Release 1.0.0

Pharmacometrics TFL Generator Requirements

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Introduction

The Pharmacometrics TFL Generator is a shiny application, written in R, intended to provide a graphical interface for creation of typical Tables, Figures, and Listings. The app generates report-ready graphics, tables, and reports; but also allows for interactivity and data exploration via input from the pharamacometrics scientist. The Pharmacometrics TFL Generator is is architected to run behind shiny-server and can handle multiple simultaneous users per application. The application runs in a mode that assigns a new R process to each new connection, ensuring no conflicts between shared objects in the R environment.

The application is intended to be fit for purpose of regulatory submissions, and as such has functionality to ensure reproducibility. Upon demand, the application will create an R script that, when sourced, will duplicate any objects created from within the application. The application also allows template loading so that a similar set of tables, figures, and listings may easily be shared between multiple users.

The functional requirements for the application are listed in the requirements traceability matrix below.

Requirements traceability matrix

Topic	RID	Requirement	Reference
Deployment	1	App is under version control	deployment_protocol.pdf
	2	Installation package and instructions work to create new app on a new Envision workflow	deployment_protocol.pdf
Data	3	NONMEM run data (tab and partab files) can be read, displayed, and summarized	data_protocol.pdf
	4	Run data can be manipulated using the code parser	data_protocol.pdf
	5	Source data can be read, displayed, and summarized	data_protocol.pdf
	6	Source data can be manipulated using the code parser	data_protocol.pdf
	7	Analysis data can be created by merging run data and source data	data_protocol.pdf
	8	Analysis data can be manipulated using the code parser	data_protocol.pdf
	9	Analysis data can be viewed and summarized	data_protocol.pdf
	10	Subject level exclusions can be specified and viewed	data_protocol.pdf
	11	Observation level exclusions can be specified and viewed	data_protocol.pdf
	12	Data cache can be cleared from the app	data_protocol.pdf
Figures	13	Serum Concentration Versus Time-Individual	figures_protocol.pdf
	14	Serum Concentration Versus Time-Groups	figures_protocol.pdf
	15	Observed Versus Predicted	figures_protocol.pdf
	16	Parameter Distribution	figures_protocol.pdf
	17	Categorical Covariance	figures_protocol.pdf
	18	Continuous Covariance	figures_protocol.pdf
	19	Correlation Pairs	figures_protocol.pdf
	20	Quantile Plot	figures_protocol.pdf
	21	Goodness of Fit	figures_protocol.pdf
	22	Figure from disk	figures_protocol.pdf
	23	Figures can quickly be created from previously created figures	figures_protocol.pdf
Tables	24	Tabulated NONMEM run summary	tables_protocol.pdf
	25	Demographic tables (categorical)	tables_protocol.pdf
	26	Demographic tables (continuous)	tables_protocol.pdf
	27	Table file from disk	tables_protocol.pdf
	28	Observation exclusions summary	tables_protocol.pdf
	29	Subject exclusions summary	tables_protocol.pdf
Listings	30	Concentration vs Time Multipanel plots	listings_protocol.pdf
	31	Image listing from disk	listings_protocol.pdf
	32	Text listing from disk	listings_protocol.pdf
	33	Subject exclusions table	listings_protocol.pdf
	34	Observations exclusions table	listings_protocol.pdf

Topic	RID	Requirement	Reference
Reporting	35	The app creates RTF output for all specified figures, tables, and listings	reporting_protocol.pdf
	36	The app creates an R script that can reproduce the analysis outside of the app	reporting_protocol.pdf
Usability enhancements	37	The app can load from a set of defaults	usability_enhancements_protocol.pdf
	38	The app writes autosave files that are usable for recovering sessions	usability_enhancements_protocol.pdf