Updates on LOINC

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Overview

1. Growth and adoption
2. Key publications and presentations
3. Highlights and discussion of recent US Federal initiatives
Growth and Adoption
45,000+ registered users in 172 countries
LOINC Codes Over Time by Release

1900+ new terms in 2.56 release
loinc.org registered users

6,000 new users per year
FDA Adoption and Promotion of LOINC
2015 to 2016
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 038

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 038 is available on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/acn123792.htm. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 038 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT:
Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149.

Submit electronic comments on this document 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.

Federal Register/ Vol. 80, No. 17/ Tuesday, January 27, 2015/ Notices 4279

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference No. and date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Software/Informatics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K. Sterility</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ All standard titles in this table conform to the style requirements of the respective organizations.
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
Public Workshop FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data, September 28, 2015

The purpose of the workshop was to receive and discuss input from stakeholders regarding proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records.

- Discussion Paper
- Date, Time and Location
- Federal Register Notice
- Webcast
Stay tuned for follow-up meeting this Fall

November
Design Considerations and Premarket Submission
Recommendations for Interoperable Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: January 26, 2016

Submit comments and suggestions regarding this draft document within 60 days of
publication in the Federal Register of the notice announcing the availability of the draft
guidance. 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. Identify all comments
with the docket number listed in the notice of availability that publishes in the Federal
Register.

For questions about this document regarding CDRH-regulated devices, email them to:
DigitalHealth@fda.hhs.gov;
For questions about this document regarding CBER-regulated devices, contact the Office of
Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-
402-8010

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
ONC 2016 Interoperability Standards Advisory
HITSC ISA 2017 Task Force

Clem, Susan Matney, and I are members

1st set of recommendations published
HITSC ISA 2017 Recommendations

Focus on needs for certified EHRs (not research)
Evolve to be more dynamic
Use consistent format for Q/A style vocab recommendations
“Best Available” -> “Recognized Standards”
Be more transparent / data-driven
Clarify listed value sets (normative, starter, etc)
LOINC / SNOMED for functional status
Add more detail re API-based approaches
Draft 2017 ISA Open For Comment

https://www.healthit.gov/standards-advisory/draft-2017
Meaningful Use Stage 3

Department of Health and Human Services

Office of the Secretary
45 CFR Part 170
2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule
87 mentions of LOINC.
Social, Psychological, and Behavioral Data

Financial resource strain
Education
Stress
Depression
Physical activity
Alcohol use
Social connection and isolation
Exposure to violence

All have specific LOINC codes identified
Work in behavioral/mental health data standards is percolating.
New HL7 WG being discussed, recent Health Affairs paper.
ABSTRACT The use of health information technology (IT) in general health care has been shown to have significant potential to facilitate the delivery of safe, high-quality, and cost-effective care. However, its application to behavioral health care has been slow, limiting the extent to which consumers seeking care for mental health or substance use disorders can derive its benefits. The goal of this article is to provide an overview of the use of health IT in behavioral health and to describe some unique challenges experienced in that domain. We also highlight current obstacles to, and recommendations for, the use of health IT in improving the quality of behavioral health care. We conclude with recommendations for prioritizing the work that we believe will move the US health care system toward more effective, efficient, and patient-centric care in behavioral health.
French LOINC Adoption

Lorsque le compte rendu des examens de biologie médicale est communiqué au prescripteur par voie électronique, l’échange se fait en utilisant une messagerie électronique sécurisée de santé. Dès lors qu’il contribue à la coordination des soins, le compte rendu des examens de biologie médicale est inséré dans le dossier médical personnel mentionné à l’article L. 1111-14.

« Art. D. 6211-5. – Un arrêté du ministre chargé de la santé détermine la nature des échantillons à conserver après la réalisation de la phase analytique ainsi que la durée et les conditions de conservation de ces échantillons. En cas de transmission d’un échantillon, le laboratoire qui a la responsabilité de la réalisation des examens du patient au sens de l’article L. 6211-19 s’assure que le laboratoire qui réalise la phase analytique respecte cette disposition dans ses procédures.
Key Publications and Presentations
Now available!

LOINC Essentials
A step by step guide to getting your local codes mapped to LOINC

Daniel J. Vreeman, PT, DPT, MSc

danielvreeman.com/loinc-essentials
Disclosure

If you buy the book, I will get some money.

This isn’t likely to be a NYT Best Seller.

I’m hoping to cover hosting/development costs.
LOINC and RELMA Release Highlights

A note about this past development cycle
Content development team has done a remarkable job tackling our backlog of term requests.

