CDISC Controlled Terminology Quarterly Webinar

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06.18.2024

Controlled Terminology P58 Public Review

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06.18.2024

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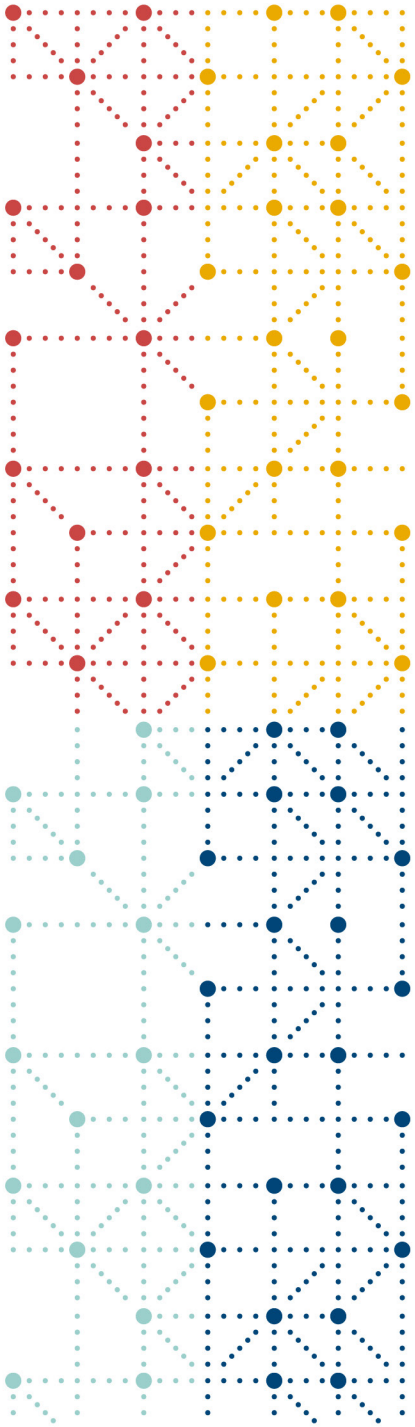


Question & Answer

1. ‘Panelist’: Question

OR

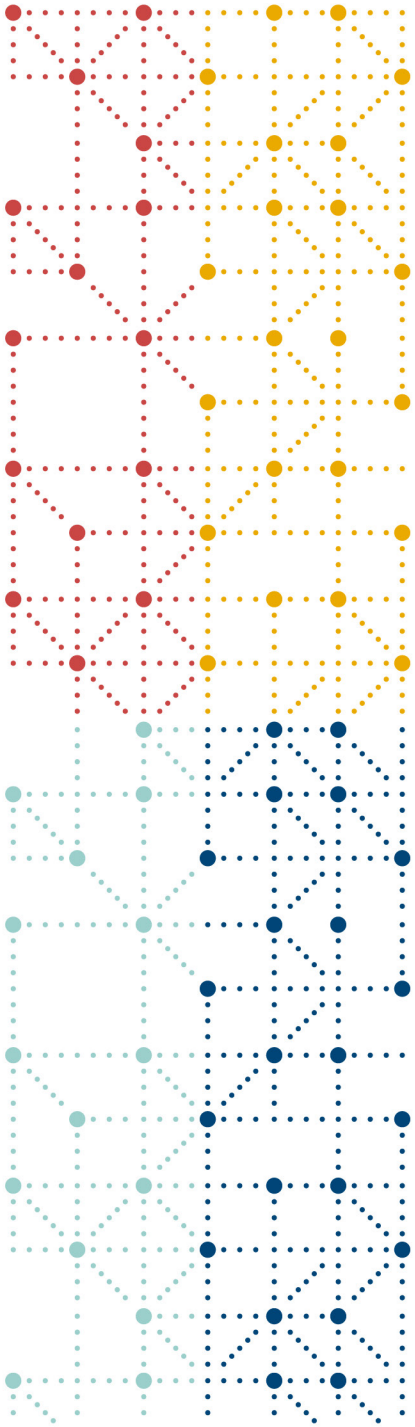
1. ‘Presentation’: Question

Examples:

1) What should be supported by ADaM datasets?
2) Is there a limit to the number of variables that can be in ADSL?

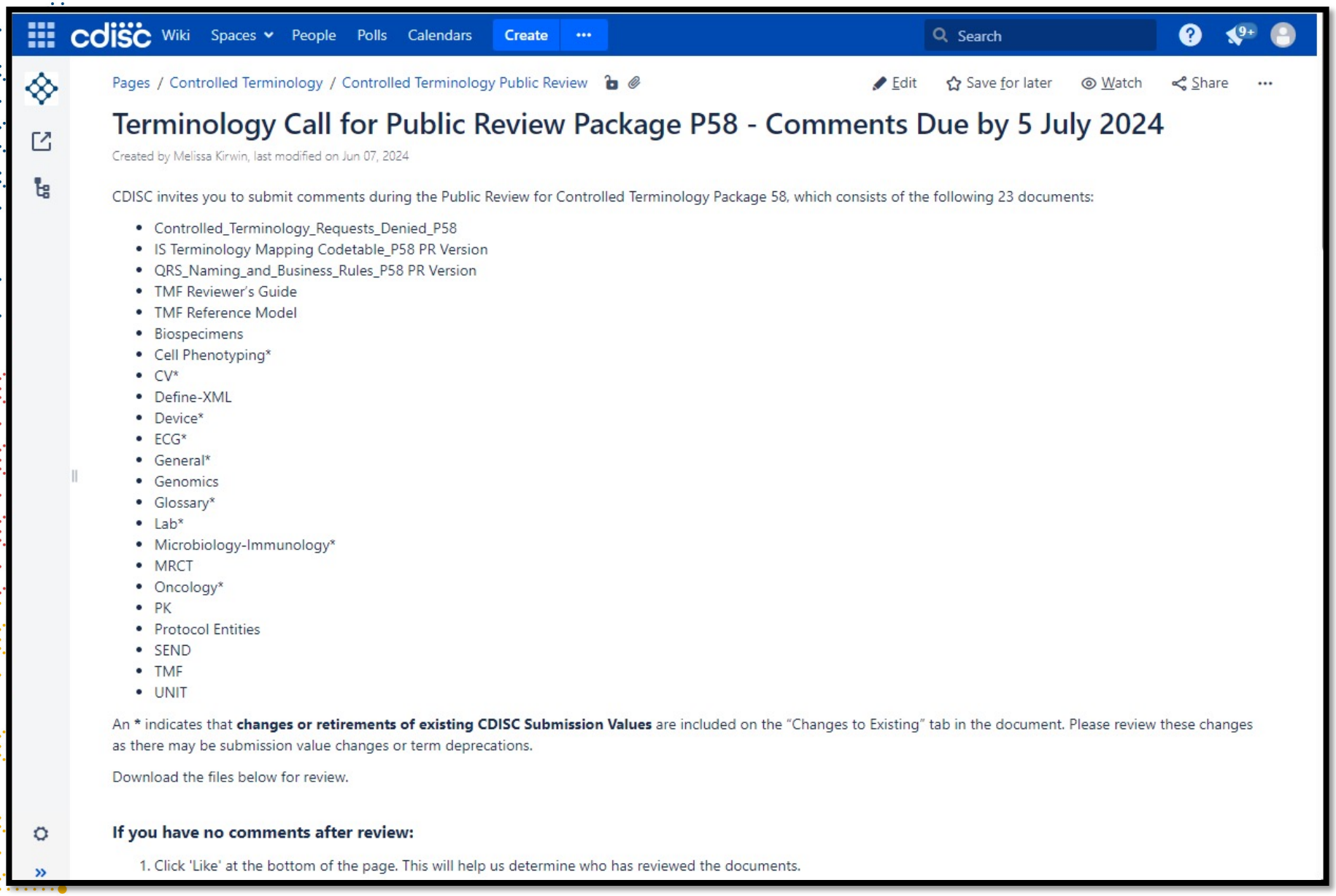
Agenda

1. Package 58 Publication Review (2024-06-07 to 2024-07-05)
   - TMF Terminology Deep Dive
   - How to submit a public review comment for Terminology
2. Questions



Controlled Terminology Package 58 Public Review

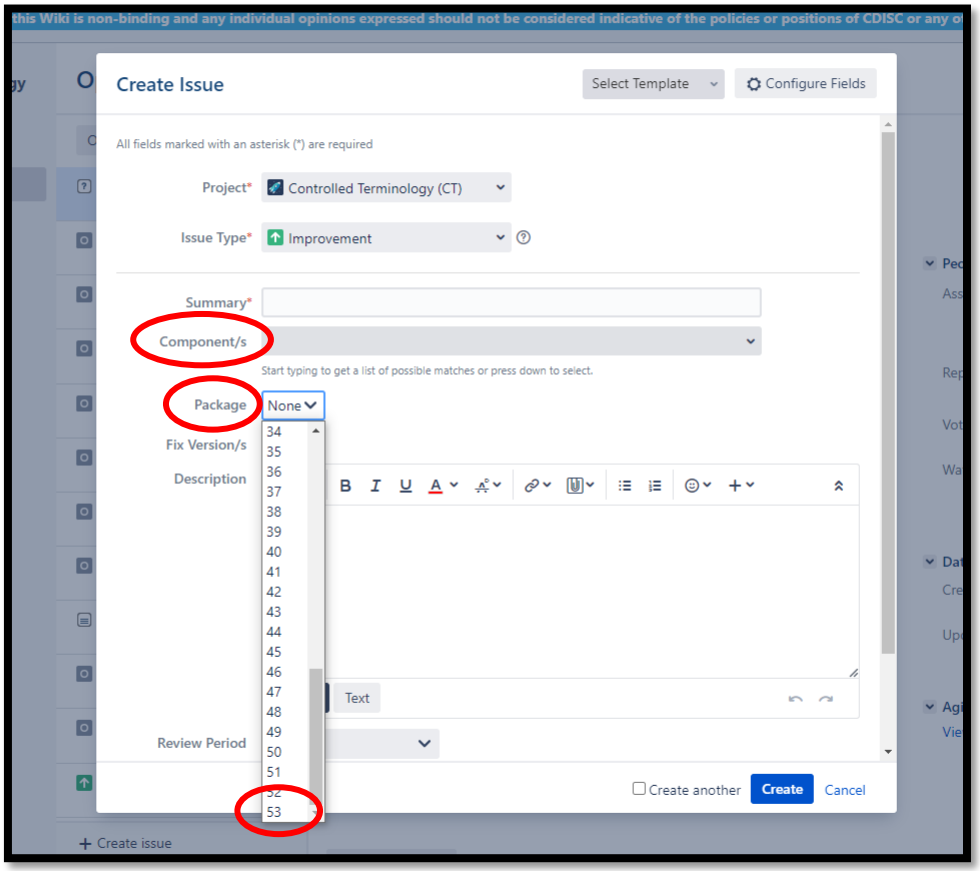
2024-06-07 to 2024-07-05



[Terminology Call for Public Review Package P58 - Comments Due by 5 July 2024 - Controlled Terminology (CT) - Wiki (cdisc.org)]

Public Review Comment Submission in JIRA

- 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 (58) – identifies the package number that is relevant to the comment.
- Failure to fill in this information may delay resolution of your comment.



Controlled Terminology Package 58 Public Review

- ADaM Team
  - No new term or changes to existing to report this quarter.
  - No denied requests

Controlled Terminology Package 58 Public Review

- Biospecimens Team
  - New Terms Added to Existing Codelists:
    - BSTEST-CD; CLMETH; SPECTYP
  - No changes to published terms
  - Denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- CDASH Team
  - New terminology related to the SOGI (Sexual Orientation and Gender Identity) CRF are included in the General CT file.
    - SCTEST-CD
    - New Codelists of valid responses to new SCTEST values:
      - SEXABRTH
      - ISXDXRS
      - GENIDENT
      - SEXORIRS

Controlled Terminology Package 58 Public Review

- Cell Phenotyping Team
  - New Terms Added to Existing Codelists:
    - CPTEST-CD
  - 4 change to existing; 4 are significant
  - Denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- Cell Phenotyping Team – Significant Changes to Existing
  - CPTEST-CD: Remove term C181279 MNPMNNP / Mono Prolif/Mono NonProlif and replace with CNEW MNSMNS / Mono Sub/Mono Sub which will be published as a new term with P58.
  - CPTEST-CD: Remove term C181277 LYVLYNV / Lym Viable/Lym NonViable and replace with CNEW Lym Sub/Lym Sub / LYSLYS which will be published as a new term with P58.

