGS3:t_PK_LTDAY.PKTYPCD) (MAPPINGS1:t_PK_LTDAY.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.25 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used

[redacted]

1 HOUR POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
3 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
8 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdePKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdePKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
rdePKLTDA4	STRING(1)	
PKSTT4	DATE - HHMM	
PKSMPI4	STRING(14) - A14	
rdePKLTDA5	STRING(1)	
PKSTT5	DATE - HHMM	
PKSMPI5	STRING(14) - A14	
rdePKLTDA6	STRING(1)	
PKSTT6	DATE - HHMM	
PKSMPI6	STRING(14) - A14	
rdePKLTDA7	STRING(1)	
PKSTT7	DATE - HHMM	
PKSMPI7	STRING(14) - A14	
rdePKLTDA8	STRING(1)	
PKSTT8	DATE - HHMM	
PKSMPI8	STRING(14) - A14	
rdePKLTDA9	STRING(1)	
PKSTT9	DATE - HHMM	
PKSMPI9	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdePKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdePKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
rdePKLTDA4	STRING(1)	
PKSTT4	DATE - HHMM	
PKSMPI4	STRING(14) - A14	
rdePKLTDA5	STRING(1)	
PKSTT5	DATE - HHMM	
PKSMPI5	STRING(14) - A14	
rdePKLTDA6	STRING(1)	
PKSTT6	DATE - HHMM	
PKSMPI6	STRING(14) - A14	
rdePKLTDA7	STRING(1)	
PKSTT7	DATE - HHMM	
PKSMPI7	STRING(14) - A14	
rdePKLTDA8	STRING(1)	
PKSTT8	DATE - HHMM	
PKSMPI8	STRING(14) - A14	
rdePKLTDA9	STRING(1)	
PKSTT9	DATE - HHMM	
PKSMPI9	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdePKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdePKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
rdePKLTDA4	STRING(1)	
PKSTT4	DATE - HHMM	
PKSMPI4	STRING(14) - A14	
rdePKLTDA5	STRING(1)	
PKSTT5	DATE - HHMM	
PKSMPI5	STRING(14) - A14	
rdePKLTDA6	STRING(1)	
PKSTT6	DATE - HHMM	
PKSMPI6	STRING(14) - A14	
rdePKLTDA7	STRING(1)	
PKSTT7	DATE - HHMM	
PKSMPI7	STRING(14) - A14	
rdePKLTDA8	STRING(1)	
PKSTT8	DATE - HHMM	
PKSMPI8	STRING(14) - A14	
rdePKLTDA9	STRING(1)	
PKSTT9	DATE - HHMM	
PKSMPI9	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY07.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY07.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY07.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time R^1 : R^1 (MAPPINGS3:t_PK_LTDAY07.PKSTTM) (MAPPINGS1:t_PK_LTDAY07.PKSTTM) (MAPPINGS2:t_PK_LTDAY07.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY07.PKSMPID) (MAPPINGS1:t_PK_LTDAY07.PKSMPID) (MAPPINGS2:t_PK_LTDAY07.PKSMPID) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY07.PKTYPCD) (MAPPINGS1:t_PK_LTDAY07.PKTYPCD) (MAPPINGS2:t_PK_LTDAY07.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used.
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY07 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY07 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY07 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PK Sample Taken? (PKVISIT) TRIAL: dpb925prd

PK Sample Taken?		
1.	Was a Postdose Pharmacokinetic Sample Taken at this visit?	(MAPPINGS3:t_PKVISIT.PKVISIT1) (MAPPINGS1:t_PKVISIT.PKVISIT1) (MAPPINGS2:t_PKVISIT.PKVISIT1) [N] ○ No [Y] ○ Yes ..... Which dosing was performed? (MAPPINGS3:t_PKVISIT.PKVISITY) (MAPPINGS1:t_PKVISIT.PKVISITY) (MAPPINGS2:t_PKVISIT.PKVISITY) [1] ○ One Postdose PK Sample Taken 0.5 - 1.5 hours only [4] ○ One Postdose PK Sample Taken 2 - 4 hours only [6] ○ One Postdose PK Sample Taken 6 - 10 hours only [2] ○ Two Postdose PK Samples Taken 0.5 - 1.5 hours and 2 - 4 hours only [8] ○ Two Postdose PK Samples Taken 0.5 - 1.5 hours and 6 - 10 hours only [5] ○ Two Postdose PK Samples Taken 2 - 4 hours and 6 - 10 hours only [3] ○ Three Postdose PK Samples Taken 0.5 - 1.5 hours, 2 - 4 hours and 6 - 10 hours

CDD: MAPPINGS1 Table: t_PKVISIT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT1	STRING(1)	
PKVISITY	NUMERIC	

CDD: MAPPINGS2 Table: t_PKVISIT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT1	STRING(1)	
PKVISITY	NUMERIC	

CDD: MAPPINGS3 Table: t_PKVISIT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT1	STRING(1)	
PKVISITY	NUMERIC	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

0.5 - 1.5 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS1:t_PK_LTDAY04.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY04.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY04.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time [Req] : [Req] (MAPPINGS1:t_PK_LTDAY04.PKSTTM) (MAPPINGS2:t_PK_LTDAY04.PKSTTM) (MAPPINGS3:t_PK_LTDAY04.PKSTTM) Sample Identifier (enter from label provided by central lab) [A14] (MAPPINGS1:t_PK_LTDAY04.PKSMPID) (MAPPINGS2:t_PK_LTDAY04.PKSMPID) (MAPPINGS3:t_PK_LTDAY04.PKSMPID) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS1:t_PK_LTDAY04.PKTYPCD) (MAPPINGS2:t_PK_LTDAY04.PKTYPCD) (MAPPINGS3:t_PK_LTDAY04.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	Design Note
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	Design Note
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY04 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY04 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY04 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

2 - 4 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY05.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY05.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY05.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time R:M1 : R:M1 (MAPPINGS3:t_PK_LTDAY05.PKSTTM) (MAPPINGS1:t_PK_LTDAY05.PKSTTM) (MAPPINGS2:t_PK_LTDAY05.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY05.PKSMPID) (MAPPINGS1:t_PK_LTDAY05.PKSMPID) (MAPPINGS2:t_PK_LTDAY05.PKSMPID) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY05.PKTYPCD) (MAPPINGS1:t_PK_LTDAY05.PKTYPCD) (MAPPINGS2:t_PK_LTDAY05.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used.
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY05 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY05 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY05 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

6 - 10 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23:59)	(MAPPINGS3:t_PK_LTDAY06.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY06.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY06.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time R^1 : R^1 (MAPPINGS3:t_PK_LTDAY06.PKSTTM) (MAPPINGS1:t_PK_LTDAY06.PKSTTM) (MAPPINGS2:t_PK_LTDAY06.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY06.PKSMPID) (MAPPINGS1:t_PK_LTDAY06.PKSMPID) (MAPPINGS2:t_PK_LTDAY06.PKSMPID) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY06.PKTYPCD) (MAPPINGS1:t_PK_LTDAY06.PKTYPCD) (MAPPINGS2:t_PK_LTDAY06.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	Design Note
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	Design Note
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY06 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY06 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY06 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

0.5 - 1.5 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY09.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY09.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY09.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY09.PKSTTM) (MAPPINGS1:t_PK_LTDAY09.PKSTTM) (MAPPINGS2:t_PK_LTDAY09.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY09.PKSMPID) (MAPPINGS1:t_PK_LTDAY09.PKSMPID) (MAPPINGS2:t_PK_LTDAY09.PKSMPID) [N] No
2 - 4 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY09.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY09.rdcPKLTDA1) (MAPPINGS2:t_PK_LTDAY09.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY09.PKSTT1) (MAPPINGS1:t_PK_LTDAY09.PKSTT1) (MAPPINGS2:t_PK_LTDAY09.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY09.PKSMPI1) (MAPPINGS1:t_PK_LTDAY09.PKSMPI1) (MAPPINGS2:t_PK_LTDAY09.PKSMPI1) [N] No
6 - 10 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY09.rdcPKLTDA2) (MAPPINGS1:t_PK_LTDAY09.rdcPKLTDA2) (MAPPINGS2:t_PK_LTDAY09.rdcPKLTDA2) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY09.PKSTT2) (MAPPINGS1:t_PK_LTDAY09.PKSTT2) (MAPPINGS2:t_PK_LTDAY09.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY09.PKSMPI2) (MAPPINGS1:t_PK_LTDAY09.PKSMPI2) (MAPPINGS2:t_PK_LTDAY09.PKSMPI2) [N] No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY09.PKTYPCD) (MAPPINGS1:t_PK_LTDAY09.PKTYPCD) (MAPPINGS2:t_PK_LTDAY09.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:

Title	Design Note
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:

Item No.	Design Note
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY09 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY09 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY09 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

0.5 - 1.5 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY10.rdePKLTDAY) (MAPPINGS1:t_PK_LTDAY10.rdePKLTDAY) (MAPPINGS2:t_PK_LTDAY10.rdePKLTDAY) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY10.PKSTTM) (MAPPINGS1:t_PK_LTDAY10.PKSTTM) (MAPPINGS2:t_PK_LTDAY10.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY10.PKSMPID) (MAPPINGS1:t_PK_LTDAY10.PKSMPID) (MAPPINGS2:t_PK_LTDAY10.PKSMPID) [N] ○ No
2 - 4 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY10.rdePKLTDA1) (MAPPINGS1:t_PK_LTDAY10.rdePKLTDA1) (MAPPINGS2:t_PK_LTDAY10.rdePKLTDA1) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY10.PKSTT1) (MAPPINGS3:t_PK_LTDAY10.PKSTT1) (MAPPINGS1:t_PK_LTDAY10.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY10.PKSMPI1) (MAPPINGS3:t_PK_LTDAY10.PKSMPI1) (MAPPINGS1:t_PK_LTDAY10.PKSMPI1) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY10.PKTYPCD) (MAPPINGS3:t_PK_LTDAY10.PKTYPCD) (MAPPINGS1:t_PK_LTDAY10.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:

Title	Design Note
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:

Item No.	Design Note
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY10 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY10 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY10 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

2 - 4 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY12.rdePKLTDAY) (MAPPINGS3:t_PK_LTDAY12.rdePKLTDAY) (MAPPINGS1:t_PK_LTDAY12.rdePKLTDAY) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY12.PKSTTM) (MAPPINGS3:t_PK_LTDAY12.PKSTTM) (MAPPINGS1:t_PK_LTDAY12.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY12.PKSMPID) (MAPPINGS3:t_PK_LTDAY12.PKSMPID) (MAPPINGS1:t_PK_LTDAY12.PKSMPID) [N] ○ No
6 - 10 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY12.rdePKLTDA1) (MAPPINGS3:t_PK_LTDAY12.rdePKLTDA1) (MAPPINGS1:t_PK_LTDAY12.rdePKLTDA1) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY12.PKSTT1) (MAPPINGS3:t_PK_LTDAY12.PKSTT1) (MAPPINGS1:t_PK_LTDAY12.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY12.PKSMPI1) (MAPPINGS3:t_PK_LTDAY12.PKSMPI1) (MAPPINGS1:t_PK_LTDAY12.PKSMPI1) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY12.PKTYPCD) (MAPPINGS3:t_PK_LTDAY12.PKTYPCD) (MAPPINGS1:t_PK_LTDAY12.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY12 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY12 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY12 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

0.5 - 1.5 HOURS POSTDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY15.rdePKLTDAY) (MAPPINGS1:t_PK_LTDAY15.rdePKLTDAY) (MAPPINGS2:t_PK_LTDAY15.rdePKLTDAY) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY15.PKSTTM) (MAPPINGS1:t_PK_LTDAY15.PKSTTM) (MAPPINGS2:t_PK_LTDAY15.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY15.PKSMPID) (MAPPINGS1:t_PK_LTDAY15.PKSMPID) (MAPPINGS2:t_PK_LTDAY15.PKSMPID) [N] ○ No
6 - 10 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY15.rdePKLTDA1) (MAPPINGS1:t_PK_LTDAY15.rdePKLTDA1) (MAPPINGS2:t_PK_LTDAY15.rdePKLTDA1) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY15.PKSTT1) (MAPPINGS1:t_PK_LTDAY15.PKSTT1) (MAPPINGS2:t_PK_LTDAY15.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY15.PKSMPI1) (MAPPINGS1:t_PK_LTDAY15.PKSMPI1) (MAPPINGS2:t_PK_LTDAY15.PKSMPI1) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY15.PKTYPCD) (MAPPINGS1:t_PK_LTDAY15.PKTYPCD) (MAPPINGS2:t_PK_LTDAY15.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY15 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY15 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY15 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdePKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdePKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: VITAL SIGNS (VS) TRIAL: dpb925prd

VITAL SIGNS		
1.	Weight *(to 1 decimal place, e.g. 65.0)*	XXX.X kg (MAPPINGS1.t_VITALS_2.WEIGHT) (MAPPINGS2.t_VITALS_2.WEIGHT) (MAPPINGS3.t_VITALS_2.WEIGHT)
2.	Hip circumference (standing)	XXX cm (MAPPINGS1.t_VITALS_2.VSHIPCIR) (MAPPINGS2.t_VITALS_2.VSHIPCIR) (MAPPINGS3.t_VITALS_2.VSHIPCIR)
3.	Waist circumference (standing)	XXX cm (MAPPINGS1.t_VITALS_2.VSWSTCIR) (MAPPINGS2.t_VITALS_2.VSWSTCIR) (MAPPINGS3.t_VITALS_2.VSWSTCIR)
4.	Blood pressure *(Average of 2 readings taken 5 minutes apart)*	XXX / (MAPPINGS1.t_VITALS_2.SYSBP) (MAPPINGS2.t_VITALS_2.SYSBP) (MAPPINGS3.t_VITALS_2.SYSBP) XXX mmHg (MAPPINGS3.t_VITALS_2.DIABP) (MAPPINGS1.t_VITALS_2.DIABP) (MAPPINGS2.t_VITALS_2.DIABP) (systolic/diastolic)
5.	Heart rate *(Average of 2 readings taken 5 minutes apart)*	XXX beats/min (MAPPINGS2.t_VITALS_2.HEART) (MAPPINGS1.t_VITALS_2.HEART) (MAPPINGS2.t_VITALS_2.HEART)
	Calculated Subject position *[hidden]*	(MAPPINGS3.t_VITALS_2.VSPOSCD1) (MAPPINGS1.t_VITALS_2.VSPOSCD1) (MAPPINGS2.t_VITALS_2.VSPOSCD1)

Form Design Note:
This form is optional. This form is to be used when one Vitals is taken at a visit.

Section Design Notes:	
Title	**Design Note**
VITAL SIGNS	All items are optional
setVSPOS_CAL	This section should be the last section on the form and is required when position of BP is consistent throughout the study.

Item Design Notes:	
Item No.	**Design Note**
3.	Delete text standing or supine as appropriate for study
itmVSPOS_CAL	This item should be used if only one position is stipulated for the trial. Remove the other Position item and adjust the calculation rule accordingly.

CDD: MAPPINGS1 Table: t_VITALS_2 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
WEIGHT	FLOAT - F5.1	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS2 Table: t_VITALS_2 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
WEIGHT	FLOAT - F5.1	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

CDD: MAPPINGS3 Table: t_VITALS_2 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
WEIGHT	FLOAT - F5.1	
VSHIPCIR	NUMERIC - N3	
VSWSTCIR	NUMERIC - N3	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
HEART	NUMERIC - N3	
VSPOSCD1	STRING(255)	

FORM: PK Sample Taken? (PKVISIT) TRIAL: dpb925prd

PK Sample Taken?		
1.	Was a Postdose Pharmacokinetic Sample Taken at this visit?	(MAPPINGS3:t_PKVISIT_PRE.PKVISIT) (MAPPINGS1:t_PKVISIT_PRE.PKVISIT) (MAPPINGS2:t_PKVISIT_PRE.PKVISIT) [N] ○ No, Predose only [Y] ○ Yes ..... Which dosing interval (in addition to Predose) was performed? (MAPPINGS3:t_PKVISIT_PRE.PKVISITY) (MAPPINGS1:t_PKVISIT_PRE.PKVISITY) (MAPPINGS2:t_PKVISIT_PRE.PKVISITY) [1] ○ One Postdose PK Sample Taken 0.5 - 1.5 hours only [4] ○ One Postdose PK Sample Taken 2 - 4 hours only [6] ○ One Postdose PK Sample Taken 6 - 10 hours only [2] ○ Two Postdose PK Samples Taken 0.5 - 1.5 hours and 2 - 4 hours only [8] ○ Two Postdose PK Samples Taken 0.5 - 1.5 hours and 6 - 10 hours only [5] ○ Two Postdose PK Samples Taken 2 - 4 hours and 6 - 10 hours only [3] ○ Three Postdose PK Samples Taken 0.5 - 1.5 hours, 2 - 4 hours and 6 - 10 hours

CDD: MAPPINGS1 Table: t_PKVISIT_PRE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT	STRING(1)	
PKVISITY	NUMERIC	

CDD: MAPPINGS2 Table: t_PKVISIT_PRE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT	STRING(1)	
PKVISITY	NUMERIC	

CDD: MAPPINGS3 Table: t_PKVISIT_PRE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PKVISIT	STRING(1)	
PKVISITY	NUMERIC	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY01.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY01.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY01.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY01.PKSTTM) (MAPPINGS3:t_PK_LTDAY01.PKSTTM) (MAPPINGS1:t_PK_LTDAY01.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY01.PKSMPID) (MAPPINGS3:t_PK_LTDAY01.PKSMPID) (MAPPINGS1:t_PK_LTDAY01.PKSMPID) [N] No
0.5 - 1.5 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY01.rdcPKLTDA1) (MAPPINGS3:t_PK_LTDAY01.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY01.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY01.PKSTT1) (MAPPINGS3:t_PK_LTDAY01.PKSTT1) (MAPPINGS1:t_PK_LTDAY01.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY01.PKSMPI1) (MAPPINGS3:t_PK_LTDAY01.PKSMPI1) (MAPPINGS1:t_PK_LTDAY01.PKSMPI1) [N] No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY01.PKTYPCD) (MAPPINGS3:t_PK_LTDAY01.PKTYPCD) (MAPPINGS1:t_PK_LTDAY01.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY02.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY02.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY02.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY02.PKSTTM) (MAPPINGS3:t_PK_LTDAY02.PKSTTM) (MAPPINGS1:t_PK_LTDAY02.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY02.PKSMPID) (MAPPINGS3:t_PK_LTDAY02.PKSMPID) (MAPPINGS1:t_PK_LTDAY02.PKSMPID) [N] No
2 - 4 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY02.rdcPKLTDA1) (MAPPINGS3:t_PK_LTDAY02.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY02.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY02.PKSTT1) (MAPPINGS3:t_PK_LTDAY02.PKSTT1) (MAPPINGS1:t_PK_LTDAY02.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY02.PKSMPI1) (MAPPINGS3:t_PK_LTDAY02.PKSMPI1) (MAPPINGS1:t_PK_LTDAY02.PKSMPI1) [N] No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY02.PKTYPCD) (MAPPINGS3:t_PK_LTDAY02.PKTYPCD) (MAPPINGS1:t_PK_LTDAY02.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used.
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used.
sctPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY03.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY03.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY03.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY03.PKSTTM) (MAPPINGS3:t_PK_LTDAY03.PKSTTM) (MAPPINGS1:t_PK_LTDAY03.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY03.PKSMPID) (MAPPINGS3:t_PK_LTDAY03.PKSMPID) (MAPPINGS1:t_PK_LTDAY03.PKSMPID) [N] No
6 - 10 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY03.rdcPKLTDA1) (MAPPINGS3:t_PK_LTDAY03.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY03.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS1:t_PK_LTDAY03.PKSTT1) (MAPPINGS2:t_PK_LTDAY03.PKSTT1) (MAPPINGS3:t_PK_LTDAY03.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS1:t_PK_LTDAY03.PKSMPI1) (MAPPINGS2:t_PK_LTDAY03.PKSMPI1) (MAPPINGS3:t_PK_LTDAY03.PKSMPI1) [N] No
PK Type Code *[hidden]*	(MAPPINGS1:t_PK_LTDAY03.PKTYPCD) (MAPPINGS2:t_PK_LTDAY03.PKTYPCD) (MAPPINGS3:t_PK_LTDAY03.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY03 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY03 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY03 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY08.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY08.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY08.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY08.PKSTTM) (MAPPINGS1:t_PK_LTDAY08.PKSTTM) (MAPPINGS2:t_PK_LTDAY08.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY08.PKSMPID) (MAPPINGS1:t_PK_LTDAY08.PKSMPID) (MAPPINGS2:t_PK_LTDAY08.PKSMPID) [N] ○ No
0.5 - 1.5 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY08.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY08.rdcPKLTDA1) (MAPPINGS2:t_PK_LTDAY08.rdcPKLTDA1) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY08.PKSTT1) (MAPPINGS1:t_PK_LTDAY08.PKSTT1) (MAPPINGS2:t_PK_LTDAY08.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY08.PKSMPI1) (MAPPINGS1:t_PK_LTDAY08.PKSMPI1) (MAPPINGS2:t_PK_LTDAY08.PKSMPI1) [N] ○ No
2 - 4 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY08.rdcPKLTDA2) (MAPPINGS1:t_PK_LTDAY08.rdcPKLTDA2) (MAPPINGS2:t_PK_LTDAY08.rdcPKLTDA2) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY08.PKSTT2) (MAPPINGS1:t_PK_LTDAY08.PKSTT2) (MAPPINGS2:t_PK_LTDAY08.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY08.PKSMPI2) (MAPPINGS1:t_PK_LTDAY08.PKSMPI2) (MAPPINGS2:t_PK_LTDAY08.PKSMPI2) [N] ○ No
6 - 10 HOURS POSTDOSE	
4. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY08.rdcPKLTDA3) (MAPPINGS1:t_PK_LTDAY08.rdcPKLTDA3) (MAPPINGS2:t_PK_LTDAY08.rdcPKLTDA3) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY08.PKSTT3) (MAPPINGS1:t_PK_LTDAY08.PKSTT3) (MAPPINGS2:t_PK_LTDAY08.PKSTT3) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY08.PKSMPI3) (MAPPINGS1:t_PK_LTDAY08.PKSMPI3) (MAPPINGS2:t_PK_LTDAY08.PKSMPI3) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY08.PKTYPCD) (MAPPINGS1:t_PK_LTDAY08.PKTYPCD) (MAPPINGS2:t_PK_LTDAY08.PKTYPCD)

Form Design Note:
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Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY08 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdcPKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY08 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdcPKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

CDD: MAPPINGS3 Table: t_PK_LTDAY08 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
rdcPKLTDA3	STRING(1)	
PKSTT3	DATE - HHMM	
PKSMPI3	STRING(14) - A14	
PKTYPCD	STRING(255)	

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY11.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY11.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY11.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY11.PKSTTM) (MAPPINGS3:t_PK_LTDAY11.PKSTTM) (MAPPINGS1:t_PK_LTDAY11.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY11.PKSMPID) (MAPPINGS3:t_PK_LTDAY11.PKSMPID) (MAPPINGS1:t_PK_LTDAY11.PKSMPID) [N] No
0.5 - 1.5 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY11.rdcPKLTDA1) (MAPPINGS3:t_PK_LTDAY11.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY11.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY11.PKSTT1) (MAPPINGS3:t_PK_LTDAY11.PKSTT1) (MAPPINGS1:t_PK_LTDAY11.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY11.PKSMPI1) (MAPPINGS3:t_PK_LTDAY11.PKSMPI1) (MAPPINGS1:t_PK_LTDAY11.PKSMPI1) [N] No
2 - 4 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY11.rdcPKLTDA2) (MAPPINGS3:t_PK_LTDAY11.rdcPKLTDA2) (MAPPINGS1:t_PK_LTDAY11.rdcPKLTDA2) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY11.PKSTT2) (MAPPINGS3:t_PK_LTDAY11.PKSTT2) (MAPPINGS1:t_PK_LTDAY11.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS2:t_PK_LTDAY11.PKSMPI2) (MAPPINGS3:t_PK_LTDAY11.PKSMPI2) (MAPPINGS1:t_PK_LTDAY11.PKSMPI2) [N] No
PK Type Code *[hidden]*	(MAPPINGS2:t_PK_LTDAY11.PKTYPCD) (MAPPINGS3:t_PK_LTDAY11.PKTYPCD) (MAPPINGS1:t_PK_LTDAY11.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY11 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY11 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY11 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS2:t_PK_LTDAY13.rdcPKLTDAY) (MAPPINGS3:t_PK_LTDAY13.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY13.rdcPKLTDAY) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS2:t_PK_LTDAY13.PKSTTM) (MAPPINGS3:t_PK_LTDAY13.PKSTTM) (MAPPINGS1:t_PK_LTDAY13.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS1:t_PK_LTDAY13.PKSMPID) (MAPPINGS3:t_PK_LTDAY13.PKSMPID) (MAPPINGS2:t_PK_LTDAY13.PKSMPID) [N] No
2 - 4 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS1:t_PK_LTDAY13.rdcPKLTDA1) (MAPPINGS2:t_PK_LTDAY13.rdcPKLTDA1) (MAPPINGS3:t_PK_LTDAY13.rdcPKLTDA1) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS1:t_PK_LTDAY13.PKSTT1) (MAPPINGS2:t_PK_LTDAY13.PKSTT1) (MAPPINGS3:t_PK_LTDAY13.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS1:t_PK_LTDAY13.PKSMPI1) (MAPPINGS2:t_PK_LTDAY13.PKSMPI1) (MAPPINGS0:t_PK_LTDAY13.PKSMPI1) [N] No
6 - 10 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS1:t_PK_LTDAY13.rdcPKLTDA2) (MAPPINGS2:t_PK_LTDAY13.rdcPKLTDA2) (MAPPINGS3:t_PK_LTDAY13.rdcPKLTDA2) [Y] Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY13.PKSTT2) (MAPPINGS1:t_PK_LTDAY13.PKSTT2) (MAPPINGS2:t_PK_LTDAY13.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY13.PKSMPI2) (MAPPINGS1:t_PK_LTDAY13.PKSMPI2) (MAPPINGS2:t_PK_LTDAY13.PKSMPI2) [N] No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY13.PKTYPCD) (MAPPINGS1:t_PK_LTDAY13.PKTYPCD) (MAPPINGS2:t_PK_LTDAY13.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
2 - 4 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY13 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY13 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY13 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: PHARMACOKINETICS (PK) TRIAL: dpb925prd

PREDOSE	
1. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY14.rdcPKLTDAY) (MAPPINGS1:t_PK_LTDAY14.rdcPKLTDAY) (MAPPINGS2:t_PK_LTDAY14.rdcPKLTDAY) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY14.PKSTTM) (MAPPINGS1:t_PK_LTDAY14.PKSTTM) (MAPPINGS2:t_PK_LTDAY14.PKSTTM) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY14.PKSMPID) (MAPPINGS1:t_PK_LTDAY14.PKSMPID) (MAPPINGS2:t_PK_LTDAY14.PKSMPID) [N] ○ No
0.5 - 1.5 HOURS POSTDOSE	
2. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY14.rdcPKLTDA1) (MAPPINGS1:t_PK_LTDAY14.rdcPKLTDA1) (MAPPINGS2:t_PK_LTDAY14.rdcPKLTDA1) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY14.PKSTT1) (MAPPINGS1:t_PK_LTDAY14.PKSTT1) (MAPPINGS2:t_PK_LTDAY14.PKSTT1) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY14.PKSMPI1) (MAPPINGS1:t_PK_LTDAY14.PKSMPI1) (MAPPINGS2:t_PK_LTDAY14.PKSMPI1) [N] ○ No
6 - 10 HOURS POSTDOSE	
3. Sample taken? Hr:Min (00:00-23-59)	(MAPPINGS3:t_PK_LTDAY14.rdcPKLTDA2) (MAPPINGS1:t_PK_LTDAY14.rdcPKLTDA2) (MAPPINGS2:t_PK_LTDAY14.rdcPKLTDA2) [Y] ○ Yes, complete details : Actual time Req : Req (MAPPINGS3:t_PK_LTDAY14.PKSTT2) (MAPPINGS1:t_PK_LTDAY14.PKSTT2) (MAPPINGS2:t_PK_LTDAY14.PKSTT2) Sample Identifier (enter from label provided by central lab) A14 (MAPPINGS3:t_PK_LTDAY14.PKSMPI2) (MAPPINGS1:t_PK_LTDAY14.PKSMPI2) (MAPPINGS2:t_PK_LTDAY14.PKSMPI2) [N] ○ No
PK Type Code *[hidden]*	(MAPPINGS3:t_PK_LTDAY14.PKTYPCD) (MAPPINGS1:t_PK_LTDAY14.PKTYPCD) (MAPPINGS2:t_PK_LTDAY14.PKTYPCD)

Form Design Note:
This Form is optional. Use this form when serial PKs are measured at a visit. Add sections for each planned timepoint. Only use this form for timepoints whose date is the same as the dosing date. If only 1 timepoint required, use only first 2 sections

Section Design Notes:	
Title	**Design Note**
PREDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
0.5 - 1.5 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
6 - 10 HOURS POSTDOSE	For all items, Yes/No radio control is optional. If not used, split Actual Time and Sample ID/Number into two separate items in each section. Use ID if central lab used otherwise use Number if local labs are used
setPKTYPCD	This section should be the last section on the form and is required.

Item Design Notes:	
Item No.	**Design Note**
itmPKTYPCD	This item will be populated by InForm upon submission of the form.

CDD: MAPPINGS1 Table: t_PK_LTDAY14 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_PK_LTDAY14 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_PK_LTDAY14 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
rdcPKLTDAY	STRING(1)	
PKSTTM	DATE - HHMM	
PKSMPID	STRING(14) - A14	
rdcPKLTDA1	STRING(1)	
PKSTT1	DATE - HHMM	
PKSMPI1	STRING(14) - A14	
rdcPKLTDA2	STRING(1)	
PKSTT2	DATE - HHMM	
PKSMPI2	STRING(14) - A14	
PKTYPCD	STRING(255)	

[redacted]

FORM: EXTENSION PHASE (EXTENSION) TRIAL: dpb925prd

EXTENSION PHASE CONFIRMATION		
1.	Is the subject entering the extension phase of the study?	(MAPPINGS3:t_EXTENSION.SUBEXTEN) (MAPPINGS1:t_EXTENSION.SUBEXTEN) (MAPPINGS2:t_EXTENSION.SUBEXTEN) [N] C No [Y] C Yes

CDD: MAPPINGS1 Table: t_EXTENSION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUBEXTEN	STRING(1)	

CDD: MAPPINGS2 Table: t_EXTENSION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUBEXTEN	STRING(1)	

CDD: MAPPINGS3 Table: t_EXTENSION Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
SUBEXTEN	STRING(1)	

FORM: MAIN PHASE APPROVAL (MAIN PHASE APPROVAL) TRIAL: dpb925prd

Main Phase Approval		
1.	Is the Main Phase data (all data up to the end of Week 12) complete with no outstanding queries?	(MAPPINGS3:t_INVSIG_MAIN.grpYes) (MAPPINGS1:t_INVSIG_MAIN.grpYes) (MAPPINGS2:t_INVSIG_MAIN.grpYes) [V] ○ Yes

CDD: MAPPINGS1 Table: t_INVSIG_MAIN Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpYes	STRING(1)	

CDD: MAPPINGS2 Table: t_INVSIG_MAIN Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpYes	STRING(1)	

CDD: MAPPINGS3 Table: t_INVSIG_MAIN Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
grpYes	STRING(1)	

FORM: CONCOMITANT MEDICATIONS (CONMEDS) TRIAL: dpb925prd New

#		Sequence Number	Drug Name (Trade Name preferred)	Unit Dose	Units	Frequency	Route	Reason for Medication	Start Date	Taken Prior to Study?	Ongoing?
1											

CONCOMITANT MEDICATIONS		
	Sequence Number	(MAPPINGS2:t_CONMEDS.CMSEQ) (MAPPINGS3:t_CONMEDS.CMSEQ) (MAPPINGS1:t_CONMEDS.CMSEQ)
1.	Drug Name (Trade Name preferred)	A100 (MAPPINGS2:t_CONMEDS.CMTERM) (MAPPINGS3:t_CONMEDS.CMTERM) (MAPPINGS1:t_CONMEDS.CMTERM)
2.*	Modified reported term *[hidden]*	A100 (MAPPINGS2:t_CONMEDS.CMMODIFY) (CM_CODE2:0.LOGS.CONMEDS.sctCM.0.ifmCMDRGCOL.CMDRGCOL) (CM_FAILED2:0.LOGS.CONMEDS.sctCM.0.ifmCM_FAILED.calCM_FAILED) (CM_SYNONYM2:0.LOGS.CONMEDS.sctCM.0.ifmCMDRGSYN.CMDRGSYN) (MAPPINGS3:t_CONMEDS.CMMODIFY) (MAPPINGS1:t_CONMEDS.CMMODIFY)
	GSK Drug synonym *[hidden]*	(MAPPINGS2:t_CONMEDS.CMDRGSYN) (MAPPINGS3:t_CONMEDS.CMDRGSYN) (MAPPINGS1:t_CONMEDS.CMDRGSYN)
	GSK Drug Collection code *[hidden]*	(MAPPINGS2:t_CONMEDS.CMDRGCOL) (MAPPINGS3:t_CONMEDS.CMDRGCOL) (MAPPINGS1:t_CONMEDS.CMDRGCOL)
	Failed coding *[hidden]*	(MAPPINGS1:t_CONMEDS.calCM_FAILED) (MAPPINGS2:t_CONMEDS.calCM_FAILED) (MAPPINGS3:t_CONMEDS.calCM_FAILED)
3.	Unit Dose	A10 (MAPPINGS1:t_CONMEDS.CMUDOS) (MAPPINGS2:t_CONMEDS.CMUDOS) (MAPPINGS3:t_CONMEDS.CMUDOS)
4.	Units	Pulldown List 1 (MAPPINGS1:t_CONMEDS.CMUNIT) (MAPPINGS2:t_CONMEDS.CMUNIT) (MAPPINGS3:t_CONMEDS.CMUNIT)
5.	Frequency	Pulldown List 2 (MAPPINGS1:t_CONMEDS.CMFREQ) (MAPPINGS2:t_CONMEDS.CMFREQ) (MAPPINGS3:t_CONMEDS.CMFREQ)
6.	Route	Pulldown List 3 (MAPPINGS1:t_CONMEDS.CMROUTCD) (MAPPINGS2:t_CONMEDS.CMROUTCD) (MAPPINGS3:t_CONMEDS.CMROUTCD)
7.	Reason for Medication	A70 (MAPPINGS1:t_CONMEDS.CMREAS) (MAPPINGS2:t_CONMEDS.CMREAS) (MAPPINGS3:t_CONMEDS.CMREAS)
8.	Start Date	Req/Unk / Req/Unk / Req/Unk (1920-2007) (MAPPINGS1:t_CONMEDS.CMSTDT) (MAPPINGS2:t_CONMEDS.CMSTDT) (MAPPINGS3:t_CONMEDS.CMSTDT)
9.	Taken Prior to Study?	(MAPPINGS3:t_CONMEDS.CMPRIOR) (MAPPINGS1:t_CONMEDS.CMPRIOR) (MAPPINGS2:t_CONMEDS.CMPRIOR) *[Y]* ○ Yes *[N]* ○ No
10.	Ongoing?	(MAPPINGS3:t_CONMEDS.CMONGO) (MAPPINGS1:t_CONMEDS.CMONGO) (MAPPINGS2:t_CONMEDS.CMONGO) *[Y]* ○ Yes **[?]** ○ No, specify End Date Req/Unk / Req/Unk / Req/Unk (2005-2007) (MAPPINGS3:t_CONMEDS.CMENDT) (MAPPINGS1:t_CONMEDS.CMENDT) (MAPPINGS2:t_CONMEDS.CMENDT)
	Medication Type *[hidden]*	(MAPPINGS3:t_CONMEDS.CMTYPCD) (MAPPINGS1:t_CONMEDS.CMTYPCD) (MAPPINGS2:t_CONMEDS.CMTYPCD)

* Item is not required

Form Design Note:
This form can be used for disease specific conmeds or as a generic conmed form. If both are required in the trial, copy this form and adjust the form title and section titles

Section Design Notes:	
Title	**Design Note**
sctCMTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	**Design Note**
3.	This item is conditional
4.	This item is conditional
5.	This item is conditional
6.	This item is optional
7.	This item is optional
8.	Time is optional
9.	This item is optional
10.	Time is optional
itmCMTYPCD	This item will be calculated by InForm

