



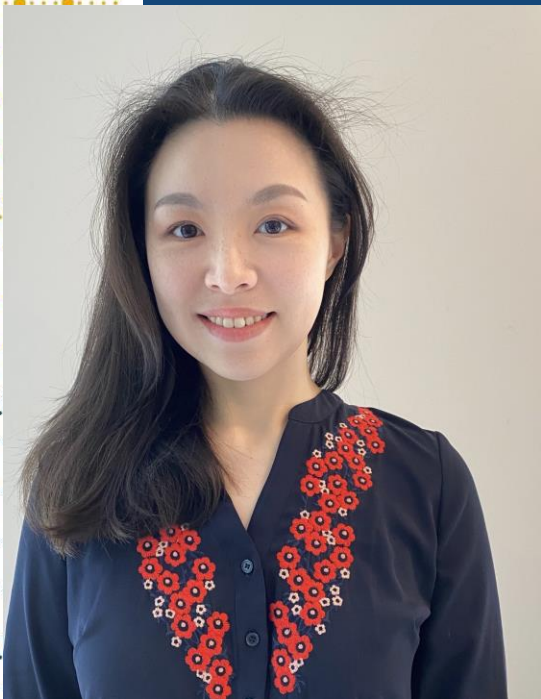
2023 CDISC TMF INTERCHANGE

BALTIMORE | 28-29 SEPTEMBER



An Overview of the NCI EVS Services and Its Collaboration with CDISC

Presented by Dr. Jordan Li;
Clinical/Biomedical Information Specialist,
National Cancer Institute's Enterprise Vocabulary Services



Meet the Speaker

Jordan Li. Ph.D.

Title: Clinical/Biomedical Information Specialist

Organization: Guidehouse; NCI-EVS

- Subject matter and terminology expert from the National Cancer Institute's Enterprise Vocabulary Services (NCI EVS).
- Over 10 years of experience creating and publishing CDISC terminology.
- Directs delivery of multiple CDISC controlled terminology teams .
- Leads the CDISC Microbiology and Immunogenicity Submission Data Standards Development (SDS) subteam.
- CDaSH and SDTM standards experts and developed standards for several CDISC disease therapeutic area projects, including Cardiovascular Imaging, Kidney Transplant, Type 1 Diabetes and multiple Traditional Chinese Medicine projects.

Jordan holds a PhD in Pharmacology and Physiology from Georgetown University.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



National Cancer Institute - Enterprise Vocabulary Services (NCI - EVS) - What We Do

Mission: Development of services and resources that address the needs of NCI and many national and international partners for controlled vocabularies.

EVS provides an array of technology products and services to support the semantic infrastructure of NCI and our collaborating organizations.

Subject Matter Expertise

Definition Writing and Analysis

Terminology Coding, Tagging and Subset bundling

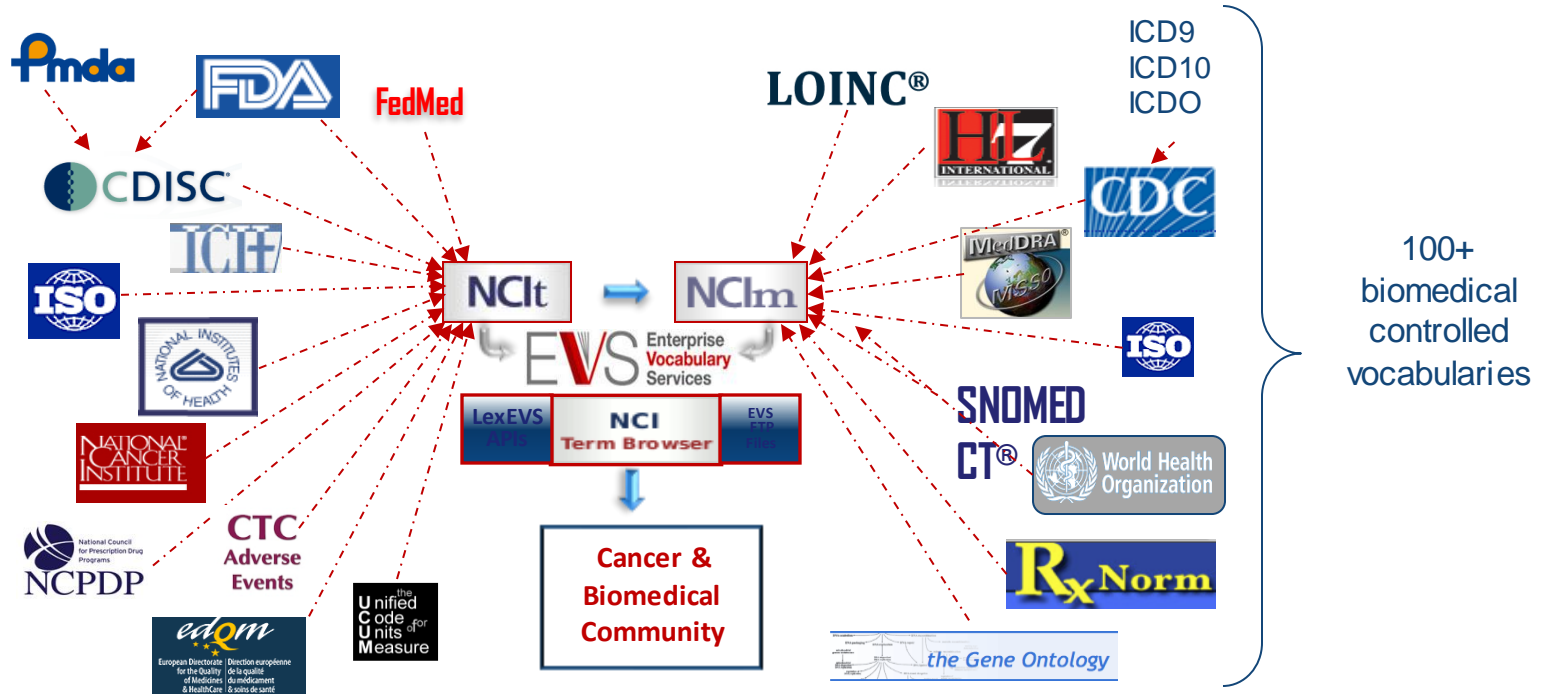
Publish, Maintain and Version Terminology

