# Controlled Terminology User Guide

Version 2.0 (Final)

Prepared by the CDISC Controlled Terminology Team

**Notes to Readers**

This is the final Version 2.0 of the CDISC Controlled Terminology User Guide.

**Revision History**

| Date | Version | Updates |
|---|---|---|
| 2026-10-30 | 2.0 | Significant rewrite of materials to reflect current CDISC CT processes |
| 2013-01-05 | 1.1 | Addition of microbiology references |
| 2011-07-11 | 1.0 | Initial final version |

*See Appendix D for Representations and Warranties, Limitations of Liability, and Disclaimers.*

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# 1 Introduction

The CDISC Controlled Terminology User Guide (CTUG) is published on the CDISC website and maintained by the CDISC Controlled Terminology Team. CDISC collaborates with the National Cancer Institute's Enterprise Vocabulary Services (NCI EVS) to define controlled terminologies that are used with the CDISC foundational standards. This user guide is designed to provide industry with clear insight and transparency into the CDISC controlled terminology development and maintenance process. In addition, the CTUG is intended to guide industry on processes and considerations when adopting CDISC terminology standards. It is the user's responsibility to be familiar with the requirements of health and regulatory authorities related to the use of controlled vocabularies in data submissions.

## 1.1 Purpose and Scope of this Document

This document is intended to guide industry on processes and considerations when adopting the standards or optimizing processes surrounding controlled terminology adoption. The objective of the CTUG is to assist the CDISC user community in understanding the development, maintenance, and implementation of controlled terminology and its impact on stakeholders in the clinical development process.

This document provides information related to the development, management, governance, and publication of CDISC Controlled Terminology (CDISC CT). It also provides direction for CDISC CT implementation. The CTUG may reference external terminologies, coding systems, or other vocabularies that are commonly used in regulatory submissions, but these are not considered part of CDISC CT; CDISC does not manage those external terminologies. The use of "CDISC Controlled Terminology" or "CDISC CT" within this document specifically refers to CDISC-developed terminologies, whereas the use of "controlled terminology" (lowercase) within the document includes both CDISC and external terminologies.

The following conventions are used throughout the document:

- "Sponsor/applicant/other" denotes the entity or organization responsible for the study.
- "Subject" denotes the study participant enrolled in a study and/or a member of the study population for whom data are being collected. Since "subject" is used consistently within the CDISC data models, "subject" was chosen to be used within this document.
- "User" denotes any user of CDISC CT, regardless of affiliation with a sponsor, applicant, or other responsible organization.

## 1.2 Who Are Controlled Terminology Stakeholders?

Controlled Terminology is used by all CDISC foundational standards, and therefore impacts users of each of the standards throughout the clinical trial lifecycle.

| Clinical trial lifecycle stage | Foundational standard | Roles | Interaction with or use of controlled terminology |
|---|---|---|---|
| Plan | USDM | Clinical research associate | • Liaises with internal regulatory groups to ensure country-specific requirements for the use of controlled terminology within data collection plans and study conduct are met |
| | | Statistician | • Uses controlled terminology to plan categorical analyses<br>• Determines if controlled terminology exists for the kind of data to be modeled (e.g., diary data; questionnaires, ratings, and scales; laboratory data)<br>• Refers to controlled terminology to plan tables, listings, and figures needed for analyses |
| | | Data manager | • Maintains sufficient awareness of controlled terminology to ensure that concepts expressed in protocols and standard operating procedures are represented by controlled terminology-conformed values and definitions |

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| Clinical trial lifecycle stage | Foundational standard | Roles | Interaction with or use of controlled terminology |
|---|---|---|---|
| Collect | CDASH | Data collection tool designer | • Makes use of controlled terminology on case report forms (CRFs), other data collection forms, and electronic data collection mechanisms, where appropriate, to ensure traceability from collection to submission<br>• Ensures that the data collection modules enable conformance to CDISC standard variables and controlled terminology |
| | | Data manager | • Ensures the use of standardized and/or sponsor/applicant/other-defined controlled terminology on data collection forms<br>• Facilitates the transformation and/or conformance of collected clinical data into standardized controlled terminology |
| | | Statistician | • Reviews controlled terminology used on CRFs, other data collection forms, and electronic data collection mechanisms to ensure the structure and content of collected data align with the intent of the statistical analyses |
| | | Clinical programmer | • Makes use of controlled terminology on the CRF, other data collection forms, and electronic data collection mechanisms to plan and program tables, listings, and figures |
| Organize | SDTM | Statistician | • References controlled terminology within the data to identify anomalies and outliers<br>• Verifies that the controlled terminology in use reflects that which is needed to do the analysis |
| | | Clinical/statistical programmer | • Checks compliance with controlled terminology to ensure correct implementation throughout the clinical trial<br>• Makes requests internally to extend terminology as required<br>• Incorporates controlled terminology into SDTM datasets and Define-XML |
| Analyze | ADaM | Statistician | • Uses controlled terminology to aid in performing statistical analyses on clinical datasets |
| | | Clinical/statistical programmer | • Checks compliance with controlled terminology to ensure correct implementation throughout the clinical trial<br>• Makes requests internally to extend terminology as required<br>• Makes use of controlled terminology from the analysis datasets to create tables, listings, and figures<br>• Makes use of controlled terminology to check data<br>• Incorporates controlled terminology into ADaM datasets and Define-XML |
| | | Author | • Uses tables, listings, and figures containing controlled terminology when presenting results from the clinical trial |
| **All stages** | All | Standards manager (data steward) | • Manages and enforces compliance with controlled terminology throughout the clinical trial<br>• Stewards the authoritative repository of controlled terminology within an organization<br>• Coordinates governance and change management |
| | | Terminology manager | • Provides and maintains controlled terminologies, both internal and external<br>• Ensures accuracy, consistency, and reusability of controlled terminologies<br>• Develops guidance on controlled terminology use<br>• Leverages existing standards content by conforming sponsor/applicant/other-defined terms to industry concepts<br>• Develops new terms and codelists/value sets following controlled terminology principles defined by the industry |
| | | medical/scientific expert | • Advises in conforming collected data to controlled terminology<br>• Reviews coding of collected data to controlled terminology<br>• Identifies gaps in controlled terminology with respect to collected data |

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The CTUG is intended to be used both by people who interact directly with the controlled terminology and by those in roles supporting direct users. Controlled terminology is generally used by each of these roles using one of the structured formats in which controlled terminology is published. Controlled terminology is intended to be used selectively to support a specific clinical scenario.

Controlled terminology is also used and managed by sponsors, contract research organizations (CROs), and vendors supporting nonclinical studies using SEND foundational standards. The roles, responsibilities, and processes between clinical and nonclinical are very different in terms of implementation (e.g., SEND datasets are currently most often generated after analysis and drafting of the final report). To avoid confusion that could result by attempting to incorporate SEND stakeholders into this clinical trial lifecycle stages table, the team determined that the rigorously controlled local sponsor and CRO processes in place for handling nonclinical terminology do not need to be represented in the table.

Sponsors/applicants/others may extend CDISC CT by adding new terms to extensible codelists or by adding new lists of sponsor/applicant/other-defined terms for specific purposes, which are susceptible to the same controls and governance processes as the CDISC CT. Additionally, data may have been collected using terms that must conform to internal or external terminologies. This conforming process requires input and decision making from subject-matter experts in both terminology and the specific therapeutic area.

# 1.3 What Is Controlled Terminology?

CDISC CT is the set of CDISC-developed or CDISC-adopted standard expressions (values) used with data items within the CDISC foundational standards. These standards focus on the core principles for defining data standards and include models, domains, and specifications required for data representation, including those for controlled terminology. CDISC CT provides a consistent semantic layer across all operational contexts, enabling interoperability of the CDISC foundational standards. Each of the foundational standards' data models include controlled terminology implementation requirements. This user guide should be used together with the CDISC foundational standards documents. CDISC CT is maintained within the National Cancer Institute's Enterprise Vocabulary Services' (NCI EVS) NCI Thesaurus (NCIt), a reference terminology and core biomedical ontology covering more than 100,000 key biomedical concepts with a rich set of terms, codes, definitions, and over 400,000 interconcept relationships.

CDISC CT is one of several terminology sources supporting CDISC foundational standards. Other dictionaries are used to support some variables within CDISC models and implementation guides, including MedDRA, WHODrug, ISO, LOINC, and SNOMED CT. Some of these are specified to be used with certain variables (i.e., LOINC and MedDRA); some are mandated by regulatory authorities through published guidances; and some are determined by the data provider.

## 1.3.1 CDISC Terminology Products

CDISC CT is published as a set of terminology products that support the use of and interoperability among CDISC foundational standards and other standards initiatives undertaken by CDISC.

- ADaM terminology supports the CDISC ADaMIGs, the Tobacco Implementation Guide (TIG), and Questionnaires, Ratings, and Scales (QRS) supplements. However, much of the controlled terminology that is used to support ADaM datasets is acquired from SDTM datasets that make use of SDTM terminology.
- CDASH terminology supports a small set of data collection elements defined within the CDASHIGs and Supplements. The full SDTM Terminology should be considered for inclusion within data collection systems and CRFs.
- CDISC Glossary is a terminology that supports the harmonization of definitions, acronyms, abbreviations, and initials of commonly used clinical terms across CDISC standards and regulatory documents, including clinical research-related terminology not necessarily used in a submission.
- DDF (Digital Data Flow) terminology supports the elements that exist within the DDF Unified Study Definitions Model (USDM).
- Define-XML terminology supports the elements that exist within the Define-XML standard, including Define-XML metadata elements related to analysis. SDTM, SEND, and ADaM terminology values are also

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acquired from their respective datasets to populate the Define-XML but these values are not included in the Define-XML terminology product.

- The MRCT Clinical Research Glossary supports researchers, patients, trial participants, caregivers, and patient advocates to help enhance health literacy and creates empowering participant-facing research communications. This glossary is developed in collaboration with the Multi-Regional Clinical Trials Center at Harvard University and Brigham and Women's Hospital.
- SDTM terminology supports the CDISC SDTM and SDTMIGs, therapeutic area user guides (TAUGs), the TIG, and QRS supplements.
- SEND terminology supports the CDISC SENDIGs, nonclinical TAUGs, and the TIG. A portion of the SEND terminology is shared verbatim with SDTM terminology.
- TMF (Trial Master File) terminology supports the semantics within the electronic trial master file.

Please refer to the ReadMe associated with each terminology product for more information.

**Note:** CDISC protocol entities terminology was retired in March 2026; previously published files will continue to be available in the archives of the NCI EVS FTP. The CDISC Protocol terminology has been superseded by the ICH M11 Protocol terminology. Refer to Section 1.3.3 for information regarding ICH terminologies.

## 1.3.2 CDISC Controlled Terminology Key Concepts

The FDA *Technical Conformance Guide*[1] states that

> controlled terminology standards are an important component of study data standardization and are a critical component of achieving semantically interoperable data exchange. Generally, controlled terminology standards specify the key concepts that are represented as definitions, preferred terms, synonyms, codes, and code system.

The CDISC CT standard comprises the following elements, which are needed to specify a complete terminology system.

### Submission Value

A *preferred term* is the most suitable name for a concept that is chosen from a potential list of names for that concept. Preferred terms are considered part of a well-formed terminology standard and are identified by the Term Type "PT" in the NCIt. Within the context of CDISC CT, the CDISC PT becomes the CDISC Submission Value in the CDISC terminology publication files and may be a single word or descriptive phrase. The CDISC Submission Value (CDISC PT) is selected as the authorized descriptor to represent a discrete concept within a terminology codelist and is required for data submission within CDISC compliant datasets.

A submission value

- identifies the precise, case-sensitive value (i.e., literal string) used to represent a concept in a CDISC dataset;
- is mandated for use in data submissions to regulatory agencies requiring CDISC standards (e.g., US FDA, Japan PMDA); and
- is established with consensus from the industry in support of the CDISC models.

### Definition

A *definition* is a concise explanation of the meaning of a word or phrase or symbol. Definitions are considered part of a well-formed controlled terminology standard and all terms in CDISC CT are defined. Without a definition, a term is likely to be misinterpreted and misused; definitions provide a level of assurance that the same term is used in a consistent way. Standardization is not possible without a single, concise explanation of the meaning of a word or phrase or symbol.

A definition

- establishes the specific meaning and semantic boundaries of the concept (i.e., submission value);
- provides a level of assurance that the term is being used consistently within and across submissions; and

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- ensures the same concept is equivalent across various contextual usages.

### Synonym

A *synonym* is a word or phrase that has the same meaning as another word or phrase in a language system and provides an alternative representation of the same concept. Synonyms are considered part of a well-formed controlled terminology standard because they provide flexibility for expressing a concept and at the same time lead the user to a consistent CDISC submission value; however, a synonym is not a substitute for the CDISC submission value in the dataset.

A synonym

- is used to map or conform collected values to CDISC submission values and
- conforms to a more exacting law of synonymy in that synonyms must always be conceptually identical to the submission value and to all other synonyms (i.e., if A = B, then B must always = A; if A = B and B = C, then A must = C). For example, % (C25613) in the unit codelist has a synonym of "Percentage" because the % symbol always equals percentage. Conversely, %(v/v) (C48571), %(w/v) (C48527), and %(w/w) (C48528) are types of percentages but are not fully synonymous with % (C25613).

### Codes/Concept Unique Identifiers

A concept-unique identifier (CUI) is a distinct code assigned to each unique concept within a particular controlled terminology system. In the context of CDISC CT, all terms are assigned NCI C-codes within the NCIt code system. Codes are considered part of a well-formed controlled terminology standard.

An NCI C-code

- identifies each unique concept within the NCIt code system;
- permanently associates the concept across all codelists and is not reused;
- singularly identifies the concept even when that concept has different CDISC submission values across codelists (e.g., see concept C17998 in the SDTM Terminology publication file); and
- is assigned to every CDISC concept, including the codelist concept and each value within the codelist (e.g., see columns A and B in the SDTM Terminology publication file).

### Codelists

A *codelist* is a finite list of preferred terms or submission values and their definitions that represent the allowable values for a specific data item. In the context of CDISC CT, the term "codelist" refers to both code sets and valid value sets.

A codelist

- conveniently bundles individual concepts into lists of related terms based on a shared characteristic,
- supports one or more model elements (e.g., variables, tests, parameters) within and across CDISC foundational standards, and
- may be extensible or nonextensible (see Section 3.1.2, Terminology Metadata).

For specific examples of these key concepts, see Section 3.1.2, Terminology Metadata, and Section 3.2.2.1, Conforming: Mapping Data to CDISC Controlled Terminology.

## 1.3.3 ICH Terminology

CDISC and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) have formalized a strategic partnership through a Memorandum of Understanding (MOU), which supports the development, curation, governance, and maintenance of ICH controlled terminologies that are critical for the implementation of ICH technical specifications and guidelines. These terminologies are standardized, interoperable, and made publicly available through the NCI Thesaurus using CDISC's established governance processes.

For more information, see the ICH Controlled Terminology page of the CDISC website.

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# 1.4 Why Use Controlled Terminology?

**Controlled terminology offers advantages to regulators, industry, and other stakeholders including healthcare professionals, study subjects, and research organizations.**

- For regulators, controlled terminology:
  - Eliminates the need to convert data from one terminology to another
  - Helps to review across studies (meta analysis)
  - Aligns with agency goals to achieve semantic interoperability of data
- For industry and other stakeholders, controlled terminology:
  - Facilitates efficient decision making on the basis of clinical data
  - Allows for resource savings by increasing efficiencies in the data lifecycle
    - Allows for the development of reusable templates for CRFs; tables, listings, and figures (TLFs); and analysis plans
    - Provides a common vocabulary and definitions to be adhered to during the trial, which helps teams reach agreement on the way data will be collected, shared, and analyzed
    - Allows for the development of standardized, automated checks for verification of trial data
  - Enhances quality through consistency by using the same terminology from collection through analysis, which facilitates the traceability of data

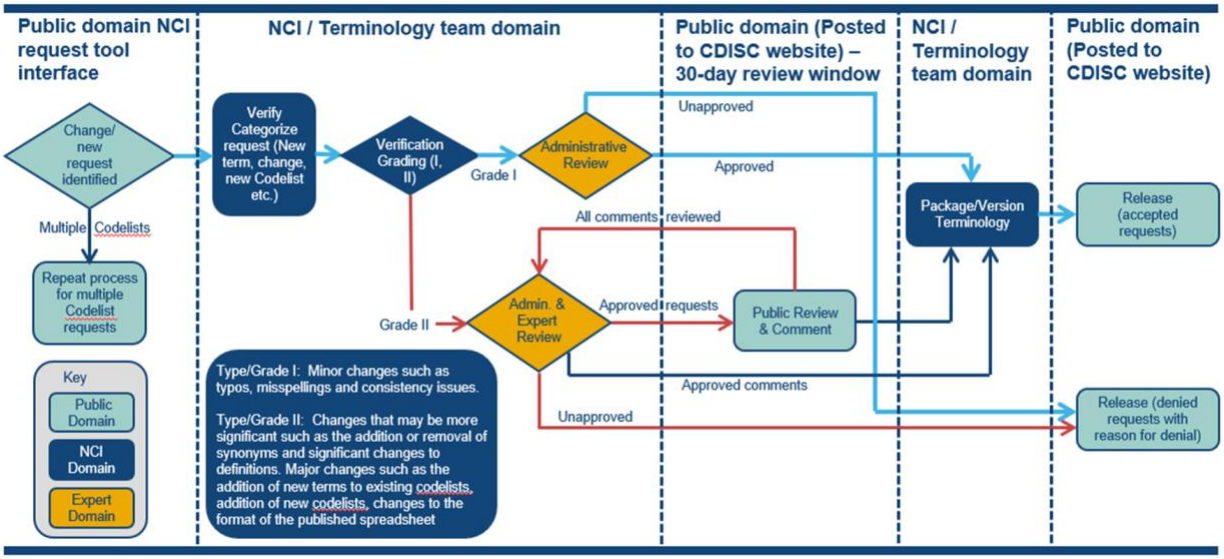
**Controlled terminology enables the exchange of data by controlling terminology within a standardized data transmission model.**

- Preserves meaning and standardizes representation of data:
  - Minimizes confusion and reduces ambiguity
  - Provides a shared vocabulary framework that can prevent the loss and/or distortion of data
  - Provides preferred terms/submission values, definitions, synonyms, codes, and codelists/value sets
  - Facilitates the integration of data from disparate sources (e.g., different collection modalities, different locales/sites)
- Ensures semantic interoperability across CDISC foundational standards via language consistency from protocol, data collection, tabulation, and analysis, to submission:
  - Eases the process for creating TLFs with clear, concise, and quality data
  - Shortens the time to data availability and readiness for performing analyses
  - Allows for effective cross-references and analysis of data when terminology is accurate and consistent

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# 2 CDISC CT Development Process

CDISC CT is developed through an open, transparent and cooperative process through which consumers of CDISC data standards collaborate with subject matter experts, and is maintained and published in the NCI EVS NCIt. CDISC CT is selected and defined based on the needs of the CDISC user community through the CDISC change request process. The following diagram illustrates this process.




CDISC CT is bundled into packages, which are assigned an alphanumeric name (a capital P followed by a number). These numbers are used to identify packages during development and public review; at any given time within the CT development cycle, up to 3 packages may be at different stages of development. Package numbers may be referenced within team working documents, public review communications emails, wiki pages, and on the CDISC website.

The following subsections provide more detail on the process.

