



EFSPI Newsletter July 2014

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Regulatory Update

EMA data transparency: The release of the final EMA policy on data transparency was postponed again to October. We will keep you posted of any further news.

EMA draft guidance on subgroups: The final set of EFSPI comments on the draft EMA guidance on subgroups in confirmatory clinical trials were submitted to EMA in early July and can be accessed via the [EFSPI website](#).

FSA draft guideline on statistical reporting: No comments were received on the European Food Safety Authority (EFSA) on their "Draft Guidance on Statistical Reporting" (see <http://www.efsa.europa.eu/en/consultations/call/140528.htm>), so EFSPI did not comment.

EMA draft reflection paper on PROs in oncology: The EMA has published a draft reflection paper on the use of patient reported outcome (PRO) measures in oncology studies (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/06/WC500168852.pdf). If you would like to comment on this document please send you comments to Christoph Gerlinger [christoph.gerlinger@bayer.com] by the **end of September**.

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5th EFSPI Statistics Leaders Forum

The fifth EFSPI Statistics Leaders Meeting was held June 11, 2014, in Basel, Switzerland. A record number of thirty (30) leaders from 8 different countries and 20 pharmaceutical companies attended. After a warm welcome by the Chair Stefan Driessen, and local host Hans-Ulrich Burger the meeting started with EFSPI President Chrissie Fletcher presenting EFSPI and their strategic objectives for 2013-2015. A recap of the 2013 Statistics Leaders Meeting was given including actions and progress. This was exemplified by the first topic on the agenda, Clinical Trial Data Transparency, a follow up on the extensive discussions at the 2013 meeting. The Working Group (WG) on Data Sharing that was formed end of 2013 presented their objectives and informed the meeting about the current five work streams in the WG. Main goals are to identify and prospectively prioritize statistical issues in data transparency, and co-ordinate and communicate on statistical contributions across Europe. The current landscape of implementation of Data Sharing in the companies was presented, including the practical issues encountered. It was also shown that different technical solutions have been put in place by various companies. EFSPI will co-ordinate authorship team with the Data sharing working group and the EFSPI/PSI Regulatory committee to respond to the final EMA policy when it will come out, which was expected mid-July already.

After a short update on Special Interest Groups (SIGs), Byron Jones, lead of the new Integrated Data Analysis SIG, presented the SIG's aims and objectives. This SIG has already set up four working group dealing with Efficacy Data in phase 2 and 3, Safety Data, Network Meta-Analyses, and IDA relative to greater Data Transparency. The aspirations of the SIG were well received and the SIG was encouraged to further collaborate with other SIGs on topics like NMA and Rare Events, and also to work on estimates for safety parameters for later use in HTA and Benefit-Risk assessments. The SIG in turn asked for case studies from the companies on certain specific areas. Next Jonathan Alsop presented the Pharmaco-Epidemiology SIG and pointed out many achievements of this SIG over the last 6 years of existence reflected by several papers, handbooks and contributions to workshops and meetings. Feedback from the Statistical Leaders noted clear benefit in revitalizing previous SIG deliverables, especially in the area of Rare Events, bias and confounding. The latter is increasingly important due to the trend of increasing observational research within Pharma.

In the afternoon in a plenary session the recent developments in the Industry, regulatory and data sciences areas were reviewed and discussed. All participants had received in advance pre-reads on the topics like IMI, EFPIAs New Clinical Trial Design Task Force, EMAs guidance on Parallel Scientific Advice Regulators and HTA, EMAs PAES Working Groups, and Big Data – Real World Data. Also a survey was sent out in advance on the level of involvement of the Statistics Leaders in these developing areas. They were also asked to identify present challenges and possible ways to address these. The pre-reads, the results from the survey as well as the engagement in the discussions during the meeting clearly showed that there is growing involvement and interest in these new areas of data and associated data science. Many statistical challenges were identified in performing HTA, observational studies and the use of secondary data bases and Big Data projects (even though the last item lacks a clear definition). Predominantly data quality and how to deal with bias and confounding were mentioned as challenging when working in this area. And a need for best statistical practices was voiced. Access to best statistical practices and methodologies developed by experts in the field (e.g., SIGs, working groups), will give statisticians opportunities to demonstrate their added value, by collaborating and partnering with other data scientists. In this era of electronic health records and access to large databases, big data will bring new opportunities for statisticians, as discussed below in the [World of Statistics Update](#). The plan is to set up small working groups on PAES and Big Data to start preparing for the challenges and opportunities in these areas.

Detailed minutes of the meeting have been finalized and can be accessed via the [EFSPI website](#). Also all presentations of the meeting are available there.

For more information about this meeting, or any other comments/question on this Forum, please contact Stefan Driessen (stefan.driessen@abbott.com).

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Scientific Update

OPEN for REGISTRATION: Generating Evidence for Health Technology Assessment, Berlin, 25th September

EFSPI is planning for two scientific meetings in 2014. The first meeting will focus on **Generating Evidence for Health Technology Assessment** and will take place at Bayer, Berlin on the **25th September**. Click [here](#) to view the agenda for the meeting and to register please click [here](#). Early bird registration until August 15th. The second meeting will focus on dose finding studies, including modelling approaches like MCP-Mod, and is planned for November.