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Controlled Terminology Package 58 Public Review

- CV Team
  - New Terms Added to Existing Codelists:
    - CVTEST-CD
  - 8 changes to existing; 4 are significant
  - No denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- CV Team – Significant Changes to Existing
  - CVTEST-CD: Update submission value for C135372 from HCVOLEVD/ Heart Chamber Volume, EVD to EDV/End Diastolic Volume
    - The original test was scientifically correct, but this test is commonly known as the End Diastolic (Blood) Volume. For clarity and easier mapping, this term is updated to align with its commonly known name.
  - CVTEST-CD: Update submission value for C135373 from HCVOLEVS /Heart Chamber Volume, EVS to ESV/End Systolic Volume
    - The original test was scientifically correct, but this test is commonly known as the End Diastolic (Blood) Volume. For clarity and easier mapping, this term is updated to align with its commonly known name.

Controlled Terminology Package 58 Public Review

- Define-XML Team
  - New Terms Added to Existing Codelists:
    - DICTNAM
  - 4 changes to existing; none are significant
  - Denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- Medical Devices Team
  - No new terms to report this quarter
  - 2 changes to existing; 2 are significant
  - No denied requests in the Denied Requests file

- Medical Devices Team – Significant Changes to existing
  - DOTEST-CD: The NCI c-codes for INDC/Indication for Use are being changed from C41184 to C112038. The c-code is being changed to align the semantics of the DOTEST-CD with an existing TSPARM-CD value.

Controlled Terminology Package 58 Public Review

- ECG Terminology Team:
  - New Terms Added to Existing Codelists:
    - EGTEST-CD
  - No changes to existing terms
  - Denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - DIR; EPOCH; ETHNICC; FDATSRS; HODECOD; LOC; MHEDTTYP; RACEC; RELSUB; RPTEST-CD; PROCEDUR; SCTEST-CD; SRTEST-CD; SSTEST-CD; TSPARM-CD; URNSTS-CD; VSTEST-CD
  - 103 changes to published terms; 6 are significant
  - Updates to Codetable Mapping Files:
    - RACE_Codetable_Mapping
    - ETHNIC_Codetable_Mapping
    - RP_Codetable_Mapping
    - SC_Codetable_Mapping
    - SR_Codetable_Mapping
    - SS_Codetable_Mapping
    - TS_Codetable_Mapping
    - UR_Codetable_Mapping
    - VS_Codetable_Mapping
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 58 Public Review

- General Team -> Significant Changes to Existing Terms - Changes
  - SCTEST-CD: Submission values of C74565 are changing from JOBCLAS/Employee Job Class to EMPSTAT/Employment Status.
    - **The original submission value is not semantically aligned with the meaning of the TEST nor its valid value list. An update to the submission value will clarify the intended use of this SCTEST value.**
  - SCTEST-CD: Retire C124436/Sex Reported at Birth and replace with CNEW/Sex Assigned at Birth.
    - **CDASH SOGI team is proposing to remove this term as it is non-preferred/antiquated. The new language is more inclusive.**
  - REASTRT: Term C102698/PREVIOUS PATIENT NONCOMPLIANCE being re-coded to CNEW/PREVIOUS SUBJECT NONCOMPLIANCE
    - **GCP guidelines require the use of 'subject' instead of 'patient' therefore these semantics need to be updated.**
  - REASTINT: Term C91752/PATIENT NONCOMPLIANCE being re-coded to CNEW/SUBJECT NONCOMPLIANCE.
    - **GCP guidelines require the use of 'subject' instead of 'patient' therefore these semantics need to be updated.**
  - FATEST: Submission value of C184473 changing from Dietary Luteinzeaxanthin to Dietary Lutein and Zeaxanthin
    - **To align the Test Name submission value with the submission value in the D1FATS codelist.**
  - TPHASE: Submission value of C54721 changing from PHASE 0 TRIAL to EARLY PHASE I.
    - **To align with ICH M11 Protocol template and to update 'old' semantics that are not used in any regulatory guidance documents.**

Controlled Terminology Package 58 Public Review

- General Team -> Significant Changes to Existing Terms - Removals
  - TSPARM-CD: The term C126058 is being retired and replaced with two new TSPARMs that would be associated with the No Yes Response codelist.
    - BRIND/Biospecimen Retention Indicator
    - BRDNAIND/Biospecimen Retention Contains DNA Indicator
  - OBSSBSR – Retire codelist. The TSPARM C126058 is being retired and replaced with two new TSPARMs that would be associated with the No Yes Response codelist.

Controlled Terminology Package 58 Public Review

- Genomics Terminology Team:
  - New Terms Added to Existing Codelists:
    - GFTEST-CD; GFANMET; GFTSDTL
  - Update to the GF_Codetable_Mapping file
  - No changes to existing terms
  - Denied requests in the Denied Requests file

Controlled Terminology Package 58 Public Review

- CDISC Glossary Team
  - 44 new terms
    - Some to support MRCT
  - 57 changes to existing; Definition updates and preferred term updates
  - 21 new References
  - 4 new acronyms, abbreviations, initials
  - No denied requests

Controlled Terminology Package 58 Public Review

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBANMET; LBTEST-CD; METHOD; MIFTSDTL; MITS-CD; RESTYPRS
  - 35 changes to published terms; 1 is significant
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 58 Public Review

- Laboratory Terminology Team
  - Significant Changes to Existing Terms (1)
    - **LBANMET:** The CDISC submission value of C204632 is changing from CKD-EPI COLLABORATION 2021 FORMULA to CKD-EPI CREATININE-CYSTATIN C WITHOUT RACE 2021 FORMULA. The paper contains multiple formulas and therefore the submission values need to be more clearly differentiated in the codelist.

Controlled Terminology Package 58 Public Review

- Laboratory Terminology Team (Units of Measure)
  - New Terms Added to Existing Codelists:
    - UNIT
  - 3 changes to existing terms; none significant
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 58 Public Review

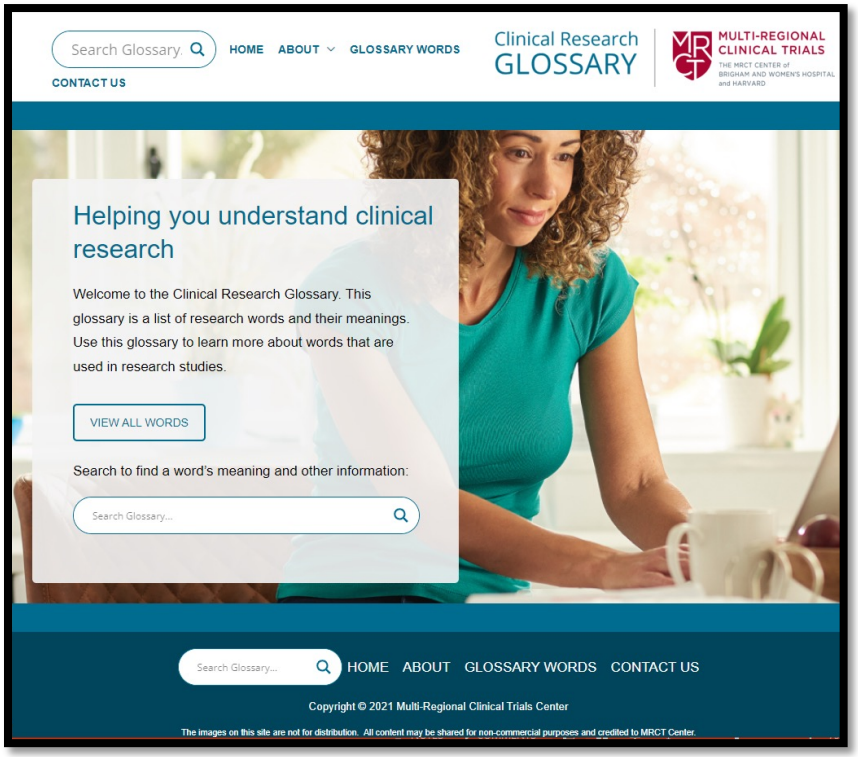
- Microbiology-Immunology Terminology Team
  - New Terms Added to Existing Codelists:
    - ISBDAGT; ISTSTDTL; MBTEST-CD; MICROORG
  - Updates to Codetable Mapping Files:
    - IS Terminology Mapping Codetable
  - Denied Requests added to Denied Requests spreadsheet
  - 98 Changes to existing term; 7 are significant

Controlled Terminology Package 58 Public Review

- Microbiology-Immunology Terminology Team
  - MICROORG
    - Updates proposed to a number of submission values so that these values sort appropriately in the codelist and are aligned with MBTEST-CD submission values.
      - C202416: change submission value from CARBAPENEM RESISTANT ACINETOBACTER BAUMANNII to ACINETOBACTER BAUMANNII, CARBAPENEM-RESISTANT
      - C150879: change submission value from CARBAPENEM RESISTANT ACINETOBACTER to ACINETOBACTER, CARBAPENEM-RESISTANT
      - C123515: change submission value from METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS to STAPHYLOCOCCUS AUREUS, METHICILLIN-RESISTANT
      - C147469: change submission value from OXACILLIN RESISTANT STAPHYLOCOCCUS AUREUS to STAPHYLOCOCCUS AUREUS, OXACILLIN-RESISTANT
      - C187917: change submission value from RIFAMPIN RESISTANT MYCOBACTERIUM TUBERCULOSIS to MYCOBACTERIUM TUBERCULOSIS, RIFAMPIN-RESISTANT
      - C76312: change submission value from VANCOMYCIN RESISTANT ENTEROCOCCUS to ENTEROCOCCUS, VANCOMYCIN-RESISTANT
      - C125980: change submission value from VANCOMYCIN RESISTANT STAPHYLOCOCCUS AUREUS to STAPHYLOCOCCUS AUREUS, VANCOMYCIN RESISTANT

Controlled Terminology Package 58 Public Review

- MRCT Plain Language Glossary
  - 9 new terms
  - 7 changes to existing terms
    - 3 definition updates
    - 4 NCI c-code updates



https://mrctcenter.org/clinical-research-glossary/

Controlled Terminology Package 58 Public Review

- Oncology Terminology Team:
  - New Terms Added to Existing Codelists:
    - ONCRSCAT; ONCRSR; TRTSET
  - 2 changes to existing; 1 is significant
  - Codetable Mapping File Updates
    - RS_Onc_Codetable Mapping
    - RS_RANO_ELLINGSTON_2017_CodMap (NEW)
    - RS_RAJKUMARIMWG_2011_CodMap (NEW)
    - RS_KUMARIMWG_2016_CodMap (NEW)
  - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 58 Public Review

- Oncology Terminology Team – Significant Changes
  - ONCRSR: Update submission value of C124430 from MRD RELAPSE to RELAPSE WITH MRD
    - **To align with preferred terminology in the medical literature. MRD Relapse will be added as a synonym to help with mapping this change.**

Controlled Terminology Package 58 Public Review

- PK Terminology Team
  - New Terms Added to Existing Codelists:
    - PKUNIT; PKUDMG; PKUDUG
  - No changes to existing terms
  - Denied Requests added to Denied Requests spreadsheet.

Controlled Terminology Package 58 Public Review

- Protocol Entities Terminology Team
  - 1 new Clinical Trial Attribute – Exploratory Objective
  - 33 changes to existing terms; 1 is significant
  - No denied requests

Controlled Terminology Package 58 Public Review

- QRS Terminology Team
  - Update to the QRS_Naming_and_Business_Rules document
  - No denied requests

Controlled Terminology Package 58 Public Review

- SDTM Domain Terminology Team
  - No new terms
  - No changes to existing
  - No denied requests

Controlled Terminology Package 58 Public Review

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - GVTEST-CD; MIRCP; SPEC; SPECIES
  - 1 change to existing; none significant
  - Denied Requests added to Denied Requests spreadsheet.

