European Federation of Statisticians in the Pharmaceutical Industry
Representing Statistical Associations in Europe

EFSPI Newsletter September 2014

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Regulatory Update

On September 5th the PSI/EFSPI regulatory committee met with the biostatistics working party (BSWP) of EMA in London for the first time. Topics covered were the upcoming priorities of the BSWP, the addendum to ICH E9 on "estimands" and sensitivity analyses, adaptive designs, and baseline covariates. There was a wide range of expertise from BSWP at the meeting and the discussion provided useful feedback to the committee on areas of focus for 2015.

One immediate follow up action is to form an expert group to comment upon the upcoming reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/06/WC500144945.pdf). This was identified as a priority area by the BSWP. Anyone interested to join this expert group can contact Christoph Gerlinger (christoph.gerlinger@bayer.com).

In early September, ICH endorsed the concept to create an addendum to ICH E9 on estimands and sensitivity analyses. Chrissie Fletcher (Amgen) and Frank Bretz (Novartis) will be representing EFPIA on the ICH Working Group which will kick-off at the ICH Conference in early November. EFSPI will also be setting up an expert group to support the discussions. Please contact Alan Phillips if you wish to contribute (Alan.Phillips@iconplc.com).

EFSPI has been invited to present at the EMA workshop on the investigation of subgroups in confirmatory clinical trials (see. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/05/WC500166223.pdf) on November 7th in London.

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Scientific Update

Generating Evidence for Health Technology Assessment, Berlin, 25th September

A well-attended meeting which covered topics such as

- recent trends in HTA (early dialogue with HTA agencies and scientific advice on their drug development programs, and applying real world data in HTA)
- statistical support for HTA (Biostatistics framework used by IQWiG, and challenges for statisticians to meet local HTA requirements)
- study design and analysis challenges (deriving minimally important differences for PRO endpoints, and designing better observational research studies)
- evidence generation (analytical strategies to increase the credibility and rigor of evidence, and a comparison of regulatory and HTA agency methods and perspectives on subgroup analyses)

Thanks to Bayer for hosting this meeting. To view the slides, click here.

A meeting on dose finding studies, including modelling approaches like MCP-Mod, is planned for November. Further details will follow.

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Special Interest Group (SIG) of the month – Integrated Data Analysis

The IDA SIG came into being in June 2013 with an announcement of our charter and a call for volunteers to join. After a start-up phase and getting ourselves organized we became fully active at the beginning of 2014. At the moment we have over thirty members representing a wide variety of companies: Amgen, Astellas, Astra Zeneca, Bayer, GSK, Eli Lilly, Mylan, Novartis, Pfizer, Roche, Sanofi, UBC. We also have some academic members.

As stated in our charter, the SIG is focused on the following topic areas: Efficacy, Safety, Network Meta Analysis (NMA) and Data Transparency and we have one or more working groups within each area. We have a monthly TC for the whole SIG and more frequent TCs for the working groups. Our minutes and shared documents are made available to the SIG members using the LillyBox system maintained by Brenda Crowe (Lilly), who is also a leader of one of the Safety working groups. This system greatly aids communication among myself, the working group leaders and members and is to be recommended.

Given the relative young age of the IDA SIG, this article can only report on our plans (which are many) rather on the results we have achieved. As co-leader, with Chrissie Fletcher (Amgen), of the NMA working group, let me begin by reporting on the current plans for this group. After much discussion and consideration we have decided to write two papers. One on the “quality of reporting of NMA in the (non-statistical) literature” and the other on the “use and benefits of including individual patient data in an NMA”. A literature search and review is currently underway and we plan to begin work on the contents of our papers in the coming months. I know the inclusion of individual patient data in an NMA is a topic that is being, or has been, considered by other groups, e.g., as part of the Get Real project, but we plan to look at this subject from an industry perspective. As with all of the working groups in the IDA SIG, we welcome new members who have expertise in the topics we plan to

research, especially those related to those of the two papers we plan to write. I am also pleased to point out that the NMA activities are being done jointly in collaboration with the EFSPI/PSI HTA SIG led by Chrissie Fletcher (Amgen).

