



EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY  
Representing Statistical Associations in Europe

## EFSPI Newsletter June 2016

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### Regulatory

#### Estimands

The **ICH E9(R1) Expert Working Group** met in Lisbon, Portugal on the 13-16<sup>th</sup> June 2016. This was the 4<sup>th</sup> time the group has met face to face and much progress was made in the development of the addendum for *E9 Statistical Principles in Clinical Trials*. Most of the discussion focused on exploring detailed technical aspects pertaining to what defines an estimand and considerations of which estimands are considered valid in practice, considering their relevance for clinical and regulatory decision making and the reliability with which they can be estimated. Agreement has been reached in a number of key areas for the scientific content relating to estimands and sensitivity analyses and work continues on drafting a document to present the concepts and guidance developed. Options for how to best integrate considerations on estimands and sensitivity analyses in the original E9 text were reviewed. There was also discussion on the implementation of estimands and sensitivity analyses in clinical trial protocols, and potential impact of the E9 addendum to other ICH guidelines. The ICH Assembly gave feedback to the working group to ensure the revised E9 remains high quality and continues to be accessible and understandable to a wide range of stakeholders.

The **1<sup>st</sup> EFSPI Regulatory Statistics Workshop** will take place on **September 12<sup>th</sup> and 13<sup>th</sup>** 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 1<sup>st</sup> 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 on the **27<sup>th</sup> September** at the **RSS, London**, 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. Details for how to register interest to attend this meeting will be available in the July EFSPi newsletter, contact Chrissie Fletcher ([fletcher@amgen.com](mailto:fletcher@amgen.com)) for more information.

## EMA extrapolation workshop

EMA held a 2-day workshop on extrapolation of adult data to the paediatric populations. There were many interesting presentations on extrapolation case studies. The slides are available via the [EMA's website](#).

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## Scientific

The **Biomarkers and Subgroups meeting** held on the 24<sup>th</sup> June in Leiden, the Netherlands was well attended by more than 50 attendees. The speakers from industry, academia as well as regulatory agencies presented various views and highlighted interesting aspects while dealing with biomarkers and subgroups: prognostic versus predictive biomarkers, exploration versus confirmation, multiplicity issues, and the role of pre-specification and the importance of biological plausibility on the level of evidence that is needed. A lively and interactive panel discussion concluded a successful meeting. The presentations together with the agenda and a summary of this day will be made available on the [EFSPi website](#).

A 1-day scientific event on **Evidence Synthesis will take place on the 22<sup>nd</sup> 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. Click [here](#) to find out more details and register for this meeting.

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## Other Events

### AFP (Germany)

APF is organizing a Workshop hosted by Parexel International in Berlin, 25th November 2016 about **Estimands and Prediction of Disease Progression**. The next APF Statistics Leader Meeting will take place 28th of October at Parexel International in Berlin.

### 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 1<sup>st</sup> 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)

Many thanks to everyone who attended the 2016 PSI Conference in Berlin - delegates, speakers, sponsors and exhibitors. The conference was a huge success and record breaking with 380 delegates attending, including 60 speakers, 50 posters, 23 parallel sessions, 18 exhibitors, 5 sponsors, 3 plenary sessions, 1 break out session, and 1 gala dinner. It was a fantastic three days packed full with statistical content and opportunities to meet new and old colleagues that PSI hope everyone has come away feeling inspired and energised with new ideas and contacts.

**PSI Journal Club - 6th July 2016 (3pm-4.30pm BST)** Estimands are an important and relatively unknown topic in clinical development. Our second event of the year is a joint event with the RSS on exactly this topic. Estimands bridge the gap between study objectives and statistical methods. When defining estimands; an iterative process linking trial objectives, estimands, trial design, statistical analysis and sensitivity analysis needs to be established. Join us to hear Alan Phillips and Peter Diggle discuss their views on how estimands have developed over the past nine years. Further details can be found at the PSI Journal Club homepage <http://www.psiweb.org/events/journal-club/journal-club-introduction>

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## **The World of Statistics**

The World of Statistics is comprised of 2,349 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](#).

## **Statisticians Compile “10 Simple Rules for Effective Statistical Practice”**

Statistics may be everywhere, but a constant challenge for researchers is that statistics aren't always understood, calculated or communicated effectively. Leading statisticians Robert Kass of Carnegie Mellon University; Brian Caffo of Johns Hopkins University; Marie Davidian of North Carolina State University; Xiao-Li Meng of Harvard University; Bin Yu of the University of California Berkeley; and Nancy Reid of the University of Toronto have penned “Ten Simple Rules for Effective Statistical Practice” to help researchers avoid pitfalls of misrepresenting data or formulating hypotheses based on faulty statistical reasoning. The list was recently published in the journal [PLOS Computational Biology](#).

## **ASA Statement on P-values Published in *The American Statistician***

The American Statistical Association's Statement on P-values and Statistical Significance has been published in the [May 2016 issue](#) of *The American Statistician*. The statement has been downloaded more than 117,000 times since it was originally released on March 7, 2016. A Spanish version will soon be posted in the supplements section of the article, thanks to the work of Professor Lucas Garibaldi and his students at the University of Río Negro in Argentina.

**[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.....**

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.

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.

Enjoy this quote (courtesy of <http://www.goodreads.com>):

“One of the first things taught in introductory statistics textbooks is that correlation is not causation.

It is also one of the first things forgotten.”

— Thomas Sowell

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