

## **Quarterly Update – February 2021**

## Attendees

Andy Nicholls Arne Schreiber Charles Mei Doug Kelkhoff Michael Carniello Eli Miller Joseph Rickert Juliane Manitz Lin Taft Mark Padgham (ROpenSci) Marly Gotti Matthias Trampisch Mike Stackhouse Nash Delcamp Nicholas Masel Pawel (Paul) Bernecki Lyn Taylor Yilong Zhang.

## Agenda

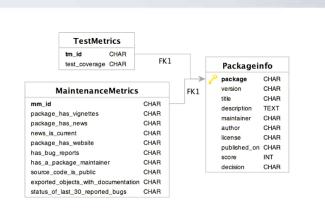
- Risk Assessment app update and demonstration Marly Gotti
- New sub-team volunteers wanted central repository
- General updates
  - Comms / website
  - The riskmetric package
  - $\circ \quad \text{R Consortium}$
  - $\circ$  Testing
  - Stats catalogue
- AOB

#### Update on the Risk Assessment app

# DATABASE

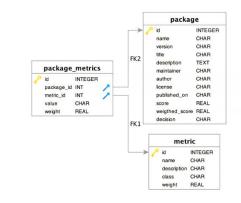
#### • Redesign database

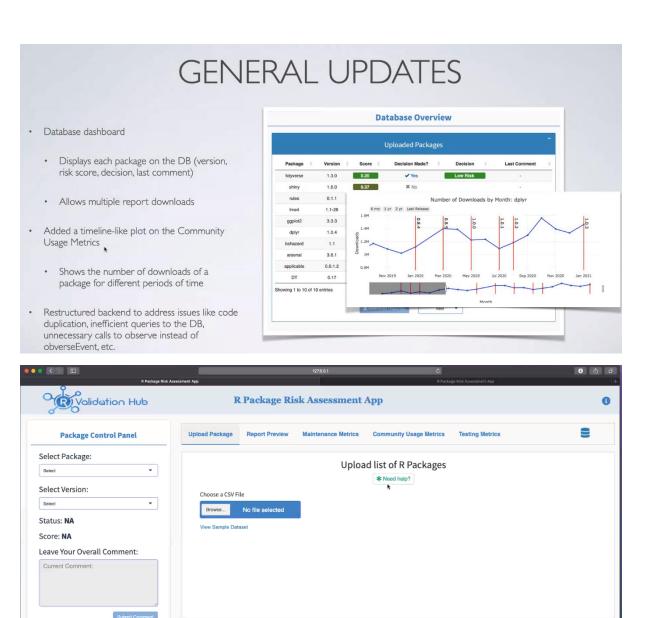
- Unite metrics into a single table
- Tables are object-centric
- New tables:
  - package table: contains each package uploaded to the db
  - metric table: stores information about each metric as established my riskmetric
  - package\_metric: relates the metric table with the package table (contains each metric information per package)
- Dynamically create SQLite database and log file
- Improve inefficient queries. Replace dbSendQuery with dbGetQuery (SendQuery + Fetch + ClearResult)



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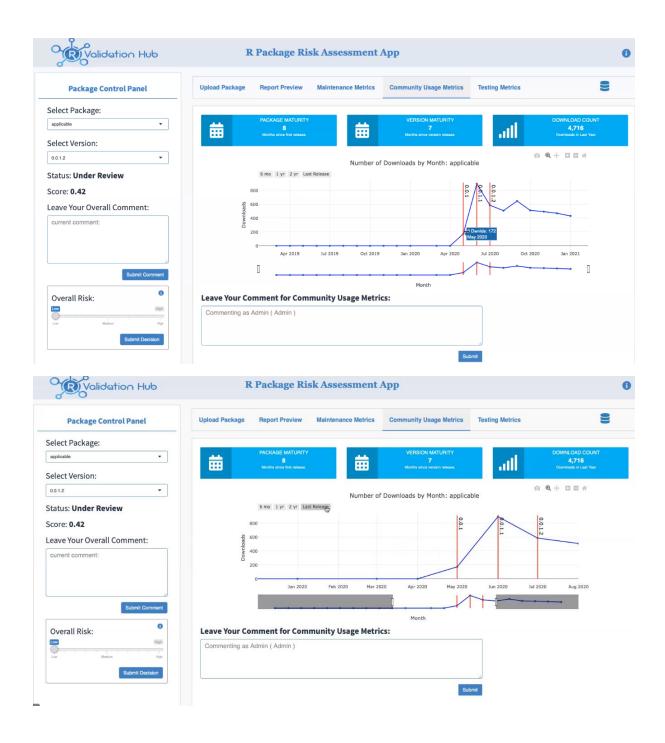


Marly selected a relative new package and showed the timeline plot. This reveals when it was released and download rate. You can select the timeline at the bottom to focus on a smaller review timeline. The Grey is the part not shown on the graph above.