Links to Other Controlled Terminologies

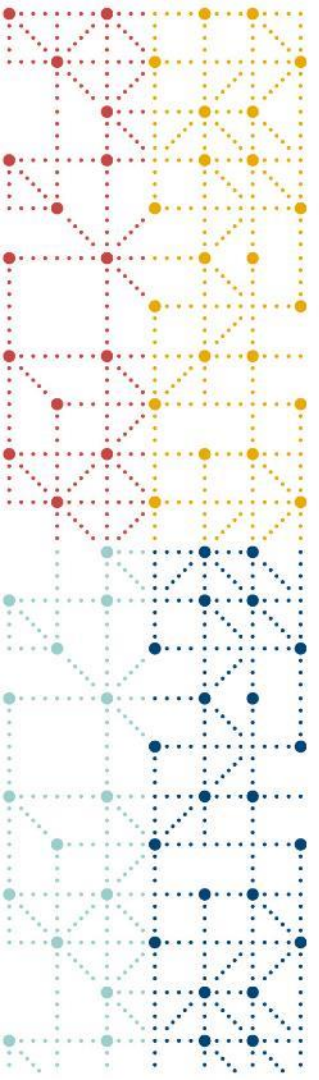
Terminology Content Expansion & Facilitation of Terminology Requests

Produce and Maintain Two Public Browsers - NCIit & NCIim

NCI EVS: Unified Terminology Services and Standards



NCI-EVS works with many national and international partners to develop, license and publish terminology, and also jointly develop software tools to support harmonization and shared standards.



NCI EVS Production Engine: NCI Thesaurus (NCIt) Term Browser

- Free, Open Access 24/7

NCI Thesaurus (NCIt) Overview

- NCI's core reference terminology. It is a free, non-license restricted biomedical coding ontology system.
 - Main function of NCIt is to *establish data semantics*.
- Adopted by FDA, CDISC and other partners as a shared standards development and coding environment.
- Allows participants to compare and harmonize with each other's content while taking advantage of full-text definitions, codes, and other features.
- User-driven concept expansion from NCI, NIH and other term source partners. It is also open to public request via the EVS term request system.
 - Anyone can suggest an addition or a change to existing concepts within the NCIt.
- Currently there are 50 source contributors tagged in NCIt concepts.
- As of April 2023, over 178,000 coded concepts stored in NCIt, including basic and translational research, clinical care, public information, healthcare and administrative activities.
- 400,000 relationships modeled between concepts.

NCIt is used to build and enrich semantics for a concept

All concepts in the NCIt are given:

- **NCIt concept code (C-code):** a unique identifier assigned to each concept by EVS to *permanently* track a specific meaning.
- **Preferred Name:** the term chosen by EVS as most *unambiguous* and widely used in the biomedical community.
- **Synonyms:** additional term(s) chosen by NCI with meaning equivalent to the Preferred Term, this helps with *mapping to other* terminologies.
- **Definition:** a text statement of the *what the concept is*. This ensures that humans and systems have a common understanding of the concept and can therefore use it accurately, precisely and consistently across users and systems.
- **Hierarchical arrangement:** concepts are modeled using a *parent-child "is-a" relationships* in the NCIt ontology environment.

Searching for a concept in the NCI Term Browser

The screenshot shows the NCI Term Browser interface. At the top, there is a red header with the NIH logo and 'NATIONAL CANCER INSTITUTE' text, and the URL 'www.cancer.gov'. Below the header, the page title is 'NCI Term Browser' and 'EVS Enterprise Vocabulary Services'. There are navigation tabs for 'Terminologies', 'Value Sets', and 'Mappings'. A search bar is located in the top right, containing the text 'C42539' and a 'Search' button. Below the search bar are radio buttons for search criteria: 'Contains', 'Exact Match' (selected), 'Begins With', 'Name', 'Code' (selected), 'Property', and 'Relationship'. A red box highlights the search bar and its options, with an arrow pointing to a red callout box labeled 'Search Box'. The main content area shows the concept 'Mole (Code C42539)' with a red box around the code and an arrow pointing to a red callout box labeled 'Unique Concept Code'. Below this, there are tabs for 'Terms & Properties', 'Synonym Details', 'Relationships', 'Mappings', and 'View All'. The 'Terms & Properties' tab is active, showing the 'Preferred Name: Mole' and three definitions: 'Definition', 'NCI-GLOSS Definition', and 'CDISC Definition'. A red box highlights the 'CDISC Definition' and an arrow points to a red callout box labeled 'Source-Specific Definition from CDISC'. Below the definitions, there is a 'Label: Mole' and 'NCI Thesaurus Code: C42539' with links for 'Search for linked caDSR metadata' and 'search value sets'. There is also an 'NCI Metathesaurus Link: C0439189' with a link 'see NCI Metathesaurus info'. Underneath, there is a section for 'Synonyms & Abbreviations: (see Synonym Details)' with a list of terms: 'M', 'mol', 'mole', 'Mole', 'MOLE', 'mole (chemical)', and 'mole(s)'. A red box highlights this list and an arrow points to a red callout box labeled 'Common Synonyms'. The CDISC logo is in the bottom left corner.

