Controlled Terminology Updates for Q2 P50 Publication / P51 Public Review

Dr. Erin Muhlbradt
Biomedical/Clinical Research Information Specialist (Contractor)
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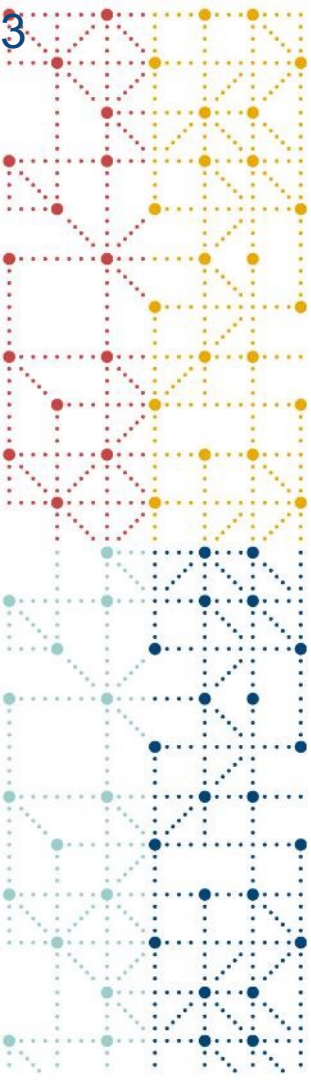
TUE 28 JUN
11:00AM – 12:30PM US ET

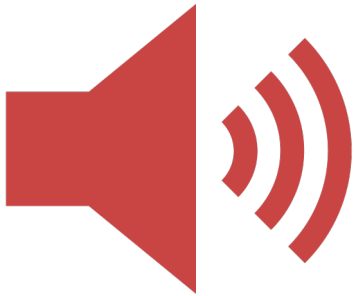
Today's Agenda

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



Housekeeping

Housekeeping



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Housekeeping

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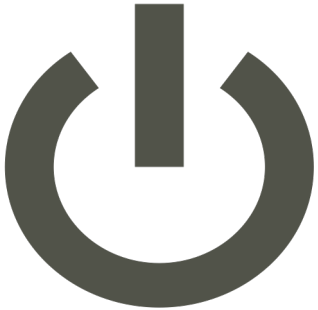
Housekeeping



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Housekeeping

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Our Presenter

Dr. Erin Muhlbradt
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CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt, PhD

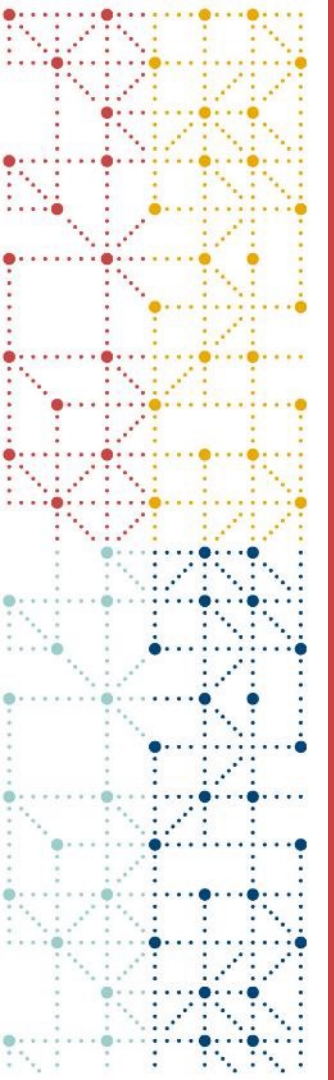
06.28.2022

Controlled Terminology P50 Publication and P51 Public Review

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

CDISC Terminology Program Lead

06.28.2022



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?

