



# Controlled Terminology Updates for Q4 – P43 Publication and P44 Public Review

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC, National Cancer Institute, NIH



TUE 13 OCT  
11:00 – 12:30 EDT



## Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



# Housekeeping

# Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  - To access – make sure that you create a login for the CDISC website if you haven't already
  - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!



# Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



# Our Presenters

- Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC, National Cancer Institute, NIH

# Controlled Terminology Updates for Q4 – P43 Publication and P44 Public Review

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC, National Cancer  
Institute, NIH



TUE 13 OCT  
11:00 – 12:30 EDT

# CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt  
10.13.2020







## Controlled Terminology P43 Publication; P44 Public Review

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC  
Inc.

10.13.2020

**cdisc**



## Question & Answer

1. 'Panelist': Question

OR

1. 'Presentation': Question

Examples:

1) What should be supported by ADaM datasets?

2) Jack: Is there a limit to the number of variables that can be in ADSL?



## Content Disclaimer

1. All content in this presentation is for education and information only. References to any specific commercial product, process, service, or corporation are also for information only, and do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.



# Agenda

1. Package 43 Publication Release (2020-09-25)
  - Changes post-public review
2. Package 44 Public Review (2020-09-18 to 2020-10-18)
  - New Additions
  - Changes to existing
3. Changes to the Controlled Terminology Page on CDISC.org
4. Questions



# Controlled Terminology Package 43 Publication

2020-09-25

# Controlled Terminology Publication Schedule

CDISC Terminology Publication Schedule

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks/30 days)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
						ADaM	Define-XML	Device	General
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019	ADaM	Define-XML	Device	General
40						CDISC Glossary	Lab	Microbiology	Oncology
40						PK	Protocol Entitles	QRS	SDTM Domain
40						SEND	Spectype Speccond	Unit	
41	12/13/2019	12/20/2019	1/17/2020	2/14/2020	3/27/2020	ADaM	Define-XML	Device	ECG
41						General	Lab	Microbiology	Oncology
41						PK	Protocol Entitles	QRS	SDTM Domain
41						SEND	Spectype Speccond	Unit	
41a	4/20/2020	n/a	n/a	n/a	5/8/2020	CDASH	CDISC Glossary	General	Lab
41a						Microbiology	PK	QRS	Spectype Speccond
41a						Unit			
42	3/13/2020	3/20/2020	4/17/2020	5/15/2020	6/26/2020	ADaM	Define-XML	Device	General
42						Lab	Microbiology	Oncology	PK
42						Protocol Entitles	QRS	SEND	Unit
43	6/12/2020	6/19/2020	7/19/2020	8/14/2020	9/25/2020	ADaM	ECG	General	Lab
43						Microbiology	Oncology	PGx	PK
43						Protocol Entitles	QRS	SEND	Unit
44	9/11/2020	9/18/2020	10/18/2020	11/13/2020	12/18/2020	ADaM	Define-XML	Device	General
44						Genomics	Glossary	Lab	Microbiology
44						Oncology	PK	Protocol Entitles	SEND
44						Spectype Speccond	Unit		
45	12/11/2020	12/18/2020	1/17/2021	2/12/2021	3/26/2021				
45									
45									

9/18/2020

*Dates in red are planned and may be adjusted slightly.*

1



# Controlled Terminology Package 43 Publication Release

- Updates to Protocol Entities, SDTM, SEND, CDASH, and ADaM Terminology
- Therapeutic Area Support:
  - QRS Terminology to support: Crohn's Disease, Psoriasis, Type 1 Diabetes and Duchenne Muscular Dystrophy Therapeutic Area User Guides.
  - SDTM Terminology to support: COVID-19, Crohn's Disease, Ebola, Heart Failure, Psoriasis, and Type 1 Diabetes Therapeutic Area User Guides.
- Other Project Support:
  - CDASH SAE

# Significant Changes Post-Public Review

- ECG Terminology:
  - EGTEST-CD:
    - Proposed TEST Name for QTCUNSAG was more than 40 characters so it was changed from 'QTc Correction Method Unspecified, Aggregate' to 'QTc Corr Method Unspecified, Aggregate'.
    - Proposed new term QTCUNSSB/QTc Correction Method Unspecified, Single Beat experience an error during processing and so was not added with P43 publication. It will be added as new with P44 publication and the proposed TEST name was changed from 'QTc Correction Method Unspecified, Single Beat' to 'QTc Corr Method Unspecified, Single Beat' to be at 40 characters or under.



