### Leadership Team

- Erin Muhlbradt, NCI-EVS
- Jordan Li, NCI-EVS
- Chris Gemma, CDISC

### Team Leaders

- Lab - philipp 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, (PGxG 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

### GGG Liaisons

- Anna Pron-Zwick, Erin Muhlbradt, Jordan Li

### Therapeutic Area Liaisons(s)

- Erin Muhlbradt, Jordan Li

### Team Characteristics

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).

### Team Mission

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 clinical investigations, sponsored by the pharmaceutical industry or a federal agency.

### 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 time point, 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 NCI-EVS. EVS generates the final, updated CDISC terminology files and posts them on the NCI Ftp site. EVS 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. 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 EVEs Ftp site. EVS 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. CDISC updates codeable mapping files on the CT webpage on CDISC.org.

CDISC staff coordinate the teams and maintain the membership through careful selection of volunteer experts from NCI, CDISC, and the community at large. Volunteers can contribute by contacting the leadership team or any team lead.

### 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.