

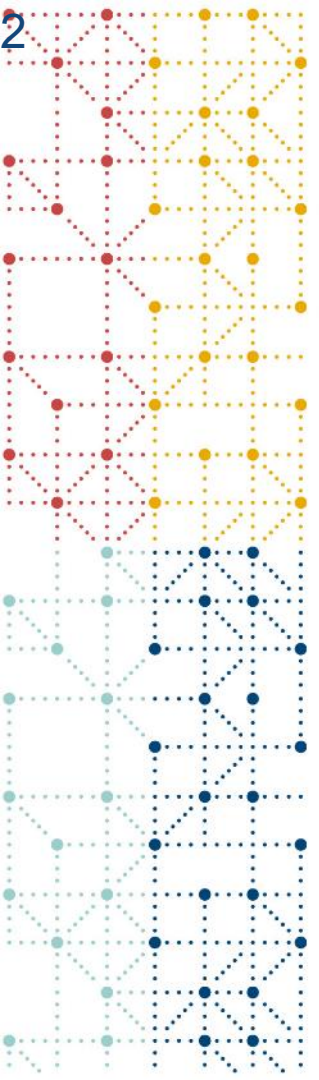


Controlled Terminology Updates for Q3

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC
Enterprise Vocabulary Services, National Cancer Institute

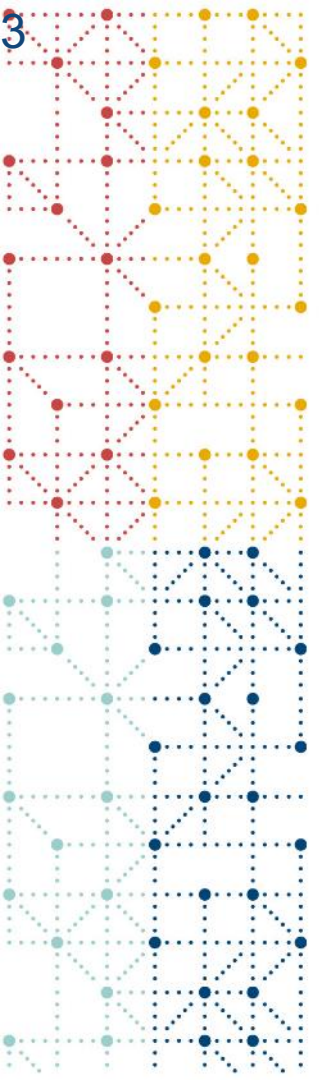


THU 30 SEP
11:00AM-11:45AM ET



Today's Agenda

1. Housekeeping
2. Speaker Introduction
3. Feature Presentation
4. Q&A
5. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping



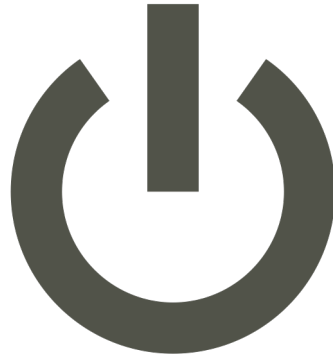
You will remain on **mute**

Housekeeping



Submit questions at any time via the
Questions tool on your GTW app

Housekeeping



Audio issues?

Shut down & restart Zoom app

Housekeeping



A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website



Today's Presenter

Erin Muhlbradt, PhD

Clinical/Biomedical Information Specialist, MSC

Enterprise Vocabulary Services

National Cancer Institute



Controlled Terminology Updates for Q3

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC
Enterprise Vocabulary Services, National Cancer Institute



THU 30 SEP
11:00AM-11:45AM ET



CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt, PhD

09.30.2021





Controlled Terminology P47 Publication and P48 Public Review

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC Inc., CDISC Terminology Program Lead

09.30.2021





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?