# Significant Changes Post-Public Review

- General Terminology:
  - RPTTEST-CD: Proposed TESTCD submission value changing from GRAVIDA to GRAVIND and proposed TEST submission value changed from 'Gravida' to 'Gravida Indicator' since the definition was presented as an "indicator" (i.e., Yes/No) question.
  - CRFATS-CD:
    - Proposed new TEST/CD value of Portion or Totality/PORTOT removed from P43 due to modeling changes in the Crohn's Disease TAUG.
  - VS\_Codetable\_Mapping: For VSTEST=Diastolic Blood Pressure; Heart Rate; Maximum Predicted Heart Rate; Pulse Rate; and Systolic Blood Pressure -> We removed the rows where the POSITION codelist was showing a body position of 'STANDING, BENT FORWARD' as we did not think that this body position was ever used in real life with those associated tests. We will wait until someone submits a use case before associating that body position with a published VSTEST value.

# Significant Changes Post-Public Review

- Microbiology Terminology:
  - MBFTSDTL: The proposed submission value of 'QUANTIFICATION CYCLE' in the new codelist 'Microbiology Findings Test Details' was changed to 'QUANTIFICATION CYCLE NUMBER' with the following explanation:
    - “The language describing PCR threshold is inconsistent across vendors/manufacturers. We have seen terms such as Ct, Cp, TOP, Cycle Threshold #, etc. from vendors to describe the same concept and the MIQE Guideline provides standardized, consistent and industry/academia-recognized PCR terminology which helps to harmonize across vendor-used terms. CDISC stresses a vendor-neutral principle so we think the best approach is to follow the MIQE Guideline and align with the standard terminology from MIQE: QUANTIFICATION CYCLE. Since CDISC representation of the PCR threshold concept in the various TAUGs show that this record has no unit, we updated the submission value to: QUANTIFICATION CYCLE NUMBER.”
- Devices Terminology:
  - The above concept is also present in the Devices DOTEST-CD/Device Properties Test Code-Name codelist and so the synonyms and definition of C161328 was updated as per the P43 publication of the same term in the MBFTSDTL codelist.

# Significant Changes Post-Public Review

- Protocol Entities Terminology:
  - Concept C15538/Study Arm was re-coded to C174447 because not all 'arms' are treatment arms in a study. This is consistent with new terminology concepts in public review with P44.

# Significant Changes Post-Public Review

- Other, less significant changes\* also made in:
  - General and Protocol Entities
- No changes made to:
  - ADaM
  - Lab
  - Oncology
  - QRS
  - SEND
  - UNIT

**\*Please note that changes have been made to the terms proposed in the public review documents (edits to proposed definitions, additions of synonyms, etc.) that were not covered in previous slides. Please refer to published CT as the definitive source for terminology.**

# QRS Controlled Terminology Package 43 Publication Release

- New Codelists:
  - **Questionnaires (QS)**
    - Quality of Life in Inflammatory Bowel Disease Questionnaire
    - New CAT Values:
      - AJCC V8
      - EORTC QLQ-LC13
      - BIS-11
    - Significant changes to IPAQ01, IPAQ02, IPAQ03, and IPAQ04
  - **Clinical Classification (RS) – Moved from RP to RS**
    - Tanner Scale Boy Clinical Classification
    - Tanner Scale Girl Clinical Classification

\*\*CDISC and FDA is continuing to assess the development and publication of QRS response terminology. The response terminology presented in P41 public review was not published with P43 terminology publication on 2020-09-25.



# P43 Codetable and Rules updates

- Updates with P43
  - DD\_Codetable\_Mapping
  - Oncology\_Codetable\_Mapping
  - RP\_Codetable\_Mapping
  - SC\_Codetable\_Mapping
  - TS\_Codetable\_Mapping
  - VS\_Codetable\_Mapping
  - Unit-UCUM\_Codetable
  - Controlled\_Terminology\_Requests\_Denied\_P43

(No new Codetable Mapping files)



# Controlled Terminology Package 44 Public Review

2020-09-18 – 2020-10-18

All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization.

