# CDISC Public Webinar – Standards Updates and Additions

04 APR 2017

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# Agenda

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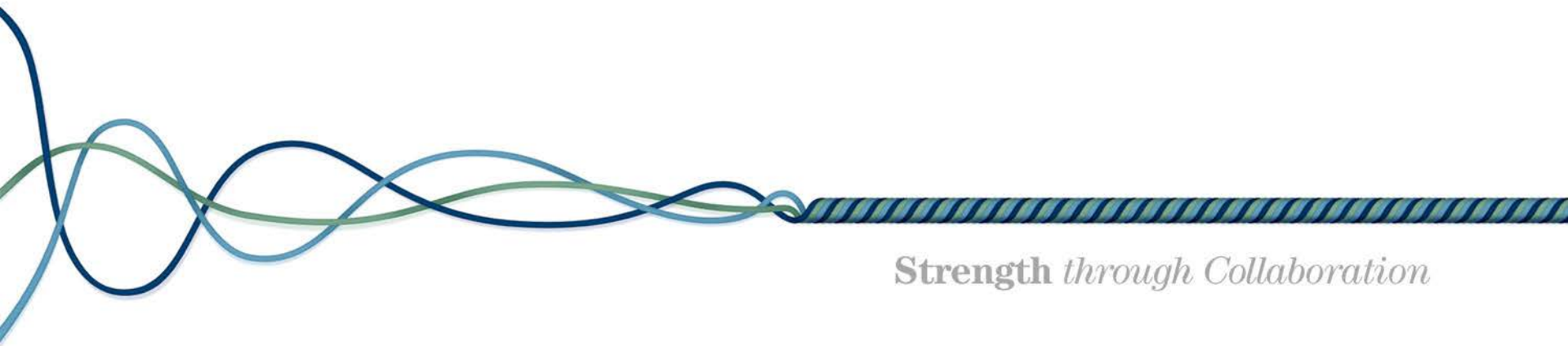
# Question & Answer

- '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 29 Publication Release (2017-03-31)
  - Changes post-public review

- Package 30 Public Review (2017-03-24 to 2017-04-24)
  - New Additions
  - Changes to existing

# 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 | | | |
|---|---|---|---|---|---|---|---|---|---|
| 24 | 9/4/2015 | 9/11/2015 | 10/9/2015 | 11/6/2015 | 12/18/2015 | Device | ECG | General | Lab |
| 24 | | | | | | Oncology | PGx | PK | SEND |
| 24 | | | | | | Unit | Virology | QRS | |
| 25 | 12/4/2015 | 12/11/2015 | 1/15/2016 | 2/12/2016 | 3/25/2016 | General | Lab | Oncology | PGx |
| 25 | | | | | | PK | SEND | Spectype Speccond | Unit |
| 25 | | | | | | Virology | QRS | | |
| 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 | | | |
| 30 | 3/17/2017 | 3/24/2017 | 4/21/2017 | 5/19/2017 | 6/30/2017 | | | | |
| 30 | | | | | | | | | |
| 30 | | | | | | | | | |
| 31 | 6/16/2017 | 6/23/2017 | 7/21/2017 | 8/18/2017 | 9/29/2017 | | | | |
| 31 | | | | | | | | | |
| 31 | | | | | | | | | |
| 32 | 9/1/2017 | 9/08/2017 | 10/6/2017 | 11/3/2017 | 12/15/2017 | | | | |
| 32 | | | | | | | | | |

1/9/2017

*Dates in red are planned and may be adjusted slightly.*

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# Controlled Terminology
# Package 29 Publication Release

# Publication Overview

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

- New terminology set:
  - Protocol Entities

- Therapeutic Area Support:
  - QRS Terminology to support: Duchenne Muscular Dystrophy, PTSD, and HIV TAUGs.
  - SDTM Terminology to support: Asthma, Ebola,  Kidney Transplant, Malaria, Prostate Cancer, Schizophrenia, Tuberculosis v2.0, and Virology TAUGs.