The Safety topic is a large one and to reflect this we have three working groups. One is on the topic of "the advantages and use of individual patient data in meta analysis of safety data", and is led by David Ohlssen (Novartis) and Sally Hollis (Astra Zeneca). Part of the motivation for this topic comes from the FDA panel meeting that was held last year to discuss the development of a possible FDA guidance for Meta Analysis. The second is on "safety labelling" and is led by Brenda Crowe (Lilly). The work of this group is quite advanced and a draft manuscript is close to completion. The third is led by Andrew Bate (Pfizer) and is working on the "integration of data in networks of observational databases (for active safety surveillance)". This topic is one that needs much more involvement from mainstream pharmaceutical statisticians, as much of the principles of randomized controlled trials are directly applicable. All three groups have plans to write papers on their chosen topics. I expect that some the activities of these three working groups will have some overlap with the EFSPI Benefit Risk SIG and we hope in future to develop a strong relationship with that SIG.

Efficacy is also a large topic and this working group, led by Georgina Bermann (Novartis), is looking at how data integration over the different phases of drug development can improve decision making and what might be useful tools to aid this. The group also plans to develop generic case studies to evaluate these tools. We would welcome examples from a range of companies to help develop the case studies.

The work of the IDA Data Transparency group has now been realigned to support the more recently formed EFSPI/PSI Data Transparency SIG and so we have not set objectives for this working group.

As already noted, the topics covered by the IDA SIG will also be of interest to other EFSPI SIGS and we hope that more joint activities, like the one with the HTA SIG, will take place in the future.

For further information, or to join one of the IDA SIG working groups, please contact Byron Jones at byron.jones@novartis.com.

Byron Jones (Novartis)
Chair of the EFSPI IDA SIG.

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Upcoming Events

BBS

Free ½ day seminar on 'Meta-Analysis of Clinical Safety Data', Thursday 2nd October 2014, Basel, Switzerland. Click here for more details.

Free 'Data Transparency Seminar', Thursday, Nov. 13, hosted by Actelion in Switzerland. More details will follow and look out for flyer on BBS website (www.ceb-institute.org/bbs) or EFSPI webpage (www.efspi.org) for details on how to register.

PSI

PSI Scientific Committee Webinar: Heart Failure Trials: 16 October 2014. Click here for more details

Real World Data SIG 1 day Scientific Meeting: 21 October 2014, hosted by Amgen, Uxbridge, UK. Click here for more details

How do Data Monitoring Committees Operate, 5 November 2014, RSS in London. Click here for more details.

AFP

The German APF will host its 68th workshop on November 28th, 2014 in Munich. Topics are subgroup analyses, experiences with EMA's Missing Data Guideline, and Clinical Data Transparency. The workshop will be held in German. For details please see http://www.biometrische-gesellschaft.de/arbeitsgruppen/pharmazeutische-forschung.html.

COMET (Core Outcome Measures in Effectiveness Trials) IV Meeting

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative will hold its fourth meeting in Rome on 19th to 20th November 2014. To view the programme, click here. To register, click here.

DIA/FDA

SAVE THE DATE: 2015 DIA/FDA Statistics Forum, April 19 - 22, 2015, Bethesda North Marriott. This unique Forum, now in its 9th year, continues the dialogue on issues including FDA guidance development and regulatory science initiatives.

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The World of Statistics

The World of Statistics movement has grown to a total of 2,348 organizations from countries across the globe. You can view the current participant and country lists by going to The World of Statistics website. To see the full list of The World of Statistics participating organization-sponsored events and activities around the world for the remainder of 2014, click here.

A recently released American Statistical Association (ASA) white paper recommends a multidisciplinary approach comprised of statisticians, mathematicians, data scientists and relevant domain scientists to tackle the challenges of the federal government's Big Data Research and Development Initiative and similar private-sector projects. The audience for the free PDF white paper, titled Discovery with Data: Leveraging Statistics with Computer Science to Transform Science

and Society, is anyone working with Big Data to advance their work—whether it be research, business or policy—including the private sector, academia and government. It was written by a dozen ASA members with expertise in Big Data.

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Job Adverts

Scientific Director, Statistical Modeling (Janssen)

For all current recruitment adverts please visit the EFSPI website:
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And finally.....

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Chrissie Fletcher
EFSPI Communications Officer