

# R “Validation” Hub Meeting

22<sup>nd</sup> January 2019

## Attendees:

Andy Nicholls (GSK) – Meeting Chair  
Lyn Taylor (PRA until 31<sup>st</sup> Jan –Phastar starting 1<sup>st</sup> Feb) – Meeting Secretary  
Bo Wang  
Bob Engle (Biogen)  
Claus Dethlefsen (Novonordisk)  
Doug Kelkhoff (Roche)  
Eric Nantz (Eli Lilly)  
Greg Cicconetti (Abbvie) – ASA BIOP Software  
John Sims (Pfizer)  
Joseph Rickert (R-Studio)  
Juliane Manitz (Merck Serono)  
Karma Tarap (JnJ)  
Keaven Anderson (Merck) – ASA BIOP Software  
Kieran Martin (Roche)  
Mark Bynens (JnJ)  
Matthias Trampisch (Boehringer-Ingelheim)  
Min Lee (Amgen) - TransCelerate  
Nate Mockler (Biogen)  
Patrice Kiener (Servier)  
Paul Schuette (FDA CDER)  
Paulo Bargo (JnJ)  
Phil Bowsher (R studio)  
Rebecca Krouse (RHO world)  
Rinki Jajoo (Merck)  
Satish Murthy (J&J)  
Xiao Ni (Novartis)  
Yilong Zhang (Merck)

## Previous Action Items

Nothing outstanding

## Meeting Agenda

- Progress update
- Next Steps
- Call for volunteers

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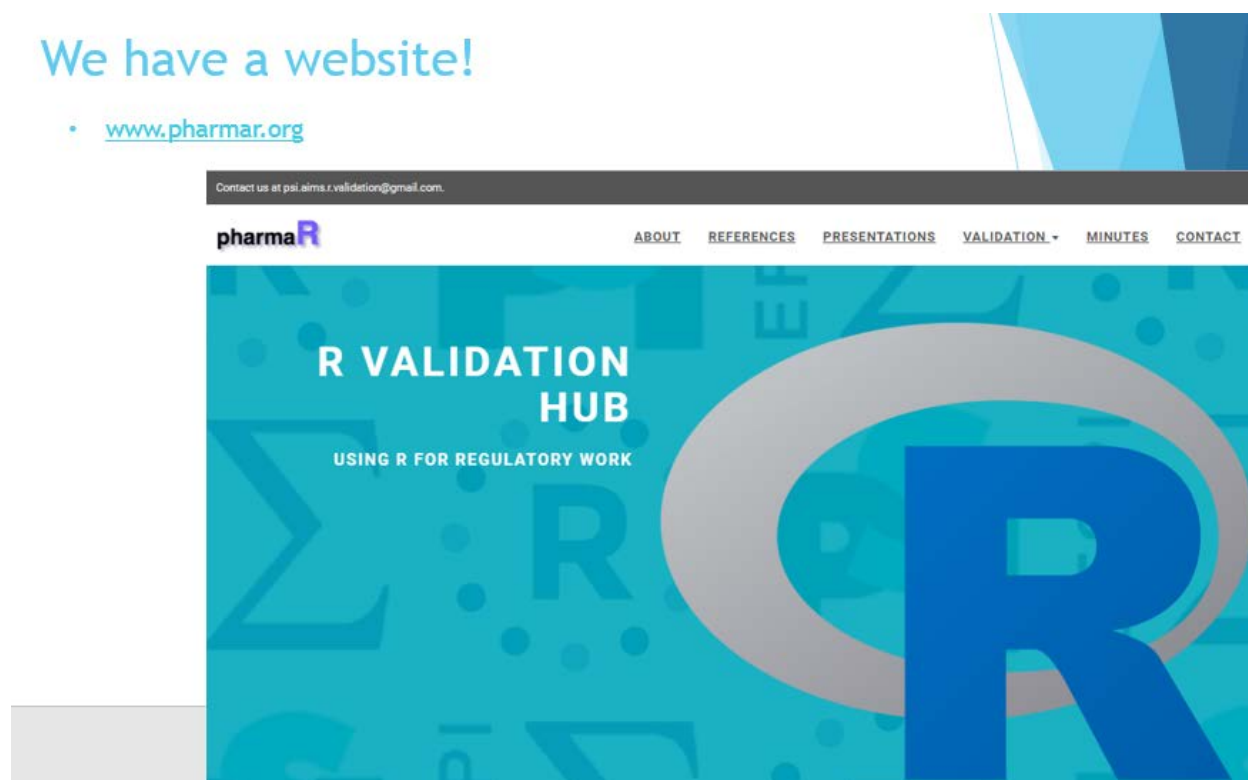
## Discussion

