



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

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## EFSPI Newsletter July 2018

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## **Regulatory**

The **ICH E9(R1) expert working group** met in Japan on the 4<sup>th</sup> to 7<sup>th</sup> June to discuss the 1000+ comments received from the public consultation on the draft ICH E9(R1) addendum. One of the consequences of the discussion is a 1-day workshop in London September 10 led by the EU members of the E9(R1) expert working group, sponsored by EFPIA/EFSPi. The two topics for the workshop are 1) *estimands in non-inferiority trials*, and 2) *estimands relating to safety objectives*. A mix of statisticians, clinicians and other interested stakeholders from Industry, Regulatory agencies, HTA agencies and academia are invited to contribute to the workshop.

The EFSPi/PSI regulatory committee is preparing for a face to face **meeting with the statisticians at the MHRA** in London in September. If you have any suggestions for topics to discuss at that meeting, or at the later meeting with the EMA Biostats working Party, please contact [Christoph Gerlinger](#) or [Anna Berglind](#).

The **expert group on subgroups** is planning a webinar sharing their initial findings sometime in the September - October timeframe. More details to come.

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.

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## **EFSPi Statistics Leaders Meeting**

On 12-July 2018, the 9th EFSPi Statistics Leaders meeting took place in Louvain-la-Neuve, Belgium. EFSPi leadership meetings are key for shaping the future strategy of the European Federation of Statisticians in the Pharmaceutical Industry. This year's meeting was an event with 30 participants from more than 20 companies. A strong community and network has emerged over time within the Statistical Leaders based in Europe. Agenda topics included updates from EFSPi, training, management of SIGs, Bayes statistics and an afternoon workshop on pragmatic trials and external controls.

On training, the EFSPi statistics leaders confirmed the need for more training and also recommended EFSPi take a leadership position. A new role assigned to oversee training will be discussed at the next EFSPi Council meeting. Key activities should include promotion of important training topics and a coordination with member organizations, including technical and soft skills training, and training for future leaders. On SIGs, the quantitative decision making SIG provided a summary of all their accomplishments since the SIG began in Q4 2017 (see SIG update below for more details). The commitment of all the SIG Chairs and all individuals participating in the SIGs was appreciated and commended by all the EFSPi Statistics Leaders. Within EFSPi the SIGs will now be managed by Maylis Coste (Servier) and Anne Danniau (Grunenthal). On Bayes statistics, EFSPi were recommended to provide a platform with regulatory statisticians to enable wide discussion across the EU Statistics community on the use of Bayesian approaches supporting drug development. In addition, non-statisticians will need training and EFSPi could help facilitate this. The afternoon workshop was a big success. Participants liked it both for its contents and its new Agile format which was a combination

of Story Mapping and World Café. We spent a few hours to create a shared understanding among the participants regarding open questions, challenges, risks, and potential EFSPi follow-up activities on pragmatic trials and external controls.

The slides of all presentations and a summary of the afternoon workshop will be shared with all participants and will also be uploaded on the EFSPi website soon. In 2019, for the 10th anniversary of the EFSPi Statistics Leaders Meeting will be hosted by Boehringer Ingelheim in Ingelheim, Germany.

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## **Special Interest Groups (SIGs)**

The SIGs oversight will henceforth be co-led by Anne Danniau, Grunenthal and Maylis Coste, Servier. They will succeed Stefan Driessen, Abbott and EFSPi thank Stefan for his oversight of the SIGs activities for many years. As many of the SIGs are joint SIGs with PS, the oversight of SIGs by EFSPi will be achieved in close collaboration with PSI.

SIGs leaders are informed that a session at the EFSPi Regulatory meeting planned in September, 23-24th, will be opened to SIGs leaders (or members) for a 5 minute presentation followed by a 10 minute debate with Statisticians from Regulatory agencies or Pharma on issues or positions resulting from the SIG activities. Proposals for this session (planned over 15.00-16.15 September, 25th) should be sent to Uli Burger ([hans\\_ulrich.burger@roche.com](mailto:hans_ulrich.burger@roche.com)) by early September.

EFSPi SIG Quantitative Decision-Making is a recent SIGs led by Gaelle Saint Hilary, Politecnico di Torino/Servier and Pierre Colin, Sanofi. Following the kick-off meeting in October 2017, the SIG team members started their activities by sharing case-studies on quantitative methods used within their companies to support decision-making. Several methodologies emerged from these sessions, in particular the computation of probabilities of success, decision-making frameworks for go/no-go decisions or interim analyses, prior elicitation, and more generally predictions and simulations. In May 2018, three working-groups were launched on decisions at the trial level, at the development level and at the portfolio level, with the short-term objective to prepare a survey to collect decision-makers' needs and preferences. In parallel, the SIG is organising jointly with the EFSPi Scientific Committee a 1-day EFSPi meeting on "decision-making in drug development" that will take place on December 12th in Servier, near Paris (Save the date! Flyer will come soon).

Updates from other active SIGs will be provided in future newsletters.

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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. The Scientific Committee together with the SIG on Decision Making are in full preparation mode. More information will follow.



### **Small Populations and level of evidence, June 27**

On Wednesday June 27 the joint EFSPi/BBS scientific meeting on 'Small populations and level of evidence' took place. A very well attended meeting with more than 100 delegates. The presentations of this meeting can be found at the EFSPi homepage under 'Past Events'

[https://www.efspi.org/EFSPI/Events/Archive\\_Items/Small\\_populations\\_and\\_level\\_of\\_evidence.aspx](https://www.efspi.org/EFSPI/Events/Archive_Items/Small_populations_and_level_of_evidence.aspx)

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)).

### **PSI (UK)**

**2018/19 Introduction to Industry Training Course** Next course starts Oct 2018. The 2018/19 course will include 3 sessions in continental Europe and 3 sessions in the UK. The course will aim to describe the drug development process, including sessions on drug discovery, toxicology, data management & role of the CRO, clinical trials, health technology assessment and marketing. Click [here](#) to read more.

**PSI One Day Meeting - Interactive Workshop about Real World Evidence: Generalisability of Treatment Comparisons for Decision Making** Tuesday 18th September 2018, Lilly 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, generalizability 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. **Early Bird registration deadline:** Friday 10th August 2018. [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, Andy Stone. **Early Bird Deadline: 15th August 2018**. [Click here](#) for more details and to register.

**Increase your business acumen and improve your soft skills! Listen now to podcast The Effective Statistician - in association with PSI** Upset about yet another traffic jam? Relax and listen to a podcast. Never miss an episode and subscribe today! We release new episodes each Tuesday. This time we cover:

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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.

CBS would like to highlight the following upcoming events:

**ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop 12-14<sup>th</sup> September 2018, Washington DC.** This workshop is sponsored by the ASA Biopharmaceutical Section in cooperation with the FDA Statistical Association. The conference lasts two days each year, with invited sessions co-chaired by statisticians from industry, academia, and FDA. In addition, short courses on related topics are offered the day prior to the workshop. Conference attendance is limited to 800 participants, so make sure to register early. Registration opens June 1. Click [here](#) for more information.

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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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