**Attendees:**

|  |  |
| --- | --- |
|  **Team Member** | **Present at meeting** |
| Craig Mcilloney (PPD) | X |
| Lyn Taylor (Phastar) | √ |
| Chris Toffis (SQN Clinical) | √ |
| Andy Nicholls (GSK) | √ |
| Yann Robert (Servier) | X |
| Jules Hernandez-Sanchez (Roche) | X |
| Markus Elze (Roche) | √ |
| Mark Bynens (JnJ) | √ |
| Karma Tarap (JnJ) | X |

Apologies for those not invited to the meeting – Accidental meeting invite issue !

**Yearly Objectives 2019**

1. **Key objective:** Automation of reporting: Most companies are working towards a time from DB lock to High Level results of 24 hours with just 5 days for the Stats analysis to be complete.  Therefore we’d look to ways to assist with this through the use of technology.
2. **Key objective:** Data visualization: Looks at technology to enhance visualization of data throughout the study
3. Work with statisticians and statistical programmers to educate them on Data Science Tools (such as R, GitHub etc)
4. Bridging the gap between SAS and other software (for example, SAS processes / global macros and do it in Git / GitHub)
5. Assist other SIGS implement their needs in software/training/support. – Reach out to SIGS (including data science SIG) and ask if we can help with any of their projects & the implementation of them.
6. R Validation Hub – Continue the work on the Hub project improving the website, and production of R metrics/ tests/ validation documentation

**Previous Action Items**

| **Action Item** | **Assigned team member(s)** | **Deadline** | **Status** |
| --- | --- | --- | --- |
| GIT SPIN article | Mark / Andy/ Markus | 16 Apr 2019 | Closed  |
| Everyone to think about which area they want to look into with the intention of SPIN articles (initially). Could expand to facilitate training.  | All | 28 Apr 2019 | Open |
| Chris agreed to anonymise his handout and we could distribute at the PSI session. Lyn to take a few copies to conference but upload to PSI site AIMS: send link to site on conference App. | Chris | 10th may | open |
| Aim to have 1st draft of conference slides by 10th May. Lyn to set up reminders ! Andy to set up meeting for 17th may to discuss content. | Lyn/Andy/Markus | 10th may – Need to extend this deadline to 17th. | open |
| Chris to look at expanding the AE App to do both exploration and then exporting to reporting  | Chris | Ongoing | Open |
| Lyn look at creating an App using GGPLOT2 that takes the Dataset, Treatment, visit ID and % column and creates graph of % response over time – and outputs in different formats to aid automated reporting.  | Lyn | Ongoing | Open |

**Agenda/Discussion**

| **Topic** | **Discussion/Decisions** |
| --- | --- |
| R Validation Hub update | https://www.pharmar.org/ Next meeting 21st May.Andy will chase the Streams (metrics & tests streams progressing well).Need more work on the website review.Perhaps we need to add a “What is R page” / “How it works” to include package structure. Could utilize something from R- studio. Mark will see if he could write something on this.Andy presenting at the R in pharma conference in August in Boston. 4 hours R validation workshop.  |
| PSI Conference 2019 | PSI conference 2019 2-5 June in QEII Centre London. Tuesday afternoon 1.5 hours. PSI AIMS SIG: DRiving the future of regulatory researchThere is a growing desire to use R in the pharmaceutical industry.  As an extensible, open source, statistical programming language R is a popular choice for simulation, bespoke statistical analyses, and machine learning.  Moreover, the relatively recent addition of the Tidyverse provides a consistent, data-centric approach to programming that is lowering the barrier to entry and proving extremely popular for new adopters.  On top of this, R’s extensibility has led to dynamic reporting tools such as Rmarkdown which is changing the way data are reported.  Following an overview of the AIMS SIGs objectives for 2019, the session will introduce the core Tidyverse concepts and explain how Rmarkdown can be used to reduce reporting times and improve quality.   The session will conclude with an overview of the R Validation Hub (<https://www.pharmar.org>) project achievements to date. Approximate timing:* AIMS SIG update and objectives - Lyn  -  10 mins.
* Tidyverse: Markus – 20 min + 10 mins questions
* RMarkdown: Andy – 20 min + 10 mins questions
* R Validation Hub update – Andy  10 mins + 10 mins questions

Chris agreed to anonymise his handout and we could distribute at the session update & send. Lyn to take a few copies to conference but upload to PSI site AIMS: send link to site on conference App.AIMS github account – may be good to set up if we have sufficient documents? Consider in future.Aim to have 1st draft of conference slides by 17th (ish)! |
| Objectives next steps? | Plan is for each member of AIMS to select an area to do some research in based on the following objectives. The plan would be to share the knowledge via SPIN and the website.1. **Key objective:** Automation of reporting: Most companies are working towards a time from DB lock to High Level results of 24 hours with just 5 days for the Stats analysis to be complete.  Therefore we’d look to ways to assist with this through the use of technology.

