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Takeda's implementation to expand Terminology and LOINC Mapping

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INTRODUCTION

Every organization defines standards to ensure alignment from collection to analysis. External data (eCOA, central laboratory) needs to be mapped to CDISC SDTM standards; this can be especially challenging for laboratory data. Documents such as Data Transfer Agreements/Specifications are used to define expectations of data that are to received from laboratory vendors. In some cases, laboratory data can be complex (Genomics, biomarkers, or Flow Cytometry, etc.) and needs to be understood in order to properly develop new Takeda Terminology for different laboratory categories.

CDISC released the LOINC to LB Mapping Guide that explains how the LOINC Codes relates to CDISC SDTM terminology and metadata. Takeda has expanded this framework to map to new tests based on this reference and provided expectations on Data Transfer Agreements to receive external data. This paper discusses Takeda's expectations and explains solutions and challenges as they expand the CDISC proposal to map the LOINC Codes.

LOINC and CDISC CONTROLLED TERMINOLOGY

LOINC® is a database and universal standard for identifying medical laboratory observations. It is intended as a universally understood concept model that identifies the test, test code and test result. In 1994, a group of researchers met in Indianapolis at the Regenstrief Institute to begin the development of such a system, which they called the Laboratory Observation Identifiers Names and Codes (LOINC®) code system and was renamed to Logical Observation Identifiers Names and Codes in 1997. The LOINC code is LOINC 2.7 version.

LOINC EXAMPLE:
For example, a laboratory test for Glucose - CDISC Terminology
Test Name : GLUC; CDISC Definition = "A measurement of the glucose in a biological specimen"; Test code: C65047

LOINC Code for component Glucose:

2345-7: Glucose [Mass/volume] in Serum or Plasma
5792-7: Glucose [Mass/Volume] in Urine by Test strip

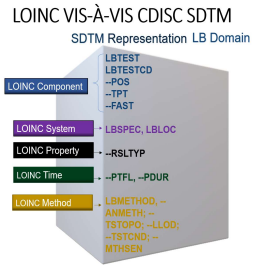
Property	Time	System	Scale	Method
MCnc	Pt	Ser/Plas	Qn	

Property	Time	System	Scale	Method
MCnc	Pt	Urine	Qn	Test Strip

•Property "MCnc" indicates the units would be in mg/dL; Scale "Qn" indicates Quantitative measurement

CDISC LB Domain and LOINC

One LOINC code maps to many CDISC concepts. One LOINC part may map to more than 1 CDISC variable. Variables in LB domain shown represents published CDISC variables and NSVs (Non-standard variables).



CDISC RESOURCES

- In 2020, CDISC published "LOINC Mapping Spreadsheet Version 1.0" based on the recommendations document for the submission of LOINC codes in regulatory applications to the FDA. No future updates will be made by CDISC and LOINC Working Group.

The following versions of related standards documents were used in the development of this example mapping file:

Standards Document	Version Identifier
CDISC SDTM Terminology	2020-06-26
SDTM	Version 1.7
SDTM Implementation Guide	Version 3.3
LOINC	Version 2.68 (Release Date: 2020-06-17)

Note: Published mapping file maps tests with LOINCs from Chemistry, Hematology, Coagulation, Toxicology, Urinalysis, Serology and does not include mappings from microbiology, pathology, genomics, vital signs, fetal/neonatal screening tests with LOINCs

- CDISC Controlled Terminology publishes every quarter and there are new CT Terms. Current 2022-06-28 version published contains terminology for CPTEST/CPTESTCD or GFTEST/GFTESTCD (Phenotyping Test and Test codes, Genomic Test and Test Codes)

REGULATORY REGULATIONS

- FDA is the only agency noted this as a requirement for LOINC Code in the Study Data Standards Catalog v7.3 in 2015 and the requirement is in effect March 15, 2020.
- FDA Study Data Technical Conformance Guide released has provided the needs of FDA and suggests to pass through the LOINC Codes received from the Laboratory.

