

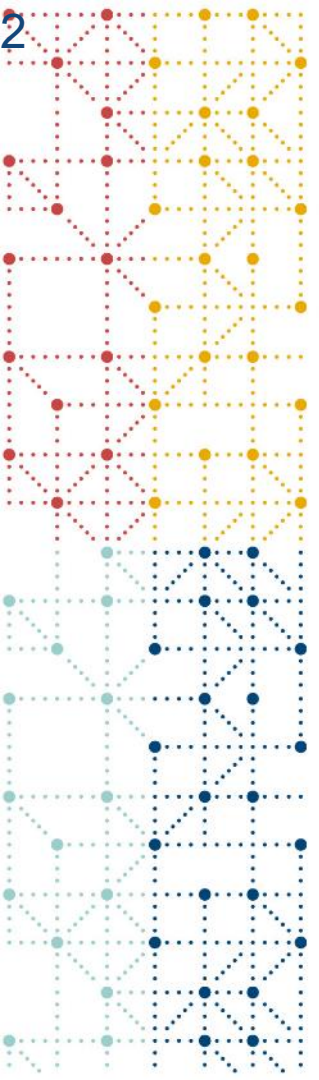


# Controlled Terminology Updates for Q1 2022 - P49 publication/P50 public review

**Dr. Erin Muhlbradt**, Biomedical/Clinical Research Information Specialist (Contractor), Enterprise  
Vocabulary Services (EVS)  
National Cancer Institute

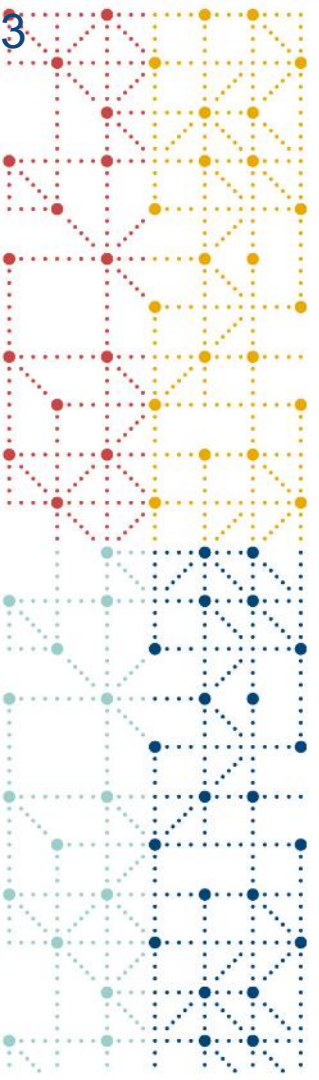


TUE 05 APR 2022  
11:00AM-12:30PM ET



## Today's Agenda

1. Housekeeping
2. Feature Presentation
3. Upcoming Learning Opportunities & Events



# Housekeeping

## Housekeeping



You will remain on **mute**

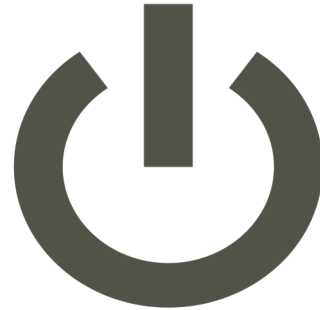


# Housekeeping



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

# Housekeeping



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using the Audio tool

# Housekeeping



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



## Our Presenter

**Dr. Erin Muhlbradt**

Biomedical/Clinical Research Information Specialist  
(Contractor)

Enterprise Vocabulary Services (EVS)  
National Cancer Institute



# Controlled Terminology Updates for Q1 2022 - P49 publication/P50 public review

**Dr. Erin Muhlbradt**, Biomedical/Clinical Research Information Specialist (Contractor), Enterprise  
Vocabulary Services (EVS)  
National Cancer Institute



