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LOINC UCUM CDISC LB Mapping: A Clinical Lab Crosswalk

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Executive Summary

LOINC UCUM CDISC LB mapping combines three different tasks. **Logical Observation Identifiers Names and Codes (LOINC)** identifies an observation; the **Unified Code for Units of Measure (UCUM)** gives units computable syntax and semantics; the **Clinical Data Interchange Standards Consortium (CDISC)** Laboratory Test Results (**LB**) domain organizes submission records and terminology. A matching test label or a parseable unit cannot establish all three. LOINC's observation axes and UCUM's dimensional rules must be assessed separately. (loinc.org) (ucum.org) (www.cdisc.org)

The verified release baseline includes **LOINC 2.83**, released **August 19, 2026** (loinc.org), UCUM artifacts **2.2, June 2024** (ucum.org), and CDISC controlled terminology dated **September 25, 2026** (www.cdisc.org). These are separate dependencies. CDISC's official LOINC-to-LB resource contains examples covering **more than 1,400 LOINC**s, with stated domain exclusions. (www.cdisc.org) It is not an exhaustive local-test dictionary. Pin the actual mapping artifacts and their documentation alongside the terminology releases.

The central design rule is to preserve the **original result and unit**, then derive a standard result only through an approved semantic and conversion path. For the synthetic glucose example below, **90 mg/dL becomes 0.90 g/L** through the exact factor **0.01**, derived from decimal prefixes. (www.nist.gov) This changes the concentration's representation, not its clinical meaning or assay comparability. An inequality remains an inequality, with its numeric standard-result field left null under the published implementation guidance. (www.cdisc.org) (www.cdisc.org)

There is also a submission-specific distinction: FDA's **October 2026** technical guide recommends submitting laboratory-supplied LOINC codes as received, without modification. (www.fda.gov) An internally inferred code therefore belongs in a separate mapping record rather than automatically becoming the submitted laboratory code. Published evidence reinforces the need for exception handling: an Intego-II study standardized **96.2%** of **163,946,741** records. (pubmed.ncbi.nlm.nih.gov) Dimensional mismatches and incompatible arbitrary units remained barriers. (pubmed.ncbi.nlm.nih.gov) That retrospective primary-care result is not a trial acceptance threshold. The implementation recommended here uses explicit no-map, conditional-map, method-review, and conversion-blocked states, with laboratory-scientist approval before production use.

Introduction and Background

Central laboratories, local laboratories, and electronic health records can describe apparently similar tests with different identifiers, specimens, methods, scales, and unit strings. Official mapping resources reflect this richer context: the Centers for Disease Control and Prevention (**CDC**) LOINC In Vitro Diagnostic (**LIVD**) test-code mapping files distinguish order codes, result codes, specimens, and device identifiers. A local test name alone is therefore an inadequate source contract for a defensible crosswalk. (www.cdc.gov)

This report treats **clinical trial laboratory data normalization** as a controlled transformation of meaning and representation. Its audience includes integration leads deciding what to retain, clinical data managers resolving discrepancies, standards programmers building LB, and real-world evidence (**RWE**) architects serving additional data models. The starting point is semantic mapping from local identifiers, which Regenstrief identifies as the most common mapping activity. Local identifiers should remain available alongside standard identifiers; LOINC documents dual coding in Health Level Seven (**HL7**) version 2 and Fast Healthcare Interoperability Resources (**FHIR**). (loinc.org) (loinc.org)

The implementation perspective is adjacent consulting and integration: IntuitionLabs lists data pipelines, integration, warehousing, and business intelligence among its services. The crosswalk below is an editorial implementation reference, with no claim of private deployment results or completed laboratory review. (intuitionlabs.ai)

