



CDISC Controlled Terminology Quarterly Webinar

Presented by Dr. Erin Muhlbradt, PhD

04.18.2024



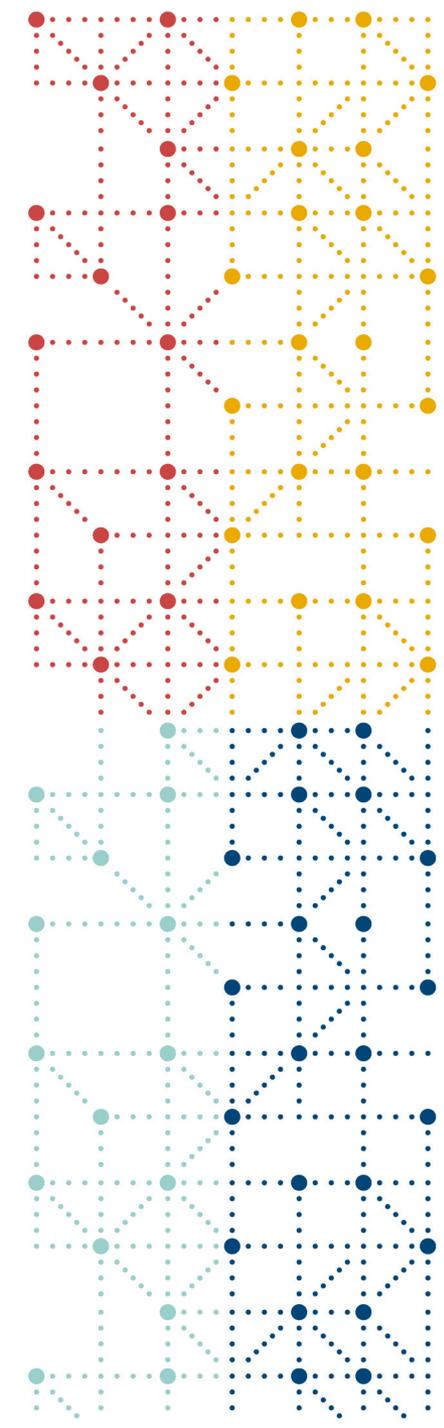


Controlled Terminology P57 Publication

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

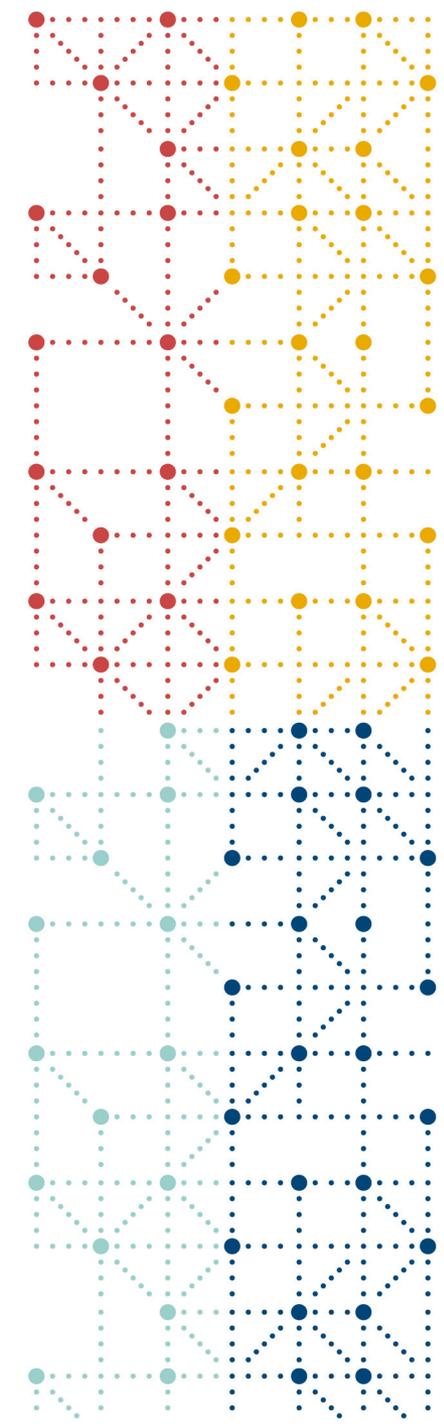
04.18.2024





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.



Question & Answer

1. 'Panelist': Question

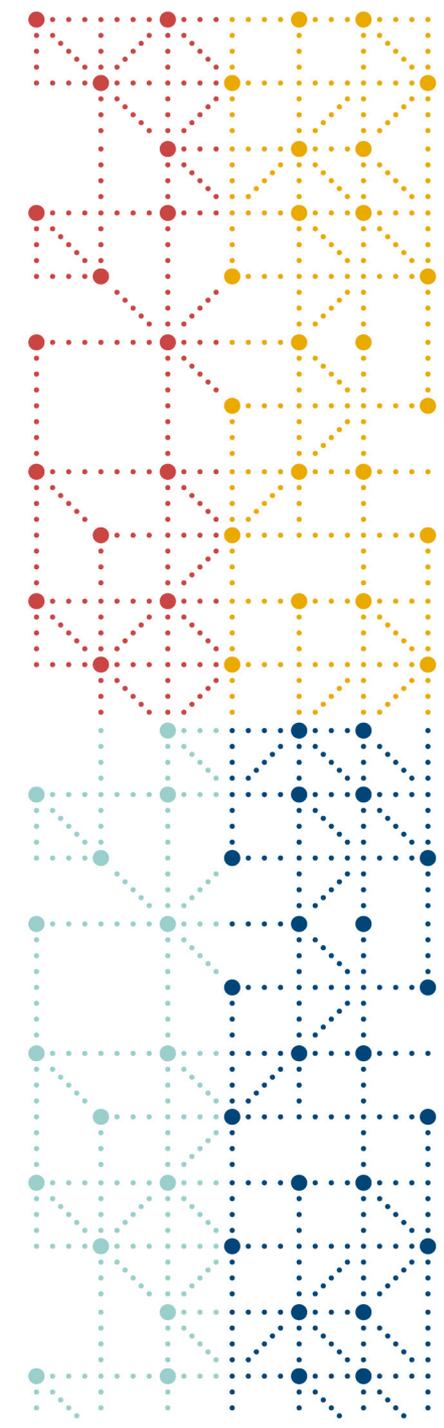
OR

1. '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?



Agenda

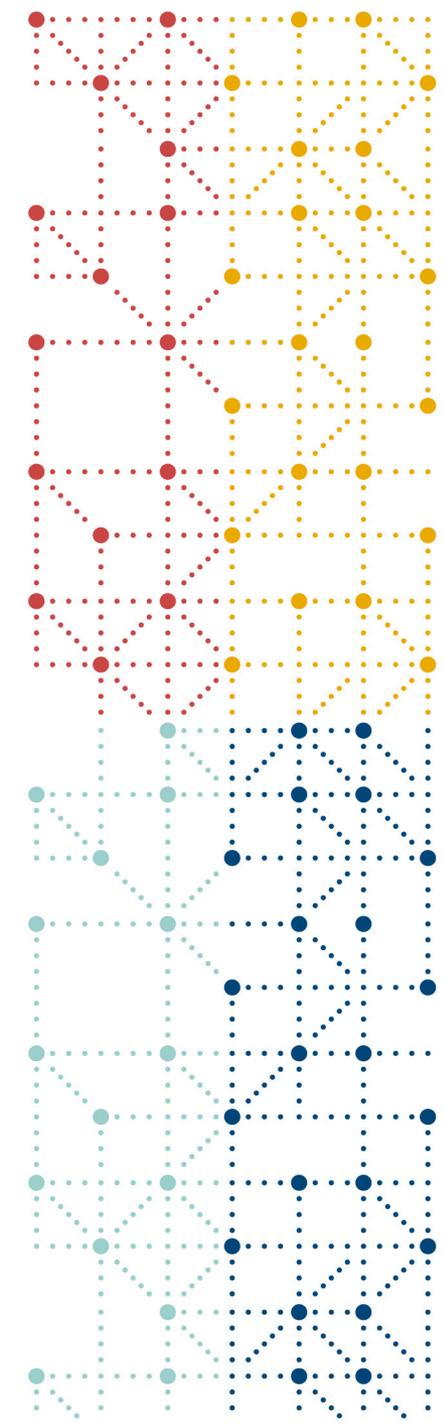
1. Package 57 Publication Release (2024-03-29)

