4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2837]

Electronic Study Data Submission; Data Standards; Support for Analysis Data Model Implementation Guide Version 1.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing support for version 1.1 of Clinical Data Interchange Standards Consortium (CDISC), Analysis Data Model Implementation Guide (ADaM IG V1.1), an update to the FDA Data Standards Catalog (Catalog). (See http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm). ADaM IG V1.1 has been available from CDISC (www.cdisc.org) since February 12, 2016. FDA is encouraging sponsors and applicants to use ADaM IG V1.1 in investigational study data provided in regulatory submissions to CDER.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-2837 for "Electronic Study Data Submission; Data Standards; Support for Analysis Data Model Implementation Guide Version 1.1." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane,Rrm. 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. 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 "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 Federal 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 the Center for Biologics Evaluation and Research (CBER) or CDER by specifying the format for electronic submissions. The implementation of electronic submission requirements for study data became effective on 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 1.1 of ADaM 1G V 1.1 is March 15, 2018. ADaM IG V.1.1 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, which will be reflected in the Catalog, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select any of those version to use.

The transition date for the end of FDA support for ADaM IG V 1.0, is March 15, 2018.

II. Electronic Access

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

Dated: September 22, 2017.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2017-21081 Filed: 9/29/2017 8:45 am; Publication Date: 10/2/2017]