



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



EFSPI Newsletter December 2016

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Regulatory

The EMA has released the [Draft guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products](#). The guidance is intended to further assist sponsors in the transition from non-clinical to early clinical development and identifies factors influencing risk for new investigational medicinal products. The document is out on consultation and Maylis Coste (Maylis.Coste@servier.com) and Bruno Boulanger (Bruno.boulanger@arlenda.com) are collating comments. If you would like to comment, please review and send any comments to Maylis and Bruno using the attached form by Friday January 27 2017.

On Nov 23rd the regulatory committee met with the MHRA statisticians in London. Topics discussed included: estimands; real world data; EMA publication of trial data; first in human studies; confidentiality of interim results; use of R and other specialist software; single arm trials for drug approval; parametric survival curve modelling; evaluation of safety and quantitative benefit-risk in drug development; and the role of statisticians and quantitative methods in drug development decision making.

The FDA released the finalised the guidance on [Non-Inferiority Clinical Trials](#) in November. Many of EFSPi's comments were incorporated.

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Scientific

The Scientific Committee is planning for at least three 1-day scientific meetings and a webinar for 2017. Preparations are ongoing, and preliminary topics for the meetings are:

- Safety analyses, a joined meeting with the PSDM (the Netherlands, aiming for June 2017)
- Advances in Clinical Trial Design (Germany, aiming for June 2017)
- Oncology

More detailed information will follow in future newsletters. If you have suggestions for contributions to any of these topics, please contact Egbert Biesheuvel (Egbert.BIESHEUVEL@danone.com).

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Country News

BIAS (Italy)

On 3rd December, the final assignments of the 1st edition of the Master in Advanced Biostatistics for Clinical Research, organized by the University of Padua in collaboration with BIAS, were presented. All students graduated with high marks. The second edition will start soon and the BIAS Committee will continue to be part of the Scientific Committee

PSI (UK)

Health Technology Assessment (HTA) Training Course, 26 - 27 Jan, 2017, Novotel, Heathrow Airport, London UK. Presented by Mark Sculpher, Neil Hawkins and members of the HTA SIG. This 2-day course will provide an introduction to the methods of health technology assessment. This includes how to estimate the costs and benefits of new interventions and analyses undertaken to support decisions about whether new interventions should be funded by health systems. The first day will include sessions on policy context and basic economic evaluation methods, as well as lectures on health measurement and valuation for HTA, evidence synthesis and decision analysis. There will also be exercises to confirm participants' understanding of key concepts. The second day will focus on sharing case studies and discussing key statistical challenges in HTA. Attendees will be encouraged to share their own HTA experiences. Click [here](#) to register and see more details. Early bird registration ends Friday 23rd December 2016.

PSI Careers Event, Wednesday 22nd February 2017, Reading University. The half-day event is open to all pharmaceutical companies, CROs and CTUs who have PSI members, and will target MSc, final year BSc and PhD students who are studying a statistics-related degree. We would also like to invite universities to run a stand to advertise statistical MSc or PhD courses, so that students can be made fully aware of their options. If you have any questions or would like to receive an invitation please contact careers@psiweb.org.

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, 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).

SFdS (France)

The **International Meeting Statistical Methods in Biopharmacy** will be held on the **14-15th September 2017** with the theme **“The future of Biostatistics in an emerging world of data sciences”**. Key themes for the meeting include: regulatory statistics and beyond, statistical inference of biostatistics of the 21st Century, successful marriage between bioinformatics and biostatistics, and recurrent event analyses. More details to register will follow in future newsletters.

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Job Opportunities

Opportunities exist [for Senior Principal Statistical Scientist](#), and [Principal Statistician](#). 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 2,198 organizations across the globe. Participating organizations in The World of Statistics include national and international professional statistical societies, colleges and universities, primary and secondary schools, businesses, government statistical agencies, and research institutes. You can view the current participant and country lists involved in the World of Statistics by going to [The World of Statistics website](#).

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As we reach the end of 2016, enjoy this quote (courtesy of [www.goodreads.com](#))

“Extraordinary claims require extraordinary evidence.”

— [Carl Sagan](#)

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Chrissie Fletcher
EFSPI Communications Officer