- Changes post-public review
- TIG Terminology
- MRCT Plain Language Glossary

2. CT Basics

- How to submit a public review comment for Terminology

3. Questions



Controlled Terminology Package 57 Publication

2024-03-29

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			
53	12/9/2022	12/16/2022	1/20/2023	2/17/2023	3/31/2023	Biospec	Cell Pheno	General	Lab
53						Microbio/Immu no	Protocol Entities	SEND	Unit
54	3/17/2023	3/24/2023	4/21/2023	5/19/2023	6/30/2023	ADaM	Biospec	Cell Pheno	CV
54						Define-XML	General	Lab	Microbio/Immu no
54						MRCT	Oncology	PK	Protocol Entities
54						SEND	Unit		
55	6/16/2023	6/23/2023	7/21/2023	8/18/2023	9/29/2023	Biospec	Cell Pheno	Devices	ECG
55						General	Genomics	Lab	Microbio/Immu no
55						MRCT	Oncology	PK	Protocol Entities
55						Unit			
56	9/15/2023	9/22/2023	10/20/2023	11/17/2023	12/15/2023	Biospec	Cell Pheno	Define-XML	ECG
56						CDISC Glossary	Lab	General	Genomics
56						Microbio/Immu no	MRCT	Oncology	SDTM Domain
56						SEND	Unit		
57	12/8/2023	12/15/2023	1/12/2024	2/9/2024	3/29/2024	ADaM	Biospec	Cell Pheno	Cardiovascular
57						ECG	General	Genomics	Lab
57						Microbio/Immu no	MRCT	Oncology	SEND
57						Unit			
58	5/31/2024	6/7/2024	7/5/2024	8/2/2024	9/27/2024				
58									
59	12/13/2024	12/20/2024	1/17/2025	2/14/2025	3/28/2025				
59									
60	5/30/2025	6/6/2025	7/4/2025	8/1/2025	9/26/2025				
60									

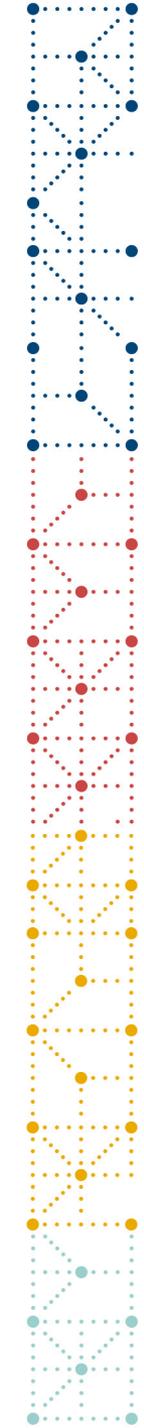
3/22/2024

Dates in red are planned and may be adjusted slightly.



Controlled Terminology Package 57 Publication Release

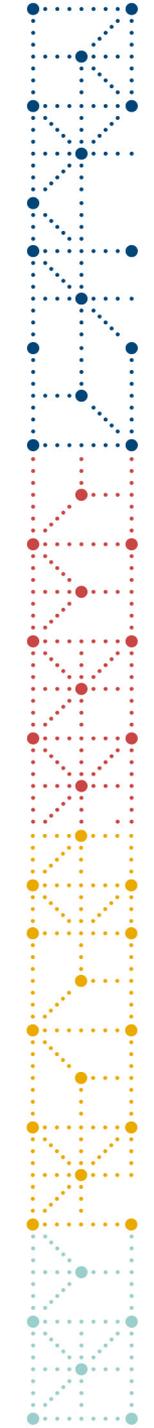
- Updates to ADaM, Define-XML, DDF, Protocol Entities, SDTM, and SEND Terminology
- Publication of **NEW** subset of CDISC Terminology MRCT Center Clinical Research Glossary
- Other Project Support:
 - Tobacco Implementation Guide (TIG)
 - DDF USDM (Phase 2)



Significant Changes Post-Public Review

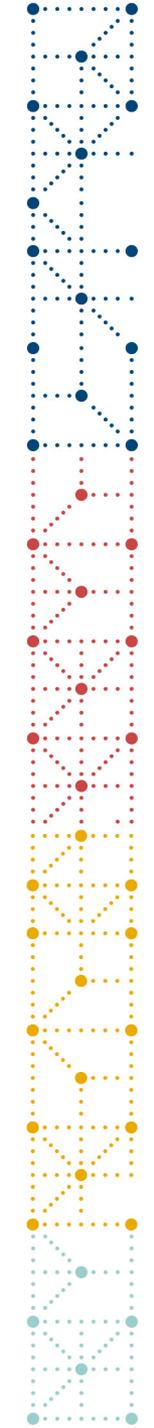
- General:

- LOC: PARIETAL PLEURA (C33273) and PHRENIC NERVE (C52813) already published in codelist.
- RETEST-CD: Predicted FEV1/FVC (C112377), Predicted Total Lung Capacity (C112388), and Predicted FEF25-75 (C119546) already published in codelist.



Significant Changes Post-Public Review

- Tobacco Implementation Guide:
 - A number of codelists were pulled from P57 publication - continued development for P58 publication
 - ADAM:
 - INPRM/Input Parameter
 - STRATA/Analysis Stratum
 - TBUTRS/Tobacco Use Transition Response
 - TPUSRS/Tobacco Product Use Status Response
 - TPCATRS/Tobacco Product Category Response
 - SEND:
 - LVLDS CRS/Reference ID Level Description Response
 - GTTEST/CD / Genetic Toxicology In vitro Test Code/Name



Significant Changes Post-Public Review

- Tobacco Implementation Guide:

- A number of codelists were pulled from P57 publication - continued development for P58 publication

- SDTM:

- SPECPT/Tobacco Product Testing Specimen Type
 - TPACN/Action Taken with Tobacco Product
 - IGDCMPLX/Ingredient Complexity Response
 - IQCAT/Category of Ingredient Quantities by Component
 - PDPARMCD/Tobacco Product Design Parameters Code
 - PDPARM/Tobacco Product Design Parameters Name
 - PTTESTCD/Tobacco Product Testing Test Code
 - PTTEST/Tobacco Product Testing Test Name
 - PTCAT/Category of Tobacco Product Testing
 - TOCAT/Category of Tobacco Products



Significant Changes Post-Public Review

Other, less significant changes* also made in:

- General, Lab, Unit, MRCT

No post-public review changes made to:

- ADaM
- Biospecimens
- Cell Phenotyping
- CV
- Define-XML
- ECG
- Genomics
- MB/IS
- Oncology
- SEND

***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.**



P57 Terminology Products Updates

- Updates on CDISC.org:

- Updated Codetable mappings:

- CV, DS, EG, GF, GI, IS, MK, Oncology, RE, RP, SC, SS, TS, and VS

- Unit-UCUM_Codetable

- Controlled_Terminology_Requests_Denied_P57

- Paired Codelists product for SDTM and SEND

- Terminology Publication Schedule

- Terminology Development Rules documents: IS; MB&MS



QRS Controlled Terminology Package 57 Publication Release

- 3 new QSCAT values:

- **PDAI** – Perianal Crohn’s Disease Activity Index Questionnaire
- **PSECDI** – Penn State Electronic Cigarette Dependence Index Questionnaire
- **SOFA** – Sepsis-related Organ Failure Assessment Questionnaire

- 3 new paired **TEST/TESTCD** codelists:

- **PDAI01TC/N** - Perianal Crohn’s Disease Activity Index Questionnaire Test Code/Name
- **PSECD1TC/N** - Penn State Electronic Cigarette Dependence Index Questionnaire Test Code/Name
- **SOFA01TC/N** - Sepsis-related Organ Failure Assessment Questionnaire Test Code/Name



QRS Controlled Terminology Package 57 Publication Release

- 12 new response codelists for the SOFA (Sepsis-related Organ Failure Assessment):

SOFA0101OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0101 TN/TC
SOFA0101STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0101 TN/TC

SOFA0102OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0102 TN/TC
SOFA0102STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0102 TN/TC

SOFA0103OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0103 TN/TC
SOFA0103STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0103 TN/TC

SOFA0104OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0104 TN/TC
SOFA0104STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0104 TN/TC

SOFA0105OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0105 TN/TC
SOFA0105STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0105 TN/TC

SOFA0106OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0106 TN/TC
SOFA0106STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0106 TN/TC

MRCT Terminology

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), in collaboration with CDISC, have built a Clinical Research Glossary containing **plain language definitions** and other semantic artifacts for concepts commonly used in clinical research.

