European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter August 2016

In this newsletter:

Regulatory

The **1st EFSPI Regulatory Statistics Workshop** will take place on ***September 12th and 13th*** in **Basel, Switzerland**. The workshop will be dedicated to opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. Key themes chosen for this workshop include: estimands, extrapolation, risk benefit assessments, and statistics in quality and quality attributes. There will also be a session allowing individuals from the audience to present on short topics followed by a panel discussion. Click here to view the agenda, and click here to register. Already more than **100 attendees** will participate.

The EMA have issued the **Draft guideline on evaluation of anticancer medicinal products in man.** Tony Sabin (Antony.Sabin@astrazeneca.com) is collating comments on this document. If you would like to provide comments on behalf of your organisation please contact Tony. Comments are due by September 7.

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 multiregional 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.

The EFSPI/PSI regulatory committee will meet with EMA's Biostatistics Working Party (BSWP) end of September and with MHRA statisticians in November. A range of topics to discuss with the BSWP

has been agreed. If you have questions for the MHRA statisticians please contact Anna Berglind (Anna.Berglind@astrazeneca.com) or Christoph Gerlinger (christoph.gerlinger@bayer.com).

EFSPI has been asked by EMA to help implementing a set of ISO standards relating to **S**ubstances, **P**roducts, **O**rganisations and **R**eferentials (SPOR) in support of regulatory activities. Please refer to EMA's ISO IDMP web page for more information: click here. If you have any questions please contact Christoph.gerlinger@bayer.com.

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Scientific

Together with the Special Interest Group on Modelling & Simulation, EFSPI is organising a **Webinar on Best Practice in Modelling and Simulation** on **Tuesday October 4th 15:00-16:30 CET**. This webinar will cover recent proposed Best Practice for M&S. Speakers will discuss how M&S can be integrated into the drug development process from discovery to post-marketing, and how M&S practitioners can keep to the appropriate best practice, when applications and impact of M&S vary so much. Speakers include Michael O'Kelly, Chris Jennison, Alun Bedding, Scott Marshall and Tom Parke. These presentations are based on the presentations given at the PSI conference in Berlin in May 2016 and also include new material. More details will follow in subsequent communications.

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.

Please note that all presentation and a summary of the **Biomarkers and Subgroups meeting** held on the 24th June in Leiden, the Netherlands are available on the EFSPI website.

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2016 EFSPI Statistics Leaders Meeting

This year thirty-four people from 8 different countries representing 29 different pharmaceutical companies and CROs attended the 2016 EFSPI Statistical Leaders Meeting. A record number of participants and companies attended the meeting. This was the 7th meeting in a row, this year held in Paris on July 5, kindly hosted by Sanofi.

The purpose of the EFSPI Statistics Leaders meeting is to bring together leaders and managers in statistics groups from the EU pharmaceutical industry to network and discuss strategies to help EFSPI set its strategic objectives for the future. On this year's agenda topics were: role of statisticians in regulatory and public interactions, role of statistics and statisticians in precision medicine and biomarkers, update from the Small Populations SIG, update from the Modelling & Simulation SIG highlighting their Best Practices handbook, and the new AIMS (Application and

Implementation of Methodologies in Statistics) SIG who presented their charter and goals. In the afternoon an interactive workshop was held to discuss the present and future of R&D in drug development and how statistical departments and statisticians may evolve relative to skills sets, expertise, roles and responsibilities.

The key messages and notes from the meeting will be discussed at the next EFSPI Council meeting in mid-September. A summary of actions and outcomes from the meeting will be available in the next EFSPI Newsletter, and all the materials from the meeting will then be posted on the EFSPI website.

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Other Events

AFP (Germany)

APF is organizing a Workshop hosted by Parexel International in Berlin, 25th November 2016 about **Estimands and Prediction of Disease Progression**. The next APF Statistics Leader Meeting will take place 28th of October at Parexel International in Berlin.

FMS (Sweden)

Joint DSBS/FMS Meeting - Every second year the Swedish and Danish societies for biopharmaceutical/medical statistics, FMS and DSBS, arrange a joint meeting and this year's meeting will take place in **Malmö, November 1st 2016**. The theme of the meeting will be ***Statistical analysis of risks and safety data*** and the program will consist of invited speaker sessions and contributing speaker sessions. The planning of the meeting is currently in progress and two examples of topics covered are extreme value modelling of safety data from clinical trials and survival analysis methods in the assessment of safety data.

PSI (UK)

Joint PSI / BBS One Day Meeting: Time-to-Event and Recurrent Event Endpoints - This exciting one-day workshop held in Basel, Switzerland on September 14th 2016 jointly with the Basel Biometric Section (BBS) will cover a wide range of statistical aspects relating to event-driven trials. We have assembled a group of very knowledgeable speakers who will share their thoughts, ideas and experiences. This will include case studies on a range of particular issues relating to planning, conduct and analysis of survival and recurrent event trials. The first half of the day will be dedicated to time-to-event endpoints with the afternoon focusing on recurrent event endpoints. Each session will be concluded with a discussion by Prof. Dr. Armin Koch (EMA & Hannover Medical School, Germany). For further details and registration please follow the link: http://psiweb.org/events/psi-events/2016/09/14/default-calendar/time-to-event-and-recurrent-event-endpoints

Sample Size Re-estimation - dealing with those known unknowns! 02 Nov 2016, Royal Statistical Society, Errol Street, London. Determining the appropriate sample size is an important part of good clinical trial design. When there is uncertainty about some of the design parameters (e.g. variability, control rate, model parameters), it can be challenging to determine up front the number of subjects required for robust evaluation of the study objectives. The aim of this PSI one day meeting is to present an overview of available methods for sample size re-estimation together with several case studies where such methods have been used in late phase clinical trials. There will be plenty of opportunity for discussion and interaction with other statisticians working in this area. 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! In 2017 we are offering a 10% discount on the full 3 day conference rate for anyone selected for a contributed presentation. We welcome abstracts on any statistical topics and have a full list online of those areas of particular interest. For full details on how to submit an abstract please visit the PSI 2017 conference website. Please note the oral presentation deadline is 18th November 2016 and the poster abstract deadline is 27th February 2017.

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Job Opportunities

Opportunities exist for 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 2,352 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.

This year's **International Conference of the Royal Statistical Society** has attracted a record number of submissions for talks and posters. The Conference, which takes place at the University of

Manchester September from 5-8, 2016, will feature keynote talks from Christl Donnelly of Imperial College London, Anne Glover, former chief scientific adviser to the president of the European Commission, Xiao-Li Meng of Harvard University, and Noel Cressie of the University of Wollongong, Australia. In addition, the three-day program includes nearly 40 invited sessions across 12 topics streams plus 11 professional development workshops and more than 100 poster presentations.

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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 Cross Validated)

"Conducting data analysis is like drinking a fine wine. It is important to swirl and sniff the wine, to unpack the complex bouquet and to appreciate the experience. Gulping the wine doesn't work."

— Daniel B. Wright

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Chrissie Fletcher
EFSPI Communications Officer