Nov 11, 2021

Food and Drug Administration
Center for Drug Evaluation and Research 5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: R Consortium R submission Pilot 1

Dear Sir/Madam:

This letter serves as an introduction to the R Consortium R submission Pilot 1. The objective of the R Consortium R submission Pilot 1 Project is to test the concept that an R-language based submission package is aligned with FDA requirements and meets the expectations of the FDA Staff, including assessing code review and analyses reproducibility. All submission materials and communications from this pilot will be shared publicly, with the aim of providing a working example for future R language based FDA submissions. This is an FDA-industry collaboration through the non-profit organization R Consortium.

The R Consortium R submission Pilot 1 submission package follows the eCTD folder structure and contains the following module 5 deliverables:

- A cover letter
- SAS transport files (xpt) data from CDISC ADaM/SDTM submission pilot CDISCPILOT01
- R code to generate 4 analysis outputs
- Outputs
- One proprietary R package "pilot1wrappers"
- An Analysis Data Reviewer's Guide (ADRG)

In this pilot, we aimed to provide a working example of R submission in eCTD format to the pharmaceutical industry in compliance with the FDA Electronic Submissions Gateway requirements. Based on the submission package, FDA Staff can review and reproduce submitted R codes. More specifically, we expect the FDA Staff to

- Receive electronic submission package in eCTD format
- Reconstruct and load the submitted proprietary R package (i.e. "pilot1wrappers"))
- Install and load open source packages used in this submission
- Reproduce the analysis results
- Share potential improvements to the submission deliverables and processes via a written communication

All data, code, material and communications from this pilot will be shared publicly.

Different open-source packages were used when generating each of the 4 analysis outputs to test wider use case scenarios. Evaluating FDA's acceptance of system/software validation evidence is not in the scope of this pilot.

On behalf of the R Consortium R Submission Working Group, we hope the pilot 1 project can establish a working example to guide the industry for future submission using the R language.

Kind regards,
The R Consortium R Submission Pilot 1 Project Team