Search Box

Unique
Concept
Code

NCI
Definition

Source-
Specific
Definition
from CDISC

Common
Synonyms



The Importance of a Concept Code – Mole (the Unit)



NATIONAL CANCER INSTITUTE www.cancer.gov

NCI Term Browser EVS Enterprise Vocabulary Services

Terminologies Value Sets Mappings

Search: C42539 ?

Contains Exact Match Begins With

Name Code Property Relationship [Advanced Search](#)

Hierarchy | Value Sets | Maps | Visited Concepts Help

Quick Links

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

Mole (Code C42539)

Terms & Properties Synonym Details Relationships Mappings View All

Synonym Details

Term	Source	Type	Code	Subsource Name
mole (chemical)	NCI-GLOSS	PT	CDR0000659802	
mole (chemical)	NCI-GLOSS	SY	CDR0000659802	
mole(s)	ICH	PT	0196	
MOLE	FDA	PT	MOLE	Potency (C-DRG-00501)
mole	HL7	PT	12856	
Mole	NCI	PT		
mole	UCUM	PT		
Mole	CDISC	SY		
mole	FDA	SY		PQCMC
MOLE	FDA	SY		SPL
Mole	NCI	SY		
mol	HL7	AB	12856	
mol	ICH	AB	0196	
mol	NCI	AB		
mol	UCUM	AB		
mol	CDISC	PT		
mol	FDA	PT		PQCMC
mol	FDA	PT		SPL
M	NCI-GLOSS	PT	CDR0000659892	
M	NCI-GLOSS	SY	CDR0000659892	

Unique
Concept Code

Mole (Code C42539)

Additional
Source
Data

Terms
from
Other
Sources

Term
Source



Relationships – Where else is “Mole” used? Association to Other Vocabularies and Codelist Bundling

NCIt Hierarchy

The “Concept_In_Subset” property indicates what other terminology source this concept is associated with. It also allows the bundling of concepts into supersets and value sets (codelists). Currently EVS maintains over 1500 value sets for 26 organizational entities.

NIH NATIONAL CANCER INSTITUTE www.cancer.gov

NCI Term Browser EVS Enterprise Vocabulary Services

Terminologies Value Sets Mappings

Search C42539

Contains Exact Match Begins With

Name Code Property Relationship

Advanced Search

Hierarchy Value Sets Maps Visited Concepts Help

Quick Links

View in Hierarchy | View History | View Graph | Add to Cart | Suggest Changes

Mole (Code C42539)

Terms & Properties Synonym Details Relationships Mappings View All

Relationships with other NCI Thesaurus Concepts

Parent Concepts:

- [Base Unit of International System of Units](#)
- [Potency Unit](#)
- [Unit of Amount of Substance](#)

Child Concepts: (none)

Role Relationships, asserted or inherited, pointing from the current concept to other concepts: (none)

Associations pointing from the current concept to other concepts:
(True for the current concept.)

Relationship	Value (qualifiers indented underneath)
Concept_In_Subset	CDISC SDTM Pharmacokinetic Parameter Unit of Measure Terminology
Concept_In_Subset	CDISC SDTM Terminology
Concept_In_Subset	CDISC SDTM Unit of Measure Terminology
Concept_In_Subset	CDISC SEND Terminology
Concept_In_Subset	Clinical Data Interchange Standards Consortium Terminology
Concept_In_Subset	FDA Pharmaceutical Quality/CMC Terminology
Concept_In_Subset	FDA Structured Product Labeling Terminology
Concept_In_Subset	HL7 Unit of Measure Terminology
Concept_In_Subset	ICH Unit of Measure Terminology
Concept_In_Subset	PQ/CMC Units of Measure Terminology
Concept_In_Subset	SPL UCUM Terminology
Concept_In_Subset	UCUM Terminology



NCI-EVS and CDISC Terminology Program

NCI EVS Partnership



CDISC and EVS have been working closely together for more than 20 years.

- EVS provides dedicated terminology experts, subject matter experts.
- Provides established terminology infrastructure and standard operating procedures.
- Responsible for CDISC controlled terminology development, harmonization, publication and maintenance.

Required and preferred by global regulatory agencies.

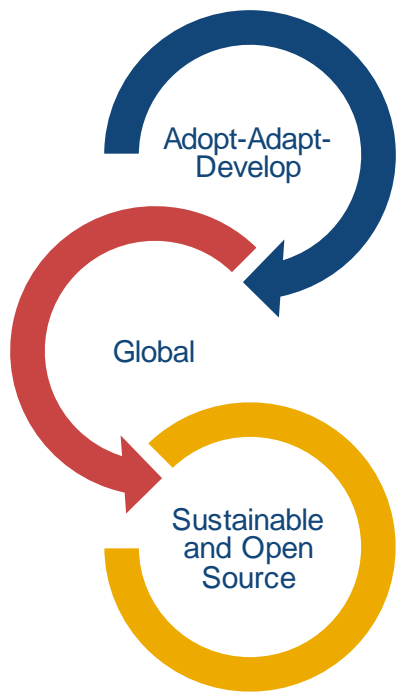
- Required by FDA and PMDA.
- Preferred NMPA and Recommended by EMA.
- Support both general clinical and non-clinical data submission.

