



# CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt and Chris Gemma  
01.09.2019





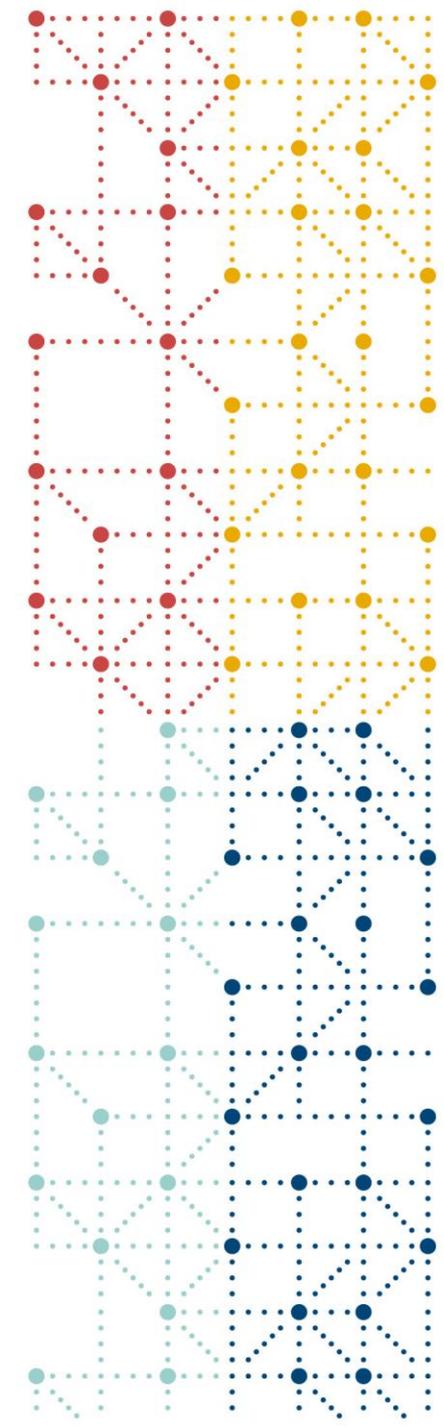
# Controlled Terminology P36 Publication and P37 Public Review

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01.09.2019





## Question & Answer

1. 'Panelist': Question

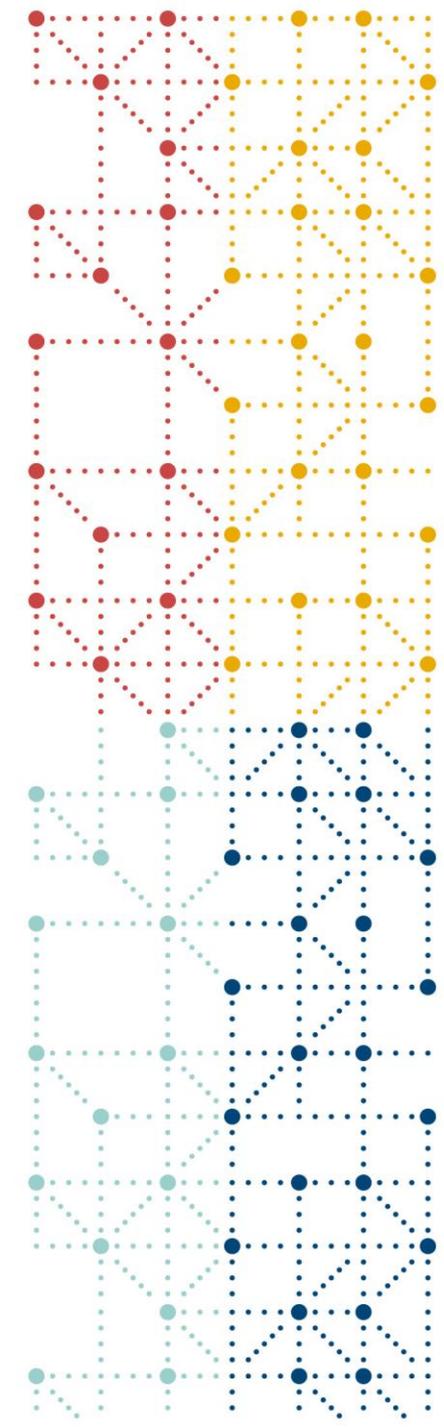
OR

1. 'Presentation': Question

Examples:

