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

EFSPI Newsletter November/December 2017

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EFSPI Statistics Leaders

On behalf of the EFSPI Council please welcome **Justine Rochon** as the new Chair of the EFSPI Statistics Leaders Meeting.   A huge thanks to **Stefan Driessen** who was the Chair for the last 6 years with great passion and dedication. In Stefan's own words, 'I feel privileged to have led the EFSPI Statistics Leaders meetings, and met with so many highly professional, skillful and experienced colleagues'. The next EFSPI Statistics Leaders meeting will take place in the summer of 2018.

Regulatory

Thanks to everyone who submitted comments on the draft ICH E9 addendum. A workshop to discuss the key comments raised will be held on the 16th January 2018 at Amgen Uxbridge.

The European Medicines Agency (EMA) has established an expert group in data anonymisation known as the technical anonymisation group (TAG) to help further develop best practices for the anonymisation of clinical reports, in the context of the Agency's policy 0070 on the publication of clinical data. The TAG includes members from academia, industry, patients and healthcare professionals with expertise in areas such as data protection, developing standards and guidance for anonymisation and re-analysis of clinical data. The TAG met for the first time on the 29th and 30th November and discussed aspects relating to: patient re-identification and any privacy risks in the light of new technological developments; the scientific utility of the published clinical data as a function of the anonymisation methodology used; and whether it is possible to successfully conduct a secondary analysis of the anonymised clinical data. A summary of the meeting will be made available on the EMA website.

EMA and the Harvard Multi-Regional Clinical Trials (MRCT) group held a workshop on *Data Anonymisation - a Key Enabler for Clinical Data Sharing* on the 30th November and 1st December at the EMA offices in London. The objectives of the workshop were to: propose guiding principles to enable international data sharing in the public interest; building on the platform of work by EMA, to review anonymisation approaches applicable to a broader set of data which ensure privacy protection and meet the standards required to maintain accessibility and the scientific utility of the data; and examine opportunities for harmonisation of international clinical data sharing, taking into consideration data protection in the different jurisdictions. Members of the EFSPI data transparency special interest group attended the workshop and will release a workshop summary in the next newsletter.

Reminder: The EMA published the **Draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development** providing current regulatory considerations regarding statistical aspects for the comparative assessment of quality attributes in the settings of pre- and post-manufacturing change, biosimilar development as well as generics development. **Bruno Boulanger (Bruno.Boulanger@arlenda.com)** is collating comments on behalf of EFSPI, so please send any comments you have on the reflection paper to Bruno by **15th January 2018.**

Country News

APF (Germany)

On November 24th APF held its annual autumn workshop in Freiburg. The topic was estimands for safety with speakers from industry, academia and from IQWiG. For detailed please see http://www.biometrische-gesellschaft.de/arbeitsgruppen/pharmazeutische-forschung.html (in

German).

FMS (Sweden)

On November 23, the Swedish Society of Medical Statistics (FMS) celebrated 30 year since the foundation 1987. The celebration took place at Uppsala University during a seminar with a wide range of statistical/medical topics.

The association was founded as a subsection of the Swedish Statistical Society with the main objective to stimulate the development and promote the use of new and established statistical methods within the medical sector as well as within the areas of pharmaceutical industry and public health.

Today the Swedish society has 270 members coming from various fields; the most common employers being academia, pharma industry and public authorities. The society organizes 2-4 meetings each year, including seminars where the programs aims to reflect the diverse interests of the association members. Every other year we co-organize meetings with our sister-associations in Denmark (DSBS) and Finland (SSL).

The association grants scholarships, for example to enable student statisticians to attend and present at conferences, and promotes discussions on applications or statistical issues through articles in Qvintensen, a quarterly magazine published by the Swedish Statistical Society.

PSI (UK)

PSI Webinar: "HTA submissions in Germany; what do statisticians need to know to be successful with their GBA dossiers" Presenter: Dr Carsten Schwenke. Part 1: 23JAN2018, 15:00 – 16:00 UK time. Part 2: 31JAN2018, 15:00 – 16:00 UK time. Part 3: 13FEB2018, 15:00 – 16:00 UK time.

