



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2354]

Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Version 1.1 of the Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide and Version 1.6 of the Study Data Tabulation Model; Clarification to Food and Drug Administration Data Standards

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 the date that support will begin for version 1.1 of the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide (SENDIG-DART) and version 1.6 of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and the dates when such new standard and version update will be required in certain submissions. The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes. An additional note is added to the Catalog clarifying the requirements for the submission of a simplified trial summary dataset to determine a study start date at the point of submission at the electronic gateway.

DATES: Support for version 1.1 of the CDISC SENDIG-DART and version 1.6 of the CDISC SDTM will begin on March 15, 2021. The requirement for electronic submissions to be submitted using version 1.1 of the CDISC SENDIG-DART will begin March 15, 2023, for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and certain biologics license applications (BLAs), and March 15, 2024, for certain investigational new drug

applications (INDs). The requirement for electronic submissions to be submitted using version 1.6 of the CDISC SDTM will begin on March 15, 2022.

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-2020-N-235 for “Data Standards; Requirements Begin for the Clinical Data Interchange Standards Consortium Version 1.1 of the Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide and Version 1.6 of the Study Data Tabulation Model. Clarification to the FDA Data Standards Catalog.” 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 240-402-6511, email: [cdertextstandards@fda.hhs.gov](mailto:cdertextstandards@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

FDA’s CDER is issuing this *Federal Register* notice to announce the date that support will begin for version 1.1 of the CDISC SENDIG-DART and version 1.6 of the CDISC SDTM and the dates when such new standard and version update will be required in certain submissions. The FDA guidance for industry “Providing Regulatory Submissions in Electronic Format--Standardized Study Data” (October 2020) (eStudy Data guidance), posted on FDA’s Study Data Standards Resources web page at <https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>, 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, certain BLAs, and certain INDs submitted to CDER or the Center for Biologics Evaluation and Research by specifying the format for electronic submissions. The eStudy Data guidance states that a *Federal Register* notice will specify any new standards and version updates to FDA-supported study data standards that will be added to the Catalog, when the support for such standards and version updates begins or ends, and when the requirement to use such standards and version updates in submissions begins or ends.

Support for version 1.1 of the CDISC SENDIG-DART and version 1.6 of the CDISC SDTM will begin on March 15, 2021, the transition date. The requirement for electronic

submissions to be submitted using version 1.1 of the CDISC SENDIG-DART will begin March 15, 2023, for NDAs, ANDAs and certain BLAs, and March 15, 2024, for certain INDs. The requirement for electronic submissions to be submitted using version 1.6 of the CDISC SDTM will begin on March 15, 2022.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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