PKView: an automated analysis tool for clinical pharmacology studies

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Abstract

PKView has been developed to automate the pharmacokinetic analyses of clinical pharmacology studies. These studies are typically conducted during the phase 1 and 2 of the clinical development process, and are pivotal for bioequivalence determination, dosing adjustment in special populations, safety evaluation with concurrent drug administration, and the investigations of many other intrinsic and extrinsic factors. The study design can vary widely depending on the study objectives and the pharmacokinetics and pharmacodynamics of the drug. The treatment scheme may range from crossover, to parallel, sequential, multiple-cohort and nested, with most studies examining multiple arms of patients. In addition, study observations can span from single visit to steady state and include the pharmacokinetics of parent drug, metabolite, and concurrent medications.

Automation of clinical study data analysis has been an ambitious project for us, due to the wide spectrum of data formats among different pharmaceutical companies and the large varieties of clinical study designs. Throughout the years, we have accumulated experiences with hundreds of NDA and BLA submissions and close to a thousand clinical studies. The recurrent scenarios (e.g., study designs, data formats, and analysis methodologies) observed from these past submissions have been categorized in a knowledgebase, with the corresponding solutions built into PKView.

The PKView platform consists of the following components

1. The data management module assists the user to load the study data in SDTM format.
2. The reporting module allows the user to generate various types analysis reports on a per study basis.
3. The meta-analysis module performs meta-analysis combing multiple studies.

The SAS code library and GUI codes of PKView are available at www.github/FDA site.