

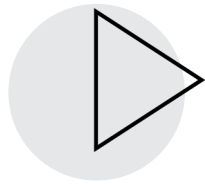
The Next Phase of Open-Source Adoption

Mike Stackhouse, Atorus

October 16th, 2023

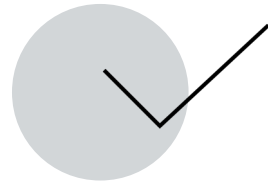


Open-Source in Pharma Timeline



< 2020

Internal development of R packages. Some packages start emerging as open-source



2020-Q1

R Validation Hub white paper is released, describing a risk based approach to R package validation



2020-Q4

More open-source packages begin emerging publicly



2021-Q1

Cross organization open-source collaborations on R packages begin



2021-Q4

Emergence of Pharmaverse



Now what?

Why Open-Source?



Clinical reporting (CRF -> Submission) forms a small part of a large chain in bringing a treatment to patients



This space can be considered “post-competitive” - as it is our treatments that set us apart



Thanks to CDISC we have industry standards that mean we all face the same challenges



We have much more to gain (than to lose) through industry collaboration around open-source



With all that we collaborate on, why not code?

Why Bother Changing?



What's the ROI of new technology?

Current processes at many organizations are optimized



If we can't make what we have any better, make something different

Enter Interactive Dashboards



Exploratory Dashboard

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STUDYID	USUBJID	SUBJID	SITEID	SITEGR1	ARM	TRT01P	TRT01PN	TRT01A	TRT01AN	TRTSDT	TRTEDT	TRTDUR	AVGDD	CUMDOSE
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Showing 21 to 30 of 254 entries

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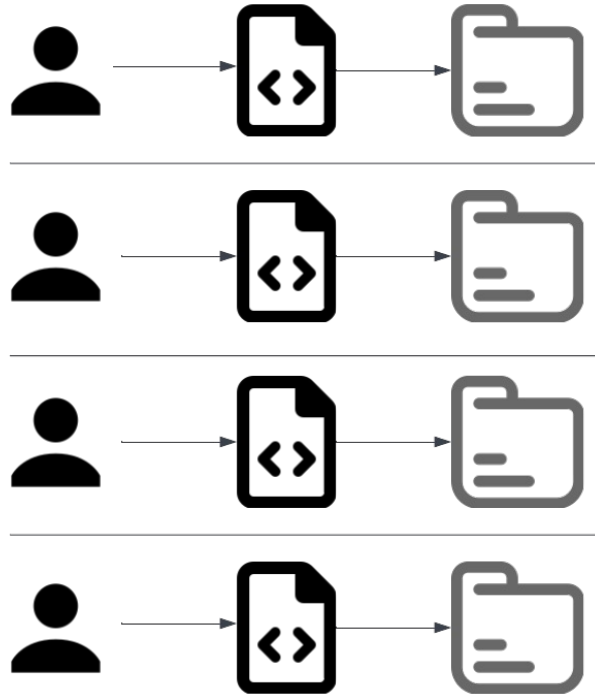
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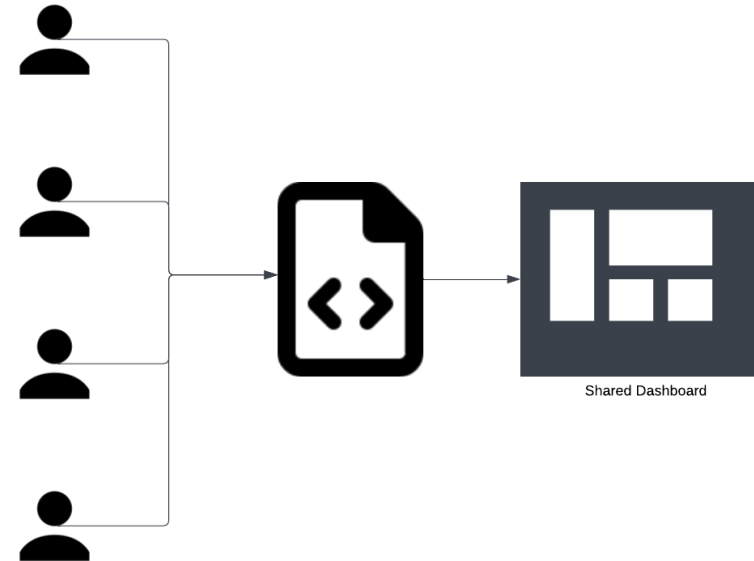
Shiny in Pharma

