PK Submit 1.1

Release Notes

July 2020

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Certara® Contact Information

Technical support

Consult the software documentation to address questions. If further assistance is needed, contact Certara Support through e-mail or our support portal.

E-mail: support@certara.com
Web: https://certara.service-now.com/csm

For the most efficient service, e-mail a complete description of the problem, including copies of the input data.

User forum.

Get tips and discuss Certara software with other users:
https://support.certara.com/forums

What's New

PK Submit 1.1 works with Phoenix 8.1, 8.2, and 8.3.

Navigation breadcrumbs: Navigation breadcrumbs are available at the top of the wizard pages.

Select a terminology file: The PK Submit options in the Phoenix *Preferences* dialog allow the importing and storing of up to five different terminology files for each standard. On the first page of PC domain Creation Wizard, there is a new option to select one of the stored terminology files.

PC variable mapping

Browse Phoenix projects for source data: For PC domain creation, use the new **Browse Phoenix Projects** button to select a worksheet from the Phoenix Data folder or a results worksheet from an object as the source of data for PK Submit.

Support for merging of ADSL (Subject-Level Analysis Dataset) and DM variables with concentration data: Importing and merging of ADSL and DM ADaM datasets is available for the SDTM standard. Select the variables to merge by clicking the new **Add ADSL or DM Variables** button on the *Map PC Variables* screen.

PCBLFL added to the mapping list and PCGRPID removed from the list: PCGRPID was removed becaused it is a constructed variable and, therefore, does not need to be mapped by the user.

Create new variables using the Data Wizard: Use the new **Data Wizard** option on the *Mapping PC Variables* screen to define new variables with formula expressions. These expressions can be saved and loaded for later use.

Replace text values detected in the input dataset concentration field with a numeric value: Any text value detected in the data mapped to PCORRES is listed in the Data Converter tool. Enter a numeric value to use instead of the text. PK Submit stores the numeric values in a PCCALCN column in the Master PC worksheet, which is then combined with PCORRES to form a PKConc analysis variable. This functionality is implemented to allow users to perform an "unconditional" substitution of BLQ values for NCA calculations.

Set a target unit concentration for concentration unit conversion: Use the Data Converter tool **Target Unit** pull-down menus to specify the desired concentration unit. These units are stored in the PCCALCNU column. PK Submit compares the units with those in PCORRESU and multiplies the values in PCORRES by the necessary factor to obtain the target units.

Data exclusion

Exclude records from statistics calculations: The **Exclude from Statistics** option in the Concentration Exclusions screen allows records, with data that match the exclusion rule, to be ignored during statistics calculations. Any excluded value will have a flag set in the Master PC worksheet. Information about the excluded records is added to the SUPPPC domain and is used for the ADPC ADaM dataset. Only in SDTM standard. For the SEND standard, records get flagged in the Master PC worksheet only (no records added to the SUPPPC).

For the SEND standard, there is a new option to indicate if a concentration exclusion flag is to be included in the PC datatset.

For the SDTM standard, concentration exclusions are recorded in the SUPPPC domain: In the previous release, exlcusions were recorded in the CO domain.

Create Time Deviation Rules: The **Time Deviation Rules** button on the Concentrations Exclusions screen derives sample collection time deviations, actual sample collection times, and percentage of sample collection time deviations and adds the data to the Master PC Worksheet as DeviationPK, ActualTime, and PercentDeviation columns, respectively. These columns are also added to the NCA_<MATRIX> worksheet(s). Use the tools in the dialog to set up the criteria for time deviation or percentage of time deviation rules. Records that exceed the rules are flagged in the DeviationRuleApplied column, which is stored in the Master PC Worksheet and the NCA_<MATRIX) worksheet(s).

Visualization of data dependencies: The **Visualization** button on the Concentration Exclusions screen displays a time vs concentration graph with tools to switch between linear and logarithmic scaling of the axis and quick sort key selection changes in order to visualize the effects of different combinations.

NCA settings configuration

Add renal clearance areas: While defining partial areas, use the **Add Clr Areas** button to have PK Submit find start and end times for each urine collection interval.

Generate accumulation ratios: Use the **Ratios** button on the NCA Parameters screen to select PK parameters, define Reference and Test occasions, and generate RAUCall, RAUINF, RAUC(Start-End times), RAUClast, RAUCtau, and RCmax columns of data in the NCA Final PK Parameters worksheet.

Generate metabolite to parent ratios: Use the **Ratios** button on the NCA Parameters screen to select PK parameters, define Reference and Test analytes, and generate MPAUCall, MPAUCINF, MPAUC(Start-End times), MPAUClast, MPAUCtau, and MPCmax columns of data in the output in the NCA Final PK Parameters worksheet.

PP creation

CTrough and CTroughD calculations available: On the first screen of the PP domain Creation Wizard, click the **Additional PK Parameters** button to set up calculation of Ctrough and CTroughD.

Output

Analysis file creation according to ADaM standards: PK Submit generates the following additional output:

ADPC ADaM Dataset – Analysis Dataset with PK Concentration Data
ADPC Validation Report
ADPP ADaM Dataset – Analysis Dataset with PK Parameter Data
ADPP Validation Report
ADRG report – Analysis Data Reviewers Guide

Supplemental qualifier domains SUPPPC and SUPPPP: PK Submit generates a supplemental qualifiers domain when creating a PC or PP domain. SUPPPC is generated for both SEND and SDTM standards. SUPPPP is generated only for the SDTM standard.

Create Submission files: Available from the **PK Submit** main menu, this option creates several folders within the project's Documents folder:

Doc: Stores the Standard Reviewer's Guide
xlsx: Stores the Excel formatted `define` files
xml: Stores the xml formatted `define` files
xpt: Stores the xpt files for the different domains.

The content of each folder depends on the selected standard.