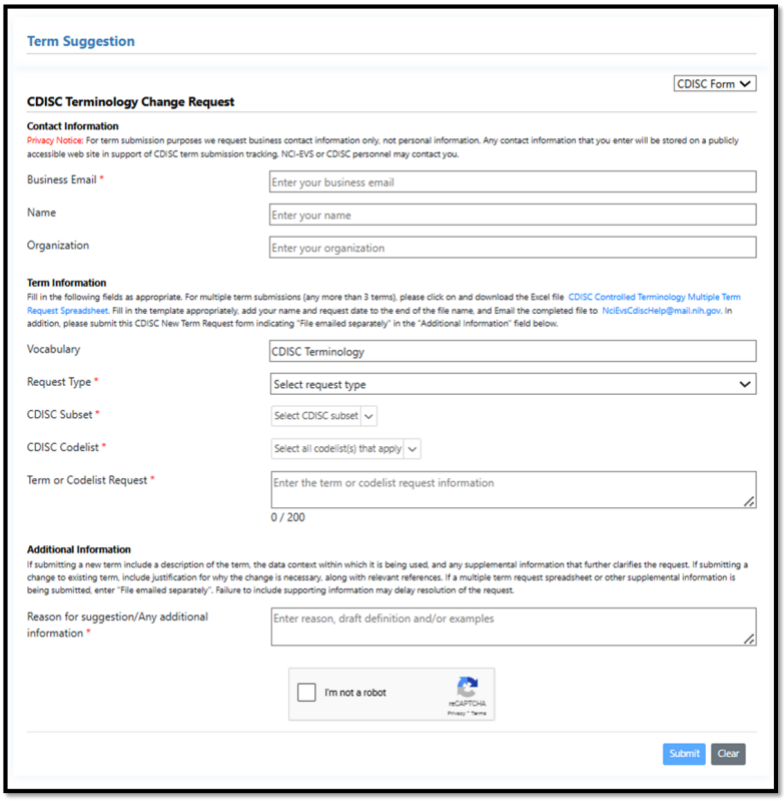
## 2.1 Change Request System

Requests to add to or modify existing CDISC CT can be made at any time. Types of valid requests include the addition of terms to existing codelists, addition of a new codelist(s), modifications to published terms (e.g., synonym or definition changes), modifications to codetable mapping files, modifications to CT Team rules documents, or terminology implementation questions. It is recommended that the individuals who are closest to the data be responsible for making request submissions on behalf of the sponsor/applicant/other, although anyone may make a change request at any time. Section 1.2, Who Are Controlled Terminology Stakeholders?, lists individual roles that generally undertake new term request submission.

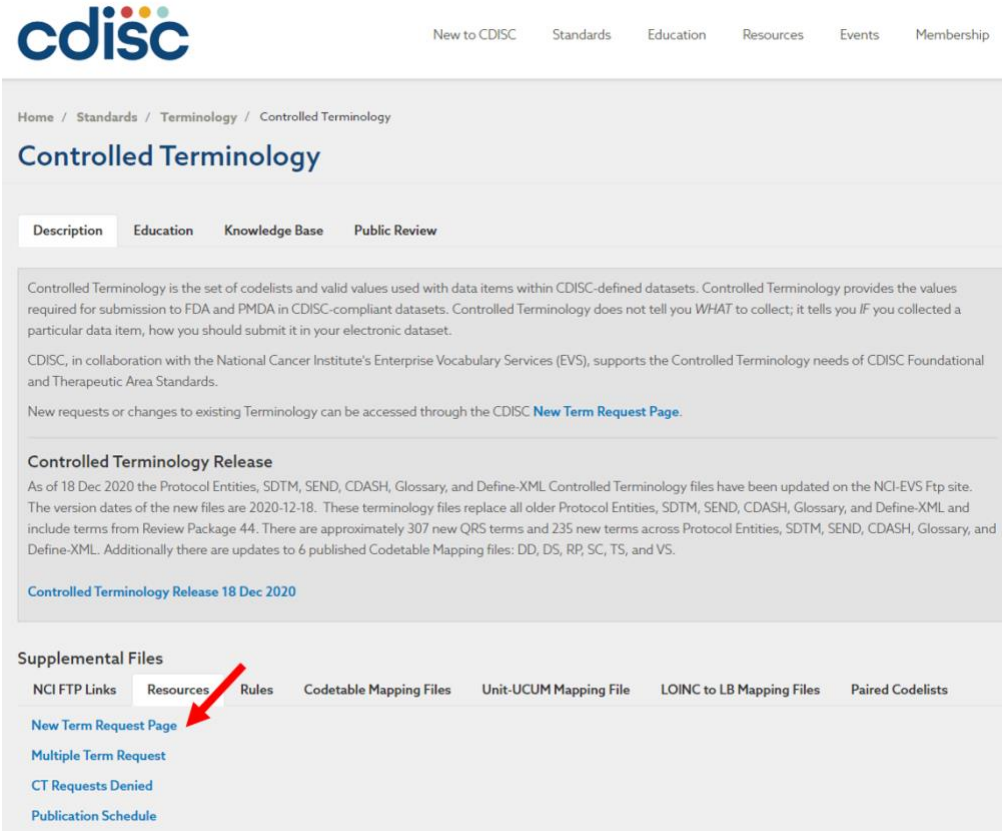
Change requests are made via the CDISC Terminology Change Request form, which is hosted by NCI EVS (see screenshot). The webform is publicly available, does not require a login, and there is no limit to the number of requests submitted. One or many changes can be requested within each form submittal. In the case of multiple term requests it is recommended that the requester use the multiple term request template (see Section 2.1.2, How to Submit a CDISC Terminology Change Request).

**Note:** Because anything submitted through the change request site will be stored on a publicly accessible website in support of CDISC term submission tracking, proprietary and personal information should not be submitted through the site.

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The webform can also be accessed via the CDISC Controlled Terminology webpage by clicking on the New Term Request link under the Resources tab.




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## 2.1.1 Should a CDISC Terminology Change Request Be Made?

### Considerations for Making a CDISC Change Request

- Regulatory authorities recommend the good terminology practice of submitting change requests for those terms not included in a published CDISC CT release.
- Inclusion of relevant terms into released CDISC CT reduces the burden of authoring a study (or analysis) data reviewers guide, since fewer explanations of extensible (sponsor/applicant/other-defined) terminology are required.
- Inclusion of relevant terms into codelists ensures conformance between the collected and tabulated data.
- Requesters have the opportunity to influence the CDISC CT team to adopt specific CDISC submission values.
- Relevant concepts in use across the industry are identified, ensuring development and maintenance of high-value terms within CDISC CT.
- The new term request may lead to discovery of concepts in use that require new modeling strategies (e.g., new variables, new domains).

### When to Make a Change Request

- Compliance: The term represents a concept that aligns with the CDISC variable.
- Reusability: The term is in use across multiple studies or exists in other codelists.
- General use: The term represents a concept in common use within the industry.
- Novelty: The term represents a new concept that is not yet covered by existing CDISC CT standards.
- Update to nonextensible codelist: The term represents a concept that may be associated with a nonextensible codelist. Because these codelists cannot be extended locally by the user, additional concepts must be submitted to be considered for inclusion.

### When Not to Make a Change Request

- The requested term is already listed as a synonym for a published term within the codelist.
- The requested term is antiquated or archaic and no longer in general use across the industry.
- There is no real-world use case in the context of clinical or nonclinical research.
- There is no available, clear, or well-established definition of the term in the medical and scientific literature.
- The term represents a concept that does not align with the CDISC variable definition and use.
- The term contains multiple concepts that should be distributed among multiple variables; combination terms will generally not be added to any codelist. Follow multiple convention or use extensible terminology.
- The term is expected to be in limited or short-term use across studies and/or users, such that long-term maintenance by CDISC is of little value to the community as a whole.

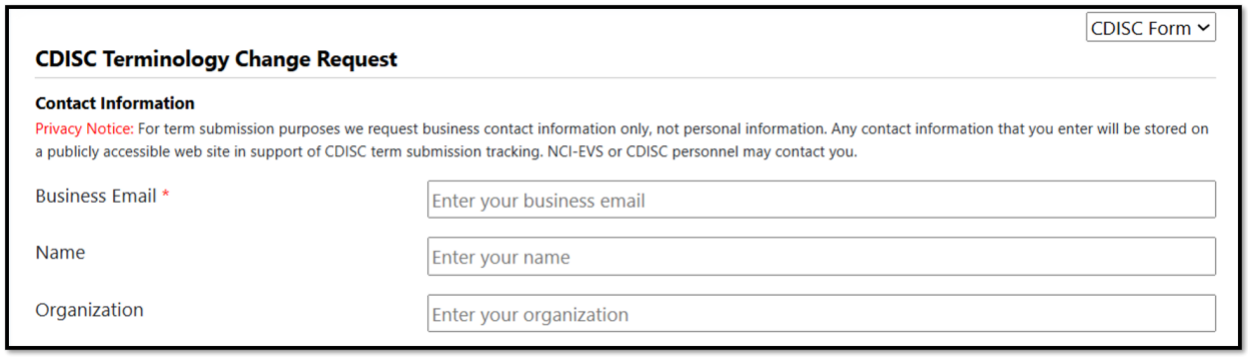
## 2.1.2 How to Submit a CDISC Terminology Change Request

Navigate to the CDISC Terminology Change Request form. The following information is required when completing the form.

### Contact Information

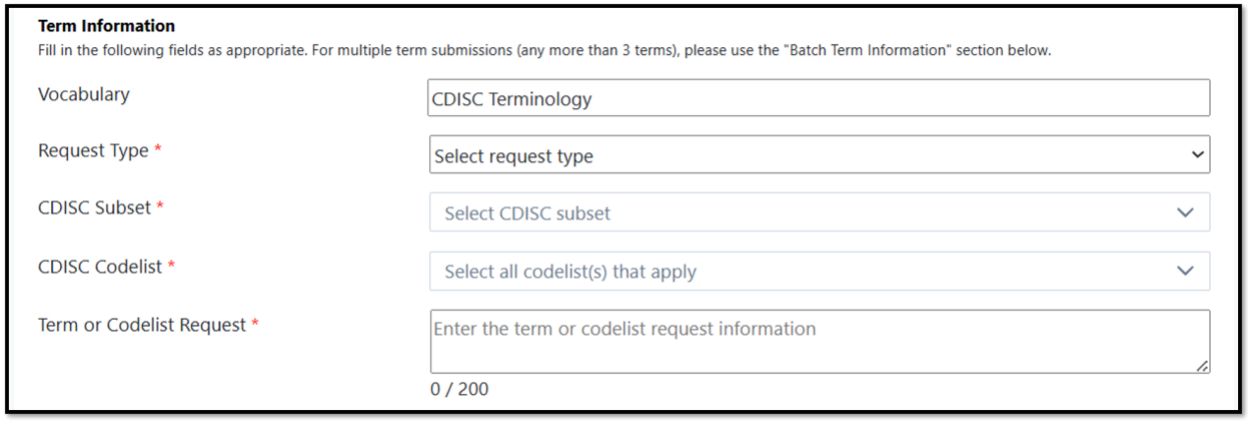
A business email address must be provided to notify the requester that the request was received and to ensure that a CT Team representative can contact the requester in case of administrative or content-related follow-up questions

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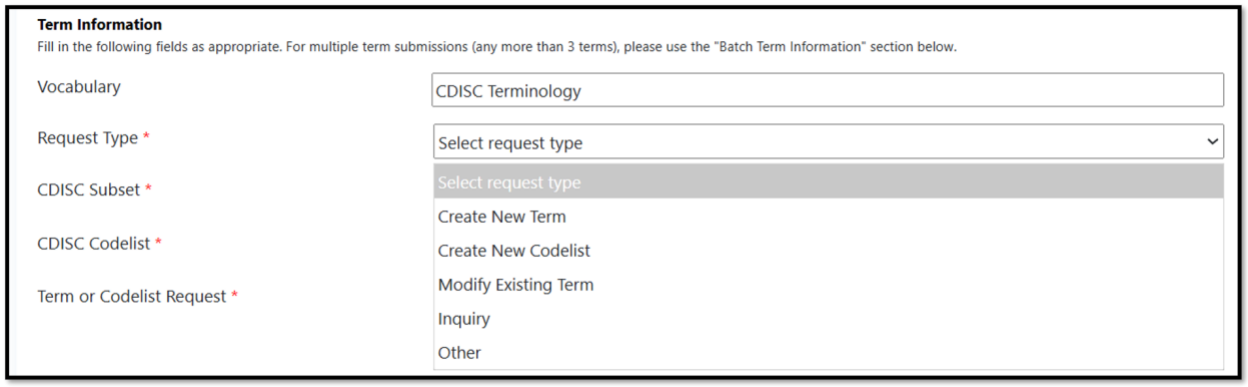



## Term Information

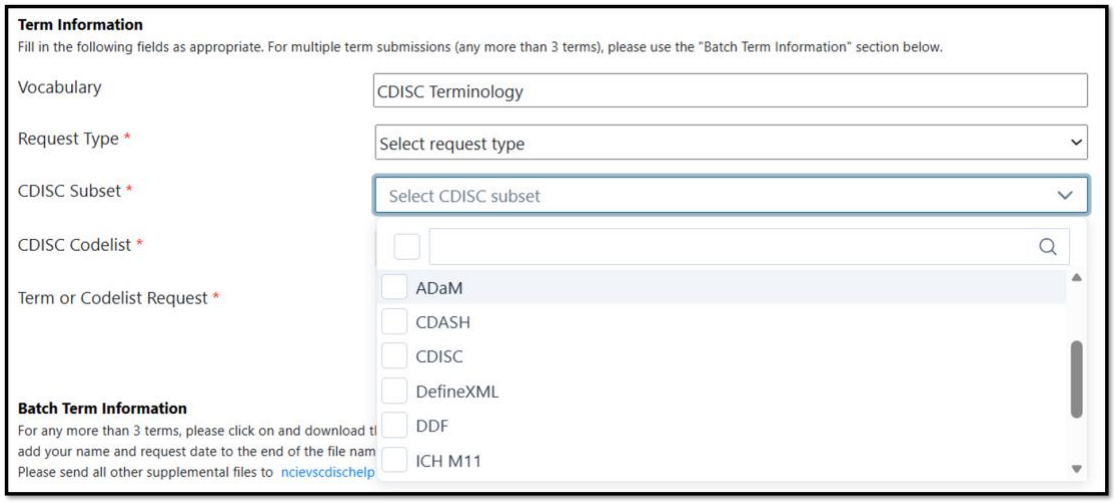
In order to characterize the type of request being submitted, certain information must be provided (i.e., request type, CDISC subset, codelist, specifics of the request).

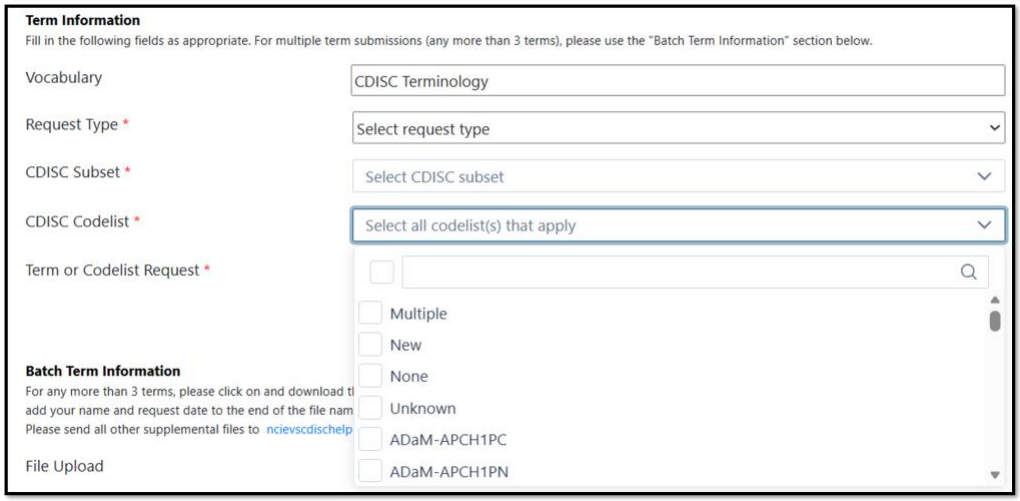



The Request Type, CDISC Subset, and CDISC Codelist fields are required fields that contain drop-down choices:




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The Term or Codelist Request field is free text, with a 200-character limit. When completing this data field, the information provided is based on the chosen Request Type.

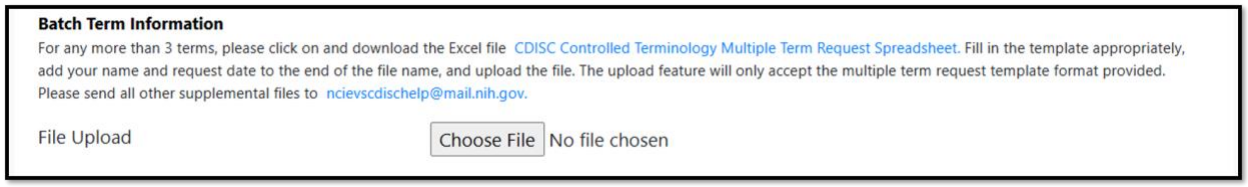
- For Create New Term: Enter the requested term name or submission value. For concepts that require a short and long name, the long name is adequate for submission on the form.
- For Create New Codelist: Enter the suggested long name for the codelist followed by the variable, test, parameter, or supplemental qualifier that the codelist is intended to support.
- For Modify Existing Term: Enter a clear description of the proposed modification, the NCI C-code of the term to be changed, and the applicable codelist(s) associated with the change.
- For Inquiry: Enter a question for the CDISC CT Team.
- For Other: Enter a description of the new or change to existing codetable mapping file, a new or change to existing CT development rules document, a terminology implementation question, and so on.




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### Batch Term Information

A template is provided to submit multiple terms or changes within a single request. The completed template can be uploaded directly to the request form. For security reasons the form will only allow the attachment of the provided template, so any other file types should be emailed directly to NciEvsCdiscHelp@mail.nih.gov.




### Additional Information

The Additional Information free-text field has no character limit. Including complete information expedites request completion and decreases the likelihood that the CT Team will need to contact the requester for clarification, which can slow request resolution considerably.

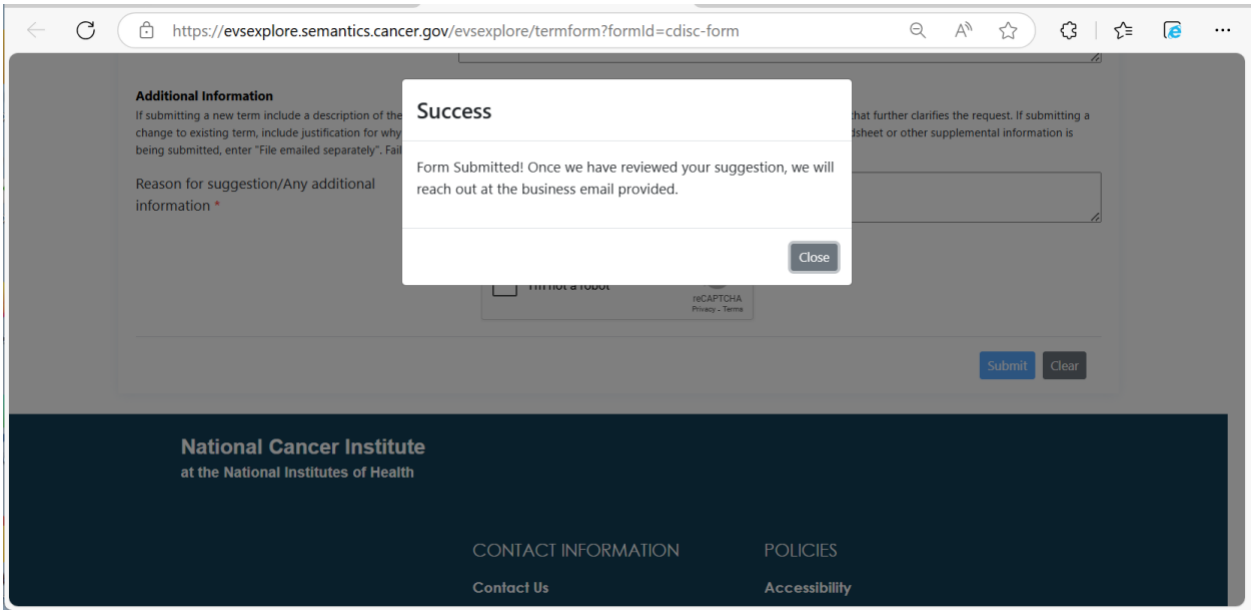



When completing this data field, provide additional details based on the chosen Request Type.

- For Create New Term: Include a definition or description of the term and how it is being used within the data context. If a definition or description from an outside source is referenced, cite the source. Synonyms may also be included. If the new term is similar in concept to an existing, published term name or definition, include the rationale for adding it.
- For Create New Codelist: Include whether the codelist is extensible, an initial list of the valid values for the codelist (does not have to be exhaustive if extensible), and a codelist description. If applicable, indicate with which implementation guide or user guide the new codelist is associated.
- For Modify Existing Term: Include the rationale.
- For Inquiry: Include supplemental information associated with the question.
- For Other: Include supplemental information associated with the change or new item request. If suggesting a change to a CDISC CT related file, include the rationale.
- If submitting a CDISC Controlled Terminology Multiple Term Request Spreadsheet, enter "File emailed separately"; all supplemental information about the request is expected to be included within the spreadsheet.