Pulldown List 1:			
RefName	**Display Text**	**Value**	**Design Note**
mestrUnitACTU	Actuation	ACTU	
mestrUnitAMP	Ampoule	AMP	
mestrUnitAPP	Application	APP	
mestrUnitBOT	Bottle	BOT	
mestrUnitCAP	Capsule	CAP	
mestrUnitCC	Cubic centimeter	CC	
mestrUnitGTT	Drops	GTT	
mestrUnitGM	Gram	G	
mestrUnitIU	International units	IU	
mestrUnitIUKG	International units per kilogram	IU/KG	
mestrUnitIUML	International units per millilitre	IU/ML	
mestrUnitL	Liter	L	
mestrUnitLPM	Litre per minute	L/MIN	
mestrUnitLOZ	Lozenge	LOZ	
mestrUnitMU	Megaunits (million units)	MU	
mestrUnitMCG	Microgram (MCG)	MCG	
mestrUnitUG	Microgram (UG)	UG	

mestrUnitMCGKG	Microgram/kilogram	MCG/KG	
mestrUnitMCGKGMIN	Microgram/kilogram/minute	MCG/KG/MIN	
mestrUnitMCGMIN	Micrograms/minute	MCG/MIN	
mestrUnitMCL	Microlitre	MCL	
mestrUnitMEQ	Milliequivalent	MEQ	
mestrUnitMEQ24HR	Milliequivalent/24 hours	MEQ/24HR	
mestrUnitMG	Milligram	MG	
mestrUnitMGPER	Milligrams percent	MG%	
mestrUnitMGHR	Milligram/hour	MG/HR	
mestrUnitMGKG	Milligram/kilogram	MG/KG	
mestrUnitMGKGHR	Milligram/kilogram/hour	MG/KG/HR	
mestrUnitMGKGMIN	Milligram/kilogram/minute	MG/KG/MIN	
mestrUnitMGM2	Milligram/metre squared	MG/M2	
mestrUnitMGML	Milligram/millilitre	MG/ML	
mestrUnitML	Millilitre	ML	
mestrUnitMLHR	Millilitre/hour	ML/HR	
mestrUnitMLMIN	Millilitre/minute	ML/MIN	
mestrUnitMMOL	Millimole	MMOL	
mestrUnitMIU	Million international units	MIU	
mestrUnitMAC	Minimum alveolar concentration	MAC	
mestrUnitNEB	Nebule	NEB	
mestrUnitPATCH	Patch	PATCH	
mestrUnitPer	Percent	%	
mestrUnitPUFF	Puff	PUFF	
mestrUnitSACH	Sachet	SACH	
mestrUnitSP	Spray	SPR	
mestrUnitSUPP	Suppository	SUPP	
mestrUnitTBSP	Tablespoon	TBLSP	
mestrUnitTAB	Tablet	TAB	
mestrUnitTSP	Teaspoon	TSP	
mestrUnitUNIT	Units	U	
mestrUnitUNK	Unknown	UNK	
mestrUnitVIAL	Vial	VIAL	

Pulldown List 2:			
RefName	**Display Text**	**Value**	**Design Note**
mestrFreq2XWK	2 times per week	2XWK	
mestrFreq3XWK	3 times per week	3XWK	
mestrFreq4XWK	4 times per week	4XWK	
mestrFreq5XD	5 times per day	5XD	
mestrFreq5XWK	5 times per week	5XWK	
mestrFreqAC	AC	AC	
mestrFreqBID	BID	BID	
mestrFreqCINF	Continuous infusion	CINF	
mestrFreqQ2WK	Every 2 weeks	Q2WK	
mestrFreqQ3WK	Every 3 weeks	Q3WK	
mestrFreqQ3M	Every 3 months	Q3M	
mestrFreqQOD	Every other day	QOD	
mestrFreqHS	HS	HS	
mestrFreqQM	Once a month	QM	
mestrFreqQWK	Once a week	QWK	
mestrFreqQD	Once daily	QD	
mestrFreqONE	Once only	ONE	
mestrFreqPC	PC	PC	
mestrFreqPRN	PRN	PRN	
mestrFreqQ2H	Q2H	Q2H	
mestrFreqQ3D	Q3D	Q3D	
mestrFreqQ4D	Q4D	Q4D	
mestrFreqQ4H	Q4H	Q4H	
mestrFreqQ6H	Q6H	Q6H	
mestrFreqQ8H	Q8H	Q8H	
mestrFreqQ12H	Q12H	Q12H	
mestrFreqQAM	QAM	QAM	
mestrFreqQH	QH	QH	
mestrFreqQID	QID	QID	
mestrFreqQPM	QPM	QPM	
mestrFreqTID	TID	TID	
mestrFreqUNK	Unknown	UNK	

Pulldown List 3:			
RefName	**Display Text**	**Value**	**Design Note**
mestrRouteOU	Both eyes	OU	
mestrRouteEP	Epidural	EP	
mestrRouteGTT	Gastrostomy tube	GTT	
mestrRouteIH	Inhalation	IH	
mestrRouteINJ	Injection	INJ	
mestrRouteIA	Intra-arterial	IA	
mestrRouteIB	Intra-bursa	IB	
mestrRouteIM	Intramuscular	IM	
mestrRouteIN	Intranasal	IN	
mestrRouteIO	Intraocular	IO	
mestrRouteIOS	Intraosteal	IOS	
mestrRouteIT	Intrathecal	IT	
mestrRouteIU	Intrauterine	IU	

mestrRouteIV	Intravenous	IV	
mestrRouteNS	Nasal	NS	
mestrRoutePO	Oral	PO	
mestrRoutePR	Rectal	PR	
mestrRouteSC	Subcutaneous	SC	
mestrRouteSL	Sublingual	SL	
mestrRouteTP	Topical	TP	
mestrRouteTD	Transdermal	TD	
mestrRouteUNK	Unknown	UNK	
mestrRouteVG	Vaginal	VG	

CDD: MAPPINGS1 Table: t_CONMEDS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_CONMEDS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_CONMEDS Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

FORM: Hypoglycaemic Events (HGEVNT) TRIAL: dpb925prd

New

#		Start date and time	End date and time	Blood Glucose Test Result	Frequency	Outcome	Intervention	Maximum Intensity	Action Taken	Serious?	Symptoms?	External assistance?	Relationship?	Withdraw?
1														

Hypoglycaemic Events		
1.	Start date and time of event HH:MM (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS2:t_HGEVNT.HGESTDTTM) (MAPPINGS3:t_HGEVNT.HGESTDTTM) (MAPPINGS1:t_HGEVNT.HGESTDTTM) Req/Unk : Req/Unk
2.	End date and time of event HH:MM (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS2:t_HGEVNT.HGEENDTTM) (MAPPINGS3:t_HGEVNT.HGEENDTTM) (MAPPINGS1:t_HGEVNT.HGEENDTTM) Req/Unk : Req/Unk
3.	Blood Glucose Test Result at Time of Event	XXX.X (MAPPINGS2:t_HGEVNT.HGEBGRES) (MAPPINGS3:t_HGEVNT.HGEBGRES) (MAPPINGS1:t_HGEVNT.HGEBGRES) (MAPPINGS2:t_HGEVNT.BGUNIT) (MAPPINGS3:t_HGEVNT.BGUNIT) (MAPPINGS1:t_HGEVNT.BGUNIT) [MG/DL] ○ Milligrams per decilitre (MG/DL) [MMOL/L] ○ Millimoles per litre (MMOL/L)
4.	Frequency	(MAPPINGS2:t_HGEVNT.HGEFRQCD) (MAPPINGS3:t_HGEVNT.HGEFRQCD) (MAPPINGS1:t_HGEVNT.HGEFRQCD) [1] ○ Single episode [2] ○ Intermittent
5.	Outcome	(MAPPINGS2:t_HGEVNT.HGEOUTCD1) (MAPPINGS3:t_HGEVNT.HGEOUTCD1) (MAPPINGS1:t_HGEVNT.HGEOUTCD1) [1] ○ Recovered / Resolved [2] ○ Recovering / Resolving [3] ○ Not Recovered / Not Resolved [4] ○ Recovered / Resolved with Sequelae [5] ○ Fatal
6.	Intervention (enter the most severe, enter details on concomitant medication page if applicable)	(MAPPINGS2:t_HGEVNT.HGEINVCD1) (MAPPINGS3:t_HGEVNT.HGEINVCD1) (MAPPINGS1:t_HGEVNT.HGEINVCD1) [1] ○ None [2] ○ Minor; Administered sugary drinks or sweets [3] ○ Immediate; glucose drinks or suppliments [4] ○ Extensive; glucose injection/infusion/glucagon
7.	Severity of hypoglycaemic event	(MAPPINGS2:t_HGEVNT.HGESEVCD) (MAPPINGS3:t_HGEVNT.HGESEVCD) (MAPPINGS1:t_HGEVNT.HGESEVCD) [1] ○ Mild [2] ○ Moderate [3] ○ Severe [X] ○ Not applicable
8.	Action Taken with Investigational Product	(MAPPINGS2:t_HGEVNT.HGEACTCD) (MAPPINGS3:t_HGEVNT.HGEACTCD) (MAPPINGS1:t_HGEVNT.HGEACTCD) [1] ○ Investigational product(s) withdrawn [2] ○ Dose reduced [4] ○ Dose not changed [5] ○ Dose interrupted [X] ○ Not applicable
9.	Does this Event meet the definition of serious? *If Yes, complete paper SAE form and fax to GSK Safety within 24 hr*	(MAPPINGS2:t_HGEVNT.HGSAE) (MAPPINGS3:t_HGEVNT.HGSAE) (MAPPINGS1:t_HGEVNT.HGSAE) [Y] ○ Yes [N] ○ No
10.	Did the subject experience symptoms usually associated with hypoglycaemia?	(MAPPINGS1:t_HGEVNT.HGESYM) (MAPPINGS2:t_HGEVNT.HGESYM) (MAPPINGS3:t_HGEVNT.HGESYM) [Y] ○ Yes [N] ○ No
11.	Did the subject require external assistance?	(MAPPINGS1:t_HGEVNT.HGEASS) (MAPPINGS2:t_HGEVNT.HGEASS) (MAPPINGS3:t_HGEVNT.HGEASS) [Y] ○ Yes [N] ○ No
12.	Is there a reasonable possibility that the hypolycaemic event may have been caused by the investigational product?	(MAPPINGS1:t_HGEVNT.HGRELIP) (MAPPINGS2:t_HGEVNT.HGRELIP) (MAPPINGS3:t_HGEVNT.HGRELIP) [Y] ○ Yes [N] ○ No
13.	Did the subject withdraw from the study as a result of this hypoglycaemic event?	(MAPPINGS1:t_HGEVNT.HGEWD) (MAPPINGS2:t_HGEVNT.HGEWD) (MAPPINGS3:t_HGEVNT.HGEWD) [Y] ○ Yes [N] ○ No

CDD: MAPPINGS1 Table: t_HGEVNT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT - F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	
HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

CDD: MAPPINGS2 Table: t_HGEVNT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	

HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

CDD: MAPPINGS3 Table: t_HGEVNT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT - F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	
HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

[redacted]

FORM: ADVERSE EVENTS (AE) TRIAL: dpb925prd

New

#		Sequence Number	Event	Start Date	Outcome	Maximum Intensity	Action Taken	Subject Withdrawn?	Relationship	Serious?
1										

ADVERSE EVENTS		
	Sequence Number	(MAPPINGS1:t_AE.AESEQ) (MAPPINGS2:t_AE.AESEQ) (MAPPINGS3:t_AE.AESEQ)
1.	Event Diagnosis Only *(if known)* Otherwise Sign/Symptom	A100 (MAPPINGS1:t_AE.AETERM) (MAPPINGS2:t_AE.AETERM) (MAPPINGS3:t_AE.AETERM)
2.*	Modified term *[hidden]*	A100 (MAPPINGS1:t_AE.AEMODIFY) (MAPPINGS2:t_AE.AEMODIFY) (AE_CODE1:0.LOGS.AE.sctAE.0.ifmAELLTCD.AELLTCD) (AE_FAILED1:0.LOGS.AE.sctAE.0.ifmAE_FAILED.oldAE_FAILED) (AE_SYNONYM1:0.LOGS.AE.sctAE.0.ifmAEMEDSYN.AEMEDSYN) (MAPPINGS3:t_AE.AEMODIFY)
	MedDRA synonym *[hidden]*	(MAPPINGS1:t_AE.AEMEDSYN) (MAPPINGS2:t_AE.AEMEDSYN) (MAPPINGS3:t_AE.AEMEDSYN)
	MedDRA lower level term code *[hidden]*	(MAPPINGS3:t_AE.AELLTCD) (MAPPINGS1:t_AE.AELLTCD) (MAPPINGS2:t_AE.AELLTCD)
	Failed coding *[hidden]*	(MAPPINGS3:t_AE.oldAE_FAILED) (MAPPINGS1:t_AE.oldAE_FAILED) (MAPPINGS2:t_AE.oldAE_FAILED)
3.	Start Date	Req / Req / Req (2005-2007) (MAPPINGS3:t_AE.AESTDT) (MAPPINGS1:t_AE.AESTDT) (MAPPINGS2:t_AE.AESTDT)
4.	Outcome / End Date	(MAPPINGS3:t_AE.AEOUTCD) (MAPPINGS1:t_AE.AEOUTCD) (MAPPINGS2:t_AE.AEOUTCD) **[1]** Recovered/Resolved, provide End Date Req / Req / Req (2005-2007) (MAPPINGS3:t_AE.AEENDT1) (MAPPINGS1:t_AE.AEENDT1) (MAPPINGS2:t_AE.AEENDT1) *[2]* Recovering/Resolving *[3]* Not recovered/Not resolved **[4]** Recovered/Resolved with sequelae, provide End Date Req / Req / Req (2005-2007) (MAPPINGS3:t_AE.AEENDT2) (MAPPINGS1:t_AE.AEENDT2) (MAPPINGS2:t_AE.AEENDT2) **[5]** Fatal, record Date of Death Req / Req / Req (2005-2007) (MAPPINGS3:t_AE.AEENDT3) (MAPPINGS1:t_AE.AEENDT3) (MAPPINGS2:t_AE.AEENDT3)
5.	Maximum Intensity	(MAPPINGS3:t_AE.AESEVCD) (MAPPINGS1:t_AE.AESEVCD) (MAPPINGS2:t_AE.AESEVCD) *[1]* Mild *[2]* Moderate *[3]* Severe *[X]* Not applicable
6.	Action Taken with Investigational Product(s) as a Result of the AE	(MAPPINGS3:t_AE.AEACTRCD) (MAPPINGS1:t_AE.AEACTRCD) (MAPPINGS2:t_AE.AEACTRCD) *[1]* Investigational product(s) withdrawn *[2]* Dose reduced *[3]* Dose increased *[4]* Dose not changed *[5]* Dose interrupted *[X]* Not applicable
7.	Did the subject withdraw from study as a result of this AE?	(MAPPINGS3:t_AE.AEWD) (MAPPINGS1:t_AE.AEWD) (MAPPINGS2:t_AE.AEWD) *[Y]* Yes *[N]* No
8.	Is there a reasonable possibility that the AE may have been caused by the investigational product?	(MAPPINGS3:t_AE.AEREL) (MAPPINGS1:t_AE.AEREL) (MAPPINGS2:t_AE.AEREL) *[Y]* Yes *[N]* No
9.	Does this Adverse Event meet the definition of serious? *If Yes, complete paper SAE form and fax to GSK Safety within 24 hr*	(MAPPINGS3:t_AE.AESER) (MAPPINGS1:t_AE.AESER) (MAPPINGS2:t_AE.AESER) *[N]* No **[Y]** Yes, check all that apply (MAPPINGS3:t_AE.AESERDTH) (MAPPINGS1:t_AE.AESERDTH) (MAPPINGS2:t_AE.AESERDTH) *[A]* Results in death (MAPPINGS3:t_AE.AESERLIF) (MAPPINGS1:t_AE.AESERLIF) (MAPPINGS2:t_AE.AESERLIF) *[B]* Is life-threatening (MAPPINGS3:t_AE.AESERHOS) (MAPPINGS1:t_AE.AESERHOS) (MAPPINGS2:t_AE.AESERHOS) *[C]* Requires hospitalisation or prolongation of existing hospitalisation (MAPPINGS3:t_AE.AESERDIS) (MAPPINGS1:t_AE.AESERDIS) (MAPPINGS2:t_AE.AESERDIS) *[D]* Results in disability/incapacity (MAPPINGS3:t_AE.AESERCON) (MAPPINGS1:t_AE.AESERCON) (MAPPINGS2:t_AE.AESERCON) *[E]* Congenital anomaly/birth defect (MAPPINGS3:t_AE.AESEROTH) (MAPPINGS1:t_AE.AESEROTH) (MAPPINGS2:t_AE.AESEROTH) **[F]** Other, specify A100 (MAPPINGS3:t_AE.AESERSPE) (MAPPINGS1:t_AE.AESERSPE) (MAPPINGS2:t_AE.AESERSPE) (MAPPINGS3:t_AE.rdcAESERCause) (MAPPINGS1:t_AE.rdcAESERCause) (MAPPINGS2:t_AE.rdcAESERCause) Was this SAE caused by an activity related to study participation (e.g., procedures)? *[N]* No *[Y]* Yes
10.	Serious Flag *[hidden]*	(MAPPINGS3:t_AE.calSeriousFlag) (MAPPINGS1:t_AE.calSeriousFlag) (MAPPINGS2:t_AE.calSeriousFlag)
* Item is not required		

Section Design Notes:	
Title	**Design Note**
ADVERSE EVENTS	One of the following items must be used: Maximum Intensity, Maximum Toxicity, or Maximum Toxicity or Intensity. The CRF designer must remove the other two items from the form

Item Design Notes:	
Item No.	**Design Note**
3.	Start Time is optional
4.	End Time is optional
5.	Grade 5 is optional

[redacted]

9.	G is an optional criterion and may be removed

CDD: MAPPINGS1 Table: t_AE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	
rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

CDD: MAPPINGS2 Table: t_AE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	
rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

CDD: MAPPINGS3 Table: t_AE Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	

rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

[redacted]

FORM: PGx-PHARMACOGENETIC RESEARCH CONSENT (GEN-CONSENT) TRIAL: dpb925prd

PGx-PHARMACOGENETIC RESEARCH CONSENT	
1. Has informed consent been obtained for PGx-Pharmacogenetic research?	(MAPPINGS3:t_GENPRO_CONSENT.GPCNS) (MAPPINGS1:t_GENPRO_CONSENT.GPCNS) (MAPPINGS2:t_GENPRO_CONSENT.GPCNS) [Y] Yes, record: Date informed consent obtained for PGx-Pharmacogenetic research Req / Req / Req [2005-2007] (MAPPINGS3:t_GENPRO_CONSENT.GPCNSDT) (MAPPINGS1:t_GENPRO_CONSENT.GPCNSDT) (MAPPINGS2:t_GENPRO_CONSENT.GPCNSDT) (MAPPINGS3:t_GENPRO_CONSENT.GPSMPCOL) (MAPPINGS1:t_GENPRO_CONSENT.GPSMPCOL) (MAPPINGS2:t_GENPRO_CONSENT.GPSMPCOL) Has a blood sample been collected for PGx-pharmacogenetic (DNA) research? [N] No [Y] Yes, record date sample taken Req / Req / Req [2005-2007] (MAPPINGS3:t_GENPRO_CONSENT.GPSMPDT) (MAPPINGS1:t_GENPRO_CONSENT.GPSMPDT) (MAPPINGS2:t_GENPRO_CONSENT.GPSMPDT) [N] (MAPPINGS2:t_GENPRO_CONSENT.GPCNRSCD) (MAPPINGS3:t_GENPRO_CONSENT.GPCNRSCD) (MAPPINGS1:t_GENPRO_CONSENT.GPCNRSCD) No, check reason [1] Subject declined [3] Subject not asked by Investigator [7] Other, specify A100 (MAPPINGS2:t_GENPRO_CONSENT.GPCNSOTH) (MAPPINGS3:t_GENPRO_CONSENT.GPCNSOTH) (MAPPINGS1:t_GENPRO_CONSENT.GPCNSOTH)
Genetics Type *[hidden]*	(MAPPINGS2:t_GENPRO_CONSENT.GPTYPCD) (MAPPINGS3:t_GENPRO_CONSENT.GPTYPCD) (MAPPINGS1:t_GENPRO_CONSENT.GPTYPCD)

Form Design Note:
This form should only exist once in the study and is conditional upon inclusion of Pharmacogenetics in the protocol.

Section Design Notes:	
Title	Design Note
setGPTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	Design Note
itmGPTYPCD	This item will be calculated by InForm

CDD: MAPPINGS1 Table: t_GENPRO_CONSENT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNS	STRING(1)	
GPCNSDT	DATE - DDMONYYYY	
GPSMPCOL	STRING(1)	
GPSMPDT	DATE - DDMONYYYY	
GPCNRSCD	STRING(1)	
GPCNSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_GENPRO_CONSENT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNS	STRING(1)	
GPCNSDT	DATE - DDMONYYYY	
GPSMPCOL	STRING(1)	
GPSMPDT	DATE - DDMONYYYY	
GPCNRSCD	STRING(1)	
GPCNSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_GENPRO_CONSENT Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNS	STRING(1)	
GPCNSDT	DATE - DDMONYYYY	
GPSMPCOL	STRING(1)	
GPSMPDT	DATE - DDMONYYYY	
GPCNRSCD	STRING(1)	
GPCNSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

FORM: PGx-PHARMACOGENETIC RESEARCH WITHDRAWAL OF CONSENT (GEN-WD) TRIAL: dpb925prd

PGx-PHARMACOGENETIC RESEARCH WITHDRAWAL OF CONSENT	
1. Has subject withdrawn consent for PGx-Pharmacogenetic research?	(MAPPINGS2:t_GENPRO_WD.GPCNSWD) (MAPPINGS3:t_GENPRO_WD.GPCNSWD) (MAPPINGS1:t_GENPRO_WD.GPCNSWD) [Y] ○ Yes [N] ○ No
2. Has a request been made for sample destruction?	(MAPPINGS2:t_GENPRO_WD.GPDSREQ) (MAPPINGS3:t_GENPRO_WD.GPDSREQ) (MAPPINGS1:t_GENPRO_WD.GPDSREQ) [N] ○ No [Y] ○ (MAPPINGS2:t_GENPRO_WD.GPDSRSCD) (MAPPINGS3:t_GENPRO_WD.GPDSRSCD) (MAPPINGS1:t_GENPRO_WD.GPDSRSCD) Yes, check reason [1] ○ Subject requested [2] ○ Other, specify (MAPPINGS2:t_GENPRO_WD.GPDSOTH) (MAPPINGS3:t_GENPRO_WD.GPDSOTH) (MAPPINGS1:t_GENPRO_WD.GPDSOTH) A100
Genetics Type [hidden]	(MAPPINGS3:t_GENPRO_WD.GPTYPCD) (MAPPINGS2:t_GENPRO_WD.GPTYPCD) (MAPPINGS1:t_GENPRO_WD.GPTYPCD)

Form Design Note:
This form will be dynamically created when question 1, Has a blood sample been collected is Yes. This form is conditional upon inclusion of Pharmacogenetics in the protocol.

Section Design Notes:	
Title	**Design Note**
sctGPTYPCD	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	**Design Note**
2.	Screen failure is an optional choice
itmGPTYPCD	This item will be calculated by InForm

CDD: MAPPINGS1 Table: t_GENPRO_WD Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNSWD	STRING(1)	
GPDSREQ	STRING(1)	
GPDSRSCD	STRING(1)	
GPDSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_GENPRO_WD Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNSWD	STRING(1)	
GPDSREQ	STRING(1)	
GPDSRSCD	STRING(1)	
GPDSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_GENPRO_WD Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
GPCNSWD	STRING(1)	
GPDSREQ	STRING(1)	
GPDSRSCD	STRING(1)	
GPDSOTH	STRING(100) - A100	
GPTYPCD	STRING(255)	

FORM: PREGNANCY INFORMATION (PREG) TRIAL: dpb925prd

PREGNANCY INFORMATION		
1.	Did the subject become pregnant during the study? *If Yes, complete the* ***paper*** *Pregnancy Notification form*	(MAPPINGS2:t_STATUS_PREG_F.PGYN) (MAPPINGS3:t_STATUS_PREG_F.PGYN) (MAPPINGS1:t_STATUS_PREG_F.PGYN) *[N]* ○ No *[Y]* ○ Yes

Form Design Note:
This is an optional form but is conditional upon females in the trial; This form will be dynamically generated to appear at the End visit if Female is selected on the Demographics form

CDD: MAPPINGS1 Table: t_STATUS_PREG_F Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGYN	STRING(1)	

CDD: MAPPINGS2 Table: t_STATUS_PREG_F Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGYN	STRING(1)	

CDD: MAPPINGS3 Table: t_STATUS_PREG_F Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGYN	STRING(1)	

FORM: PREGNANCY INFORMATION (PREG M) TRIAL: dpb925prd

PREGNANCY INFORMATION		
1.	Did a female partner of the male subject become pregnant during the study? *If Yes, complete the* ***paper*** *Pregnancy Notification form*	(MAPPINGS2:t_STATUS_PREG_M.PGFPYN) (MAPPINGS3:t_STATUS_PREG_M.PGFPYN) (MAPPINGS1:t_STATUS_PREG_M.PGFPYN) *[0]* ○ No *[1]* ○ Yes *[3]* ○ Not Applicable Check Not Applicable if female partner not of childbearing potential or no female partner

Form Design Note:
This is an optional form, but is conditional upon males in the trial. This form will be dynamically generated if the male is selected on the Demography form

CDD: MAPPINGS1 Table: t_STATUS_PREG_M Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGFPYN	STRING(1)	

CDD: MAPPINGS2 Table: t_STATUS_PREG_M Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGFPYN	STRING(1)	

CDD: MAPPINGS3 Table: t_STATUS_PREG_M Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
PGFPYN	STRING(1)	

FORM: STATUS OF TREATMENT BLIND (BLIND) TRIAL: dpb925prd

STATUS OF TREATMENT BLIND		
1.	Was the treatment blind broken during the study?*If yes, complete the Adverse Event form and/or Investigational Product forms as appropriate*	(MAPPINGS2:t_BLIND.BLBRK) (MAPPINGS3:t_BLIND.BLBRK) (MAPPINGS1:t_BLIND.BLBRK) *[N]* ○ No [Y] ○ Yes, complete the followinu : Date blind broken Req / Req / Req (2005-2007) (MAPPINGS2:t_BLIND.BLDT) (MAPPINGS3:t_BLIND.BLDT) (MAPPINGS1:t_BLIND.BLDT) (MAPPINGS2:t_BLIND.BLREASCD) (MAPPINGS3:t_BLIND.BLREASCD) (MAPPINGS1:t_BLIND.BLREASCD) Reason blind broken *[1]* ○ Medical emergency requiring identification of investigational product for further treatment [2] ○ Other, specify (MAPPINGS2:t_BLIND.BLRSOTH) (MAPPINGS3:t_BLIND.BLRSOTH) (MAPPINGS1:t_BLIND.BLRSOTH) A200

Item Design Notes:	
Item No.	Design Note
1.	Time blind broken is optional

CDD: MAPPINGS1 Table: t_BLIND Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BLBRK	STRING(1)	
BLDT	DATE - DDMONYYYY	
BLREASCD	STRING(1)	
BLRSOTH	STRING(200) - A200	

CDD: MAPPINGS2 Table: t_BLIND Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BLBRK	STRING(1)	
BLDT	DATE - DDMONYYYY	
BLREASCD	STRING(1)	
BLRSOTH	STRING(200) - A200	

CDD: MAPPINGS3 Table: t_BLIND Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BLBRK	STRING(1)	
BLDT	DATE - DDMONYYYY	
BLREASCD	STRING(1)	
BLRSOTH	STRING(200) - A200	

FORM: INVESTIGATIONAL PRODUCT (IP) TRIAL: dpb925prd

New

#		IP	Start DT	Stop DT
1				

INVESTIGATIONAL PRODUCT		
1.	Investigational Product	(MAPPINGS3:t_EXPOSURE_IP01.EXINVPCD) (MAPPINGS1:t_EXPOSURE_IP01.EXINVPCD) (MAPPINGS2:t_EXPOSURE_IP01.EXINVPCD) [76] ○ Run-in Phase [77] ○ Main Phase
2.	Start Date	Req / Req / Req (2005-2007) (MAPPINGS3:t_EXPOSURE_IP01.EXSTDT) (MAPPINGS1:t_EXPOSURE_IP01.EXSTDT) (MAPPINGS2:t_EXPOSURE_IP01.EXSTDT)
3.	Stop Date	Req / Req / Req (2005-2007) (MAPPINGS3:t_EXPOSURE_IP01.EXENDT) (MAPPINGS1:t_EXPOSURE_IP01.EXENDT) (MAPPINGS2:t_EXPOSURE_IP01.EXENDT)

Form Design Note:
This form is required when IP is administered. If Planned Timepoint is not used, but repeats are needed, make this form repeating. Use this form for: Multiple assessments (per visit) running log (per study))

Item Design Notes:	
Item No.	**Design Note**
1.	This item is optional and should be modified according to the trial design
2.	Time is optional
3.	Time is optional

CDD: MAPPINGS1 Table: t_EXPOSURE_IP01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

CDD: MAPPINGS2 Table: t_EXPOSURE_IP01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

CDD: MAPPINGS3 Table: t_EXPOSURE_IP01 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

[redacted]

FORM: INVESTIGATIONAL PRODUCT (IP_EXT) TRIAL: dpb925prd

INVESTIGATIONAL PRODUCT		
1.	Investigational Product	(MAPPINGS3:t_EXPOSURE_IP02.EXINVPCD2) (MAPPINGS1:t_EXPOSURE_IP02.EXINVPCD2) (MAPPINGS2:t_EXPOSURE_IP02.EXINVPCD2) [78] ○ Extension Phase
2.	Start Date	Req / Req / Req (2000-2007) (MAPPINGS3:t_EXPOSURE_IP02.EXSTDT) (MAPPINGS1:t_EXPOSURE_IP02.EXSTDT) (MAPPINGS2:t_EXPOSURE_IP02.EXSTDT)
3.	Stop Date	Req / Req / Req (2005-2007) (MAPPINGS3:t_EXPOSURE_IP02.EXENDT) (MAPPINGS1:t_EXPOSURE_IP02.EXENDT) (MAPPINGS2:t_EXPOSURE_IP02.EXENDT)

Form Design Note:
This form is required when IP is administered. If Planned Timepoint is not used, but repeats are needed, make this form repeating. Use this form for: Multiple assessments (per visit) running log (per study))

Item Design Notes:	
Item No.	**Design Note**
1.	This item is optional and should be modified according to the trial design
2.	Time is optional
3.	Time is optional

CDD: MAPPINGS1 Table: t_EXPOSURE_IP02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD2	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

CDD: MAPPINGS2 Table: t_EXPOSURE_IP02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD2	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

CDD: MAPPINGS3 Table: t_EXPOSURE_IP02 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
EXINVPCD2	STRING(2)	
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	

FORM: CONCOMITANT MEDICATIONS EXTENSION PHASE (CMEDS EXT) TRIAL: dpb925prd New

#		Sequence Number	Drug Name (Trade Name preferred)	Unit Dose	Units	Frequency	Route	Reason for Medication	Start Date	Taken Prior to Study?	Ongoing?
1											

CONCOMITANT MEDICATIONS		
	Sequence Number	(MAPPINGS3:t_CONMEDS_03.CMSEQ) (MAPPINGS1:t_CONMEDS_03.CMSEQ) (MAPPINGS2:t_CONMEDS_03.CMSEQ)
1.	Drug Name (Trade Name preferred)	A100 (MAPPINGS3:t_CONMEDS_03.CMTERM) (MAPPINGS1:t_CONMEDS_03.CMTERM) (MAPPINGS2:t_CONMEDS_03.CMTERM)
2.*	Modified reported term *[hidden]*	A100 (MAPPINGS3:t_CONMEDS_03.CMMODIFY) (MAPPINGS1:t_CONMEDS_03.CMMODIFY) (MAPPINGS2:t_CONMEDS_03.CMMODIFY) (CM_SYNONYMS:0.CommonCRF.CONMEDS_03.sdCM_2.0.frm/CMDRGSYN,CMDRGSYN) (CM_CODED:0.CommonCRF.CONMEDS_03.sdCM_2.0.frm/CMDRGCOL,CMDRGCOL) (CM_FAILED:0.CommonCRF.CONMEDS_03.sdCM_2.0.frm/CM_FAILED,calCM_FAILED)
	GSK Drug synonym *[hidden]*	(MAPPINGS3:t_CONMEDS_03.CMDRGSYN) (MAPPINGS1:t_CONMEDS_03.CMDRGSYN) (MAPPINGS2:t_CONMEDS_03.CMDRGSYN)
	GSK Drug Collection code *[hidden]*	(MAPPINGS3:t_CONMEDS_03.CMDRGCOL) (MAPPINGS1:t_CONMEDS_03.CMDRGCOL) (MAPPINGS2:t_CONMEDS_03.CMDRGCOL)
	Failed coding *[hidden]*	(MAPPINGS3:t_CONMEDS_03.calCM_FAILED) (MAPPINGS1:t_CONMEDS_03.calCM_FAILED) (MAPPINGS2:t_CONMEDS_03.calCM_FAILED)
3.	Unit Dose	A10 (MAPPINGS3:t_CONMEDS_03.CMJDOS) (MAPPINGS1:t_CONMEDS_03.CMJDOS) (MAPPINGS2:t_CONMEDS_03.CMJDOS)
4.	Units	Pulldown List 1 (MAPPINGS3:t_CONMEDS_03.CMUNIT) (MAPPINGS1:t_CONMEDS_03.CMUNIT) (MAPPINGS2:t_CONMEDS_03.CMUNIT)
5.	Frequency	Pulldown List 2 (MAPPINGS3:t_CONMEDS_03.CMFREQ) (MAPPINGS1:t_CONMEDS_03.CMFREQ) (MAPPINGS2:t_CONMEDS_03.CMFREQ)
6.	Route	Pulldown List 3 (MAPPINGS3:t_CONMEDS_03.CMROUTCD) (MAPPINGS1:t_CONMEDS_03.CMROUTCD) (MAPPINGS2:t_CONMEDS_03.CMROUTCD)
7.	Reason for Medication	A70 (MAPPINGS3:t_CONMEDS_03.CMREAS) (MAPPINGS1:t_CONMEDS_03.CMREAS) (MAPPINGS2:t_CONMEDS_03.CMREAS)
8.	Start Date	Req/Unk / Req/Unk / Req/Unk (1920-2007) (MAPPINGS3:t_CONMEDS_03.CMSTDT) (MAPPINGS1:t_CONMEDS_03.CMSTDT) (MAPPINGS2:t_CONMEDS_03.CMSTDT)
9.	Taken Prior to Study?	(MAPPINGS3:t_CONMEDS_03.CMPRIOR) (MAPPINGS1:t_CONMEDS_03.CMPRIOR) (MAPPINGS2:t_CONMEDS_03.CMPRIOR) *[Y]* ○ Yes *[N]* ○ No
10.	Ongoing?	(MAPPINGS3:t_CONMEDS_03.CMONGO) (MAPPINGS1:t_CONMEDS_03.CMONGO) (MAPPINGS2:t_CONMEDS_03.CMONGO) *[Y]* ○ Yes *[N]* ○ No, specify End Date Req/Unk / Req/Unk / Req/Unk (2005-2007) (MAPPINGS3:t_CONMEDS_03.CMENDT) (MAPPINGS1:t_CONMEDS_03.CMENDT) (MAPPINGS2:t_CONMEDS_03.CMENDT)
	Medication Type *[hidden]*	(MAPPINGS3:t_CONMEDS_03.CMTYPCD) (MAPPINGS1:t_CONMEDS_03.CMTYPCD) (MAPPINGS2:t_CONMEDS_03.CMTYPCD)

* Item is not required

Section Design Notes:	
Title	**Design Note**
setCMTYPCD_1	This section is required and should be the last section on this form.

