**Attendees:**

|  |  |
| --- | --- |
|  **Team Member** | **Present at meeting** |
| Craig Mcilloney (PPD) | √ |
| Lyn Taylor (PRA) | √ |
| Chris Toffis (Amgen) | √ |
| David Inman (GSK) | √ |
| Wilmar Igl (AZ) | X |
| Yann Robert (Servier) | √ |

**Previous Action Items**

| **Action Item** | **Assigned team member(s)** | **Deadline** | **Status** |
| --- | --- | --- | --- |
| Each member to come up with 2 or 3 areas which you would like to focus our initial work as a SIG on. Email ideas to Craig & Lyn (including the full group if you wish) | All | 31st May 2016 | Completed per attached spreadsheet |

**Agenda topics**

| **Topic/Lead** | **Discussion/Decisions** |
| --- | --- |
| Craig feedback from SIG leaders meeting | * Other SIG leaders provided names of people who would like to join the committee who may be experts in key areas. If we need help we can bring these on board.
* Craig described how the SIG leaders split into groups and brain stormed to provide key areas for us to focus on. The following are some examples of their suggestions:
* More help for statisticians about CDISC
* Standardization & validation in use of R
* Increase speed of production – how can we bring in efficiencies
* Graphical representation – standard code to help
* Bayesian programming
* Benefit risk standardization
* Spotfire / Rshiny / alternative packages to SAS (will SAS have a monopoly in years to come?)
* Standardization and TransCelerate (10 companies who meet to discuss how we move forward as an industry – now partnership with CDISC).
* Exploratory tools for statisticians
* Big data – process & getting ready
* Regulatory submissions
* Estimands
* Liaison with PHUSE

In some cases, the AIMS SIG should be seen as facilitators rather than developers as the skill set may not be within this team to be able to or have time to work in these areas.Anything we create should provide case studies, examples & demonstrations of how it is used so that we share experience in the application methods.SIG Leaders Prioritization:**100% in agreement that R should be the key focus*** How can we validate R, so that regulators are happy with the validation – Could work with Mango solutions and ask them to update us on their progress, however as an industry we can’t be reliant on 1 vendor so we need to work alongside them and give bigger solutions. EISAI – have worked on this and we could reach out to them. CRAN project – can we draw from their group?R Foundations’s guidance https://www.r-project.org/doc/R-FDA.pdf
* How can we provide code/ best practices for people to take forward?
* Focus on areas that R is better than SAS. Ensure we don’t duplicate what SAS are developing for release. Also don’t want to develop R code which is available in other validated software. R is much better at graphics (especially interactive graphics than SAS). Rshiny is often used for internal exploratory use so could produce a guide to its use that would not require validation (could also look at Spotfire)

It was agreed, that we don’t need to validate R, when it’s for exploratory analysis, but if being used for submission work then we need to validate. **Estimands**Put Estimands on hold, because what will be required is not yet defined by the ICH requirements. Stay in close contact Chrissy Fletcher & the ICH E9 addendum revision group. Once Addendum implemented (+ 6 months), then we can re-look at this and the 2nd priority on the list. |

**Action Items**

| **Action Item** | **Assigned team member(s)** | **Deadline** | **Status** |
| --- | --- | --- | --- |
| Report back to the group areas in their experience that R does it better than SAS. It can be either “Hints & Tips” in R used for exploratory uses (could be a quick gain) or more “regulatory R use” which would need validation.Such as: Hints & Tips: R Shiny – interactive graphics much better than SAS but SAS can do this (awkwardly) & spotfire designed to do this & validated. | All | 30 October 2016 | Open |
| Lyn to set up call, to be held before Christmas (hopefully) but after SAS & Mango presentations | Lyn | 12 November 2016 | Open |
| Lyn to try to arrange a presentation from SAS and research what SAS are currently developing in the next release (9.5?) | Lyn | 30 October 2016 | Open |
| Email Mango to invite them to present to us on their current R development & validation progress | Craig | 30 October 2016 | Open |
| To send the feedback from the SIG meeting to the group | Craig | 30 October 2016 | Open |