



# CDISC Controlled Terminology Quarterly Webinar

Presented by:

Dr. Erin Muhlbradt, PhD

Dr. Jordan Li, PhD

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# Controlled Terminology P58 Public Review

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

Dr. Jordan Li, Clinical/Biomedical Information Specialist, MSC Inc., a Guidehouse company

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



Pages / [Controlled Terminology](#) / [Controlled Terminology Public Review](#)

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# 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 Existing" tab in the document. Please review these changes as there may be submission value changes or term deprecations.

Download the files below for review.

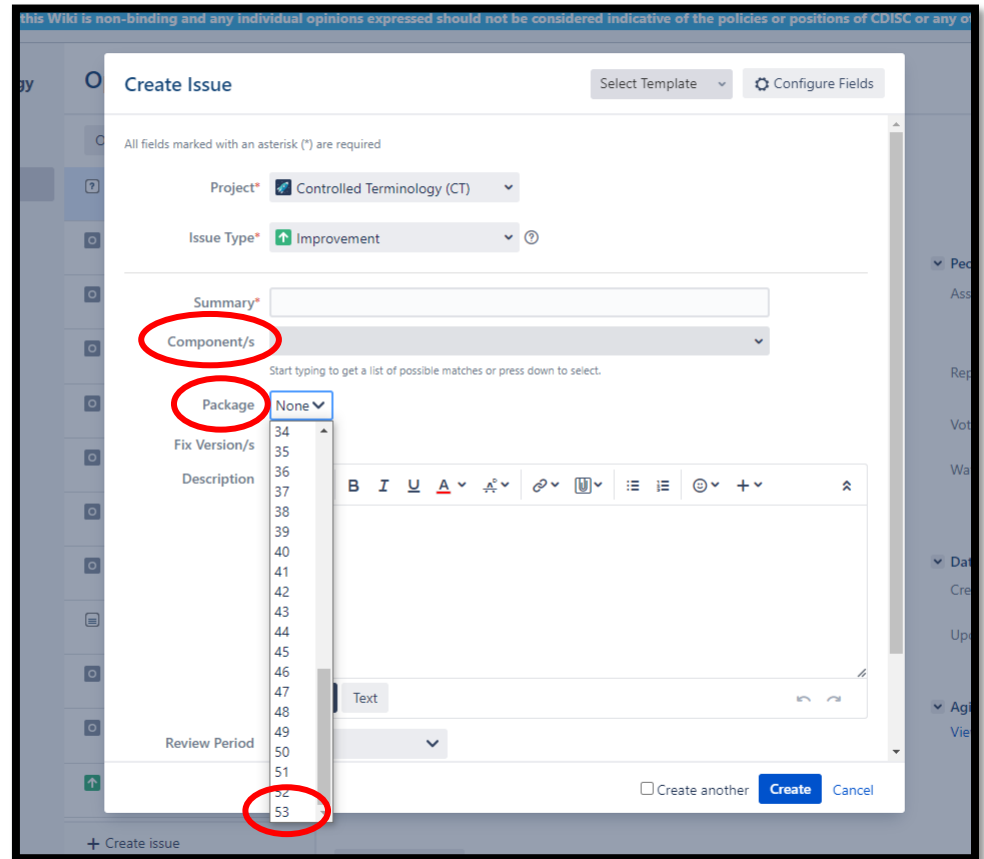
## If you have no comments after review:

1. Click 'Like' at the bottom of the page. This will help us determine who has reviewed the documents.

[Terminology Call for Public Review Package P58 - Comments Due by 5 July 2024 - Controlled Terminology \(CT\) - Wiki \(cdisc.org\)](https://www.cdisc.org/public-review/controlled-terminology-package-58)

# 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:
    - CPTTEST-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.



