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

TBD, 2025

Dear Sir/Madam:

This letter serves as an introduction to the R Consortium R Submission Pilot 5, focusing on the submission of data submitted in the JavaScript Object Notation (JSON) format. The objective of this portion of the R Consortium R submission Pilot 5 Project is to test the concept that a 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 which include datasetjson as transport file . This is an FDA-industry collaboration through the non-profit organization R Consortium.

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

- A cover letter
- Data files in JSON format generated using R
- R code to generate 5 ADaM datasets which were used to generate the outputs from the Pilot 1 R submission
- Outputs that were regenerated from Pilot 1 using these R ADaM datasets generated in this project
- 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 packages in eCTD format
- Install and load open source R packages used in this submission
- Reproduce the JSON datasets and 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 to create the submission package. 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 R submission Pilot 5 can establish a working example to guide the industry for future submission using the R language.

Kind Regards,

The R Consortium R Submission Pilot 5 Project Team