CDISC Controlled Terminology Quarterly Webinar

Presented by Dr. Erin Muhlbradt, PhD

04.18.2024

Controlled Terminology P57 Publication

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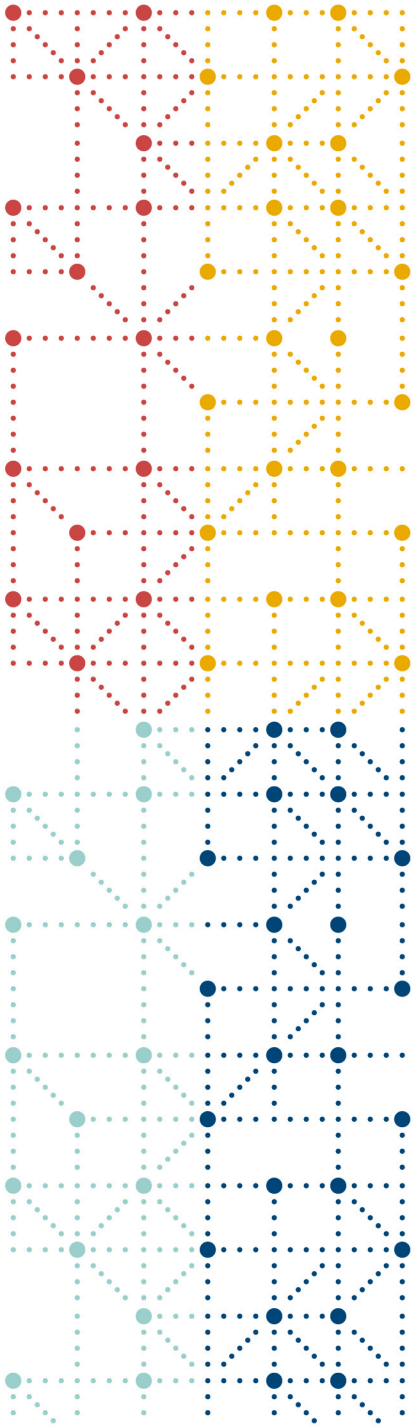
04.18.2024

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	1/20/2022	2/17/2023	3/31/2023	Biospec	Cell Pheno	General	Lab
53						Microbio/Immuno	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/Immuno
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/Immuno
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/Immuno	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/Immuno	MRCT	Oncology	SEND
57						Unit			
58	5/31/2024	6/7/2024	7/5/2014	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:
      - LVLDSCRS/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
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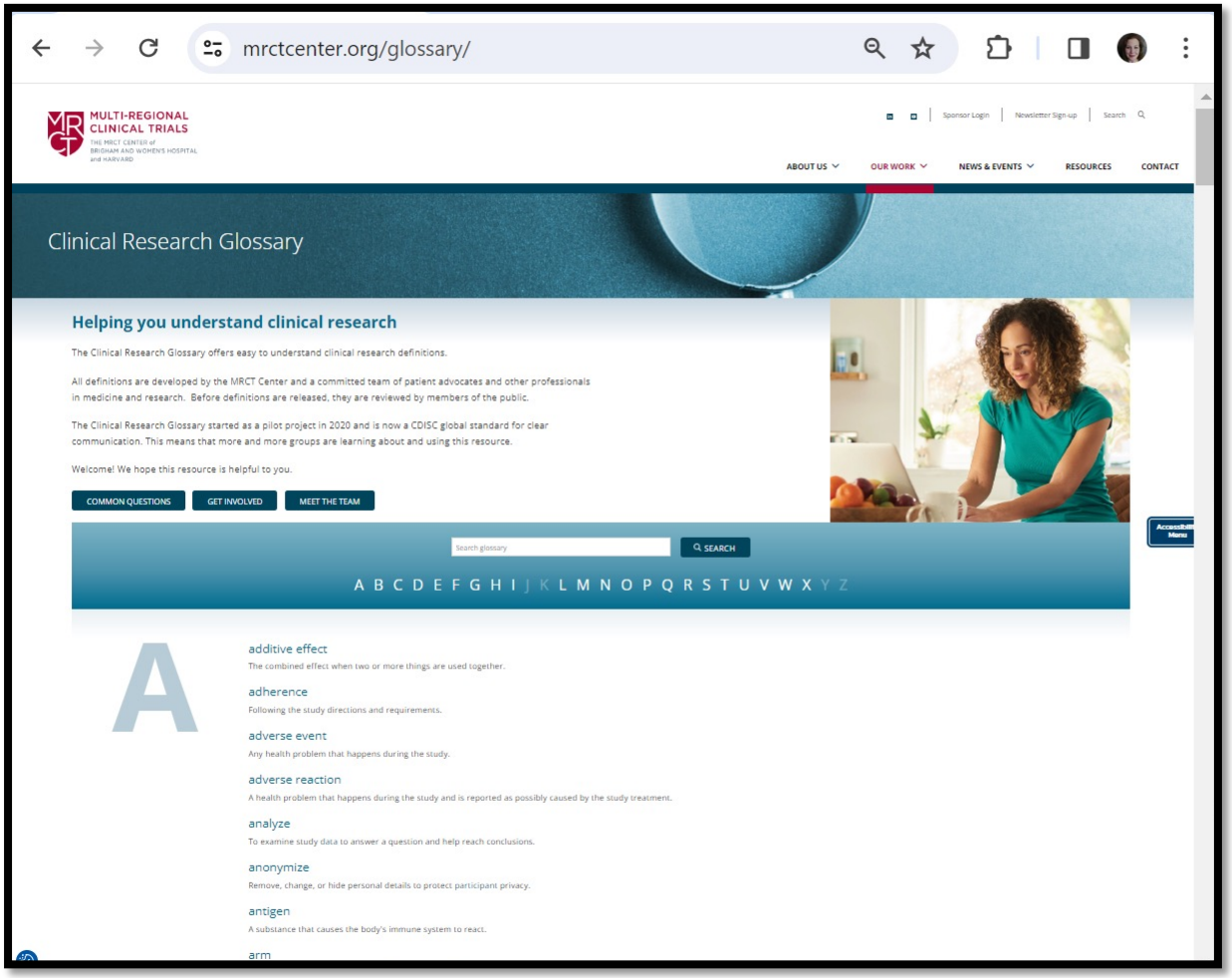
SOFA0105OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0105 TN/TC
SOFA0105STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0105 TN/TC
SOFA0106OR - Sepsis-related Organ Failure Assessment Questionnaire ORRES for SOFA0106 TN/TC
SOFA0106STR - Sepsis-related Organ Failure Assessment Questionnaire STRESC for SOFA0106 TN/TC

