



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

EFSPI Newsletter May 2015

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Council News

Congratulations to Marisa Barnes (Switzerland) who has taken over as EFSPI Vice-President. Marisa will become the EFSPI President in December 2015.

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Regulatory

ICH E9 Survey

On behalf of the International Conference on Harmonisation (ICH), an expert working group is developing an addendum to the E9 guidance document (Statistical Principles for Clinical Trials). The addendum will focus on issues surrounding estimands, missing data and sensitivity analyses in the design and analysis of clinical trials. The purpose of this survey is to gather data on related current practices, primarily focused on clinical trials involving drugs, vaccines and biologics. The survey is being distributed to various regions within ICH, including industry and regulatory communities. If a question is not applicable to your job role, please select "I am unable to answer this question/not applicable to my job role".

The ICH E9 Revision 1 working group thanks you in advance for your participation. Please complete the survey by **Friday 5th June 2015**.

Link to survey: <https://www.surveymonkey.com/r/VPMV57Z>

New FDA draft guidance on adaptive design for medical device clinical studies

The US Food and Drug Administration (FDA) has recently issued a draft guidance on [Adaptive Design for Medical Device Clinical Studies](#). As this guideline contains substantial statistical content PSI/EFSPI will be preparing comments through the Regulatory Committee. If you would like to comment, please use the form

http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=W500004016 (this is the EMA template for comments on draft guidance, which we will use in the absence of an FDA template). The form should be returned by Friday, 3 July 2015 to jurgen.hummel@ppdi.com or alun.bedding@roche.com.

Individuals in organisational groups are encouraged to pool their comments and contribute one consolidated set. Representatives from the PSI/EFSPI Regulatory Committee will review all comments and submit one consolidated response, which will be sent to the FDA and published on the PSI and EFSPI websites.

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Scientific

EFSPI will be holding three scientific meetings in 2015:

- A joint meeting with BBS in Basel on **Health Technology Assessments** on the 23rd June 2013, click [here](#) for the flyer and registration details
- A joint meeting with PSI on **Estimands** in September 2015
- A meeting on **Dose Finding studies in Clinical Studies** in Q4 2015

EFSPI is preparing a webinar on Benefit-Risk in June. We will keep you informed as more details become available.

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6th EU Statistics Leaders meeting

The agenda for the 6th EU Statistical Leaders Meeting (July 1, Brussels) has been set and all speakers/presenters have been confirmed. The forum will this year focus on the following areas: Benefit-Risk, Real World Evidence, Estimands, and Data Transparency. It is expected to become yet again a very useful meeting for the Statistics Leaders to exchange experiences, share ideas, network, and discuss how to best progress our EU Statistics community. This year the intention is to provide even more time for discussions in the one-day meeting by limiting the time for presentations and to have more pre-reads available. Attendance to the forum and the meeting are on personal invitation only and these have been sent out in April. For more information about this meeting, or any other comments/questions on this Forum, please contact Stefan Driessen (stefan.driessen@abbott.com).

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SIG (Special Interest Groups) News

Toxicology SIG 2 Day Meeting

The 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 (e.g. 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, EFSPi/PSI Tox SIG Chair ThomasG@UKorg.huntingdon.com.

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Other Upcoming Events

PSI (UK)

Statistical Innovations in Clinical Trials One-Day Meeting - Adaptive Designs Workshop at Amgen (Uxbridge) in collaboration with Cytel, 29 June, 2015. Registration: £50 + VAT. To register please [click here](#).

Presentations from Cyrus Mehta (Cytel) on "Statistical and Operational Challenges of VALOR, an Adaptive Phase-3 Trial for Acute Myeloid Leukemia", Alun Bedding and Julian Zhou (Roche) on "Innovative Considerations on a Phase 2a Dose-Finding Strategy Using Bayesian Methods and MCP-Mod", Peter Colman (UCB) on "Defining, Understanding and Communicating Decision Criteria in Early Clinical Development", and Kevin Carroll (KJC Statistics) on "Tackling Real Problems in Multi Regional Clinical Trials".