TUE 05 APR 2022  
11:00AM-12:30PM ET



## Controlled Terminology P49 Publication and P50 Public Review

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

CDISC Terminology Program Lead

04.05.2022





## 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?





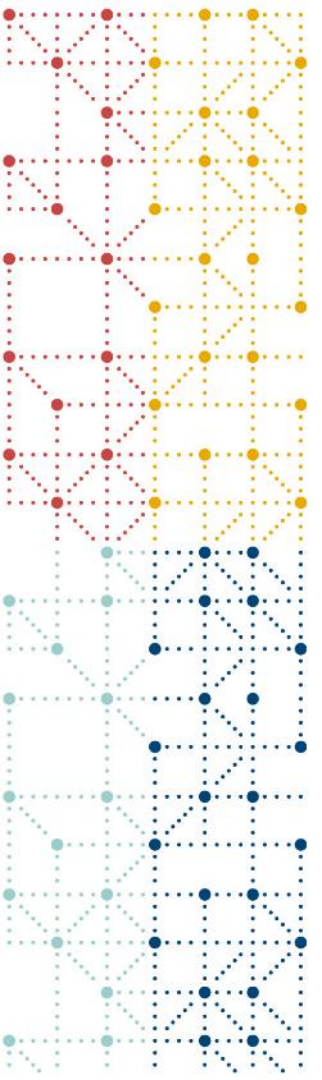
## Content Disclaimer

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 49 Publication Release (2022-03-25)
  - Changes post-public review
2. Package 50 Public Review (2022-03-18 to 2022-04-15)
  - New Additions
  - Changes to existing
3. Questions



# Controlled Terminology Package 49 Publication

2022-03-25

# 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			
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/Immun
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/Immun
48						Oncology	PK	Protocol Entities	SDTM Domain
48						SEND	Unit		
49	12/10/2021	12/17/2021	1/14/2022	2/11/2022	3/29/2022	Biospecimens	CP	Genomics	General
49						Microbio/Immun	Lab	PK	Protocol
49						SEND	Unit		
50	3/11/2022	3/18/2022	4/15/2022	5/13/2022	6/24/2022	CP	General	Genomics	Microbio/Immun
50						Lab	Oncology	Protocol Entities	QRS
50						SEND	Unit		
51	6/10/2022	6/17/2022	7/22/2022	8/19/2022	9/30/2022				
51									
51									
52	9/16/2022	9/23/2022	10/21/2022	11/18/2022	12/16/2022				
52									
52									
53	12/9/2022	12/16/2022	1/20/2023	2/17/2023	3/31/2023				
53									
53									



# Controlled Terminology Package 49 Publication Release

- Updates to Protocol Entities, SDTM, and SEND Terminology
- Therapeutic Area Support:
  - N/A
- Other Project Support:
  - SDTMIGv3.4

# Significant Changes Post-Public Review

- Cell Phenotyping:
  - CPTTESTCD for 'T-Lymphocytes Helper Gamma-Delta' changed from TLCHGD to TLHGD in publication file.
  - A number of proposed new CPTTEST values were removed from P49 as they were published in previous packages.
    - TLym Help
    - TLym Help Sub
    - BLym Naive Mat
    - BLym Trans
    - TLym Help Reg Sub
    - Leukocytes/Total Cells
    - B-Lymphocytes/Total Cells

# Significant Changes Post-Public Review

- General:
  - LOC:
    - A number of proposed new LOC values were removed from P49 as they were published in previous packages:
      - BRAIN, FOURTH VENTRICLE
      - SEMIMEMBRANOSUS MUSCLE
      - FRONTAL BONE
    - Submission value change for C52888 from 'ADDUCTOR POLLICIS MUSCLE' to 'ABDUCTOR POLLICIS LONGUS MUSCLE' to align it with CDISC definition and NCI c-code.
  - METHOD: SUSCEPTIBILITY WEIGHTED IMAGING was removed from the package as it is synonymous with an existing term. Synonyms were added instead.
  - MHEDTTYP: Two values pulled from package for further discussion in P51 based on a public review comment; team needs more dataset context
    - SURGICAL PROCEDURE
    - INITIAL DEVICE USAGE
  - SSTEST-CD: Submission value update for new term from 'AVAILFU/Availability for Follow-Up' to 'FUAVSTAT/Follow-Up Availability Status'



