4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2853]

Electronic Study Data Submission; Data Standards; Support for Study Data Tabulation Model Implementation Guide Version 3.2

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) are announcing support for the 3.2 version (see section II. Exceptions) of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model Implementation Guide (SDTM IG 3.2), an update to the FDA Data Standards Catalog (Catalog), and availability of validation rules for the 3.2 version. SDTM IG 3.2 has been available from CDISC since December 2013. FDA is encouraging sponsors and applicants to use SDTM IG 3.2 (see section II. Exceptions) in investigational study data provided in regulatory submissions to CBER and to CDER.

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 20993-002, 301-796-5333, email: ronald.fitzmartin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" (eStudy Data) posted on FDA's Study Data Standards Resources Web page at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k-1) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data is December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a Federal Register notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support (see section II. Exceptions) of the 3.2 version of CDISC STDM IG is March 15, 2017. Although SDTM IG version 3.2 is supported as of this Federal Register notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2018. The Catalog will list March 15, 2018, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

II. Exceptions

The following SDTM IG 3.2 domains have not completed testing and acceptance and are not supported at this time: Death Details and Exposure as Collected. The therapeutic area (TA) standards (http://www.cdisc.org/) that are included in SDTM IG 3.2 have not completed testing

and acceptance and are not supported at this time. The specific domain and the TA standard are listed in the table that follows:

SDTM IG 3.2 Domain	TA User Guide
1. Healthcare Encounters	Cardiovascular Studies, 1.0; Polycystic Kidney Disease, 1.0; Asthma, 1.0
2. Microscopic Findings	Tuberculosis, 1.0; Parkinson's,1.0
3. Morphology	Cardiovascular Studies,1.0; Parkinson's,1.0; Polycystic Kidney Disease,1.0; Alzheimer's,1.0; Multiple Sclerosis,1.0
4. Procedures	Cardiovascular Studies,1.0; Polycystic Kidney Disease,1.0; Alzheimer's,1.0
5. Reproductive System	Polycystic Kidney Disease, 1.0
6. Disease Response	Tuberculosis,1.0
7. Skin Response	Asthma,1.0

Sponsors and applicants with questions on how to implement the FDA-supported study data standards should contact and work with FDA technical staff. For questions, contact CDER at cder-edata@fda.hhs.gov or CBER at cber.cdisc@fda.hhs.gov.

III. 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.

IV. Electronic Access

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

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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