The screenshot shows the MRCT Center Clinical Research Glossary website. The browser address bar displays mrctcenter.org/glossary/. The website header includes the MRCT logo (Multi-Regional Clinical Trials, The MRCT Center of Brigham and Women's Hospital and Harvard) and navigation links for Sponsor Login, Newsletter Sign-up, and Search. A main navigation menu contains links for ABOUT US, OUR WORK, NEWS & EVENTS, RESOURCES, and CONTACT. The page title is "Clinical Research Glossary". Below the title, a section titled "Helping you understand clinical research" provides an overview of the glossary's purpose and development. It states that the glossary offers easy-to-understand clinical research definitions, developed by the MRCT Center and a team of patient advocates and other professionals. It also mentions that the glossary started as a pilot project in 2020 and is now a CDISC global standard for clear communication. A "Welcome!" message follows. Below this text are three buttons: "COMMON QUESTIONS", "GET INVOLVED", and "MEET THE TEAM". To the right of the text is a photograph of a woman in a green shirt sitting at a table with a laptop and fruit. Below the text and buttons is a search bar with the placeholder text "Search glossary" and a "SEARCH" button. Below the search bar is a navigation bar with letters A through Z. The main content area shows the letter "A" and a list of terms with their definitions: "additive effect" (The combined effect when two or more things are used together.), "adherence" (Following the study directions and requirements.), "adverse event" (Any health problem that happens during the study.), "adverse reaction" (A health problem that happens during the study and is reported as possibly caused by the study treatment.), "analyze" (To examine study data to answer a question and help reach conclusions.), "anonymize" (Remove, change, or hide personal details to protect participant privacy.), "antigen" (A substance that causes the body's immune system to react.), and "arm".

MRCT Terminology



Clinical Research Glossary

Home | Glossary | phase

phase

A step in the overall [clinical research](#) process to

Example of *phase* in a sentence

Research is done in *phases* to make sure a study treatment

More Info

A phase is a step in the research process. Phases of research have separate goals.

Phase 1 studies are usually the first to enroll humans and test

Phase 2 studies test if the drug, device or treatment works.

Phase 3 studies compare the study treatment to the usual, standard

Phase 4 studies continue to collect data after a study treatment has been marketed.

Other info to think about when joining a study

You may see the term "phase" when you are reading about clinical

Before you [enroll](#) in a [clinical trial](#) you may want to ask about more about the information the study team already has about being tested.

NIH NATIONAL CANCER INSTITUTE www.cancer.gov

EVS Enterprise Vocabulary Services

NCI Term Browser

Terminologies | Value Sets | Mappings

Search ?

Contains Exact Match Begins With
 Name Code Property Relationship

[Back to search results](#) [Advanced Search](#)

[Hierarchy](#) | [Value Sets](#) | [Maps](#) | [Visited Concepts](#) [Help](#)

[Quick Links](#)

[View in Hierarchy](#) | [View History](#) | [View Graph](#) | [Add to Cart](#) | [Suggest Changes](#)

Trial Phase (Code C48281)

Terms & Properties | **Synonym Details** | Relationships | Mappings | View All

Terms & Properties

Preferred Name: Trial Phase

Definition: Clinical trials are broken into three or four phases: Phase I tests a new drug or treatment for safety in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people to measure whether the treatment actually benefits patients, and whether its benefits exceed its risks; and Phase IV takes place after the drug or treatment has been licensed and marketed.

CDISC-GLOSS Definition: A stage in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998] See also Phase 0-5, epoch (if reference is to a single trial), phase (within a study), clinical research and development.

CDISC Definition: A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]

MRCT Ctr-CDISC Definition: A step in the overall clinical research process to test a new drug, device, or treatment.

Label: Trial Phase

NCI Thesaurus Code: C48281 ([Search for linked caDSR metadata](#)) ([search value sets](#))



MRCT-CDISC Terminology

- Published out of the NCIt in the usual formats.
- Stored on the NCI Ftp, in the CDISC Ftp folder.
- Direct links available on [CDISC.org/ControlledTerminology](https://cdisc.org/ControlledTerminology) webpage

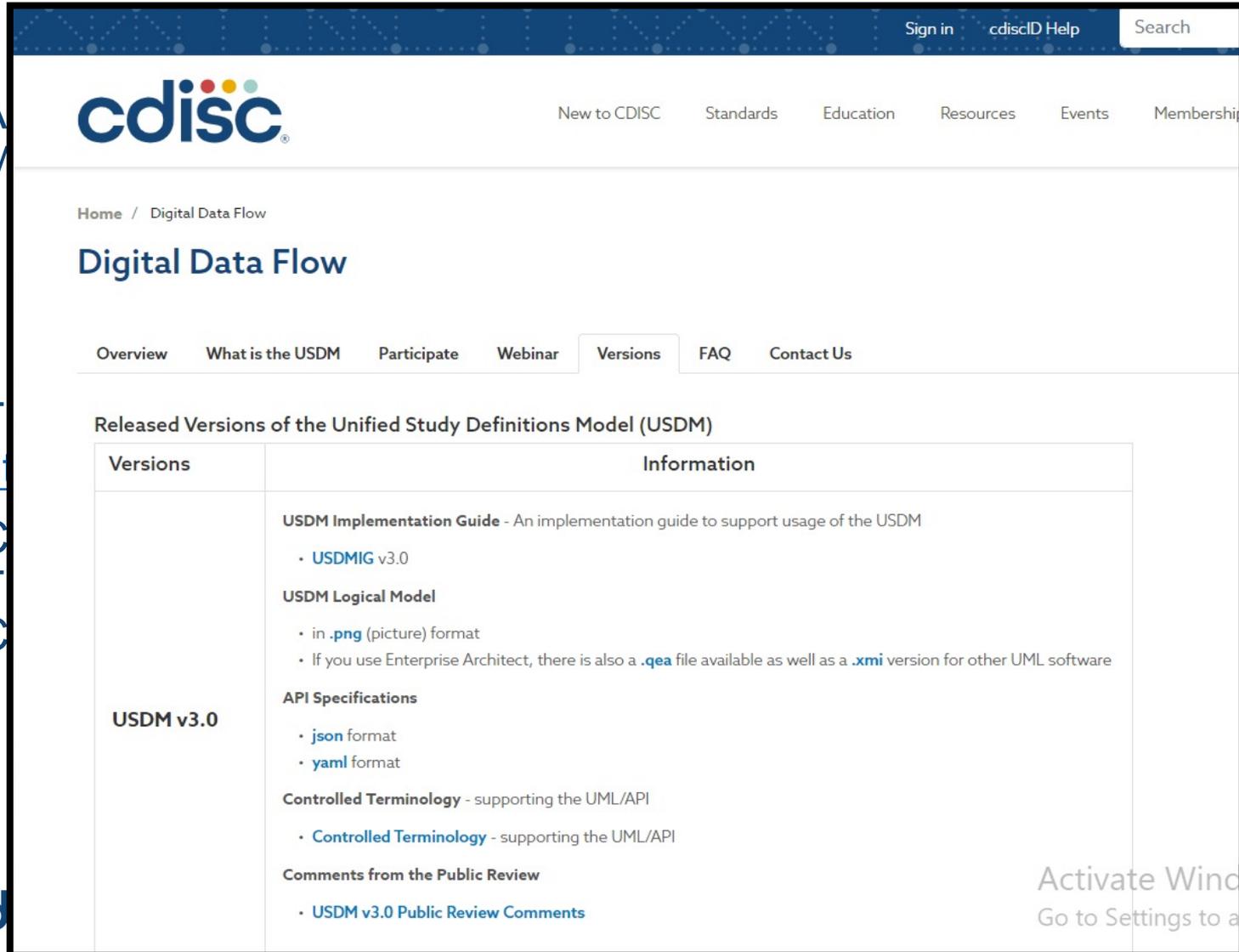
← → ↻ 🌐 evs.nci.nih.gov/ftp1/CDISC/MRCT%20Center%20Clinical%20... ☆ 📁 🖨️ 👤