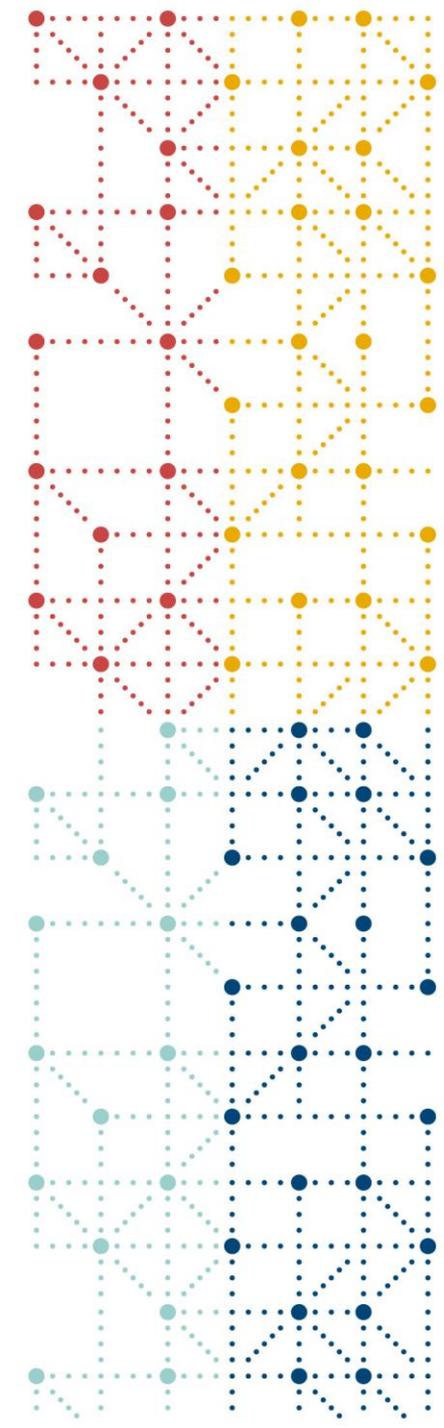
1) What should be supported by ADaM datasets?

2) Jack: Is there a limit to the number of variables that can be in ADSL?



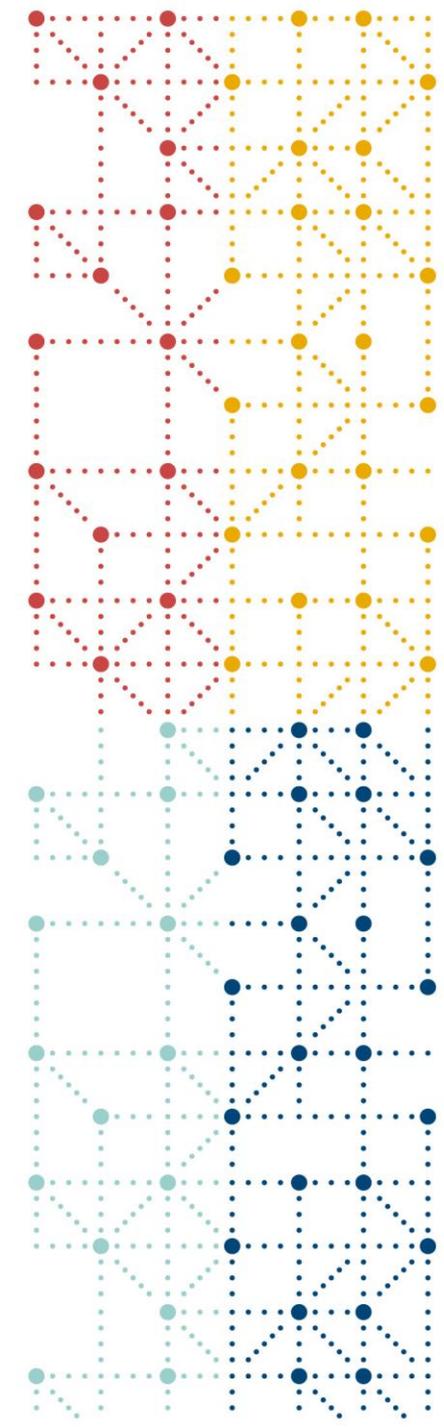
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# Agenda

1. Package 36 Publication Release (2018-12-21)
  - Changes post-public review
2. Package 37 Public Review (2018-12-21 to 2019-01-18)
  - New Additions
  - Changes to existing
3. Questions