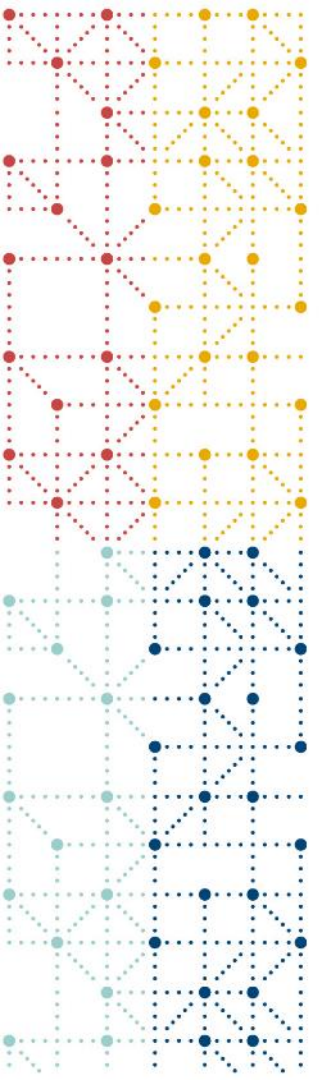
Content Disclaimer

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 47 Publication Release (2021-09-24)
 - Changes post-public review
2. Package 48 Public Review (2021-09-17 to 2021-10-15)
 - New Additions
 - Changes to existing
3. Questions



Controlled Terminology Package 47 Publication

2021-09-24

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			
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 Entities	SEND
44						Spectype	Unit		
45	12/11/2020	12/18/2020	1/17/2021	2/12/2021	3/26/2021	ADaM	Define-XML	General	Lab
45						Microbiology	Oncology	PK	Protocol Entities
45						SDTM Domain	SEND	Spectype	Unit
46	3/12/2021	3/19/2021	4/16/2021	5/14/2020	6/25/2021	Define-XML	General	Lab	Microbiology
46						Oncology	PK	Protocol Entities	QRS
46						SEND			
47	6/11/2021	6/18/2021	7/16/2021	8/13/2021	9/24/2021	CDASH	Cell Pheno	Define-XML	ECG
47						General	Genomics	Lab	Microbio/Immuno
47						Oncology	PK	Protocol Entities	SDTM Domain
47						SEND	Unit		
48	9/10/2021	9/17/2021	10/15/2021	11/12/2021	12/17/2021	ADaM	Biospecimens	Cell Pheno	ECG
48						General	Glossary	Lab	Microbio/Immuno
48						Oncology	PK	Protocol Entities	SDTM Domain
48						SEND	Unit		
49	12/10/2021	12/17/2021	1/14/2022	2/11/2022	3/25/2022				
49									
49									
50	3/11/2022	3/18/2022	4/15/2022	5/13/2022	6/24/2022				
50									
50									
51	6/10/2022	6/17/2022	7/22/2022	8/19/2022	9/30/2022				
51									
51									

9/15/2021

Dates in red are planned and may be adjusted slightly.

Controlled Terminology Package 47 Publication Release

- Updates to Protocol Entities, SDTM, SEND, CDASH, and Define-XML Terminology
- Therapeutic Area Support:
 - QRS Terminology to support: Sponsor requests
 - SDTM Terminology to support: Pancreatic Cancer and Crohn's Disease Therapeutic Area User Guides
- Other Project Support:
 - LOINC-LB Mapping
 - SDTMIGv3.4
 - CDASH SAE

