4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0092]

Study Data Technical Conformance Guide and Data Standards Catalog; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Study Data Technical Conformance Guide, Version 2.0 (Guide), and an update to the Data Standards Catalog (Catalog). The Guide supplements the final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" (eStudy Data guidance) and provides specifications and recommendations for, as well as general considerations on, submitting standardized study data using FDA-supported data standards specified in the Catalog. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions.

DATES: Submit either electronic or written comments on these documents at any time.

ADDRESSES: Submit written requests for a copy of the Study Data Technical Conformance Guide and the Data Standards Catalog to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993-0002, 301-796-5333, ronald.fitzmartin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of Version 2.0 of the Guide and an update to the Catalog. The Guide supplements the final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" (available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm), and provides technical recommendations to sponsors for the electronic submission of standardized animal and human study data and related information contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and investigational new drug applications (INDs). The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (which was added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)) for standardized study data contained in NDA, ANDA, BLA, and IND submissions.

The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. It is not intended to replace the need for sponsors to communicate directly with review divisions regarding data standards implementation approaches or issues.

The Guide is organized as follows:

Section 1: "Introduction"--provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: "Planning and Providing Standardized Study Data"--recommends and provides details on preparing an overall study data standardization plan, a study data reviewer's guide, and an analysis data reviewer's guide.

Section 3: "Exchange Format--Electronic Submissions"--presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

Section 4: "Study Data Submission Format: Clinical and Nonclinical"--presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and Standard for Exchange of Nonclinical Data (SEND).

Section 5: "Therapeutic Area Standards"--presents supplemental considerations and specific recommendations when sponsors submit study data using FDA-supported therapeutic area standards.

Section 6: "Terminology"--presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: "Electronic Submission Format"--provides specifications and recommendations on submitting study data using the electronic Common Technical Document format.

Section 8: "Data Validation and Traceability"--provides general recommendations on conformance to standards, data validation rules, data traceability expectations, and legacy data conversion.

In the Federal Register of February 6, 2014 (79 FR 7201), FDA announced the availability of Version 1.0 of the Study Data Technical Conformance Guide. The comment period on the Guide ended on May 7, 2014. We reviewed all comments received and revised it accordingly. Updates to Version 2.0 include, but are not limited to:

Section 2: Added a subsection to include an Analysis Data Reviewer's Guide.

Section 3: Clarified dataset sizes, column lengths, special characters for variables, and datasets.

Section 4: Clarified general considerations and domain specifications for SDTM and ADaM.

Section 6: Clarified a number of subsections, including controlled terminology, medications, pharmacologic class, and indication, and added a World Health Organization Drug Dictionary.

Section 7: Clarified the electronic submission format and the folder structure for study datasets.

Section 8: Renamed the section "Data Validation and Traceability" from "Data Fitness" and clarified several of the subsections, including Traceability Issues and Legacy Data Conversion.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the Guide and the Catalog at either http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm or http://www.regulations.gov.

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-00206 Filed 01/09/2015 at 8:45 am; Publication Date: 01/12/2015]