



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

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## EFSPI Newsletter March 2018

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## **Regulatory**

In March, the FDA and Heads of Medicines Agencies (HMA) held workshops on complex trial designs. On the 22<sup>nd</sup> March 2018, the FDA held a 1-day workshop on ***Promoting the use of complex innovative designs in clinical trials***. The workshop involved four sessions focused on: 1) General Considerations for Complex Adaptive Clinical Trial Designs to Support the Effectiveness and Safety of Drugs or Biologics; 2) General Considerations for Other Innovative Designs Including External/Historical Control Subjects, Bayesian Designs, and Master Protocols; 3) Clinical Trial Simulations for Confirmatory Trial Design and Planning; and 4) Complex Innovative Design Pilot Program. For more information click [here](#).

On the 23<sup>rd</sup> March 2018, the HMA Clinical Trials Facilitation Group (CTFG) held a 1-day workshop on Complex Study Designs. The workshop began with a plenary session where a competent authority, Industry and Academia gave their perspectives on complex trial designs, opportunities, and challenges. Then a series of breakout sessions followed discussing: scientific integrity, study design and transparency; pro's and con's of master/complex protocols and safety and regulatory challenges; and statistics, companion diagnostics and publication policies. For more information click [here](#).

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.

Thanks to **Alan Phillips (ICON)** and **Bruno Boulanger (Arlenda)** for submitting joint EFSPi and EFPIA comments on the *draft ICH E9(R1) addendum* and the *reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development* which were submitted in February and March respectively. A copy of the comments are available [here](#) on the EFSPi website.

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## **Scientific**

On March 23 EFSPi and PSDM held a scientific meeting on *Recent Advances in Clinical Trials* at Astellas, Leiden, the Netherlands. With almost 70 attendees and high-quality presentations it was a very successful event. In particular, the pilot of the first formal debate was a successful exercise on the motion: ***"This house believes the arrival of Big Data makes controlled clinical trials obsolete"***. Slides of the presentations will be made available on our [website](#).

The scientific committee is planning for a 1-day meeting on **'Small Population'** most likely end June or early July, and a 1-day meeting on 'Decision making in Clinical Development' later in the year. More information will follow in future newsletters.

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## Country News

### BBS (Switzerland)

BBS are holding 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 agenda. The Seminar fee is 100 CHF for industry and free for all others. Please register by sending an email in advance to [fred.sorenson@xcenda.com](mailto:fred.sorenson@xcenda.com). Registration will close by Friday, April 13, 2018.

### PSI (UK)

#### **Statistical Excellence in the Pharmaceutical Industry Award launched**

Nominations are being sought for the 2018 Award for Statistical Excellence in the Pharmaceutical Industry, jointly run by the Royal Statistical Society (RSS) and Statisticians in the Pharmaceutical Industry (PSI). The award recognises a most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. Nominees can be based anywhere in the world and do not need to be a member of PSI or the RSS. The award will be presented at the [Annual PSI Conference which will be held in Amsterdam from 3rd - 6th June 2018](#). Further information and the nomination form are now available [online](#). Nominations can be made until [midnight on Friday 20th April 2018](#).

#### **PSI Toxicology SIG Webinar**

The Toxicology SIG are running a free webinar on **17 April 2018, at 14:00 - 15:00 UK Time**. Dr Bernd-Wolfgang, Principal Statistician at Bayer, will be presenting on Statistical Analysis of the Comet-Assay. Further information will be available on the PSI website in the coming weeks. Register for free [here](#).

**Webinar: Basket, Umbrella and Platform trials - Experiences and practical considerations** 18th April 10:30 - 12:30 UK Time. Presenters: Max Parmar (MRC), James Matcham (AZ) and Julia Saperia (MHRA). Trials designed to answer a range of questions, often incorporating multiple treatment arms are increasingly being considered in all phases of clinical research in both the pharmaceutical industry and public sector trials. A variety of terms including platform, umbrella and basket designs have been used to describe particular versions of this general framework. During this webinar a regulatory speaker will consider what is meant by the different terms and potential regulatory hurdles, while speakers from industry and the public sector will share their practical experiences of these types of trials. Click [here](#) to register.

**PSI Training Course on Health Technology Assessment** 24th - 25th April 2018. Location: AstraZeneca, Gothenburg, Sweden. This two day course will provide an introduction to the methods of health technology assessment. Topics covered include HTA policy, Evidence Synthesis, Measuring and Valuing Health, and Key Statistical Challenges (such as treatment switching, extrapolation, and NMA). We have 5 expert presenters, Anja Schiel from the Norwegian Medicines Agency, Mark Sculpher sits on the NICE diagnostics advisory committee, Neil Hawkins has acted as an external consultant on the NICE scientific advice programme, and Jan McKendrick and Jonathan Alsop who are experienced statisticians with expertise in pricing, reimbursement, and HTA-related activities. [Click here](#) to register.

**PSI Toxicology SIG Workshop 2018** 24<sup>th</sup> and 25<sup>th</sup> April 2018 at the Crowne Plaza Hotel, Heathrow,

London, UK. The workshop provides an opportunity for those working within Toxicology and the wider non-clinical areas to get together and share ideas, have discussions and benefit from presentations from Statisticians and Scientists working within these areas. The topics being discussed during the 2018 workshop include: self-administration/abuse potential, statistical methods for analysing the Ames test, the role of a non-clinical statistician, bioassay validations and statistics in safety testing. The fee for the 2-day workshop (including dinner, bed and breakfast) is £225 and represents great value for money. [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.

### PSDM (The Netherlands)

In March the PSDM organised two successful events:

The first event was on "Overview of CDASH and introduction to the new CDASHIG 2.0" hosted by SAS Institute and targeted towards the data managers community (which is also part of the local PSDM organisation). More information can be found on the website (<https://psdm.nl/events/>) and slides of the presentations will be made available soon. The second was a joint event with the EFSPi on 'Recent Advances in Clinical Trial Design'. See scientific update above.

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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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