4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0001]

Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities." Convened by the Duke-Robert J. Margolis Center for Health Policy at Duke University in partnership with the Critical Path Institute and supported by a cooperative agreement with FDA, the purpose of the public workshop is to bring the stakeholder community together to discuss challenges and opportunities to advance the development and application of analysis data standards in drug development and regulatory review. This public workshop is being organized to fulfill FDA's commitment in section (I)(J)(5)(c) of the Prescription Drug User Fee Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (PDUFA VI goals letter; available at https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf) to convene a public workshop to advance the development and application of analysis data standards. FDA will use the information from this public workshop to inform ongoing and

future analysis data standards initiatives and strategic planning to improve the efficiency of regulatory review of electronic submissions.

DATES: The public workshop will be held on June 12, 2019, from 9 a.m. to 4:30 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. For more information, please check the following website: https://www.tommydouglascenter.com/. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Mary Jo Salerno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3541, Silver Spring, MD 20993-0002, 240-402-0420, MaryJo.Salerno@fda.hhs.gov. If contacting in writing, please use the subject line "Analysis Data Standards Public Workshop."

SUPPLEMENTARY INFORMATION:

I. Background

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables. Establishing common study data standards provides new opportunities to transform the vast, diverse, and continually increasing amount of clinical study data into useful information to speed the delivery of new therapies to patients. Having standard, uniform study data enables FDA scientists to combine data from multiple studies to explore many new research questions and gain new

insights. Data standards also help FDA receive, process, review, and archive submissions more efficiently and effectively by preventing submission reviewers from having to navigate a high volume of less-structured data, which allows reviewers more time to focus on the scientific review.

The Center for Drug Evaluation and Research (CDER) established the Data Standards Program in 2010. The program has led CDER's efforts to standardize data and has helped FDA meet its commitments in the Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 (PDUFA V). Accomplishments to date include the following: (1) publication of a final guidance entitled "Providing Regulatory Submissions in Electronic Format--eCTD Specifications"; developing a repeatable test process to ensure data standards meet FDA needs; (2) working with FDA's Center for Biologics Evaluation and Research to compile a prioritized list of disease and therapeutic areas for which additional data standardization is needed; and (3) working with partners to develop a series of use cases for clinical study data related to Human Immunodeficiency Virus therapies, vaccines, and comparative clinical endpoint bioequivalence studies.

Standards models that span the data lifecycle from data collection (e.g., Clinical Data Acquisition Standards Harmonization (CDASH)) to tabulated representation (e.g., Standard for the Exchange of Nonclinical Data (SEND) and Study Data Tabulation Model (SDTM)) are foundational for analysis data standards (e.g., Analysis Data Model (ADaM)). FDA is conducting this public workshop to support the PDUFA VI goals to advance the development and application of analysis data standards.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will address a range of issues related to the development and implementation of analysis data standards. Items for discussion will include stakeholder experience implementing analysis data standards in electronic submissions. Input will be sought on the key challenges and opportunities to: (1) improve the efficiency, predictability, and quality of data submissions; (2) support data traceability; and (3) support optimal implementation of analysis data standards. Input will also be sought on approaches to reduce the variability of formats used to submit study data, improve the integration of data across studies, and enable the use of data from sources other than traditional clinical trials.

III. Participating in the Public Workshop

Registration: To register for the public workshop, visit the following website: https://healthpolicy.duke.edu/events/analysis-data-standards-workshop. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by June 10, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Duke-Margolis will post on its website if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy, 202-791-9561, sarah.supsiri@duke.edu, no later than June 5, 2019.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Webcast participants will be able to submit questions and comments via the webcast portal. Following the workshop, archived video footage will be available on the Duke-Margolis website at https://healthpolicy.duke.edu/events/analysis-data-standards-workshop. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Before joining the streaming webcast of the public workshop, we recommend that you review these technical system requirements. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that transcripts will not be available.

Workshop Materials: All event materials will be provided to registered attendees via email before the workshop and will also be publicly available on the Duke-Margolis website at https://healthpolicy.duke.edu/events/analysis-data-standards-workshop.

Dated: April 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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