# 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; SSTEEST-CD; TSPARM-CD; URNSTS-CD; VSTEEST-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

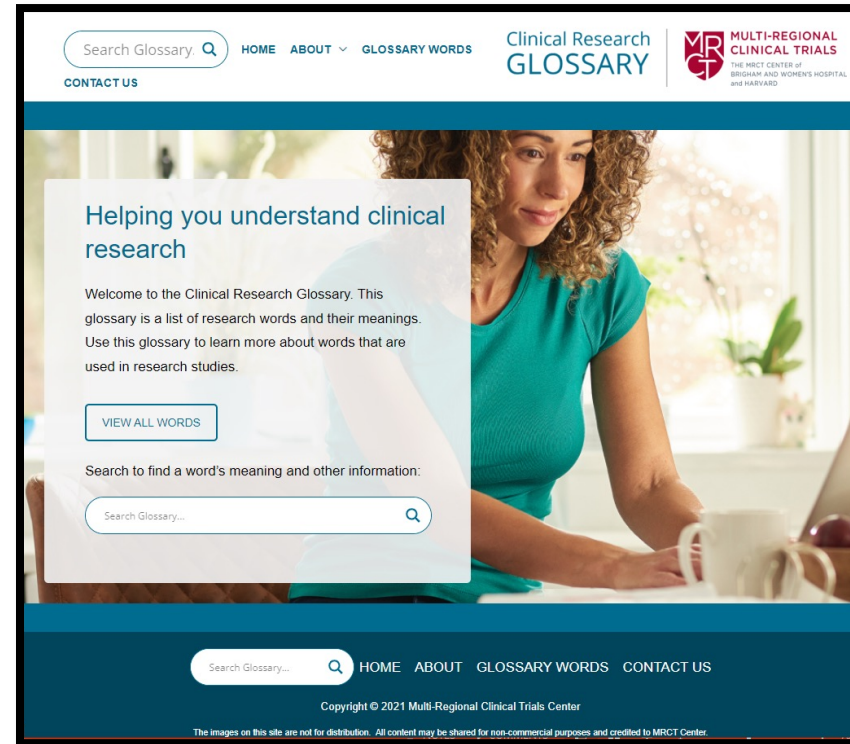
- Microbiology-Immunology Terminology Team

- 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.

A decorative graphic on the left side of the slide. It consists of a grid of small dots connected by thin lines. The dots are colored in red, yellow, light blue, and dark blue. The lines are also colored to match the dots they connect, creating a complex, interconnected pattern that resembles a network or a data structure.

## 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.

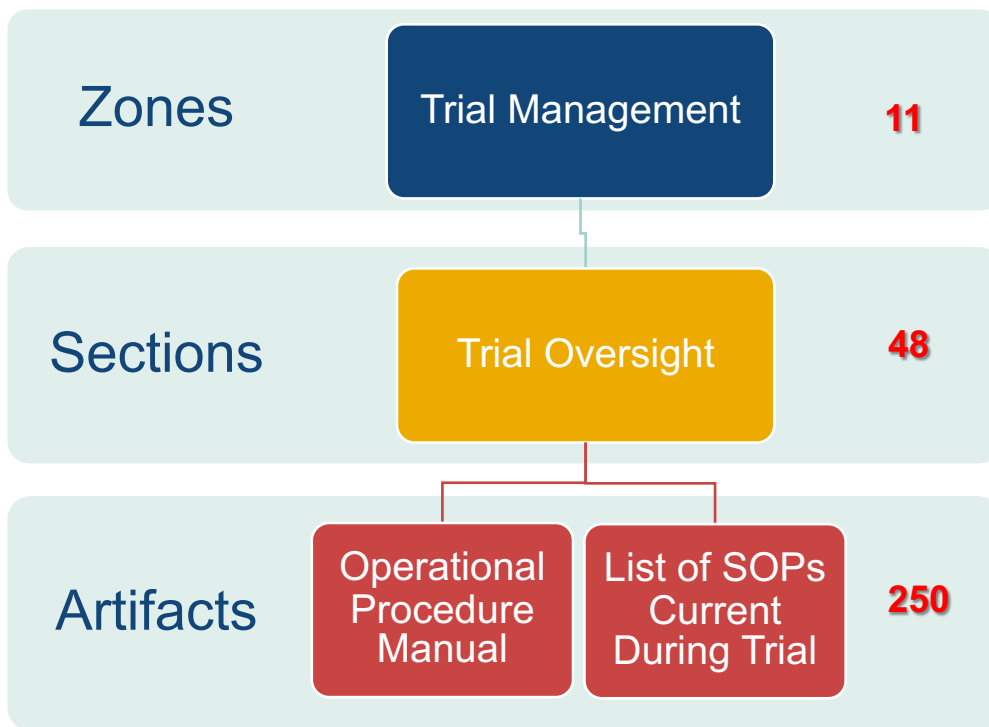
# TMF Reference Model Version 3.4 (Draft)