# Controlled Terminology Package 36 Publication

2018-12-21

# 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			
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	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				
38									
38									
39	6/14/2019	6/21/2019	7/19/2019	8/16/2019	9/27/2019				
39									
39									
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019				
40									
40									



# Controlled Terminology Package 36 Publication Release

- Updates to **SDTM, SEND, CDASH, ADaM and Glossary Terminology.**
- **Therapeutic Area Support:**
  - QRS Terminology to support: **Major Depressive Disorder Therapeutic Area User Guide.**
  - SDTM Terminology to support: **Lung Cancer, HIV, Huntington's Disease, and Post-Traumatic Stress Disorder Therapeutic Area User Guides.**



# Significant Changes Post-Public Review

- Lab Terminology Team:
  - LEAD is already published in CDISC lab codelist. Will not be added a second time.
- General Terminology Team:
  - BRACHIUM will not be added as a new term to the LOC codelist. The general CT team, upon discussion with EVS anatomists, agree that the correct medical definition of the concept of 'Arm' means the upper arm. Therefore we will not add a new term but rather add synonyms to the existing term 'ARM' as well as updating the definition to make clearer the term's usage.
  - DBTWMENN/Number of Days Between Menses will not be added as a new term to the RPTTESTCD/RPTTEST codelist. This term was found to be definitionally identical to the existing term MENS DUR as a result of a public review comment.



# Significant Changes Post-Public Review

- SEND Terminology Team:

- THECOMA, BENIGN will not be added as a new term to the NEOPLASM codelist yet. THECOMA, BENIGN currently exists as a submission value in that codelist but is an Ovary-specific term. The SEND team will need to discuss re-coding and/or retirement of the existing term with P38.

- Glossary Team:

- 'data integrity' was proposed as a new term with P36 but was found to already exist as C142476 so the definition of the existing term was updated instead.
- 'study monitoring' was proposed as a new term with P36 but was found to already exist as C142707 so the Glossary preferred term of that existing term will be updated instead.
- The Glossary preferred term of 'monitoring' was updated to be 'study monitoring' to ensure consistency and clarity with the concept that is being defined.



# Significant Changes Post-Public Review

- Other, less significant changes\* also made in:
  - General, Lab, SEND, Glossary
- No changes made to:
  - Devices
  - Microbiology
  - Oncology
  - PK
  - SDTM Domain
  - 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.**



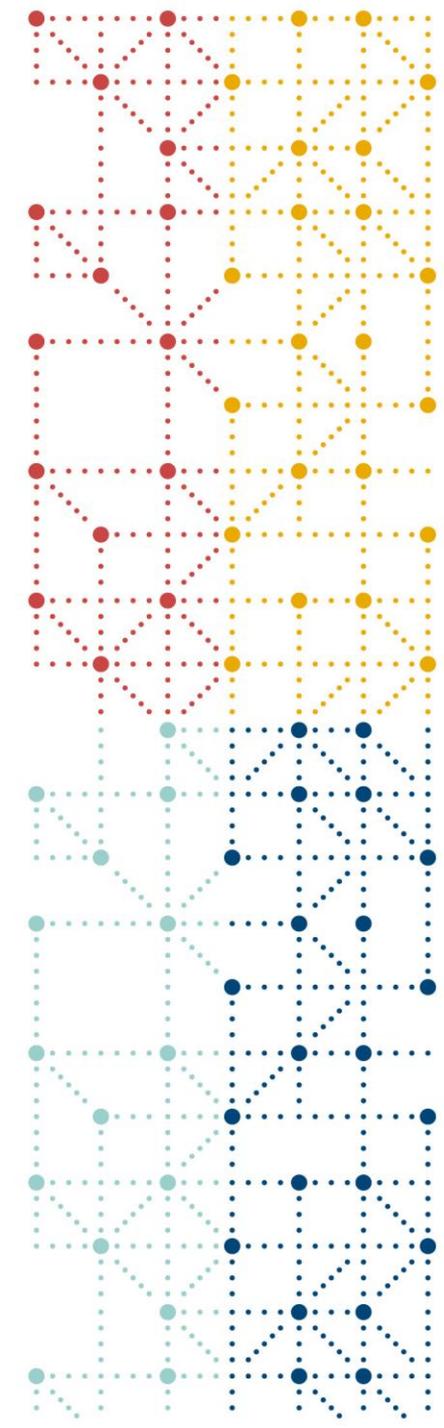
# QRS Controlled Terminology Package 36 Publication Release

- New Codelists:
  - **Clinical Classification (RS)**
    - COVI Anxiety Scale Clinical Classification (Major Depressive Disorder TAUG)



# Format issues associated with CDISC publication 2018-12-21 ->

- During the production of CDISC terminology Package 36 publication, a text file with aberrant quotations was used to generate the odm.xml and OWL/RDF formats of CDISC terminology version 2018-12-21
- This affects the ADaM, CDASH, Glossary, SDTM, and SEND terminologies.
- The .xls, .html, and .pdf formats were not affected.
- Therefore the .txt, odm.xml, and .OWL/RDF file formats for the 2018-12-21 publication was replaced on the NCI Ftp site on 2019-01-07.



