R “Validation” Hub Meeting

18 Feb 2020

Attendees:

Andy Nicholls (GSK) – Meeting Chair
Lyn Taylor (Phastar) – Meeting Secretary

Aldir
Bob Engle (Biogen)
Bryant Chen (Brex)
Colleen McLaughlin (Nuventra Pharma Sciences)
Doug Kelkhoff (Roche)
Eli Miller (Covance)
Eric Nantz (Eli Lilly)
Evelyn Du (TEVA)
John Green (Eco Stats)
John Sims (Pfizer)
Joseph Rickert (R Studio)
Kamila Duniec
Keaven Anderson (Merck)
Lin Taft (GSK)
Matilde Sanchez-Kam (SanchezKam LLC)
Melvin Munsaka (Abbvie)
Michael Stackhouse (Atorus research)
Min Lee (Amgen)
Nash Delcamp (Cognigen)
Natalie
Noam Ross (Eco Health Alliance)
Patric Stracke (Sanofi)
Patrice Kiener (Inmodelia)
Paul Schuette (FDA)
Paulo Bargo (J&J)
Phil Bowsher (R Studio)
Phillip Clarke (RCPE)
Pieter-Jan Stiers (GLPG)
Raj Malathker (Janssen)
Rebecca Krouse (RHO Inc.)
Satish Murthy (Johnson & Johnson)
Tomas Drgon (FDA)
Yilong Zhang (Merck)

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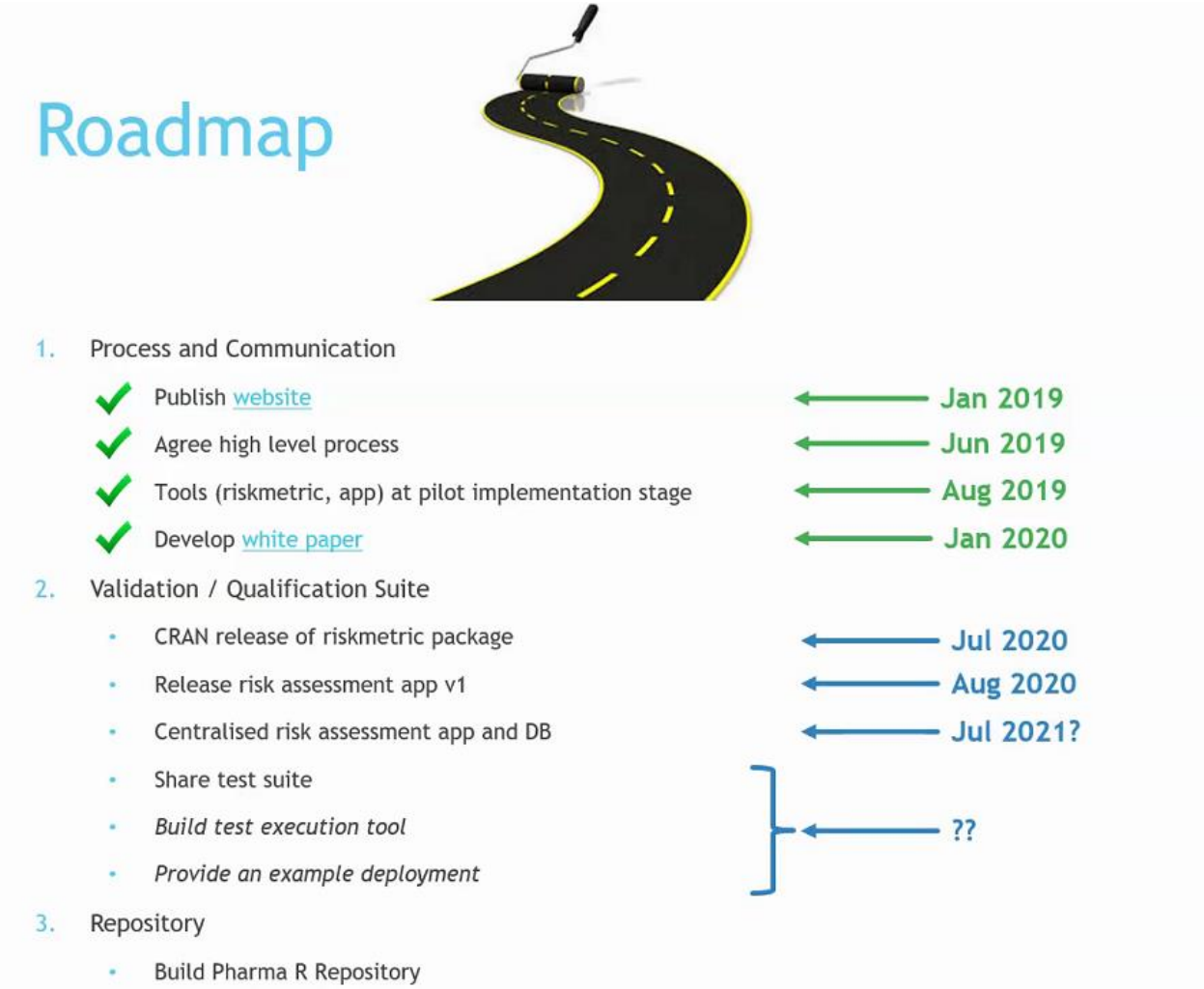
Agenda:

- Summary updates from the workstream leaders
- Call for volunteers

Discussion:



Andy provided a summary of what we've achieved to date and the plan for the future. Please note that if you haven't received the white paper for review contact Andy and he will forward you a copy.

To date, work has focused on the collation of guidance in order to bring together known resources, link into the R foundation guidance and help to clearly provide definitions that will be used in the work going forward. The next phase is to put into practice some tools to enable validation / qualification.

The team aim to finish work on the riskmetric package and release a first version of the app by R/Pharma conference 2020. The GitHub repository for the app will be available sooner where you can go and download documentation however, the next stage is to provide a database in order to link the two together and provide easier access instead of having to clone the repository. The aim is to create a fully hosted app by next year's R/Pharma conference 2021.

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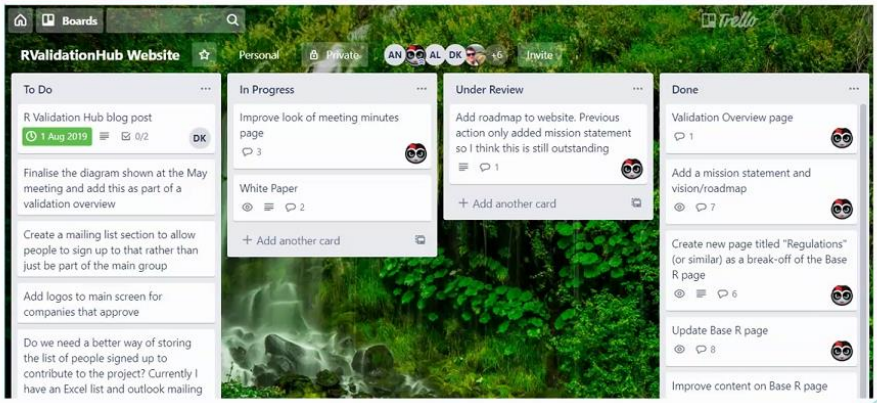
Website

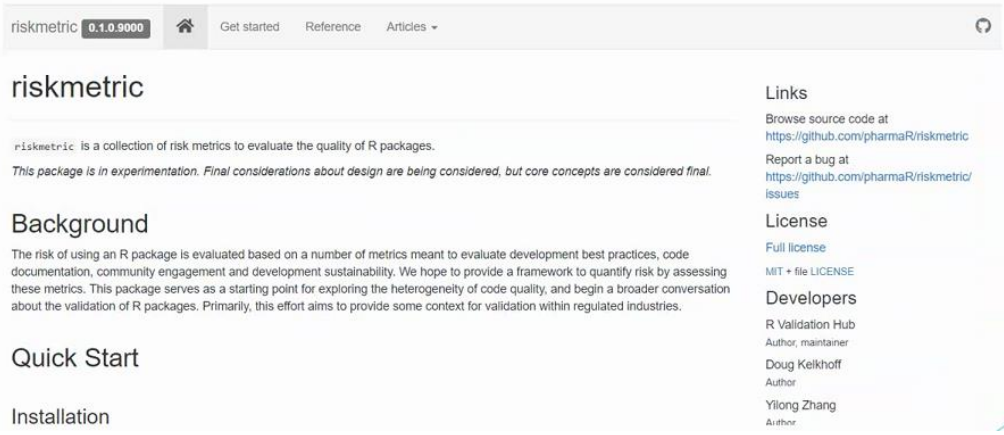
- To undergo redesign for new logo
- Trello board available for suggestions