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 Model	Unique ID Number
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 27<sup>th</sup>, 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 Document	Site Level MILESTONE/EVENT	Dating Conventions	Artifact Owner	Artifact Location	Wet Ink Signatur	SOP Referenc	Translation Requirec	Current Artifact Nat	Additional Metadat	CDISC Definition
		Version Date								Documentation describing how clinical trial records are managed and stored.
		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	CDISC 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 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.

- 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 27<sup>th</sup>, 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 A1 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(ies)” 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 Existing Values" tab.

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 between windows.

>	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.



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 notice that CDISC invites users to submit comments during the public review for Controlled Terminology Package 57, which consists of 18 documents. A list of these documents is provided, including "Controlled\_Terminology\_Requests\_Denied\_P57", "IS Terminology Mapping Codetable\_P57 PR Version", "Rules\_for\_JS\_P57 PR Version", "Rules\_for\_MB\_and\_MS\_P57 PR Version", "ADaM", "Biospecimens", "Cell Phenotyping", "CV", "Define-XML", "ECG\*", "General", "Genomics", "Lab\*", "Microbiology-Immunology\*", "MRCT", "Oncology", "SEND", and "UNIT". A footer note explains that an asterisk indicates changes or retirements of existing CDISC Submission Values.

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.

cdisc Wiki Spaces People Polls Calendars Create Search

Pages / Controlled Terminology / Controlled Terminology Public Review Edit Save for later Watch Share

## Terminology Call for Public Review Package P57 - Comments Due by 12 Jan 2024

Created by Chris Gemma, last modified by Melissa Kirwin on Dec 15, 2023

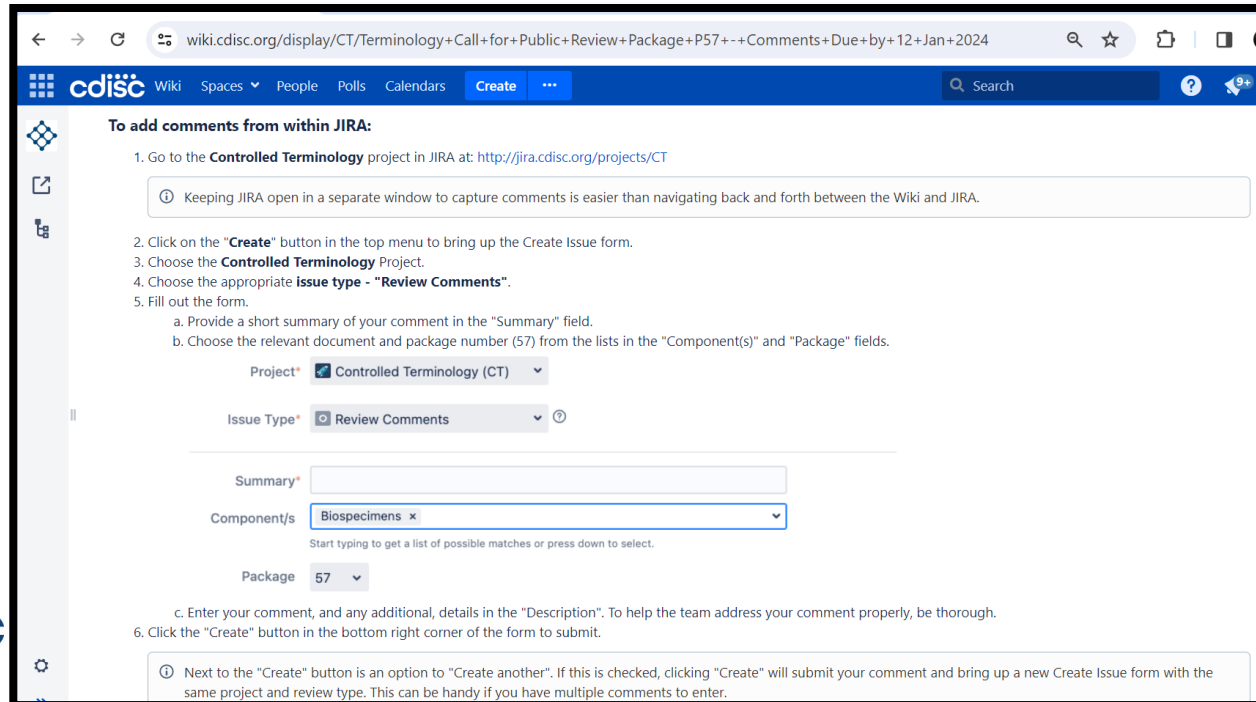
CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 57, which consists of the following 18 documents:

- Controlled\_Terminology\_Requests\_Denied\_P57
- IS Terminology Mapping Codetable\_P57 PR Version
- Rules\_for\_JS\_P57 PR Version
- Rules\_for\_MB\_and\_MS\_P57 PR Version
- ADaM
- Biospecimens
- Cell Phenotyping
- CV
- Define-XML
- ECG\*
- General
- Genomics
- Lab\*
- Microbiology-Immunology\*
- MRCT
- Oncology
- SEND
- UNIT

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.
  - 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.



The screenshot shows a web browser window displaying a CDISC Wiki page titled "To add comments from within JIRA:". The page contains a list of instructions for users to submit comments through the JIRA system. The instructions are as follows:

1. Go to the **Controlled Terminology** project in JIRA at: <http://jira.cdisc.org/projects/CT>
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.

The form fields shown in the screenshot are:

- Project\***:  Controlled Terminology (CT)
- Issue Type\***:  Review Comments
- Summary\***:
- Component/s**:
- Package**:

Additional notes from the page:

- Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.
- 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

The screenshot displays the JIRA System Dashboard for CDISC. The browser address bar shows the URL [jira.cdisc.org/secure/Dashboard.jspa](https://jira.cdisc.org/secure/Dashboard.jspa). The page header includes the CDISC logo, navigation menus for Dashboards, Projects, Issues, Boards, Plans, and Templates, and a 'Create' button. A search bar is also present. A blue banner below the header 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."

## 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	≡

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**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
<a href="#">Browse Projects</a>	<a href="#">My Unresolved Reported Issues</a>
<a href="#">Search for Issues</a>	<a href="#">Votes</a>
<a href="#">Create Issue</a>	<a href="#">Watches</a>

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# 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](https://jira.cdisc.org/projects/CT/issues/CT-1013?filter=allopenissues). The navigation bar includes the CDISC logo, JIRA, and various menu items: Dashboards, Projects, Issues, Boards, Plans, and Templates. A blue 'Create' button is highlighted with a red box and a red arrow. The main content area shows the issue details for 'ISBDAGNT example value' in the 'Controlled Terminology' project. The issue is currently in the 'In Progress' state. The details section includes fields for Type (Question), Resolution (Unresolved), Priority (To be assigned), Component/s (IS Codetable Mapping), Labels (None), and Package (57). The description states: '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 lists 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.

# 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 also includes fields for 'Issue Type' (Review Comments), 'Summary', 'Component/s', 'Fix Version/s' (None), and 'Description'. The 'Create' button is visible at the bottom right of the form.

