

R submission Pilots to FDA

By the R consortium R submission Working Group

Presenter:

Ning Leng, People and Product Lead, Product Development Data Sciences,
Roche-Genentech (*we are hiring!*)

The R Consortium R Submission Working Group:

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



Pilot 1 Submission to FDA:

A successful open pilot that showcased using R in FDA submission

		DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH OFFICE OF TRANSLATIONAL SCIENCES OFFICE OF BIOSTATISTICS	
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	Vcdsub5vevprod\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 format Reconstruct and load the submitted proprietary R package Install and load open-source packages used in this submission Reproduce the analysis results Share potential improvements to the submission deliverable and processes via a written communication FDA 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. 			

The Submission pilot 1 execution team

Ning Leng, Heng Wang (Roche)
 Mike Stakehouse, Eli Miller (Atorus)
 Yilong Zhang, Peikun Wu (Merck)

Next Steps

- Pilot 2: shiny based pilot submission to FDA
- Pilot 1 extensions: pilots to additional agencies (Japan-PMDA, HTAs)

Key Links

- <https://rconsortium.github.io/submissions-wg/>
 - Webpage
- <https://github.com/RConsortium/submissions-pilot1-to-fda>
 - Final submission folder for Pilot 1 - following eCTD required folder structure

All materials are open to the public

Anyone is welcome to join the working groups! (info@r-consortium.org)

Thank you!