**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) |  |
| Sophie Canete (Bordeaux University Hospital) |  |
| Jules Hernandez-Sanchez (Roche) |  |

**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 | |
| Next Rshiny installment | Chris | Mid Jan SPIN Article | Open | |
| 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?  How do EFSPI members receive SPIN or can ensure our articles are part of the EFSPI newsletter. | Craig | 5th Sept | | 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.  Action: Lyn to update the Website with new SIG member list |
| Objectives for next 12 months (June 2016-June 2017)/  All | 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) – Add Roche (Contact Alun Bedding?) * 1 article in each SPIN newsletter |
| Article writing progress/ Chris (All) | Deadlines are: approx 20th of the month in January, April, July and October  Currently suggestions for articles.   1. R Shiny. –multiple articles to follow – Chris **- 2nd installment Mid Jan 2018 deadline** 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**   1. High performance in R vs SAS – Yann 2. How to submit a submission package to FDA including R - Yann |
| Conference preparation for a parallel session | Chris’s progressing well with development of a break out session on R-shiny, could easily last 1 hour. Ask people to bring lap top to the session and pre-load with a file. Will include the use of R-Shiny to produce safety (AE) reporting.  PSI parallel sessions are 1 hr 30 to 1 hr 45 long. We propose 1 hour hands on workshop, 20 min introduction which covers current top tips for using R including brief touch on validation, what approach should be used to put together regulatory package & store information out of R, 10 min wrap up / Q&A. We don’t think we should invite Mango as focus of the session is not on validation and we think we have enough to cover the session.  The conference will be held at the Beurs Van Berlage, Amsterdam, from **3rd to 6th June 2018**  Need to discuss who can attend? Chris obviously needs to be there. Lyn should be able to go and is happy to present introduction unless Chris or Craig want to do this? Who else can offer support for the workshop? Chris did you want others helping you from Amgen or AIMS people?  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. |
| 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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