



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4565]

Electronic Study Data Submission; Data Standards; Support for Version Update of the Medical Dictionary for Regulatory Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for the most current version of Medical Dictionary for Regulatory Activities (MedDRA), end of support for earlier versions of MedDRA, and an update to the FDA Data Standards Catalog (Catalog) for study data provided 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) and the Center for Drug Evaluation and Research (CDER).

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

ADDRESSES: You may submit comments as follows:

Electronic Submission

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-4565 for "Electronic Study Data Submission; Data Standards; Support for Version Update of the Medical Dictionary for Regulatory Activities." 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 Dockets Management Staff. 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, Rm. 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, cderdatastandards@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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 <https://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 NDAs, ANDAs, BLAs, and INDs to CBER or CDER by specifying the format for electronic submissions. This provision required that the electronic format for submission of applications be specified in guidance and effective no sooner than 24 months after issuance of the final guidance. 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).

FDA currently supports and requires MedDRA for the coding of adverse events in studies submitted to FDA’s CBER or CDER in NDAs, ANDAs, BLAs, and INDs in the electronic common technical document (eCTD) format. However, the requirement to code adverse events

using MedDRA in the most current version (available at <https://www.meddra.org>) does not apply to postmarketing studies that are submitted in eCTD sections 5.3.5.4 and 5.3.6 (<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163175.pdf>).

Generally, the studies included in a submission are conducted over many years and may have used different MedDRA versions to code adverse events. The expectation is that sponsors or applicants will use the most current version of MedDRA at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support and requirement to use the most current version of MedDRA is March 15, 2018. Although the use of the most current version is supported as of this *Federal Register* notice and sponsors or applicants are encouraged to begin using it, the use of the most current 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.” The Study Data Technical Conformance Guide provides additional information and recommendations on the coding of adverse events (<https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf>).

FDA will no longer support version 8 or earlier of MedDRA. FDA support for earlier versions of MedDRA will end for studies that start after March 15, 2019. The FDA Data Standards Catalog will be updated to list March 15, 2019, as the “date support ends.” Studies that start after March 15, 2019, will be required to use the most current version of MedDRA.

Dated: August 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-18471 Filed: 8/30/2017 8:45 am; Publication Date: 8/31/2017]