



Posit/RStudio Pharma Updates:

Reproducibility and Beyond - Feb 2024



>Hello Again!



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>Open Source Drug Development

- NEST: Now & Future
- Open Source NDAs
- Novo Nordisk: Journey to an R-based FDA submission
- Posit: Benefit Corporation
- Increasing Number of Pharmas use R in Submissions

“Mission: Support Open-Source Scientific Software”



>Return on Investment (ROI)

- Partnerships and collaborations with external partners
- Streamlined Workflows
- Talent out of university more likely to know open-source programming languages
- Latest developments more rapidly
- Switch between languages and contexts more easily
- Time savings in creating standard TLGs
- Time savings in creating customized TLGs
- Access to free solutions to support creating a clinical submission



>Small/Medium Pharmas & Biotechs

“How do we get started?”

- Start Simple
- “Since 2017, GSK has embarked on various initiatives aimed at creating a ‘multilingual’ Statistics, Programming, and Data Science community”
- The Need for Speed - AccelerateR-ing R Adoption in GSK
- Shiny in the exploratory space
- pharmacokinetics (PK) and pharmacodynamics (PD)
- use R to generate TABLES, LISTINGS, AND FIGURES (TLFs)
- Discuss the availability of using R prior to submission & here



➤ Create an Open Source Language Version and Package Plan!

- Which R packages are needed? This is usually driven by business demand
- Share a survey or form with the statistical programmers, biostatisticians, and clinical data scientists to discover which packages are currently being used
- R and Python versions in use

“Is there a list of R packages that are currently accepted for regulatory R submissions?”



➤ Create Standard Operating Procedures (SOP) to “Validate” Packages

- R Validation Hub’s Risk-Based Approach
- Transcelerate Modernization of Statistical Analytics (MSA)
- Posit Validation information is here:
- Further Validation with testthat
- Or Buy validation documentation, testing and packages via Valtools



➤Freeze Packages in Posit Package Manager

“The documents and tools above, and the implemented risk-based approach, allow organizations to establish a baseline of pharma specific packages that are deemed controlled for internal use”

- Internal Repository of Packages for Clinical Trials
- Packages selected specifically by Quality & IT for clinical trials
- In addition to R, organizations can create curated repositories for Python packages from PyPI

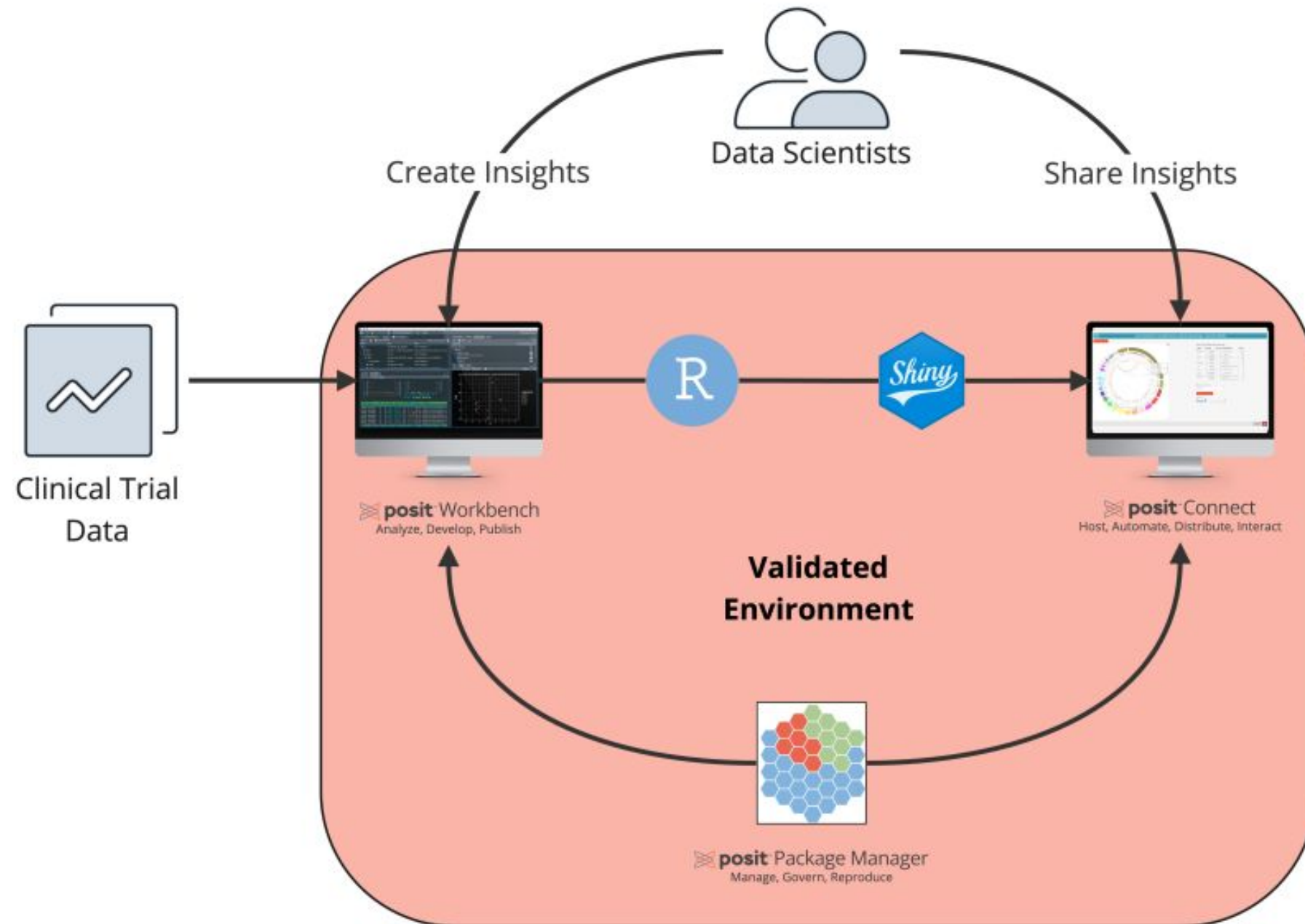


➤Deploy Frozen/Controlled Packages into Site/System Library

- Pre-install all “validated” packages in a site library
- And then Organization will often test/validate once
- Setting repository locations by the IT Admin in Rprofile.site
- IT will often configure the user-interface of the RStudio IDE to discourage end-user package installation
- For different R versions, IT can also create a process to set the appropriate repositories depending on the active version of R selected by users in RStudio



Validated Posit Team SCE



➤ Other Tools for CSR, Interactivity & Reporting

- Quarto
- renv
- pak
- gt
- Great Tables
- Shinylive
- webR & here
- copilot



Thank you!

- Shiny Day
- rinpharma.com