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Controlled Terminology (CT)

SPACE SHORTCUTS

- File lists
- Product requirements

PAGE TREE

- Guiding Principles
- Administrative Documents
- Public Review
  - Call for Public Review Package P44 -**
  - Public Review Archive
- Terminology Teams
- Change Control Logs
- Requests Denied
- File lists
- CDISC CT Meeting Minutes
- Product requirements

Space tools

Dashboard / Controlled Terminology / Public Review

Call for Public Review Package P44 - Comments Due by 18 Oct 2020

Created by Dana Booth, last modified by Ann White on Sep 17, 2020

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 44, which consists of the following 15 documents:

- Terminology Development Rules for ADaM
- Define-XML
- Devices
- General
- Genomics (formerly PGx)
- CDISC Glossary\*
- Laboratory\*
- Microbiology/Immunology\*
- Oncology
- PK
- Protocol Entities
- SEND\*
- SPECTYPE\_SPECCOND
- Units of Measure
- P44 Requests Denied

An \* indicates that **changes or retirements of existing CDISC Submission Values** are included on the "Changes to Existing" tab in the document. Please review these changes as there may be submission value changes or term deprecations.

**Comments due: 18 Oct 2020**

**Instructions for Reviewers**

Register and/or Log in WIKI and in JIRA to provide comments. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account: Wiki and JIRA use the same login credentials.

Download the files below for review.

**If you have no comments after review:**

- Click 'Like' at the bottom of the page. This will help us determine who has reviewed the documents.

**To add comments from within JIRA:**

- Go to the **Controlled Terminology** project in JIRA at: <http://jira.cdisc.org/projects/CT/issues/>

Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.

- Click on the "Create" button in the top menu to bring up the Create Issue form.
- Choose the **Controlled Terminology** Project

<https://wiki.cdisc.org/display/CT/Call+for+Public+Review+Package+P44+-+Comments+Due+by+18+Oct+2020>



# Controlled Terminology Package 44 Public Review

- ADaM Team

- No Additions or Changes being proposed for ADaM-associated terminology this quarter.
- ADaM CT Development Rules document

# Controlled Terminology Package 44 Public Review

- Define-XML Team
  - New Codelist
    - ADaM Occurrence Data Structure Subclass/OCCSC with term ADVERSE EVENT
  - 1 change to published term: Update definition of BDSISC codelist

# Controlled Terminology Package 44 Public Review

- Medical Devices Team
  - New Terms Added to Existing Codelists:
    - DOTEST-CD
  - No changes to existing terms

# Controlled Terminology Package 44 Public Review

- ECG Terminology Team:
  - New Terms Added to Existing Codelists:
    - EGTEST-CD
  - 2 changes to published terms, none significant

# Controlled Terminology Package 44 Public Review

- General Terminology Team:

- New Terms Added to Existing Codelists:

- CRFATS-CD; DTHDX-CD; FREQ; GASTRO-CD; HODECOD; LOC; MEDEVAL; NCOMPLT; PROTMLST; RPTTEST-CD; SCTEST-CD; TSPARM-CD
    - To support the Crohn's Disease, Psoriasis, and Ebola TAUGs.

- Updates to Codetable mapping Files:

- DD\_Codetable\_Mapping
    - DS\_Codetable\_Mapping
    - RP\_Codetable\_Mapping
    - SC\_Codetable\_Mapping
    - TS\_Codetable\_Mapping

- 6 changes to published terms; None significant

# Controlled Terminology Package 44 Public Review

- Genomics (née PGx) Terminology Team:
  - New Terms Added to Existing Codelists:
    - GENSMP; METHOD
  - 2 changes to published terms; None significant

# Controlled Terminology Package 44 Public Review

- CDISC Glossary Team

- 23 new terms being added to the CDISC glossary in the following clusters:
  - XML
  - Reports
  - Pre-approval Access
  - Plain Language Writing
  - Virtual Studies
  - Observational Studies
  - Artificial Intelligence
- 4 new Acronyms, Abbreviations, Initials
- 26 additional sources
- 53 changes to existing; 11 significant [see next slide]

# Controlled Terminology Package 44 Public Review

- CDISC Glossary Team [Significant Changes]
  - Removal of the following Glossary terms:
    - clinical protocol
    - multicenter study
    - study coordinator
    - supporting variables
    - termination (of subject)
    - therapeutic intervention
    - unequal randomization
  - Changes to 4 Preferred Terms:
    - construct validation (COA) -> construct validation (re COA)
    - content validation (COA) -> content validation (re COA)
    - criterion validation (COA) -> criterion validation (re COA)
    - Phase -> phase (of clinical development)



