Automate the Preparation of NCA Clinical and Non-clinical Data in CDISC-ready Formats

Electronic submission of clinical and non-clinical study data must be in a format that the FDA can review, process, and archive, such as the CDISC Study Data Tabulation Model (SDTM) and Standard Exchange for Non-clinical Data (SEND).\(^1\)

Submissions to the FDA that do not comply with CDISC SDTM or SEND requirements could delay the regulatory review process. The requirement for using SDTM/SEND formats electronic submission for INDs will go into effect on December 17, 2017.\(^2\)

**Phoenix® CDISC Workflow Templates**

Certara has developed SDTM and SEND Workflow Templates that prepare non-compartmental analysis (NCA) data into the format required by the FDA for electronic submission. Once NCA is completed in Phoenix WinNonlin™, the SDTM and SEND Workflow Templates automate the creation of the Pharmacokinetic Parameters (PP) and Pharmacokinetic Concentration Data (PC) domains in the required SDTM or SEND format. You can choose either the CDISC SDTM or SEND Workflow Template, or benefit from savings, and implement both templates.

**Accelerate CDISC SDTM and SEND Submissions**

Regardless of whether you receive bioanalytical data in a CDISC SDTM or SEND format from an external partner or internal biostatistics group, or the data needs to be converted to the SDTM or SEND format, the Phoenix Workflow Templates can be used to prepare your NCA data in the SDTM or SEND format for regulatory submission. Phoenix Technology Services works closely with you to perform a gap analysis to map data from your NCA workflow into the Workflow Templates.

**Ensure Compliance**

Leveraged by leading pharmaceutical companies, the Phoenix SDTM and SEND Workflow Templates provide an automated solution that prepares NCA data to meet the electronic format requirements of the FDA. The benefit? Avoid delays and streamline the filing process for your clinical and non-clinical data submissions.
What’s included?

- Phoenix SDTM or SEND Workflow Template that creates data in the standard CDISC SDTM or SEND format as required by the FDA
- Phoenix plugin that outputs the data created in the workflow template into a file format accepted by the FDA
- Example of a completed project with example NCA analysis and data mapped to the template
- Specification document that shows how the template maps to the STDM or SEND format
- Up to 10 days of Phoenix Technology Services for training, compliance gap analysis, implementation, and modification of the STDM or SEND Workflow Template and Plugin to meet customer requirements

References

2. FDA Data Standards Catalog, v 4.5.1. August 31, 2016.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara’s solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.