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

EFSPI Newsletter August 2017

In this newsletter:

EFSPI celebrates 25 years

Congratulations EFSPI celebrating 25 years

EFSPI was founded on August 3, 1992 by 7 countries and currently has 10 national organisations that are members: Belgium (SBS/BVS),Denmark (DSBS), Finland (SSL), France (SFdS B&S), Germany (APF), Italy (BIAS), Netherlands (PSDM), Sweden (FMS), Switzerland (BBS) and UK (PSI). Collectively the national organisations within EFSPI serve approximately 2800 statisticians and statistical programmers.

The **objectives** of EFSPI are:

• To promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry
• To offer a collective expert input on statistical matters to national and international authorities and organisations
• To exchange information on and harmonise attitudes to the practise of statistics in the European Pharmaceutical Industry and within member groups

These objectives are met through the activities led by the Scientific Committee, the Regulatory group, and the individual national associations. In recent years, the annual EFSPI Statistics Leaders meeting has further extended the networking and exchange of information across EFSPI. Enabling national associations in Europe to collaborate, debate important scientific issues and promote the statistical profession is at the heart of EFSPI and **thanks to all** who have participated and supported EFSPI.

Regulatory

The second **EFSPI regulatory statistics workshop** will take place on the **5th-6th October 2017** in Basal, Switzerland. This workshop will be dedicated to opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. Click here to view the agenda and to register click here.   Specific focus areas include multiplicity, estimands, predictive biomarkers/companion diagnostics and early development. Development issues in a range of disease areas will be discussed in addition to a contributed short topics session. Materials from the first workshop can be found here.

The EFSPI-PSI regulatory committee will meet with EMA's BSWP in October and with the MHRA statisticians in November. Currently we are working on the discussion points for the agendas. Please send your question or topic to Christoph Gerlinger (Christoph.Gerlinger@bayer.com) or to Anna Berglind (Anna.Berglind@astrazeneca.com).

We are awaiting the publication of the draft of the addendum to ICH E9 on estimands. We plan to run a meeting to discuss the draft in due time. We are also planning a webinar on the addendum.

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 February 28 2018.

Scientific

The webinar '**Spotlight on the Integrated Data Analysis**' will take place on **Thursday 28th October in the afternoon**. This webinar reprises the three presentations given during the special session at the PSI 2017 annual conference devoted to the IDA Special Interest Group. The common theme between them is that they all deal with either collecting, reporting or analysing safety data. More details can be found on the EFSPI website.

A 1-day meeting on **Oncology and Survival Analyses** will take place on Friday 17th of November at BMS in Brussels. Survival analysis methods, or 'Time to event' methods originally developed to analyse trial endpoints in oncology are now used in many other indications. At this meeting, you will hear about recent advances in survival analysis methods. Registration is open and more information can be found on the EFSPI website.

A 1-day EFSPI/PSI **HTA scientific meeting** will take place on **Tuesday 28th November** hosted by **MSD** in **London, UK**. The meeting will provide an update on latest trends in HTA, including: the Real-World Evidence Navigator tool created by the IMI GetReal project; the EUnetHTA Joint Action 3 initiative and methodology being researched; introduction to value-based frameworks and estimands in HTA. Patient perspectives in HTA will be discussed including how to involve patients in HTA. HTA related methodological considerations will be highlighted including approaches to handle treatment switching in HTA. Industry HTA case studies will also be presented. Registration for the meeting will open from September onwards via the PSI website.

Asterix

EFSPI is one of the partners in the FP-7 projects, called Asterix, on new innovative methodology for rare diseases. This consortium is reaching its final stage, and as a result, Asterix is organising a Symposium **on New Methodology for Clinical Trials in Rare Diseases** on **September 18 and 19** in **Zaandam** (the Netherlands)

*** REGISTRATION IS OPEN ***

It will discuss key topics such as novel novel approaches to randomization, sequential designs, multiple endpoints, meta-analyses and Goals Attainment Scaling by using examples and explanations in common, non-technical language. Special attention is dedicated to patient involvement in general and the Patient Think Tank.

More information can be found on the Asterix website http://www.asterix-fp7.eu/agenda/symposium/

Special Interest Groups

Following the EFSPI Statistics Leaders meeting held in July 2017, a new Special Interest Group on **Decision-making support** is being formed. The purpose of this SIG is to share and promote quantitative tools to evaluate, compare and optimize drug development plans and business strategies in the pharmaceutical industry, in terms of success and/or risk.

The main aims of this new SIG are as follows:

- To share anonymised cases studies of how quantitative decision-making methods have been used within pharmaceutical companies, including but not limited to statistical methodologies for Go/No-Go decisions (e.g. probability of success), comparisons of development plans, optimal allocation of resources (e.g. operations, number of patients, trial duration) and portfolio value assessment
- To discuss and make recommendations on existing methodologies in terms of approaches and interpretation
- To develop new methodologies or practices where needed
- To promote the role of the statistician in supporting decision-making in pharmaceutical companies and/or other stakeholders
- To propose trainings, public meetings or publications to share methods and experiences

If you are stimulated by the challenging topics in the remit of this SIG and would like to join, please send an email to Maylis Coste maylis.coste@servier.com and Sylvain Nicolas Sylvain.Nicolas@sanofi.com.   Please also indicate if you would be interested to chair the SIG.

The **Benefit-Risk SIG** are pleased to announce a webinar on '**Measuring patient and physician benefit-risk preferences in antipsychotic clinical trials**' on the **26th September 2017 at 3pm GMT / 4pm CET** presented by **Dr Eva Katz, Janssen**. Find out more and register here for the event. Only limited space is available.

