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

EFSPI Newsletter November 2016

In this newsletter:

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.

A friendly reminder that we are collecting comments for the **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 multiregional clinical trials with the aim of increasing their acceptability in global regulatory submissions. Aaron Dane (AaronDane@danestat.com) is collating comments, so if you would like to comment please review and send comments to Aaron using the attached form by Friday December 16 2016.

The FDA released the finalised the guidance on **Non-Inferiority Clinical Trials** in November – Happy Reading. We will check to what extent EFSPI's comments were accepted and report in the next newsletter

On Nov 23rd the regulatory committee met with the MHRA statisticians in London. A summary of the meeting will be provided in the next newsletter.

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Scientific

The last scientific event of 2016 on **Evidence Synthesis** took place on 22nd of November in Brussels and was a successful meeting with a variety of presentations and an interactive panel discussion at the end of the meeting. Presentations of the meeting will be available on the EFSPI website soon.

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)
- Advances in Clinical Trial Design
- 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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Other Events

BIAS (Italy)

The BIAS seminar, "CDISC Italian User Network Day: data standards and their application", was held on October 21st 2016 in Milan, in collaboration with CDISC and with the support of SAS Italy. International speakers from different countries shared a variety of experiences with CDISC and interacted with the 80 participants. Presentations ranged from the validation and traceability of CDISC datasets to the use of SAS Clinical Data Integration and standards driven End-2-End flow using SAS Life Science Analytics Framework; a case study related to the data submission to the FDA was also discussed. A speech from Rhonda Facile, CDISC Vice President, provided an update on CDISC news, particularly on CFAST and on various therapeutic areas. At the end of the meeting, a Q&A session was organized to trigger discussions on specific items.

The BIAS Committee is working on future events that will be announced as soon as possible.

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. Early bird deadline: 23rd December 2016. Click here to register and see more details.

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, Principal Statistician, and Senior Manager Statistical Programming. 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 2,360 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. These organizations are located in 131 countries spanning 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.

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And finally.....

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To view previous newsletters please see the EFSPI website in the "News" area.

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.

Enjoy this quote (courtesy of www.quotegarden.com/statistics.html)

"Statistics may be defined as "a body of methods for making wise decisions in the face of uncertainty."

W.A. Wallis.

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Chrissie Fletcher

EFSPI Communications Officer