

# 2026 CDISC SEND Spring F2F Public Meeting





# Today's Agenda

- Welcome
- Current State of SEND (SEND Leadership Team)
- FDA Presentations (Benita Dharmaraj, Stephanie Leuenroth-Quinn and Lina Cong)
- Break
- PHUSE Update (Michael DeNieu, Susan DeHaven and Kevin Snyder)
- TRTVDESC Trial Summary Parameter – Use and Importance (Bill Houser)

# Housekeeping

- Audience will be on mute during this session.

Shhhh...



- Please submit via Q&A in the Teams App.

Questions?



- First, restart Teams.
- Second, check your local internet connection strength

Audio Issues?



- A recording of this webinar and slides will be available on Public Webinar Archive on CDISC website.

Recording



# The Current State of SEND

CDISC SEND Leadership Team  
22 April 2026





# Agenda

1. SEND Implementation Guide v4.0 Status
2. Controlled Terminology Update
3. SEND Scope Update
4. What Is Next for SEND

# CDISC SEND Industry Leadership



**Christy Kubin**

Associate Director, SEND  
Charles River Laboratories  
SEND Industry Colead



**Keith Moseley**

Supervisor, SEND  
Labcorp  
SEND Industry Colead



**Erin Tibbs-Slone**

SEND Senior Specialist  
Charles River Laboratories  
SEND Industry  
Incoming Colead



**Chloe Bosworth**

SEND Specialist II  
Inotiv  
SEND Industry  
Incoming Colead

Emeritus leads not pictured: William Houser (Bristol Myers Squibb)  
Audrey Walker (Charles River Laboratories)  
Ben Sefing (Merck)



## Current Status of SENDIG v4.0



# SENDIG v4.0 Public Review

- Ended on April 06, 2026.
- The SEND Leadership Team would like to extend our sincere gratitude to all stakeholders who participated in the public review of SENDIG v 4.0.
- The feedback provided during this period is invaluable to ensuring that our final standards are both robust and practically applicable. We recognize the significant time and effort required to review these materials, and we appreciate your commitment to advancing SEND through this collaborative process.





# Public Review Comments

335 comments were received:

- 323 SENDIG comments
- 6 POC Dataset comments
- 6 Conformance Rule comments

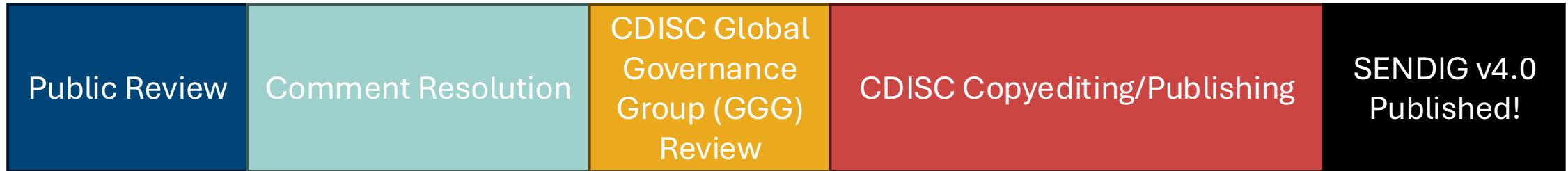


# Next Steps for SENDIG v4.0

Targeted Publication: **Q4 2026**



Current Status



\*Note that SDTM and SEND must publish at the same time, and SDTM will follow the same process of comment resolution, CDISC GGG review, CDISC copyediting/publishing and publication.

## SENDIG v4.0 Publication Includes:

- SEND Implementation Guide (SENDIG v4.0)
- SENDIG v4.0 Proof of Concept Datasets
- SEND Conformance Rules (v6.0)
- SDTM v3.0





## Next Steps for SENDIG v4.0

- The SEND team is working to resolve all public review comments received.
- We are also coordinating with the SDTM team as they work through their public review comments.





# Controlled Terminology Update

## SEND Controlled Terminology (CT)

- Latest version of SEND CT was published March 27, 2026.
- This version of CT contains the codelists needed for SENDIG v4.0.
- Several CT codelists have been replaced with new CT codelists in SENDIG v4.0.
- Several CT codelists have been added in support of new concepts or to provide standardization for existing concepts.



## SENDIG v4.0 CT

- 32 New Codelists developed for SENDIG v4.0 to support new domains and to create SEND-specific lists previously shared with SDTM.
  - EGFINDRS
  - GLPTYP
  - HOUSEGRP
  - MICAT
  - MIFINDRS
  - MIMETH
  - MIRESMOD
  - PCSTRESC
  - SEGLEAD
  - SEGMETH
  - SEGSEV
  - SEGTEST
  - SEGTESTCD
  - SLBCAT
  - SNVCAT
  - SNVMETH
  - SNVTSTCD
  - SNVTST
  - SOETSTCD
  - SOETST
  - SSKCAT
  - SSKTSTCD
  - SSKTST
  - SSPMETH
  - WATER
  - WTRDLVRY
  - TRTVATT
  - SOECAT
  - ROETYPRS
  - SPOSIT
  - PKCAT
  - SNVSCAT
- 65 changes to CDISC submission values, definition changes, and/or additions of synonyms and/or removals for existing terms/codelists.





## SEND CT and IG Versions

- With the creation and addition of new codelists, only terminology versions published after March 2026 will be appropriate for use with SENDIG v4.0.
- The ReadMe tab in the SEND Terminology file lists the SENDIG versions supported by that CT publication.

