ALTASCIENCES

SEND

STANDARD FOR EXCHANGE OF NONCLINICAL DATA

The Standard for Exchange of Nonclinical Data (SEND) is an implementation of the CDISC Standard Data Tabulation Model (SDTM) for nonclinical studies. It defines a consistent format for presenting nonclinical data.

This standardized format enables more efficient data review while improving data quality, accessibility, and predictability.

SEND 3.0

Required for single and repeat-dose general toxicology and carcinogenicity studies starting on or after:

- December 17, 2016 – NDA, ANDA, and certain BLA submissions to CDER
- December 17, 2017 – IND submissions to CDER

SEND 3.1/3.1.1

Required for single and repeat-dose general toxicology, carcinogenicity, and cardiovascular and respiratory safety pharmacology studies starting on or after:

- March 15, 2019 – NDA, ANDA, and certain BLA submissions to CDER
- March 15, 2020 – IND submissions to CDER
- March 15, 2023 – IND, NDA, ANDA, and certain BLA submissions to CBER

Additional Study Types:

- *In Vivo* Micronucleus and Comet Assay studies starting on or after:
  - March 15, 2025 – IND, NDA, ANDA and BLA submissions to CBER

Altasciences helps you seamlessly apply the SEND standard to your data.

Our SEND specialists are active members and leaders within the CDISC SEND Consortium and PhUSE (Pharmaceutical User Software Exchange) nonclinical working groups. As industry contributors to the development of SEND standards, we stay at the forefront of evolving guidelines.

This allows us to proactively support our clients in navigating implementation challenges and maintaining compliance with changing standards.

To ensure your nonclinical data is successfully accepted, we provide:

- SAS Transport files (XPT format)
- Define file (XML format)
- Nonclinical Study Data Reviewer's Guide [nSDRG] (PDF format)

Additional SEND services include:

- Dataset generation in multiple formats (XPT, XML, and XLSX)
- Creation of Data Definition "Define" files, version 2.0 or 2.1 (Define-XML v2.0 or Define-XML v2.1)
- Validation and quality control review
- Interim and draft datasets available upon request
- Comprehensive datasets merged from multiple sources and data types
- Specific domains or whole studies for warehouse applications and legacy studies
- Creation of simplified TS.xpt files for submission

contact@altasciences.com | **altasciences.com**