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Agenda

1. Package 50 Publication Release (2022-06-24)
   - Changes post-public review
2. Package 51 Public Review (2022-06-17 to 2022-07-15)
   - New Additions
   - Changes to existing
3. Questions

Controlled Terminology Package 50 Publication

2022-06-24

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			
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	Biospecimens	Cell Pheno	Genomics	General
49						Microbio/Immuno	Lab	PK	Protocol Entities
49						SEND	Unit		
50	3/11/2022	3/18/2022	4/15/2022	5/13/2022	6/24/2022	Cell Pheno	General	Genomics	Microbio/Immuno
50						Lab	Oncology	Protocol Entities	QRS
50						SEND	Unit		
51	6/10/2022	6/17/2022	7/15/2022	8/19/2022	9/30/2022	Biospec	Cell Pheno	Define-XML	Devices
51						General	Genomics	Lab	Microbio/Immuno
51						Oncology	Protocol Entities	SDTM Domain	SEND
						Unit			
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	1/20/2022	2/17/2023	3/31/2023				
53									
53									
54	3/17/2023	3/24/2023	4/21/2023	5/19/2023	6/30/2023				
54									

Controlled Terminology Package 50 Publication Release

- Updates to ADaM, CDASH, Protocol Entities, SDTM, and SEND Terminology
- Therapeutic Area Support:
  - Type 1 Diabetes, Psoriasis, and PTSD
- Other Project Support:
  - N/A

Significant Changes Post-Public Review

- Protocol Entities:
  - Study Blinding Entity, Attributes, Valid Value sets, and changes to existing terms removed from package to be re-considered with P51 public review.
- Microbiology/Immunology:
  - MBTEST-CD:
    - New MBTEST-CD values Herpes Simplex Virus 1/2, Herpes Simplex Virus 1/2 DNA, and Dengue Virus 1/2/3/4 RNA removed from package for further discussion with P52.
    - New MBTEST-CD value Legionella pneumophila removed from package as it is already published in P49.
  - ISBDAGT:
    - A signifiicant number of terms removed from package for further discussion with P52

Significant Changes Post-Public Review

- Lab:
  - LBTEST-CD:
    - New LBTEST-CD values Neutrophils/Lymphocytes, Lymphoma Cells/Total Cells, and Monoclonal Prot Immunoglobulin Isotype removed from package as it is already published in P49.
    - Existing LBTEST-CD value of Methylphenobarbital/MPHNBRB changed c-codes from C184627 to C75366 (merge due to synonymy in NCIt)
  - UNIT:
    - New UNIT value V*s is synonymous with Weber (C42556), which is already published. Synonym added instead.

Significant Changes Post-Public Review

Other, less significant changes* also made in:

- General, Microbiology/Immunology, Lab

No post-public review changes made to:

- Cell Phenotyping
- 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.**

P50 Terminology Products Updates

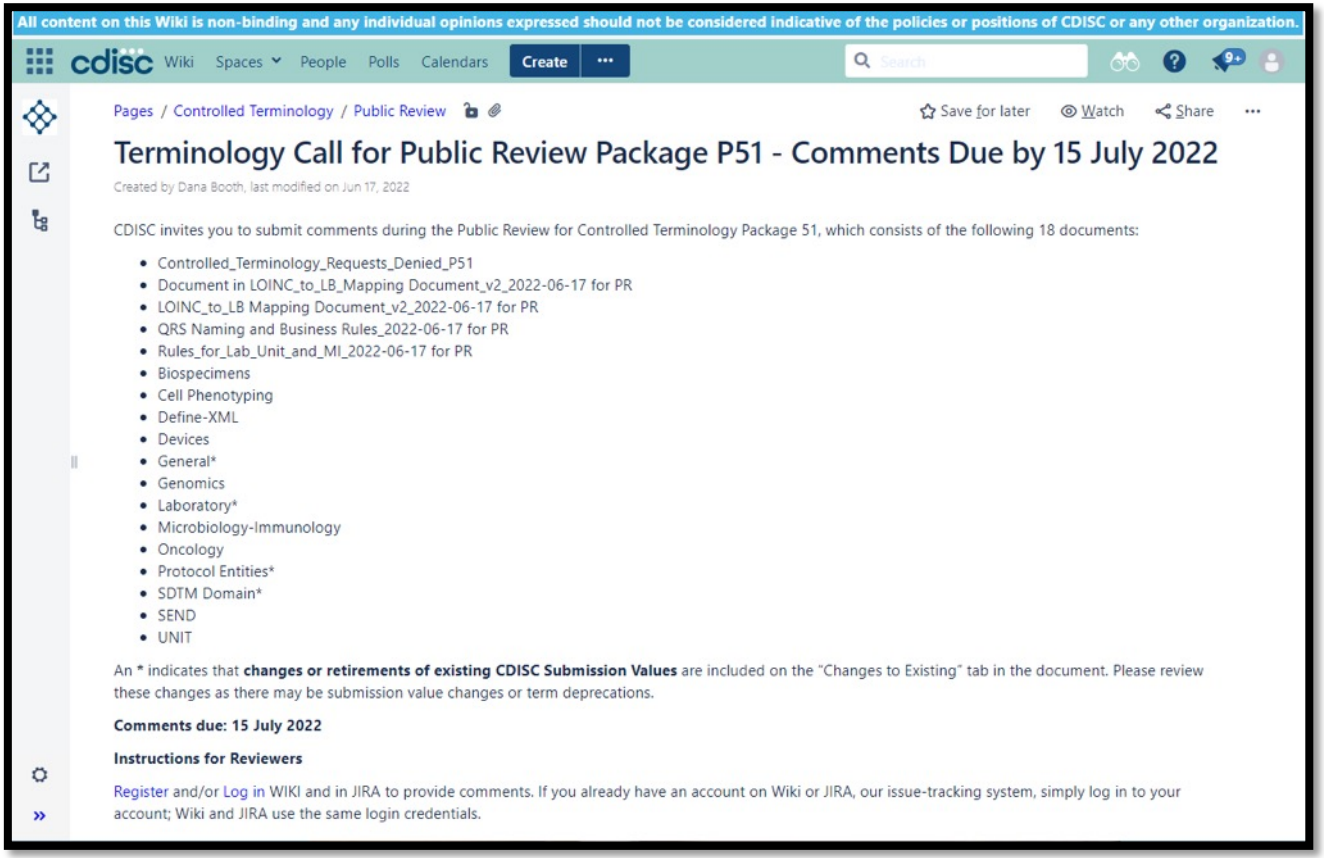
- Updates on CDISC.org:
  - Codetable mappings:
    - TS_Codetable_Mapping
  - Unit-UCUM_Codetable
  - Controlled_Terminology_Requests_Denied_P50
  - Paired Codelists product for SDTM, SEND, ADaM
  - Terminology Publication Schedule
  - Terminology development Rules
    - Update to QRS Naming and Business Rules document
    - New Genomics Team terminology development rules document

QRS Controlled Terminology Package 50 Publication Release

- 4 new ADaM Parameter QRS paired codelists:
  - Craig Handicap Assessment and Reporting Technique-Short Form Questionnaires Parameter Code/Name
  - Hamilton Depression Rating Scale - 17 Item Clinical Classification Parameter Code/Name
- 10 new --CAT values
  - Clinician-Administered PTSD Scale (Current) DSM-5 With DSM IV Scoring 2016 Version (CC)
  - Global Dystonia Severity Rating Scale (GDRS) (CC)
  - Brief Fatigue Inventory (BFI) (QS)
  - Stanford Sleepiness (SSS) (QS)
  - Beck Depression Inventory-Second Edition (QS)
  - Scales for Outcomes in Parkinson's Disease - Autonomic Dysfunction (SCOPA-AUT) (QS)
  - Parkinson's Disease Questionnaire-39 (PDQ-39) (QS)
  - Lung Cancer Symptom Scale (LCSS) (QS)
  - Activities-Specific Balance Confidence Scale (ABC) (QS)
  - REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ) (QS)
- 2 new TEST/TESTCD codelist pairs
  - Stanford Sleepiness Scale Questionnaire Test Code/Nam
  - Clinician-Administered PTSD Scale (Current) DSM-5 With DSM IV Scoring 2016 Version Clinical Classification Test Code/Name
- 2 new codelists for response terminology
  - Stanford Sleepiness Scale Questionnaire ORRES for SSS0101 TN/TC
  - Stanford Sleepiness Scale Questionnaire STRESC for SSS0101 TN/TC

