The CDISC Terminology Teams support the terminology needs of CDISC foundational standards and therapeutic area standards. Depending on the scope and complexity of the new/modified terms to be developed, each term undergoes a 3-month development cycle. The team evaluates the requests received, incorporating as much as possible into the package for each quarterly release. Each quarter a public review comment period followed by a publication release. All approved controlled terminology is stored and can be accessed via the NCIt. CDISC also produces a diff file that programatically lists all changes from last quarter's release to the current quarter’s release: this file is also posted to the NCI Ftp site. CDISC updates codeable mapping files on the CT webpage on CDISC.org. CDISC communicates the update to their user community via list-serv and website updates.

Scope

The CDISC Terminology Teams support the terminology needs of all CDISC foundational standards and disease/therapeutic area standards. Depending on the scope and complexity of the new/modified terms to be developed, each term undergoes a 3-month development cycle. The team evaluates the requests received, incorporating as much as possible into the package for each quarterly release. Each quarter has a public review comment period followed by a publication release. All approved controlled terminology is stored on the NCI Ftp site. CDISC also produces a diff file that programatically lists all changes from last quarter’s release to the current quarter’s release: this file is also posted to the NCI Ftp site. CDISC updates codeable mapping files on the CT webpage on CDISC.org. CDISC communicates the update to their user community via list-serv and website updates.

Deliverables

- CDISC terminology teams develop quarterly updates to the CDISC terminology standards: SDTM, SEND, ADaM, CDASH, and Protocol. The CDISC Glossary team develops yearly updates to the Glossary terminology standard. All terminology sets are published in 6 formats: .xls, .txt, .html, OWL/RDF, .pdf, and .omd.xml.
- Development and maintenance of codeable mapping files, which are publicly reviewed and posted to the CDISC website.
- Development and maintenance of rule sets that outline terminology norms across all CDISC codelists and within individual codelists.
- Development and maintenance of the CT Implementation Guide.

Stakeholders/Constituency

- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Organizations specializing in Medical Devices and Diagnostics
- Contract Research Organizations & Consultants
- Academic Research Labs and Organizations
- Laboratories
- CDISC Therapeutic Area Teams
- CDISC Foundational Teams
- CDISC SHARE
- IT Vendors

Collaborations

NCI-EVS, SDS and subteams, Medical Devices team, PGx team, SEND and subteams, CDASH team, ADaM, CDISC, Therapeutic Area teams. Data Exchange Standards team, Global Governance Group, goRENI and Regenstrief Institute.

Operating Model

- There is an ongoing need to add or modify terminology for existing codelists to support CDISC user community requests as well as foundational and therapeutic area standards.
- All requests for new terms or modifications to existing terms are made through the New Term Request webpage: https://ncitermform.nci.nih.gov/ncitermform/?version(cdisc), which can also be accessed via the CDISC Terminology website.
- Most terminology sub-teams meet weekly for 1-2 hours weekly to discuss requests that come in from the New Term Request Page. Meetings are canceled if there is nothing to discuss. Meeting dates/stores are on this page: https://wiki.cdisc.org/x/iUjX.
- CT Meeting quorum is defined as at least 1 team lead plus 3 additional team members, not including NCI-EVS or CDISC personnel.
- New CT teams may be created as needed based on the needs of CDISC standards. Individual CT teams may be dissolved if they are no longer needed.
- CT teams adhere to the CT Guiding Principles: Guiding Principles