>54,000 CDISC terms are coded and tagged in NCI Thesaurus (NCIt)

- All CDISC-tagged concepts contain a CDISC definition to ensure that all users understand and use the concept in the same way.
- 8 subsets of CDISC terminology, each with one-to-many codelists.
- Over 1300 published codelists associated with CDISC terminology in NCIt.

CDISC terminology standards average 35,000 downloads/month in more than 60 countries.

CDISC Terminology Objectives and Development Principles



Support CDISC foundational and therapeutic area standards and CDISC teams. Fulfill CDISC user requests and support the user community.

Develop CDISC submission values with clear definitions; Create codelists and concept coding; define relationships between and among CT and CDISC model elements.

Two-Way process:

- Use CDISC models to guide and drive terminology decisions.
- Terminology analysis influences domain modeling and structuring.

Consider the impact of changes.

Communicate early and often with stakeholders.

Focus on re-use of existing terminology.

Commit to consistent decision-making; follow best terminology practice rules.



CDISC CT Are Made by Their Users

- Currently 16 active CDISC controlled terminology teams that develop CT to support various CDISC standards and to fulfill CDISC user requests.
 - New volunteers welcome! (Join us)
- Led and overseen by NCI-EVS, industry subject matter- and data standards experts with rich experience and extensive knowledge in cardiovascular medicine, pharmacokinetics/pharmacogenomics, oncology, laboratory sciences, human physiology, and immunology studies, etc.
 - CDISC terminology covers a wide variety of scientific and medical disciplines.
 - Used by and support both clinical and non-clinical studies.
- Made and consumed by their users: clear, consistent, practical, user-friendly.



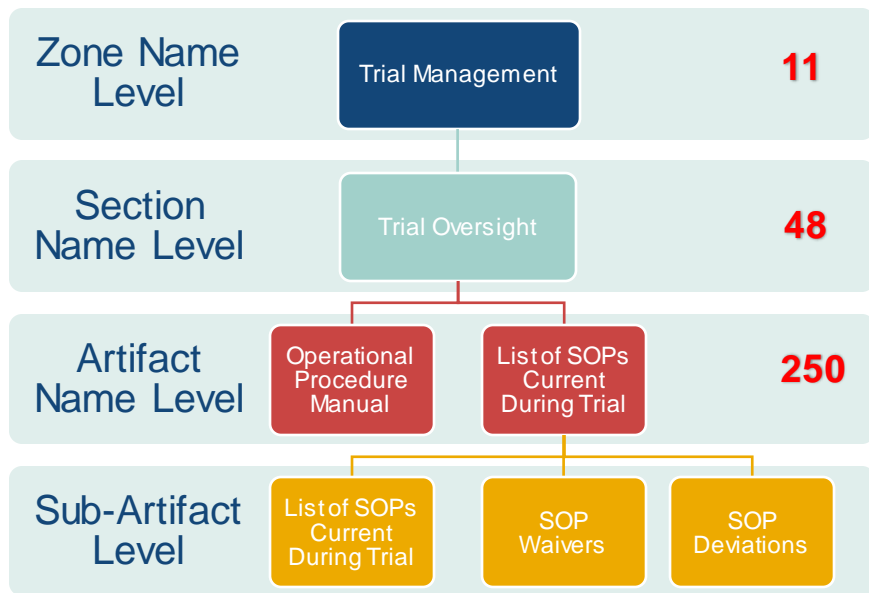
Controlled Terminology to Support TMF Standards

- **Artifacts for TMF-RM**
- **Metadata Standards for eTMF-EM**

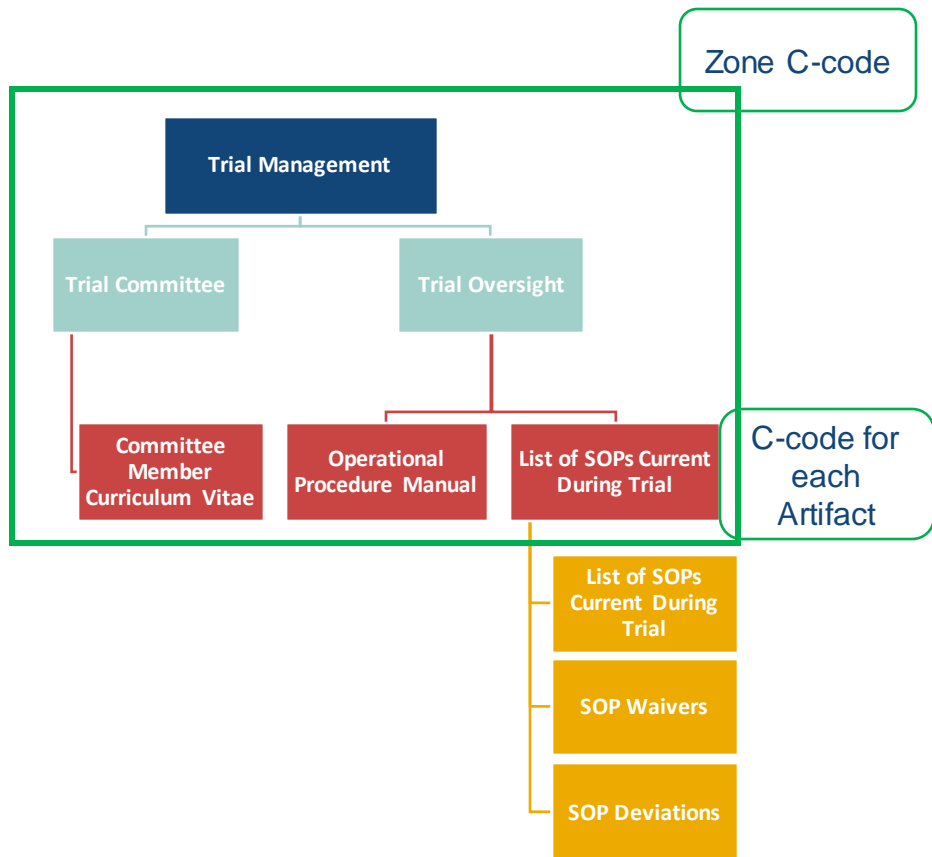
Terminology Organization and Bundling Basics

