



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1206]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the *Federal Register* of July 7, 2020. The document announced the dates that support and requirement will begin for version 1.7 of the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model (SDTM) Implementation Guide (IG) 3.3, and for version 2.1 of the Define-Extensible Markup Language (Define-XML). The document provided the incorrect dates for these electronic study data standards. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035, [cderdatastandards@fda.hhs.gov](mailto:cderdatastandards@fda.hhs.gov), or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of July 7, 2020 (85 FR 40658), in FR Doc. 2020-14512, the following correction is made:

On page 40659, in the first column, the last three sentences of the document are corrected to read as follows: “Support for version 1.7 of the CDISC SDTM IG 3.3 and version 2.1 of the Define-XML will begin on March 15, 2021, and the date that the requirement begins for CDISC version 1.7 SDTM IG 3.3 and version 2.1 of the Define-XML for new drug applications, abbreviated new drug applications, certain biologics license applications, and noncommercial investigational new drug applications will be March 15, 2022. Support and requirement for version 1.3 of the CDISC SDTM IG 3.1.3 will end on March 15, 2021.”

Dated: August 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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