Analysis Data Reviewer's Guide

[Organization Name]

[Submission Name]

This is a shortened ADRG. For a full ADRG example, see:

https://github.com/RConsortium/submissions-pilot1-to-fda/blob/main/m5/datasets/rconsortiumpilot1/analysis/adam/datasets/adrg.pdf

7. Macro Programs

Submitted R programs have [specific patterns] in filenames. All internally developed R functions are saved in the r0pkgs.txt file. The recommended steps to unpack these R functions for analysis output programs are described in the Appendix.

The table below contains the software version and instructions for executing the R analysis output programs:

Program Name	Output Table Number	Title
tlf-01-disposition.txt	Table x.y.z	Disposition of Patients
tlf-02-population.txt	Table x.y.z	Participants Accounting in Analysis Population (All Participants Randomized)
tlf-03-baseline.txt	Table x.y.z	Participant Baseline Characteristics (All Participants Randomized)
tlf-04-efficacy.txt	Table x.y.z	ANCOVA of Change from Baseline Glucose (mmol/L) at Week 24 LOCF Efficacy Analysis Population
tlf-05-ae-summary.txt	Table x.y.z	Analysis of Adverse Event Summary (Safety Analysis Population)
tlf-06-ae-spec.txt	Table x.y.z	Analysis of Participants With Specific Adverse Events (Safety Analysis Population)

Proprietary R Analysis Package	Package Version	Analysis Package Description
esubdemo	0.1.0	A demo project for analysis and reporting of clinical trials

Open-source R Analysis Package	Package Version	Analysis Package Description
r2rtf	0.3.0	Create RTF tables
haven	2.4.3	Import SAS datasets
table1	1.4.2	Tables of descriptive statistics
emmeans	1.6.3	Calculate least-squares means
dplyr	1.0.7	Manipulate datasets

Appendix: Instruction to Execute Analysis Program in R

1. Install R

Download and install R 4.1.0 for Windows from https://cran.r-project.org/bin/windows/base/old/4.1.0/R-4.1.0-win.exe.

2. Define working directory

Create a temporary working directory, For example, "C:\tempwork". Copy all submitted R programs into the temporary folder. All steps below should be executed in this working directory represented as "." in the example R code below.

3. Specify R package repository

The R packages are based on CRAN at 2021-08-31. To install the exact R package versions used in this project, run the code below to set the snapshot repository.

```
options(repos = "https://mran.microsoft.com/snapshot/2021-08-31")
```

4. Install open-source R packages

In the same R session, install the required packages by running the code below.

```
install.packages(c("r2rtf", "haven", "table1", "emmeans", "dplyr", "pkglite"))
```

5. Install proprietary R packages

All internal R packages are packed in the file r0pkgs.txt. In the same R session, restore the package structures and install them by running the code below. Adjust the output path as needed to use a writable local directory.

```
pkglite::unpack("r0pkgs.txt", output = ".", install = TRUE)
```

6. Update path to dataset and TLFs

INPUT path: to rerun the analysis programs, define the path variable

- Path for ADaM data: path$adam

OUTPUT path: to save the analysis results, define the path variable

- Path for output TLFs: path$output

All these paths require to be defined before executing the analysis output program. For example:

```
path = list(adam = "/path/to/esub/analysis/adam/datasets/") # Modify to use actual location

path$outtable = path$outgraph = "." # Outputs saved to the current folder
```

7. Execute analysis program

To reproduce analysis results, one can rerun the following four programs:

- tlf-01-disposition.txt

- tlf-02-population.txt
- tlf-03-baseline.txt
- tlf-04-efficacy.txt
- tlf-05-ae-summary.txt
- tlf-06-ae-spec.txt