CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt, PhD

With Special Guest: Sylvia Baedorf Kassis, MPH

07.18.2023

Controlled Terminology P54 Publication and P55 Public Review

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07.18.2023

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. <u>Package 54 Publication Release</u> (2023-06-30)

   • Changes post-public review

2. <u>Package 55 Public Review</u> (2023-06-23 to 2023-07-21)

   • MRCT Plain Language Glossary

   • New Additions

   • Changes to existing

   • Feedback requested – CT publication cadence

1. Questions

Controlled Terminology Package 54 Publication

2023-06-30

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			
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
51						Unit			
52	9/16/2022	9/23/2022	10/21/2022	11/18/2022	12/16/2022	Cell Pheno	Define-XML	Define-XML	General
52						Glossary	Lab	Microbio/Immuno	Oncology
52						Protocol Entities	SEND	Unit	
53	12/9/2022	12/16/2022	1/20/2022	2/17/2023	3/31/2023	Biospec	Cell Pheno	General	Lab
53						Microbio/Immuno	Protocol Entities	SEND	Unit
54	3/17/2023	3/24/2023	4/21/2023	5/19/2023	6/30/2023	ADaM	Biospec	Cell Pheno	CV
54						Define-XML	General	Lab	Microbio/Immuno
54							Oncology	PK	Protocol Entities
54						SEND	Unit		
55	6/16/2023	6/23/2023	7/21/2023	8/18/2023	9/29/2023	Biospec	Cell Pheno	Devices	ECG
55						General	Genomics	Lab	Microbio/Immuno
55						MRCT	Oncology	PK	Protocol Entities
55						Unit			
56	9/15/2023	9/22/2023	10/20/2023	11/17/2023	12/15/2023				
56									
56									
57	12/8/2023	12/15/2023	1/12/2024	2/9/2024	3/29/2024				
57									
57									
58	3/15/2024	3/22/2024	4/19/2024	5/17/2024	6/28/2024				
58									

6/26/2023

Dates in red are planned and may be adjusted slightly.

Controlled Terminology Package 54 Publication Release

- Updates to ADaM, DDF, Define-XML, Protocol Entities, SDTM, and SEND Terminology

- Other Project Support:
  - COVID-19 v2.0 TAUG
  - Cardiovascular Imaging TAUG
  - Tobacco Implementation Guide (TIG)
  - SEND Genetic Toxicology Implementation Guide

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Significant Changes Post-Public Review

- General:
  - VSTEST-CD: Proposed new term 'Extracellular Body Water' is a synonym of existing published term C191364/Extracellular Water, which was published in P53. Therefore we will add synonyms to the existing term.

- Cell Phenotyping:
  - CPTEST/CD: 'DC Granulocytes' removed from package as it was published in a previous package.
  - CPTEST/CD: Merge C187711 into C187713 - 'BLym Mem Sw Sub/BLym Mem Sw' (C187711) into 'BLym Mem Sw Sub/BLymMSw' (C187713).

Significant Changes Post-Public Review

Other, less significant changes* also made in:
- General

No post-public review changes made to:
- ADaM
- Biospecimens
- CV
- Define-XML
- Lab
- MB/IS
- Oncology
- PK
- Protocol
- 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.

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P54 Terminology Products Updates

- Updates on CDISC.org:
  - Updated Codetable mappings:
    - DD, IS, Oncology, RE, TS, and VS
  - Unit-UCUM_Codetable
  - Controlled_Terminology_Requests_Denied_P54
  - Paired Codelists product for SDTM and SEND
  - Terminology Publication Schedule
  - Terminology Development Rules documents:
    - QRS
    - IS
    - MB and MS
    - PK

QRS Controlled Terminology Package 54 Publication Release

- 8 new --CAT values
  - 4 CCCAT values
  - 4 QSCAT values

- 6 new paired TEST/TESTCD codelists
  - Comfort Behavior Scale Clinical Classification Test Code/Name (CBS01)
  - Canadian Cardiovascular Society Grading of Angina Pectoris Clinical Classification Test Code/Name (CCSGA1)
  - Functional Assessment of Chronic Illness Therapy-Item GP5 Version 4 Questionnaire Test Code (FAC101)
  - Modified Cigarette Evaluation Questionnaire-Screening Clinical Classification Test Code/Name (MCEQ01)
  - Observer Global Impression Generic Modification Version Questionnaire Test Code/Name (OGI01)
  - Questionnaire on Smoking Urges-Brief Test Code/Name (QSUB01)

- 2 new response codelists
  - Canadian Cardiovascular Society Grading Scale of Angina Pectoris Clinical Classification ORRES/STRESC for CCSGAS101 TN/TC

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Controlled Terminology Package 55 Public Review

2023-06-23 to 2023-07-21

Edit   Save for later   Watch   Share   ...

