



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

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## EFSPI Newsletter August 2018

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**Regulatory**

The 3<sup>rd</sup> EFSPi Regulatory Statistics Workshop will take place on the **24/25th September 2018 in Basel, Switzerland**. The agenda includes sessions on estimands and case studies, complex data types and designs in confirmatory trials, basket/umbrella trials, use of clinical practice data to support confirmatory trials, phase I dose escalation trials and contributed short topics. The program flyer can be found [here](#) on the EFSPi website.

The EMA issued a **draft Questions and answers on Data Monitoring Committees issues** ([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2018/08/WC500252790.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/08/WC500252790.pdf)). Please contact Christoph Gerlinger ([christoph.gerlinger@bayer.com](mailto:christoph.gerlinger@bayer.com)) or Anna Berglind ([anna.berglind@astrazeneca.com](mailto:anna.berglind@astrazeneca.com)) if you wish to comment.

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## **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](#), which is available on the EFSPi website, and registration is open, click [here](#).

### **New - Poster Session – Call for abstracts!**

For the first time, we will have a poster session at a 1-day scientific meeting. If you wish to present a poster relating to decision making in clinical development, please send an abstract to Gaëlle Saint-Hilary ([gsainthilary@gmail.com](mailto:gsainthilary@gmail.com)) by October 31<sup>st</sup> 2018. The notification of acceptance will be provided by November 9<sup>th</sup> 2018.

Other events of interest:

**IDEAS Dissemination Workshop** Wednesday 26th September 2018, Novartis, Basel, Switzerland. The aim of the workshop is to translate and promote novel methodologies developed by IDEAS and is geared towards statisticians and trialists with an interest in novel methods for early phase clinical trials. Therefore, it will be of interest to those working in academia, industry, HTA or regulatory authorities. [Click here](#) for further information and to register.

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## **Country News**

### **APF (Germany)**

Registration for the annual fall meeting 23. November 2018 in Berlin on Visualization is now open ([http://www.biometrische-gesellschaft.de/fileadmin/AG\\_Daten/PharmazeutischeForschung/PDFs/Agenda\\_APF\\_72\\_Berlin\\_Nov\\_2018\\_Agenda\\_Anfahrt\\_Anmeldung\\_.pdf](http://www.biometrische-gesellschaft.de/fileadmin/AG_Daten/PharmazeutischeForschung/PDFs/Agenda_APF_72_Berlin_Nov_2018_Agenda_Anfahrt_Anmeldung_.pdf)).

### **BIAS/IBIG (Italy)**

An Italian Biostatistics Group (IBIG) Forum will be organized in Padova on 22-23 November including the following topics: Bayesian Statistics in Clinical Trials, Micro-Randomized Trials and Expedited Approval Programs. The forum will take place at the NH Hotel in Padova, Italy. For more details click [here](#).

In addition, IBIG will be a partner of the 4<sup>th</sup> edition of the Master in Advanced Biostatistics for Clinical Research organized by the University of Padova.

## **PSI (UK)**



### **VIDEO OF THE MONTH: PSI Webinar: HTA submissions in Germany, what do statisticians need to know to be successful with their GBA dossiers - Part One**



The so called early benefit assessment in Germany was introduced in 2011 as basis for price negotiations of the institutional sick funds and the pharmaceutical company. Since then, all new drug substances are to be assessed at the Federal Joint Committee (G-BA, Gemeinsamer Bundesausschuss) by indication. A new indication always requires a new procedure. In a first step, the additional benefit over a comparator has to be shown based on the rules of evidence based medicine and the available clinical data. The marketing authorization holder has to submit a benefit dossier with all available clinical data for the drug substance in the indication. A template for the dossier is provided by G-BA and defines how the data is to be shown. This template has statistical implications with regards to the presentation of the clinical data including subgroup analyses, surrogate endpoints, direct and indirect comparisons, meta-analyses and others. Carsten Schwenke - being the most experienced statistician for HTA submissions in Germany - presents this webinar series.

### **Video-on-Demand - Conference Sessions now available online!**

Visit the PSI [video-on-demand](#) page to access videos from this year's conference. Including Stephen Ruberg's keynote speech on Statistics and Data Science and the Regulatory Town Hall. View a recent episode: [Vacation episode 2018 - some thoughts about why we do what we do!](#). If you missed the PSI conference, please check out the following episode: [Best of PSI 2018 - my personal view](#). Search for The Effective Statistician in your podcast app and subscribe now!

### **Only a few spaces left! PSI One Day Meeting - Interactive Workshop about Real World Evidence: Generalisability of Treatment Comparisons for Decision Making**

Tuesday 18th September 2018, Lilly Germany, Werner-Reimers-Straße 2-4, 61352 Bad Homburg, Germany. RWE data are an increasingly valuable resource in drug development. One area where this data is being used regularly is in the generalisability of treatment comparisons. In a very interactive way this event will focus on:

- New advances in indirect comparisons
- Generalisability approaches for clinical trial data into the real world setting

- Cross-design approaches combining observational and randomized data

This event is for you if you need to know about indirect comparison for HTA submission or need to know how your clinical trial data would look like in a real world setting. Speakers come from leading universities (e.g. Bristol), HTA bodies (e.g. IQWiG) as well as pharma companies. [Click here](#) for more details and to register.

**Do you have colleagues who look baffled when you talk about statistics?** Thursday 20th September 2018, Premier Inn Reading Central, Reading, UK. **Presenter:** 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. [Click here](#) for more details and to register.

**PSI Training - Regulatory Interactions for Statisticians** 26th - 27th September 2018, Crowne Plaza Heathrow. The objective of this course 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. The focus will be on clinical development. The course will be presented by experienced statisticians from the MHRA, FDA and those with expansive pharmaceutical company employment and representatives from a company regulatory affairs department including Daphne Lin (FDA), Yolanda Barbachano (MHRA), Khadija Rantell (MHRA), Natasha Jarrett, Steve Slater, and Andy Stone. [Click here](#) for more details and to register.

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## **Council of Biopharmaceutical Statistics (CBS)**

The **Council of Biopharmaceutical Statistics (CBS)**, created in 2015, promotes communication and harmonization across leading professional statistical organisations. CBS increases collaborations between organizations, improves the co-ordination of scientific working groups set up in multiple organisations, prioritises statistical issues, identifies opportunities for organizations to partner in education events and publications, and aims to maximise the use of resources available across the member organizations. Click [here](#) for more information about CBS.

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## **Job Opportunities**

Opportunities exist for **Head Global Statistics (based within the EU), Director Biostatistician Phase I, CHEF de PROJET BIOSTATISTICIEN(NE) Oncologie, BIOSTATISTICIEN(NE) expérimenté(e) Oncologie.**

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, 199 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.

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## **Follow us on Twitter and LinkedIn**

Get the latest news and updates about EFSPi by following us on Twitter at @EFSPiTweet. Also, when you use Twitter to spread the word about EFSPi, be sure to use the hashtag “#EFSPi”. You also can follow developments in EFSPi via LinkedIn.

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## **And finally.....**

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