Index of /ftp1/CDISC/MRCT Center Clinical Research Glossary

<u>Name</u>	<u>Last modified</u>	<u>Size</u>	<u>Description</u>
Parent Directory		-	
.DS_Store	2024-03-29 04:49	8.0K	
Archive/	2024-03-29 04:50	-	
CDISC MRCT Center Clinical Research Glossary_Changes.txt	2024-03-29 04:49	25K	
CDISC MRCT Center Clinical Research Glossary_Changes.xls	2024-03-29 04:49	58K	
CDISC MRCT Center Clinical Research Glossary_ReadMe.docx	2024-03-29 04:49	16K	
CDISC MRCT Center Clinical Research Glossary.OWL.zip	2024-03-29 04:49	14K	
CDISC MRCT Center Clinical Research Glossary.html	2024-03-29 04:49	57K	
CDISC MRCT Center Clinical Research Glossary.odm.xml	2024-03-29 04:49	61K	
CDISC MRCT Center Clinical Research Glossary.pdf	2024-03-29 04:49	17K	
CDISC MRCT Center Clinical Research Glossary.txt	2024-03-29 04:49	32K	
CDISC MRCT Center Clinical Research Glossary.xls	2024-03-29 04:49	80K	
MRCT Publication Date Stamp.txt	2024-03-29 04:49	66	
ReadMe.txt	2024-03-29 04:49	2.1K	

Apache/2.4.54 (Unix) Server at nciws-p1086-c.nci.nih.gov Port 8081

DDF USDM Terminology



The screenshot shows the CDISC website's "Digital Data Flow" page. The navigation bar includes "Sign in", "cdiscID Help", and a search box. The main navigation menu has "New to CDISC", "Standards", "Education", "Resources", "Events", and "Membership". The breadcrumb trail is "Home / Digital Data Flow". The page title is "Digital Data Flow". A secondary navigation bar includes "Overview", "What is the USDM", "Participate", "Webinar", "Versions" (which is active), "FAQ", and "Contact Us".

The main content area is titled "Released Versions of the Unified Study Definitions Model (USDM)". It contains a table with two columns: "Versions" and "Information".

Versions	Information
USDM v3.0	<p>USDM Implementation Guide - An implementation guide to support usage of the USDM</p> <ul style="list-style-type: none">• USDMIG v3.0 <p>USDM Logical Model</p> <ul style="list-style-type: none">• in .png (picture) format• If you use Enterprise Architect, there is also a .qea file available as well as a .xmi version for other UML software <p>API Specifications</p> <ul style="list-style-type: none">• json format• yaml format <p>Controlled Terminology - supporting the UML/API</p> <ul style="list-style-type: none">• Controlled Terminology - supporting the UML/API <p>Comments from the Public Review</p> <ul style="list-style-type: none">• USDM v3.0 Public Review Comments

• A
M

•

• T

h

• C

T

C

cd

Activate Windows
Go to Settings to activate Windows.

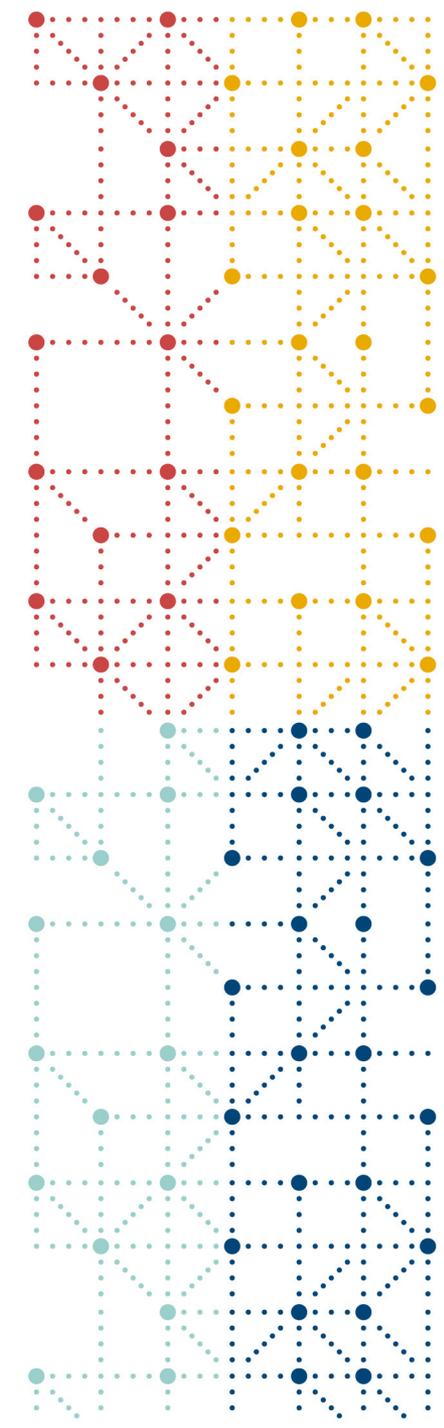
ons

nts

e-3-

e:

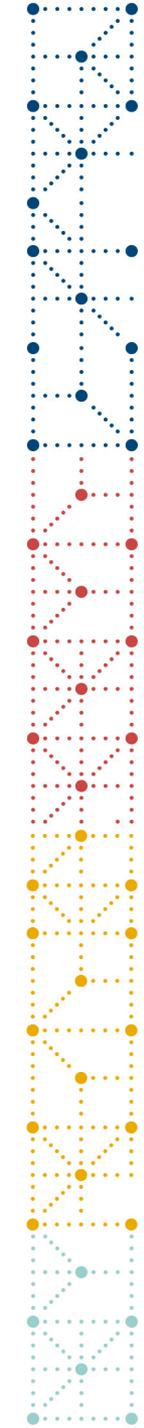
f:



Controlled Terminology Public Review

-WHY

-HOW TO



Public Review – WHY???

Fulfills a requirement that all SDOs must adhere to.

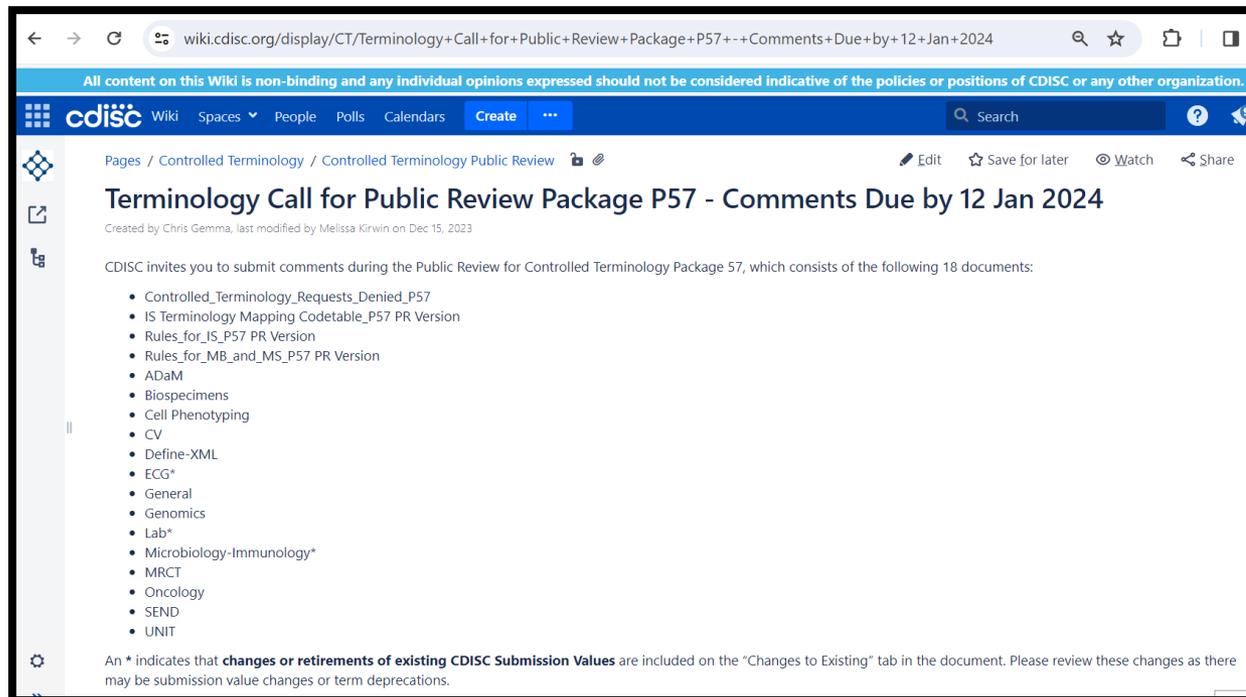
- For CDISC to maintain its status as a standards development organization, it must ensure that all of its standards are publicly reviewed.

