



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

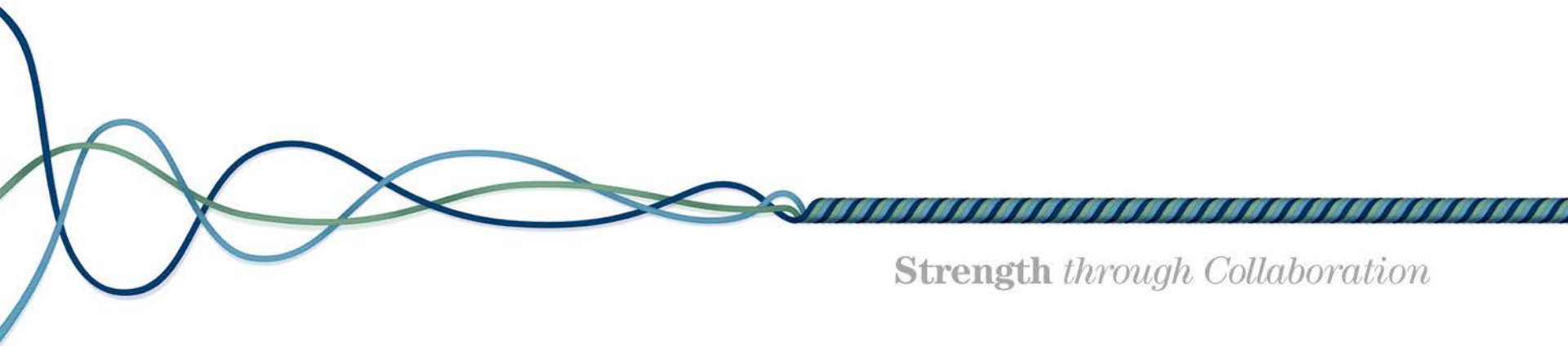
*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

A decorative graphic at the bottom of the slide consisting of several overlapping wavy lines in dark blue, teal, and light blue. These lines transition into a horizontal band with a diagonal hatched pattern in teal and dark blue.

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 33 Publication Release (2018-03-30)
 - Changes post-public review
- Package 34 Public Review (2018-03-23 to 2018-04-20)
 - New Additions
 - Changes to existing

Controlled Terminology Publication Schedule

The slide features a decorative border of green four-pointed stars. There are 12 stars in total, arranged in a circular pattern around the central text. The stars are evenly spaced and have a slight 3D effect with a darker green outline.

Controlled Terminology Package 33 Publication Release

Publication Overview

- Updates to SDTM, SEND, CDASH and Protocol Terminology.
- Therapeutic Area Support:
 - QRS Terminology to support: Lung Cancer, Duchenne Muscular Dystrophy, C. difficile-associated diarrhea, and PTSD Therapeutic Area User Guides.
 - SDTM Terminology to support: CV Imaging, Huntington's Disease, Lung Cancer, and TCM-Coronary Artery Disease/Angina Therapeutic Area User Guides.

Significant Changes Post-Public Review

- General Terminology Team:
 - INTMODEL – Team agrees not to add ADAPTIVE to this codelist; they agree it is not an interventional study design in and of itself but rather describes the plan to modify a study design during the study if required.
 - OBSSMO – Team agrees not to add CROSS-SECTIONAL to this codelist; this is more like observational study time perspective and not so much a observation study design model.
- Lab Terminology Team:
 - LBTEST/CD – NEUTHSG/Neutrophils, Hypersegmented will not be added with P33 as this is already published in existing CT.
 - LBTEST/CD – ESTRIOU/Estriol, Unconjugated will not be added with P33 as this is already published as ‘Estriol, Free’ in existing CT.