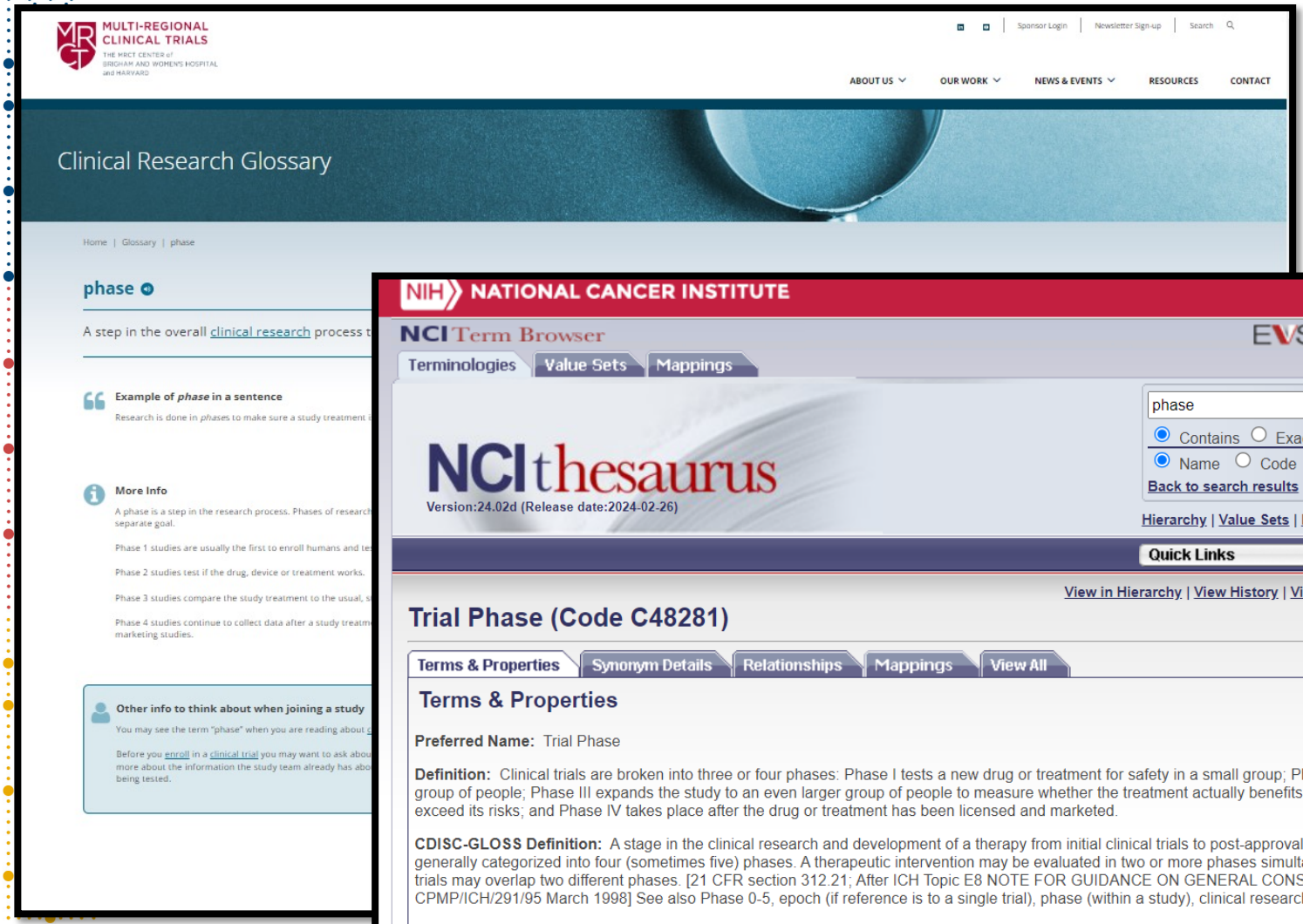
MRCT Terminology

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.



