



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

EFSPI Newsletter February 2016

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Council News

After 18 years of service, Francois Aubin is stepping down from the EFSPI Council. Francois joined the EFSPI Council in 1998, as one of two representatives for the SFdS “Société Française de

Statistique". Francois has been an active contributor to EFSPI over many years, engaging in all EFSPI activities, and he is a member of the EFSPI Scientific Committee. More recently, Francois led EFSPI as EFSPI President in 2010-2013, and he successfully led the development of the new EFSPI website launched in 2015. Francois will remain a member of the EFSPI Scientific Committee.

The EFSPI Council wish to thank Francois for his tremendous support to EFSPI over a long tenure, and thank him for his continued support to EFSPI via the Scientific Committee. The EFSPI Council welcomes **Emmanuel Pham** who has joined the EFSPI Council replacing Francois.

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Regulatory

The EFSPI PAES (Post-Authorisation Efficacy Study) working group reviewed the draft PAES EMA guideline. Key comments raised included: recommending statistical considerations were considered more in the guideline; ensuring alignment with the PASS (Post-Authorisation Safety Study) guideline and processes in order to ensure harmonized procedures; providing further clarification on the differentiation of study types including their weaknesses and strengths for different types of questions of interest; further discussion on when can statistical tests be conducted e.g. where randomization is involved for example in pragmatic trials; clarification on when would placebo controlled trials in the post authorization setting be feasible; and additional feedback was given on the limitations and strengths of Registries. The comments raised by EFSPI were consolidated with those collated by EFPIA, and this was a successful collaboration. The final set of EFPIA-EFSPI comments shows some heterogeneity in how different sponsors value observational trials vs RCTs especially when considering issues relating to internal and external validity of these different types of studies. A follow up workshop with industry representatives was suggested to EMA.

EMA plans a draft reflection paper and a subsequent workshop on the extrapolation of adults' safety and efficacy data to the pediatric populations on May 17th to 18th in London (http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2016/01/WC500199753.pdf). If you are an expert in this domain and want to contribute to the workshop of to comment the draft please contact Christoph Gerlinger (christoph.gerlinger@bayer.com).

EMA's draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development is planned for Q2. If you want to contribute to the EFSPI comments please contact Bruno Boulanger (bruno.boulanger@arlenda.com).

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Scientific

EFSPI is planning for at least three meeting events in 2016: two regular 1-day scientific events, and our 1st annual EFSPI Statistical Workshop.

1st annual EFSPI Statistical Workshop – September 12 and 13 in Basel – SAVE the DATE!

The idea for the 1st annual EFSPI Statistical Workshop started in 2015, and this statistical workshop being initiated in 2016 will be dedicated to the opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. We have started well in our preparations and a Scientific Committee has already been installed with representatives from all parties involved. More information will follow as soon as possible. Please mark this important date in your calendar!

Two other EFSPI scientific events are in the planning phase:

- 1-day scientific event on **June 24, Biomarkers and Subgroups in Leiden, the Netherlands** (A joint event of EFSPI and PSDM hosted by Astellas).

This event is open for registration!

When biomarkers are used to identify sub-groups of patients who are likely to benefit from new therapies, a whole host of challenges arises, and many of them are of a statistical nature. In this meeting, experts from industry, academia and regulatory agencies will come together to discuss these challenges, with a focus on practical applications. Confirmed speakers include Norbert Benda (BfarM), Andrew Grieve (ICON plc), Tim Friede (University of Göttingen), Andrew Stone (Astra Zeneca), Sebastian Jobjornssen (Chalmers University) and Hans-Ulrich Burger (Novartis).

- 1-day scientific event on **Evidence Synthesis** planned for November, further details to follow.

In addition, EFSPI is preparing a **webinar** before the summer break, the final topic is not yet decided. We will keep you informed as more details become available.

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Special Interest Groups (SIGS)

Benefit-Risk Assessment - Survey on Multi-Criteria Decision Analysis (MCDA)

Structured frameworks have been recognized as an important tool to improve transparency, consistency and communication when assessing the benefits and risks of medicines. For more complex assessments, quantitative methodologies such as MCDA have been proposed by various initiatives. However, the implementation poses some practical challenges. The Benefit-Risk SIG is conducting a survey to gather information about these challenges.