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### Submit




Upon successful submission of the form, a pop-up window will appear that confirms submission. The change request is recorded on an NCI JIRA site and assigned a change request number, which is a unique alphanumeric request code (e.g. CDISC-####) that can be used to track the request. Requesters receive an email from NCI EVS personnel with the change request number and indication that the request has been forwarded to CDISC for evaluation. For information on tracking a change request, see Section 2.5.2.

## 2.1.3 Best Practices for Submitting CDISC Terminology Change Requests

### Before Submitting a Change Request

- Review Section 2.1.1: Does the proposed request meet the criteria?
- Review the most recent version of published CDISC CT: Has the proposed term already been published?
- Review the latest draft CT package on the most recent Terminology Call for Public Review wiki page: Is the proposed term in the process of being published?
- Review the Denied Requests file: Has the proposed change previously been denied?
- Review the most recent published foundational standard implementation guides and TAUGs, which define the meaning and use of domains and variables. CDISC models guide terminology development. Is the potential change request appropriate for a given domain's scope?
- Consider the impact of a requested change. Some changes (e.g., submission value changes) are highly disruptive across the industry. For example, a requested change to a submission value for the sake of consistency will generally not be approved by the controlled terminology team.
- Check whether the term being requested is already published as a synonym for an existing submission value by comparing the CDISC CT synonym column with user internal dictionary(ies).
- Review published literature and/or consult with internal subject matter experts to determine whether the request should be submitted as a new term or as a synonym to an existing CDISC submission value.

### Ensuring Successful and Timely Processing of a Change Request

- Consult the published CDISC Terminology Development Rules documents to ensure that the request conforms to the development rules used by the relevant controlled terminology team (see also Section 4.3, Team Rules for CDISC CT Development).

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- Use the multiple term request template for change requests containing more than 3 items.
- For multiple change requests, ensure that lists are deduplicated and are in general use within the industry.
- The NCIt contains many concepts beyond those currently in use by CDISC. Search the NCIt for the term of interest and, if published, include the NCI C-code of the concept in the request.
- Consult the NCI Metathesaurus (NCIm), which brings together a wide variety of terminologies and ontologies that are published separately. The NCIm is a useful resource for developing appropriate submission values, synonyms, and definitions.
- If requesting a term that appears to be similar in concept to an existing published term in the codelist, include the reasoning for why the published term is not sufficient.
- If the requested term exists in another published CDISC codelist, include the codelist name along with the published NCI C-code.
- Include a reference to the CDISC TAUG associated with the request, if applicable.
- For new codelist requests, provide the associated CDISC variable, TEST/CD, PARM/CD, or non-standard variable (NSV).
- When requesting new --TEST/CD or --PARM/CD values, include contextual information such as:
    - Examples of expected response values
    - Units of measure for the result values
    - Specimen type
    - Assay/measurement methodology
    - Test timing information
- When requesting units of measure,
    - Include the associated domain, TEST, and/or Topic (i.e., --TRT or --TERM).
    - CDISC units of measure will not precoordinate information that is contained within other CDISC variables (e.g., --TEST, --SPEC, --METHOD). For example, "mol/mol Creatinine" is not a valid unit of measure for a test of "Albumin/Creatinine", since creatinine is in the test name as the denominator.
        - An entity/substance (e.g., cells, creatinine) may be included in the unit of measure when the analyte (i.e., test or administered substance) is normalized to that entity/substance.
            - For example, a test of homovanillic acid may be normalized to moles of creatinine when measured in urine. In this instance, LBTEST = "Homovanillic Acid" and LBSTRESU = "mmol/mol CREATININE".
    - Mathematically synonymous units of measure (e.g., L/g = mL/mg = uL/ug) share the same NCI C-code and appear only once in a unit of measure codelist, with a single preferred submission value. Other mathematically synonymous unit values may be listed as CDISC synonyms. Before requesting a new unit of measure, check if another mathematically synonymous value is already published. It may be more appropriate to request the term to be added as a synonym to the published term.

### Timing for Submitting Change Requests

- Submit a change request as soon as the need for a change is identified, regardless of the status of the CT cycle.
- Change requests submitted at least 3 months before the end of the package cut-off may be considered for inclusion in that public review package. Terms included in a public review package will be published at the end of the following quarter.
- Refer to the CDISC Publication Schedule for cut-off dates for change request submissions slated for biannual publication.

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- Terms that have been requested but have not yet been published may be used in the submission as extensible terminology but should be considered for use at the requester's own risk.
- CT teams review requests in the order received and according to the process timeline outlined in Section 2.5, Process Timeline.
- Certain requests may not be processed within a single 6-month period:
  - Codelists for which there are a large number of open change requests
  - Concepts that require extensive research and/or additional information from the requester
  - Concepts that are submitted toward the end of the development cycle
  - QRS instruments requiring copyright permission

# 2.2 Controlled Terminology Development Teams

CDISC CT is developed by multiple teams of volunteers comprising terminologists, subject-matter experts, data and standards personnel from regulated industries and CROs, academic researchers, and regulatory authorities, in addition to one or more team leads. CDISC CT teams operate under a team charter using a well-established, consensus-driven standards development process (COP-001) to support the terminology needs of CDISC foundational teams, therapeutic area teams, and the CDISC user community.

The CT teams

- meet the needs of the global user community by ensuring sustainable, transparent, and accessible terminology development, publication, and maintenance;
- focus on standard terminology codelist management and publication through the development of submission values, definitions, and codelists/value sets;
- ensure harmonization of CDISC CT across CDISC standards, as well as external vocabulary initiatives; and
- focus on terminology process improvements to meet the demands of the user community and standards development teams.

## 2.2.1 Principles and Objectives

### Principles

CDISC CT teams have developed a unified set of guiding principles that inform their development work. These principles and the work of the teams

- use CDISC models and guides to drive terminology decisions,
- influence domain modeling via terminology analysis,
- consider the impact of changes,
- commit to collaborative communication,
- focus on reuse of existing terminology,
- commit to consistent decision making, and
- are responsive to emerging needs

The development of controlled terminology adheres to an "**adopt-adapt-develop**" philosophy. Teams identify, evaluate and utilize existing terminology (either external terminologies or CDISC CT) when appropriate and adequate for the needs of the model (**adopt**). Teams may expand existing vocabularies for evolving needs or where incomplete (**adapt**). Finally, if there is no existing external terminology that can be adopted or adapted, teams may develop new terminology (**develop**).

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### Objectives

The objective of the CDISC CT teams is to create, modify, and update terms that support valid value sets for CDISC variables, NSVs, and TESTs/PARMs, as well as related supplemental products that promote the correct usage of CDISC variables and NSVs. To accomplish this objective and in the spirit of transparency, the teams

- resolve change requests and public review comments in a timely manner;
- seek to understand requests fully by following up with requesters before making a decision;
- advise the user community on terminology best practices and usage of concepts; and
- keep good records of discussions, decisions, and reasons for denial.

## 2.2.2 CT Team Operating Principles

- **Team composition:** A CDISC CT team consists of volunteers from the CDISC user community and a team lead or leaders, one of whom is always an NCI EVS representative (see also Section 2.2)
- Decision-making process
  - The CDISC terminology teams make decisions based on consensus: general agreement from the majority of team members.
  - If consensus cannot be reached, then the CDISC terminology team will invite opinions from additional subject-matter experts. If consensus is still not reached, the CDISC terminology team will escalate the issue to the appropriate foundational standards team leadership. If broader input is required, the team may escalate the issue to the CDISC Global Governance Group (GGG).
  - In the case of escalation, the CDISC terminology team will defer to the decision made by the foundational team or GGG leadership.
- Meeting quorum
  - The meeting quorum for a CDISC terminology team is 3 team members plus the team lead(s).
  - Certain agenda topics may require the attendance of a majority of team members and/or specific team members for due diligence in decision making.
  - Certain agenda topics may require invited external subject matter experts and/or a term requester representative for due diligence in decision making.
  - The meeting agenda can be adjusted based on the availability of participants.
- **Change request assignment:** Change requests are assigned to the appropriate CDISC controlled terminology team based on the team's subject-matter expertise.
- Order of change request review
  - The CDISC terminology teams will review the change requests in the order they are received.
  - An exception is made for change requests to support CDISC's funded projects; these are accelerated through the terminology development process to meet project timelines.
- Team tasks
  - Additions/new
    - Terms to existing codelists
    - Codelists
    - Codetable mapping files
    - CT team rules documents
  - Changes to existing
    - Terms in existing codelists (e.g., synonym or definition changes)
    - Codelists

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        - Codetable mapping files
        - CT team rules documents
    - Answering terminology implementation questions
    - Providing rationale for denial of change requests (see Section 4.4)
    - Reviewing and dispositioning of public review comments
    - Providing consultation to foundational standards teams and project teams
- Terminology teams conduct independent research
    - Terminology teams will independently confirm that the proposed change request is appropriate to include for public review (see Section 2.3).
    - Teams communicate with requesters for additional information related to the change request, as needed.
    - Independent research may be required and is completed by CDISC terminology team members, NCI EVS personnel, or other subject matter experts, as needed.
    - Team discussions/questions, requester responses, and final decisions are noted in the team working documents, which are stored on the CDISC wiki.
- Reasons for denied change requests
    - Change requests may be denied for a variety of reasons (see Section 2.1.1 and Section 2.1.3).
    - In some instances, not enough information is provided by the requester when queried by the CT team after receipt of the initial change request. The requester will be contacted by email up to 2 times by a representative of the CT team. If information is not received 3 weeks after the second email is sent, the request may be denied.

#### 2.2.2.1 QRS Team Operating Principles

##### QRS Instrument Copyright Verification

**Note:** If an instrument is copyrighted, CDISC must obtain permission prior to developing CDISC CT.

While CDISC is required to obtain copyright permission prior to developing CDISC CT and a QRS Supplement, the QRS Team is encouraged to gather information and provide contacts to assist CDISC in verifying whether an instrument is copyrighted or in the public domain. The following steps are required to confirm copyright status.

- **If the instrument is copyrighted,** document the copyright owner's or organization's contact information (e.g., owner name, email address, mailing address) and include this supporting information with the new term request submitted to CDISC. CDISC will use these details to contact the copyright owner or organization and initiate the copyright permission approval process.
- **If no specific copyright statement exists, the instrument may be in the public domain.**
    1. Review the terms of use regarding permissible use of content on the website where the document/instrument question resides. If those terms of use impose restrictions or permit use, then comply. In the latter event, ensure that the terms of use specifically address the work in question and assert the authority to permit use. Include this supporting information with the new term request submitted to CDISC.
    2. If no copyright notice is displayed and the work was published before March 1, 1989, it generally can be assumed that the document or instrument is not protected by copyright (i.e., it is in the public domain). Include this supporting information with the new term request submitted to CDISC.
- **If no copyright notice is displayed and the work was published after March 1, 1989**, presume it is copyrighted and that permission for use must be obtained from the copyright holder. There are different ways to identify or establish copyright and copyright holder.

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1. The QRS Terminology Team has many members from different pharmaceutical companies. They should research within their own companies to see if they have any copyright information or contact information about the QRS Instrument.
2. The therapeutic area or project team should also be requested to do research within their companies to establish the copyright information or identify contact information.
3. A search may need to be performed on the US Copyright Office website's public records system.

**QRS CT Development**

- The CDISC QRS CT Team develops CDISC CT to match the language used by the QRS developer for both copyrighted and public domain instruments. See the CDISC QRS Naming and Business Rules document for more information.
- Create QS/FT/CC --CAT, --TEST/CD, and/or response CT following the guidelines outlined in the QRS Naming and Business Rules document.
  - CDISC develops QS/FT/CC --CAT and --TEST/CD for both copyrighted and public domain instruments.
  - CDISC develops QRS response CT only for instruments that are in the public domain.
- The QRS Naming and Business Rules file is updated periodically and posted to the CDISC QRS website page, under the QRS Resources tab.

**QRS CT Review Process**

- Draft terminology undergoes the following reviews:
  - Team review. The QRS CT team reviews the draft terminology collectively and assists in addressing any questions and issues.
  - Individual review. Following the team review, the draft terminology must be independently reviewed by another team member.
- QRS CT is not publicly reviewed because the content is owned by the QRS developer and therefore not subject to change.

## 2.3 Public Review Process

Public review is a key quality step in the CDISC standards development process. CDISC relies on user input to ensure that neutral, consensus-based standards are developed and adopted by a diverse global community interested in improving clinical research. **To receive email announcements for CDISC CT public review,** submit the form at the top of this page.

At the end of each June and December, CDISC terminology team leads collate the resolved and/or approved term requests (including new terms/codelists, changes to existing terms, denied requests, and codetable mapping files) into an Excel-formatted review package and perform a quality control check of the content. These CDISC CT public review files are posted to the CDISC wiki for a period of 30 days. An email notification is sent from CDISC alerting the user community that public review is open. Instructions for submitting comments through JIRA are also included on the wiki page. A CDISC wiki account is required to participate in CDISC public review; instructions for signing up are on the CDISC wiki homepage.

The CDISC CT public review files are organized according to terminology team subject matter expertise and area of responsibility (e.g., Laboratory, ECG, CDISC Glossary). Each terminology file contains the following information:

- A ReadMe tab that summarizes the number of new terms proposed for existing codelists, the number of new codelists with proposed terms, and the number of changes to existing terms
- A tab for each codelist to which new terms are proposed to be added (new codelists are identified with the word "New" in the tab name)
- A single tab for Changes to Existing Codelists that includes a summary of the proposed change and, in the case of proposed removals of terms, change implementation instructions

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- Tabs for new/updated codetable mapping files

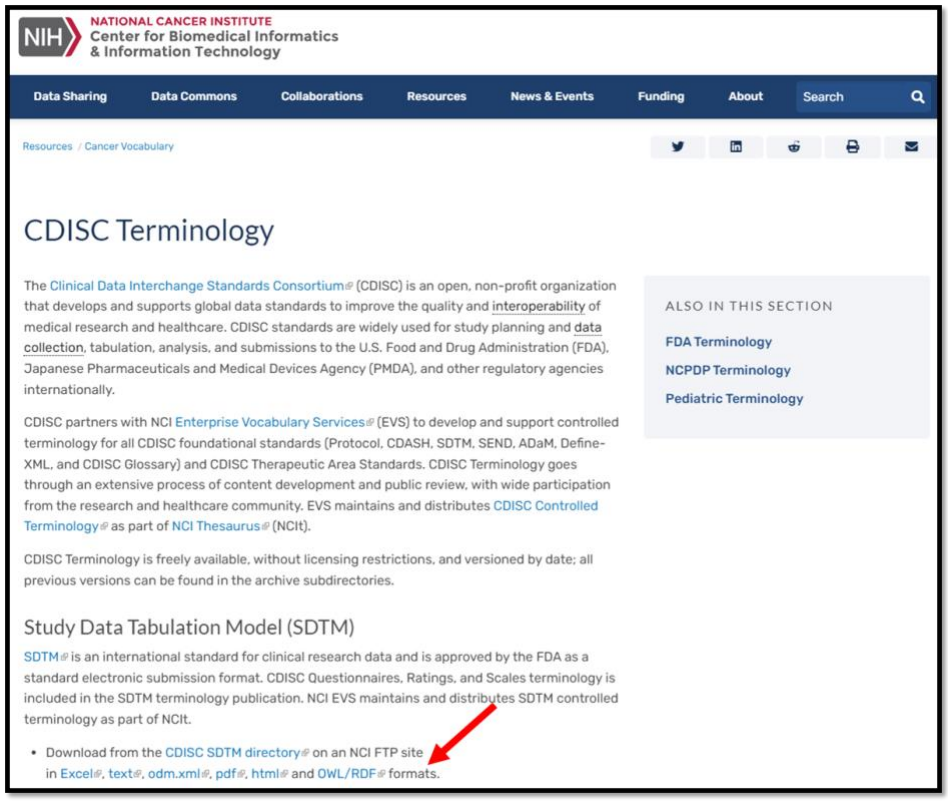
File(s) containing new/updates to terminology development rules documents are included in the public review package along with CT Denied Requests.

The CDISC CT teams review and resolve their assigned JIRA comments at the end of the public review period. The JIRA submitter will receive an email notification that their JIRA comment has been resolved; JIRA must be opened to see the final disposition on the comment.

## 2.4 Publication

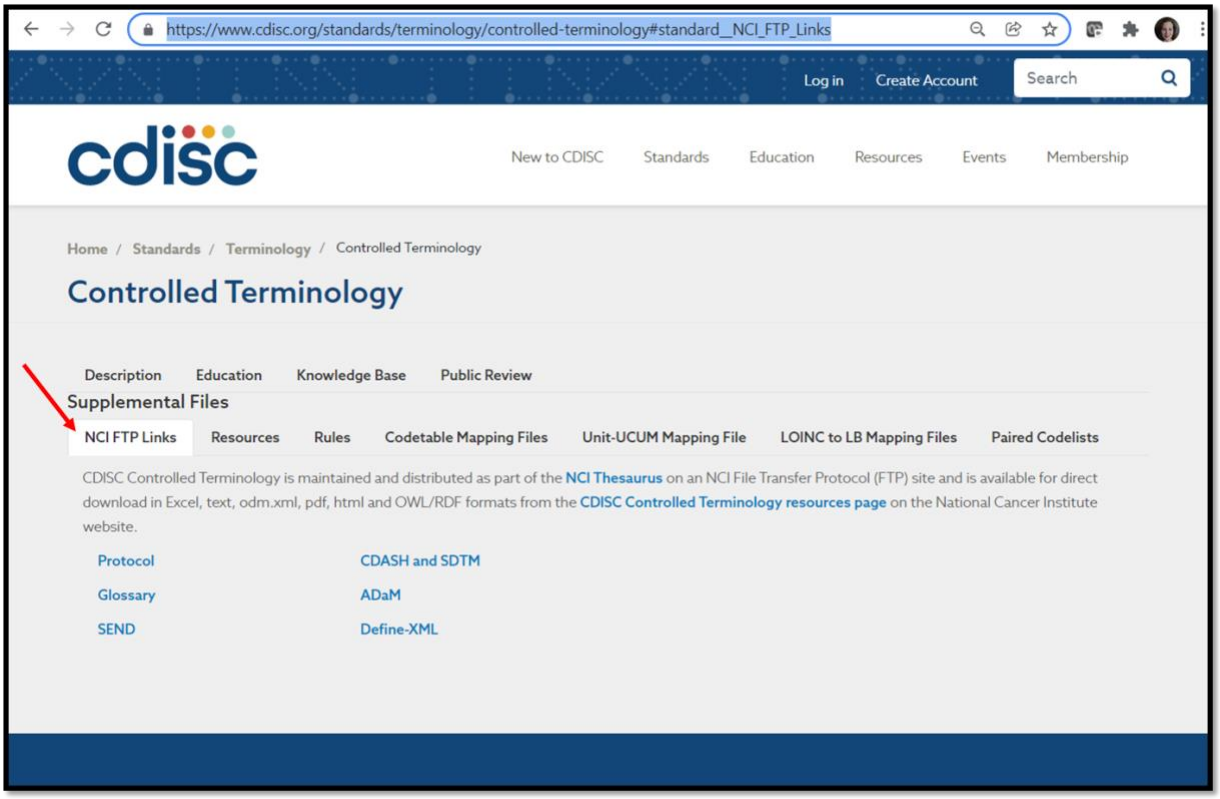
Generally, on the last Friday of March and September the CDISC CT files are posted to the CDISC folder on the NCI FTP server. If a terminology product has not changed, the file is not replaced and will continue to reflect the previous publication date. CDISC maintains a publication schedule showing current and future publication dates; see Section 2.5.1 for more information.

Links to download the CDISC CT file types can be found on the NCI EVS CDISC Terminology page. (Previous versions of CDISC CT files are retained as well, in archive subdirectories.)