Controlled Terminology Package 51 Public Review

2022-06-17 to 2022-07-15



https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P51+-+Comments+Due+by+15+July+2022

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

- Biospecimens Team
  - New Terms Added to Existing Codelists:
    - CLMETH; SPECTYPE
  - New Terms Added to New Codelists:
    - ACCPARTY (to support the --PARTY variable in BE and DT domains)
  - 1 change to published terms; none significant

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

- Cell Phenotyping Team
  - New Terms Added to Existing Codelists:
    - CPTEST-CD
  - No changes to published terms

Controlled Terminology Package 51 Public Review

- Define-XML Team
  - New Terms Added to Existing Codelists:
    - BDSSC, DICTNAM
  - 1 change to published term; none significant

Controlled Terminology Package 51 Public Review

- Medical Devices Team
  - New Terms Added to New Codelists:
    - ACCPARTY (to support the --PARTY variable in BE and DT domains)

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - DATEST-CD; EVAL; FATEST-CD; FREQ; GASTRO-CD; INTEGU-CD; LOC; MEDEVAL; OETEST-CD; RACE; RACEC; RETEST-CD; RISKSOC; RPTEST-CD; SDTMIGRS; SDTMVRS; TSPARM-CD; VSTEST-CD
    - To support the: DRAGON IMI project; SDTMIGv3.4
  - New Terms added to New Codelists
    - STDMDVRS/Commercial SDTMIG Medical Device Version Response: Response codelist for a new (P51) TSPARM-CD value
  - Updates to Codetable Mapping Files:
    - GI_Codetable_Mapping
    - IG_Codetable_Mapping (**new for Integumentary System domain)
    - MK_Codetable_Mapping
    - RACE_RACEC_Codetable_Mapping
    - RP_Codetable_Mapping
    - SC_Codetable_Mapping
    - TS_Codetable_Mapping
    - VS_Codetable_Mapping
  - 35 changes to published terms; 29 are significant

Controlled Terminology Package 51 Public Review

- General Terminology Team:
  - P51 Significant Changes: EVAL vs MEDEVAL codelists
    - Background:
      - EVAL codelist supports the EVAL variable – contains the role of the evaluator (e.g., ADJUDICATOR)
      - MEDEVAL codelist supports the EVALID variable – a unique identifier for an evaluator when multiple evaluators need to be distinguished (e.g., ADJUDICATOR 1, ADJUDICATOR 2, ADJUDICATOR 3)
    - MEDEVAL codelist has gotten messy….
      - contained a mix of roles AND role identifiers (e.g., READER, READER 1, READER 2, HEMATOLOGIST, ONCOLOGIST)
    - In P50 the team added new terms to MEDEVAL with numeric identifiers at the end of the submission value **and** existing MEDEVAL terms that better fit with EVAL variable were added to EVAL codelist.
    - In P51, the team is proposing to remove 24 terms from the MEDEVAL codelist that do not have numeric identifiers. (These have been previously added to EVAL)

Controlled Terminology Package 51 Public Review

- General Terminology Team:
  - P51 Significant Changes [Cont'd.]
    - SCTEST-CD:
      - C74580/SKINTYP/Skin Type is being moved from SCTEST-CD to INTEGU-CD codelists to align with domain scope.
    - MUSCTS-CD:
      - C139219/LBMTBMR/Lean Body Mass to Total Body Mass Ratio is being moved from MUSCTS-CD to VSTEST-CD to align with domain scope.
    - MHEDTTYP:
      - Submission value 'INTIAL DIAGNOSIS' being updated to 'INITIAL DIAGNOSIS' to correct the misspelling.

