CDISC Public Webinar – Standards Updates and Additions

18 JUL 2017

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Agenda

- Controlled Terminology Quarterly Updates
  - Chris Gemma, Project Manager, CDISC Q&A
  - Dr. Erin Muhlbradt, CDISC Project Lead, NCI EVS
- CDISC Online Education & Event Updates
  - John Ezzell, Education Manager, CDISC
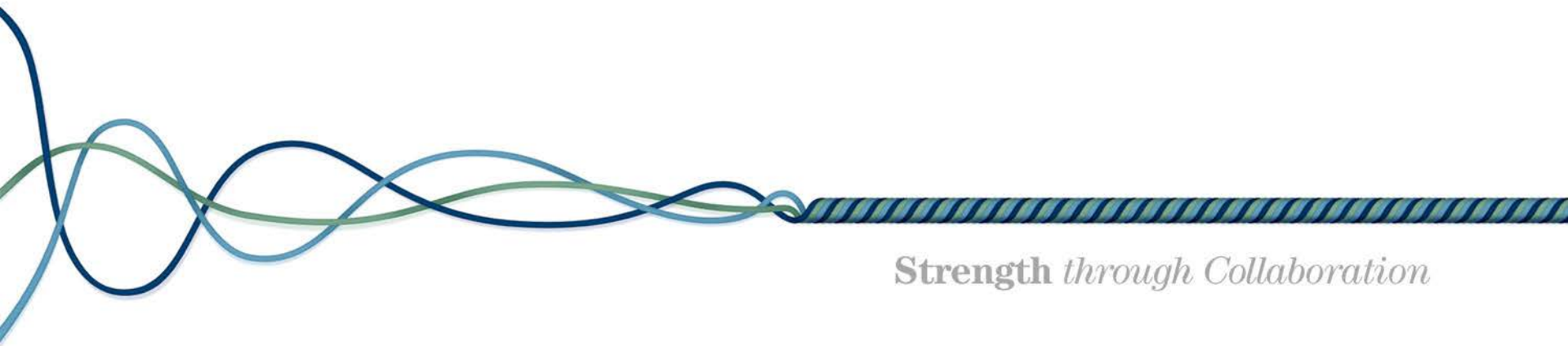
Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

1) What should be supported by ADaM datasets?
2) Is there a limit to the number of variables that can be in ADSL?

CDISC CONTROLLED TERMINOLOGY

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

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Controlled Terminology Agenda

- Package 30 Publication Release (2017-06-30)
    - Changes post-public review

- Package 31 Public Review (2017-06-23 to 2017-07-21)
    - New Additions
    - Changes to existing

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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			
26	3/11/2016	3/18/2016	4/15/2016	5/13/2016	6/24/2016	CV	Device	General	Lab
26						Oncology	SEND	Spectype Speccond	Unit
26						Virology	QRS		
27	6/10/2016	6/17/2016	7/15/2016	8/19/2016	9/30/2016	CV	General	Lab	Oncology
27						PGx	PK	SEND	Spectype Speccond
27						Unit	Virology	QRS	
28	9/2/2016	9/9/2016	10/7/2016	11/4/2016	12/16/2016	CV	Device	ECG	General
28						Lab	Oncology	PK	SEND
28						Unit	Virology	QRS	
29	12/9/2016	12/16/2016	1/27/2017	2/17/2017	3/31/2017	CV	Device	ECG	General
29						Lab	Oncology	PGx	PK
29						Protocol Entities	SEND	Spectype Speccond	Unit
29						Virology	QRS		
30	3/17/2017	3/24/2017	4/21/2017	5/19/2017	6/30/2017	CV	ECG	General	Lab
30						Oncology	PGx	PK	QRS
30						SEND	Sectype Speccond	Unit	Virology
31	6/16/2017	6/23/2017	7/21/2017	8/18/2017	9/29/2017	CV	ECG	General	Lab
31						Microbiology	Oncology	PGx	PK
31						Protocol Entities	SEND	Unit	
32	9/8/2017	9/15/2017	10/13/2017	11/10/2017	12/22/2017				
32									
32									
33	12/15/2017	12/22/2017	1/19/2018	2/16/2018	3/30/2018				
33									
33									
34	3/16/2018	3/23/2018	4/20/2018	5/18/2018	6/29/2018				
34									

6/30/2017

Dates in red are planned and may be adjusted slightly.

1

Controlled Terminology
Package 30 Publication Release

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Publication Overview

- Updates to SDTM, SEND, and Protocol Terminology.
    - No changes to CDASH or ADaM

- Therapeutic Area Support:
    - QRS Terminology to support: Duchenne Muscular Dystrophy, PTSD, TBI, and Nutrition TAUGs.
    - SDTM Terminology to support: CV Imaging, Ebola, Kidney Transplant, and Prostate Cancer TAUGs.

