



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

EFSPI Newsletter September 2015

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Regulatory

On September 14th the EFSI/PSI regulatory committee met face-to-face with MHRA statisticians in London for a two hour meeting. First a discussion was held on follow up activities regarding topics discussed at previous meetings, in particular the efforts to develop best practices for modelling and simulation (which were presented at the 2015 PSI Conference by the Modelling & Simulation Special Interest Group), and on the valuable efforts by PSI to reach out to Small and Medium Enterprises (SMEs) to increase awareness of key statistical principles fundamental to drug development and how SMEs can seek statistical advice. Other topics discussed included subgroup analyses; post- authorisation efficacy studies; methods for dose response evaluation; recent experiences of parallel scientific advice involving regulators and/or payers; data transparency; use of Bayesian approaches in confirmatory trials; comparison between Europe and US of initiatives aimed to accelerate the development of promising new medicines and biosimilars.

On October 9th the committee will meet with EMA's Biostatistics working party.

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Scientific

There is one remaining EFSPi Scientific meeting for 2015:

12th November – European Statistical Meeting on Dose Selection in Late Phase Clinical Development, Brussels

In this meeting we will hear from EU regulators and experts in this field as well as presentations

of case studies of the evolving methodology in this area

Registration is open and early bird registration before or on 1st of October. More information can be found on the EFSPi website or by [clicking](#) here.

In addition, the Scientific Committee is planning for new 1-day scientific events in 2016. If you have ideas or suggestions for topics, please e-mail Egbert Biesheuvel (egbert.biesheuvel@danone.com).

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Special Interest Groups (SIGs)

As described in the August newsletter, a new SIG on small populations is being formed. Anyone interested to join this SIG can contact Egbert Biesheuvel (egbert.biesheuvel@danone.com).

A new SIG called AIMS, which stands for Application and Implementation of Methodologies in Statistics, is also being formed. This SIG will be relevant to statisticians and programmers who have expertise or a strong interest in developing their technology toolkit, with a focus of supporting industry enhancements relating to methodology and software. More information will be available in a future newsletter.

As a reminder, volunteers are always welcome to join the SIGs. It is not necessary to be an expert in the area of interest to be able to join a SIG, rather having a strong interest in the area and being motivated with an eagerness to learn and contribute is highly valuable. Existing SIGs include the following:

- Biomarker (leader = Athula Herath, heratha@MedImmune.com)
- Benefit-risk (leader = Alexander Schacht, schacht_alexander@lilly.com)
- Health Technology Assessment, HTA (leader = Chrissie Fletcher, fletcher@amgen.com)
- Integrated Data Analysis (leader = Byron Jones, byron.jones@novartis.com)
- Medical Devices (leader = Roland Marion-Gallois , roland.marion-gallois@medtronic.com)
- Modelling & Simulation (leader = Chris Campbell, ccampbell@mango-solutions.com)
- Real World data (leader = George Quartey, quarteyg@gene.com)
- Toxicology (leader = Gareth Thomas, ThomasG@UKOrg.Huntingdon.com)

Please contact the SIG leaders noted above if you are interested to participate in a SIG.

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Other Events

APF (Germany)

APF is organizing:

- A workshop hosted by AbbVie in Ludwigshafen, **29th November 2015**, about **Bayesian Methods in Clinical Development**
- A **German Stats Leader Meeting** hosted by Bayer in Berlin, **2nd October 2015**

Click [here](#) for more information.

FMS (Sweden)

FMS are holding their **Autumn Meeting** on the **20 October 2015**. Topics include: health economics, health care databases and statistical research in hospitals. The meeting will be held at Centre for Mathematical Science at Lund University, Sölvegatan 18, Lund, SWEDEN. The registration for the meeting is free. Please register before the 10th October 2015, for registration click [here](#). For any questions, please contact Aldana.Rosso@skane.se.

