4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1840]

Electronic Study Data Submission; Data Standards; Validation Rules for Study Data Tabulation Model Formatted Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing the availability of a document entitled "Validation Rules for Study Data Tabulation Model (SDTM) Formatted Studies." CDER is making this document available to improve the standardization and quality of clinical data submitted to CDER, as well as to improve the predictability of data quality and usefulness.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993, email: edata@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: CDER supports the regulatory submission of standardized clinical study data based on the Clinical Data Interchange Standards Consortium SDTM. Upon receipt of the data, CDER validates the data using a set of validation rules. The "Validation Rules for SDTM Formatted Studies" is an Excel file that provides a human readable description of a rule set for validation. Submitters of clinical study data can use this information to understand how FDA validates the data. The file is available on FDA's Study Data Standards Resources Web page at

http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm. It contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support useful analysis). The rules may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

Dated: November 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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