Controlled Terminology Package 51 Public Review

- Genomics Terminology Team:
  - New Terms Added to Existing Codelists:
    - GFTEST-CD; GFTSTDTL; GFANMET
    - To support the new/draft GF example datasets being prepared by the Genomics team for publication to the Knowledge Base (currently post internal review)
      - Sequence Rearrangements
      - Variable Number Tandem Repeats
      - Variant Profiles
  - No changes to published terms
  - Updates to Codetable Mapping Files:
    - GF_Codetable_Mapping

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST-CD, METHOD, MITS-CD, MIFTSDTL, RESTYPRS
    - To support LB_LOINC Mapping
  - 29 changes to published terms; 10 significant
  - Update to LOINC_to_LB Mapping File

Controlled Terminology Package 51 Public Review

- Laboratory Terminology Team
  - LBTEST-CD:
    - C181139/CD40LS/Soluble CD40 Ligand will be merged into C174308 (TNF5S/Soluble TNF Superfamily Member 5) with synonym additions.
    - C181138/CD40S/Soluble CD40 will be merged into C174312 (TNFR5S/Soluble TNF Receptor Superfamily Mem 5) with synonym additions.
    - C127631/PAH/P-Aminohippurate Sodium will be removed from the codelist and replaced with P51 term CNEW/PAHPP/Para Aminohippurate.
      - P-Aminohippurate Sodium is given to the subject but P-Aminohippurate (PAH; P-Aminohippuric Acid) is measured. Therefore the new term is more correct/precise to what is being measured.
  - MITS-CD:
    - C127771/TUMCECE/Tumor Cells/Total Cells will be merged into C123556 (NEOCECE/Neoplastic Cells/Total Cells) with synonym additions.
    - Submission value for C154801 will be updated from TMCE/Tumor Cells to NEOCE/Neoplastic Cells.
      - This language is more precise and consistent with the relative measurement concept also in the list (NEOCECE).

Controlled Terminology Package 51 Public Review

- Laboratory Terminology Team
  - Update to LOINC_to_LB_Mapping Document:
    - Changes to Excel file specified in the orange colored ‘changes’ tab:
      - Updates to <<Pending>> in the ‘CDISC LBTEST/TESTCD NCI C-code’ column – Addition of C-codes
      - Submission value updates for LBTESTCD value
        - MNMTNEXR -> MTNMTEXR
        - MNMTN -> MTNNMTN
      - SDTMIGv3.4 updates -> Change from Suppqual variable to SDTMv2.0 variables in Column Headers
      - Addition of columns containing NCI C-codes for codelist concepts in codelists: LBPTFL, LBRESTYP, LBRESSCL; LBTSTOPO; LBTMTHSN; LBTSTCND; LBCNDAGT
      - Removal of value ‘CONTROL ON SPECIMEN’ from LBTSTCND column
    - Updates to ReadMe tab document

Controlled Terminology Package 51 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
  - 3 changes to published terms; none significant

Controlled Terminology Package 51 Public Review

- Microbiology-Immunology Terminology Team
  - New Terms Added to Existing Codelists:
    - ISBDAGT; MBTEST-CD; MICROORG
  - New Terms Added to New Codelists:
    - ISFTSDTL; To support the ISTSTDTL variable
  - 9 Changes to existing term; none significant

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

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

Controlled Terminology Package 51 Public Review

- Protocol Entities Terminology Team
  - New Terms to Protocol Entities Terminology
    - 1 new Entities: Study Blinding and Unblinding
    - 6 attribute for the new entity: Study Blinding and Unblinding
    - Valid value list for attribute: Study Blinding Schema
  - 2 changes to existing terms; 2 significant
    - Two attributes being removed from the Study Design Attribute Terminology codelist:
      - Blinding - This will become an attribute to the entity above
      - Trial Blinding Schema - This will become an attribute to the entity above

Controlled Terminology Package 51 Public Review

- QRS Terminology Team
  - No New Terms for public review
  - No changes to existing terms
  - Update to Terminology Development Rules Document
    - QRS Naming and Business Rules_2022-06-17

Controlled Terminology Package 51 Public Review

- SDTM Domain Terminology Team
  - 2 changes to existing; 2 are significant
    - AD and AX are being removed from the SDTM domain abbreviations codelist
      - These are ADaM dataset naming conventions, not an SDTM domain. This convention in described in both the SDTMIG and ADaMIG and therefore is unnecessary to include in this codelist, whose scope is focused in SDTM domains.