https://mrctcenter.org/glossary/

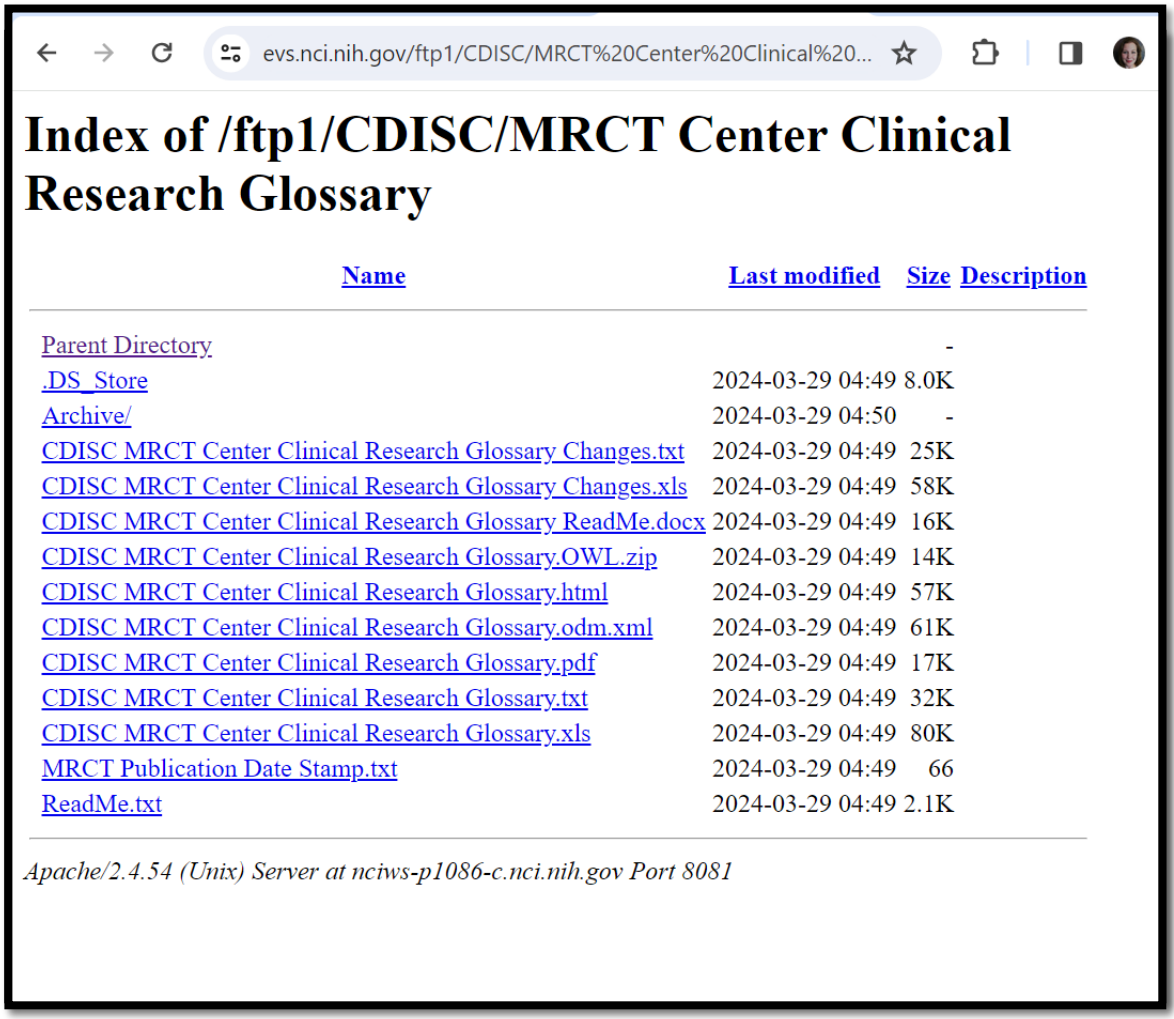
MRCT Terminology



cdisc

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 webpage



DDF USDM Terminology

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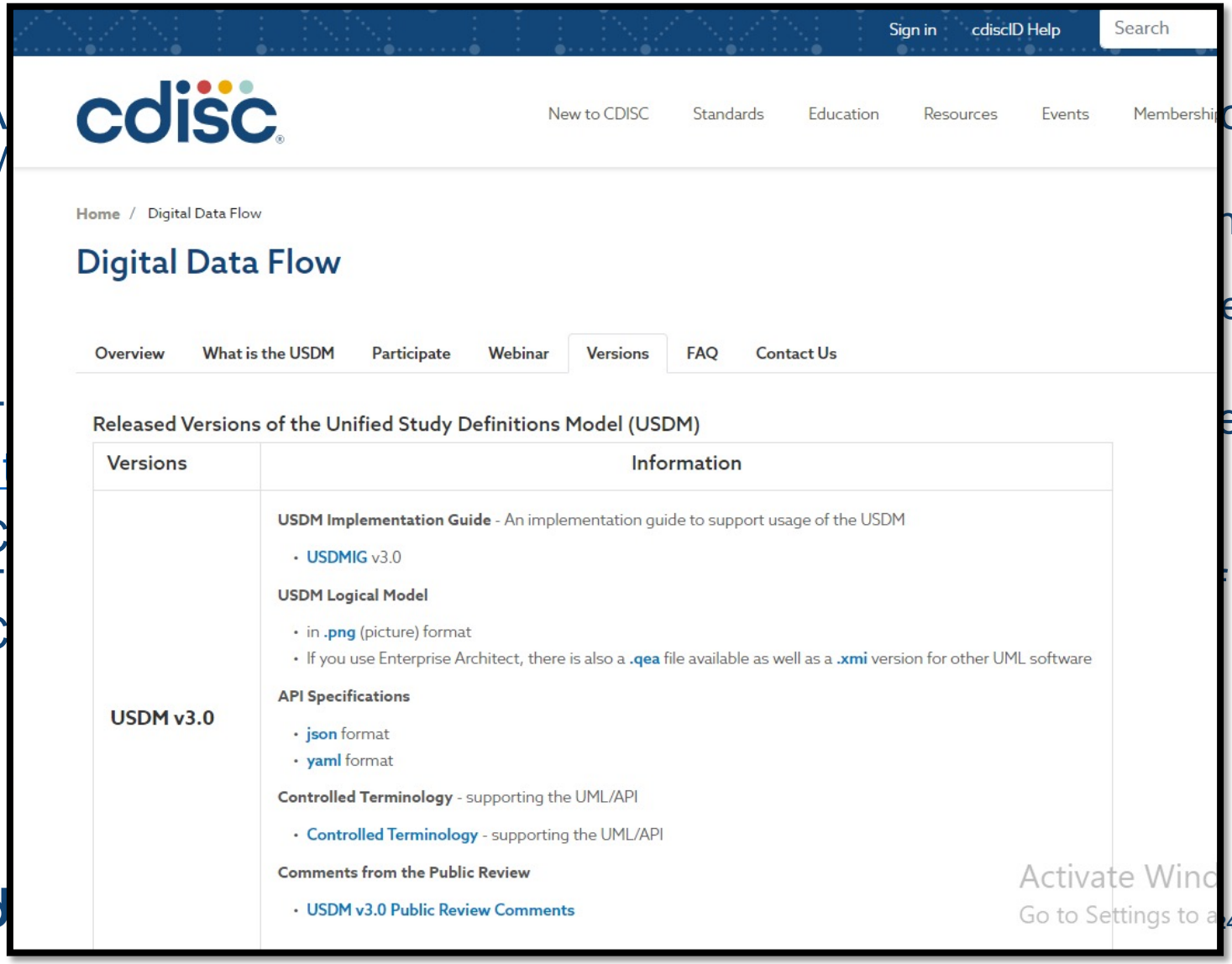


Controlled Terminology Public Review

-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.

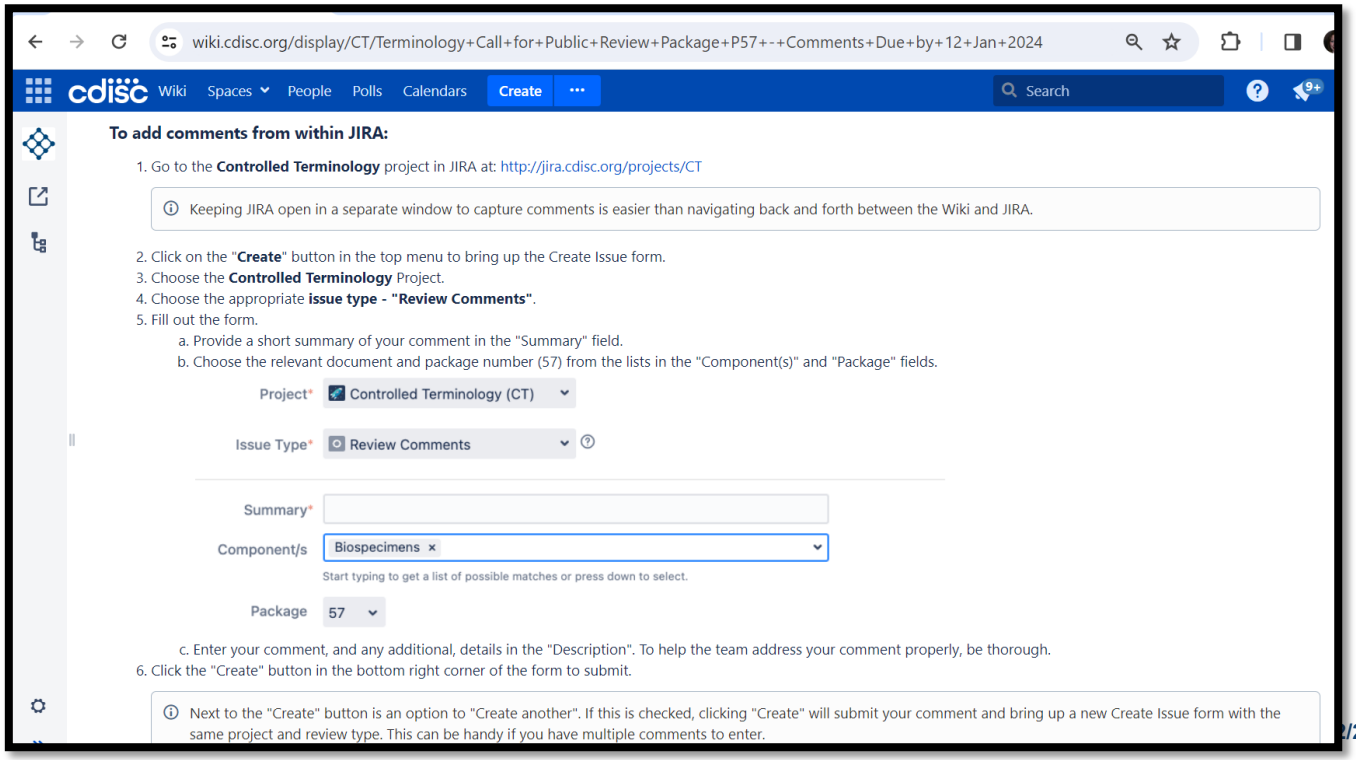
Increases the quality of the final product.

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.

