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

EFSPI Newsletter November 2018

In this newsletter:

Regulatory

Please send your comments on EMA's draft Questions and answers on Data Monitoring Committees issues to Anna Berglind (Anna.Berglind@astrazeneca.com) by 28 February 2019.

back to top

Scientific

Decision making in Clinical Development, December 12

On Wednesday December 12 the scientific meeting on 'Decision making in Clinical Development' will take place at Servier in Paris. Taking decisions during the development of a new drug requires combining many and varying pieces of information. Decision-makers need quantitative tools to support informed decisions, with transparent processes that synthesize the whole available information in order to evaluate the success associated to different options. More information can be found on the flyer, click here to register.

2019

The Scientific Committee is planning for three 1-day scientific meetings for 2018. The first one day

meeting will be on “Recent developments in biomarkers and subgroups in drug development”, which will take place in March hosted by Astra Zenaca in Göteborg, Sweden. The most likely date will be March 20, but formal confirmation will follow soon. In addition, we are starting with planning two additional 1-day events, one before summer, one after. More information will follow.

back to top

EFSPI SIG – new Oncology Estimand SIG

Earlier this year, Evgeny Degtyarev (Novartis, evgeny.degtyarev@novartis.com) and Kaspar Rufibach (Roche, kaspar.rufibach@roche.com) have initiated a working group that works on embedding oncology endpoints into the estimand framework. As of now, the working group has 30 members (13 from Europe and 17 from US) representing 18 companies and it has now been established as an EFSPI SIG.

The scope of this newly-established EFSPI SIG is to provide answers to the following questions:
- How can T2E endpoints be embedded in the addendum framework, and what are key estimands in Oncology?
- How do the 5 strategies to handle intercurrent events proposed in the addendum apply to T2E endpoints?
- How can established methods to analyse questions in oncology, e.g. treatment switching or various censoring schemes, be embedded in the addendum framework?
- The addendum in its current version does not require a causal interpretation of a proposed estimand. However, are there parts in the drug development lifecycle that require a causal interpretation of an estimand? Being aware that the hazard ratio from Cox regression does not admit a causal interpretation, what are effect measures for T2E endpoints that are amenable to such a causal interpretation?

The scope of this SIG is to provide answers to the above questions. To this end, five sub teams have been formed (treatment switching, censoring, causal methods, haematology case studies, and solid tumour case studies) and a variety of activities are ongoing and planned, such as:
- Collaborating with experts to refine and possibly extend available methods.
- Publishing reviews of the available methods, case studies, and white papers with recommendations, for statisticians and non-statisticians.
- Interacting with regulators and the broader clinical community to obtain a better understanding of their requirements. Work with them to agree on common definitions of estimands in oncology.
- Providing trainings, workshops and talks.
- Promoting good practice through templates for study protocols and statistical analysis plans.

If your company is not represented yet in the SIG and you would like to contribute please reach out to Evgeny or Kaspar.

back to top

Country News

APF (Germany)

On November 22nd APF held the German Statistics Leaders Meeting at Parexel Berlin. Topics included

randomization implementation, fostering statistical innovation, and local reimbursement topics. On November 23rd APF held its annual fall workshop at Parexel Berlin on the topic of Visualization with some 100 participants. Frank Langer, Christoph Gerlinger, and Hans-Jürgen Lomp were re-elected as the APF leadership team. The fall workshop 2019 will be held on Friday November 29th at AbbVie in Ludwigshafen.

IBIG (Italy)

IBIG Forum 22-23 November in Padua was a big success with a well-balanced mix of people from the industry and academia. International speaker was Prof. Tianchen Qian from the University of Harvard who presented the innovative Micro-Randomized Trials applied to mobile Health.

In May 2019 IBIG will launch the Italian Bayesian Day that will take place in Turin. Collaboration between IBIG and University of Padua for the Advanced Master in Biostatistics was confirmed also for 2019.

PSI (UK)

FEATURED VIDEO: PSI Conference 2018: Preference elicitation strategies in drug development

Achieving reimbursement has become increasingly challenging due to resource limitations and the emergence of novel, often costly, medicines. At the same time, policy makers have encouraged patient involvement in clinical decision making. Embedding preference elicitation activities within drug development is becoming increasingly important for pharmaceutical companies to ensure that the right medicines are progressed, and that the value of these new medicines are better represented. This talk presents the rationale and strategies for including preference elicitation activities within drug development and will present case studies where drug development questions have been addressed using preference elicitation methods.

The Effective Statistician - Finish this year strong! Leadership and year-end review meetings

In last week's episode, Gary Sullivan – a statistician and leadership expert – speaks about what leadership is, why technical statisticians should worry about it and when it's time to improve it.

Listen to the episode here:
- Why should statisticians care about leadership and developing their leadership skills? Interview with Gary Sullivan

In many organizations, one of the last activities of the year is to check how you performed this year against your goals. In this week's episode, we give you practical tips on how to prepare successfully for these discussions with your supervisor.

Listen now and wow your supervisor during your performance review:

- How to prepare for your year end review to stand out!

You can listen to the podcast on the homepage but also on your "podcast" app on your iPhone. If you own an android, you may use an app like Stitcher. Just search for "the effective statistician" in your app. Finally, you can also find it on Spotify.

