



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

EFSPI Newsletter October 2015

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[The World of Statistics](#)

World of Statistics Day October 20th 2015

Three cheers for Statistics! Hopefully on the 20th October you were able to celebrate the World of Statistics Day 2015. A number of famous statisticians have shaped and influenced the development and use of statistics across a wide range of applications. For example Florence Nightingale who was one of the first people to collect statistics on health policy, and R A Fisher who laid the foundations for most of experimental design, analysis of variance and much of statistical inference. Click [here](#) to read more about famous statisticians. The early beginnings of statistics are said to have begun around 450 BC when Hippias of Elis used the average value of the length of a king's reign (the mean) to work out the date of the first Olympic Games, some 300 years before his time. And in 1958 Edward L Kaplan and Paul Meier developed the Kaplan–Meier estimator that gave doctors a simple statistical way of judging which treatments work best. Let's not forget that in 2008 Hal Varian, chief

economist at Google, noted that statistics would be “the sexy profession of the next ten years”. Click [here](#) to see a history of statistics timeline, courtesy of the RSS and ASA.

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 the remainder of 2015, [click here](#).

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Regulatory

On Oct. 9th the EFSP/PSI regulatory committee met with EMA’s Biostatistics Working Party (BSWP) in London. Topics discussed were the upcoming BSWP guidance document on subgroups and the reflection paper on statistical considerations in comparing quality attributes. Both are expected to be released next year. Further topics discussed included the measurement of treatment benefit in a survival setting, the ICH E9 Addendum on estimands and sensitivity analysis, and multiplicity. A summary of the meeting for circulation is currently being drafted.

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Scientific

There is one remaining EFSP/PSI 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 EFSP/PSI 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**

Click [here](#) for more information.

PSI (UK)

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.

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.

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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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Fun picture of the month (courtesy of www.pinterest.com):



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