# Learnings & Reflection from Case Studies

What's next for the R Validation Hub

Community Meeting 2023-06-27

Juliane Manitz, Doug Kelkhoff, Andy Nicholls, Lyn Taylor, Joseph Rickert, Paulo Bargo, Keaven Anderson, Eric Milliman, Aaron Clark and Preetham Palukuru

...on behalf of the R Validation Hub, an R Consortium-funded ISC Working Group



# Agenda

- 1. R Validation Hub Updates
- 2. Recap Case Studies
- 3. Discussion Rounds
  - o Package score thresholds (low, medium, or high vs accepted/rejected) and metric weights
  - Repository for common packages and their metrics
  - Sharing test data and test cases
  - Ensuring and documenting R package reviewers have the right technical expertise

### R Validation Hub Updates

- Passing the baton. Doug taking over for Andy in the lead role.
- Team Survey
  - felt we were doing well to deliver technical products
  - but want to renew our focus on planning and communication
- Calls for Volunteers!
  - Growing a Communications workstream (improving consistency of branding, channels of communication, year-long planning)
  - Building a network of leadership sponsors
- Advanced Notice: Upcoming Events
  - R/Pharma summit at posit::conf (Sept 18)
  - R/Pharma 2023 (Oct 24-26)

# **Case Studies Recap**

### **Case Studies**

- R validation hub initiated a three-part presentation series on "case studies"
- Eight pharma companies participated a case series sharing different experiences on building a GxP framework with R
- Highlight aspects that were easy to implement which those which were more challenging.
- Recordings of these sessions are available on the R Validation minutes page.
- Discussion and exchange to be continued on GitHub, where you are welcome to contribute and learn from others.

### **Case Studies: Common Themes**

- All implementations follow the risk validation process for R packages as outlined in the white paper
- Classification of package quality into high/medium/low or a binary high/low categorization, however the approach to the assessments themselves varies.
- High importance of test coverage as assessment metric
- Trusted resources: R Foundation, thus core R (base and recommended packages) are treated as a collective of "low risk" packages; some organizations also trust Rstudio developments, i.e. tidyverse, etc.
- The majority focused risk assessments only on "Intended-for-Use" packages but several also ran metrics on the Imports.

### Case Studies: Differences in Approach

- Varied degrees of automation in risk classification and qualification i.e. either complete automation or no automation
- Different weights were assigned to the testing coverage and various suggested metadata metrics: acceptable threshold for test coverage ranges between 50-80% for low-risk packages
- Different risk remediation strategies have been applied:
  - some organizations will immediately introduce their own unit tests,
  - others restrict package use to only the tested subset of package functionality.

## Case Studies: Shared Challenges

- R package assessment is a resource-intense activity
  - Time has proven to be a considerable challenge.
  - Ensuring R package reviewers have the right technical expertise
  - Alignment of different contributors across the organization: IT, Quality Assurance and with their own Statistics, Data Science, or Programming lines.
- Finding appropriate test datasets, test cases and expected model output
- Long-term management and maintenance as well as oversight of the risk-based package assessment process

### **Discussion Rounds**

- Package score thresholds (low, medium, or high vs accepted/rejected) and metric weights
  [Aaron]
- Repository for common packages and their metrics [Coline]
- Sharing test data and test cases [Juliane]
- Ensuring and documenting R package reviewers have the right technical expertise [Preetham]

### Discussion Rounds (1/4 with Aaron)

### Package risk scores & metric weights!

### Let's back up first!

What is {riskmetric}?



### **Question for the chat:**

To what extent have you (or your organization) used {riskmetric}?

- a. Never used it, and don't plan to
- b. We're considering using it, but haven't gotten very far
- c. Played with it a bit, but we don't use it formally. We came up with our own method that is...
  - o c1: similar or borrows ideas from {riskmetric}
  - o c2: nothing like {riskmetric}
- d. We use components or all of {riskmetric} in our R-package validation process

# Package scores!

Discussion: How do you feel about **risk scores?** Are they integral to your review process? Do you even care about them? Enter "Care" / "Don't Care" in the chat!

Through our case study work, we've seen many leverage the **low, medium, or high** risk categories. We enhanced the {riskassessment} app to allow users to set "risk decision thresholds" automatically, tagging packages based on pkg score:



### Package scores! (cont'd)

### UPLOADED PACKAGES **▲** Excel **★** CSV Search: PACKAGE VERSION # SCORE . DECISION # DECISION BY DECISION DATE # LAST COMMENT EXPLORE METRICS A3 1.0.0 0.72 High Risk Auto Assigned 2023-06-23 2023-06-23 15:28:05

### So the big question is:

• How high is too high? Put it in the chat!