Significant Changes Post-Public Review

- ECG Terminology Team:
  - New EGLEAD submission values were upper-cased to conform to CDISC CT rules.

- General Terminology Team:
  - RPTEST-CD values were held from publication and will be put out with P31 along with updates to existing term definitions to ensure that there is clear distinction between terms.
  - METHOD: KIMS being held from publication so that the team can determine whether it is significantly different from existing term Kinetic Microparticle Immunoassay (Code C111240).

- Lab Terminology Team:
  - Addition to LBTEST-CD of INTP/Interpretation removed from package to be further discussed in P32
  - Lymphotoxin Alpha is already published in LBTEST-CD codelist as C132375.

Significant Changes Post-Public Review

- PGx Terminology Team:
  - GENRCAT codelist (PFRESCAT) being held from publication by PGx team for further review to determine what belongs there versus another variable.

- SEND Terminology Team:
  - Update to SEND Severity codelist being held from publication while the SEND team updates guidance on the use of this codelist and SEV variable.

- UNIT (Lab) Terminology Team:
  - cmH20 and mL/cmH2O already exists in UNIT codelist
  - U/g Hb held from publication while the lab CT team discusses philosophy of including analytes in unit terms.

Significant Changes Post-Public Review

- Other, less significant changes* also made in:
  - General, Oncology, PGx, UNIT
- No changes made to:
  - CV
  - PK
  - QRS
  - SPECCTYPE/SPECCOND
  - Microbiology/Virology

*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 30 Publication Release

- New Codelists:
  - Questionnaire (QS)
    - Baby Eating Behaviour Questionnaire Concurrent Version Questionnaire (Nutrition TA)
    - Baby Eating Behaviour Questionnaire Retrospective Version Questionnaire (Nutrition TA)
    - Clinical Global Impression Original Version Questionnaire Treatment Satisfaction Questionnaire for Medication Version 1.4
    - Clinical Global Impression Generic Modification Version Questionnaire
    - Patient Global Impression Generic Modification Version Questionnaire
    - Life Events Checklist for DSM-5 Standard Version Questionnaire (PTSD)
    - The PTSD Checklist for DSM-5 Questionnaire (TBI, PTSD)
    - Pediatric Outcomes Data Collection Instrument, Pediatric Parent-Reported Version Questionnaire (DMD)
    - Pediatric Outcomes Data Collection Instrument, Adolescent Parent-Reported Version Questionnaire (DMD)
    - Pediatric Outcomes Data Collection Instrument, Adolescent Self-Reported Version Questionnaire (DMD)
    - RAND Social Support Survey Instrument Questionnaire (PTSD)
  - Clinical Classification (RS)
    - Psoriasis Area and Severity Index Clinical Classification

Controlled Terminology
Package 31 Public Review

P31 Public Review

Terminology Call for Public Review Package P31 - Comments Due by 21 July 2017

Created by Joe Ben Clark, last modified by Chris Gemma on Jun 23, 2017

Introduction

CDISC Controlled Terminology Package 31 is ready for public review. The public review package consists of 11 documents:

- CV*
- ECG
- General*
- Laboratory Tests*
- Microbiology* (previously Virology)
- Oncology*
- PGx
- PK
- Protocol
- SEND
- Units of Measure

An **Asterisk *** indicates that **changes to previously existing CDISC Submission Values** are also included on the "Changes to Existing" tab in the document. Please review these changes.

Instructions for Reviewers

Wiki and JIRA use the same credentials, Register and/or Log in WIKI and in JIRA before starting. 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:

1. Go to the **Controlled Terminology** project in JIRA at: http://jira.cdisc.org/projects/CT/issues/

   ⓘ Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.

2. Click on the "**Create**" button in the top menu to bring up the Create Issue form.
3. Choose the **Controlled Terminology** Project.
4. Choose the appropriate **issue type - "Review Comments"**.
5. Fill out the form.
   a. Provide a short summary of your comment in the "Summary" field.
   b. Choose the relevant document from the list in the "Component(s)" field.
   c. Enter your comment, and any additional details in the "Description". To help the team address your comment properly, be thorough.

https://wiki.cdisc.org/x/pQOWAg

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Controlled Terminology Package 31 Public Review

- CV Terminology Team:
  - New Terms Added to Existing Codelists:
    - CVTEST, CVTESTCD
    - CV Imaging TAUG
  - 10 changes to published terms (including 1 major change below):
    - Retirement of Mean Atrial Pressure, Estimated (C130056) – Please use CVTEST = Mean Blood Pressure, Estimated; LOC = Heart, Right Atrium (or other chambers of the heart).