Item Design Notes:	
Item No.	**Design Note**
3.	This item is conditional
4.	This item is conditional
5.	This item is conditional
6.	This item is optional
7.	This item is optional
8.	Time is optional
9.	This item is optional
10.	Time is optional
itmCMTYPCD	This item will be calculated by InForm

Pulldown List 1:			
RefName	**Display Text**	**Value**	**Design Note**
mestrUnitACTU	Actuation	ACTU	
mestrUnitAMP	Ampoule	AMP	
mestrUnitAPP	Application	APP	
mestrUnitBOT	Bottle	BOT	
mestrUnitCAP	Capsule	CAP	
mestrUnitCC	Cubic centimeter	CC	
mestrUnitGTT	Drops	GTT	
mestrUnitGM	Gram	G	
mestrUnitIU	International units	IU	
mestrUnitIUKG	International units per kilogram	IU/KG	
mestrUnitIUML	International units per millilitre	IU/ML	
mestrUnitL	Litre	L	
mestrUnitLPM	Litre per minute	L/MIN	
mestrUnitLOZ	Lozenge	LOZ	
mestrUnitMU	Megaunits (million units)	MU	
mestrUnitMCG	Microgram (MCG)	MCG	
mestrUnitUG	Microgram (UG)	UG	
mestrUnitMCGKG	Microgram/kilogram	MCG/KG	
mestrUnitMCGKGMIN	Microgram/kilogram/minute	MCG/KG/MIN	
mestrUnitMCGMIN	Micrograms/minute	MCG/MIN	
mestrUnitMCL	Microlitre	MCL	

mestrUnitMEQ	Milliequivalent	MEQ	
mestrUnitMEQ24HR	Milliequivalent/24 hours	MEQ/24HR	
mestrUnitMG	Milligram	MG	
mestrUnitMGPER	Milligrams percent	MG%	
mestrUnitMGHR	Milligram/hour	MG/HR	
mestrUnitMGKG	Milligram/kilogram	MG/KG	
mestrUnitMGKGHR	Milligram/kilogram/hour	MG/KG/HR	
mestrUnitMGKGMIN	Milligram/kilogram/minute	MG/KG/MIN	
mestrUnitMGM2	Milligram/metre squared	MG/M2	
mestrUnitMGML	Milligram/millilitre	MG/ML	
mestrUnitML	Millilitre	ML	
mestrUnitMLHR	Millilitre/hour	ML/HR	
mestrUnitMLMIN	Millilitre/minute	ML/MIN	
mestrUnitMMOL	Millimole	MMOL	
mestrUnitMIU	Million international units	MIU	
mestrUnitMAC	Minimum alveolar concentration	MAC	
mestrUnitNEB	Nebule	NEB	
mestrUnitPATCH	Patch	PATCH	
mestrUnitPer	Percent	%	
mestrUnitPUFF	Puff	PUFF	
mestrUnitSACH	Sachet	SACH	
mestrUnitSP	Spray	SPR	
mestrUnitSUPP	Suppository	SUPP	
mestrUnitTDSP	Tablespoon	TDLSP	
mestrUnitTAB	Tablet	TAB	
mestrUnitTSP	Teaspoon	TSP	
mestrUnitUNIT	Units	U	
mestrUnitUNK	Unknown	UNK	
mestrUnitVIAL	Vial	VIAL	

Pulldown List 2:			
RefName	**Display Text**	**Value**	**Design Note**
mestrFreq2XWK	2 times per week	2XWK	
mestrFreq3XWK	3 times per week	3XWK	
mestrFreq4XWK	4 times per week	4XWK	
mestrFreq5XD	5 times per day	5XD	
mestrFreq5XWK	5 times per week	5XWK	
mestrFreqAC	AC	AC	
mestrFreqBID	BID	BID	
mestrFreqCINF	Continuous infusion	CINF	
mestrFreqQ2WK	Every 2 weeks	Q2WK	
mestrFreqQ3WK	Every 3 weeks	Q3WK	
mestrFreqQ3M	Every 3 months	Q3M	
mestrFreqQOD	Every other day	QOD	
mestrFreqHS	HS	HS	
mestrFreqQM	Once a month	QM	
mestrFreqQWK	Once a week	QWK	
mestrFreqQD	Once daily	QD	
mestrFreqONE	Once only	ONE	
mestrFreqPC	PC	PC	
mestrFreqPRN	PRN	PRN	
mestrFreqQ2H	Q2H	Q2H	
mestrFreqQ3D	Q3D	Q3D	
mestrFreqQ4D	Q4D	Q4D	
mestrFreqQ4H	Q4H	Q4H	
mestrFreqQ6H	Q6H	Q6H	
mestrFreqQ8H	Q8H	Q8H	
mestrFreqQ12H	Q12H	Q12H	
mestrFreqQAM	QAM	QAM	
mestrFreqQH	QH	QH	
mestrFreqQID	QID	QID	
mestrFreqQPM	QPM	QPM	
mestrFreqTID	TID	TID	
mestrFreqUNK	Unknown	UNK	

Pulldown List 3:			
RefName	**Display Text**	**Value**	**Design Note**
mestrRouteOU	Both eyes	OU	
mestrRouteEP	Epidural	EP	
mestrRouteGTT	Gastrostomy tube	GTT	
mestrRouteIH	Inhalation	IH	
mestrRouteINJ	Injection	INJ	
mestrRouteIA	Intra-arterial	IA	
mestrRouteIB	Intra-bursa	IB	
mestrRouteIM	Intramuscular	IM	
mestrRouteIN	Intranasal	IN	
mestrRouteIO	Intraocular	IO	
mestrRouteIOS	Intraosteal	IOS	
mestrRouteIT	Intrathecal	IT	
mestrRouteIU	Intrauterine	IU	
mestrRouteIV	Intravenous	IV	
mestrRouteNS	Nasal	NS	
mestrRoutePO	Oral	PO	
mestrRoutePR	Rectal	PR	

mestrRouteSC	Subcutaneous	SC	
mestrRouteSL	Sublingual	SL	
mestrRouteTP	Topical	TP	
mestrRouteTD	Transdermal	TD	
mestrRouteUNK	Unknown	UNK	
mestrRouteVG	Vaginal	VG	

CDD: MAPPINGS1 Table: t_CONMEDS_03 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS2 Table: t_CONMEDS_03 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

CDD: MAPPINGS3 Table: t_CONMEDS_03 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CMSEQ	STRING(255)	
CMTERM	STRING(100) - A100	
CMMODIFY	STRING(100) - A100	
CMDRGSYN	STRING(255)	
CMDRGCOL	STRING(255)	
calCM_FAILED	STRING(255)	
CMUDOS	STRING(10) - A10	
CMUNIT	STRING(255) - ACTU, AMP, APP, BOT, CAP, CC, GTT, G, IU, IU/KG, IU/ML, L, L/MIN, LOZ, MU, MCG, UG, MCG/KG, MCG/KG/MIN, MCG/MIN, MCL, MEQ, MEQ/24HR, MG, MG%, MG/HR, MG/KG, MG/KG/HR, MG/KG/MIN, MG/M2, MG/ML, ML, ML/HR, ML/MIN, MMOL, MIU, MAC, NEB, PATCH, %, PUFF, SACH, SPR, SUPP, TBLSP, TAB, TSP, U, UNK, VIAL	
CMFREQ	STRING(255) - 2XWK, 3XWK, 4XWK, 5XD, 5XWK, AC, BID, CINF, Q2WK, Q3WK, Q3M, QOD, HS, QM, QWK, QD, ONE, PC, PRN, Q2H, Q3D, Q4D, Q4H, Q6H, Q8H, Q12H, QAM, QH, QID, QPM, TID, UNK	
CMROUTCD	STRING(255) - OU, EP, GTT, IH, INJ, IA, IB, IM, IN, IO, IOS, IT, IU, IV, NS, PO, PR, SC, SL, TP, TD, UNK, VG	
CMREAS	STRING(70) - A70	
CMSTDT	DATE - DDMONYYYY	
CMPRIOR	STRING(1)	
CMONGO	STRING(42)	
CMENDT	DATE - DDMONYYYY	
CMTYPCD	STRING(255)	

FORM: Hypoglycaemic Events Extension Phase (HGEVNT EXT) TRIAL: dpb925prd

New

#		Start date and time	End date and time	Blood Glucose Test Result	Frequency	Outcome	Intervention	Maximum Intensity	Action Taken	Serious?	Symptoms?	External assistance?	Relationship?	Withdraw?
1														

Hypoglycaemic Events		
1.	Start date and time of event HH:MM (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS1:t_HGEVNT_EXT1.HGESTDTTM) (MAPPINGS2:t_HGEVNT_EXT1.HGESTDTTM) (MAPPINGS3:t_HGEVNT_EXT1.HGESTDTTM) Req/Unk : Req/Unk
2.	End date and time of event HH:MM (00:00-23:59)	Req / Req / Req (2005-2007) (MAPPINGS1:t_HGEVNT_EXT1.HGEENDTTM) (MAPPINGS2:t_HGEVNT_EXT1.HGEENDTTM) (MAPPINGS3:t_HGEVNT_EXT1.HGEENDTTM) Req/Unk : Req/Unk
3.	Blood Glucose Test Result at Time of Event	xxx.x (MAPPINGS1:t_HGEVNT_EXT1.HGBEGRES) (MAPPINGS2:t_HGEVNT_EXT1.HGBEGRES) (MAPPINGS3:t_HGEVNT_EXT1.HGBEGRES) (MAPPINGS3:t_HGEVNT_EXT1.BGUNIT) (MAPPINGS1:t_HGEVNT_EXT1.BGUNIT) (MAPPINGS2:t_HGEVNT_EXT1.BGUNIT) [MG/DL] ○ Milligrams per decilitre (MG/DL) [MMOL/L] ○ Millimoles per litre (MMOL/L)
4.	Frequency	(MAPPINGS3:t_HGEVNT_EXT1.HGEFRQCD) (MAPPINGS1:t_HGEVNT_EXT1.HGEFRQCD) (MAPPINGS2:t_HGEVNT_EXT1.HGEFRQCD) [1] ○ Single episode [2] ○ Intermittent
5.	Outcome	(MAPPINGS3:t_HGEVNT_EXT1.HGEOUTCD1) (MAPPINGS1:t_HGEVNT_EXT1.HGEOUTCD1) (MAPPINGS2:t_HGEVNT_EXT1.HGEOUTCD1) [1] ○ Recovered / Resolved [2] ○ Recovering / Resolving [3] ○ Not Recovered / Not Resolved [4] ○ Recovered / Resolved with Sequelae [5] ○ Fatal
6.	Intervention (enter the most severe, enter details on concomitant medication page if applicable)	(MAPPINGS3:t_HGEVNT_EXT1.HGEINVCD1) (MAPPINGS1:t_HGEVNT_EXT1.HGEINVCD1) (MAPPINGS2:t_HGEVNT_EXT1.HGEINVCD1) [1] ○ None [2] ○ Minor; Administered sugary drinks or sweets [3] ○ Immediate; glucose drinks or suppliments [4] ○ Extensive; glucose injection/infusion/glucagon
7.	Severity of hypoglycaemic event	(MAPPINGS3:t_HGEVNT_EXT1.HGESEVCD) (MAPPINGS1:t_HGEVNT_EXT1.HGESEVCD) (MAPPINGS2:t_HGEVNT_EXT1.HGESEVCD) [1] ○ Mild [2] ○ Moderate [3] ○ Severe [X] ○ Not applicable
8.	Action Taken with Investigational Product	(MAPPINGS3:t_HGEVNT_EXT1.HGEACTCD) (MAPPINGS1:t_HGEVNT_EXT1.HGEACTCD) (MAPPINGS2:t_HGEVNT_EXT1.HGEACTCD) [1] ○ Investigational product(s) withdrawn [2] ○ Dose reduced [4] ○ Dose not changed [5] ○ Dose interrupted [X] ○ Not applicable
9.	Does this Event meet the definition of serious? *If Yes, complete paper SAE form and fax to GSK Safety within 24 hr*	(MAPPINGS3:t_HGEVNT_EXT1.HGSAE) (MAPPINGS1:t_HGEVNT_EXT1.HGSAE) (MAPPINGS2:t_HGEVNT_EXT1.HGSAE) [Y] ○ Yes [N] ○ No
10.	Did the subject experience symptoms usually associated with hypoglycaemia?	(MAPPINGS3:t_HGEVNT_EXT1.HGESYM) (MAPPINGS1:t_HGEVNT_EXT1.HGESYM) (MAPPINGS2:t_HGEVNT_EXT1.HGESYM) [Y] ○ Yes [N] ○ No
11.	Did the subject require external assistance?	(MAPPINGS3:t_HGEVNT_EXT1.HGEASS) (MAPPINGS1:t_HGEVNT_EXT1.HGEASS) (MAPPINGS2:t_HGEVNT_EXT1.HGEASS) [Y] ○ Yes [N] ○ No
12.	Is there a reasonable possibility that the hypolycaemic event may have been caused by the investigational product?	(MAPPINGS3:t_HGEVNT_EXT1.HGRELIP) (MAPPINGS1:t_HGEVNT_EXT1.HGRELIP) (MAPPINGS2:t_HGEVNT_EXT1.HGRELIP) [Y] ○ Yes [N] ○ No
13.	Did the subject withdraw from the study as a result of this hypoglycaemic event?	(MAPPINGS3:t_HGEVNT_EXT1.HGEWD) (MAPPINGS1:t_HGEVNT_EXT1.HGEWD) (MAPPINGS2:t_HGEVNT_EXT1.HGEWD) [Y] ○ Yes [N] ○ No

CDD: MAPPINGS1 Table: t_HGEVNT_EXT1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT - F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	
HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

CDD: MAPPINGS2 Table: t_HGEVNT_EXT1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	

HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

CDD: MAPPINGS3	Table: t_HGEVNT_EXT1	Key Type: PATIENTVISIT
Column Name	**Column Data Type**	**Design Note**
HGESTDTTM	DATE - DDMONYYYY HHMM	
HGEENDTTM	DATE - DDMONYYYY HHMM	
HGBEGRES	FLOAT - F5.1	
BGUNIT	STRING(6)	
HGEFRQCD	STRING(1)	
HGEOUTCD1	STRING(1)	
HGEINVCD1	STRING(1)	
HGESEVCD	STRING(1)	
HGEACTCD	STRING(1)	
HGSAE	STRING(1)	
HGESYM	STRING(1)	
HGEASS	STRING(1)	
HGRELIP	STRING(1)	
HGEWD	STRING(1)	

FORM: ADVERSE EVENTS EXTENSION. (AE EXT) TRIAL: dpb925prd

New

#		Sequence Number	Event	Start Date	Outcome	Maximum Intensity	Action Taken	Subject Withdrawn?	Relationship	Serious?
1										

ADVERSE EVENTS

	Sequence Number	(MAPPINGS3:t_AE_EXT1.AESEQ) (MAPPINGS1:t_AE_EXT1.AESEQ) (MAPPINGS2:t_AE_EXT1.AESEQ)
1.	Event Diagnosis Only *(if known)* Otherwise Sign/Symptom	A100 (MAPPINGS3:t_AE_EXT1.AETERM) (MAPPINGS1:t_AE_EXT1.AETERM) (MAPPINGS2:t_AE_EXT1.AETERM)
2.*	Modified term *[hidden]*	A100 (MAPPINGS3:t_AE_EXT1.AEMODIFY) (AE_CODE2:0.0:CommonCRF.AE_EXT1.sctAE_1.0.ItmAELLTCD.AELLTCD) (MAPPINGS1:t_AE_EXT1.AEMODIFY) (AE_SYNONYM2:0:CommonCRF.AE_EXT1.sctAE_1.0.ItmAEMEDSYN.AEMEDSYN) (AE_FAILED2:0.CommonCRF.AE_EXT1.sctAE_1.0.ItmAE_FAILED.calAE_FAILED) (MAPPINGS2:t_AE_EXT1.AEMODIFY)
	MedDRA synonym *[hidden]*	(MAPPINGS3:t_AE_EXT1.AEMEDSYN) (MAPPINGS1:t_AE_EXT1.AEMEDSYN) (MAPPINGS2:t_AE_EXT1.AEMEDSYN)
	MedDRA lower level term code *[hidden]*	(MAPPINGS3:t_AE_EXT1.AELLTCD) (MAPPINGS1:t_AE_EXT1.AELLTCD) (MAPPINGS2:t_AE_EXT1.AELLTCD)
	Failed coding *[hidden]*	(MAPPINGS3:t_AE_EXT1.calAE_FAILED) (MAPPINGS1:t_AE_EXT1.calAE_FAILED) (MAPPINGS2:t_AE_EXT1.calAE_FAILED)
3.	Start Date	Req / Req / Req (2005-2007) (MAPPINGS3:t_AE_EXT1.AESTDT) (MAPPINGS1:t_AE_EXT1.AESTDT) (MAPPINGS2:t_AE_EXT1.AESTDT)
4.	Outcome / End Date	(MAPPINGS3:t_AE_EXT1.AEOUTCD) (MAPPINGS1:t_AE_EXT1.AEOUTCD) (MAPPINGS2:t_AE_EXT1.AEOUTCD) [1] Recovered/Resolved, provide End Date Req / Req / Req (2005-2007) (MAPPINGS3:t_AE_EXT1.AEENDT1) (MAPPINGS1:t_AE_EXT1.AEENDT1) (MAPPINGS2:t_AE_EXT1.AEENDT1) [2] Recovering/Resolving [3] Not recovered/Not resolved [4] Recovered/Resolved with sequelae, provide End Date Req / Req / Req (2005-2007) (MAPPINGS3:t_AE_EXT1.AEENDT2) (MAPPINGS1:t_AE_EXT1.AEENDT2) (MAPPINGS2:t_AE_EXT1.AEENDT2) [5] Fatal, record Date of Death Req / Req / Req (2005-2007) (MAPPINGS3:t_AE_EXT1.AEENDT3) (MAPPINGS1:t_AE_EXT1.AEENDT3) (MAPPINGS2:t_AE_EXT1.AEENDT3)
5.	Maximum Intensity	(MAPPINGS3:t_AE_EXT1.AESEVCD) (MAPPINGS1:t_AE_EXT1.AESEVCD) (MAPPINGS2:t_AE_EXT1.AESEVCD) [1] Mild [2] Moderate [3] Severe [X] Not applicable
6.	Action Taken with Investigational Product(s) as a Result of the AE	(MAPPINGS3:t_AE_EXT1.AEACTRCD) (MAPPINGS1:t_AE_EXT1.AEACTRCD) (MAPPINGS2:t_AE_EXT1.AEACTRCD) [1] Investigational product(s) withdrawn [2] Dose reduced [3] Dose increased [4] Dose not changed [5] Dose interrupted [X] Not applicable
7.	Did the subject withdraw from study as a result of this AE?	(MAPPINGS3:t_AE_EXT1.AEWD) (MAPPINGS1:t_AE_EXT1.AEWD) (MAPPINGS2:t_AE_EXT1.AEWD) [Y] Yes [N] No
8.	Is there a reasonable possibility that the AE may have been caused by the investigational product?	(MAPPINGS3:t_AE_EXT1.AEREL) (MAPPINGS1:t_AE_EXT1.AEREL) (MAPPINGS2:t_AE_EXT1.AEREL) [Y] Yes [N] No
9.	Does this Adverse Event meet the definition of serious? *If Yes, complete paper SAE form and fax to GSK Safety within 24 hr*	(MAPPINGS3:t_AE_EXT1.AESER) (MAPPINGS1:t_AE_EXT1.AESER) (MAPPINGS2:t_AE_EXT1.AESER) [N] No [Y] Yes, check all that apply (MAPPINGS3:t_AE_EXT1.AESERDTH) (MAPPINGS1:t_AE_EXT1.AESERDTH) (MAPPINGS2:t_AE_EXT1.AESERDTH) [A] Results in death (MAPPINGS3:t_AE_EXT1.AESERLIF) (MAPPINGS1:t_AE_EXT1.AESERLIF) (MAPPINGS2:t_AE_EXT1.AESERLIF) [B] Is life-threatening (MAPPINGS3:t_AE_EXT1.AESERHOS) (MAPPINGS1:t_AE_EXT1.AESERHOS) (MAPPINGS2:t_AE_EXT1.AESERHOS) [C] Requires hospitalisation or prolongation of existing hospitalisation (MAPPINGS3:t_AE_EXT1.AESERDIS) (MAPPINGS1:t_AE_EXT1.AESERDIS) (MAPPINGS2:t_AE_EXT1.AESERDIS) [D] Results in disability/incapacity (MAPPINGS2:t_AE_EXT1.AESERCON) (MAPPINGS3:t_AE_EXT1.AESERCON) (MAPPINGS1:t_AE_EXT1.AESERCON) [E] Congenital anomaly/birth defect (MAPPINGS2:t_AE_EXT1.AESEROTH) (MAPPINGS3:t_AE_EXT1.AESEROTH) (MAPPINGS1:t_AE_EXT1.AESEROTH) [F] Other, specify (MAPPINGS2:t_AE_EXT1.AESERSPE) (MAPPINGS3:t_AE_EXT1.AESERSPE) (MAPPINGS1:t_AE_EXT1.AESERSPE) A100 (MAPPINGS2:t_AE_EXT1.rdcAESERCause) (MAPPINGS3:t_AE_EXT1.rdcAESERCause) (MAPPINGS1:t_AE_EXT1.rdcAESERCause) Was this SAE caused by an activity related to study participation (e.g., procedures)? [N] No [Y] Yes
10.	Serious Flag *[hidden]*	(MAPPINGS2:t_AE_EXT1.calSeriousFlag) (MAPPINGS3:t_AE_EXT1.calSeriousFlag) (MAPPINGS1:t_AE_EXT1.calSeriousFlag)

* Item is not required

Section Design Notes:	
Title	**Design Note**
ADVERSE EVENTS	One of the following items must be used: Maximum Intensity, Maximum Toxicity, or Maximum Toxicity or Intensity. The CRF designer must remove the other two items from the form

Item Design Notes:	
Item No.	**Design Note**
3.	Start Time is optional
4.	End Time is optional
5.	Grade 5 is optional

[redacted]

9.	G is an optional criterion and may be removed

CDD: MAPPINGS1 Table: t_AE_EXT1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	
rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

CDD: MAPPINGS2 Table: t_AE_EXT1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	
rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

CDD: MAPPINGS3 Table: t_AE_EXT1 Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
AESEQ	STRING(255)	
AETERM	STRING(100) - A100	
AEMODIFY	STRING(100) - A100	
AEMEDSYN	STRING(255)	
AELLTCD	STRING(255)	
calAE_FAILED	STRING(255)	
AESTDT	DATE - DDMONYYYY	
AEOUTCD	STRING(1)	
AEENDT1	DATE - DDMONYYYY	
AEENDT2	DATE - DDMONYYYY	
AEENDT3	DATE - DDMONYYYY	
AESEVCD	STRING(1)	
AEACTRCD	STRING(1)	
AEWD	STRING(1)	
AEREL	STRING(1)	
AESER	STRING(1)	
AESERDTH	STRING(255)	
AESERLIF	STRING(255)	
AESERHOS	STRING(255)	
AESERDIS	STRING(255)	
AESERCON	STRING(255)	
AESEROTH	STRING(255)	
AESERSPE	STRING(100) - A100	

rdcAESERCause	STRING(1)	
calSeriousFlag	STRING(255)	

FORM: STUDY CONCLUSION (CONC) TRIAL: dpb925prd

STUDY CONCLUSION		
1.	Date of subject completion or withdrawal	Req / Req / Req (2005-2007) (MAPPINGS2:t_DISPOSIT_SCRNFAIL.DSDTTM) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.DSDTTM) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.DSDTTM)
2.	Was this subject a run-in / screen failure or did the subject withdraw from the study?	(MAPPINGS2:t_DISPOSIT_SCRNFAIL.SFFAILDSWD) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.SFFAILDSWD) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.SFFAILDSWD) [N] ○ No [Y] ○ (MAPPINGS2:t_DISPOSIT_SCRNFAIL.rdcSFFailReas) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.rdcSFFailReas) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.rdcSFFailReas) Yes, specify primary reason for failure/withdrawal [-99] ○ (MAPPINGS2:t_DISPOSIT_SCRNFAIL.DSREASCD) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.DSREASCD) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.DSREASCD) Primary reason for withdrawal [1] ○ Adverse event [2] ○ Lost to follow-up [3] ○ Protocol violation [4] ○ Subject decided to withdraw from the study [5] ○ Lack of efficacy [6] ○ Sponsor terminated study [7] ○ Disease progression [17] ○ Non-compliance [23] ○ Insufficient therapeutic effect [24] ○ Did not meet treatment eligibility criteria [27] ○ Hypoglycaemic events (non-SAE) [37] ○ Lack of glycaemic control [Z] ○ Other, specify (MAPPINGS2:t_DISPOSIT_SCRNFAIL.DSRSOTH) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.DSRSOTH) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.DSRSOTH) A200 [-98] ○ (MAPPINGS2:t_DISPOSIT_SCRNFAIL.SFREASCD) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.SFREASCD) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.SFREASCD) Run-in/Screen failure, select primary reason [1] ○ Adverse event [2] ○ Lost to follow-up [3] ○ Protocol violation [4] ○ Subject decided to withdraw from the study [5] ○ Prohibited medication use [6] ○ Did not fulfill eligibility criteria [8] ○ Non-compliance [11] ○ Lack of glycaemic control [OT] ○ Other, specify (MAPPINGS2:t_DISPOSIT_SCRNFAIL.SFRSOTH) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.SFRSOTH) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.SFRSOTH) A200
LOG STATUS		
3.	Did the subject experience any adverse events during the study?	(MAPPINGS2:t_DISPOSIT_SCRNFAIL.rdcConcAEAny) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.rdcConcAEAny) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.rdcConcAEAny) [N] ○ No [Y] ○ Yes
4.	Were any concomitant medications taken by the subject prior to screening and/or during the study?	(MAPPINGS2:t_DISPOSIT_SCRNFAIL.rdcConcCMAny) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.rdcConcCMAny) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.rdcConcCMAny) [N] ○ No [Y] ○ Yes
5.*	Q1 *[hidden]*	(MAPPINGS2:t_DISPOSIT_SCRNFAIL.AXCOMPLETERADIO) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.AXCOMPLETERADIO) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.AXCOMPLETERADIO) [Y] ○ Yes [N] ○ No
6.*	Q2 *[hidden]*	(MAPPINGS2:t_DISPOSIT_SCRNFAIL.REASONRADIO) (MAPPINGS3:t_DISPOSIT_SCRNFAIL.REASONRADIO) (MAPPINGS1:t_DISPOSIT_SCRNFAIL.REASONRADIO) [?] ○ PF_SC_LOST [?] ○ PF_SC_DEATH [?] ○ PF_SC_SPONSORDECISION [?] ○ PF_SC_PHYSICIANDECISION [?] ○ PF_SC_PATIENTDECISION [?] ○ PF_SC_AE [?] ○ PF_SC_CRITERIA [?] ○ PF_SC_OTHER
* Item is not required		

Form Design Note:
This form is optional and is to be used when screen failures or run-in failures are to be captured in the trial.

Item Design Notes:	
Item No.	**Design Note**
1.	Time is optional
2.	Choices after Subject decided to withdraw from the study (including other) are optional choices. Other is required for primary reason for withdrawal but not for the run-in/screen failures radio
3.	This item is not part of the SI datasets
4.	This item is not part of the SI datasets

CDD: MAPPINGS1 Table: t_DISPOSIT_SCRNFAIL Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DSDTTM	DATE - DDMONYYYY	
SFFAILDSWD	STRING(1)	
rdcSFFailReas	NUMERIC	
DSREASCD	STRING(2)	
DSRSOTH	STRING(200) A200	
SFREASCD	STRING(2)	
SFRSOTH	STRING(200) - A200	
rdcConcAEAny	STRING(1)	
rdcConcCMAny	STRING(1)	
AXCOMPLETERADIO	STRING(1)	
REASONRADIO	STRING(42)	

CDD: MAPPINGS2 Table: t_DISPOSIT_SCRNFAIL Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DSDTTM	DATE - DDMONYYYY	
SFFAILDSWD	STRING(1)	
rdcSFFailReas	NUMERIC	
DSREASCD	STRING(2)	
DSRSOTH	STRING(200) - A200	
SFREASCD	STRING(2)	

[redacted]

SFRSOTH	STRING(200) - A200	
rdcConcAEAny	STRING(1)	
rdcConcCMAny	STRING(1)	
AXCOMPLETERADIO	STRING(1)	
REASONRADIO	STRING(42)	

CDD: MAPPINGS3 Table: t_DISPOSIT_SCRNFAIL Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DSDTTM	DATE - DDMONYYYY	
SFFAILDSWD	STRING(1)	
rdcSFFailReas	NUMERIC	
DSREASCD	STRING(2)	
DSRSOTH	STRING(200) - A200	
SFREASCD	STRING(2)	
SFRSOTH	STRING(200) - A200	
rdcConcAEAny	STRING(1)	
rdcConcCMAny	STRING(1)	
AXCOMPLETERADIO	STRING(1)	
REASONRADIO	STRING(42)	

CRB Electronic Signature Affidavit
By my dated signature below, I, [***First Name***] [***Last Name***], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.
Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.
To this I do attest by supplying my password and clicking the button marked **Submit** below.

CRF Electronic Signature Affidavit
By my dated signature below, I, [***First Name***] [***Last Name***], verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.
Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.
To this I do attest by supplying my password and clicking the button marked **Submit** below.

DOSING DIRECTIONS FOR STUDY 925

Directions for "Study Medication"
You will take a total of 3 capsules every morning

Take 1 capsule from Bottle A in the morning before breakfast
Take 1 capsule from Bottle B in the morning before breakfast
Take 1 capsule from Bottle C in the morning before breakfast

Do NOT take your study medication on the morning of a clinic visit. Bring bottles of medication to all clinic visits.

Fast for at least 10 hours before each clinic appointment. When fasting do NOT eat or drink anything except water.

31 Aug 05

DOSING DIRECTIONS FOR STUDY 925

- If you have any questions contact the study doctor immediately
- If you miss a dose do not take extra next time but call the study doctor for instructions
- Keep your study medication in a safe and secure location
- Take your study medication only as directed

Do NOT take your study medication on the morning of a clinic visit. Bring bottles of medication to all clinic visits.

Fast for at least 10 hours before each clinic appointment. When fasting do NOT eat or drink anything except water.

31 Aug 05

Protocol Identifier	Subject Identifier	Date Given to Subject	Next Scheduled Visit Date
DPB100925		Day Month Year	Day Month Year

WEEKLY GLUCOSE LOG

Measure Blood Glucose according to instructions from Study Doctor. Bring all cards with you to your next visit.

		DD MMM YY	DD MMM YY	DD MMM YY	DD MMM YY	DD MMM YY	DD MMM YY	DD MMM YY
	Date	/ /	/ /	/ /	/ /	/ /	/ /	/ /
	Week Day							
1	Before Breakfast (Fasting)							
2	Before Lunch							
3	Before Dinner							
4	At Bedtime							
Site Use Only (Below)								
Site Comments:								

US:ENG (USA/English)

Protocol Identifier	Subject Identifier	
DPB100925		

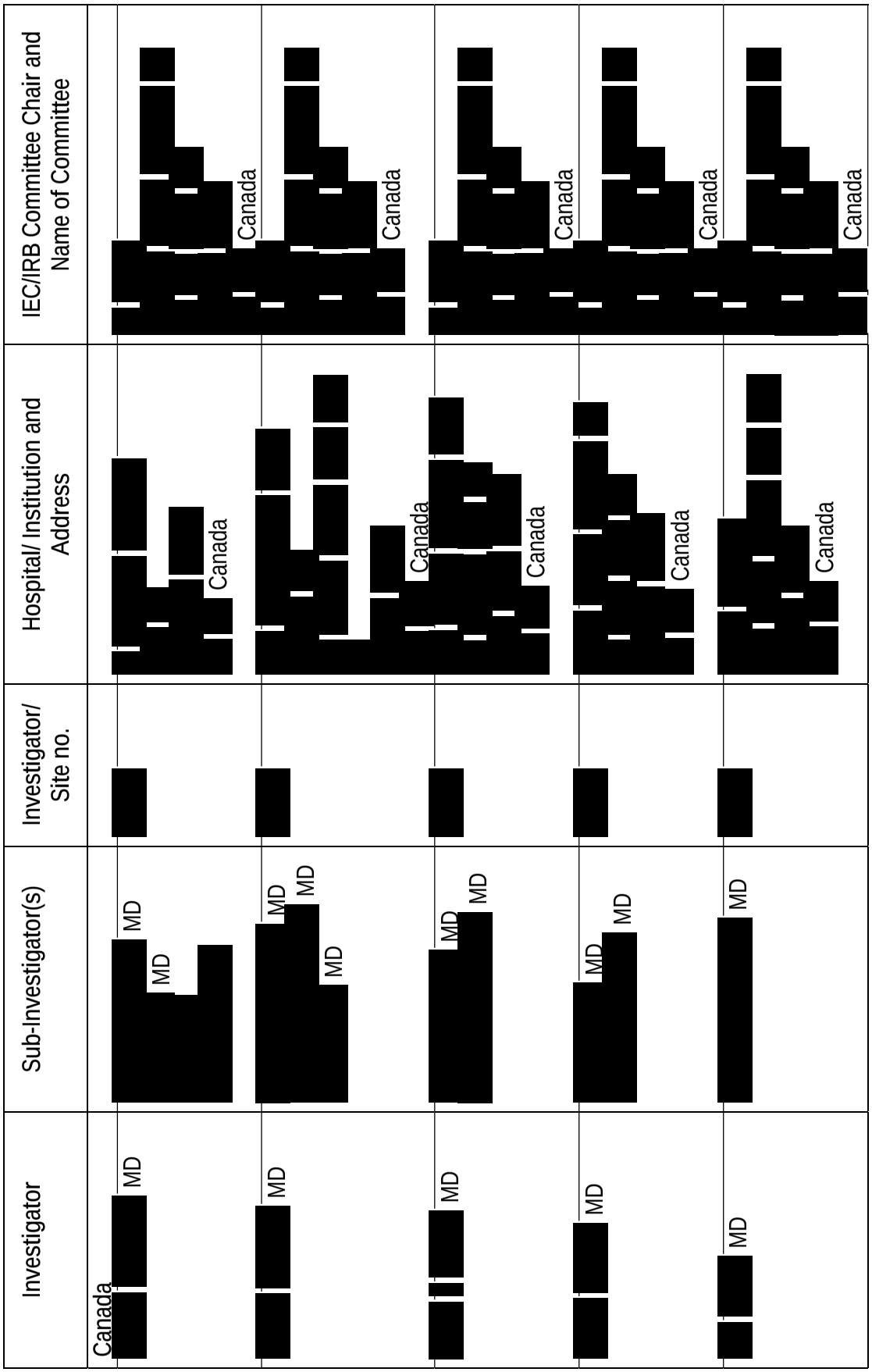
HYPOGLYCAEMIC SYMPTOMS LOG

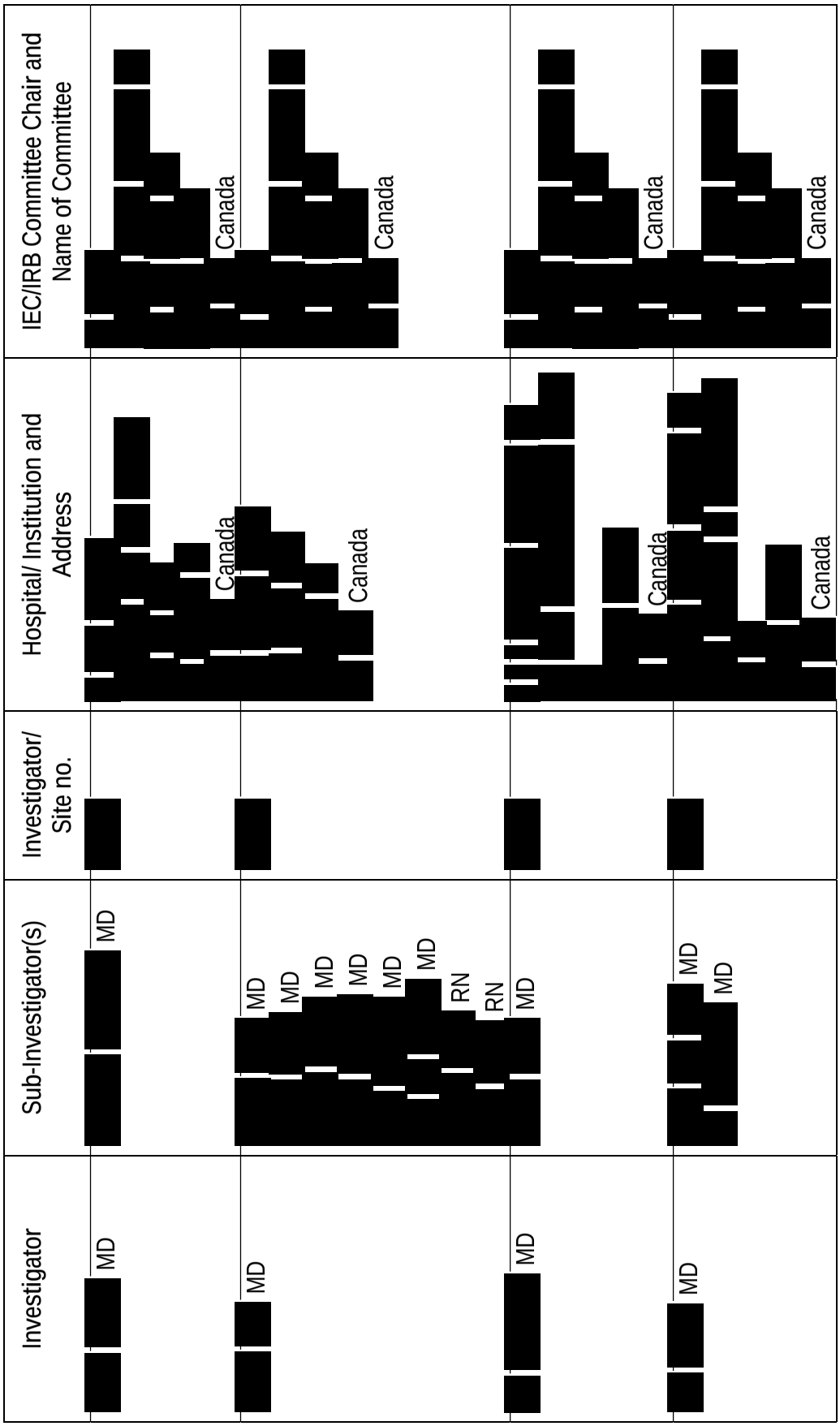
	Date	Time	Date	Time	Date	Time
	e.g., DD MMM YY	*e.g., HH:MM*	*e.g., DD MMM YY*	*e.g., HH:MM*	*e.g., DD MMM YY*	*e.g., HH:MM*
	23 APR 04	*14:45*	*29 APR 04*	*10:20*	*30 APR 04*	*11:35*
Start Date/Time:	/ /	:	/ /	:	/ /	:
Stop Date/Time:	/ /	:	/ /	:	/ /	:
Glucose Result:						
Symptom(s)						
Start Date/Time:	/ /	:	/ /	:	/ /	:
Stop Date/Time:	/ /	:	/ /	:	/ /	:
Glucose Result:						
Symptom(s)						