# Significant Changes Post-Public Review

- Lab:
  - LBTEST-CD:
    - New LBTEST-CD values INDOCYGR/Indocyanine Green pulled from package as it is already published in LBTEST-CD codelist (C184512).
  - MITS-CD:
    - New MITS-CD values ARV7/Androgen Receptor Variant 7 pulled from package as it is already published in MITS-CD codelist (C184703).
- SEND:
  - CHAGNAMR:
    - NCI c-code change for TETRACHLORVINPHOS from C163708 to C152434 (terms merged in NCI).
    - NCI c-code change for DIAZINON from C163646 to C169912 (terms merged in NCI).

# Significant Changes Post-Public Review

Other, less significant changes\* also made in:

- Microbiology/Immunology, PK

No post-public review changes made to:

- Biospecimens
- Genomics
- Lab
- Oncology
- Protocol Entities
- 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.**

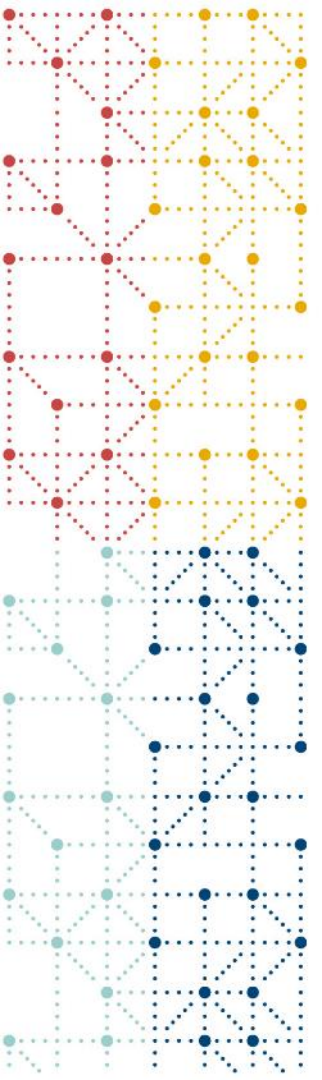
# P49 Terminology Products Updates

- Updates with P49
  - Codetable mappings:
    - DS\_Codetable\_Mapping
    - Oncology\_Codetable\_Mapping
    - RACE\_ETHNIC\_Mapping
    - RP\_Codetable\_Mapping
    - SC\_Codetable\_Mapping
    - SS\_Codetable\_Mapping
  - \*NEW codetable mapping file: GF
  - Unit-UCUM\_Codetable
  - Controlled\_Terminology\_Requests\_Denied\_P49
  - Paired Codelists product for SDTM and SEND
  - Terminology Publication Schedule
  - QRS Naming and Business Rules



# QRS Controlled Terminology Package 49 Publication Release

- 2 new --CAT values (QS)
- 2 new TEST/TESTCD codelist pairs
  - SF-6Dv2 Health Utility Survey Acute, English Version 2.0 Questionnaire
  - SF-6Dv2 Health Utility Survey Standard, English Version 2.0 Questionnaire
- 4 New TEST/CD values added to SF36 v2.0 Acute and SF36 v2.0 Standard questionnaires.



# Controlled Terminology Package 50 Public Review

2022-03-18 to 2022-04-15

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Pages / [Controlled Terminology](#) / [Public Review](#) Save for later Watch Share ...