Scope matters before field mapping. CDISC distinguishes multiple specimen-based findings domains, so a laboratory feed should not automatically be assigned entirely to LB. Similarly, a common data model (**CDM**) can preserve source values without reproducing submission structures: the Observational Medical Outcomes Partnership (**OMOP**) Measurement specification retains a verbatim result field. These are complementary representations with different purposes. (www.cdisc.org) (ohdsi.github.io)

Publication baseline: October 13, 2026; source verification: October 15, 2026. The FDA landing page provides the **October 2026** Study Data Technical Conformance Guide, which was checked on **October 15, 2026**. This report uses that edition for the detailed LOINC recommendation: submit laboratory-supplied codes as received, without modification. Recheck the applicable catalog before submission. (www.fda.gov) (www.fda.gov)

Key Changes

Separate observation identity from numeric representation

The proposed change to the integration process is architectural, not a claim that a new regulation requires every laboratory to adopt a new workflow. Maintain distinct decisions for **local-test identity**, **LOINC meaning**, **unit interpretation**, and **submission representation**. LOINC describes its fully specified names through the observation axes; UCUM defines unit semantics using dimensional analysis. One decision cannot substitute for the other. (loinc.org) (ucum.org)

For a LOINC selection, examine:

- **Component:** Identify what is measured, including relevant molecular or challenge context.

- **Property:** Distinguish mass concentration from substance concentration and other properties.
- **Timing:** Determine whether the observation represents a point or a collection interval.
- **System:** Establish the specimen or system represented by the result.
- **Scale:** Distinguish quantitative, ordinal, and other result scales.
- **Method:** Preserve a method distinction when it affects clinical interpretation.

These labels are LOINC's defined axes. Their use as explicit review checkpoints is the implementation recommendation in this report. In particular, an analyzer change does not automatically require a different code; LOINC's mapping guidance ties method-specific coding to meaningful clinical differences. (loinc.org) (loinc.org)

Treat unit strings as structured expressions

A UCUM expression is a machine-readable representation rather than a universal list of laboratory display labels. FHIR's UCUM binding uses **case-sensitive expressions**; implementations should not uppercase or lowercase them indiscriminately. UCUM distinguishes its case-sensitive and case-insensitive symbol systems, while the National Library of Medicine (**NLM**) implementation documentation also warns against blanks within expressions. (hl7.org) (ucum.org) (ucum.nlm.nih.gov)

This distinction affects seemingly harmless cleaning rules. Preserve the source display string, then resolve it through an approved alias table to a UCUM expression. A failed lookup should create a review item, not an automatically guessed expression. The Common UCUM Units resource itself excludes strings whose definitions or usage patterns could not be established. (ucum.org)

Keep submission terminology as another mapping layer

CDISC unit terminology enumerates submission values, while UCUM constructs expressions. The Unit-UCUM resource links those representations. For example, CDISC documents UCUM mm[Hg] and submission value mmHg; copying a valid UCUM string verbatim is therefore not a general submission rule. (www.cdisc.org) (www.cdisc.org)

Mathematical synonymy also differs from codelist membership. CDISC explains that its UNIT codelist includes g/L without separately enumerating equivalent mg/mL and ug/uL expressions. Maintain separate fields for **source unit**, **approved UCUM expression**, and **CDISC submission unit**. This makes a unit conversion and its terminology decision separately inspectable. (www.cdisc.org)

Implementation Considerations and Process Changes

Establish the minimum source contract

A useful source contract records enough information to distinguish the observation, reproduce the transformation, and explain uncertainty. An Agency for Healthcare Research and Quality (**AHRQ**) hosted mapping worksheet includes specimen, unit, normal range, and method columns, illustrating why a two-column code replacement is insufficient. (hcup-us.ahrq.gov)

The following checklist is an editorial specification for that contract:

- **Source identity:** Retain laboratory, feed, local test code, local description, and source dictionary version.
- **Observation context:** Capture specimen, timing, method, analyzer or assay identifier, and result scale where available.
- **Raw result:** Preserve the complete reported string, comparator, unit display, and source precision.
- **Source interpretation:** Retain laboratory reference intervals, flags, comments, and applicable population context.
- **Analytical limits:** Record detection or quantitation limits and their units without substituting them for measured results.
- **Standard identifiers:** Separate laboratory-provided LOINC from internally proposed LOINC and their review states.
- **Transformation provenance:** Store the unit alias, expression, target unit, conversion rule, and implementation version.
- **Operational lineage:** Link the transformed row to source message, accession, collection time, correction history, and reviewer decision.

