Use of Python and Spotfire for Quality Control of Pharmacometric Analysis Dataset Preparation

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Objectives: Pharmacometric analyses are commonly included components in regulatory filings. The quality of the analyses and results is highly dependent upon the quality of the data. Quality control (QC) is a very important component in the process of delivering high-quality pharmacometric analysis datasets. A QC checklist was created to define standard checks required for the preparation of pharmacometric analysis datasets. We describe tools developed using Python and Spotfire in order to improve the efficiency of the QC process and implement the checks.

Methods: Described below is the functionality of the Python and Spotfire based tools in order to facilitate the QC.

Python
- Reads dataset specification and pharmacometric analysis dataset
- Extracts dataset and variable attributes from both and compares them
- Generates bar, scatter and histogram plots of continuous and categorical variables
- Outputs frequency table of all variables in the dataset
- Provides summary statistics for all numeric variables

Spotfire
- Developed visualizations that include scatter plots of nominal and actual times, nominal and actual doses, dosing over time, and concentrations over time and bar charts of lab results and physical measurements.
- Normal ranges from the National Library of Medicine MedlinePlus for various lab tests are integrated into the bar charts to check out of range values.

Results: Implementation of Python and Spotfire tools have facilitated the standardization of the QC checks and streamlined the QC process. Ensures the dataset and variable attributes are same between specs and the dataset. Spotfire visualizations allow the programmer to explore the data, detect anomalies in single data points or distributions. Summary statistics help to identify issues such as inappropriate negative or missing values.
Conclusion: Implementation of these QC tools have led to efficiencies in the QC process resulting in high quality pharmacometric analysis datasets.