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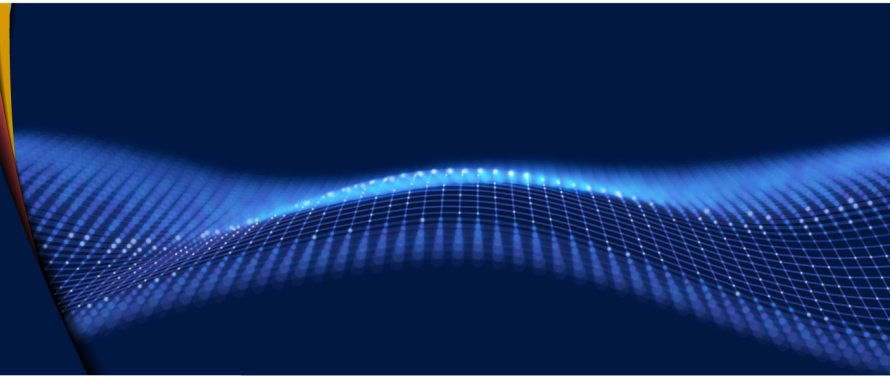
2022
CHINA
INTERCHANGE
29-30 JULY | VIRTUAL EVENT



State of the SEND Standard

Lou Ann Kramer, SEND Team CDISC Leader

Meet the Speaker

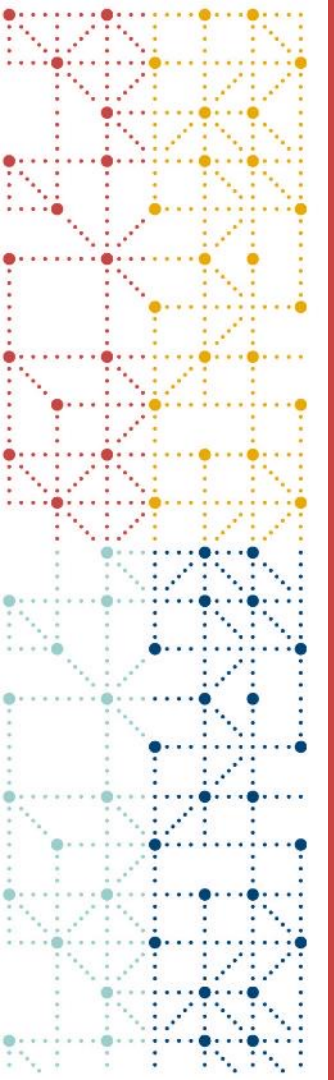
Lou Ann Kramer

Title: Senior Director, Standards Development

Organization: CDISC

Lou Ann Kramer has over 30 years' experience at a major pharmaceutical company where she held roles in IT, early phase Clinical, and managed non-clinical submissions for over a decade. Just prior to joining CDISC she was a consultant for clients around the globe at a SEND software company. Lou Ann led the CDISC SEND team for 15 years during which the team delivered four new releases of the SEND IG (SENDIG v3.0, v3.1, v3.1.1, and SENDIG-DART v1.1)

As a full-time CDISC staff member she continues to work with the SEND team, leads the CDISC Conformance Rules Operational Group and multiple collaborative forums with FDA. She also participates in PHUSE Nonclinical. Lou Ann has a BS in Computer Science and BS in Mathematics.

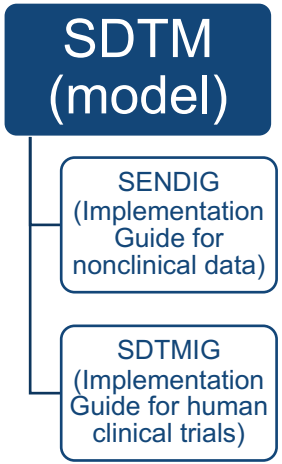


Agenda

1. News from the SEND Team
    - What is important now (development plans)
    - What is on the horizon
2. Scope of the next major SENDIG release
    - Domains New to SEND
    - Endpoints and Concepts New to SEND
    - New Appendix
    - JIRA Issue Tracking

News from the SEND Team

What is SEND?