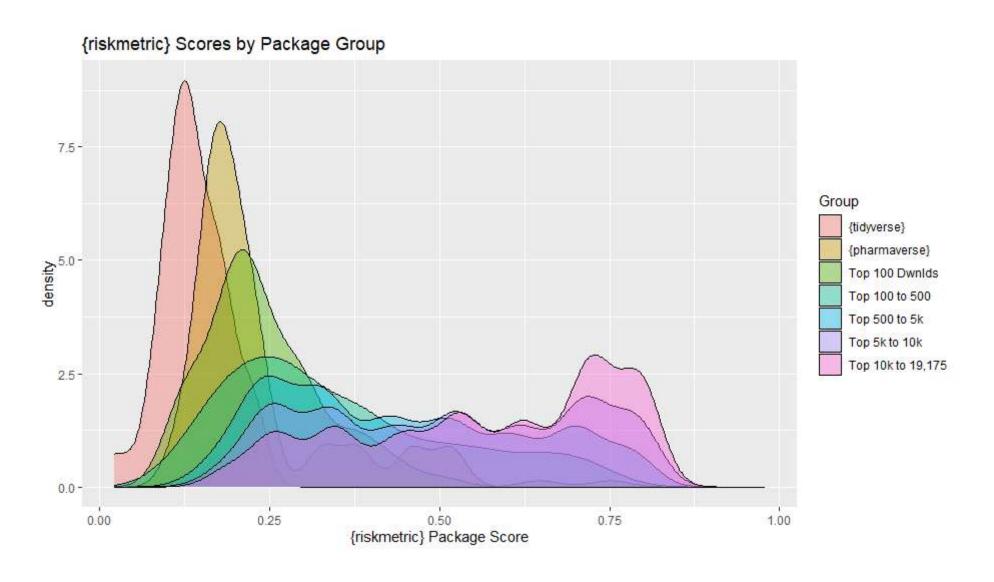
Ultimately, it's up to you. But it'd be nice to have some of consensus. Here is some data to help us make these decisions...