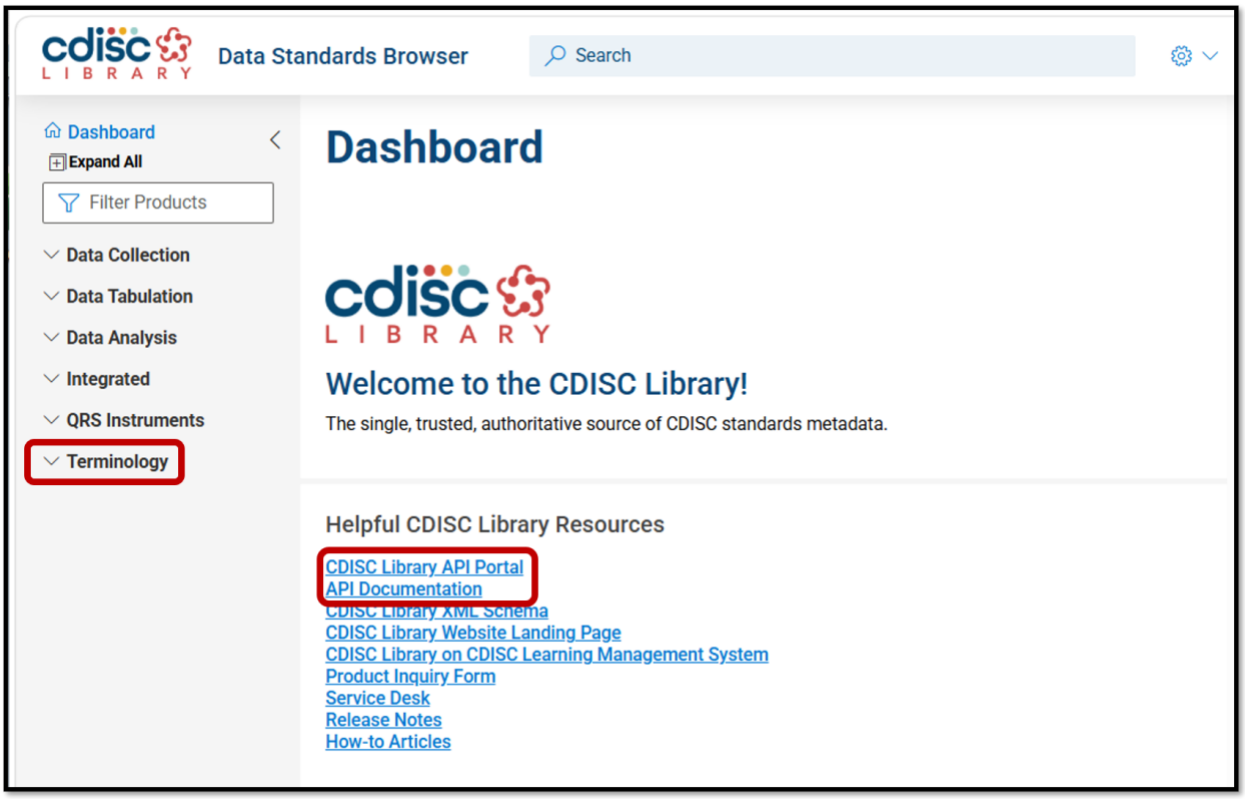



Links to download the CDISC CT file types also can be found on the CDISC Controlled Terminology page.

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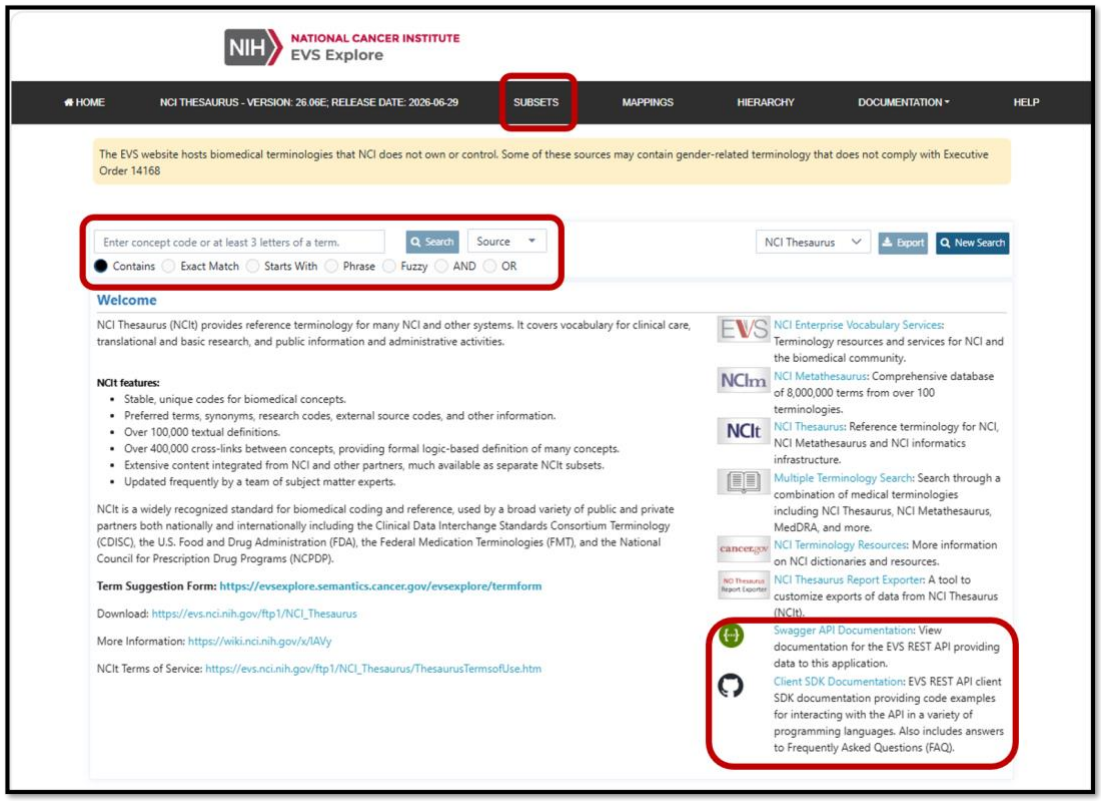



CDISC Terminology can be accessed through the CDISC Library, with searching/browsing functionality, downloadable file exports, and API.




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Finally, CDISC Terminology can also be accessed through the NCI EVS Explore Browser, a cloud-based interface for searching, browsing, and exploring biomedical terminologies within the NCI Thesaurus. The CDISC terminology subsets can be explored directly through the EVS Explore Subset Browser. API access is also available.




Note that there is a delay in content availability across these resources after NCI FTP file publication, due to the amount of processing required for CDISC Library and EVS Explore browser updates.

## 2.4.1 Versioning

A cumulative version of CDISC CT is published in March and September of each year (biannually). The publication date of the instance of CDISC CT is used as the version identifier. This date also relates to the terminology development package number; the association between the two can be found in the ReadMe tab of the CDISC Term Request Tracking file (see Section 4.5).

This version date is managed via file type metadata discussed in Section 3.2.2 of this document. Changes between consecutive versions are described in versioned terminology changes files in Section 4.1 of this document. Record-level change history, from 2014 onward, can be found in the CDISC library.

See Section 4.1.2 of the CDISC Define-XML standard for how to represent the version date of CDISC CT in the dataset metadata for submission.

## 2.4.2 Notification

Once the CDISC terminology files are uploaded to the NCI FTP server, an email notification is sent from CDISC alerting the user community that CDISC CT files are available for download. To receive email announcements for CDISC CT publication, submit the form on the top of this page. A summary explanation of the CDISC CT publication is available on the CDISC Controlled Terminology page.

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# 2.5 Process Timeline

Annual CDISC CT events include publications at the end of March and September, and public review at the end of June and mid-December. In order to achieve this biannual publication schedule, multiple CDISC CT packages are in development concurrently, although they may be at different points in the process. Refer to Section 2.1.3, Best Practices, for timing considerations when making a change request.




**Note:** The number of weeks under each step indicates the time allocated for that task.

## 2.5.1 Publication Schedule

The CDISC Terminology Publication Schedule can be access via the Resources tab under the Supplemental Files section of the CDISC Controlled Terminology page. This file provides the planned dates for CDISC Terminology public reviews and publications scheduled for the next 12 months and is available for download from the CDISC website.

## 2.5.2 Tracking CDISC Change Requests

Submitted change requests can be tracked through a sequentially assigned EVS change request number, at the time the request is received. The EVS change request number (in the format CDISC-####) is used in all email communications between CDISC, EVS, and the requester. The EVS change request number remains with the change request for its entire lifecycle, from development to public review to publication.

Multiple documents reference the EVS change request number and can be accessed to track/monitor the status of the request:

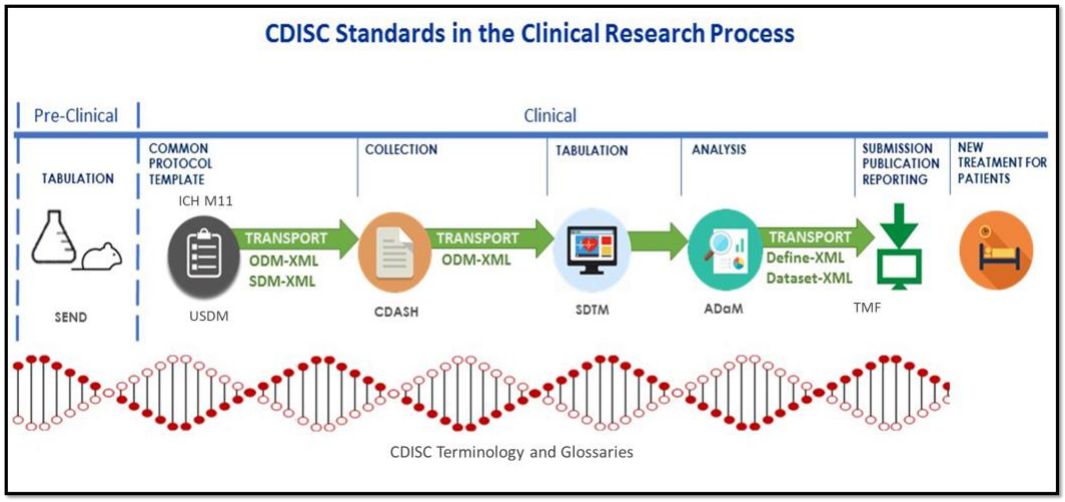
- Terminology team working documents on the CDISC wiki
- CDISC CT Public Review files
- CDISC CT Denied Requests file
- CDISC CT Change files
- CDISC Term Request Tracking file

The requester must review these documents biannually to check progress on the change request through the development lifecycle. While the CDISC change request will be acknowledged via email upon receipt, the CDISC terminology team will not communicate directly with the requester regarding the status of the change request as it moves through the development lifecycle. If the reference to the change request cannot be found in any of these documents, email NciEvsCdiscHelp@mail.nih.gov and EVS personnel will help determine the status of the change request.

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# 3 CDISC CT Implementation

CDISC CT underpins all components of the preclinical and clinical study process, as illustrated in the following figure. Multiple subsets of the CDISC CT superset are maintained for CDISC by NCI EVS to support each stage of the preclinical and clinical lifecycle. A description of these subsets can be found in Section 1.3.1, CDISC Terminology Products.




This section contains information about terminology storage, file types, and metadata, as well as file type implementation.

## 3.1 CDISC CT Codelist References in Implementation Guides

CDISC CT comprises submission values organized into codelists, which are associated with variables defined by CDISC standards to produce CDISC-conformant datasets. CDISC implementation guides represent the CT codelists in metadata tables with the short name of a CDISC codelist bounded by parenthesis under the following column headers.

- **ADaMIG: Codelist/Controlled Terms** column. This column is blank when no CDISC codelist is attributed.
- **CDASHIG: Controlled Terminology Codelist Name** column. This column contains "N/A" when no CDISC codelist is attributed.
- **SDTMIG and SENDIG:**
  - SDTMIG v4.0/SENDIG v4.0 and later versions, **Codelist** column. This column contains a short reference to an external terminology (e.g., Codelist = "MedDRA" for the variable AEDECOD).
  - SDTMIG v3.4/SENDIG v3.1.1 and earlier versions, **Controlled Terms, Codelist or Format** column
    - For SDTMIG, the column contains a single asterisk "*" indicating that CT was not available at the time of publication. The foundational standards teams expected that users may have their own controlled terminology and/or the CDISC CT teams may develop codelists in the future. (**Note:** SENDIG does not use the asterisk convention.)
    - The column contains the single applicable value from the DOMAIN codelist (e.g., Controlled Terms, Codelist or Format = "VS" to represent the Vital Signs Domain).
    - The column contains a short reference to an external terminology (e.g., Controlled Terms, Codelist or Format = "MedDRA" for the variable AEDECOD).

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# 3.2 Terminology Storage, Types, and Metadata

## 3.2.1 Terminology File Storage and Types

### Terminology File Storage

CDISC CT is stored and maintained in the NCIt. Terminology updates are made biannually and posted to the CDISC folder on the NCI EVS FTP site for download and use. Links to all published CDISC CT files and formats are available on the NCI website.

CDISC CT is also stored in the CDISC Library. The CDISC Library is a metadata repository that uses linked data to deliver CDISC standards metadata, including relationships between standards, to software applications that automate standards-based processes. CDISC Library Release Notes are publicly available via the CDISC wiki and include extensive information on terminology updates and system behavior.

### Terminology File Types

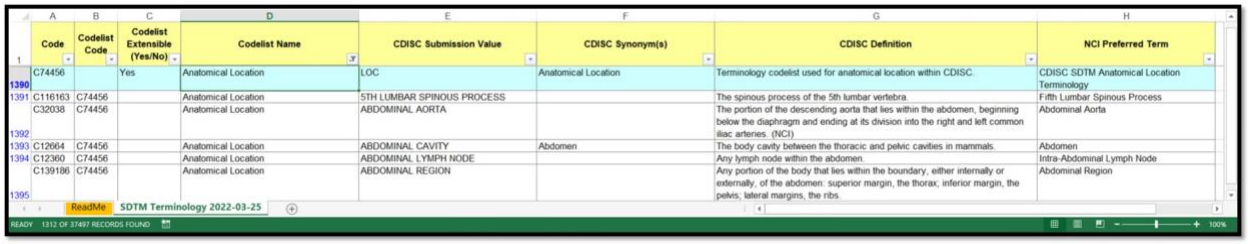
CDISC CT is presented in the following file types (see Section 3.3 regarding implementation):

- text (.txt)
- Excel (.xls)
- PDF (.pdf)
- HTML (.html)
- OWL/RDF (.OWL)
- ODM (.odm.xml)

## 3.2.2 Terminology Metadata

### File Structure

CDISC CT is extracted from the NClt through an automated process that creates reports organized into terminology sets (e.g., SDTM terminology, SEND terminology, ADaM terminology) and associated codelists. The controlled terminology file is composed of columns that contain information regarding terminology arranged in rows. In the Excel and HTML files, the rows in light blue indicate the start of a new codelist. The blue rows contain information about the codelist itself: codelist extensibility, codelist name (i.e., long name), submission value (i.e., short name), and the CDISC definition. The subsequent white rows contain the list of valid values for that particular codelist.



| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| 1 | Code | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name | CDISC Submission Value | CDISC Synonym(s) | CDISC Definition | NCI Preferred Term |
| 1390 | C74456 | | Yes | Anatomical Location | LOC | Anatomical Location | Terminology codelist used for anatomical location within CDISC. | CDISC SDTM Anatomical Location Terminology |
| 1391 | C116163 | C74456 | | Anatomical Location | 5TH LUMBAR SPINOUS PROCESS | | The spinous process of the 5th lumbar vertebra. | Fifth Lumbar Spinous Process |
| 1392 | C32038 | C74456 | | Anatomical Location | ABDOMINAL AORTA | | The portion of the descending aorta that lies within the abdomen, beginning below the diaphragm and ending at its division into the right and left common iliac arteries. (NCI) | Abdominal Aorta |
| 1393 | C12664 | C74456 | | Anatomical Location | ABDOMINAL CAVITY | Abdomen | The body cavity between the thoracic and pelvic cavities in mammals. | Abdomen |
| 1394 | C12360 | C74456 | | Anatomical Location | ABDOMINAL LYMPH NODE | | Any lymph node within the abdomen. | Intra-Abdominal Lymph Node |
| 1395 | C139186 | C74456 | | Anatomical Location | ABDOMINAL REGION | | Any portion of the body that lies within the boundary, either internally or externally, of the abdomen: superior margin, the thorax; inferior margin, the pelvis; lateral margins, the ribs. | Abdominal Region |

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READY 1312 OF 37497 RECORDS FOUND

- **Code:** A concept code (i.e., C-code) begins with the character "C" followed by a sequence of numbers which uniquely identifies each concept. This column contains a mixture of codelist codes (blue rows), each of which is followed by value code(s) (white rows) associated with that codelist. Note that although each concept is unique, the concept may appear in more than one codelist; for example, C12434 BLOOD is present in both the SDTM Anatomical Location (LOC) and SDTM Specimen Type (SPECTYPE) codelists.
- **Codelist Code:** Identifies the C-code for the codelist containing the associated term (i.e., CDISC submission value).

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- **Codelist Extensible (Yes/No):** Indicates whether users may extend the CDISC CT codelist by adding terms not published in the codelist version. The extensibility attribute in this column only applies to the codelist, not the valid values within the codelist.
  - A "No" value indicates that the published CDISC codelist contains the only allowable submission values for a CDISC variable.
  - A "Yes" value indicates that a user may include values in the dataset that are not published in the CDISC codelist (i.e., extended terms), as long as they do not have the same meaning as an existing submission value or synonym within that codelist.
  - When extensibility is left blank, it indicates the codelist is not currently used to support a CDISC model element. For example, the extensibility attribute for many of the codelists in the CDISC protocol terminology and CDISC Glossary is not applicable for submission.

  As a reminder, change requests for both extensible and nonextensible codelists will be considered by the CDISC terminology teams. See Section 2.1 for how to submit a change request and Section 5.3 for best practices for management of extensible and nonextensible codelists.
- **Codelist Name:** Identifies the long name for the codelist containing the associated term (i.e., CDISC Submission Value).
- **CDISC Submission Value:** Identifies the precise, case-sensitive value (i.e., literal string) used to represent a concept in a CDISC dataset. The blue row contains the codelist short name.
- **CDISC Synonym(s):** Identifies commonly used synonyms for the CDISC submission value in Column E. These are included as an aid for data collection and mapping to CDISC submission values.
- **CDISC Definition:** Provides the descriptive meaning for a CDISC submission value. If CDISC has chosen to adopt an outside source definition, the source is noted in parentheses at the end of the CDISC Definition (e.g., NCI, FDA, HL7).
- **NCI Preferred Term:** Establishes the relationship between the CDISC submission value and the NCIt preferred term, which provides the fully specified name of the concept represented by the NCI C-code.

For more information about these key concepts, see Section 1.3.2.

### File Version Date

The publication date of the file is used as the CT version identifier (see Section 2.4.1). This version date identifier is located prominently in the Excel, HTML, and PDF files, and in the SourceSystemVersion element in the ODM-XML file. In the CDISC Library, an additional column of metadata is appended on the far right of the CDISC CT Excel file download that contains the name of the terminology standard and the version date.

For the .txt and .OWL files, the version date is located in the Publication Date Stamp file. This .txt file is located in the CDISC folders of the NCI FTP site. The first column of the file contains information regarding the quarter and year of the most recent publication. The second column contains the date that corresponds to the version date that is present on the tab of the Excel file. The third column contains the date of any subsequent published updates to that release, if applicable. The fourth column contains information about why a publication file was updated and reposted to the FTP site. A new date stamp file is released with each biannual publication of terminology and older date stamp files are stored in the FTP archive folders.

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# 3.3 Terminology File Type Implementation

## 3.3.1 File Type Examples

For the following illlustrations of CDISC CT as presented in Excel, HTML, PDF, text, ODM, and OWL/RDF, the contents of each file type are equivalent. The examples show the standard SDTM controlled terminologies for VSTESTCD and VSTEST values of systolic and diastolic blood pressure.