New Terminology to Support the Trial Master File (TMF) Reference Model (RM)

The Trial Master File Reference Model

- The Trial Master File (TMF) Reference Model (RM) provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature.
- The TMF contains those essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements (ICH Guideline for Good Clinical Practice, E6, Section 8).
- Formerly a sub-group of the DIA, the TMF RM group became part of CDISC back in 2022.
- For more information about the TMF Reference Model, see below links:
  - https://www.cdisc.org/standards/trial-master-file-reference-model
  - https://www.cdisc.org/tmf

Structure of the TMF Reference Model

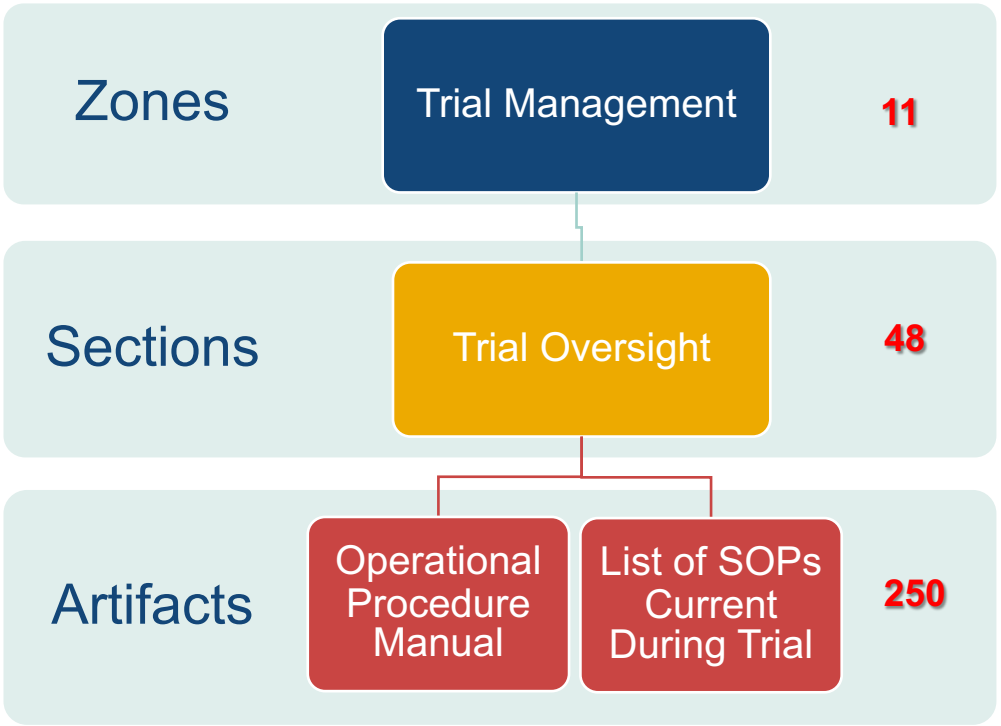
- The TMF Reference Model provides descriptions of different document types, such as records, listings, forms, user manuals, brochures, reports, etc., which one would expect to find in a TMF, at both Sponsor and Investigator site. These different document types are collectively referred to as the “artifacts” in the Model.
    - The (draft) version 3.4 of the TMF RM contains about 250 “artifacts”.
- The “artifacts” are first organized by specific Zones, which group the like artifacts together. There are 11 Zones in the RM: Trial Management (Zone 1); Central Trial Documents (Zone 2); Regulatory (Zone 3); IRB/IEC and Other Approvals (Zone 4); Site Management (Zone 5); Investigational Product (IP) and Trial Supplies (Zone 6); Safety Reporting (Zone 7); Centralized and Local Testing (Zone 8); Third Parties (Zone 9); Data Management (Zone 10); Statistics (Zone 11).
- Additionally, the artifacts are further organized by “Sections” within each Zone.
- The Artifacts are created and exist at many levels such as trial, country, and site.

TMF Reference Model Version 3.4 (Draft)

TMF Reference Model							Version 3.4	27-Sep-2024				
Zone	Zone Name	Section #	Section Name	Artifact	Artifact name	Purpose/Guidance	Recommended Subartifacts - Documents/documentation recommended to be filed to the artifact.	Core or Recommended for inclusion	ICH Code	ISO 14155 Reference (Device Studies)	Artifact name in v1.3 EDM Reference Mod	Unique ID Numbe
01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	Document Transfer Documentation Evidence of Quality Review Request to Lock TMF Trial Master File Plan Trial Master File Index Trial Master File Report	Recommended	5.5.7			001
01	Trial Management	01.01	Trial Oversight	01.01.02	Trial Management Plan	To describe overall strategy for timelines, management and conduct of the trial and typically makes reference to other artifacts. Artifact can include details on contingency plan covering details for site start up planning.	Clinical Development Plan Project Management Plan Trial Management Plan	Recommended	2.2			002
01	Trial Management	01.01	Trial Oversight	01.01.03	Quality Plan	To describe the operational techniques and activities undertaken within the quality management system to verify that the requirements for quality of the trial-related activities have been fulfilled. Relevant parts may include, but not be limited to, a plan written for internal oversight of study quality management, an audit plan, data verification steps, serious breach assessments; also includes escalation in the event of a quality issue being identified and all corrective and preventative actions determined. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	Quality Documentation Quality Plan Quality Report	Recommended	5.1	7.11 9.1 a		003

Click here to download the latest published version (3.3.1) of the TMF RM: https://www.cdisc.org/standards/foundational/trial-master-file-reference-model/tmf-reference-model-v3-3-1

Coding and Definitions for the TMF concepts



- **Three-level Value Control:** Provide coding and semantics to the values from Zone, Section, and Artifacts. Each concept in these 3 levels were given unique C-codes for permanent tracking as well as clear and consistent definitions.
- **11 codelists created for the TMF Zones.** Each Zone codelist contains its related “sections” and “artifacts”.

TMF Terminology Summary

- For CDISC Controlled Terminology Package 58 review, we are offering *unique* definitions for 210 “artifacts” and 36 “sections” across 11 “zone” codelists, in the “Terminology_P58_TMF” PR file.
  - In case you are wondering what happened to the other 40 artifacts out of the 250, the following artifacts appear in every zone: Relevant Communications; Tracking Information; Meeting Material; Filenote. The TMF CT team decided that they have the same semantic and operational meanings, and therefore will have the same definitions and c-codes for every TMF Zone codelist. (In other words, they are only defined once, but they will appear in every zone codelist with the same definitions. This is referred as “re-useability” of a concept).
  - The following TMF “Section” concepts will also be defined once and reused in every zone: General; Trial Status Reporting.

TMF Terminology Summary, Continued…

- These definitions have gone through a robust development, review, and consensus process with a diverse group of TMF experts and industry professionals for use in the exchange of TMF artifacts and to support the TMF Reference Model.

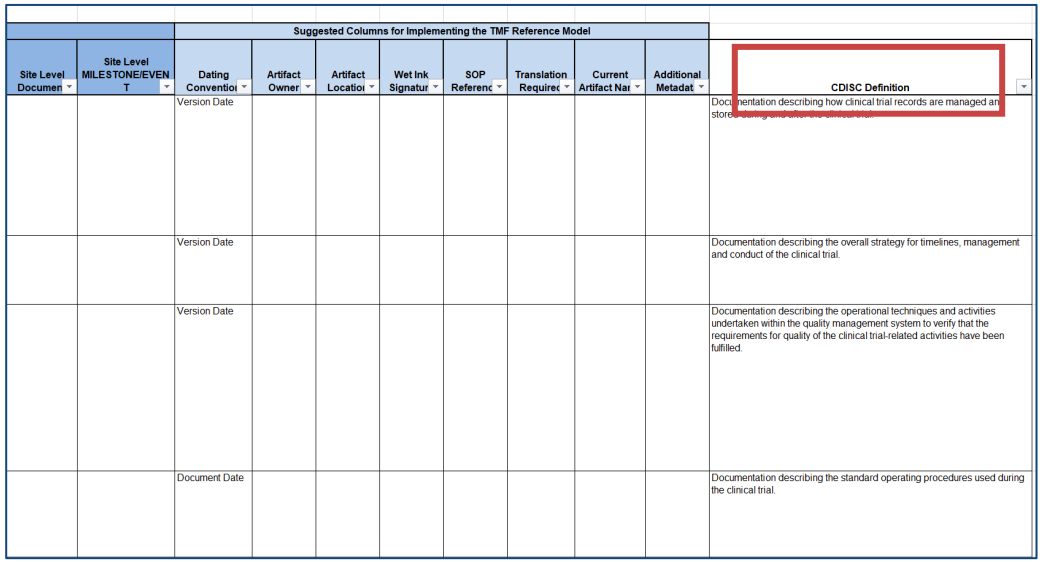
- Each zone, section and artifact will also be assigned a unique NCI C-code. C-codes are not included for P58 terminology public review. However, they will be published on September 27th, with the TMF terminology subset, which will be available for download on https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology

Package 58 – TMF Files for Review

There are three TMF terminology review and supplemental files in this package:

1. Version-3.4-TMF-Reference-Model_Draft
2. Terminology_P58_TMF (This is the standard CDISC Controlled Terminology Public Review document.)
3. Trial Master File Reference Model Package 58 Terminology – Reviewer's Guide

Version-3.4-TMF-Reference-Model_Draft File



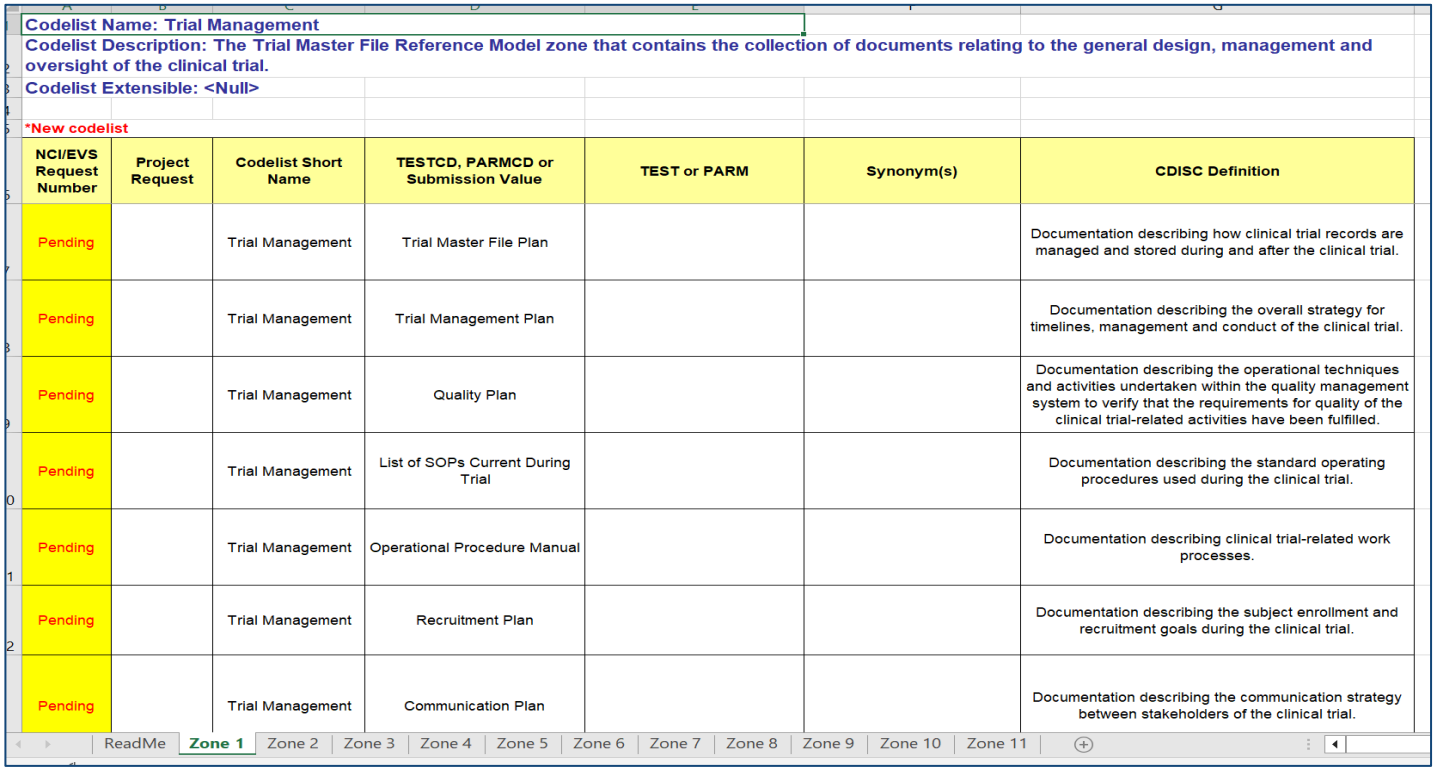
		Suggested Columns for Implementing the TMF Reference Model								
Site Level Documen	Site Level MILESTONE/EVENT	Dating Conventio	Artifact Owner	Artifact Locatio	Wet Ink Signatur	SOP Referenc	Translation Require	Current Artifact Nar	Additional Metadat	CDISC Definition
		Version Date								Documentation describing how clinical trial records are managed an stored during and after the clinical trial.
		Version Date								Documentation describing the overall strategy for timelines, management and conduct of the clinical trial.
		Version Date								Documentation describing the operational techniques and activities undertaken within the quality management system to verify that the requirements for quality of the clinical trial-related activities have been fulfilled.
		Document Date								Documentation describing the standard operating procedures used during the clinical trial.

