



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

EFSPI Newsletter October 2016

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Regulatory

Reminder: the EMA have released a new [Draft ICH guideline E17 on general principles for planning and design of multi-regional clinical trials](#). The purpose of this document is to outline general principles for the planning and design of multi-regional clinical trials with the aim of increasing their acceptability in global regulatory submissions. Aaron Dane (aarondane@danestat.com) is collating comments. If you would like to provide comments on behalf of your organisation please contact Aaron. Comments are due by December 16.

An EFSPI/EFPIA workshop on estimands will take place on the **19th January 2017** at Amgen, Uxbridge, UK. The aim of the workshop is to discuss with cross-functional stakeholders a new **estimand framework** being introduced in the addendum to **ICH E9 Statistical Principles for Clinical Trials [ICH E9(R1)]**. EMA and EFPIA representatives from the ICH E9 Working Group will share the latest perspectives and highlight key aspects of the proposed addendum to E9 before it is released for public consultation in 2017. Representatives from EFPIA and EFSPI will be invited to participate in the workshop. For more details, please email Chrissie Fletcher (fletcher@amgen.com).

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Scientific

A 1-day scientific event on **Evidence Synthesis** will take place on the **22nd November, Brussels** (hosted by BMS). This meeting will discuss methodological considerations relating to synthesizing evidence to support drug development and market access activities. Topics to be discussed include: how to use evidence from network meta-analyses (NMA) to inform clinical trial design;

NMA in an ANOVA framework; conducting frequentist NMA in R; conducting NMA using individual patient level data; and how to compare treatments when the network of evidence is disconnected. Case studies will also be presented. Click [here](#) to find out more details and register for this meeting.

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Other Events

APF (Germany)

APF is organizing a Workshop hosted by **Parexel** in **Berlin** on the **25th November 2016** about **Estimands and Prediction of Disease Progression**.

PSI (UK)

Introduction to Simulation 8-9 November, Heathrow, London. The aim of this 2 day course is to provide participants an understanding of simulation techniques. The course, presented by Les Hudson, will include methods for generating samples of univariate, correlated bivariate and multivariate normal data. Example code for the methods discussed will be provided in both SAS and R and a variety of practical examples will be presented. [Click here to see more!](#)

Dose Finding in Drug Development using MCP-Mod 01 - 02 March 2017, Heathrow, London. This two day course will introduce and discuss methods for Phase II dose finding studies, including a review of basic multiple comparisons and modelling methods, as traditionally used in these studies. A unified strategy for designing and analysing dose finding trials denoted MCP-Mod, combining multiple comparisons and modelling, will be the focus of the course. MCP-Mod was the first statistical methodology to receive CHMP Qualification Opinion (2014) and was recently recognised by the FDA under the Fit-for-Purpose Initiative (2016). The course ends with a review of regulatory considerations. [Click here to see more!](#)

PSI Conference 2017, Abstract Submission OPEN! PSI are pleased to announce that registration is now open for the 2017 PSI Conference, being held on 14th – 17th May 2017 at the Grange Hotel, London. The theme will be **“Celebrating 40 years of promoting statistical insight”**. Please click [HERE](#) to confirm your place now and take advantage of the discounted Early Bird Rate. We are pleased to have already announced our two keynote speakers Richard Stephens and David Spiegelhalter, more details can be found on the [website](#). We are also excited to be able to offer the choice of two pre-conference training courses. We also have a number of other plenary and parallel sessions with speakers from industry, academia and regulatory agencies, including Lisa LaVange (Director of the Office of Biostatistics in the Center for Drug Evaluation and Research at the USA FDA). We are already receiving abstracts for contributed talks and posters, with the first deadline for oral presentations approaching on the 18th November. All the details on how to submit an abstract are on the [Conference website](#).

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Job Opportunities

Opportunities exist for [Principal Statistician](#), [Senior Manager Statistical Programming](#), [TA expert statistician in Oncology](#), [TA expert statistician in metabolism](#), and [multiple positions in quantitative](#)

[sciences](#). 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 2,199 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](#).

Prominent British statistician Sir David Cox has been named the inaugural recipient of the International Prize in Statistics. Susan Ellenberg, chair of the International Prize in Statistics Foundation, made the historic announcement via [video statement](#).

If you missed something at [JSM 2016](#) or weren't able to attend, the educational presentations and plenary session recordings are now available online. This year's event was one of the largest, drawing more than 7,000 statistics professionals from around the world to exchange ideas and explore opportunities for collaboration. In the meantime, mark your calendars to join us next year, July 29-August 3, 2017 for [JSM 2017](#) at the Baltimore Convention Center in Baltimore, Maryland.

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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.....

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Enjoy this quote (courtesy of www.goodreads.com)

“The non-scientist in the street probably has a clearer notion of physics, chemistry and biology than of statistics, regarding statisticians as numerical philatelists, mere collector of numbers.”

— **Stephen Senn**

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Chrissie Fletcher
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