

Controlled Terminology Updates for Q3 – P41a-P42-P43

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC



Tuesday, 2020-07-07
11:00 – 12:30 EDT



Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



Housekeeping



Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
 - To access – make sure that you create a login for the CDISC website if you haven't already
 - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!



Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



Our Presenters

- Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC

CDISC Controlled Terminology

Presented by Dr. Erin Muhlbradt
07.07.2020





Controlled Terminology P41a and P42 Publications; P43 Public Review

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC Inc.

07.07.2020

cdisc



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. Package P41a Publication Release (2020-05-08)
2. Package 42 Publication Release (2020-06-26)
 - Changes post-public review
3. Package 43 Public Review (2020-06-19 to 2020-07-19)
 - New Additions
 - Changes to existing
4. Questions



Controlled Terminology Package 41a Publication

2020-05-08

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			
39	6/14/2019	6/21/2019	7/19/2019	8/16/2019	9/27/2019	Devices	ECG	General	Lab
39						Microbiology	Oncology	PK	Protocol Entities
39						SDTM Domain	SEND	SEND-AR	Unit
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019	ADaM	Define-XML	Device	General
40						CDISC Glossary	Lab	Microbiology	Oncology
40						PK	Protocol Entities	QRS	SDTM Domain
40						SEND	Spectype Speccond	Unit	
41	12/13/2019	12/20/2019	1/17/2020	2/14/2020	3/27/2020	ADaM	Define-XML	Device	ECG
41						General	Lab	Microbiology	Oncology
41						PK	Protocol Entities	QRS	SDTM Domain
41						SEND	Spectype Speccond	Unit	
41a	4/20/2020	n/a	n/a	n/a	5/8/2020	CDASH	CDISC Glossary	General	Lab
41a						Microbiology	PK	QRS	Spectype Speccond
41a						Unit			
42	3/13/2020	3/20/2020	4/17/2020	5/15/2020	6/26/2020	ADaM	Define-XML	Device	General
42						Lab	Microbiology	Oncology	PK
42						Protocol Entities	QRS	SEND	Unit
43	6/12/2020	6/19/2020	7/17/2020	8/14/2020	9/25/2020				
43									
43									
44	9/11/2020	9/18/2020	10/16/2020	11/13/2020	12/18/2020				
44									
44									

4/21/2020

Dates in red are planned and may be adjusted slightly.

Controlled Terminology Package 41a Publication Release

- Updates to SDTM, SEND, CDASH, and CDISC Glossary Terminology
- CDISC CT Version Date: 2020-05-08
- Therapeutic Area Support:
 - QRS Terminology to support: COVID-19 Therapeutic Area User Guide.
 - SDTM/CDASH/Glossary Terminology to support: COVID-19 Therapeutic Area User Guide.

Controlled Terminology Package 41a Publication Release

- General Terminology Team:
 - New Terms Added to Existing Codelists:
 - PROCEDUR; RETEST-CD; SCTEST-CD; TSPARM-CD; VSTEST-CD; RACEC
 - 4 New Codelists:
 - Health Care Encounters Dictionary Derived Term (HODECOD)
 - Mode of Subject Contact (CNTMODE)
 - COVID-19 Findings About Test Name (C19FAT)
 - COVID-19 Findings About Test Code (C19FATCD)
 - No changes to published terms

Controlled Terminology Package 41a Publication Release

- CDISC Glossary Team
 - 8 additions to the CDISC Glossary:
 - epidemic
 - pandemic
 - endemic disease
 - immediately life-threatening disease or condition
 - medical countermeasure
 - morbidity rate
 - mortality rate
 - pre-approval access

Controlled Terminology Package 41a Publication Release

- CDISC CDASH Terminology
 - New Terms Added to Existing Codelists: Race As Collected (RACEC)
 - To support the WHO ISARIC CRF annotation

Controlled Terminology Package 41a Publication Release

- Laboratory Terminology Team
 - New Terms Added to Existing Codelists:
 - LBTEST-CD; METHOD; CLMETH; SPECTYPE
 - 4 changes to published terms:
 - FIO2/Fraction of Inspired Oxygen: Definition updated to better differentiate this term from FIO2/PAO2
 - PO2/Partial Pressure Oxygen: Synonyms added
- Units of Measure
 - 2 changes to published terms
 - mL/24h added as a synonym to C67410/mL/day in the UNIT and PKUNIT codelists – to support the WHO ISARIC CRF annotation