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# Significant Changes Post-Public Review

- General Terminology Team:
  - RELATIVE, BIOLOGICAL not being added to RELSUB codelist since this is already published as BIOLOGICALLY RELATED (C71384).
  - TREATMENT is already published in TTYPE codelist.
  - The addition of the synonym 'Ductus Deferens' to VAS DEFERENS (C74456) was already done in P28.

- Lab Terminology Team:
  - The flow cytometry terminology will not be published in P29; it will be on hold until the Flow Cytometry team models more complex use cases to ensure that the modeling strategy is correct.

- PK Terminology Team:
  - AILAMZD/Accum Index using Lambda z norm by dose will not be published in PKPARM-CD codelist – The request was withdrawn by the requester as it was submitted in error.

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# Significant Changes Post-Public Review

- Oncology Terminology Team:
  - In TUIDRS codelist, NON-TARGET CONTRAST ENHANCING and NON-TARGET CONTRAST NON-ENHANCING submission values have been changed to: NON-TARGET ENHANCING and NON-TARGET NON-ENHANCING.

- SEND Terminology Team:
  - The codelists for SNVCAT, SNVSCAT, SNVMETH, SNVTST-CD will not be published with P29. These are on hold until the SEND Nervous System Domain goes out for public review.

- Virology Terminology Team:
  - In ISTEST codelist, EBOV Specific IgM Antibody Secreting Cells and EBOV Specific IgG Antibody Secreting Cells submission values have been changed to: EBOV Specific IgM AB Secreting Cells and EBOV Specific IgG AB Secreting Cells.

# Significant Changes Post-Public Review

- Other, less significant changes* also made in:
  - ECG, General, Lab, Oncology, PK, Protocol Entities, SEND, Virology

- No changes made to:
  - CV
  - Device
  - PGx
  - SPECCTYPE/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.

# Controlled Terminology
# Package 29 Publication Release

- Questionnaires, Ratings, and Scales (QRS) Terminology Team
  - New Codelists:
    - Questionnaire (QS)
      - Combat Exposure Scale Questionnaire (PTSD TAUG)
      - Edinburgh Postnatal Depression Scale Questionnaire (HIV TAUG)
      - Health Assessment Questionnaire Disability Index Without Pain Visual Analog Scale
      - Treatment Satisfaction Questionnaire for Medication Version 1.4
    - Clinical Classification (RS)
      - North Star Ambulatory Assessment Clinical Classification (Duchenne Muscular Dystrophy TAUG)

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# Controlled Terminology
# Package 30 Public Review

# P30 Public Review

✏ Edit    ☆ Save for later    👁 Watching    ↪ Share

## Terminology Call for Public Review Package P30 - Comments Due by 24 April 2017

Created by Joe Ben Clark, last modified by Erin Muhlbradt just a moment ago

### Introduction

CDISC Controlled Terminology Package 30 is ready for public review. The public review package consists of 12 documents:

- CV*
- ECG
- General*
- Laboratory Tests*
- Oncology*
- PGx
- PK
- QRS*
- SEND*
- Specimen Type/Specimen Condition
- Units of Measure
- Virology*

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.

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

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# Controlled Terminology Package 30 Public Review

- CV Terminology Team:
  - New Terms Added to Existing Codelists:
    - CVTEST, CVTESTCD.
    - CV Imaging TAUG
  - 12 changes to published terms (including 3 major changes below):
    - Retirement of Left Atrium Dimension (C99970) – Please use CVTEST = Major Axis Cross-sec Diameter, EVS with a LOC = HEART, LEFT ATRIUM. This measurement is also typically performed with an echocardiography view of "apical 4-chamber view".
    - Retirement of Left Ventricle Dimension, End-Diastole (C99976) - Please use CVTEST=Minor Axis Cross-sec Diameter, EVD and LOC = HEART, LEFT VENTRICLE.
    - Retirement of Left Ventricular Dimension, End-Systole (C99977) - Please use CVTEST=Minor Axis Cross-sec Diameter, EVS and LOC = HEART, LEFT VENTRICLE.