Significant Changes Post-Public Review

- Protocol Terminology Team:
 - INTMODEL – Team agrees not to add ADAPTIVE to this codelist; they agree it is not an interventional study design in and of itself but rather describes the plan to modify a study design during the study if required.
 - OBSSMO – Team agrees not to add CROSS-SECTIONAL to this codelist; this is more like observational study time perspective and not so much a observation study design model.
 - TBLIND – This codelist will not be added to the Protocol entities terminology set until the general CT team can review the proposed definition changes and new terms to this codelist (P35).
- SDTM Domain Abbreviations Team:
 - SUPPMB appeared twice in the new terms tab. One of these should be SUPPMS.

Significant Changes Post-Public Review

- Other, less significant changes* also made in:
 - General, Oncology, Protocol, Domains Abbreviations, SEND, UNIT
- No changes made to:
 - CV
 - ECG
 - Microbiology
 - PK
 - SPECTYPE-SPECCOND

*** 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 33 Publication Release

- New Codelists:
 - **Questionnaire (QS)**
 - Functional Assessment of Cancer Therapy-Bone Marrow Transplant Version 4 Questionnaire (Sponsor)
 - Functional Assessment of Chronic Illness Therapy-Dyspnea 10 Item Short Form Questionnaire (Lung Cancer)
 - Functional Assessment of Chronic Illness Therapy-Fatigue Scale Version 4 Questionnaire (Sponsor)
 - Pediatric Functional Assessment of Chronic Illness Therapy-Fatigue Questionnaire (Sponsor)
 - Trauma Symptom Checklist for Children Questionnaire (PTSD)
 - Trauma Symptom Checklist for Young Children Questionnaire (PTSD)
 - **Clinical Classification (RS)**
 - ATLAS Score (CDAD)

OWL/RDF format of SDTM CT

- The initial version of the OWL/RDF format of SDTM controlled terminology for 2018-03-30, which was posted to the NCI Ftp, site did not contain codelist definitions.
- This has been identified and corrected. The file was re-posted to the NCI Ftp site on 2018-04-03.
- No other terminology sets were affected.

Controlled Terminology Package 34 Public Review

P34 Public Review



Controlled Terminology Package 34

Public Review

- Medical Devices Terminology Team:
 - New Terms Added to Existing Codelists:
 - DOTESE/CD
 - To support Colorectal Cancer (CrCa) TAUG
 - No changes

Controlled Terminology Package 34

Public Review

General Terminology Team:

- New Terms Added to Existing Codelists:
 - ACN; LOC; MEDEVAL; NCOMPLT; POSITION; RELSUB; ROUTE; VNFATS; VNFATS-CD
 - To support Vaccines TAUG.
- New Codelists:
 - OTHEVENT: Responses for DSDECOD when DSCAT=OTHER EVENT
 - CDFATS; CDFATSCD: Findings about codelist to support the C. difficile-associated Diarrhea (CDAD) TAUG
- 19 changes to published terms (including 3 significant changes):
 - See next slide...

Controlled Terminology Package 34

Public Review

General Terminology Team:

- 19 changes to published terms (including 3 significant changes):
 - RELSUB: Coding update. C100807 and C42708 are merging in NCIt. The older c-code will be kept. Therefore, the C-code for C100807/CHILD, BIOLOGICAL will change.
 - EVAL: Coding update. C100807 and C42708 are merging in NCIt. Therefore the C-code for C42708/CHILD will change to CNEW (NCI PT=Child Relation).
 - DSCAT: Coding update for OTHER EVENT. Based on the CDISC definition, this concept encompasses things not driven by protocol. Therefore the NCI C-code/NCI PT pairing is incorrect. The NCI C-code will be updated and the NCI PT of this new term will be Non-Protocol Disposition Event.

Controlled Terminology Package 34

Public Review

- Lab Terminology Team:
 - New Terms Added to Existing Codelists:
 - LBTEST, LBTESTCD, METHOD
 - 28 changes to published terms (including 10 significant changes):
 - LBTEST/CD: A set of 10 excretion rate terms were defined and coded as being urine-excretion specific. Excretion rates can be assessed in other biological fluids such as sweat and bile. Therefore we will remove 'urine' from the CDISC definitions and NCI PTs and create new NCI C-codes that encompass a generic biospecimen excretion.

