1. SEND Home on the CDISC Website
2. SEND Home on the CDISC Wiki (Access may be restricted to SEND Team Members)

SEND Leadership Team (SLT)

- Audrey Walker (Industry Leader) (a)
- William Houser (Advisor/Past Leader) (a)
- Ben Sefing (Future/Next Leader) (a)
- Lou Ann Kramer (CDISC Leader) (a)
- Dana Booth (CDISC Project Manager, Foundational Standards) (a)

SEND Leadership Team Extended (SLTX)

- Audrey Walker (Leader) (a)
- William Houser (Advisor, Past Leader) (a)
- Lou Ann Kramer (CDISC Leader) (a)
- Dana Booth (CDISC Project Manager, Foundational Standards) (a)
- Brian Argo
- Mary Jo Brucker
- Sue DeHaven (PhUSE Liaison)
- Marc Ellison
- Anthony Fata
- Robert Friedman
- Jamie Gilliam
- Joseph Horvath
- Christy Kubin
- Louis Norton, Advisor
- Debra Oetzman
- Dan Potenta
- Ben Sefing
- Erin Tibbs-Slone
- Michael Wasko (b)
- Fred Wood (b, Advisor)
- *one open seat* (b)
- FDA CBER Liaisons:
  - Virginia Hussong
  - Lisa Lin
- FDA CDER Liaisons
  - Jesse Anderson
  - Dave Epstein

a- CDISC TLC (Technical Leadership Committee) member

b- CDISC (Cross-team) Global Governance Group voting member

SEND Change Control Board (CCB)

- Jamie Gilliam (Leader)
- William Houser
- Lou Ann Kramer
- Louis Norton
- Debra Oetzman
- Audrey Walker
- Michael Wasko
- Fred Wood
- FDA Liaison: Patricia Brundage

Team Mission and Scope

The CDISC SEND team develops standards that support both the regulatory submission of nonclinical data as well as the operational use and exchange of nonclinical data throughout the industry.

This team is responsible for overall development and maintenance of the production SEND Implementation Guides (IGs) and their alignment with the SDTM.

SEND is one of the required standards for data submission to the FDA. Details on the requirements for the FDA are specified in the FDA's Data Standards Catalog for IND, NDA, ANDA, and certain BLA submissions. For more information, please visit the FDA Guidance on Standardized Data.

The SEND deliverables are available to the public at: www.cdisc.org/SEND.

SEND Subteams (leader)

SEND Controlled Terminology: Craig Zwickl

SEND Conformance Rules: Christy Kubin

SEND CCB: Jamie Gilliam

SEND for CBER: Lisa Lin, Sue DeHaven

Cell Phenotyping (Cross-CDISC team): Craig Zwickl, Erin Muhlbradt

Dermal / Ocular Toxicity : Brian Argo

Exposure : Debra Oetzman, Wenxian Wang

Genotoxicity (Gene Tox) : Michael Wasko

Immunogenicity Specimen Assessments: Robert Friedman, Alex Kistner, Anthony Fata

Pharmacokinetic Concentrations & Parameters: Marc Ellison

Safety Pharmacology: Christy Kubin

Developmental & Reproductive Toxicology : Mary Jo Brucker

Macro and Microscopic: Daniel Potenta, Joseph Horvath, Ben Sefing

Tumor Combinations: Charlotte Keenan

Tumor Findings: Daniel Potenta

For more details on SEND initiatives, please see the SEND Home Wiki page at: SEND Home

Stakeholders

- Regulatory Authorities
- Pharmaceutical Sponsors
- Nonclinical Research Scientists & Pathologists
- Contract Research Organizations
- Independent Consultants
- Information Technology Tool Developers
- Service Providers

Collaborations

The SEND Team maintains representatives on the many CDISC cross-team initiatives. SEND also maintains 2 - 3 seats on the CDISC governance.

The SEND team partners with the INHAND organization for pathology-related terminology (http://www.toxpath.org/inhand.asp).

SEND also has a strong presence on the FDA/PhUSE Computational Sciences Symposium (CSS) (http://www.phuse.eu/css), including several leadership positions and significant overlap in membership with the Nonclinical Topics working group.

Operating Model

- ***Core Team*** membership comprises all SEND members, with well over one hundred active members currently.
- ***Subteams*** are formed to manage long-term subject areas.
- ***Change Control Board (CCB)*** assesses and recommends action on changes requested regarding production SEND deliverables.
- ***SEND Leadership Team -*** sets direction for the team and is responsible to CDISC leadership for the SEND Team; consists of past, current, and future team leaders.

- ***SEND Leadership Team - Extended (SLTX)*** assists in setting direction, with representation at the CDISC TLC and the CDISC GGG (Global Governance Group).

- **Work-Streams,** when needed, are for all tasks that are not within the scope of the listed subteams and expected to have a clear start and end (ie, shorter term need). Work-streams are initiated by the CCB or SEND leadership.

- **Leadership Mentors** - To develop new leaders on the SEND team, an experienced SLTX member will co-lead or mentor a newer leader for any new Work-Streams. All Subteams and Work-streams are governed by the SLTX and all work is reviewed by the Core Team.
- **Business Integrators -** are individuals who have demonstrated expertise with alignment across all domains and are often needed to review key concepts early in their development. Such individuals will often be needed in specific sessions at F2F weeks. This includes the following individuals:

William Houser, Lou Ann Kramer, Christy Kubin, Louis Norton, Debra Oetzman, Ben Sefing, Audrey Walker, Mike Wasko, Fred Wood, Craig Zwickl

Meetings

- SEND Core Team meets monthly on Wednesdays for 90 minutes. Active members meet face-to-face at the FDA two times each year.
- SEND Leadership Team Extended (SLTX) - meets monthly on Wednesdays for 90 minutes (alternating bi-weekly with Core Team).
- SEND subteams and CCB meet biweekly.
- Work-streams meet as needed.