

SENDIG v4.0 Public Review

CDISC SEND Leadership Team
4 March 2026





Agenda

1. SEND Implementation Guide v4.0
2. SENDIG v4.0 Proof of Concept Datasets
3. SEND Conformance Rules v6.0

Housekeeping



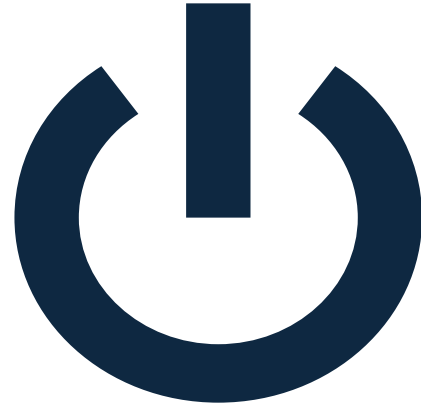
You will remain on **mute**

Housekeeping



Submit questions at any time via the Q&A section on your Teams app

Housekeeping



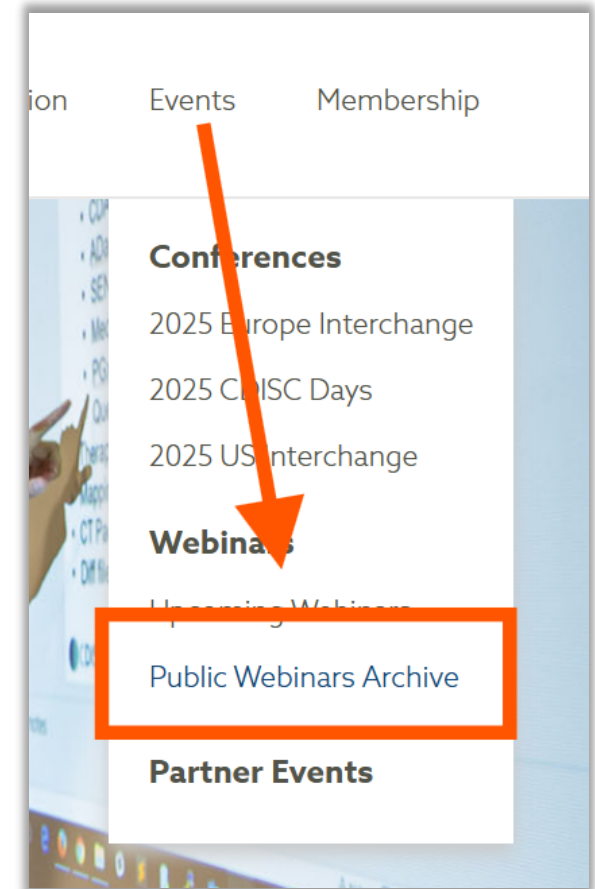
Audio Issues?

First, close and restart your Teams App
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Housekeeping



Webinar Recording



A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

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SENDIG v4.0 Public Review Includes:

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



SEND Implementation Guide (SENDIG v4.0)

Background and Overview

- SENDIG v4.0 - major revision to previous version (SENDIG v3.1.1).
- Result of years of work, some portions going back over a decade.
- The project scope is extensive and includes the addition of both new study types and new endpoints.



Section 4: Assumptions for Domain Models

- Rewritten and reorganized to provide clarity and decisive guidance.
- Additional sections were added to better organize information.
- New information was added to provide implementation guidance on topics that apply to more than one domain.
- In general, conformance rules that apply to multiple domains are explained in Section 4 to ensure the implementation guidance and context is clear.





Domain Tables

An introductory table has been added to provide key information about each domain.

The domain table structure has been updated to provide clearer, more granular information.

- The old "Controlled Terms, Codelist, or Format" column has been split into three columns: "Codelist", "Allowed Controlled Terms", and "Format".
- The old "CDISC Notes" column has been split into two columns: "Notes" and "Examples".

Columns for "Variable Group", "Root Variable C-code", and "Root Variable Definition" have also been added.