PSI (UK)

The **PSI/EFSPi Toxicology SIG** will be holding their next 2 day meeting on the **13th and 14th October 2015, near Heathrow airport**. Current hot topics that may be up for discussion include: Analysis of large datasets (eg telemetry data), analysis of anti-drug antibody assays, experimental design, benchmark dose approaches and updates on approaches to conducting carcinogenicity studies. If you would like to register interest for this meeting, please contact Gareth Thomas, PSI ToxSIG Chair ThomasG@UKorg.huntingdon.com.

A one day meeting on “**Beyond the detail seeing the whole picture; Graphical representations, what's in it for us?**” is taking place on the **9th October at the RSS, London**. This meeting aims to cover a wide variety of areas where graphics can, and are, being used within the pharmaceutical industry and beyond. By sharing and engaging in multiple and varied examples attendees will come away from the meeting with a renewed appreciation of the benefits of graphical representations and ideas of where these tools could prove useful within their own areas of work. Please [click here](#) for more information.

The **Pharmaceutical Statistics Journal Club** next event focussing on dealing with missing data in clinical trials is scheduled for **2pm BST, Thursday 15th October 2015**. For more information, please see www.psiweb.org/events/journal-club.

A one-day meeting on “**The Innovative, Challenging and Diversified World of Respiratory Disease**” is scheduled for the **13th November at Roche, Welwyn Garden City, UK**. The meeting aims to cover a wide range of respiratory diseases and design considerations when working in this therapeutic area. Please [click here](#) for more information.

A training course on “**Adaptive Designs**” is scheduled for the **24th and 25th November at London Stanstead airport**. The course will focus on the practical implementation of the types of adaptive designs. [Click here](#) to view the flier and [Click here](#) for more information.

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. Please note the deadline for an oral Abstract is 30th November 2015. For further information and in order to submit an abstract, please go to <http://psiweb.org/events/2016-conference>.

A workshop on “**Clinical Trials in Small Populations**” is scheduled for the **30th November and 1st December at the RSS, London**. This two-day workshop will offer an interactive training day for statisticians and an open day with invited talks by medical statisticians from industry and academia, patient representatives and regulators. [Click here](#) for more information.



The World of Statistics

The World of Statistics movement has grown to a total of 2,367 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 events and activities planned for 2015, [click here](#).

Don't forget to celebrate [World Statistics Day \(WSD\) 2015](#) on the **20th October 2015**.



Job Opportunities

Opportunities exist for a Principal/Senior Principal Biostatistician, a Senior Epidemiologist, and a Senior Quantitative Safety Scientist. 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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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.

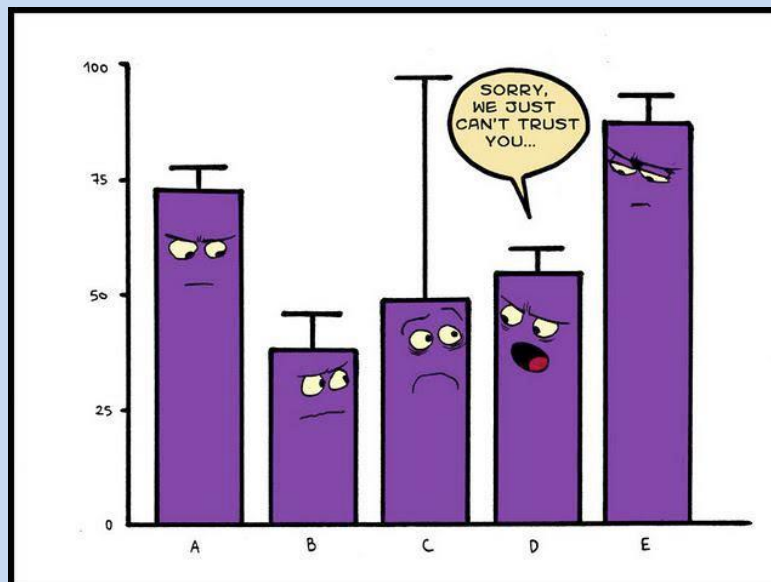
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And finally.....

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

Fun picture of the month (thanks to <http://andrewgelman.com/>):



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Chrissie Fletcher
EFSPI Communications Officer