- The development and organization of controlled terminology are driven by the model structure it serves.
 - how do we organize the controlled terminology so it can best support the “overall structure” of the model and be the most user friendly?
- For example, some of the CDISC Terminology is grouped by CDISC Domains.
 - CDISC has what they call physiology/body system domains such as: Cardiovascular Domain/CV (for collection of heart assessment data), GI domain (for collection of GI assessment data), Respiratory/RE Domain (for collection of lung function test data).
 - Assessment Codelists are created for EACH domain.
 - ✓ Cardiac Output, belong in the CV codelist.
 - ✓ Number of Polyps is in the GI codelist.
 - If you are running a study on treating a heart disease, you are more likely to collect data related to heart findings:
 - Superset: weed through the GI and RE tests just to find the heart assessment you need?
 - Domain-specific Valuesets: Much easier to find what you need in the CV codelist for heart related tests. (CDISC CT approach)

Organization of TMF CT – Initial Plan for Artifacts in RM



- **Three-level Value Control:** Provide coding and semantics to the values from Zone, Section, and Artifacts. Each concept in these 3 levels will be given unique C-codes for permanent tracking as well as clear and consistent definitions.
 - Plans to also control sub-artifacts in the future.
- **Two-level Grouping:**
 - All Artifacts related to a **Zone**.
 - Artifacts related to a **Section**.



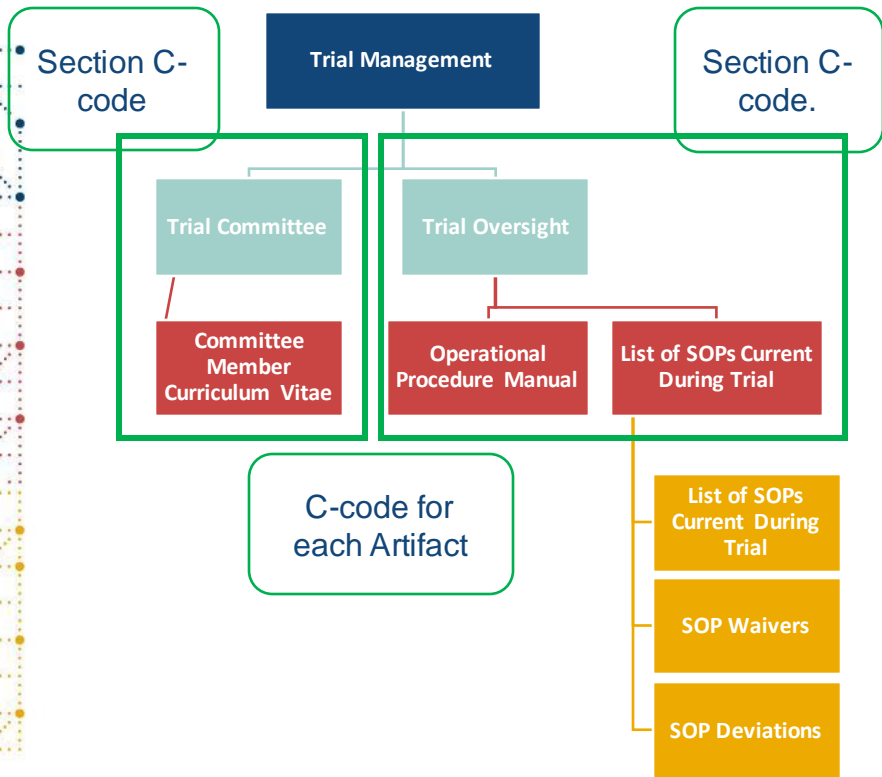
Group artifacts into their related Zone

Codelist Name: Trail Management Zone Related Artifacts

- Unique C-code and definition for this codelist.

All 37 related artifacts across 5 sections from this Zone will be grouped into this codelist.

- Unique C-code and definition for each artifact.



Group artifacts into their related Sections

Codelists Names:

- Trial management Zone - Trail Oversight
Section Related Artifacts
 - Unique C-code and definition for this Section as a codelist.
 - 20 related artifacts mapped to this codelist with unique C-code and definitions.

- Trial management Zone - Trail Committee
Section Related Artifacts
 - Unique C-code and definition for this Section as a codelist.
 - 7 related artifacts mapped to this codelist with unique C-codes and definitions.

