

DS08: Clearing the Fog Surrounding LOINC

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Agenda

- Why?
- What is LOINC?
- LOINC's purpose
- LOINC Names
- LOINC Components
- FDA Inclusion
- Global Adoption
- Future Development

Why?

- 15th March 2020
- LOINC inclusion
- Mandatory

**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 Regenstrief Institute

November 2017

What is LOINC?

Logical

Observation

Identifiers

Names and

Codes

2955-3

2947-0

9086-0

LOINC's Purpose

- First established in 1994 by the Regenstrief Institute
- Freely available database
- Different sources of data
- A specialist may be able to interpret
- Provide **interoperability** between different systems

LOINC Names

- The LOINC code is a **unique permanent identifier**
- Not intended to be understood by humans
- Permanent
- LOINC Name is the visible display text of a LOINC term
- 3 main LOINC name types:
 - **Fully-Specified Name (FSN)**
 - **Long Common Name (LCN)**
 - **Short Name**

Fully Specified Name (FSN)

- Essential defining characteristics of a term
- Includes all information needed to distinguish between clinically important differences
- Defines the uniqueness of each LOINC term
- Comprised of five or six components
- It makes use of abbreviations in naming

Example: Sodium:SCnc:Pt:Urine:Qn

Long Common Name (LCN)

- Primary display name of a LOINC term
- More descriptive and interpretable
- Removes abbreviations and uses common names

Example: Sodium [Moles/volume] in Urine

Short Name

- Mainly used for column header, report labels etc.
- Older systems that could have character limits
- The target character limit for the Short Name is 40
- Not always practicable
- Not all LOINC terms feature a Short Name
- Cannot be used as an identifying key in any database

Example: Sodium Ur-sCnc

Display Name

- In development
- Provider-friendly
- In beta-stage as of December 2018
- Available for viewing when searching LOINC codes

Example: Sodium (U) [Moles/Vol]

Consumer Name

- In development
- Consumer-friendly
- In alpha-stage
- Available for viewing when searching LOINC codes

Example: Sodium, Urine

Full Examples

LOINC Code	FSN	LCN	Short Name	Display Name	Consumer Name
2955-3	Sodium:SCnc:Pt:Urine:Qn	Sodium [Moles/volume] in Urine	Sodium Ur- sCnc	Sodium (U) [Moles/Vol]	Sodium, Urine
2947-0	Sodium:SCnc:Pt:Bld:Qn	Sodium [Moles/volume] in Blood	Sodium Bld- sCnc	Sodium (Bld) [Moles/Vol]	Sodium, Blood

LOINC Components

- A LOINC FSN can be comprised of five or six dimensions:
 - Component
 - Property
 - Timing
 - System
 - Scale
 - Method
- Delineated from each other by “:”

Component

- Analyte that is being measured or observed
- Component subparts: Analyte Name^Challenge^Adjustments
- Challenge: specifies stimulus before a measurement takes place
- Adjustments: used to add an additional consideration taken for adjustment
- ^ delineates between each subpart within Component

Property

- Describes the characteristic or attribute of that analyte
- LOINC terms are not distinguished by units of measure
- Not a different LOINC code for all the varying units of a test
- Should relate to a distinguishing characteristic of a name
- Considered to be the most difficult area when mapping

LOINC Abbreviation	Property
MCnt	Mass content
MCnc	Mass concentration
SCnc	Substance concentration

Timing

- Used for distinction between measurements completed at a point in time versus those over a period of time

LOINC Abbreviation	Timing
Pt	Point in time
24H	24 hour collection
7D	7 days (lookback period)

System

- Information needed to determine the specimen or system on which the observation was made
- Can have a subpart: Super System
- System^SuperSystem
 - Used to identify a sample from a source that is not from a patient
 - Default value is Patient and not normally shown in the LOINC term

LOINC Abbreviation	System
Tiss	Tissue
Ser/Plas	Serum or Plasma
XXX	Unknown

Scale

- Used to distinguish between different data types

LOINC Abbreviation	Scale
Ord	Ordinal
Nom	Nominal
Qn	Quantitative

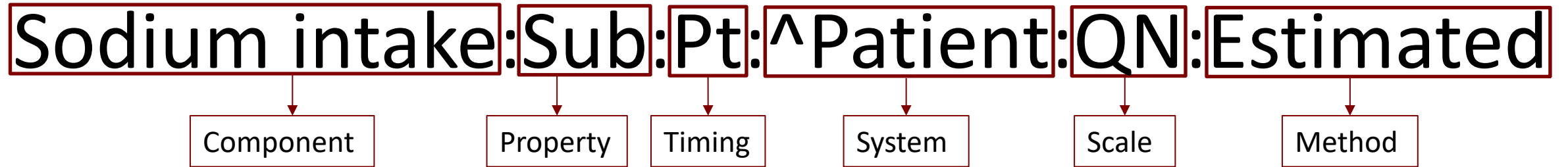
Method

- Optional
- Not all have a method
- Used to describe the technique used for the measurement
- General level
- When technique could affect interpretation

