



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.

>218

packages shipped
since we
began piloting

>63

submission ready
packages completed
and shipped

>1500

submission
ready files created

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.