Terminology Call for Public Review Package P55 - Comments Due by 21 July 2023

Created by Alana St. Clair, last modified on Jun 23, 2023

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 55, which consists of the following 19 documents:

- Controlled_Terminology_Requests_Denied_P55
- IS Terminology Mapping Codetable_P55
- QRS Naming and Business Rules
- Rules for IS
- Rules for MB and MS
- Rules for Lab, Unit, and MI
- Biospecimens
- Cell Phenotyping
- Devices
- ECG
- General
- Genomics
- Lab
- Microbiology-Immunology
- MRCT
- Oncology
- PK
- Protocol Entities
- 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: 21 Jul 2023

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:

https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P55+-+Comments+Due+by+21+July+2023

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https://www.cdisc.org/public-review/controlled-terminology-package-55

Public Review Comment Submission – Process Update!

- Two pieces of information are CRITICAL to getting your review comment seen by the CT teams:
  - Component – identifies the name of the specific PR file relevant to the comment.
  - Package (55) – identifies the package number that is relevant to the comment.

- Failure to fill in this information may delay resolution of your comment.

Controlled Terminology Package 55 Public Review

- MRCT Plain Language Glossary
  - 118 new terms

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https://mrctcenter.org/clinical-research-glossary/
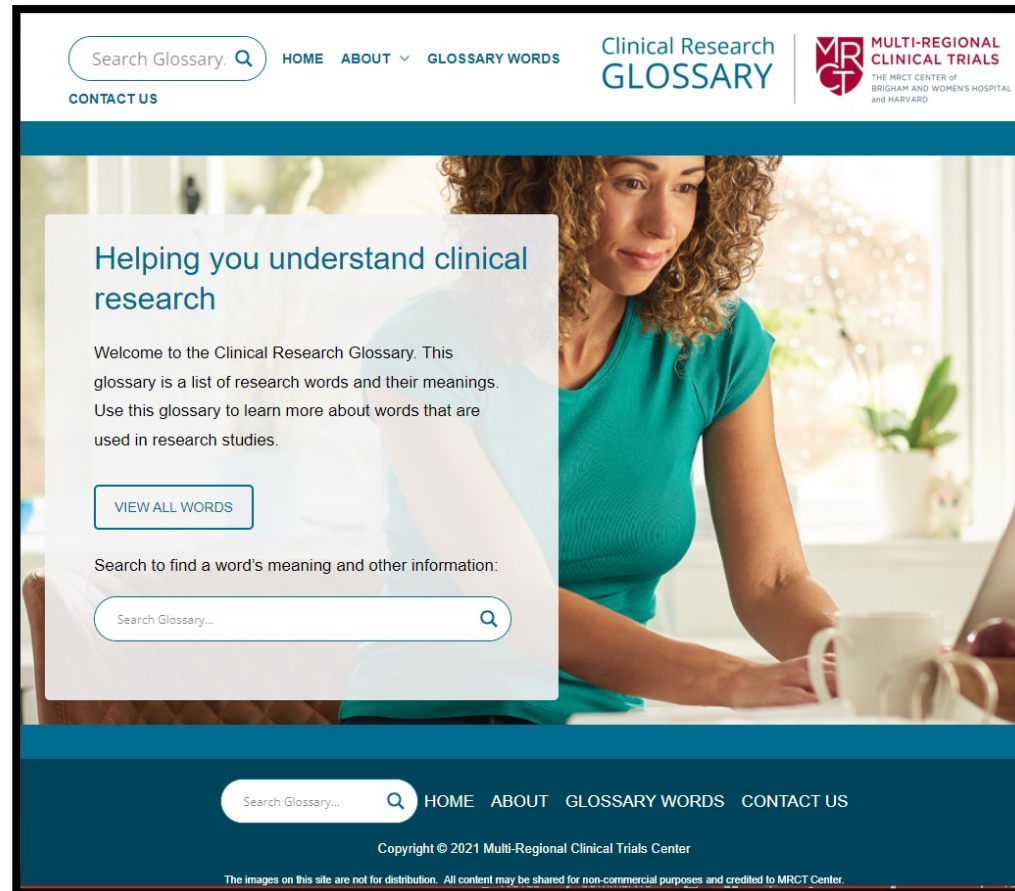
Controlled Terminology Package 55 Public Review

- ADaM Team
  - No new term or changes to existing to report this quarter.
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 55 Public Review

- Biospecimens Team
  - New Terms Added to Existing Codelists:
    - BEDECOD
  - No changes to published terms
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 55 Public Review

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

Controlled Terminology Package 55 Public Review

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

Controlled Terminology Package 55 Public Review

- CV Team
  - No new term or changes to existing to report this quarter.
  - No denied requests.

