STANDARD FOR THE EXCHANGE OF NONCLINICAL DATA (SEND*)

FDA Pilot Submission Checklist

Get started with your first test/pilot FDA SEND submission by researching the SEND submission requirements. Access valuable SEND resources in one convenient location.

Here's a SEND checklist to follow as you prepare for your first SEND test/pilot submission:

Project Set-Up

- ☐ Obtain submission identification number (one for each study)
- ☐ Identify study(ies) to be submitted
- ☐ Gather documents (protocol, amendments, report, key dates)
- ☐ Obtain Study Data Reviewers Guide (SDRG) template

Dataset Generation

- ☐ Generate SEND dataset following established procedures
- ☐ Prepare the SDRG and Define-XML files

Dataset Review

- ☐ Execute quality checking activities
- ☐ Run the SEND dataset through the validator tool to identify errors, warnings, etc.

Dataset Submission

- ☐ Electronically package the SEND dataset in submission file structure
- ☐ Obtain shipping address, prepare accompanying letter, shipping paperwork
- ☐ Package and ship to FDA

** 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 that begin after December 17, 2016 must comply with this format.*

Covance Inc., headquartered in Princeton, NJ, USA, is the drug development business of Laboratory Corporation of America Holdings (LabCorp). COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

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

© Copyright 2016, Covance Inc.

COVANCE
SOLUTIONS MADE REAL®