Controlled Terminology Package 41a Publication Release

- Microbiology Terminology Team
 - New Terms Added to Existing Codelists:
 - MICROORG; MBTEST-CD

MBTEST-CD

SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2
SAR2IGG	SARS-CoV-2 IgG Antibody
SAR2IGM	SARS-CoV-2 IgM Antibody
SAR2IGA	SARS-CoV-2 IgA Antibody
SAR2IGGM	SARS-CoV-2 IgG/IgM Antibody
MERSRNA	MERS-CoV RNA
SAR2RNA	SARS-CoV-2 RNA
RSV	Respiratory Syncytial Virus
ADENOVIR	Adenoviridae
CRONAVIR	Coronaviridae
MERSRNA	MERS-CoV RNA
SAR2RNA	SARS-CoV-2 RNA

Controlled Terminology Package 41a Publication Release

- Microbiology Terminology Team
 - 2 changes to 1 existing term
 - MICROORG: CDISC Submission value of SARS CORONAVIRUS updated to SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS. Also 'SARS-CoV' added as a synonym to this term.
 - New terms from P42 being published early with this package:
 - MICROORG: SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2
 - MBTEST/CD: Severe Acute Resp Syndrome Coronavirus 2/SARSCOV2

QRS Controlled Terminology Package 41a Publication Release

- New Codelists:
 - **Clinical Classification (RS)**
 - National Early Warning Score 2 (NEWS2)
 - Richmond Agitation-Sedation Scale (RASS)
 - Riker Sedation-Agitation Scale (SAS)

Controlled Terminology Package 41a Publication Release

- SEND Terminology Team
 - New Terms Added to Existing Codelists:
 - LBTEST/CD; VSTEST/CD
 - 6 changes to existing terms -> LBTEST/CD, UNIT, PKUNIT as described previously

*Because SEND makes use of some SDTM terminology, SEND Terminology will also be updated with this package release to reflect changes in shared codelists.

P41a Codetable Updates

- Updates with P41a
 - RACEC_ETHNICC_Mapping
 - SC_Codetable_Mapping
 - TS_Codetable_Mapping
 - VS_Codetable_Mapping
 - Unit-UCUM_Codetable

Controlled Terminology Package 41a Publication

No Additions or Changes being proposed by the following codelist-associated teams:

- ADaM Team
- Define-XML Team
- Medical Devices Team
- ECG Terminology Team
- Oncology Terminology Team
- CDISC PGx Terminology Team
- Protocol Entities Terminology Team



Controlled Terminology Package 42 Publication

2020-06-26

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/30 days)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019	ADaM	Define-XML	Device	General
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41a	4/20/2020	n/a	n/a	n/a	5/8/2020	CDASH	CDISC Glossary	General	Lab
41a						Microbiology	PK	QRS	Spectype Speccond
41a						Unit			
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42						Lab	Microbiology	Oncology	PK
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43	6/12/2020	6/19/2020	7/19/2020	8/14/2020	9/25/2020	ADaM	ECG	General	Lab
43						Microbiology	Oncology	PGx	PK
43						Protocol Entities	QRS	SEND	Unit
44	9/11/2020	9/18/2020	10/18/2020	11/13/2020	12/18/2020				
44									
44									

6/19/2020

Dates in red are planned and may be adjusted slightly.

Controlled Terminology Package 42 Publication Release

- Updates to SDTM, SEND, ADaM, Define-XML, and Protocol Terminology
- Therapeutic Area Support:
 - QRS Terminology to support: Psoriasis and Type 1 Diabetes Therapeutic Area User Guides.
 - SDTM/SEND Terminology to support: Lung Cancer Therapeutic Area User Guides.

Significant Changes Post-Public Review

- General Terminology:
 - D1FATS-CD: Proposed TESTCD submission values changing from EXINTSTY to EXCINTSY and EXDURAT to EXCDUR
 - PROCEDUR:
 - 'EXTRACORPOREAL MEMBRANE OXYGENATION' added with P41a so no need to add to this package.
 - New concept 'HOLTER MONITORING' changed to 'HOLTER CONTINUOUS ECG RECORDING' to align with existing submission value in other codelists.
 - VSTEST-CD: The new VSTEST/CD value of Capillary Refill Time/CPLRFLT, which was published with the P41a COVID-19 publication had its c-code changed from C168165 to C168125. Mis-coded with the 2020-05-08 publication.

