4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2012-N-0780]

Regulatory New Drug Review: Solutions for Study Data Exchange Standards; Notice of Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Announcement of meeting, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting entitled "Regulatory New Drug Review: Solutions for Study Data Exchange Standards" the purpose of which is 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 also seeks input from stakeholders and other members of the public on this topic and a set of premeeting questions discussed below.

DATES: The meeting will be held on November 5, 2012, from 10 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Office of Planning & Informatics, 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, FAX: 301-847-8443, email: CDERDataStandards@hhs.fda.gov.

SUPPLEMENTARY INFORMATION:

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments regarding this document. Given that time will be limited at the public meeting, FDA encourages all interested persons to comment in writing to ensure that their comments are considered. The deadline for submitting responses regarding the premeeting questions is October 5, 2012.

Submit electronic responses to the premeeting questions to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

Registration: Registration is required in advance and participation will be limited. Send registration information (including name, title, firm name, country of citizenship, address, telephone and fax number, and email address) to Fatima Elnigoumi, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 1195, Silver Spring, MD, 20993, 301-796- 4863, email: CDERDataStandards@hhs.fda.gov. Registrations will be accepted in the order that they are received with a limit of 300. If you need special accommodations due to a disability, please contact Fatima Elnigoumi at least 7 days in advance.

I. Background

The current study data exchange format supported by FDA is the ASCII-based SAS Transport (XPORT) version 5 file format. Although XPORT has been an exchange format for many years, it is not an extensible modern technology. Moreover, it is not supported and maintained by an open, consensus-based standards development organization.

FDA would like to discuss the current and emerging open study data exchange standards that will support interoperability. Currently, the use of XPORT can be described as an example of the exchange of study data between two or more systems using a specified file format (e.g., XML, SQL, ASCII). However, the desired path forward is to achieve interoperability with other systems where the exchange of data between systems can be reviewed, analyzed, and reported with minimal need for data integration.

Based on feedback from this meeting and other information, an evaluation of the cost-benefit of a migration to a new study data exchange standard--on both FDA and regulated industry--will be conducted to inform next steps, which will include an action plan.

II. Premeeting Questions to Stakeholders

FDA seeks input from stakeholders and other members of the public on the following premeeting questions:

1. What are the most pressing challenges that industry faces with regard to study data management? Please address each of the following areas: (a) Study design/set-up, (b) capture, (c) integration, (d) analysis, (e) reporting, and (f) regulatory submission. What opportunities/ solutions exist to meet <u>each</u> challenge?

2. How could FDA's regulatory requirements make the study data management process more efficient?

3. What does industry need to make clinical trials data management more effective and efficient? Please describe the tools, techniques, and processes that would help as well as the regulatory guidance documents that would be useful in this area.

4. What data standards are you currently using for the conduct of regulated research studies?

5. Would Health Level Seven v3[1] (e.g., messages, structured documents and Clinical Data Architecture) be a viable study data exchange standard? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

6. Would CDISC Operational Data Model[2] be a viable study data exchange standard? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

7. Are there other open data exchange standards that should be evaluated? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

8. What would be a reasonable phased implementation period for each recommended exchange standard? And should supporting multiple, concurrent study data exchange standards be evaluated (please explain advantages and disadvantages of this approach)? What can FDA do to help industry to be more prepared for, or reduce burden of, a migration to a new study data exchange standard?

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[1] See http://www.hl7.org for system description.
[2] See http://www.cdisc.org for system description.

9. FDA encourages sponsors to design study data collection systems so that relationships between data elements, as well as relationships across data domains, can be captured at the point of data entry. Describe the challenges, to and opportunities for, accomplishing this goal.

10. What other comments would you care to share with FDA concerning the general topic of data exchange standards?

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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