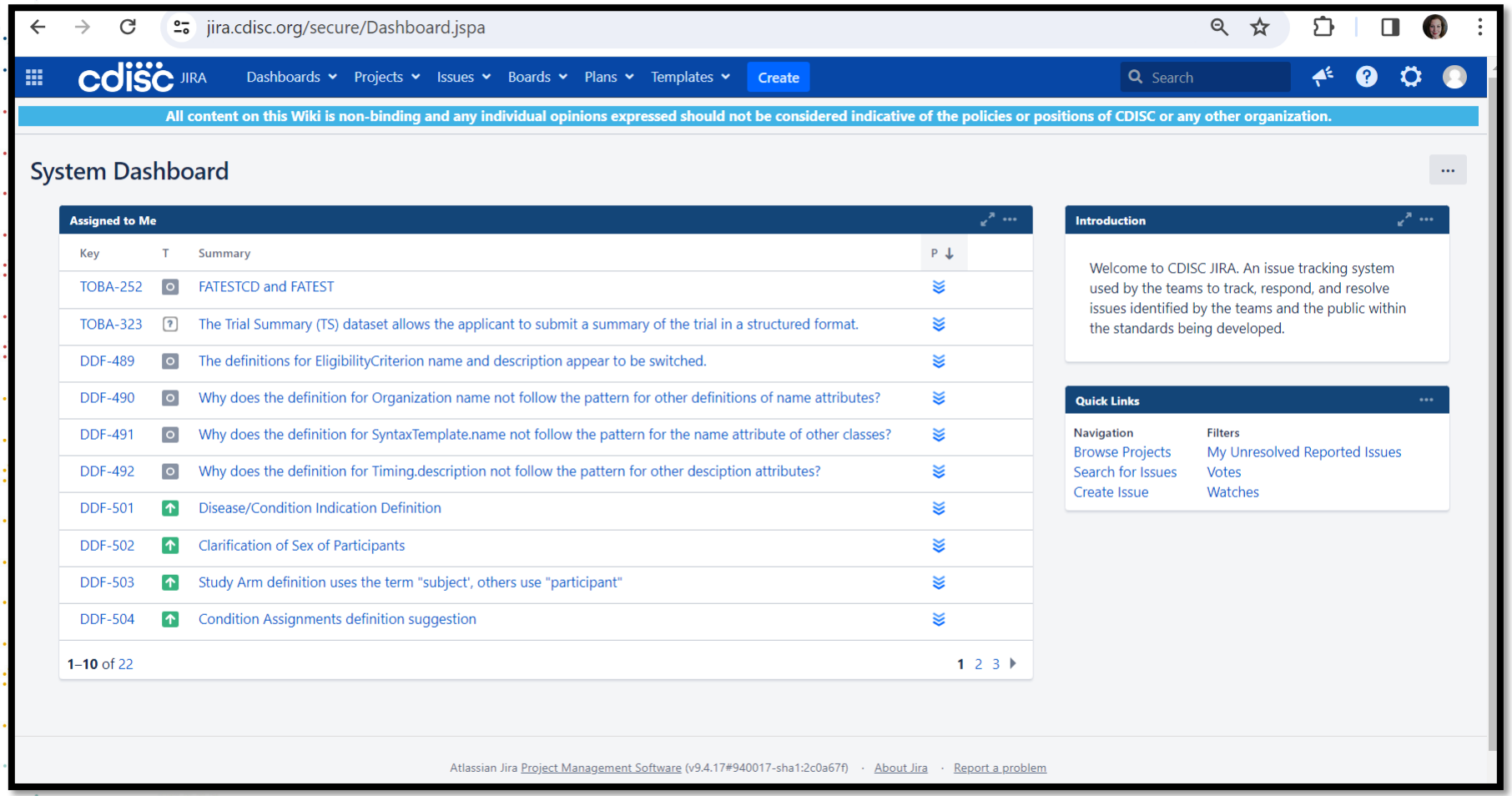
CDISC Public Review Process

- 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.