In addition we are planning for a webinar in the second half of 2014. More details will follow.

The Scientific Committee is glad to announce that two new candidates, Alexandra Green (Takeda, UK) and Axel Krebs-Brown (Astellas, NL) have joined our committee!

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Association of the month - PSDM

The logo for PSDM consists of the letters 'P', 'S', 'D', and 'M' in a large, serif font. The 'P' and 'D' are yellow, while the 'S' and 'M' are blue.

Pharmaceutische Statistiek & Data Management

The **PSDM** (Pharmaceutical Statistics and Data Management) is a Dutch network group of statisticians, clinical programmers and data managers predominantly working in and for the pharmaceutical industry.

In the early nineties the need to establish a national network to stimulate interactions at a local level was acknowledged. It was decided to set up a multidisciplinary network - open to statisticians, data managers and programmers - to encourage cooperation and interaction between these special fields.

Hence, the PSDM was founded in 1993 as a working group of the Biometrical Section (BMS) of the Dutch Society of Statistics (VVS) and right from the start, became an active member of EFSPI.

The current board of the PSDM represents all three disciplines and consists of people from Pharma, CROs and Specialised Nutrition.

Aims/objectives

The aim of the PSDM is to facilitate professional conduct and development of its members and to provide a platform for the exchange of expertise and ideas by organizing scientific meetings, workshops and courses. The PSDM is an independent, non-profit organization, and explicitly targets the organisation of high quality meetings and courses at minimal costs.

Activities

Traditionally the PSDM aims to organize two annual events. The fields of interest are broad and cover all areas of the human and veterinary drug development process. Presentations given by members and invited guests can cover both theoretical and practical aspects of the topic of interest. For example, in September 2013 we had a local meeting on Risk-based monitoring: opportunities and challenges in clinical development. As 2013 has been The International Year of Statistics, the BMS and the PSDM organised the symposium "The future of (Bio)Statistics" in November.

An important aspect of all our meetings is to offer the opportunity to meet colleagues in an affordable and informal way.

If you are interested to know more about us please visit the **PSDM website** (www.psdm.nl) or feel free to contact us!

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Upcoming Events

PSI Cross-Over Trials in Clinical Research, 13-14 August - presented by Stephen Senn

Venue: Park Inn, Heathrow

The emphasis is on practical matters: how should one plan and analyse cross-over trials if one is genuinely interested in finding out the effects of treatment. The approach is grounded in practical pharmacological considerations and unrealistic approaches to adjusting for carry-over will be avoided. The examples are all genuine.

Approaches to analysis with SAS will be explained (many of the programs used are available on the web for downloading in R and GenStat versions also) and there will be an opportunity for course delegates to raise their own practical concerns and for these to be discussed.

Registration is now open on the [Events page](#) of the PSI website

Prior Elicitation: The world isn't flat, so why is your prior? 3 September 2014

Venue: GSK Stevenage

With confirmed speakers, Nicky Best (GSK), Nelson Kinnersley (Roche), Tony O'Hagan (Sheffield University), Kate Ren (Sheffield University, Beat Neuenschwander (Novartis). Other speakers TBC.

For further details or to register please [click here](#)

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. Planning is now underway and we are preparing an exciting programme. This will bring together individuals interested in the development and application of “core outcome sets” in many different areas of health care.

There will be an introductory workshop on the first day giving a whistle-stop tour of core outcome sets and the COMET Initiative in preparation for the two days ahead.

There is no registration fee for the meeting, and lunch and the meeting dinner will be provided free of charge. The number of spaces is limited, which may mean that we have to close registration some time in advance of the meeting. We therefore encourage early registration to avoid disappointment. Delegates will be responsible for the costs of their own travel and accommodation.

To view the programme, [click here](#).

To register, [click here](#).

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The World of Statistics

The World of Statistics movement has grown to a total of 2,340 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](#).

[Statistics and Science: A Report of the London Workshop on the Future of the Statistical Sciences](#) is the product of a high-level meeting in London last November attended by 100 prominent statisticians from around the world. This invitation-only summit was the capstone event of the International Year of Statistics, a year-long celebration during 2013 that drew as participants more than 2,300 organizations from 128 countries.

Among the greatest challenges and opportunities noted in the report is the rise of Big Data, which are databases that dwarf in size any databases statisticians previously encountered. It is a challenge for several reasons: problems of scale, different kinds of data, the “look-everywhere” effect, privacy and confidentiality concerns and reinventing the “statistical” wheel by collectors of Big Data. Click [here](#) to read the full summary of the report, or better still, read the full report using the link above!

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Job Adverts

[Scientific Director, Statistical Modeling](#) (Janssen)
[Biostatistician/methodologist - oncology](#)

For all current recruitment adverts please visit the EFSPI website:

<http://www.efspi.org/index.php?p=ADVERTISEMENTS&fid=9>

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And finally.....

If you are currently seeking to hire a statistician and wish to post a job advert, see the “Advertisements” area on the EFSPI website at www.efspi.org and view the “Job Postings” for instructions. EFSPI are offering one free advert for every 3 adverts posted on the website.

To add your e-mail address to the EFSPI mailing list, click on "Sign up to our newsletter" on the homepage of the EFSPI website.

To view previous newsletters please see the EFSPI website in the “[News](#)” area.

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