Controlled Terminology Package 34

Public Review

- SPECTYPE/SPECCOND (Lab) Terminology Team:
 - New Terms Added to Existing Codelist:
 - SPECTYPE
 - No changes
- Unit (Lab) Terminology Team:
 - New Terms Added to Existing Codelist:
 - UNIT
 - No changes

Controlled Terminology Package 34

Public Review

- Microbiology Terminology Team:
 - New Terms Added to Existing Codelists:
 - MICROORG, MBTEST, MBTESTCD, CLTMDTYP.
 - New CT rule: for controlled MB tests for organisms identified at the strain level, the Microbiology CT team has agreed to use the NCI C-code as the MBTESTCD value.
 - 2 changes to published terms: None significant (add/remove synonym or update definition)

Controlled Terminology Package 34

Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - TUIDRS, TRTEST, TRTESTCD, TRPROPRS.
 - 1 change to published terms: None significant (add synonym)

Controlled Terminology Package 34

Public Review

- PGx Terminology Team:
 - New Terms Added to Existing Codelists:
 - GENSMP, GENRCAT
 - No changes

Controlled Terminology Package 34

Public Review

- PK Terminology Team:
 - 4 changes to published terms: None significant (update definitions)

Controlled Terminology Package P34

Public Review

- Protocol Entities Terminology Team:
 - Changes to 1 published term – Definition update for ‘Stratification Factor’, which is an attribute of the Protocol Entity = Study Design.

Controlled Terminology Package 34

Public Review

- SEND Terminology Team:
 - New Terms Added to Existing Codelists:
 - SPEC
 - New Codelist:
 - NULLFLAV: Supports the TSVALNF variable in the TS domain in SENDIG 3.1.
 - 2 changes to published terms (including 1 major changes below):
 - SPEC: The NCI C-code of LYMPH NODE, CERVICAL, SUPERFICIAL was incorrectly assigned when this term was first published. The C-code will change from C77654 to C33659.

Controlled Terminology Package 34

Public Review

- CV Terminology Team:
 - No public review files
- SDTM Domain Abbreviations Terminology Team:
 - No public review files
- ECG Terminology Team:
 - No public review files
- QRS Terminology Team:
 - No public review files

Other Updates and Announcements

- The multiple term request template has been updated.
 - ❖ The new template was posted on 2018-03-30.
 - ☐ Clarified instructions.
 - ☐ Removal of columns that are not necessary.
 - ☐ Changes to existing tab allows for copy/paste directly from published Excel files.
 - ❖ The old template will still be accepted by NCI and CDISC staff but we urge you to make use of the updated template.
- Update on Column Header change proposal from P33.
 - ❖ P33 public review comments were collected (thank you!)
 - ❖ CDISC will continue gathering inputs from the community – no decision yet.



Strength *through collaboration.*

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

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UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Durham, NC	18-22 Jun 2018	SDTM, CDASH, ADaM Primer, ADaM T&A	19 Mar 2018	19 May 2018	 Duke Clinical Research Institute
Chicago, IL	16-20 Jul 2018	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	16 April 2018	16 Jun 2018	PRAHEALTHSCIENCES


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UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
Europe Interchange , Berlin, DE	23-27 April 2018	SDTM, ADaM Primer, ADaM T&A, CDASH, Define-XML, Controlled Terminology, SEND, Standards from the Start	23 Feb 2018	23 Mar 2018	
Milan, Italy	14-18 May 2018	SDTM, ADaM Primer, ADaM T&A, CDASH, Define-XML	14 Feb 2018	14 April 2018	

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UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Osaka, Japan	11-15 Jun 2018	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	11 March 2018	11 May 2018	

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Q&A

