**Series title:** Getting the Questions Right

**Series goals:** Joan and Jurgen will draft offline?

| **Ideas/date** | **Topic (Lead Planners)** | **Who** | **Comments** | **Proposed Date** | **Goals** |
| --- | --- | --- | --- | --- | --- |
| 1 / Mar | Getting the Questions Right (Jurgen) | **Rob Hemmings** (chairperson of scientific advice working party/group at EMA, lead person of ICH E9 working group), **Wolfgang** (clinician) @ Novartis | - Include call for ICH comments  - Promote estimands as a cross functional topic, partnership among all stakeholders  - Differentiate the what and the how  - science and math overlap, talking about science here  - who should be leading the effort on estimands? Who should be at the table? | March 15  11:00am – 12:30pm  (DST begins March 11) |  |
| 2 / May | Getting the Questions Right in Respiratory Clinical Trials (Frank, Joan) | **Oliver Keene**, **Bjoern Holzhauer**, **?** @ AZ, **Greg Levin** (discussant) | Bretz: Oliver Keene from GSK (has published) and/or Bjoern Holzhauer from Novartis have real case studies and expertise in this area  Joan: AZ has case study as well  Can this be joint effort? Choose one case study to highlight?  Keep the main dialogue relevant to all not just one TA  Suggest having Greg Levin from FDA too (Susan will reach out) | May ? |  |
| 3 / Jun? | Getting the Questions Right in Safety and Benefit Risk |  | Joan: Can we tag in Safety here Bill?  **Bretz:** Some people started thinking about this. Let me know if you want me to dig out names  Safety Monitoring WG  Patient Community perspective |  |  |
| 4 / Sep | Getting the Questions Right in Alzheimer’s Clinical Trials (Hong, Steve) | **Hong** @ Lilly | - ASA SWG subgroup on estimands  - 2017 workshop at medical conference (re-share some/all of this content) | early Sep after Labor Day weekend |  |
| 5 / Oct | Getting the Questions Right: Advancing Interpretation (Linda, Joe) | Medical writing, Regulatory Affairs, Patient Engagement, FDA | - Reg Affairs DIA Community has 5 working groups (ie labeling, intelligence/policy)  Joan: Sharon Hertz (FDA) and Eric Brodsky (FDA)  - Patient experience  - PRO  - Labels/Interpretation/Missing Data/Estimands (ASA webinar Feb 22, 12-2pm)  - Genentech, Allison Campbell? | After first week of Oct |  |
| 6/ Nov | Getting the Questions Right: Next Steps (Steve, Joan, Frank) |  | Munish’s comments (new topic or to be added above?)  Joan: Steve Ruberg, Frank Bretz and Tom Permutt speakers on Next Steps | Late Nov | frame things in what people understand (endpoints) and move to where we are going |
|  |  |  |  |  |  |
|  | Getting the Questions Right for Reimbursement discussions |  | **Bretz:** Ralf Bender (IQWIG) and Chrissie Fletcher (Amgen) have thought about this |  |  |
|  | Getting the Questions Right in Oncology Clinical Trials |  | Bill Wang |  |  |
|  | Upcoming ICH training material |  | **Bretz:** At the January workshop, Frank Petavy will give a presentation with the purpose of sharing highlights of the training material - not to get feedback on it as it is nearly finalised but to give feedback on whether it meets the gap that has been identified in the comments |  |  |
|  | Estimand for time to first and recurrent event data |  | **Bretz:** E9(R1) focus/thinking is mostly on longitudinal data. The estimand framework still applies for time to first and recurrent event data – but there are some very important subtleties (especially with terminal events and competing risks) that our community is not aware of.  A cross-industry group around Mouna Akacha and James Roger has thought deeply and it is time that they spread their experiences and case studies (in a non-technical sense) |  |  |
|  | Principal Stratum |  | **Bretz:** Seems like this is least well know concept in E9(R1), but “causality” is at the same time the underlying “philosophy”. The more education we have here, the better |  |  |

To Do (Dec 19 2017):

1. Matt to ask Tshaka for contact names – Medical writing, Reg affairs (we already have Munish for Clin Research), Study Endpoints, Patient Engagement – **Communicate to Tshaka this is our Grand Challenge idea** DONE
2. Steve will contact Tom re: Feb meeting. Coordinate date with Juergen N/A
3. Juergen to contact Frank to confirm Wolfgang and see if he’s interested to speak at closeout of the session (**Bretz:** Once you are ready for formally reach out to Wolfgang, I’m happy to connect him with you guys) DONE
4. Joan to reach out to AZ respiratory, Susan to reach out to Maria Costa @ GSK (**Bretz:** I know Maria (she will join Novartis in March). Certainly a good person but I would not have put her into the “estimand bucket”?)
5. Susan to reach out to Bill Wang – he mentioned at our last core mtg DONE
6. Joan to ask Steve Ruberg about Patient Engagement Now Steve W is reaching out?
7. Munish to coordinate with us any additional thoughts on these sessions/any additional
8. Matt organize a time to meet in early Jan DONE
9. Susan communicate to full core team, cc Tshaka and Maral DONE