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Controlled Terminology Package 31 Public Review

- ECG Terminology Team:
  - 5 changes to published terms:
    - None significant (add/remove synonym and update definition)

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Controlled Terminology Package 31 Public Review

General Terminology Team:

- New Terms Added to Existing Codelists:
  - DTYPE; FREQ; GASTRO-CD; LOC; MEDEVAL; MUSCTS-CD; NCOMPLT; OETEST-CD; RACEC; RETEST-CD; RPTEST-CD; RSKASMT; SCTEST-CD; TPHASE; TINDTP; TSPARM-CD; VSRESU
  - To support CrCa, DMD, Ebola, Kidney Transplant TAUGs.
- New Codelist
  - DMFATS-CD – to support DMD TAUG
- 21 changes to published terms (including 3 major changes *Next slide*)

Controlled Terminology Package 31 Public Review

General Terminology Team [Cont'd]:

- 21 changes to published terms (including 3 major changes below):

  - Request to change the date format in the txt date stamp file to ISO8601 format (YYYY-MM-DD) for all terminology publications going forward.

  - LOC - ODONTOGENIC TISSUE (C33794) will be replaced with TOOTH (C12506).
    - Because this term was meant for the anatomical location codelist, tissue types belong in SPECTYPE codelist. This was the incorrect granularity of term to be put into this codelist.

  - LOC – Update submission value of C12774 from ARTERY, PULMONARY to PULMONARY ARTERY BRANCH
    - Coming off of the pulmonary trunk, all of the things considered 'pulmonary arteries' are more precisely, semantically described as pulmonary artery branches. Most people consider the pulmonary arteries the left and right pulmonary arteries but this isn't anatomically precise.

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Controlled Terminology Package 31 Public Review

- Lab Terminology Team:
  - New Terms Added to Existing Codelists:
    - LBTEST, LBTESTCD, MITS, MITSCD
    - Malaria, Prostate Cancer, and Colorectal Cancer TAUGs.
  - 13 changes to published terms (including 3 major changes below):
    - Retirement of Reticulocyte Distribution Width (C114218) – The submission value and definition does not reflect lab tests that are actually done in practice. Therefore this will be retired and replaced with Ret Volume Distribution Width/RDWR (new in P31).
    - Retirement of Ret. Mean Corpuscular Hemoglobin (C117855) - The submission value and definition does not reflect lab tests that are actually done in practice. Therefore this will be retired and replaced with Ret. Corpuscular Hemoglobin Concentration Mean/CHCMR (new in P31).
    - The laboratory test name of C127632/Proliferating Erythroid Cells/Total Cells is longer than 40 characters. Submission value being updated to: Proliferating Erythroid/Total Cells, which matches existing synonym.

Controlled Terminology Package 31 Public Review

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

Controlled Terminology Package 31 Public Review

- Microbiology (Virology) Terminology Team:
  - New Terms Added to Existing Codelists:
    - MICROORG, MBTEST, MBTESTCD, MSTEST, MSTESTCD.
  - 21 changes to published terms (including 9 major changes below):
    - 8 terms retiring from the MSTEST-CD codelist: C116250, C116249, C116248, C116247, C116254, C116253, C116252, C116251
      - Per FDA guidance, for tests concerning 50% inhibition on microbial growth/replication, please use the newly released EC50 terms (see P31 MSTEST-CD tab); for tests concerning 50% inhibition on microbial enzymatic activity, please use the newly released IC50 and IC95 terms (see P31 MSTEST-CD tab).
    - MBTEST: Submission value change from Mycobacterium Tuberculosis (C128982) to Mycobacterium tuberculosis
      - Following established Linnean naming conventions, species level word should start with a lowercase "t" in "Tuberculosis".

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Controlled Terminology Package 31 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - TUIDRS, TRTEST, TRTESTCD
    - Colorectal Cancer TAUG.
  - Updated mapping codetables for TU, TR, and RS domains – additions shown in red font
  - 5 changes to published terms (including 1 major change below):
    - Retire Tumor Antigen Response (C123628) from codelist and please use existing term TMRESP/Tumor Marker Response. The oncology SDS team did not feel that these terms were sufficiently different enough to warrant multiple concepts.

