

LOINC* Sharing

External Data in Clinical Trial

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*Logical Observation Identifiers Names and Codes



The Disclaimer



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Agenda

- 1 LOINC & LOINC Code
- 2 FDA Submission Requirement
- 3 Implementation in MSD
- 4 Q&A

What is LOINC?

“LOINC is a common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.”

[What LOINC is - LOINC](#)

LOINC[®]
from Regenstrief



free

Freely Available for everyone

More than 172 countries using LOINC

Nearly 30 countries adopted LOINC as National Standard



2 Updates per year

Logical Observation Identifiers Names and Codes

LOINC is:

A common language for laboratory tests and other clinical observations that enables the electronic exchange of clinical data.

A single concept that represents a combination of relevant aspects that belong to test or measurement.

- The substance or entity being measured or observed.

**Component
(Analyte)**



- The characteristic or attribute of the analyte.

Property



- The interval of time over which an observation was made.

TIME



- The specimen or thing upon which the observation was made.

**System
(Specimen)**



- How the observation value is quantified or expressed

Scale



- A high-level classification of how the observation was made.

Method



CASE: LOINC CODE 10834-0

Part Description

LP14885-5 Globulin
Globulins include alpha 1, alpha 2, beta, and gamma globulins. The alpha 1 fraction consists of alpha 1 antitrypsin, alpha 1 lipoprotein, and alpha 1 acid glycoprotein. The alpha 2 fraction consists of alpha 2 macroglobulin, haptoglobin, and apolipoprotein B. The beta fraction consists of transferrin, hemopexin, complement factors, antithrombin III, and immunoglobulins. The gamma fraction contains the immunoglobulins G,A,M,D, and E. Increases in the gamma fraction of CSF protein are often found in Multiple Sclerosis (MS).

LOINC Part	Example from 10834-0	Mapping to CDISC
COMPONENT	Globulin	-TEST/-TESTCD
PROPERTY	MCnc (Mass concentration)	
TIME	Pt (Point in time)	-TPT
SYSTEM	Serum	-SPEC/-LOC
SCALE	Qn (Quantitative)	
METHOD	Calculated	-METHOD/-ANMETH

FDA Requirement for LOINC

FDA Data Standards Catalog v6.1 (09-09-2019)										
For full description of column headings, see Instr. & Column Descriptions tab										
Terminology Standard	Terminology Standards Development and/or Maintenance Organization	Version(s)	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Examples of Use	Statutory, Regulatory, or Guidance Authority	Information Sources
Logical Observation Identifiers Names and Codes (LOINC)	Regenstrief Institute	Latest Version	CBER, CDER	10/20/2017		03/15/2020 [1] 03/15/2021 [2]		Use in SDTM LBLOINC	<u>Standardized Study Data</u>	<u>LOINC</u> <u>Study Data Technical Conformance Guide</u>

FDA requires the submission of LOINC codes

- ✓ Human Clinical Trial Data
- ✓ LB Domain datasets
- ✓ Study Start after March 15th, 2020

Resource for LOINC Implementation

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following
Guidance Document(s):

*Guidance for Industry Providing Regulatory Submissions in Electronic
Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at
cdcr-edata@fda.hhs.gov or CBER at cber.cdsc@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2018

Recommendations for the Submission of LOINC® Codes in Regulatory Applications to the U.S. Food and Drug Administration

LOINC Working Group:

U.S. Food and Drug Administration (FDA), U.S. National
Institutes of Health (NIH), Clinical Data Interchange Standards
Consortium (CDISC), and Regeneron Institute

November 2017

[Study-Data-Technical-Conformance.pdf \(fda.gov\)](#)

[Recommendations-for-the-Submission-of-LOINC-Codes-in-Regulatory-Applications-to-the-U.S.-Food-and-Drug-Administration.pdf \(fda.gov\)](#)

LOINC Code	Component	LOINC Short Name	CDISC LBTEST	CDISC LBSPEC			
53835-5	1,5-Anhydroglucitol	1,5-Anhydroglucitol SerPI-mCnc	1,5-Anhydroglucitol	SERUM OR PLASMA			
53835-5	1,5-Anhydroglucitol	1,5-Anhydroglucitol SerPI-mCnc	1,5-Anhydroglucitol	SERUM			
53835-5	1,5-Anhydroglucitol	1,5-Anhydroglucitol SerPI-mCnc	1,5-Anhydroglucitol	PLASMA			
14569-8	17-Hydroxyprogesterone	17OHP SerPI-sCnc	17-Hydroxyprogesterone	SERUM OR PLASMA			
14569-8	17-Hydroxyprogesterone	17OHP SerPI-sCnc	17-Hydroxyprogesterone	SERUM			
ReadMe	Chemistry	Hematology	Coagulation	Toxicology	Urinalysis	Serology	Misc