# Controlled Terminology Package 44 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - BSTEST-CD; LBANMET; LBTEST-CD; METHOD; MITS-CD; CLMETH
    - To support Crohn's Disease TAUG
  - 17 changes to published terms; 7 significant changes [see next slide]

# Controlled Terminology Package 44 Public Review

- Laboratory Terminology Team (Significant Changes)
  - METHOD:
    - Re-coding of RULER, CALIPER, and PH METER with new c-code, CDISC Submission Value, Definition, and NCI Preferred Term.
      - The semantics behind the terms in the METHOD codelist should not reflect devices, but rather the techniques associated with said devices.
    - Terms C158268/VISUAL ANALOG SCALE (100 MM) and C158269/VISUAL ANALOG SCALE (50 MM) will be moved into the QRSMETHOD codelist due to approved modeling changes in a developing TAUG.
  - LBTEST-CD:
    - Concept C165976 (NAP2/Neutrophil-Activating Peptide 2) will be merged with C165955/Chemokine (C-X-C Motif) Ligand 7 as they are synonymous.

# Controlled Terminology Package 44 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
  - 3 changes to published terminology; None Significant

# Controlled Terminology Package 44 Public Review

- Laboratory Terminology Team (SPECTYPE\_SPECCOND)
  - New Terms Added to Existing Codelists:
    - SPECTYPE
  - 1 change to published terminology; Not Significant

# Controlled Terminology Package 44 Public Review

- Microbiology Terminology Team

- New Terms Added to Existing Codelists:

- MBTEST-CD

- 118 Changes to existing terms: ALL significant!

- The Microbiology/Immunology team is proposing to retire the SDTM Species/SPCIES codelist. This codelist was originally created to support the non-standard variable PFNSPCES (--NSPCES) published in the provisional PGx Implementation Guide v1.0. The CDISC Genomics team has approved to deprecate the PF domain and the --NSPCES variable in favor of the new GF domain. Therefore this codelist is no longer needed.

# Controlled Terminology Package 44 Public Review

- Oncology Terminology Team:
  - 2 changes to existing terms; None significant

# Controlled Terminology Package 44 Public Review

- PK Terminology Team
  - New Terms Added to Existing Codelists:
    - PKPARAM-CD; PKUNIT
  - No changes to existing terms

# Controlled Terminology Package 44 Public Review

- Protocol Entities Terminology Team
  - 10 Attributes for the published entity 'Study Product'
  - No changes to existing terms



# Controlled Terminology Package 44 Public Review

- QRS Terminology Team
  - No Additions or Changes in public review for QRS-terminology this quarter.

# Controlled Terminology Package 44 Public Review

- SDTM Domain Terminology Team
  - No Additions or Changes being proposed for SDTM Domain-associated terminology this quarter.

# Controlled Terminology Package 44 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - FXFINDRS; LOC; MITEST-CD; NEOPLASM; NONNEO; SPEC; STSPRM-CD
    - To support the SENDIG-DART; extensions to the SEND MI domain; INHAND Hematolymphoid System publication
  - New Terms Added to New Codelist:
    - MISXMAT
  - 44 changes to published term; 33 are significant

# Controlled Terminology Package 44 Public Review

- SEND Terminology Team
  - Significant Changes to the SEND Codetable Mapping Files
    - Note: 2020-09-25: The SEND Leadership Team has decided to remove the SEND codetable mapping files from this page in December 2020, coincident to the CT P44 publication. It is unclear at this time how the files are to be used to support a SEND submission, which is causing some confusion among the user community. These files will no longer be updated beginning with CT Package 43.
    - SEND Codetable mapping files will be re-introduced when SEND leadership has a better understanding of how this content would be integrated into the CDISC library and how it would be used by the non-clinical community and regulatory reviewers.

# Controlled Terminology Package 44 Public Review

- SEND Terminology Team (Changes to Existing)
  - NEOPLASM:
    - C27096/SARCOMA, UNDIFFERENTIATED, MALIGNANT: Remove from codelist. This appears to be a human-specific neoplasm in which the SEND Submission value and definition do not match. Please use C9118 instead of this term.
    - C92180/ADENOMA, SERTOLIFORM TUBULAR, BENIGN: Remove from codelist. This is redundant with C67012. Please use that term instead.
    - C84357/YOLK SAC TUMOR, BENIGN: Remove from codelist. This term is not generally reported, though the malignant variant is. Therefore team would prefer not to maintain it any longer.
    - C124610/LEIOMYOMA, MESOVARIAL, MALIGNANT: Remove from codelist. This term is not generally reported, though the benign variant is. Therefore team would prefer not to maintain it any longer.
    - C103392/OSTEOFIBROMA, BONE, BENIGN: Remove from codelist. Please use existing term C3740 OSTEOFIBROMA, BENIGN.