Significant Changes Post-Public Review

- CDASH:
 - New term added to SADCRR codelist: UNKNOWN DECHALLENGE
 - New term added to SARCRR codelist: UNKNOWN RECHALLENGE
- Cell Phenotyping:
 - Submission value updates:
 - TESTCD for 'BLym/Total Cells' changed to "BLYCECE"
 - TESTCD for "Mono Classic" changed to 'MNCL'
 - TESTCD for "Mono NonClassic" changed to "MNNCL"
 - TEST for "LYS" changed to "Lym Sub"
 - TEST for "LYSLY" changed to "Lym Sub/Lym"
 - TEST for "LYVLYNV" changed to "Lym Viable/Lym NonViable"
 - TEST for "MNPMNNP" changed to "Mono Prolif/Mono NonProlif"
 - TEST for "MNS" changed to "Mono Sub"
 - TEST for "MNSMN" changed to "Mono Sub/Mono"
 - TEST for "TGBDBBK" changed to "Target Bound, Delta Bound Background"
 - TEST for "TGFDFBK" changed to "Target Free, Delta Free Background"
 - TEST for "TGTDTBK" changed to "Target Total, Delta Total Background"

Significant Changes Post-Public Review

- Genomics:
 - Proposed GFTEST=Variable Number Tandem Repeats/VNTR removed from package.
 - Will be published in future once Genomics team creates additional examples for the CDISC example repository.
- Lab:
 - Proposed MITS/MITSCD=Mitotic Figures/MITOFIG removed from package.
 - Please use existing term C135470
- PK:
 - Proposed changes to PKPARAM/CD values C85571, C85572, C85767 removed from package.
 - Will be re-reviewed in P48 along with similar proposed changes
- Protocol:
 - ReadMe updated to reflect codelist extensibility change from “NA” to null/blank

Significant Changes Post-Public Review

- Other, less significant changes* also made in:
 - CDASH, Cell Phenotyping, General, Microbiology-Immunology, SDTM Domain, SEND
- No changes made to:
 - Define-XML
 - ECG
 - Oncology
 - 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.**

P47 Terminology Products Updates

- Updates with P47
 - Codetable mappings
 - EG_Codetable_Mapping
 - GI_Codetable_Mapping
 - MK_Codetable_Mapping
 - Oncology_Codetable_Mapping
 - RP_Codetable_Mapping
 - SC_Codetable_Mapping
 - TS_Codetable_Mapping
 - VS_Codetable_Mapping
 - Unit-UCUM_Codetable
 - Controlled_Terminology_Requests_Denied_P47
 - Terminology Development Rules
 - Rules for all Codelists
 - Rules for Lab, Unit, and MI
 - Rules for Oncology
 - Paired Codelists product for SDTM and SEND

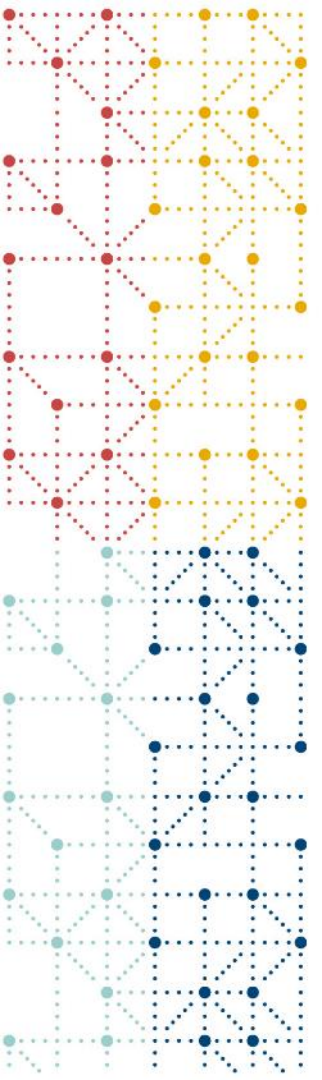
QRS Controlled Terminology Package 47 Publication Release

- No New Codelists
- New terms added to the Test Code and Test Name codelists associated with the: EOR01TN/EOR01TC (European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire - Core 30 Version 3.0)
- The Barnes Akathisia Rating Scale (BARS) moved from QSCAT to CCCAT codelist
 - The Barnes Akathisia Rating Scale Test Name and Test Code codelist names changed to reflect reclassification as a Clinical Classification.