### General Meeting Housekeeping:

Please log into Webex with your full name to ensure you are recorded as being on the call in the meeting minutes. Please keep yourselves on mute if not speaking. Please check discussion in Slack between meetings and contribute where you can, as that will drive most discussion, given meeting time is short. To make sure you are included in the project, please ensure any new members who want to join contact [psi.aims.r.validation@gmail.com](mailto:psi.aims.r.validation@gmail.com) so we can add you to the group and ensure you get meeting invites.

### Website Progress:

Andy introduced the PharmaR.org website, which is now Live! References, Presentations, Minutes and Contact page is all functional with content.



The Validation page is where most content will be stored. The Base R drop down summarizes the opinion that using Base R packages is of minimal risk – hopefully not too controversial but please review & comment on the content.

The R Packages drop down has draft text which we’d like you to review. We’ve split package metrics into “maintenance” of the package and “community usage and testing” (see website for more detail).

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The team were invited to go to the Website (<https://www.pharmar.org/>) or GitHub page (<https://github.com/pharmaR>) to review. On GitHub, if you go to content, you can submit a pull request or use Slack channel to provide feedback.

## Next Steps

- **Review website content!!!**
  - Thanks to Reinhold, Kieran and Yilong in particular for contributions so far
  - Reviewers needed!
- **Create example validations**
- **Begin work on a metrics package?**
  - Additional support from
    - R Consortium?
    - Transcelerate?
- **Requirements / Tests**
- **Announce the existence of pharmar.org within your organisation!**
- **Bigger announcements to follow**

Next Steps for the website will be to start to push packages through the metrics gathering process and build a picture of risk for them. Andy will start with dplyr and hopes to demonstrate the risk associated with the package by using the metrics listed on the website. This can then be used as an example to take other packages through the metrics.

Ideally we want to put together an R package that pulls the metrics automatically. However, given we are volunteers it's a lot of work to do in our free time. Andy asked Joe Rickert how we could go about getting this project resourced/funded. We could apply for a new project to fund it, or we can apply for additional funding (opens in March) under this project ID to fund creation of the Metrics package. We could also apply to be a Top level project in ISC which secures funding for a longer period of time (say 3 years) so there are options available which Lyn & Andy can discuss further with Joe.

We also need a strategy of what we'll discuss at the useR conference this year and dissemination of information about the project to the wider team. Andy/Joe, to have further discussion regarding a communication pathway.

Kieran Martin highlighted that there is a package available in R that could be used to pull metrics, if we can use that package may save some work. Andy responded that there is: “packagemetrics” – from ROpenSci and “packageMetrics2” - from mango.

Paulo Bargo asked if we should publish a white paper to raise the profile of what we are doing in a peer review journal. It was agreed that this is a good idea and Andy is already writing a white paper for GSK which uses a lot of the content also put onto the website.

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Patrice Kiener suggested that we should contact the authors of the packages “Package Metrics” and see if they are happy to join our team. Andy responded that it’s a good idea, and we can definitely try to “packageMetrics” but as “packageMetrics2” is written by Mango, and then produce ValidR software, they may not be willing to join.

Eric Nantz raised that there is a package by Jim Hester: “itdepends” which pulls in details of the dependencies that a package relies upon which may also be useful.