These fields should be populated from evidence rather than inferred from an analyte label. CDC explicitly marks some LIVED codes as not manufacturer-verified, showing why the origin and verification status of a proposed mapping deserve separate fields. (www.cdc.gov)

Map original and standard results independently

The **Study Data Tabulation Model (SDTM)** defines the original result as what was originally received or collected. In LB, use **LBORRES** for that result and **LBORRESU** for its unit. Populate **LBSTRESC**, the standard character result, through the approved normalization rule; **LBSTRESN** is its numeric representation when appropriate, and **LBSTRESU** identifies the standard unit. These paired representations preserve the original reporting while supporting standardized use. (www.cdisc.org) (www.cdisc.org) The cited base-variable definitions are published in an earlier model edition; CDISC states that SDTM 2.0 preserves existing metadata meanings apart from introduced variables and domains. The study's adopted model and guide still govern implementation. (www.cdisc.org)

Do not remove a comparator, round away a meaningful bound, or overwrite source text during parsing. A staging representation should retain both the raw string and its parsed components. The crosswalk places the approved short code in **LBTESTCD** and its test name in **LBTEST**. **LBSPEC**, **LBMETHOD**, and **LBLOINC** hold different kinds of context; they should not be compressed into a test-name suffix that downstream systems cannot reliably interpret. (hl7.org) (www.cdisc.org)

Distinguish laboratory codes from internal candidates

The FDA October 2026 guide recommends submitting LOINC codes only when available from clinical laboratories, retaining the received codes and leaving unavailable codes blank. An internal mapping program may still generate candidates for semantic reconciliation, but its candidate field needs a different provenance and release rule. This distinction prevents a locally inferred identifier from being presented as laboratory-supplied data. (www.fda.gov)

The guide's prose uses `LB.LOINC` and `LB.METHOD`; published SDTM implementation material uses **LBLOINC** and **LBMETHOD**. Treat this as a documentation-to-variable reconciliation issue, not permission to invent dotted dataset variable names. Confirm the study's implementation guide and metadata before generating files. (www.fda.gov) (www.cdisc.org)

Worked Source-to-Target Crosswalk

Worked crosswalk (Hypothetical Example)

These **synthetic records** have no completed scientist review. **2345-7** identifies glucose mass concentration in serum or plasma (loinc.org); **14749-6** represents substance concentration. (loinc.org) Controlled terminology pairs **GLUC** with **Glucose**. (evs.nci.nih.gov) Actual assay suitability requires review.

Milli represents one thousandth and deci one tenth. Therefore **1 mg/dL = 0.01 g/L**, and **90 × 0.01 = 0.90**. Both sides describe mass concentration; this exact decimal conversion needs no molecular mass. (www.nist.gov) (www.bipm.org)

Table 1 records the complete mapping decision. “Pending” indicates unresolved metadata or approval. Within the standard-result cell, values are listed as **LBSTRESC**; **LBSTRESN**; **LBSTRESU**.

