4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1424]

Transport Format for the Submission of Regulatory Study Data; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) are announcing a pilot project to evaluate the Clinical Data Interchange Standard Consortium (CDISC) Submission Data Standards (SDS) Extensible Markup Language (XML) transport format for the submission of regulatory study data. The current study data transport format supported by FDA is the SAS Transport (XPORT) version 5 file format. Although XPORT has been a reliable exchange format for many years, it is not an extensible modern technology. SDS XML is an extension of the CDISC Operational Data Model, which is a vendor neutral, platform-independent format for the exchange and archive of study data. FDA is announcing an invitation to sponsors to participate in this pilot project to evaluate the SDS XML transport format.

DATES: Submit either electric or written requests for participation in the pilot project by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to http://www.regulations.gov. Summit written requests and comments to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1062, 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. 1160, Silver Spring, MD 20993, 301-796-5333, ronald.fitzmartin@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the 1999 "Guidance to Industry: Providing Regulatory Submissions in Electronic Format" FDA recommended that regulatory submissions of clinical data to FDA utilize SAS Institute's open transport called XPORT version 5 format (XPORT). The XPORT format was developed in the late 1980s and there have been no version updates since 1999. XPORT is now considered by many to be an outdated transport technology for transferring data across different hardware and operating systems.

Following a Federal Register Notice, FDA held a public meeting on November 5, 2012, entitled "Regulatory New Drug Review: Solutions for Study Data Exchange Standards." The purpose of the public meeting was to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. FDA indicated, in the Notice and at the meeting, based on feedback received at the public meeting and other information sources, it would undertake further requirements analysis in support of expected evaluation projects.

II. Project Participation

FDA envisions several pilot projects conducted to evaluate new transport formats. The purpose of this pilot project is to obtain additional experience with CDISC SDS XML format. A successful pilot may allow CDER and CBER to routinely receive study data that employ CDISC SDS XML format as the transport format once an alternatives analysis is completed. As part of this pilot, FDA would like to have sponsors participate in the preparation and submission of previously submitted study datasets using the SDS XML transport format. Participation in this evaluation will be outside of the regulatory pathway and, as such, will not be used to make regulatory decisions.

FDA expects that the pilot will assess the technical capability of SDS XML to exchange and archive regulatory study data in investigational new drug applications, new drug applications, and biologics licensing applications.

III. Requests for Participation

Requests to participate in the SDS XML pilot project are to be identified with the docket number found in brackets in the heading of this document. Interested persons should include the following information in the request: Contact name, contact phone number, email address, name of the sponsor, address, and license number. Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot project. FDA is seeking a limited number of sponsors (approximately three to five, but no more than six) to participate in this project. The elapsed time duration of the pilot is expected to be approximately 12 months but may be extended as needed. Participants should be willing to provide previously submitted study data using both the SAS XPORT version 5 format and the CDISC SDS XML format.

Dated: November 20, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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