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

EFSPI Newsletter October 2017

In this newsletter:

Regulatory – ICH E9 addendum, regulatory statistics workshop
Scientific – Oncology and Survival meeting, HTA meeting
Special Interest Groups – Data Transparency
Country news - PSI (UK)
Job opportunities
The World of Statistics – European Statistics Day
Other news – update on COMET
Follow us on Twitter and LinkedIn
And finally…..

Regulatory

*****Reminder*** The ICH E9 draft addendum [ICH E9(R1)] has been released for public consultation, click here to access the draft addendum.** Comments are due by the 28th February 2018. Alan Phillips along with colleagues from the regulatory committee will consolidate comments. Please send comments on the draft addendum using the comments template on the EMA website (see link above) to Alan Phillips (Alan.Phillips@iconplc.com) by the **30th November 2017**. Statisticians are encouraged to distribute the draft addendum to cross-functional stakeholders, in particular clinicians, and to collate comments within their companies/institutions prior to submitting them to Alan. In addition, a workshop to discuss the addendum is being planned by the regulatory committee to take place on the **16th January 2018**. Clinicians and statisticians who attended the previous workshop a year ago will regroup to discuss the comments submitted.

The second **EFSPI regulatory statistics workshop** took place on the **5th-6th October 2017** in Basal, Switzerland. Approximately 200 industry, regulatory, and academics registered for the workshop, including clinicians who attended the first day and the session on estimands. The topics discussed included the draft FDA guideline on multiple endpoints, estimands with case study presentations, role of early development in regulatory approval, predictive biomarkers for therapeutic decision making and disease specific drug development issues. Materials from the workshop can be found here.

Reminder: The EMA published the **Draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development** providing current regulatory considerations regarding statistical aspects for the comparative assessment of quality attributes in the settings of pre- and post-manufacturing change, biosimilar development as well as generics

development. **Bruno Boulanger (Bruno.Boulanger@arlenda.com)** is collating comments on behalf of EFSPI, so please send any comments you have on the reflection paper to Bruno by **15th January 2018.**

back to top

Scientific

A 1-day meeting on **Oncology and Survival Analyses** will take place on **Friday 17th of November** at BMS in Brussels. Survival analysis methods, or 'Time to event' methods originally developed to analyse trial endpoints in oncology are now used in many other indications. At this meeting, you will hear about recent advances in survival analysis methods. Click here to register for the meeting.

A 1-day EFSPI/PSI **HTA scientific meeting** will take place on **Tuesday 28th November** hosted by **MSD** in **London, UK**. The meeting will provide an update on latest trends in HTA, including: the Real-World Evidence Navigator tool created by the IMI GetReal project; the EUnetHTA Joint Action 3 initiative and methodology being researched; introduction to value-based frameworks and estimands in HTA. Patient perspectives in HTA will be discussed including how to involve patients in HTA. HTA related methodological considerations will be highlighted including approaches to handle treatment switching in HTA. Industry HTA case studies will also be presented. Click here to register for the meeting.

back to top

Special Interest Groups

Call for Volunteers – EFSPI Data Transparency SIG

Are you working in the data transparency, data anonymization, or data de-identification area?
Are you involved in preparing clinical documents to be submitted within EMA Policy 70?
Yes? - the Data Transparency SIG are looking for additional volunteers.

The Data Transparency Special Interest Group is a group of cross-pharma and academia statisticians, and others in related fields, working together on topics addressing the challenges and opportunities of patient level data sharing. As the data transparency environment continues to evolve and with the move to quantification of risk of re-identification, there is a need for statisticians (both from industry and academia) to have an awareness and understanding of these issues and techniques. A current area of focus is practicalities in the delivery of redacted clinical trial documents and their associated risk quantification via EMA Policy 70.

Outputs from this SIG will be used to inform, educate and pass on learnings within EFSPI, its affiliations and beyond.

Interested in finding out more? Please contact Rebecca Sudlow (Rebecca.sudlow@roche.com)

back to top

Country News

PSI (UK)

Do you have colleagues who look baffled when you talk about statistics? Statistics Fundamentals for Clinical Trials for Non-Statisticians (or 'How to speak stats in a day!'), **14th November, 2017, Reading, UK**. Presented by Gemma Hodgson this is a 1-day course, aimed to introduce statistics to people who work on Clinical Trials, but who are not Statisticians. No previous knowledge of Statistics is assumed as we start right at the beginning with the basics. For more information on the agenda and how to register please click here.