0

Submit Decision

Overall Risk:



Return to Dashboard						
			Database Over	rview		
			Uploaded Packa	iges		
Package	Version	Score	Decision Made?	0	Decision	Last Comment
tidyverse	1.3.0	0.20	🖌 🖌 Yes		Low Risk	
shiny	1.6.0	0.37	× No			
rules	0.1.1	0.50	× No			-
Ime4	1.1-26	0.20	× No			
ggplot2	3.3.3	0.21	× No			S.
dplyr	1.0.4	0.18	🖌 Yes		Medium Risk	9 - E
bshazard	1.1	0.82	🖌 Yes		High Risk	•
arsenal	3.6.1	0.31	× No			
applicable	0.0.1.2	0.42	¥ No			2021-02-15 20:15:
DT	0.17	0.29	× No			
Showing 1 to 10 of 10 e	ntries					Previous 1

For the Overall Risk Score, 1 is high risk, and 0 is low risk. NOTE that the decision score is assigned by the user – based on their personal preference to risk. The current "Score" is based on the current version of riskmetrics but an option to configure weightings is due in future. If new are metrics added to rismetric today, they will not exist in the app.

It's just a proof of concept shown, for example, if you look at dplyr – score 0.18 so low score, but the user decision gave it a median risk. You can then go back to dplyr to check the rationale behind the decision of the user to rate it higher than the app selected.

Database dashboard is work in progress and intention is to add a second table that allows the user to add a second table to change the weight for each metric. This will allow the score for the package to change based on the weight you assign each metric. Weight of 0 means the metric wont be counted.

Package Control Panel	Upload Package	Report Preview	Maintenance Metrics	Community Usage Metrics	Testing Metrics	9
elect Package:						
lplyr 👻	цС	PRESENCE OF VIGNETTI YES The package has 9 vignettes		ASSOCIATED WEBSITE URL YES Website: https://dobyr.sidyverse.org	ٌ ال	NEWS? YES The package has a NEWS file
elect Version:	•	The package has a vignettes	••••	website: https://dpiy.suyverse.org		The package has a rective the
.0.4 🔻	Λ	NEWS IS CURRENT? YES		BUGS PUBLICLY DOCUMENTI		BUG CLOSURE 83.33%
atus: Reviewed	ıC .	EWS file contains an entry for the curre number		Bug reports URL: https://github.com/tidyverse/c	plyr/essues	Percentage of last 30 bugs closed
core: <b>0.18</b>		DOCUMENTATION		SOURCE CODE PUBLIC?		HAS A MAINTAINER?
eave Your Overall Comment:	<u>111</u>	99.65% Percentage of exported objects docu	mented IC	YES Source code URL: https://github.com/lidyver	10'13/Jyr	YES Hadley Wickham <hadley@rstudio.com></hadley@rstudio.com>
surrent comment:						
	Leave Your G	Comment for Main	tenance Metrics:			
	Commenting a	as Admin ( Admin )				
Submit Comment						
0	L				Submit	
Overall Risk:					Submit	

Currently the name of the metric & description comes from the App. However, to be able to populate new metrics in the app, we'd need the riskmetrics package to house the Label & description which currently it doesn't have. So the app assigned these based on the variable name.

Marly asked the wider group if there was anyone interested in contributing to the app to get in touch with her. Welcome to add issues on github and come with ideas for progress/development.

There was a question, if a new metric is added to riskmetrics, how long would it take to get into the App? – it would be quicker if the labels and description of the metrics came from the riskmetrics package – at the moment they are assigned within the App.

Is there any restriction of the choice of database – currently single live sql database doing live queries, if you want to change to a different database internally, then you could do an issue on github and do that.

## **Central Repository**

	koadmap mid-2020	
1.	Process and Communication	
	V Publish website	Jan 2019
	Agree high level process	Jun 2019
	Tools (riskmetric, app) at pilot implementation stage	Aug 2019
	V Develop white paper	Jan 2020
2.	Validation / Qualification Suite	
	CRAN release of riskmetric package	
	Release risk assessment app v1	Aug 2020
	<ul> <li>Centralised risk assessment app and DB</li> </ul>	
	Share test suite	
	<ul> <li>Build test execution tool</li> </ul>	
	Provide an example deployment	
3.	Repository	
	Build Pharma R Repository	

Conversation ongoing regarding structure of a repository and how this may be possible to get started. Doug Kelkhoff updated the group. How packages get reviewed/assessed/approved and how we'd build that into a repository assessment of risk, for use with big pharma /small pharma/ regulators is all under discussion. If people are interested in getting involved in the team please reach out. There is also a new slack channel Rvalidationhub slack.com kicked off for discussion.

### **General Updates**

Riskmetrics package is close to CRAN release.

Conferences that the R validation hub will be attending: JSM Aug  $7^{th}$ - $12^{th}$ .

- ASA biopharma workshop (BIOP 2021) 21-23 sept 2021
- PSI: virtual 21 to 23 June 2021
- Hopefully
  - Use R! 5-9 July 2021
  - DIA: 27 June-1 July 2021
  - o JSM 7-12 Aug

Please come "visit" us/share our sessions/ and reach out to us for discussion.

The R consortium are working on a RTS Certification for statistical accreditation for someone working in a SAS/R regulatory environment. Please get in touch if you want more detail.

Mike Stackhouse and team are working on a stats catalogue collating documentation detailing differences between SAS & R.

Testing sub-stream: At GSK they are built a suit of tests for qualification of R. The plan is to release this perhaps in April/May and hence this can be used as the basis of the testing stream. The tests are based on datasets that are available in literature.

Thank you for attending!