Local test	Specimen	Method and scale	LOINC and origin	Original unit	UCUM expression	Conversion rule	LBTEST CD / LBTEST	LBORRES / LBORRESU	Standard result fields	Uncertainty and reviewer status
GLU_A	Serum	Enzymatic; quantitative	2345-7; lab supplied	mg/dL	mg/dL	Multiply by 0.01 to g/L	GLUC / Glucose	90 / mg/dL	0.90; 0.90; g/L	Synthetic; approval pending
GLU_B	Plasma	Enzymatic; quantitative	2345-7; lab supplied	g/L	g/L	Identity	GLUC / Glucose	0.90 / g/L	0.90; 0.90; g/L	Semantic review pending
GLU_C	Serum	Enzymatic; quantitative bound	2345-7; lab supplied	mg/dL	mg/dL	Convert bound, retain comparator	GLUC / Glucose	<5 / mg/dL	<0.05; null; g/L	Censored; approval pending
GLU_D	Unknown matrix	Method pending; quantitative	No approved code	mg/dL	mg/dL, syntax only	Hold normalization	Test identity pending	90 / mg/dL	Not released	Specimen query open
ASSAY_X	Serum	Local immunoassay; quantitative	Method-sensitive candidate unresolved	AU/mL	Not approved	No authorized conversion	Terminology review pending	12 / AU/mL	Not derived	Assay unit unresolved

Local test	Specimen	Method and scale	LOINC and origin	Original unit	UCUM expression	Conversion rule	LBTEST CD / LBTEST	LBORRES / LBORRESU	Standard result fields	Uncertainty and reviewer status
GLU_E	Serum	Enzymatic; quantitative	Internal candidate 2345-7; no supplied code	mg/dL	mg/dL	Multiply by 0.01 after approval	GLUC / Glucose	90 / mg/dL	0.90; 0.90; g/L after approval	Internal candidate separate; LBLOINC blank

The table separates **semantic approval** from **numeric convertibility**: GLU_D lacks specimen context, ASSAY_X lacks an approved assay-unit interpretation, and GLU_E keeps its internal candidate separate from the submitted code. Review states are proposed controls; the code-origin distinction follows FDA's recommendation. (ucum.nlm.nih.gov) (ucum.org) (www.fda.gov)

One-to-many mappings need conditional rules rather than duplicate output records. If one local code is reused for different specimens, resolve the target using the actual specimen and other discriminating attributes. If those attributes are missing, retain the candidate set and request clarification. Method-sensitive differences require documented clinical interpretation. (loinc.org)

Do not convert glucose mass concentration to substance concentration merely by selecting another unit spelling. Mass and amount of substance are different base quantities. NLM's conversion documentation requires molecular weight for the additional transformation. Any such rule must identify the analyte-specific basis, target property, and resulting LOINC interpretation; this report deliberately uses the simpler mass-to-mass example. (www.bipm.org) (ucum.nlm.nih.gov)

Exception Handling and Result Semantics

Define exceptions before mapping the full catalog

An exception is a defined processing outcome. CSIRO emphasizes map purpose and version coverage; CDISC's examples have explicit domain boundaries. Retain the no-map reason and intended destination instead of choosing an arbitrary nearest match. (ontoserver.csiro.au) (www.cdisc.org)

Table 2 separates common exception paths and their release consequences. The states are editorial implementation choices, not additional CDISC controlled terminology.

Path	Trigger	Processing decision	Evidence needed to release
No map	No suitable concept or feed outside map scope	Retain local identity; assess the correct domain and permitted terminology route	Documented domain decision and approved test definition
One-to-many	Local code spans specimens, scales, or methods	Apply context-dependent rules; hold unresolved candidate selection	Source attributes sufficient to select one meaning
Method-sensitive	Assay technique changes clinical interpretation	Obtain laboratory-scientist review; avoid merging solely on analyte name	Approved method-specific interpretation

Path	Trigger	Processing decision	Evidence needed to release
Non-convertible unit	Dimensional mismatch, undefined arbitrary unit, or absent assay relationship	Preserve original result; do not fabricate a standard numeric result	Validated conversion basis or explicit decision to retain separate series
Qualitative result	Negative, positive, reactive, or other categorical value	Apply approved character terminology; do not invent a numeric concentration	Scale and answer terminology confirmed
Censored result	Result contains a bound such as less than	Preserve comparator; convert bound only through a valid rule	Bound, unit, limit type, and standard character result reconciled