**Ideas for work in this area:**Shiny Apps for standard CDISC analyses: AEs – study pop.Chris’s AE / Lab reporting APPs… evolve them to be able to upload new data – query/explore & export to PDF the report. - perhaps have an App button which extracts all standard AE report to reporting format.Joe Cheng (Shiny author) presentation at R in Pharma conference – dplyr filter & run to get code. <https://github.com/jcheng5/rpharma-demo> and also check out: <https://openfda.shinyapps.io/LRTest/>Yann- need to consider validation of the App. – Could cover the topic for SPIN of how to go about the validation of an App. If we output the code, then we could QC the code rather than the app or we could somehow validate the app, then don’t need to validate the code[ACTION: Chris – look into AEs automation] 1. **Key objective:** Data visualization: Looks at technology to enhance visualization of data throughout the study**Ideas for work in this area:**Look at the Lifecycle of graphics – When create a graph we need to make it usable for powerpoint & study reports. Often the ones produced in SAS for part of the TFls gets recreated in excel in order to be good enough for powerpoint / CSR.Instead of creating PDF (includes metadata – protocol ID & header), perhaps also create a PNG version which is graph alone usable for powerpoint – create a better formatRstudio allows you to do presentations straight away. Slidy presentation from R Markdown

Objective: Doing a demo – proof of concept. So perhaps show how to create 1 graphic to put into multiple formats using R / Rshiny or SAS.Yann: For abstracts & posters need to define fixed DPI resolution, and in SAS that’s not good. So have to extract from SAS & draw in specific software.Aim is to avoid having to redraw in Excel. - So possibly create an App using GGPLOT2 that takes Dataset, visit, % column and creates graph of % response over time – in different formats. Lyn to explore and look into efficacy graphic… ask Jules for help if needed!1. Work with statisticians and statistical programmers to educate them on Data Science Tools (such as R, GitHub etc)

**Ideas for work in this area:**Andy keen on this area as GSK are doing some work already looking at this concept. Suggest articles on high level Git concept, then how to use and perhaps how to link to SAS (per item 4 below). Mark also interested in this area.1. Bridging the gap between SAS and other software (for example, SAS processes / global macros and do it in Git / GitHub)
2. Assist other SIGS implement their needs in software/training/support. – Reach out to SIGS (including data science SIG) and ask if we can help with any of their projects & the implementation of them.
3. R Validation Hub – Continue the work on the Hub project improving the website, and production of R metrics/ tests/ validation documentation
 |
| Article writing progress/ All | Deadlines are: approx 20th of the month in January, April, July and OctoberCurrent suggestions for future articles.1. Markus – follow up article on the use of Git with examples/scenarios (October 20th)
2. Andy – Write up on the Quantitative decision making shiny application.
3. R Markdown- part of Rstudio (mention that you get R Notebook within this) to write and publish HTML, PDF, DOC – Jules
4. R Shiny. – intelligent dynamic of AE reporting etc. Chris.
5. High performance in R vs SAS – Yann
6. How to submit a submission package to FDA including R – Any volunteers
7. officer – Andy
8. A showcase of available packages specific to the pharmaceutical industry (e.g. rpact for trial design, diffdf for differences between datasets, subgroup explorer for interaction with clinician, AdEPro for AE visualization – markus (or for psi 2020)
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| References | AIMS SIG information: <https://www.psiweb.org/sigs-special-interest-groups/aims>Our R validation project documentation will be stored on: <https://github.com/pharmaR> with Website: https://www.pharmar.org/Discussion forum: [https://rvalidationhub.slack.com](%20https%3A/rvalidationhub.slack.com%0D)Email for valid Hub: psi.aims.r.validation@gmail.com |

**Action Items**

| **Action Item** | **Assigned team member(s)** | **Deadline** | **Status** |
| --- | --- | --- | --- |
| Those members with no current actions to consider what they can look into aligned to our objectives with the intention of putting together SPIN articles. Could expand to facilitate training sessions in future.  | All | Ongoing | Open |
| Chris agreed to anonymise his handout and we could distribute at the PSI session. Lyn to take a few copies to conference but upload to PSI site AIMS: send link to site on conference App. | Chris | 10th may | open |
| Aim to have 1st draft of conference slides by 10th May. Lyn to set up reminders ! Andy to set up meeting for 17th may to discuss content. | Lyn/Andy/Markus | 17th | open |
| Chris to look at expanding the AE App to do both exploration and then exporting to reporting  | Chris | Ongoing | Open |
| Lyn look at creating an App using GGPLOT2 that takes the Dataset, Treatment, visit ID and % column and creates graph of % response over time – and outputs in different formats to aid automated reporting.  | Lyn | Ongoing | Open |