If you have ideas for the website, or would like to be involved with maintenance of the website please contact Parker and Julianne.

riskmetric

- Package source on GitHub - Help wanted!
- Website live



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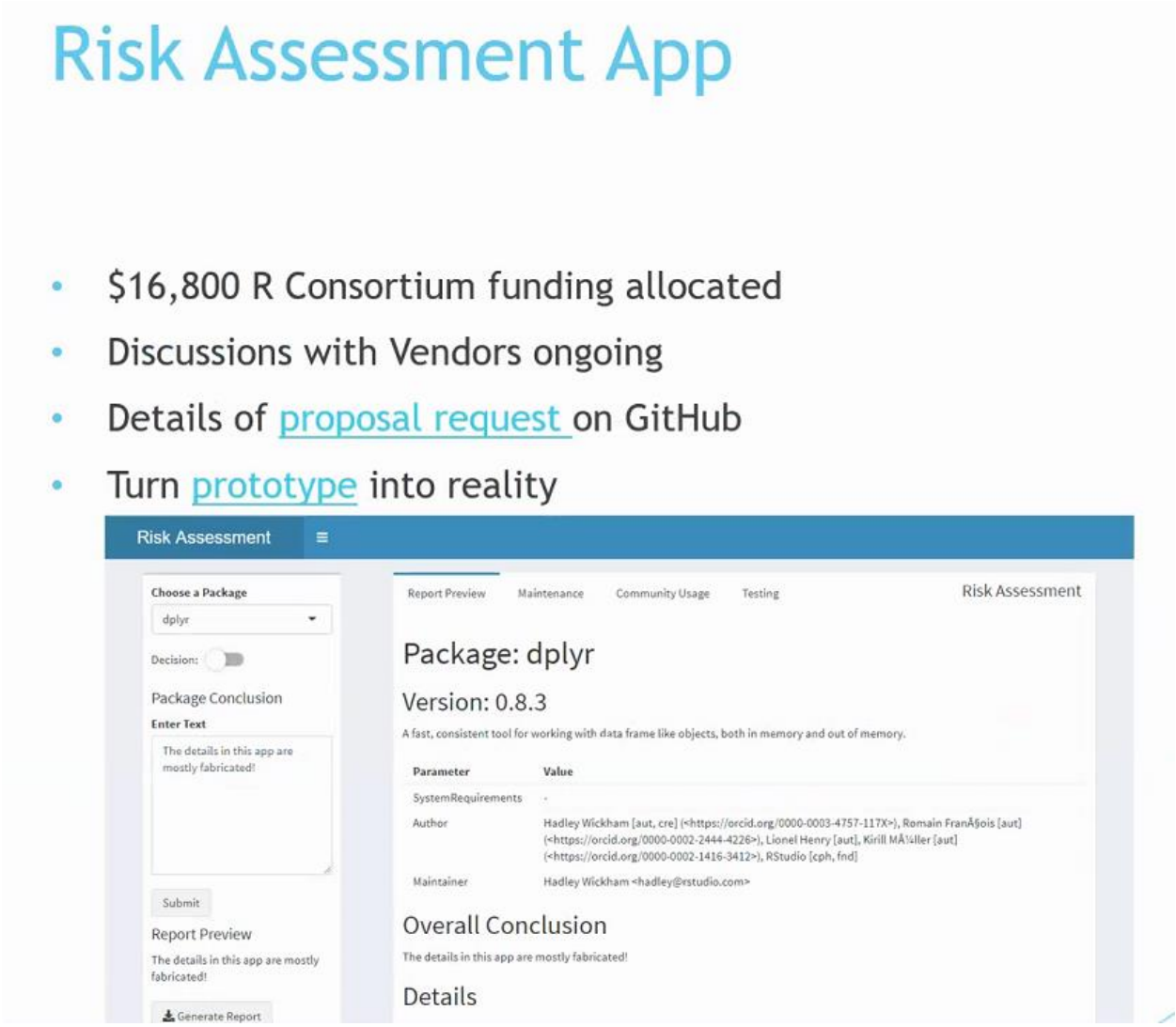
Three contributors have now provided input to the package development. You can contribute code, however it’s not expected to always be involved at that level, it is also encouraged and valuable to the team to have contributors weigh in on how to quantify metrics. If you go to the GitHub Issues log and provide feedback that would be great.

