



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

EFSPI Newsletter May 2016

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Regulatory

EFSPI Regulatory Statistics Workshop

The 1st EFSPI Regulatory Statistics Workshop will take place on **September 12th and 13th** in **Basel, Switzerland**. The workshop will be dedicated to opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. Key themes chosen for this workshop include: estimands, extrapolation, risk benefit assessments, and statistics in quality and quality attributes. There will also be a session allowing individuals from the audience to present on short topics followed by a panel discussion. Book before the 1st August for **Early Bird rates (Industry €250, Academic €175)**. Click [here](#) to view the agenda, and click [here](#) to register.

Data Sharing Workshop

The EFSPI Data Sharing Working group is organizing a workshop at the end of September to share experiences of EMA POL-0070 *Publication of clinical data for medicinal products* for human use with respect to anonymizing clinical documents and patient level data sets. Volunteers are sought from statistics, regulatory writing, data privacy and/or disclosure groups to present and share their experiences. Please contact Chrissie Fletcher (fletcher@amgen.com) if you may be willing to present a case study.

Summary of meeting with EMA Biostatistics Working Party Q4 2015

The EFSPI/PSI regulatory committee met with EMA's Biostatistics Working Party (BSWP) on Oct. 9th 2015 in London. An update was provided on the actions taken in response to the previous meeting:

EFSPI has formed a cross-industry working group to discuss and develop a best practice for subgroup analysis; and EFSPI has formed an expert group on estimands to discuss this important topic across the EU community.

The ongoing work on the ICH E9 Addendum on estimands and sensitivity analysis was shared. Both *de facto* and *de jure* estimands will be of interest in most trials, and prioritising will be difficult. Whilst a primary estimand should be defined for each trial, the treatment label may describe and use several estimands to communicate treatment effects effectively to prescribers and patients. Regulatory and HTA decisions may also be based on different estimands. The proposed analysis framework will differentiate between different estimators of the same estimand in addition to estimators of different estimands. One relevant question is whether MMRM (which estimates the hypothetical effect if everyone would have adhered to treatment, therefore for those who did well from a safety point of view) can ever be a good estimator in an ITT setting.

Current statistical issues and potential regulatory statistical concerns for the future were discussed. The BSWP is working on the reflection paper on statistical considerations in comparing quality attributes. EFSPI has recently formed a working group on this subject. The final guideline for subgroups is aimed to be published mid to late 2016. Real world data and inferences is a topic for the future, with questions such as can we design smart studies based on clinical practice in order to inform labels and re-imburement decisions, and can real world data answer questions on causal drug effects?

Other topics discussed included the measurement of treatment benefit in a survival setting focusing on treatment estimators and OS/PFS consistency; data maturity; and estimating effects in the presence of treatment switching. It was agreed that it is hard to answer any of these questions generally, as many require situation specific answers. Alpha adjustments for interim analyses were also discussed and contrasted to approaches generally used in the US. Where there is a chance that a study is stopped early for efficacy then an alpha adjustment is mandatory in Europe. However if a study can only be stopped for futility, then an alpha adjustment is not necessary.

EMA extrapolation workshop

EMA held a 2-day workshop on extrapolation of adult data to the paediatric populations http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/2015/10/event_detail_001230.jsp&mid=WC0b01ac058004d5c3. There were many interesting presentations on extrapolation case studies. The slides will be shared shortly on the EMA's website.

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Scientific

- 1-day scientific event on **June 24, Biomarkers and Subgroups in Leiden, the Netherlands** (A joint event of EFSPI and PSDM, hosted by Astellas).

Registration is open – you can register using [this link](#)

When biomarkers are used to identify sub-groups of patients who are likely to benefit from new therapies, a whole host of challenges arises, and many of them are of a statistical nature. In this meeting, experts from industry, academia and regulatory agencies will come together to discuss these challenges, with a focus on practical applications. Confirmed speakers include Norbert Benda

(BfarM), Andrew Grieve (ICON plc), Tim Friede (University of Göttingen), Andrew Stone (Astra Zeneca), Sebastian Jobjornssen (Chalmers University) and Hans-Ulrich Burger (Novartis).

- 1-day scientific event on **Evidence Synthesis, 22nd November, Brussels** (hosted by BMS).

This meeting will discuss methodological considerations relating to synthesizing evidence to support drug development and market access activities. Topics to be discussed include: how to use evidence from network meta-analyses (NMA) to inform clinical trial design; NMA in an ANOVA framework; conducting frequentist NMA in R; conducting NMA using individual patient level data; and how to compare treatments when the network of evidence is disconnected. Case studies will also be presented. Registration details for this meeting will be available shortly, see the EFSPi website for latest details (www.efspi.org).

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7th EU Statistics Leaders Meeting 2016

This year the meeting will focus on the increasing interactions of EFSPi (and its member base) with regulatory bodies and public-private initiatives (such as IMI), the evolving concept of Precision Medicine, including the relationship with Biomarkers. The AIMS (Application and Implementation of Methodologies in Statistics) SIG will present their goals and objectives, and there will be a workshop exploring the Present and Future of Statistical Departments within the EU landscape. We expect over 30 participants again this year and look forward to a very good and interactive meeting.

Note that this meeting is on personal invitation only. If you want to know more about it, please contact Stefan Driessen (stefan.driessen@abbott.com).

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Other Events

FMS (Sweden)

Joint DSBS/FMS Meeting - Every second year the Swedish and Danish societies for biopharmaceutical/medical statistics, FMS and DSBS, arrange a joint meeting and this year's meeting will take place in **Malmö, November 1st 2016**. The theme of the meeting will be ***Statistical analysis of risks and safety data*** and the program will consist of invited speaker sessions and contributing speaker sessions. The planning of the meeting is currently in progress and two examples of topics covered are extreme value modelling of safety data from clinical trials and survival analysis methods in the assessment of safety data.

PSI (UK)

PSI Training course: **Design and Analysis of N of 1 Trials** presented by Stephen Senn, Radisson Blu Hotel, Heathrow Airport, London on the **5th July 2016**. Early Bird deadline: *6th June*. N of 1 trials are trials in which individual patients are repeatedly treated with experimental and control treatments in a deliberate and designed manner using principles of control, randomisation and replication. Their uses include personalising treatment and increasing efficiency by reducing the number of patients it is necessary to study. For further details or to register please visit www.psiweb.org and click on Events; payment now available online.

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Job Opportunities

Opportunities exist for a [Senior Biostatistics Manager / Associate Biostatistics Director](#). 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 2,344 organizations across the globe. You can view the current participant and country lists involved in the World of Statistics by going to [The World of Statistics website](#). To see the events and activities planned for 2016, [click here](#).

[Nominations](#) are open for the first International Prize in Statistics, to be awarded at the ISI World Statistics Congress in Marrakech in July, 2017. The purpose of the Prize is to call public attention to the important role that statistics, data analysis, probability, and understanding of uncertainty have played and are playing in the advancement of society, science, technology and human welfare. The Prize was created by five international statistical societies (American Statistical Association, International Biometric Society, International Statistical Institute, Institute of Mathematical Statistics, Royal Statistical Society). **Nominations are open through August 15, 2016.**

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And finally.....

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Enjoy this quote (courtesy of <http://virtualmuseumofstatistics.info/gallery.html>):

Statisticians, like artists, have the bad habit of falling in love with their models.

(George Box)

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Chrissie Fletcher
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