The objective of this survey is to identify the barriers with the various stakeholders from various types of organizations (Regulatory/HTA agencies, Pharmaceutical companies, Academics) in implementing MCDA. The outcome of this survey will give the SIG the opportunity to work on some recommendations and tools to overcome these challenges. We would be grateful if you could spare us a few moments (15 minutes) of your time to respond to this survey by the **end of March 2016**. Please cascade this email to anyone who may provide a valuable input (e.g . Physicians, Regulatory, Safety representatives in your organizations). [Please click on the link to assess this survey](#)

If anyone has any questions or comments, please contact the Benefit-Risk SIG - MCDA sub-team by emailing **Guillemette de La Borderie** (GdeLaBorderie@mt-pharma-eu.com).

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7th EU Statistical Leaders meeting 2016

The next EU Statistical Leaders Meeting will take place on the **5th July 2016**. The meeting will be held in France, kindly hosted by Sanofi. Possible themes for the meeting include: modeling in drug development, personalized medicine and biomarkers, risk-based monitoring, data science, leadership skills for statisticians, and statisticians' engagement in regulatory policy and in public-private initiatives.

We are very much looking for people that want to sit in the Organizing Committee and help with the agenda and the set-up of the meeting. If you are interested, please contact Stefan Driessen (stefan.driessen@abbott.com).

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Other Events

PSI (UK)

PSI Structured Benefit-Risk Assessment – Methodology and Practice - this 2 day training course taking place in the London Heathrow area on the 8th-9th March 2016 includes a practical workshop whereby participants will critically evaluate the benefit-risk balance of medicinal and healthcare product(s) in a robust and transparent manner. Keynote speakers include Prof Deborah Ashby (Imperial College) and Prof Larry Phillips (LSE). More information can be found [here](#) and go to www.psiweb.org to register.

PSI/RSS 2016 Award for Statistical Excellence in the Pharmaceutical Industry launched -

Nominations are being sought for the PSI/RSS Award for Statistical Excellence in the Pharmaceutical Industry. The award recognises a most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. For more details please see http://www.statslife.org.uk/news/2631-2016-award-for-statistical-excellence-in-the-pharmaceutical-industry-launched#.Vo_c-0sDi-E.twitter. Nominations can be

made until midnight on March 31st 2016.

The **PSI 2016 annual conference** will be taking place on 22nd- 25th May 2016 at the Pullman Hotel, Berlin. The theme of the 2016 Conference is “Promoting Statistical Insight and Collaboration in Drug Development” and registration will open soon. Sessions will include an update on estimands, subgroups, dose exposure modelling, decision criteria, use of biomarkers in translational activities, clinical registries and many more with speakers from industry, academia and regulatory agencies. The deadline for poster abstracts is 29 February 2016 - please visit the website for more information. <http://www.psiweb.org/events/2016-conference/2016-conference-abstracts>. For further information please go to <http://psiweb.org/events/2016-conference>.

As part of the PSI conference in Berlin this year, an interactive careers seminar for students local to the Berlin area will take place on Wednesday 25th May 2016 at the Pullman Hotel (Berlin). This event is aimed at students studying mathematics and statistics courses. We welcome BSc, MSc and PhD students with mathematics/statistical elements that would be interested in learning about statistics within the pharmaceutical industry. If you have contacts in the Berlin area in Maths & Statistics departments we would be grateful if you could let them know of this event. Any interested students can register to attend this event **for free** using this link: www.surveymonkey.co.uk/r/ZTM5K55. Places are limited and registration **by 31st March 2016** guarantees a place at the seminar. Registration will close on 30th April 2016.

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Job Opportunities

Opportunities exist for a [Senior Biostatistics Manager / Associate Biostatistics Director](#). For all current recruitment adverts and more information on how to submit recruitment adverts, please visit the EFSPi website: [Job postings](#). If you are currently seeking to hire a statistician and wish to post a job advert, EFSPi are offering one free advert for every 3 adverts posted on the website.

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The World of Statistics



The World of Statistics is comprised of 2,378 organizations across the globe. You can view the current participant and country lists involved in the World of Statistics by going to [The World of Statistics website](#). To see the events and activities planned for 2016, [click here](#).

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Follow us on Twitter and LinkedIn

Get the latest news and updates about EFSPI by following us on Twitter at @EFSPItweet. Also, when you use Twitter to spread the word about EFSPI, be sure to use the hashtag “#EFSPI”. You also can follow developments in EFSPI via LinkedIn.

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And finally.....

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Chrissie Fletcher

EFSPI Communications Officer

