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Automation of Population Pharmacokinetic-Pharmacodynamic Modeling Reports Using the RShiny Application: TFL Generator

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Objectives: Population pharmacokinetic–pharmacodynamic modeling has become a mainstream tool for supporting internal decision making and regulatory submissions. Appropriate workflow and automation will significantly maximize the productivity of pharmacometricians. In formal reports, tables, figures and lists (TFL) are usually associated with time-consuming quality checks. The objectives of this work were to develop a qualified RShiny [1] tool to efficiently generate TFLs in templated reports and minimize quality checks.

Methods: The developed application was created using RShiny, writing output to rich text format. For submission-quality products, GGgplot2 and GridExtra drive most graphics, while LaTex drives tables and listings. This tool was designed to reliably access to input and output datasets, reporting of pre- and post-processing graphical/tabular results.

Results: The TFL Generator was designed to be efficiently applied across projects/programs with minimal modification. The development of the first version of TFL Generator is complete and further improvements are ongoing. The application provides flexible options for modifying elements of the TFLs, create new TFL templates from the app; download, modify, and share these templates for TFLs with other users through the interface. To enhance flexibility of the for data manipulation, an R script parser is also included. The full R script producing the report is generated from QC'ed R script, saved and can be supplied to regulators.

Conclusions: Pharmacometric analyses play an important role in model-informed drug development for better decision making. The PharmacometricsTFL Generator provides pharmacometricians with a qualified tool for formal reporting of analysis results. This is expected to allow more time to focus on the scientific challenges.

References:

1. Winston Chang, Joe Cheng, JJ Allaire, Yihui Xie and Jonathan McPherson (2015). shiny: Web. Application Framework for R. R package version 0.12.1. http://CRAN.R-project.org/package=shiny

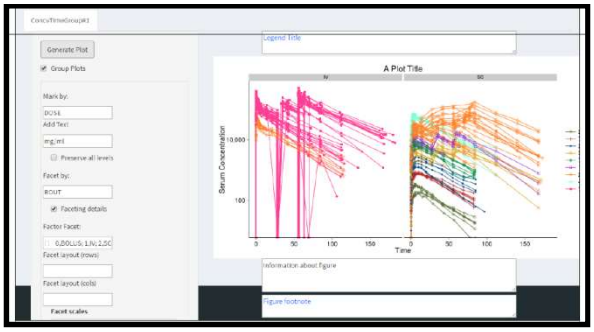

Figure 1: An example of the TFL Generator user-friendly generation of exploratory plots.