- CDISC draft definitions for the artifacts can be read and reviewed in the context of the TMF Reference Model file, in the "V 3.4 Clean" tab, and column AI of "CDISC Definition".

Zone	Definition of Zone Contents	CDSIC Definition
01 - Trial Management	Records related to the general design, management and oversight of the study; includes information about the trial team; project management and tracking; committees and charters, and training.	The Trial Master File Reference Model zone that contains the collection of documents relating to the general design, management and oversight of the clinical trial.
02 - Central Trial Documents	Includes the IB, Protocol, and Amendments, Sample CRF, ICF, and the CSR, as well as any ancillary documents directly related to the above. Capture study documents that are related to the protocol, key subject documentation such as the ICF, questionnaire, diary, participation card and clinical study reports including pharmacokinetics in accordance with applicable regulatory standards	The Trial Master File Reference Model zone that contains the collection of documents relating to the clinical study protocol, investigator's brochure, key subject documentation and study reports for the clinical trial.
03 - Regulatory	Records related to Regulatory Submissions and Approvals (to/from Health Authorities), Regulatory Filing and Registration Information, and Regulatory Notifications specific to the clinical trial.	The Trial Master File Reference Model zone that contains the collection of documents relating to the interactions with regulatory authorities, including submissions, decisions, notifications, and registrations for the clinical trial.
04 - IRB / IEC and other Approvals	Official communications and exchanges with IRB's/IECs, including central, national, regional and local. Includes records related to IRB/IEC submissions, approvals, acknowledgments, as well as oversight information about the IRB/IEC.	The Trial Master File Reference Model zone that contains the collection of documents relating to the interactions with the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), including submissions, decisions, acknowledgments, and oversight information about the IRB/IEC for the clinical trial.
05 - Site Management	Records related to selection, setup and management of investigational sites. Includes central site training and central monitor training. In addition, documentation related to unselected sites. At the trial or country level, this section pertains to multi-site records and communications, such as newsletters, "all-sites" communications, etc. Site specific details will be managed in the Investigator Site Specific File.	The Trial Master File Reference Model zone that contains the collection of documents relating to the selection, setup, initiation and management of the investigational sites as well as multi-site records and communications for the clinical trial.
06 - IP and Trial Supplies	Records related to the products under investigation including comparators - including instructions for shipping, storage, handling, returns and destruction, regulatory requirements, certificates, treatment allocation and decoding, inventory information - also includes supplies needed to fulfill the trial protocol requirements including shipping and returns – and any relevant communications.	The Trial Master File Reference Model zone that contains the collection of documents relating to the management, shipping, storage, dispensing, and destruction of Investigational Product(s) and supplies for the clinical trial.
07 - Safety Reporting	Records related to trial-specific Safety and Pharmacovigilance management: This includes the safety management plan, safety database line listings, safety reports, and non-submission communications/documentation	The Trial Master File Reference Model zone that contains the collection of documents relating to the safety and pharmacovigilance management of the clinical trial.
08 - Central and Local Testing	Records related to all specialty testing vendors, including central and local laboratories, on a global study level, a country level or a site level. Records include certification (and expiration dates), procedure manuals, current normal value ranges and the test facility staff curriculum vitae (CV). The content should be modified based on the testing utilized.	The Trial Master File Reference Model zone that contains the collection of documents relating to the testing vendors and sample management, including central and local testing facilities for the clinical trial.
09 - Third Parties	Records related to the establishment and maintenance of a relationship between Sponsors and the Vendors / 3rd-Parties serving Sponsors by contract on the study. (ex, delegation of responsibilities)	The Trial Master File Reference Model zone that contains the collection of documents relating to the establishment, maintenance and oversight of relationships between sponsors and vendors for the clinical trial.
10 - Data Management	Records related to Data Management activity on the study. Includes subject data (completed CRFs or Final EDC Data). Database definition	The Trial Master File Reference Model zone that contains the collection of documents relating to data management activities for the clinical trial.
11 - Statistics	Records related to Biostatistics and Statistical Programming activity on the study.	The Trial Master File Reference Model zone that contains the collection of documents relating to biostatistics and statistical programming activities for the clinical trial.

- Updated CDISC definitions for the TMF Zones can be found in the “Instructions and Glossary” tab, column C.

Terminology_P58_TMF File



Codelist Name: Trial Management

Codelist Description: The Trial Master File Reference Model zone that contains the collection of documents relating to the general design, management and oversight of the clinical trial.

Codelist Extensible: <Null>

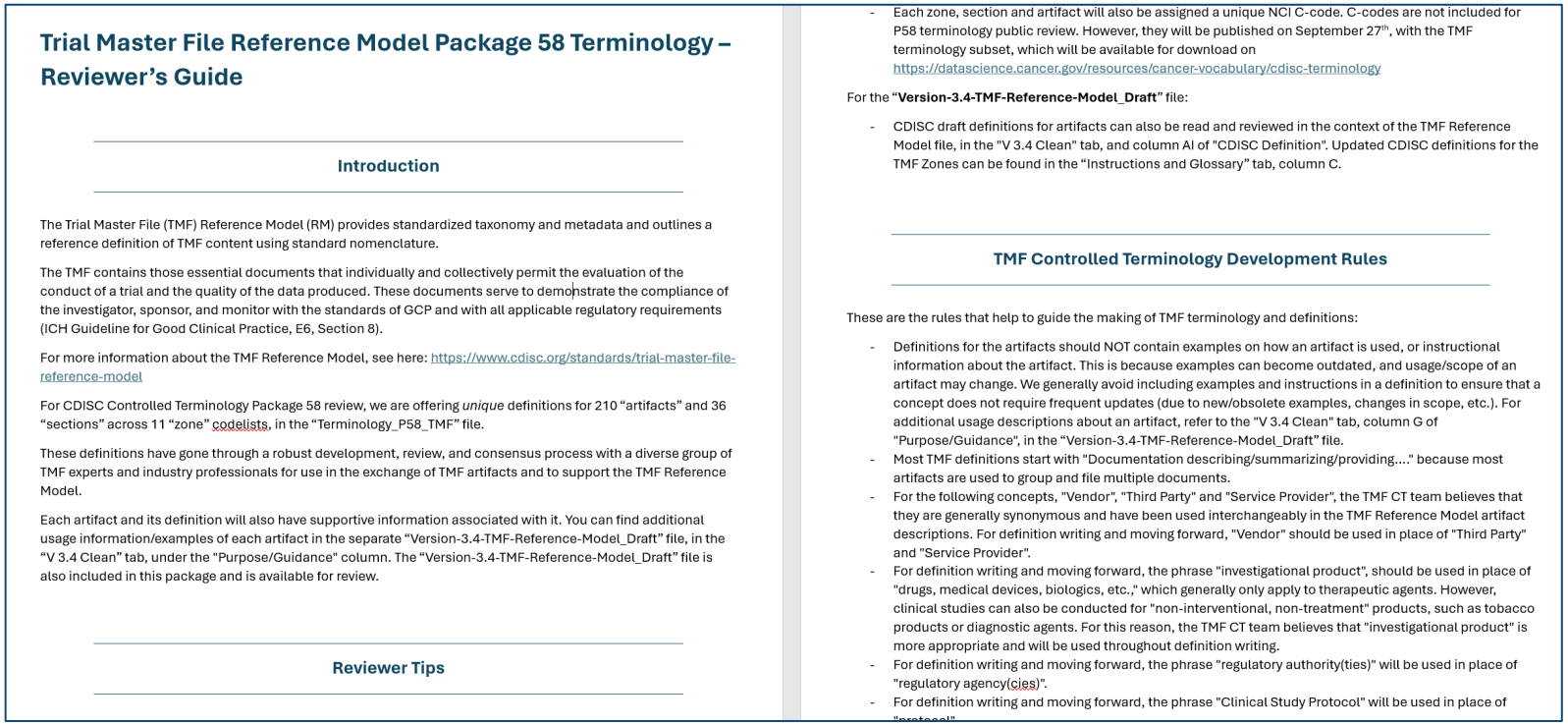
*New codelist

NCI/EVS Request Number	Project Request	Codelist Short Name	TESTCD, PARMCD or Submission Value	TEST or PARM	Synonym(s)	CDISC Definition
Pending		Trial Management	Trial Master File Plan			Documentation describing how clinical trial records are managed and stored during and after the clinical trial.
Pending		Trial Management	Trial Management Plan			Documentation describing the overall strategy for timelines, management and conduct of the clinical trial.
Pending		Trial Management	Quality Plan			Documentation describing the operational techniques and activities undertaken within the quality management system to verify that the requirements for quality of the clinical trial-related activities have been fulfilled.
Pending		Trial Management	List of SOPs Current During Trial			Documentation describing the standard operating procedures used during the clinical trial.
Pending		Trial Management	Operational Procedure Manual			Documentation describing clinical trial-related work processes.
Pending		Trial Management	Recruitment Plan			Documentation describing the subject enrollment and recruitment goals during the clinical trial.
Pending		Trial Management	Communication Plan			Documentation describing the communication strategy between stakeholders of the clinical trial.

ReadMe | Zone 1 | Zone 2 | Zone 3 | Zone 4 | Zone 5 | Zone 6 | Zone 7 | Zone 8 | Zone 9 | Zone 10 | Zone 11

- Each "zone" in the TMF Reference Model is defined and its definition can be found in the rows 1-2 of the tabs named Zone 1, Zone 2, Zone 3…to Zone 11. Each TMF Zone concept also serves as the "Codelist" level concept that is used to bundle and group its related "sections" and "artifacts".
- Definitions for the TMF Sections can be found in this file. Section definitions are NOT included in the Reference Model File v3.4.

Trial Master File Reference Model Package 58 Terminology – Reviewer's Guide Document



Trial Master File Reference Model Package 58 Terminology – Reviewer's Guide

Introduction

The Trial Master File (TMF) Reference Model (RM) provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature.

The TMF contains those essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements (ICH Guideline for Good Clinical Practice, E6, Section 8).

For more information about the TMF Reference Model, see here: https://www.cdisc.org/standards/trial-master-file-reference-model

For CDISC Controlled Terminology Package 58 review, we are offering *unique* definitions for 210 "artifacts" and 36 "sections" across 11 "zone" codelists, in the "Terminology_P58_TMF" file.