Significant Changes Post-Public Review

- Lab Terminology:
 - LBTEST-CD: Proposed TESTCD submission value changing from 'DOXYCLT' to 'DCA' and proposed TEST submission value changing from 'Beta and Gamma Tocopherol' to 'Beta+Gamma Tocopherol'
- METHOD:
 - Removing new term 'RESTING FUNCTIONAL MRI' from package for further discussion on how to model 'Resting' concept in SDTM.
 - Removing a number of Numerical Rating Scales, Verbal Rating Scales, Visual Analog Scales, and Likert scale terms due to modeling changes in Psoriasis TAUG.

Significant Changes Post-Public Review

- Oncology Terminology:
 - 'TRTINTNT: Term 'RADIOSENSITIZATION' moved to 'TRTSET' codelist
- PK Terminology:
 - PKPARM-CD: Proposed submission value for PKPARM changed from 'Distribution Half-Life' to 'Half-Life Distribution'

Significant Changes Post-Public Review

- Other, less significant changes* also made in:
 - Define-XML, General, Lab, Microbiology, Oncology, and Protocol Entities
- No changes made to:
 - Device
 - QRS
 - SEND
 - 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 42 Publication Release

- New Codelists:
 - **Questionnaires (QS)**
 - European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire - Lung Cancer Module Questionnaire
 - New CAT Values:
 - AJCC V8
 - EORTC QLQ-LC13
 - BIS-11
 - Significant changes to International Physical Activity Questionnaire (October 2002) Long Last 7 Days Self-Administered Format Questionnaire (IPAQ03) and International Physical Activity Questionnaire (August 2002) Short Last 7 Days Self-Administered Format Questionnaire (IPAQ04)

**CDISC is continuing to assess the development and publication of QRS response terminology. The response terminology presented in P41 public review was not published with P41 terminology publication on 2020-03-27.

P42 Codetable and Rules updates

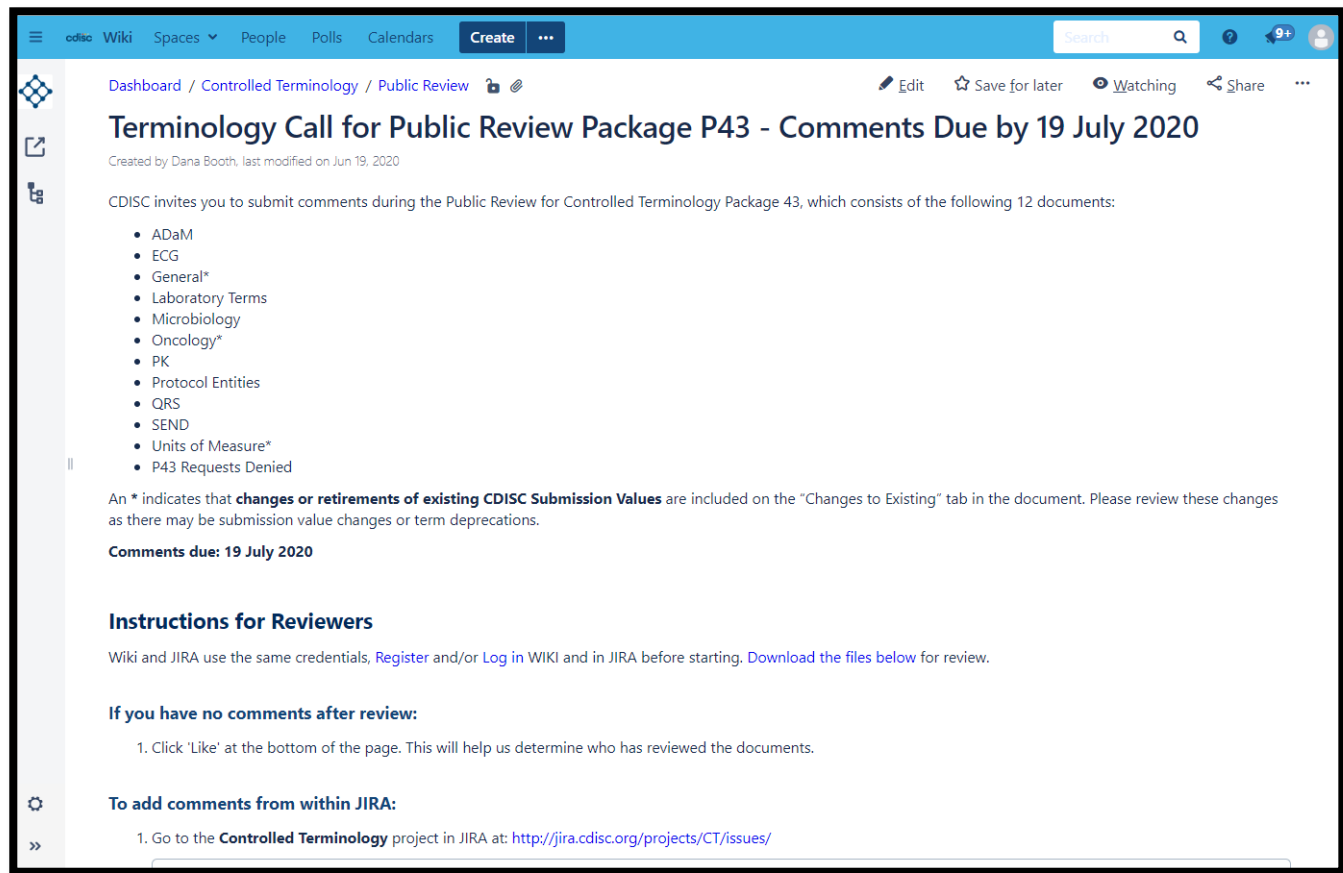
- Updates with P42
 - DS_Codetable_Mapping
 - Oncology_Codetable_Mapping
 - SC_Codetable_Mapping
 - TS_Codetable_Mapping
 - VS_Codetable_Mapping
 - Unit-UCUM_Codetable
 - Rules for Oncology
 - Rules for MB and MS
 - Controlled_Terminology_Requests_Denied_P42