Contact Doug or Yilong if you can help to contribute to the discussion and to see the priority of issues that are trying to get resolved.

It was questioned whether the wider team can assume anything that is not assigned to someone is available for them to volunteer to help with. Doug recommends that prior to taking on an assignment, that you attend the bi-weekly meetings where they discuss what is priority to tackle first, and discuss any detail about the issues. Reach out to Doug to see how to contribute. If you go to the readme on GitHub, there is information about the timing of those meetings and how to get the invite. It would be great to have more people contributing.

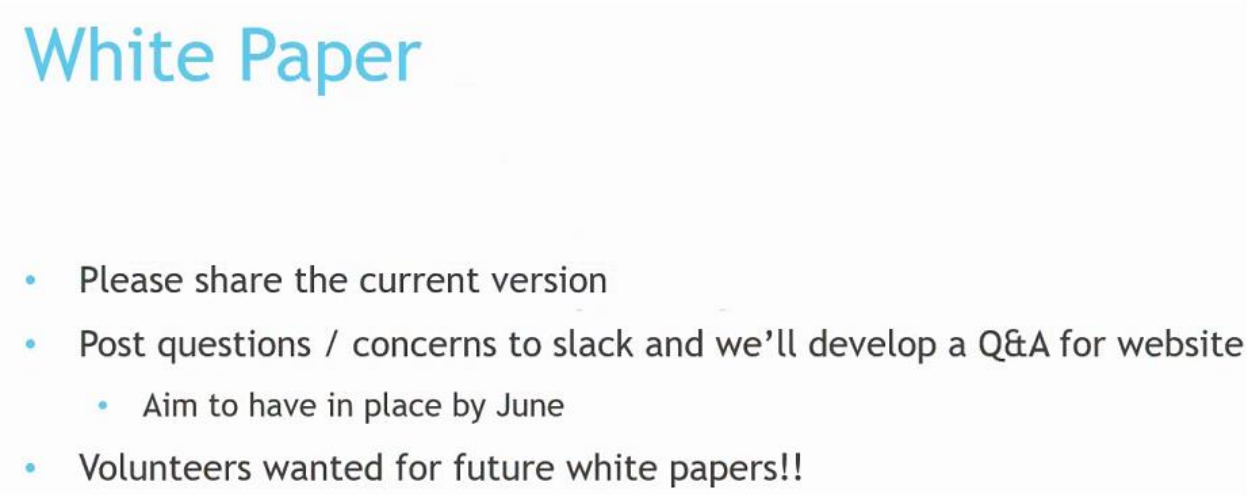


The plan is to have this app ready for August 2020, which will connect to the Riskmetrics package and enable the user to pull out information using an App.

Two weeks ago, everyone collaborating in the R Validation Hub, would have received a copy of the white paper. This document is a cumulation of the thinking over the last year. The team wanted to release the paper to enable the start of a wider debate outside of this group. It is hoped that the release will enable it to reach heads of department and bioinformatics/ wider groups. The paper is presented as a snapshot of thinking at this time, and it will not be a final set of thinking. There will be areas of improvement and further releases of guidance.

If you have comments, please contribute on Slack. If you would like to contribute to a future paper which will contain the evolved thinking then let Andy know.

The paper doesn’t go into detail on Remediation, Qualification and Containers which a future version would hopefully provide more information on. Please get involved via Slack to contribute to a future version.



The current version will not change, but future versions will revise our thinking and add detail.

For feedback, we want to know areas that you think the Hub's direction needs to go in, in order to address issues and questions. We also hope to have a Q&A area on the website to address questions/concerns on the paper.

Please post all feedback via slack.

