CDISC Controlled Terminology

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Controlled Terminology P37 Publication and P38 Public Review

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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 37 Publication Release</u> (2019-03-29)
    - Changes post-public review

2. <u>Package 38 Public Review</u> (2019-03-22 to 2019-04-29)
    - New Additions
    - Changes to existing

3. Questions

Controlled Terminology Package 37 Publication

2019-03-29

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)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
34	3/16/2018	3/23/2018	4/20/2018	5/18/2018	6/29/2018	Devices	General	Lab	Microbiology
34						Oncology	PGx	PK	SEND
34						Protocol Entities	Spectype Speccond	Unit	
35	6/15/2018	6/22/2018	7/20/2018	8/17/2018	9/28/2018	Devices	ECG	General	Lab
35						Microbiology	Oncology	PGx	PK
35						Protocol Entities	SDTM Domain	SEND	Spectype Speccond
35						Unit			
36	9/7/2018	9/14/2018	10/12/2018	11/9/2018	12/21/2018	Devices	General	Glossary	Lab
36						Microbiology	Oncology	PK	SDTM Domain
36						SEND	Spectype Speccond	Unit	
37	12/14/2018	12/21/2018	1/18/2019	2/15/2019	3/29/2019	Devices	ECG	Lab	Microbiology
37						Oncology	PGx	PK	QRS
37						SEND	SEND-AR	Spectype Speccond	Unit
38	3/15/2019	3/22/2019	4/29/2019	5/24/2019	6/28/2019	Devices	ECG	General	Lab
38						Microbiology	Oncology	PK	Protocol Entities
38						SDTM Domain	SEND	SEND-AR	Unit
39	6/14/2019	6/21/2019	7/19/2019	8/16/2018	9/27/2019				
39									
39									
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019				
40									
40									
41	12/13/2020	12/20/2019	1/17/2020	2/14/2020	3/27/2020				
41									
41									

Controlled Terminology Package 37 Publication Release

- Updates to SDTM, SEND, CDASH, ADaM and Protocol Terminology.

- Therapeutic Area Support:
  - QRS Terminology to support: Major Depressive Disorder Therapeutic Area User Guide.
  - SDTM Terminology to support: Colorectal Cancer, HIV, Huntington's Disease, and Animal Rule Therapeutic Area User Guides.

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Significant Changes Post-Public Review

- Lab Terminology:
  - Proposed LBTEST-CD values of Glycated Albumin is already published. We will not add but instead will consider adding synonyms with P39 (Glycosylated Albumin).
  - Proposed LBTEST-CD values of Beta Protein and Beta Protein/Total Protein are synonymous with already published terminology of 'Beta Globulin' and 'Beta Globulin/Total Protein'. We will not add but instead will consider adding synonyms with P39.

- General Terminology:
  - SC_Codetable_Mapping File
    - Added published response terminology for HANDDOM/Dominant Hand and STDNTIND/Student Indicator

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Significant Changes Post-Public Review

- ## SEND Terminology:
  - Removed FOLLICLES, DECREASED/ABSENT from consideration for the NONNEO codelist. Need to have further discussions around what the terminology should encompass. This may be two separate concepts.

- ## SEND-AR Terminology:
  - AGECAT (Age Category Response), TRTTYP (Treatment Type), CHAGCAT (Chemical Challenge Agent Category Response), and DVDECOD (Standardized Deviation Term) codelists will not be published at this time.
  - ACPARM-CD: The following parameters are no longer needed by FDA: Biological Agent Genetic Characteristics, Biological Agent Characterized Indicator, Chemical Agent Category, Chemical Ag Metabolite Name, and Chemical Ag Metabolite CAS Number.
  - SSTYP: EFFICACY, POST-EXPOSURE RADIOMITIGATION will be added to the codelist.

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Significant Changes Post-Public Review

- Other, less significant changes* also made in:
  - General, Lab, Oncology, SEND-AR, and SEND.

- No changes made to:
  - Devices
  - ECG
  - Microbiology
  - PK
  - QRS
  - Spectype/Speccond
  - Units

*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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QRS Controlled Terminology Package 37 Publication Release

- New Codelists:
  - **Questionnaires (QS)**
    - Patient Health Questionnaire - 2 Item Questionnaire (Major Depressive Disorder TAUG)
  - **QRSMTHOD** (QRS Method)

- Changes to Existing:
  - Removal of the Male and Female Tanner Scales (TANNER SCALE GIRL, TANNER SCALE BOY) – These will be modeled in the RP domain.
  - Removal of the CGIGUY1 codelist
  - Addition of a term to the Epworth Sleepiness Scale codelists

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P37 codetable updates

- Codetable Mapping Files
  - based on published Terminology
  - show relationships between terms in different Controlled Terminology codelists.
  - provide human and machine-readable linkages between published terms across multiple codelists and may be helpful for data QA/QC, CRF building, and data mapping.