Future Plans – Additional Valuesets to Support the TMF RM

- Grouping by artifacts needed and included at the Trail, Country, Site Levels.
- Grouping by artifacts needed and included at the Trail Level Milestone, Country Level Milestone and Site Level milestone.
- Value-set organization of the artifacts are driven by the model and how TMF users consume and use this data.
- Ability to retrieve artifacts and standards metadata only relevant to, and needed by a specific purpose(s), e.g. TMF documents included only at the trial and site levels.
- Customized (artifact) terminology to support the RM in the way you need.

TMF Level					
Trial Level Document	Trial Level MILESTONE/EVEN T	Country/ Region Level Docume	Country Level MILESTONE/EVEN T	Site Level Documen	Site Level MILESTONE/EVEN T
X	01 First Country RA Approval	X	02 Clinical Infrastructure Ready		
X	01 First Country RA Approval	X	02 Clinical Infrastructure Ready		
X	01 First Country RA Approval				
X	01 First Country RA Approval	X	01 First Country RA Approval		
X	01 First Country RA Approval	X	01 First Country RA Approval	X	01 First Country RA Approval

Future Plans – Codify the Metadata Standards in “Exchange.XML”

Provide unique identifier codes and semantics for the metadata standards used by the eTMF-Exchange Mechanism.

Specifically, we will control the attributes under the 6 tags in the Exchange.xml:

- <BATCH>Tag
- <OBJECT>Tag
- <FILE>Tag
- <SIGNATURE>Tag
- <AUDITRECORD>Tag
- <METADATA>Tag

5.3.2. <OBJECT> Tag

The <OBJECT> tag is used to encapsulate individual objects that are being exchanged. For each artifact included in the exchange there will be an <OBJECT> tag. An artifact is defined as a single record within the TMF. Each artifact must have its own <OBJECT> tag.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
OBJECTID	Object ID	Yes	A system-readable identifier for an electronic record that represents a real-world TMF object. Generated by a source system and doesn't change over time.	To be able to identify the artifact and provide artifact traceability between the source and receiving system.	Text
OBJECTLEVEL	TMF RM Study Level	Yes	Identify the Artifact TMF study level as outlined in the current TMF reference model	Used to ensure that the artifact is filed at the correct level within the receiving system.	Text (Trial, Country, Site)
COUNTRYID	Study Country ID	Yes – For country or site level documents	Unique identifier for a study country	Used to file the artifact within the correct country within the receiving system.	ISO-3166 Alpha-3 i.e. CAN, FRA etc.
SITESYSTEMID	Study Site ID	Yes - For site level documents	Unique system identifier for a study site	Unique system identifier for a study site that is generated by the source system or receiving system. Used to file the artifact within the correct site within the receiving system.	Text
SITEID	Study Site Number	Yes – For site level documents	Unique human identifier for a study site	Unique human readable identifier for a study site. Could also be used to file the artifact within the correct site and could be identical to the SITESYSTEMID	Text
UNIQUEID	TMF RM Unique ID Number	Yes	Unique identifier for a specific TMF RM Artifact	Used to index objects against the correct artifact type within the receiving system.	Number on 3 digits i.e. 001, 010

The screenshot shows the CDISC Library Data Standards Browser interface. On the left is a navigation tree with categories: Data Collection, Data Tabulation, Data Analysis, QRS Instruments, and Terminology. The 'Data Tabulation' section is expanded, listing various standards including SDTM v2.0, v1.8, v1.7, v1.6, v1.5, v1.4, v1.3, v1.2, SDTMIG v3.4 (highlighted), SDTMIG-MD v1.1, SDTMIG v3.3, SDTMIG-AP v1.0, SDTMIG v3.2, SDTMIG-MD v1.0, SDTMIG v3.1.3, SDTMIG v3.1.2, SENDIG v3.1.1, SENDIG-AR v1.0, SENDIG-DART v1.1, SENDIG v3.1, and SENDIG v3.0. The main content area displays details for 'SDTMIG v3.4', including its status (Final), effective date (2021-11-29), and implementation (SDTM v2.0). Below this, there are tabs for 'Classes' (General Observations, Interventions, Events, Findings, Findings About, Special-Purpose) and a 'General Observations' section with a description: 'The majority of observations collected during a study can be divided among three general classes: Interventions, Events, or Findings. Datasets by Timing variables. As a general rule, any valid Identifier or Timing variable is permissible for use in any submission dataset based on a general ob'.

To learn more - Past Webinars:

- **CDISC Library: Ideas for using the CDISC Library:**
<https://www.cdisc.org/events/webinar/cdisc-library-ideas-using-cdisc-library-and-look-whats-coming-next>
- **CDISC Library Virtual Workshop:**
<https://www.cdisc.org/events/webinar/cdisc-library-virtual-workshop>

Both the TMF Reference Model and Terminology will be stored in the CDISC Library

CDISC models and controlled terminology are stored in the CDISC library. You can:

- Access and easily browse multiple versions of the CDISC Foundational Standards' metadata and Controlled Terminology.
- Retrieve machine-readable standards metadata using multiple media-types: JSON, XML, ODM, CSV, Excel (moving away from spreadsheet for metadata consumption and simplifying automation).
- Create Diff Reports, which deliver machine-readable (JSON, Excel) metadata comparisons that compute and display differences between the content in two versions of a standard.
- Model relationships between and within variable- and value- level metadata.
- Check conformance against standards metadata.