Early benefit assessment was introduced in Germany in 2011 as a basis for price negotiations between payers and pharmaceutical companies. Since then, all new drug substances have to be assessed at the Federal Joint Committee (G-BA), by indication. This series of webinars by Dr C. Schwenke will focus on the statistical implications and how to deal with the requirements by G-BA and their methodological support institute IQWiG and should be of particular interest to statisticians who work in HTA and those who deal with requests from their local German affiliate. For more information and how to register, please see the links above.

PSI Training Course on Missing Data **6th - 7th March 2018**, Crowne Plaza Hotel, Heathrow, UK Presented by: Michael O'Kelly. This course will provide participants with an understanding of missing data, its link with what is to be estimated in a study (the "estimand"), and statistical modelling approaches. The 2 day course includes workshops: participants will undertake a number of practical exercises on missing data in SAS. In addition, participants will have the opportunity to gain insight into some of the more useful new methodologies for missing data, with a view to being at the service of the real scientific question of interest. Multiple imputation (MI) will be emphasised - due to this method's flexibility. Click here to register.

PSI Toxicology Special Interest Group The Toxicology SIG is a small group of statisticians who mainly work, or have an interest in, toxicology data. We also expand our discussions to include nearly all areas of pre-clinical development, including Safety Assessment, Safety Pharmacology, Genetic Toxicology, Carcinogenicity, use of historical control data and general assay supporting, including

Anti-Drug Antibody assays. We are in the process of putting together a regular series of Webinars on such topics, and organising our next workshop for **April 2018** following the success of our last workshop in March 2017. If you work in these areas, or know someone who is, please get in touch so that we can share our thoughts with you. We welcome anyone across the globe to get involved in our work. For more information and to be added to our email distribution list, please contact gareth.thomas@envigo.com.

2018 PSI Conference: Amsterdam 3 - 6 June 2018   A record breaking 80 contributed abstracts have been submitted. Act now and **click here to register** to receive the early bird fee, up until the 21st March 2018!

PSI Pre-Conference Course: Demystifying Causal Inference - Assessing efficacy when patients depart from randomised treatments 3rd June, 2018 Presented by: Prof. Ian White & Prof. Sabine Landau. Randomised trials provide a gold standard design for assessing the effectiveness of an intervention or treatment, based on an intention to treat analysis. However, this suffices only to answer a narrow question about the effectiveness of offering the intervention, based on comparing the average outcome between randomised groups. This course aims to introduce participants to the concepts of causal inference in randomised trials and the statistical methods used to answer various causal questions. It will focus on worked examples from different clinical areas, modelling issues and the key assumptions, and how these methods can be implemented in standard statistical software. More information will follow on the PSI website and registration will open soon!

SSL (Finland)

A webinar was held in Finland on the 22nd of November with the following topics and speakers:

Fabian Hoti (Statfinn): "Assessing real-world effectiveness - within individual models"
Aki Linden (4Pharma): "Network meta-analysis using generalized linear mixed model"
Jari Ahvenainen (Datoil): "Visualize Their Dreams - How to Keep a Clinician Happy?"
Katja Vaahtera (PerkinElmer): "Customer service in IVD-research – challenges and possibilities with the data".

The webinar was attended by approximately 25 participants.

Job Opportunities

Opportunities exist for **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.

The World of Statistics

The World of Statistics is comprised of 2, 198 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.

International Conference on Analytics, Data Science Gathered Leaders in Poland

The Fifth International Workshop on Advanced Analytics and Data Science took place November 7 in Warsaw. Academic and industry leaders discussed the potential of predictive analytics, shared experiences on how organizations can uncover new business opportunities using analytical tools, and addressed how employers and educators can collaborate to fill the analytics skills gap. The theme of the event was "The Power of Predictive Modeling and Importance of Data Imputation." Organized by the Warsaw School of Economics and in connection with SAS Poland, the event included presentations from experts in academia, business,

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And finally.....

To add your e-mail address to the EFSPI mailing list, click on "Sign up to our newsletter" on the homepage of the EFSPI website.

To view previous newsletters please see the EFSPI website in the "News" area.
EFSPI wishes everyone a Merry Christmas and a Happy New Year.

Chrissie Fletcher
EFSPI Communications Officer