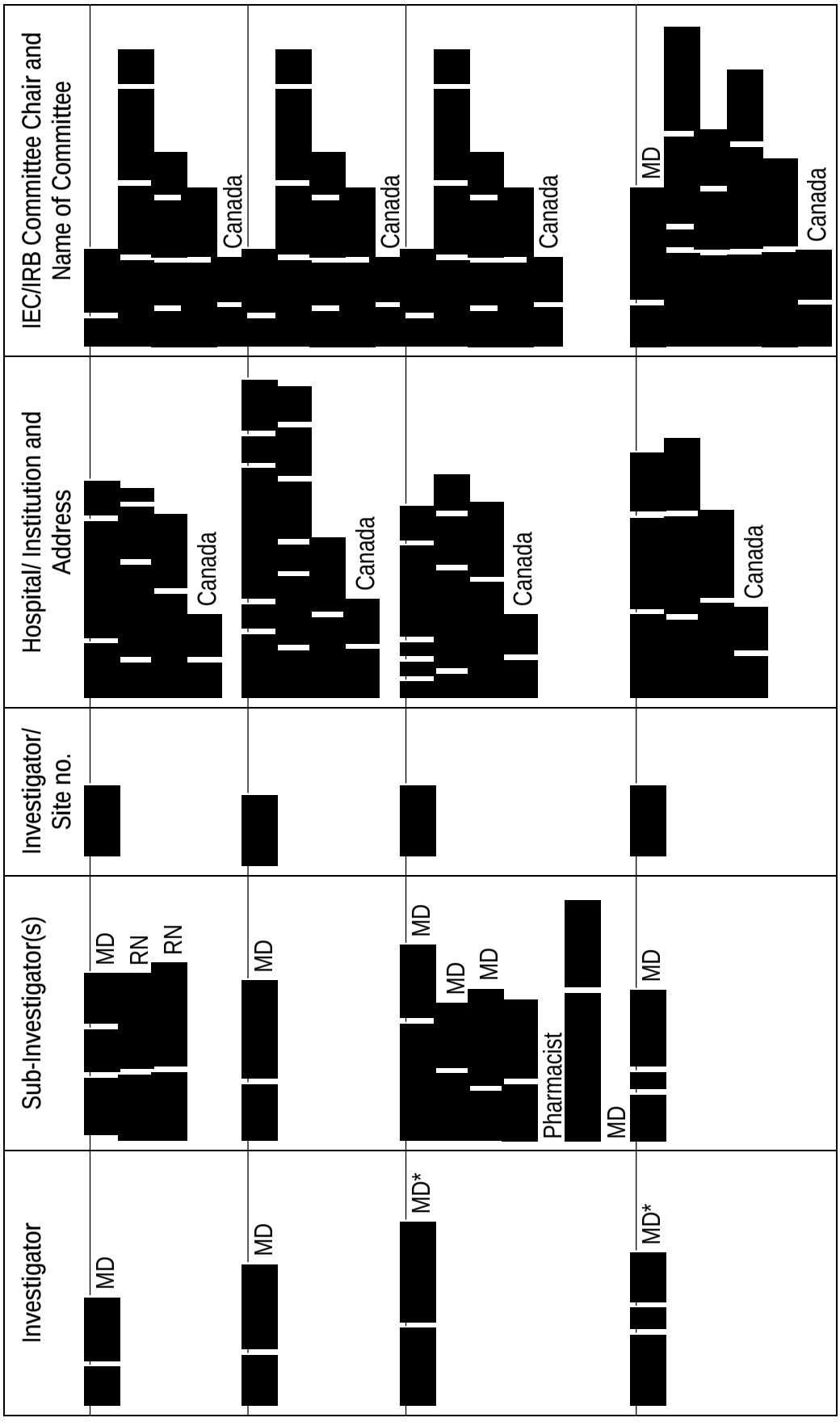
Site Comments:

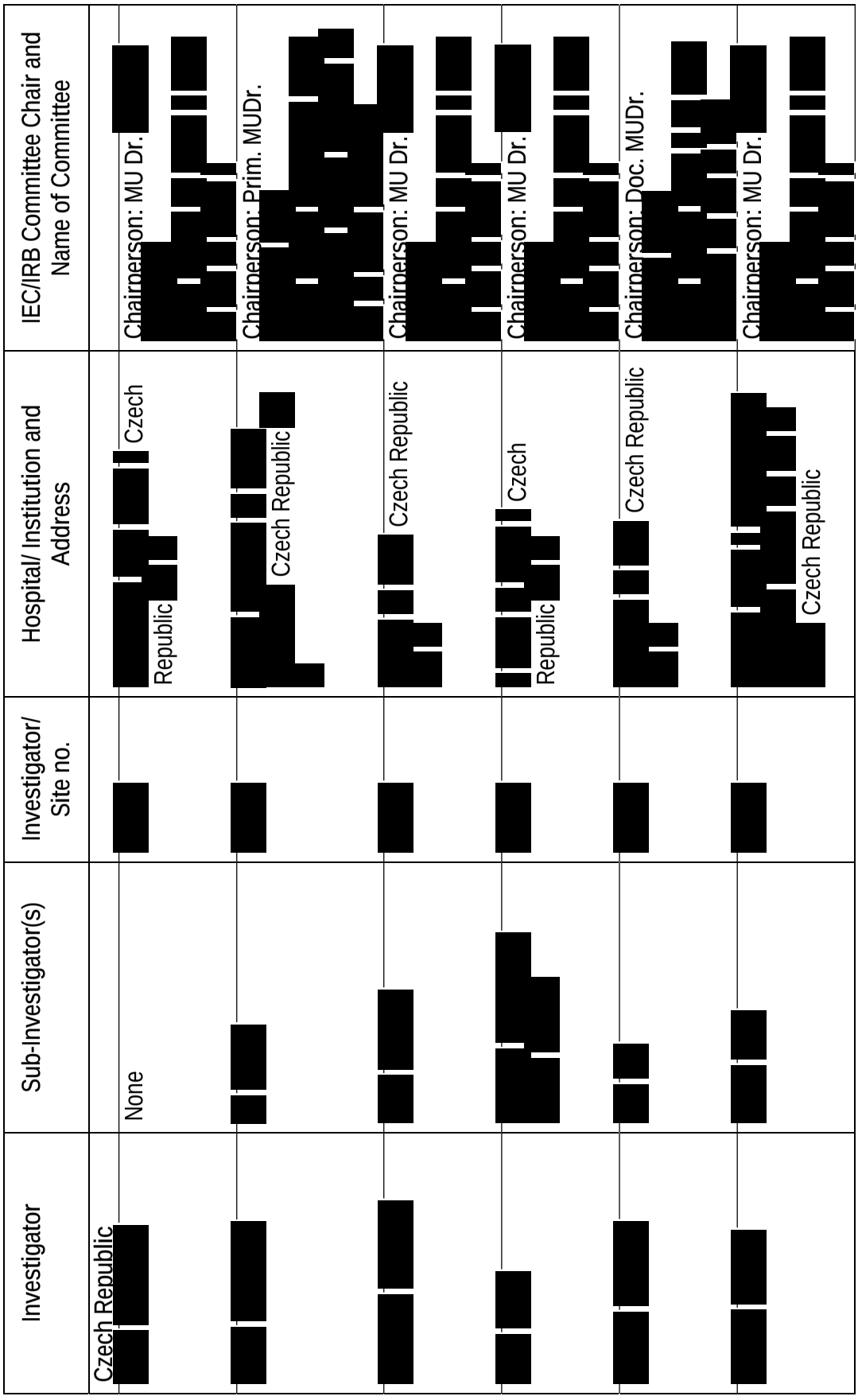
US:ENG (USA/English)

LIST OF INVESTIGATORS AND IECS/IRBS FOR DPB100925


Investigator
Sub-Investigator(s)
Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
Canada
MD
MD
MD


Investigator
MD
MD
Sub-Investigator(s)
MD
MD
MD
MD
MD
MD
RN
RN
MD
MD
MD
Investigator/ Site no.
Hospital/ Institution and Address
Canada
Canada
Canada
Canada
IEC/IRB Committee Chair and Name of Committee
Canada
Canada
Canada
Canada


Investigator
MD
MD
MD*
MD*
Sub-Investigator(s)
MD
RN
RN
MD
MD
MD
MD
Pharmacist
MD
MD
Investigator/ Site no.
Hospital/ Institution and Address
Canada
Canada
Canada
Canada
IEC/IRB Committee Chair and Name of Committee
Canada
Canada
Canada
MD
Canada


Investigator
Sub-Investigator(s)
Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
Czech Republic
None
Czech Republic
Chairnerson: MU Dr.
Czech Republic
Chairnerson: Prim. MUDr.
Czech Republic
Chairnerson: MU Dr.
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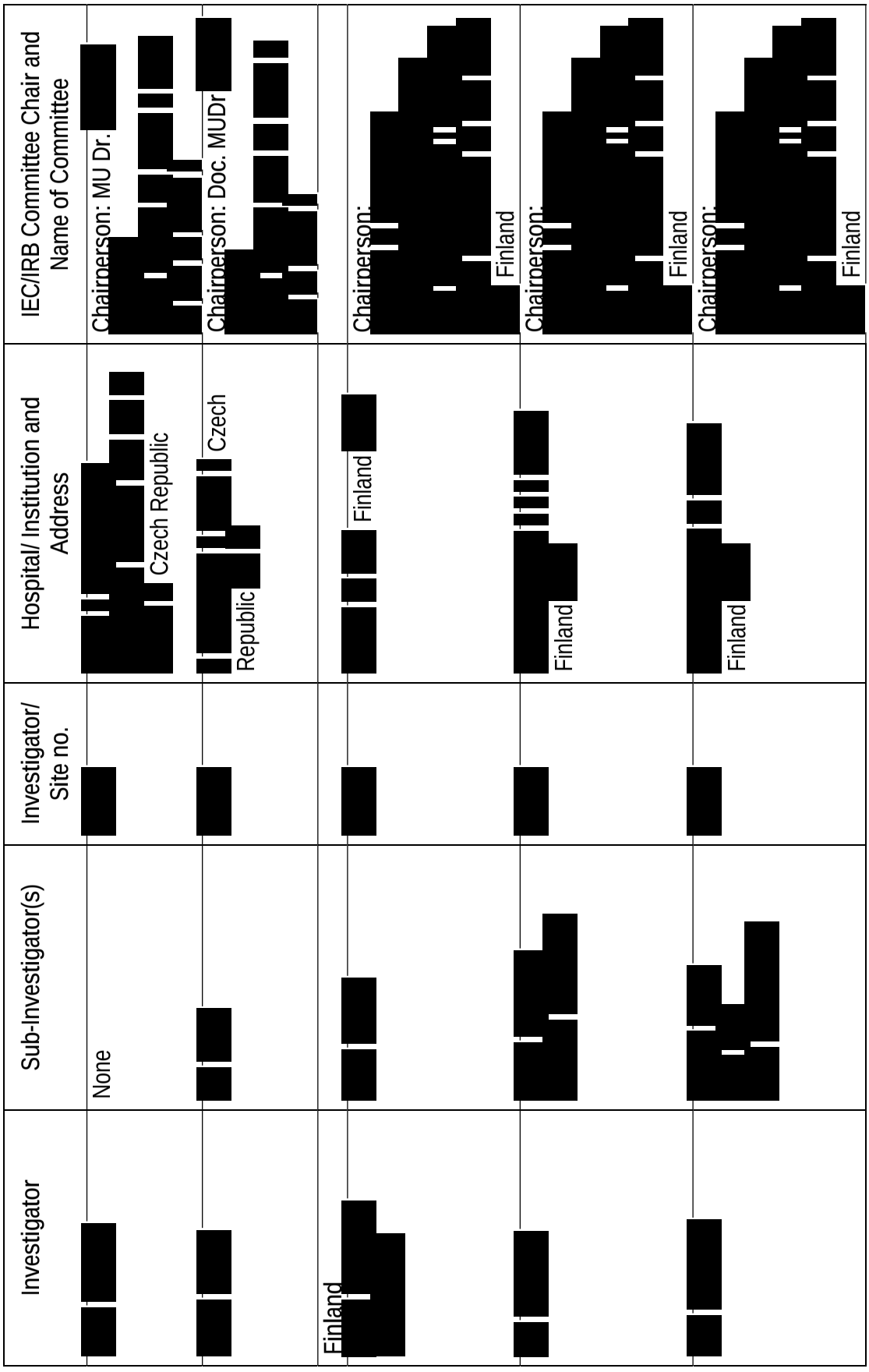
Investigator
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Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
None
Czech Republic
Chairperson: MU Dr.
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Chairperson: Doc. MUDr
Finland
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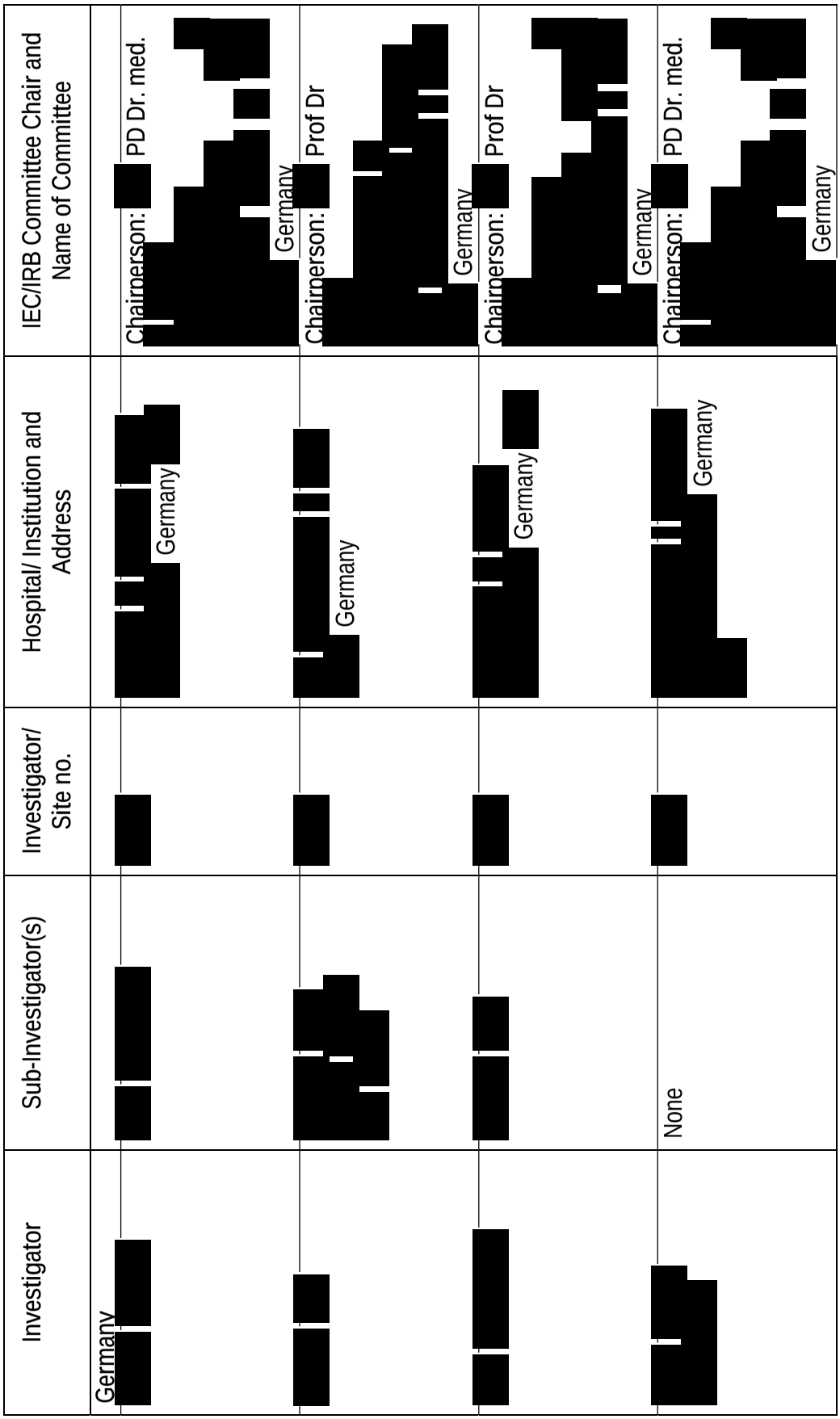
Finland


Investigator
Sub-Investigator(s)
Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
Germany
Germany
Germany
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None
Chairperson: PD Dr. med.
Germany
Chairperson: Prof Dr
Germany
Chairperson: Prof Dr
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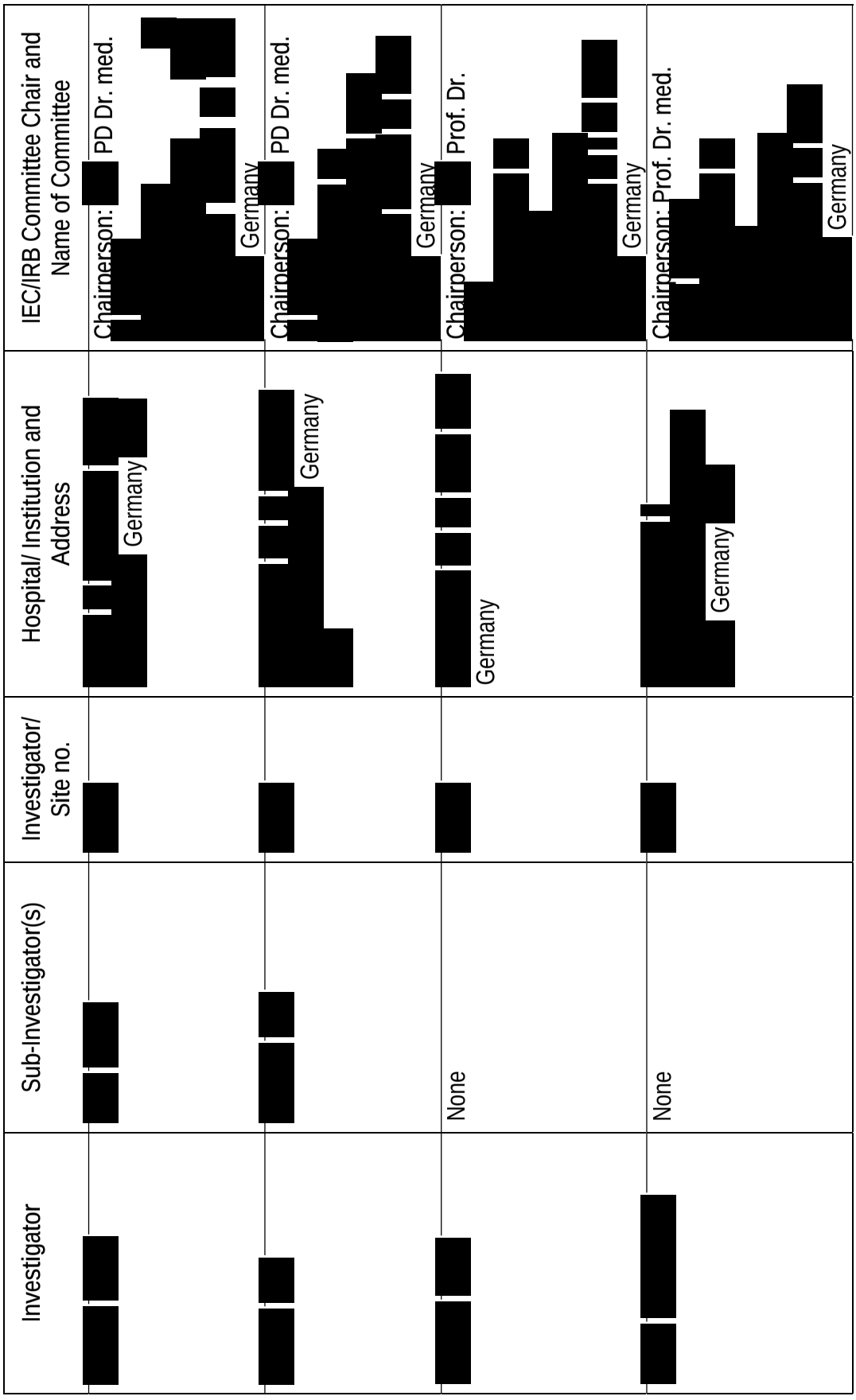
Chairperson: PD Dr. med.
Germany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Investigator/ Site no.
Hospital/ Institution and Address
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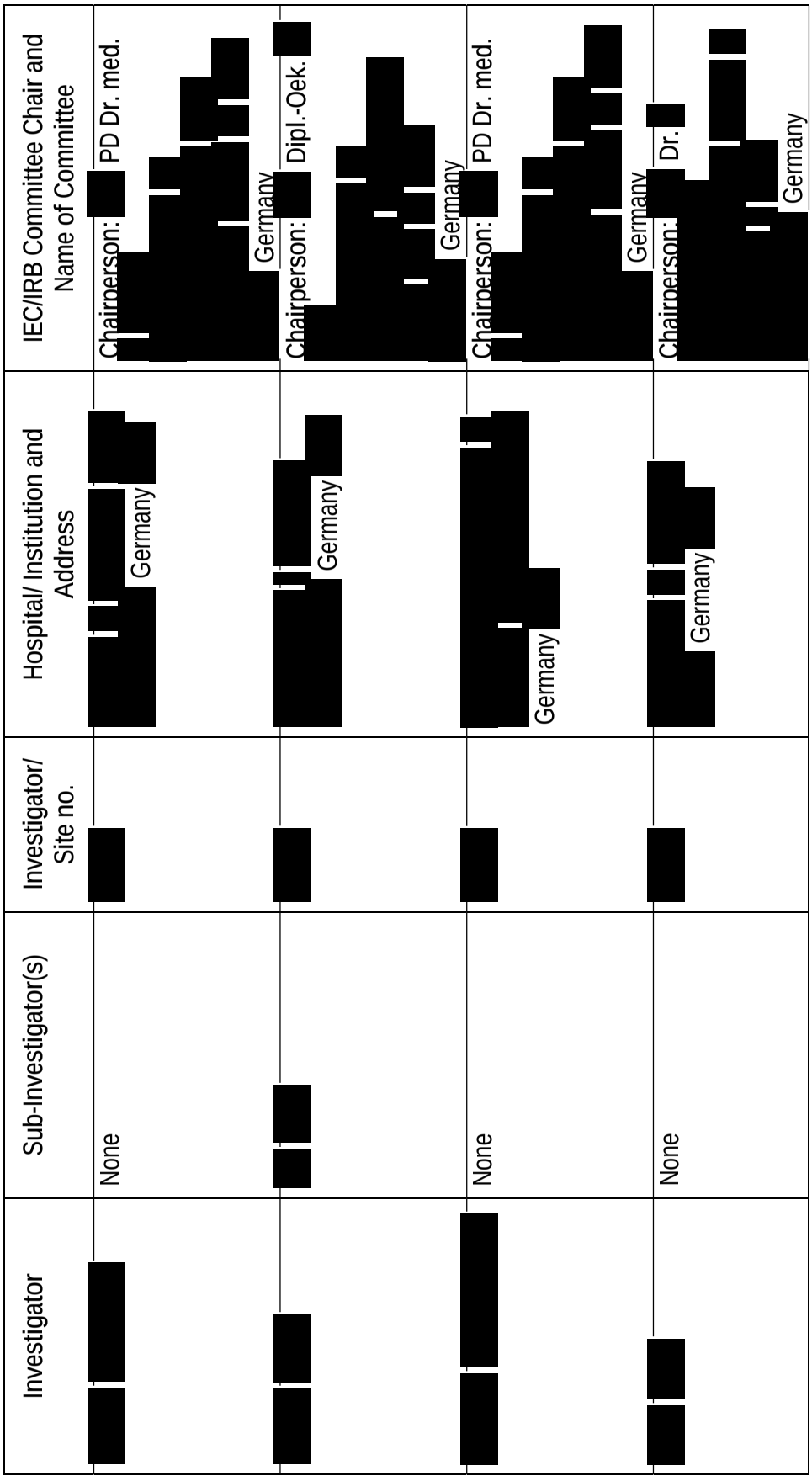
Investigator
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Hospital/ Institution and Address
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None
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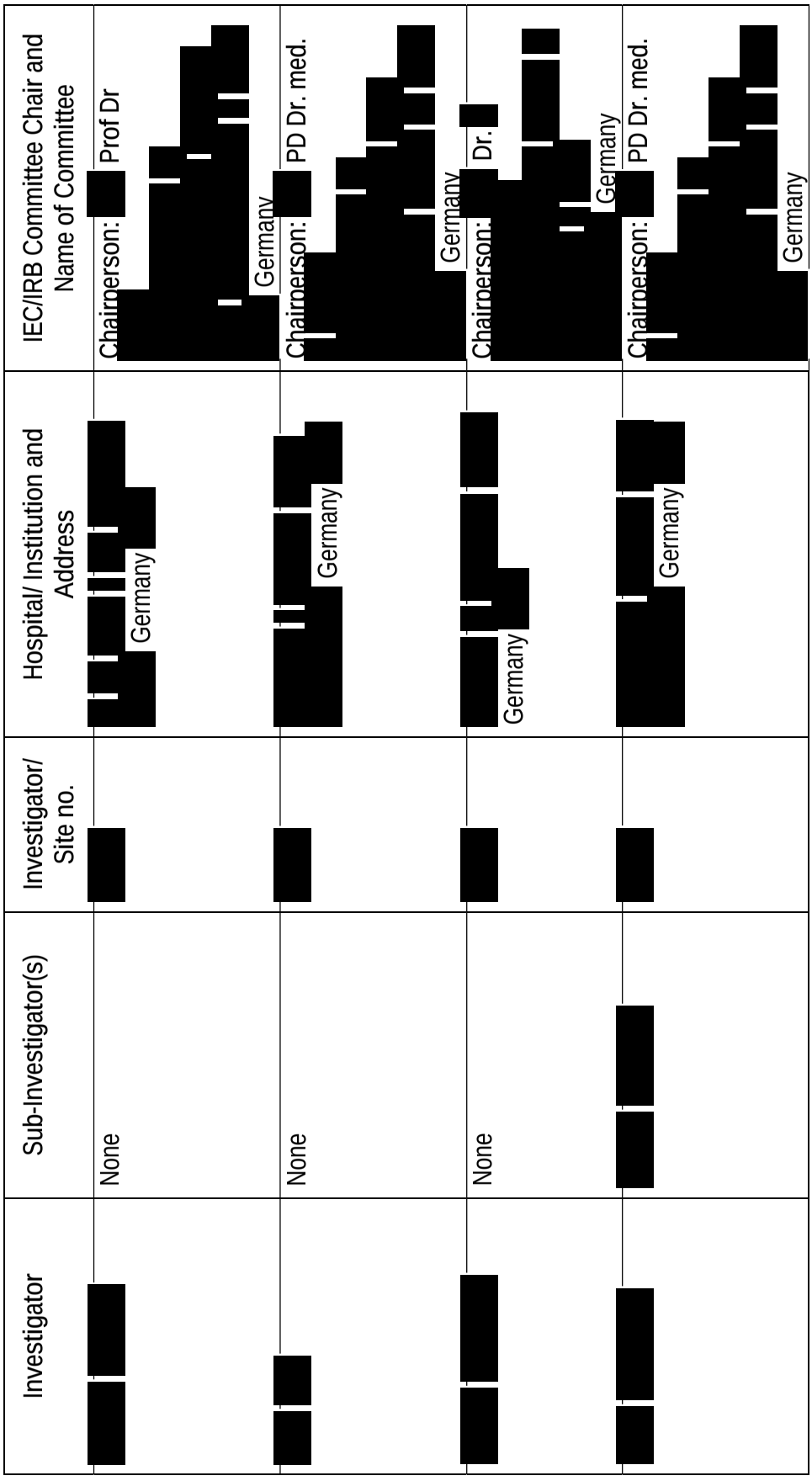
Chairperson:
PD Dr. med.
Dipl.-Oek.
Dr.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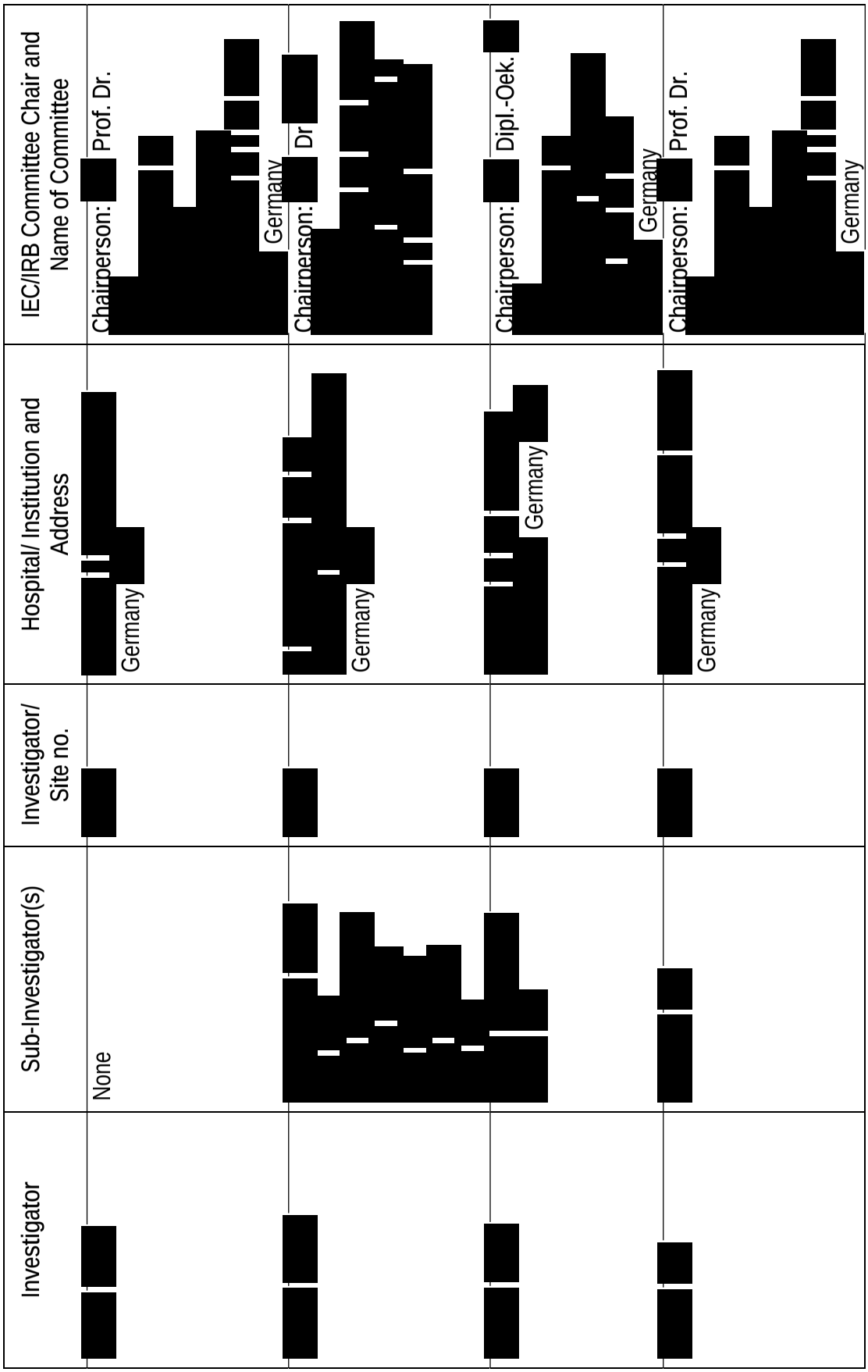
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Hospital/ Institution and Address
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Chairperson: Dr
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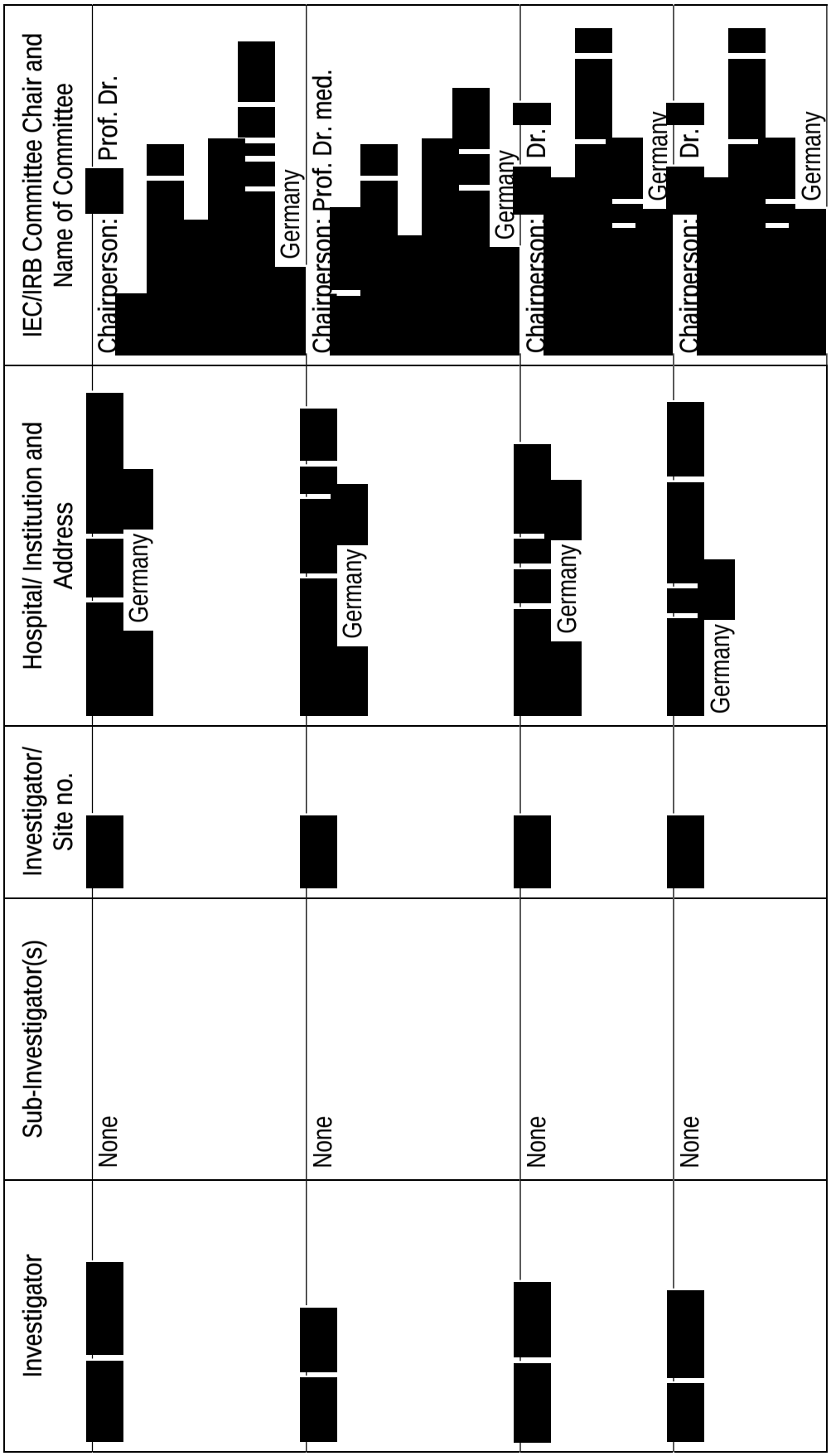
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Hospital/ Institution and Address
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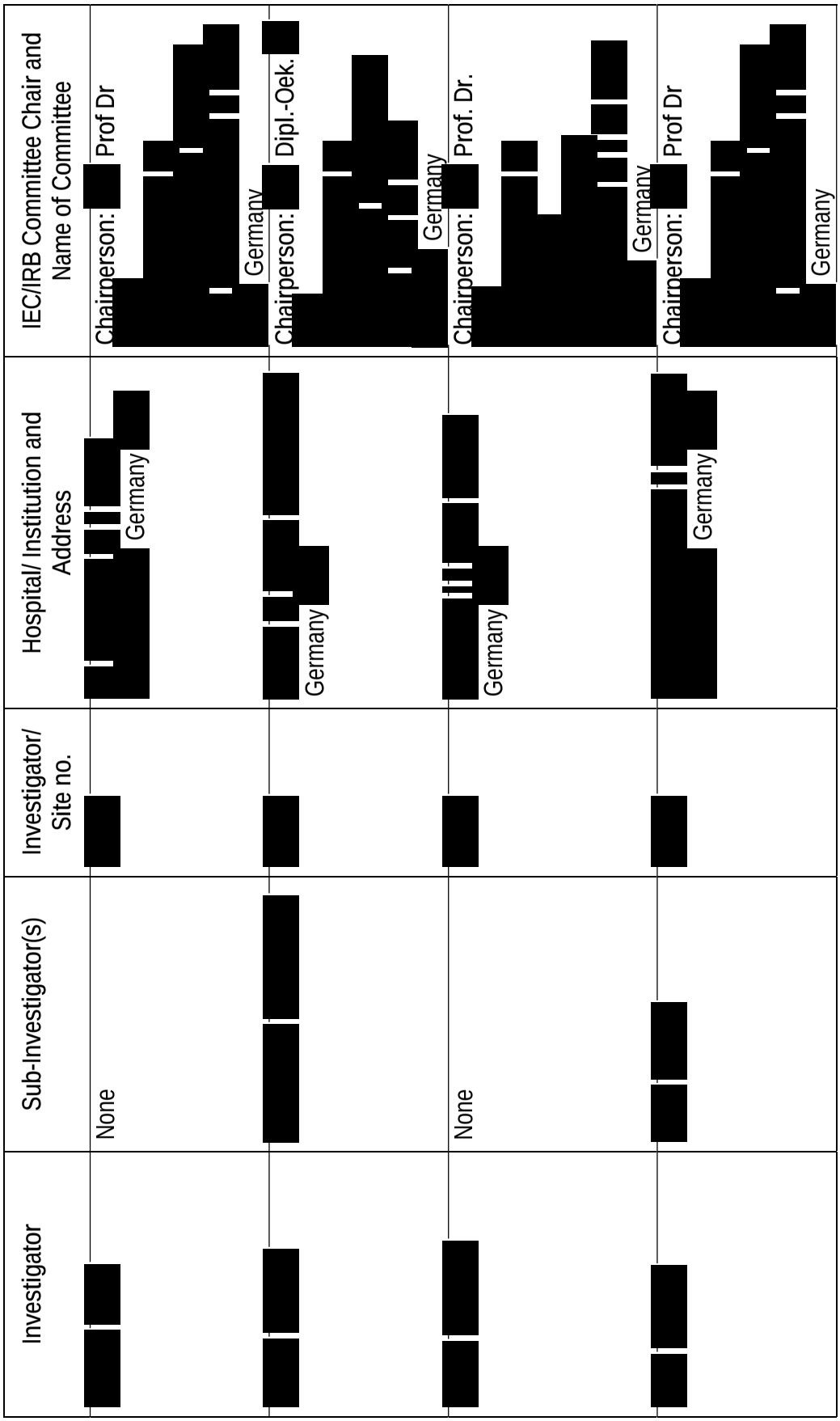
Chairperson: Dr.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Hospital/ Institution and Address
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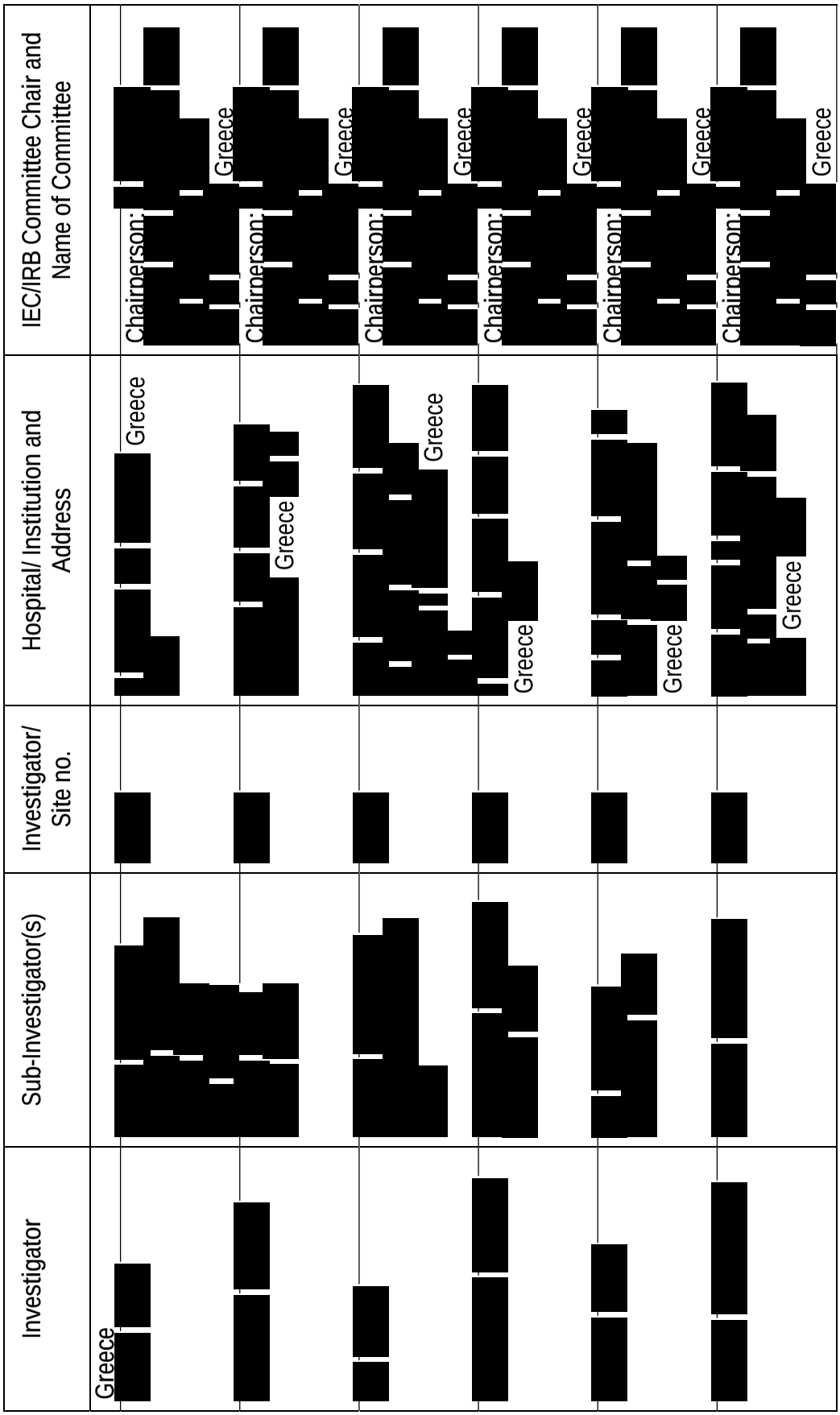
Chairperson: Prof Dr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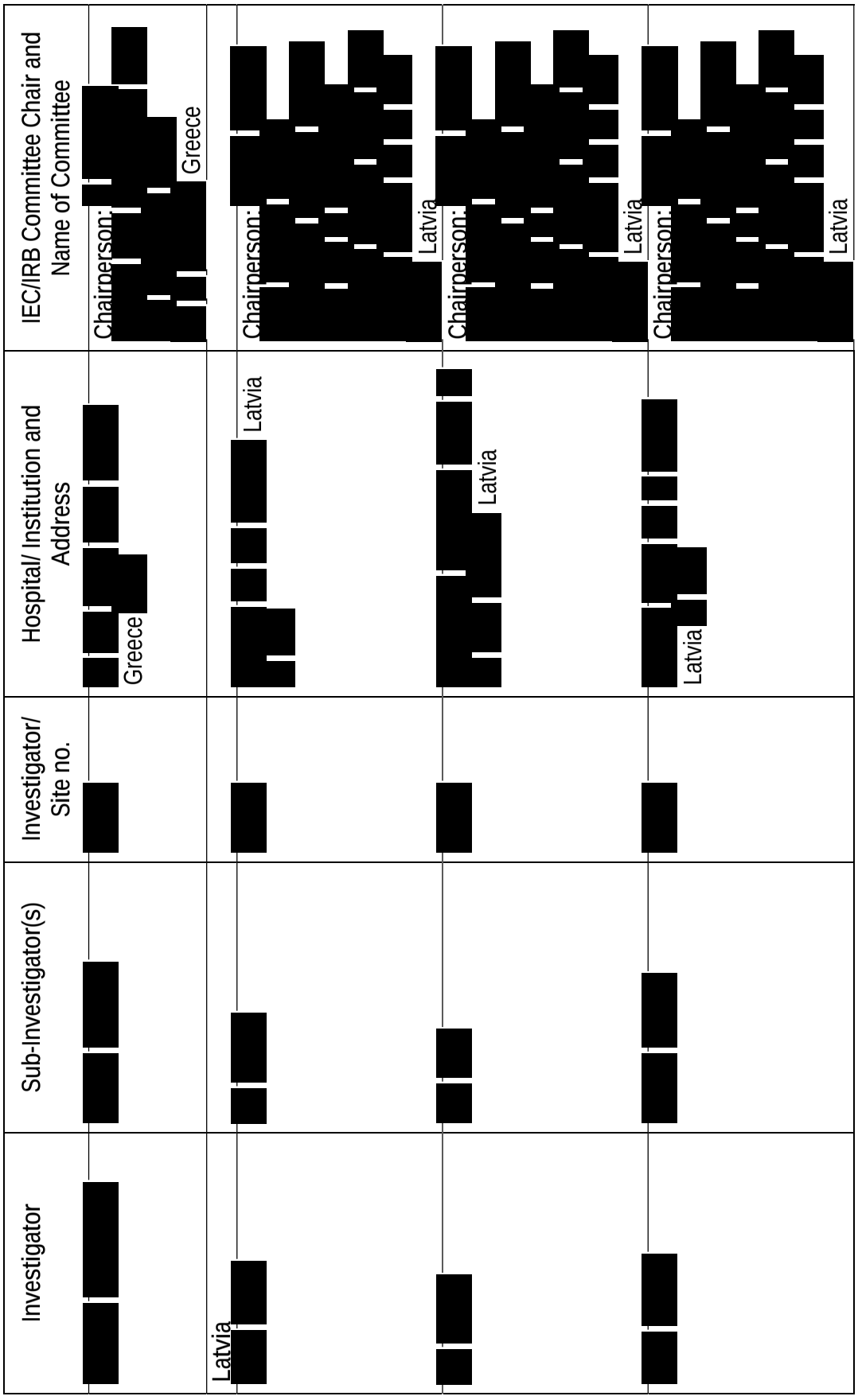
Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
Greece
Chairperson: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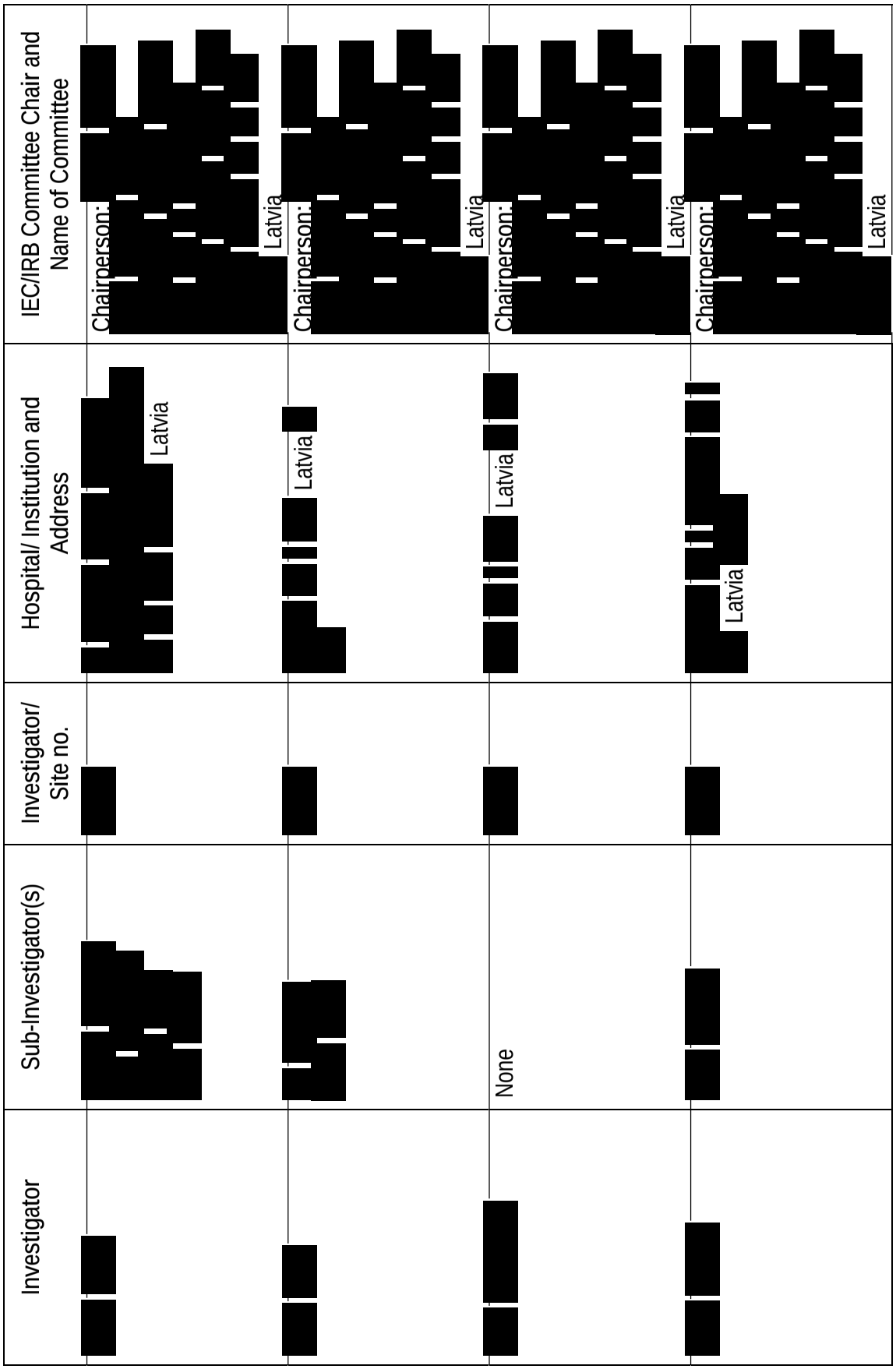
Hospital/ Institution and Address
Investigator/ Site no.
Sub-Investigator(s)
Investigator
Chairperson:
Greece
Latvia