# Controlled Terminology Package 37 Public Review

2018-12-21 – 2019-01-18



# Terminology Call for Public Review Package P37 - Comments Due by 18 January 2019

Created by Chris Gemma on Dec 19, 2018

## Introduction

CDISC Controlled Terminology Package 37 is ready for public review. The public review package consists of 13 documents:

- Device
- ECG
- General\*
- Laboratory Terms\*
- Microbiology
- Oncology\*
- Rules for Oncology
- PK
- QRS\*
- SEND\*
- SEND Animal Rule
- SPECTYPE SPECCOND
- Units of Measure\*
- P37 Requests Denied

An \* indicates that changes to existing CDISC Submission Values are included on the "Changes to Existing" tab in the document. Please review these changes as there 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 ha

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P37++Comments+Due+by+18+January+2019>

# Controlled Terminology Package 37 Public Review

- Medical Devices Team
  - New Terms Added to Existing Codelists:
    - **DOTEST-CD; DUTEST-CD**
    - **To support HIV TAUG.**
  - No changes to existing terms



# Controlled Terminology Package 37 Public Review

- ECG Terminology Team
  - New Terms Added to Existing Codelists:
    - EGMETHOD
  - No changes to existing terms

# Controlled Terminology Package 37 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - ETHNICC; FRM; LOC; MUSCTS/CD; NVTEST/CD; OETEST/CD; PROCEDUR; RACEC; RPTEST/CD; SCTEST/CD; TSPARM/CD; TTYPE; VSTEST/CD
    - To support the Huntington's Disease and HIV TAUGs.
  - 8 changes to published terms: Including 2 significant changes (detailed on next slide)
  - Updates to Codetable mapping Files:
    - DS\_Codetable\_Mapping
    - ETHNIC\_ETHNICC\_Mapping
    - RACE\_RACEC\_Mapping
    - SC\_Codetable\_Mapping
    - TS\_Codetable\_Mapping
    - VS\_Codetable\_Mapping

# Controlled Terminology Package 37 Public Review

- General Terminology Team Significant Changes to Existing Terms:
  - MODTRN -> The submission values for HETEROSEXUAL CONTACT and HOMOSEXUAL CONTACT shall be changed to OPPOSITE-SEX SEXUAL CONTACT and SAME-SEX SEXUAL CONTACT, respectively.
  - Reason: Request by FDA to align the submission values with preferred terminology.



# Controlled Terminology Package 37 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST/CD; METHOD; MIFTSDDL
    - To support Colorectal Cancer TAUG.
  - 19 change to published terms: Including 3 significant changes (detailed on next slide)

# Controlled Terminology Package 37 Public Review

- Laboratory Terminology Team Significant Changes to Existing Terms:
  - Submission value changes:
    - C154753/Calcium, Albumin Corrected LBTEST submission value to be changed to Calcium Corrected for Albumin (for consistency).
    - C154736/E-selectin LBTEST submission value to be changed to E-Selectin (to correct a naming error).
  - Retirement of a term:
    - C100426/Beta-Trace Protein/BTP will be removed from the codelist. C100426 is synonymous with C103432/Prostaglandin D2 Synthase. We will add 'Beta-Trace Protein' as a synonym to existing published concept Prostaglandin D2 Synthase.



# Controlled Terminology Package 37 Public Review

- Laboratory Terminology Team (Specimens)
  - New Terms Added to Existing Codelists:
    - **SPECCOND; SPECTYPE**
  - 3 Changes to existing terms: None significant (synonym additions).

# Controlled Terminology Package 37 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
    - To support Huntington's Disease TAUG.
  - 4 Changes to Existing terms: 1 significant
    - Retirement of C71480/cycle/sec. This concept will be merged with C42545/ Hz (Hertz). Outside of the electromagnetic context, we cannot see a use for a generic cycles/sec term.