Protocol Terminology Codelist Extensibility

Code	Codelist Code	Codelist Extensible (Y/N/NA)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C179587			Biological Sample Attribute Terminology	Biological Sample Attribute Terminology	Biological Sample Attribute Terminology	A terminology value set relevant to the attributes of the biological sample.
C179744	C179587		Biological Sample Attribute Terminology	Biological Sample Accountability		The activities describing the documentation of the storage, inventory tracking, and disposition of the biological sample.
C70945	C179587		Biological Sample Attribute Terminology	Biological Sample Collection		The activities describing biological sample collection, such as specimen type, timing and methodology.
C70700	C179587		Biological Sample Attribute Terminology	Biological Sample Collection Method		A description of the methodology by which biological material is obtained from a subject.
C178869	C179587		Biological Sample Attribute Terminology	Biological Sample Collection Timing		A description of the timing for the collection of a biological sample, in relation to a study-specific event or time period.
C179745	C179587		Biological Sample Attribute Terminology	Biological Sample Handling	Biospecimen Handling; Handling of Biological Samples; Handling of Biological Specimens	A description of the management of biological sample handling, including methods of collection, processing, shipping, and storage.
C179746	C179587		Biological Sample Attribute Terminology	Biological Sample Preparation		The activities describing how the biological sample is made ready for storage, processing, and/or analysis.
C181231	C179587		Biological Sample Attribute Terminology	Biological Sample Retention	Biospecimen Retention	A textual description as to whether and/or how biological samples are retained for research purposes.
C179747	C179587		Biological Sample Attribute Terminology	Biological Sample Shipping	Biological Sample Shipment; Biological Sample Transport	The activities describing the logistical considerations for transporting a biological sample from the sender to the receiver.
C179748	C179587		Biological Sample Attribute Terminology	Biological Sample Storage		The activities describing the physical or environmental conditions under which the biological sample is maintained.

Protocol-specific codelist extensibility changed from “NA” to <null> (i.e., blank).



Controlled Terminology Package 48 Public Review

2021-09-17 to 2021-10-15

cdisc Wiki Spaces People Polls Calendars Create ... Search

Dashboard / Controlled Terminology / Public Review Edit Save for later Watch Share ...

Terminology Call for Public Review Package P48 - Comments Due by 15 October 2021

Created by Dana Booth; last modified on Sep 16, 2021

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 48, which consists of the following 15 documents:

- Controlled_Terminology_Requests_Denied_P48
- ADaM
- Biospecimens
- Cell Phenotyping
- ECG*
- General*
- CDISC Glossary*
- Laboratory
- Microbiology/Immunology
- Oncology
- PK
- Protocol Entities
- SDTM Domain
- SEND*
- UNIT*

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: 15 October 2021

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:

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

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P48+-+Comments+Due+by+15+October+2021>

Controlled Terminology Package 48 Public Review

- ADaM Team
 - New Terms Added to Existing Codelists:
 - DTYPE

Controlled Terminology Package 48 Public Review

- Biospecimens Team
 - New Terms Added to Existing Codelists:
 - BSTEST-CD; CLMETH; SPECCOND; SPECTYPE
 - No Changes to existing terms

Controlled Terminology Package 48 Public Review

- CDASH Team
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 48 Public Review

- Cell Phenotyping Team
 - New Terms Added to Existing Codelists:
 - CPTTEST-CD
 - No Changes to existing terms

Controlled Terminology Package 48 Public Review

- Define-XML Team
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 48 Public Review

- Medical Devices Team
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 48 Public Review

- ECG Terminology Team:
 - New Terms Added to 2 New Codelists:
 - HEGRDMTH/Holter ECG Read Method Response to support the TSPARM/CD = ECG Read Method/EGRDMETH (C119564)
 - TWOFFMTH/ECG T Wave Offset Method Response to support the TSPARM/CD = ECG Twave Algorithm/EGTWVALG (C119582)
 - Updates to Codetable Mapping Files:
 - EG_Codetable_Mapping
 - 1 change to published terms; 1 significant
 - Published submission value of C114177 updated to “INSUFFICIENT NUMBER OF BEATS TO COMPLETELY EVALUATE ECG” to fix a typo.