The **Integrated Data Analysis SIG** are pleased to announce a webinar on the **28th September 2017 at 2pm GMT / 3pm CET** reprises three presentations given in a special session at the 2017 PSI Conference. Topics and speakers include:

- *Lessons from Meta-Analyses of Randomized Clinical Trials for Analysis of Distributed Networks of Observational Databases* –Andrew Bate (Pfizer)
- *A Unified Framework for Synthesis of Safety Data in the Presence of Varying Exposure and Risk* – Sally Hollis (University of Manchester)
- *Reporting Adverse Drug Reactions in Product Labels: Suggestions for Improvement* –Sally Lettis(GSK)

Click here for more information.

Country News

BIAS (Italy)

The next national BIAS congress will be organized in Parma on **September 28ᵗʰ and 29ᵗʰ.** This edition will be focused on "***Biostatistics beyond clinical trials: epidemiology, pharmacoeconomics, personalized medicine, machine learning and other hot topics"***. The Epidemiology session will involve Italian experts from both the Academia and the Industry, and it will aim to depict how observational and real world studies can play a strategic role in the development of new drugs and their importance in the surveillance of marketed products. A panel of experts leaded by Eva Pagano (AOU Città della Salute e della Scienza, Torino) will talk about pharmacoeconomy and its growing importance in the decision making process of the health authorities. Presentations on machine-learning (Dario Gregori, University of Padua), personalized medicine and estimands (Mouna Akacha, Novartis Pharma AG) complete the scientific program of the Congress.

PSI (UK)

Abstract Submission OPEN for the PSI Conference 2018 PSI are pleased to announce that the count down to the PSI Conference 2018 has now begun! The conference will be held in **Amsterdam** on the **3 - 6th June 2018** and the theme is Breaking Boundaries in Drug Development. We are now taking submissions for any of your contributed oral or poster abstracts. We accept abstracts on any topic but have provided a list of topics we are particularly interested in, including; Machine Learning, Pre-clinical, Real World Data, Safety Data, Genomics, Bayesian and many more. You can see the full list and download the abstract template [here](#)! The deadline for oral abstract submissions is **24th November 2017**. We hope to see you in Amsterdam!

 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.](mailto:gareth.thomas@envigo.com)

Improving Influence and Increasing Impact: Essential Skills for Industry Statisticians Presented by Andy Grieve, Gemma Hodgson, Margaret Jones on the **21st September, 2017, UCB, Slough**. The landscape is changing across the pharma industry and as statisticians, in order to continually add value, we must make sure we adapt. This course is aimed at statisticians who want to improve their consultancy style interactions within their internal project teams and/or with external customers and understand the impact of their own behaviours and interaction preferences. [Click here](#) to register.

PSI one-day event on Estimands - Examples for Statisticians **27th September, 2017, QuintilesIMS**, Reading, UK. As we approach the imminent release of the ICH E9 Addendum, Estimands is moving from a concept to reality with some Regulators already asking "What is your Estimand?". But where do you start when defining your Estimand? What is the Estimand of interest and to whom? What inter-current events could determine your Estimand and thus your analysis methodology? The Statisticians in the Pharmaceutical Industry (PSI) Scientific Committee have put together this one day meeting to provide Statisticians with real world examples of how Estimands have been defined. Presenters will give their insight into discussions with colleagues, working groups and regulators and there will be plenty of opportunity to ask your questions on defining an Estimand. For more

information on the agenda and how to register please click here.

Do you have colleagues who look baffled when you talk about statistics? Statistics Fundamentals for Clinical Trials for Non-Statisticians (or 'How to speak stats in a day!'), **14th November, 2017, Reading, UK**. Presented by Gemma Hodgson this is a 1-day course, aimed to introduce statistics to people who work on Clinical Trials, but who are not Statisticians. No previous knowledge of Statistics is assumed as we start right at the beginning with the basics. For more information on the agenda and how to register please click here.

One-day meeting: Use of Extrapolation methods 22nd November, 2017, GSK, Stevenage, UK. Use of extrapolation techniques is playing an increasingly important role in the development of new medicines particularly with regard to special populations such as paediatrics and rare diseases. This meeting will include speakers from industry, academia and regulatory (including Rob Hemmings from MHRA). Please look out for an eNews update on this meeting in the autumn with full speaker details.

SFdS (France)

The **International Meeting Statistical Methods in Biopharmacy** will be held on **the 14-15th September 2017** with the theme "***The future of Biostatistics in an emerging world of data sciences***". Key themes for the meeting include: regulatory statistics and beyond, statistical inference of biostatistics of the 21st Century, successful marriage between bioinformatics and biostatistics, and recurrent event analyses. More details to register will follow in future newsletters.

Other news/events

IMI Project PREFER – patient preferences in benefit-risk assessments – replay of the webinar now available

Presented by Conny Berlin and Rachael L. DiSantostefano. Organized by the EFSPI/PSI Benefit-Risk SIG. In a 1-hour webinar on the 12 of July 2017 organized by the EFSPI/PSI benefit-risk special interest group Conny Berlin, who is the industry project leader of the public-private IMI PREFER project, and Rachael L. DiSantostefano, member of IMI PREFER, presented about the objectives of the project and how they will be achieved. A benefit-risk example was also discussed. The webinar ended with a Q&A session. The replay of the webinar is available now here: https://www.benefit-risk-assessment.com/webinar-on-imi-project-prefer-patient-preferences-in-benefit-risk-assessments/

Job Postings

Opportunities exist at ICON/DOC for Statistical Programmers. 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, 196 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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To view previous newsletters please see the EFSPI website in the "News" area.

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Chrissie Fletcher
EFSPI Communications Officer