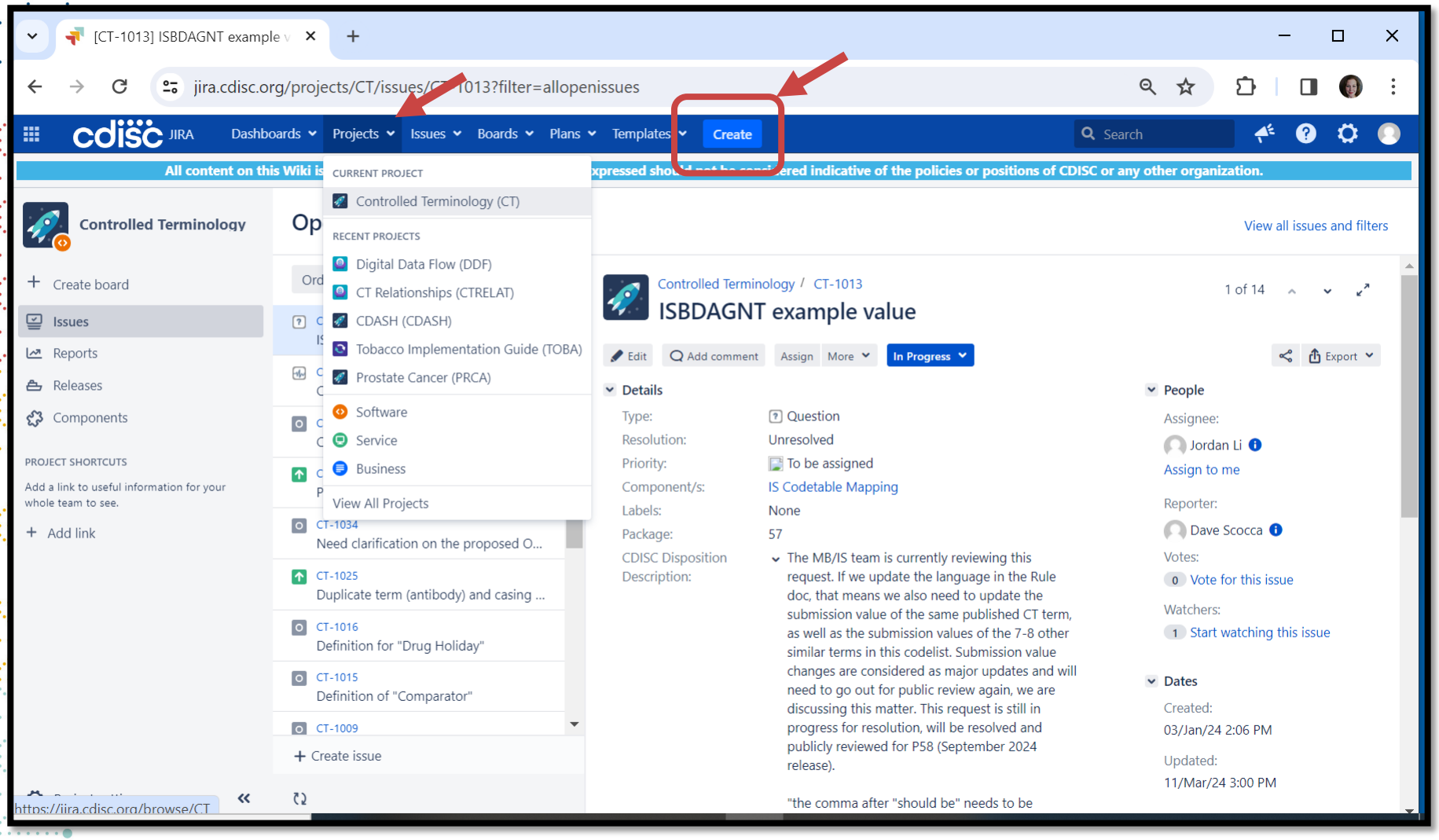
STEP 1: Navigate to JIRA

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



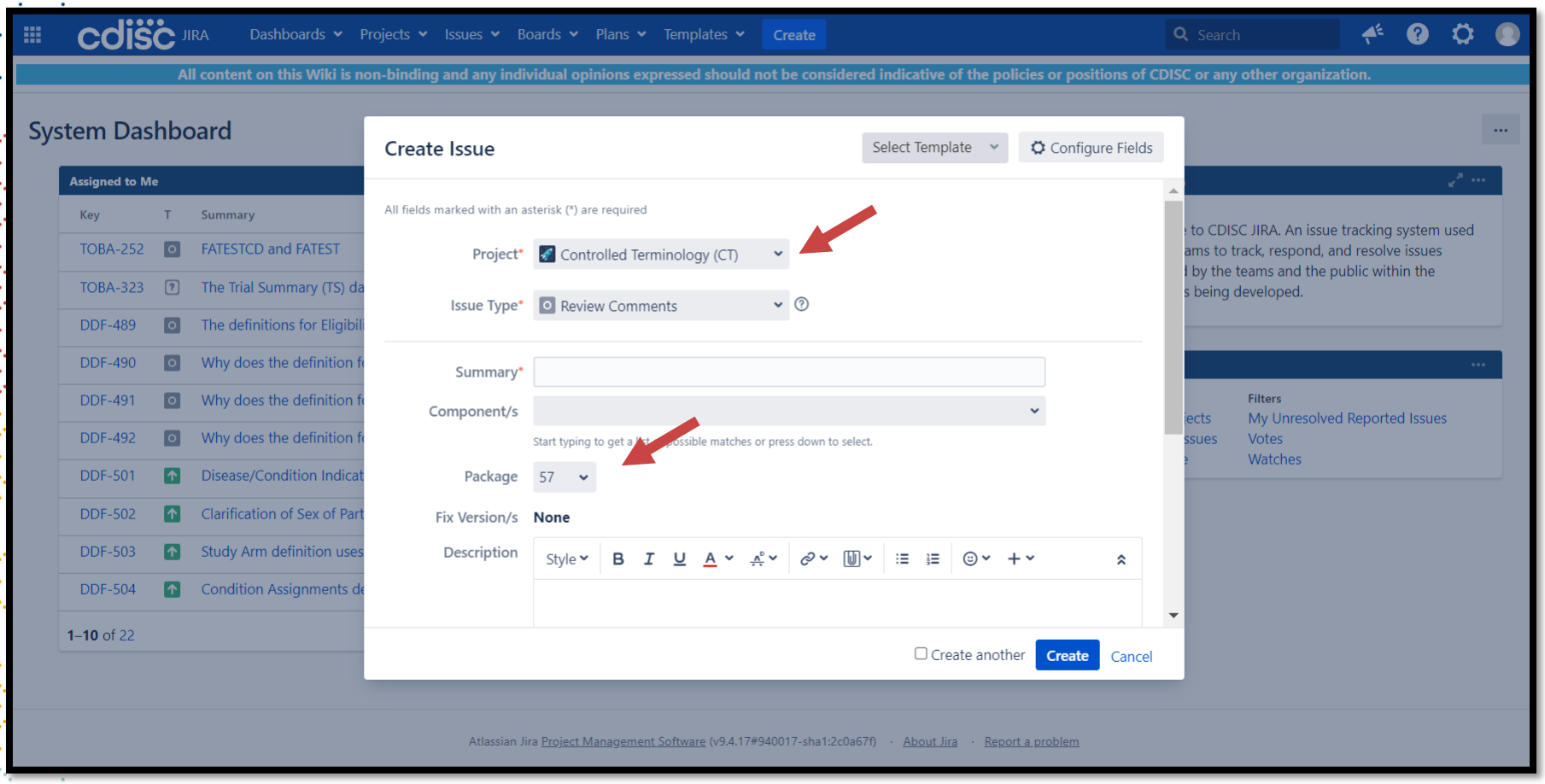
STEP 2: Click Create

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



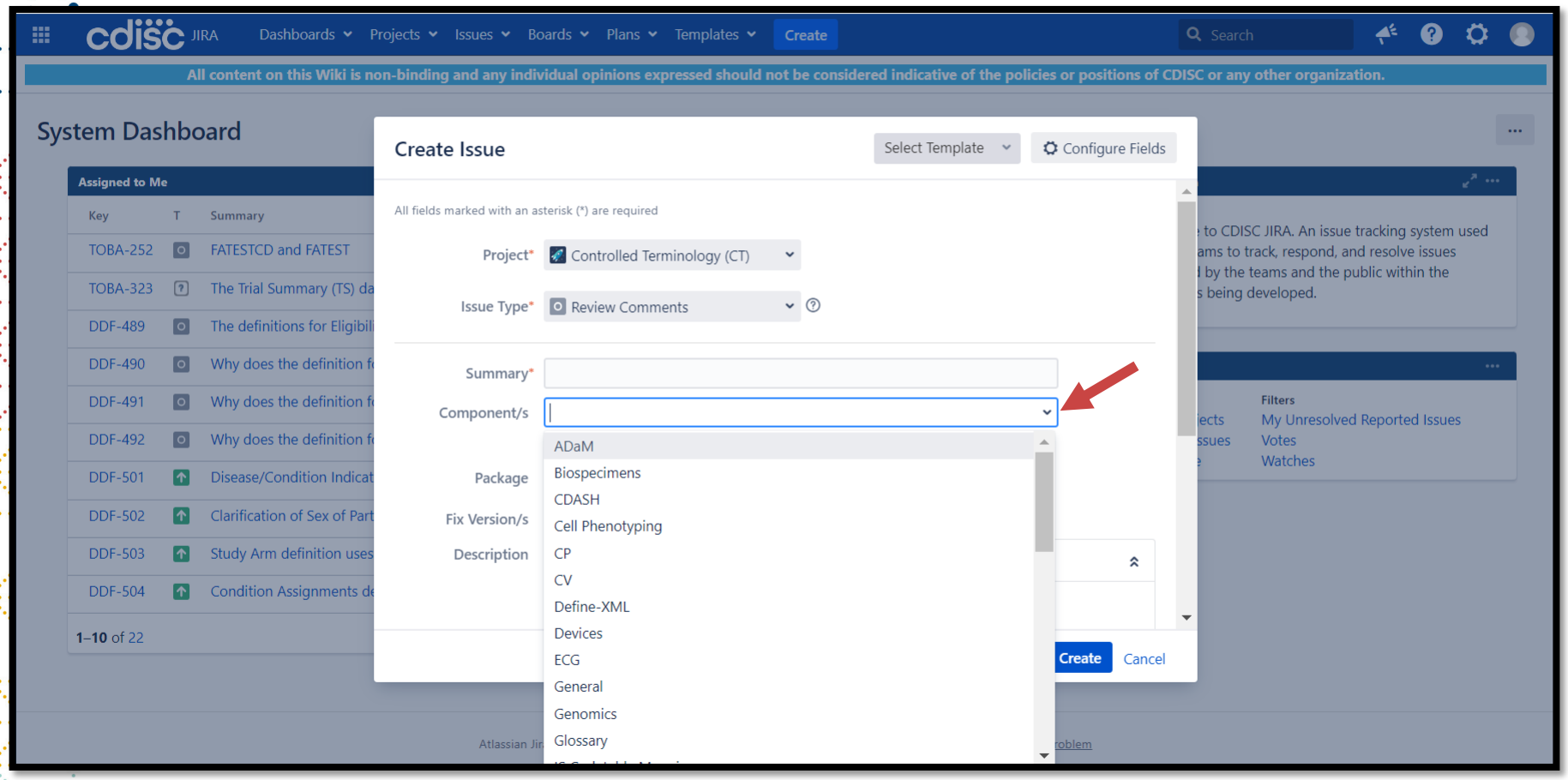
STEP 3: Fill out the “Create Issue” form

