

# CDISC Controlled Terminology

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



# Panelists

- Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC
- Chris Gemma, Project Manager, CDISC



## 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?



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# Controlled Terminology Agenda

- Package 35 Publication Release (2018-09-28)
  - Changes post-public review
- Package 36 Public Review (2018-09-14 to 2018-10-12)
  - 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			
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	CV	Device	ECG	General
32						Glossary	Lab	Microbiology	Oncology
32						PK	Protocol Entities	SEND	Spectype Speccond
						Unit			
33	12/15/2017	12/22/2017	1/19/2018	2/16/2018	3/30/2018	CV	ECG	General	Lab
33						Microbiology	Oncology	PK	Protocol Entities
33						SDTM Domain Abbreviations	SEND	Spectype Speccond	Unit
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				
37									
37									
38	3/15/2019	3/22/2019	4/29/2019	5/24/2019	6/28/2019				
38									
38									
39	6/14/2019	6/21/2019	7/19/2019	8/16/2018	9/27/2019				

9/18/2018

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

The slide features ten blue, four-pointed stars arranged in a circular pattern around the central text. The stars are evenly spaced and have a slight glow effect.

Controlled Terminology  
Package 35 Publication Release



# Publication Overview



- Updates to **SDTM**, **SEND**, **CDASH** and **Protocol Terminology**.
- Therapeutic Area Support:
  - QRS Terminology to support: **Bipolar and General Anxiety Disorder, Huntington's Disease, and Lung Cancer** Therapeutic Area User Guides.
  - SDTM Terminology to support: **Colorectal Cancer, CV Imaging, HIV, Huntington's Disease, Lung Cancer, Nutrition, and PTSD** Therapeutic Area User Guides.





# Significant Changes Post-Public Review



- Lab Terminology Team:

- Proposed new LBTESTCD NUCCELL has already been published in the codelist.
- Proposed new LBTESTCD submission value IGGIDX changed to CSFIGIDX for clarity.
- Proposed new LBTESTCD submission value MNUCCE changed to MNC for consistency.
- Proposed new LBTEST/CD of Calcium, Total Protein Corrected/CACRTP already exists in published CT as C147314.
- METHOD: PALM METHOD and CONTRAST-ENHANCED X-RAY were listed twice.
- METHOD: Proposed new term VQ SCAN already exists in codelist as VENTILATION PERFUSION LUNG SCAN/ C38100. Instead we have added 'VQ Scan' as a synonym to the existing term.



# Significant Changes Post-Public Review



- Microbiology Terminology Team:
  - Proposed new MBTESTCD submission value ADENOVAB changed to ADENOVAG since the term was capturing the Antigen, not the Antibody.
- PK Terminology Team:
  - Proposed new PKPARMCD submission value CLRPCLOR changed to CLRPCLEV since the PKPARM is changing from Renal CL as Pct CL Oral to Renal CL as Pct CL EV (Extravascular Administration).
- SEND Terminology Team:
  - The proposed codelist TAPHSCLS, which was to be the response codelist for the TSPARM value of 'Test Article Physical Substance Class' is being removed from consideration for publication within this package and will be considered for a future release. The requester needs to reconsider the response values.



# Significant Changes Post-Public Review



- ECG Terminology Team:
  - Proposed submission values for EGMETHOD were upper-cased to follow convention.
- General Terminology Team:
  - Proposed new RELSUB of SON, BIOLOGICAL already exists in codelist as C150888.
  - Proposed new RELSUB of DAUGHTER, BIOLOGICAL already exists in codelist as C150887.
  - Proposed new LOC of CALCANEUM already exists in codelist as CALCANEUS/C32250. Instead we have added 'Calcaneum' as a synonym to the existing term.



# Significant Changes Post-Public Review

- Other, less significant changes\* also made in:
  - General, Lab, PK, SEND
- No changes made to:
  - Devices
  - Oncology
  - PGx
  - Protocol Entities
  - SDTM Domain
  - 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 35 Publication Release

- **New Codelists:**
  - **Questionnaire (QS)**
    - Functional Assessment of Chronic Illness Therapy-Dyspnea Scale 33 Item Bank Questionnaire (Lung Cancer TAUG)
    - Functional Assessment of Cancer Therapy-Bladder Version 4 Questionnaire (Sponsor request)
    - Non-Small Cell Lung Cancer Symptom Assessment Questionnaire v1.0 Questionnaire (Lung Cancer TAUG)
    - Symptoms of Major Depressive Disorder Scale v1.0 Questionnaire (Sponsor request)
  - **Clinical Classification (RS)**
    - Children's Depression Rating Scale, Revised Clinical Classification (Bi-Polar and GAD TAUGs)
    - Unified Huntington's Disease Rating Scale '99 Clinical Classification (Huntington's Disease TAUG)
    - Hamilton Anxiety Rating Scale (Sponsor request)