Exceptions can overlap: qualitative results may have ambiguous specimens, and numeric assays may have incompatible units. LOINC recognizes ordinal answers such as negative or reactive; UCUM arbitrary-unit meaning depends on the assay. Keep semantic and conversion states independently queryable. (loinc.org) (ucum.org)

Preserve ranges, flags, and analytical limits

Reference intervals belong to the specific reporting context. Preserve **LBORNRL0/LBORNRI** as the original interval text and derive **LBSTNRLO/LBSTNRHI** only when the interval supports numeric conversion to the standard unit. Do not parse a textual decision interval as though it were necessarily a numeric reference interval. SDTM distinguishes character original limits from numeric standardized limits. (www.cdisc.org)

The following controls are recommended:

- **Range alignment:** Apply the approved unit transformation to eligible bounds, retaining source population and assay context.
- **Flag basis:** Record whether **LBNRIND** uses original or standard ranges and explain the basis in study metadata.
- **Clinical significance:** Keep significance assessments separate; LBNRIND is not a clinical-significance indicator. (www.cdisc.org)
- **Quantitation limits:** Keep lower and upper quantitation limits distinct from the result and align their units with **LBSTRESU**. (www.cdisc.org)
- **Qualitative answers:** Retain a character result and its approved answer terminology without manufacturing a numeric surrogate.
- **Censoring:** For the synthetic less-than result, keep **<0.05** in **LBSTRESC** and leave **LBSTRESN** null; analysis imputation belongs under the analysis plan rather than replacing the observed bound. (www.cdisc.org)

For interoperable output, FHIR also distinguishes a point quantity from one carrying a comparator. Its Observation resource permits **dataAbsentReason** only when the observation value is absent, and a reference range can include textual information. These structures reinforce the need to distinguish “not performed,” “qualitative,” “below a bound,” and “missing” in the source model before serialization. (hl7.org) (hl7.org) (hl7.org)

Validation, Provenance, and Release Control

Validate three different propositions

First, validate **syntax**: can the unit expression be parsed by the pinned implementation? Second, validate **mathematical compatibility**: do the relevant dimensions and transformation functions permit the requested conversion? Third, validate **clinical suitability**: are the specimen, measurand, method, scale, and reporting context appropriate for the intended comparison? NLM documents dimension checking through base-unit exponents, while the Joint Committee for Traceability in Laboratory Medicine (**JCTLM**) evaluates reference materials, procedures, and services relevant to measurement comparability. (ucum.nlm.nih.gov) (jctlm.org)

These checks answer different questions. UCUM annotations in braces do not contribute unit semantics, and special units can require inverse functions rather than a single multiplier. A parser success therefore cannot authorize a generic conversion for every annotated, logarithmic, or assay-defined expression. NLM's service additionally rejects annotation mismatches, illustrating how an implementation can impose constraints beyond core unit semantics. (ucum.org) (ucum.org) (ucum.nlm.nih.gov)

Clinical comparability remains a laboratory question even after codes and units agree. International Federation of Clinical Chemistry and Laboratory Medicine (**IFCC**) recommendations discuss whether a calibrator produces equivalent clinical-sample results across measurement procedures for the same measurand. Preserve method and calibration context where needed; obtain qualified laboratory review before pooling result series for an intended clinical use. (publications.jrc.ec.europa.eu) (jctlm.org)

Make every transformed row reproducible

Recommended release controls are:

- **Freeze dependencies:** Record source dictionaries, LOINC, UCUM artifacts, CDISC terminology, mapping files, and implementation versions. This research verified public mapping-resource descriptions; downloadable workbook rows were not independently audited. Inspect each exact workbook and ReadMe before adopting its rows.
- **Preserve inputs:** Retain source result, unit, comparator, supplied codes, and correction lineage.
- **Test positive paths:** Verify approved conversions with representative values, precision boundaries, and valid comparators.
- **Test rejection paths:** Include unknown units, incompatible dimensions, incomplete specimens, and unsupported special-unit cases.
- **Reconcile records:** Account for input, accepted, held, corrected, and excluded records without silently losing rows.
- **Check reversibility:** Where mathematically appropriate, compare forward and reverse conversion before display rounding.
- **Review differences:** Assess changed mappings and affected historical records before promoting a release.
- **Approve use:** Require accountable terminology, programming, and laboratory decisions for the relevant release.