Controlled Terminology Package 48 Public Review

- General Terminology Team:
 - New Terms Added to Existing Codelists:
 - D1FATS-CD; DTHDX-CD; FATHEST-CD; FRM; HODECOD; LOC; MEDEVAL; MHEDTTYP; ROUTE; RPTEST-CD; STENRF; VNFATS-CD
 - To support the Type 1 Diabetes – Exercise and Nutrition and Vaccine TAUGs
 - Updates to Codetable Mapping Files:
 - DD_Codetable_Mapping
 - RP_Codetable_Mapping
 - TS_Codetable_Mapping
 - 30 changes to published terms; 4 significant changes [see next slide]

Controlled Terminology Package 48 Public Review

- General Terminology Team:
 - 4 Significant Changes to existing:
 - CRFATS-CD and FATEST-CD
 - Remove C177934/Diameter of Primary Lesion - Remove from codelist and replace with Largest Diameter of Primary Lesion/PLLDIAM that was published with P47.

Controlled Terminology Package 48 Public Review

- Genomics (née PGx) Terminology Team:
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 48 Public Review

- CDISC Glossary Team
 - 19 new terms to be added to the Glossary
 - **Vaccine-related terms:** incidence, incidence rate, prevalence, vaccine efficacy, vaccine effectiveness, morbidity, symptom, sign, virulence, zoonosis.
 - **Other terms:** record, structured health record information, follow-up (clinical study), long term follow-up (clinical study), non-inferiority (NI) trial, early termination of trial, phase 2b, randomized controlled trial (RCT), meta-analysis protocol
 - 72 proposed changes to existing, e.g.,
 - Clarifications to Trial Phases
 - Definitions updates based on whole glossary QC
 - Monitoring Cluster
 - Trial suspension/temporary halt/termination cluster
 - 26 new Acronyms, Abbreviations, and Initials
 - 3 changes to existing Acronyms, Abbreviations, and Initials
 - 21 new definitions sources

Controlled Terminology Package 48 Public Review

- Laboratory Terminology Team (Laboratory-related)
 - New Terms Added to Existing Codelists:
 - LBTEST-CD, METHOD, MITS-CD, RESTYPRS
 - To support LOINC Mapping and SDMTIGv3.4
 - 6 changes to published terms; none significant

Controlled Terminology Package 48 Public Review

- Laboratory Terminology Team (Units of Measure)
 - New Terms Added to Existing Codelists:
 - UNIT
 - 6 changes to published terms; 1 significant change
 - C67469 “v/v” being removed from the codelist. v/v in and of itself does not give enough information to be useful. Existing published terms %, RATIO, L/L, fraction of 1, or %(v/v) could be used instead. Or new term requests could be submitted for more specific types of terms.

Controlled Terminology Package 48 Public Review

- Microbiology-Immunology Terminology Team
 - New Terms Added to Existing Codelists:
 - MBTEST-CD; MICROORG; MSRESCAT
 - To support SDTMIGv3.4
 - 1 Changes to existing term; none significant

Controlled Terminology Package 48 Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - TUIDRS; ONCRTS-CD
 - Update to Codetable Mapping file tabs:
 - TU_Codetable_Mapping
 - RS_ONC_Codetable_Mapping
 - RS_LUGANO_Mapping
 - No changes to existing terms

Controlled Terminology Package 48 Public Review

- PK Terminology Team
 - New Terms Added to Existing Codelists:
 - PKPARAM-CD; PKUNIT
 - 60 changes to existing term; none significant