These definitions have gone through a robust development, review, and consensus process with a diverse group of TMF experts and industry professionals for use in the exchange of TMF artifacts and to support the TMF Reference Model.

Each artifact and its definition will also have supportive information associated with it. You can find additional usage information/examples of each artifact in the separate "Version-3.4-TMF-Reference-Model_Draft" file, in the "V 3.4 Clean" tab, under the "Purpose/Guidance" column. The "Version-3.4-TMF-Reference-Model_Draft" file is also included in this package and is available for review.

Reviewer Tips

- Each zone, section and artifact will also be assigned a unique NCI C-code. C-codes are not included for P58 terminology public review. However, they will be published on September 27th, with the TMF terminology subset, which will be available for download on https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology

For the "**Version-3.4-TMF-Reference-Model_Draft**" file:

- CDISC draft definitions for artifacts can also be read and reviewed in the context of the TMF Reference Model file, in the "V 3.4 Clean" tab, and column AI of "CDISC Definition". Updated CDISC definitions for the TMF Zones can be found in the "Instructions and Glossary" tab, column C.

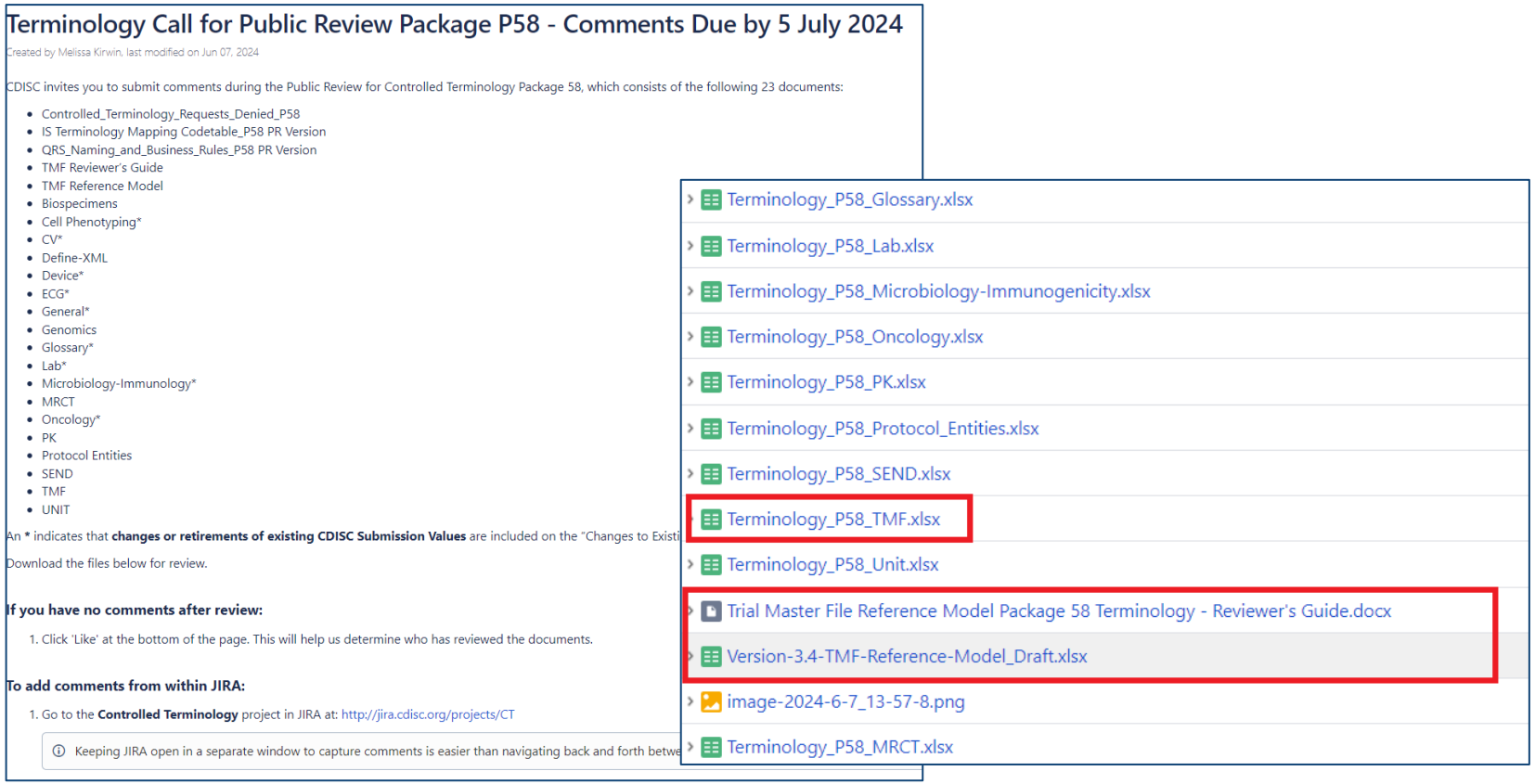
TMF Controlled Terminology Development Rules

These are the rules that help to guide the making of TMF terminology and definitions:

- Definitions for the artifacts should NOT contain examples on how an artifact is used, or instructional information about the artifact. This is because examples can become outdated, and usage/scope of an artifact may change. We generally avoid including examples and instructions in a definition to ensure that a concept does not require frequent updates (due to new/obsolete examples, changes in scope, etc.). For additional usage descriptions about an artifact, refer to the "V 3.4 Clean" tab, column G of "Purpose/Guidance", in the "Version-3.4-TMF-Reference-Model_Draft" file.
- Most TMF definitions start with "Documentation describing/summarizing/providing…." because most artifacts are used to group and file multiple documents.
- For the following concepts, "Vendor", "Third Party" and "Service Provider", the TMF CT team believes that they are generally synonymous and have been used interchangeably in the TMF Reference Model artifact descriptions. For definition writing and moving forward, "Vendor" should be used in place of "Third Party" and "Service Provider".
- For definition writing and moving forward, the phrase "investigational product", should be used in place of "drugs, medical devices, biologics, etc.," which generally only apply to therapeutic agents. However, clinical studies can also be conducted for "non-interventional, non-treatment" products, such as tobacco products or diagnostic agents. For this reason, the TMF CT team believes that "investigational product" is more appropriate and will be used throughout definition writing.
- For definition writing and moving forward, the phrase "regulatory authority(ties)" will be used in place of "regulatory agency(cies)".
- For definition writing and moving forward, the phrase "Clinical Study Protocol" will be used in place of "protocol"

- This file helps to explain the TMF terminology content and development rules. It contains reviewer's tips and directions on the review process and how to comment through the CDISC JIRA platform.

Where to find the P58 TMF CT Public Review Files



Terminology Call for Public Review Package P58 - Comments Due by 5 July 2024

Created by Melissa Kirwin, last modified on Jun 07, 2024

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 58, which consists of the following 23 documents:

- Controlled_Terminology_Requests_Denied_P58
- IS Terminology Mapping Codetable_P58 PR Version
- QRS_Naming_and_Business_Rules_P58 PR Version
- TMF Reviewer's Guide
- TMF Reference Model
- Biospecimens
- Cell Phenotyping*
- CV*
- Define-XML
- Device*
- ECG*
- General*
- Genomics
- Glossary*
- Lab*
- Microbiology-Immunology*
- MRCT
- Oncology*
- PK
- Protocol Entities
- SEND
- TMF
- UNIT

An * indicates that **changes or retirements of existing CDISC Submission Values** are included on the "Changes to Existi

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

Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth betwe

Terminology_P58_Glossary.xlsx
Terminology_P58_Lab.xlsx
Terminology_P58_Microbiology-Immunogenicity.xlsx
Terminology_P58_Oncology.xlsx
Terminology_P58_PK.xlsx
Terminology_P58_Protocol_Entities.xlsx
Terminology_P58_SEND.xlsx
Terminology_P58_TMF.xlsx
Terminology_P58_Unit.xlsx
Trial Master File Reference Model Package 58 Terminology - Reviewer's Guide.docx
Version-3.4-TMF-Reference-Model_Draft.xlsx
image-2024-6-7_13-57-8.png
Terminology_P58_MRCT.xlsx

- https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P58+-+Comments+Due+by+5+July+2024
- Comments due by July 5

The CDISC TMF Controlled Terminology Team

- Karen Roy, CDISC
- Kelley Robinson, Sention Therapeutics
- Kristen Bretzius, Pharvaris
- Laura Naranjo, Pharma IQ
- Robin Parks, University of Alabama at Birmingham
- Michelle Henry
- Caroline Tientcheu, Molecular Partners

- Monica Alaimo, Syneos Health
- Melissa Miller, Acadia Pharmaceuticals
- Tonia Huggins, Sage Therapeutics
- James Markley, Just in Time GCP
- Yen Phan, Codlad
- Vidya Jayapalan, Takeda
- Luciana Giodini, Chiesi Group
- TMF RM Zone Leads

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.

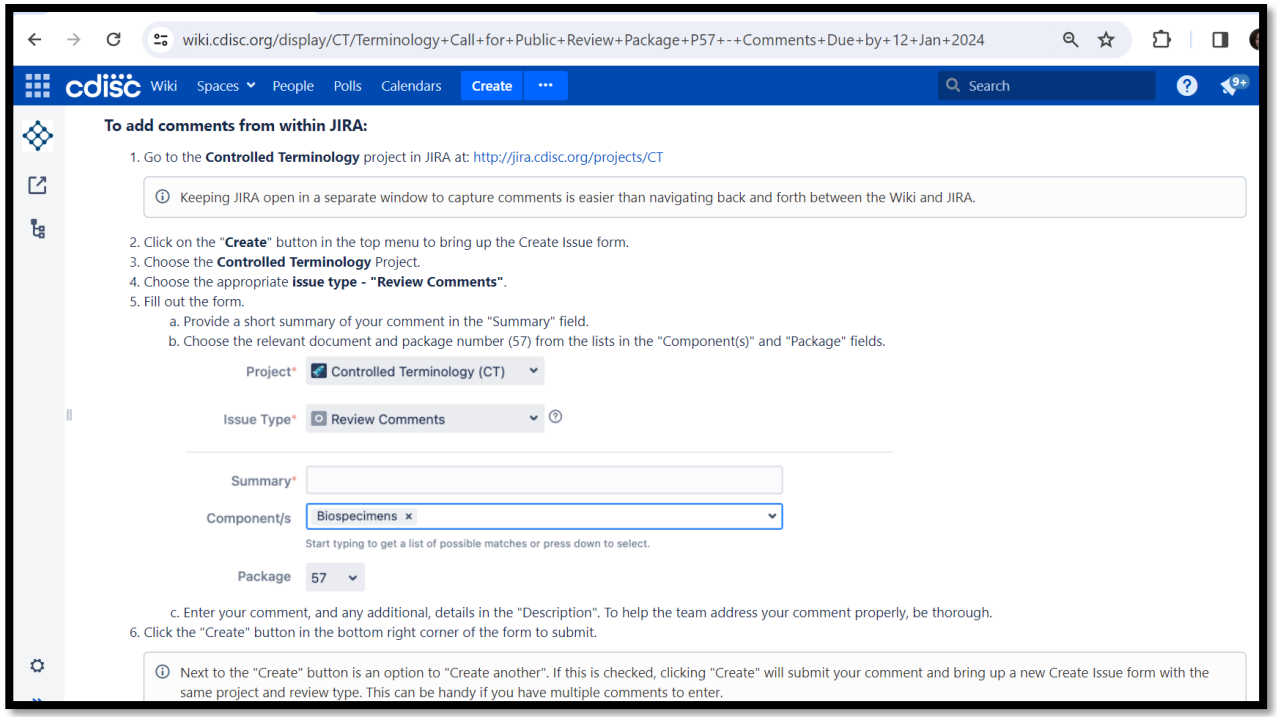
Increases the quality of the final product.

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.

