SEND Leadership Team (SLT)
Lou Ann Kramer (Leader)*
Fred Wood (Past Leader)*
Mary Jo Brucker
Jennifer Feldmann
Louis Norton
Troy Smyrnios
Peggy Zorn
Tim Kropp (FDA Point Person)
*CDISC TLC (Technical Leadership Committee) member

SEND Change Control Board (CCB)
Brandy Harter (Leader)
Jennifer Feldmann
Louis Norton
Audrey Walker
Fred Wood
Craig Zwickl
Peggy Zorn
(Lou Ann Kramer, SEND Leader)

SEND Sub-teams
SEND Controlled Terminology
Peggy Zorn
Reproductive Toxicology (and Pilot)
Mary Jo Brucker
Jennifer Feldmann
William Houser
Debra Oetzman
Fred Wood
SEND IG
Brandy Harter
Jennifer Feldmann
SEND IG
Peggy Zorn
FDA CDER Pilot Liaison
Lauren Murphree-Mihalck

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

This team is responsible for overall development and maintenance of the production SEND IG (Implementation Guide) and its alignment with SDTM. SEND IG v3.0 was released in 2011 (available at: www.cdisc.org/SEND). This version supports single-dose and repeat-dose general toxicology and carcinogenicity studies.

SENDIG v3.0 is the preferred standard of FDA CDER for nonclinical study data and is included in the FDA’s Study Data Specifications (v1.6).

SEND Team Structure and Operations
- **Core Team** membership is open to all interested parties with over eighty-five members currently.
- **Sub-teams** formed to manage long-term subject areas
- **Change Control Board (CCB)** assesses and recommends action on changes requested regarding the production SEND IG.
- **SEND Leadership Team (SLT)** sets direction for the team, with representation from the CDISC TLC.
- **Work-Streams** initiated by the SLT and CCB for all tasks that are not within the scope of the aforementioned sub-teams and expected to have a clear start and end (ie, shorter term need).

SEND Work-Stream Leaders and Cross-team Integrators
When a task, issue, or group of issues is identified for a Work-Stream, by the SEND CCB, an experienced SEND member leads the Work-Stream and reports back to the CCB and Core Team until the topics reach closure.

- Reproductive Toxicology (and Pilot): Jennifer Feldmann, GET, Brandt Harter
- Safety Pharmacology: Jennifer Feldmann, Troy Smyrnios, Audrey Walker
- SEND IG: Peggi Zorn, Louis Norton
- FDA CDER Pilot Liaison: Lauren Murphree-Mihalck

Collaborations and Meetings
The SEND Team maintains two representatives on the CDISC cross-team governance in addition to a long-standing practice of working closely with the CDISC SDS team and CDISC Controlled Terminology. This year, SEND has joined the CDISC SHARE effort.

- SEND Core Team meets bi-weekly on Wednesdays for 90 minutes
- SEND sub-teams meet bi-weekly on alternating weeks from Core
- Work-streams and CCB meet as needed
- FDA/PhUSE CSS WG6 subteams meet regularly via teleconference

2014 Deliverables
- SEND IG v3.1 drafted and vetted through the CDISC governance process, including public comment period
- SEND IG v3.1 comments addressed and production-ready version published
- Controlled terminology required for v3.1 vetted through the CDISC CT processes, included in production package
- Piloting of Reproductive Toxicity phase 1 study data
- Piloting of Safety Pharmacology study data

Stakeholders/Constituency
- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Contract Research Organizations & Consultants
- Information Technology Tool Developers & Service Providers

Upd July 2014