Controlled Terminology Package 48 Public Review

- Protocol Entities Terminology Team
 - New Terms to Protocol Entities Terminology
 - 4 new Entities: Quality Assurance; Quality Control; Reference; Informed Consent
 - 1 attribute for the new entity 'Reference
 - 3 attributes for the new entity 'Informed Consent'
 - 4 attributes for the published entity 'Protocol Statement'
 - 2 attributes for the published entity "Study Monitoring"
 - No changes to existing terms

Controlled Terminology Package 48 Public Review

- QRS Terminology Team
 - No content for public review

Controlled Terminology Package 48 Public Review

- SDTM Domain Terminology Team
 - No New Terms Added to Existing Codelists:
 - 1 change to existing term; none significant

Controlled Terminology Package 48 Public Review

- SEND Terminology Team
 - New Terms Added to Existing Codelists:
 - NEOPLASM, NONNEO, SPEC
 - New Term Added to New Codelists:
 - STCNTRL/SEND Control Type: to support the STSPRMCD=TCNTRL
 - 3 changes to published term; 1 is significant
 - Codelist C48660 – Null Flavor Reason – Change submission value from “NOT APPLICABLE” to “NA” to conform with FDA's technical rejection criteria.

CDISC Membership

Become a Member!

Join 500+ member organizations that contribute to bringing clarity to data.

Already a Member?

Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.

JOIN US



Email:
membership@cdisc.org



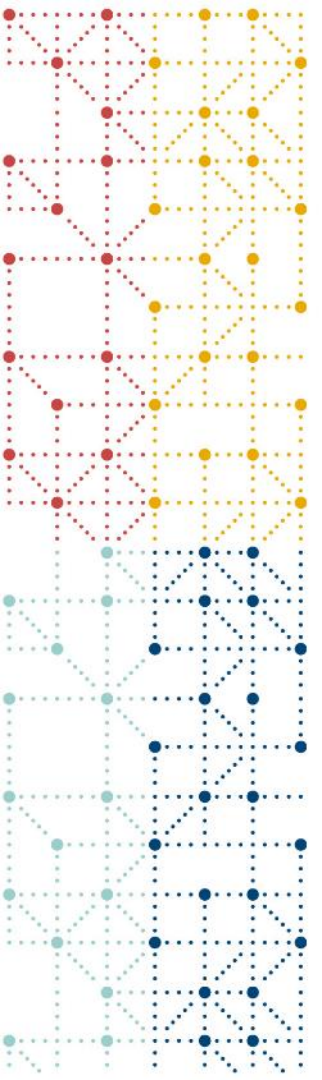


If you are interested in contributing to any of the CDISC Terminology initiatives, please contact us...

Erin Muhlbradt, muhlbradtee@mail.nih.gov
Dana Booth, dbooth@cdisc.org

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





Q&A



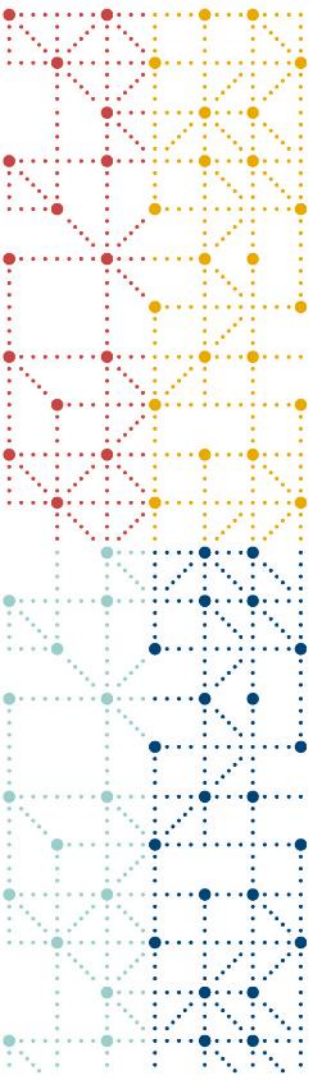
CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