IEC/IRB Committee Chair and Name of Committee
Hospital/ Institution and Address
Investigator/ Site no.
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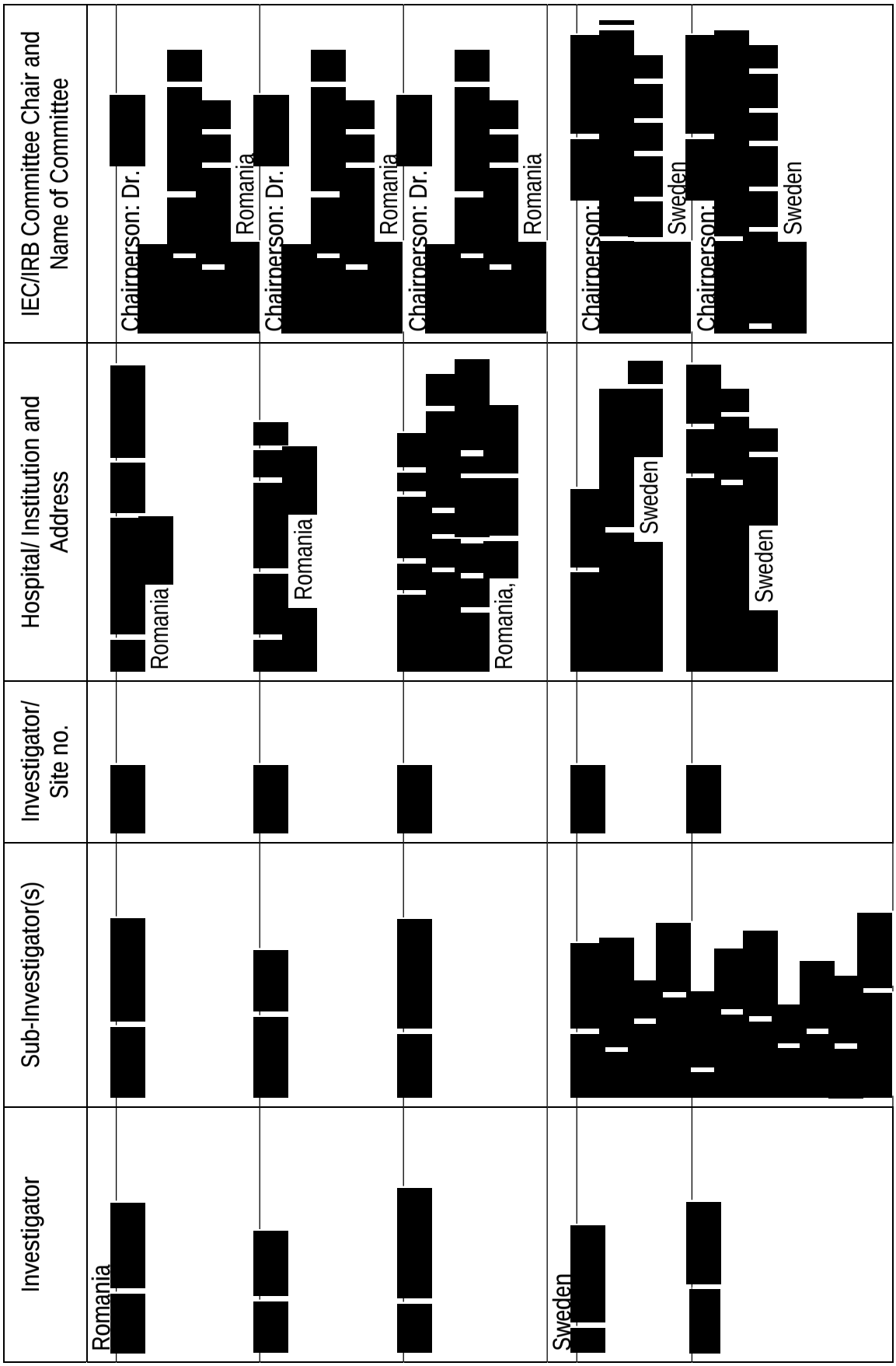
Investigator
Sub-Investigator(s)
Investigator/ Site no.
Hospital/ Institution and Address
IEC/IRB Committee Chair and Name of Committee
Romania
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Romania
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Chairperson: Dr.
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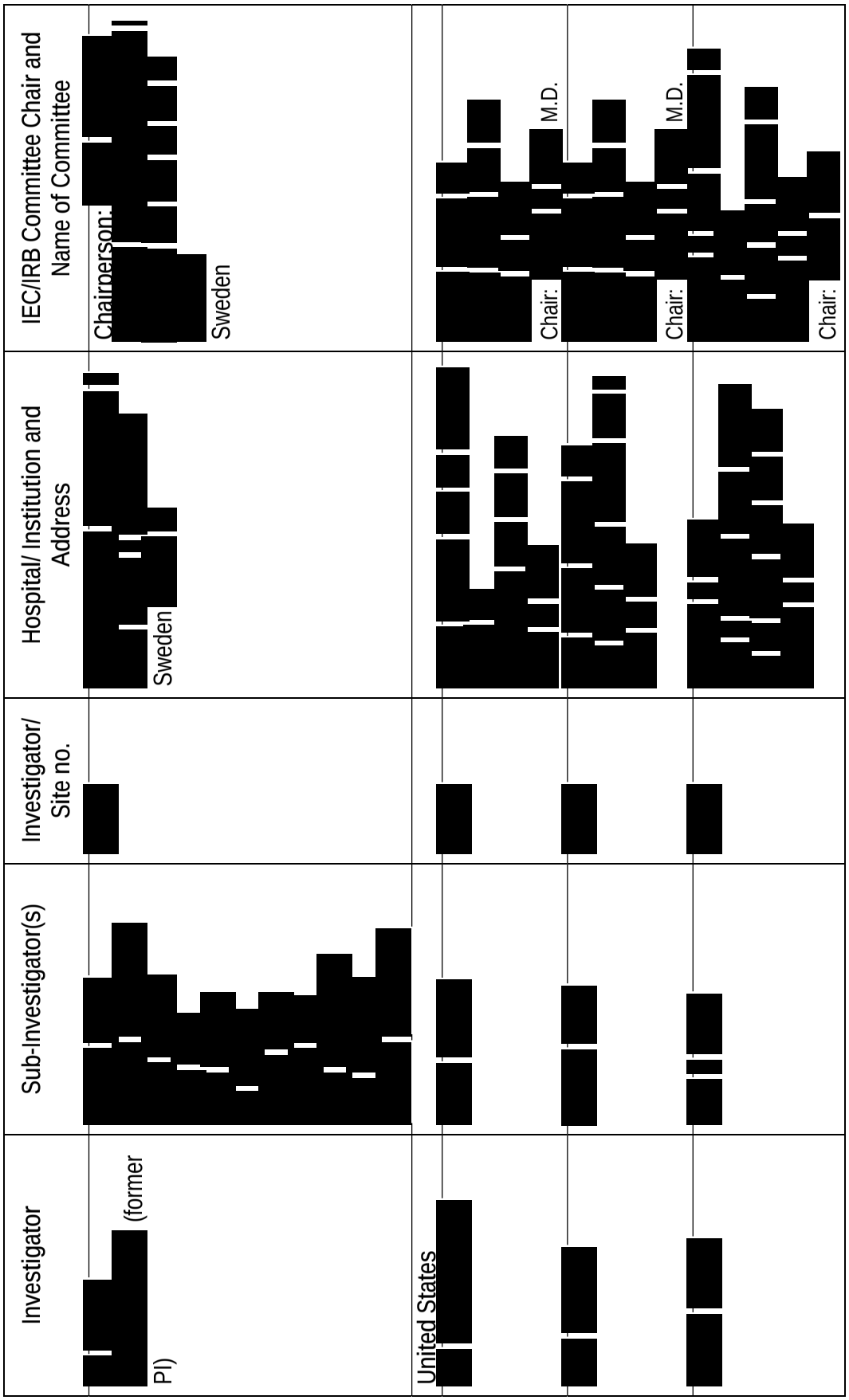
Investigator
(former PI)
United States
Sub-Investigator(s)
Investigator/ Site no.
Hospital/ Institution and Address
Sweden
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Chairperson:
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M.D.
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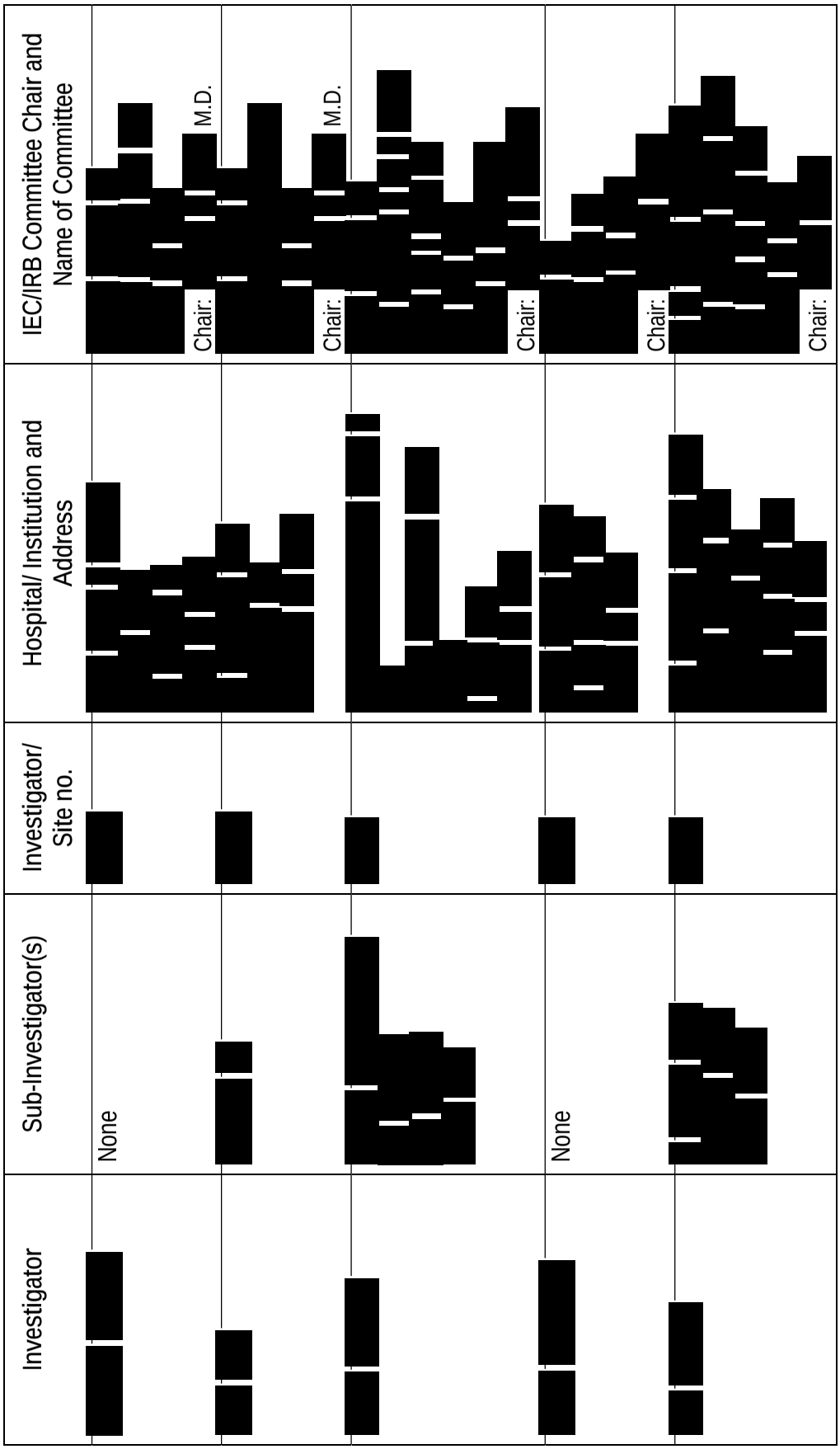
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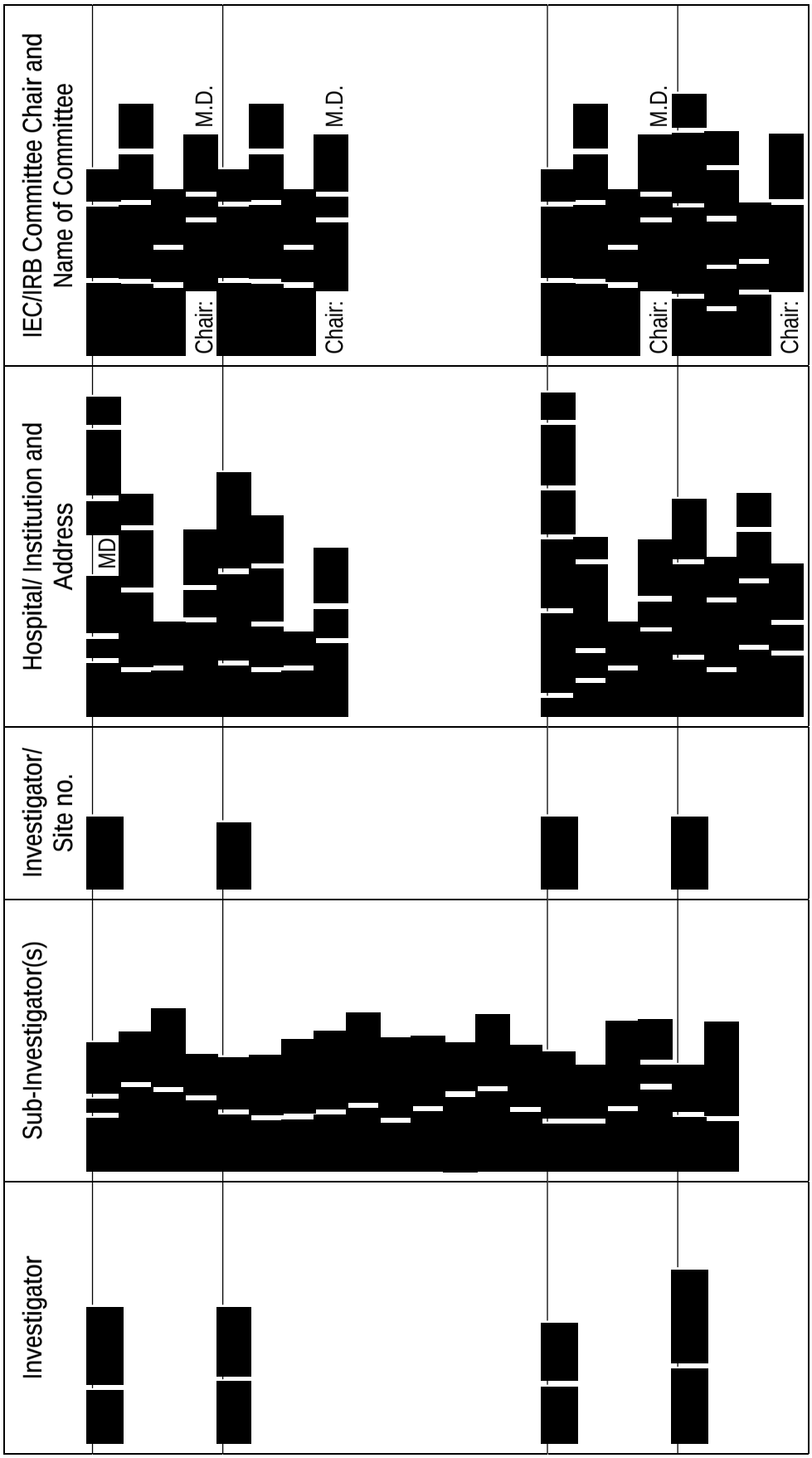
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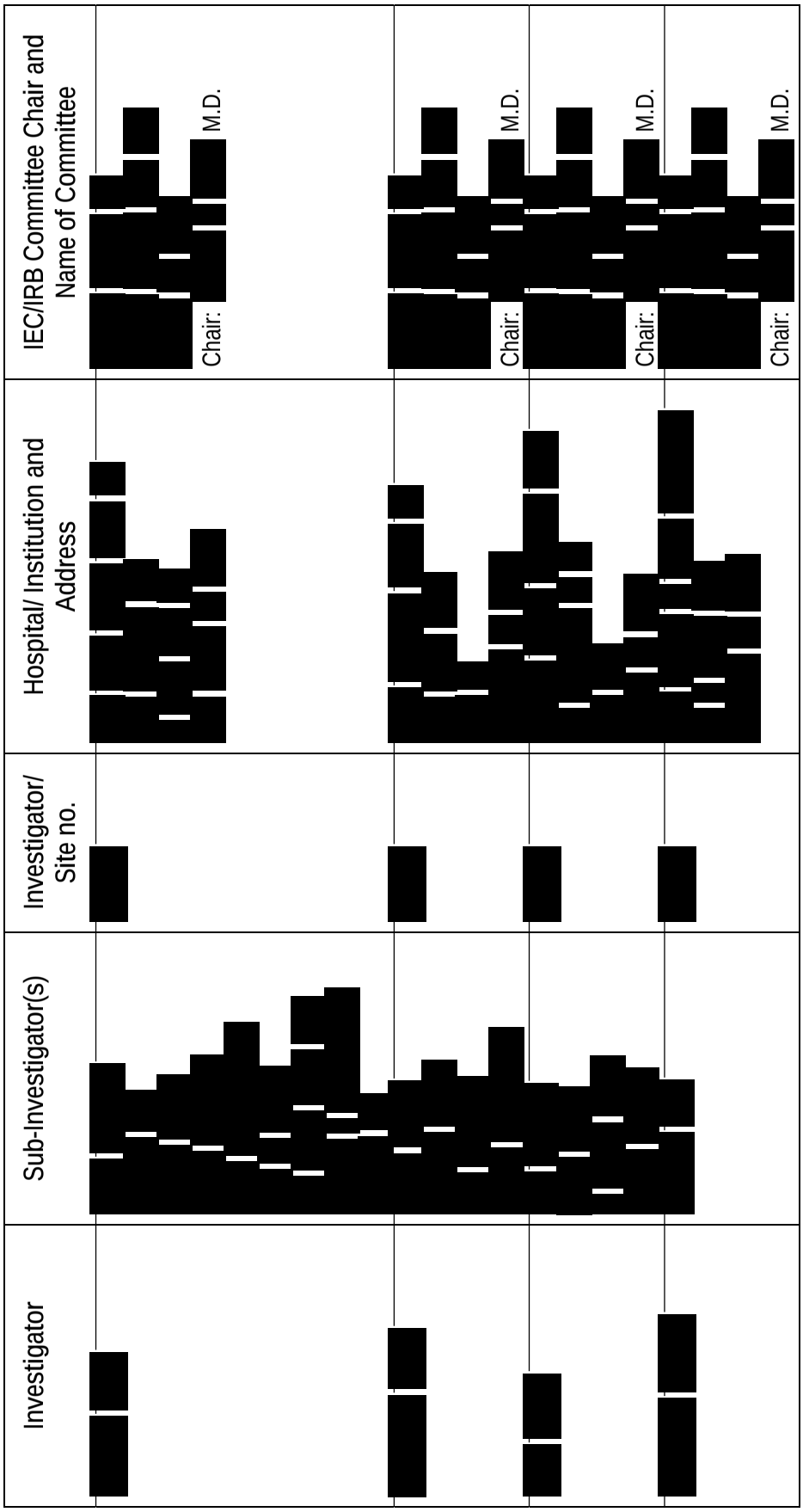
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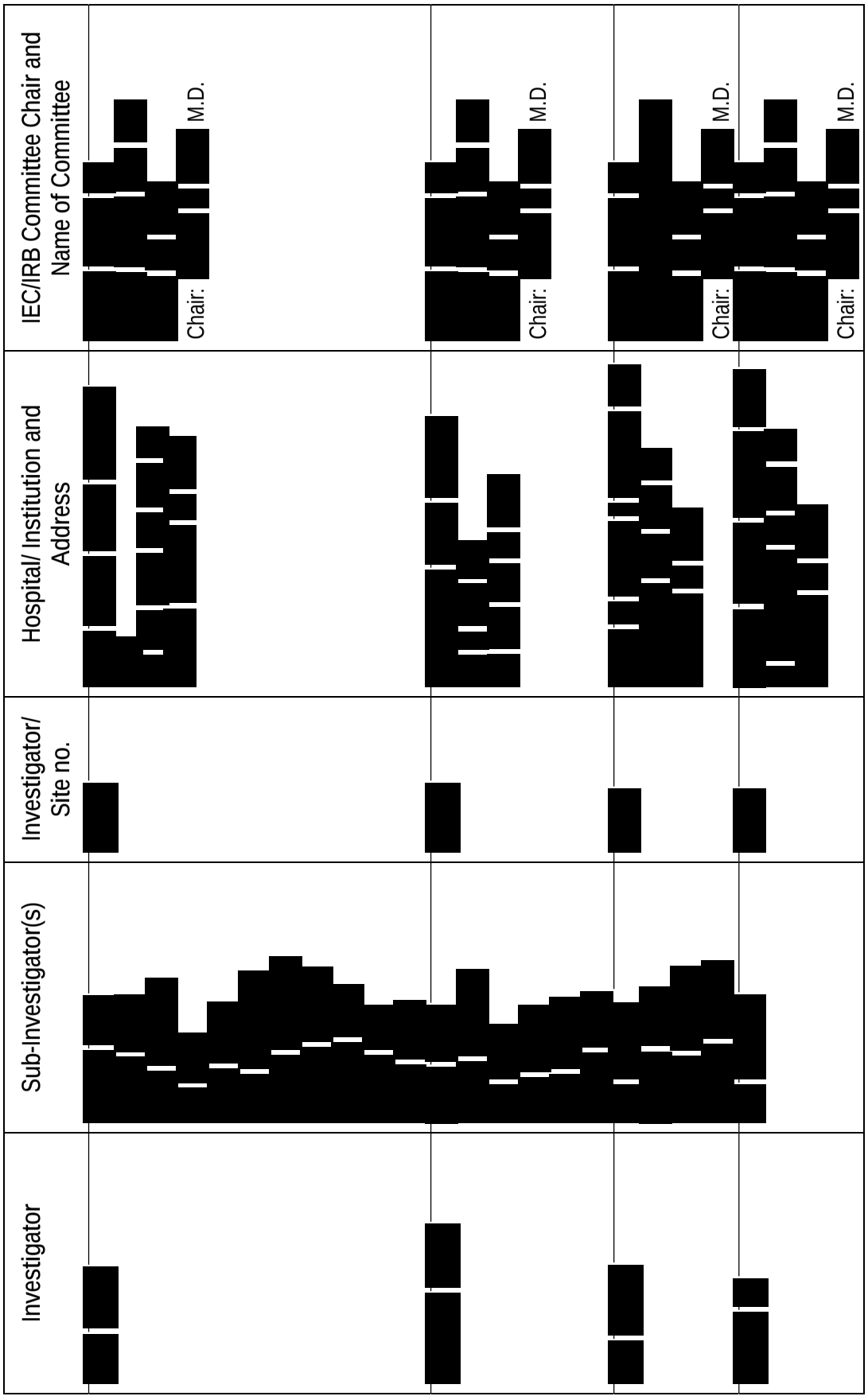
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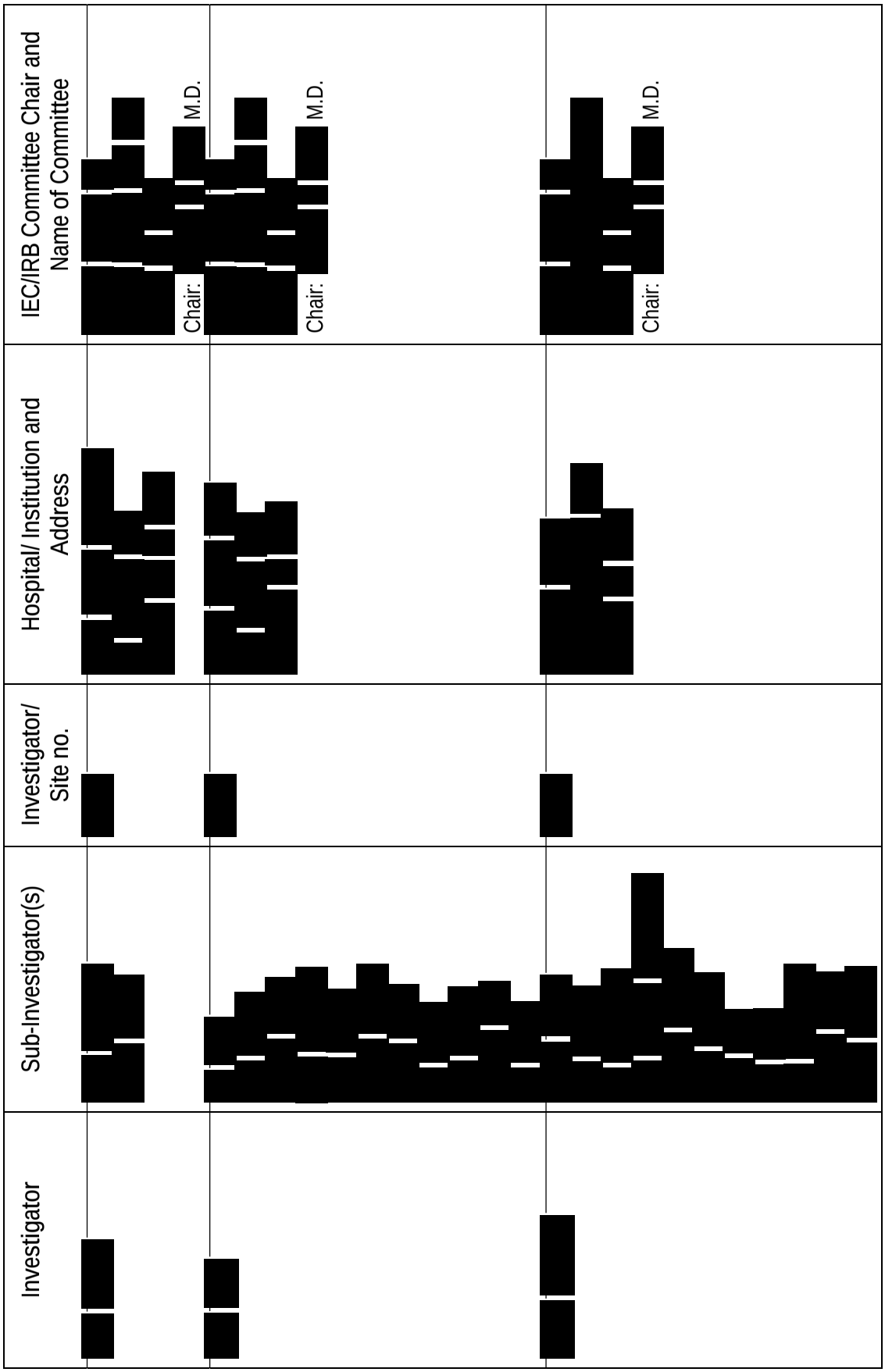
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Hospital/ Institution and Address
Investigator/ Site no.
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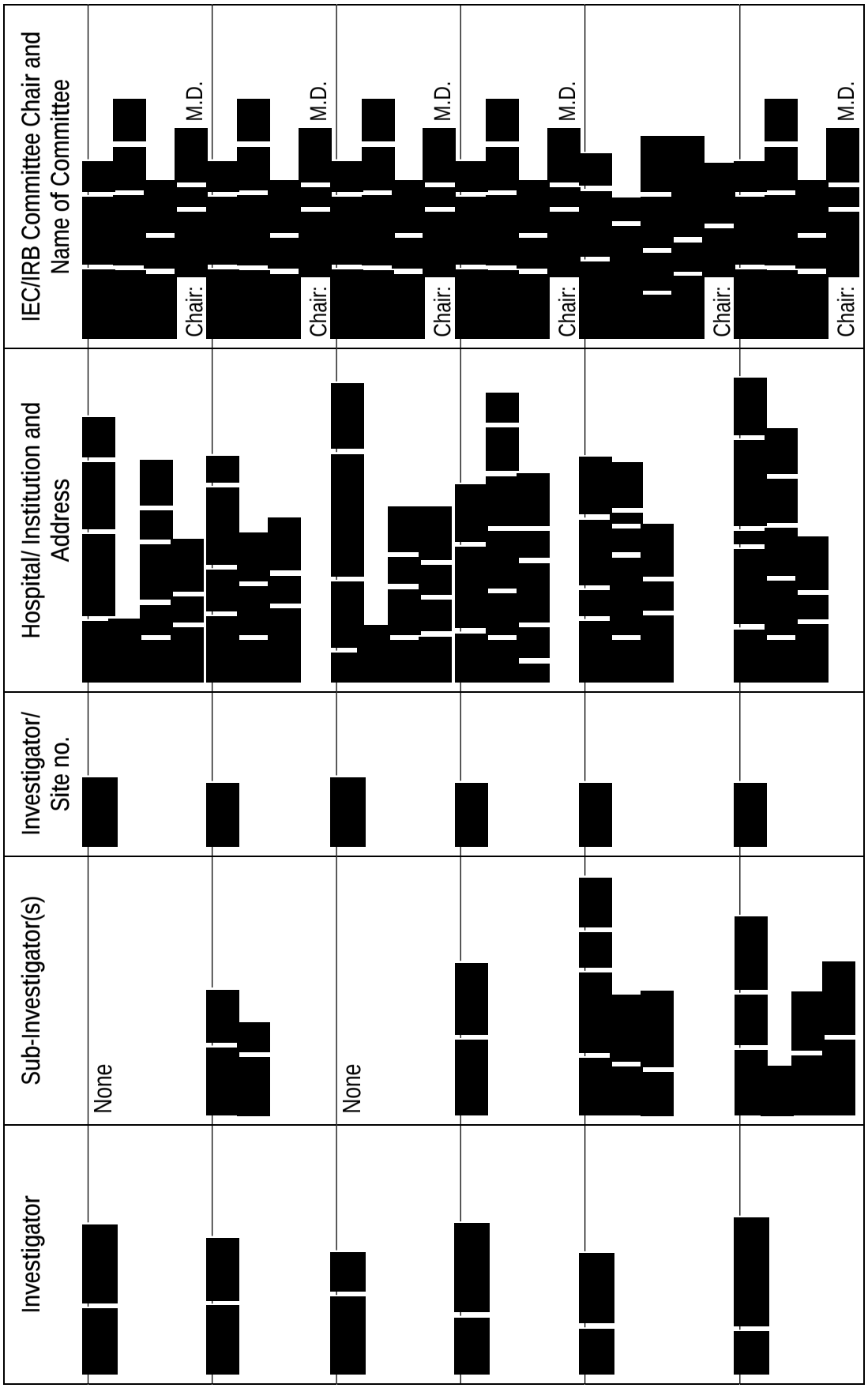
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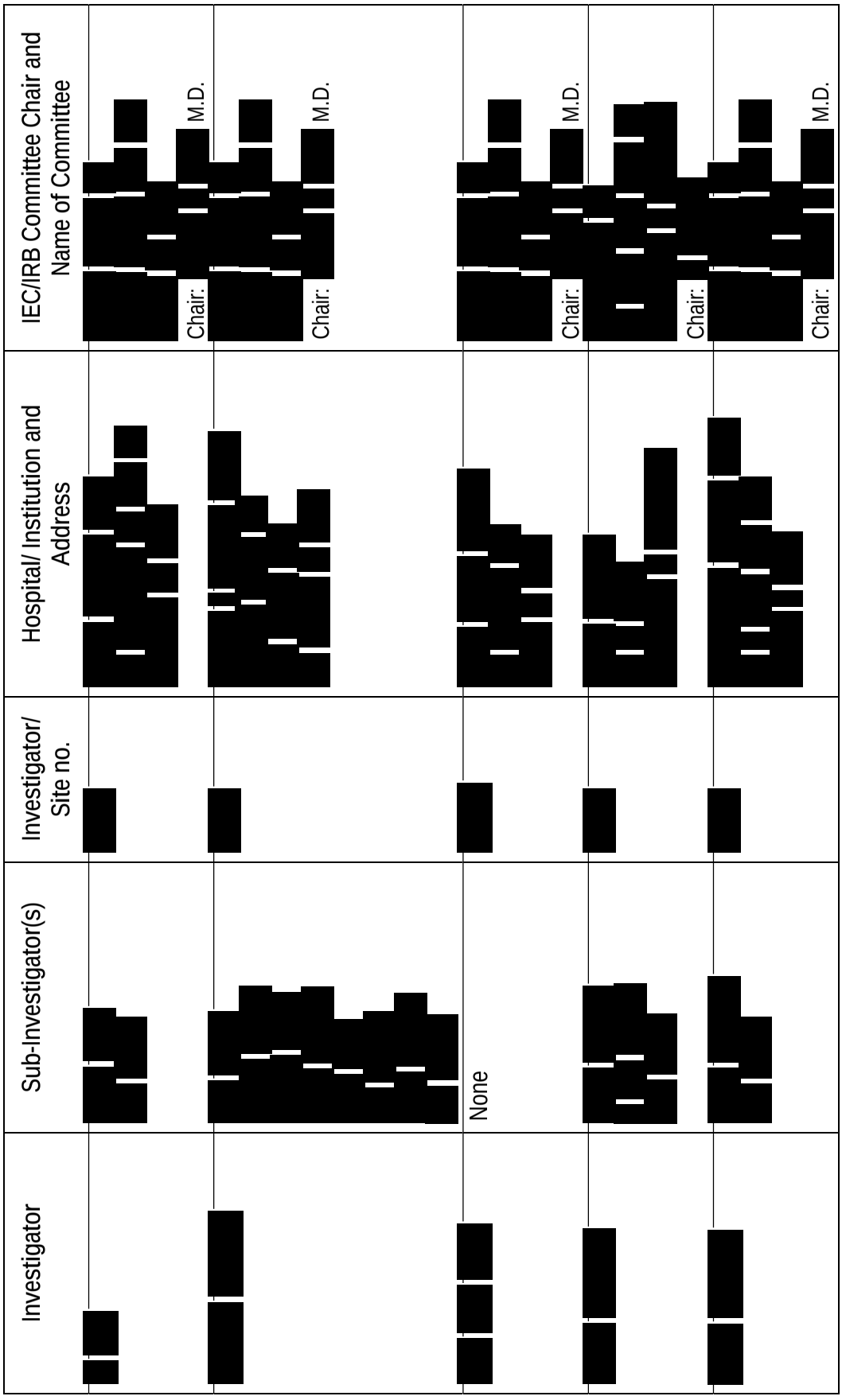
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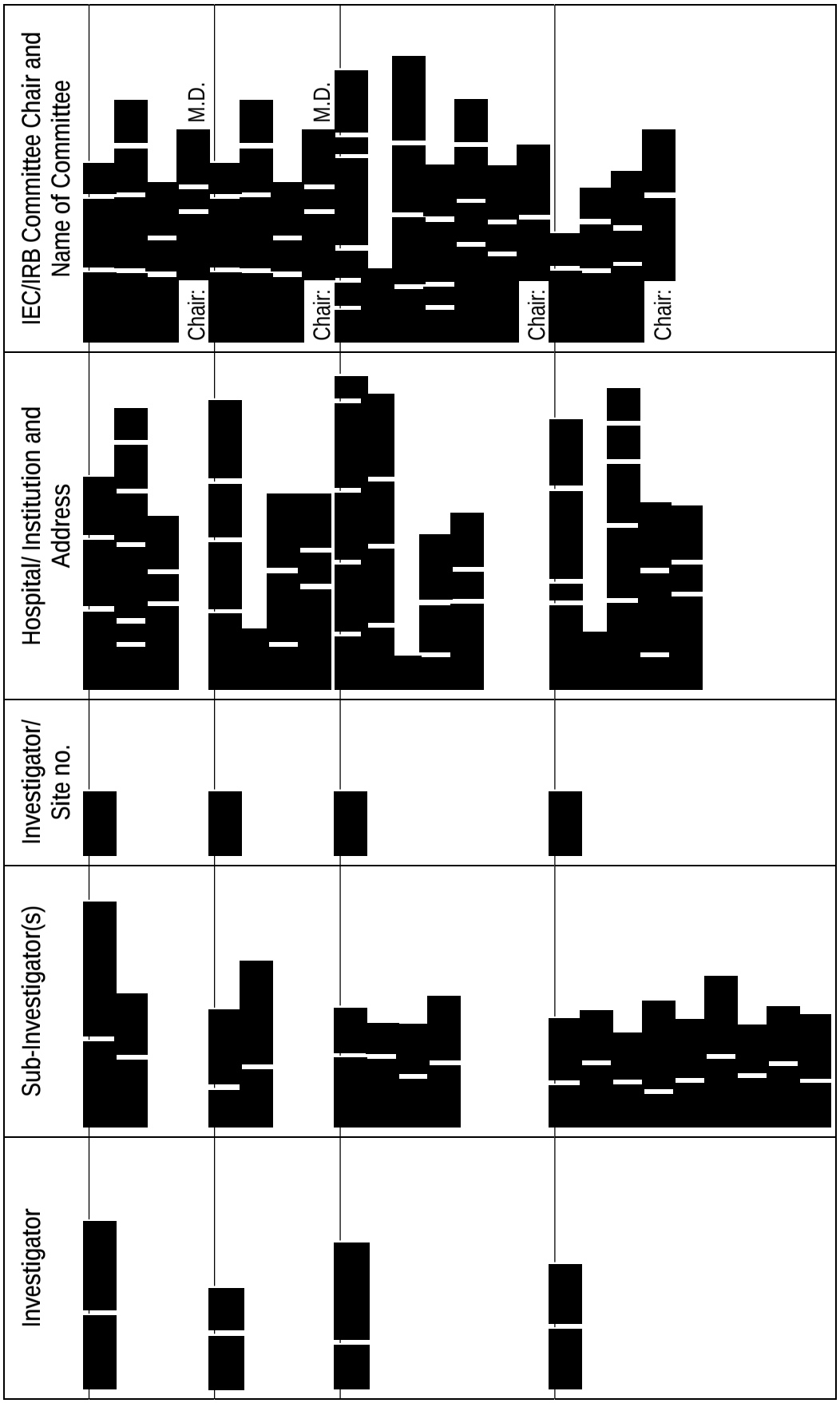
IEC/IRB Committee Chair and Name of Committee
Hospital/ Institution and Address
Investigator/ Site no.
Sub-Investigator(s)
Investigator
M.D.
Chair:
M.D.
Chair:
Chair:
Chair:
* Did not randomise subjects