These are implementation controls rather than invented universal thresholds. International Council for Harmonisation (**ICH**) E6(R3) calls for documented transfer or migration and appropriate reconciliation to avoid data loss or unintended changes. The European Health Data and Evidence Network (**EHDEN**) common-data-model transformation assessment likewise considers implementation quality and documentation.

(database.ich.org) (www.ehden.eu)

Record the **standard release** separately from the **software implementation release**. UCUM's artifact page identifies version 2.2 (ucum.org), while NLM's demonstration documentation describes definitions from version 2.1. (ucum.nlm.nih.gov) This does not establish that all deployed NLM tools use the older version; it shows why a demonstration page cannot prove the dependency version of another production service. NLM also directs users to perform their own accuracy tests. (ucum.nlm.nih.gov)

Data Analysis and Evidence

What published measurements establish

A published Intego-II primary-care evaluation processed **163,946,741 quantitative records**, containing **2,019 distinct unit strings**. (pubmed.ncbi.nlm.nih.gov) It reported standardizing **157,874,970 records, or 96.2%**. (pubmed.ncbi.nlm.nih.gov) Among standardized records, **83.4%** were harmonized to reference units. (pubmed.ncbi.nlm.nih.gov) The remaining **16.6%** primarily involved dimensional mismatches or incompatible arbitrary units. (pubmed.ncbi.nlm.nih.gov) The different denominators are essential: the harmonization percentage is not the percentage of all source records.

These results describe one retrospective database and its implementation. They do not measure clinical-trial LB completeness, prove assay interchangeability, or establish a required project performance target. The fetched evidence is the original study's indexed abstract, not an independently inspected full-text methods analysis. Use the figures to motivate separate standardization and harmonization measurements, not to forecast another pipeline's yield. (pubmed.ncbi.nlm.nih.gov)

A separate **2022 LOINC-UCUM Mapping Assistant (LUMA)** paper mapped **159 of 176** quantitative LOINC properties with confidence using its study-era terminology baseline. (mdpi-res.com) It also reports that different properties can share a base-unit representation. (mdpi-res.com) This property-level finding is not a current record-level coverage estimate. It supports a narrower conclusion: unit dimensions constrain a candidate map without uniquely determining observation meaning.

Measure the pipeline with explicit denominators

Table 3 proposes project metrics. These formulas are **editorial measurement definitions**, not published benchmarks; the project must define the eligible population, observation date, and release for every denominator.

Metric	Calculation	Interpretation and required qualification
Mapping coverage	Approved mapped local-test definitions / in-scope local-test definitions	Report distinct-definition coverage separately from record-weighted coverage

Metric	Calculation	Interpretation and required qualification
High-confidence coverage	Records meeting documented semantic approval criteria / in-scope records	State the approval criteria; a model score alone is insufficient
Unit-parse success	Eligible unit-bearing records accepted by the pinned parser / eligible unit-bearing records	Keep blank, qualitative, and truly unitless results in defined categories
Dimensional-compatibility failures	Rejected dimension checks / attempted conversion checks	Excludes rows never eligible for numeric conversion
Converted-result reconciliation	Reconciled converted records / converted records requiring reconciliation	Define tolerance, precision handling, and treatment of bounds in advance
Unresolved ambiguity count	Count of open mapping decisions at the release cutoff	Break down by specimen, method, scale, unit definition, and ownership

The useful comparison is between successive, identically defined releases. Report the held population and its reasons alongside coverage, rather than improving a percentage by quietly removing difficult records.