cdisc

**Thank you for your attendance and support of
CDISC!**



Questions & Answers

Audience Questions

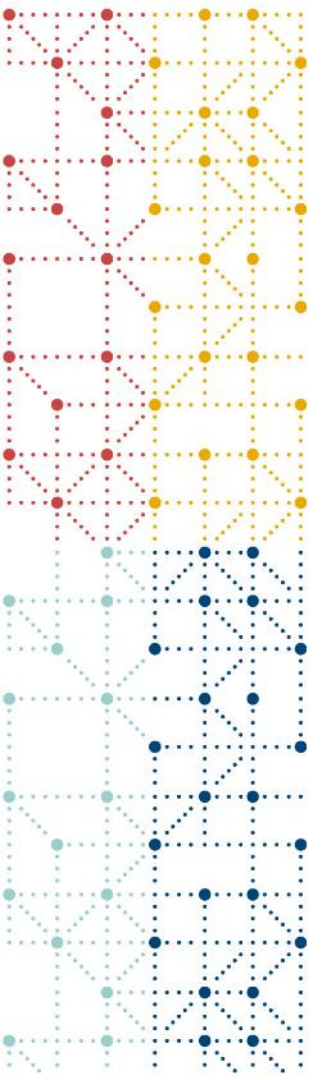
Could you please clarify why FATEST/FATESTCD codelist has been reintroduced lately in CDISC Terminology?



Audience Questions



Can you please elaborate a bit about what paired codelists are and where they are located on the CDISC website?



Upcoming Learning Opportunities

New Virtual Training Methods

Blended Learning from CDISC

Online Resources
+ In-Person Instruction
More Personalized Learning

Classes Starting Soon!



CDISC Redefines Data Standards Training **NEW VIRTUAL CLASSROOM!**

- 100% Instructor Led
- Immediate Feedback
- Small Class Sizes
- Remote Convenience



cdisc

- Information available at: www.cdisc.org
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: training@cdisc.org