- Updates with P37
  - DS_Codetable_Mapping – DSCAT-DSDECOD response codelist linkages
  - EG_Codetable_Mapping
  - Oncology_Codetable_Mapping – Lugano and Rajkumar Multiple Myeloma response criterion
  - RACEC-ETHNICC_Codetable – Includes Chinese Ethnicities
  - SC_Codetable_Mapping
  - TS_Codetable_Mapping
  - VS_Codetable_Mapping

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Poll Question?

- **Is your company making use of the codetable mapping files produced by CDISC controlled terminology teams?**

  ❑ **Yes, we find them very useful!**

  ❑ **Yes, but we have some suggestions for how to make them better.**

  ❑ **Not yet but perhaps in future.**

  ❑ **No. What are codetable mapping files?**

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Controlled Terminology Package 38 Public Review

2019-03-22 – 2019-04-29*

https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P38+-+Comments+Due+by+29+April+2019

Controlled Terminology Package 38 Public Review

- Medical Devices Team
  - New Terms Added to Existing Codelists:
    - DOTEST-CD
  - No changes to existing terms

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Controlled Terminology Package 38 Public Review

- ECG Terminology Team
  - New Terms Added to Existing Codelists:
    - EGMETHOD, EGLEAD, EGSTRESC, HESTRESC
  - Updates to Codetable mapping Files:
    - EG_Codetable_Mapping
  - 5 changes to published terms: Including 1 significant change
    - EGMETHOD: Update of submission value of C132356 from 8 LEAD STANDARD to 8 LEAD STANDARD, NON-HUMAN

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Controlled Terminology Package 38 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - DIR, FREQ, FRM, LOC, NCOMPLT, PROTMLST, RACEC, RELSUB, RETEST-CD, and TTYPE
    - To support the Type 1 Diabetes, Lung Cancer TAUGs
  - New Codelists: SDTMVRS, SDTMIGRS, CTAUGRS, FDATSRS
  - Updates to Codetable mapping Files:
    - DS_Codetable_Mapping
    - RACE_RACEC_Mapping
    - TS_Codetable_Mapping
  - 10 changes to published terms: Including 2 significant changes (detailed on next slide)

Controlled Terminology Package 38 Public Review

- General Terminology Team Significant Changes to Existing Terms:
  - TDIGRP: The General terminology team is proposing to retire this codelist because the SDTMIG and FDA technical conformance guide state that SNOMEDCT should be used for responses to the TSPARM/CD value of TDIGRP.
  - CDFATS-CD: Retire Number of Occurrences/NUMOCCUR (C150827) as it is no longer included within the CDAD TAUG. It will be replaced with the existing term 'Number of Episodes'.

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Controlled Terminology Package 38 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST-CD, METHOD
    - To support LOINC mapping, Animal Rule.
  - New Codelists: LBANMET
  - 9 change to published terms: Including 1 significant change
    - C74629/Reactive Lymphocytes will be retired and merged with C64818/ Lymphocytes Atypical. It was determined that in the context of lab data, these are synonymous.

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Controlled Terminology Package 38 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
    - To support LOINC mapping.
  - 2 Changes to Existing terms: None significant.

Controlled Terminology Package 38 Public Review

- Microbiology Terminology Team
  - New Terms Added to Existing Codelists:
    - MBTEST/CD; ISTEST/CD
  - Microbiology Rules Document update
  - 11 changes to existing terms; 1 significant change
    - Retire C135409 Deoxyribonucleic Acid/DNA from the codelist. In accordance with SDTMIG v3.4, when testing for microbial genetic and antigenic materials (DNA, RNA, antigen, etc.), the name of the microorganism and its genetic/antigenic material are pre-coordinated into the MBTEST value, therefore, there is no need for, and is incorrect to have a standalone MBTEST = DNA.

Controlled Terminology Package 38 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - TUIDRS, TUTEST-CD, ONCRSR
  - Updates to Codetable mapping Files:
    - TU_Codetable_Mapping
    - RS_ONC_Codetable_Mapping
    - RS_RANO_Codetable_Mapping
  - 3 change to published terms: Including 2 significant changes
    - TUIDRS:
      - Remove C150897/ORGAN OF INTEREST from the codelist: Please use new term 'LOCATION OF INTEREST' (new with P38) as it is broader and can encompass anatomical locations beyond organs.
      - Remove C48190/ABSENT from the codelist: This was added as a response value for a TUTEST (Targeted Examination) that was ultimately determined not to be appropriate to add. This response does not currently fit as a response for any published TUTEST so we will remove it from the codelist. It could be added in future if a TUTEST is published that has this as a response.

