charles river

SAFETY ASSESSMENT

# Selecting a SEND Vendor? Be Sure to Ask These Questions

## Capabilities

**Can you produce SEND-compliant domains for the data you are producing?**

Example: Can your TK/PK/bioanalysis vendor produce compliant PC (bioanalysis) and PP (toxicokinetic) domains in the .xpt or .xlsx format?

*Why it matters:* Smaller vendors may not have invested in SEND capabilities. This forces you to invest in yet another vendor that can create SEND data from their contributing reports, increasing your costs (money and time) for data conversion.

## Data Compilation

**When do you create SEND dataset packages?**

Example: During or after the study?

*Why it matters:* Creating a SEND package is a lengthy and complex process. If a provider waits until the report is completed to begin execution, this negatively impacts your delivery timelines.

TIP: Highlight SEND requirements up front in the contract.

## Data Conversation Vendor Services

**What do third party data conversion services need to create the data package?**

Example: Will they work from PDF files, or will they need the testing facilities to produce electronic extracts, study logs and daily dosing records?

*Why it matters:* Data conversion vendors can convert the data from different types of sources. Their process depends on the capabilities of you and/or your testing facilities. Many vendors will want to wait until reports are finalized before starting the conversion process. This can potentially jeopardize your timeline for submission.

TIP: Remember that additional requests for data from the testing facility could lead to additional costs.

**2008**
Began preparing SENDIG v3.x pilot data and preparing SEND dataset packages

**>100**
Total number of complete dataset packages generated per month across CRL sites

**60+**
SEND analysts on the CRL SEND Team

## Why should you trust CRL with your SEND Dataset?

CRL has actively volunteered with CDISC since 2007. CRL volunteers serve as SEND Subteam Leads and members of the CDISC Global Governance Group. As part of the CDISC SEND team, CRL has been involved in the development of the CDISC SEND Implementation Guides (SENDIG v3.0 and 3.1), and the DART IG (currently at v1.1).

## Review Process

**What is the QC process and timing?**

Example: Do you perform the QC review in parallel with the QA audit of the animal data?

*Why it matters:* By performing QC in parallel with the audit of animal data, any findings can be addressed before the report's final review, ensuring that SEND datasets accurately represent the final report.

**Will the SEND data be verified against study plans, study amendments, deviations and reports?**

Example: SEND data should be verified against study plans, study amendments, deviations and reports.

*Why it matters:* A statement must be provided in the Study Data Reviewers Guide (nSDRG) claiming the SEND data accurately represents the report. Without the verification steps mentioned, the vendor cannot make that claim.

## What happens if there is a discrepancy?

Example: How do the datasets get corrected?

*Why it matters:* When SEND compilation is performed at the testing facility, the team has access to all study conduct materials. Any discrepancies can be brought to the Study Director and business units to be addressed in a timely fashion. Discrepancies can be resolved within the source systems, and tables regenerated and re-audited as appropriate.

TIP: A third party will not have access to study-related data (logs, dosing sheets). Consider the consequences and impact this might have on your timeline.

charles river

askcharlesriver@crl.com • www.criver.com