



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

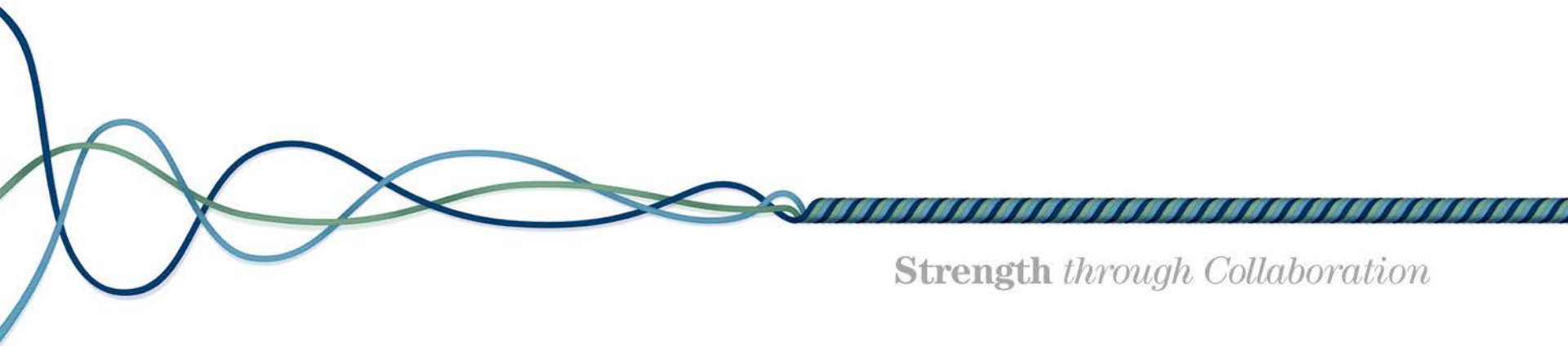
*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

A decorative graphic consisting of several overlapping wavy lines in dark blue, light blue, and teal, extending horizontally across the lower portion of the slide. The lines eventually merge into a solid horizontal band with a diagonal hatched pattern.

Strength *through Collaboration*

CDISC CONTROLLED TERMINOLOGY

Presented by Chris Gemma and Erin Muhlbradt, Ph.D.



Strength *through Collaboration*

Question & Answer

- 'Panelist': Question
- OR
- '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

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.

Controlled Terminology Agenda

- Package 32 Publication Release (2017-12-22)
 - Changes post-public review
- Package 33 Public Review (2017-12-22 to 2018-01-19)
 - New Additions
 - Changes to existing

Controlled Terminology Publication Schedule



Controlled Terminology Package 32 Publication Release

Publication Overview

- Updates to SDTM, SEND, and Protocol Terminology.
- CDISC Glossary
- Therapeutic Area Support:
 - QRS Terminology to support: Lung Cancer, Breast Cancer, Duchenne Muscular Dystrophy, Nutrition, and PTSD Therapeutic Area User Guides.
 - SDTM Terminology to support: Breast Cancer, CV Imaging, Duchenne Muscular Dystrophy, HIV, Huntington's Disease, Lung Cancer, Prostate Cancer, PTSD, and Vaccines Therapeutic Area User Guides.

Significant Changes Post-Public Review

- PK Terminology Team:
 - 5 new PKPARM/CD values removed from P32 for further discussion. Out for public review with P33.
- General Terminology Team:
 - SUPRATORIAL BRAIN terminology removed from P32 for further discussion based on public review comment. Will be discussed with P34.
 - SCTEST-CD value of 'Living Arrangement' removed from P32 for further discussion based on public review comment. Request denied with P33 and denial reason can be found in the Denied Requests file.
- Lab Terminology Team:
 - LBTEST/CD of 'S. pneumoniae Sero 19F IgG AB' was duplicated. Two new terms were added: S. pneumoniae Sero 19F IgG AB, S. pneumoniae Sero 19A IgG AB.

Significant Changes Post-Public Review

- Oncology Terminology Team:
 - TRTEST-CD: 'New Lesion Sum of Diameter' not added with P32. Instead team proposes to use existing TRTEST value of 'Sum of Diameters' with TRGRPID identifying whether the lesion is new.
 - ONCRTS-CD: TESTCDs changed to NEWLIND, NEWLWIND, NTLWIND. 'IND' is used to denote an indicator-type question in CDISC CT.
 - ONCRSR: Synonyms removed because the CT philosophy for the development of oncology response terminology has been to keep the terms independent of the individual criterion they are coming from. CAT value contains this information.