Ensures accessibility to draft standards.

Increases the quality of the final product.

CDISC Public Review Process

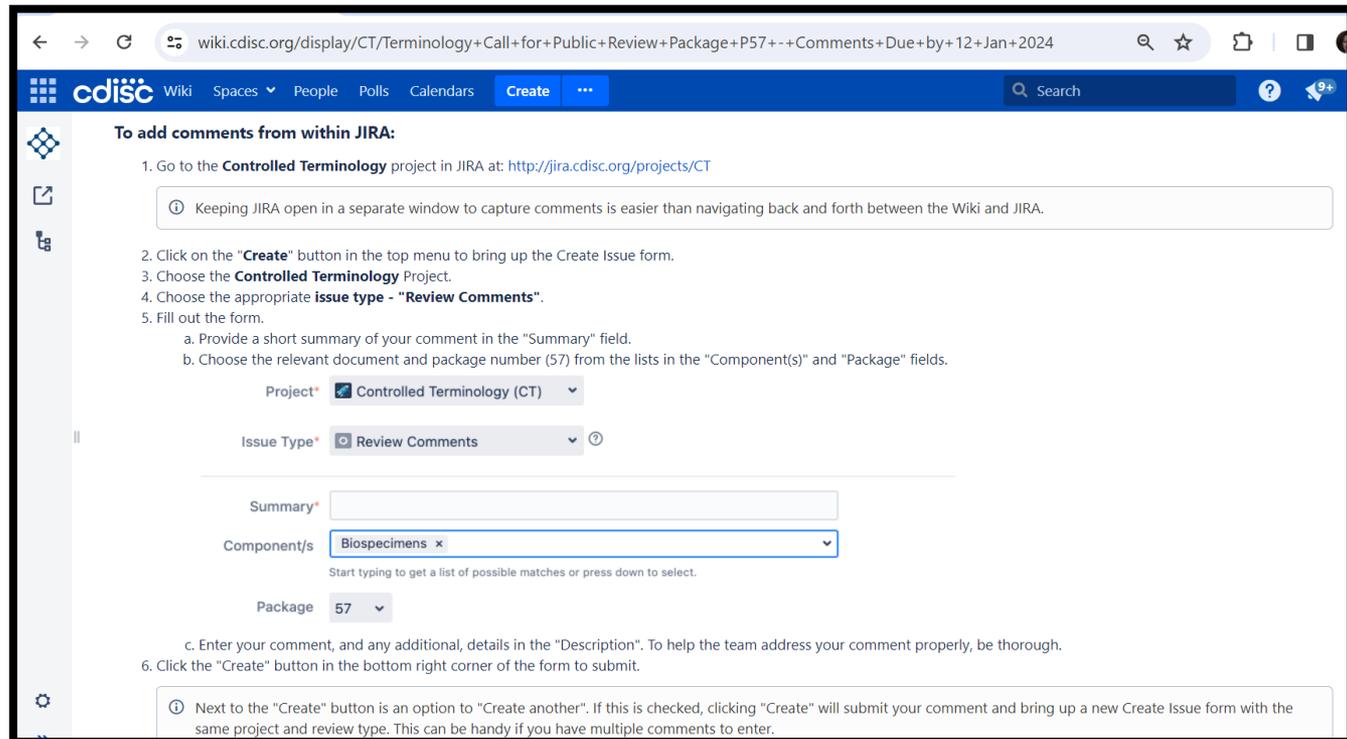
- Twice per year, CDISC releases a ‘package’ of terminology for review.
 - Beginning of June
 - Middle of December
- The files associated with each ‘package’ are accessible through the CDISC wiki.
 - <https://wiki.cdisc.org/display/CT/Controlled+Terminology+Public+Review>
 - Files are downloadable from the Wiki site
 - The package may include additional artifacts, e.g., Terminology development Rules Documents and Denied Requests.



The screenshot shows a web browser displaying a page on the CDISC Wiki. The page title is "Terminology Call for Public Review Package P57 - Comments Due by 12 Jan 2024". The page content includes a list of 18 documents for review, such as "Controlled_Terminology_Requests_Denied_P57", "IS Terminology Mapping Codetable_P57 PR Version", and "Rules_for_JS_P57 PR Version". A note at the bottom states: "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."

CDISC Public Review Process

- CDISC uses JIRA to capture public review comments. The CDISC wiki page contains a link and instructions on how to access the Controlled Terminology JIRA project.
 - CDISC CT Public Review is four weeks long.
 - CDISC CT teams disposition all comments (4 weeks).
 - Appropriate updates are made to the terminology prior to publication processing.



The screenshot shows a web browser window displaying a CDISC Wiki page titled "To add comments from within JIRA:". The page provides a step-by-step guide for users to submit review comments through the JIRA system. The instructions include navigating to the JIRA project, selecting the "Controlled Terminology" project, choosing the "Review Comments" issue type, and filling out a form with fields for Project, Issue Type, Summary, Component/s, and Package. A "Create" button is highlighted in the top menu of the browser. A note at the bottom of the page explains the "Create another" option next to the "Create" button.

wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P57+---Comments+Due+by+12+Jan+2024

cdisc Wiki Spaces People Polls Calendars Create Search

To add comments from within JIRA:

1. Go to the **Controlled Terminology** project in JIRA at: <http://jira.cdisc.org/projects/CT>
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 and package number (57) from the lists in the "Component(s)" and "Package" fields.
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.

STEP 1: Navigate to JIRA

- <https://jira.cdisc.org/projects/CT/issues>
- Uses same login as CDISC wiki

cdisc JIRA Dashboards Projects Issues Boards Plans Templates Create Search

All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization.

System Dashboard

Assigned to Me

Key	T	Summary	P ↓
TOBA-252	○	FATESTCD and FATEST	≡
TOBA-323	?	The Trial Summary (TS) dataset allows the applicant to submit a summary of the trial in a structured format.	≡
DDF-489	○	The definitions for EligibilityCriterion name and description appear to be switched.	≡
DDF-490	○	Why does the definition for Organization name not follow the pattern for other definitions of name attributes?	≡
DDF-491	○	Why does the definition for SyntaxTemplate.name not follow the pattern for the name attribute of other classes?	≡
DDF-492	○	Why does the definition for Timing.description not follow the pattern for other description attributes?	≡
DDF-501	↑	Disease/Condition Indication Definition	≡
DDF-502	↑	Clarification of Sex of Participants	≡
DDF-503	↑	Study Arm definition uses the term "subject", others use "participant"	≡
DDF-504	↑	Condition Assignments definition suggestion	≡

1-10 of 22 1 2 3 ▶

Introduction

Welcome to CDISC JIRA. An issue tracking system used by the teams to track, respond, and resolve issues identified by the teams and the public within the standards being developed.

Quick Links

Navigation	Filters
Browse Projects	My Unresolved Reported Issues
Search for Issues	Votes
Create Issue	Watches

Atlassian Jira Project Management Software (v9.4.17#940017-sha1:2c0a67f) · [About Jira](#) · [Report a problem](#)

STEP 2: Click Create

- <https://jira.cdisc.org/projects/CT/issues>

The screenshot shows the Jira CDISC interface. The browser address bar displays the URL: jira.cdisc.org/projects/CT/issues/CT-1013?filter=allopenissues. The navigation bar includes 'cdisc JIRA', 'Dashboards', 'Projects', 'Issues', 'Boards', 'Plans', 'Templates', and a 'Create' button highlighted with a red box. The main content area shows the issue details for 'ISBDAGNT example value' under the 'Controlled Terminology / CT-1013' project. The issue is currently 'In Progress'. The details section includes:

- Type: Question
- Resolution: Unresolved
- Priority: To be assigned
- Component/s: IS Codetable Mapping
- Labels: None
- Package: 57
- CDISC Disposition: The MB/IS team is currently reviewing this request. If we update the language in the Rule doc, that means we also need to update the submission value of the same published CT term, as well as the submission values of the 7-8 other similar terms in this codelist. Submission value changes are considered as major updates and will need to go out for public review again, we are discussing this matter. This request is still in progress for resolution, will be resolved and publicly reviewed for P58 (September 2024 release).

