

Oct 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, Sample Number TBD

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 a R-language based submission package can meet the needs and the expectations of the FDA Staff, including assessing code review and analyses reproducibility. All submission materials and communications from this pilot will be publicly available, with the aim of providing a working example for future R language based FDA submissions. This is a FDA-industry collaboration through the non-profit organization R consortium.

The R consortium R submission pilot 1 submission package follows eCTD folder structure to put following item in module 5:

- A cover letter
- xpt data from CDISC ADaM/SDTM submission pilot [CDISCPILLOT01](#)
- R code to generate 4 analysis outputs
- Generated outputs
- One proprietary R package “pilot1wrappers”
- An ADaM reviewer’s guide (ADRG)

In this pilot, we aimed to provide a working example of R submission in eCTD format to the pharmaceutical industry that can pass the FDA electronic submissions portal. 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(s) (i.e. “pilot1wrappers”)
- Install and load open sourced packages used in this submission
- Reproduce the analysis results
- Share potential improvement areas of the submission materials and processes via a written communication

All data, code, material and communications will be publicly available.

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