METHODOLOGY

1.Establish atmosphere of trust and open communication between Takeda and CROs and vendors on capability and CDISC Conformance

2.Create a Standard Data Transfer Agreement (DTA) with specifications

a) At a minimum, sections to include can be Persons of contact, Method of data exchanges, List of tests needed with additional information of Administrative versus Safety, File formats (SAS or raw), Data variables identifying type, LOINC code details with additional SDTM Domain additional variables. Not all LOINC codes map to only LB domain.

- •The LOINC code specified in the LBLOINC variable in SDTM applies to the original result (LBORRES).
- •Sponsor should not attempt to derive LOINC codes if they are not provided by the laboratory.
- •For laboratory tests where LOINC Code is not submitted, the reason for its omission should be noted in the Study Data Reviewers Guide (cSDRG).
- •When LOINC codes have a status of deprecated it should not be submitted.

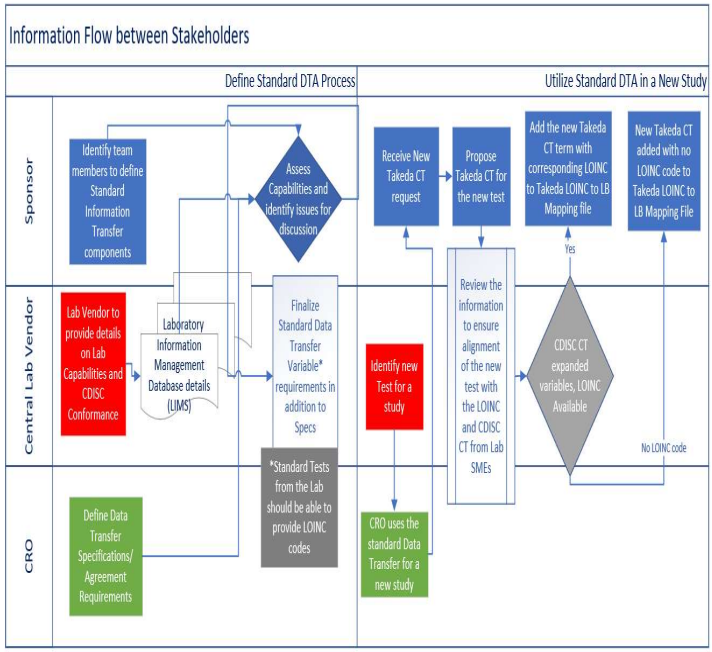
b)Each sponsor should have a strategy to extend CDISC "LOINC Mapping Spreadsheet" to align new sponsor specific CT with LOINC details from the Regenstrief Institute published LOINC file.

c)Implement Sponsor Standards Library specifications using sponsor-specific Controlled Terminology at CRO and Lab Vendor

d)When there are no LOINC Codes associated with the test, the lab vendor must send "Not Mapped" or "Not Available" and provide a reason in the Data Transfer variable

BRIDGING THE GAP:

1. Recommend creating CDISC/PhUSE sub-group to align LOINC and CDISC CT since new LOINC codes and CDISC Controlled Terms are published at regular intervals
2. Recommend Lab Vendor Laboratory Information Management System (LIMS) to output CDISC CT (LBTEST/LBTESTCD) in addition to LOINC Code
3. Sponsors, Lab Vendors and CROs need deeper implementation understanding between LOINC and CDISC CT



CONCLUSION:

1. LOINC to CDISC CT needs to be extended as new terms are developed across various domains
2. System and tools are to be developed, when available will support to mapping these discrete information and support mapping in SDTM
3. SMEs on the laboratory tests are needed to support Clinical research to use LOINC Code and CDISC CT alignment for lab test and devices.

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REFERENCES

- Recommendations document for the submission of LOINC codes in regulatory application: https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm586363.pdf
- SDTM CT Terminology (current): https://evs.nci.nih.gov/ftp1/CDISC/SDTM/
- Delivering LOINC Codes in Future – Bridging Gaps within Clinical Lifecycle: Veena Nataraj, Diane Piper CDISC Interchange 2018
- FDA Study Data Standards Resources: https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources
  - FDA Study Data Standards Data Catalog:
  - FDA Study Data Technical Conformance Guide

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