SEND SOLUTIONS

Efficient. Enlightening. Trusted.

The Standard for the Exchange of Nonclinical Data (SEND) is the FDA electronic, standardized format[1] for submitting your nonclinical study data with increased efficiency. Plus, it's so much more. SEND delivers an enlightening new view of your nonclinical study data that enables you to gain fresh insights and a valuable research database while complying with the FDA regulations.

Efficient – Streamlining Your Submission

Streamline your FDA submission process and avoid delays in reaching your drug development milestones:

- Receive data in standardized SEND format – avoiding manual effort and risk of errors
- Easily confirm that study data and reports align before submission
- Achieve smoother FDA submissions that are streamlined and secure

Enlightening – Enabling Better Decision Making

View your SEND dataset with more flexibility to gain new insights and make better decisions:

- Analyze data within or between studies and against historical controls
- Easily confirm that study data and reports align before submission
- Identify trends and anomalies, and then take decisive action
- Visualize results for stakeholder communication and decision making
- Share and compare data more readily with partners

1. The Standard for the Exchange of Nonclinical Data (SEND) is the new FDA format for submitting your nonclinical study data. All carcinogenicity and toxicology submissions to the FDA for studies begun after December 17, 2016 must comply with this format.

EXPERIENCE THAT MATTERS

With Covance you get a proven SEND process, an experienced team and a partner uniquely positioned to help you comply with SEND requirements:

- Part of the CDISC SEND Consortium and FDA/PhUSE Working Group 6 developing the standards and controlled terminology
- Leading the way with a team of dedicated experts implementing SEND with clients since 2012
- Successfully delivering SEND today with more than 125 billion data points delivered and thousands of studies performed to date
- Validating the SEND process by submitting early pilot datasets to the FDA

COVANCE®
SOLUTIONS MADE REAL®

Easy. Expert. Prepared.

Easy – Securely Receive SEND

- Covance has implemented SEND using a suite of software tools including, Pristima®, SEND Savante™, and the Pinnacle 21 validator tool for high dataset integrity
- Your data arrives in SEND.XPT file format, can be opened with SAS Viewer software, and easily saved to spreadsheet format for viewing
- Receive your file transfer securely via FTP file transfer, or Covance StudyTracker®, which uses 128-bit Secure Socket Layers (SSL) – the highest level of encryption available

Expert – Advisors at the Ready

Ease into SEND and develop your standard operating procedures and your IT technical roadmap. Now, you have a team behind you – knowledgeable Covance SEND experts.

- Learn what's needed
- Share best practices
- Get help in developing your SEND implementation plan

Prepared- Comply with the Existing and Evolving Requirements

SEND v3.0 regulatory requirement effective 17th December 2016

- Single- and Repeat-Dose Toxicity
- Carcinogenicity

SEND v3.1 regulatory requirement effective 15th March 2019

- Cardiovascular Safety Pharmacology *NEW*
- Respiratory Safety Pharmacology *NEW*
- Single- and Repeat-Dose Toxicity
- Carcinogenicity

Note: includes non-GLP studies if used in regulatory submission

STANDARDIZED SEND DATA DOMAINS

- Body Weight Gains – BG
- Body Weights – BW
- Cardiovascular Test Results - CV
- Clinical Observations – CL
- Comments – CO
- Death Diagnosis – DD
- Demographics – DM
- Disposition – DS
- ECG Test Results – EG
- Exposure – EX
- Food and Water Consumption – FW
- Laboratory Test Results – LB
- Macroscopic Findings – MA
- Microscopic Findings – MI
- Organ Measurements – OM
- Palpable Masses – PM
- Pharmacokinetics Concentrations – PC
- Pharmacokinetics Parameters – PP
- Pooling – POOLDEF
- Related Records – RELREC
- Respiratory Test Results - RE
- Subject Characteristics – SC
- Subject Elements – SE
- Supplemental Qualifiers – SUPP datasets
- Trial Arms – TA
- Trial Elements – TE
- Trial Sets – TX
- Trial Summary – TS
- Tumor Findings – TF
- Vital Signs – VS

CONTACT US TO BECOME SEND SAVVY.

Learn more about our drug development solutions at **www.covance.com**

The Americas +1.888.COVANCE (+1.888.268.2623) +1.609.452.4440
Europe / Africa +00.800.2682.2682 +44.1423.500888
Asia Pacific +800.6568.3000 +65.6.5686588

COVANCE®
SOLUTIONS MADE REAL®