



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2015-N-1887]

AGENCY: Food and Drug Administration, HHS.

Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) is interested in supporting demonstration projects to test the capability and evaluate performance of using an end-to-end Electronic Health Record (EHR)-to-Electronic Data Capture (EDC) single-point data capture approach, using established data and implementation standards in a regulated clinical research environment. A demonstration project should ideally test the use of a standards-based technology solution to enable the collection of related healthcare and clinical research information within a single system and workflow. Stakeholders may include regulated industry, EHR and EDC vendors, academic medical centers, and other interested parties.

DATES: Submit either electric or written requests for participation in the demonstration project by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the documents 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. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments 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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993-002, 301-796-5333, ronald.fitzmartin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The information systems, as well as the underlying data models, that define both clinical care and clinical research are widely disparate. This was not an issue for the conduct of clinical research prior to use of EHRs or EDC because data were captured on paper case report forms. However, much has changed in the past decade for clinical research where EDC systems are now ubiquitous for the capture of clinical trials data. Similarly, EHRs have had widespread adoption and are rapidly becoming a standard part of clinical care.

In 2013, FDA published a final guidance on “Electronic Source Data in Clinical Investigations” which encourages use of electronic source data in the conduct of clinical trials intended for inclusion in investigational and new drug applications. The electronic capture of data from EHRs and healthcare devices, such as electrocardiogram management systems, digital imaging and mobile health devices, as well as electronic Patient Reported Outcomes Instruments has the potential to improve the reliability, quality, traceability, provenance and integrity of data from electronic source to regulatory submission.

Demonstration projects should assess and report value and challenges of the EHR-to-EDC single-point capture of source data in a clinical research environment. Streamlining clinical research at the source may open up opportunities to improve clinical trial design and execution, speed the cycle of clinical research and get medicines to market faster.

Specifically, the use of a standards-based technology solution in clinical trials has the potential to:

- Eliminate duplication of data by capturing and transmitting electronic source data;
- auto-populate the electronic study forms from EHRs;
- reduce transcription errors and improve the quality of data;
- encourage entering source data at the point of care;
- facilitate remote monitoring of data to reduce the number of onsite visits by regulated biopharmaceutical industry;
- improve site monitoring to minimize the need for cross-reference data in multiple sources;
- make it easier for investigators to conduct clinical research;
- facilitate the inspection and reconstruction of clinical investigations by FDA; and
- improve the standards-based technology solution to encourage widespread adoption.

II. Questions to Stakeholders

1. What other potential benefits to stakeholders can be achieved through the use of a standards-based technology solution focusing on EHR and EDC integration?
2. What are the challenges to the implementation of a standards-based technology solution focusing on EHR and EDC integration?

3. What are the gaps between the data collected in a healthcare setting by EHRs vs. clinical research data required for regulated drug development?
4. Are there any perceived regulatory obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration? (Examples include: Source data verification, remote monitoring, 21 CFR Part 11, patient privacy, access control and confidentiality safeguards.) If yes, what approach(es) would you recommend to overcome these obstacles?
5. Are there any obstacles to the implementation of a standards-based technology solution focusing on EHR and EDC integration?
6. What standards-based solutions may exist?

III. Requests for Response

Comments, proposed approaches, interest to participate, and responses to the questions are to be identified with the docket number found in brackets in the heading of this document. Interested parties should include the following information in the request: Contact name, contact phone number, email address, name of the stakeholder, and address. Once requests for participation are received, FDA will contact interested stakeholders to discuss demonstration projects. The elapsed time duration of any project is expected to be approximately 12 months but may be extended as needed.

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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