(No new Codetable Mapping files)



Controlled Terminology Package 43 Public Review

2020-06-19 – 2020-07-19



The screenshot shows a CDISC Wiki page. The top navigation bar includes 'cdisc Wiki', 'Spaces', 'People', 'Polls', 'Calendars', and a 'Create' button. A search bar is on the right. The page title is 'Terminology Call for Public Review Package P43 - Comments Due by 19 July 2020'. Below the title, it says 'Created by Dana Booth, last modified on Jun 19, 2020'. The main content area starts with 'CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 43, which consists of the following 12 documents:'. This is followed by a bulleted list of document categories: ADaM, ECG, General*, Laboratory Terms, Microbiology, Oncology*, PK, Protocol Entities, QRS, SEND, Units of Measure*, and P43 Requests Denied. A note explains that an asterisk indicates changes or retirements of existing CDISC Submission Values. The page also includes sections for 'Comments due: 19 July 2020', 'Instructions for Reviewers', and 'If you have no comments after review:'. The 'Instructions for Reviewers' section mentions that Wiki and JIRA use the same credentials and provides links to register or log in. The 'If you have no comments after review:' section has a single instruction to click 'Like'. The 'To add comments from within JIRA:' section has an instruction to go to a specific JIRA project link.

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Terminology Call for Public Review Package P43 - Comments Due by 19 July 2020

Created by Dana Booth, last modified on Jun 19, 2020

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 43, which consists of the following 12 documents:

- ADaM
- ECG
- General*
- Laboratory Terms
- Microbiology
- Oncology*
- PK
- Protocol Entities
- QRS
- SEND
- Units of Measure*
- P43 Requests Denied

An * indicates that **changes or retirements of 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.

Comments due: 19 July 2020

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/>

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P43+-+Comments+Due+by+19+July+2020>

Controlled Terminology Package 43 Public Review

- ADaM Team
 - New Terms Added to Existing Codelists:
 - DTYPE

Controlled Terminology Package 43 Public Review

- Define-XML Team
 - No Additions or Changes being proposed for Define-XML-associated terminology this quarter.

Controlled Terminology Package 43 Public Review

- Medical Devices Team
 - No Additions or Changes being proposed for medical devices-associated terminology this quarter.

