4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1349]

Electronic Study Data Submission; Data Standards; Support for the Logical Observation Identifiers Names and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is encouraging sponsors and applicants to provide Logical Observation Identifiers Names and Codes (LOINC) codes (available at http://loinc.org/) for clinical laboratory test results in investigational study data provided in regulatory submissions submitted to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. LOINC code is defined as electronic messages for laboratory test results and clinical observations. The decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives. FDA invites public comment on appropriate steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. The LOINC common terminology will be listed in the FDA Data Standards Catalog that is posted to FDA's Study Data Standards Resources Web page at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments 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 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, rm. 3128, 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, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

LOINC is a clinical terminology housed by the Regenstrief Institute, a nonprofit medical research organization associated with Indiana University (available at http://www.regenstrief.org/). LOINC was initiated in 1994 as a response to the demand for

electronic movement of clinical data from laboratories that produce the data to consumers of clinical data. LOINC codes are universal identifiers for laboratory and other clinical observations that enable semantically interoperable clinical data exchange. The purpose of LOINC is to facilitate the exchange and pooling of clinical data for clinical care, outcomes management, and research.

The laboratory portion of the LOINC database contains the categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, and more. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, and selected survey instruments.

FDA is now encouraging sponsors and applicants to provide LOINC codes for laboratory test data in investigational studies provided in regulatory submissions (e.g., investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs)) when those LOINC codes are available (e.g., from the clinical laboratory that performed the test). FDA supports LOINC-coded laboratory test results because: (1) LOINC is widely used among clinical laboratories, (2) LOINC-coded lab data make the information easier to understand and analyze, and (3) the currently supported exchange standard for laboratory test results in clinical trials, the Study Data Tabulation Model (available at http://www.cdisc.org/sdtm) already supports the exchange of LOINC codes. FDA's decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives.

FDA recognizes that there are additional steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. FDA invites public comment on what those additional steps should be, along with a suggested sequence and timing of those steps. For example, the Agency recognizes that the high level of granularity inherent in LOINC has presented coding challenges and that these challenges have led to the creation of subsets of LOINC to help facilitate coding.

- Should FDA identify a LOINC subset for its use case?
- If yes, should FDA create its own subset or leverage existing subsets?
- Which LOINC subsets should FDA consider?
- What steps can FDA take to minimize the burden to sponsors and applicants in adopting LOINC within their organizations to support regulatory submissions?

II. Comments

Interested persons may submit either electronic comments to http://www.regulations.gov or written comments regarding this notice to the Division of Dockets Management (see ADDRESSES). 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.

Dated: May 6, 2015.

Leslie Kux,
Associate Commissioner for Policy.
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