This section contained Principal Investigator's Curriculum Vitae and has been excluded to protect Principal Investigator privacy.

CONFIDENTIAL

Written Informed Consent Form

Study Identification: DPB100925

Study Title: A 12-Week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects With Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension.

Version Number: 2 Date: 13-Mar-2005

Company Name: GlaxoSmithKline

Subject Identification: Insert subject ID here

The consent form may contain words and/or phrases you do not understand. Please ask your study doctor or study nurse to explain any information that is not clear to you.

You will receive a signed copy of this consent form for your records.

The study doctor and/or the institution is /are paid to conduct this research study by GlaxoSmithKline.

Purpose of Study

You have been asked to take part in a clinical research study to find out whether a new investigational product, GW823093, is effective in helping people like you control their blood sugar. You are being asked to take part in this study because you have type 2 diabetes mellitus and are between 18 and 75 years old.

Before you decide whether to participate it is important for you to know why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it, if you wish, with friends, relatives and your personal doctor (i.e., general practitioner or primary care physician). Ask the study doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

If you qualify and agree to participate in this study, the study doctor or nurse will inform your primary care physician that you are participating in a clinical study if you do not object.

Description of the Study

GW823093 is an investigational drug that is being developed to treat type 2 diabetes mellitus. It works by lowering your blood sugar level. If you decide to take part in the study, you will need to come to the clinic for 19 visits over an approximately 31 week period. This study is aimed at determining the best dose to be used in the treatment of diabetes. Approximately 366 subjects at about 100 centers in North America and Europe are expected to take part in this study.

If you qualify and agree to take part, you will be assigned by chance to one of the following 6 total daily doses in the first 12-weeks of ("Main Phase") the research study:

1) 2.5 mg
2) 7.5 mg
3) 15 mg
4) 30 mg
5) 45 mg
6) Placebo (inactive substance)

Regardless of the group you are in, you will need to take three capsules a day to make the total daily dose of medication you will have been assigned. You will be given three bottles of study medication and you will have to take 1 capsule from each bottle within one hour of waking up and right before your breakfast, for the entire duration of the study. The study doctor or clinic staff will give you special dosing cards that will help remind you to take your study medication as instructed.

There is a one-in-six (about 17%) chance you will be placed into the placebo group and neither you or the study doctor will know which group you are in and whether you are taking active investigational product or not. Placebo is a capsule that does not contain active medication and is important for the validity of this protocol. Regardless of the group you are placed in, at some point in the study everyone in the study will receive placebo. Even though the study doctor does not know what group you are in, in case of emergency the study doctor can rapidly find out what you are taking, if needed.

The treatment period of this study is made up of two separate parts called the "Main Phase" and the "Extension Phase." Each part consists of approximately 12 weeks of treatment. Everyone in the study will participate in both parts of the study. If you are chosen, by chance, to be in the Placebo (inactive substance) group for the first part of the study you will be automatically switched to the 2.5 mg capsule group in the "Extension Phase". If you are chosen, by chance, to be in any other group besides the Placebo group

you will remain in the same group and be taking the same amount of study medication for both treatment parts of the study.

There are certain medications you must not take during the study. The study doctor or staff will tell you about these medicines and which of these you must stop before you can participate in this study. You will also be told which medicines you may continue to use during the study. You should ask the study doctor or staff right away if you have any questions about what medicines you can or cannot take while you participate. You should not change medicines, the amount of medicine you are taking or start taking a new medicine while you are in the study until you speak with your study doctor or if instructed to do so by your doctor in the case of an emergency. If you need to change your medicine or start a new medicine while you are in the study you should contact the study doctor right away.

Procedures

Altogether there are three main periods in the study: Screening Period (2 visits - Visits 1 and 2), Treatment Period (16 Visits - Visit 3 through Visit 18), and Follow-up Period (1 visit - Visit 19). You may be in the study for a total of 31 weeks and will come to the office for 19 scheduled visits to your study doctor.

From 11 p.m. on the evening before each study visit (except Visit 1), you will be asked not to eat or drink anything except water. This is because you will have lab tests done the next morning in the clinic that could be affected if you were to eat or drink anything after 11 p.m.

You will have an ECG (a painless tracing of your heart rhythm) six times during the course of the study (at Visits 2, 5, 9, 12, 16 and 18).

About 28 ounces, or about 54 and ½ tablespoons of blood will be taken out of your arm during the whole study if you come to the center for all of the 19 visits.

In addition to the blood samples collected in this study for immediate laboratory testing, the study staff will collect exploratory blood samples for freezing at Visits 5, 9, 12 and 18 (or your final visit) and extra blood samples at Visits 2, 5, 9, 12, 16 and V18 (or your final visit). Researchers will freeze these exploratory blood samples and put them in long-term storage for future testing of markers (characteristics) specific to type 2 diabetes to better understand this disease and its long-term complications. Researchers will analyze the extra blood samples throughout the study to gather more information about the drug being tested. No genetic testing will be done on any of these samples.

Visit 1 (Pre-Screening)

Before you enter this study, you will be screened to see if you are eligible to participate. At this first visit you will be asked about your medical history and your current medical conditions. You will have blood drawn for laboratory tests that will help the study doctor determine if you are eligible to take part in the study. If you are pregnant, lactating, breast feeding or planning to become pregnant you will not be allowed to enter the study.

Visit 2 (Screening)

About 1 week after your pre-screen visit, you will again be screened to see if you are eligible to participate in the study. At this second visit your vital signs (blood pressure and pulse) will be taken, your height and weight will be measured and you will have a complete physical exam. You will have an ECG (a painless tracing of your heart rhythm). You will be asked about your medical history, your current medical conditions and your use of alcohol. If you are female, you will be asked about which contraceptive method, if any, you use. You will have blood drawn for laboratory tests, lab tests for storage and a pregnancy test for women of childbearing potential. If you are pregnant, lactating, breast feeding or planning to become pregnant you will not be allowed to enter the study. You will also provide a urine sample for laboratory tests. If you are currently taking any medication for your type 2 diabetes and you agree to participate, you will be asked to stop taking those at Visit 2, and you should not take them for the rest of the study. Your study doctor will ask you about any prescription medications you may be taking and he or she will let you know what medications you will be allowed or not allowed while you choose to participate in the study. Also, you will be asked to stop taking any over-the-counter medications you are taking, including vitamins and herbal medications, and should not take them for the time you are in the study. You should discuss this with the study doctor and your regular doctor if you have any questions.

Regardless of the group you are placed in, at some point in the study everyone in the study will receive placebo. This means that for a defined period you will not be taking any medication to control your blood sugar. This is an important and planned part of the study and the study doctor will carefully monitor your test results and you will be withdrawn from the study if your blood sugar rises to unsafe levels. Your home glucose monitoring is an important safety measure in the study. You should measure your blood glucose at home as instructed and notify the study doctor immediately if your blood sugar levels get near 270 mg/dL or a number decided upon by the study doctor.

You will be given diet and exercise advice at every visit in the study (except visit 1). It is important that you follow this advice carefully and notify the study doctor if you are unable, for whatever reason, to follow the diet and exercise advice you will have been

given. Appropriate diet and exercise for the person with type 2 diabetes mellitus can help reduce blood sugar levels and proper diet and exercise advice should be followed.

Visits 3 through Visit 18 (Treatment Period)

If you are eligible to take part in the study, you will come back to the office within about one week after the second visit for your next visit. Your study doctor will again ask you about any prescription medications you may be taking. You should discuss this with the study doctor and your regular doctor if you have any questions.

At this visit (Visit 3), and then again during the course of the study, you will have a physical exam. At all study visits your heart rate and blood pressure will be measured and blood and urine samples will be taken for laboratory tests and storage. You will be weighed at every visit during the study, and waist and hip measurements will be taken occasionally throughout the study. If you are a woman of child bearing potential, pregnancy tests will be done throughout the study to make sure you are not pregnant. You should tell the study doctor immediately if you know or suspect that you have become pregnant during your participation in the study. You will also be asked if you have experienced any changes in your health or taken any new medications since your last visit. You will have an ECG (a painless tracing of your heart rhythm on paper) .

<u>GLUCOSE AND HYPOGLYCEMIA LOGS</u>

You will receive a glucose meter and test strips during this study. You will be instructed on the proper use of the glucose meter. Every morning during the study, *before* breakfast you should measure your blood sugar level. It is best to test your blood sugar right when you wake up, before you have juice, coffee or anything else to eat or drink, and before you take the investigational product. The site staff will also give you a diary card called the “GLUCOSE LOG” where you will write the results of your blood sugar tests. The clinic staff will review the results of your morning blood sugar tests with you at each visit to the clinic.

If your blood sugar level is above 270 mg/dl [15 mmol/L] on more than two consecutive days (taken by you in the morning before breakfast at home) during the study, you should call the clinic as soon as possible to discuss it with them. You should first repeat the test yourself before calling the clinic. They may need you to come in to the clinic for a blood test to make sure that level is correct. This is very important for your safety. If your blood sugar cannot be adequately controlled on the investigational product to which you have been assigned, the study doctor may withdraw you from this study. If you are withdrawn from this study because your blood sugar is not well controlled according to study defined guidelines, your study doctor will recommend alternative treatments for control of your type 2 diabetes mellitus.

You will be instructed on signs and symptoms of hypoglycemia (or low blood sugar). These signs and symptoms may include dizziness, shakiness, or nausea. While taking the investigational product, anytime that you experience symptoms of hypoglycemia, you will be asked to measure your blood sugar level and record this result on a diary card called the "HYPOGLYCEMIC SYMPTOMS LOG". You will also be asked to record the date of this blood sugar measurement along with the hypoglycemic symptom experienced. You must bring the HYPOGLYCEMIC SYMPTOMS LOG to all study visits.

At every visit except the final visit to the office, you will meet with a staff member who will give you advice on diet and exercise.

Starting with Visit 3 and repeated at every visit during the study (except for the final visit); you will be given the investigational product and instructions on how to take the medication. During the course of treatment you must take the study medication exactly as directed and return the unused medication, including the container, to your study doctor at the next visit. You should take the investigational product within one hour of waking up, except on days when you come to the clinic. On those days you should not take the investigational product but should bring it in with you to the clinic.

Pharmacokinetic Testing
During the course of clinical research it is necessary to understand how investigational products are used and distributed throughout the body. This is called the study of pharmacokinetics or PK. Essentially PK is the understanding of what happens to the investigational product once it is taken into the body.

There are 2 kinds of PK testing (Intensive and Sparse) that will be done in this study. You will be asked to participate in one or the other but not both *(Site will choose either one of the following paragraphs depending on what will have been agreed before hand)*

Intensive PK testing

For this test, you will be asked to come to the study clinic early on visits 5, 10 and 12. At the selected visits you will have blood drawn before you take your study medication in the clinic and then at specified intervals after you have taken your study medication and eaten a meal provided by the clinic. You will have ten (10) total blood samples (2 mL per sample) taken by means of a needle in your vein at each PK visit over the course of 8 hours. You will be asked to remain in the clinic for the duration of your PK visit and will be asked to not eat or drink anything except for that provided by the study staff. You

should discuss the intensive PK testing with the study staff and make sure that all of your questions are answered.

Sparse PK testing

For this test, you will be asked to provide an additional six blood samples (2 mL each) over the course of the study. At three specified visits (Visit 6, Visit 12 and Visit 17) you will have blood drawn (2 mL) in the clinic before you take your study medication. You will then need to provide 3 additional blood samples at the visit(s) of your choosing. You will have the option to have all of your post-dose sparse PK blood samples taken at a single visit or you may choose to have them taken at separate visits. The study staff can help explain this to you. Sample 1 will have to be obtained between 30 minutes and 1.5 hours after the morning dose of the experimental medication. Sample 2 will have to be obtained 2 to 4 hours post-dose and Sample 3 will be 6 to 10 hours post-dose. You will be asked to either remain in the clinic or to return to the clinic for the next PK sample. You should discuss the sparse PK testing with the study staff and make sure that all of your questions are answered.

Visit 19 (Follow-Up Phase)

One week after completing the 30 weeks of Screening and Treatment, you will be asked to return to the clinic for a follow-up visit. Blood and urine samples will be taken for laboratory tests, your blood pressure and heart rate will be measured and you will be asked whether you have experienced any health problems or bad effects, or taken any new medications since your last clinic visit.

After the follow-up visit, you will have finished the study.

Early Termination (Completed only if you stop the study after you receive the study tablets at the initial treatment visit)

If for any reason you complete Visit 2, but do not complete the entire study, you should make every attempt to return to the clinic to complete the following procedures:

Physical examination, vital signs (blood pressure and pulse), weight, waist and hip measurements, ECG, blood and urine samples for laboratory assessments, pregnancy tests for women, report of adverse events, report of new medications taken and return of study medication (if already dispensed).

Risks or Discomforts

Your condition may not improve, or it may worsen, while taking the investigational product.

General risks associated with type 2 diabetes and the investigational product:

High Blood Sugar

It is possible that an increase in blood sugar (hyperglycemia) could occur while taking investigational product. Typical signs of hyperglycemia that would be seen in people with type 2 diabetes include:

- intense thirst
- dry mouth
- a need to urinate frequently
- a loss of appetite
- blurred vision
- dry skin
- weakness
- sleepiness
- confusion

Lack of control of high blood sugar in the long-term can lead to other problems over many years, such as:

- blindness
- kidney failure
- changes in sensations (feelings) in your hands and feet

If ignored or untreated, a prolonged severe increase in blood sugar can even lead to serious illness, progressing to coma or death. Therefore, tell your study doctor as soon as possible if you have these symptoms. In addition, you should inform the study doctor at any time your fasting blood sugar is higher than 270 mg/dl [15 mmol/L] on two or more consecutive days (from the home glucose tests you take every morning during the study). During the study, if your blood sugar becomes too high, the study doctor may withdraw you from the study.

Low Blood Sugar

It is possible that using the investigational product could lower your blood sugar too much (hypoglycemia), although there is no clinical or other evidence that the investigational product does this. Low blood sugar can make you feel tired, dizzy, and/or nauseated (sick to your stomach).

Other typical signs of low blood sugar include:

- hunger
- sweating
- palpitations (fast or irregular heart beats)
- tremor (shakiness)

These symptoms can be treated in the short term by eating sugary foods/drinks. If necessary, the study doctor may withdraw you from the study so that you can be treated with another medication chosen by your study doctor or regular doctor.

If ignored or untreated, a prolonged decrease in blood sugar can lead to serious consequences, the worst cases being coma or death. Therefore, your study doctor should be told as soon as possible if you have these symptoms. During this study, you should measure your blood sugar anytime you experience symptoms of hypoglycemia and then record the blood sugar result in the HYPOGLYCEMIC SYMPTOMS LOG.

Results from previous studies with GW823093 in human volunteers

In studies that have been conducted giving GW823093 to people, GW823093 was well tolerated by volunteers and people with type 2 diabetes mellitus at single doses up to 50 mg and multiple doses up to 45 mg for 10 days in a row. The highest dose that you may be given in this study is 45mg. In the clinical studies to date the most frequent complaints from people taking GW823093 were headache, nausea and fatigue. None of these complaints were considered serious by the study doctors involved. The drug has not caused any changes that were of clinical significance on cardiovascular (heart) measures or in clinical laboratory tests of a variety of organs such as the liver and kidneys.

There may be risks, inconveniences or side effects associated with GW823093 that are not known at this time. Any major new findings noticed during this research study which may affect your condition or your decision to stay in this study will be given to you by your doctor.

GW823093 may cause allergic reactions in some people. In general, allergic reactions to medicines are more likely to occur in people who have allergies to other drugs, foods, or environmental elements such as dust or grass. If you have allergies to other medicines, food products, environmental elements, or if you have asthma, you should tell your doctor. Symptoms of allergic reactions may include redness, swelling, or itching. Other allergy symptoms could be difficulty breathing, wheezing or enlargement of the tongue. If you experience any of these, contact the study doctor for a check-up and treatment.

Certain procedures, including office blood pressure monitoring, home glucose monitoring and ECGs are part of the clinical study. While these procedures may be uncomfortable to some people, they present practically no risk to you. Blood pressure and heart rate monitoring would normally be carried out by a doctor or nurse in routine visits to the doctor and present practically no risk to you; ECGs are painless tracings of your heart rhythm on paper; home glucose monitoring has been used by millions of people with diabetes and presents only a minimal risk of infection and slight discomfort when performing the needle stick.

Other risks

Blood samples will be taken. Risks associated with drawing blood with a needle and syringes are pain, bruising at the site of the needle stick, bleeding, and on rare occasions, fainting, lightheadedness and infection. A small amount of blood will be taken at each visit and your body will quickly make up for this small loss.

For Women Only: Women who have had a hysterectomy, bilateral tubal ligation, or are postmenopausal will be allowed to participate in this study. Women who are capable of having children and for whom the following apply may participate in the study:

- You had a negative pregnancy test at screening and throughout the study and:
  - You have a male partner who is sterile prior to your entry into the study **and** is your only sexual partner, **or**
  - You use double-barrier methods of contraception, namely condoms with the use of caps (with spermicide) and IUDs, **or**
  - You use hormonal contraceptives (oral, depots, patches etc.) with double-barrier methods of contraception as outlined above, **or**
  - You abstain from sexual intercourse, **or**
  - You are with a same sex partner and do not participate in bisexual activities where there is any risk of pregnancy.

Since GW823093 is an investigational drug, there may be unknown risks to an unborn or nursing child. If you are a woman of childbearing potential or breast feeding, you should tell your doctor.

Benefits

The investigational product might help your diabetes, but there is no guarantee that this study will help you. Your condition might not improve or might get worse while you are

in this study. You will receive study-related visits, procedures, tests, and investigational product at no cost.

Information gained from this study may help develop new treatments for diabetes patients in the future.

Alternative Treatment

Before you decide whether or not to take part in this study, you may wish to consider other treatment options for your diabetes. There are other ways to treat your condition, including a variety of drugs that have been approved for the treatment of diabetes (such as Glucophage, Glucovance, Amaryl, Diaβeta, Diabinese, Micronase, Avandia, Actos, Avandamet and insulin).

Your study doctor will describe these and possibly other medications to you based on your medical history and the treatment you have received to date.

You do not have to participate in this study to receive treatment for your condition. The study doctor will tell you more about the risks and benefits of participating in this study as compared to the risks and benefits of alternative treatments.

Compensation for Study-Related Injury

If, as part of participating in the study, you are injured by the investigational product GW823093 or study-related procedures done to you in accordance with the study protocol, GSK will pay for reasonable and necessary medical expenses to treat the injury that are not covered by your medical insurance. GSK is not offering to compensate you for any other expenses, but you do not waive any legal rights by signing this consent form. For more information, contact the study doctor or a member of the study staff.

Country Medical Directors to add country-specific text for compensation.

Payment to Subjects

You will be reimbursed $__ for travel expenses per visit for participating. For convenience, these payments will be made at the end of your participation in this study.

If you withdraw or are discontinued before completing this study, or if the study ends early, you will receive a partial payment based upon the number of visits completed.

Expenses/Costs

You will still be responsible for the cost of your usual ongoing medical care, including procedures and/or non-study medications that your study doctor or regular doctor requires during this study as part of your usual medical care. If you have any questions, please ask the study doctor, a member of the study staff, and/or your insurance company.

There are no anticipated costs or expenses to you for participating in this study. You will receive physical exams, ECGs, ambulatory blood pressure monitoring and blood and urine tests at no cost, as a result of being in this study.

Contact(s) for Answers to Pertinent Questions about Research and Subject's Rights and Contact(s) in the Event of an Injury

If you believe you have sustained an injury or believe you have experienced a reaction to the study preparation, or if you have any questions about the research, contact:

INVESTIGATOR~
ADDRESS1~
ADDRESS2~
ADDRESS3~
ADDRESS4~
CITY~, STATE~ ZIP_CODE~
PHONE~

If you have questions concerning your rights as a research subject, you may contact:

IRB
ADDRESS
ADDRESS
PHONE

Termination of Subjects' Study Participation

Although it is not expected, the study doctor may end your participation in this study if he/she decides that it is not in the best interest of your health to continue. Your participation in the study may also be ended if you fail to follow instructions of the study doctor or if the study sponsor stops the study.

Your participation in the study may also be ended if GSK stops the study or stops enrolling new patients into the study while you are in the screening phase of the study (not yet assigned to a study arm).

Voluntary Participation and Subjects Right to End Participation

Your participation in this study is voluntary. If you do decide to take part, you will be given this information to keep and be asked to sign this consent form. You may refuse to take part in this study, or once in the study you may decide to discontinue participation at any time. You must inform your study doctor if you decide to do this. Your decision not to take part in the study or to stop participating in the study will not affect your current or future medical care, or any benefits to which you may otherwise be entitled.

Confidentiality and Data Privacy

Maintaining confidentiality is important to GlaxoSmithKline. Your personal information (for example, your gender, age, the details of your medical conditions) and other information (the data collected by GlaxoSmithKline as part of the study) will be identified by a number (i.e., coded). Your name will not appear in any publications or reports produced from this study.

GlaxoSmithKline will keep the information and the results collected about you in this study. Your name and address are not included in the information kept by GlaxoSmithKline - only your study doctor will keep this information. GlaxoSmithKline has told your study doctor to keep the information about you in a secure place. GlaxoSmithKline will comply with internal procedures to protect personal and other information even in countries where data privacy laws are less strict than in Europe/US.

By agreeing to take part in this research study you will be allowing certain persons to see the information about you (both personal, including your name, and other information) held by the study doctor. Your information will be looked at to confirm that it is correct and that it is related to you. This will be done by selected people working for GlaxoSmithKline and organisations acting on behalf of GlaxoSmithKline, [Include here IECs/IRBs where local practices allow it], and the government regulatory authorities. These persons are required to maintain the confidentiality of your information.

Your information will be processed electronically (i.e., by a computer) or manually and analysed to determine the outcome of this study. GlaxoSmithKline may use your information for other medical/health care purposes related to development of this drug. For this purpose only your coded information will be used.

Your information may/could be sent to regulatory authorities, to the IEC/IRB, to other doctors and/or organisations working with GlaxoSmithKline. It may also be sent to other GlaxoSmithKline sites in this country and in other countries [STILL COMPLETE OTHER COUNTRIES] where there may be different or lesser standards for looking after it. GlaxoSmithKline will apply the same standard in the protection of your information to the extent permitted by law.

