4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0643]

Draft Guidance for Industry on Electronic Source Data in Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Electronic Source Data in Clinical Investigations." This document revises and updates the draft guidance entitled "Electronic Source Documentation in Clinical Investigations." This revised draft document provides guidance to sponsors, contract research organizations (CROs), data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. The revised draft guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug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; Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; and Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4173, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT:

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Office of Planning and Informatics,

Center for Drug Evaluation and Research,

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10903 New Hampshire Ave.,

Bldg. 51, rm. 1160,

Silver Spring, MD 20993-0002,

301-796-5333.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Electronic Source Data in Clinical Investigations." This document revises and updates the draft guidance entitled "Electronic Source Documentation in Clinical Investigations." This revised draft document provides guidance to sponsors, CROs, data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. The revised draft guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.

With the use of computerized systems for capturing clinical study data, it is common to find at least some source data recorded electronically. Common examples include clinical data initially recorded in electronic health records maintained by hospitals and institutions, electronic laboratory reports, electronic medical images from devices, and electronic diaries provided by study subjects.

Capturing source data electronically should help to: (1) Eliminate unnecessary duplication of data; (2) reduce the possibility for transcription errors; (3) encourage entering source data at the time of a subject's visit; (4) eliminate transcribing source data before entering the data into an electronic data capture system; (5) promote real-time data access for review; and (6) ensure the accuracy and completeness of the data.

In the Federal Register of January 7, 2011 (76 FR 1173), FDA announced the availability of the draft guidance entitled "Electronic Source Documentation in Clinical Investigations." Based on public comment, we have revised the January 2011 draft guidance to clarify a number

of points made by industry. The Agency is publishing the draft guidance as a revised draft guidance to collect additional public comments. This revised draft guidance addresses source data (from clinical investigations) used to fill the predefined fields in an electronic case report form (eCRF), according to protocol. The draft guidance discusses the following topics related to electronic source data:

- Identifying and specifying authorized source data originators;
- Creating data element identifiers to facilitate sponsors, FDA, and other authorized parties in examining the audit trail of data;
- Capturing source data into the eCRF using either manual or electronic capture methods; and
- Investigator responsibilities with respect to reviewing and retaining electronic data.

The revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CDR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document 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. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The draft guidance pertains to sponsors, clinical investigators, contract research organizations, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others, or keep certain records and make them available to FDA inspectors. The information collection discussed in the draft guidance is contained in our investigational new drug regulations (21 CFR 312) and approved under OMB control number 0910-0014, including §§ 312.62(b) and 312.58(a). In addition, the collection of information in 21 CFR part 11, as discussed in the draft guidance, is approved under OMB control number 0910-0303. OMB approval of the information collection in the guidance entitled "Computerized Systems Used in Clinical Investigations," as mentioned in the draft guidance, is discussed in the May 10, 2007 (72 FR 26638), Federal Register Notice of Availability of that guidance. The capture, review, and archiving of electronic source data, as described in the draft guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have and are experienced with using the computer-based equipment and software necessary to be consistent with the guidance.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/RegulatoryInformation/Guidances/default.htm, or http://www.regulations.gov.

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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