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Footer Text

7/20/23   21

Controlled Terminology Package 55 Public Review

- Medical Devices Team
  - New Terms Added to Existing Codelists:
    - DUTEST-CD
    - To support the COVID-19 v2.0 TAUG
  - Denied Requests added to Denied Requests spreadsheet

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Controlled Terminology Package 55 Public Review

- DDF Team
  - No new term or changes to existing to review this quarter.
  - No denied requests.

- HOWEVER!
  - DDF Controlled Terminology to support Phase 2 of the USDM was publicly reviewed along with DDF Unified Study Definitions Model (USDM), which was published in early July.
  - We will be PUBLISHING the DDF terminology to support Phase 2 with the CDISC P55 publication on 2023-09-29.

Controlled Terminology Package 55 Public Review

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

Controlled Terminology Package 55 Public Review

- ECG Terminology Team:
  - New Terms Added to Existing Codelists:
    - HESTRESC
  - Update to ECG Codetable Mapping File
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 55 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - CNTMODE; FREQ; HODECOD; LOC; NCOMPLT; NVTEST-CD; OTHEVENT; PROCEDUR; PROTMLST; RELSUB; RETEST-CD; RPTEST-CD; SCTEST-CD; TTYPE
  - 7 changes to published terms; none significant
    - Definition updates
  - Updates to Codetable Mapping Files:
    - DS_Codetable_Mapping
    - RE_Codetable_Mapping
    - RP_Codetable_Mapping
    - SC_Codetable_Mapping
    - TS_Codetable_Mapping
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 55 Public Review

- Genomics Terminology Team:
  - No new term
  - 6 changes to published terms; none significant
    - Definition updates
  - No denied requests.

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Controlled Terminology Package 55 Public Review

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

Controlled Terminology Package 55 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST-CD; MITS-CD, RESTYPRS
  - 3 changes to published terms; none significant
    - Synonym updates
  - Denied Requests added to Denied Requests spreadsheet.
  - Terminology development rules document update: Lab_Unit_and_MI

Controlled Terminology Package 55 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
  - 1 changes to published terms; one is significant
    - Proposed CDISC submission value update to C70480, from 'log EID 50/dose' to 'log10 EID 50/dose': The 10 is missing from the submission value but is reflected in the synonym, definition, and NCI Preferred Term. The omission of 10 in the submission value is an error.
  - Denied Requests added to Denied Requests spreadsheet.

Controlled Terminology Package 55 Public Review

- Microbiology-Immunology Terminology Team
  - New Terms Added to Existing Codelists:
    - ISBDAGT; ISTEST-CD, MBTEST-CD, MICROORG
  - 32 Changes to existing term; 9 are significant
  - Updates to Codetable Mapping Files:
    - IS Terminology Mapping Codetable
  - Updates to Terminology Team Development Rules Documents:
    - IS
    - MB/MS
  - Denied Requests added to Denied Requests spreadsheet.

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Controlled Terminology Package 55 Public Review

- Microbiology-Immunology Terminology Team (Significant Changes)
  - ISFTSDTL:
    - C191284 – Submission value update from '50% Focus Reduction Neutralization Titer' to '50% FOCUS REDUCTION NEUTRALIZATION TITER'
    - C191279 – Submission value update from '50% Inhibitory Concentration' to '50% INHIBITORY CONCENTRATION'
    - C189121 – Submission value update from '50% Neutralization Titer' to '50% NEUTRALIZATION TITER'
    - C191283 – Submission value update from '50% Plaque Reduction Neutralization Titer' to '50% PLAQUE REDUCTION NEUTRALIZATION TITER'
    - C191281 – Submission value update from '80% Inhibitory Concentration' to '80% INHIBITORY CONCENTRATION'
    - C191280 – Submission value update from '80% Neutralization Titer' to '80% NEUTRALIZATION TITER'
    - C191282 – Submission value update from '90% Inhibitory Concentration' to '90% INHIBITORY CONCENTRATION'
    - C189122 – Submission value update from '90% Neutralization Titer' to '90% NEUTRALIZATION TITER'
  - MICROORG:
    - C86881 – Submission value update from 'Escherichia coli Serogroup O111' to 'ESCHERICHIA COLI SEROGROUP O111'

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Controlled Terminology Package 55 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - ONCRSCAT
  - 1 Change to existing term; none are significant
    - Definition update
  - Denied Requests added to Denied Requests spreadsheet.

