4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0710]

Electronic Study Data Submission; Data Standard Support End Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) are announcing the end of support for the 3.1.1. version of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) Implementation Guide (SDTM IG 3.1.1.). SDTM IG 3.1.2, which has been available since October 2009, is the newer standard supported by FDA. Support for SDTM IG 3.1.1 will end on January 28, 2015.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

FDA encourages sponsors to submit standardized study data using Agency-supported data standards (see http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm).[1] An Agency-supported data standard means that FDA has established processes and technology infrastructure to support the receipt, processing, review, and archiving of study data using the standard. As data standards evolve, FDA will periodically end support for old standards in favor of newer standards that are better suited to meet FDA data management and review needs. FDA maintains a catalog of the supported data standards for study data submissions at http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM292505.xls.

To facilitate the transition to newer standards, FDA is committed to providing a transition period of 24 months during which both older and newer standards are supported. FDA first began supporting SDTM IG 3.1.2 on October 30, 2009, over 2 years ago.

This notice establishes that CBER, CDER, and CDRH are ending support for SDTM IG 3.1.1. effective January 28, 2015. Effective immediately, submitters are strongly encouraged to use SDTM IG 3.1.2 instead. The support end date is the date past which study data using the standard may not be submitted, unless special arrangements have been made in advance with the Agency.

FDA recognizes the challenges associated with adopting a new standard, particularly because studies are often conducted and study data are standardized months to years before

[1] Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), requires electronic submission of drug and biologic applications beginning no earlier than 24 months after issuance of a final guidance. The final guidance, to be issued under section 745A of the FD&C Act following public notice and opportunity for comment, will specify the format required for such electronic submissions. The action announced in this notice,

submission to the Agency. Submitters seeking a special arrangement to provide data using SDTM IG 3.1.1 beyond the established support end date should submit a waiver request. A waiver request process will be posted at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm for CDER and http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm for CBER by November 1, 2012. The waiver process will be put into place to support the transition and allow for submission of clinical data in SDTM IG 3.1.1 format data in cases where SDTM IG 3.1.2 is otherwise not feasible and/or when such submission has been determined as having no negative impact to the review process.

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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although applicable to electronic submission of standardized study data, is not being taken under section 745A of the FD&C Act and is not intended to trigger the mandatory submission requirements under that section.