# Controlled Terminology Package 44 Public Review

- SEND Terminology Team (Changes to Existing, cont'd.)
  - FXFINDRS:
    - Remove from Codelist: CLEFT JAW; CLEFT LIP; CLEFT MANDIBLE; CLEFT MAXILLA; CLEFT PALATE; CLEFT FACE -> Use new term CLEFT and add anatomical part into (e.g., JAW, LIP, FACE, etc.) the --LOC or --RESLOC variables.
    - Remove from Codelist: FEWER DIGITS -> Use existing term REDUCED NUMBER and put anatomical part into --LOC or --RESLOC.
    - Remove from Codelist: FUSED PLACENTA -> Please use existing concept FUSED and put PLACENTA in LOC or RESLOC
    - Remove from Codelist: OPACITY OF THE LENS -> Please use existing concept OPACITY and put Lens in LOC or RESLOC
    - Remove from Codelist:

# Controlled Terminology Package 44 Public Review

- SEND Terminology Team (Changes to Existing, cont'd.)

- FXFINDRS:

- Remove from Codelist: Put anatomical

Existing c-code	Existing CDISC Submission Value	New C-code	New CDISC Submission Value
C12450 2	BLUNT-TIPPED TAIL	CNEW	BLUNT-TIPPED
C12452 1	CURLED TAIL	CNEW	CURLED TAIL
C12452 7	DOMED HEAD	CNEW	DOMED
C94569	ERUPTED TOOTH	CNEW	ERUPTED
C12454 4	HOOKEED TAIL	CNEW	HOOKEED
C84784	IMPERFORATE ANUS	CNEW	IMPERFORATE
C12455 2	KINKED TAIL	CNEW	KINKED
C12456 7	OPEN EYE	CNEW	OPEN
C12456 9	OVERRIDING AORTA	CNEW	BIVENTRICULAR OVERRIDE
C84492	PATENT DUCTUS ARTERIOSUS	CNEW	PATENT
C12458 2	SHARED PLACENTA	C38019	SHARED
C12458 9	THREE-CHAMBERED HEART	CNEW	THREE-CHAMBERED
C84742	TRANSPOSITION OF GREAT VESSELS	CNEW	TRANSPPOSED
C12459 1	TWO-CHAMBERED	CNEW	TWO-CHAMBERED
C2888	UNEXPANDED LUNG	CNEW	UNEXPANDED
C12459 ~	WAVY RIB	CNEW	WAVY

# Other P44 happenings....

C174446	C66741		Vital Signs Test Code	TEMP	Body Temperature; Temperature	A measurement of the temperature of the body.	Body Temperature
C174446	C67153		Vital Signs Test Name	<del>TEMP</del> Temperature	Body Temperature; Temperature	A measurement of the temperature of the body.	Body Temperature





# Changes to Controlled Terminology Page on CDISC.org

<https://www.cdisc.org/standards/terminology/controlled-terminology>

cdisc.org/standards/terminology/controlled-terminology

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## Controlled Terminology

Description Education Knowledge Base Public Review

Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you *WHAT* to collect; it tells you *IF* you collected a particular data item, how you should submit it in your electronic dataset.

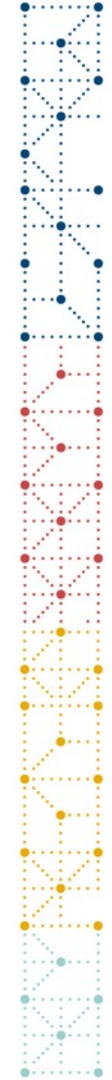
CDISC, in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS), supports the Controlled Terminology needs of CDISC Foundational and Therapeutic Area Standards.

New requests or changes to existing Terminology can be accessed through the CDISC [New Term Request Page](#).

As of 25 Sept 2020 the Protocol Entities, SDTM, SEND, CDASH, and ADaM Controlled Terminology files have been updated on the NCI-EVS Ftp site. The version dates of the new files are 2020-09-25. These terminology files replace all older Protocol Entities, SDTM, SEND, CDASH, and ADaM files and include terms from Review Package 43. There are approximately 86 new QRS terms and 275 new terms across Protocol Entities, SDTM, SEND, CDASH, and ADaM. Additionally there are updates to 6 published Codetable Mapping files: DD, Oncology, RP, SC, TS, and VS.