## Terminology Call for Public Review Package P50 - Comments Due by 15 April 2022

Created by Dana Booth, last modified on Mar 22, 2022

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 50, which consists of the following 12 documents:

- [Controlled\\_Terminology\\_Requests\\_Denied\\_P50](#)
- [Cell Phenotyping](#)
- [General\\*](#)
- [Laboratory\\*](#)
- [Microbiology/Immunology\\*](#)
- [Oncology](#)
- [Protocol Entities\\*](#)
- [QRS](#)
- [QRS naming and Business Rules\\_2022-03-18](#)
- [Rules\\_for\\_Genomics\\_2022-03-18](#)
- [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 April 2022**

**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.

**To add comments from within JIRA:**

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

① Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.

2. Click on the **"Create"** button in the top menu to bring up the Create Issue form.
3. Choose the **Controlled Terminology** Project.
4. Choose the appropriate **issue type** - **"Review Comments"**.

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P50+-+Comments+Due+by+15+April+2022>

# Controlled Terminology Package 50 Public Review

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



# Controlled Terminology Package 50 Public Review

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

# Controlled Terminology Package 50 Public Review

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



# Controlled Terminology Package 50 Public Review

- Cell Phenotyping Team
  - New Terms Added to Existing Codelists:
    - CPTTEST-CD
  - 2 changes to published terms; none significant

# Controlled Terminology Package 50 Public Review

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



# Controlled Terminology Package 50 Public Review

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

# Controlled Terminology Package 50 Public Review

- ECG Terminology Team:
  - No new term or changes to existing to report this quarter.

# Controlled Terminology Package 50 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - COLSTYP; EVAL; FATEST-CD; FDATSRs; LOC; MEDEVAL; NVTEST-CD; OETEST-CD; PROCEDUR; TBLIND; VNFATS-CD
    - To support the: Type 1 Diabetes – Exercise and Nutrition and Vaccine TAUG: SDTMIGv3.4
  - New Terms added to New Codelists
    - CMSPSTAT/Commercial Sponsor Status Response: Response codelist for a published TSPARM-CD value.
  - Updates to Codetable Mapping Files:
    - TS\_Codetable\_Mapping
  - 18 changes to published terms
    - A few changes to note (see next slide)



# Controlled Terminology Package 50 Public Review

- General Terminology Team:

NCIEVS Request Number	Therapeutic Area Request	Codelist Short Name	TESTCD, PARMCD or Submission Value	TEST or PARM	Synonym(s)	CDISC Definition
CDISC-5246		MEDEVAL	RADIOLOGIST 3			A radiologist performing the assessment who is given the designation of three.
Pending		MEDEVAL	CARDIOLOGIST 1			A cardiologist performing the assessment who is given the designation of one.
Pending		MEDEVAL	CLINICAL PATHOLOGIST 1			A clinical pathologist performing the assessment who is given the designation
Pending		MEDEVAL	DERMATOLOGIST 1			
Pending		MEDEVAL	DEVELOPMENTAL BEHAVIORAL PEDIATRICIAN 1			
Pending		MEDEVAL	DEVELOPMENTAL PSYCHOLOGIST 1			
Pending		MEDEVAL	ENDOCRINOLOGIST 1			
Pending		MEDEVAL	FORENSIC PATHOLOGIST 1			

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TOP 2

NCIEVS Request Number	Therapeutic Area Request	Codelist Short Name	TESTCD, PARMCD or Submission Value	TEST or PARM	Synonym(s)	CDISC Definition
Pending		EVAL	ADJUDICATOR			An individual that presides over and arbitrates between individuals or organizations.
Pending		EVAL	CARDIOLOGIST			A physician who specializes in the diagnosis and treatment of heart disorders.
Pending		EVAL	CLINICAL PATHOLOGIST			A physician specializing in medical diagnosis based on laboratory analysis and the macroscopic and the microscopic changes to tissues and organs caused by disease.
Pending		EVAL	DERMATOLOGIST			A doctor who specializes in diagnosis and treatment of skin conditions.
Pending		EVAL	DEVELOPMENTAL BEHAVIORAL PEDIATRICIAN			A pediatrician who specializes in diagnosing and treating developmental and behavioral disorders in children.
Pending		EVAL	DEVELOPMENTAL PSYCHOLOGIST			A psychologist who specializes in diagnosing and treating emotional and behavioral problems associated with developmental delay or disability.
Pending		EVAL	ENDOCRINOLOGIST			A physician who specializes in diagnosing and treating conditions affecting the endocrine system.
Pending		EVAL	FORENSIC PATHOLOGIST			A physician specializing in the diagnosis of both the cause of death and the manner of death of another human being.