You have the right to ask the study doctor about the data being collected on you for the study and about the purpose of these data. You have the right to ask the study doctor to allow you to see your personal information and to have any needed corrections to it made.

Disclosure of Protected Health Information by Subject in the US

As part of the study, medical information about you will be collected and analysed. This medical information can include laboratory blood tests, ECG and your medical history. By signing this document, you authorise the study doctor and staff to use this information in conducting the study, and to provide access to or copies of this information to the study sponsor or to others working with the sponsor to monitor the progress of the study or analyse the study data. Access to this information is necessary for the sponsor to check that the study is being done correctly, and to collect and analyse data about the safety and effectiveness of the investigational product. This authorisation to use or disclose the information as described above is not time-limited (that is, will not automatically expire).

You agree that, while the study is still in progress, you may not be given access to medical information about you that is related to the study. This may include, for example, information about whether you are receiving investigational product or placebo, or any other information that is "blinded" (that is, kept secret during the study to prevent bias). While a request for access to medical information can be denied, the study doctor and staff will not automatically deny a request, but will consider whether it's medically appropriate under the circumstances to allow access. Your agreement that you may be denied access to your study-related medical information during the study will not be used to deny you access to that information after the study is completed at all locations and study results are analysed.

You may decide not to sign this authorisation (by signing this consent form), or you may revoke this authorisation in writing at any time. However, you can only participate in the study if you authorise the use and disclosure of the information as described above. If you decide not to sign this authorisation/consent form, you will not be enrolled in the study. If you sign this authorisation and decide later to revoke this authorisation, you will

be dropped from the study at that time. Information collected up to the time you revoke this authorisation will continue to be used as study data if it is scientifically appropriate to do so.

You should know that, once information is disclosed under this authorisation to someone who is not a health care provider, the information is no longer protected by the federal privacy rules called the "HIPAA privacy regulations" and could be disclosed to others by the recipient. You will be given a copy of this authorisation/consent after you have signed and dated it.

Tissue Samples (including blood)

As a part of the study, blood and urine samples will be collected. These samples will be used to establish your eligibility for entry into the study, monitor your condition during the study, and to gather information about how your diabetes responds to the investigational product.

Any samples stored in conjunction with this study will not be labelled with information that directly identifies you. GlaxoSmithKline will have a key that links the samples to your name and will keep the key separately from the samples. Collected samples may be transferred to GlaxoSmithKline or to other researchers working with GlaxoSmithKline.

Collected samples may be stored and used for other research purposes, such as research into the cause or development of elevated laboratory parameters or research into the understanding of type 2 diabetes.

In addition to the blood samples being collected for immediate laboratory testing, extra blood samples will be collected at Visits 5, 9, 12 and 18. These samples will be frozen and placed in long-term storage for future testing of markers specific to type 2 diabetes to better understand this disease and its long-term complications. No genetic testing will be done on these samples.

The results of research using collected samples may have commercial or intellectual property value. GlaxoSmithKline and/or others will claim sole ownership of any research results consistent with this consent and you will not receive any financial benefit that might come from the research. You agree that GlaxoSmithKline can apply for patents.

Notification of New Information

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, we will tell you about new information that may affect your willingness to stay in this study.

I confirm that I have read the statements in the informed consent form dated [version and date] for this study. I confirm that the study information and procedures have been explained to me by [name(s)] on [date] during the consent process for this study.

I confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.

I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this study.

I agree to take part in this study.

Subject's Signature _____ **Date:** _____

Printed name of Subject _____

***Signature of Legally Acceptable Representative** _____ **Date:** _____

***Printed name of Legally Acceptable Representative** _____

***Signature of Witness** _____ **Date:** _____

***Printed name of Witness** _____

Signature of Person conducting Consent _____ **Date:** _____

Printed Name of Person conducting Consent _____

* Used in accordance with local requirements

Subject Informed Consent Form for Pharmacogenetic Research

GlaxoSmithKline Protocol Title: A 12-Week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects With Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension.

GlaxoSmithKline Protocol Number: DPB100925
Study Doctor: _____
Site Address: _____
_____
_____
Site Phone Number: _____
Subject Number: _____

This form is in addition to the consent form you signed for the clinical study for DPB100925.

Purpose and Description of the Research
The purpose of this consent form is to explain what pharmacogenetic research is and to ask you to give a blood sample that may be used in this research. The sponsor of the research is the GlaxoSmithKline group of companies [referred to as GSK in this consent].

Pharmacogenetics is the study of differences in how our bodies react to or handle medicines. Your genes, pieces of genes, or genetic material may have an effect on how your body responds to or handles a medicine. If it appears that there is a difference in response to or handling of GW823093, GSK may study these differences using your genes, pieces of genes, or genetic material taken from your blood sample. In special cases, your sample may not be used. This might happen if there are not enough subjects, if the study is stopped for other reasons, or if no questions are raised about how people respond to or handle GW823093.

The study doctor and institution are paid by GSK to conduct this research. This study will have about 366 subjects at about 100 sites in North America and Europe.

Procedures
If you agree to take part in this research, a trained person will take about *10 ml (or 2 teaspoons)* of your blood. If there is a problem processing your sample, then we may ask you to give another sample.

Voluntary Participation
Participation in this pharmacogenetic research is voluntary. You may withdraw from this research at any time. GSK may keep your sample for up to 15 years after the last subject completes the study or GSK may destroy your sample before then. You may decide not to take part now or you may decide to take part and then change your mind. If you decide not to take part or to withdraw after starting the study, you do not have to give a reason and there will be no change to your medical treatment or to your participation in the GW823093 study. If you

withdraw from this research, your sample will be destroyed and GSK will only keep and study information collected/generated up to that point.

Alternatives
You have the choice not to take part in this research.

Benefits
There will be no direct benefit to you by taking part in this pharmacogenetic research. You may help scientists understand why people react to or handle GW823093 differently. This may help identify people who are more likely to respond to or experience side effects from GW823093.

Risks and Discomfort
The physical risks of giving this blood sample are the same as those for any blood sample taken from a vein. You may feel faint, experience mild pain, bruising, irritation or redness at the site of puncture. In rare cases, you may develop an infection.

Another risk of this research is the possibility of someone not involved in the research finding out your research results or that you took part in this study. GSK has taken reasonable steps to keep your research information confidential. However, if you let others know that you took part in this research or your research results (if obtained by you); there is a possibility that this could affect your insurance or employment.

Compensation for Study-Related Injury
If you are physically injured by the properly performed blood draw and you have followed the directions of the study staff, the sponsor will cover the reasonable medical expenses necessary to treat the injury. No other compensation is offered by GSK, but you do not waive any legal rights by signing this consent form.

Privacy
To protect your privacy, your sample and medical information will be labeled (or "coded") with your study subject number, not your name. Your study doctor and his or her staff will keep the link between your subject number and your name.

Your study doctor has been told to keep your pharmacogenetic information including your consent in a separate, secure file, which is **not** part of your medical records. GSK will control access to its files that hold your information and results. Your name will **not** be in any publications or reports about this research.

GSK or those working with GSK (for example, other researchers) will only work with your sample for the use stated in this consent. Samples will be stored securely. GSK will require anyone who works with your sample to agree to hold the research information and any individual results in confidence.

If your sample is studied, your study doctor and his or her staff may have access to your pharmacogenetic research results. Your individual results will only be shared with you through the study doctor if you request to see the results and it is a requirement of a governmental agency

or other legal authority that GSK make these results available. GSK will not release individual results to anyone else (e.g., family members, primary care physicians, insurers, or employers) under any circumstance, unless required by law. Your results are not for clinical diagnosis or treatment.

Medical information, samples and research results from you and other research participants may be studied by GSK to make medicines or tests to determine the body's response to or handling of medicine. Your information and any results will be put on a computer and stored in electronic databases. International regulations for information on computers and relevant laws on processing personal information will be followed. Your information, sample, and results could be sent to other researchers working with GSK and to other GSK sites.

By agreeing to take part in this research, you will allow your medical information, sample, and pharmacogenetic results to be checked as part of collecting and analyzing study results. The people who may check this research include GSK, people working with GSK on this research, ethics committees *(US - institutional review boards)*, and regulatory authorities *(US – such as the FDA; Europe – such as the EMEA)*.

Disclosure of Protected Health Information
Authorization to use or disclose your medical information as described above is not time-limited (that is, will not expire). If you decide not to sign this consent, you will not be included in the study. You may withdraw this authorization at any time in writing. If you sign this consent and decide later to withdraw the authorization, you will be withdrawn from the study at that time. Information collected up to the time you withdraw your authorization will continue to be used as study data. Once information is disclosed under this authorization to someone who is not a health care provider, the information is no longer protected by the US privacy rules (called the HIPAA privacy regulations) and could be disclosed to others by the recipient.

Compensation
You will not receive any payment for taking part in this pharmacogenetic research.

Commercial Issues
GSK and/or others intend to claim sole ownership of any research results consistent with this consent. The results of this research may have commercial or intellectual property value. You agree that GSK can apply for patents. You will not receive any financial benefit that might come from the research.

Contact Name
Contact _____ at telephone number _____ at any time if you have questions about this study, an injury related to the blood draw for this research, or withdrawal from this research. For questions about your rights as a research subject, contact _____ of the *Institutional Review Board/Ethics Committee* at telephone number _____.

CONSENT

A copy of this Consent Form (signed and dated) must be given to the subject or legal representative.

My signature below indicates that:
1. I have read this form and the research has been explained to me.
2. I have been able to discuss the research and ask questions. I am satisfied with the answers.
3. I have been given the time to consider whether or not to take part in this research.
4. I voluntarily agree to take part in this research.

Subject's Name: _____ **(*Please Print*)**

Subject's Signature: _____ **Date:** _____
(*or that of Legal Representative*) **(Day/Month/Year)**
(*Written by Subject or Legal Representative*)

Individual Obtaining the Subject's Consent:

Name: _____ ***(Please Print)***

Signature: _____ **Date:** _____
(Day/Month/Year)

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Treatments and Sequences defined for study

		Treatments	
Sequence	**Code**	**Description**	**Period**
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	A	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	B	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	C	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	D	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	E	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	F	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1

Schedule Summary

Schedule No.	Created by	Lock 1	Lock 2	Blind Status
1	[redacted]	Locked	Locked	Unblinded

Report generated by: [redacted] **on:** 01-SEP-2006

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Schedule Details

Schedule: 1

Date Generated: 21-DEC-2004
Date Unblinded: 31-MAY-2006
Generated by: [redacted]

Stratum	Block Size	Rand. No. Range	No. in Range	Seed
male and drug naive	6	[redacted]	498	8098509
female and drug naive	6		498	6182901
male and prior oral monotherapy anti-diabetic agent	6		498	2486393
female and prior oral monotherapy anti-diabetic agent	6		498	1814921

Allocation Ratios for male and drug naive

Treatment Sequence	Ratio
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1

Allocation Ratios for female and drug naive

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Treatment Sequence	Ratio
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1

Allocation Ratios for male and prior oral monotherapy anti-diabetic agent

Treatment Sequence	Ratio
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1

Treatment Sequence	Ratio
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1

Allocation Ratios for female and prior oral monotherapy anti-diabetic agent

Treatment Sequence	Ratio
15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	1
2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	1
30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	1
45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	1
7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	1
Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	1

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Schedule No: 1
Stratum male and drug naive

Randomisation Number	Treatment / Sequence
[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by

Randomisation Number	Treatment / Sequence
[redacted]	15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg	[redacted]	GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg
[redacted]	GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by

Randomisation Number	Treatment / Sequence
[redacted]	15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by
[redacted]	2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Schedule No: 1
Stratum female and drug naive

Randomisation Number	Treatment / Sequence
[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase

Randomisation Number	Treatment / Sequence
[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg	[redacted]	GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg	[redacted]	GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase

Randomisation Number	Treatment / Sequence
[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase

Randomisation Number	Treatment / Sequence
[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Schedule No: 1
Stratum male and prior oral monotherapy anti-diabetic agent

Randomisation Number	Treatment / Sequence
[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by
[redacted]	45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by
[redacted]	30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg
[redacted]	GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase	[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase		Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase		30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase		45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase		30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by	[redacted]	2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

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Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the

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Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

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Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

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Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg
[redacted]	GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

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Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by

Randomisation Number	Treatment / Sequence
[redacted]	30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Schedule No: 1
Stratum female and prior oral monotherapy anti-diabetic agent

Randomisation Number	Treatment / Sequence
[redacted]	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by

Randomisation Number	Treatment / Sequence
[redacted]	30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

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Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the

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Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the

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Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

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StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by	[redacted]	30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase	[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg	[redacted]	GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	[redacted]	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by	[redacted]	45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
[redacted]	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase
	7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase
	15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase
	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase
	2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg	[redacted]	GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by	[redacted]	7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase	[redacted]	Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by	[redacted]	15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence	Randomisation Number	Treatment / Sequence
[redacted]	extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase	[redacted]	45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase

Master Schedule Detail Report

StudyID: *DPB100925*
Description: *A 12-week, parallel-group, double-blind, randomized, placebo-controlled, dose ranging study to evaluate the efficacy, safety and tolerability of GW823093 administered as monotherapy in subjects with T2DM, followed by a 12-week active treatment extension.*

Randomisation Number	Treatment / Sequence
[redacted]	followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by
[redacted]	30mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase 30mg GW823093 in the main phase followed by 30mg GW823093 in the extension phase Placebo in the main phase followed by 2.5mg GW823093 in the extension phase 7.5mg GW823093 in the main phase followed by 7.5mg GW823093 in the extension phase 15mg GW823093 in the main phase followed by 15mg GW823093 in the extension phase 45mg GW823093 in the main phase followed by 45mg GW823093 in the extension phase 2.5mg GW823093 in the main phase followed by 2.5mg GW823093 in the extension phase

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MODULAR APPENDIX: STATISTICAL METHODS

Statistical Appendix 1.1 contains the SAS statistical output from the dose-response modelling in Figure 11.14.

Statistical Appendix 1.2 contains the SAS statistical output from the dose-response modelling on the log-scale in Exploratory Figure 11.60.

The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	F M
TRTTYPCD	2	1 2
REGIONCD	3	01 02 03
dose	6	0 2.5 7.5 15 30 45

Dimensions

Covariance Parameters	1
Columns in X	15
Columns in Z	0
Subjects	1
Max Obs Per Subject	350
Observations Used	350
Observations Not Used	0
Total Observations	350

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.6374

Fit Statistics

-2 Res Log Likelihood	856.3
AIC (smaller is better)	858.3
AICC (smaller is better)	858.3
BIC (smaller is better)	862.1

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	339	0.07	0.7916
TRTTYPCD	1	339	55.40	<.0001

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Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
dose	5	339	9.09	<.0001
REGIONCD	2	339	9.08	0.0001
BLHBA1C	1	339	0.89	0.3457

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|
linear	-0.6315	0.1052	339	-6.00	<.0001
quadratic	0.2116	0.1046	339	2.02	0.0438
cubic	-0.08226	0.1060	339	-0.78	0.4383

Least Squares Means

Effect	dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper	Cov1	Cov2	Cov3
dose	0	WORK.EFF	0.4611	0.1047	339	4.40	<.0001	0.05	0.2551	0.6671	0.01097	-0.00013	-0.00005
dose	2.5	WORK.EFF	0.1779	0.1073	339	1.66	0.0982	0.05	-0.03314	0.3890	-0.00013	0.01151	2.398E-6
dose	7.5	WORK.EFF	-0.06680	0.1042	339	-0.64	0.5220	0.05	-0.2718	0.1382	-0.00005	2.398E-6	0.01086
dose	15	WORK.EFF	0.01236	0.1015	339	0.12	0.9032	0.05	-0.1873	0.2120	-7.98E-6	8.046E-6	-4.64E-6
dose	30	WORK.EFF	-0.3361	0.1072	339	-3.14	0.0019	0.05	-0.5470	-0.1253	0.000119	-0.00011	-0.00002
dose	45	WORK.EFF	-0.3788	0.1053	339	-3.60	0.0004	0.05	-0.5860	-0.1716	-0.00011	0.000091	0.000016

Least Squares Means

Effect	dose	Cov4	Cov5	Cov6
dose	0	-7.98E-6	0.000119	-0.00011
dose	2.5	8.046E-6	-0.00011	0.000091
dose	7.5	-4.64E-6	-0.00002	0.000016
dose	15	0.01030	-5.09E-6	-0.00001
dose	30	-5.09E-6	0.01149	-0.00009
dose	45	-0.00001	-0.00009	0.01109

Differences of Least Squares Means

Effect	dose	_dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
dose	0	2.5	WORK.EFF	0.2832	0.1508	339	1.88	0.0612	0.05	-0.01341	0.5798
dose	0	7.5	WORK.EFF	0.5279	0.1481	339	3.57	0.0004	0.05	0.2366	0.8192
dose	0	15	WORK.EFF	0.4487	0.1459	339	3.08	0.0023	0.05	0.1618	0.7357
dose	0	30	WORK.EFF	0.7972	0.1491	339	5.35	<.0001	0.05	0.5040	1.0904
dose	0	45	WORK.EFF	0.8399	0.1492	339	5.63	<.0001	0.05	0.5463	1.1335
dose	2.5	7.5	WORK.EFF	0.2447	0.1496	339	1.64	0.1027	0.05	-0.04948	0.5389
dose	2.5	15	WORK.EFF	0.1656	0.1477	339	1.12	0.2629	0.05	-0.1249	0.4560

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The Mixed Procedure

Differences of Least Squares Means

Effect	dose	_dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
dose	2.5	30	WORK.EFF	0.5141	0.1524	339	3.37	0.0008	0.05	0.2144	0.8137
dose	2.5	45	WORK.EFF	0.5567	0.1497	339	3.72	0.0002	0.05	0.2622	0.8513
dose	7.5	15	WORK.EFF	-0.07915	0.1455	339	-0.54	0.5868	0.05	-0.3654	0.2071
dose	7.5	30	WORK.EFF	0.2693	0.1497	339	1.80	0.0728	0.05	-0.02504	0.5637
dose	7.5	45	WORK.EFF	0.3120	0.1481	339	2.11	0.0358	0.05	0.02078	0.6032
dose	15	30	WORK.EFF	0.3485	0.1476	339	2.36	0.0188	0.05	0.05807	0.6389
dose	15	45	WORK.EFF	0.3912	0.1464	339	2.67	0.0079	0.05	0.1033	0.6790
dose	30	45	WORK.EFF	0.04267	0.1509	339	0.28	0.7775	0.05	-0.2541	0.3394

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The Mixed Procedure

Model Information

Data Set	WORK._DATA
Dependent Variable	Estimate
Covariance Structure	Unstructured
Subject Effect	Effect
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Between-Within

Class Level Information

Class	Levels	Values
Effect	1	dose
dose	6	0 15 30 45 2.5 7.5

Dimensions

Covariance Parameters	21
Columns in X	3
Columns in Z	0
Subjects	1
Max Obs Per Subject	6
Observations Used	6
Observations Not Used	19
Total Observations	25

Parameter Search

CovP1	CovP2	CovP3	CovP4	CovP5	CovP6	CovP7	CovP8	CovP9	CovP10	CovP11	CovP12	CovP13
0.01097	-0.00013	0.01151	-0.00005	2.398E-6	0.01086	-7.98E-6	8.046E-6	-4.64E-6	0.01030	0.000119	-0.00011	-0.00002

Parameter Search

CovP14	CovP15	CovP16	CovP17	CovP18	CovP19	CovP20	CovP21	Res Log Like	-2 Res Log Like
-5.09E-6	0.01149	-0.00011	0.000091	0.000016	-0.00001	-0.00009	0.01109	-9.3837	18.7674

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	Effect	0.01097
UN(2,1)	Effect	-0.00013
UN(2,2)	Effect	0.01151
UN(3,1)	Effect	-0.00005
UN(3,2)	Effect	2.398E-6
UN(3,3)	Effect	0.01086
UN(4,1)	Effect	-7.98E-6

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The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(4,2)	Effect	8.046E-6
UN(4,3)	Effect	-4.64E-6
UN(4,4)	Effect	0.01030
UN(5,1)	Effect	0.000119
UN(5,2)	Effect	-0.00011
UN(5,3)	Effect	-0.00002
UN(5,4)	Effect	-5.09E-6
UN(5,5)	Effect	0.01149
UN(6,1)	Effect	-0.00011
UN(6,2)	Effect	0.000091
UN(6,3)	Effect	0.000016
UN(6,4)	Effect	-0.00001
UN(6,5)	Effect	-0.00009
UN(6,6)	Effect	0.01109

Fit Statistics

-2 Res Log Likelihood	18.8
AIC (smaller is better)	18.8
AICC (smaller is better)	18.8
BIC (smaller is better)	18.8

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept	0.3387	0.07721	0	4.39	.
mydose	-0.03628	0.01039	0	-3.49	.
mydose*mydose	0.000456	0.000225	0	2.02	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
mydose	1	0	12.20	.
mydose*mydose	1	0	4.10	.

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The Mixed Procedure

Model Information

Data Set	WORK.EFF
Dependent Variable	STDCHGBL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
SEX	2	F M
TRTTYPCD	2	1 2
REGIONCD	3	01 02 03
dose	5	0.9162907319 2.0149030205 2.7080502011 3.4011973817 3.8066624898

Dimensions

Covariance Parameters	1
Columns in X	14
Columns in Z	0
Subjects	1
Max Obs Per Subject	291
Observations Used	291
Observations Not Used	0
Total Observations	291

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.5621

Fit Statistics

-2 Res Log Likelihood	677.4
AIC (smaller is better)	679.4
AICC (smaller is better)	679.5
BIC (smaller is better)	683.1

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Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	281	0.16	0.6875
TRTTYPCD	1	281	40.36	<.0001
dose	4	281	5.69	0.0002
REGIONCD	2	281	4.84	0.0086
BLHBA1C	1	281	1.45	0.2301

Estimates

Label	Estimate	Standard Error	DF	t Value	Pr > |t|
linear	-0.4384	0.09984	281	-4.39	<.0001
quadratic	-0.08346	0.09848	281	-0.85	0.3975
cubic	-0.06114	0.09882	281	-0.62	0.5366

Least Squares Means

Effect	dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper	Cov1	Cov2
dose	0.9162907319	WORK.EFF	0.1805	0.1006	281	1.79	0.0739	0.05	-0.01758	0.3786	0.01013	-0.00003
dose	2.0149030205	WORK.EFF	-0.04959	0.09785	281	-0.51	0.6127	0.05	-0.2422	0.1430	-0.00003	0.009574
dose	2.7080502011	WORK.EFF	0.02326	0.09535	281	0.24	0.8074	0.05	-0.1644	0.2109	-0.00001	-9.82E-6
dose	3.4011973817	WORK.EFF	-0.3314	0.1010	281	-3.28	0.0012	0.05	-0.5302	-0.1326	-0.00010	-5.01E-6
dose	3.8066624898	WORK.EFF	-0.3752	0.09878	281	-3.80	0.0002	0.05	-0.5697	-0.1808	0.000051	-7.91E-6

Least Squares Means

Effect	dose	Cov3	Cov4	Cov5
dose	0.9162907319	-0.00001	-0.00010	0.000051
dose	2.0149030205	-9.82E-6	-5.01E-6	-7.91E-6
dose	2.7080502011	0.009091	0.000024	-0.00003
dose	3.4011973817	0.000024	0.01020	-0.00008
dose	3.8066624898	-0.00003	-0.00008	0.009758

Differences of Least Squares Means

Effect	dose	_dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
dose	0.9162907319	2.0149030205	WORK.EFF	0.2301	0.1405	281	1.64	0.1027	0.05	-0.04657	0.5067
dose	0.9162907319	2.7080502011	WORK.EFF	0.1572	0.1387	281	1.13	0.2579	0.05	-0.1158	0.4303
dose	0.9162907319	3.4011973817	WORK.EFF	0.5119	0.1433	281	3.57	0.0004	0.05	0.2299	0.7940
dose	0.9162907319	3.8066624898	WORK.EFF	0.5557	0.1406	281	3.95	<.0001	0.05	0.2789	0.8326
dose	2.0149030205	2.7080502011	WORK.EFF	-0.07285	0.1367	281	-0.53	0.5945	0.05	-0.3419	0.1962
dose	2.0149030205	3.4011973817	WORK.EFF	0.2818	0.1407	281	2.00	0.0461	0.05	0.004971	0.5587
dose	2.0149030205	3.8066624898	WORK.EFF	0.3256	0.1391	281	2.34	0.0199	0.05	0.05183	0.5994

CONFIDENTIAL

The Mixed Procedure

Differences of Least Squares Means

Effect	dose	_dose	Margins	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
dose	2.7080502011	3.4011973817	WORK.EFF	0.3547	0.1387	281	2.56	0.0111	0.05	0.08163	0.6278
dose	2.7080502011	3.8066624898	WORK.EFF	0.3985	0.1375	281	2.90	0.0041	0.05	0.1278	0.6692
dose	3.4011973817	3.8066624898	WORK.EFF	0.04379	0.1418	281	0.31	0.7578	0.05	-0.2354	0.3230

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The Mixed Procedure

Model Information

Data Set	WORK._DATA2
Dependent Variable	Estimate
Covariance Structure	Unstructured
Subject Effect	Effect
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Between-Within

Class Level Information

Class	Levels	Values
Effect	1	dose
dose	5	0.9162907319 2.0149030205 2.7080502011 3.4011973817 3.8066624898

Dimensions

Covariance Parameters	15
Columns in X	2
Columns in Z	0
Subjects	1
Max Obs Per Subject	5
Observations Used	5
Observations Not Used	18
Total Observations	23

Parameter Search

CovP1	CovP2	CovP3	CovP4	CovP5	CovP6	CovP7	CovP8	CovP9	CovP10	CovP11	CovP12	CovP13
0.01013	-0.00003	0.009574	-0.00001	-9.82E-6	0.009091	-0.00010	-5.01E-6	0.000024	0.01020	0.000051	-7.91E-6	-0.00003

Parameter Search

CovP14	CovP15	Res Log Like	-2 Res Log Like
-0.00008	0.009758	0.7809	-1.5619

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	Effect	0.01013
UN(2,1)	Effect	-0.00003
UN(2,2)	Effect	0.009574
UN(3,1)	Effect	-0.00001
UN(3,2)	Effect	-9.82E-6

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The Mixed Procedure

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(3,3)	Effect	0.009091
UN(4,1)	Effect	-0.00010
UN(4,2)	Effect	-5.01E-6
UN(4,3)	Effect	0.000024
UN(4,4)	Effect	0.01020
UN(5,1)	Effect	0.000051
UN(5,2)	Effect	-7.91E-6
UN(5,3)	Effect	-0.00003
UN(5,4)	Effect	-0.00008
UN(5,5)	Effect	0.009758

Fit Statistics

-2 Res Log Likelihood	-1.6
AIC (smaller is better)	-1.6
AICC (smaller is better)	-1.6
BIC (smaller is better)	-1.6

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept	0.3809	0.1202	0	3.17	.
mydose	-0.1902	0.04343	0	-4.38	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
mydose	1	0	19.18	.

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This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the ***GSK Clinical Study Register****.*

Table 1: Protocol Level Administration

Study Number: DPB100925

Study Title: A 12-week, Parallel-Group, Double-blind, Randomised, Placebo-Controlled, Multicentre, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg, 45mg) Administered Orally, Once Daily as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Study Sponsor	Medical Writing: Protocol Authorship	Statistics Group	Data Management Group	Randomisation	Site of Manufacture & Assembly	Medical Writing: Clinical Report Authorship	Site of EU release	Location of Study Master File	GCP Regulatory inspection
Address	Names of authors and their Address	Address	Address	Company and Address	Address	Names of authors and their Address	Address	Address	Name of Agency
GlaxoSmithKline, New Frontiers Science Park, Third Avenue, Harlow, Essex CM19 5AW. UK	[redacted] (no longer with GSK), [redacted] (no longer with GSK) MDC Clinical Metabolic, GlaxoSmithKline, 2301 Rennaissance Blvd, King of Prussia, PA 19406. [redacted] Biomedical Data Sciences, Statistics & Programming, GlaxoSmithKline, Greenford Road, Greenford, Middlesex, UB6 0HE, UK. [redacted] CPK, GSK, Research Triangle Park, Five Moore Drive, PO Box 13398, Durham,	GlaxoSmithKline, Biomedical and Data Services Biostatistical and Programming, Greenford Road, Greenford, Middlesex UB6 0HE. UK	GlaxoSmithKline, Greenford Road, Greenford, Middlesex UB6 0HE. UK New Frontiers Science Park, Third Avenue, Harlow, Essex, CM19 5AW. UK	Randomisation code provided by: [redacted] Biomedical and Data Services Biostatistical and Programming, GlaxoSmithKline, Greenford Road, Greenford, Middlesex UB6 0HE. UK GSK's RAMOS was the IVRS system.	GlaxoSmithKline, Five Moore Drive Research Triangle Park North Carolina, 27709, USA and 801 River Rd. Conshohocken PA 19428, USA and 1250 S. Collegeville Rd. Collegeville PA 19426, USA. Quality Assurance: GSK Research & Development, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK	[redacted] CVM MDC-Clinical, GlaxoSmithKline, New Frontiers Science Park, Third Avenue, Harlow, Essex, CM19 5AW. UK. [redacted] Biomedical Data Sciences, Statistics & Programming, GlaxoSmithKline, Greenford Road, Greenford, Middlesex, UB6 0HE, UK. [redacted] (Contract Medical Writer), 100 North Road, Hythe, Kent, CT21 5DX. UK	GSK R&D, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406, USA	MPA - Sweden

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Study Number: DPB100925

Study Title: A 12-week, Parallel-Group, Double-blind, Randomised, Placebo-Controlled, Multicentre, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg, 45mg) Administered Orally, Once Daily as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Study Sponsor	Medical Writing: Protocol Authorship	Statistics Group	Data Management Group	Randomisation	Site of Manufacture & Assembly	Medical Writing: Clinical Report Authorship	Site of EU release	Location of Study Master File	GCP Regulatory inspection
	Nth Carolina 27709. USA. [redacted] MV Discovery Medicine Metabolic, GSK, Five Moore Drive, PO Box 13398, Durham, Nth Carolina 27709. USA. [redacted] CVM MDC – Clinical, GlaxoSmithKline, Greenford Road, Greenford, Middlesex, UB6 0HE, UK.								

Table 2 Country Level Administration

Study Number: DPB100925

Study Title: A 12-week, Parallel-Group, Double-blind, Randomised, Placebo-Controlled, Multicentre, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg, 45mg) Administered Orally, Once Daily as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Participating Countries	Monitoring	Responsible for which sites	Laboratory Assessments	Sites of distribution in Europe	Audits		
					Were Audits done?	Centre Number of Site(s)	Conducted by:
Country Name	Address of resource	Centre Numbers	Laboratory name and address	Address	yes/no	Centre numbers	Name and address of audit group
Canada	GlaxoSmithKline, 7333 Mississauga Road north, Mississauga, Ontario, L5N 6L4. Canada	[redacted]	Quest Diagnostics ClinicalTrials, 7600 Tyrone Avenue Van Nuys, CA 91405, USA	GlaxoSmithKline, Five Moore Drive, research Triangle Park, North Carolina 27709, USA.	No	NA	NA
Czech Republic	Pharmnet s.r.o. , Clinical Research Associate Address: Peckova 13, 186 00 Praha 8, Czech Republic.	[redacted]	Quest Diagnostics Clinical Trials, Unit B1, Parkway West Crawford Lane, Heston, Middlesex, TWA 9QA, UK	GSK R&D, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK			
Finland	GlaxoSmithKline, Piispansilta 9A, 02230 Espoo Finland.	[redacted]	GlaxoSmithKline, Department of Drug Metabolism and PharmacoKinetics, 709 Swedeland Road, King of Prussia, PA 19406, USA	[redacted] Rajatorpantie 41B, 01641 Vantaa Finland			
Germany	GlaxoSmithKline GmbH & Co KG Theresienhoehe 11, Munich	[redacted]	Linco Diagnostics Inc, 15 Research Park Dr, St. Charles, Mo	GSK R&D, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK			

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Study Number: DPB100925

Study Title: A 12-week, Parallel-Group, Double-blind, Randomised, Placebo-Controlled, Multicentre, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg, 45mg) Administered Orally, Once Daily as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Participating Countries	Monitoring	Responsible for which sites	Laboratory Assessments	Sites of distribution in Europe	Audits		
					Were Audits done?	Centre Number of Site(s)	Conducted by:
Greece	248, Kifissias Avenue, 152 32, Halandri, Athens, GREECE	[redacted]	63304. USA Quest/ Nichols Institute, 33608 Ortega Highway, San Juan Capistrano, Ca 92690. USA	GSK R&D, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK			
Latvia	Latvia Branch Office, Bruninieku Street 5, Riga LV1001.	[redacted]		GSK R&D, New Frontiers Science Park South, Third Ave, Harlow, Essex, CM19 5AW. UK			
Romania	GlaxoSmithKline (GSK) Romania, Opera Center 1, Str. Costache Negri 1-5, sector 5, Bucuresti, Romania, 050552	[redacted]		GlaxoSmithKline (GSK) Romania, Opera Center 1, Str. Costache Negri 1-5, sector 5, Bucuresti, Romania, 050552			
Sweden	Kliniskt prövningscentra, SU / Sahlgrenska, Gröna Stråket 8, 413 45 Göteborg, Sweden Klinisk Forskningsavdelning, ingång 33, Universitetssjukhuset, 205 02 Malmö	[redacted]		Apoteket, SU/Sahlgrenska Apoteket, Universitetsjukhuset Malmö			

Study Number: DPB100925

Study Title: A 12-week, Parallel-Group, Double-blind, Randomised, Placebo-Controlled, Multicentre, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg, 45mg) Administered Orally, Once Daily as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension

Participating Countries	Monitoring	Responsible for which sites	Laboratory Assessments	Sites of distribution in Europe	Audits		
					Were Audits done?	Centre Number of Site(s)	Conducted by:
	Sweden Kliniskt Forskningscentra Danderyds Sjukhus AB, 182 88 Stockholm			Apoteket, Danderyds Sjukhus AB			
United States	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406. USA	[redacted]		GlaxoSmithKline, Five Moore Drive, research Triangle Park, North Carolina 27709, USA.			

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MODULAR APPENDIX: INDEPENDENT DATA MONITORING COMMITTEE

IDMC Name: IDMC for Study DPB100925

IDMC Recommendations: The IDMC recommendation after all meetings was to continue the study as planned.

There were no deviations from the plans outlined in the Charter. The primary study contact for the sponsor changed throughout the duration of the study from [redacted] to [redacted] and finally to [redacted]

A copy of the IDMC Chater is attached.

CHARTER FOR THE INDEPENDENT

DATA MONITORING COMMITTEE (IDMC)

Protocol: DPB100925, Phase 2b

Title: A 12-week, parallel-group, double-blind, randomized, placebo-controlled, multicenter, dose-ranging study to evaluate the efficacy, safety and tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), administered orally, once daily, as monotherapy in subjects with type 2 diabetes mellitus followed by a 12-week active treatment extension

Charter approved by GlaxoSmithKline: 01/AUG/2005

IDMC Approved:
Signature: Print name: Date:

[redacted] **MD**
IDMC Co-Chairperson

[redacted] **MD**
IDMC Co-Chairperson

[redacted] **MD**

[redacted] **MD**

Prof [redacted] **PhD**

[redacted] **MD**

Charter developed in accordance with:

GSK SOP-WWD-1020 v02, effective 24-Sep-2004 and

GSK DS-WWD-1020 v02, effective 24-Sep-2004

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1. PURPOSE

The purpose of this charter is to describe the procedures that the Independent Data Monitoring Committee (IDMC) will follow during its review of safety and specified efficacy data collected during the conduct of GlaxoSmithKline (GSK; "the Sponsor") study DPB100925, a phase 2b dose ranging study of GW823093 (a dipeptidyl peptidase IV inhibitor).

2. RESPONSIBILITIES

The primary responsibility of the IDMC is to assess safety data in order to protect the ethical and safety interests of the subjects recruited into study DBP100925, while protecting, as far as possible, the scientific validity of the study. The IDMC will routinely review specified efficacy data (HbA1c and FPG), but may request additional efficacy data if considered necessary in order to support the assessment of safety data.

Specific responsibilities of the IDMC are to:

1. Review the IDMC Charter supplied by the Sponsor, and to make recommendations to the Sponsor for any change(s) to the charter. All IDMC members will agree and sign the final Charter;
2. Discuss and agree the type of information needed for review by the IDMC, in order to meet the overall responsibility of the IDMC;
3. Recommend the format for the presentation of this information;
4. Review data collection methods and safety monitoring procedures and make recommendations for additions or adjustments, as applicable;
5. Review study safety and specified efficacy data at scheduled meetings, and at *ad hoc* meetings if required;
6. Recommend stopping rules for safety when appropriate, and present evidence supporting the need for possible termination or change of all or part of the study to the Sponsor;
7. Request the services of external consultants in agreement with the sponsor as necessary for the critical interpretation of data derived from the study;
8. Record minutes for the closed sessions and record any/all recommendations from the closed portions of the meetings;
9. Provide any interim reports should safety concerns be identified, and provide a final safety report at the end of the study.