Common UCUM Units drew on raw strings from **more than 23 laboratory sources**, but even that resource excluded unclear definitions. Its scope is evidence for managing aliases carefully, not a promise to interpret every incoming string. (ucum.org) (ucum.org)

For the synthetic conversion, exact decimal arithmetic verifies $90 \times 0.01 = 0.90$, with reverse conversion recovering **90** before rounding. This calculation checks the scale rule only. It does not validate the specimen, assay, reference interval, or clinical use. The prefix definitions supply the factor; the acceptance evidence for a production rule must additionally cover those semantic decisions. (www.nist.gov) (www.bipm.org)

Implications and Future Directions

Maintain several views of the same observation

An integration architecture can support submission, interoperability, and RWE without making any one target its only record of truth. In FHIR, **Quantity.unit** is display text, while its code and system identify a machine-readable representation; the UCUM system identifier is <http://unitsofmeasure.org>. Preserve the source display alongside the computable expression instead of assuming the display is already UCUM. (hl7.org) (hl7.org)

OMOP similarly retains source measurement and unit information as well as standard concepts, with reference ranges expressed in the numeric result's units. These are useful design precedents for keeping an immutable source representation and reproducible derived views, while still implementing each destination's actual specification. (ohdsi.github.io) (ohdsi.github.io)

Three decisions follow:

- **Integration leads:** Fund source-context capture and exception ownership as part of the interface, not as a later spreadsheet cleanup.
- **Standards programmers:** Freeze the applicable model, implementation guide, terminology, and mapping artifacts as separate dependencies.

- **Clinical and RWE teams:** Require suitability review before interpreting normalized series as comparable clinical evidence.

Version management should use the originating standards bodies. NCI makes terminology archives available and describes CDISC terminology as freely usable; LOINC permits use without license fees subject to its conditions, while UCUM has its own conditional license. Packaging related resources together does not make their license terms identical. (www.cancer.gov) (www.cancer.gov) (loinc.org) (ucum.org)

Published and developing specifications also need different treatment. CDISC identifies the Study Data Tabulation Model Implementation Guide (**SDTMIG**) 3.4 with SDTM 2.0 (www.cdisc.org), while its October training notice describes SDTM 3.0 and SDTMIG 4.0 as unfinished. (learnstore.cdisc.org) Agency context differs as well: FDA explains that technical guidance is nonbinding (www.fda.gov) and center applicability varies (www.fda.gov), while the European Medicines Agency (**EMA**) describes voluntary clinical-study-data pilot submissions. (www.ema.europa.eu) Recheck the applicable FDA catalog and study context instead of declaring a universal mandate. (www.fda.gov)

The corresponding advisory perspective remains integration and reproducibility. IntuitionLabs describes implementation and integration services; the technical priorities here are transparent mappings, explicit exceptions, and evidence appropriate to the intended use. (intuitionlabs.ai)

Conclusion

A defensible LOINC-to-CDISC LB mapping starts with observation meaning and ends with a reproducible submission representation. It retains the local identifier and original result, resolves the specimen and method context, interprets units through an approved expression, and applies only a justified conversion. LOINC and UCUM supply different parts of that evidence; neither a terminology match nor a unit parser should carry the entire decision. (loinc.org) (ucum.nlm.nih.gov)

The worked crosswalk demonstrates the intended separation. A synthetic glucose mass-concentration value can undergo an exact decimal unit conversion. A missing specimen creates a semantic exception. An arbitrary assay unit creates a different conversion question. An internally assigned LOINC candidate remains distinguishable from a code supplied by the laboratory. Keeping these states explicit makes review decisions inspectable without implying that all incomplete mappings require the same response. (ucum.org) (www.fda.gov)

Teams should release a mapping only when the source context, result handling, unit rule, destination terminology, and provenance support its intended use. They should measure catalog coverage, record coverage, parse success, conversion failures, and unresolved ambiguity separately. Those measures guide remediation without substituting a universal percentage for laboratory judgment.

