R "Validation" Hub Meeting

15 November 2018

Attendees:

Andy Nicholls (GSK) – Meeting Chair, PSI AIMS SIG
Lyn Taylor (PRA) – Meeting Secretary, PSI AIMS SIG

Alun Bedding (Roche)
Chris Toffis (Syne qua non) – PSI AIMS SIG
Greg Cicconetti (Abbvie) – ASA BIOP Software
Eric Nantz (Eli Lilly)
John Mertic (Linux Foundation)
John Sims (Pfizer)
Joseph Rickert (R-Studio)
Jules Hernandez-Sanchez (Roche) – PSI AIMS SIG
Keaven Anderson (Merck) – ASA BIOP Software
Kieran Martin (Roche)
Martin Gregory (Merck KGaA)
Min Lee (Amgen) - TransCelerate
Nate Mockler (Biogen)
Patric Stracke (Sanofi)
Paul Schuette (FDA CDER)
Rebecca Krouse (RHO world)
Reinhold Koch (Roche)
Satish Murthy (J&J)
Steve Noga (RHO world)
Thomas Drgon (FDA)
Xiao Ni (Novartis)
Yilong Zhang (Merck)

Previous Action Items

Action Item	Assigned team member(s)	Deadline	Status
Set up meeting for 1 months time	Lyn Taylor (PRA)	5th Oct	Closed
To think about how you want to shape the future of the project and what you can contribute so we can discuss at the next meeting	All	25 Oct	Closed

R "Validation" Hub Meeting

15 November 2018

Discussion

Andy Nicholls demonstrated the plan for the R Validation Hub Website. The PDF Web mock up will be available after the meeting to view on the RValidationHub Slack Channel.

- Mission/About Tab
    - Containing mission statement and Who we are such as names & email addresses
    - Containing the Logo for the supporting organizations R Consortium, PSI, ASA Bio.
- Using R – Getting started Tab
    - Links to FDA documents, R consortium documents and our interpretation of them such as statement that Base R and Recommended packages have been through sufficient testing such that it is the belief of our group no further testing of these is required. Hence, the Validation Hub focuses on the additional R packages that can be downloaded.
- R Package Information tab with sub-level tabs for the following.
    - Overview
    - Requirements
    - Risk Assessment - Metrics table listing important risks
    - Testing
    - Packages – Available for download on each package the Metrics & Tests

Questions raised in the meeting.

1. Do you envisage calculating a risk score for each package?
   - Yes, perhaps suggested risk or recommended risk containing maybe a low, medium, high risk rating or perhaps a numeric score based on the metrics
2. What do you consider risk?
   - The level of confidence that we have to believe that the package does what it says it does. The risk is based on the Author, downloads, years of use and all the metrics that contribute to our confidence to trust that a package works. Low risk = heavily tested by the community, news feed, bugs revised.
3. Is there concern, that if you provide a risk assessment, that people will use the package without understanding what it does? Other repositories don't contain a risk assessment so do we really need it?
   – Yes, companies want packages behind a firewall to control access to potentially unsafe /unreliable packages. Having a source for risk assessment would be useful because different organizations have different views on acceptable level of risk, definitely helps that there would be a repository with the information stored in a Hub or even just methods of how to get the information.
   - It is useful because we have to provide a suggested risk based criteria before we can even start to put an approach together in our organizations. Therefore this group could try to establish a

reasonable Risk based criteria, then we can take this back to individual company quality organizations to suggest an approach for R package testing that is sensible.
- Agree, if you go to an organization who doesn't know R, they don't know where to start with how to test the functionality, therefore this could provide a baseline for them to review and then they can bring in our own interpretation on if it's enough to meet their needs.

4. Where would the risk assessment come from and who is going to populate the fields?
   - People will be asked to become an approved contributor. Metrics we can gather electronically using existing or new packages. Therefore if you go into the website, it collects live metrics. However, the interpretation of these metrics needs to be agreed by this work stream.
5. How about if we have different levels of validation, you could have it so that you need to pass at least level 1 to get into the Hub but that we assign level 2 or 3 based on the metrics and tests built into the package and if we have checked these key features work.
   - That could be something that comes later, for now we are just looking to have a central storage of metrics
   - It would be good to have several metrics agreed upon that can be used to transfer into a risk score. If we start with the risk score on the hub, then we could move towards having a repository that stores the ones that just meet a set criteria.
6. What about just using the number of downloads?
   - We may have 20 metrics available on the Hub, (one of which is number of downloads), then if a company just wants to use that one metric to base their level of risk on, then that's fine, but having it all in one place enables people to view the risk metrics and decide on their own way of using them.
7. Joe Rickert confirmed that the ISC is moving towards projects having their own GitHub page which contains the documentation of the project (including meeting minutes). Will this approach be adopted here. It was requested to share more content on the GitHub page and include the meeting minutes.
   - Yes, the backbone of the project (the webpage as described above) will be on GitHub - pharmaR.github.io. You will be able to select a package and export the information about that package such as the metrics, requirements and tests that exist in the repository. Everyone will be able to access the site, but you will have to apply to be a contributor to the site so we can have some control over the content. Once approved though, then you can add content on the requirements and tests for packages. The intention would be to have the risk assessment produced as automated as possible, however, we also need some ability to add guidance/comments especially for packages that may have conflicting metrics such as long established trustworthy packages that are no longer being regularly updated or maintained because they work well as they are.
   We can also put minutes onto this site.

R "Validation" Hub Meeting

15 November 2018

Transcelerate

Min Lee provided an update on the Transcelerate project and how that project and this one can avoid duplication.

The Transcerlate project is almost approved (pending BOD approval) –so not formally approved yet. The original intent is to create a comprehensive framework on how to validate an R environment. Touching on all aspects of how to create an R environment that is reproducible and traceable from output to source. It would include guidance of maintenance of versions and dependencies. It will look at the environment as a whole, and the issues we have when using this software to create a framework for a validated environment. The role would not be to actually create a validated environment, but to create the framework of what you would need to do. Transceralate want to develop something quite quickly with clearly defined scope. The way it's structured is that Transceralate will have dedicated resources to achieve a delivery of agreed scope that can then be shared with Transcerate members but some work may be able to be shared wider. It is anticipated there would be a white paper on how to produce an environment that is traceable and how you can validate open source community packages.

Therefore the PSI/R Consortium project and Transcelerate can work together, and will make sure work is not duplicated.

If there is an effort on the PSI/R Consortium validation hub project to produce a Risk assessment and defining a criteria, then it could be that the Transcelerate project looks at what we've done and changes their focus based on what we are doing. In fact, the Risk assessment could be something the Transcerlate project can help us with. Perhaps the Hub provides the risks/metrics, but Transcerlate help us to interpret it. The exact workings will evolve over time and with members represented on both groups, we will ensure no duplication of effort. Hence the projects will complement each other.

Actions

Action Item	Assigned team member(s)	Deadline	Status
Andy to share the PDF with the team for comments and start a Slack Channel discussion. Everyone encouraged to ask questions, give comments and can follow up on Slack for more discussion post meeting.	Andy	30 Nov 2018	Open
Set up Next call – Mid Jan	Lyn	30 Nov 2018	Open