



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

EFSPI Newsletter March 2016

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Council News

The EFSPI Council thanks Giampaolo Giacobelli, who is stepping down as a representative for Italy (BIAS), for his support to EFSPI. The EFSPI Council welcomes **Marco Costantini** who has joined the EFSPI Council replacing Giampaolo.

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Regulatory

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 or 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).

The US National Institute of Health in conjunction with the FDA has published a draft template for phase II and III clinical study protocols

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-043.html>. If you have comments on this draft please contact Christoph Gerlinger (christoph.gerlinger@bayer.com) by April 13th.

EMA published an External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use, see http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/03/WC500202621.pdf

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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).

Registration is open – you can register NOW by following [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** 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)

The SIG Small Populations is a new SIG that started in January 2016. The purpose of this SIG is to provide a forum for statisticians working in the Pharmaceutical Industry engaged in the topic of rare diseases or small populations. For further information please go to http://www.efspi.org/EFSPI/SIGs/Small_Populations_SIG/EFSPI/Special_Interest_Groups/Small_Populations_SIG.aspx?hkey=dc735663-0879-4f59-8a09-db9000581c59.

The next telecom will be on Friday April 29, 2 pm CEST.

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Other Events

PSI (UK)

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>.

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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 2,338 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.**

The ASA "[Statement on Statistical Significance and P-Values](#)" includes six principles underlying the proper use and interpretation of the p -value and is intended to improve the conduct and interpretation of quantitative science and inform the growing emphasis on reproducibility of science research. "The p -value was never intended to be a substitute for scientific reasoning," said Ron Wasserstein, the ASA's executive director. "Well-reasoned statistical arguments contain much more than the value of a single number and whether that number exceeds an arbitrary threshold. The ASA statement is intended to steer research into a 'post $p < 0.05$ era.'" The statement is published in [The American Statistician](#) along with more than a dozen discussion papers to provide further perspective on this broad and complex topic.

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And finally.....

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

'It is the mark of a truly intelligent person to be moved by statistics.' George Bernard Shaw

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Happy "Egg-EFSPi" Easter!

Chrissie Fletcher
EFSPi Communications Officer