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



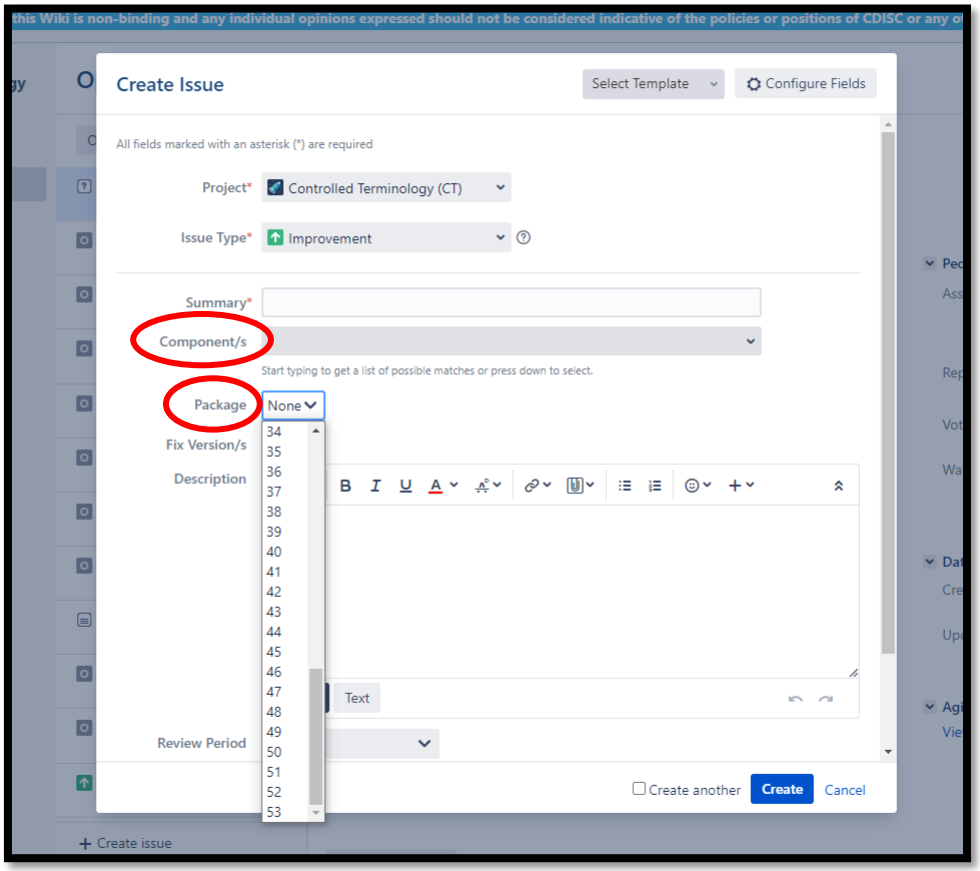
STEP 3: Fill out the “Create Issue” form [cont’d]