PSI and DIA Journal Club: Statistical Considerations for Innovative Designs in Clinical Trials

Date: Tuesday 11th December 2018
Time: 16:00 - 17:30 UK Time

Our next journal club, held jointly with the DIA, features two papers on the topic of Statistical Considerations for Innovative Designs in Clinical Trials. Please join us to hear Jason Yuan and Xiangmin Zhang present their recent work:

DISCUSSANTS: Dr. Jim Hung (FDA) and Peter Zhang *(Otsuka)*
SPEAKER: Jason Yuan *(Allergan)*
Clinical Study Design to Assess Both Short- and Long-term Efficacy in Addition to Group Sequential Test on Safety. Therapeutic Innovation & Regulatory Science 2018, Vol. 52(6) 690-695

SPEAKER: Xiangmin Zhang *(FDA)*
The plan of enrichment designs for dealing with high placebo response. Pharmaceutical Statistics, Volume 17, Issue1, January/February 2018 Pages 25-37

Please click here for further information regarding the webinar. Click here to register.

PSI Webinar: How to use prior knowledge and still give new data a chance?

Date: Wednesday 19th December 2018
Time: 15:00 – 17:00 (UK time)
Presenters: Rob Hemmings *(MHRA)*, Armin Koch *(Institute for Biostatistics, Hannover Medical School)*, Kristina Weber *(Institute for Biostatistics, Hannover Medical School)*
Discussants: Nicky Best *(GSK) (on behalf of the EFSPI/PSI Historical Data SIG)*, Lisa LaVange *(University of North Carolina, Chapel Hill)*
Chair: Byron Jones *(Novartis)*

The paper to be presented and discussed appeared earlier this year in Pharmaceutical Statistics (Weber, Hemmings, Koch, 17, 329-341) and is motivated by the opportunities and challenges for using Bayesian methods with informative priors to support drug development and licencing when only a small pool of patients is available, as in the case of rare diseases and paediatric population. With a small study population, meeting the expected level of evidence required for regulatory approval can be challenging. The specific focus of the paper is on the use of data-based priors in the decision-making process of paediatric extrapolation, and results are presented comparing different frequentist and Bayesian meta-analytic methods for combining adult and paediatric data. Click here to register.

PSI Webinar: HTA Submissions in the UK

Date: Monday 21st January 2019
Time: 10:00 – 12:00 (UK time)
Presenters: Jessica Purchase, Group Health Economics Manager *(F. Hoffmann-La Roche Ltd, Welwyn)* and Monica Daigl, HTA Statistician and Health Economist *(F. Hoffmann-La Roche Ltd, Basel)*

This webinar focuses on the National Reimbursement side: the National Institute for Health and Care Excellence (NICE) - who they are, what is involved in the Health Technology Appraisal (HTA) assessment, how they make decisions. We'll also review where the devolved nations come in: how do the Scottish Medicines Consortium (SMC) and All Wales Medicines Strategy Group (AWMSG) differ from NICE in decision making? Finally, through the use of a real world example, we'll explore the key drivers and barriers experienced in decision making: specifically, the challenges associated with correct comparators and predicting of long term outcomes.

This will lead to the second part of the webinar. We will focus on two advanced statistical techniques to inform health economic models: modelling of time to event endpoints such as progression free and overall survival beyond the duration of a clinical study to predict long-term outcomes; and network meta analyses to estimate the value of a drug in the absence of direct comparative evidence. Finally, we provide our key recommendations for the future of clinical trial design, to support access for the UK market. Click here to register.

Toxicology Special Interest Group Free Webinars

The Toxicology Special Interest Group holds quarterly free webinars. Our upcoming webinars are on the following topics:

Tuesday 11th December 2018 - Thomas Steger-Hartmann on Big Data

Tuesday 19th February 2019 - Professor Malcolm Macleod on Data Quality and Pre-Clinical Research

Tuesday 16th April 2019 - TBC

Tuesday 18th June 2019 - TBC

All take place at 14:00 UK time. Full details will be released closer to each webinar, or contact Gareth Thomas (gareth.thomas@envigo.com) to be kept up to date on all ToxSIG activities.

One-Day Event: New Emerging Topics around Estimands and ICH Addendum

Tuesday 29th January 2019, IQVIA, Reading, UK

The draft ICH E9 addendum on estimands and sensitivity analysis was released back in July 2017 and (more than 1000) comments are back. All stakeholders are gaining the necessary experience and familiarity with estimands along with the associated challenges and methodologies. The language and thinking behind causal inference is well suited to this area.

The PSI Scientific Committee have put together this one-day meeting to share and discuss new emerging topics around estimands and the ICH addendum. The aims of the event are to:

- Share the feedback from the public consultation on the draft ICH E9 addendum
- Explore the estimand concept within health technology assessments
- Describe how casual inference fits into the area of estimands
- Present case studies illustrating the implementation of the estimand framework and the use of causal inference methodology

Click here to register.

back to top

Job Opportunities

Opportunities exist for **Biostatistician Project Leaders – Early Phases, and Medical Affairs**, and for Principal and Senior Statisticians, and Principal and Senior Modelling and Simulation Statisticians.

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, 360 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.

back to top

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back to top

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back to top

Chrissie Fletcher
EFSPI Communications Officer