



INSTRUCTIONS FOR R-PROJECTS 2

FRAME STORY

You are working as a modelling scientist in the DMPK (Drug Metabolism and Pharmacokinetics) group at Big Pharma Inc. BPI889, a follow-up compound to indinavir, is under development as a treatment against HIV/AIDS. You will perform the data management, basic graphical exploration and an initial statistical analysis on the data from the phase IIb study.

The phase IIb study focused on the pharmacodynamics of BPI889 with CD4 lymphocyte count used as a biomarker in HIV-positive patients. The design was double-blinded, randomized, parallel study with four arms: 200 mg, 400 mg and 800 mg of study drug (BPI889) and a comparator. Study duration was 20 weeks with active treatment, preceded by a run-in period of 2 weeks. The primary endpoint of the study was time to recovery (TTR) which is defined as the time from start of treatment until reaching a CD4 count >500 cells/mm³. The dose response is to be defined based on TTR and relative to the comparator.

PROJECT 2

You have been given two data files: **BPI889_PD_run-in.csv**, which contains the data of the run-in period of the study and **BPI889_demographics.tab**, which contains the demographic data matching the individuals in **BPI889_PD_run-in.csv**.

You have also been given a template for the report: **project_2_template.Rmd**, which will guide you on what to do and will create the report through markdown language.

The project includes the following aspects: importing data, combining the data (run-in and demographics), manipulating data to a suitable format, summarise data numerically, and perform a graphical evaluation of both the PD biomarker and the demographic data.

TASK – PROJECT 2

Download the required files from the course at the student portal. The files are available under **Document/Course material–R/Project 2/**. Open R studio and in R studio open the report template. Follow the instructions of the report template.

If you are working on the university student computers, open R studio by going into programs and “kursprogram”. Choose R studio and open the report template from inside R studio. Remember to save all files on your home directory to avoid losing files in between sessions.

REPORT – PROJECT 2

Hand in the personalised report file through the student portal. For deadline please see the student portal. Similar as for project 1, make sure to verify your code before handing in. Your script must run on a new system with a similar folder structure, related to the project review.

The project review will be a peer review-assessment of the report. You will receive the code to review through the student portal after the deadline with time for assessing.