The 'People' section shows the assignee as Jordan Li and the reporter as Dave Scocca. The 'Dates' section shows the issue was created on 03/Jan/24 at 2:06 PM and updated on 11/Mar/24 at 3:00 PM. The description of the issue is partially visible at the bottom: "the comma after 'should be' needs to be".

STEP 3: Fill out the “Create Issue” form

- Make Sure Project field is set to “Controlled Terminology (CT)”
- Make sure “Package” is set to the correct number

The screenshot shows the JIRA 'Create Issue' form. The 'Project' field is set to 'Controlled Terminology (CT)' and the 'Package' field is set to '57'. Red arrows point to these fields. The form includes a 'Summary' field, a 'Component/s' dropdown, and a 'Description' field with a rich text editor. The background shows the JIRA System Dashboard with a table of assigned issues.

Key	T	Summary
TOBA-252	<input type="radio"/>	FATESTCD and FATEST
TOBA-323	<input type="radio"/>	The Trial Summary (TS) da
DDF-489	<input type="radio"/>	The definitions for Eligibil
DDF-490	<input type="radio"/>	Why does the definition f
DDF-491	<input type="radio"/>	Why does the definition f
DDF-492	<input type="radio"/>	Why does the definition f
DDF-501	<input checked="" type="radio"/>	Disease/Condition Indicat
DDF-502	<input checked="" type="radio"/>	Clarification of Sex of Part
DDF-503	<input checked="" type="radio"/>	Study Arm definition uses
DDF-504	<input checked="" type="radio"/>	Condition Assignments de

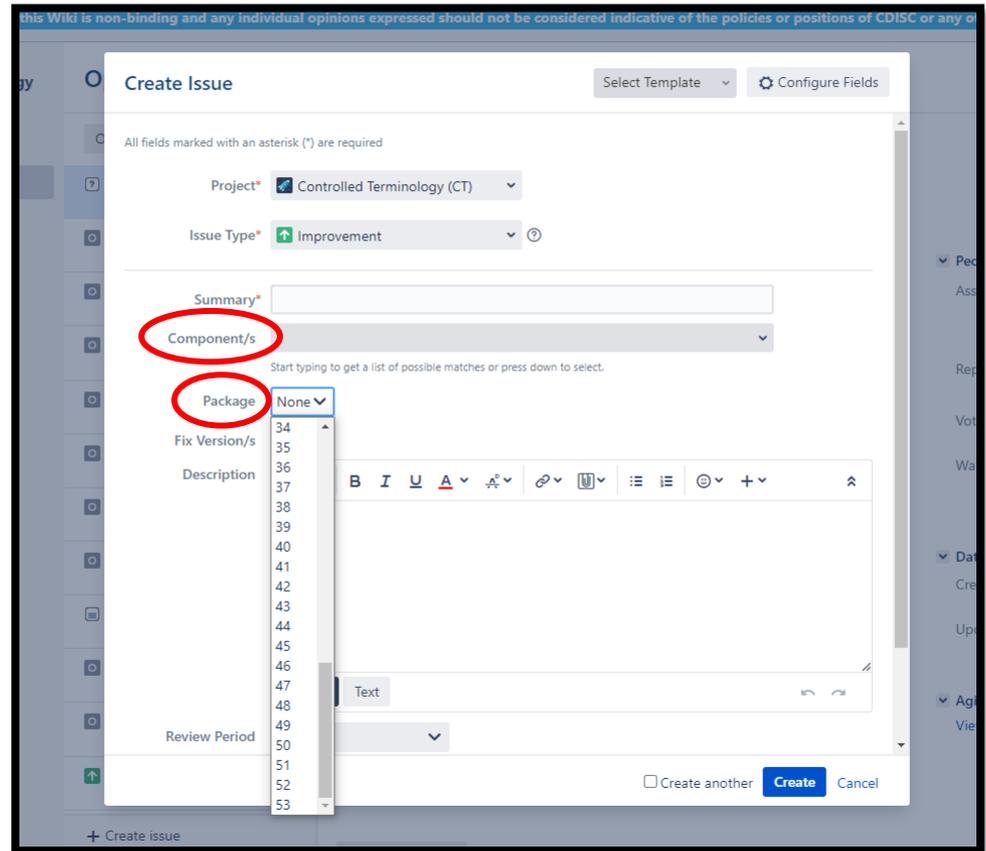
STEP 3: Fill out the “Create Issue” form [cont’d]

- Make Sure **Component/s** field is filled in:
 - Values correspond to the individual PR File you are reviewing

The screenshot shows the CDISC JIRA interface. The top navigation bar includes 'cdisc JIRA', 'Dashboards', 'Projects', 'Issues', 'Boards', 'Plans', 'Templates', and 'Create'. A search bar and utility icons are on the right. A disclaimer banner reads: "All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization." The main content area is titled "System Dashboard" and features a table "Assigned to Me" with columns for Key, T, and Summary. The table lists 22 items, with the first 10 visible. A "Create Issue" modal form is overlaid on the dashboard. The form has a "Select Template" dropdown and a "Configure Fields" button. Below these, a note states: "All fields marked with an asterisk (*) are required". The form fields are: "Project*" (Controlled Terminology (CT)), "Issue Type*" (Review Comments), "Summary*" (empty text box), "Component/s" (dropdown menu with a red arrow pointing to it), "Package" (Biospecimens), "Fix Version/s" (Cell Phenotyping), and "Description" (CP). The dropdown menu for "Component/s" is open, showing a list of components: ADaM, Biospecimens, CDASH, Cell Phenotyping, CP, CV, Define-XML, Devices, ECG, General, Genomics, and Glossary. At the bottom of the form are "Create" and "Cancel" buttons.

CRITICAL Pieces of Information

- Two pieces of information are **CRITICAL** to getting your review comment seen by the CT teams:
 - Component – identifies the name of the specific PR file relevant to the comment.
 - Package (57) – identifies the package number that is relevant to the comment.
- Failure to fill in this information may delay resolution of your comment.



STEP 3: Fill out the “Create Issue” form [cont’d]

- Make sure Summary field is filled in
- Make sure Description field is filled in

The screenshot shows the JIRA 'Create Issue' form overlaid on a 'System Dashboard'. The form has a title bar with 'Select Template' and 'Configure Fields' buttons. The 'Summary*' field is empty and has a red arrow pointing to it. Below it is the 'Component/s' dropdown menu. The 'Package' is set to '57'. The 'Fix Version/s' is set to 'None'. The 'Description' field is empty and has a red arrow pointing to it. The form also includes a rich text editor toolbar with options for bold, italic, underline, text color, background color, link, unlink, list, and emoji. At the bottom of the form, there is a 'Create another' checkbox, a 'Create' button, and a 'Cancel' button. The background dashboard shows a table of issues assigned to the user, with columns for 'Key', 'T', and 'Summary'. The table lists issues like TOBA-252, TOBA-323, DDF-489, DDF-490, DDF-491, DDF-492, DDF-501, DDF-502, DDF-503, and DDF-504. The footer of the dashboard includes the Atlassian Jira Project Management Software version information and links for 'About Jira' and 'Report a problem'.



Helpful pieces of information for the Description Field (Free Text Field)

- **WHAT/WHERE:** Tell exactly what the issue is

“I don’t like the definition of Term X in codelist Y”

- **WHY:** Tell us why you are submitting a comment

“The definition is too narrow and does not take into account data context Z”

- **HOW:** Tell us exactly how to fix it

The draft definition should be changed from

“This is the draft definition.”

to

“This is the commenter’s updated draft definition.”

STEP 4: Hit the Create Button

- If you are submitting more than one comment, click the 'Create another' box to bring up a new form.

The screenshot shows the JIRA interface with a 'Create Issue' modal window. The modal has a title bar with 'Create Issue', 'Select Template', and 'Configure Fields'. The form fields are: Summary* (text input), Component/s (dropdown), Package (57), Fix Version/s (None), and Description (rich text editor). At the bottom right of the modal, there is a checkbox for 'Create another', a blue 'Create' button, and a 'Cancel' button. A red arrow points to the 'Create' button.