Controlled Terminology Package 51 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - NONNEO; SPEC
  - No change to published terms

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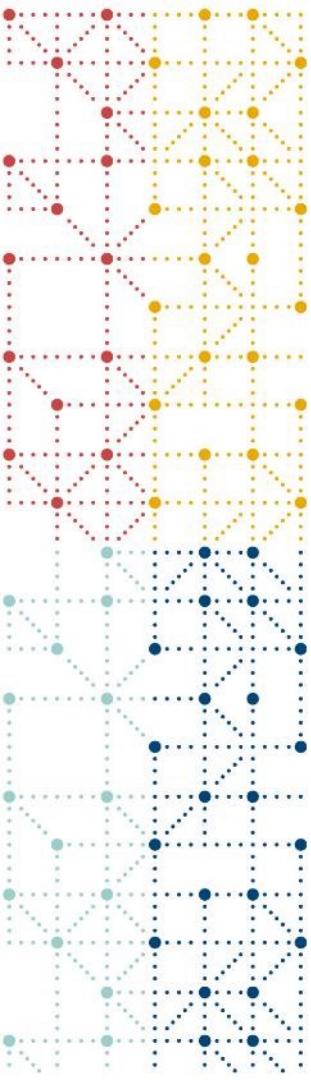
If you are interested in contributing to any of the CDISC Terminology initiatives, please contact us…

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

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

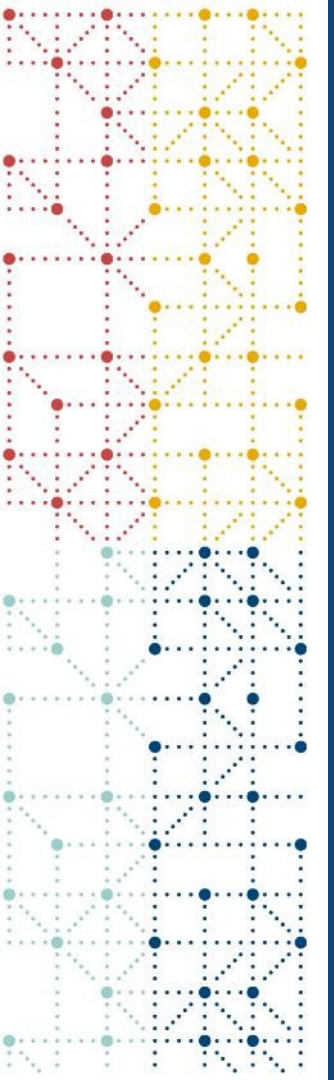


Q&A

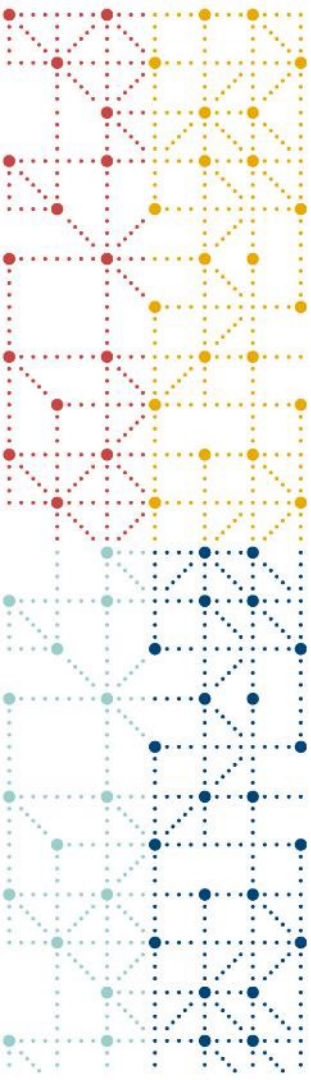
CDISC Education: Upcoming Learning Opportunities

Bernard Klinke

Thank you for your attendance and support of CDISC!