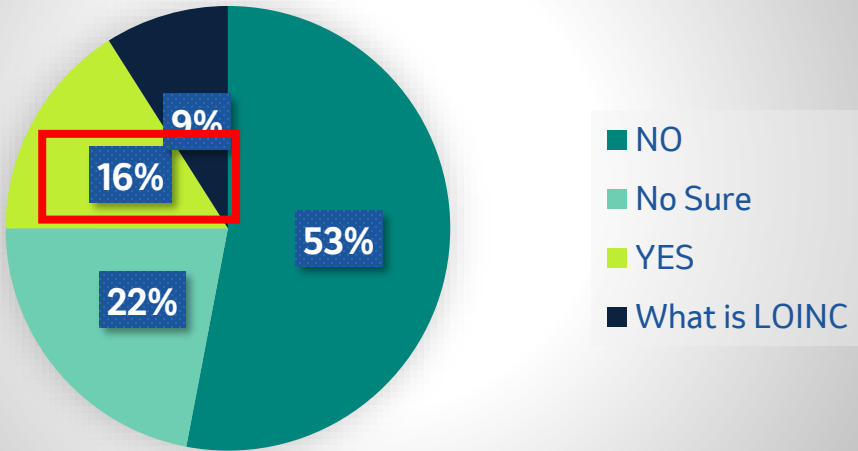
LOINC Implementation

- POPULATE LBLOINC FIELD
- SUBMIT LATEST VERSION OF LOINC
- SUBMIT APPROPRIATE LOINC
- SUBMIT AS RECEIVED
- STAY SAME VERSION
- DOCUMENTATION

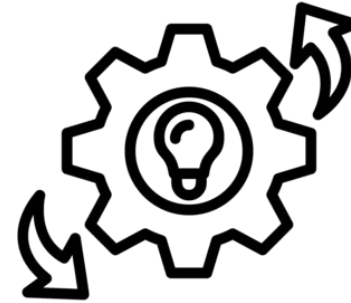
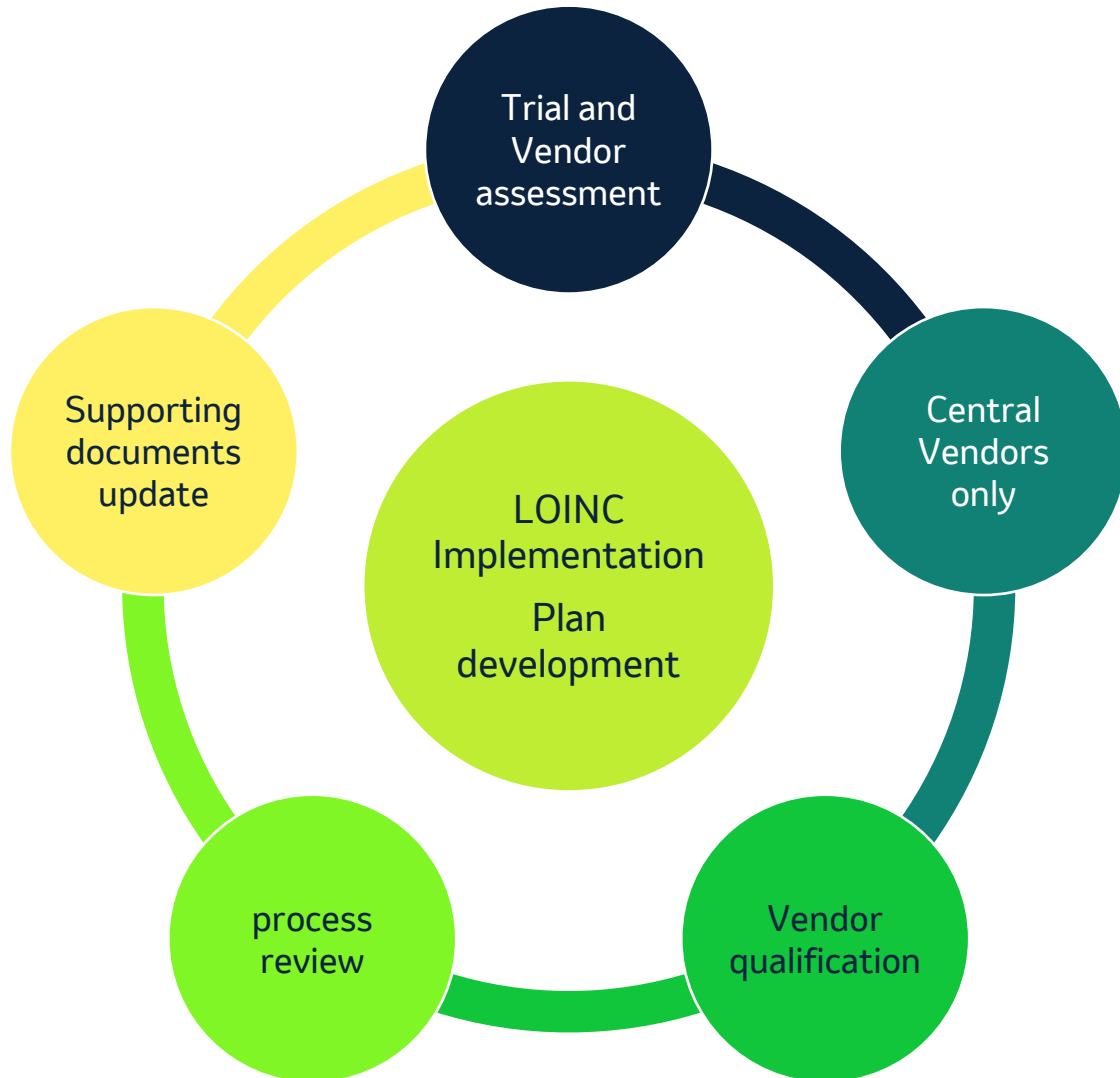
LOINC Submission Requirements

15%-50%
total trials

Collection of LOINC Codes



LOINC Implementation – In Our Company



- ✓ Data Transfer specification contains population requirement for LOINC
- ✓ Training session with central vendor
- ✓ Auto-check implemented for clinical data



Thank you!