• Future  
MEDE

# Controlled Terminology Package 50 Public Review

- Genomics (née PGx) Terminology Team:
  - NEW Terminology Development Rules Document:
    - [Rules\\_for\\_Genomics\\_2022-03-18](#)
      - Describe relationships between TEST/TSTDTL
      - Describes where to put Gene Names/Symbols (NOT in GFTEST-CD!)

# Controlled Terminology Package 50 Public Review

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

# Controlled Terminology Package 50 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST-CD, METHOD, MITS-CD, MIFTSDDL
    - To support Type 1 Diabetes TAUG
  - 42 changes to published terms; 10 significant
    - C184627 (Methylphenobarbital) merged into C75366 due to synonymy. No submission value changes.
    - Continued on next slide.....

# Controlled Terminology Package 50 Public Review

- Laboratory Terminology Team
  - Significant changes – Monoclonal Spike Protein determined to be synonymous with Monoclonal Protein
    - C117844/Monoclonal Protein Spike being merged into C92291/Monoclonal Protein (synonyms being added)
    - C156508/Monoclonal Protein Spike/Total Protein being merged into C147397/Monoclonal Protein/Total Protein (synonyms being added)
    - C163467 submission value being updated: Monoclonal Protein Spike Excretion Rate -> Monoclonal Protein Excretion Rate (synonyms being added)
    - C158218 submission value being updated: Monoclonal Protein Spike Region -> Monoclonal Protein Region (synonyms being added)

# Controlled Terminology Package 50 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
  - 21 changes to published terms; 21 significant changes
    - (many) Submission value update: 'sec' -> 's' to align with standard unit nomenclature
    - C67412 Submission value update: 'mL/min/1.73m2' to 'mL/min/1.73 m2'
    - C117968 Submission value update: 'dpm/100mg' to 'dpm/100 mg'
    - C67247 (10<sup>9</sup> cells) being retired from the codelist and replaced with CNEW (10<sup>9</sup> Therapeutic Cells)
      - This unit should only be used for cell dosing and not for cell counts where cell is inherent to the test value. This change will ensure better use of correct UNIT values.

# Controlled Terminology Package 50 Public Review

- Microbiology-Immunology Terminology Team
  - New Terms Added to Existing Codelists:
    - ISBDAGT; ISTEEST-CD; MBTEST-CD; MICROORG; OIPPARM-CD
  - 24 Changes to existing term; 1 significant
    - MBTESTCD Submission value for C142232 changing from SPNAB to SPNIGGAB -> Aligns the TESTCD better to the TEST name and definition.

# Controlled Terminology Package 50 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - ONCRSCAT
  - No changes to existing terms



# Controlled Terminology Package 50 Public Review

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

# Controlled Terminology Package 50 Public Review

- Protocol Entities Terminology Team
  - New Terms to Protocol Entities Terminology
    - 2 new Entities: Expanded Access; Study Blinding
    - 1 attribute for the new entity 'Expanded Access'
    - 1 attribute for the new entity 'Study Blinding'
    - Valid value list for attribute: Expanded Access Study Type
    - Valid value list for attribute: Trial Blinding Schema Response
  - 2 changes to existing terms; 2 significant
    - Two attributes being removed from the Study Design Attribute Terminology codelist
      - Blinding - This will become an entity in its own right.
      - Trial Blinding Schema - This will become an attribute of the new Entity Trial Blinding.

