Release 1.0.0

Pharmacometrics TFL Generator Qualification Plan

Authored by	Date

Approved by	Date

Introduction

Metrum Research Group (MetrumRG) intends to qualify the Pharmacometrics TFL Generator through a series of activities involving functional requirements development, test development, test documentation, testing, and reporting. This document provides the overall qualification plan, and outlines the required elements of the project.

Definitions

The following terms may be used throughout the set of qualification documents:

Envision: Metworx facilitated platform for leveraging the functionality of shiny-server with the compuational backing of Metworx

Functional Requirements: Processes and functionality that systems (software or hardware) are intended to accomplish.

Metworx: A MetrumRG Ruby on Rails web application that provides an interface to launching AWS computational infrastructure and performing work with the infrastructure in a unified process.

Qualification: Successful demonstration, through documentation and testing, of an information system's (or component of the system) functionality, that provides a high degree of assurance that the system will consistently and reproducibly yield a product or result meeting its predetermined specification, expected performance, and/or quality attributes.

TFL: Tables, figures, and listings in the typical pharmacometrics workflow

Validation: Successful demonstration, through documentation and testing, of a software's intrinsic functionality (correct coding, syntax, start up and run without error).

Workflow: The combination of an individually created AWS computational infrastructure and the associated graphical workspace (RStudio, PiranaJS) brought together by Metworx

Pharmacometrics TFL Generator Overview and Quality Framework

Pharmacometrics TFL Generator is a web application, written in R, heavily utilizing the R:::shiny package intended to provide a graphical user interface (GUI) for creating TFL's in the typical pharmacometrics workflow. The application allows point and click TFL generation, providing output as individual TFL's, a report ready RTF of the TFL's, and an accompanying R script to replicate the analysis.

Pharmacometrics TFL Generator Qualification Requirements

MetrumRG intends to qualify the Pharmacometrics TFL Generator through a series of activities involving functional requirements development, test development, test documentation, testing, and reporting. The required elements and required documents associated with the project are described in Table **??**. These elements are generally intended to be followed in the order listed.

Element	Description	Output
Qualification Plan	High-level background and outline of the steps to be taken to qualify Pharmacometrics TFL Generator, including a list of required documents	Qualification Plan document/section
Requirements Traceability Matrix	Document that maps Requirements to test and documentation references	Requirements Matrix
Qualification Protocols	Planned stepwise testing sequences to demonstrate that the system capabilities meet the stated requirements	Test protocols
Qualification Report	Documented results of the qualification testing and a narrative summary of the results including an acceptability assessment	Final report describing outcome qualification testing, problems encountered, and resolution.
Quality Assurance Release	Official declaration of acceptance and level of release (for training or use in production)	Release document issued upon satisfactory completion of qualification activities

Pharmacometrics TFL Generator Release and Training

This qualification plan intends to provide assurance that the application meets its functional requirements and to release Pharmacometrics TFL Generator for post-qualification training and deployment into a production environment. In order for release into a production environment, training is required for administrators and users.

Management of Pharmacometrics TFL Generator Changes

Once the Pharmacometrics TFL Generator is qualified, all future Pharmacometrics TFL Generator modifications are managed through SOP M4 - Change Management.