cdisc JIRA Dashboards Projects Issues Boards Plans Templates Create

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### System Dashboard

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

### Create Issue

Select Template Configure Fields

All fields marked with an asterisk (\*) are required

Project\* **Controlled Terminology (CT)**

Issue Type\* **Review Comments**

Summary\*

Component/s

Package **57**

Fix Version/s **None**

Description

Create another Create Cancel

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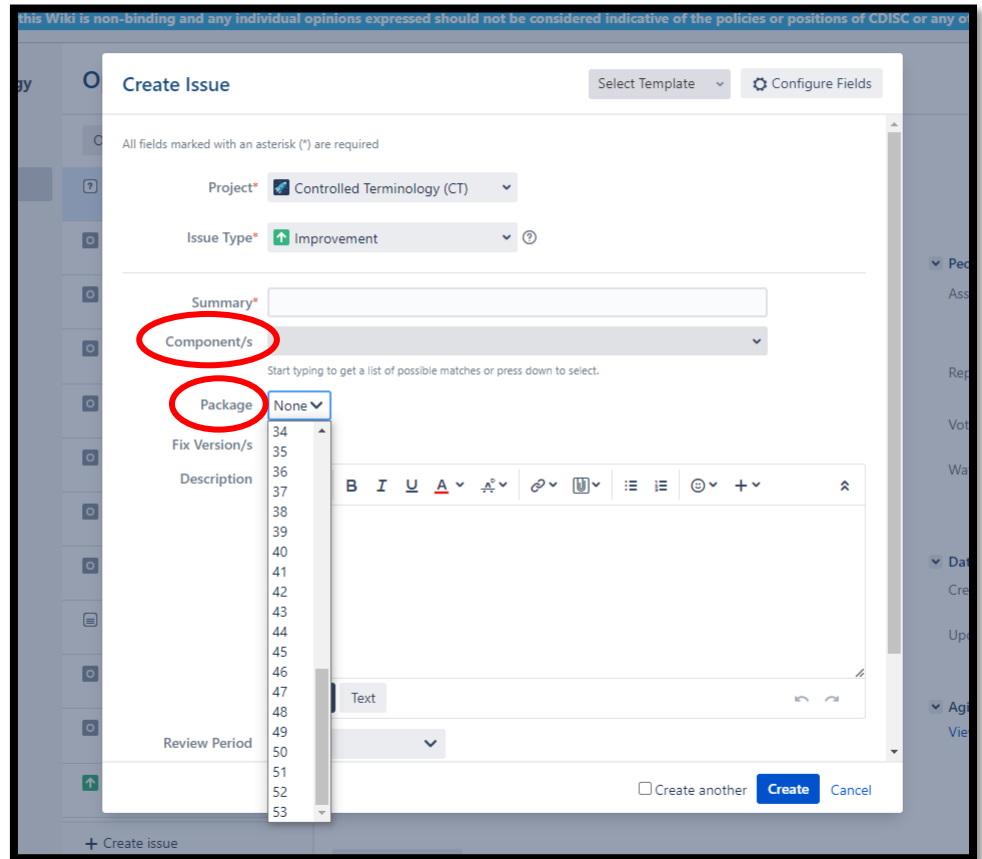
# STEP 3: Fill out the “Create Issue” form [cont’d]

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

The screenshot shows the 'Create Issue' form in the CDISC JIRA system. The form is titled 'Create Issue' and includes a 'Select Template' dropdown and a 'Configure Fields' button. Below the title, a note states: 'All fields marked with an asterisk (\*) are required'. The form contains several fields: 'Project\*' (Controlled Terminology (CT)), 'Issue Type\*' (Review Comments), 'Summary\*' (empty), and 'Component/s' (empty). A red arrow points to the 'Component/s' field, which has a dropdown menu open. The dropdown menu lists the following components: ADaM, Biospecimens, CDASH, Cell Phenotyping, CP, CV, Define-XML, Devices, ECG, General, Genomics, and Glossary. The 'Create' button is located at the bottom right of the form, and the 'Cancel' button is next to it. The background shows the 'System Dashboard' with a table of assigned issues and a search bar at the top.

# 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

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' options. 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 its rich text editor toolbar. At the bottom of the form, there are 'Visual' and 'Text' tabs, and a 'Create' button with a 'Cancel' button next to it. The background dashboard shows a table of issues assigned to the user, with columns for 'Key', 'T', and 'Summary'. A search bar and navigation menu are visible at the top of the JIRA interface.