Domain Specification Updates

Old Structure

5.1.1 Demographics – DM

dm.xpt, Demographics - Special-Purpose Domains. One record per subject, Tabulation.

New Structure

DM – Overview

This domain contains essential demographic information that describes each subject in a nonclinical study.

| | |
|------------|---|
| File Name | dm |
| Label | Demographics |
| Class | Special Purpose |
| Definition | A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical or nonclinical study. One record will exist for each subject. |
| Structure | One record per subject. |
| Purpose | Tabulation |

Domain Specification Updates

Old Structure

| Variable Name | Variable Label | Type | Controlled Terms, Codelist, or Format | Role | CDISC Notes | Core |
|---------------|----------------|------|---------------------------------------|------|-------------|------|
|---------------|----------------|------|---------------------------------------|------|-------------|------|

| Variable Name | Variable Label | Type | Codelist | Allowed Controlled Terms | Format | Role | Variable Group | Root Variable C-code | Root Variable Definition | Notes | Examples | Core |
|---------------|----------------|------|----------|--------------------------|--------|------|----------------|----------------------|--------------------------|-------|----------|------|
|---------------|----------------|------|----------|--------------------------|--------|------|----------------|----------------------|--------------------------|-------|----------|------|

New from SDTM

New Structure

Section 3.1.1 provides detailed explanation on the content of each column.



SENDIG v4.0 Controlled Terminology

Several Controlled Terminology (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.

In these cases, the SENDIG v4.0 public review version may not have the most up to date CT codelist name in the Codelist column of the domain table. The Codelist column will be updated with the link to the correct CT codelist once a version of Controlled Terminology is published that includes that codelist (tentative publication March 2026).*

The Codelist column update will occur prior to the publication of SENDIG v4.0.

*There is no need to enter JIRA items asking to update the Codelist column.



SENDIG v4.0 Controlled Terminology

- 32 New Codelists developed for SENDIG v4.0 to support new domains and to create SEND-specific lists previously shared with SDTM.
 - EGFINDRS
 - GLPTYT
 - 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.



SENDIG v4.0 Controlled Terminology

- 9 Existing SDTM Codelists added for SEND
 - ITESTCD
 - ITEST
 - TSTOPOBJ
 - CPCAT
 - CELSTATE
 - CPTTESTCD
 - CPTTEST
 - TESTCOND
 - METHOD
- New terms to support SENDIG v4.0 added to 12 existing SEND codelists.
 - FWTESTCD
 - FWTEST
 - MIRCP
 - NONNEO
 - STSPRMCD
 - STSPRM
 - MATESTCD
 - MATEST
 - MITESTCD
 - MITEST
 - SDOMAIN
 - TKDESCRS





New Domains for SENDIG v4.0

Existing SEND Findings Domains:

- GV (Genetic Toxicology In Vivo Test Results)

Findings Domains New to SEND:

- CP (Cell Phenotyping)
- IS (Immunogenicity Specimen Assessments)
- NV (Nervous System Tests)
- OE (Ophthalmic Examinations)





New Domains for SENDIG v4.0

Findings Domains New to SDTM for SEND:

- PI (Pharmacokinetics Input)
- SK (Skin Test Results)

Study References Domains New to SDTM for SEND:

- SX (Scoring Scale)

Relationship Domains New to SDTM:

- NS-- (Non-Standard Variables)





New/Modified Variables in Existing Domains

Variables Promoted to Standard from SUPPQUAL:

- --CALCN: Added to LB
- --RESMOD: Added to CL, MA, MI
 - Will have Controlled Terminology for MI domain only.

