



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

EFSPI Newsletter June 2018

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Regulatory

The EFSP/PSI regulatory committee helped organize two successful plenary sessions at the PSI conference in Amsterdam June 4-6. In the “What matters most? – a scientific advice role play” session Oliver Keene (GSK), Stephen Ruberg (Analytix Thinking), David Wright (AstraZeneca), and Alexander Schacht (Eli Lilly), did a brilliant job discussing estimands in a scientific advice setting, playing the roles and providing the perspectives from the industry, the patient, the regulator, and the payer, respectively. In the role play the pharmaceutical company PatientFirst Pharmaceuticals proposed a Phase III clinical study for a potential new treatment for COPD, and was seeking a joint scientific advice from a regulatory and HTA agency, with the support from a well-informed COPD patient. The panel, with the help of the chair Mouna Akacha, led an interesting and thought provoking discussion on estimands, and on what really matters most, and to whom. The conference ended with a Regulatory Townhall, where following an interesting talk by Julien Tanniou on current Regulatory Hot topics, Anja Schiel led a discussion addressing questions from the audience with the help of Steven Teerenestra, Benjamin Hofner, Julien Tanniou, and John Adler representing different European Health Authorities and Industry, respectively. The panel did a fantastic job discussing a range of topics including estimands, Real World Evidence, pragmatic clinical trials, HTA, regulatory guidelines, transparency, and so forth.

The regulatory committee is now busy 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 Biostatistics working Party, please contact [Christoph Gerlinger](#) or [Anna Berglind](#).

The **ICH E9 working group** met in Japan in early June to review the comments submitted on the draft E9 addendum (ICH E9(R1)). Thanks to everyone who contributed to the set of consolidated comments submitted on behalf of EFSP and EFPIA. The ICH E9 working group were able to discuss key themes raised in the comments, and the detailed comments are being reviewed. Further progress on activities to finalise the E9 addendum will be provided at upcoming scientific meetings and conferences.

The **3rd EFSP 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 EFSP website.

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EFSP Statistics Leaders Meeting

The 9th EFSP Statistics Leaders meeting is taking place on Thursday 12th July in Belgium. Key themes being discussed include Bayesian statistics in pharmaceutical development, pragmatic trials and external controls, and update on the Special Interest Groups (SIGs) with experiences from the Quantitative Decision Making SIG being shared. A summary of the meeting will be provided in a future newsletter. For more information please contact Justine Rochon (justine.rochon@boehringer-ingelheim.com).

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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.

SSL (Finland)

The Finnish Pharmaceutical Statisticians organisation (SSL) had the yearly Spring meeting in Turku on 25th May. The topic of the meeting was **Future Forum**. Olavi Kilkku from Orion Pharma gave a plenary talk and then it was time for group sessions with following topics:

- Biostatistics vs. Data science
- Future topics from industry perspective
- New study designs
- Estimands / E9 Addendum
- Other (than statistical) skills needed in the future?
- Future of programming

Each group presented the key points of their discussions in the combined session and the meeting was summed up with general discussion about the forthcoming challenges and opportunities for biostatisticians. In summary "In the statistical field it's getting more and more difficult to master everything, but for a statistician who educates him/herself and also understands the role of communication and team work, the world is full of opportunities".

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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:

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.

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.

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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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