STEP 5: A link to the newly created issue will appear on the top right of the page.

The screenshot shows the JIRA System Dashboard interface. At the top, there is a navigation bar with the CDISC logo, menu items for JIRA, Dashboards, Projects, Issues, Boards, Plans, and Templates, and a 'Create' button. A search bar is also present. Below the navigation bar, a blue banner contains a disclaimer: "All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization." The main content area is titled "System Dashboard" and features a table of issues assigned to the user. A notification in the top right corner, highlighted with a red circle, states: "Issue CT-1045 - This is a test only has been successfully created." Below the notification is a welcome message: "Welcome to CDISC JIRA. An issue tracking system used by the teams to track, respond, and resolve issues identified by the teams and the public within the standards being developed." A "Quick Links" section is located at the bottom right of the dashboard, listing navigation and filter options.

Key	T	Summary	P ↓
TOBA-252	🔍	FATESTCD and FATEST	⋮
TOBA-323	?	The Trial Summary (TS) dataset allows the applicant to submit a summary of the trial in a structured format.	⋮
DDF-489	🔍	The definitions for EligibilityCriterion name and description appear to be switched.	⋮
DDF-490	🔍	Why does the definition for Organization name not follow the pattern for other definitions of name attributes?	⋮
DDF-491	🔍	Why does the definition for SyntaxTemplate.name not follow the pattern for the name attribute of other classes?	⋮
DDF-492	🔍	Why does the definition for Timing.description not follow the pattern for other description attributes?	⋮
DDF-501	📈	Disease/Condition Indication Definition	⋮
DDF-502	📈	Clarification of Sex of Participants	⋮
DDF-503	📈	Study Arm definition uses the term "subject", others use "participant"	⋮
DDF-504	📈	Condition Assignments definition suggestion	⋮

1-10 of 22 1 2 3 ▶

Atlassian Jira Project Management Software (v9.4.17#940017-sha1:2c0a67f) · [About Jira](#) · [Report a problem](#)

Comment Resolution by the CT Team

The image shows a screenshot of the Jira CDISC interface. The top navigation bar includes the CDISC logo, JIRA, and various menu items like Dashboards, Projects, Issues, Boards, Plans, and Templates. A search bar and user profile are also visible. A blue banner at the top states: "All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization."

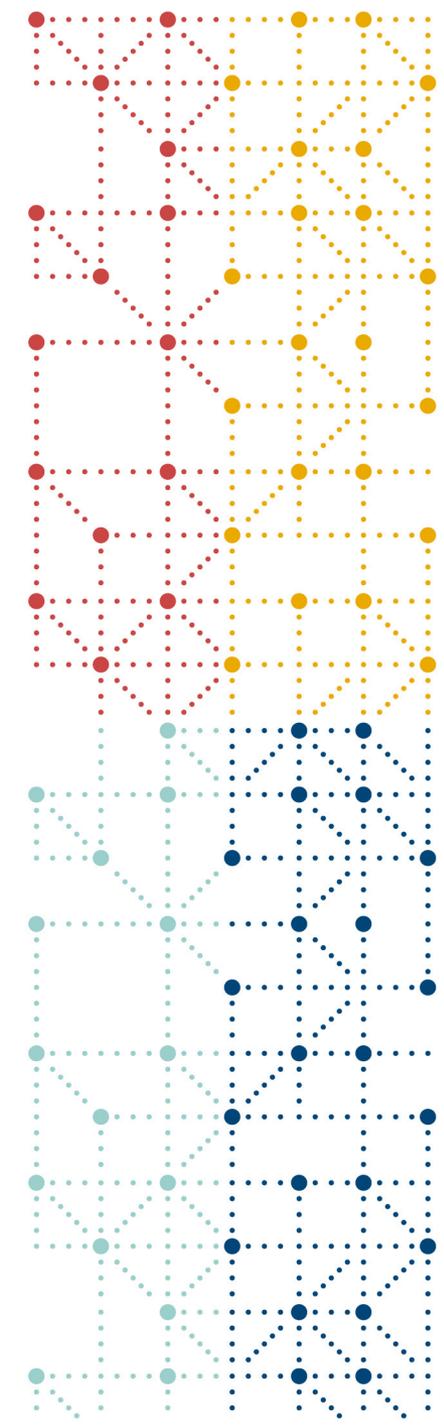
The main content area displays "Controlled Terminology" and "Edit Issue : CT-1045". A "Configure Fields" button is present. The issue form is open, showing the following fields:

- Reporter: Erin Muhlbradt
- CDISC Disposition: A dropdown menu is open, showing options: None, Question answered, Considered for future, Persuasive, Persuasive with modification, Not persuasive, Not persuasive with modification, Considered-no action required, and Out of scope. A red arrow points to the "None" option.
- CDISC Disposition Description: A text area with a red arrow pointing to it.
- Affects Version/s: None
- Fix Version/s: None
- Epic Link: A dropdown menu with a red arrow pointing to it.

At the bottom right of the form, there are "Update" and "Cancel" buttons, with a red arrow pointing to the "Update" button. The background shows a sidebar with "Controlled Terminology" and "Issues" sections, and a right-hand panel with "Unassigned" and "Assign to me" options.

Questions for Webinar Participants:

- Have you ever participated in CDISC public review?
 - Yes
 - No
- If you have participated in CDISC public review anytime in the past, how long, on average, did you spend on the review task?
 - 0-1 Hours
 - 1-3 Hours
 - 4 or more Hours
- If you have participated in CDISC public review anytime in the past, was your comment resolved satisfactorily?
- If you have not submitted a public review comment, what has prevented you from participating in CDISC public review?
 - No Access to CDISC Wiki
 - Submitting Comments Takes Too Much Time
 - Public Review File Formats are Confusing
 - Submitting Public Review Comments through JIRA is Confusing or Cumbersome
 - Someone Else from My Company is Tasked with this Action
 - Not Part of My Job Description
 - Other, specify?
- How can we improve the CT public review process?



A Special Thank you

Our sincerest thanks to the team at AdClin® for once again undertaking a comprehensive review of the CDISC codetable mapping files and CDISC CT. Their feedback allowed us to significantly improve the quality of the codetable mapping files posted on 2024-03-29.



CDISC Membership

Become a Member!

Join 500+ member organizations that contribute to bringing clarity to data.

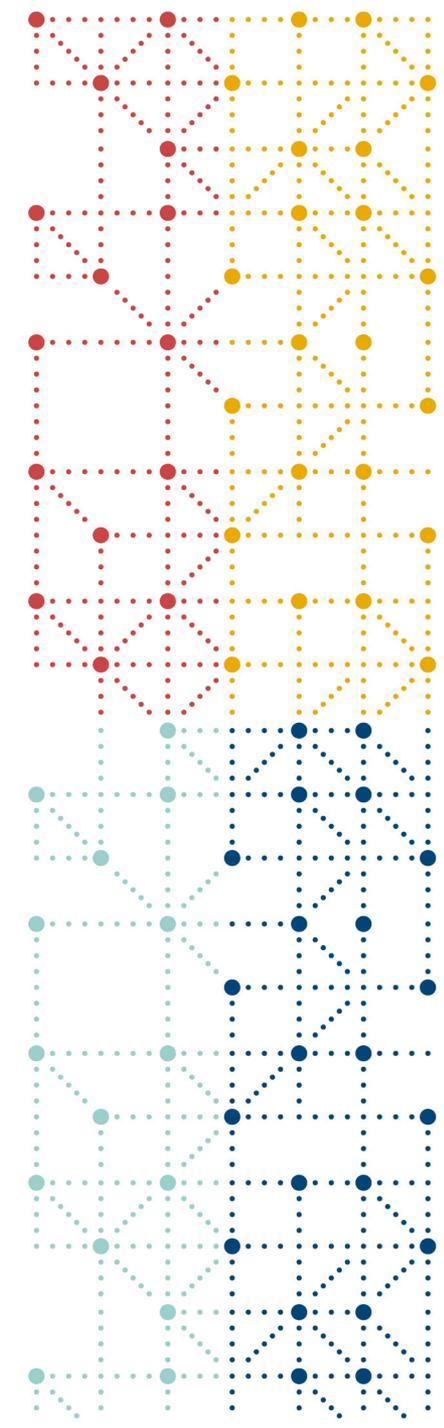
Already a Member?

Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.