# Controlled Terminology Package 30 Public Review

- ECG Terminology Team:
    - New Terms Added to Existing Codelists:
        - EGSTRESC; EGLEAD.
    - 12 changes to published terms:
        - None significant (add/remove synonym and update definition)

# Controlled Terminology Package 30 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - CONROL, DTHDXCD, DIR, DISCHDX, FREQ, GNRLOBSC, METHOD, RETEST-CD, RPTEST-CD, SCTEST-CD, SRTEST-CD, TSPARM-CD, URNSTS-CD, VSTEST-CD.
    - Duchenne Muscular Dystrophy, Kidney Transplant, and Vaccines TAUGs.
  - 5 changes to published terms (including 2 major changes below):
    - The SDTM DDTEST and DDTESTCD codelist short names are being changed to DTHDX and DTHDXCD. SEND had previously published its own DDTEST and DDTESTCD codelists and we cannot have multiple codelists with the same name but different c-codes.

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# Controlled Terminology Package 30 Public Review

- Lab Terminology Team:
  - New Terms Added to Existing Codelists:
    - LBTEST, LBTESTCD, MITEST, MITESTCD, MIFTSDTL.
    - Kidney Transplant TAUG.
  - New Codelist:
    - AJCCGRD – response values to support a new MIFTSDTL term AJCC TUMOR GRADE
  - 24 changes to published terms (including 1 major change below):
    - Retirement of Reticulocyte Distribution Width (C114218) - RDWr is done as a relative and absolute count. This term is too vaguely defined to determine which it belongs to. Therefore this will be retired and two new terms will be created.

# Controlled Terminology Package 30 Public Review

- SPECTYPE/SPECCOND (Lab) Terminology Team:
  - New Terms Added to Existing Codelist:
    - SPECCOND.

- Unit (Lab) Terminology Team:
  - New Terms Added to Existing Codelist:
    - UNIT.

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# Controlled Terminology Package 30 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - TUIDRS, TRTEST, TRTESTCD, ONCRTS-CD.
    - Prostate Cancer TAUG.
  - 3 changes to published terms (including 2 major changes below):
    - The submission value of BRUGGERMAN MRD 2010 is changing to BRUGGEMANN MRD 2010 – spelling error.
    - The submission value of HARTMANN PANCREATIC CANCER 2012 is changing to HARTMAN PANCREATIC CANCER 2012 – spelling error.

# Controlled Terminology Package 30 Public Review

- PGx Terminology Team:
  - New Terms Added to Existing Codelists:
    - BSTEST, BSTESTCD, PFTEST, PFTESTCD, PGTEST, PGTESTCD.
  - New Codelist
    - GENRCAT - Pharmacogenomics/Genetics Findings Result Category codelist to support the PFRESCAT variable.
  - 1 change to published terms:
    - None significant (add/remove synonym and update definition)

# Controlled Terminology Package 30 Public Review

- PK Terminology Team:
  - New Terms Added to Existing Codelists:
    - PKPARM, PKPARMCD.

# Controlled Terminology Package 30 Public Review

- QRS Terminology Team:
  - New Codelists:
    - CGI GUY, CGI, and PGI --TEST and --TESTCD.
  - 9 changes to published terms:
    - Retirement of the terminology to support the Clinical Global Impression Questionnaire (CGI). The TEST, TESTCD codelists and CAT value are being retired and replaced with 3 new instruments, the CGI GUY, CGI and PGI. Please refer to the ReadMe tab of the QRS P30 public review file for more information.

# Controlled Terminology Package 30 Public Review

- SEND Terminology Team:
  - New Terms Added to Existing Codelists:
    - SPEC, OMTEST, OMTESTCD.
  - 9 changes to published terms (including 1 major change below):
    - Sponsor's Reference ID (C90457) is being retired from codelist and replaced with Sponsor's Study Reference ID (CNEW). The intention of this term was always to capture 'The reference identifier by which the study is known to the sponsor.' The published term and definition does not adequately capture this semantic meaning, and in fact defines something different. Therefore C90457 will be removed from the codelist and a new term will be created with the more precise semantic meaning.

