



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

EFSPI Newsletter May 2018

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Regulatory

A 'Regulatory Town hall' will be held at the PSI conference in Amsterdam between the 3-6 June 2018. There will be a couple of short talks and a Q&A session with panelists from health authorities and industry.

The Regulatory Committee is organizing a Webinar on Subgroup analyses at June 13 (time TBD). Aaron Dane from DaneStat is giving the webinar. See the [PSI website](#) for more information.

The **3rd 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. More information can be found [here](#) and registration is open 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

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.

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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 12-14th 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.

JSM (the Joint Statistical Meetings) 28th July – 2nd August 2018, Vancouver, Canada. JSM is the largest gathering of statisticians and data scientists held in North America. Over 6.500 attendees are expected from 52 countries with more than 100 exhibitors. Attendees have a choice of more than 600 sessions including invited, contributed and poster presentations in topics ranging from statistical applications to methodology and theory to the expanding boundaries of statistics, such as analytics and data science. 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](http://www.worldofstatistics.org) website.

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