On track to make great progress on submissions in the queue.

We have a large body of pending work in non-lab areas.
LOINC Team Updates
Special welcome and introduction of our newest LOINC team members

Tim Briscoe
Katie Allen
Mary Zabriskie
Sara Armson (transition to content development)
Support for a larger team the result of increased external funding success
Farewell to Katy Holck...
We’re Hiring!

We have three positions available: an entry-level and an experienced content developer, and a systems engineer.

If you know people who’d be great LOINCers, send them my way!

loinc.org/jobs
LOINC Award for Distinguished Contributions
LOINC Award Honors Outstanding Contributors to Advancement of Health Data Interoperability

by Daniel Vreeman – last modified 2016-07-13 09:01

INDIANAPOLIS (June 30, 2016) -- LOINC, the world’s most commonly used universal code system for identifying medical test results, observations and other clinical measurements, has announced the inaugural recipients of the LOINC Award for Distinguished Contributions. The new award honors individuals whose work advances the interoperability that ensures that medical data can be recorded, electronically exchanged and ultimately used to improve health -- when and where needed.

J. Gilbert Hill, M.D., Ph.D., of Canada and Cindy Johns, MSA of the United States were presented with the award at the annual LOINC meeting in June. Both are long-time active members of the LOINC participant community.

Hill, who worked at the Hospital for Sick Children in Toronto as director of the Clinical Biochemistry Service for 30 years, then as consultant to the electronic Child Health Network (eCHN) for 20 years, is an internationally respected scientist who, working with Canada Health Infoway, has influenced terminology standardization and the employment of LOINC for lab tests across Canada for over a decade.

Johns, a senior information technology specialist for LabCorp with responsibility for maintaining LabCorp's LOINC database, has presented LOINC courses throughout the medical laboratory industry. Three years ago she was recognized at the American Society for Clinical Pathologists with a Lifetime Achievement Award and currently serves on the organization's Board of Directors.

In addition to hospital systems, clinical laboratories, health information exchanges and other private and quasi-private sector entities, LOINC users include ministries and departments of health around the world. U.S. government agencies in the LOINC community include the National Library of Medicine, the departments of Veterans Affairs and Defense, the Indian Health Service, the National Cancer Institute and the Centers for Disease Control and Prevention.

LOINC is used in 172 countries and is available in Chinese, Dutch, Estonian, French, German, Greek, Italian, Korean, Portuguese, Russian, Spanish, and Turkish in addition to English.

LOINC traces its roots to the mid-1990s when Regenstrief Institute investigators, using their extensive experience with electronic medical records, developed the Indiana Network for Patient Care, the nation's first citywide health information exchange. They found they could receive data from various INPC-member institutions but that the clinical content was difficult to interpret because each used a different code for the same test or observation. A blood sugar result at one institution might be called a blood glucose score at another and something different at a third facility. It was as if the computer system was receiving messages in Vulcan, Klingon and Ferengi when all it had been programmed to understand was English.

To solve the problem the Regenstrief researcher-clinicians, led by Clement McDonald, M.D., developed the lingua franca they called LOINC, short for Logical Observation Identifiers Names and Codes. The Regenstrief Institute is the owner, developer, and overall steward for LOINC.

"Today, LOINC is the most accepted and used international standard of names and codes for medical results, observations and other clinical measurements in the world," said Regenstrief Institute investigator Daniel Vreeman, DPT. "Thanks to dedicated people like Gil Hill and Cindy Johns we are constantly expanding both in terms of codes and users with the ultimate goal of improving human health." Vreeman serves as associate director for terminology services in the Center for Biomedical Informatics at the Regenstrief Institute.

With support from the National Library of Medicine, the Regenstrief Institute and other organizations, LOINC is an open, freely available standard. Updates to LOINC are issued twice annually.

