**Attendees:**

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

**Yearly Objects 2016-2017**

* Prepare to have a parallel session at conference
* establish relationships with other companies who use the tools we are talking about
* Expand membership of the group (1 or 2 more)
* 1 article in each SPIN newsletter

**Previous Action Items**

| **Action Item** | **Assigned team member(s)** | **Deadline** | | **Status** |
| --- | --- | --- | --- | --- |
| Intro to Validation article | Lyn | 13th September 2017 – send for review  Finalise by Mid Oct for SPIN Article | Closed – Sent | |
| Next Rshiny installment | Chris | Mid Jan SPIN Article | Open - Postponed | |
| SAS & R for MCMC | Dave | Mid April SPIN Article | Open | |
| How to get our articles into EFSPI newsletters & when do they come out. Can the AIMS sig be added to the EPSPI website as well – perhaps link to PSI website?  How do EFSPI members receive SPIN or can ensure our articles are part of the EFSPI newsletter. | Craig | 7th November | | Open |

**Agenda/Discussion**

| **Topic/Lead** | **Discussion/Decisions** |
| --- | --- |
| AIMS SIG Members | Welcome to Jules Hernandez-Sanchez (Roche) who joins the SIG this month.  Wilmar Igl is now contracting and has confirmed he no longer has time to be on the SIG Committee.  News from Chris, that he will have to withdraw from the group (hopefully temporarily until early next year) - ACTION: Lyn to set up meeting with Chris & Craig to discuss plans for PSI conference session, likelihood of his return and whether we can still access any of Chris’s material?  Lyn has updated the Website with new SIG member list |
| Article writing progress/ Chris (All) | Deadlines are: approx 20th of the month in January, April, July and October  Need a suggestion for Mid January article.  Current suggestions for future articles.   1. R Shiny. –multiple articles to follow – Chris - 2nd installment on hold due to Chris leaving the group for a while 2. R notebook (literate programming) - Chris 3. literate programming and Reproducible research Cloud computing – Wilmar is moving from AZ to contractor position and so will no longer have time to write articles - New volunteer needed if we want articles in these topics 4. Linking R with other software (ie. BUGS / SAS)   Dave to write something on MCMC in SAS & R (likely to be over winter 2017-2018). Will need support for R part. Chris or internal GSK help on BUGS & R – **Aim for mid April 2018 deadline depending on GSK project work**   1. High performance in R vs SAS – Yann 2. How to submit a submission package to FDA including R – Yann 3. R Markdown- part of Rstudio to write and publish HTML, PDF, DOC - Jules |
| Conference preparation for a parallel session | Currently 4 options   1. If Chris is still able to supply any workshop material on use of R-Shiny to produce safety (AE) reporting. We could turn it into an interactive demonstration/ presentation. Considering that a hands-on R workshop may be hard as people would have to bring laptops pre-loaded with files & the conference is not in a hotel so they would have to carry it for the full day around with them. Likely people turn up without laptop or can’t down load the file causing technical difficulties. So a presentation may be simpler 2. Turn the articles we’ve written into presentations: so far we have an AIMS introduction, Introduction to IDEs & Rstudio, Introduction to Shiny, R validation. – Could link this in with the above if we have Chris’s material. 3. Could look outside of R, such as Spotfire or other tools used by ST’s that are not SAS and invite experts from our companies to present. Both Craig & Yann have experts in Spotfire. 4. Invite other speakers such as Mango or another service provider who presents on R shiny for example. The group wanted to avoid inviting a single service provider given R should be free software.   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. Chris TBC. Craig confirmed that the Main speakers at the AIMS session (perhaps 1 or 2), 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.  ACTION: To **submit an article on LinkedIN on the 29th November advertising the session. The idea is to have a series of postings that are advertising/providing a little detail on the various sessions at the conference to encourage people to want to come. So it’s really an awareness of your session and its highlights, who it is aimed at and what you are going to cover.**  **ACTION: Lyn to set up follow up meeting to discuss above, on 21st Nov 9am (UK)**  Should we also plan for an event at USE R conference (if we could get budget to go)? |
| Yann | Recommendation for R installation:  One non validated platform: This system is used for exploratory or internal analysis self-managed by users which allows download of any packages, any versions.  One validated platform: This has a fix version of validated R packages (all are validated for regulatory use). How this would work needs discussion, however companies could select Mango to validate this system using the ValidR solution or they could designate the time to internally validate the packages themselves. However this would be a lot of duplication, if all companies did the same work. Therefore – perhaps we should consider a collaboration or consortium?  Suggestions for the collaboration? Consortium Of Regulated R Packages (CORRP) (!)  Anyone can join (pharmaceutical, laboratory, university hospital R users), to join you must validate XX packages to a degree accepted by the Consortium board. Mango hence could join if they wanted and for companies already paying Mango they could come to an agreement to keep paying Mango to fund their entry by Mango submitting packages on behalf of the company – In time, this may lead to more packages being available to them without having to pay Mango.  Alternatively we just invite Mango to be a Key Partner, and release all of their packages for everyone to use, at first it could be a loss of money for them, but it could also give them additional clients who ask Mango for specific validation.  A validated package would have stored online documentation about the version validation which could be referenced in regulatory work.  ACTION: Lyn to contact R foundation (Mark Schwartz) to see if they would be interested in setting up a set of validated packages to avoid a company monopolizing the market and moving away from the free nature of R. Perhaps companies could buy into the scheme to fund R foundation to do the validation? Justification is that we need to keep the R source open. Is this something R foundation have looked into or discussed? Where do they see R going in the future. |
| Long standing items we might come back to/ All | * SPIN Competition? – Ask people to write How and Why they use R in the pharmaceutical industry: Find a company to sponsor? * R-foundation interaction |

**Action Items**

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| SAS & R for MCMC | Dave | Aim for Mid April SPIN Article | Open |
| How to get our articles into EFSPI newsletters & when do they come out. Can the AIMS sig be added to the EPSPI website as well – perhaps link to PSI website?  How do EFSPI members receive SPIN or can ensure our articles are part of the EFSPI newsletter. | Craig | 7th November | Open |
| Set up meeting with Chris this week & then further AIMS meeting on 21st November 9am UK | Lyn | 7th Nov | Open |
| Contact R validation to see if they would consider looking into validation of more packages | Lyn | 21st nov | Open |