NIDILRR uses information submitted by grantees as part of their Annual Performance Reports for these reviews.

5. *Continuation Awards:* In making a continuation award, the Administrator of the Administration for Community Living may consider, under 45 CFR part 75, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Administrator also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department. Continuation funding is also subject to availability of funds.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Patricia Barrett, U.S. Department of Health and Human Services, 400 Maryland Avenue SW., Room 5142, PCP, Washington, DC 20202–2700. *Telephone:* (202) 245–6211 or by email: *patricia.barrett@acl.hhs.gov.*

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: June 22, 2015.

John Tschida,

Director, National Institute on Disability, Independent Living, and Rehabilitation Research.

[FR Doc. 2015–15746 Filed 6–25–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1887]

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

AGENCY: Food and Drug Administration, HHS.

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 August 10, 2015.

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.

[FR Doc. 2015–15644 Filed 6–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2245]

Unique Device Identification: Direct Marking of Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Unique Device Identification: Direct Marking of Devices.'' Direct marking is an important feature of FDA's unique device identification system. This document is intended to assist industry and FDA staff to understand FDA's requirements for direct marking of devices with a unique device identifier (UDI). In addition, FDA is seeking information on what processes should be considered to meet the definition of ''reprocessing'' for purposes of UDI direct marking requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 24, 2015.

ADDRESSES: An electronic copy of the draft guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Unique Device Identification: Direct Marking of Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002, 301–796–5995, email: *GUDIDSupport@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 and section 614 of the Food and Drug Administration Safety and Innovation Act amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The unique device identification system final rule was published on September 24, 2013 (78 FR 58786) (the UDI Rule).

21 CFR 801.45 requires a device bear a permanent UDI marking if the device is intended to be used more than once and intended to be reprocessed before each use. It details the UDI format when provided as a direct marking, and provides criteria for exceptions to this UDI direct marking requirement. As explained in the preamble of the UDI Rule, UDI direct marking requirements apply to devices that are intended to be used for months or years, sometimes many years. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. UDI direct marking helps to ensure the adequate identification of such devices through their distribution and use. However, the UDI Rule does not define ''intended to be used more than once'' and ''reprocessed.'' FDA's interpretation of these terms is included in this draft guidance, but FDA seeks additional information on its current definition of ''reprocessing'' for purposes of UDI direct marking requirements.

FDA guidance entitled ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Guidance for Industry and Food and Drug Administration Staff'' issued on March 17, 2015 (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf*) (the Reprocessing Guidance), indicates that reprocessing of reusable devices