The IDMC Chairpersons are responsible, in conjunction with the Sponsor, for the selection of replacement members, if a member is unable to continue participation. The Sponsor has the final decision when selecting replacement members. No substitution of members, either by a Chairperson or other members, is permissible for individual

meetings, without the prior consent of the Sponsor.

The IDMC will select one or more members responsible for taking notes at each meeting and for producing minutes of the meetings.

3. CONDUCT OF IDMC MEETINGS

3.1. Schedule of meetings

The IDMC will meet at predefined times to evaluate key safety data and to identify potential treatment harm. Additional *ad hoc* meetings may also be arranged if needed to review specific findings of clinical concern.

The first IDMC meeting will be a telephone conference, to discuss and finalise the IDMC charter. This meeting should be held prior to the study start, or as soon as possible thereafter. The committee will review and agree with the content of the Charter or make recommendations for its amendment.

The IDMC will meet face-to-face as soon as is practical after the first teleconference. The IDMC will sign the finalised IDMC charter, and will receive an overview from the Sponsor of the GW823093 clinical plan anticipated under the scope of this charter, as well as pre-clinical and clinical safety data.

The first meeting to review safety data from study DPB100925 will be held approximately eight weeks after the first subject has been randomised to receive study treatment. The IDMC will meet by telephone conference at this time and approximately every six weeks thereafter. This frequency may be adjusted, if deemed necessary by the IDMC, depending on enrolment rates and the rate of safety events.

The IDMC may also convene for *ad hoc* meetings. The decision to meet *ad hoc* is at the discretion of the IDMC Chairpersons and will be based on the "real time" review of subjects with treatment related serious adverse events (SAEs), subjects withdrawn due to adverse events (AEs) or hypoglycemia and subjects with elevated troponin-I (>1.5ng/mL) (see Section 3.4). Where possible, *ad hoc* meetings will be held within 5 working days of receiving these data.

3.2. Composition of the IDMC and Quorum

The IDMC members will provide appropriate expertise to meet the overall responsibility of the IDMC. The composition of the IDMC is shown in Appendix A. The IDMC members cannot participate in the study as investigators or as study subject care physicians.

The IDMC will be supported by a Statistical Data Analysis Center (SDAC) which will be external to the Sponsor. Details of the SDAC are provided in Appendix A.

The IDMC statistician (Professor [redacted] at least one co-chairperson and at least two of the three other committee members are required at scheduled meetings, telephone conferences, or *ad hoc* meetings. In the event that a member cannot be present at a

meeting, a Chairperson will seek their input prior to a final decision, and the minutes of these discussions will be documented. All proposals, motions, or recommendations to be made to the Sponsor are to be made in accordance with the guidelines described in Section 8; Procedures for Communicating Recommendations to the Sponsor.

The IDMC (coordinated through the co-chairs) may also convene meetings or discussions with one or more additional external consultants should it be deemed necessary for review of specific cases or safety concerns. In this event, the Sponsor must be notified prior to the meeting and in accordance with the Sponsor liaison arrangements described in Section 7. Any external consultants engaged must have prior approval from the sponsor and sign a Sponsor confidentiality agreement prior to the meeting and cannot vote in the consensus decision. External consultants cannot be principal investigators or sub-investigators in any GW823093 study at the time of consultation, nor can they knowingly administer medical care to a study subject.

No IDMC member may delegate his or her participation in case of absence, without the prior agreement of the Sponsor. In the event that a member is unable to continue participation in the IDMC, the committee will recommend a replacement to the Sponsor, which has final approval as to the replacement. IDMC membership is to be for the anticipated duration of the clinical study. The Sponsor may also consult the IDMC on an *ad hoc* basis over the subsequent 6 months during post-study data review, until the final clinical study safety report is completed.

3.3. Meeting Format

Meetings will consist of open and closed sessions. Open sessions will provide an opportunity to discuss the process relating to IDMC meetings and data production and distribution. The Sponsor's Primary Study Contact or designee and at least one Medical Monitor will attend the open sessions. During an open session, employees of the Sponsor may be invited to make presentations and will be available for questions if requested by the IDMC. No unblinded study data will be discussed during open sessions. Minutes will be produced from the open sessions and will be the responsibility of the sponsor. The minutes from open sessions will be distributed to the IDMC and sponsor participants within two-weeks of the meeting.

The closed session will consist of two parts, the statistical analysis and the executive parts. The IDMC statistician will present and answer questions regarding the safety data report during the statistical analysis session. The IDMC will deliberate, vote, and formulate recommendations during the executive part of the session. Sponsor employees will be excluded from any deliberations or closed sessions of IDMC meetings unless requested by the IDMC. The Sponsor's Primary Study Contact or designee and at least one Medical Monitor will be available to receive comments at the end of the closed sessions.

A vote of the committee will be taken at the conclusion of each closed session. A recommendation to proceed with, modify or terminate the study will be produced after each meeting. IDMC recommendations will be by a majority vote of the IDMC members, and all efforts should be made to achieve consensus (i.e. each member should

be able to support the decision made). Where recommendations are not unanimous, the minutes will document the views of individual IDMC members. The IDMC should propose and document a process to resolve any discussions which result in a split decision.

Minutes will be produced from the closed sessions but those minutes will not be shared with the sponsor or any sponsor representatives until the study has completed and the data have been unblinded. If there are any actions required from the closed session these will be captured in the minutes and the sponsor will be notified without the unblinding of any study data. The IDMC will present its recommendation(s) and/or requested actions promptly to the Sponsor (see also Section 7; Sponsor Liaisons and Section 8; Procedures for Communicating Recommendations to the Sponsor). The minutes from any closed session must be archived for distribution at study completion.

3.4. Data to be Reviewed

The IDMC will receive safety data as summarised below.

The Sponsor will provide study data to the SDAC, and the SDAC will generate IDMC reports for each scheduled meeting in the form of summary tables and subject data listings. Blinded reports, with data in aggregate form, will not routinely be produced, but may be provided for open sessions if requested by the IDMC. Unblinded data reports will be produced for closed sessions. Treatment groups will be randomly assigned letters A to F. Subjects will be considered randomized if they have a randomization treatment number assigned in the Sponsor's enrolment-tracking system. The code for the treatment groups A to F will be provided to the IDMC members by the SDAC separately from the study data. Unblinded reports and treatment group codes will be provided to IDMC members five working days before each scheduled meeting.

SDAC reports will be provided directly to the IDMC. No SDAC or IDMC member may disclose reports to anyone other than a fellow SDAC/IDMC member without the prior agreement of an IDMC Chairperson.

The Sponsor will also provide case narratives on subjects reporting SAEs, subjects withdrawn due to AEs (including elevated liver enzymes and elevated bilirubin) and subjects withdrawn due to hypoglycemia. The sponsor will also provide narratives for those subjects with elevated troponin-I (> 1.5 ng/mL). Narratives will be sent to the SDAC lead representative (Prof [redacted] for addition of treatment information and subsequent circulation to the IDMC members. The narratives will be provided, as described in Appendix D, either in real-time (treatment-related SAEs, withdrawals due to AEs and hypoglycemia and elevated troponin-I) or within 5 working days of scheduled IDMC meetings (other SAEs).

In addition, the IDMC will receive data as described in Appendix D on serious adverse events for subjects participating in any other clinical study of GW823093 which is ongoing during the extent of the DBP100925 study period.

The IDMC will routinely review specified efficacy data (HbA1c and FPG), and may request additional efficacy data if considered necessary in order to support the assessment of safety data or to support an IDMC recommendation to the Sponsor.

Reports to be reviewed by the IDMC will be presented by treatment group and will include, but are not limited to the following:

1	Number of subjects randomized.
2	Distribution of subjects randomized across clinical sites.
3	Numbers of subjects with ALT, AST, ≥2×, ≥3×, ≥5×, ≥8×, ≥10x the upper limit of the reference range (ULRR)
4	Numbers of subjects with total bilirubin elevations ≥1.5×, ≥2×, ≥3×, ≥5×, ≥8×, ≥10x ULRR
5	Number of subjects with ALT or AST levels ≥3x ULRR and a concurrent total bilirubin level ≥2x ULRR, or an isolated ALT or AST ≥5x ULRR
6	Number of subjects with troponin-I levels <0.2 ng/mL, ≥0.2 ng/mL to 1.5 ng/mL and >1.5 ng/mL
7	Summary of all adverse events
8	Summary of withdrawals due to adverse events or hypoglycemia
9	Summary of all serious adverse events
10	Summary of hypoglycemic events
11	Summary of ECG data
12	Summary of blood pressure data and heart rate data
13	Summary of fasting plasma glucose, by group and visit
14	Summary of HbA1c, by group and visit

Subject listings and graphs of data associated with 3 to 14 will be generated at the discretion of the IDMC.

Formal statistical comparisons between treatment groups will be performed as agreed by the IDMC. The methodology to be used for any formal analysis will be determined by the IDMC statistician. Additional considerations in relation to the review of safety data are provided in Appendices B and D. Appendix F also provides some guidance for modification and/or termination of the study.

3.5. Meeting minutes

During each meeting or telephone conference, minutes capturing discussions and recommendations by each member must be carefully documented. The IDMC will agree which IDMC member will be responsible for compiling and distributing the minutes to the remaining IDMC members. The minutes will be reviewed and approved within five working days of each meeting. A written statement of the final recommendation from each meeting will be relayed to the Sponsor (see Section 7; Sponsor Liaisons). It is the responsibility of an IDMC Chairperson to update absent IDMC members of meeting events.

Minutes of open sessions will be the responsibility of the sponsor and will be distributed to the IDMC and sponsor participants within two weeks of the meeting. The final

recommendation from each meeting will be sent to the Primary Study Contact. Minutes from closed sessions will be restricted to IDMC members until the completion of the clinical study and unblinding of the study data by the Sponsor. The SDAC members other than the IDMC statistician will only have access to the statistical analysis component of the closed session and will not have access to the executive session minutes.

At the end of the study and after treatment is unblinded by the Sponsor, the IDMC will forward to the Sponsor the following:

- Copies of all meeting minutes, and any interim safety reports
- A summary safety report
- Recommendations for safety monitoring in subsequent studies

4. CONFIDENTIALITY

All members of the IDMC will have a signed confidentiality agreement with the Sponsor. In addition, members will treat as confidential the reports, meeting discussions, minutes and recommendations of the IDMC. SDAC staff will also sign a confidentiality agreement.

5. CONFLICT OF INTEREST GUIDELINES

Members of the IDMC must declare the extent of any known financial or other interests, including equity holdings in GSK or its products, or in a competitor company or its products, upon appointment to the Committee and in the event of any material change(s) during their tenure.

Certain activities are not viewed as constituting conflicts of interest but must be reported annually to the Sponsor: the participation as members in educational activities supported by the Sponsor for other products of the Sponsor; the participation as members in other research projects supported by the Sponsor; occasional scientific consulting to the Sponsor on issues not related to the product in the study.

6. REIMBURSEMENT

IDMC members will be paid a competitive rate within all applicable guidelines based on time required for meeting preparation, meetings attendance, reviewing subject data and report generation. IDMC members will also be reimbursed *per diem* and for reasonable expenses related to attending face to face meetings, such as travel cost, accommodation, and meals. No other payment or future consideration will be provided.

7. SPONSOR LIAISONS

The potential for bias to arise must be minimized. To this end:

- Contact between IDMC members and study investigators should be avoided to the extent possible

- The randomisation code will be sent to the SDAC by a Sponsor employee who is not involved in the development of GW823093
- Any communication between the IDMC and the Primary Study Contact or any members of the Clinical Study Team will be made in a manner that keeps these persons blinded to the study data.
- Only essential information should be sent to the Sponsor by the IDMC (e.g. if the IDMC has not detected a potential safety concern, then the IDMC should send a 'no action required' statement, nothing more).
- In the event that the recommendation is 'no action required' the IDMC will notify the Primary Study Contact or designee. No further communication is necessary from the IDMC. The Primary Study Contact will inform the Sponsor Advisory Group (SAG), Global Safety Board (GSB), Medical Monitors and the Global Clinical Safety and Pharmacovigilance (GCSP) department representative of the 'no action required' recommendation.
- In the event that the recommendation is anything other than 'no action required' the IDMC will notify the SAG representative (Murray Stewart, MD) in a **blinded** fashion. The SAG representative will contact the Global Safety Board (GSB) and will initiate and arrange direct communication between the GSB and the IDMC. In no event will the SAG representative be unblinded to study data unless the GSB has agreed to such action.
- All efforts to protect and maintain the blind of the Sponsor including the SAG, Primary Study Contact, Medical Monitor and GCSP representative must be preserved until the Sponsor's GSB has reviewed the IDMC recommendation and decided on the course of action in consultation with the IDMC.

The following arrangements are in place for liaison between the IDMC and the Sponsor (see Appendix C for contact details):

Primary Study Contact: Whenever the IDMC communicates with the Primary Study Contact, that person must first establish that the discussion will not include unblinded data. Unblinded data will not be shared with the Primary Study Contact or Clinical Study Team unless and until the study is terminated.

Primary Study Contact Responsibilities:

- First point of contact for study conduct and medical case questions.
- Recipient of all final written communications including post-meeting statements confirming the IDMC recommendations and final report and meetings minutes upon completion of the study.
- First point of contact for the IDMC recommendation of 'no action required', and forwarding of this recommendation to the SAG, Medical Monitors and GCSP.
- Contact for confirmation of IDMC member replacement and/or engagement of external consultant(s).

Sponsor Advisory Group: The Sponsor Advisory Group (SAG) is a body of senior GSK managers who provide guidance and direction to the Clinical Study Team through interacting with the IDMC. Unblinded data should not be shared with the SAG unless it

is to confirm an IDMC recommendation to modify or discontinue the clinical study or to terminate a single treatment arm within the study, which has already been discussed and agreed by the GSB. The SAG will not share unblinded data with the Clinical Study Team unless the study is terminated.

SAG Responsibilities:

- Review the draft IDMC charter, and make recommendations for change(s).
- Endorsement of *ad hoc* requests (i.e., for an additional Advisory Consultant) from the IDMC as might arise in accordance with the IDMC's role in monitoring subject safety.
- Initial contact for the IDMC in the event of a recommendation other than 'no action required', and communication of this recommendation in a blinded fashion to the GSB.
- Liaise with GSB and IDMC to initiate and arrange communication between the GSB and the IDMC as required.
- Provide product and therapy area expertise to the GSB in the event that IDMC recommends a change to the study.
- Communicate the GSB-endorsed recommendation to the Clinical Study Team.

Should issues arise that require input from the Sponsor that are not already provided for in this Charter, other contacts may be made. Depending on the situation, an IDMC Chairperson and the Primary Study Contact will decide on the appropriate individual to contact.

8. PROCEDURES FOR COMMUNICATING RECOMMENDATIONS TO THE SPONSOR

Based on its mandatory reviews, duly voted and passed IDMC recommendations will be transmitted in writing to the Sponsor within three working days (or less if considered urgent) of the meeting at which the recommendations were formulated and passed. After each meeting, the IDMC will recommend one of the following actions:

1. **Continue the study** according to the protocol and any related amendments (no action required).
2. **Continue the study, but amend the study protocol.** Amendments may include, but are not limited to, changes to inclusion/exclusion criteria, frequency of safety monitoring, alterations in study procedures, and follow-up period for purposes of safety as defined in the protocol.
3. **Discontinue a treatment arm of the study** (with provisions for orderly discontinuation in accordance with good medical practice).
4. **Discontinue the study** (with provisions for orderly discontinuation in accordance with good medical practice).

Figure 1 describes the Sponsor's actions upon receipt of the IDMC recommendation.

9. RESPONSIBILITIES OF THE SPONSOR

All personnel having direct responsibility for the conduct of the study will remain blinded to treatment groups until such time as defined in the protocol or the Sponsor acts on an IDMC recommendation to terminate the entire study. The Sponsor's representatives will:

1. Assist the IDMC as required to carry out its designated functions.
    a. Provide a contact for the distribution of information required by the IDMC.
    b. Provide clinical information to the SDAC for any subject(s).
2. Inform the IDMC in writing of any potential safety concern(s) that were previously unreported.
3. Review the IDMC recommendations and proceed as outlined in Figure 1. The Sponsor reserves the right to make the final decision with regard to all recommendations.
4. Inform the investigators, IRBs and the regulatory authorities promptly of any amendment to the study and the reasons for this, if the study or a treatment arm is terminated prematurely or suspended. The Clinical Study Team will follow procedures as described in the protocol.
5. Provide regulatory authorities with the final safety report and any interim reports should potential safety concerns be identified.
6. Report any serious adverse event(s) to regulatory authorities in accordance with reporting obligations. In addition, GCSP will forward necessary IDMC recommendations to regulatory authorities in accordance with reporting obligations to each regulatory agency.

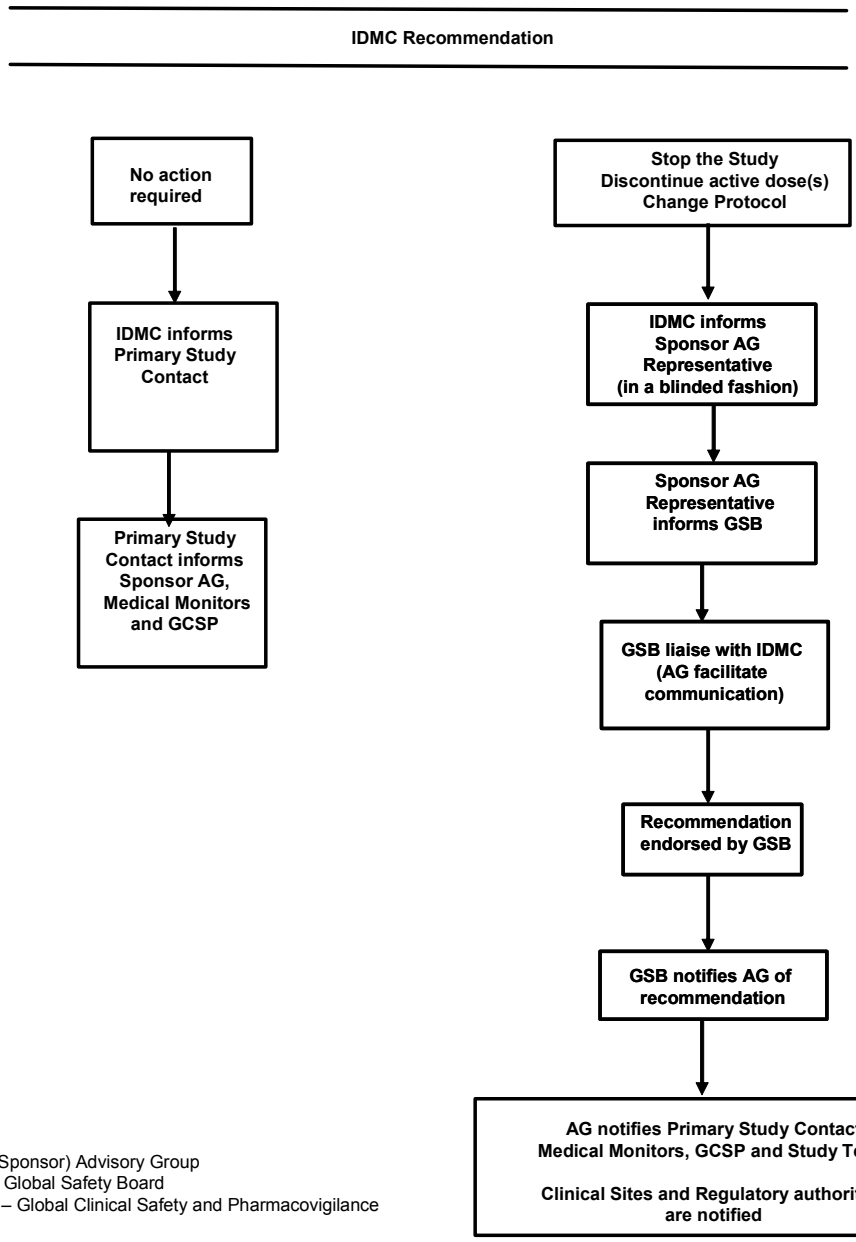
10. RESPONSIBILITIES OF THE STATISTICAL DATA ANALYSIS CENTER

The SDAC will:

1. Generate IDMC reports of safety data as outlined in Section 3.4, in the form of summary tables and subject data listings.
2. Compile individual subject demography and other study information to allow assessment of subjects of potential clinical concern by the IDMC.
3. Not divulge treatment codes to non-SDAC/IDMC personnel until the study has completed per protocol or the study is terminated for cause.
4. Prepare any additional information requested by a Chairperson of the IDMC.
5. Provide routine safety review material for consideration by IDMC members five working days prior to each scheduled IDMC meeting.

The sources of data to be provided by the Sponsor to the SDAC are summarised in Appendix E.

Figure 1. Sponsor's actions upon receipt of an IDMC recommendation



Key:
AG – (Sponsor) Advisory Group
GSB – Global Safety Board
GCSP – Global Clinical Safety and Pharmacovigilance

Appendices

Appendix A: Independent Data Monitoring Committee Members

Full Name and Degree	Address	Telephone/FAX	E-mail
[redacted] **MD** **Co-Chairperson**	Dr. [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] Canada	Ph: [redacted] Fax [redacted]	[redacted]
[redacted] **MD** **Co-Chairperson**	[redacted] [redacted] [redacted] [redacted] [redacted] United Kingdom	Ph: [redacted] Fax: [redacted]	[redacted]
[redacted] **MD** **F.R.C.P.**	[redacted] [redacted] [redacted] [redacted] [redacted]	Ph: [redacted] Fax: [redacted]	[redacted]

Statistical Data Analysis Center

SDAC Lead representative:

Full Name and Degree	Address	Telephone/FAX	E-mail
Prof [redacted] PhD	[redacted]	Ph: [redacted] Fax: [redacted]	[redacted]

IDMC External Consultant(s):

Full Name and Degree	Address	Telephone/FAX	E-mail
[redacted] MD, MPH	[redacted] *overnight delivery at:* [redacted]	Ph: [redacted] Fax: [redacted]	[redacted]

Appendix B: General Considerations for the IDMC

This appendix lists some of the considerations to be taken into account by the IDMC. These issues include both the magnitude of the observed differences and their consistency as well as the importance of the differences to the health and the safety of the subjects in the study. It is important for these issues to be stated in advance to assure both the subjects and the investigators that the IDMC will carefully consider the issues of safety and will recommend protocol changes if questions of safety arise.

If important adverse events occur between planned meetings, and a substantial trend emerges, an *ad hoc* meeting of the IDMC will be called. It is important to recognize that the IDMC will review all the relevant data available and may request additional analyses before they make any recommendations that the study be modified.

Interpretation of safety data is very complex and requires both clinical and statistical experts reviewing the data in concert. A number of considerations for interpretation of these data can be stated and these include:

a. Whether the ascertainment of outcomes could be biased because of the differences in treatment programs (ascertainment bias);

b. Whether the results are consistent for other variables which should be associated with the primary outcome variable in question;

c. Whether the results could be due to concomitant therapy and not due to the differences in the treatment groups;

d. Whether it is likely that the current trends could be reversed if the study were to be continued unmodified;

e. Whether and how much additional precision could be obtained by continuing the study under the present protocol; and,

f. Whether there would be significant loss in the overall assessment of the validity of the study by the medical community by discontinuation or change in the protocol.

All of these considerations require expert evaluation and are the major role of the IDMC. The IDMC will consider these issues on a regular basis to assure the safety of the subjects and to assure the investigators and the medical community that the risks of this study are being evaluated and the subject's safety is being kept foremost in mind.

Appendix C: Sponsor Contacts

Refer to **Section 7: *Sponsor Liaisons*** for complete description of sponsor roles and responsibilities

Primary Study Contact:

Full Name and Degree	Address	Telephone/FAX	E-mail
MDC [redacted]	GlaxoSmithKline 2301 Renaissance Blvd. King of Prussia, PA 19406	Tel: [redacted] Fax: [redacted]	[redacted]

Primary Study Contact Responsibilities:

- First point of contact for study conduct and medical case questions.
- Recipient of all final written communications including post-meeting statements confirming the IDMC recommendations and final report and meetings minutes upon completion of the study.
- First point of contact for the IDMC recommendation of 'no action required', and forwarding of this recommendation to the SAG, Medical Monitors, GCSP and GSB.
- Contact for confirmation of IDMC member replacement and/or engagement of external consultant.

Medical Monitors

Full Name and Degree	Address	Telephone/FAX	E-mail
MDC [redacted] MD	2301 Renaissance Blvd., RN0410 King of Prussia, PA 19406	Tel: [redacted] Cell: [redacted] Fax: [redacted]	[redacted]
MDC [redacted] MD	Greenford Road, Greenford, Middlesex UB6 0HE	Tel: [redacted] Cell: [redacted] Fax [redacted]	[redacted]

Sponsor Advisory Group:

Full Name and Degree	Address	Telephone/FAX	E-mail
MDC [redacted] MD	New Frontiers Science Park, Third Avenue, Harlow, Essex CM19 5AW	Tel: [redacted] Fax: [redacted]	[redacted]
BDS [redacted] PhD	2301 Renaissance Blvd., RN0410 King of Prussia, PA 19406	Tel: [redacted] Fax: [redacted]	[redacted]
GCSP [redacted] MD	1250 S. Collegeville Road UP4340 Collegeville, PA 19426	Tel: [redacted] Fax: [redacted]	[redacted]

** **Dr. [redacted] is first point of contact for Sponsor Advisory Group**

Sponsor Advisory Group (SAG) Responsibilities:

- Endorsement of *ad hoc* requests (i.e., for an additional Advisory Consultant) from the IDMC as might arise in accordance with the IDMC's role in monitoring subject safety.
- Initial contact for the IDMC in the event of a recommendation other than 'no action required', and communication of this recommendation in a blinded fashion to the GSB.
- Liaise with GSB and IDMC to initiate and arrange communication between the GSB and the IDMC as required.
- Provide product and therapy area expertise to the GSB in the event that IDMC recommends a change to the study.
- Communicate the GSB-endorsed recommendation to the Clinical Study Team.

Appendix D: Data Processing and Flow

The Sponsor GCSP department will provide the following to the SDAC lead representative (Prof [redacted] for circulation to the remaining members of the IDMC:

- Line listings and case narratives on all SAEs reported as related to study treatment in DBP100925.*
- Line listings and case narratives on all SAEs reported as related to study treatment in any clinical study of GW823093 on-going during the extent of DBP100925.*
- Line listings and case narratives on all SAEs in DBP100925.**

The Sponsor Clinical Study Team will provide the following to the SDAC lead representative for circulation to the remaining members of the IDMC:

- Case narratives on subjects withdrawn due to adverse events (including elevated liver enzymes, and elevated bilirubin). Case narratives will also be provided for subjects with elevated troponin-I (> 1.5 ng/mL) and for subjects withdrawn due to hypoglycemia.*

The Sponsor Clinical Study Team may also provide protocol information (i.e., study design, treatment arms) and safety data that is subject to regulatory reporting criteria for each study using GW823093 outside of DBP100925 in which an event has occurred.

The Sponsor Statistics and Programming department will provide the SDAC with data required to produce summaries for the IDMC scheduled meetings.

The SDAC lead representative will be responsible for providing the treatment decode information for subjects contained in the 'real-time' and scheduled reports to other IDMC members via a secure system. For studies other than DBP100925, this information can be requested from the Sponsor if required.

* Provided in a "real-time" basis

** Provided 5 days prior to scheduled IDMC meetings

Appendix E: Data Sources

The type of information, source, and specific data points required to generate the reports outlined in Section 3.4 include, but are not limited to the following:

Type of information	Source	Cleaned and Validated [1]	Specific data points
Subject numbers, treatment assignment	RAMOS reports	yes	Subject identification number Randomization number Date of randomization
Subject demography	eCRF	no	Date of birth Gender Weight Height Race
AEs	eCRF	no	AE information
Medical history	eCRF	no	Pre-existing conditions Baseline medications Change in medications since randomization Start date for new medication
SAEs	OCEANs	no	SAE information
Clinical chemistry	QUEST	yes*	Test performed (Y/N) Date of sample Reference Range ALT AST Total and direct Bilirubin Alkaline Phosphatase Troponin I
ECG	eCRF	no	ECG information
Vital signs	eCRF	no	Systolic Blood Pressure Diastolic Blood Pressure Heart Rate

RAMOS = Registration and Medication Ordering System

OCEANs = Operating Companies Event Accession & Notification System

[1] "Cleaned and Validated" consistent with GSK Biomedical Data Sciences SOPs.

* Validated by Quest specifications but not to GSK SOP standards.

Appendix F: Guidance for Modification and/or Termination of the Study

The primary role of the IDMC is to independently protect the safety of the subjects who choose to participate in DPB100925. The IDMC should use their scientific and medical expertise to render judgements regarding potential study modifications and /or termination. These judgements should be based on the IDMC's full access to safety data, treatment codes and selected efficacy data provided by the SDAC. The IDMC also has an obligation to discuss their judgements that may affect the progress of the trial with the senior group of safety officials at the sponsor company known as the Global Safety Board (GSB). The guidance provided below may be used to facilitate IDMC discussion on modifying or potentially terminating the DPB100925 trial. The criteria suggested are not a substitute for the medical, scientific or statistical expertise of the IDMC body. In addition to the selected efficacy data being reported to the IDMC (FPG and HbA1c) additional data may be requested and will be provided as available by the SDAC to help the IDMC review safety issues or reach a decision.

The expertise of the IDMC in consideration of the data in clinical context is the most important determining factor for identification of a concern that may affect the progress of the clinical study. In all cases the sponsor's GSB should be promptly consulted, following the procedures outlined, if the IDMC has any safety or ethical concerns that may warrant a change in DPB100925.

LIVER

In general evidence of drug induced transaminitis or concomitant bilirubin elevation with transaminitis should be of particular concern. Hy's law (*Nature Reviews/Drug Discovery,* June 2005 pp: 489-499) may be applied for considering the potential for progression to serious liver injury. Increases in individual transaminases should be considered in their relative incidence comparing the active treatment groups and the placebo group. Generally, increases in ALT, total bilirubin or alkaline phosphatase ≥ 2X ULRR that occur at an incidence roughly 2-fold greater in the active treatment groups compared to placebo may be of concern, however during the early stages of the trial when the sample size is small these incidences should be interpreted with caution. Individual increases in ALT or AST ≥ 5X the ULRR or ALT/AST increases ≥ 3x ULRR with concomitant increases in bilirubin ≥ 2X ULRR (Hy's Law) in active treatment groups may also be of concern.

As general guidance the following table (Table 1) indicates the estimated event rates and number of observed events within an active dose group that may be of concern for various sample sizes when considering concomitant ALT/AST and bilirubin elevations or ALT/AST elevations.

- Lower bound of 95% CI around percentage of patients with ALT/AST ≥ 3xULRR and BIL ≥ 2xULRR or ALT/AST ≥ 5xULRR at any time is ≥ 2%. This would correspond to the following point estimates:

Table 1: Event Rates and 95% Confidence Intervals

Number of patients	Number of patients with ALT/AST ≥ 3xULRR and BIL ≥ 2xULRR **or** ALT/AST ≥ 5xULRR at any time	% patients with ALT/AST ≥ 3xULRR and BIL ≥ 2xULRR **or** ALT/AST ≥ 5xULRR at any time	95% CI
10	1	10.0%	(0.3%, 44.5%)
10	2	20.0%	(2.5%, 55.6%)
20	2	10.0%	(1.2%, 31.7%)
20	3	15.0%	(3.2%, 37.9%)
30	2	6.7%	(0.8%, 22.1%)
30	3	10.0%	(2.1%, 26.5%)
40	3	7.5%	(1.6%, 20.4%)
40	4	10.0%	(2.8%, 23.7%)
50	3	6.0%	(1.3%, 16.5%)
50	4	8.0%	(2.2%, 19.2%)
60	4	6.7%	(1.8%, 16.2%)
60	5	8.3%	(2.8%, 18.4%)

For example, at an early look, there would be concern within an active dose group if 2 or more patients reported ALT ≥ 3xULRR and BIL ≥ 3xULRR out of a total of 10 (rate 20.0%). Assuming the last look is performed on 60 patients, there would be concern within a dose group if 5 or more patients reported ALT ≥ 3xULRR and BIL ≥ 2xULRR (rate 8.3%).

HEART

The exploratory cardiac biomarkers measured in the study are CK-MB and cardiac troponin I (cTnI). The cTnI and CK-MB biomarkers were specifically chosen to monitor for myocarditis and the use of these cardiac biomarkers are exploratory for this purpose and are intended specifically as population biomarkers. Generally, elevations of CK-MB ≥ 2 X ULRR that occur at an incidence roughly 1.5 fold greater in active treatment groups compared to placebo may be of concern. Elevations of troponin I (cTnI) that exceed the estimated 99th percentile for healthy subjects (estimated at ~0.2 ng/mL which equals the lower limit of detection for the current assay) and that occur at an incidence roughly 1.5 fold greater in active treatment groups compared to placebo may be of concern. During the early stages of the trial when the sample size is small these incidences should be interpreted with caution. cTnI values will be provided to the SDAC in three ranges which are based on information provided by the assay manufacturer, the scientific literature and the specific reporting capability of Quest Diagnostics. The three cTnI reporting ranges are:

<0.2 ng/mL

≥0.2 ng/mL to ≤ 1.5 ng/mL

>1.5 ng/mL

Case narratives (real-time) will be provided to the SDAC for all values of cTnI reported as > 1.5 ng/mL. The IDMC should consider the clinical context of any abnormal laboratory finding. The CK-MB and cTnI biomarkers are not intended to monitor for ischemic heart disease in this protocol but are employed to monitor for the potential of myocarditis. The ranges suggested above are derived from data in healthy individuals and the potential differences of the type 2 diabetic population and background cardiovascular disease should be considered when making any determination. The consultant cardiologist should be contacted if the IDMC determines this expertise is necessary for interpretation of any cardiac findings.

Cardiac findings other than abnormal CK-MB and/or cTnI that manifest as Adverse Events and/or abnormal ECG findings that occur at an incidence roughly 2-fold greater in active treatment groups compared to placebo may be of concern.

HEMATOLOGY

Hemoglobin values < LLRR and/or reductions in hemoglobin from baseline ≥ 1 g/dL that occur at an incidence roughly 2-fold greater in active treatment groups compared to placebo may be of concern, however during the early stages of the trial when the sample size is small these incidences should be interpreted with caution. As provided in the charter case narratives will be written (real-time) by the sponsor and delivered to the SDAC for individuals with decreases in hemoglobin from baseline of ≥ 2 g/dL. Similar guidance as illustrated in Table 1 can be used for decreases in hemoglobin from baseline ≥ 2 g/dL

ADVERSE EVENTS

Adverse events in any body system that may represent additional risk to participating subjects should be closely followed. As detailed in the charter case narratives will be prepared by the sponsor and delivered to the IDMC for SAEs and adverse events leading to withdrawal. In general, treatment related adverse events that occur disproportionately in subjects randomized to active treatment or at a frequency roughly two-fold greater than placebo should be investigated, however during the early stages of the trial when the sample size is small these incidences should be interpreted with caution

Appendix G: Abbreviations/Acronyms

AE	Adverse Event
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BDS	Biomedical Data Sciences
CK-MB	Creatine kinase isoenzyme MB
cTnI	Cardiac Troponin I
eCRF	Electronic Case Report Form
ECG	Electrocardiogram
FPG	Fasting Plasma Glucose
GCSP	Global Clinical Safety and Pharmacovigilance
GSB	GlaxoSmithKline Global Safety Board
GSK	GlaxoSmithKline
HbA1c	Glycosylated hemoglobin
IRB	Institutional Review Board
OCEANs	Operating Companies Event Accession & Notification System
LLRR	Lower Limit of the Reference Range
RAMOS	Registration and Medication Ordering System
SAE	Serious Adverse Event
SAG	Sponsor Advisory Group
SDAC	Statistical Data Analysis Center
SOP	Standard Operating Procedure
IDMC	Independent Data Monitoring Committee
ULRR	Upper Limit of the Reference Range
WWD	World Wide Development

Investigator Signature Page

STUDY TITLE: A 12-Week, Parallel-Group, Double-Blind, Randomised, Placebo-Controlled, Multicentre, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects with Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension - Report of data from main phase

I have read this report and confirm that to the best of my knowledge Study DPB100925 was carried out as described in the GlaxoSmithKline Report GM2006/00396/00

Name of Investigator: **Prof. Dr. med.** [redacted]

Affiliation: [redacted]

Signature of Investigator: _____

Date: Oct. 20, 2006

Sponsor Signatory Signature Page

STUDY TITLE: A 12-Week, Parallel-Group, Double-Blind, Randomised, Placebo-Controlled, Multicentre, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093 (2.5mg, 7.5mg, 15mg, 30mg and 45mg), Administered Orally, Once Daily, as Monotherapy in Subjects With Type 2 Diabetes Mellitus followed by a 12-week Active Treatment Extension - Report of data from main phase

Study: DPB100925 Development Phase: II

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Sponsor Signatory: Dr [redacted] DM FRCP

Title of Sponsor Signatory: Vice President, Clinical Development, Alternative Development Program, GlaxoSmithKline, Upper Merion, USA

Signature: [redacted]

Date: 24th November 2006