The practical deliverable is therefore a maintained decision system: a versioned crosswalk, documented exceptions, tested transformations, and accountable review. Preserve enough information to rebuild each derived record, and revisit the mapping when its source dictionary, terminology, method, or intended use changes. That approach aligns the integration process with the broader expectation for documented transfer and reconciliation across the data life cycle. (database.ich.org)

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://loinc.org/start>
2. <https://ucum.org/ucum>
3. <https://www.cdisc.org/kb/articles/ucum-and-cdisc-codelists>
4. <https://loinc.org/kb/loinc-release-notes>
5. <https://ucum.org/docs/artifacts>
6. <https://www.cdisc.org/standards/terminology/controlled-terminology>
7. <https://www.nist.gov/pml/owm/metric-si-prefixes>
8. <https://www.cdisc.org/standards/foundational/sdtm/sdtm-v1-6>
9. <https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3/html>
10. <https://www.fda.gov/media/153632/download>
11. <https://pubmed.ncbi.nlm.nih.gov/41061385/>
12. <https://www.cdc.gov/laboratory-systems/php/livd-test-codemapping/index.html>
13. <https://loinc.org/mapping>
14. <https://intuitionlabs.ai/>
15. <https://www.cdisc.org/kb/articles/where-does-my-lab-data-go-sdtmig-v3-4>
16. <https://ohdsi.github.io/CommonDataModel/cdm54.html>
17. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document>
18. <https://loinc.org/kb/faq/mapping>
19. <https://hl7.org/fhir/R4/ucum.html>
20. <https://ucum.nlm.nih.gov/ucum-lhc/demo.html>
21. <https://ucum.org/docs/common-units>
22. https://hcup-us.ahrq.gov/datainnovations/clinicaldata/AppendixK_2LOINCCodesMap.pdf
23. <https://intuitionlabs.ai/articles/cdisc-standards-sdtm-adam-guide>
24. <https://www.cdisc.org/standards/foundational/sdtm/sdtm-v2-0>
25. <https://hl7.org/fhir/R4/datatypes.html>
26. <https://loinc.org/2345-7>
27. <https://loinc.org/14749-6>
28. <https://evs.nci.nih.gov/ftp1/CDISC/SDTM/SDTM%20Terminology.pdf>
29. <https://www.bipm.org/en/measurement-units/si-prefixes>
30. <https://ucum.nlm.nih.gov/ucum-service.html>
31. <https://www.bipm.org/en/measurement-units/si-base-units>
32. https://ontoserver.csiro.au/site/wp-content/uploads/2022/02/Map_Implementation_Guidance_20210131.pdf
33. <https://hl7.org/fhir/R4/observation.html>

34. <https://jctlm.org/about-us/>
35. <https://publications.jrc.ec.europa.eu/repository/handle/JRC106621>
36. https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
37. <https://www.ehden.eu/open-calls/harmonisation-fund/>
38. https://mdpi-res.com/d_attachment/applsci/applsci-12-05848/article_deploy/applsci-12-05848.pdf?version=1654692200
39. <http://unitsofmeasure.org>
40. <https://www.cancer.gov/about-nci/organization/cbiit/vocabulary/cdisc>
41. <https://loinc.org/kb/license>
42. <https://ucum.org/license>
43. <https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-4>
44. <https://learnstore.cdisc.org/product?catalog=SDTMPart2>
45. <https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources>
46. <https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/use-clinical-study-data-medicine-evaluation>
47. <https://www.fda.gov/media/185927/download>

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About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore [AI enablement](#), [pharma and biotech software development](#), [data engineering and BI](#), and [Veeva services](#). [Contact IntuitionLabs](#) to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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