[Controlled Terminology Release 25 Sept 2020](#)

- Explanation of publication section now includes information on which codetable mapping files have been updated.



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## Controlled Terminology

Description Education Knowledge Base Public Review

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## Controlled Terminology

Description Education Knowledge Base **Public Review**

Public Review - Controlled Terminology

### Controlled Terminology Package 44 Public Review

Comments Due by: 18 October 2020

- [A Short History of CDISC and SAS Transport Files](#)
- [CDISC-Annotated CRF Repository in Japanese](#)
- [Controlled Terminology: FAQs](#)
- [Domain vs. Dataset: What's the Difference?](#)
- [LOINC and the SDTM](#)
- [Sex and Gender](#)
- [Special Values: \\*MULTIPLE\\* and \\*OTHER\\*](#)
- [UCUM and CDISC Codelists](#)
- [Why is an Image like a Specimen?](#)
- [Why Not Just Use SNOMED?](#)

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[Controlled Terminology Release 25 Sept 2020](#)

### Supplemental Files

- [NCI FTP Links](#)
- [Resources](#)
- [Rules](#)
- [Codetable Mapping Files](#)
- [Unit-UCUM Mapping File](#)
- [LOINC to LB Mapping Files](#)

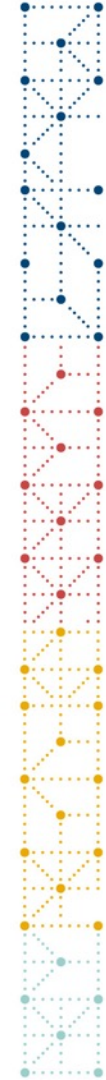
CDISC Controlled Terminology is maintained and distributed as part of the [NCI Thesaurus](#) on an NCI File Transfer Protocol (FTP) site and is available for direct download in Excel, text, odm.xml, pdf, html and OWL/RDF formats from the [CDISC Controlled Terminology resources page](#) on the National Cancer Institute website.

<a href="#">Protocol</a>	<a href="#">CDASH and SDTM</a>
<a href="#">Glossary</a>	<a href="#">ADaM</a>
<a href="#">SEND</a>	<a href="#">Define-XML</a>

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- CDASH and SDTM publication files are in the same Ftp folder.



Supplemental Files

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Supplemental Files

[NCI FTP Links](#) [Resources](#) **Rules** [Codetable Mapping Files](#) [Unit-UCUM Mapping File](#) [LOINC to LB Mapping Files](#)

[Rules for all codelists](#)  
[Rules for Lab and Unit](#)  
[Rules for Microbiology](#)  
[Rules for Oncology](#)  
[Rules for PK](#)  
[Rules for Protocol Entities](#)



Supplemental Files

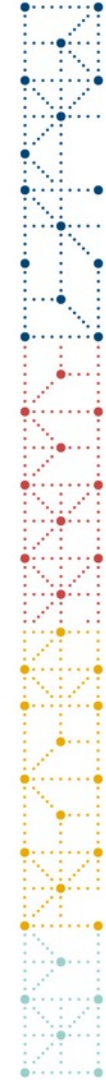
[NCI FTP Links](#) [Resources](#) [Rules](#) [Codetable Mapping Files](#) **Unit-UCUM Mapping File** [LOINC to LB Mapping Files](#)

The Unified Code for Units of Measure (UCUM) contains a blueprint for the creation of compliant units of measure from more than 300 terminal unit symbols. UCUM is used in healthcare to populate electronic health records, such as laboratory records in [LOINC](#), and in the [ISO IDMP](#) standard.

CDISC must specify a single, preferred unit of measure for the pharmaceutical industry to use in data submissions to regulators. Since UCUM does not control mathematical synonymy nor cover all units of measure required by the pharmaceutical industry, CDISC publishes submission values for units of measure across multiple codelists that support variables within CDISC findings, interventions, and trial design domains.

To seamlessly toggle between UCUM and CDISC Units, a mapping has been built and is updated quarterly with the CDISC Controlled Terminology publication. For each published CDISC submission value across all UNIT-based codelists in SDTM terminology, the mapping provides valid UCUM expressions associated with that unit concept. This allows a collected UCUM-compliant unit of measure to be easily matched to the appropriate CDISC submission value associated with that concept.