### Excel (XLS)

| Code | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name | CDISC Submission Value | CDISC Synonym(s) | CDISC Definition | NCI Preferred Term |
|---|---|---|---|---|---|---|---|
| C66741 | | Yes | Vital Signs Test Code | VSTESTCD | Vital Signs Test Code | The test code given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure. | CDISC SDTM Vital Sign Test Code Terminology |
| C25299 | C66741 | | Vital Signs Test Code | DIABP | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| C25298 | C66741 | | Vital Signs Test Code | SYSBP | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |
| C67153 | | Yes | Vital Signs Test Name | VSTEST | Vital Signs Test Name | The test name given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure. | CDISC SDTM Vital Sign Test Name Terminology |
| C25299 | C67153 | | Vital Signs Test Name | Diastolic Blood Pressure | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| C25298 | C67153 | | Vital Signs Test Name | Systolic Blood Pressure | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |

### HyperText Markup Language (HTML)

**CDISC SDTM Controlled Terminology**

CDISC SDTM Controlled Terminology, 2020-03-27

Legend:
CodeList
CodeListItem
NCI attributes

**Codelist Definitions**

| OID | Name (CDISC Submission Value) | DataType Extensible | NCI Code | CDISC Synonym | CDISC Definition | Preferred Term |
|---|---|---|---|---|---|---|
| | CDISC Submission Value [ODM:CodedValue] | | | | | |
| Back to top | | | | | | |
| CL.C66741.VSTESTCD | Vital Signs Test Code (VSTESTCD) | text Extensible: Yes | C66741 | Vital Signs Test Code | The test code given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure. | CDISC SDTM Vital Sign Test Code Terminology |
| | DIABP | | C25299 | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| | SYSBP | | C25298 | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |
| Back to top | | | | | | |
| CL.C67153.VSTEST | Vital Signs Test Name (VSTEST) | text Extensible: Yes | C67153 | Vital Signs Test Name | The test name given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure. | CDISC SDTM Vital Sign Test Name Terminology |
| | Diastolic Blood Pressure | | C25299 | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| | Systolic Blood Pressure | | C25298 | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |

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## Portable Document Format (PDF)

### VSTESTCD (Vital Signs Test Code)

NCI Code: C66741, Codelist extensible: Yes

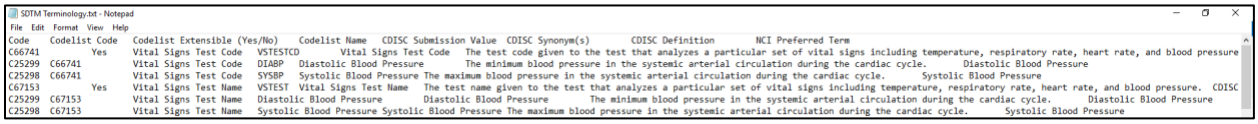
| C66741 | VSTESTCD | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C25299 | DIABP | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| C25298 | SYSBP | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |

### VSTEST (Vital Signs Test Name)

NCI Code: C67153, Codelist extensible: Yes

| C67153 | VSTEST | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C25299 | Diastolic Blood Pressure | Diastolic Blood Pressure | The minimum blood pressure in the systemic arterial circulation during the cardiac cycle. | Diastolic Blood Pressure |
| C25298 | Systolic Blood Pressure | Systolic Blood Pressure | The maximum blood pressure in the systemic arterial circulation during the cardiac cycle. | Systolic Blood Pressure |

## Text (TXT)



```
SDTM Terminology.txt - Notepad
File  Edit  Format  View  Help
Code    Codelist Code   Codelist Extensible (Yes/No)    Codelist Name   CDISC Submission Value  CDISC Synonym(s)        CDISC Definition        NCI Preferred Term
C66741          Yes     Vital Signs Test Code   VSTESTCD        Vital Signs Test Code   The test code given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure
C25299  C66741          Vital Signs Test Code   DIABP   Diastolic Blood Pressure        The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.       Diastolic Blood Pressure
C25298  C66741          Vital Signs Test Code   SYSBP   Systolic Blood Pressure The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.       Systolic Blood Pressure
C67153          Yes     Vital Signs Test Name   VSTEST  Vital Signs Test Name   The test name given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure.  CDISC
C25299  C67153          Vital Signs Test Name   Diastolic Blood Pressure        Diastolic Blood Pressure        The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.       Diastolic Blood Pressure
C25298  C67153          Vital Signs Test Name   Systolic Blood Pressure Systolic Blood Pressure The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.       Systolic Blood Pressure
```

## Operational Data Model Extensible Markup Language (ODM.XML)

```
<CodeList OID="CL.C66741.VSTESTCD" Name="Vital Signs Test Code" DataType="text" nciodm:ExtCodeID="C66741" nciodm:CodeListExtensible="Yes">
    <Description>
        <TranslatedText xml:lang="en">The test code given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure.</TranslatedText>
    </Description>
    <EnumeratedItem CodedValue="DIABP" nciodm:ExtCodeID="C25299">
        <nciodm:CDISCSynonym>Diastolic Blood Pressure</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>Diastolic Blood Pressure</nciodm:PreferredTerm>
    </EnumeratedItem>
    <EnumeratedItem CodedValue="SYSBP" nciodm:ExtCodeID="C25298">
        <nciodm:CDISCSynonym>Systolic Blood Pressure</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>Systolic Blood Pressure</nciodm:PreferredTerm>
    </EnumeratedItem>
</CodeList>
<CodeList OID="CL.C67153.VSTEST" Name="Vital Signs Test Name" DataType="text" nciodm:ExtCodeID="C67153" nciodm:CodeListExtensible="Yes">
    <Description>
        <TranslatedText xml:lang="en">The test name given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart rate, and blood pressure.</TranslatedText>
    </Description>
    <EnumeratedItem CodedValue="Diastolic Blood Pressure" nciodm:ExtCodeID="C25299">
        <nciodm:CDISCSynonym>Diastolic Blood Pressure</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>Diastolic Blood Pressure</nciodm:PreferredTerm>
    </EnumeratedItem>
    <EnumeratedItem CodedValue="Systolic Blood Pressure" nciodm:ExtCodeID="C25298">
        <nciodm:CDISCSynonym>Systolic Blood Pressure</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>Systolic Blood Pressure</nciodm:PreferredTerm>
    </EnumeratedItem>
</CodeList>
```

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**Web Ontology Language (OWL)**

```
<mms:PermissibleValue rdf:ID="C66741.C25299">
  <mms:inValueDomain rdf:resource="#C66741"/>
  <cts:nciPreferredTerm rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >Diastolic Blood Pressure</cts:nciPreferredTerm>
  <cts:nciCode rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >C25299</cts:nciCode>
  <cts:cdiscDefinition rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >The minimum blood pressure in the systemic arterial circulation during the cardiac cycle.</cts:cdiscDefinition>
  <cts:cdiscSynonyms rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >Diastolic Blood Pressure</cts:cdiscSynonyms>
  <cts:cdiscSubmissionValue rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >DIABP</cts:cdiscSubmissionValue>
</mms:PermissibleValue>
<mms:PermissibleValue rdf:ID="C66741.C25298">
  <mms:inValueDomain rdf:resource="#C66741"/>
  <cts:nciPreferredTerm rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >Systolic Blood Pressure</cts:nciPreferredTerm>
  <cts:nciCode rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >C25298</cts:nciCode>
  <cts:cdiscDefinition rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.</cts:cdiscDefinition>
  <cts:cdiscSynonyms rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >Systolic Blood Pressure</cts:cdiscSynonyms>
  <cts:cdiscSubmissionValue rdf:datatype="http://www.w3.org/2001/XMLSchema#string"
  >SYSBP</cts:cdiscSubmissionValue>
</mms:PermissibleValue>
```

## 3.3.2 Conforming: Mapping Data to Controlled Terminology

CRF-captured data can be transformed/mapped into controlled terminology, in the form of CDISC submission values or valid values from external terminologies. Using controlled terminology from the beginning builds in traceability and transparency, and reduces the problems associated with trying to convert legacy codelists and variables to the submission standards (See CDASHIG v2.1). However, several factors can make it difficult to conform to controlled terminology.

- Existing or legacy standard CRFs and data dictionaries
- Disparate data from multiple sources
- Granularity differences between data collection and tabulation models
- Comprehensibility of values within a pick list
- Need for codelist extensibility
- Clinician preferences
- Regional terminology norms

This section describes how data can be conformed to controlled terminology submission values for collection, tabulation and analysis.

### 3.3.2.1 Conforming: Mapping Data to CDISC Controlled Terminology

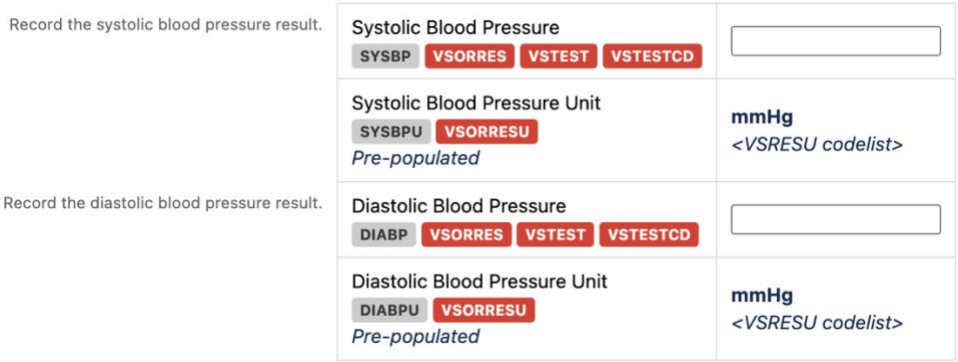
eThis section describes how data can be conformed to CDISC CT submission values for collection, tabulation, and analysis.

**CDASH**

This example shows a vital signs data collection form. The abbreviated example form shows CDASHIG and SDTMIG variable names.

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**Title: Vital Signs**




**CRF Metadata**

| CDASH Variable | Order | Question Text | Prompt | CRF Completion Instructions | Type | SDTMIG Target Variable | SDTMIG Target Mapping | Controlled Terminology Code List Name | Permissible Values | Pre-Populated Value | Query Display | List Style | Hidden |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SYSBP | 11 | What was the result of the systolic blood pressure measurement? | Systolic Blood Pressure | Record the systolic blood pressure result. | Integer | VSORRES; VSTEST; VSTESTCD | VSORRES where VSTESTCD = "SYSBP" | | | | Prompt | | |
| SYSBPU | 12 | What was the unit of the systolic blood pressure measurement? | Systolic Blood Pressure Unit | Record or select the original unit in which these data were collected, if not preprinted on CRF. | Text | VSORRESU | VSORRESU where VSTESTCD = "SYSBP" | (VSRESU) | | mmHg | Prompt | | |
| DIABP | 13 | What was the result of the diastolic blood pressure measurement? | Diastolic Blood Pressure | Record the diastolic blood pressure result. | Integer | VSORRES; VSTEST; VSTESTCD | VSORRES where VSTESTCD = "DIABP" | | | | Prompt | | |
| DIABPU | 14 | What was the unit of the diastolic blood pressure measurement? | Diastolic Blood Pressure Unit | Record or select the original unit in which these data were collected, if not preprinted on CRF. | Text | VSORRESU | VSORRESU where VSTESTCD = "DIABP" | (VSRESU) | | mmHg | Prompt | | |

## SDTM

Conforming collected data values to controlled terminology ensures alignment with target data structure requirements. In this case, that target is SDTM, and the requirements for the target CDISC CT are defined in the SDTMIG. The SDTM target variables to present the data collected in the preceding Vital Signs CRF are shown in the following table, which depicts the relevant portion of the SDTMIG VS (Vital Signs) domain specification (see SDTMIG v4.0).

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| Variable Name | Variable Label | Type | Codelist | Allowed Controlled Terms | Format | Role | Variable Group | Root Variable C-code | Root Variable Definition | Notes | Examples | Core |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| VSTESTCD | Vital Signs Test Short Name | Char | (VSTESTCD) | | | Topic | Test Focus | C82503 | The standardized or dictionary-derived short sequence of characters used to represent the measurement, test, or examination. | See Variable Lengths. | "SYSBP"; "DIABP"; "BMI" | Req |
| VSTEST | Vital Signs Test Name | Char | (VSTEST) | | | Qualifier | Test Focus | C82541 | The standardized or dictionary-derived name of the measurement, test, or examination. | See Test Name (--TEST) Greater than 40 Characters. | "Systolic Blood Pressure"; "Diastolic Blood Pressure"; "Body Mass Index" | Req |
| VSORRES | Result or Finding in Original Units | Char | | | | Qualifier | Result Value | C117221 | The result of the measurement, test, or examination, as originally received or collected. | See Original and Standardized Results. | | Exp |
| VSORRESU | Original Units | Char | (VSRESU) | | | Qualifier | Result Units | C82586 | The unit of measure for the result (as originally received or collected) of the measurement, test, or examination. | See Original and Standardized Results. | | Exp |

To conform the data, one must understand the study data values collected, derived, or assigned for a given domain. These values must then be matched to appropriate CDISC submission values via the Codelist Code/Codelist Name columns in the preferred CDISC CT file type. Three of the target SDTM variables in this example have an associated codelist.

- VSTESTCD is not collected in the example CRF, but must be **assigned** a value based on the CRF question text, and the assigned value must conform to the VSTESTCD codelist.
- VSTEST is not collected in the example CRF, but must be **assigned** a value based on the CRF question text, and the assigned value must conform to the VSTEST codelist.
- VSORRESU is collected, and the target SDTM variable must **conform** to the VSRESU codelist.

VSORRES is also collected, but the variable in SDTM has no CDISC CT associated with it.

The following example SDTM dataset shows the results of transforming the data as collected into SDTM structure using controlled terminology. **Note:** Collected data that is not shown on the example CRF is used to populate additional variables.

*vs.xpt*

| STUDYID | DOMAIN | USUBJID | VSSEQ | VSTESTCD | VSTEST | VSPOS | VSORRES | VSORRESU | VSSTRESC | VSSTRESN | VSSTRESU | VSSTAT | VSREASND | VSLOC | VSLAT | VSLOBXFL | VISITNUM | VISIT | VISITDY | VSDTC | VSDY |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ABCD | VS | ABC-001-001 | 1 | SYSBP | Systolic Blood Pressure | SITTING | 154 | mmHg | 154 | 154 | mmHg | | | ARM | LEFT | | -1 | SCREENING | 1 | 2011-08-16T04:20 | -31 |
| ABCD | VS | ABC-001-001 | 2 | SYSBP | Systolic Blood Pressure | SITTING | 152 | mmHg | 152 | 152 | mmHg | | | ARM | LEFT | Y | 1 | VISIT 1 | 32 | 2011-09-16T04:20 | 1 |
| ABCD | VS | ABC-001-001 | 3 | DIABP | Diastolic Blood Pressure | SITTING | 44 | mmHg | 44 | 44 | mmHg | | | ARM | LEFT | | -1 | SCREENING | 1 | 2011-08-16T04:20 | -31 |
| ABCD | VS | ABC-001-001 | 4 | DIABP | Diastolic Blood Pressure | SITTING | 48 | mmHg | 48 | 48 | mmHg | | | ARM | LEFT | Y | 1 | VISIT 1 | 32 | 2011-09-16T04:20 | 1 |

**Note:** A similar mapping process for collected data is followed for applying CDISC SEND CT to nonclinical data models published in the SENDIG.

### ADaM

The translated SDTM values can be used for analysis in ADaM datasets. Although there is very limited CDISC CT for PARAMCD and PARAM, in this example the user has chosen to apply the controlled values for VSTEST, VSTESTCD, and VSSTRESU to construct the PARAMCD and PARAM values. Note: This type of construction requires control and maintenance of the PARAMCD and PARAM values by the user.

ADaM specifies a finite set of controlled terminology, including values for derivation type. The DTYPE variable in analysis datasets describes and traces the derivation of the value being analyzed (AVAL). For example, if the record is created using the average value, the DTYPE submission value would be populated as shown in the following table. advs.xpt

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*advs.xpt*

| PARAMCD | PARAM | SRCDOM | SRCVAR | SRCSEQ | AVAL | DTYPE | AVISIT | AVISITN |
|---|---|---|---|---|---|---|---|---|
| SYSBP | Systolic Blood Pressure (mmHg) | VS | VSSTRESN | 1 | 154 | AVERAGE | Screening | 1 |
| SYSBP | Systolic Blood Pressure (mmHg) | VS | VSSTRESN | 2 | 152 | AVERAGE | Visit 1 | 2 |
| DIABP | Diastolic Blood Pressure (mmHg) | VS | VSSTRESN | 3 | 44 | AVERAGE | Screening | 1 |
| DIABP | Diastolic Blood Pressure (mmHg) | VS | VSSTRESN | 4 | 48 | AVERAGE | Visit 1 | 2 |

PARAM (Parameter) values constructed from SDTM values in VSTEST and VSSTRESU may also be presented in the analysis summary table, as shown here.

| Summary of Blood Pressure Parameters | | | |
|---|---|---|---|
| Parameter<br>Visit | Treatment A<br>(N=xxx) | Treatment B<br>(N=xxx) | All Subjects<br>(N=xxx) |
| Systolic Blood Pressure (mmHg) | | | |
| Screening | | | |
| Visit 1 | | | |
| Diastolic Blood Pressure (mmHg) | | | |
| Screening | | | |
| Visit 1 | | | |

**Define-XML**

This example shows how the CDISC CT values appear when the Define-XML document is viewed in an appropriate browser. For details of the underlying XML syntax for codelist item representation, see CDISC Define-XML Specification v2.1, Section 4.4.1.2 . If the coded term is an abbreviation, a code, or a score (as for questionnaires) or simply requires additional clarification, the decode codelist should be created with a decode provided for each of the terms. The NCI Preferred Term should be used as a decode value when CDISC does not provide a decode value in a linked TEST or PARM codelist.[2]

**Vital Signs Test Code [C66741][CDISC/NCI SDTM 2017-09-29]**

| Permitted Value (Code) | Display Value (Decode) |
|---|---|
| DIABP [*C25299*] | Diastolic Blood Pressure |
| SYSBP [*C25298*] | Systolic Blood Pressure |

**Derivation Type [C81224][CDISC/NCI ADaM 2017-09-29]**

| Permitted Value (Code) | Display Value (Decode) |
|---|---|
| AVERAGE [*C81209*] | Average of Value Derivation Technique |

When referencing CDISC CT or other external terminologies, the name and version of the dictionary should be populated in the Define-XML Dictionary and Version attributes in the ExternalCodelist XML element. The Dictionary attribute uses CDISC submission values from the DICTNAM codelist published in the Define-XML terminology file. The format of the version identifier varies across providers. Beginning with Define-XML 2.1, there is a requirement that each CDISC CT publication referenced within the specification be identified in a Standards element and each codelist that is drawn from CDISC CT must identify the source publication set and version.

### 3.3.2.2 Conforming: Mapping Data to External Terminology

In the source data for SDTM, some data have already been conformed to external terminologies (e.g., MedDRA) such that the values themselves must not be manipulated further. In these cases, only the dictionary metadata is of interest. CDISC CT has a codelist for dictionary names. See Section 3.3.2 and the Define-XML specification for implementation of external terminologies in Define-XML.

Many external terminologies are specified for use in CDISC implementation and user guides. References to these external terminologies are available in the Controlled Terms, Codelist, or Format column of the domain specification tables in the SDTMIG and SENDIG.

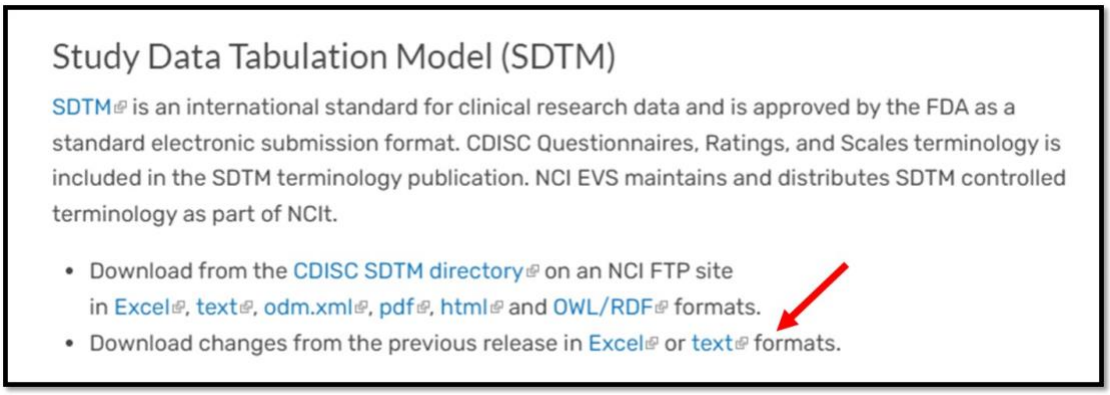
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# 4 CDISC CT Related Files

This section contains information about supporting content that is published concurrently with CDISC CT to aid in the use and management of CDISC CT.