The controlled terminology in this spreadsheet supports the Standard for the Exchange of Nonclinical Data Implementation Guide (SENDIG v3.0, SENDIG v3.1, SENDIG v3.1.1, and SENDIG v4.0), the SEND Developmental and Reproductive Toxicology Implementation Guide (SENDIG-DART v1.2), the SEND Animal Rule Implementation Guide (SENDIG-AR v1.0), and the SEND components of the Tobacco Implementation Guide (TIG v1.0). It represents all SEND controlled terminology developed and in production to date as well as specific SEND codelists that are in production to date. Additional terminology will be developed on an ongoing basis to support all CDISC standards. Other future additions to the SEND terminology set will be handled via the terminology change request and maintenance process.





## SEND CT and IG Versions

- To maintain backwards compatibility, codelists that were replaced are not removed from the terminology.
- When implementing SENDIG v4.0, attention will be required to ensure the correct codelists are applied and terms selected.





# SEND Scope Update



## SENDIG v4.0 Scope

Comprehensive Appendix detailing the scope of SENDIG v4.0.

This replaces both the scope statement present in previous implementation guides and the Confirmed Data Endpoints for Exchange (CoDEx). This information is now all in one document.

Clarifies which studies and study endpoints are considered confidently modeled for exchange using SENDIG v4.0.

Information is organized into three sections:

- Study Designs and Study Types
- Endpoints
- Experimental Design Concepts and Additional Domains



## Studies confidently modelled for SENDIG v4.0

- For a study to be considered confidently modelled for SEND v4.0, more than just the overarching study type should be considered.
- Even though a study may be considered as in scope for SENDIG v4.0, the usefulness of the dataset is dependent upon the endpoints that are confidently modelled.
- Study designs/endpoints related to DART or Animal Rule are not in scope for SENDIG v4.0 exclusively. See the SENDIG-DART and SENDIG-AR, respectively.



## Study Designs and Study Types

- This subsection has been presented in a manner that mimics the CT codelists for easier understanding.
- A key is used to identify if each study design and study type are confidently modelled for SENDIG v4.0
- Notes/comments are supplied against study types where additional information may be needed for clarity.



# Endpoints

- **This is not an exhaustive list.** The CDISC team have not evaluated all available endpoints.
  - Any endpoint not listed in this document has not been evaluated, and as a result it cannot be confirmed as confidently modelled for SENDIG v4.0.
- Within the endpoint's tables, links to example pages have been included to demonstrate some use cases.
- Decision tree has been included to aid in immunology data placement for IS, CP and LB endpoints.
- Notes/comments are supplied against endpoints where additional information may be needed for clarity.



# Experimental Design Concepts and Additional Domains

- Contains information surrounding Special-purpose, Intervention, Events, Trial Design, Relationship and Study References domains.
- Experimental design concepts that are not yet designated as modelled may still be successfully exchanged if the preparer and receiver agree upon the modelling.
- Within the table links to example pages or corresponding appendix within the SENDIG have been included.
- Notes/comments are supplied against domains where additional information may be needed for clarity.





# What is Next for SEND?



# SEND Survey: Shape the Future of CDISC SEND Standards

- Survey to stakeholders to request feedback on 19 requested SEND projects.
- Closed on March 6, 2026.
- Thank you to all participants!
  - 64 respondents
  - Representatives include Sponsors, CROs, Software/Service Providers, Government/Regulatory Agencies, Consortia

## Survey: Shape the Future Direction of CDISC SEND Standards Development

Dear Nonclinical Stakeholders,

The CDISC SEND Team is requesting your expertise to support the prioritization of the next projects for Standard for Exchange of Nonclinical Data (SEND) development. This is your opportunity to influence the evolution of CDISC SEND standards.

By providing your input, you help ensure that future development efforts prioritize the most important technical challenges facing our industry today. While final project selections will be determined using a combination of factors, your feedback ensures that stakeholder needs are represented in these deliberations.

Please review the project descriptions below and rate their importance to you using a scale where 10 indicates the project is the highest priority and should be worked on immediately and 1 indicates the project is not a priority and should not move forward. A rating of 0 indicates you have no opinion about the project.

**Please submit your priority ranking by 06 Mar 2026. Thank you for your time and for contributing to the continued improvement of CDISC nonclinical data standards.**

## List of Projects:

1. Biologic Endpoints and Study Types
2. Complement Analysis Examples
3. Complex Split Study Designs
4. CVM Studies
5. Genomic Findings (GF) Domain
6. In Vitro/Ex Vivo for Genetox/Safety pharm/Dermal/Ocular
7. In vivo for Genetox
8. Integrate DART/Multi-phase Studies
9. Modeling Efficacy in SEND
10. Modeling for TDAR, KLH, etc.
11. Pharmacodynamic Study Design
12. Redesign CL Domain
13. Secondary Pharmacology Data Standardization
14. Studies With Animals As Own Control
15. Surgical Studies
16. Test Article Treatment Relevance
17. Treatment vehicle full scope
18. Virtual Controls
19. 360i and USDM





## Project Selection:

Survey results are being reviewed and analyzed. These results will be used in conjunction with other factors for the final selection of projects.

Key stakeholders such as FDA's feedback on priorities will be considered.

CDISC priorities will also shape the selection of projects.





## Next Steps:

Selected projects will be announced.

Project charters with defined scope will be created.

New teams will be formed and a call for members will be issued.

There will be opportunities for team leads and team participants. Expertise needed will include CDISC modelling and scientific expertise.

Team deliverables and timelines will be established.





**Thank you!**

**And Thank You to the Volunteers  
who have made this possible!**

**Become a volunteer!**  
**[www.cdisc.org/volunteer](http://www.cdisc.org/volunteer)**