Controlled Terminology Better Support the RM and the Exchange of TMF Content

Create Clear Standards and Formalize the model with regulatory authorities

- Concept coding at Zone, Section and Artifact levels – unique and permanent tracking for each TMF concept at each level.
- Definition proofing: clearly, consistently and meaningfully defined individual concepts (instead of plain language description now used by the reference model).
- Standardized TMF concepts will help to better support the Reference Model itself, which will further help to formalize the TMF-RM with regulatory agencies.
- Terminology analysis and placement influences RM modeling and structuring – users will have a better understanding of where to add and place a new or existing artifact.

Enhance the Trial Master File Exchange Mechanism Standard

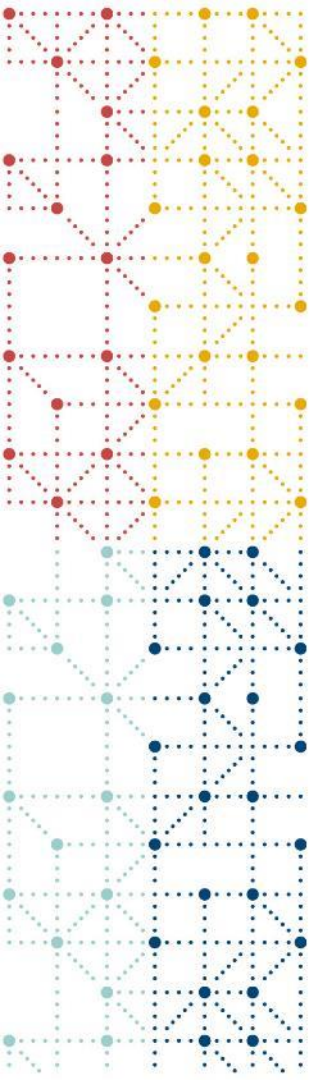
- Codified artifacts and metadata standards will be used in the “exchange.xml” to support the automatic transfer of TMF content between sponsors, CROs and other stakeholders in the eTMF-EMS.
- Enhance communication among sponsors, partners, and CROs.

Maintain community engagement

- From the start: controlled terminology is made by their users: need to be clear, consistent, practical and useful.
- To the end: user community governance and quality assurance through public outreach, review and commenting.

Imported into the CDISC Library

- Searching for specific artifacts, mapping relationships between artifacts.
- Control changes and version history.
- Retrieve versioned reference model and TMF terminology from the library.
- Create views of content and metadata for various types of trials.



cdisc



Additional Slides – More Info

CDISC Controlled Terminology Page



[New to CDISC](#) [Standards](#) [Education](#) [Resources](#) [Events](#) [Membership](#) [Members Only](#)

[Home](#) / [Standards](#) / [Terminology](#) / [Controlled Terminology](#)

Controlled Terminology

[Description](#) [Education](#) [Knowledge Base](#) [Public Review](#)



CDISC, in collaboration with the [National Cancer Institute's Enterprise Vocabulary Services \(EVS\)](#), supports the Controlled Terminology needs of CDISC Foundational and Therapeutic Area Standards.

Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you *WHAT* to collect; it tells you *IF* you collected a particular data item, how you should submit it in your electronic dataset.

New requests or changes to existing Terminology can be accessed through the CDISC [New Term Request Page](#).

Controlled Terminology Release

As of 30 June 2023 the ADaM, DDF, Define-XML, Protocol Entities, SDTM, and SEND Controlled Terminology files have been updated on the NCI-EVS Ftp site. The version dates of the new files are 2023-06-30. These terminology files replace all previous ADaM, DDF, Define-XML, Protocol Entities, SDTM, and SEND terminology files and include terms from Review Package 54. There are approximately 71 new QRS terms and 917 new terms across ADaM, DDF, Define-XML, Protocol Entities, SDTM, and SEND terminology files.

Additionally there are:

- Update to six published Codetable Mapping files: DD, IS, Oncology, RE, TS, and VS
- Update to four Terminology Development Rules documents: QRS, IS, MB and MS, and PK
- Update to Unit-UCUM Codetable Mapping file
- Update to Controlled Terminology Request Denied file
- Update to CDISC Terminology Publication Schedule
- Update to the SDTM and SEND paired view files

[Controlled Terminology Release 30 June 2023](#)



CDISC CT Landing Page - <https://www.cdisc.org/standards/terminology/controlled-terminology>

- Public announcement will be made about the new CT public review and publication (email blast from CDISC)
- High-level summary will be provided on updates made to specific CDISC terminology subsets.
- Link to the NIH CDISC Terminology Homepage for download.
- Other supporting documents (CT rules, etc.) will be published and hosted on this page.

Terminology Public Review and Comment Resolution – CDISC WIKI

Terminology Call for Public Review Package P55 - Comments Due by 21 July 2023

Created by Alana St. Clair, last modified on Jun 23, 2023

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 55, which consists of the following 19 documents:

- Controlled_Terminology_Requests_Denied_P55
- IS Terminology Mapping Codetable_P55
- QRS Naming and Business Rules
- Rules for IS
- Rules for MB and MS
- Rules for Lab, Unit, and MI
- Biospecimens
- Cell Phenotyping
- Devices
- ECG
- General
- Genomics
- Lab
- Microbiology-Immunology
- MRCT
- Oncology
- PK
- Protocol Entities
- 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 the document carefully.

Comments due: 21 Jul 2023

Instructions for Reviewers

Register and/or Log in WIKI and in JIRA to provide comments. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account.