LOINC Abbreviation	Method
CT	Computer tomography
IA	Immunoassay

Full Example

- LOINC Code: 9086-0



FDA Inclusion

- Submission of new studies beginning 15th March 2020
- Only require Laboratory codes to be submitted
- Considered to be most closely in line with the CDISC SDTM LB domain
- One term can represent a concept through the components
- Unchanging once the LOINC code is applied – Pre-coordination
- LB domain contains three separate components instead that can be dynamic – Post-coordination

Pre- vs Post-coordination

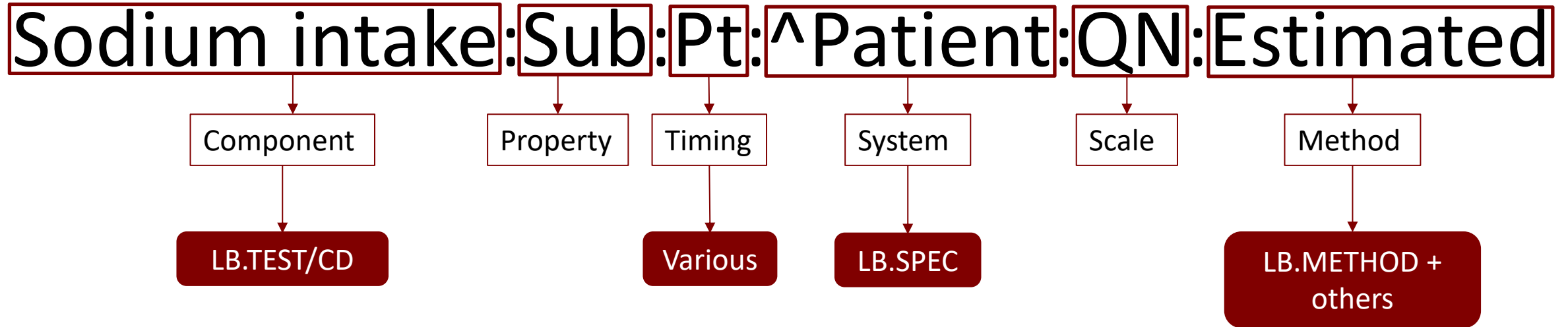
- LOINC is pre-coordinated
- CDISC LB is post-coordinated
- Pre-coordinated data is considered to be static
- Post-coordinated data has components that are compiled as needed

CDISC Comparison

- LOINC and LB domain share characteristics in results
- LB.LBLOINC variable already supported in LB domain
- Currently optional
- Mandatory for submission of new studies after 15th March 2020

CDISC Comparison

- Current LOINC analogues of the LB domain
- LOINC Code: 9086-0



CDISC Comparison

- Not always aligned
- LOINC components of Scale and Property do not have a comparable analogue in LB
- LB.LBORRES variable aligns with the LOINC code
- LB.LBLOINC is taken from original result; not a converted form

Global Adoption

- At the time of writing, LOINC version 2.66
- 91,000+ codes
- 81,000+ registered users
- 175 countries
- 20 translations

LOINC Community

- Development propelled forward by the community
- New terms added at the request of users
 - New lab tests
 - New data models
 - Information previously been unstructured being transitioned
- Continual update of database
- Encompassing more institution's local test names
- Greater adoption of the standard

Future Developments

- There are major releases for LOINC twice per year in June and December
- LOINC cannot be used to develop new set of observation standards
- Working group may make additional recommendations as required
- Complete alignment of the pre-coordinated from LOINC and post-coordinated CDISC LB domain

Conclusion

- LOINC enables institutions to make fast comparisons of results
- Patient's data travels quickly
- Studies progress fast and efficiently
- Rising member group and request for new terms signifies standard adoption
- Continuous development

Conclusion

- LB.LBLOINC will become a mandatory variable for FDA
- Codes not meant to be understood by humans
- LOINC Names provide this information
- FSN provides the full definition of a term
 - split into five or six component parts
- Updated twice per year

Thank you!

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