Variables New to SDTM for Nonclinical Use:

- MASSID: Added to CL, MA, MI, PM
- --ROEBE: Added to BW, CV, EG, LB, OM, RE, VS
- --ROELNM: Added to BW, CV, EG, LB, OM, RE, VS
- --ROETYP: Added to BW, CV, EG, LB, OM, RE, VS

Variables New to SDTM:

- AGERLO, AGERHI: Added to DM
- --RSCNT: Added to EG



New/Modified Variables in Existing Domains

Existing SDTM Variables Added to Domains:

- ETCDD: Added to Findings Domains
- ELEMENT: Added to Findings Domains
- FOCID: Added to PM
- --ANTREG: Added to PC, PP
- --CAT: Added to CV, MI, RE
- --DETECT: Added to MI
- --DIR: Added to EX
- --DUR: Added to LB
- --ENDY: Added to SE
- --ENINT: Added to LB, VS
- --FAST: Added to EX
- --GRPID: Added to EX, TX
- --LAT: Added to CV, EX, PC, PP, RE
- --LOBXFL: Added to BW, CV, EG, LB, OM, RE, VS
- --LOC: Added to CV, RE
- ---LLOQ: Added to LB
- --METHOD: Added to OM, VS
- --OCCUR: Added to EX
- --REASOC: Added to EX
- --RECID: Added to CL, MA, MI, PM
- --REPNUM: Added to CV, EG, RE, VS
- --RSTIND: Added to CV, EG, RE, VS
- --RSTMOD: Added to CV, EG, RE, VS
- --SCAT: Added to CV, EG, MI, RE
- --SEV: Added to EG
- --STDY: Added to SE
- --STINT: Added to LB, VS
- --TSTDTL: Added to OM, PC, SC
- --ULOQ: Added to LB, PC



New/Modified Variables in Existing Domains

Other Variable Updates:

- --LOC updated to --RESLOC in CL and PM



Deprecated Domains:

- BG (Body Weight Gain)
- TF (Tumor Findings)
- SUPP-- (Supplemental Qualifiers)

Variables Removed from the SENDIG:

- | | |
|------------|------------|
| • AGETXT | • LBTOX |
| • DDRESCAT | • LBTOXGR |
| • EGREFID | • SEUPDES |
| • EGXFN | • SITEID |
| • EXDOSFRQ | • TABRANCH |
| • LBNRIND | • TATRANS |
| • LBORNRHI | • VISITDY |
| • LBORNRLO | • --BLFL |
| • LBSTNRC | • --BODSYS |
| • LBSTNRHI | • --DRVFL |
| • LBSTNRLO | • --EVLINT |



Trial Summary and Set Codes

A new appendix was added to detail the use of Trial Summary and Set codes.

Provides more detailed guidance on the population of parameters including:

- Type
- Format
- Codelist
- Allowed Controlled Terms
- Inclusion Criteria
- Allow Multiple Rows
- Notes





Multi-domain examples

Examples that include multiple domains and demonstrate how the domains work together.

Examples include:

IS, CP, and LB

PC, PP, and PI

CL, PM, MA, MI, and RELREC

OE, SK, and NV with SX domains





SENDIG v4.0 Scope

Replaces 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



Define-XML Document

Information regarding the CDISC Define-XML Document and its relationship to SENDIG v4.0 has been consolidated into one appendix.

Information includes:

- Study-level Metadata guidance
- Dataset-level Metadata guidance and examples
 - Keys guidance and examples
- Variable-level Metadata guidance for Codelists, Origin Types, Comments for SEND and Methods
- Value-level Metadata examples

Revision History

Lists significant changes from SENDIG v3.1.1 to SENDIG v4.0.

Significant changes include:

- Addition of domains, assumptions, variables, and examples
- Modeling of new concepts
- Removal of content
- Extensive rewrites of implementation guidance

Types of changes are categorized as:

- Added
- Updated
- Moved
- Removed
- Revision history is organized into 5 sections:
 - General Changes
 - Non-Domain Section Changes
 - New and Deprecated Domains
 - New, Removed, and Updated Variables
 - Specifications, Assumptions, and Examples Updates





SENDIG v4.0 Proof of Concept Datasets

SENDIG v4.0 POC

- POC datasets provide an idealized example of the SENDIG v4.0 standard applied to specific study scenarios.
- POC datasets are examples and are not a source for implementation guidance.
- FDA (CDER/CBER) is a key stakeholder and has provided feedback on the POC datasets as a part of the development process.