# Controlled Terminology Package 36 Public Review



# P36 Public Review



Pages / Controlled Terminology / Public Review

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## Terminology Call for Public Review Package P36 - Comments Due by 12 October 2018

Created by Chris Gemma, last modified by Erin Muhlbardt on Sep 19, 2018

### Introduction

CDISC Controlled Terminology Package 36 is ready for public review. The public review package consists of 12 documents:

- Device
- General
- General Codetable Mapping
- CDISC Glossary\*
- Laboratory Terms\*
- Microbiology
- Oncology
- PK
- SDTM Domain\*
- SEND
- SPECTYPE SPECCOND
- Units of Measure

An \* 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 as they may be submission value changes or term deprecations.

### 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.
6. Click the "Create" button in the bottom right corner of the form to submit.

Next to the "Create" button is an option to "Create another". If this is checked, clicking "Create" will submit your comment and bring up a new Create Issue form with the same project and review type. This can be handy if you have multiple comments to enter.

# Controlled Terminology Package 36 Public Review

- Medical Devices Terminology Team:
  - New Terms Added to Existing Codelists:
    - DOTEST-CD; DUTEST-CD
    - To support Huntington's Disease TAUG.
  - No changes to existing terms





# Controlled Terminology Package 36 Public Review

## General Terminology Team:

- New Terms Added to Existing Codelists:
  - ETHNICC, FREQ, FRM, GASTRO-CD, LOC, MARISTAT, MODTRN, NCOMPLT, NVTEST-CD, PROCEDUR, RACE, RACEC, RETEST-CD, RPTEST-CD, ROUTE, SCTEST-CD, TBLIND, TSPARM-CD, VSTRESU, VSTEST-CD
  - To support PTSD and HIV TAUGs.
- No New Codelists
- Updates to Codetable mapping Files
  - These are in a separate file to the General PR file
  - SC, TS, VS, RACEC\_RACE, ETHNICC\_ETHNIC
- 5 changes to published terms: None significant (update definitions and add synonyms)



# Controlled Terminology Package 36 Public Review



- Glossary Terminology Team:
  - 60 New Terms Added to the CDISC glossary:
  - 31 changes to published terms (including 16 significant changes):
    - Updates to 15 preferred terms
      - To ensure that the granularity of the terms matches the granularity of the definition
      - For consistency with other terms of the same type
    - Removal of 'investigational treatment': The glossary has many other similar terms that are used more frequently. The team is not convinced that it is significantly different enough from other published terms in the list to justify it as a separate term.
  - 7 New Terms Added to the Acronyms, Abbreviations, and Initials List
  - 45 changes to published Acronyms, Abbreviations, and Initials



# Controlled Terminology Package 36 Public Review



- Lab Terminology Team:
  - New Terms Added to Existing Codelists:
    - LBTEST-CD; MITS-CD; METHOD
  - 20 changes to published terms (including 4 significant changes):
    - LBTEST-CD: CYACIDU/Acid Urate Crystals -> Retire from codelist. This will be merged into Uric Acid Crystals/CYURIAC (C74684)
    - LBTEST-CD: THYAMAB/Thyroid Antimicrosomal Antibodies -> Retire from codelist. This is synonymous with Thyroperoxidase Antibody/THYPXDAB (C81991). C81991 will be merged into C96638. Please use C96638 instead of C81991.