# Controlled Terminology Package 37 Public Review

- Microbiology Terminology Team
  - New Terms Added to Existing Codelists:
    - MBTEST/CD; MSTEST/CD; ISTEEST/CD
    - To support HIV and SEND Animal Rule TAUGs.
  - No changes to existing terms

# Controlled Terminology Package 37 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - ONCRSCAT, ONCRSR
  - 13 change to published terms: Including 2 significant changes (detailed on next slide)
  - Updates to Codetable mapping Files:
    - TU\_Codetable\_Mapping
    - TR\_Codetable\_Mapping
    - RS\_ONC\_Codetable\_Mapping
    - RS\_RAJKUMAR\_MM\_Codetable\_Map
  - Oncology CT Rules Document

# Controlled Terminology Package 37 Public Review

- Oncology Terminology Team Significant Changes to Existing Terms:
  - **UNEQUIVOCAL PROGRESSION** and **PRESENT WITHOUT UNEQUIVOCAL PROGRESSION** are being removed from the TRPROPRS codelist.
  - Reason: Unequivocal progression is a judgement on non-target lesion/tumors taken collectively. It is not an individual lesion/tumor level assessment. In RS, PD will continue to be used; it was noted that unequivocal progression is not synonymous because it is context dependent. Please use 'PRESENT' instead. Please refer to the draft Oncology CT Rules document in P37 for additional information.



# Controlled Terminology Package 37 Public Review

- PK Terminology Team
  - New Terms Added to Existing Codelists:
    - PKPARAM/CD
  - 3 Changes to Existing Terms: None significant (definition updates, synonym additions).



# Controlled Terminology Package 37 Public Review

- QRS Terminology Team
  - New Terms Added to New Codelists
    - QRSMTHOD
    - GDS02PC/PN – to support analysis
  - 14 Changes to existing terms: all significant.
    - The Boy and Girl Tanner scales are no longer considered QRS instruments and instead it is recommended that they be represented in the RP domain. Please see the RPTTEST-CD tab in the General P37 public review file for new test values.

# Controlled Terminology Package 37 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - NONNEO; SRETST/SRETSTCD; FXFINDRS
  - 8 change to published terms: Including 5 significant changes
    - NEOPLASM codelist:
      - The submission value of C4247/HISTIOCYTOMA, FIBROUS, MALIGNANT will be changing to FIBROSARCOMA, PLEOMORPHIC, MALIGNANT. FIBROSARCOMA, PLEOMORPHIC, MALIGNANT is the INHAND preferred term so SEND will adopt that as their own submission value.
      - The NCI c-code for PITUICYTOMA, BENIGN/C7157 will be changing to C94524. The NCI preferred term will be changing to Pituicytoma. This was determined to be a better mapping.
      - The NCI c-code for TERATOMA, MALIGNANT/C4286 will be changing to C4287. The NCI preferred term will be changing to Malignant Teratoma. This was determined to be a better mapping.

# Controlled Terminology Package 37 Public Review

- SEND Terminology Team

- 8 change to published terms: Including 5 significant changes [Cont'd.]
  - NONNEO Codelist:
    - MESENCHYMAL PROLIFERATIVE LESION, BENIGN is no longer considered a neoplasm and as such will be moving to the NONNEO codelist.
    - The CDISC submission value for C120868/BASOPHILIC GRANULES will be changing to BASOPHILIC GRANULES, ANTISENSE OLIGONUCLEOTIDE. Since Basophilic Granules can be seen due to other conditions (besides being induced by treatment with antisense oligonucleotide) the CDISC submission value is being updated to align better with the intended meaning described in the definition.



