CERTARA

PK Submit™

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

PK Submit – the First and Only Technology Solution to Automatically Generate PK CDISC Domains During Non-Compartmental Analysis (NCA)

Ensuring compliance with regulatory agencies' electronic submission guidelines for preclinical and clinical data is required – for the FDA as well as the PMDA. These guidelines, including the use of CDISC study data standards, apply to any new drug application (NDA), investigational new drug application (IND), abbreviated new drug application (ANDA), and certain biologics license application (BLA) filings. Preparing data in these standardized formats requires that scientists either become experts in CDISC implementation or otherwise delegate this task, which can introduce inefficiency. Moreover, the many tedious, complex, time-consuming, and error-prone steps involved in creating Study Data Tabulation Model (SDTM) and Standard for Exchange of Nonclinical Data (SEND) datasets requires a great deal of quality control.

PK Submit is integrated with Phoenix WinNonlin® and supports the automatic generation of a complete electronic PK regulatory submission package, including all necessary CDISC domains, during the normal process of setting up and executing an NCA – all from the same source, by a PK scientist who is not a CDISC expert, and within minutes.

PK Submit allows you to:

- ✓ Optimize R&D productivity
- ✓ Reduce risk of errors and audits
- ✓ Easily collaborate with CROs

Solve data management issues faster with PK Submit

- Creates a complete electronic PK regulatory submission package
- Automatically generates CDISC domains while executing an NCA with no additional effort
- Allows users to easily apply exclusions and comments
- Remains current with CDISC controlled terminology and implementation guides
- Provides an intuitive, simple, single interface
- Supports all study designs and types
- Increases data standardization and quality and therefore confidence in your data
- Developed by Certara, a CDISC Registered Solutions Provider and experts in PK analysis using Phoenix WinNonlin, the gold standard for PK/PD analysis
- Automates time consuming tasks

Certara is a CDISC Registered Solutions Provider

SDTM and SEND CDISC Domain Generation

Automatically create regulatory compliant CDISC domains in **less time, with fewer resources, and with fewer errors.**

PK scientists can use PK Submit to generate all required Analysis Dataset Model (ADaM) 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.

After uploading and combining data in PK Submit, the software validates the output into the desired version of SDTM or SEND. The user requires only an understanding of the imported data.

CDISC domains generated by PK Submit

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

Intuitive, Simple, Single Interface

Achieve the full submission through one interface – built with PK scientists in mind and eliminating the need to become experts in the nuances of CDISC implementation and uses database technology to efficiently store user settings to minimize repetitive tasks.

Easily load, harmonize, append, and merge data from multiple sources.

Stay current with CDISC controlled terminology and implementation guides.

Use with all study designs and types.

Complete Electronic PK Regulatory Submission Package

To decrease the opportunity for errors and potential 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.

Save significant drug development time with PK Submit!

About Certara

Certara optimizes R&D productivity, commercial value and patient outcomes through its unique portfolio of model-informed drug development, regulatory science, and market access solutions. In fact, 90+% of all novel drugs approved by the US FDA in the past six years were supported by Certara software or services. Its clients include 1,600 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 60 countries.

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