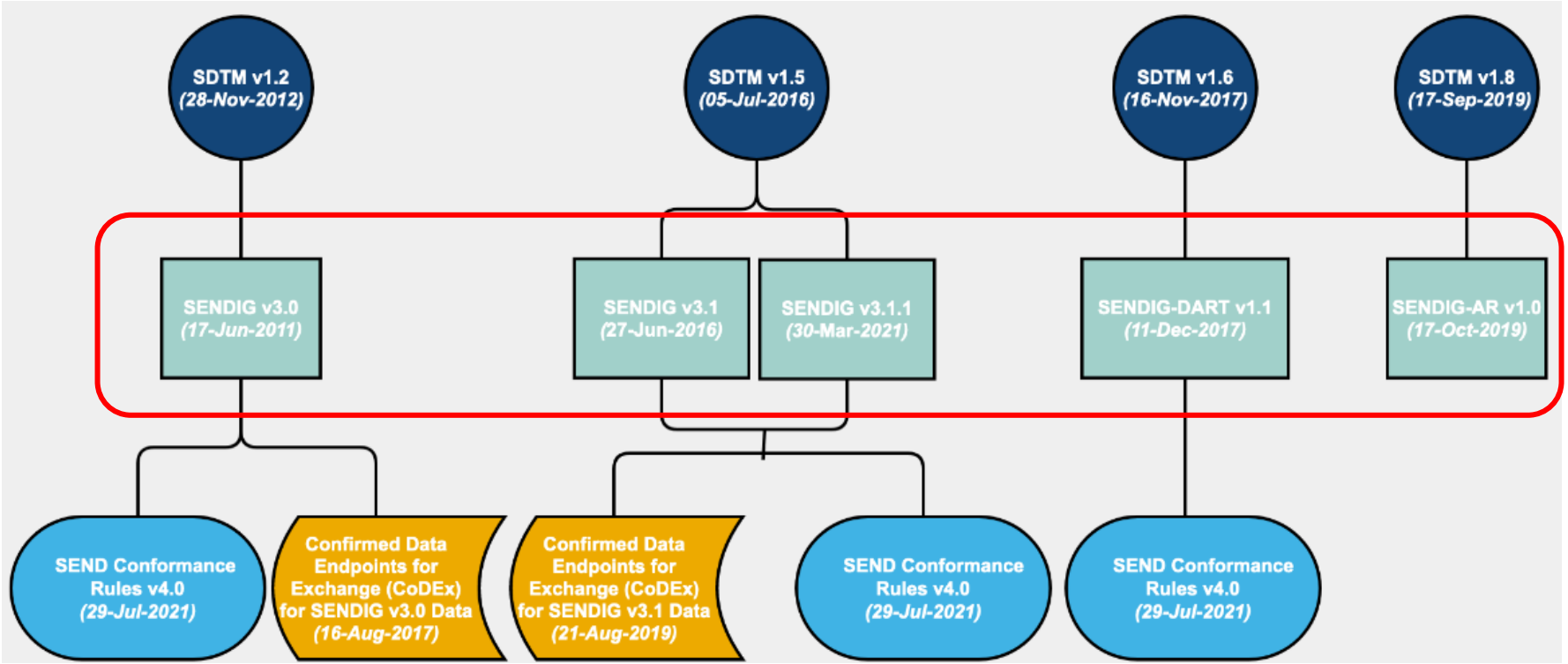


Standard for Exchange of Nonclinical Data (SEND)

- is one implementation of the SDTM (Study Data Tabulation Model)
- is described in the SEND Implementation Guide (SEND IG)
- is developed by the CDISC volunteers on the SEND Team
- is owned and maintained by CDISC, and made available to the public here: www.cdisc.org/send
- Is a required standard in submissions to the US FDA
- integrates with the eCTD Module 4 Tabulations folder for regulatory submission

Published SENDIG Versions

https://www.cdisc.org/standards/foundational/send



Current Development

- SENDIG-DART v1.2, Q2 2023
- SENDIG-GeneTox v1.0, Q3 2023
- Next major release of SENDIG, 2024

Deliverables for each release:

- Conformance Rules (next version is v5.0)
  - Cumulative document including rules for all SENDIG versions
  - Introduces new rules for SENDIG- DART v1.2 and SENDIG-GeneTox v1.0
- Pilot Datasets ***NEW***
  - Prior to IG publication: Proof of Concept data sets for public use (conceptual data for tool and database development)
  - After IG publication: Fit for Use data sets for public use (anonymized real data to assess usability of data and tools)
- Content in CDISC Library for CDISC member organizations to access standards metadata and controlled terminology

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Future Development *Considerations*

- Safety Pharmacology CNS studies, data endpoints
- Dermal Ocular studies, data endpoints
- Additional DART study types, data endpoints
- Additional Genotoxicity study types, data endpoints
- Improving the metadata presentation (aligning with SDTM v2.0 metadata presentation)
- Improving current IGs (clarify content and standardize terminology)
- Representing test article relative findings in a standard format
- Continuing to work more effectively as a team in a more “remote” world

On the horizon: topics that inform the future of SEND

- Analytical power of the data, reducing variability
  - Further realizing the power of cross-study, cross-class analyses
  - Expanding controlled terminology would significantly improve the standardization of data
  - Even standardization of the study protocol and report are being discussed for future (in and outside of CDISC)
  - Higher quality in data increases the power of searches as well
- Translational Research based on SEND
- Interest in In Vitro test data

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The next major release of SENDIG

Domains New to SEND

- Pharmacokinetic Input
- Scoring Scales
- Cell Phenotyping
- Immunogenicity Specimen Assessments
- Ophthalmic Examinations
- Procedural Agents (under consideration)

Deprecation of the following domains:

- Tumor Findings (TF) domain
- Body Weight Gains (BG) domain

Examples of Endpoints and Concepts New to SEND

- Improved handling of result modifiers, - - RESMOD (MA, MI)
- Sexual maturity data (MI)
- Reproductive cycle phase data (MI)
- Anti-mortem organ measurements (OM)
- Targeted staining assessment (MI)
- MIDETECT – time in days until tumor detection (MI)
- Planned concentration and units (EX)
- Planned volume and units (EX)
- TCNTRL with controlled terminology (TX)
- Multiple baseline variables (findings domains)
- Standardized exchange of treatment vehicle component information (TS)
- Controlled terminology for CLRESCAT variable (CL)

JIRA Issue Tracking (>500 Items)

Examples:

- Clarifications/Corrections
- Deprecation of VISITDY
- Clarification of guidance for use of timing variables
- New Appendix to consolidate references to Define XML specifications
- New parameter codes (TS, TX)

New Appendix – Confidently Modeled*

A new appendix will be added to the implementation guide describing the data the CDISC SEND team considers to be confidently modeled for exchange.

The intent is to eliminate the need for a separate document, such as the CoDEx documents that exist for SENDIG v3.0, v3.1, and v3.1.1

*Name of appendix has not yet been determined

Thank You!