Controlled Terminology Package 43 Public Review

- ECG Terminology Team:
 - New Terms Added to Existing Codelists:
 - EGTEST-CD
 - 2 changes to published terms, none significant

Controlled Terminology Package 43 Public Review

- General Terminology Team:
 - New Terms Added to Existing Codelists:
 - D1FATS-CD; DTHDX-CD; EVAL; FDATSRS; FREQ; LOC; POSITION; PROCEDUR; RETEST-CD; RPTEST-CD; SCTEST-CD; TTYPE; VSTEST-CD
 - To support the Ebola, Heart Failure, and Type 1 Diabetes TAUGs.
 - New Codelists: CRFATS-CD (Crohn's Disease Findings About)
 - To support the Crohn's Disease TAUG.
 - Updates to Codetable mapping Files:
 - DD_Codetable_Mapping
 - RP_Codetable_Mapping
 - SC_Codetable_Mapping
 - TS_Codetable_Mapping
 - VS_Codetable_Mapping
 - 26 changes to published terms; 11 significant (see next slide)

Controlled Terminology Package 43

Public Review

- General Terminology Team:
 - 11 Significant Changes:
 - LOC: Misspelling in submission value 'CIRCUMFLEX, OBTUSE MARGINALS, LEFT **POSTEROLETERAL** AND LEFT POSTERIOR DESCENDING ARTERY BRANCHES'. Change to 'CIRCUMFLEX, OBTUSE MARGINALS, LEFT **POSTEROLATERAL** AND LEFT POSTERIOR DESCENDING ARTERY BRANCHES'
 - VSTEST-CD: For Temperature/TEMP (C25206), the intent of this term was to capture 'Body Temperature' and yet the original c-code assigned to this concept is defining temperature generically. Recent requests to add 'Core Body Temperature' and 'Peripheral Body Temperature' lead the team to consider updating the c-code.
 - Submission values will remain the same but the NCI c-code, CDISC synonyms, definition, and NCI Preferred Term will change.
 - RPTEST-CD: Removal of the Tanner Scale Test values: Tanner Scale for Boy, Genitalia Stage; Tanner Scale for Boy, Pubic Hair Stage; Tanner Scale for Girls, Breast Stage; Tanner Scale for Girls, Pubic Hair Stage ->
 - The Tanner scale terms previously in RPTEST-CD are being moved to the RS domain as clinical classifications.

Controlled Terminology Package 43 Public Review

- CDISC Glossary Team
 - No Additions or Changes being proposed for CDISC glossary this quarter.

Controlled Terminology Package 43 Public Review

- Laboratory Terminology Team
 - New Terms Added to Existing Codelists:
 - BEDECOD; LBANMET; LBTEST-CD; METHOD; MITS-CD; MIFTSDTL
 - To support T1D TAUG
 - 18 changes to published terms, no significant changes

Controlled Terminology Package 43 Public Review

- Laboratory Terminology Team (Units of Measure)
 - 24 changes to published terminology; 2 significant changes
 - The CDISC submission values of C67330 (osm) and C73736 (uOsM) are being updated to conform to the standard base symbol for 'Osmole', which is 'Osm'.
 - C67330 -> osm to Osm
 - C73736 -> uOsM to uOsm

Controlled Terminology Package 43 Public Review

- Laboratory Terminology Team (SPECTYPE_SPECCOND)
 - No Additions or Changes being proposed for specimen-associated terminology this quarter.

Controlled Terminology Package 43 Public Review

- Microbiology Terminology Team
 - New Terms Added to Existing Codelists:
 - MICROORG; MBTEST-CD
 - New terms added to new codelists: MBFTSDTL (Microbiology Findings Test Details) to support the MBTSTDTL variable.
 - 1 change to existing term, none significant

Controlled Terminology Package 43 Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - TUIDRS; TRTEST-CD; ONCRSCAT
 - 2 changes to existing terms; 1 significant change
 - ONCRSR: C158264/MINIMAL RESPONSE is being retired from the codelist. It was determined by Oncology team and NCI-EVS that Minimal Response is synonymous with Minor Response (C123598), which is also in the codelist. Therefore C158624 will be merged into C123598. MR will remain as the submission value and 'Minimal Response' will be added as a synonym to C123598 to help with mapping.
 - Updates to Codetable mapping Files:
 - TU_Codetable_Mapping
 - TR_Codetable_Mapping
 - RS_ONC_Codetable_Mapping
 - RS_iRANO_Codetable_Mapping (**new**)

Controlled Terminology Package 43 Public Review

- CDISC PGx Terminology Team
 - No Additions or Changes being proposed for PGx-associated terminology this quarter.

