**Attendees:**

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| **Team Member** | **Present at meeting** |
| Craig Mcilloney (PPD) | √ |
| Lyn Taylor (PRA) | √ |
| Chris Toffis (Amgen) | √ |
| Dave Inman (GSK) | √ |
| Yann Robert (Servier) | √ |
| Helene Savel (Bordeaux University Hospital) | X |
| Sophie Canete (Bordeaux University Hospital) | X |
| Jules Hernandez-Sanchez (Roche) | X |

**Previous Action Items**

Not addressed as this was an ad-hoc meeting: carrying all items forward to next meeting.

**Agenda/Discussion**

| **Topic/Lead** | **Discussion/Decisions** |
| --- | --- |
| Conference advert/ All | Lyn has been working with Chris to be able to convert his R-Shiny AE tabulation work into a presentation/demonstration. Lyn confirmed she will be able to do this and present the work at the PSI conference. Chris still may be able to attend, however will not know until 2018. Therefore we proceed with Lyn leading the demonstration and will acknowledge Chris as the author at the session.  Therefore the session plan would be:   1. Introduction to AIMS  -  Craig 2. Summary of our articles to date (IDEs and RStudio, Validation,  introduction to R-shiny)  - **We are looking for another PSI AIMS member to present this work. Any volunteers who can attend the conference?** 3. R-shiny demonstration/presentation of AE data – Lyn   Craig to email Paul to say Lyn & Craig will present with 1 more person. For the linked in article we propose a brief summary like:   * PSI/EFSPI Application and Implementation of Methodologies in Statistics (AIMS) SIG are pleased to announce details of their session at the PSI Conference 2018.  The session will consist of a summary of our work to date including introductions to RStudio, R-Shiny and a brief touch on concepts of R validation followed by a demonstration of how R-Shiny can be used to create interactive AE tabulations which could be re-run by medics for safety signal detection.   PSI parallel sessions are 1 hr 30 to 1 hr 45 long. The conference will be held at the Beurs Van Berlage, Amsterdam, from **3rd to 6th June 2018. Lyn & Craig confirmed they will attend. Jules & Yann TBC. Craig confirmed that for the Main speakers at the AIMS session, PSI can offer a 50% conference fee discount for the 3-days or a 1 day free (the presenting day).** Does not include travel/hotel. |
| Yann | The following is taken from the MHRA meeting minutes: Usage of R and other specialist software  **Question:** The PSI committee for Applications & Implementation of Methodologies is aware that the use of R has increased within our industry over the last few years, especially for analyses using specialist statistical methodology. This applies in a similar way to other specialist statistical software (eg Win-Bugs). There is a perception that regulatory authorities would not accept statistical analyses performed with open-source software (such as R). What, if any, reservations does the MHRA have about the use of R and other specialist statistical software, and what can we do as an industry to overcome them and provide reassurance regarding their use?  **Answer:** There are no regulations that restrict the use of software. Validation principles to show the results are accurate need to be applied, including which functions used and how they are accessed. All validation processes need to be traceable.  The 2014 publication by the R Foundation - Regulatory Compliance and Validation Issues  A Guidance Document for the Use of R in Regulated Clinical Trial Environments was recommended. https://www.r-project.org/doc/R-FDA.pdf  There is a specialist group in the FDA who have validated certain R functions. A list of packages maybe to choose from is provided in the task view for reproducible research: https://cran.r-project.org/web/views/ReproducibleResearch.html. If using specialist software the following is needed• Check the method used is acceptable• Be transparent about what is being used• Be able to trace the source of routines• Demonstrate SOPs are complied with for validation of user generated software routines• Ensure version control and track changesIt was suggested that companies may wish to cooperate to validate routines and packages within R, or public/private initiatives (such as IMI) could be used for that. Alternatively, specific uses of R code could go through the EMA qualification procedure.Lyn to contact Max Kuhn to see if anyone at Pfizer would join the group. |