



EFSPI Newsletter June 2014

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Regulatory Update

EMA transparency policy: EMA announced in June that the final policy on publication of clinical trial data (POL-000070) is expected to be released in July. Following discussions with key stakeholders during May, the EMA will be allowing requestors to download and print clinical study reports. See www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002124.jsp for more information. The EFSPI data transparency working group will be reviewing the final policy when it is released and will provide an assessment of the final policy. The group also continue to work on a guidance for best practice in re-analysis and secondary analyses of clinical trial data, the impact of this new policy to Biostatistics, minimal requirements for data sharing, and ensuring patient confidentiality.

EMA draft guidance on subgroups: Thanks to everyone who provided comments. We are finalizing the EFSPI comments in the EFSPI/PSI regulatory committee and we will submit the comments in early July.

The European Food Safety Authority (EFSA) has released for public consultation their "Draft Guidance on Statistical Reporting" (see <http://www.efsa.europa.eu/en/consultations/call/140528.htm>). If you would like to comment on this document please send you comments to Christoph Gerlinger [christoph.gerlinger@bayer.com] by the **11th July**.

Last but not least, 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/WC50016

[8852.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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SIG of the month: Epidemiology and Drug Safety

The Epidemiology and Drug Safety SIG has now been in operation since 2008 and continues to provide a forum for discussing statistical issues relating to epidemiology and drug safety across the pharmaceutical industry. Our objective is to discuss methodological aspects related to real world evidence generation and form a consensus on the best statistical practice in various areas of Pharmaco-epidemiology and Drug Safety.

The SIG Steering Team consists of 7 members:

Name	Company
George Quartey	Genentech (Chair)
Maurille Feudjo-Tepie	Amgen
Joseph Kim	IMS Health
Jixian Wang	Celgene
Nilani liyanage	Ipsen
Jonathan Alsop	Numerus Ltd
Arlene Gallagher	MHRA

The SIG spent a great deal of time collaborating and sharing experiences of Epidemiology and Drug Safety research. Achievements to-date include: 1-Day meeting on data mining (Roche); article on data mining in SPIN; review of draft regulatory documents; PSI conference parallel sections with MHRA and publications on various topics in Pharmaceutical Statistics and other journals.

Plans for 2014 include:

- New pharmaco-epidemiology Handbook for Statisticians (Q3 2014)
- One-Day Scientific Meeting on “*Post Authorization Safety and Effectiveness Studies: Regulatory-Industry Perspectives and Challenges*” at Amgen Uxbridge planned for 21st October 2014. Key topics to be discussed include:
 - Recent Changes in EU Legislations: PASS and PAES. (*Andrew Thompson-MHRA*)
 - PASS and PAES Process: Who are reviewers, What is their perspective and How it is organized, how do they react to Practical challenges such as market penetration issues etc. (*Jim Slattery-EMA*)
 - Some reflections on how industry can organize themselves to rise to these new demands—[*Dr Andrew Roddam (GSK) and Dr Jamie Robinson (Roche)*].
 - Methodological Challenges in conducting PASS/PAES effectively [*Dr Maurille Feudjo-Tepie (Amgen)*]
 - PAES/PASS data Opportunities and Challenges and How the CPRD can optimally be used to answer some of these questions/requests [(*Arlene Galagher-MHRS*)]

In addition to the Steering Committee the SIG mailing list contains over 100 other individuals (both PSI members and non-members) who have been involved in SIG events or have requested to be included on email updates sharing SIG events and relevant related materials that may be of interest. If you would like to be added to our affiliate's mailing list, or are interested in attending our workshop in October 2014, please email me: (quarteyg@gene.com), or go to the SIG area on the PSI or EFSPi website.

George Quartey (Genentech)

Chair, Epidemiology Special Interest Group

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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-one (31) leaders from 8 different countries and 20 pharmaceutical companies attended.

The meeting started with the strategic objectives for EFSPi for 2013-2015. Also a recap of the 2013 Statistics Leaders Meeting was given including follow up actions and progress. This was exemplified by the first topic on the agenda, a follow up on the extensive discussions at the previous 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. Main goals of the group 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. After a short update on Special Interest Groups (SIGs) the new SIG Integrated Data Analysis presented itself. It has set up four working groups dealing with Efficacy Data in phase 2 and 3, Safety Data, Health Technology Assessment and Network Meta-Analyses, and Data Transparency. In the next presentation the SIG Pharmaco-Epidemiology showed the many achievements over the last 6 years of their existence with several papers, handbooks and contributions to workshops and meetings.

In the afternoon in a plenary session the recent developments in the data area and data science 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 finally on the trending topic 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 and the challenges they see and what can be done about it, also by EFSPi. 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.

Detailed minutes and actions out of the meeting are being finalized and will be discussed in more detail in next Newsletter. Also by then all the presentations will be available on our website. 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

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, details for how to register will follow shortly.

The second meeting will focus on dose finding studies, including modelling approaches like MCP-Mod, and is planned for November.

The Scientific Committee is still looking for new candidates who are willing to join our committee. If you are interested or want to know more, please contact our chair Egbert Biesheuvel (egbert.biesheuvel@ziggo.nl)

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Upcoming Events

PSI has their next upcoming Journal Club Teleconference on Hot Topics, 17 July 2014. Click [here](#) to see the flyer. Don't forget the journal clubs are free to attend and provide useful opportunities for scientific discussion.

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The World of Statistics

The World of Statistics movement has grown to a total of 2,383 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](#).

SAS's JMP division has introduced a new, on-demand webcast video series called "Analytically Speaking." This complimentary webcast series features thought-leaders sharing insights that come with years of developing best practices and enjoying great success with analytics. Among the featured presenters are [David J. Hand](#), a two-time president of the Royal Statistical Society and author of the book *The Improbability Principle*; [Kaiser Fung](#), author of *Numbers Rule Your World*; [John Pullinger](#), immediate past president of the Royal Statistical Society (RSS) who recently was named United Kingdom national statistician; [Roger Hoerl](#) and [Ronald Snee](#), authors of *Statistical Thinking: Improving Business Performance*; [Dick De Veaux](#), professor in the Department of Mathematics and Statistics at Williams College; SAS cofounder and JMP chief architect [John Sall](#); and legendary statisticians [Stu Hunter](#) and [David Salsburg](#). [Click here to access the "Analytically Speaking" webcast series.](#)

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Job Adverts

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.....

The EFSPi Council met following the EFSPi Statistics Leaders meeting in mid-June. Work is progressing to re-design the EFSPi website and we're aiming to launch the new website towards the end of 2014.

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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Chrissie Fletcher
EFSPi Communications Officer