# Controlled Terminology Package 50 Public Review

- QRS Terminology Team
  - New Terms Added to Existing Codelists:
    - QRSMTHOD
  - No changes to existing terms
  - Update to Terminology Development Rules Document
    - QRS Naming and Business Rules\_2022-03-18

# Controlled Terminology Package 50 Public Review

- SDTM Domain Terminology Team
  - No new term or changes to existing to report this quarter.

# Controlled Terminology Package 50 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - DESIGN; SVSTST-CD; SNDIGVER; NONNEO
  - 1 change to published term; 1 is significant
    - Update c-code for 'MUCOSA, NASAL' from C33205 to CNEW. Coding incorrect based on term and CDISC definition.



*To the amazing and dedicated CDISC Controlled Terminology Team members and reviewers, YOU are the heart and soul of CDISC terminology!*

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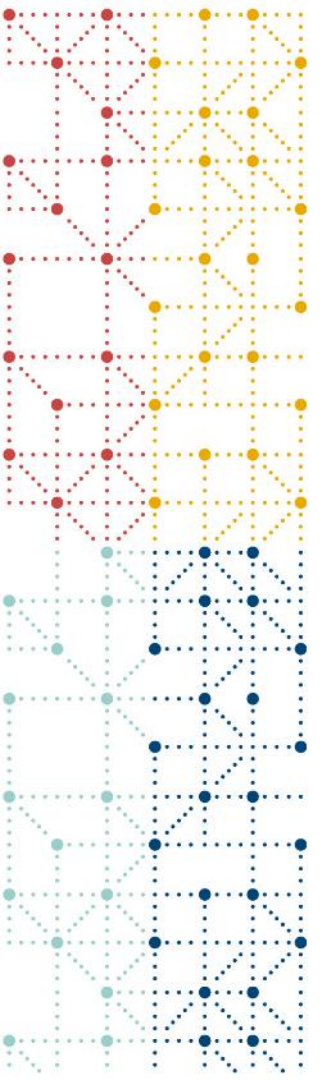
**If you are interested in contributing to any of the CDISC Terminology initiatives, please contact us...**

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



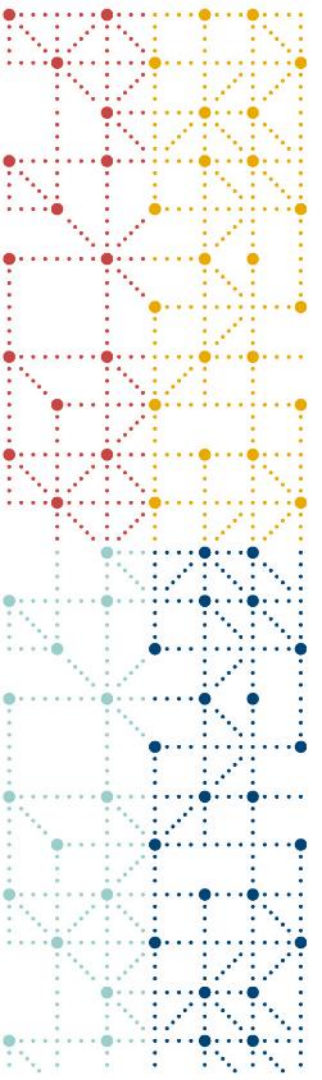
# CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



cdisc

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



# Questions & Answers

# Audience Questions



for sec, C42535 that is what you want to change?

Would it work for us to implement the pending changes for EVAL and MEDEVAL?

# Audience Questions

Any chance that subject could be turned to participant?