# Controlled Terminology Package 30 Public Review

- Virology Terminology Team:
  - New Terms Added to Existing Codelists:
    - MICROORG, MBTEST, MBTESTCD.
  - 9 changes to published terms (including 5 major changes below):
    - ASTROVIRUS (C112231), CALICIVIRUS (C14304), CORONAVIRUS (C113205), FILOVIRUS (C112031), ADENOVIRUS (C14179) submission values are changing. These terms are defined at the family-level hence the submission values as published are incorrect. The submission values will be changing such that the end of the term changes from –VIRUS to –VIRIDAE, in order to follow ICTV and NCBI Taxonomies (E.g., ASTROVIRUS -> ASTROVIRIDAE).

# Strength *through collaboration.*

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

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

# Q&A

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# CDISC Online Education & Event Updates

John Ezzell, CDISC

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# Upcoming Webinars

| Topics | Presenters | Webinar Date |
|---|---|---|
| CDISC Members Only Mini-Training - Considerations in Submitting Data not Modeled in the SDTMIG | Fred Wood, Accenture Jerry Salyers, Accenture | 06 APR 2017, 11:00 AM EST |
| CDISC Members Only Mini-Training - Demystifying Biomarkers | Jonathan Neville, Critical Path Institute Bess LeRoy, CDISC | 11 MAY 2017, 11:00 AM EST |

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

# Standard currently out for review

- Vaccines TA User Guide v1
  - Comments Due by: 21 Apr 2017

- BRIDG v5.0
  - Comments Due by: 1 May 2017

- Define XML v2.1
  - Comments Due by: 5 May 2017

- Controlled Terminology, Package 30
  - Comments Due by: 24 Apr 2017

# UPCOMING NORTH AMERICA PUBLIC COURSES

| Location | Dates | Courses Offered: | Discount period ends: | Late fees kick(ed) in: | Host |
|----------|-------|------------------|------------------------|-------------------------|------|
| South San Francisco, CA | 15-19 May 2017 | SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, Controlled Terminology | 13 Feb 2017 | 15 Apr 2017 | PointCross |
| Toronto, ON | 5-9 Jun 2017 | SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML | 6 Mar 2017 | 5 May 2017 | McDOUGALL SCIENTIFIC INSIGHTS YOU CAN TRUST |
| Whippany, NJ | 17-21 Jul 2017 | SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML | 18 Apr 2017 | 18 Jun 2017 | BAYER Bayer HealthCare |

*Visit cdisc.org/public-courses for information on other CDISC Public Training events.*

# UPCOMING EUROPE PUBLIC COURSES

| Location | Dates | Courses Offered: | Discount period ends | Late fees kick(ed) in: | Host |
|---|---|---|---|---|---|
| London, UK | 24-28 Apr 2017 | See web. | 24 Feb 2017 | 24 Mar 2017 | CDISC |
| Frankfurt, Germany | 19-23 Jun 2017 | SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A | 20 Mar 2017 | 20 May 2017 | CLINIPACE WORLDWIDE |
| 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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CDISC — 2017 Europe Interchange — LONDON · ENGLAND 24–28 April 2017

# UPCOMING ASIA PUBLIC COURSES

| Location | Dates | Courses Offered | Discount period ends: | Late fees kick(ed) in: | Host |
|----------|-------|-----------------|----------------------|------------------------|------|
| Tokyo, Japan | 5-9 Jun 2017 | SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, ODM | 14 Jun | 5 May | Croit |
| Beijing, China | 18-20 Sep | SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML | TBD | TBD | TBD |

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**CDISC** 2017 Japan Interchange  TOKYO • JAPAN 13–15 June 2017

*Any more questions?*

*Thank you for attending this webinar.*

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**Inform Patient Care & Safety Through Higher Quality Medical Research**

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