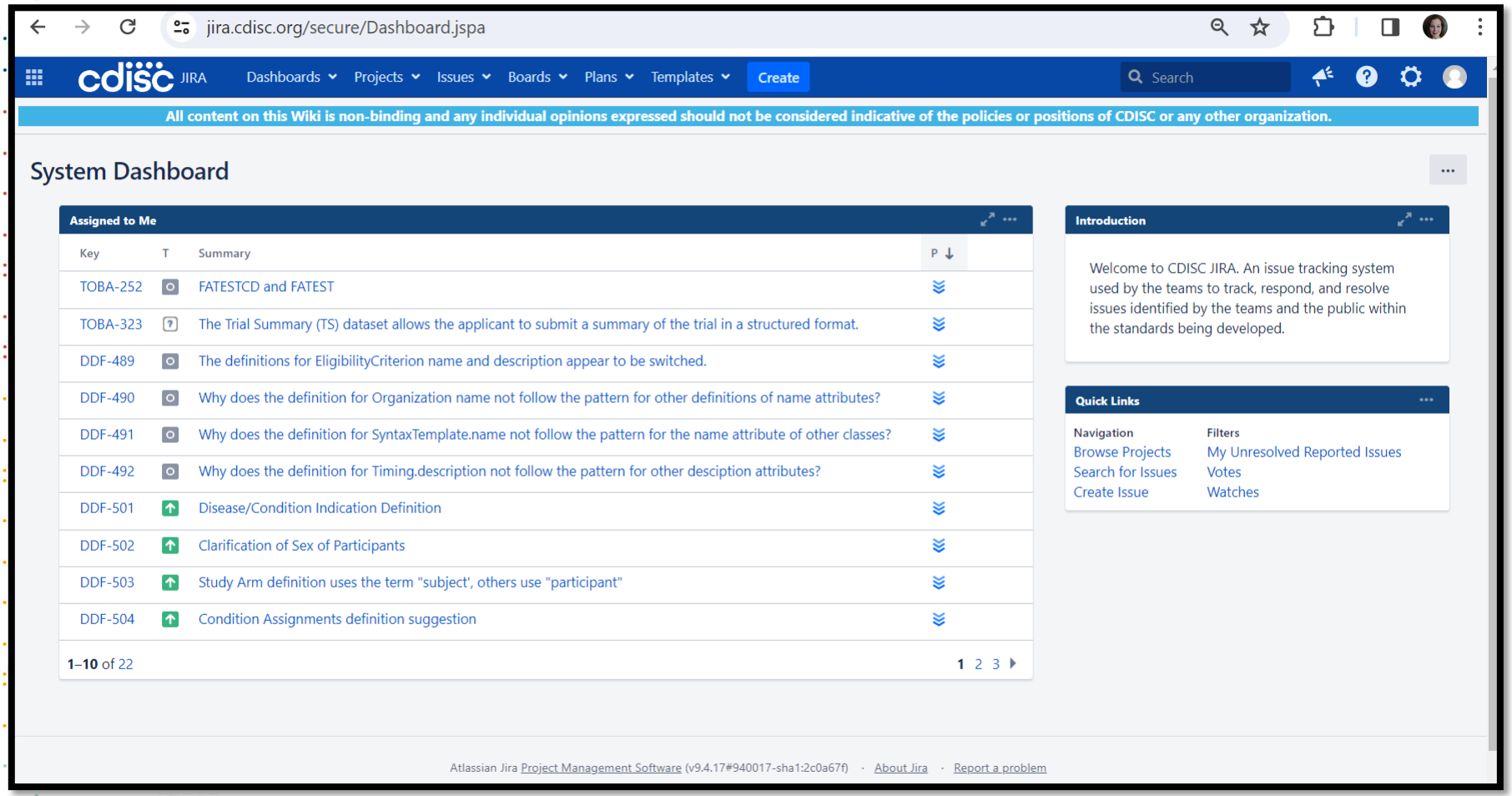
CDISC Public Review Process

- 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.
  - JIRA uses the same login as CDISC.org and CDISC wiki
- 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.