SENDIG v4.0 POC Datasets

- General Toxicity – Small Molecule
- General Toxicity – Gene Therapy
- General Toxicity – Vaccine Adjuvant
- Safety Pharmacology – FOB
- Safety Pharmacology – Cardiovascular
- Carcinogenicity
- Dermal
- Ocular



SENDIG v4.0 POC Content

Study designs were chosen to illustrate SENDIG v4.0 content such as the addition of new data, the use of new controlled terminology, and the use of new variables.

- New domains (CP, GV, IS, NV, OE, PI, SK, SX)
- New variables (AGERHI, AGERLO, --LOBXFL, --ROEBE, --ROELNM, --ROETYP, --CALCN, --RESMOD, MASSID)
- New PARMCDs (ADJUVCOM, ADJUVNM, PLPSTRG, PLPSTRGU, PLVOLLV, PLVOLLVU)
- New MITEST values
 - Targeted Histologic Staining Exam, Qual
 - Sexual Maturity Microscopic Exam, Qual
 - ReproCycle Phase Microscopic Exam, Qual
- New CT codelists (EG)

SENDIG v4.0 POC Content

There are also examples of important new or updated SEND concepts including:

- Use of TXGRPID, allowing for multiple versions of the same TXPARAMCD in the TX
- Use of Structured Vehicle Description (TRTVDESC), supporting cross study analysis and potential data re-use
- Examples of adjuvant dosing, co-administered dosing, delimited values, EXFAST and other EX concepts
- Use of MASSID and MIDTECT on a carcinogenicity study
- Use of --RECID in RELREC
- Use of element baseline and ETCD/ELEMENT on a Latin Square study design
- Inclusion of scored data and the use of the scoring scale domain
- Define files for each POC dataset
- Example tumor.xpt generated from SEND data*

* CDISC does not provide formal guidance for the generation of the tumor.xpt. This is only an example showing how one *might* use SEND datasets to produce this file.



SEND Conformance Rules (v6.0)



SEND Conformance Rules Catalog v6.0

- The rule catalog contains rules for all published SEND implementation guides.
- For the purposes of this public review, please concentrate your comments on the new SENDIG v4.0 conformance rules.





SEND Conformance Rules Catalog v6.0

Rules are presented in the new harmonized format.

- Rule identification and versioning has been updated.
- Both success and failure criteria are included for each rule.





SENDIG v4.0 Conformance Rules

- 655 rules
- 142 rules were deprecated
- 463 new rules were created
- 192 rules are related to SENDIG v3.1.1 rules





Review Instructions

Submitting Comments

Public Review closes **06-April-2026**; targeted Publication: **Q4 2026**

- WIKI

- <https://wiki.cdisc.org/>
- The CDISC Wiki is a collaborative tool to share information relevant to the development and use of clinical research data standards. WIKI is built on Confluence. By creating a CDISC Wiki account and logging into the system, you are accepting our Terms of Use.

- JIRA

- <https://jira.cdisc.org/>
- Jira is an issue management system used for tracking comments on standards submitted from Staff, Volunteers, and the Public. It is also used for internal issue tracking of IT, and Project Management of Publications, Events, and Communication to name a few.

You only need **one account** to access both WIKI and JIRA

Submitting Comments – Best Practices

- Publication timeline is dependent on resolution of Public Review comments
- How you can help – provide specific, actionable feedback
 - Include section and subsection, if applicable
 - Be specific about proposed edits
 - Suggested wording, additions, or deletions
 - Identified gaps or inconsistencies
 - Clear recommendation for changes
 - Provide rationale for the proposed change where it may facilitate comment resolution

Clear, actionable comments increase the likelihood of the comment being addressed as intended



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