SUBJID to something like PARTID



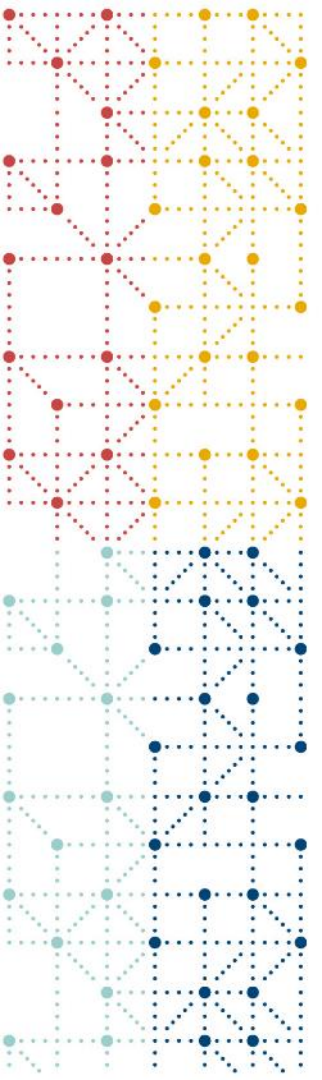


## Audience Questions



- For the Findings About Test Codes, are the Topics in the Codelist Name (ex: Asthma/ASFATS) linked to FACAT/FASCAT, or linked to a therapeutic area?

- Also, the topic specific findings about test codes are all extensible except for CVFATSCD/CVFATS – is there a reason these are non-extensible?



# Upcoming Events



# April - May

2022



Europe Interchange Trainings

# July

Asia



Virtual Training Event

*Regional discounts will appear at checkout.*

# September

US



Virtual Training Event

- Information available at: [www.cdisc.org](http://www.cdisc.org)
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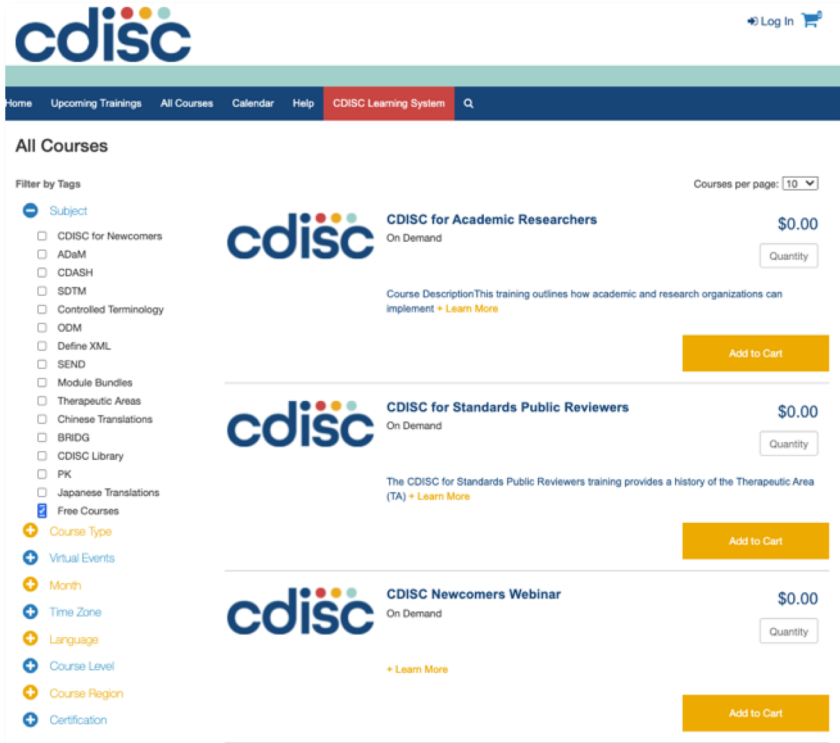


WEBINARS



WORKSHOPS

# Free CDISC Courses



The screenshot shows the CDISC Learning System website. The top navigation bar includes links for Home, Upcoming Trainings, All Courses, Calendar, Help, and CDISC Learning System. The main content area is titled "All Courses" and features a "Filter by Tags" section on the left with various categories like Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The "Subject" filter is expanded, showing a list of checkboxes for various topics. Three course cards are displayed, each with the CDISC logo, title, "On Demand" status, a price of "\$0.00", a "Quantity" input field, and an "Add to Cart" button. The courses are: "CDISC for Academic Researchers", "CDISC for Standards Public Reviewers", and "CDISC Newcomers Webinar".

