

CDISC Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission. This page aims to provide readers a better understanding of what to expect, and not to expect, from a TA standard. See also the Overview of Therapeutic Area User Guides module freely available from the CDISC Online Learning Platform (<https://www.cdisc.org/education/online-training>).

Hyperlinked words on this page serve as cross-references to sections in the latter half of the page.

What to Expect from a TA Standard

A TA standard typically provides advice, examples, and explanations related to the use of the Clinical Data Acquisition Standards Harmonization (CDASH) model, the Study Data Tabulation Model (SDTM), and/or the Analysis Data Model (ADaM), and the implementation guides for each in the context of human clinical trials, within the context of the therapeutic area for which the guide is named.

Advice might include:

- Guidance on which domains and datasets to use in collecting and storing data
- Guidance on which variables to use to represent data items
- Guidance on the definition of non-standard (supplemental) variables, when the currently defined standard variables are insufficient for the task
- Guidance on relating data across domains and datasets

Examples might include:

- Annotated sample case report forms (CRFs) compliant with CDASH
- CDASH metadata associated with the sample CRFs
- Examples of SDTM datasets, with text describing the situational context and pointing out records of note
- Sample analysis datasets compliant with ADaM, with dataset-, variable-, and/or value-level metadata
- Table shells, mock reports, and diagrams illustrating the kinds of statistical analysis that can be performed based on the ADaM datasets

Explanations might include:

- Discussion of why and how the standards were applied as shown in the examples, including clinical background relevant to modeling decisions
- Diagrams ([concept maps](#)) that illustrate clinical processes, concepts, and/or relationships among data items
- Where applicable, links to proposed additions to [foundational standards](#) (e.g., proposed new domains or variables)

Additional content might include:

- Links to [Biomedical Concepts](#) for some core TA data
- Links to patient-oriented resources about the TA, so that readers may familiarize themselves with the TA
- A brief clinical discussion of some of the more central[†] concepts to the TA, to aid those handling the data (e.g., data managers, statisticians, programmers) recognize the concepts and apply CDISC standards appropriately

[†] To the best of the team's knowledge. As CDISC is not comprised of clinical experts, the selection of concepts to cover, and any clinical discussion related to them, relies heavily on team clinicians, clinical and regulatory guidelines, academic works, and input from contributing organizations. Clinical guidelines, articles, and other works consulted by the team during the development of a standard are cited where appropriate, and a full list of works cited and consulted is usually included in the appendices, under "References".

A TA standard does **not** include:

- Advice on what data to collect or how to analyze it
- Information and advice already included in the [foundational standards](#)
- Definitive [controlled terminology](#)
- Implementation advice or terminology for questionnaires, ratings, or scales
- Regulatory guidance or advice
- Clinical guidance or advice

Remember...



CDISC standards specify **how** to structure the data to support efficient data sharing for regulated clinical trials.

CDISC standards **do not** specify what data should be collected or how to conduct clinical trial protocols, assessments, or endpoints.

General caveats for TA standards

- TA standards are user guides. TA standards never replace or supersede the [foundational CDISC standards](#) or their implementation guides, nor should they be used as a substitute for any other CDISC standard.
- TA standards do not repeat content already published in another CDISC standard.
- TA standards are not and do not try to be exhaustive documentation of every possible kind of data that could be collected in relation to their particular therapeutic area or indication.
- TA standards generally try to focus on those concepts identified by clinical and regulatory experts as most common and/or of greatest interest to their therapeutic area or indication (provided that the concept is not already discussed in a more authoritative CDISC standard), but the inclusion of a concept in a TA standard is not a substitute for clinical or regulatory advice.
- The advice and examples presented in TA standards are influenced by ongoing internal standards development at CDISC. If a modeling approach seems inconsistent with another published standard, it may be a reflection of potential or upcoming changes to the standards.
- Examples in TA standards use CDISC [Controlled Terminology](#) where possible, but some values that seem to be controlled terminology may still be under development at the time of publication, or even especially plausible "best guess" placeholder values. Do not rely on any source other than the CDISC value set in the NCI Thesaurus (available at <http://www.cancer.gov/research/resources/terminology/cdisc>) for controlled terminology.
- As with all CDISC standards, TA standards are living documents. Over time, new standards are developed that impact others, science may change, etc. CDISC collects errata and other needed changes for each TA standard according to COP-001. When a number of significant changes are noted for a TA standard, and resources are available, all collected changes will be incorporated into an updated version of the standard.

What's in a name? "TA Standard" vs. "TAUG"

"TAUG" is the prefix for the short name (and file name) for TA standards. Working backwards: "G" stands for "guide", because the document's purpose is to function as a how-to; "U" stands for "user", which indicates the target audience (*users* of CDISC standards, as opposed to implementers); and "TA" stands for "therapeutic area", because the document focuses not on a specific foundational standard, but on a specific therapeutic area or indication. In short: "TAUG" stands for "therapeutic area user guide", an informative data standard that focuses on a specific therapeutic area.

What are Biomedical Concepts?