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>

Public Review Documents

File

- > Terminology_P55_Microbiology-Immunogenicity.xlsx
- > Terminology_P55_MRCT.xlsx
- > Terminology_P55_Oncology.xlsx
- > Terminology_P55_PK.xlsx
- > Terminology_P55_Protocol_Entities.xlsx
- > Terminology_P55_UNIT.xlsx
- > Controlled_Terminology_Requests_Denied_P55.xlsx
- > IS Terminology Mapping Codetable_2023-09-29_P55 PR Version.xls
- > QRS_Naming_and_Business_Rules_2023-09-29_P55 PR Version.xlsx
- > Rules for IS_2023-09-29_P55 PR Version.docx
- > Rules for MB and MS_2023-09-29_P55 PR Version.docx
- > Rules_for_Lab_Unit_and_MI_2022-12-16_P55 PR Version.docx
- > Terminology_P55_Biospecimens.xlsx
- > Terminology_P55_Cell_Phenotyping.xlsx
- > Terminology_P55_Device.xlsx
- > Terminology_P55_ECG.xlsx
- > Terminology_P55_General.xlsx
- > Terminology_P55_Genomics.xlsx
- > Terminology_P55_Lab.xlsx
- > image2023-6-23_10-21-36.png

> Terminology_P58_TMF-
RM.xlsx

- Instructions on how to enter comments through **CDISC JIRA – CT Project**.



Terminology Public Review and Comment Resolution – CDISC JIRA CT Project

The screenshot shows a JIRA issue page for the 'Controlled Terminology' project. The issue title is 'FATEST/FATESTCD of PLDIAM, request from Chron's Disease TA - Why not record using the TU/TR based domains?'. The issue is currently 'Unresolved' and has a priority of 'None'. The component is 'TMF-RM' and the package is '58'. The description discusses the definition of TU/TR and TRTESTCD, and asks for justification for not using these terms in the Pancreatic Cancer TAUG collection style. The page includes a sidebar with navigation options, a list of other open issues, and a right-hand panel with details about the issue's status, assignee, reporter, and dates.

Controlled Terminology Open issues Switch filter View all issues and filters

Order by Priority Order Down Arrow

- CT-792 FATEST/FATESTCD of PLDI...
- CT-793 FATESTCD/FATEST - RESC...
- CT-796 FATEST/FATESTCD - ORC...
- CT-789 D1FATS; D1FATSCD - Sho...
- CT-790 PAFATS/PAFATSCD - PRYS...
- CT-797 FATEST/FATESTCD - ACN...
- CT-954 CT Requests Denied - MU...
- CT-953 RPTTEST-CD Number of S...

Controlled Terminology / CT-792 1 of 36 Share Export

FATEST/FATESTCD of PLDIAM, request from Chron's Disease TA - Why not record using the TU/TR based domains?

Edit Add comment Assign More Open

Details

Type: Review Comments Resolution: Unresolved

Priority: Trivial

Component/s: **TMF-RM**

Labels: none

Package: **58**

Description

The definition for TU/TR includes lesions. TUTESTCD includes an indicator for the primary lesion and TRTESTCD includes LDIAM for Longest Diameter. What's the justification for not using these, especially since the Pancreatic Cancer TAUG includes an example of this collection style (Section 3.1, Example 4)?

Attachments

Drop files to attach, or browse.

People

Assignee: Unassigned Assign to me

Reporter: Daniel Sinnett Vote for this issue

Watchers: 1 Start watching this issue

Dates

Created: 23/Mar/21 11:35 AM

Updated: 09/Dec/22 1:36 PM

Agile

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CDISC Terminology

The Clinical Data Interchange Standards Consortium® (CDISC) is an open, non-profit organization that develops and supports global data standards to improve the quality and interoperability of medical research and healthcare. CDISC standards are widely used for study planning and data collection, tabulation, analysis, and submissions to the U.S. Food and Drug Administration (FDA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and other regulatory agencies internationally.

CDISC partners with NCI Enterprise Vocabulary Services® (EVS) to develop and support controlled terminology for all CDISC foundational standards (Protocol, CDASH, SDTM, SEND, ADaM, Define-XML, and CDISC Glossary) and CDISC Therapeutic Area Standards. CDISC Terminology is developed through an extensive process of content development and public review, with input from the research and healthcare community. EVS® maintains and distributes CDISC Terminology® as part of NCI Thesaurus® (NCIT).

Index of /ftp1/CDISC

Notes have been released on the latest updates to the NCI Thesaurus. See our news article for full details!

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<https://www.cancer.gov/research/resources/terminology/cdisc>

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Change Request Tracker.xls	2023-06-30 14:55	3.8M	
ControlledTerminologyODM.pdf	2011-04-08 15:32	391K	
ControlledTerminologyODM_v1.pdf	2022-04-06 19:29	269K	
DDF/	2022-12-16 16:00		-
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Glossary/	2022-12-16 16:20		-
Protocol/	2019-09-27 12:31		-
ReadMe.txt	2017-12-22 17:31	1.7K	
SDTM/	2022-06-24 17:17		-
SEND/	2022-03-25 15:46		-
schema/	2022-02-24 22:01		-
xsl/	2019-06-28 10:34		-

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

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- Plan to publish twice a year for TMF terminology; aiming for 2024 publication.
- 6 formats** can be directly downloaded from this page: .xls, .txt, .html, .odm-xml, .OWL/RDF, .pdf
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