Media Contacts
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+1 317-843-2276
caisen@lupui.edu
Translations
Updated Linguistic Variants
Chinese (China)
French (Canada)
French (France)
Italian (Italy)
Spanish (Spain)
Turkish (Turkey)
Content Highlights

Swapna Abhyankar, MD
RELMA Highlights
Mapping Feature Highlights

Multi-word replacements in Check the Test Names in Local Term File

Filter by user tags with NOT on View all Working Set grid

Map local terms right on View all Working Set Terms

New Comment button on the mapping screen

New search restriction on Hierarchy & Search Limits screen: Exclude non-routine challenge tests
<table>
<thead>
<tr>
<th>CDA Recommended Sections and Entries</th>
<th>LOINC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 R Evaluation + Plan note</td>
<td>51847-2</td>
</tr>
<tr>
<td>2 R Evaluation note</td>
<td>51848-0</td>
</tr>
<tr>
<td>3 R Plan of care</td>
<td>18776-5</td>
</tr>
<tr>
<td>4 R History of Past illness Narrative</td>
<td>11348-0</td>
</tr>
<tr>
<td>5 R Physical findings Narrative</td>
<td>29545-1</td>
</tr>
<tr>
<td>6 R Reason for visit Narrative</td>
<td>29299-5</td>
</tr>
<tr>
<td>7 O Advance directives</td>
<td>42348-3</td>
</tr>
<tr>
<td>8 O Allergies and adverse reactions Document</td>
<td>48765-2</td>
</tr>
<tr>
<td>9 O Chief complaint + Reason for visit Narrative</td>
<td>46239-0</td>
</tr>
<tr>
<td>10 O Chief complaint Narrative - Reported</td>
<td>10154-3</td>
</tr>
<tr>
<td>11 O History of family member diseases Narrative</td>
<td>10157-6</td>
</tr>
<tr>
<td>12 O Functional status assessment note</td>
<td>47420-5</td>
</tr>
<tr>
<td>13 O Physical findings of General status Narrative</td>
<td>10210-3</td>
</tr>
<tr>
<td>14 O History of Present illness Narrative</td>
<td>10164-2</td>
</tr>
<tr>
<td>15 O History of Immunization Narrative</td>
<td>11369-6</td>
</tr>
<tr>
<td>16 O History of medical device use</td>
<td>46264-8</td>
</tr>
<tr>
<td>17 O History of Medication use Narrative</td>
<td>10160-0</td>
</tr>
<tr>
<td>18 O Mental status Narrative</td>
<td>10190-7</td>
</tr>
<tr>
<td>19 O Diet and nutrition Narrative</td>
<td>61144-2</td>
</tr>
<tr>
<td>20 O Problem list - Reported</td>
<td>11450-0</td>
</tr>
<tr>
<td>21 O History of Procedures Document</td>
<td>47519-4</td>
</tr>
<tr>
<td>22 O Relevant diagnostic tests/laboratory data Narrative</td>
<td>30954-2</td>
</tr>
<tr>
<td>23 O Review of systems Narrative</td>
<td>10187-3</td>
</tr>
<tr>
<td>24 O Social history Narrative</td>
<td>29762-2</td>
</tr>
<tr>
<td>25 O Vital signs</td>
<td>8716-3</td>
</tr>
</tbody>
</table>
Collaboration Updates

IEEE (heard)
IHTSDO
CMS (new)
Duke University - ADAPTABLE (new)
RSNA
Other possibilities
Continue EPG meetings

Still working on a contract amendment to allow us to distribute SNOMED CT codes for answers outside of the initial domain areas.

(We originally asked about this in March 2015)

Trying to engage to prevent duplicative work in radiology and functioning observables, but little tangible progress.

Possible update of joint guidance on use of LOINC and SNOMED CT together.
IHTSDO

Alpha (phase 3) Edition Technology Preview releases April 2016

3 Formats: RF2, OWL, Excel (with term names!)

13756 LOINC Terms associated with SNOMED CT post-coordinated Expressions

4070 LOINC Part to SNOMED CT mappings

Covers majority (around 75%) of the Top 2000 LOINC Lab Observations and Parts needed to represent them.

1500+ SNOMED CT codes added to produce the expressions
Centers for Medicare and Medicaid Services

Post Acute Care Data Element Standardization and Interoperability
2016 through 2021 (hopefully)
Recently awarded contract with CMS to create and update LOINC for assessment data elements that will be included in the CMS Data Element Library.
Background

IMPACT Act (2014) requires CMS to make certain assessment data elements standardized and interoperable.

Why? For data exchange by post-acute care and other providers to support care coordination and improved outcomes.

CMS must like the data elements to adopted HIT standards, including LOINC.
Scope

Instruments:
- Nursing Home Minimum Data Set (MDS)
- Long-term Care Hospital CARE Data Set (LCDS)
- In-Patient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)
- Home Health Outcome and Assessment Information Set (OASIS).

Focus on legacy data elements (that are expected to be retained) and new data elements.