Rebecca Krouse agreed to be the link between our group and the ROpenSci packagemetrics package as she was on that group before.

## Volunteers

- 2-3 volunteers to review / add to current content
- Owner(s) of stream to look at automation of package metrics
  - ~~What should we collect?~~ Done?
  - How do we collect that information?
  - Who builds it?
- Owner(s) of stream to manage requirements / tests
  - How can we make best use of GitHub?
  - How do we link this to the website?

The following Volunteers were identified in the meeting to work on the following streams:

- Review of the website content by 8<sup>th</sup> Feb: Min Lee, Juliane Manitz, John Simms, Keaven Andersen, Direct review back to Andy or message via slack as you prefer.
- Look into how to automate the package metrics (currently “risk assessment” channel on Slack for discussion but we can rename it): Yilong Zhang, Rebecca Krouse, Doug Kelkhoff, Matthias Trampisch, Eric Nantz
- Manage requirements / tests: Nate Mockler agreed to look into this at Biogen. Keaven Anderson (Merck) also interested in this stream as they currently discussing it at Merck [Post meeting note: using gsDesign and need to test it for regulatory use]. Andy confirmed there are other volunteers from GSK who will also join this group (names TBC). No slack channel yet for this but we can create one.

Suggest, that the people above reach out to each other via Slack or Email and assign a leader for each stream group. Please try to meet and then provide feedback at the upcoming future meetings.

Doug Kelkhoff asked that as the current website is statically generated, how will that play out if the intention is to be able to run metrics on 100’s of packages in real time. Andy responded that we ideally

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want to keep all package metrics on GitHub so it's live, but in future we will need to look at how this comes back to the website. If we have to relaunch the website to make metrics live, then we can do that now we own the website domain. It was suggested that we could perhaps use R Shiny app to do this. Matthias Trampisch from Boehringer has done this before and can present how to do it at the next meeting.

Andy reminded the team to use the Slack channel for our discussion, and if anyone doesn't have access to let Andy know. This makes the meeting discussions easier as we'll make progress between meetings rather than waiting for all the discussion at the same meeting.

Other than requesting feedback on the Website content by 8<sup>th</sup> Feb, there are no other identified timelines for the other streams (package metrics / Manage requirements / tests) but the groups are requested to target the next meeting for coming back with plans for next steps in these streams.

### Actions

| Action Item   | Assigned team member(s)  | Deadline              | Status |
|---|--|-----------------------|--------|
| Set up meeting for week commencing 4 <sup>th</sup> March  | Lyn  | 12 <sup>th</sup> Feb  | Open   |
| Communication, dissemination of information about the project to the wider group<br>Possible Funding discussion if we need to write a package to pull metrics         | Andy / Lyn / Joe Rickert   | 12 <sup>th</sup> Feb  | Open   |
| dplyr through metrics gathering process   | Andy   | 4 <sup>th</sup> March | Open   |
| Review of the website content: Direct review back to Andy or message via slack as you prefer.   | Kieran Martin, Min Lee, Juliane Manitz, John Simms, Kieven Andersen (+Any anyone else) | 8 <sup>th</sup> Feb   | Open   |
| Look into how to automate the package metrics and provide feedback at next meeting (currently “risk assessment” channel on Slack for discussion but we can rename it) | Yilong Zhang, Rebecca Krouse, Doug Kelkhoff, Matthias Trampisch, Eric Nantz            | 4 <sup>th</sup> March | Open   |
| Start to look at the Manage requirements / tests stream. No slack channel yet for this but we can create one.   | Nate Mockler & Keaven Anderson & GSK rep.  | 4 <sup>th</sup> March | Open   |
| Start to discuss the white paper  | Andy   | 4 <sup>th</sup> March | Closed |
| Present to the group at the next meeting on how R Shiny may be used to push the live metrics from GitHub to a website.  | Matthias Trampisch   | 4 <sup>th</sup> March | Open   |