R consortium

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

June 13, 2025

Dear Sir/Madam:

This letter serves as an introduction to the R Consortium R Submission Pilot 4. The objective of this portion 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 web-assembly version 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
- Shiny application R code inspired by the R Consortium Pilot 2 Submission application updated to support compilation in WebAssembly assembled as a text file with the pkglite R package
- Supporting R script with functions to facilitate code preparation and application complilation assembled as a text file with the pkglite R package
- 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 application components as well as specific instructions for executing the Shiny application on a local R environment. More specifically, we expect the FDA Staff to

- Receive electronic submission packages in eCTD format
- Install and load open source R packages used as dependencies of the included Shiny application
- Reconstruct and compile the submitted Shiny application using Web Assembly
- Optionally execute the submitted Shiny application in R.
- 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 4 project can establish a working example to guide the industry for future submission of Shiny applications created with the R language.

Kind Regards,

The R Consortium R Submission Pilot 4 Project Team