Significant Changes Post-Public Review

- Other, less significant changes* also made in:
 - Devices, General, Lab, Glossary
- No changes made to:
 - CV
 - ECG
 - Microbiology
 - Protocol Entities
 - SEND
 - SPECTYPE-SPECCOND
 - 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 32 Publication Release

- New Codelists:
 - **Questionnaire (QS)**
 - International Physical Activity Questionnaire (August 2002) Short Last 7 Days Self-Administered Format (Nutrition)
 - International Physical Activity Questionnaire (August 2002) Long Last 7 Days Self-Administered Format (Nutrition)
 - International Physical Activity Questionnaire (November 2002) Long Last 7 Days Telephone Format (Nutrition)
 - International Physical Activity Questionnaire (August 2002) Short Last 7 Days Telephone Format (Nutrition)
 - Deployment Risk and Resilience Inventory-2 Questionnaire (PTSD)

QRS Controlled Terminology Package 32 Publication Release

- New Codelists:
 - **Functional Test (FT)**
 - Ten Meter Walk/Run Test (Duchenne Muscular Dystrophy)
 - Rising From Floor Test (Duchenne Muscular Dystrophy)
 - Four Stair Descend Test (Duchenne Muscular Dystrophy)
 - Four Stair Ascend Test (Duchenne Muscular Dystrophy)
 - **Clinical Classification (RS)**
 - Veterans Administration Lung Study Group (VALG) (Lung Cancer)
 - AJCC TNM Staging System 7th Edition (Breast Cancer, Lung Cancer)

CDISC Glossary



CDISC Glossary

Controlled Terminology Package 33 Public Review

P33 Public Review

Controlled Terminology Package 33

Public Review

- CV Terminology Team:
 - New Terms Added to Existing Codelists:
 - CVTEST, CVTESTCD
 - CV Imaging TAUG
 - 2 changes to published terms (including 1 major change):
 - Proposed Submission Value change: CVTEST -> Observed Cardiac Device to Obs Med Device In The Intended Location
 - Proposed Submission Value change: CVTESTCD -> CARDDEV to OBMDILOC.
 - Reason: The CV team re-reviewed the data element that this term came from and realized that it was not specific for a cardiac device, but more general; to be used for any medical device. The data element itself was meant to assess 3 separate things: Observed Medical Device In The Intended Location, Observed Medical Device Not In The Intended Location, and Observed Foreign Body. The CT is being updated to reflect this meaning.

Controlled Terminology Package 33

Public Review

- ECG Terminology Team:
 - New Terms Added to Existing Codelists:
 - EGMETHOD
 - No changes

Controlled Terminology Package 33

Public Review

General Terminology Team:

- New Terms Added to Existing Codelists:
 - DIR; EVAL; GNRLOBSC; INTMODEL; LOC; MEDEVAL; MUSCTS-CD; NVTEST-CD; OETEST-CD; OBSSMO; PROCEDUR; RETEST-CD; RPTTEST-CD; SCTEST-CD; VSTEST-CD; VSRESU
 - To support Huntington's Disease and TCM-Coronary Artery Disease, Angina TAUGs.
- Codetable Mapping Upddates
 - TS; SC; VS domains
- 14 changes to published terms (None significant (add/remove synonym and update definition))

Controlled Terminology Package 33

Public Review

- Lab Terminology Team:
 - New Terms Added to Existing Codelists:
 - LBTEST, LBTESTCD, MITS, MITSCD, METHOD
 - Lung Cancer TAUGs and LOINC mapping.
 - 106 changes to published terms (including 2 significant changes):
 - Submission Value change: LBTEST/CD -> Proerythroblast/PERTHRBL will change to Rubriblast/BLASTRUB.
 - Submission Value Change: LBTEST/CD -> Pronormoblasts/Total Cells / BLSTPNCE will change to Rubriblast/Total Cells / BLSTRBCE.
 - Reason: In both cases the CDISC Lab terminology team agreed to modify all submission values such that they are using the 'Rubri' cell naming classification as per CAP guidelines in the CDISC submission values.

Controlled Terminology Package 33

Public Review

- SPECTYPE/SPECCOND (Lab) Terminology Team:
 - 2 changes to published terms
 - None significant (add/remove synonym and update definition)
- Unit (Lab) Terminology Team:
 - New Terms Added to Existing Codelist:
 - UNIT
 - 48 changes to published terms
 - None significant (add/remove synonym and update definition)

Controlled Terminology Package 33

Public Review

- Microbiology Terminology Team:
 - New Terms Added to Existing Codelists:
 - MICROORG, MBTEST, MBTESTCD, ISTEEST, ISTEESTCD.
 - Anti-drug Antibody terminology in ISTEEST/CD codelists.
 - 4 changes to published terms (including 4 major changes below):
 - Submission value change: MBTEST/CD -> Microbial Organism Detected/MCORGDET to Microbial Organism Identification/MCORGIDN.
 - Reason: This test can be used for virus, bacteria, protozoa, fungi, etc. and for results that are above and/or below species level; The result of this test should be the name of the organism. 'Detection' is not the correct term for this usage.
 - Retirement of (C132419) Taxonomic Ident Below Species Level/TXIDBSL.
 - Reason: Please use Microbial Organism Identification/ MORGIDN. Team decided not to control the level of name chosen by the sponsor company. Wanted more flexibility to reflect the actual result obtained.

