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

EFSPI Newsletter January 2018

In this newsletter:

New President for EFSPI

Welcome **Uli Berger** who has taken over as EFSPI President effective January 2018 through to end of 2019. Uli is one of two Basel Biometrics Society (BBS) representatives on the EFSPI Council and he is the Global Biostatistics TA Head for Neuroscience and Ophthalmology in Roche, Switzerland. The EFSPI Council will to thank Marisa Bacchi for her great leadership of EFSPI for the last 2 years.

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Regulatory

A workshop to discuss the key Industry comments on the ICH E9(R1) document was held on the 16th January 2018 at Amgen Uxbridge. Approximately 50 representatives, including statisticians and clinicians, from Industry, Regulatory and Academic institutions attended the workshop. The key themes emerging from the consolidated set of comments submitted by EFPIA and EFSPI and which were debated in the workshop included the following: (i) what are the pros and cons for each strategy for handling intercurrent events, share examples showing how the strategies inter-relate with each other; (ii) how can the different estimand strategies be applied to a typical pivotal oncology study; and (iii) are there intercurrent events that could be considered standard and does

any intercurrent event closely relate to a specific strategy, and what is the role of analysis sets described in ICH E9 in the context of the estimand framework. The feedback from the workshop will be used to finalise the Industry comments ready for submission to EMA by the end of February 2018.

EFSPI submitted comments to EMA on their Reflection paper on use of extrapolation in development of medicines for paediatrics. Thanks to those who reviewed the document and provided comments.

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Scientific

The Scientific Committee is planning for three 1-day scientific meetings for 2018:

A one day meeting on **Recent Advances in Clinical Trials** will take place on **Friday 23rd of March** at Astellas, Leiden, the Netherlands. This meeting will offer participants the opportunity to interact with speakers from academia, regulatory agencies and industry on recent developments in designing clinical trials. Apart from presentations on a diverse range of topics including the use of modelling and simulation in designing a study, there will be a formal debate. The motion of the debate is: ***"This house believes the arrival of Big Data makes controlled clinical trials obsolete"*** Members of the audience are invited to submit short contributions to the debate in writing to the organisers. **Registration** is open and more information can be found on our website (www.efspi.org).

In addition, we are planning for a 1-day meeting on 'Small Population' and a 1-day meeting on 'Decision making in Clinical Development' later in the year. More information will follow in subsequent newsletters.

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EFSPI/PSI SIG Updates

Data Sharing SIG

The EFSPI/PSI Data Sharing SIG is focused on the practical and operational implications of data sharing of study documentation and datasets. Members of the SIG attended a number of key meetings of the data sharing community in November and December 2017, both in London, UK.

Data Anonymisation – a Key Enabler for Clinical Data Sharing 30th Nov – 1st Dec 2017.
The meeting was attended by about 110 people and hosted jointly by the EMA and MRCT. It aimed to propose guiding principles to enable international data sharing, building on the work done by EMA (related to Policy 0070) to review data anonymisation approaches and examine opportunities for harmonisation of international clinical data sharing, taking into consideration data protection in the different jurisdictions. Attendees ranged from regulators, academics, pharma and pharma bodies, patients and patient advocates, legal, data privacy and many more.

The Evolution of Policy 0070: EMA Clinical Data Publication 6th – 7th Dec 2017.
The meeting was hosted by DIA and its objectives were to learn about the latest

developments relating to the implementation of Phase 1 of EU Policy 0070 from regulators as well as industry; benefit from the various perspectives on regulatory, legal aspects and practical challenges from sponsor organisations; leverage best practices on the practical implementation through case studies by the exchanging of views between regulators, industry, patients, academia and other stakeholders. Transparency elements of the forthcoming Clinical Trial Regulation and in greater part on legal issues relating to commercially confidential information (CCI), including ongoing litigation between sponsors and EMA regarding Access to Documents (policy 0043) were also discussed. An update from the EMA TAG (Technical Advisory Group) was also provided, and vendors demonstrated tools and systems for anonymising data and/or documents.

To summarise, both meetings provided a great opportunity to network with a wide range of colleagues and stakeholders, to ask questions and interact with the EMA, to understand legal and data privacy aspects in more depth, to hear from experts in data anonymization across the globe, get the patient perspective and observe that services, technology and tools which can play a role in implementation are quickly evolving.

Following these meetings, look out for further communications from the EMA/MRCT meeting organising committee and EMA TAG plus ongoing activities as part of industry groups such as the EFSPI/PSI Data Sharing SIG and PhUSE Data Transparency WG. Interested to know more or get involved? Just contact us below.

Katherine Tucker (Roche), Janice Branson (Novartis) January 2018 on behalf of the EFSPI/PSI Data Sharing SIG. Contact Katherine.tucker@roche.com, Janice.branson@novartis.com.

Agenda meeting 1: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2017/11/WC500238088.pdf
Agenda meeting 2: http://www.diaglobal.org/Tools/Content.aspx?type=eopdf&file=%2fproductfiles%2f6605336%2f17119_pgm%2Epdf
EMA policy 0070: http://www.ema.europa.eu/ema/?curl=pages/special_topics/general/general_content_000555.jsp
EMA clinical data website: https://clinicaldata.ema.europa.eu/web/cdp/home
UKAN Anonymisation Decision-Making Framework (ADF): http://ukanon.net/ukan-resources/ukan-decision-making-framework/

HTA SIG

The Health Technology Assessment (HTA) SIG is pleased to highlight the University of Bern is running a Network meta-analysis training course using R on the 28th – 30th August 2018 on the Greek Island of Kea. See here for more details.

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Country News

PSI (UK)

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!

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Job Opportunities

Opportunities exist for **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, 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.

Royal Statistical Society Announces Important Statistics of 2017

Over the past 365 days, statistics have come and statistics have gone. But, none more striking than these important ones of 2017 compiled by the Royal Statistical Society (RSS) in its effort to look back on all that was statistics in the United Kingdom and internationally, as well.

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And finally.....

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To view previous newsletters please see the EFSPI website in the "News" area.

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Chrissie Fletcher
EFSPI Communications Officer