Controlled Terminology Package 43 Public Review

- PK Terminology Team
 - New Terms Added to Existing Codelists:
 - PKPARM-CD; PKUNIT; PKUDMG
 - 3 changes to existing terms; none significant.

Controlled Terminology Package 43 Public Review

- Protocol Entities Terminology Team
 - Protocol Entity of **Study Product**
 - 1 Attribute for the entity of **Study Product** with associated valid value set
 - 1 value set for the **Study Arm Type** attribute
 - 6 changes to existing terms; none significant

Controlled Terminology Package 43 Public Review

- QRS Terminology Team
 - New Terms Added to New Codelists
 - QRSMTHOD
 - Changes to existing terms:
 - The Tanner scale terms previously in RPTTEST-CD are being moved to the RS domain as clinical classifications.

Controlled Terminology Package 43 Public Review

- SDTM Domain Terminology Team
 - No Additions or Changes being proposed for SDTM Domain-associated terminology this quarter.

Controlled Terminology Package 43 Public Review

- SEND Terminology Team
 - New Terms Added to Existing Codelists:
 - DSTRBN; FXFINDRS; NEOPLASM; NONNEO; SPEC; SNDIGVER
 - 1 change to published term; none significant



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

Erin Muhlbradt, muhlbradtee@mail.nih.gov
Dana Booth, dbooth@cdisc.org

CDISC New term request form:
<https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>



**Thank you for your attendance and support of
CDISC!**

Controlled Terminology Updates for Q3 – P41a-P42-P43

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, MSC



Tuesday, 2020-07-07
11:00 – 12:30 EDT



Q&A

Audience Questions



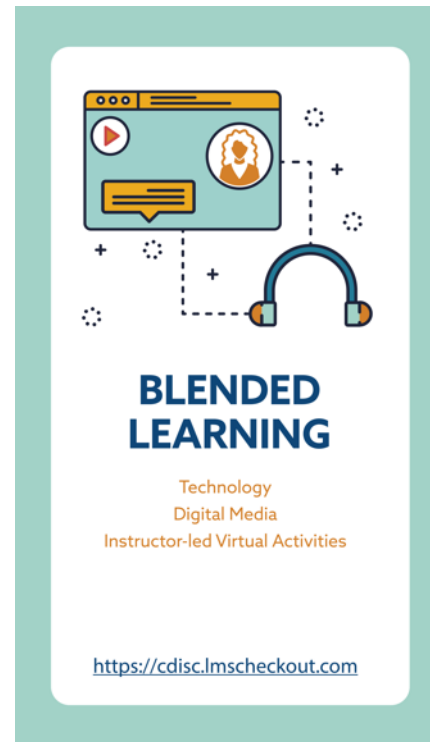
Why do we have updates do RACEC codelist when we should avoid using that and using just RACE codelist instead?



Upcoming Learning Opportunities

NEW Blended Learning from CDISC

- Self-paced online training combined with remote instructor-led Q&A
 - Developed by standards experts
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 - Four global time zones
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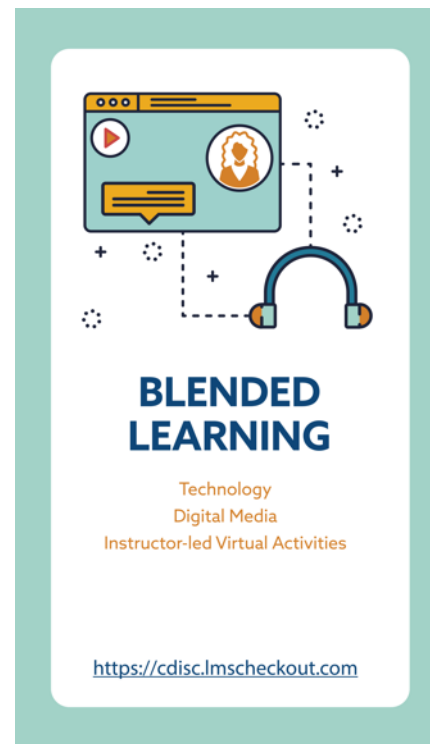
- Sessions starting soon!

