



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

EFSPI Newsletter December 2018



Merry Christmas and thanks to everyone who has supported EFSPI in 2018

In this newsletter:

Regulatory – draft regulatory guideline under review

Scientific – decision making in clinical development, 2019 meetings

EFSPI Special Interest Group – 1-day HTA SIG meeting, process for setting up a new SIG

Country news – IBIG (Italy), PSI (UK)

Job opportunities – Biostatistician Project Leaders in Early Phases and Medical Affairs, Principal and Senior Statisticians, Principal and Senior Modelling and Simulation Statisticians

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Regulatory

The FDA have released a draft guidance on ***Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products***. Please send comments to Anna Berglind (Anna.Berglind@astrazeneca.com) by the 18th January 2019.

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.

The FDA released a draft guidance on [Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements](#). The deadline for comments was the end of December.

[back to top](#)

Scientific

Decision making in Clinical Development, December 12

On December 12 EFSPi held a scientific meeting on [Decision making in drug development](#) at Servier in Suresnes, near Paris. This event was co-organized with the Special Interest Group on Decision Making. With almost 60 attendees, a poster session, and high-quality presentations, it was a very successful event. Slides of the presentations will be made available on the EFSPi [website](#).

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 Zeneca 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 SIGs

HTA 1-day Meeting

*A 1-day HTA meeting will take place on **Friday 15th February 2019** hosted by **MSD in Berlin, Germany**.* This 1-day scientific meeting organised by the EFSPi/PSI HTA SIG will provide an update on latest trends in HTA in Europe. HTA research methods will provide insights on topics such as meta-analyses and evidence synthesis with few studies, estimands in oncology, analysing adverse events with varying follow-up times, handling missing data in real world data, and subgroup analyses. Industry HTA case studies will also be presented. To view the flyer click [here](#) and to register for this event visit the [EFSPi website](#).

Setting up a new SIG

Special Interest Groups are important to EFSPi as they allow a dedicated group of experts and individuals to collaborate and discuss across a range of stakeholders and organisations a specific area or key topic of interest. If anyone is interested in setting up a new SIG, please click [here](#) to see a summary of the existing SIGs and to access slides describing how to set up a new SIG.

For further information on existing SIGs please contact Anne Danniau

(Anne.Danniau@grunenthal.com) or Maylis Coste (maylis.coste@servier.com) who oversee the SIGs for EFSPi.

[back to top](#)

Country News

IBIG (Italy)

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)

2019 PSI CONFERENCE: 2 - 5 June, London Data Driven Decision Making in Medical Research

For those of you who are interested in attending, but may be challenged by your manager why you should attend the PSI conference, have a look at this article on "[10 reasons for your supervisor to approve your attendance at the PSI conference 2018](#)" and consider bolstering up your arguments with the submission of a poster to show that you'll be an active contributor to the conference. You can download the abstract template [here](#), up to the 28th February 2019.

Act now and [click here to register](#) to receive the early bird fee, up to the 20th March 2019!



Visit the Video-on-Demand Platform here!



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 - The past, presence and future of estimands! Interview with Chrissie Fletcher and Mouna Akacha

If you ask someone within the pharma world of statisticians on what is the hottest topic, you most likely will just get: Estimands! Many scientific events, conference sessions, publications and presentations are organized around this topic. Thus, I'm super happy, that we have Mouna and

Chrissie on the podcast as they have presented about this topic at various occasions. In this episode, you will learn about

- the importance of the concept itself and its implications
- the terminology of the estimand framework
- and how it relates to missing data terminology

The episode covers the following questions and gives some examples on the different parts of the framework:

- What is the history of the estimands and how is it related to missing data?
- What is ICH E9 and why does it need an update now?
- What are the different parts of an estimand and how do they relate to each other?
- Is the estimand framework only applicable to clinical trials in the regulatory setting or is this something to be considered beyond the regulatory approval of new medications?

Listen to the episode here: <https://theeffectivestatistician.com/the-past-presence-and-future-of-estimands-interview-with-chrissie-fletcher-and-mouna-akacha/>

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.

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.

Toxicology Special Interest Group Free Webinars

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

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.

[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](#)

And finally.....

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[back to top](#)

Chrissie Fletcher
EFSPi Communications Officer