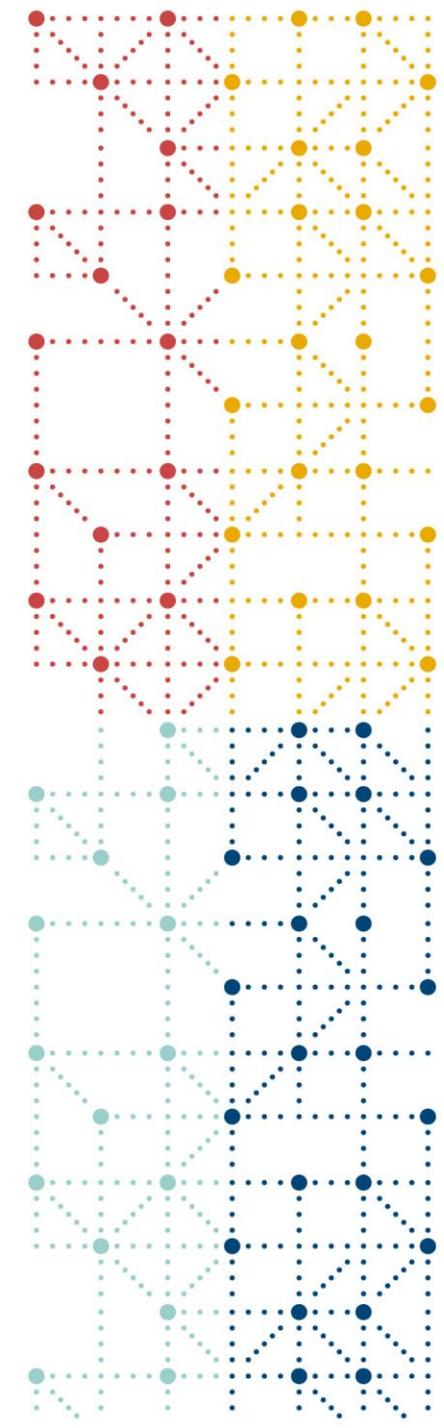
# Controlled Terminology Package 37 Public Review

- SEND Animal Rule Terminology Team (to support the Animal Rule TAUG)
  - New Terms Added to Existing Codelists:
    - SBCSND/SBCSND CD; SSTYP; STSPRM/STSPRM CD
  - New terms added to new codelists:
    - SEXMAT; STRPSTAT; TRTTYP; ACPARM-CD; CAGTCAT; BACAT; CHAGCAT; RNASRC; RANIOTYP; AGESMETH; AGE CAT; RSTMODRS; DVDECOD.
  - No changes to existing terms



# Controlled Terminology Package 37 Public Review

- CV Terminology Team:
  - No public review files
- 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
- SDTM Domain Team:
  - No public review files

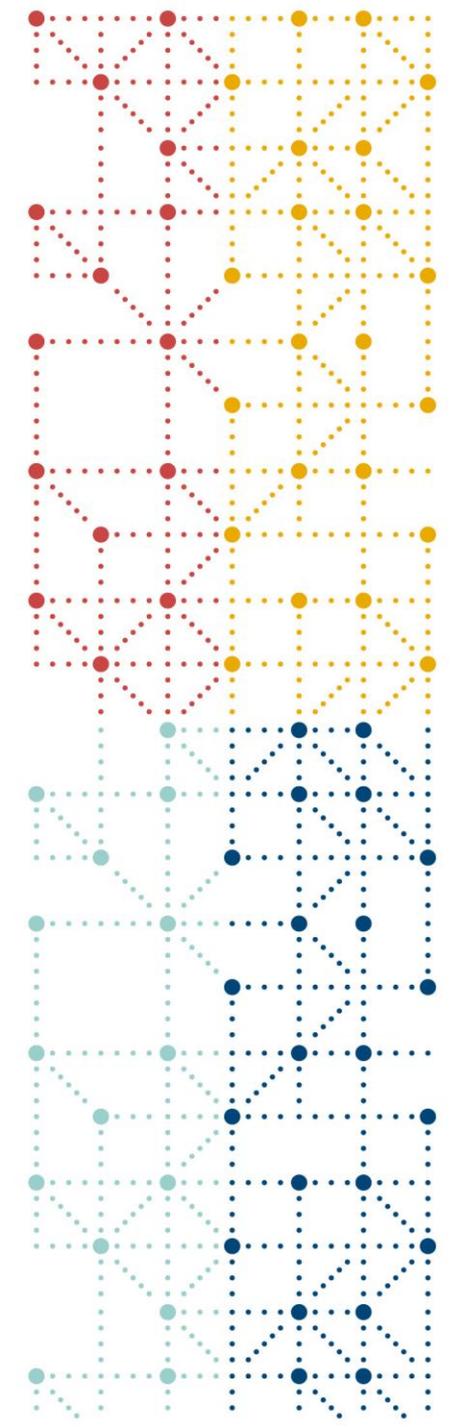


**If you are interested in contributing  
to the CDISC Terminology Initiative,  
please contact us...**

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\*The CDISC glossary team is actively recruiting!





Q&A



# CDISC Education: Upcoming Learning Opportunities

Saad Yousef





Thank you for your attendance and support of  
CDISC!