

Shiny App Validation in Regulatory Submissions



Community Meeting
12:00 EST
25th Feb, 2025

R Consortium Pragmatic Support with Global Reach

- R Consortium Community **Grants** and Sponsorships Over **USD \$1.4 Million**
- Organize large scale **collaborative projects**
 - **R Validation Hub**
 - R-Ladies
 - R Submissions Working Group
- Co-host multidisciplinary **data science forums**
 - Stanford Data Institute
- Direct support for key **R events**
 - useR!, New York R, R/Medicine, R/Pharma, more
- Direct support for **R User Groups**



Join the R Consortium!

The R Validation Hub is a Working Group under the R Consortium



- Enhance the R ecosystem
- Help ensure the future of R
- **Collaborate** with your peers across industry
- Provide **leadership** in the **R Community**
- **Protect** your **investment** in R
- Support open source

Our Membership

ASA

Biogen

esri

Genentech

Google

GSK

Janssen

Johnson & Johnson

Lander Analytics

Merck

Microsoft

Oracle

Parexel

Pfizer

Posit

Procogia

Sanofi

Swiss Re

... and more!



Structure of today's community meeting

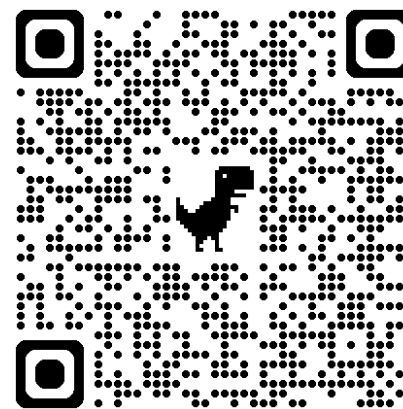
- Primer on today's topic
- Polling about Shiny apps to learn more about everyone
- Briefing on Shiny app pilots to FDA
- Discussion



Today's Topic

Thank you for responding to our survey we sent out last year to hear from you on what topics you wish to have spotlighted at our meetings! Our topic was born out of many requests to hear more about Shiny apps and validation related to Shiny apps.

- Shiny App Validation in Regulatory Submissions
 - *Today's discussion can be about validation of Shiny apps in general, as well*
- Shiny apps are complex
 - Dynamic inputs/interactions and reproducibility
 - General expectation of no errors
 - User accessibility (new to apps, etc.)
 - ...and more!



Submit to our survey here!



Let's learn about each other!

- Have you ever *used* Shiny-based apps?
- What is your experience level with *developing* Shiny apps?
- Do you or does your company typically use Shiny for data exploration, presentations, outputs for regulatory submission, or both/neither?

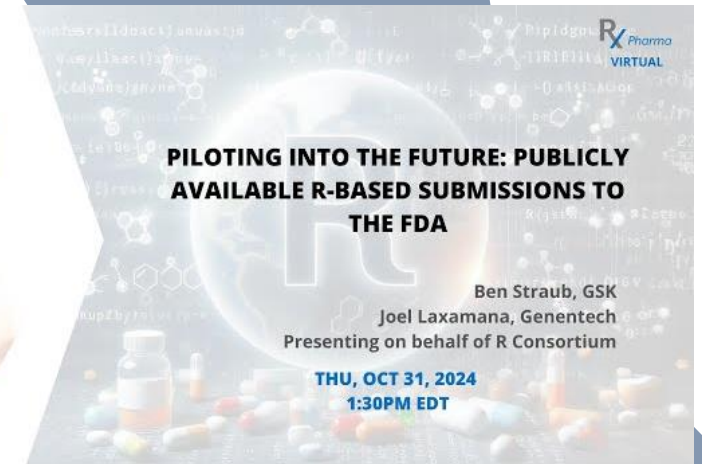


Join the Mentimeter to submit your responses (it's anonymous!)



Shiny App Pilots to the FDA

- R Submissions Working Group
- General focus on process rather than content (ex: moving R files)
- Emphasis that Shiny apps not to replace standard analysis programs
- *Pilot 2* ([GitHub webpage for pilot](#))
 - 3 tables and 1 figure, using SDTM and ADaM as source data
 - Finding of moving away from pkglite; package availability on CRAN
 - Successful review by FDA in September 2023
- *Pilot 4* ([GitHub webpage for pilot](#) / [R Consortium post link](#))
 - Objective of exploring novel technologies for bundling Shiny apps into self-contained packages
 - “More to come with Containers!”
 - Under active review as of late November 2024



Discussion Questions

- App validation versus package validation?
- At what point are you comfortable with considering an app go be “validated?” Do you expect them to be validated to the same rigor as a package is?
- Do you believe Shiny apps should be used in regulatory submissions? What are the pros and cons? Is it worth the time investment of developing an app and validating it?
- What other components of Shiny apps may complicate their ability to be validated?



Thank you for joining!