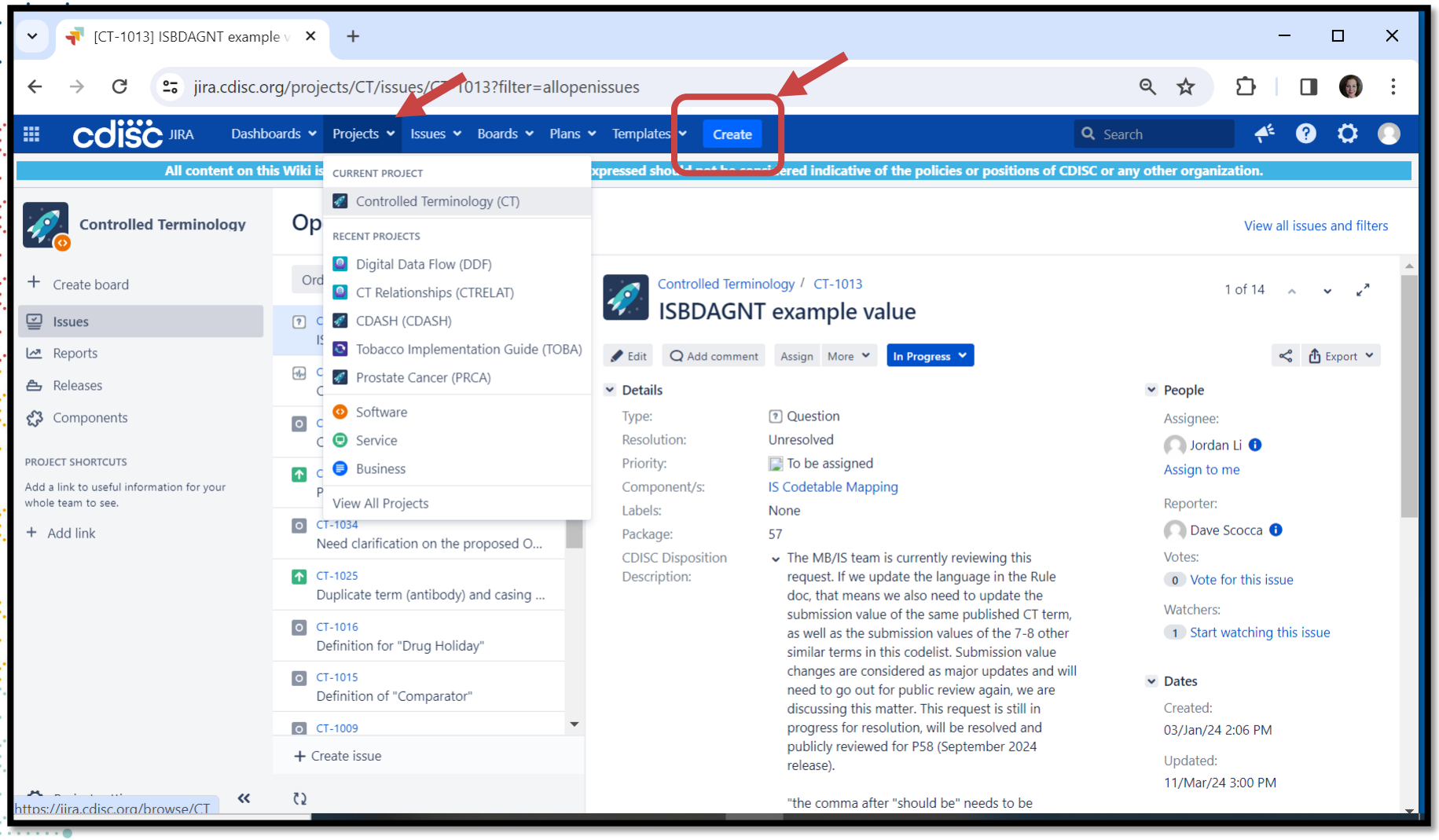
STEP 1: Navigate to JIRA

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



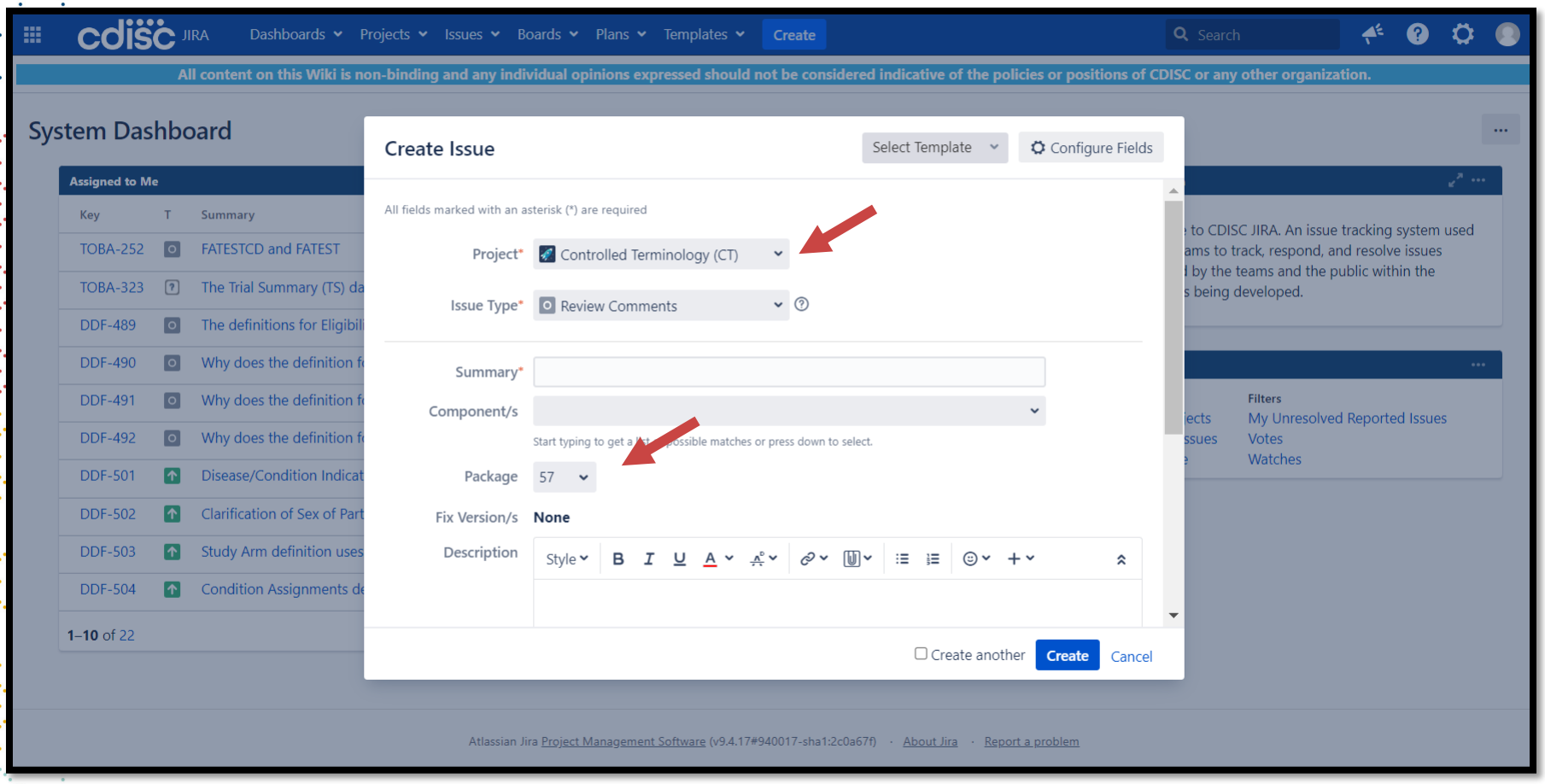
STEP 2: Click Create

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



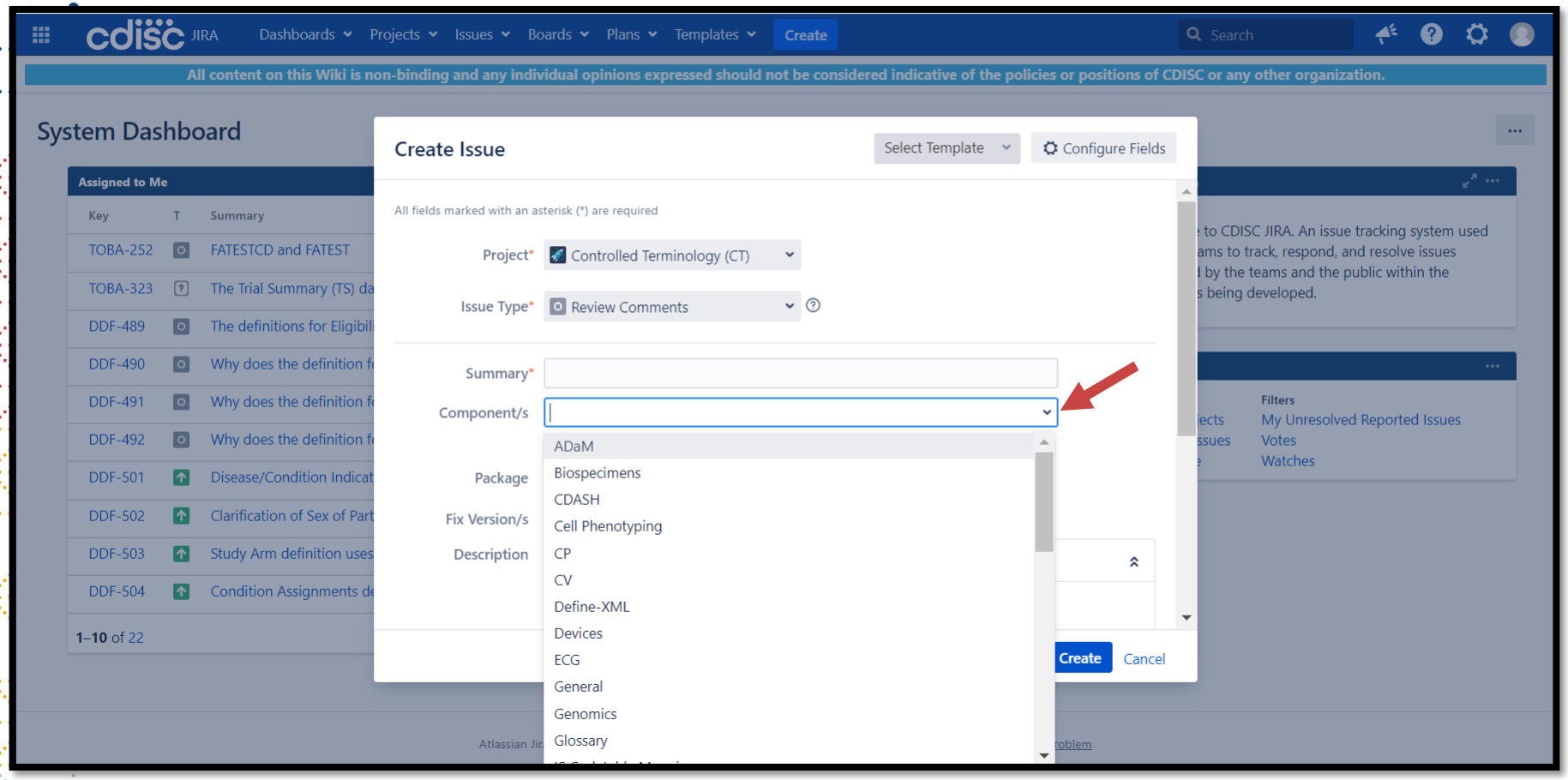
STEP 3: Fill out the “Create Issue” form

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



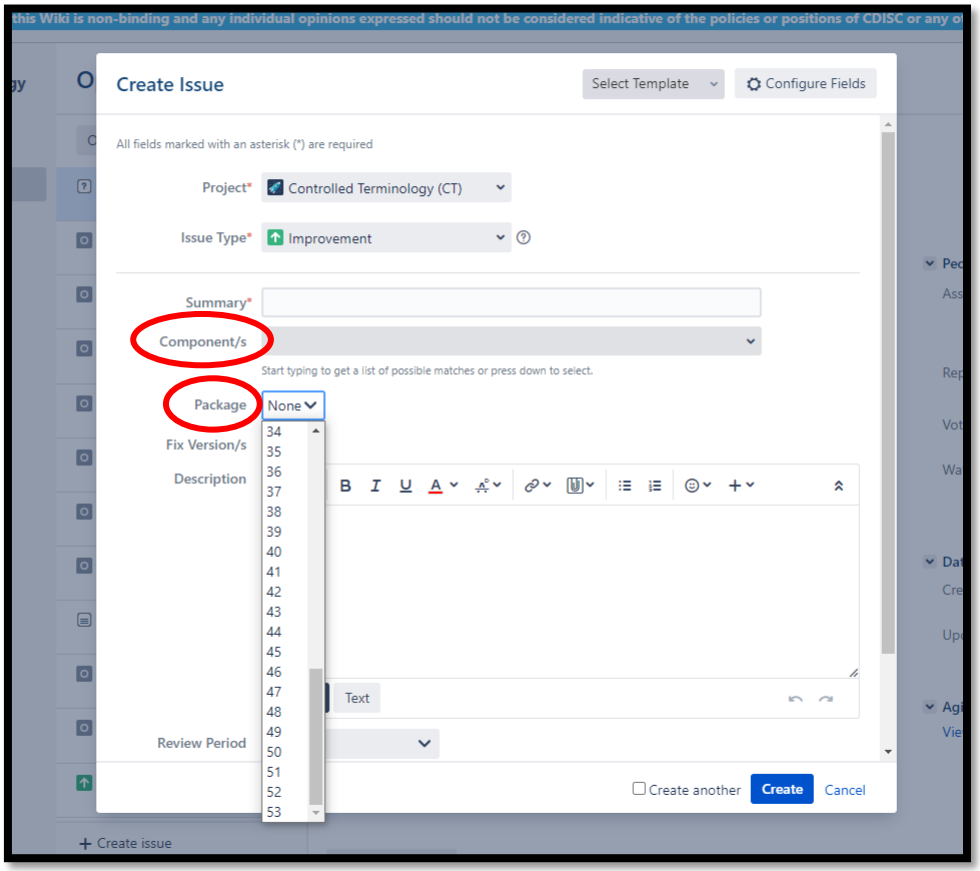
STEP 3: Fill out the “Create Issue” form [cont’d]

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



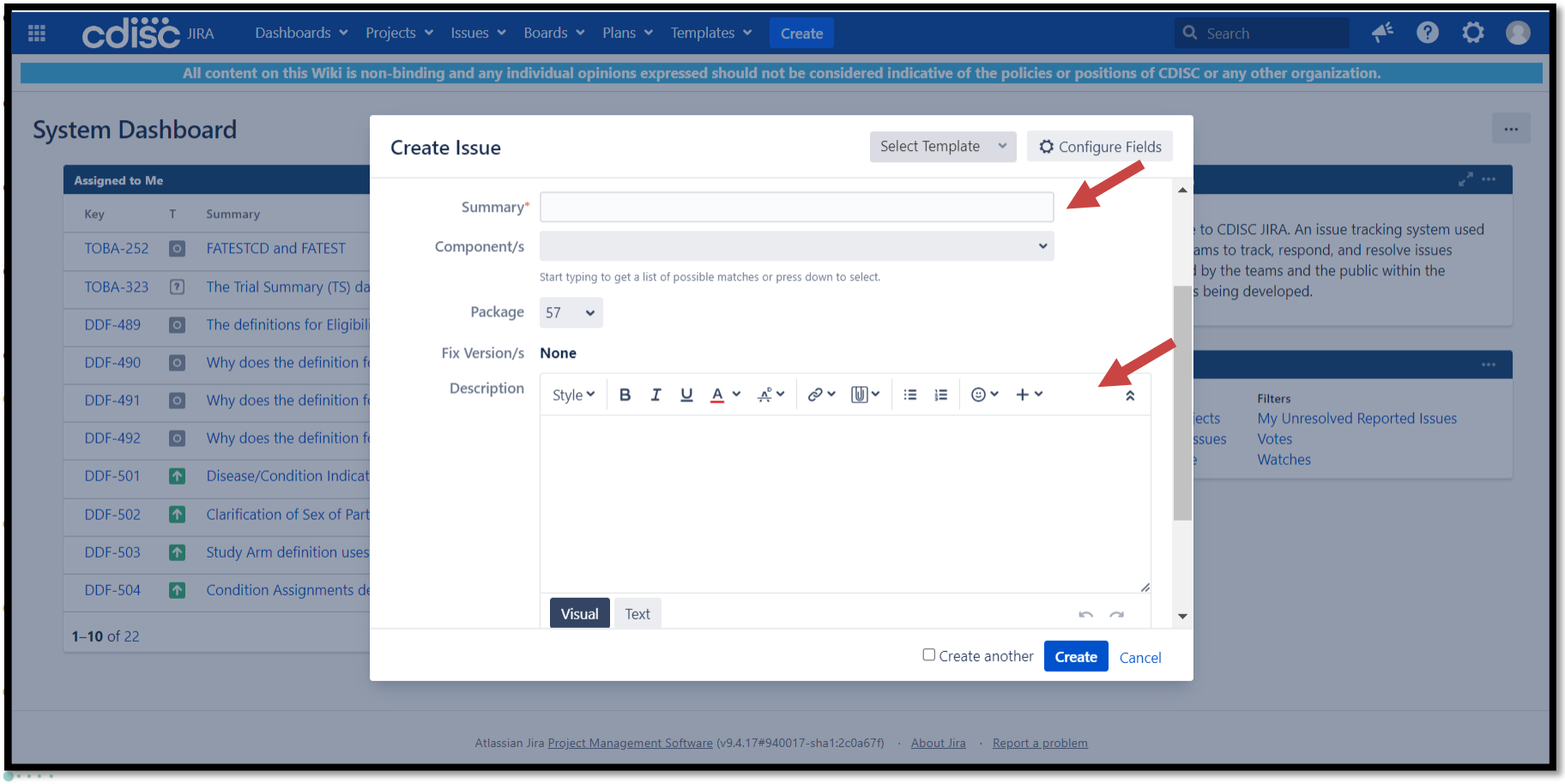
CRITICAL Pieces of Information

- 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 (58) – 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