BLEND
ED LEARNING



VIRTUAL
TRAINING



CLASSROOM
TRAINING



PRIVATE
TRAINING



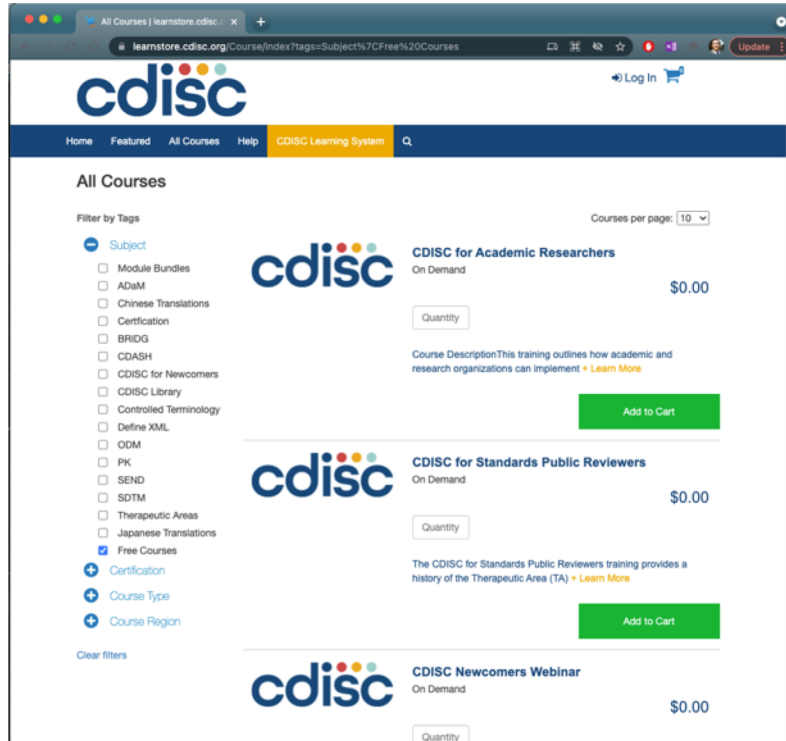
WEBINARS



WORKSHOPS

cdisc

Free CDISC Courses



The screenshot shows the CDISC Learnstore website interface. The browser address bar displays the URL learnstore.cdisc.org/Course/Index?tags=Subject%7CFree%20Courses. The website header includes the CDISC logo, a "Log In" button, and a navigation menu with "Home", "Featured", "All Courses", "Help", and "CDISC Learning System". The main content area is titled "All Courses" and features a "Filter by Tags" section on the left. Under the "Subject" filter, the "Free Courses" checkbox is selected. The course list includes:

- CDISC for Academic Researchers**: On Demand, \$0.00. Description: "This training outlines how academic and research organizations can implement..."
- CDISC for Standards Public Reviewers**: On Demand, \$0.00. Description: "The CDISC for Standards Public Reviewers training provides a history of the Therapeutic Area (TA)..."
- CDISC Newcomers Webinar**: On Demand, \$0.00.

Each course entry includes a "Quantity" input field and an "Add to Cart" button. The "CDISC for Academic Researchers" and "CDISC for Standards Public Reviewers" entries also have "Learn More" links in their descriptions.

[Http://learnstore.cdisc.org](http://learnstore.cdisc.org)



2021 US INTERCHANGE

With Standards - Science Will Prevail!

Now fully virtual!



Live Stream | 20-21 October

Conference & Trade Show



2021 CHINA INTERCHANGE

With Standards - Science Will Prevail!



Beijing | 19-20 November

Conference | Trade Show

Upcoming Webinars

Digital Data Flow: Project Information and Call for Volunteers

5 October 2021, 11am - 12:30pm EDT

[REGISTER NOW!](#)

CDISC, in collaboration with [TransCelerate's Digital Data Flow Project](#), is developing a reference architecture, which will serve as a standard model for the development of a Study Definitions Repository. The Repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards.

Deliverables will include a logical data model, supporting Controlled Terminology, API specifications and related conformance tests.

Join us as we share project progress and how to get involved.

[Read the press release announcing the project.](#)

Panelist(s)

Dave Evans, CDISC President & CEO

John Owen, CDISC Head of Partnership & Development

Christine Connolly, CDISC Senior Project Manager

Language

English

CDISC Open Source Alliance (COSA) Spotlight

18 November 2021, 11am - 12:30pm EST

[REGISTER NOW!](#)

To drive innovative approaches to standards-based automation, CDISC has initiated the [CDISC Open-Source Alliance \(COSA\)](#), which supports, promotes, and sometimes sponsors open-source software projects that create tools for implementing or developing CDISC standards.

Join us to learn the basics of how you can leverage the first [COSA-approved tools](#) to facilitate the implementation of CDISC standards in your systems.

- TFL Designer
- Visual Define-XML Editor
- Odmlib

We will also share how open-source developers can learn to [apply for inclusion](#) in the COSA Directory.

Panelist(s)

Sam Hume, VP Data Science, CDISC

Dmitry Kolosov, Expert Statistical Programmer, Parexel

Bhavin Busa, VP of Clinical Data Services & Operations, Vita Data Sciences

Language

English

Upcoming Webinars

Controlled Terminology Updates for Q4 2021

21 December 2021, 11am - 12:30pm EST

[REGISTER NOW!](#)

This quarterly webinar series addresses the latest Controlled Terminology release package as well as content currently in 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.

Panelist(s)

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services, National Cancer Institute

Language

English

Thank you!



Contact the Events inbox:
events@cdisc.org



Contact Education inbox:
training@cdisc.org



Contact Bernard directly:
bklinke@cdisc.org