



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

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

### **Electronic Study Data Submission; Data Standards; Support End Date for Case Report Tabulation Data Definition Specification Version 1.0**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the end of support for Version 1.0 of Clinical Data Interchange Standards Consortium Case Report Tabulation Data Definition Specification (Define.xml) and an update to the FDA Data Standards Catalog. Use of Define.xml Version 2.0, which has been available since March 2013, is the newer standard supported by FDA. FDA support for Define.xml Version 1.0 will end for studies that start 12 months after March 15, 2017.

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: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2014-N-1840 for "Electronic Study Data Submission; Data Standards; Support End Date for Case Report Tabulation Data Definition Specification Version 1.0." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<http://www.regulations.gov> or at the Division of Dockets Management 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 <http://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 docket, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Fatima Frye, 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, fatima.frye@fda.hhs.gov; or Jack Zhang, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7318, Silver Spring, MD 20993-0002, 240-402-8187, jack.zhang@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, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or CBER by specifying the format for electronic submissions. The eStudy Data guidance states that a Federal Register notice will specify the transition date for updates to standards (with the month and day for the transition date corresponding to March 15).

The transition date for the end of FDA support for Define.xml Version 1.0 is March 15, 2017. Therefore, FDA support for Define.xml Version 1.0 will end for studies that start after

March 15, 2018. The FDA Data Standards Catalog (see <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>) will be updated to list March 15, 2018, as the "date support ends."

## **II. Electronic Access**

Persons with access to the Internet may obtain the referenced material at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

Dated: March 10, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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