



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

Sep 16, 2022

Dear Sir/Madam:

This letter serves as an introduction to the R Consortium R submission Pilot 2. The objective of the R Consortium R submission Pilot 2 Project is to test the concept that a Shiny application created with the R-language can be successfully bundled into a submission package and transferred successfully 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 2 submission package follows the eCTD folder structure and contains the following module 5 deliverables:

- A cover letter
- SAS transport files (xpt) from CDIS ADaM/SDTM submission pilot CDISCPILLOT01
- One proprietary R package “pilot2wrappers” which enables execution of the Shiny application
- 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
- Reconstruct and load the submitted proprietary R package (i.e. “pilot2wrappers”)
- Install and load open source packages used in this submission
- Execute the Shiny application within an R session
- Share potential improvements to the submission deliverables and processes via a written communications



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 created with the R language.

Kind regards, The R Consortium R Submission Pilot 2 Project Team