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Controlled Terminology Package 31 Public Review

- PGx Terminology Team:
  - New Terms Added to Existing Codelists:
    - BSTEST, BSTESTCD, PFTEST, PFTESTCD, PGTEST, PGTESTCD.
    - Colorectal Cancer TAUG.
  - No change to published terms

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Controlled Terminology Package 31 Public Review

- PK Terminology Team:
    - New Terms Added to Existing Codelists:
        - PKPARM, PKPARMCD.
    - No change to published terms

Controlled Terminology Package 31 Public Review

- QRS Terminology Team:
  - No public review files

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Controlled Terminology Package 31 Public Review

- Protocol Entities Terminology Team:
  - Protocol Entity = Clinical Trial
    - 21 attributes
    - 4 response codelists
  - No change to published terms

Controlled Terminology Package 31 Public Review

- SEND Terminology Team:
  - New Terms Added to Existing Codelists:
    - SPEC, NONNEO, NCDPHASE
  - 4 changes to published terms
    - None significant (add/remove synonym and update definition)

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

Erin Muhlbradt, muhlbradtee@mail.nih.gov
Chris Gemma, cgemma@cdisc.org

Q&A

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CDISC Online Education & Event Updates

John Ezzell, CDISC

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Standard currently out for review

- Terminology Call for Package 31
  - Comments Due by: 21 Jul 2017

- Colorectal Cancer v1.0
  - Comments Due by: 11 Aug 2017

Upcoming Webinars
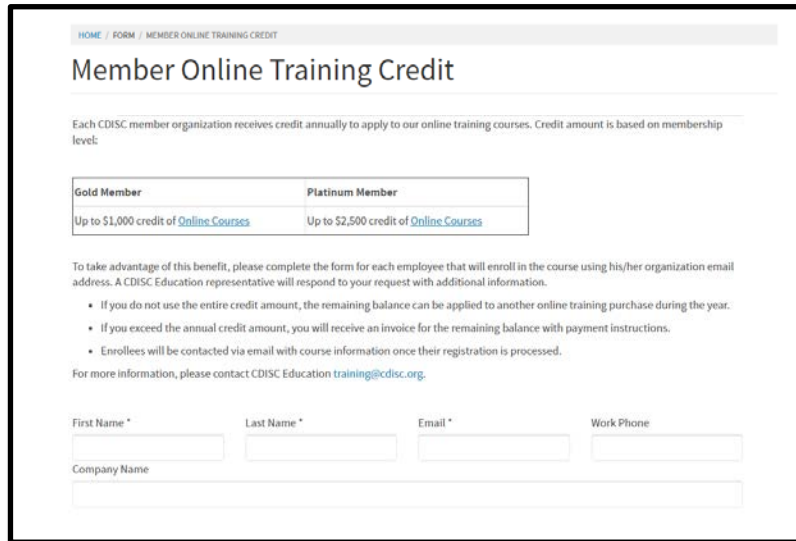
Topics	Presenters	Webinar Date
CDISC Members Only Mini-Training - Governance for Data Capture Standards	Gary Walker, Associate Director, Quintiles Michael Ward, Data Standards Consultant, Eli Lilly Melissa Binz, Study Data Management, Pfizer Judy Tran, Manager, Medidata Solutions	THU, 03 AUG 2017 10:00 AM - 11:30 AM CDT
CDISC Tech Webinar - CDISC SHARE 2.0	Dr. Lauren Becnel, VP, Strategy and Innovation, CDISC Anthony Chow, Senior Manager, Technical Development, CDISC Dr. Sam Hume, Head of Data Exchange Technologies, CDISC	WED, 16 AUG 2017 10:00 AM - 11:30 AM CDT

Webinar details and registration at www.cdisc.org/webinars

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For more information, please contact CDISC Education training@cdisc.org.

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Seattle, WA	25-29 Sep 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	25 Jun 2017	25 Aug 2017	Ax10 PARTNERS IN RESEARCH
Austin, TX	13-17 Nov 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, Controlled Terminology, SEND, Standards from the Start, ODM, SDTM for Medical Device	13 Aug 2017	3 Nov 2017	CDISC

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UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
Leiden, Netherlands	11-15 Sep 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	12 Jun 2017	13 Aug 2017	OCS Consulting
Copenhagen, Denmark	2-10 Nov 2017	SEND, SDTM, ADaM Primer, ADaM T&A, Define-XML	2 Aug 2017	3 Oct 2017	SCUBED

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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 Sep 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	11 Jun	11 Aug	Croit
Beijing, China	19-20 Sep	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	19 Jun	1 Sep	PAREXEL. PPD
Tokyo, Japan	4-8 Dec 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	4 Oct	4 Nov	Croit

Visit cdisc.org/public-courses for information on other CDISC Public Training events.
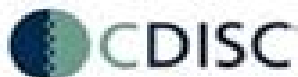
CDISC   2017 China Interchange   BEIJING · CHINA
21–22 September 2017

Any more questions?

Thank you for attending this webinar.

CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research

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