Prioritized to target data elements used to construct IMPACT Act quality measures and in health information exchange activities.
Linking Assessment Data Elements to HIT Standards

Supporting Health Information Exchange Across the Care Continuum

<table>
<thead>
<tr>
<th>Identifying Data Element Question and Answer Pairs Across Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDS</td>
</tr>
</tbody>
</table>

Mapping Data Elements (Question and Answers Pairs) to Nationally Accepted HIT Standards

Data Elements Mapped to HIT Vocabulary Standards:

- LOINC
- SNOMED

Data Elements Mapped to Document Exchange Standards:

- CCDA

Slide credit - Jennie Harvell
Regenstrief’s Role

5 year award:
base year + 4 option years

Our work
Answer questions/resolve issues
Update modeling as needed
Create new codes where needed
Duke University
ADAPTABLE Trial
beginning Sept 2015
ADAPTABLE Trial

First major randomized comparative effectiveness trial conducted by the National Patient-Centered Clinical Research Network (PCORnet)

Aims to identify the optimal dose of aspirin therapy for secondary prevention in atherosclerotic cardiovascular disease.

Includes both patient-reported and EHR data
Connection to LOINC

After vetting, patient-reported data elements from ADAPTABLE (i.e., symptoms, side effects and quality of life) will be submitted for inclusion in LOINC for use in future studies.

DV to advise on use of existing LOINC content, how LOINC serves as universal catalog, and efficient submission mechanisms.
RSNA
Phase II: Oct 2015 through September 2017
You’ve heard about the good progress thus far...

CT, MR, US, NM, complete (mostly)

XR is well underway

Next up: mammography
Annex - RadLex-LOINC Radiology Playbook User Guide

Welcome to the RadLex-LOINC Radiology Playbook User Guide. This work is the result of a multi-year collaboration between Regenstrief Institute and the Radiological Society of North America (RSNA), supported by the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The participants have developed a model that combines and unifies the useful aspects of LOINC Radiology and the RSNA RadLex Playbook. Both of these terminology initiatives are designed to represent concepts of radiology orderables and results and their attributes.

Each term in the unified Playbook model has a name (a.k.a. description), and takes on a number of attributes. This guide is intended to describe the semantics, syntax, and proper usage of those attributes. Within the terminology, these attributes are used as building blocks to construct several types of standard names, including a fully specified name, long name, and short name.

A list of the Playbook attributes is shown below. Attributes are organized according to attribute groups, consisting of the major bullet headings below, and by more specific sub-attributes, shown in the minor bullets below and denoted by a dot after the attribute group, such as Pharmaceutical.Route.

- Modality
  - Modality.Subtype
- Anatomic Location
  - Anatomic Location.Region Imaged
  - Anatomic Location.Imaging Focus
  - Anatomic Location.Laterality.Presence
  - Anatomic Location.Laterality
- View
  - View.Aggregation
  - View.View type
  - View.View type.Maneuver
- Pharmaceutical
  - Pharmaceutical.Substance Given
  - Pharmaceutical.Route
  - Pharmaceutical.Timing
- Reason for Exam
- Guidance
  - Guidance for.Presence
  - Guidance for.Approach
  - Guidance for.Action
  - Guidance for.Object
- Subject

The chapters that follow provide a guide to the usage of each of the above attributes.

Feedback Welcome
Governance
Main Deliverables

Integrated governance process for new terms

Creating single point-of-contact and governance structure for the unified terminology

New joint LOINC/RadLex Committee to be advisory body (Approved at Clinical LOINC Meeting 02/2014)

LOINC codes as the primary identifier for radiology procedures (e.g. the universal codes) while linking to the RadLex attribute/values for each term so that they can be used as meta-data
Agreement covering IP issues, non-duplication, etc was signed by RSNA and Regenstrief in September 2015.
Ongoing discussion topics

- Scope of orderables, protocols, procedure steps
- Translations
- Playbook->CPT mapping
- Recommended approach to local “extensions”
Distribution Artifacts
Distribution Artifacts

LOINC Table, RELMA (Regenstrief)
As is today

LOINC RSNA Playbook Table (Regenstrief)
December 2015 LOINC release
Will be expanded with other modalities as completed

RadLex Playbook Table (RSNA)
Format determined by RSNA
New format for Version 2 (learned a lot from LOINC)
Includes “EXPORTED_TO_LOINC” attribute that points people to LOINC as we complete our work
Other Possibilities

Social determinants of health
Chronic kidney disease data elements
“Equivalence class” roll-ups
We are breaking for lunch until 1pm