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



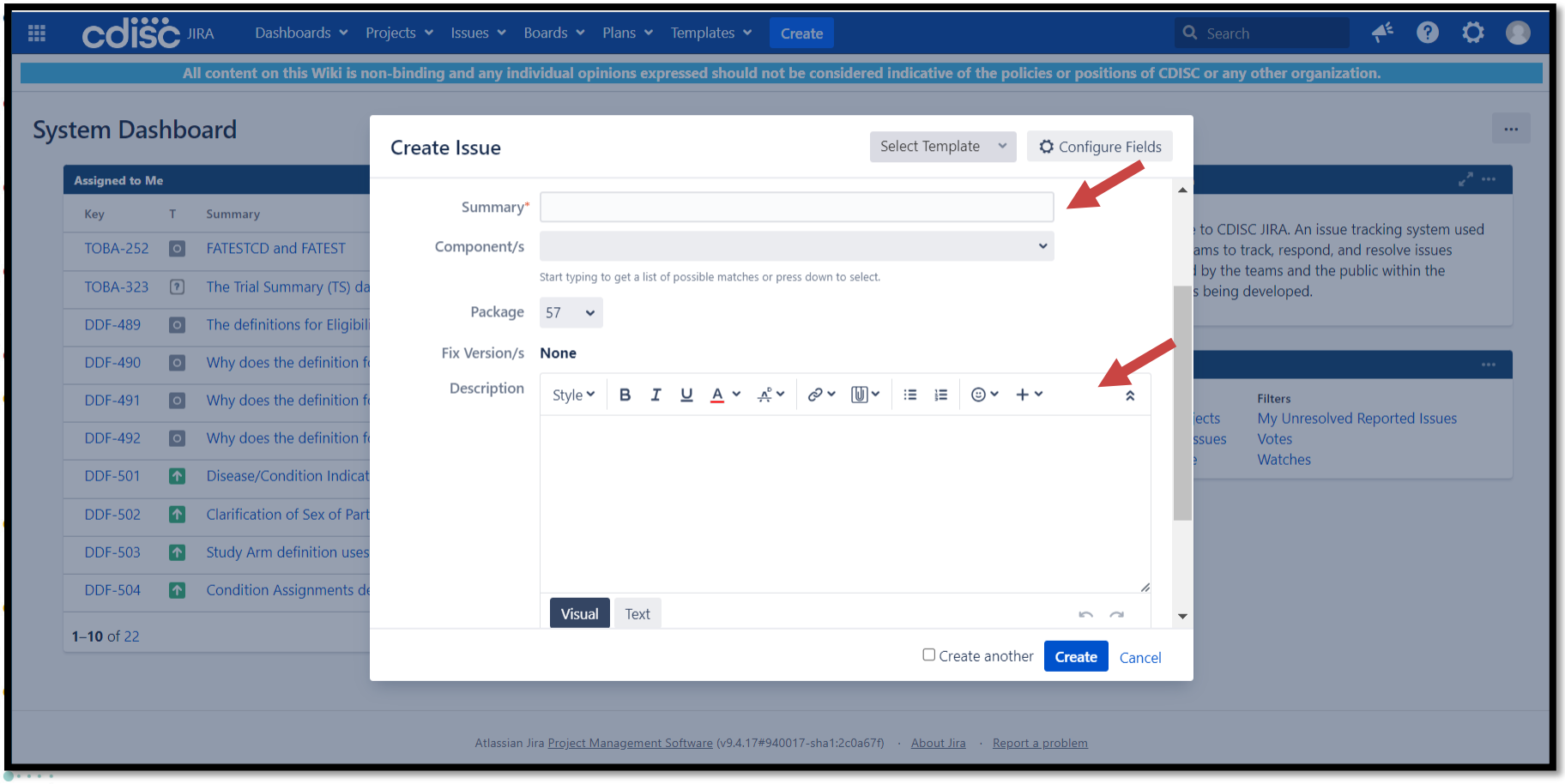
CRITICAL Pieces of Information

- 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



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

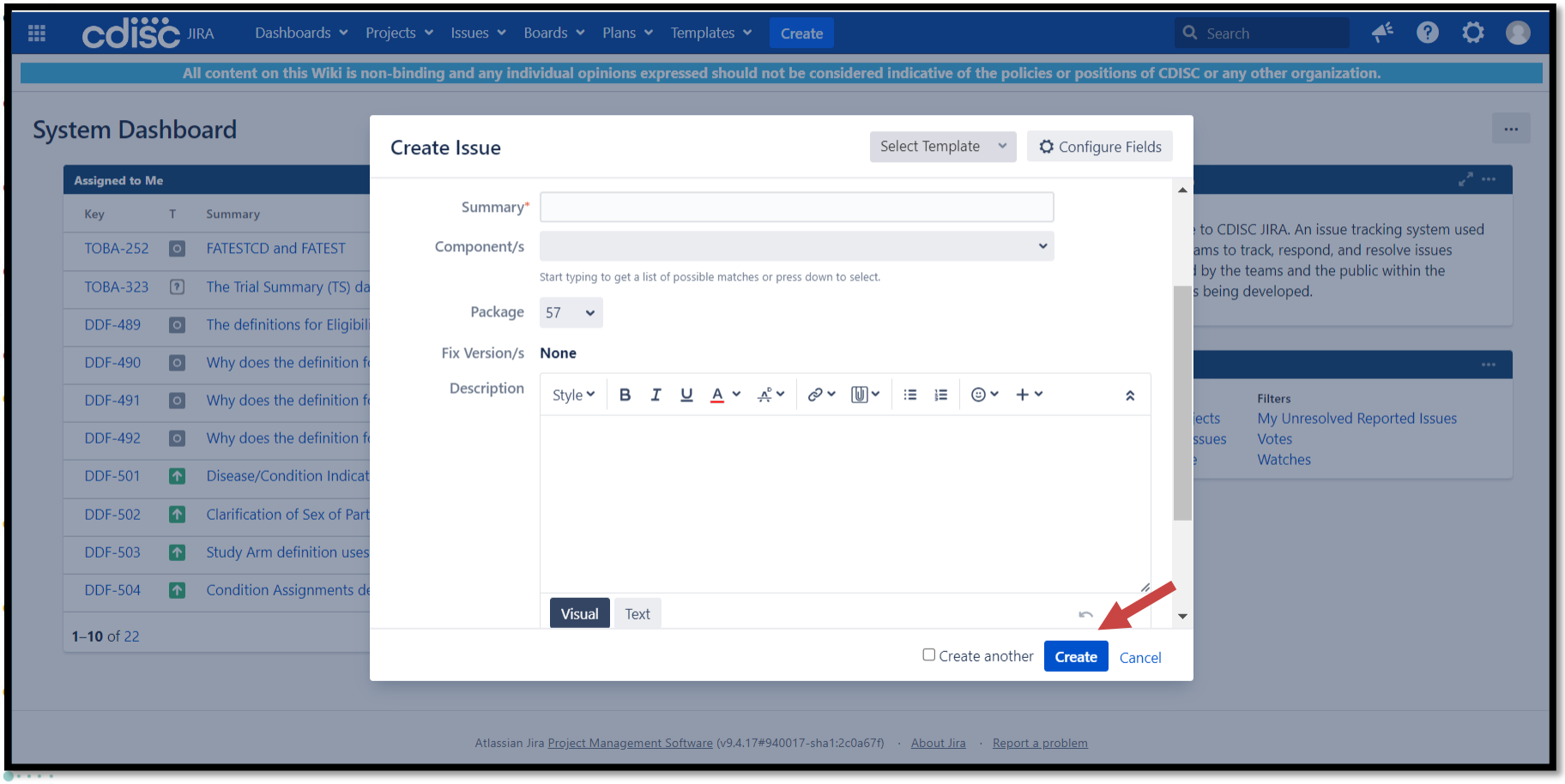
"This is the draft definition."

to

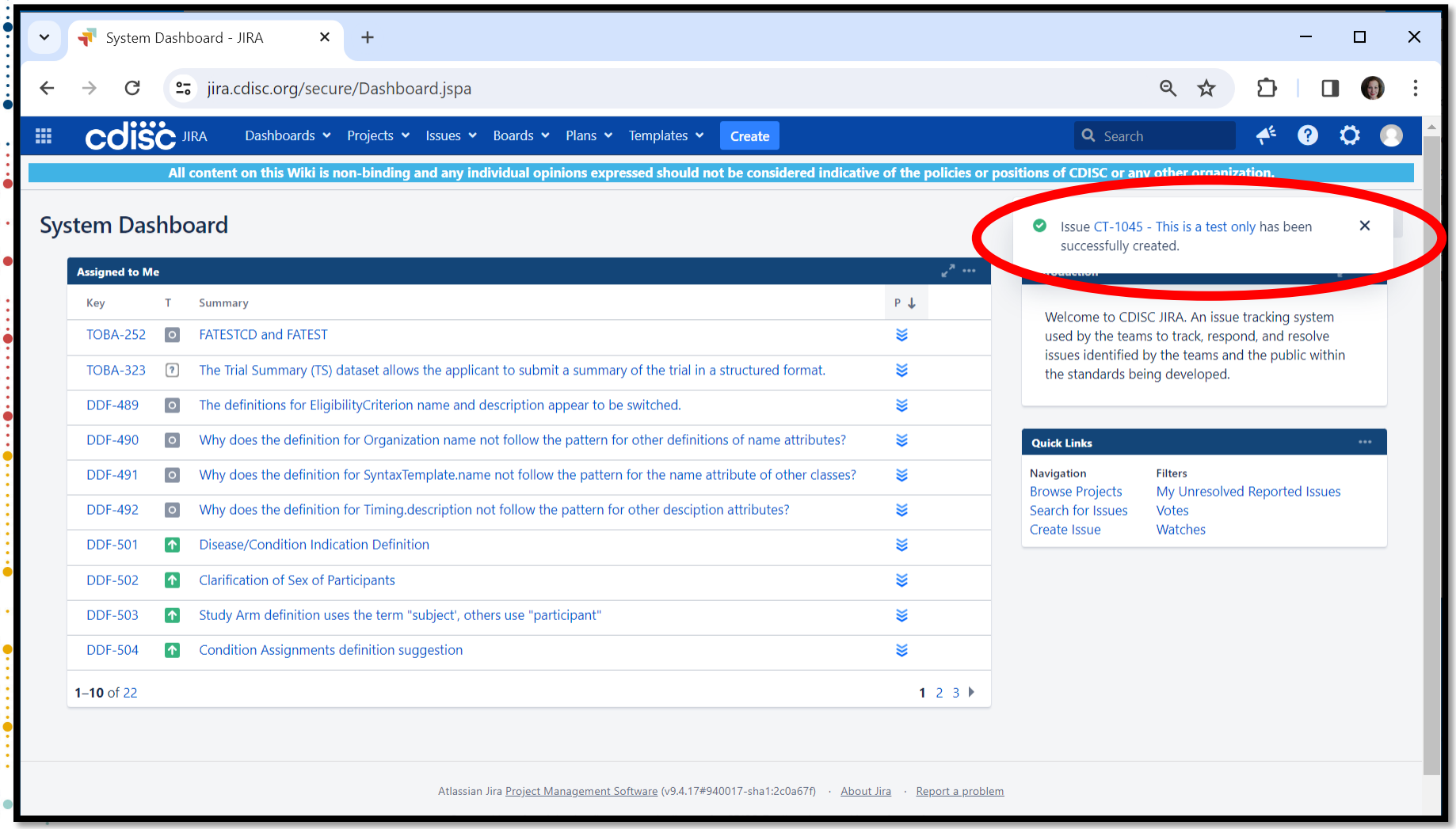
"This is the commenter's updated draft definition."

