



## EFSPI Newsletter April 2016

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### Council News

The EFSPI Council thanks Paolo Morelli, who is stepping down as a representative for Italy (BIAS), for his support to EFSPI. The EFSPI Council welcomes **Fabio Montanaro** who has joined the EFSPI Council replacing Paolo.

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### Regulatory

The EFSPI/PSI regulatory committee commented on the ICMJE data sharing proposal, which would require authors to make available de-identified individual patient-level data (IPD) underlying clinical trial results included in a manuscript no later than 6 months after the release of the publication, and a data sharing plan to be included in registering a clinical trial. Click [here](#) to view the EFSPI/PSI comments.

Marisa Bacchi, EFSPI President, will give an invited presenta at the EMA workshop on extrapolation in May. Click [here](#) for more information about the workshop.

Please hold the date of **September 12<sup>th</sup> and 13<sup>th</sup>** for the **1<sup>st</sup> EFSPI regulatory statistics workshop** to be held in **Basel**, Switzerland. The detailed programme will be circulated shortly.

The EFSPI Data Sharing Working group is organizing a workshop at the end of September to share experiences of EMA POL-0070 *Publication of clinical data for medicinal products* for human use with respect to anonymizing clinical documents and patient level data sets. Volunteers are sought from

statistics, regulatory writing, data privacy and/or disclosure groups to present and share their experiences. More details will follow in the next newsletter, please contact Chrissie Fletcher ([fletcher@amgen.com](mailto:fletcher@amgen.com)) with any queries.

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## **Scientific**

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

**Registration is open – you can register using [this link](#)**

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, 22<sup>nd</sup> November, Brussels** (hosted by BMS).

This meeting will discuss aspects relating to network meta-analysis. Further details will follow in the next EFSPi newsletter.

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## **7<sup>th</sup> EU Statistics Leaders Meeting 2016**

This one-day meeting, organized for the 7<sup>th</sup> time, will consider and discuss the (new) developments in the area of Pharmaceutical Statistics. The forum of Statistics Leaders based in Europe will explore how it can best develop our profession and direct and engage itself optimally for the challenges that lie ahead, including the interaction with other professional bodies. The outcome of the meeting will also help direct the strategy for EFSPi.

This year the meeting will focus on the increasing interactions of EFSPi (and its member base) with regulatory bodies and public-private initiatives (such as IMI), the evolving concept of Precision Medicine, including the relationship with Biomarkers. The AIMS (Application and Implementation of Methodologies in Statistics) SIG will present their goals and objectives, and there will be a workshop exploring the Present and Future of Statistical Departments within the EU landscape. We expect over 30 participants again this year and look forward to a very good and interactive meeting.

Note that this meeting is on personal invitation only. If you want to know more about it, please contact Stefan Driessen ([stefan.driessen@abbott.com](mailto:stefan.driessen@abbott.com)).

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## **Other Events**

## FMS (Sweden)

**New president** – Paul Dickman is the new president of FMS. He is a Professor of Biostatistics at the Department of Medical Epidemiology and Biostatistics (MEB) at Karolinska Institutet in Stockholm. In his role as president, he aims to help stimulate the development and promote the use of new and established statistical methods within the medical sector as well as within the areas of pharmaceutical industry and public health. **Paul says**, “*My impression is that the profile of biostatistical science in Sweden has improved in the last 15 years. I feel there is an increased level of understanding and respect for biostatistics among biomedical scientists, although there remains more work to be done. FMS as an organisation has an important role to play in advancing our discipline and I look forward to the opportunity of working with our members.*”

**Joint DSBS/FMS Meeting** - Every second year the Swedish and Danish societies for biopharmaceutical/medical statistics, FMS and DSBS, arrange a joint meeting and this year's meeting will take place in **Malmö, November 1<sup>st</sup> 2016**. The theme of the meeting will be **Statistical analysis of risks and safety data** and the program will consist of invited speaker sessions and contributing speaker sessions. The planning of the meeting is currently in progress and two examples of topics covered are extreme value modelling of safety data from clinical trials and survival analysis methods in the assessment of safety data.

## PSI (UK)

It is now only a few weeks until the PSI Conference in Berlin and the registration deadline is fast approaching on **Monday 9<sup>th</sup> May** so please register soon to avoid missing out. PSI are pleased to confirm that representatives from the EMA will be participating in this year's conference. On Tuesday 24<sup>th</sup> May **Frank Petavy (EMA)** will be joined by **Oliver Keene (GSK)** and **Kaspar Rufibach (Roche)** discussing the latest updates on Estimands. There will also be a chance for delegates to participate in an interactive breakout session on this current topic during the conference. A chance to put your questions to the experts! On Wednesday 25<sup>th</sup> May the conference will close with a regulatory hot topics panel session with **Andrew Thomson (EMA)** discussing extrapolation joined by **David Brown (MHRA)** speaking on biosimilars and **Norbert Benda (BfArM)** on multiplicity. A session not to be missed! The final agenda is available to view on the PSI website or via the Conference App. The Gala Dinner will be held at a spectacular venue, the Wasserwerks, and will include the award ceremony 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. Finally, you can also follow <http://twitter.com/@PSIUpdate> on Twitter for PSI news. Just use the conference hashtag **#PSIConf2016** to tweet about this year's conference.

## SSL (Finland)

The annual meeting celebrating 15 years anniversary of the SSL (Statisticians in Finnish Pharma Industry) was held 14<sup>th</sup> of April. Theme of the meeting was past, present and future of biostatistics in Finland. Speakers included honorary professor Juhani Tuominen, the first biostatistician in Finland and the founder of Biostatistics master program in the university of Turku, who gave a lecture of the history of biostatistics in Finland. Professors Mervi Eerola (Professor and Director of the Center of Statistic in the University of Turku) and Jaakko Nevalainen (Professor of Biostatistics in Tampere University) provided the view of academia regarding statistics especially for Life Science areas in the Finnish universities. Finally Elina Asikanius, a statistician from Hoffman La Roche located in Basel shared a case example highlighting the actual work of a biostatistician in a global pharmaceutical

company.

New board was selected in the official part of the annual meeting. Former secretary Riku Kivimäki is now the new Chair of SSL. Based on the theme of the anniversary meeting, the focus for the forthcoming year of SSL is in the strengthening of interaction with academia in order to be prepared to face the future of pharma statistics, for example the emerge of data sciences and digitalization.

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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 2,341 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](#).

**[Nominations](#) are open for the first International Prize in Statistics**, to be awarded at the ISI World Statistics Congress in Marrakech in July, 2017. The purpose of the Prize is to call public attention to the important role that statistics, data analysis, probability, and understanding of uncertainty have played and are playing in the advancement of society, science, technology and human welfare. The Prize was created by five international statistical societies (American Statistical Association, International Biometric Society, International Statistical Institute, Institute of Mathematical Statistics, Royal Statistical Society). **Nominations are open through August 15, 2016.**

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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.

## **And finally.....**

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.

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.

Enjoy this quote (courtesy of <http://www.brainyquote.com>):

*'To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science.'* Albert Einstein

Chrissie Fletcher  
EFSPi Communications Officer