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Controlled Terminology Package 38 Public Review

- PK Terminology Team
  - New Terms Added to Existing Codelists:
    - PKPARM-CD, PKUNIT
  - No changes to existing terms

Controlled Terminology Package 38 Public Review

- Protocol Entities Terminology Team
  - Protocol Entity: Study Population
  - 14 Attributes
  - No changes to existing terms

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Controlled Terminology Package 38 Public Review

- SDTM Domain Terminology Team
  - New Terms Added to Existing Codelists:
    - DOMAIN - OI

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Controlled Terminology Package 38 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - NONNEO, SPEC, STSPRM/CD, SVSTST/CD
  - 15 change to published terms: Including 2 significant changes
    - SPECIES codelist:
      - FERRET – We are updating the c-code of C77097, which is coded to the generic 'Ferret' concept but in non-clinical research Mustela Putorius is the genus and species of ferret specifically used so we are updating the coding to reflect that.
      - PIG – We are updating the c-code of C14280, which is coded to the generic 'Pig' concept but in non-clinical research 'Sus scrofa' is the genus and species specifically used so we are updating the coding to reflect that.

Controlled Terminology Package 38 Public Review

- SEND Animal Rule Terminology Team (to support the Animal Rule TAUG)
  - New Terms Added to Existing Codelists:
    - ACPARM/CD, RNAIOTYP, STSPRM-CD
  - New terms added to new codelists:
    - BIRRMRS, RNTIMRS, EORNTI, CHAGNAMR, GENUSSPC
  - No changes to existing terms

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Controlled Terminology Package 38 Public Review

- Lab Terminology Team:
  - No public review files for SPECTYPE or SPECCOND codelists

- PGx Terminology Team:
  - Please see Lab METHOD and Changes to Existing tabs for new additions and changes to existing METHOD terms related to genetic/genomic assessments.

- Protocol Entities Terminology Team:
  - No public review files

- Glossary Team:
  - No public review files

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Call for Volunteers!

- The CDISC Protocol Entities team and the CDISC Glossary team are looking for additional volunteers:

  - ➢ <u>Protocol Entities Team</u>: focused on harmonizing terms and definitions used within the context of the clinical study protocol. We are looking for individuals with experience in protocol writing and development, familiarity with interventional and/or observational study protocols (including epidemiological protocols).
  - ➢ <u>CDISC Glossary Team</u>: focused on harmonizing terms and definitions used in the various standards initiatives undertaken by CDISC to support clinical research. We are looking for individuals with experience in general knowledge of the end-to-end clinical development process and global regulations.

  - ❖ For each team, the time commitment is about one hour per week. CDISC team volunteers may qualify for complimentary access to CDISC authorized, online training and public courses (space permitting).
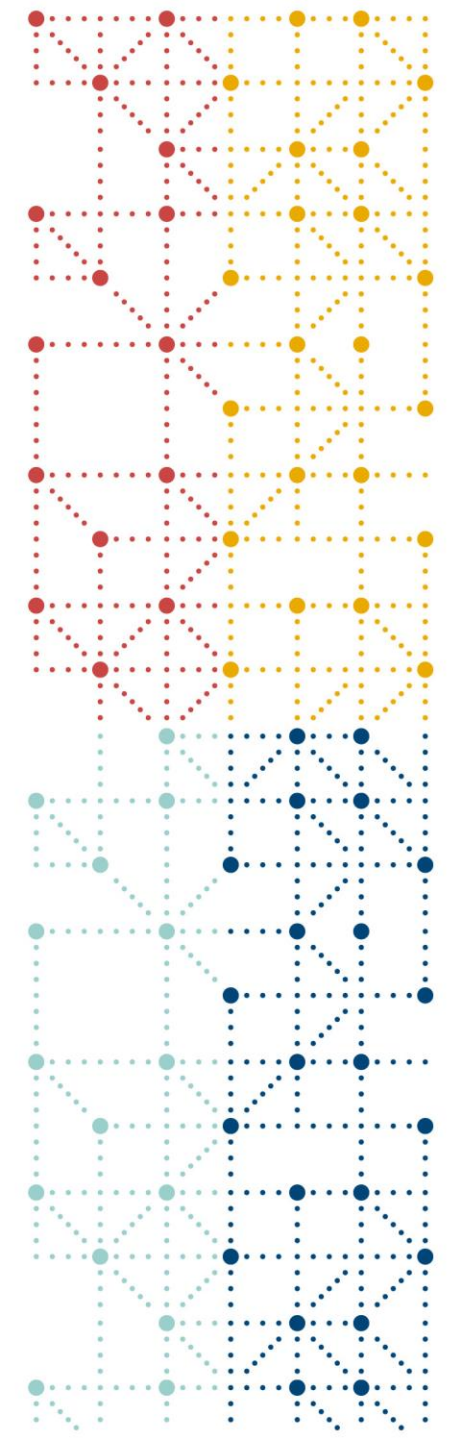
If you are interested in contributing to the CDISC Terminology Initiative, please contact us…

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*The CDISC glossary team is actively recruiting!

Q&A

CDISC Education: Upcoming Learning Opportunities

Saad Yousef

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Thank you for your attendance and support of CDISC!

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