

1. Terminology Home on the CDISC Wiki (Access may be restricted to Controlled Terminology Team Members)

<p>Leadership Team</p> <ul style="list-style-type: none"> • Erin Muhlbradt, NCI-EVS • Jordan Li, NCI-EVS • Chris Gemma, CDISC <p>Team Leaders</p> <ul style="list-style-type: none"> • Lab - philip pochon, Anna Pron-Zwick • PK - Lacey Wallace, Jordan Li • General - Erin Muhlbradt • QRS - Jordan Li, Roberta Rosenberg • SEND - Craig M. Zwickl, Erin Muhlbradt • ECG - Jordan Li • Oncology - Erin Muhlbradt (SDS Subteam Liaison - Melanie Paules) • Device - Erin Muhlbradt (MDIG Subteam Liaison - Kit Howard) • Microbiology - Anna Pron-Zwick, Jordan Li • CV - Jordan Li, Amy Palmer • PGx - Erin Muhlbradt, (PGxIG Subteam Liaison - Christine Connolly) • Glossary - Helle Gawrylewski • Protocol Entities - Melissa Cook, Erin Muhlbradt • SDTM Domain Abbreviations - Chris Gemma • CT Relationships Team - Donna Sattler, Anthony Chow, Erin Muhlbradt • Flow Cytometry/Immunophenotyping Team - Craig M. Zwickl, Erin Muhlbradt • CT User Guide - Ward Puttemans, Anna Pron-Zwick, Erin Muhlbradt <p>GGG Liaisons</p> <p>Anna Pron-Zwick, Erin Muhlbradt, Jordan Li</p> <p>Therapeutic Area Liaison(s)</p> <p>Erin Muhlbradt, Jordan Li</p>
<p>Team Characteristics</p> <p>The CDISC Controlled Terminology program consists of more than 15 active terminology teams responsible for developing terminology to support CDISC foundational standards and therapeutic areas. These teams consist of terminology and subject matter experts, data and standards personnel from pharmaceutical, biologics and device companies, CROs, academic researchers, and regulatory authorities. The US National Cancer Institute's Enterprise Vocabulary Services (NCI-EVS) provides team leadership and management, adherence to terminology best practices, definition writing, subject matter expertise, terminology publication, and maintenance. CDISC terminology is incorporated as part of the NCI Thesaurus (ncit.nci.nih.gov).</p>

<p>Team Mission</p> <p>CDISC, in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS), supports the controlled terminology needs of CDISC Foundational and Therapeutic Area Standards. CDISC Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to regulators in CDISC-compliant datasets. CDISC Glossary seeks to harmonize definitions (including acronyms, abbreviations, and initials) used in the various standards initiatives undertaken by CDISC in clinical research. Glossary also serves the community of clinical researchers by selecting and defining terms pertaining to clinical research, particularly eClinical investigations, sponsored by the pharmaceutical industry or a federal agency.</p> <p>Terminology Development Cycle: The CDISC terminology teams follow a quarterly process for CDISC terminology updates. The CDISC Glossary team follows a yearly update cycle. New term requests and requests for changes come in through the CDISC new term request system (powered by NCI-EVS) and the CDISC terminology teams develop each request in the order received. Therapeutic area requests have priority over user requests. At a pre-determined timepoint, the package is closed and sent out for a four-week open, public review. Public review comments are addressed by CDISC CT teams and EVS does final QA/QC on the content before loading into NCIt. EVS generates the final, updated CDISC terminology files and posts the files on the NCI Ftp site. EVS also produces a diff file that programmatically lists all changes from last quarter's release to the current quarter's release; this file is also posted to the NCI Ftp. CDISC updates codetable mapping files on the CT webpage on CDISC.org. CDISC communicates the update to their user community via list-serv and website updates.</p>
<p>Scope</p> <p>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 EVS Ftp site and can be accessed via the CDISC website.</p> <p>CDISC staff coordinate the teams and maintain the membership through careful selection of volunteer experts who can contribute to its various sub-teams with their technical or therapeutic-based subject matter expertise. Volunteers can contribute by contacting the leadership team or any team lead.</p>
<p>Deliverables</p> <ul style="list-style-type: none"> • 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 odm.xml. • Development and maintenance of codetable 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.

<p>Stakeholders/Constituency</p> <ul style="list-style-type: none"> • 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
<p>Collaborations</p> <p>NCI-EVS, SDS and subteams, Medical Devices team, PGx team, SEND and subteams, CDASH team, ADaM team, SHARE team, Therapeutic Area teams, Data Exchange Standards team, Global Governance Group, goRENI and Regenstrief Institute.</p>
<p>Operating Model</p> <ul style="list-style-type: none"> • 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 here: https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc, which can also be accessed via the CDISC Controlled Terminology website. • Most terminology sub-teams meet weekly for 1-2 hours weekly to address requests that come in from the New Term Request Page. Meetings are canceled if there is nothing to discuss. Meeting date/times are stored on this page: https://wiki.cdisc.org/x/UJIX. • 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

