European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter January 2015

In this newsletter:

Regulatory Update

EMA/EFPIA workshop on the importance of dose finding and dose selection for the successful development, licensing and lifecycle management of medicinal products

On 4/5 December 2015 there was a joint EMA/EFPIA workshop on the importance of dose finding and dose selection. The experience of regulators is that a single dose is chosen based from a limited number of doses and selected using pairwise comparisons. Presentations during the workshop focused on model based assessments of dose-exposure-response relationships with the goal to make recommendations on which regulators and drug developers agree and that will result in improved dose finding strategies.

There was strong representation at the workshop from regulatory authorities (FDA, EMA and PDMA), who all put forward a strong message that dose finding should be done using a model based paradigm and not hypothesis testing. The main messages from the meeting can easily be summarized by using points given by Jose Pinheiro namely selection of dose for Phase 3 is an estimation problem and more efficient using model based methods. A wider dose range and larger number of doses should be used. Adaptive dose-ranging leads to efficiency and longitudinal analysis can be extremely powerful.

Details of the workshop and presentations are can be found at the following link:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2014/06/event_detail_000993.jsp&mid=WC0b01ac058004d5c3

Following on from this workshop EFSPI/PSI are planning to form a small working group to look at methods in D-E-R (Dose-Exposure-Response) for dose selection. If you are interested in being part of this working group, please contact Alun Bedding at alun.bedding@roche.com by end of February 2015.

IOM report on sharing clinical trial data

The US Institute of Medicine published a 235-page report on "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk" which can be downloaded as pre-print from http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx free of charge. It addresses the guiding principles for sharing data and the roles of the different stakeholders from trial participants and investigators to regulatory agencies and medical journals. The report makes suggestions on the timing and of the governance of sharing clinical trial data. Finally it gives an outlook on the future landscape of data sharing.

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Scientific Update

EFSPI will be involved in four meetings in 2015:

- A joint meeting on **Health Technology Assessments** with the BBS in Basel on the 23rd June 2015
- A joint meeting with the PSI on **Estimands** in September,
- A meeting on Late stage **Dose Finding studies in Clinical Studies**, in September – October with potential location Brussels,
- A meeting on Biomarkers & Subgroups, in November and will have a special theme – more information will follow.

Dates and locations will be confirmed in subsequent newsletters and available on the EFSPI website. In addition, the Scientific Committee will meet with representatives of all national organisations to pull together a summary of all planned meetings taking place in 2015 including proposed topics and agenda's. We hope this will provide you with a better overview of all important dates and topics of meetings within all of the EFSPI associations.

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Other Upcoming Events

AFP (Germany)

The APF is organizing a session on Benefit-Risk Assessment during the 61. Biometrisches Kolloquium 15.-18. March 2015 in Dortmund http://www.statistik.tu-dortmund.de/Biom2015/ . The APF Fall Meeting is planned for November 27th 2015 in Ludwigshafen.

BIAS (Italy)

Bias is organising an event on 'Data Visualization in Clinical Research' on the 20th March 2015 in Milan, Italy. The agenda will be available soon on the EFSPI website and the event will be held in English.

PSI (UK)

PSI Training Course: Regulatory Interactions for Statisticians, 11th-12th February 2015, London. The course objective is to inform statisticians about the likely interactions they might have with regulatory agencies, both during a submission and at other times during drug development, and give advice on how to make these interactions most effective, Click here for further details.

PSI Careers Event 2015 The next PSI Careers event will be held on the 18th February at the University of Sheffield. The half-day event will include individual company stands, a series of themed presentations and a workshop designed to give students an insight into the role of a pharmaceutical statistician or statistical programmer. The event is open to MSc students, as well as final year BSc and PhD students, studying a statistics-related course. To register for the event, or for further information, please contact Vicky.Marriott@boehringer-ingelheim.com.

PSI Training Course: Cross-over trial in Clinical Research, 4th – 5th March 2015, Heathrow, London. The emphasis is on practical matters: how should one plan and analyse cross-over trials if one is genuinely interested in finding out the effects of treatment. The approach is grounded in practical pharmacological considerations and unrealistic approaches to adjusting for carry-over will be avoided. The examples are all genuine. Click here for further details.

PSI 2015 Conference: PSI invites you to join us at the 2015 PSI Conference "Relevant **Applications in a Changing Environment" at The Millennium Gloucester** Hotel, London between 10 to 13 May 2015. The latest draft of the PSI Conference Session Plan is available to view on the PSI website here *http://psiweb.org/docs/default-source/default-document-library/copy-of-session-plan_15jan2015.xlsx?sfvrsn=0*. Please be aware the early bird deadline is fast approaching on **16th February** and places are filling up fast so don't forget to secure your place soon. Need some more encouragement? Then take a look at our short promotional video to hear why some familiar faces will attend: *http://psiweb.org/members/news/news-item/2015/01/20/psi-conference-video*. We're still accepting abstracts for our contributed sessions so please continue to submit them to PSI2015conference@mci-group.com. The deadline for abstracts is **2nd March**. We welcome abstracts on any subject but would be particularly interested in the following: Data transparency case studies, Modelling and simulation, Challenges and issues in early clinical development, and Presentations from career young statisticians. If you are a career young statistician (less than 5 years working in the pharmaceutical industry) then there will be a dedicated contributed session for you. This is a great opportunity to gain experience in presenting in a friendly environment and to network with peers at other companies.

Austrian–Japan joint Statistics Workshop

This joint meeting on "Innovative Clinical Trial Designs for Accelerating Medical Product Development" will take place on March 20-27 2015 in Osaka, Japan. Keynote Speakers include Frank Bretz (Novartis Pharma AG, Switzerland) and James Hung (FDA, US). Pre-conference short course on sub group analysis (Alex Dmitrienko), adaptive designs & multiple testing (Peter Bauer, Franz König, Florian Klinglmüller, Martin Posch), and challenges of clinical trials (James Hung). For more details and registration please visit: http://statistics.msi.meduniwien.ac.at/hp/jsps2015/

DIA/FDA

DIA/FDA statistics forum, Apr 20 - Apr 22 2015, Bethesda, US. Featured topics include

Biosimilars/Analytical Similarity Adaptive Design, Bayesian Working Group Feedback, Sentinel Initiative and Postmarketing Surveillance, Statistical Issues Related to Health Technology Assessment, Subgroup Analysis, Benefit-Risk, Estimands and Sensitivity Analyses, and FDA and Industry Town Hall. For more information click here.

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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ASA Podcasts

A podcast series sponsored by Biopharmaceutical Section of American Statistical Association (ASA) is available where key opinion leaders from pharmaceutical industry and regulatory agencies talk about upcoming statistical conferences and events, and discuss current issues in Biopharmaceutical statistics. Click here to view the podcast from Chrissie Fletcher discussing EFSPI and access the full series of podcasts.

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The World of Statistics

The World of Statistics movement has grown to a total of more than 2,361 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.

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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.

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