Questions & Answers



Upcoming Events

July

Asia

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September

US

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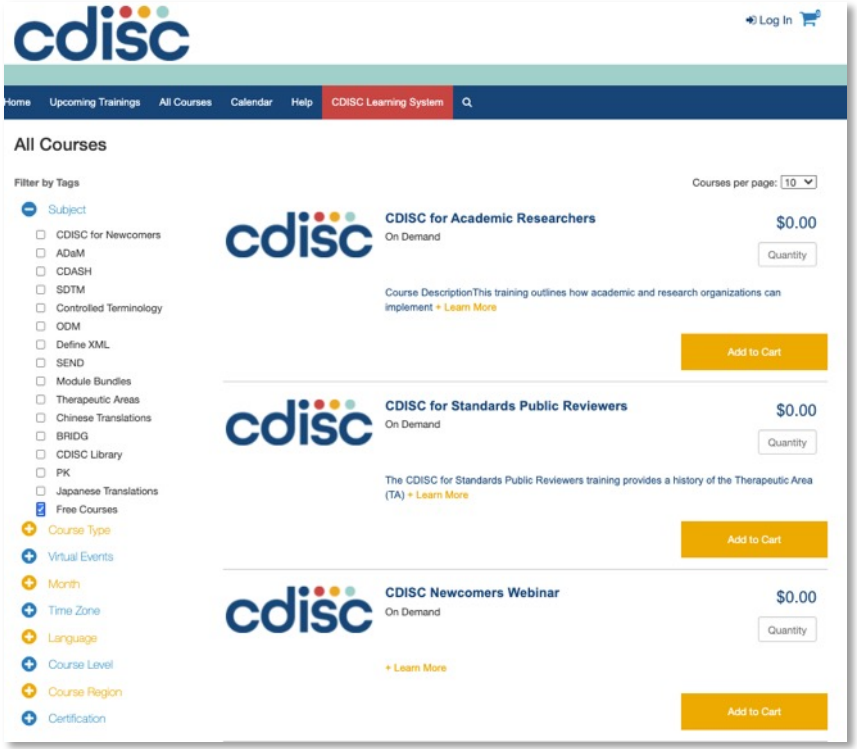

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Upcoming Webinars

Date	Title
30 JUN	COSA Spotlight for Q2
7 JUL	Developing Standards for Cell and Gene Therapy Product Monitoring
12 JUL	Pediatrics User Guide Public Review
8 SEP	QRS Office Hours
15 SEP	Genomics Findings Office Hours
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public review

2022 CHINA INTERCHANGE

CDISC VIRTUAL CONFERENCE

29-30 JULY

2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX

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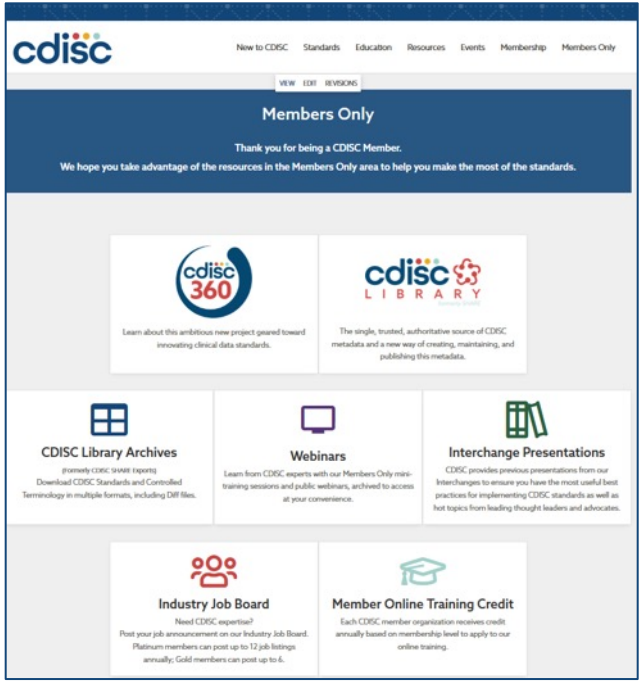

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bklinke@cdisc.org