## 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 CDISC JIRA interface. At the top, there's a navigation bar with 'cdisc JIRA' and various menu items like 'Dashboards', 'Projects', 'Issues', 'Boards', 'Plans', 'Templates', and 'Create'. A search bar is on the right. Below the navigation bar is a blue banner with 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. The table has columns for "Key", "T", and "Summary". The issues listed include TOBA-252, TOBA-323, DDF-489, DDF-490, DDF-491, DDF-492, DDF-501, DDF-502, DDF-503, and DDF-504. A "Create Issue" dialog box is overlaid on the dashboard. The dialog has a title "Create Issue" and two buttons: "Select Template" and "Configure Fields". The form fields are: "Summary\*" (text input), "Component/s" (dropdown menu), "Package" (dropdown menu with "57" selected), "Fix Version/s" (set to "None"), and "Description" (rich text editor with a toolbar). At the bottom of the dialog, there is a "Create another" checkbox, a blue "Create" button, and a "Cancel" button. A red arrow points to the "Create" button. The footer of the JIRA interface includes "Atlassian Jira Project Management Software (v9.4.17#940017-sha1:2c0a67f) · About Jira · Report a problem".

# 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 box 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.

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	⋮

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# Comment Resolution by CDISC CT Teams

The image shows a JIRA interface for CDISC. The top navigation bar includes 'cdisc JIRA', 'Dashboards', 'Projects', 'Issues', 'Boards', 'Plans', 'Templates', and a 'Create' button. A search bar is on the right. A blue banner below the navigation bar 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 is titled "Controlled Terminology" and "Edit Issue : CT-1045". A "Configure Fields" button is visible. The "Edit Issue" modal 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".
- CDISC Disposition Description: A text area.
- Affects Version/s: None
- Fix Version/s: None
- Epic Link: A dropdown menu.

At the bottom of the modal are "Update" and "Cancel" buttons. Red arrows point to the dropdown menu, the "Update" button, and the "CDISC Disposition Description" field.



**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](mailto: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>



# CDISC Membership

## Become a Member!

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

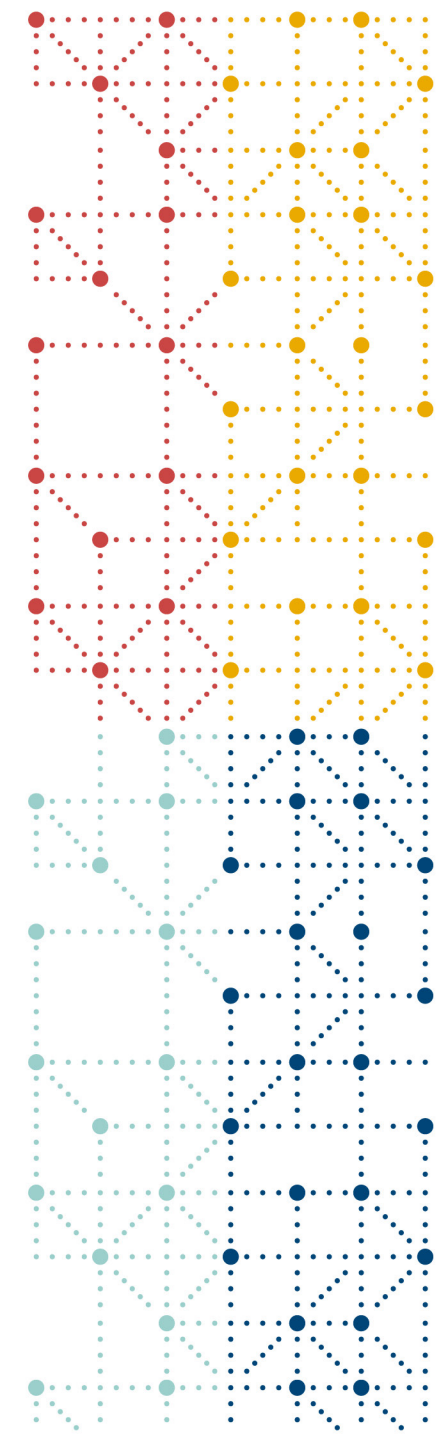
## Already a Member?

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



Email: [membership@cdisc.org](mailto:membership@cdisc.org)





## Q&A



# CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



Thank you for your attendance and support of  
CDISC!