Controlled Terminology Package 55 Public Review

- PK Terminology Team
  - New Terms Added to Existing Codelists:
    - PKPARM-CD
  - 44 Change to existing term; none significant
    - Definition Updates
  - No Denied Requests

Controlled Terminology Package 55 Public Review

- Protocol Entities Terminology Team
  - New Terms to Protocol Entities Terminology
    - 1 new Entity: Biomarker
    - 2 attribute for the new entity: Biomarker
    - 1 valid value set for new attribute: Biomarker Category
  - 2 changes to existing terms; none significant
    - Definition updates
  - No denied requests

Controlled Terminology Package 55 Public Review

- QRS Terminology Team
  - No New Terms or changes for public review
  - Update to QRS Naming and Business rules document
  - Denied Requests added to Denied Requests spreadsheet.

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Controlled Terminology Package 55 Public Review

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

Controlled Terminology Package 55 Public Review

- SEND Terminology Team
  - No new term or changes to existing to report this quarter.
  - No Denied Requests.

Announcement: CDISC Terminology Publication Cadence

Currently -> CDISC publishes updates to CDISC terminology on a <u>quarterly</u> schedule: March, June, September, December

Under Strong Consideration -> CDISC leadership is considering changing the publication cadence for CDISC Controlled Terminology to <u>biannual releases </u>(twice per year): March and September

- CDISC is also considering mechanisms by which draft terminology can be made available to the user community.

*CDISC is currently interested in receiving feedback on this proposal!

Feedback can be sent to Erin Muhlbradt **(muhlbradtee@mail.nih.gov)**

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

CDISC Membership

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

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Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.
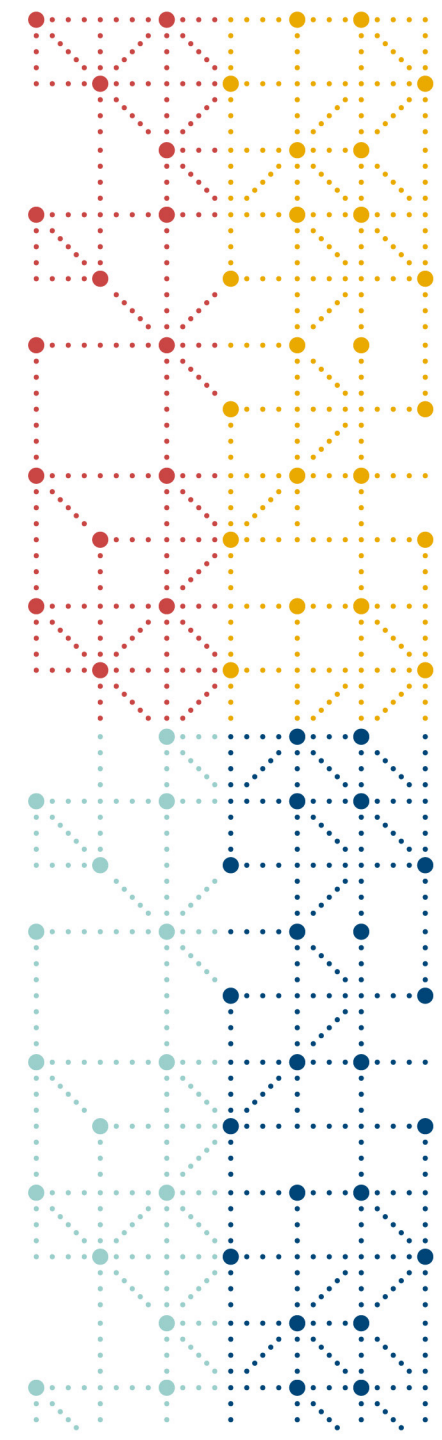
Email: membership@cdisc.org

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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.nih.gov/ncitermform/?version=cdisc

Q&A

CDISC Education: Upcoming Learning Opportunities

Bernard Klinke

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Thank you for your attendance and support of CDISC!

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