## 4.1 CDISC CT Change Files

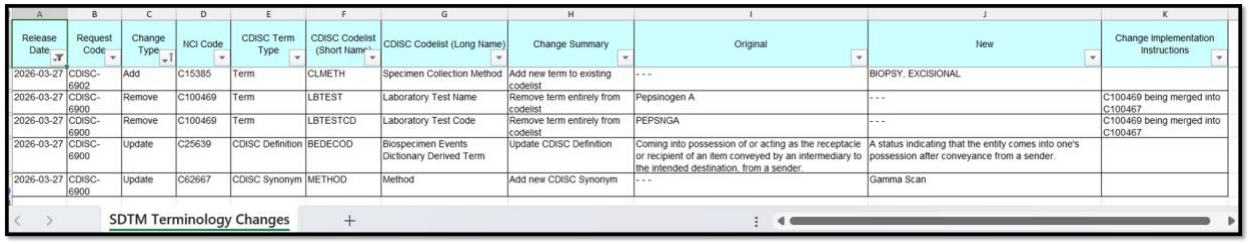
Each CDISC CT terminology publication includes files listing changes from the previous release. These change files are presented in Excel and text formats and are stored on the NCI's CDISC Terminology resources page. Older versions of change files can be found in the Archive folder within the FTP directory.




Changes between any 2 releases of CDISC CT can be generated using a freely available, open-source Java program developed by NCI EVS (download from github site).

CDISC CT change files enable users to

- perform terminology change analyses, including impacts on mapping;
- check on the publication status of a change request using the EVS change request number (Request Code in column B);
- determine how a change request was implemented (e.g., verbatim, modified);
- search and filter on a subset of changes (e.g., definition updates, synonym changes, new or removed terms; Change Summary in column H); and
- evaluate and implement updates required for removed terms (Change Implementation Instructions in column K)



| Release Date | Request Code | Change Type | NCI Code | CDISC Term Type | CDISC Codelist (Short Name) | CDISC Codelist (Long Name) | Change Summary | Original | New | Change Implementation Instructions |
|---|---|---|---|---|---|---|---|---|---|---|
| 2026-03-27 | CDISC-6902 | Add | C15385 | Term | CLMETH | Specimen Collection Method | Add new term to existing codelist | --- | BIOPSY, EXCISIONAL | |
| 2026-03-27 | CDISC-6900 | Remove | C100469 | Term | LBTEST | Laboratory Test Name | Remove term entirely from codelist | Pepsinogen A | --- | C100469 being merged into C100467 |
| 2026-03-27 | CDISC-6900 | Remove | C100469 | Term | LBTESTCD | Laboratory Test Code | Remove term entirely from codelist | PEPSNGA | --- | C100469 being merged into C100467 |
| 2026-03-27 | CDISC-6900 | Update | C25639 | CDISC Definition | BEDECOD | Biospecimen Events Dictionary Derived Term | Update CDISC Definition | Coming into possession of or acting as the receptacle or recipient of an item conveyed by an intermediary to the intended destination, from a sender. | A status indicating that the entity comes into one's possession after conveyance from a sender. | |
| 2026-03-27 | CDISC-6900 | Update | C62667 | CDISC Synonym | METHOD | Method | Add new CDISC Synonym | --- | Gamma Scan | |

SDTM Terminology Changes

This screenshot, taken from the CDISC CT Changes file from CDISC P61 (v2026-03-27), is for illustrative purposes only.

## 4.2 Codetable Mapping Files

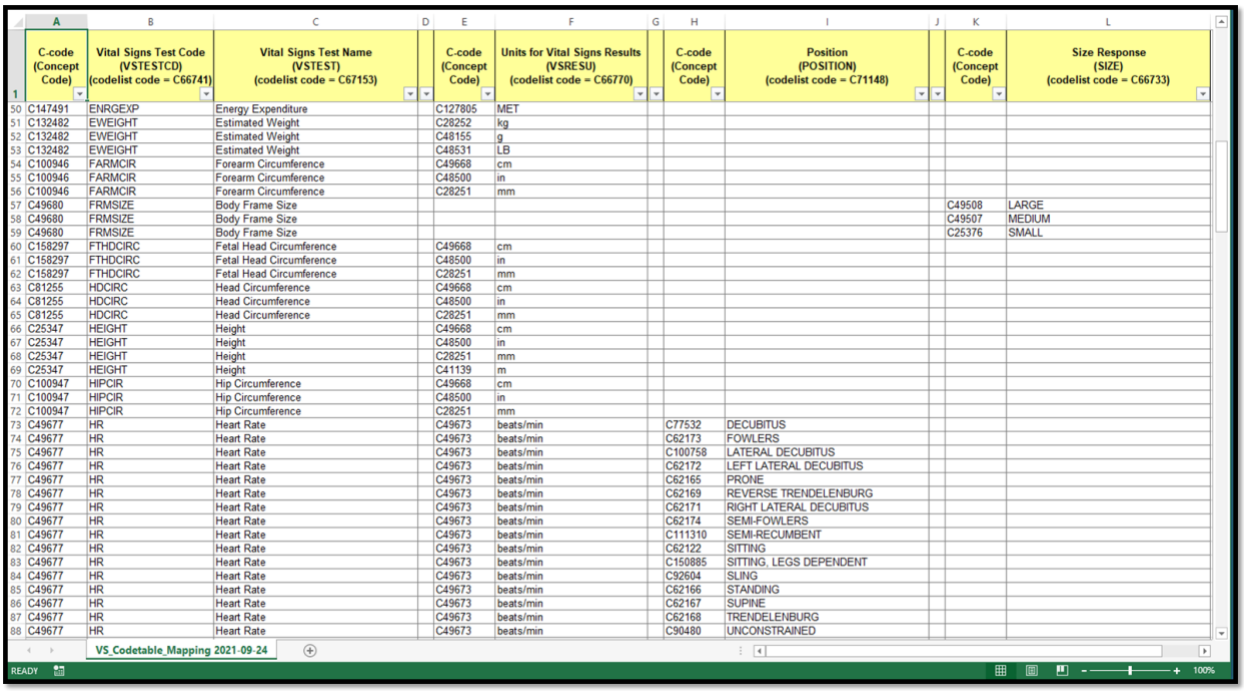
Controlled Terminology consists of lists of questions (e.g., variables, TESTs, PARMs) or answers (e.g., response codelists, qualifier variable codelists), both of which are commonly referred to as codelists and are published

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alphabetically in the CT publication. The terms within these codelists may have relationships to other terms within other codelists not readily apparent in the 2-dimensional CDISC CT publication files; for example:

- A TESTCD/PARMCD codelist is paired with a TEST/PARM codelist wherein a NCI C-code for a concept is assigned a different CDISC submission value across each codelist, necessitating sorting/filtering on the NCI C-codes to identify paired submission values.
- A particular test in the EGTEST codelist has a limited set of relevant responses from the EGSTRESC codelist such that they constitute the appropriate subset of response terms.
- A particular test in the VSTEST codelist has a limited set of relevant units of measure for numeric results from the VSRESU codelist such that they constitute the appropriate subset of response terms.

To address this issue, the CDISC CT teams have created Codetable Mapping Files based on published CDISC CT, which show relationships between terms in different Controlled Terminology codelists across domain-specific variables. These supplemental files provide human and machine-readable linkages between published terms across codelists and are useful for data QA/QC, CRF building, and data mapping. Codetable mapping files are developed and maintained by subject matter experts on CDISC CT teams as new terminology is developed (see Section 2.2.2). The files undergo biannual CT public review (see Section 2.3) and are up-versioned based on codelist additions; the CDISC CT version date identifier can be found in the tab name of the file. They are presented in Excel format and stored on the Controlled Terminology page on the CDISC website. Additions or changes can be requested through the CDISC Controlled Terminology Change Request site; see Section 2.1.2 of this document for instructions on how to submit a change request.



| | A | B | C | D | E | F | G | H | I | J | K | L |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | C-code (Concept Code) | Vital Signs Test Code (VSTESTCD) (codelist code = C66741) | Vital Signs Test Name (VSTEST) (codelist code = C67153) | | C-code (Concept Code) | Units for Vital Signs Results (VSRESU) (codelist code = C66770) | | C-code (Concept Code) | Position (POSITION) (codelist code = C71148) | | C-code (Concept Code) | Size Response (SIZE) (codelist code = C66733) |
| 50 | C147491 | ENRGEXP | Energy Expenditure | | C127805 | MET | | | | | | |
| 51 | C132482 | EWEIGHT | Estimated Weight | | C28252 | kg | | | | | | |
| 52 | C132482 | EWEIGHT | Estimated Weight | | C48155 | g | | | | | | |
| 53 | C132482 | EWEIGHT | Estimated Weight | | C48531 | LB | | | | | | |
| 54 | C100946 | FARMCIR | Forearm Circumference | | C49668 | cm | | | | | | |
| 55 | C100946 | FARMCIR | Forearm Circumference | | C48500 | in | | | | | | |
| 56 | C100946 | FARMCIR | Forearm Circumference | | C28251 | mm | | | | | | |
| 57 | C49680 | FRMSIZE | Body Frame Size | | | | | | | | C49508 | LARGE |
| 58 | C49680 | FRMSIZE | Body Frame Size | | | | | | | | C49507 | MEDIUM |
| 59 | C49680 | FRMSIZE | Body Frame Size | | | | | | | | C25376 | SMALL |
| 60 | C158297 | FTHDCIRC | Fetal Head Circumference | | C49668 | cm | | | | | | |
| 61 | C158297 | FTHDCIRC | Fetal Head Circumference | | C48500 | in | | | | | | |
| 62 | C158297 | FTHDCIRC | Fetal Head Circumference | | C28251 | mm | | | | | | |
| 63 | C81255 | HDCIRC | Head Circumference | | C49668 | cm | | | | | | |
| 64 | C81255 | HDCIRC | Head Circumference | | C48500 | in | | | | | | |
| 65 | C81255 | HDCIRC | Head Circumference | | C28251 | mm | | | | | | |
| 66 | C25347 | HEIGHT | Height | | C49668 | cm | | | | | | |
| 67 | C25347 | HEIGHT | Height | | C48500 | in | | | | | | |
| 68 | C25347 | HEIGHT | Height | | C28251 | mm | | | | | | |
| 69 | C25347 | HEIGHT | Height | | C41139 | m | | | | | | |
| 70 | C100947 | HIPCIR | Hip Circumference | | C49668 | cm | | | | | | |
| 71 | C100947 | HIPCIR | Hip Circumference | | C48500 | in | | | | | | |
| 72 | C100947 | HIPCIR | Hip Circumference | | C28251 | mm | | | | | | |
| 73 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C77532 | DECUBITUS | | | |
| 74 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62173 | FOWLERS | | | |
| 75 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C100758 | LATERAL DECUBITUS | | | |
| 76 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62172 | LEFT LATERAL DECUBITUS | | | |
| 77 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62165 | PRONE | | | |
| 78 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62169 | REVERSE TRENDELENBURG | | | |
| 79 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62171 | RIGHT LATERAL DECUBITUS | | | |
| 80 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62174 | SEMI-FOWLERS | | | |
| 81 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C111310 | SEMI-RECUMBENT | | | |
| 82 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62122 | SITTING | | | |
| 83 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C150885 | SITTING, LEGS DEPENDENT | | | |
| 84 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C92604 | SLING | | | |
| 85 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62166 | STANDING | | | |
| 86 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62167 | SUPINE | | | |
| 87 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C62168 | TRENDELENBURG | | | |
| 88 | C49677 | HR | Heart Rate | | C49673 | beats/min | | C90480 | UNCONSTRAINED | | | |

VS_Codetable_Mapping 2021-09-24

READY

## 4.3 Team Rules for CDISC CT Development

A set of documents are produced by CDISC CT teams that contain conventions, philosophies, and terminology development rules to be followed during the terminology development process (see Section 2.2.2). These documents assist, guide, and govern the CDISC CT teams, ensuring consistent decision making when developing new CDISC CT. They also help the CDISC user community understand the rules the CDISC CT teams follow and anticipate future CDISC terms. These documents are located on the CDISC Controlled Terminology page; updates to these documents are publicly reviewed during the CT review cycle and published biannually.

**Note:** QRS terminology rules documentation is located on the CDISC website QRS page in an Excel file.

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## 4.4 CDISC CT Requests Denied

The CT Requests Denied file, containing a cumulative list of CDISC change requests that have been denied through the current terminology release, is stored on the CDISC Controlled Terminology page, under the Resources tab.

Each tab in the CT Requests Denied file corresponds to a terminology team overseeing one to many codelists in a particular subject matter area. The EVS change request number is included in each tab of the file and can be referenced to find a change request of interest (column E, Request Code).

Denied requests are publicly reviewed with each public review package and comments are submitted through the CDISC JIRA process (see Section 2.3). Additionally, comments or questions about published denied requests are to be submitted through the CDISC Change Request webpage. If new information regarding a denied request is provided, the CDISC CT team may reconsider the request.

The CT Requests Denied file enables users to

- check on the publication status of a change request;
- determine whether a term or change has previously been requested and denied, and the reason it was denied; and
- identify alternative implementation instructions provided by the CDISC CT teams.

See also Section 5.4, What to Do When a Change Request Is Denied.

## 4.5 CDISC Change Request Tracking File

The CDISC Change Request Tracking file contains a cumulative list of CDISC change requests received and the final disposition of each request, if completed. This Excel file is updated biannually and can be accessed (1) via the NIH National Cancer Institute's CDISC Terminology resources page or (2) via the CDISC Controlled Terminology page (Supplemental Files > NCI FTP Links).

The CT Change Request Tracking file enables users to

- check on the publication status of a change request using the EVS change request number (column C, Request Code) and
- identify the publication package within which the requested change was dispositioned (column L, Final Outcome).

Column L, Final Outcome, indicates whether the change request was denied. The CDISC CT Requests Denied file (see Section 4.4) provides denial details. If the column is blank, that means that the request has not yet been dispositioned as per the latest version of CDISC CT.

## 4.6 External Terminology Standards Mapping to CDISC CT

This section contains information about mapping between external terminology standards and CDISC CT that may aid in the conformance of collected data to CDISC submission values.

### 4.6.1 US FDA's LOINC Requirement and Mapping

The US FDA *Data Standards Catalog*[3] requires the submission of Logical Observation Identifiers Names and Codes (LOINC) within clinical LB (and by default LC) domain datasets when the LOINC is provided by the lab/instrument vendor. If the LOINC code is not made available by the laboratory, the --LOINC variable values will not be populated in the dataset. The FDA *Study Data Technical Conformance Guide*[1] and a recommendations document for submitting LOINC codes in US regulatory applications[4] provide guidance on this requirement.

To illustrate mapping principles between LOINC and CDISC variables and terminology, the CDISC LAB Team developed a file containing examples for more than 1400 LOINC codes across the Chemistry, Hematology, Coagulation, Toxicology, Urinalysis, Serology, and other classes that would be mapped to the CDISC LB domain. The published zip file containing a ReadMe and example mapping document is available on the CDISC Controlled Terminology page. This file is for illustrative purposes only, and there are no plans to update this resource.

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### 4.6.2 CDISC Units of Measure and UCUM

The Unified Code for Units of Measure (UCUM) contains a blueprint for creating machine-readable units of measure from more than 300 terminal unit symbols. UCUM is commonly used in healthcare to populate electronic health records such as laboratory records in LOINC. To conform collected UCUM units of measure to CDISC Unit submission values, a Unit-UCUM Codetable file has been developed by CDISC. This file is updated biannually and published with the CDISC CT. For additional information on how to use this mapping file, see the CDISC Knowledge Base article.

### 4.6.3 NCI Metathesaurus (NCIm)

The NCIm is a free, non-license-restricted, curated biomedical terminology resource that provides rich synonymy and mappings among codes and terms across many commonly used biomedical terminologies. NCIm brings together a wide variety of terminologies and ontologies that are published separately, such as NCIt (which includes CDISC CT), CTCAE, GO, various ICDs, LOINC, MedDRA, and SNOMED CT, and semantically links them into a single NCIm concept code.

NCIm enables users to

- reference a single, curated mapping resource;
- search, compare, and contrast terms across a wide variety of reputable sources;
- consistently perform concept mapping activities within and across organizations (e.g., conforming internal dictionary terms, real-world data); and
- formulate appropriate CDISC CT change requests (see Section 2.1.3 for more information)

NCIm content is accessible through a public browser (EVS Explore) and the EVS REST API, and is updated biannually.

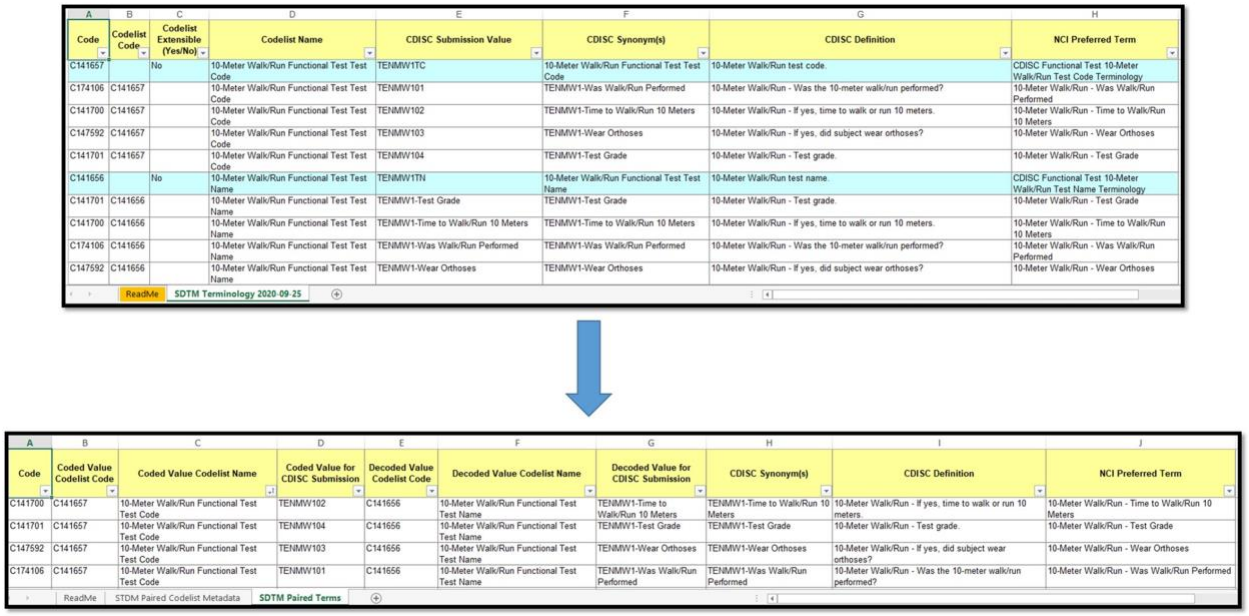
## 4.7 Paired Codelists

The CDISC models define 2 topic variables, --TESTCD and --PARMCD, with submission values restricted to <=8 characters. These topic variables are paired with synonym qualifier variables, --TEST and --PARM, with submission values restricted to <=40 characters. Refer to Section 2.2.2 of this guide and SDTMIG Section 4.2.1, Variable-Naming Conventions, for more information on character restrictions for submission values. Codelists associated with the variable pairings are considered "paired codelists" because they contain conceptually synonymous submission values with the same NCI C-code.

To simplify viewing the relationship between paired codelist values, supplemental files for SEND, SDTM, and ADaM CT are generated that display paired submission values with the same NCI C-code on the same row. These files (published biannually, as applicable) are posted on the CDISC Controlled Terminology page, under the Supplemental Files section.

The following figure illustrates how the standard view of SDTM CT paired codelists is transposed into a single combined view.