Previous

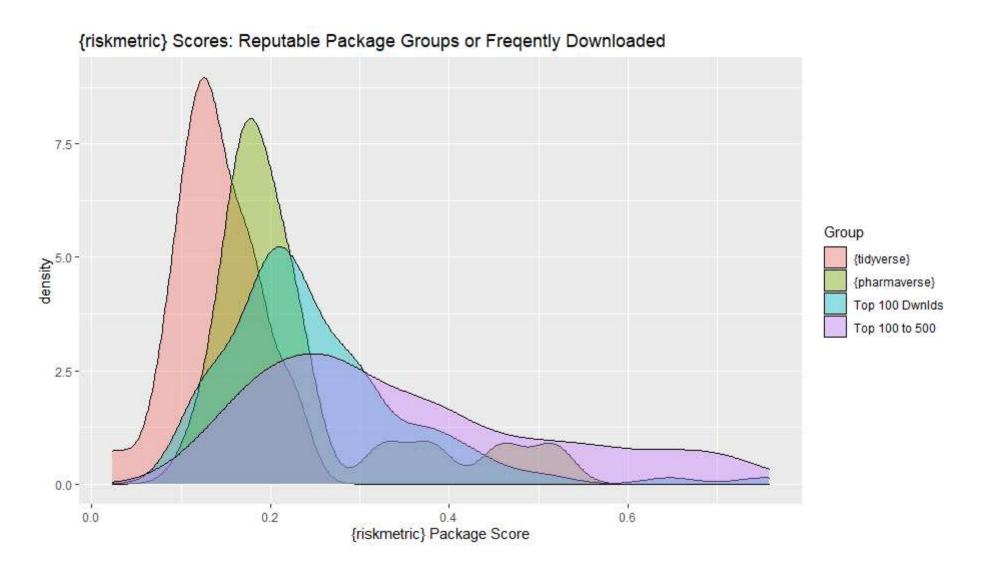
2

Next

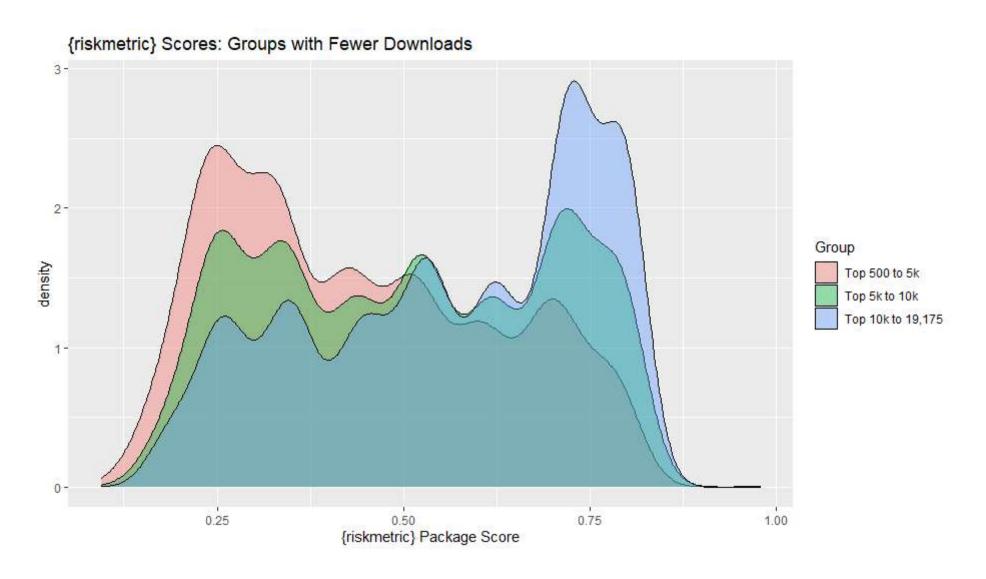
### We scored all of CRAN (19,715 pkgs)



### Pkg Groups and Highly Downloaded



### Groups with fewer downloads



### Package Weights!

```
a: news_current: News file has an entry for the current version of the package.
```

b: has\_vignettes: package contains vignettes.

c: size\_codebase: a logistic rating of the number of lines of code in the package.

d: has\_bug\_reports\_url: package links to a location to file bug reports.

e: bugs\_status: fraction of the last 30 bugs which have been closed.

f: license: the package ships with an acceptable license.

g: export\_help: fraction of exported objects that are documented.

h: reverse\_dependencies: (log10) number of packages that depend on this package.

i: downloads\_1yr: logistic rating of the number of package downloads in the past year.

j: dependencies: number of package dependencies.

k: has\_website: package has an accompanying website.

I: r\_cmd\_check: weighted sum of errors/warnings/notes from R CMD Check.

m: remote\_checks: weighted sum of OS flavor R CMD check results.

n: has\_maintainer: package has a maintainer.

o: **exported\_namespace**: fraction of exported objects that are documented.

p: has\_news: package has a NEWS file.

q: has\_source\_control: package has an associated version-controlled repository.

r: covr\_coverage: fraction of lines of code which are covered by a unit test.

In the chat - say 'up-weight covr\_coverage' or 'up-weight r' or to up-weight or down-weight a metric!

## Do you want scoring data for CRAN?

If you complete our survey, I'll send the data (and code to reproduce my analysis). Of course, you could write a script to do it yourself. But it took 10 hours to run on my laptop, so taking a 10-minute survey would be waaaay easier!



### Stay tuned...

- Presentation @ userR! Conf 2023 in Basel, Switzerland
- Full deployment of {riskassessment} app with top 1k downloaded CRAN pkgs uploaded for companies to collaborate on

### Discussion Rounds (2/4 with Coline)

# Repository for common packages and their metrics

- Does a "one-stop-shop" repository for packages resolve pharma challenges? If not, what is missing?
- Beyond just fetching packages, what are we lacking for building trust?
- How are opinions of packages shared?
- Unit testing is great for development, but is it right for quality assessment? Do we need something more?
- If evidence of quality is shown in a standard comput environment (ie, a rockerverse image), what remaining gaps might prevent immediate company adoption?

### Discussion Rounds (3/4 with Juliane)

### Sharing test data and test cases

- Do you use the CDISC data?
- Do you use example data from standard statistical textbooks?
- Do you share observed differences in implementations at CAMIS (Comparing Analysis Method Implementations in Software)
- How do we channel test cases back to package developer?

### Discussion Rounds (4/4 with Preetham)

# Ensuring and documenting R package reviewers have the right technical expertise

- Who reviews R packages? What is the role of software engineers, statisticians, clinical experts?
- How do we reconcile different interpretations of package quality when viewed from these different roles?
- What can the R Validation Hub do to elevate discussions beyond pure code quality?