A Biomedical Concept (BC) is a unit of knowledge, created by a unique combination of the characteristics that define observations of real world phenomena in clinical research and/or healthcare, which represents biomedical knowledge that borrows from medical knowledge, statistical knowledge, BRIDG, and the CDISC standards. Metadata for BCs include the properties of the data items that are parts of the concepts, controlled terminology for those data items, and the ways in which the concepts relate to each other.

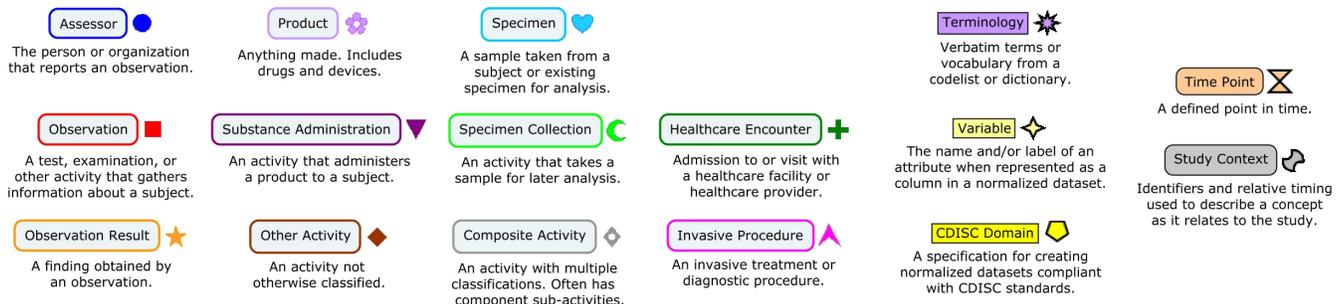
BCs are maintained in the Shared Health and Research Electronic (SHARE) metadata repository. SHARE is the authoritative source for BCs.

What are concept maps?

Concept maps are graphical tools for organizing and representing knowledge. They include concepts, usually enclosed in circles or boxes of some type, and relationships between concepts, indicated by a connecting line linking two concepts. Words on the line, referred to as linking words or linking phrases, specify the relationship between the two concepts. We define concept as a perceived regularity or pattern in events or objects, or records of events or objects, designated by a label.

– Alberto J. Cañas & Joseph D. Novak, *What is a Concept Map?* Read the rest [here](#).

The concept maps in CDISC standards use the following coding for the classification of concepts:



This classification is based on classes in the Biomedical Research Integrated Domain Group (BRIDG) model (available at: <http://bridgmodel.nci.nih.gov/>). These color-symbol pairs have been used to highlight kinds of things that occur commonly in clinical data and therefore give rise to common patterns of data. Concepts whose class does not have an assigned code have a thinner, black outline, and no accompanying symbol. These may include the subject of an observation, as well as characteristics, or attributes, of the coded concepts.

What is controlled terminology?

Within the context of CDISC standards, controlled terminology is vocabulary for which the meaning and (to some extent) the use have been pre-determined. You may have been in a conversation where two people used different definitions for the same word, to the increasing frustration and/or confusion of all: that kind of situation is what controlled terminology seeks to prevent. By enforcing the same definition for variables, values, etc. in data reporting, controlled terminology decreases the risk of semantic misalignment and facilitates the comparison of data between studies.

CDISC controlled terminology is a value set within the NCI Thesaurus, which can be found at: <http://ncit.nci.nih.gov>, and which is explained in more detail at: <https://wiki.nci.nih.gov/display/VKC/NCI+Thesaurus+Terminology>. CDISC controlled terminology is available at: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>.

What are foundational standards?

CDISC's foundational standards are the standards upon which all other CDISC products are based, hence the name "foundational". Each foundational standard focuses on a particular aspect of clinical data processing, such as collection or tabulation, and is intended to be applicable to that aspect regardless of TA or other form of clinical context. TA standards, on the other hand, are intended to be (in the fullness of time) applicable across any of the fields covered by the foundational standards, each within the context of their particular TA.

Who or what is...

... CD ISC?	The Clinical Data Interchange Standards Consortium is a global, non-profit standards development organization. CDISC develops standards for the transfer and storage of clinical data and metadata, including the TA standards discussed on this page and the foundational standards upon which the TA standards are based. For more information, see: http://www.cdisc.org .
... CF AS T?	The Coalition for Accelerating Standards and Therapies is a collaborative initiative that sponsors many of the TA standards. For more information, see: http://www.cdisc.org/cfast .
... C- Pat h?	The Critical Path Institute is the co-founder of the CFAST initiative, alongside CDISC, and an active contributor to many CFAST-sponsored standards. For more information, see: http://c-path.org/ .
... NC IE VS?	The U.S. National Cancer Institute' Enterprise Vocabulary Services is CDISC's partner in developing controlled terminology for use alongside CDISC standards. For more information, see: http://evs.nci.nih.gov/ .

For more information on these and other CDISC partnerships, see: <http://www.cdisc.org/cdisc-partnerships>.

A great many thanks to everyone who has contributed to the development of a therapeutic area standard. As with all CDISC products, each TA standard is truly an illustration of strength through collaboration.