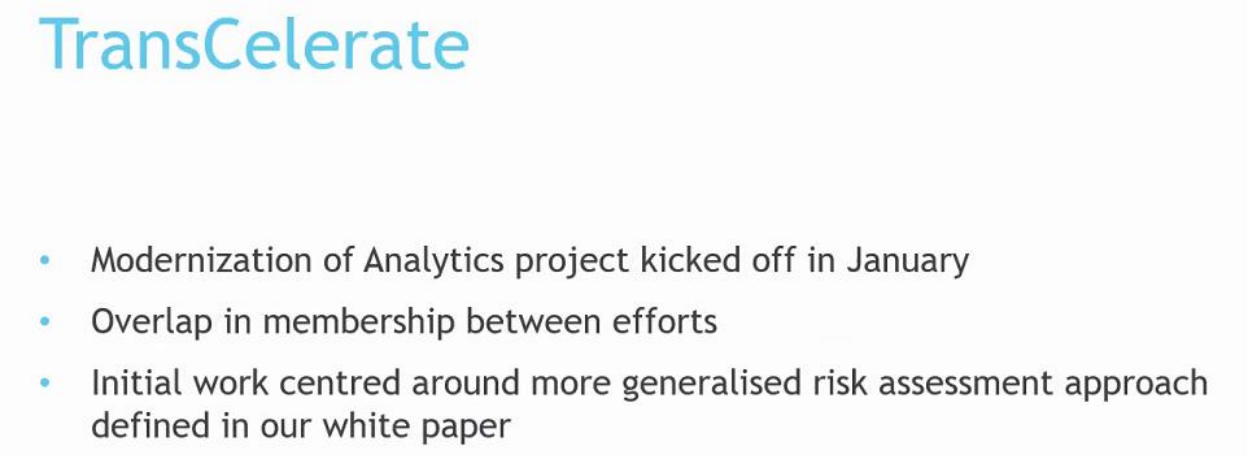
Thomas Drgon asked for more detail regarding the funding awarded by the R consortium [regarding the risk assessment app]. Andy clarified that you can look at the proposal through the link included in the slides. Joe added that although this is a one-time funding for a clear single objective, if the group achieve this objective and then want to develop further objectives, then the Hub can request further funding.

Keaven Anderson is working with Tilo Blenk on the release of qualification test guidance. TransCelerate is now getting active in this area and hence we expect synergy between the two groups.

If you look at an R package and classify it as medium/high risk and as such you want to mediate that risk assessment by providing some testing, we want to provide guidance on how to do that. Eventually It would be good to collate and store tests for packages, but this stream is part of a wider group looking at what level of testing is appropriate.

There would be interest in sharing how companies are getting packages qualified. Keaven is going through a few prototypes, the methods may vary based on if the packages use statistical testing or not. Keaven would be interested in getting examples from other companies in order to develop a framework.

In this field it seems easier to learn by doing, rather than pre-specification of the process. For different packages, we are likely to have different needs of the testing required. The balance between qualification of the install (based on a prior assumption that if the package is installed correctly then it will produce the expected results), will be different to testing that the package actually does what we expect it to do. We need to define requirements and then align testing to suit. Finding a balance between qualification of install and testing the package results could be the focus of a further white paper.



Several of the companies represented in this R Validation Hub are also on the TransCelerate group “Modernization of Analytics”. Their initiative is broader than ours (including all open source analytics software and closed source such as SAS). They are looking at what approach should we be taking if we are bringing in new tool, in a modern environment, to feel confident in using them in a regulatory “validated” environment.

There may be areas, where TransCelerate can progress areas quicker than the R Validation Hub, because they are dedicated resource as opposed to volunteers.

This is a volunteer effort and we need volunteers to come forward. This can be in various areas such as:

- Thinking about advertising and sharing / dissemination of our work.
- Technical development of the tools
- Critical thinking.

If you are interested please get in touch with the steam leaders directly or through psi.aims.r.validation@gmail.com

Previous Action Items

Actions

Action Item	**Stream Leads and/or Exec rep**	**Deadline**	**Status**
Website content updates	Juliane Manitz, Parker Sims	NA	Ongoing
Risk assessment workstream – rickmetrics package	Yilong Zhang, Doug Kelkhoff	NA	Ongoing
Requirements/tests workstream set objectives + milestones	Keaven Anderson	NA	Ongoing
Progression of the White Paper and feedback via Slack.	Andy Nicholls	NA	Ongoing
Collect examples of audit processes in pharma to demonstrate the non open source arena to see if this can be used by R open Source.	Doug & Noam **(All)**	NA	Ongoing