



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

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## EFSPI Newsletter April 2018

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## **Regulatory**

On the 13<sup>th</sup> April 2018 Health Canada released a draft guidance on **Public Release of Clinical Information** with comments due by the 25<sup>th</sup> June 2018. Click [here](#) to view the draft guidance. The EFSPi/PSI Data Sharing Special Interest Group will be reviewing this draft guidance. Anyone wishing to contribute to the review of this draft guidance please contact Rebecca Sudlow ([rebecca.sudlow@roche.com](mailto:rebecca.sudlow@roche.com)).

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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## **Scientific**

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

On Wednesday June 27 the scientific meeting on Small populations and level of evidence will take place at Idorsia, near Basel. In this joint EFSPi/BBS scientific meeting speakers from regulatory agencies (Anja Schiel, Norwegian Medicines, and Dan O'Connor, MHRA), academic institutes (Stephen Senn) and pharma companies (a.o. case studies from Roche and Actelion) will present their view. In the afternoon Nicole Gusset (patient representative of SMA) will give a patient perspective in our meeting. More information can be found [here](#) and to register click [here](#).

### **Recent Advances in Clinical Trials, March 23**

The slides of the presentations from the scientific meeting on *Recent Advances in Clinical Trials* are available on our website, click [here](#).

### **Decision making in Clinical Development, after summer**

In addition, the scientific committee is planning for a 1-day meeting on 'Decision making in Clinical Development' later in the year. More information will follow.

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## **Country News**

### **BBS (Switzerland)**

BBS held a workshop on **New developments in HTA, adaptive designs and Multiplicity – in remembrance of Willi Maurer** on the 17<sup>th</sup> April hosted by Novartis in Switzerland. Click [here](#) to see the slides.

### **PSI (UK)**

**Pharmaceutical Statistics March/April is now available.** The current edition of Pharmaceutical Statistics is now available on the [Wiley website](#). In this issue there are three papers on methods in survival data, including the use of Tobit regression. Other topics include the use of historical controls, model-based drug development and sample size re-estimation.

**PSI Webinar: Patient Reported Outcomes (PROs) - Clinically meaningful interpretation.**

Tuesday 8th May 2018 14:00 - 15:30 UK Time. Presented by: Kim Cocks (Adelphi Values), Andrew Thompson (EMA) and Christoph Gerlinger (Bayer)". This webinar will include an overview of how PROs tools are developed and used in clinical trial settings and how results can be clinically and meaningfully interpreted. In addition, a regulatory viewpoint will be shared on the key considerations for PROs. The talks will also include examples and case-studies showing the derivation of validated thresholds for treatment responders and interpretation of PROs in the context of regulatory approval. [Click here](#) to register.

**Training Course: Multiple Testing in Confirmatory Clinical Trials** 9th May 2018, Crowne Plaza, London Heathrow. Presented by: Carl-Fredrik Burman and Lisa Hampson. **Early bird registration deadline: Monday 9th April 2018.** Regulatory agencies require strong control of the Type I Error for all confirmatory statistical tests. Multiplicity issues can arise for several reasons, e.g. the possibility of winning on two different endpoints (like PFS and OS), interim analyses, or testing for effects in several patient groups. This course will focus on the principles underlying multiple comparison procedures and their applications to confirmatory clinical trials. We will describe simple ways to construct valid multiple tests, and will explore how tests can be incorporated into recycling strategies. Group-sequential and some common adaptive tests will also be described. Concepts will be introduced through a combination of lectures, exercises, and discussion sessions where groups will focus on the issues that might be encountered when designing and communicating statistical tests. [Click here](#) to register.

**2018 PSI Conference: Amsterdam 3 - 6 June 2018** The theme for the conference is "**Breaking Boundaries in Drug Development**", composed of a range of plenary and parallel sessions, from Developing Leadership and Influence to Machine Learning. For further details please visit the [conference webpage](#).

**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.

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## **Special Interest Groups**

### **Health Technology Assessment (HTA) Update**

The International Society of Pharmacoeconomics and Outcomes Research (ISPOR) has released a report outlining the 2018 top 10 trends in health economics and outcomes research. Click [here](#) to view the report. ISPOR has released a number of good practices for outcomes research, click [here](#) to see a listing of available reports.

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## **Job Opportunities**

Opportunities exist for **CHEF de PROJET BIOSTATISTICIEN(NE) Oncologie, BIOSTATISTICIEN(NE) expérimenté(e) Oncologie, Biostatistician/Senior Biostatistician, Senior Quantitative Safety Scientist, Clinical Development Statistician, Global Development Statistical Specialist, Biostatistician Project Leader Oncology and Biostatistician Oncology**. 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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