CERTARA

PK Submit™

Create Complete Pharmacokinetic (PK) Regulatory Submission-Ready CDISC Domains in Minutes

Save weeks of development time

PK Submit shortens timelines by coupling analysis and electronic dataset generation

Reduce risk of errors and audits

PK Submit generates the entire PK regulatory submission package from one source

Optimize R&D productivity

Automated NCA workflows allow research teams to focus on their core comptetencies

Integrates into Phoenix WinNonlin and Pinnacle 21 for more efficiency in PK and regulatory submission workflows

SDTM and SEND CDISC Domain Generation

PK scientists can use PK Submit to generate all required electronic submission datasets for SDTM, and SEND CDISC domains at the source – a solution that is integrated into their workflow to increase accuracy, improve data organization, and ensure compliance.

Intuitive, Simple, Single Interface

Achieve the full PK submission through one interface – built with PK scientists in mind and eliminating the need to become experts in the nuances of CDISC implementation.

Complete Electronic PK Regulatory Submission Package

To decrease the risk for errors and regulatory audits, the reports and electronic records should be generated from one source. Therefore, 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.

ADaM datasets and CDISC domains generated by PK Submit

- ADPC
- ADPP
- CO
- PC
- PP
- POOLDEF
- RELREC
- SUPPPC
- SUPPPP

Learn more at www.certara.com/software/pk-submit-cdisc-technology-solution/

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 62 countries.

For more information, visit **www.certara.com**.