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| Code | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name | CDISC Submission Value | CDISC Synonym(s) | CDISC Definition | NCI Preferred Term |
|---|---|---|---|---|---|---|---|
| C141657 | | No | 10-Meter Walk/Run Functional Test Test Code | TENMW1TC | 10-Meter Walk/Run Functional Test Test Code | 10-Meter Walk/Run test code. | CDISC Functional Test 10-Meter Walk/Run Test Code Terminology |
| C174106 | C141657 | | 10-Meter Walk/Run Functional Test Test Code | TENMW101 | TENMW1-Was Walk/Run Performed | 10-Meter Walk/Run - Was the 10-meter walk/run performed? | 10-Meter Walk/Run - Was Walk/Run Performed |
| C141700 | C141657 | | 10-Meter Walk/Run Functional Test Test Code | TENMW102 | TENMW1-Time to Walk/Run 10 Meters | 10-Meter Walk/Run - If yes, time to walk or run 10 meters. | 10-Meter Walk/Run - Time to Walk/Run 10 Meters |
| C147592 | C141657 | | 10-Meter Walk/Run Functional Test Test Code | TENMW103 | TENMW1-Wear Orthoses | 10-Meter Walk/Run - If yes, did subject wear orthoses? | 10-Meter Walk/Run - Wear Orthoses |
| C141701 | C141657 | | 10-Meter Walk/Run Functional Test Test Code | TENMW104 | TENMW1-Test Grade | 10-Meter Walk/Run - Test grade. | 10-Meter Walk/Run - Test Grade |
| C141656 | | No | 10-Meter Walk/Run Functional Test Test Name | TENMW1TN | 10-Meter Walk/Run Functional Test Test Name | 10-Meter Walk/Run test name. | CDISC Functional Test 10-Meter Walk/Run Test Name Terminology |
| C141701 | C141656 | | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Test Grade | TENMW1-Test Grade | 10-Meter Walk/Run - Test grade. | 10-Meter Walk/Run - Test Grade |
| C141700 | C141656 | | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Time to Walk/Run 10 Meters | TENMW1-Time to Walk/Run 10 Meters | 10-Meter Walk/Run - If yes, time to walk or run 10 meters. | 10-Meter Walk/Run - Time to Walk/Run 10 Meters |
| C174106 | C141656 | | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Was Walk/Run Performed | TENMW1-Was Walk/Run Performed | 10-Meter Walk/Run - Was the 10-meter walk/run performed? | 10-Meter Walk/Run - Was Walk/Run Performed |
| C147592 | C141656 | | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Wear Orthoses | TENMW1-Wear Orthoses | 10-Meter Walk/Run - If yes, did subject wear orthoses? | 10-Meter Walk/Run - Wear Orthoses |

ReadMe | SDTM Terminology 2020-09-25

| Code | Coded Value Codelist Code | Coded Value Codelist Name | Coded Value for CDISC Submission | Decoded Value Codelist Code | Decoded Value Codelist Name | Decoded Value for CDISC Submission | CDISC Synonym(s) | CDISC Definition | NCI Preferred Term |
|---|---|---|---|---|---|---|---|---|---|
| C141700 | C141657 | 10-Meter Walk/Run Functional Test Test Code | TENMW102 | C141656 | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Time to Walk/Run 10 Meters | TENMW1-Time to Walk/Run 10 Meters | 10-Meter Walk/Run - If yes, time to walk or run 10 meters. | 10-Meter Walk/Run - Time to Walk/Run 10 Meters |
| C141701 | C141657 | 10-Meter Walk/Run Functional Test Test Code | TENMW104 | C141656 | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Test Grade | TENMW1-Test Grade | 10-Meter Walk/Run - Test grade. | 10-Meter Walk/Run - Test Grade |
| C147592 | C141657 | 10-Meter Walk/Run Functional Test Test Code | TENMW103 | C141656 | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Wear Orthoses | TENMW1-Wear Orthoses | 10-Meter Walk/Run - If yes, did subject wear orthoses? | 10-Meter Walk/Run - Wear Orthoses |
| C174106 | C141657 | 10-Meter Walk/Run Functional Test Test Code | TENMW101 | C141656 | 10-Meter Walk/Run Functional Test Test Name | TENMW1-Was Walk/Run Performed | TENMW1-Was Walk/Run Performed | 10-Meter Walk/Run - Was the 10-meter walk/run performed? | 10-Meter Walk/Run - Was Walk/Run Performed |

ReadMe | STDM Paired Codelist Metadata | SDTM Paired Terms

# 4.8 Controlled Terminology Relationships

The Controlled Terminology Relationships metadata tables are stored on the CDISC Controlled Terminology page, under the Resources tab. There are currently 2 published versions of the CT Relationships product.

Relationships exist between CDISC codelists and CDISC variables associated with observation classes and domains. Due to differences in publication frequency, a late binding effect can exist between CDISC models, implementation guides, and biannual CT publications leading to an ambiguous state where it is not always clear whether a CDISC variable has associated CT. In addition, value-level metadata are not clearly identified in any of the CDISC standards. To remedy this, CT Relationships metadata tables provide a singular, explicit, and complete view of CT across clinical data tabulation activities. This information is provided in Excel format and in YAML, a machine-readable format with hyperlinks to the CDISC Library.

These metadata tables seek to explicitly show the relationships between published CT codelists and terminology subsets and those CDISC variables, tests, parameters, and NSVs used as supplemental qualifiers published in SDTM, SDTMIG, therapeutic area user guides, and regulatory documents.

CT Relationships metadata tables go through CDISC GGG internal and public review processes prior to publication. These tables provide a means with which to

- improve process automation to create Trial Design datasets for regulatory submissions;
- streamline input to data validation software for additional terminologies requirements for regulatory submissions;
- enable data to comply to CT requirements upfront, providing high-quality data at SDTM dataset generation;
- enable software integration with CDISC Library;
- identify valid terminology subsets for domain- and variable-specific contexts;
- identify the complete set of relationships between codelists and CDISC model elements; and
- assist users in building value level metadata to support the generation of Define-XML.

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# 5 Considerations for Terminology Management

This section contains considerations for terminology management within an organization.

## 5.1 General Considerations

### Terminology Adoption - Risk Analysis

Sponsors/applicants/others will likely already have established controlled terminology sets. It is therefore suggested that these legacy sets be initially compared to the CDISC CT sets. Outcomes of this review would include (but are not limited to):

- How do the CDISC CT sets affect the business processes, concept meaning, and data handling rules?
- How do the CDISC CT sets affect the ability to integrate new studies with legacy studies (e.g., technical documents as part of a new drug application)?
- Will this impact our ability to mine data? And to what extent? How can we mitigate these risks?
- Will user templates need to be altered (e.g., CRF standards, protocol template, SAP template)?
- How will we manage CT subsetting and the terminology master set?
- How will the sponsor/applicant/other manage potential contradictions between terms added in real time to extensible CT sets and those agreed each quarter by CDISC?

In a situation where there are sponsor/applicant/other legacy controlled terminology sets, it is best practice to implement the CDISC CT at the compound level as a single, well defined and stakeholder agreed adoption step on a go-forward basis. This should occur once the submission and data mining landscape is well understood for that particular compound. Wider scale, blanket CT adoptions can be difficult to manage due to the heterogeneity of development phases across a sponsor/applicant/other portfolio (i.e., integration/mining requirements will differ from compound to compound). Blanket adoptions are better suited to companies with no defined legacy standard.

### Stakeholders

It is vital to identify the organization stakeholders. These are typically those involved in clinical trial development:

- CRF design
- Data management
- Clinical
- Medical
- Clinical pharmacology
- Statistical programming
- Statistics
- Medical writing
- Pharmacovigilance

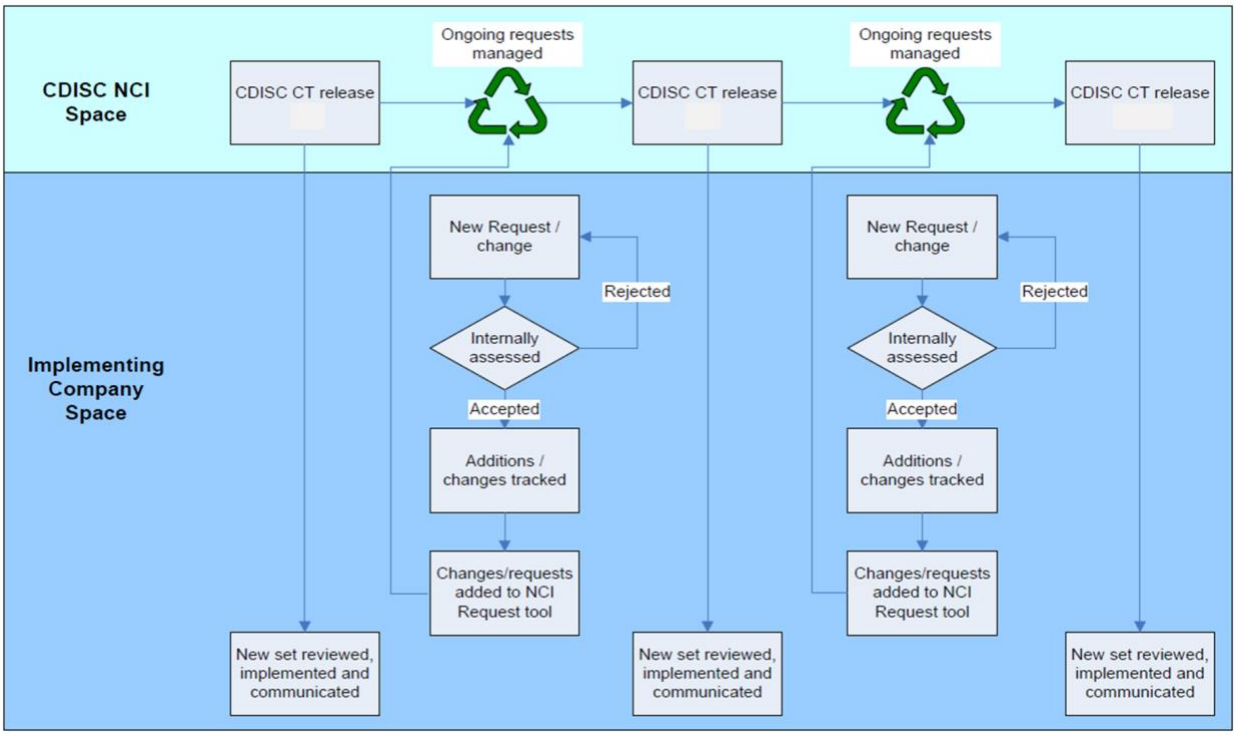
Terminology leaders in companies interested in adopting the CDISC CT sets need to ensure that the key terminology concepts and expectations are understood throughout these stakeholder groups. ***All*** are fundamental to the consistency of adoption.

### Terminology Infrastructure

In order to define terminology infrastructure at a sponsor/applicant/other level it is important to understand the wider CDISC CT landscape. CDISC is not resourced to approve new/changed terms in real time to every industry requester and has adopted the approach described in Section 2.5 (i.e., biannual releases). This does not directly support users who are operating under ever-decreasing R&D metrics who need terms approved in real time.

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Therefore, the landscape should be twofold between CDISC biannual releases and sponsor/applicant/other governance groups responding to project teams in real time. The basic flow may look as follows.




The process of implementing new versions of CDISC CT will vary according to the user. The sponsor/applicant/other's terminology infrastructure must be defined and dedicated resources should be assigned to manage the CT sets. Basic user requirements of this infrastructure include (but not limited to):

- Be able to respond to new valid value requests on study critical paths (out of the CDISC release cycle)
- Govern any additions to the extensible CT sets to ensure requests do not contradict either the existing CDISC CT set or any prior agreed additions to the extensible CT sets
- Be able to track, manage and version the new requests (real time)
- Document internal process decision tree which details the new CT requests for the extensible codelists
- Ensure that a process is in place to routinely upload new requests to the CDISC CT new term request link
- Ensure that the CDISC quarterly releases are assessed against the existing implemented CDISC CT sets (including out-of-cycle sponsor/applicant/other extensible additions) to understand any non-backward compatible changes/issues
- Manage standardized terminology subsets (if study builds are internal to a sponsor/applicant/other)
- Ensure all stakeholders are trained in both CDISC CT and user-specific implementations

It is recommended that this group comprise experts in the CDISC models. Once all leadership stakeholders agree to implement the new process, make infrastructure available, conduct risk analyses, and provide training, companies are better placed to adopt the terminology.

## Standards Implementation Within Companies/Organizations

The CDISC CT sets cannot be implemented in isolation from the CDISC models. Therefore, it is suggested that any terminology group within an organization should be part of a wider standards team that maintains oversight and governance across all applied models. This approach will ensure any sponsor/applicant/other decisions made around standards or terminology will support sponsor/applicant/other-specific interpretation of the CDISC models.

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Terminology ensures semantic interoperability within and across studies; therefore, it should be implemented at the beginning of the process and carried through consistently. Clinical trials are detailed in the study protocol and, even at this stage, terminology is a major factor. For example, Severity/Intensity Scale for Adverse Events and Completion/Reason for Non-Completion codelists are detailed in many protocols. Investigators are trained on the protocol and its definitions, and they report findings and events based on this training. These data are entered into the clinical data management system (CDMS), extracted, and then converted to SDTM datasets. If the CDISC CT set was not the basis for the protocol-defined terminology, there is a risk of losing the meaning of the initial observation in any mapping/transformation exercise. Sponsors/applicants/others adopting the CDISC CT sets are therefore strongly advised against a "back-end" mapping process where legacy codelists are translated or mapped to CDISC CT toward the end of the biometrics process, and are instead advised to adopt controlled terminology at the beginning of the process. For the same reason, retro-mappings across an entire compound set are discouraged.

## 5.2 Perspectives Related to CDISC CT Versions

### Regulatory Perspective

Each health authority or regulatory agency has expectations related to the use of controlled terminology, which are stated in published guidance. Because different divisions of a regulatory agency may have different rules and regulations pertaining to controlled terminology use, it is advised to follow the specific guidance from the applicable division.

- **Data standards catalogs** specify which terminology sources and versions are supported and/or required for data submission (e.g., US FDA *Data Standards Catalog*,[3], Japan PMDA *Data Standards Catalog*[5]).
- **Technical conformance guides** specify the CT version that should be used within a study and give instructions for documenting exceptions.
    - The US FDA *Study Data Technical Conformance Guide*[1] recommends that sponsors use "the most recent version of the dictionary available at the start of a clinical or non-clinical study. If a new version becomes available after the start of the study, sponsors may use the most current version of the dictionary for that clinical or nonclinical study."
    - The Japan PMDA provides guidance in the *Technical Conformance Guide on Electronic Study Data Submissions*.[6]
- Sponsor/applicant/other discussions with the regulatory agency about **terminology use** within the study are critical to managing expectations for the study data submission. The technical conformance guides from both the US FDA and Japan PMBA specify that the version of terminology used for the study should be described in the study data reviewers guide and in the Define-XML.

### Sponsor/Applicant/Other Perspective

- Be aware of regulatory expectations regarding terminology version usage in a data submission.
- Be aware of the version of the SDTMIG and/or TAUG in use in the study in order to determine the most appropriate CDISC CT version for use.
- Changes across CDISC CT versions are specified in the CDISC CT Change Files (see Section 4.1) and may include:
    - Additions or removals of terms
    - Updates to submission values (high impact), synonyms (low impact), and definitions (low impact)
    - Updates to NCI C-codes
    - Codelist changes
        - Additions or removals of codelists
        - Changes to codelist extensibility
- Be aware of the impact of mixing CDISC CT versions across studies for the same product (e.g., pooled data analysis, data mining).

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- Map/conform internal dictionaries to CDISC submission values within a version of CDISC CT, where appropriate.
  - Multiple mapping files to multiple versions of CDISC CT may need to be maintained because terms may have been added or removed or CDISC submission values may have changed across versions of CDISC CT.
  - Review approved and denied requests to ensure alignment between sponsor/applicant/other terminology and CDISC CT.
  - It is recommended to adopt CDISC submission values as extensible terms from the latest version of CDISC CT to minimize duplicate work when up-versioning.

### Data Validation Perspective

The following contains CDISC CT version management considerations related to the use of automated data validation tools.

- Data validator tool rule sets are based on published CDISC conformance rules and regulatory agency business rules, and may contain additional rules based on the tool provider's interpretation of CDISC implementation guides and regulatory guidances. As a result, different data validator tools and versions may generate differing outputs (e.g., reject, error, warning) for the same dataset.
  - Sponsors/applicants/others are responsible for evaluating data validator tool outputs and are expected to address or explain outputs in accordance with regulatory guidances.
- Some common CT-related data issues are regularly triggered by data validation tools:
  - Paired codelist consistency (e.g., paired values misaligned or one of the paired values missing)
  - Extension to a nonextensible codelist
  - Term not found in extensible codelist
    - The extended term needs to be listed in the define file as an extension (see Section 3.1.2, Terminology Metadata).
    - Consider submitting a change request (see Section 2.1, Change Request System).

## 5.2.1 CDISC IG Version Considerations

Users should be aware of the impact of changes across different versions of CDISC CT and the impacts those changes have when using a particular CDISC implementation guide. CDISC CT teams develop terminology based on the latest published version of the CDISC IG resulting in CT becoming out of sync with earlier IG versions. Therefore, users need to consider the timing of up-versioning to a more recent CT package. When a user transitions to a new version of the IG, it is recommended to use the latest version of CDISC CT that supports the published IG version being transitioned to.

## 5.2.2 What to Do When Terms or Codelists Change

In addition to new terms being added to CDISC CT codelists, other changes may occur within the CT including semantic changes, deprecations, and codelist placement. A complete list of all changes in the CDISC CT publication can be found in the CDISC CT Change files (see Section 4.1). The following table addresses frequently asked questions related to these types of changes.

| Question | Recommendation |
|---|---|
| What to do when an extensible term becomes a CDISC term? | Compare newly published concept(s) against sponsor/applicant/other lexicon and update CDISC submission value mappings as appropriate.<br>Compare newly published synonym(s) against sponsor/applicant/other lexicon and update CDISC submission value mappings as appropriate.<br>Refer to the JIRA request number for submitted change requests to find the published CDISC submission value in a CDISC CT publication (see Section 2.5.2) |

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| Question | Recommendation |
|---|---|
| What to do when a submission value changes? | Compare updated submission values against sponsor/applicant/other lexicon and update CDISC submission value mappings as appropriate.<br>Users may choose to continue using the old submission value if they do not choose to up-version the CT for an existing study. |
| What to do when an NCI C-code changes? | In the instance where the user chooses to move to the latest version of CDISC CT, review the Change Implementation Instructions of the CDISC CT Change File and take appropriate action.<br>The user may choose to continue using the old NCI C-code until a newer version of CDISC CT is implemented internally. |
| What to do when terms or codelists are deprecated? | In the instance where the user chooses to move to the latest version of CDISC CT, review the Change Implementation Instructions of the CDISC CT Change File and take appropriate action.<br>One may continue using the deprecated term (if in an extensible codelist) or codelist as extensible terminology if deemed necessary and appropriate by the user.<br>In the instance where the user chooses to continue using an earlier version of CDISC CT, the term or codelist deprecation may not be applicable for the user and can be ignored. |
| What to do when terms are moved from one codelist to another? | Terms may move from one codelist to another due to scope changes across different versions of IGs (e.g., LBTEST-CD to MBTEST-CD for antibody testing). Codelists also may be merged to promote reuse of semantics (e.g., Contact Setting (SETCON) codelist retired and terms moved into Environmental Setting (SETTING) codelist).<br>Review the Change Implementation Instructions of the CDISC CT Change File and take appropriate action.<br>In the instance where the user chooses to continue using earlier versions of an implementation guide and CDISC CT, the term or codelist change may not be applicable for the user and can be ignored. |
| Where can information be found about known issues related to CDISC CT? | Visit the CDISC Knowledge Base for articles, information on known issues, and the QRS portal. |

# 5.3 CDISC CT Codelist Extensibility

## Considerations for Extensible CDISC CT Codelists

- Ensure that extensible terms are not synonymous with existing, published concepts in the CDISC CT codelist. See Section 3.3.2, Conforming: Mapping Data to Controlled Terminology, for information on how to conform collected data to CDISC submission values.
- Document the use of extensible terms in the Define-XML and in the relevant reviewer's guide.
  - Refer to Section 6 of the FDA *Technical Conformance Guide*.[1]
  - Refer to Define-XML sections on codelist extensions.
- Note that data validation software may flag extensible values.
- Consider submitting extensible terms through the CDISC Change Request system (see Section 2.1).
- Consider using submission values from more recent releases of CDISC CT as extensible terms, in cases where relevant terms are unavailable in an earlier version of CDISC CT that is being used in the study. **Note:** The use of CDISC CT terms as extensible terms will make CT updates easier and future ready.
- When a term is missing from an extensible CDISC CT codelist and the term currently exists in another CDISC CT codelist, consider using the submission value from the latter CDISC codelist as an extensible term. This is especially useful in the case where domain scope changes across IG versions necessitate the movement of terms from one codelist to another (i.e., LB to MB).

## Considerations for Nonextensible CDISC CT Codelists

Nonextensible codelists limit the valid values for a variable, thus preventing variable misuse and/or limiting the scope of the variable as appropriate for particular analysis and submission purposes. The following should be considered when working with nonextensible codelists:

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When a collected value does not conform to a submission value in a nonextensible codelist, populate the variable value with the collected term and note the divergence in the Define-XML and explain it in the relevant reviewer's guide. Ideally, the exclusive use of terms in nonextensible codelists should be enforced in data collection systems to prevent issues with data mapping and data validation. Change requests for nonextensible codelists will be considered by the CDISC terminology teams (see Section 2.1).

