



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

EFSPI Newsletter November 2015

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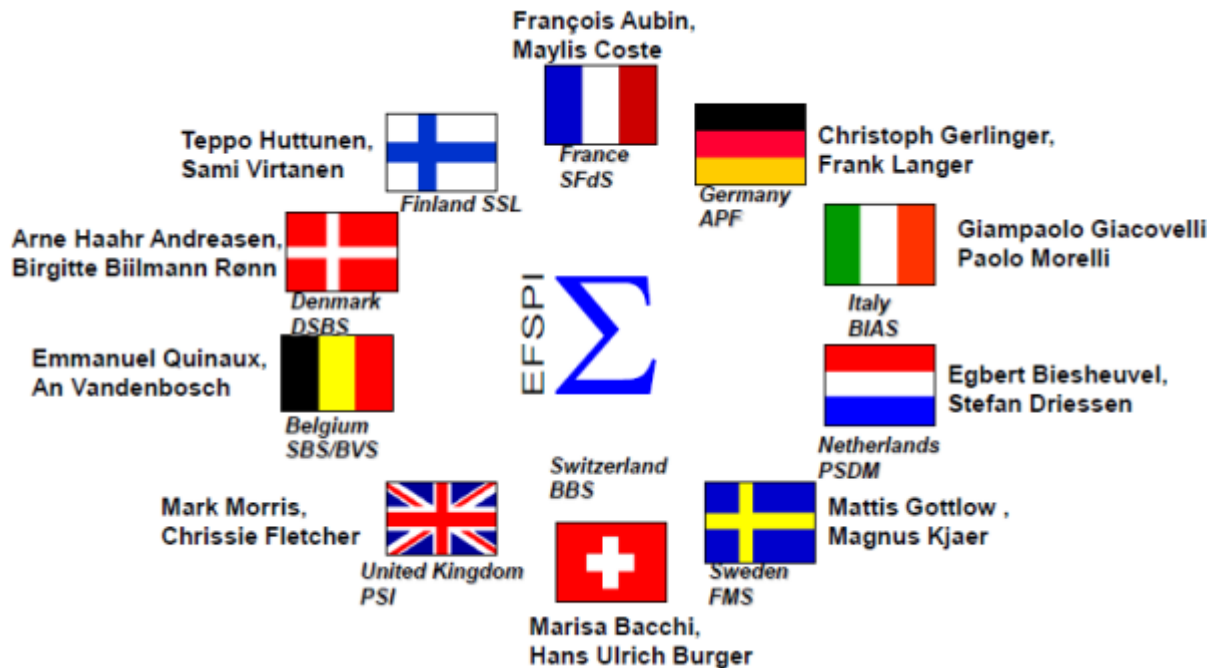
[And finally.....fun picture of the month](#)

EFSPI Council

Effective December 2015 Marisa Bacchi, BBS Switzerland, will become the EFSPI President for 2-years. The Council thanked Chrissie Fletcher for her leadership of EFSPI over the last 3 years. Chrissie transitions to the Vice President role, in addition to continuing with leading Communications activities. After 17 years on the EFSPI Council as one of the French representatives, Francois Aubin has announced he will be stepping down from the Council. Francois has made significant contributions to EFSPI over this time. In particular, Francois contributed to organising numerous 1-

day scientific meetings, he held the EFSPI President role between the end 2010 to the end 2012, and most recently led the re-design of the EFSPI website. EFSPI expresses a huge 'Thank You' to Francois for his outstanding support to EFSPI. EFSPI also thanks Pekka Heikkilae and Toni Sarapohja from Finland for their contributions to EFSPI and welcomes Teppo Huttunen and Sami Virtanen who have joined the Council to represent Finland.

The list of current EFSPI members include:



The EFSPI Council met in mid-November. A new 3-year strategic plan is being drafted for 2016-2018 and will be finalised in Q1 2016.

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Regulatory

EMA has published the draft guidance on post approval efficacy studies (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/11/WC500196379.pdf). The expert working to comment is led by Hermann Huss (Hermann-josef.huss@bayer.com). Please contact Hermann if you wish to contribute as additional members of the working group are most welcome. Comments should be sent by the end of the year.

EMA plans a workshop on the extrapolation of adults' safety and efficacy data to the pediatric populations. If you are an expert in this domain and want to contribute please contact Christoph Gerlinger (christoph.gerlinger@bayer.com).

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Special Interest Groups (SIGs)

EFSPI/PSI are pleased to announce a new SIG is being established to recognise the continual need for statisticians and programmers to develop their technology toolkit and support industry enhancements. The new

Application and Implementation of Methodologies in Statistics (AIMS) Special Interest Group

will support PSI/EFSPI members to further develop their understanding of new analytical tools and approaches. It will have a wide reaching remit which will cover items such as:

- New analytical tools
- Enhancement of existing analysis software packages
- Evolution of industry data standards and guidelines

If you have an interest and passion for technology and enabling others to put it to use in practice please contact Craig McIloney (craig.mcilloney@ppdi.com) or Lyn Taylor (TaylorLyn@prahs.com). This is an exciting new area of focus so we are keen to hear from you.

The new SIG on small populations is still seeking volunteers. Anyone interested to join this SIG can contact Egbert Biescheuvel (egbert.biesheuvel@danone.com).

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Scientific

The EFSPI 1-day scientific meeting held on the **12th November on Dose Selection in Late Phase Clinical Development**, Brussels was well attended. The materials presented are in the process of being loaded on to the [EFSPI website](#).

If you have ideas or suggestions for scientific meetings for 2016, please e-mail Egbert Biescheuvel (egbert.biesheuvel@danone.com).

Other Events

A calendar of events that each local association is planning for 2016 is in development and will be available on the EFSPi website in early 2016.

PSI (UK)

The next PSI Journal Club is joint with the DIA and sponsored by Wiley on the topic of Decision Rules and Probability of Program Success. The webinar event is scheduled for 3.30 pm (UK time, GMT) on the 15th December 2015. Details are available at www.psiweb.org/events/journal-club.

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. For further information please go to <http://psiweb.org/events/2016-conference>.

ASA

The ASA's impactful public awareness campaign—[This is Statistics](#)—is unveiling new resources to tell students about the many exciting careers in statistics. Please forward to colleagues and contacts at schools and Universities to help promote a career in statistics.

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.



The World of Statistics

The World of Statistics is comprised of 2,374 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 the remainder of 2015, [click here](#).

The following article published in Nature may be of interest to you and your Industry colleagues: [How scientists fool themselves—and how they can stop](#). There's also an accompanying commentary on blind data analysis: [Blind analysis: Hide results to seek the truth](#), and an interesting editorial: [Let's think about cognitive bias](#).

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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.....

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.

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

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Chrissie Fletcher

EFSPI Communications Officer