Email: membership@cdisc.org





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

Erin Muhlbradt, muhlbradtee@mail.nih.gov

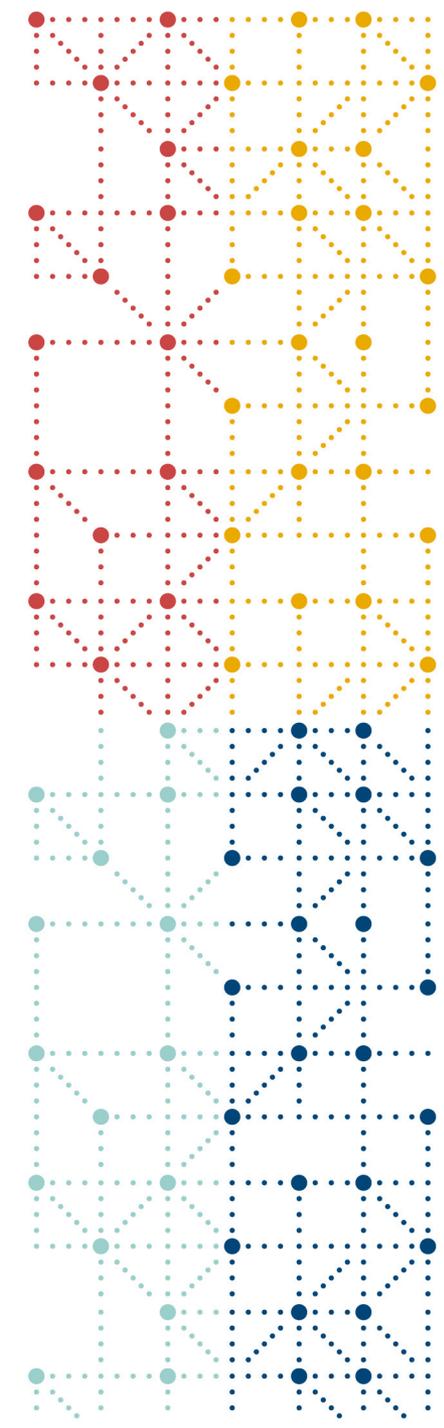
OR

<https://www.cdisc.org/volunteer>

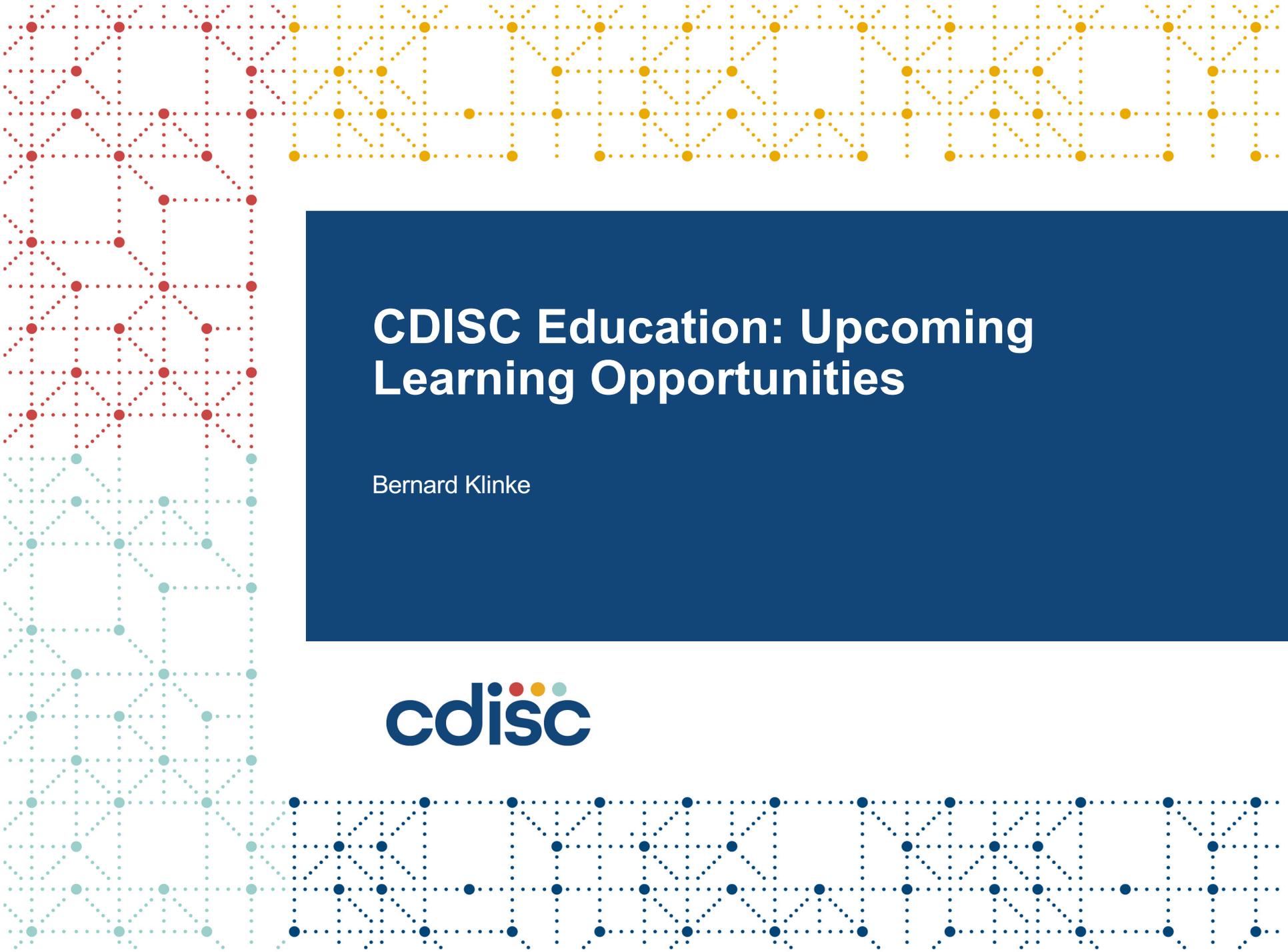
[CDISC New term request form:](https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc)

<https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>





Q&A

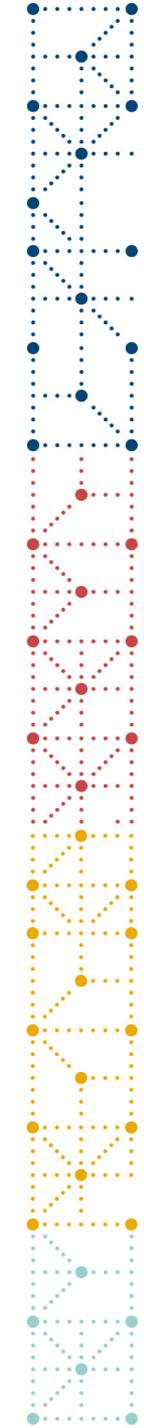


CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



Thank you for your attendance and support of
CDISC!



CDISC Terminology Publication Cadence

Previously, CDISC published updates to CDISC Controlled Terminology on a quarterly schedule: end March, end June, end September, mid December.

Starting in 2024 CDISC is changing the publication cadence for CDISC Controlled Terminology to **biannual releases** (twice per year): end-March and end-September

	A	B	C	D	E	F	G	H	I	J
1	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			
2	57	12/8/2023	12/15/2023	1/12/2024	2/9/2024	3/29/2024	ADaM	Biospec	Cell Pheno	CV
3	57						ECG	General	Genomics	Lab
4	57						Microbio/Immuno	MRCT	Oncology	SEND
5	57						Unit			
6	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 (8 wks)	Codelists to be Included			
7	58	5/31/2024	6/7/2024	7/5/2024	8/2/2024	9/27/2024				
8	58									
9	59	12/13/2024	12/20/2024	1/17/2025	2/14/2025	3/28/2025				
10	59									
11	60	5/30/2025	6/6/2025	7/4/2025	8/1/2025	9/26/2025				

- ### Milestone Dates
- P57 Publication date: 3/29/2024
 - P58 Public Review date: 6/7/2024
 - P58 Publication date: 9/27/2024
 - P59 Public Review date: 12/20/2024
 - P59 Publication – end-March 2025
 - P60 Public Review – early-June 2025
 - P60 Publication – end-Sept 2025
 - P61 Public Review – Mid-Dec 2025