4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0974]

Development of Prioritized Therapeutic Area Data Standards; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the intent to prioritize and develop therapeutic area data standards to facilitate the conduct of clinical research and the regulatory review of medical products. Therapeutic area disease and domain specific data standards should enable and enhance the ability to integrate, analyze, report, and share regulatory information. FDA has developed a roadmap that provides its current thinking on therapeutic area priorities and has posted it on the FDA Web site. FDA is actively participating with regulated industry, the Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute, Health Level 7's (HL7) Clinical Interoperability Council, and other stakeholders to support the development of these therapeutic area standards. The therapeutic area standards will be developed collaboratively based on open, consensus-based data standards development methodology.

DATES: To ensure that the Agency considers your comments, submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for a copy of the roadmap to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903

New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on FDA's objective to develop prioritized therapeutic area data standards or on the roadmap 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. See the SUPPLEMENTARY INFORMATION section for electronic access to the roadmap.

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 20993-0002,

CDERDataStandards@fda.hhs.gov, or

Amy Malla,

Center for Biologics Evaluation and Research (HFM-25),

1401 Rockville Pike, suite 200N,

Rockville, MD 20852-1448,

301-827-6085.

SUPPLEMENTARY INFORMATION:

I. Background

Traditionally, clinical study data submitted to FDA is in a format that is unique to each individual sponsor; furthermore the data quality varies. This has created inefficiencies in the review process and impeded efforts to analyze the data across applications when such analyses could be beneficial to detect trends in safety or efficacy or for other reasons. Sponsor adoption of available clinical trial data standards (CDISC/SDTM) for the submission of product applications have helped to improve the quality and standardization of submitted data. However, such a voluntary approach has proved insufficient to support both the current business requirements as well as efforts to modernize the review environment.

In 2011, the Center for Drug Evaluation and Research (CDER) identified a set of disease and therapeutic areas that could benefit from further standardization. These content area standards are primarily intended to support the efficient evaluation of medical products as noted previously in this document. Several factors were considered in the identification of these areas: (1) Areas of particular need, (2) areas with existing data standardization projects underway, and (3) areas with greater drug development pipeline activity. The initial prioritization was based on the number of active investigational new drug applications (or INDs) and input from review divisions, as well as from industry. The three tiers of priority were assembled into a roadmap and posted on the FDA Web site at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm. The roadmap sets out a sequence of standardization efforts to achieve significant results by December 2017. CDER established a small grants program to fund projects that develop disease and domain-specific therapeutic area data standards.

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act of 2012, which includes the reauthorization of the Prescription Drug User Fee Act (PDUFA V). Under section XII of the PDUFA V performance goals, FDA agreed to create a plan for distinct therapeutic area data standards and to prioritize and develop the data standards in collaboration with CDISC and other open standards organizations. FDA is seeking public comment on the roadmap and will consider the comments as the Agency develops its proposed project plan which is due to be issued for review and comment by June 30, 2013. In addition, FDA will publish notices soliciting input on, and engagement in, standards development activities, and will periodically issue guidances specifying the completed data standards, formats, and terminologies that sponsors should use to submit data in applications.

II. Comments

Interested persons may submit either written comments regarding the roadmap, as well as recommendations on how the therapeutic area data standards development effort could be accomplished more rapidly, to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the roadmap at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm,

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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