4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2363]

Electronic Study Data Submission; Data Standards; Support for Standard for Exchange of Nonclinical Data Implementation Guide Version 3.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing support for the 3.1 version of Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND IG 3.1), the end of support for the 3.0 version of SEND IG, and an update to the FDA Data Standards Catalog (Catalog). (See http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.) SEND IG 3.1 has been available from CDISC (www.cdisc.org) since July 2016. FDA is encouraging sponsors and applicants to use SEND IG 3.1 in investigational study data provided in regulatory submissions 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. 1115, Silver Spring, MD 20993-0002, 301-796-5333, email: CDERDataStandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published 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 https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Food, Drug and Cosmetic Act (21 U.S.C. 379k-1(a)) 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 FDA's Center for Biologics Evaluation and Research or CDER by specifying the format for electronic submissions. The initial timetable for implementing electronic submission requirements for study data was 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 of version 3.1 of CDISC SEND IG is March 15, 2018. Although SEND IG version 3.1 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, 2019. The Catalog will list March 15, 2019, 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.

The transition date for the end of FDA support for SEND IG 3.0 is March 15, 2018. Therefore, FDA support for SEND IG 3.0 will end for studies that start after March 15, 2019. The Catalog will be updated to list March 15, 2019, as the "date support ends."

II. Electronic Access

Persons with access to the Internet may obtain the referenced material at https://www.fda.gov/ectd.

Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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