SDTM Blended Learning*			
	Start Date	Live Q&A	Language
Americas	5 AUG – 9 SEP	Weekly	English
Europe	25 AUG – 29 SEP	Weekly	English
Japan	4 AUG – 8 SEP	Weekly	Japanese
China	3 – 29 SEP	Weekly	Mandarin

*Includes 19 modules & weekly Q&A sessions

CDASH Blended Learning**			
	Start Date	Live Q&A	Language
Americas	5 – 19 AUG	Weekly	English
Europe	1 – 15 SEP	Weekly	English
Japan	4 – 18 AUG	Weekly	Japanese
China	3 – 17 SEP	Weekly	Mandarin

**Includes eight modules & weekly Q&A sessions



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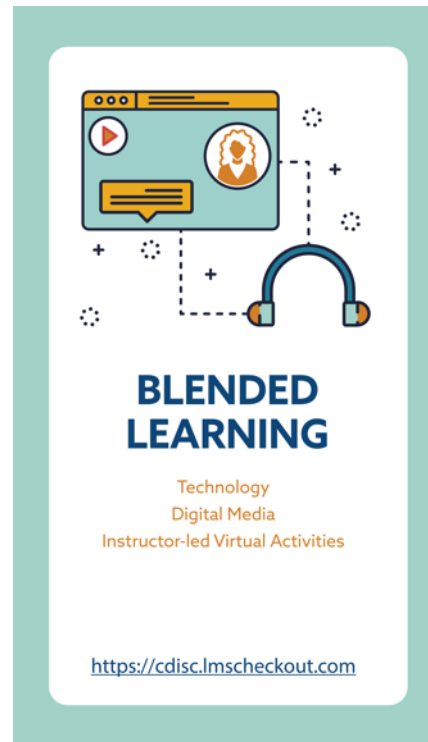
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2020 Webinars

Date	Webinar Title
14 JUL 2020	QRS Updates: Logically Skipped Items, EVAL and More
21 JUL 2020	Introducing the CDASH eCRF Project + CDISC Standards for Animal Rule Studies
28 JUL	Leveraging Clinical Research Data Standards in Academia: What's in it for Me?
13 OCT 2020	Controlled Terminology Updates for Q4



Visit <https://www.cdisc.org/events/education/webinars> for information on additional Public Training events.

Join CDISC in July for a free webinar!

QRS Updates: Logically Skipped Items, EVAL and More

Get updates on how to handle missing data and evaluator in QRS domains. Specifically, we'll discuss how to represent:

- Missing data which happens due to instrument logic
- Missing data for an unknown reason
- "Check all that apply" responses
- "Other specify" responses
- Administrator/evaluator information when it's collected on a QRS instrument
- We'll also share the latest supplements in progress.

Date and Time:

TUE 14 JUL 2020

11:00 AM - 12:30 PM Eastern US Daylight Time

Presenters:

Dana Booth, SDS QRS Subteam Co-Lead

Steve Kopko, SDS QRS Subteam Co-Lead



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Join CDISC for a Virtual CDISC for Newcomers (Virtual)

New to [CDISC Standards](#)? Attend our workshop geared to getting you started with standards to amplify the full potential of data, drive operational efficiencies and expedite the regulatory review process. The workshop goes over examples of the standards, along with how to build them into the process of writing a protocol, collecting and tabulating data, and using the data in analysis. The CDISC [Data Exchange standards](#) are reviewed and the [CDISC Library](#) is discussed.

The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

- [Agenda](#):
- Topic 1: What is CDISC?
- Topic 2: Why Are Standards Needed?
- Topic 3: Overview of Regulatory Requirements
- Topic 4: Overview of CDISC Models
- Topic 5: CDISC Connects Research Globally
- Topic 6: Therapeutic Area User Guides
- Topic 7: Data Exchange Standards
- Topic 8: Implementing CDISC Standards
- Topic 9: CDISC Library
- Topic 10: How Does CDISC Work?

[Date and Time](#):

WED 15 JUL 2020

12:00 – 4:00 PM Eastern US Daylight Time



BLEND ED LEARNING

Technology
Digital Media
Instructor-led Virtual Activities

<https://cdisc.lmscheckout.com>



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don't forget to fill out the feedback survey!

