

Insight into growing use of R

R Consortium Pilot Submission

Python and R programming are creating its own niche in the pharmaceutical industry despite being hindered by SAS & other several factors

The R submission working group is a cross -industry pharma working group focusing on improving practices of R-based clinical trial regulatory submission. Easier R-based clinical trial regulatory submissions Pilot 1 – Test Submission

- 2021.11 Initial submission to FDA
- 2022.12 Received FDA response
- 2022.02 Revised submission to FDA
- 2022.03 Received final FDA response

Source: <https://www.r-consortium.org/blog/2021/12/08/successful-r-based-test-package-submitted-to-fda>

The FDA Approach

- In FDA policy: sponsors may use R in their submissions
- The FDA does not require any particular software to be used for clinical trial submissions
- No regulations restrict the use of open-source software (including R) at the FDA
- Any software (R included) used to prepare data analysis from clinical trials must comply with several FDA regulations
- The R Foundation provides a guidance document for the use of R in regulated clinical trial environments

Source: User 2012 conference Poster – Jae Brodsky, Office of Biostatistics, FDA



Advantages and Challenges of Using R/Python

- **Advantages**
 - Cost
 - Ease of Use
 - Community
 - Packages
 - Web Application (R Shiny)
- **Challenges**
 - Support
 - Hardware Needs, RAM
 - Packages of Various Quality
 - Internal Packages
 - Reproducibility (not just R but all versions of packages)

FDA Views on R

- All results from data should be reproducible independent of software used
- The FDA has used R for its own reports
- In submissions, FDA reviewers would like to know:
 - which R functions were accessed;
 - how they were accessed; and that the results are accurate, reliable and consistent
- (Interesting side-note: as a government agency, its reports must be Section 508 compliant, one part of which demands that reports be accessible to readers with limited color vision)

Source: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/guidance-industry-computerized-systems-used-clinical-trials>

Comparison Table: SAS, R, and Python

Criterion	SAS	R	Python
Cost	High	Low	Low
Learning	High	Low	Low
Data Manipulation	High	High	High
Analytic Modelling	High	High	Medium
Graphical Capability	Low	High	Medium
Text Processing	Low	Medium	High
Big Data	Medium	Low	Medium
Usages in Pharma Industry	High	High	Medium
Current Jobs in Market	High	Medium	Low
Customer support	High	Low	Medium
Advancements in tool	High	Low	Medium

Source: SAS vs R vs Python | 13 Most Wonderful Comparisons To Know (educba.com)