RSS (Royal Statistical Society)

Professional Statisticians' Forum Webinar, Thursday 4 June 2015, 2:00 – 3:30pm (BST).

A free-to-attend, telephone-based (virtual) meeting for professional statisticians (holders of CStat and GradStat status)

A CONCEPTUAL, TECHNICAL AND PRACTICAL FRAMEWORK FOR MISSING DATA IN LONGITUDINAL CLINICAL STUDIES: CRITICAL SKILL AND IMPORTANT HABITS FOR STATISTICIANS, PRESENTED BY CRAIG MALLINCKRODT, LILLY PHARMACEUTICALS R&D.

Dial-in details: Phone number: +44 (0) 330 336 6002, Passcode: 476 766 1144. If you are outside of the UK please click [here](#) for a local rate number you can use.

Web address: <https://rss-uk.globalmeet.com/RSS> (select "Enter as a guest")

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.

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The World of Statistics

The World of Statistics movement has grown to a total of 2,362 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](#).

On **October 20** this year, the global statistical community will showcase their achievements and their ongoing work to help this vision come true as part of **World Statistics Day 2015**.



The logo for World Statistics Day 2015.

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: Biostatistician Professional, Senior Statistician, Project Statistician, and Biostatistician. For all current recruitment adverts please visit the EFSPi website: [Job postings](#).

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Have you seen the new EFSPi website?

EFSPi are pleased to announce the release of its new website keeping its usual URL <http://www.efspi.org>. Feedback on the new website is welcomed, please contact Francois Aubin (email: francois.aubin@venncro.com).

WELCOME TO THE NEW EFSPi WEBSITE
THE NEW WEBSITE WAS LAUNCHED ON 10TH FEBRUARY 2015
WE HOPE YOU WILL FIND IT OF INTEREST AND WILL VISIT IT REGULARLY



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GO

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- Integrated Data Analysis SIG
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- Toxicology SIG

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SOCIAL NETWORK



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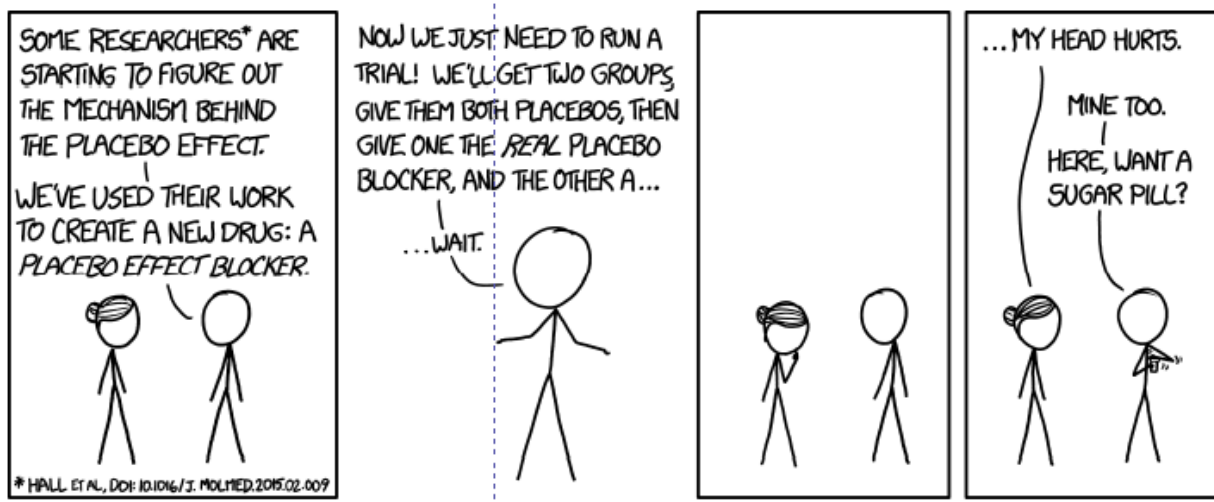
And finally.....

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