# Controlled Terminology Package 36 Public Review

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



# Controlled Terminology Package 36 Public Review

- Microbiology Terminology Team:
  - New Terms Added to Existing Codelists:
    - MBTEST-CD; MSTEST-CD
  - 2 changes to published terms (none significant; updates to definition)



# Controlled Terminology Package 36 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - ONCRTS-CD, TRPROPRS, TRTSET
    - To support the Lung Cancer TAUG
  - 5 change to published terms: None significant (add synonym, update definition)
  - Updates to Codetable mapping Files
    - TUTEST-CD\_TUIDRS Mapping
    - TRTEST-CD\_TRPROPRS Mapping
    - ONCRTS-CD\_ONCRSR Mapping
    - RS\_RANO Mapping
    - RS\_RECIST1.1 Mapping
    - RS\_iRECIST Mapping



# Controlled Terminology Package 36 Public Review

- PGx Terminology Team:
  - New Terms Added to Existing Codelists:
    - PFTEST-CD
    - To support the Huntington's Disease and Lung Cancer TAUGs.
  - No changes to existing terms



# Controlled Terminology Package 36 Public Review

- PK Terminology Team:
  - New Terms Added to Existing Codelists:
    - **PKPARAM-CD**
  - No changes to existing terms





# Controlled Terminology Package 36 Public Review

- SDTM Domain Abbreviations Terminology Team:
  - New Terms Added to Existing Codelists:
    - DOMAIN
  - 1 change to published terms (including 1 significant changes)
    - DOMAIN: SUPPBW -> Remove from codelist. A number of special purpose SUPP domains were published in error. Special purpose domains are not allowed to have supplemental datasets as per the SDTMIG3.2. Additionally BW is not an SDTM domain.



# Controlled Terminology Package 36 Public Review



- SEND Terminology Team:
  - New Terms Added to Existing Codelists:
    - NEOPLASM SNDIGVER, PPTMDARS
  - 8 changes to published terms (including 1 major change):
    - NEOPLASM: HISTIOCYTOMA, FIBROUS, MALIGNANT -> Submission value changing from HISTIOCYTOMA, FIBROUS, MALIGNANT to FIBROSARCOMA, PLEOMORPHIC, MALIGNANT. Sponsors should be migrating to the use of INHAND terminology and the INHAND publication indicates that 'Fibrosarcoma, Pleomorphic' is the preferred term.



# Controlled Terminology Package 36 Public Review

- CV Terminology Team:
  - No public review files
- ECG Terminology Team:
  - No public review files
- Protocol Entities Terminology Team:
  - No public review files
- QRS Terminology Team:
  - No public review files





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

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## Q&A




# CDISC Education: Upcoming Learning Opportunities

Saad Yousef



# UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Host
Bethesda, MD	8-12 Oct 2018	SDTM, SDTM-MD, ADaM, Define-XML, CDASH, SDTM 'Diff;', SHARE Workshop	-	
Seattle, WA	29 Oct – 2 Nov	SDTM, Define-XML, CDASH, ADaM	-	

*Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.*

The 2019 CDISC Public Training Schedule is being put together. We will have training events in Gaithersburg, MD, Chicago, IL, the Bay Area, Durham, NC, Princeton, NJ, San Diego, CA, and more.



# UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Host
Copenhagen, Denmark	8-16 Nov 2018	SDTM, SEND, ADaM, Define-XML	8 Aug 2018	 S-CUBED
Reading, UK	21-25 Jan 2019	SDTM, CDASH, ADaM, Define-XML	22 Oct 2018	 IQVIA™
Madrid, Spain	11-15 Feb 2019	SDTM, CDASH, ADaM, Define-XML	12 Nov 2018	 GEICAM spanish breast cancer group
Amsterdam, Netherlands	6-10 May 2019	SDTM, SDTM-MD, SEND, ADaM, Define-XML, ODM, Controlled Terminology, CDASH, CDISC for Newcomers	TBD	 CDISC
Frankfurt, Germany	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	4 Mar 2019	

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# UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Host
Tokyo, Japan	21-25 Jan 2019	SDTM, CDASH, ADaM, Define-XML	21 Oct 2018	
Osaka, Japan	3-7 Jun 2019	SDTM, CDASH, ADaM, Define-XML	3 Mar 2019	
Tokyo, Japan	2-6 Sep 2019	SDTM, CDASH, ADaM, Define-XML	2 Jun 2019	

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# Upcoming Webinars

Date	Webinar Title
18 Oct	<a href="#"><u>CDISC Standars Public Webinar: Nutrition TAUG Public Review</u></a>
25 Oct	<a href="#"><u>CDISC Members-Only Mini-Training Series - ODM v2 Overview</u></a>
13 Dec	<a href="#"><u>CDISC Members Only Mini-Training Series: Disease Milestones</u></a>
8 Jan 2019	<a href="#"><u>Controlled Terminology Mapping/Alignment Across Codelists</u></a>

Learn more at <https://www.cdisc.org/events/education/webinars>.



Thank you for your attendance and support of CDISC!



## Q&A