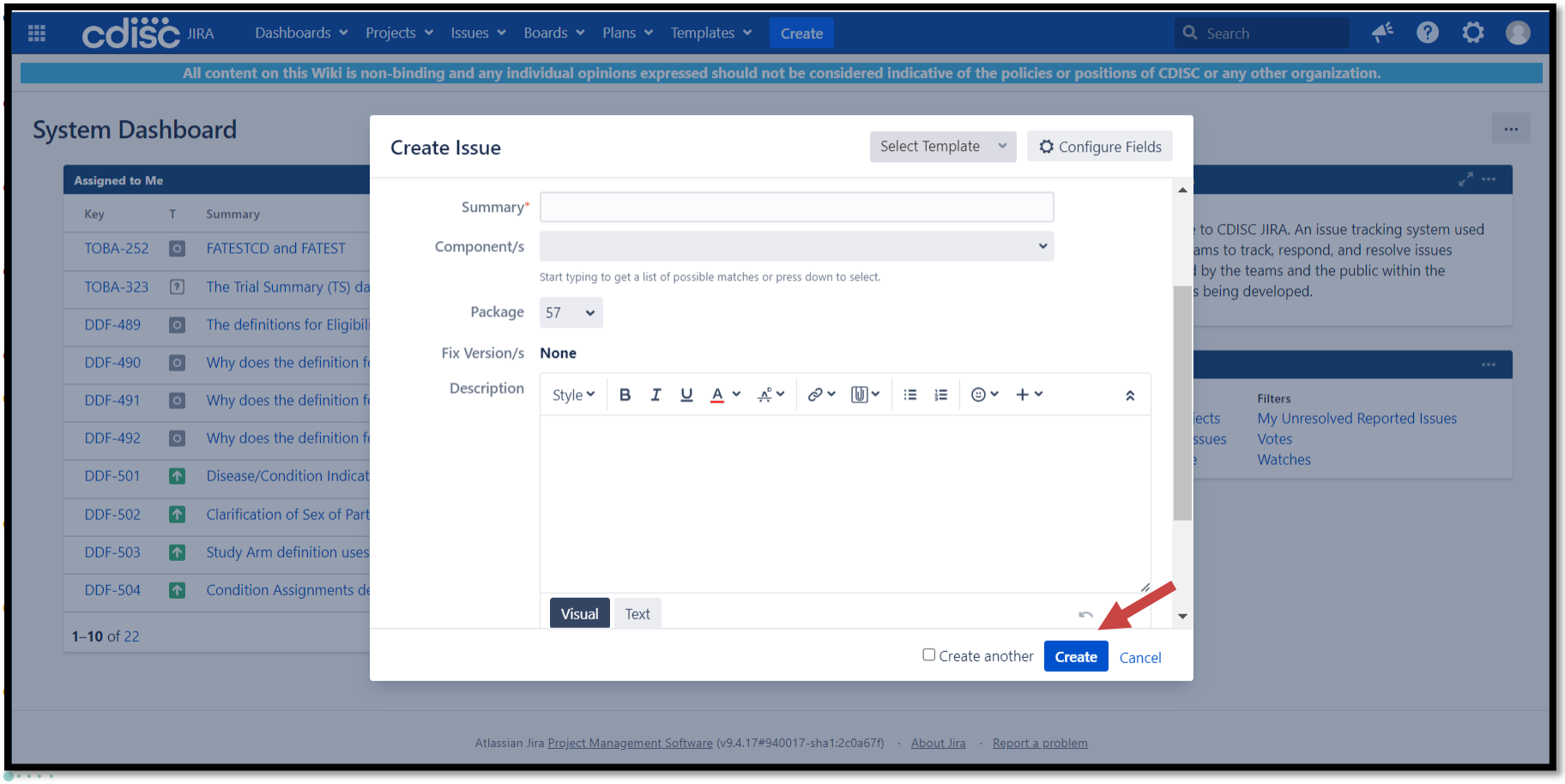
"This is the draft definition."

to

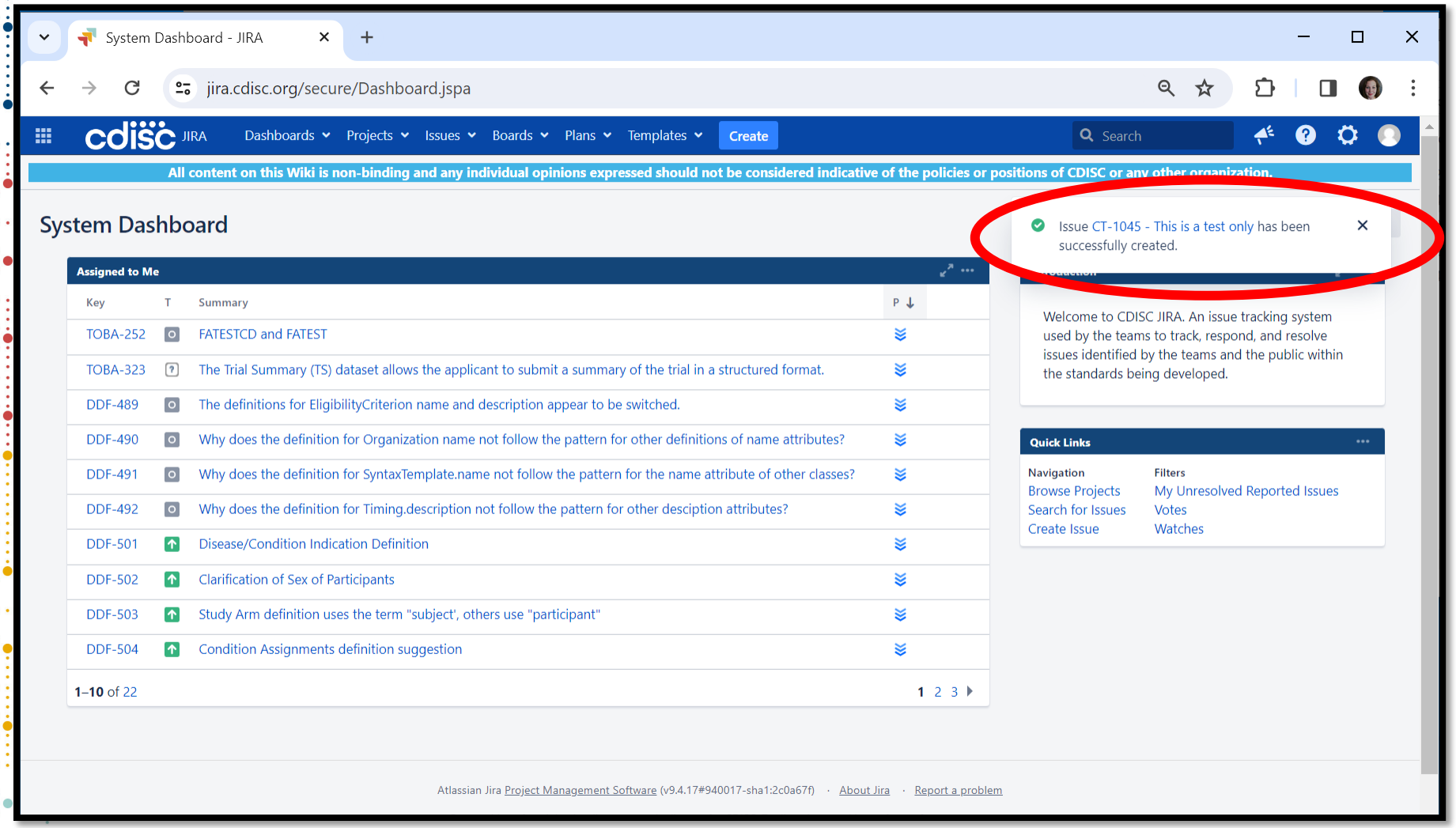
"This is the commenter's updated draft definition."

STEP 4: Hit the Create Button

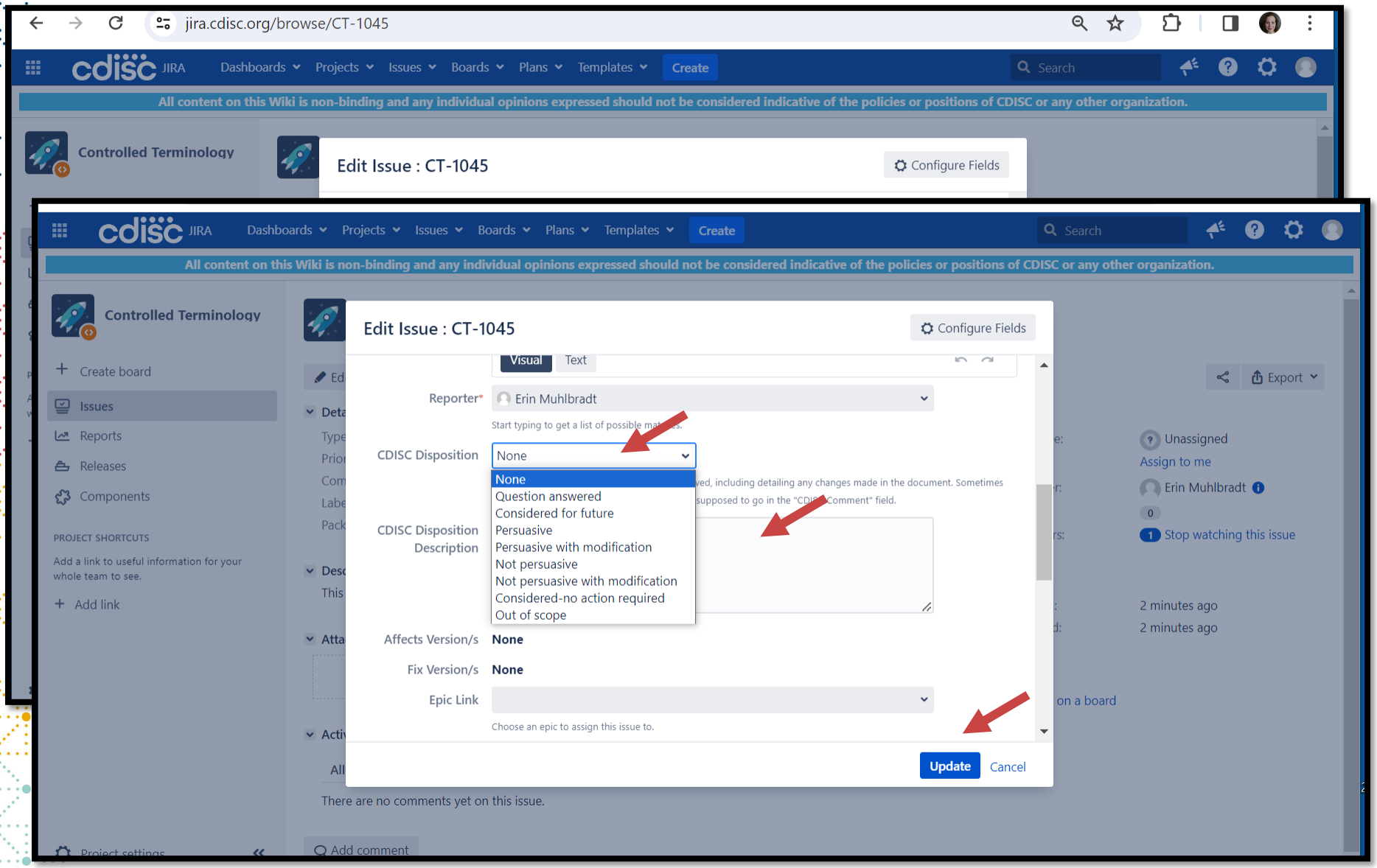
- If you are submitting more than one comment, click the ‘Create another’ box to bring up a new form.



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



Comment Resolution by CDISC CT Teams



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

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

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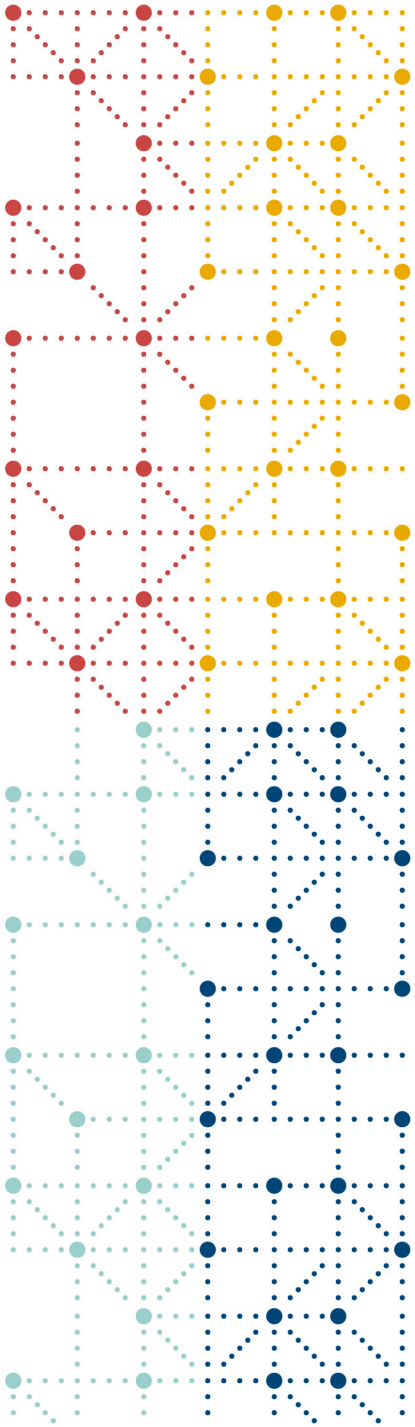
Join 500+ member organizations that contribute to bringing clarity to data.

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



Q&A

CDISC Education: Upcoming Learning Opportunities

Bernard Klinke

Thank you for your attendance and support of CDISC!