CERTARA

PK Submit™:

Reduce the time & complexity to prepare and analyze pharmacokinetic (PK) datasets

Certara's PK Submit is a plug-in for Phoenix that helps scientists dramatically increase the speed to complete a non-compartmental analysis (NCA) and create validated PK-related CDISC submission datasets. By guiding the user through each step of the NCA, PK Submit makes it easy to focus on delivering valuable scientific conclusions from the study data.

How do you benefit from PK Submit?

- **Optimize R&D productivity** with a guided, intuitive user interface focused on the key decision points in NCA. Convenient tools enable you to prepare and analyze your data in a fraction of the time.
- **Reduce risk of errors** using an automated, repeatable process to get consistent results across studies
- **Save development time** since PK Submit can rapidly create a CDISC compliant, comprehensive regulatory submission package for PK data or for data sharing

Guided, Intuitive User Interface

Complete the full NCA PK analysis and be able to create CDISC compliant output files through one interface – built with PK scientists in mind and eliminating the need to create complex workflows needed to prep data for analysis. PK Submit walks scientists through each step of the process with prompts and tools to guide them through the process.

Convenient Tools

Interact with the library of tools provided in PK submit to simplify critical decisions and take quick action. Our new suite of tools covers all the common needs across the data preparation process as well as the analysis.

Data preparation tools

- Map input data to standard structure and terminology
- Merge multiple sources in a single step
- Create new variables or derive them using expressions
- Apply complex BLQ substitution rules
- Adjust time and day variables to meet analysis requirements
- Identify and flag through samples
- Exclude samples graphically
- Correct for baseline concentrations
- Normalize concentrations by dose
- Duplicate pre-dose and trough concentrations within and across profiles

Analysis tools

- Set NCA options
- Slope selector for NCA
- Select PK parameters for reporting
- Exclude parameter values from CDISC reporting
- Calculate commonly used ratio parameters
- Easy unit conversions
- Include dose-normalized partial AUCs in the PP domain

Output tools

- Automatically create PC and PP CDISC SDTM and SEND domains
- Ensure your CDISC domains are agency ready with built in validation using Pinnacle 21
- Create master concentration and parameter files for table and graph creation

Automated, repeatable process

Designed with 30 years of expertise and the guidance of the largest pharmaceutical companies in the world, the PK Submit process has the flexibility to handle all common study designs while providing a repeatable and predictable experience for scientists. Each step of the process is recorded in audit logs to track any changes and exceptions and can be rerun at any time to recalculate the results. To decrease the risk of errors and regulatory audit findings, reports and electronic records are generated from one source.

Comprehensive regulatory submission package

PK Submit was designed to create the entire PK regulatory submission package, including the CDISC domains, validation report, study data reviewers guide, and define file. With its integration into Pinnacle 21, the industry leading CDISC validation and submission readiness software, PK Submit ensures that regulatory submission processes are even more efficient. These files can be exported for collaboration with other parties or to create regulatory data submissions.

CDISC domains and ADaM datasets generated by PK Submit:

- PC
- PP
- CO
- POOLDEF
- RELREC
- SUPPPC
- ADPC
- ADPP
- ADNCA (Coming in v2.1)

Certara Software division's ISO 27001 certification

As part of PhoenixTM PK/PD platform, PK Submit is ISO 27001 certified. We prioritize protecting your valuable information assets, demonstrated by our ISO 27001 certification for Certara Software's information security management systems (ISMS). Our certification shows our commitment to safeguarding your data with confidentiality, integrity, and availability. With ISO 27001, you can trust our robust security controls, rigorous risk assessments, and continuous improvement efforts for peace of mind.

About Certara

At Certara, we accelerate medicines to patients, partnering with life science innovators. Together we advance modern drug development with biosimulation, regulatory science, and market access solutions.

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