ALTASCIENCES
PRECLINICAL SERVICES

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 which specifies a way to present nonclinical data in a consistent format.

The format enables more efficient review of nonclinical data, offering improved 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
- December 17, 2017 – IND submissions

SEND 3.1

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

- March 15, 2019 – NDA, ANDA, and certain BLA submissions
- March 15, 2020 – IND submissions

Altasciences can

help you

seamlessly apply the SEND standard

to your data.

Our SEND specialists are active members of the CDISC SEND Consortium and PhUSE (Pharmaceutical User Software Exchange) nonclinical working groups. As an industry leader and participant in the development of SEND standards, we continuously review trends and changes to the implementation guidelines to assist our clients with the challenges of adhering to the evolving standards.

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

- SAS Transport Files (XPT format)
- Define file (XML format)
- Study Data Reviewers Guide [nSDRG] (DOC format)

Additional SEND services include:

- Dataset generation in multiple formats (XPT, XML, and XLSX)
- Creation of Data Definition “Define” file version 2.0
- Validation and quality control review
- Interim 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.xpts for submission