SEND solutions

Efficient. Enlightening. Trusted.

The Standard for the Exchange of Nonclinical Data (SEND) is the electronic, standardized FDA format* 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, enabling you to gain fresh insights and a valuable research database, all while complying with the FDA regulations.

Experience that matters

With Labcorp, 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 Groups developing the standards and controlled terminology
- Leading the way with a team of dedicated experts implementing SEND with clients since 2012
- Successfully delivering SEND, with more than 5 billion data points delivered and thousands of studies performed to date
- Validating the SEND process by submitting early pilot datasets to the FDA

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

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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
- Fetal Measurements – FM
- Food and Water Consumption – FW
- Fetal Pathology Findings – FX
- Implantation Classification – IC
- Laboratory Test Results – LB
- Macroscopic Findings – MA
- Microscopic Findings – MI
- Organ Measurements – OM
- Palpable Masses – PM
- Pharmacokinetic Concentrations – PC
- Pharmacokinetic Parameters – PP
- Nonclinical Pregnancy Results – PY
- Pooling – POOLDEF
- Related Records – RELREC
- Respiratory Test Results - RE
- Subject Characteristics – SC
- Subject Elements – SE
- Subject Repro Stages – SJ
- Supplemental Qualifiers – SUPP
- Trial Arms – TA
- Trial Elements – TE
- Trial Repro Paths – TP
- Trial Repro Stages – TT
- Trial Sets – TX
- Trial Summary – TS
- Tumor Findings – TF
- Vital Signs – VS

EASY. EXPERT. PREPARED.

Easy – Securely receive SEND

- Labcorp 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 arrive 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 Labcorp Axway Managed File Transfer (MFT)

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 Labcorp SEND experts.

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

Prepared – Comply with existing and evolving requirements

SEND v3.1 regulatory requirement effective March 15, 2019

- Cardiovascular safety pharmacology
- Respiratory safety pharmacology
- Single- and repeat-dose toxicity
- Carcinogenicity

DART v1.1 and CBER regulatory requirements effective March 15, 2023

- Embryo-fetal development
- Prepared for vaccine, gene and gene therapy, blood product and more submissions to the FDA OVRR, OTAT and OBRR offices

SEND v3.1.1 and define v2.1 regulatory requirements effective March 15, 2023

- Pharmacokinetic Parameters and Concentrations updates
- Compliance with new XML standard and conformance rules

Note: Includes non-GLP studies if used in regulatory submission.

* 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.

Learn more at labcorp.com

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