- When an extensible codelist becomes nonextensible in a newer version of CDISC CT, and the choice is made to implement the newer version of CT:
  - Consider submitting a change request to the CDISC CT team to evaluate additional values.
  - Extended values that were used previously should not continue to be used, unless CDISC adds those values to the nonextensible codelist.

## 5.4 What to Do When a Change Request Is Denied

Please refer to Section 4.4, CDISC CT Requests Denied.

In the Denied Requests file, review the Final Decision Reason for Request Denied column and take appropriate action to update the sponsor/applicant/other lexicon.

- Denied request reasoning can be publicly commented on and/or a change request can be made.
- This is especially important for a change request submitted to a nonextensible codelist (see Section 5.3, CDISC CT Codelist Extensibility).

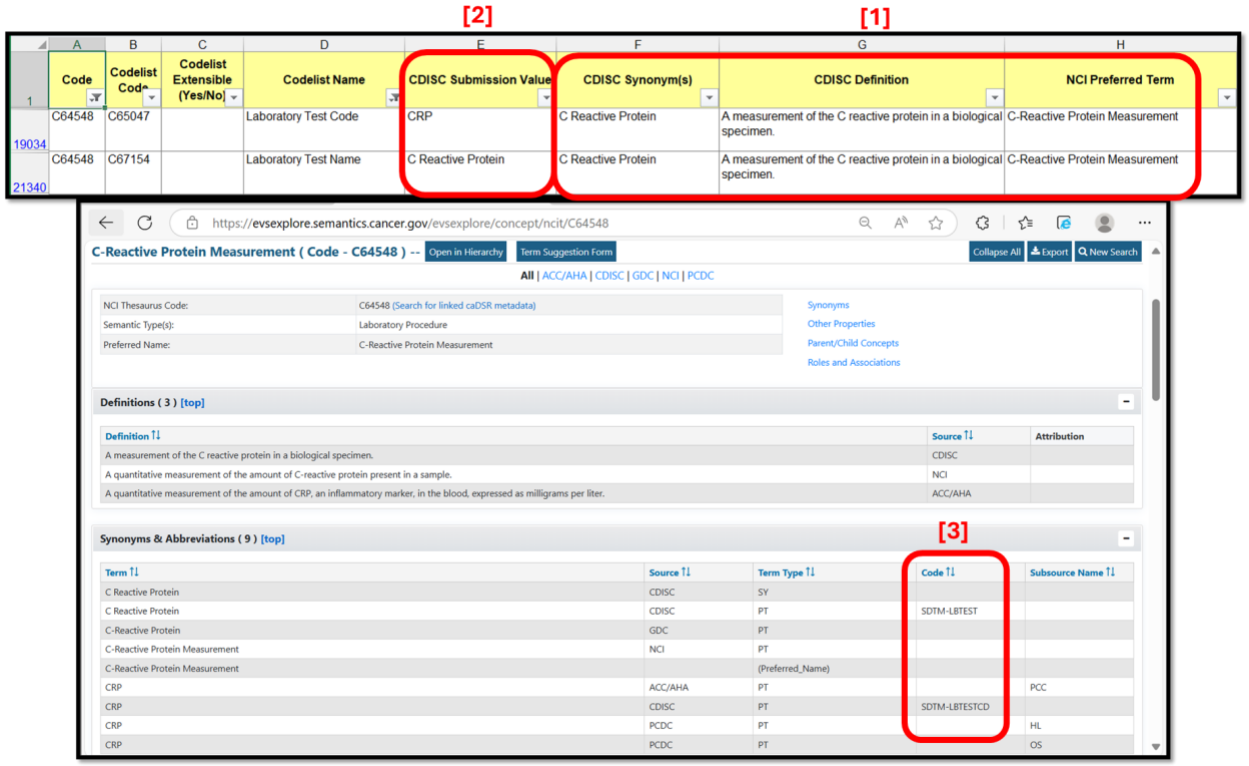
The most common reasons for request denial are:

- **The concept already exists in published CDISC CT**. Review the Final Decision Reason for Request Denied column and take appropriate action to update the sponsor/applicant/other lexicon.
- **The change request is inconsistent with the published standard.** Review the Final Decision Reason for Request Denied column and take appropriate action to update the sponsor/applicant/other lexicon.
- **The requester has not provided enough information** for the team to resolve the request (after at least 2 attempts at follow-up by the CT team). Continue using the requested term as extensible terminology as long as the codelist is extensible. Note that use of the extensible term is at risk; see Section 2.1.1, Should a CDISC Terminology Change Request be Made?. If additional information becomes available, the user can resubmit the request.
- **The term is expected to be in limited and/or short-term use** across studies and/or sponsors/applicants/others, such that long-term maintenance by CDISC is of little value to the user community. Continue using the requested term as extensible terminology as long as the codelist is extensible (see Section 2.1.1).

## 5.5 NCIt C-Code Management

- All CDISC concepts are mapped to existing NCIt C-codes based on semantic synonymy. If the concept is found to be semantically unique, a new NCIt C-code is generated and assigned to that CDISC concept. See Section 1.3.2, CDISC Controlled Terminology Key Concepts, for more information about C-codes.
- A CDISC concept can be a member of more than one codelist, therefore a NCIt C-code may appear within a terminology publication more than once. As illustrated in the following figure, the single concept, linked to a single NCIt C-code, will have the same CDISC Synonym(s), CDISC Definition, and NCI Preferred Term [1] across multiple codelists. However, the single concept may have the same or different CDISC Submission Value [2] across multiple codelists. This relationship is managed within NCIt using the Code field [3] of the Synonyms and Abbreviations table.

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- An NCI C-code is linked to a unique NCI concept and remains linked with that concept indefinitely. Retired NCI C-codes will not be used for any new concepts. If an NCI C-code has been incorrectly attached to a CDISC concept, an NCI C-code update will be listed in the Changes to Existing Codelists tab of the public review file (see Section 2.3). This change will be explained in the CDISC CT Change File (see Section 4.1) upon publication.

## 5.6 User-defined Values and Codelists

Users may have their own internal, user-defined terminology standards for data collection and/or submission where there are data elements within the CDISC model(s) that do not have associated CDISC CT or other terminology maintenance organization terminologies. Terminology management practices described in the CTUG and by other terminology maintenance organizations may be considered by users when defining their internal practices.

- "User-defined" refers to:
  - Any terminology (values and/or codelists) that is **NOT** governed by a terminology maintenance organization
  - Any lexicon internally developed and maintained by a user of CDISC standards (e.g., sponsor, applicant, CRO, laboratory, governmental organization, academic organization)
- It is recommended that internal terminology governance practices are set up to control the maintenance of user-defined terminology. User-defined terminology should be reconciled with newly published standard controlled terminologies.
- It is recommended that organizations follow the naming conventions for user-defined values described in the QRS Naming and Business Rules (for domains QS, FT, and CC) and Rules for All Codelists (for all other domains).

The following table lists sections within this document related to or helpful for the management of user-defined terminology.

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| Topic | Section |
|---|---|
| Should my user-defined term become part of CDISC CT or stay as a user-defined term? | Section 2.1, Change Request System |
| | Section 5.3, CDISC CT Codelist Extensibility |
| How can I anticipate what CDISC CT teams will do with my term request? | Section 4.3, Team Rules for CDISC CT Development |
| Where can I find CDISC rules and best practices to integrate into my own internal processes? | Section 2.2.2, CT Team Operating Principles |
| | Section 5.7, CDISC IG Conventions for User-Defined Terminology |
| What resources are available to help me reconcile user-defined terminology with newly published CDISC CT? | Section 2.5.2, Tracking CDISC Change Requests |
| | Section 4.5, CDISC Change Request Tracking File |
| | Section 4.4, CDISC CT Requests Denied |

# 5.7 CDISC IG Conventions Related to Controlled Terminology

## The --ALL Convention for Tests Not Done

SDTMIG Section 4.5.1.2, Tests Not Done, describes a TEST/TESTCD convention for when a test or group of tests is not done and is explicitly captured with a "Yes/No" or "Done/Not Done" question. In the case where a single record is used to represent a group of tests that were not done, a TEST/TESTCD convention is used for this purpose (the dashed lines indicate a 2-letter domain code):

- --TESTCD = --ALL (e.g., LBALL, EGALL)
- --TEST = <Domain description> (e.g., Laboratory Test Results, ECG Test Results)

These TEST/TESTCD values will not be added to any Findings domain TEST/TESTCD codelists because semantically these are not true assessments (i.e., no result values); these tests are operational values that indicate a group of tests were not done. They are considered to be extensible terminology.

Note that this information may not be relevant for QRS-related domains and terminology. Refer to the SDTMIG for more information.

## The Multiple Convention for Non-result Qualifiers

SDTMIG Section 4.2.8.3, Multiple Values for a Non-result Qualifier Variable, describes a variable value convention for when multiple values exist for a non-result qualifier variable in a SDTM dataset. If multiple values exist (e.g., due to a "Check all that apply" instruction on a CRF), then the value for the qualifier variable should be "MULTIPLE" and a SUPP--/NSV dataset should be used to store the individual responses. The values reported in the SUPP--/NSV dataset may still be subject to CDISC CT, where a CDISC codelist exists for the parent non-result qualifier variable.

The value of "MULTIPLE" will generally not be added to any CDISC CT codelist that supports a non-result qualifier variable because in this instance "MULTIPLE" is not the answer. Rather, it is a pointer to a list of 2 or more answers, which are stored in a SUPP--/NSV dataset. "MULTIPLE" can be considered to be an extensible term for extensible codelists. In the case where the user decides to use the value of "MULTIPLE" for nonextensible codelists, its usage should be explained in the study data reviewer's guide. See this CDISC Knowledge Base article for additional information on this topic.

# 5.8 The Use of "OTHER" or "OTHER, SPECIFY"

"OTHER" or "OTHER, SPECIFY" are not added to any CDISC CT codelist because the concepts are clinically insignificant. Instead, these concepts indicate that a collected data value was not present in the list of prespecified values on the data collection form. In extremely rare cases, a CDISC CT team may choose to add "OTHER" or "OTHER, SPECIFY" into a codelist if the values within that codelist are being taken from an external terminology.

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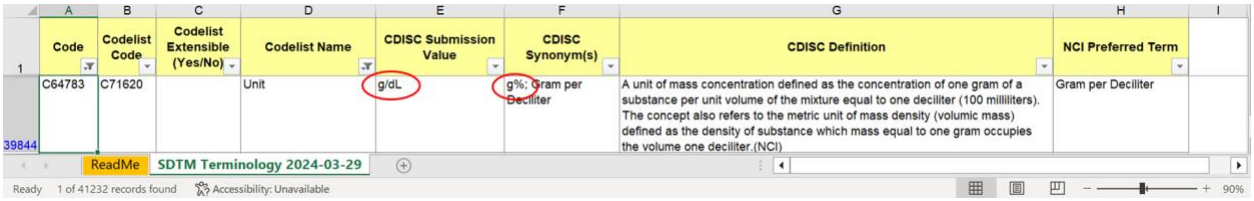
In some cases, a finite list of valid values within a data collection field is not known, or a list of valid values of specific interest to the study are presented but the user requires flexibility to collect unspecified values. Therefore, the use of "OTHER" or "OTHER, SPECIFY" allows the user to enter free-text data as applicable. In the case where it is determined that "OTHER" or "OTHER, SPECIFY" should be put into submission datasets, these can be considered as extensible terms for extensible codelists. In the case of a nonextensible codelist, their usage should be noted in the Define-XML and explained in the relevant reviewer's guide.

See the SDTMIG and CDASHIG for how to handle "OTHER" or "OTHER, SPECIFY" in data collection systems. This Knowledge Base article provides additional information on this topic.

# 5.9 Considerations for Units of Measure

## Use CDISC Submission Values for --ORRESU

- The unit for the original result (--ORRESU) variable represents the unit of measure for the **result** as originally received or collected for the measurement, test, or examination. The --ORRESU value must still be represented using a consistent nomenclature because units of measure are notoriously inconsistent in the way they are represented in medical literature, sponsor/applicant/other dictionaries, laboratory information management systems, and across languages. For example:
  - The unit of measure gram per deciliter can be represented in multiple ways: g/dL, G/DL, g/decL, g%, g/dcl, gm/dL.
  - Exponents can be represented in multiple ways: 10^9/L, 10*9/L, 10**9/L, 10E9/L, $10^9$/L, Ten to the Ninth Power Per Liter, G/L, Giga/L.
- The variable --ORRESU is supported by multiple unit-of-measure codelists. Users may need to conform the received/collected unit of measure to a published CDISC submission value from the UNIT codelist and only submit that CDISC submission value in the SDTM dataset.
  - For example, the laboratory reported the unit for the result of a serum albumin test as g%. The unit of measure g% was then conformed to the CDISC submission value of g/dL (C64783) as per the published SDTM UNIT codelist.
  - For more information about conforming collected values to CDISC submission values, see Section 3.2.2, Terminology Metadata, and Section 3.3.2.1, Conforming: Mapping Data to CDISC Controlled Terminology.



| | A | B | C | D | E | F | G | H | I |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Code | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name | CDISC Submission Value | CDISC Synonym(s) | CDISC Definition | NCI Preferred Term | |
| 39844 | C64783 | C71620 | | Unit | g/dL | g%; Gram per Deciliter | A unit of mass concentration defined as the concentration of one gram of a substance per unit volume of the mixture equal to one deciliter (100 milliliters). The concept also refers to the metric unit of mass density (volumic mass) defined as the density of substance which mass equal to one gram occupies the volume one deciliter.(NCI) | Gram per Deciliter | |

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- For data traceability purposes, the unit of measure as originally received or collected can be represented in an SDTM dataset using a supplemental qualifier (non-standard variable). CDISC recommends the use of the CDASH variable --CRESU (Collected Non-Standard Unit) as a suppqual/NSV in SDTM datasets for this purpose.

## Principles of Mathematical Synonymy

- *Mathematical synonymy* refers to the concept of different mathematical expressions, formulas, or terms that convey the same meaning or represent the same underlying mathematical idea.
- NCI EVS and CDISC terminology teams adhere to these mathematical synonymy principles. In the context of units of measure, 2 or more units of measure that provide the same numeric value and have a conversion factor of 1 are considered to be mathematically synonymous. This principle is especially important for units that contain at least a numerator and denominator; this compound unit must change at exactly the same magnitude to be considered a mathematical synonym. For example,

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  - Centipoise = Millipascal Second = cP
  - Giga/L = 10^9/L
  - g/L = mg/mL = ug/uL = ng/nL
- As discussed, the variable --ORRESU is supported by several unit of measure codelists (e.g., UNIT, PKUNIT, VSRESU).
  - Terms from the CDISC Submission Value column in the published CT list should be submitted in the dataset.
  - When a collected unit is not available in this column, the synonym column should be reviewed to see if a published submission value from the UNIT codelist is available for use. For example, "g/L" and "mg/mL" are mathematically synonymous, but "g/L" is the published submission value in the UNIT codelist while "mg/mL" is a published synonym for that concept.
- If the unit of measure concept is deemed to be unique (i.e., not published in CDISC CT), the unit can be used as an extensible term in the dataset and a change request may be submitted.

## Unit of Measure Requirements for Japan PMDA and US FDA Data Submissions

- Per the Japan PMDA, "The use of SI units is required for all variables and parameters of test results to be stored in the Findings class domain of the SDTM dataset, as long as SI units are applicable."[6]
- The US FDA expects SI units to be used in the Laboratory Findings (LB) domain. It has also requested the use of a custom domain (LC) that represents laboratory findings using US conventional units.[1]
  - **At the time of publication of this user guide**, it is unclear when this recommendation is meant to be implemented. Always check with the FDA reviewer assigned to the study to clarify expectations.
  - **At the time of publication of this user guide**, the LC domain is not published in any version of the SDTMIG so it would be considered a custom domain.
  - Refer to the CDISC Knowledge Base article on standardized lab units for more information.
  - Per the US FDA, "It is ideal if both conventional and SI units come directly from the lab vendor."[1]

## Unit Conversions

- It is not the responsibility of CDISC to standardize unit conversions.
- Units in data submissions must be aligned with regulatory submission and CDISC model requirements.
- In general, laboratory vendors provide results with units that have been converted, but they do not provide the conversion factors used.
  - Central laboratory vendors provide results in raw collected units, SI standard units, and region-specific conventional units, as per the data transfer specification or agreement.
  - Local laboratories may provide data in region-specific units, which can lead to the reporting of different units for a particular test than what is required for SDTM mapping. Therefore, unit conversion is necessary to ensure that units are standardized.
- Recipients of laboratory data may need to do their own unit conversions for a number of reasons. For example, unit differences between local and central lab vendors may necessitate unit conversions to a standardized unit of measure for the same test.

## "Unitless" Data

- Not every test result has an applicable unit of measure for reporting purposes. CDISC CT teams will deny the addition of a unit of measure if the requested term is included in the --TEST/TESTCD or other standard CDISC variable (e.g., --RESTYP) associated with the assessment.
  - Common examples include pH measurements, urine dipstick measurements, and numeric ratings scales or categorical results.
  - Another common example is direct counts of entities (e.g., tumors, lesions, cells, events).

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- In the case where the count is the focus of the measure and the entity is included in the --TEST/--TESTCD or other variable, the count of the entity is considered unitless.
- Conversely, in the case where the entity count is performed per a designated denominator (e.g., unit of time, area, volume, mass), the denominator is considered to be a unit of measure.

- "RATIO" and "titer" will continue to be published in the UNIT codelist to support older versions of the SDTMIG.

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# Appendices

## Appendix A: Authoring Team

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|---|---|
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| Venkat Lajapathirajan | PPD/Thermo Fisher Scientific |
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| Craig Zwickl | Merck & Co., Inc. |

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# Appendix B: Glossary and Abbreviations

The following abbreviations and terms are used in this document. Additional terms are defined within this document; see also the CDISC Glossary, available on the CDISC website and via the NCI Enterprise Vocabulary Services.

| | |
|---|---|
| ADaM | Analysis Data Model |
| ADaMIG | ADaM Implementation Guide |
| CDASH | Clinical Data Acquisition Standards Harmonization |
| CDASHIG | CDASH Implementation Guide |
| CDISC | Clinical Data Interchange Standards Consortium |
| CDMS | Clinical data management system |
| CRF | Case report (or record) form |
| CRO | Contract research organization |
| CT | Controlled Terminology |
| CTCAE | Common Terminology Criteria for Adverse Events |
| CTUG | Controlled Terminology User Guide |
| CUI | Concept unique identifier |
| DDF | Digital data flow (initiative) |
| Define-XML | CDISC standard for transmitting metadata that describes any tabular dataset structure |
| Domain | A collection of observations with a topic-specific commonality about a subject |
| FDA | (US) Food and Drug Administration |
| GGG | (CDISC) Global Governance Group |
| GO | Gene Ontology standardized, structured vocabulary/dictionary |
| HL7 | Health Level Seven International |
| ICD | International Classification of Diseases |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| ISO | International Organization for Standardization |
| LOINC | Logical Observation Identifiers, Names, and Codes |
| MedDRA | Medical Dictionary for Regulatory Activities |
| NCI | (NIH) National Cancer Institute |
| NCI EVS | NCI Enterprise Vocabulary Services |
| NCIm | NCI Metathesaurus |
| NCIt | NCI Thesaurus |
| NIH | National Institutes of Health |
| ODM | (CDISC) Operational Data Model |
| PDF | Portable data format |
| PMDA | (Japan) Pharmaceuticals and Medical Devices Agency |
| QRS | Questionnaires, Ratings, and Scales |
| SAP | Statistical analysis plan (or protocol) |
| SDTM | Study Data Tabulation Model |
| SDTMIG | SDTM Implementation Guide (for Human Clinical Trials) |
| SEND | Standard for Exchange of Nonclinical Data |

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| | |
|---|---|
| SENDIG | SEND Implementation Guide |
| SI | Système International/International System of Units |
| SNOMED CT | Systematized Nomenclature of Medicine – Clinical Terms |
| TAUG | Therapeutic area user guide |
| TIG | Tobacco Implementation Guide |
| TLF | Tables, listings, and figures |
| TMF | Trial master file |
| UCUM | Unified Code for Units of Measure |
| USDM | Unified Study Definitions Model (DDF) |
| WHO | World Health Organization |
| WHODrug | WHO Drug Dictionary, global medicinal information dictionary |

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# Appendix C: References


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# Appendix D: Representations and Warranties, Limitations of Liability, and Disclaimers

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