One-day meeting: Use of Extrapolation methods 22nd November, 2017, GSK, Stevenage, UK. Use of extrapolation techniques is playing an increasingly important role in the development of new medicines particularly with regard to special populations such as paediatrics and rare diseases. This meeting will include speakers from industry, academia and regulatory (including Rob Hemmings from MHRA). Please look out for an eNews update on this meeting in the autumn with full speaker details.

Abstract Submission OPEN for the PSI Conference 2018 Submissions are still being accepted for any of your contributed oral or poster abstracts. We accept abstracts on any topic, but have provided a list of topics we are particularly interested in including; Machine Learning, Pre-clinical, Real World Data, Safety Data, Genomics, Bayesian and many more. Click here to see the full list and download the abstract template! The deadline for oral abstract submissions is **24th November 2017.** Remember, anyone selected for an Oral presentation will be eligible for **10% off the 3-day conference price.**

PSI Pre-Conference Course: Demystifying Causal Inference - Assessing efficacy when patients depart from randomised treatments 3rd June, 2018 Presented by: Prof. Ian White & Prof. Sabine Landau Randomised trials provide a gold standard design for assessing the effectiveness of an intervention or treatment, based on an intention to treat analysis. However, this suffices only to answer a narrow question about the effectiveness of offering the intervention, based on comparing the average outcome between randomised groups. This course aims to introduce participants to the concepts of causal inference in randomised trials and the statistical methods used to answer various causal questions. It will focus on worked examples from different clinical areas, modelling issues and the key assumptions, and how these methods can be implemented in standard statistical software. More information will follow on the PSI website and registration will open soon!

PSI Training Course on Missing Data 6th - 7th March 2018, Crowne Plaza Hotel, Heathrow, UK Presented by: Michael O'Kelly. This course will provide participants with an understanding of missing data, its link with what is to be estimated in a study (the "estimand"), and statistical modelling approaches. The 2 day course includes workshops: participants will undertake a number of practical exercises on missing data in SAS. In addition, participants will have the opportunity to gain insight into some of the more useful new methodologies for missing data, with a view to being at the service of the real scientific question of interest. Multiple imputation (MI) will be emphasised - due to this method's flexibility. Click here to register.

PSI Toxicology Special Interest Group The Toxicology SIG is a small group of statisticians who mainly work, or have an interest in, toxicology data. We also expand our discussions to include nearly all areas of pre-clinical development, including Safety Assessment, Safety Pharmacology, Genetic Toxicology, Carcinogenicity, use of historical control data and general assay supporting, including

Anti-Drug Antibody assays. We are in the process of putting together a regular series of Webinars on such topics, and organising our next workshop for **April 2018** following the success of our last workshop in March 2017. If you work in these areas, or know someone who is, please get in touch so that we can share our thoughts with you. We welcome anyone across the globe to get involved in our work. For more information and to be added to our email distribution list, please contact gareth.thomas@envigo.com.

back to top

Job Opportunities

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.

back to top

The World of Statistics

The World of Statistics is comprised of 2, 197 organisations 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.

European Statistics Day was commemorated on October 20, and this year's theme was "The Value of Official Statistics as a Public Good." European Statistics Day is commemorated annually in the four years between each World Statistics Day. It aims to raise awareness of European citizens to the importance of official statistics. In particular, European Statistics Day provides an opportunity for European statisticians to interact with all users of official statistics and to engage with the wider public on statistical issues. The 20th of October was designated the World Statistics Day by the United Nations General Assembly in 2010 and is celebrated worldwide every 5 years.

Eurostat has published a new digital publication titled "The Life of Women and Men in Europe - a Statistical Portrait." This digital publication, which contains texts, graphs, dynamic data visualizations and illustrations, aims at comparing women and men in their daily lives. It also shows how similar or different the everyday life of women and men is in European countries and is available in 24

languages.

back to top

Other News

Update on COMET

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area. **The COMET Handbook Version 1.0** is available here. COMET has had interactions with EMA, EFPIA, NICE, HTAi and many other organisations around COS and many use the COMET database. Click here for more information about the COMET initiative.

back to top

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back to top

And finally.....

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back to top

Chrissie Fletcher
EFSPI Communications Officer