



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

EFSPI Newsletter June 2015

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Regulatory

The EFSPI/PSI regulatory committee will meet with MHRA statisticians in September. We plan to send in our consolidated questions before the summer holidays, so please let us know YOUR questions by mailing them to Christoph.Gerlinger@Bayer.com by July 10th.

We are still looking for volunteers to comment the upcoming EMA reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development, see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/06/WC500144945.pdf.

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Scientific

The 1-day joint meeting on **Health Technology Assessments** held in Basel with BBS on the 23rd June 2015 as a great success with over 80 attendees. The topics included trends in HTA, use of HTA for medical devices and diagnostics, and HTA applications of methods and analyses. Click [here](#) to access the materials from the meeting.

Thanks to those who dialed into the PSI/EFSPI benefit-risk webinar's held in June that discussed latest methodology as well as sharing case studies of B-R assessments. Click [here](#) to access the materials.

EFSPI will be holding two other scientific meetings in 2015:

- A joint meeting with PSI on **Estimands** on the 28th September 2015 in London
- A meeting on **Dose Finding studies in Clinical Studies** in Q4 2015

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Other Events

PSI

For those unable to attend the PSI 2015 conference, please [click here](#) to see a brief video. Speaker slides, audio recordings and photos are now available to members on the PSI website. The PSI scientific committee are already busy planning next year's conference, which will be held at the Pullman Hotel in Berlin 22-25th May 2016. Registration will open September 2015.

Free webinar: Drug Development beyond the FDA/EMA - Opportunities and Challenges in Asia Pacific Development Pathways, Thursday 16 July 2015. This webinar aims to focus on the needs of the China FDA (cFDA) and Japan's Pharmaceutical and Medical Device Agency (PMDA) providing both insights into the regulatory requirements, real life examples of local development plans and key things to consider when looking to include these countries in multi-regional trials. More details [here](#).

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.

ISCB

The 36th Annual Conference of the International Society for Clinical Biostatistics, which will take place in Utrecht, The Netherlands, August 23-27, 2015 (<http://www.iscb2015.info/>).

The conference is a scientific forum for international exchange of theory, methods and applications of biostatistics in medical research and practice. ISCB 2015 is intended for statisticians, clinicians and members of other disciplines, such as epidemiologists, clinical chemists and clinical pharmacologists interested in the field of clinical biostatistics.

Multiple Comparisons Procedures Conference

The IXth International Multiple Comparisons Procedures (MCP) Conference will be held in Westin Hotel, Hyderabad, India from September 2, 2015 to September 5, 2015. The conference will cover the latest methodological and applied developments in the areas of multiple comparisons and adaptive designs in clinical trials. There will be pre-conference workshops on September 2 and the main conference will be from September 3 to September 5. Keynote speech will be by Dr. Jason Hsu on "Errors in Multiple Testing Big and Small, Now and Then, More or Less". There will also be a panel discussion on FDA Multiplicity Guidance Document led by Dr. John Scott and Dr. Mohammad Huque of FDA and prominent industry statisticians. Abstract submissions are now open. For further details and submission of abstracts visit <http://www.mcp-conference.org/hp/2015/> or write to Dr. Vishwanath (Mahesh) Iyer vishwanath.iyer@novartis.com.

2015 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop

The ASA Biopharmaceutical Section FDA-Industry Statistics Workshop is sponsored by the ASA Biopharmaceutical Section in cooperation with the FDA Statistical Association. Each year, approximately 800 regulatory, academia and industry colleagues gather together to share insights into key trends in statistical topics relevant to pharmaceutical and medical device development. The 2015 Workshop takes place September 16-18 in Washington D.C. at the Marriott Wardman Park. The plenary includes presentations and panel discussion on The Future of Precision Medicine. As part of the plenary program, Susan A. Murphy, Professor of Statistics and Professor of Psychiatry at the University of Michigan, will discuss the use of mobile devices in micro-randomized trials. For more information click [here](#).

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The World of Statistics

The World of Statistics movement has grown to a total of 2,373 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](#).

World Statistics Day 2015 will be celebrated October 20. The event is being organized globally the United Nations Statistics Division. [Go to its website](#) to learn more about the event and be sure to go back periodically for updated information.

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Job Opportunities

Opportunities exist for: Biostatistical Specialist, and Biostatistician Professional. For all current recruitment adverts please visit the EFSPi website: [Job postings](#).

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Follow us on Twitter and Linkedn

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 Linkedn.

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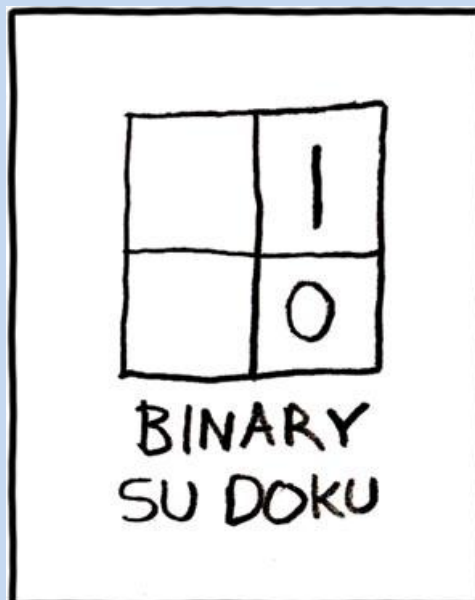
And finally.....

If you are currently seeking to hire a statistician and wish to post a job advert, see the "Advertisements" area on the EFSPi website at www.efspi.org and view the "Job Postings" for instructions. EFSPi are offering one free advert for every 3 adverts posted on the website.

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 [xkcd](#)):



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Chrissie Fletcher
EFSPi Communications Officer