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### All Courses

Filter by Tags Courses per page: 10

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  - Controlled Terminology
  - ODM
  - Define XML
  - SEND
  - Module Bundles
  - Therapeutic Areas
  - Chinese Translations
  - BRIDG
  - CDISC Library
  - PK
  - Japanese Translations
  - Free Courses
- Course Type
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**2022 EUROPE INTERCHANGE  
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**2022 JAPAN INTERCHANGE  
CDISC VIRTUAL CONFERENCE**

**13-14 JUNE**

# COSA OpenStudyBuilder Workshop

Friday, April 29th

Register for FREE!

**Register on the Europe Interchange registration page –  
no requirement to register for the main conference.**

The OpenStudyBuilder is an open-source project for clinical study specification. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.





# 2022 CHINA INTERCHANGE

29 - 30 JULY | BEIJING



WITH STANDARDS – UNLOCK THE POWER OF DATA



# 2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX



WITH STANDARDS – UNLOCK THE POWER OF DATA

# Upcoming Webinars

Date	Webinars
19 April	QRS Office Hours
28 June	Controlled Terminology Updates for Q2 – P50 Publication / P51 Public Review

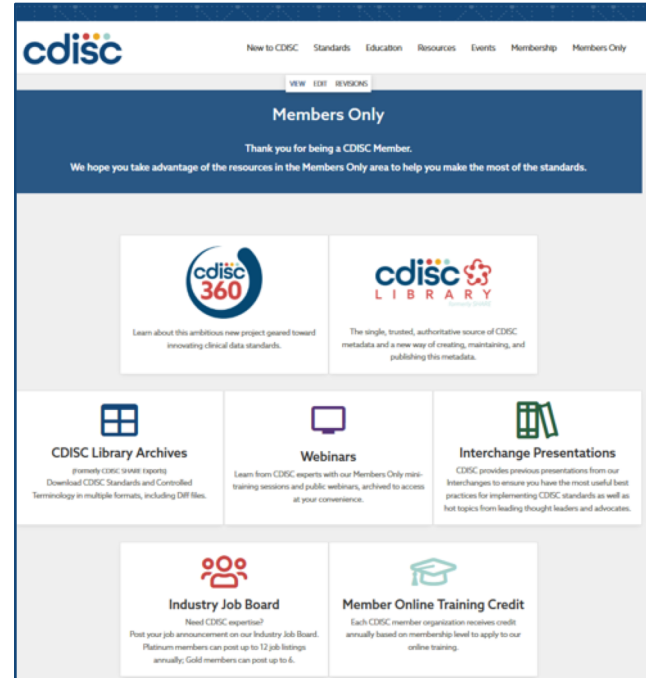
Webinars – Dates TBD	
SDTM Genomics Findings Office Hours	ADaM Office Hours
SEND Office Hours	QRS Quarterly Updates

Ideas or suggestions for webinar topics?  
Any topics you would love to see us cover?

Let us know via our topic suggestion form:  
<https://www.cdisc.org/form/webinartopicreg>

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- To ensure the CDISC standards remain open and free
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- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace



The screenshot displays the CDISC website's 'Members Only' section. At the top, the CDISC logo is on the left, and navigation links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only' are on the right. Below the navigation is a 'VIEW EDIT REVISIONS' button. The main heading is 'Members Only' with a sub-heading 'Thank you for being a CDISC Member.' and a message: 'We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.'

The content is organized into several tiles:

- cdisc 360**: Learn about this ambitious new project geared toward reworking clinical data standards.
- cdisc LIBRARY**: The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.
- CDISC Library Archives**: formerly CDISC Grant Reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars**: Learn from CDISC experts with our Members Only mini-training sessions and public webinars, archived to access at your convenience.
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