

R submission Pilots to FDA - *By the R consortium R submission Working Group*

Presenter(s): Ning Leng, Roche-Genentech , Eric Nantz, Eli Lilly, on behalf of the R submission W/G



R Submission Working Group:

A cross industry collaboration to improve open-source language usage in the regulatory setting

Pilot 1 Submission to FDA:

Successful open pilot that showcased R based FDA submission

	Pilot 1 (finished)	Pilot 2 (submitted)	Pilot 3 (submitted)	Pilot 4
Main Purpose	TLF	Shiny	ADaM	Shiny in Container
Operational feasibilities tested				
Submission of Analytical codes	.r files		.r files	
Submission of proprietary R package	pkglite	golem + pkglite	Github repo	
Dependency management	mran snapshot	renv	renv	Container, WebAssembly

<div><div><div>FDA</div><div>U.S. FOOD & DRUG ADMINISTRATION</div></div><div>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH OFFICE OF TRANSLATIONAL SCIENCES OFFICE OF BIOSTATISTICS</div></div>	
STATISTICAL REVIEW AND EVALUATION	
NDA/BLA #:	BLA 111111 (R pilot submission)
Applicant:	R Consortium's R Submission Working Group
Statistical Analyst	Hye Soo Cho, AIS Hye Soo Cho -S
Supervisor	Maria Matilde Kam, AIS Maria Matilde S. Kam -S
Date(s):	March 10, 2022
Objectives of the submission	To test and support R-based clinical trial application submission
Location of datasets and programs	\\cdsesub3\evsprod\BLA111111\0002
Reviewed tables and figures	Table 14-2.01, Table 14-3.01, Table 14-3.02, Figure 14-1
Summary	
<ul style="list-style-type: none">An FDA analyst was able to complete the following tasks:<ul style="list-style-type: none">Receive electronic submission package in eCTD formatReconstruct and load the submitted proprietary R packageInstall and load open-source packages used in this submissionReproduce the analysis resultsShare potential improvements to the submission deliverable and processes via a written communicationFDA agrees that the initial phase of the R Pilot submission has been completed.For future reference, FDA suggest calculating 95% confidence intervals in a consistent manner.	

Key Links

- Webpage: <https://rconsortium.github.io/submissions-wg/>
- Pilot 1: <https://github.com/RConsortium/submissions-pilot1-to-fda>
- Pilot 2: <https://github.com/RConsortium/submissions-pilot2-to-fda>
- Pilot 3: <https://github.com/RConsortium/submissions-pilot3-adam-to-fda>

All materials are open to the public
Anyone is welcome to join the working groups! (info@r-consortium.org)