[Unit-UCUM Codetable](#)



## Supplemental Files

[NCI FTP Links](#)   [Resources](#)   [Rules](#)   **[Codetable Mapping Files](#)**   [Unit-UCUM Mapping File](#)   [LOINC to LB Mapping Files](#)

Controlled Terminology consists of question (e.g., Variables, TESTs and PARMs) and answer(e.g., response codelists, qualifier variable codelists), which are commonly referred to as codelists and are published alphabetically in the Controlled Terminology publication.

The terms within these codelists may have relationships to other terms within other codelists. For instance, a single TEST in the EGTEST codelist may have a finite set of responses located in the EGSTRESC codelist that constitutes a subset of the EGSTRESC codelist. Another instance, a single VSTEST value may have a constrained set of units of measure that are valid for the numeric responses to that VSTEST. These relationships are not readily apparent in the Controlled Terminology publication files.

To address this issue, the Controlled Terminology Teams have created Codetable Mapping Files based on published Terminology, which show relationships between terms in different Controlled Terminology codelists. These supplemental files provide human and machine-readable linkages between published terms across multiple codelists and may be helpful for data QA/QC, CRF building, and data mapping. These files are for clinical use only.

The Controlled Terminology teams will continue to update these files as new Terminology is published, as well as develop new domain Codetable Mapping Files. If you are interested in seeing specific content developed, please submit the request through the [New Term Request Site](#). CDISC is concurrently working on the development of electronically consumable formats of this content to be published out of [CDISC Library](#).

**Note: 2020-09-25: The SEND Leadership Team has decided to remove the SEND codetable mapping files from this page in December 2020, coincident to the CT P44 publication. It is unclear at this time how the files are to be used to support a SEND submission, which is causing some confusion among the user community. These files will no longer be updated beginning with CT Package 43.**

[SDTMIG3.2 Variable\\_Codelist](#)

[DD Codetable](#)

[DS Codetable](#)

[CV Codetable](#)

[ECG Codetable](#)

[Oncology Codetable](#)

[Racec-Ethnicc Codetable](#)

[RP Codetable](#)

[SC Codetable](#)

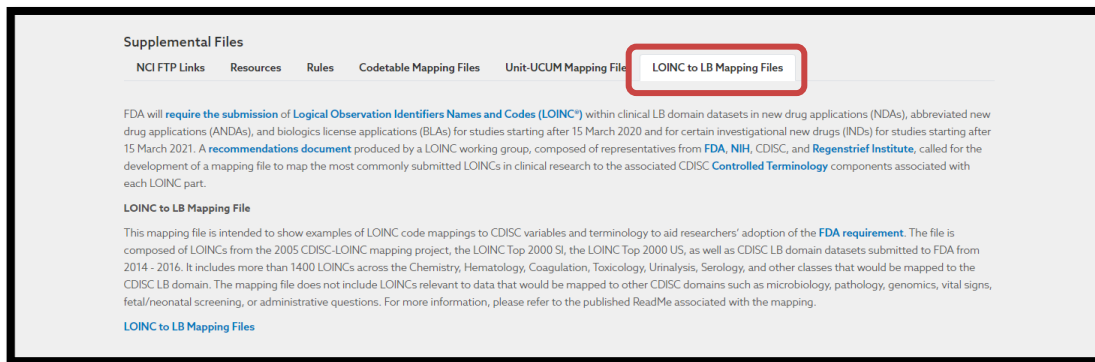
[SEND Codetable](#)

[SS Codetable](#)

[TS Codetable](#)

[VS Codetable](#)

# LOINC to LB Mapping file is now posted!



Supplemental Files

[NCI FTP Links](#) [Resources](#) [Rules](#) [Codetable Mapping Files](#) [Unit-UCUM Mapping Files](#) **[LOINC to LB Mapping Files](#)**

FDA will [require the submission of Logical Observation Identifiers Names and Codes \(LOINC<sup>®</sup>\)](#) within clinical LB domain datasets in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) for studies starting after 15 March 2020 and for certain investigational new drugs (INDs) for studies starting after 15 March 2021. A [recommendations document](#) produced by a LOINC working group, composed of representatives from [FDA](#), [NIH](#), [CDISC](#), and [Regenstrief Institute](#), called for the development of a mapping file to map the most commonly submitted LOINC<sup>®</sup>s in clinical research to the associated CDISC [Controlled Terminology](#) components associated with each LOINC part.

