Terminology Home on the CDISC Website

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

<table>
<thead>
<tr>
<th>Leadership Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erin Muhlbradt, NCI-EVS</td>
</tr>
<tr>
<td>Jordan Li, NCI-EVS</td>
</tr>
<tr>
<td>Chris Gemma, CDISC</td>
</tr>
</tbody>
</table>

**Team Leaders**

- 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 Paulas
- 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 Connelly
- 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

**GGG Liaisons**

Anna Pron-Zwick, Erin Muhlbradt, Jordan Li

**Therapeutic Area Liaison(s)**

Erin Muhlbradt, Jordan Li

**Team Characteristics**

The CDISC Terminology program is a collaborative effort of over 200 members from various organizations that are responsible for developing terminologies that support the needs of the CDISC community. The program is organized into several sub-teams, each focusing on specific aspects of terminology development and maintenance.

**Team Mission**

CDISC, in collaboration with the National Cancer Institute (NCI), provides a framework for integrating terminology into clinical research. The program aims to support the development and maintenance of terminologies that are used across various clinical research domains. The mission of the Terminology program is to provide a comprehensive set of terminologies that are compliant with CDISC standards and are accessible to the research community.

**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

**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 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 dates/ times are stored on this page: https://wiki.cdisc.org/x /UIJX
- 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 dissolving if they are no longer needed.
- CT teams adhere to the CT Guiding Principles: Guiding Principles

**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 teams evaluate 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 website and can be accessed via the CDISC website.

**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 .odm.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.