**R consortium**

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

February 28, 2025

Dear Sir/Madam:

This letter serves as an introduction to the R Consortium R Submission Pilot 4. The objective of the R Consortium R submission Pilot 4 Project is to test the concept that a Shiny application created with the R-language can be successfully compiled into a container format created and executed by the Docker runtime and transferred to FDA reviewers. 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 Shiny applications. This is an FDA-industry collaboration through the non-profit organization R Consortium.

The R Consortium R submission Pilot 4 submission package follows the eCTD folder structure and contains the following module 5 deliverables:

- A cover letter
- SAS transport files (xpt) from CDISC ADaM/SDTM submission pilot CDISCPILOT01
- Text file(s) containing the Docker container image build instructions
- Shiny application R code based on the R Consortium Pilot 2 Submission
- An Analysis Data Reviewer's Guide (ADRG)

In this pilot, we aimed to provide a working example of a Shiny application created with R contained within a 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. The aforementioned ADRG contains a comprehensive description of the Shiny applicaiton components as well as specific instructions for executing the Shiny application within a Docker container, as well as optional installation of a local R environment to evaluate the Shiny application in a traditional R session. More specifically, we expect the FDA Staff to

- Receive electronic submission packages in eCTD format
- Install the Docker container runtime
- Build the Docker container image for the Shiny application
- Execute the Shiny application using the Docker container image
- 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 Shiny application. 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 2 project can establish a working example to guide the industry for future submission of Shiny applications compiled as a Docker container.

Kind Regards,

The R Consortium R Submission Pilot 4 Project Team