**LOINC to LB Mapping File**

This mapping file is intended to show examples of LOINC code mappings to CDISC variables and terminology to aid researchers' adoption of the [FDA requirement](#). The file is composed of LOINC<sup>®</sup>s from the 2005 CDISC-LOINC mapping project, the LOINC Top 2000 SI, the LOINC Top 2000 US, as well as CDISC LB domain datasets submitted to FDA from 2014 - 2016. It includes more than 1400 LOINC<sup>®</sup>s across the Chemistry, Hematology, Coagulation, Toxicology, Urinalysis, Serology, and other classes that would be mapped to the CDISC LB domain. The mapping file does not include LOINC<sup>®</sup>s relevant to data that would be mapped to other CDISC domains such as microbiology, pathology, genomics, vital signs, fetal/neonatal screening, or administrative questions. For more information, please refer to the published ReadMe associated with the mapping.

[LOINC to LB Mapping Files](#)



**If you are interested in contributing to the  
CDISC Terminology Initiative, please contact  
us...**

Erin Muhlbradt, [muhlbradtee@mail.nih.gov](mailto:muhlbradtee@mail.nih.gov)  
Dana Booth, [dbooth@cdisc.org](mailto:dbooth@cdisc.org)

CDISC New term request form:  
<https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>







# Q&A

# CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



**Thank you for your attendance and support of  
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# Audience Questions



How do I leave comments on the public review?



# Upcoming Learning Opportunities

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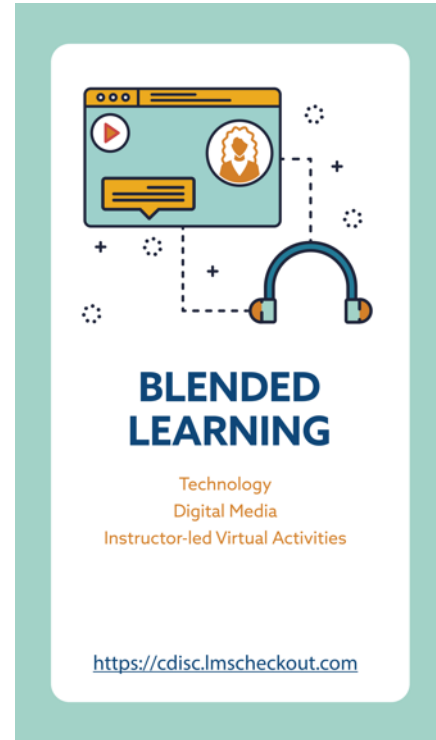
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- SDTM Theory & Application
- SDTM for Medical Devices
- SDTM Advanced Topics
- SEND Implementation

# 2020 Webinars

Date	Webinar Title
15 OCT	Type 1 Diabetes Pediatrics & Devices Publication
20 OCT	Linking Data in SDTM
22 OCT	Introducing the Next Generation CDISC Library
27 OCT	Introducing the Analysis Results Standard: Project Start Up & Call for Volunteers



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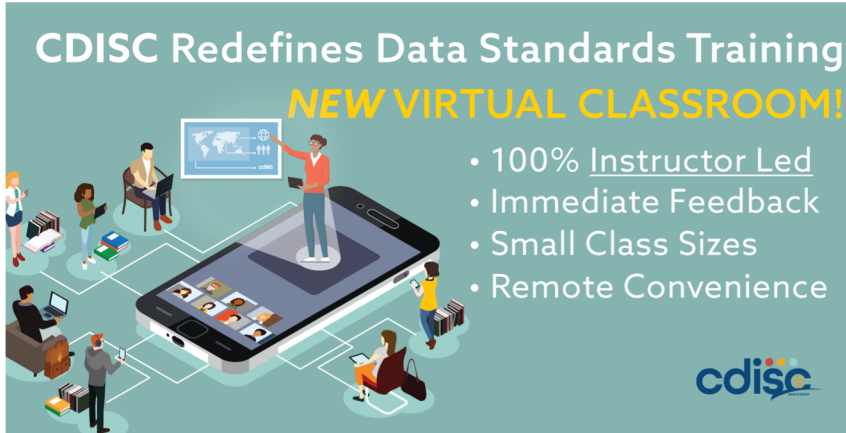


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Questions, comments, concerns? Email [bklinke@cdisc.org](mailto:bklinke@cdisc.org)

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