Controlled Terminology Package 33

Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - TRTEST, TRTESTCD, TRPROPRS, ONCRSCAT.
 - From Lugano Criteria
 - Codetable Mapping Update: iRECIST mapping for RS domain.
 - 4 change to published terms (including 1 major changes below):
 - Submission Value Change: TRTEST-> Sum of Products of Perpendicular Diameters to Sum of Products of Perpendicular Diam.
 - Reason: The Test Name is over 40 characters.

Controlled Terminology Package 33

Public Review

- PK Terminology Team:
 - New Terms Added to Existing Codelists:
 - PKPARM, PKPARMCD.
 - The 5 new PKPARM/CD values were removed from P32, rediscussed, and re-released for public review with P33.
 - 10 changes to published terms: None significant (add/remove synonym and update definition)

Controlled Terminology Package 33

Public Review

- Protocol Entities Terminology Team:
 - Protocol Entity = Study Design
 - 16 attributes
 - 6 response codelists
 - Changes to published terms (denoted by red updates) are consistent with changes being made in General P33 file. These are shared terms in SDTM.

Controlled Terminology Package 33

Public Review

- SDTM Domain Abbreviations Terminology Team:
 - New Term Added to Existing Codelists:
 - DOMAIN
 - To support SDTMIG v3.3
 - 79 changes to published terms (including 17 major changes below):
 - Retirements of 17 two-letter domain abbreviations.
 - Reason: A number of domain abbreviations are being retired from the codelist because they are not being used in published TAUGs or IGs. In future, CDISC will only published 2-letter domain abbreviations when the domain is incorporated into a published IG or UG.

Controlled Terminology Package 33

Public Review

- SEND Terminology Team:
 - New Terms Added to Existing Codelists:
 - NONNEO, SPEC, STSPRM-CD, SEV, MITEST-CD
 - 10 changes to published terms (including 8 major changes below):
 - Retirement of C90424 Microscopic Examination/MIEXAM in the MITEST-CD codelist.
 - Reason: Please replace with GHISTXQL/ General Histopathologic Exam, Qual (new term in P33).
 - Submission Value change: SPEC -> COSTOCHONDRAL JOINT changing to COSTOCHONDRAL JUNCTION.
 - Reason: This isn't technically a joint but rather a synchondrosis. The word order of the existing submission value was causing confusion.
 - C48662, C70666, C25570, C61376, and C70667 being retired from the SEV codelist and replaced with new terms in the SEV tab.
 - Reason: The meaning of each severity term may change based on the number of values within the Severity scale. Since there are at least 3-, 4-, and 5-level severity scales, the SEND team decided to make the terms explicit.

Controlled Terminology Package 33

Public Review

- PGx Terminology Team:
 - No public review files
- Device Terminology Team:
 - No public review files
- QRS Terminology Team:
 - No public review files

Proposal: Rename column header in all CDISC Controlled Terminology publication files from *CDISC Submission Value* to *CDISC Preferred Term*.

- CDASH, SEND, SDTM, and ADaM terminology is designed for regulatory submissions. However, Protocol Entities terminology is designed to support a future CDISC protocol standard, while the CDISC Glossary terminology is meant to be used as a reference resource for authoritative and regulatory definitions of commonly used terms within clinical research. Additionally, CDASH, SEND, SDTM, and ADaM standards may be used in non-regulated clinical research.
- Therefore, the current column header 'CDISC Submission Value' in the CDISC controlled terminology publications may be a misnomer. CDISC leadership would prefer a wholesale change to all terminology publications therefore they are requesting, for public review, a proposal to change the column header in all controlled terminology publications from *CDISC Submission Value* to *CDISC Preferred Term*. This change does not apply to any previously published and archived controlled terminology releases.
- This proposed change will impact existing models, tools and processes for terminology consumption by sponsors, CROs, and other CDISC terminology users. In order for the CDISC user community to assess the impact of this change, NCI-EVS has created a draft release package of SDTM Terminology with this change implemented. The package of files can be found here: https://cbiit-download.nci.nih.gov/evs/CDISC/P32_ColumnHeaderDraft_SDTM.zip.
- Please submit a JIRA comment with P33 controlled terminology public review if you agree or disagree with this proposal.

Other Updates and Announcements

Cancer.gov Update

CDISC Wiki Update

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<https://www.cancer.gov/research/resources/terminology/cdisc>

<https://wiki.cdisc.org/x/gsr0AQ>

Upcoming CDISC Webinar

- CDISC Newcomers Webinar
 - New to CDISC?
 - Looking for a refresher on CDISC Basics?
 - Join our foremost CDISC experts for a public webinar
 - 18 January 2018 – 10am CST
 - For registration, visit our webinars page at www.cdisc.org/education/webinars



Strength *through collaboration.*

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

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