Complexity of Developing Shiny

Standard Clinical Programming

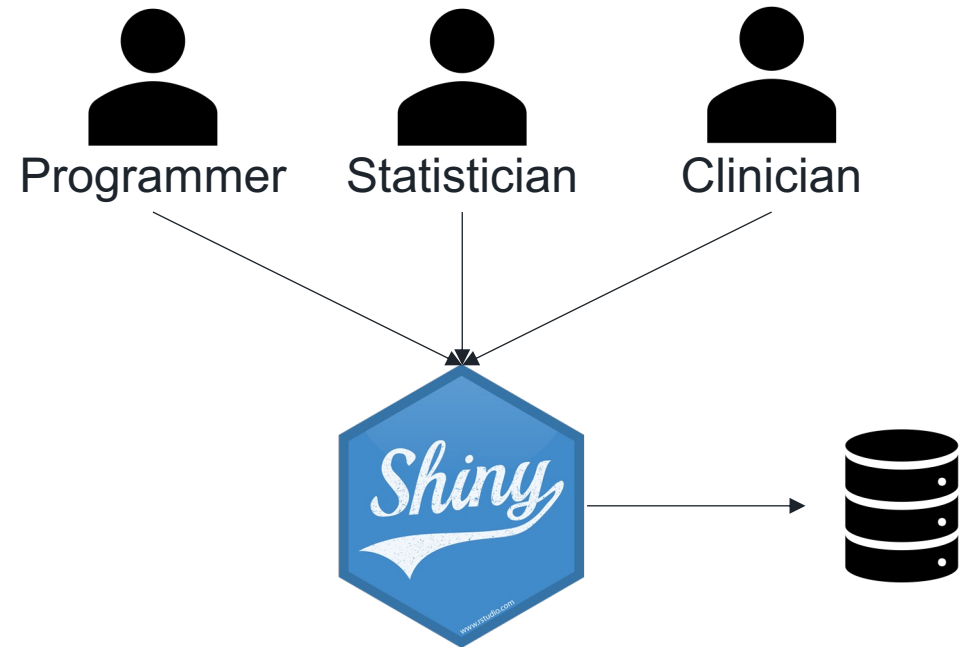


Collaborative Development



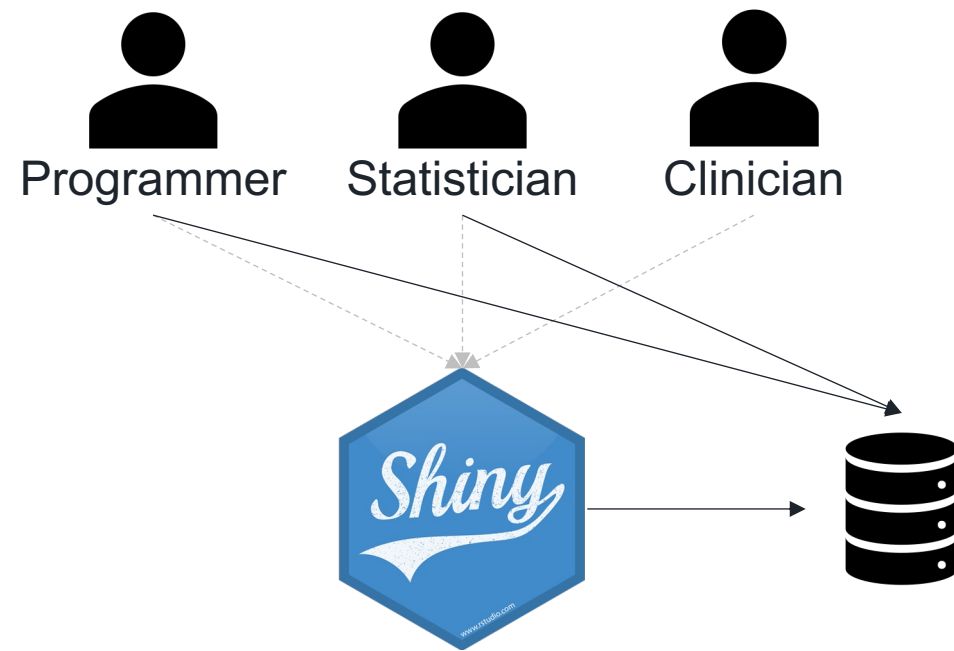
Complexity of Hosting Shiny

- Application likely runs under service account
- Individuals with separate roles connect to application



Added Shiny Complexity

- Programmers, Statisticians have direct access to GxP data
- Clinicians may access app, but not data directly



Data Access Consideration

What's the Opportunity?

Decrease review cycles and iterations

- Close the gap between exploration and validated outputs

One language

- Shiny applications built on same data processing as GxP pipeline