STEP 4: Hit the Create Button

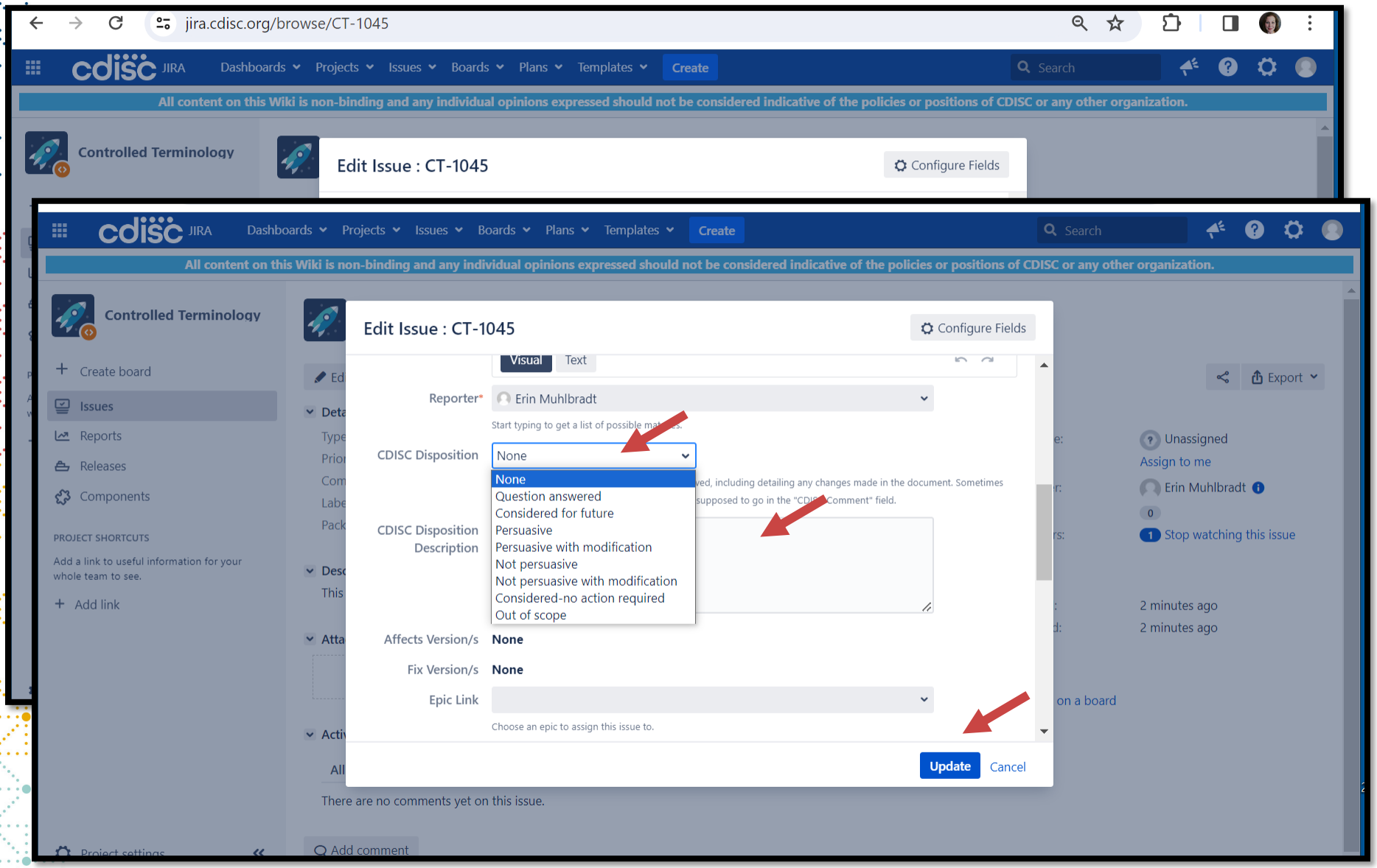
- If you are submitting more than one comment, click the ‘Create another’ box to bring up a new form.



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



Comment Resolution by the CT Team



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?

To the amazing and dedicated CDISC Controlled Terminology Team members and reviewers, YOU are the heart and soul of CDISC terminology!

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?

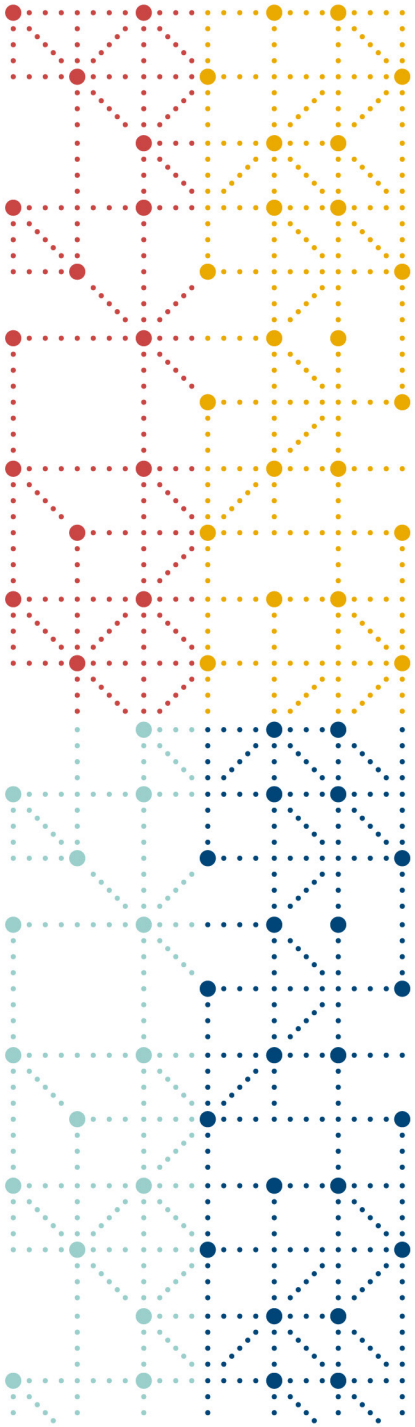
Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.

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://nciterm form.nci.nih.gov/nciterm form/?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
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7	58	5/31/2024	6/7/2024	7/5/2014	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