



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

EFSPI Newsletter March 2017

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Regulatory

Regulatory guidelines and EMA workshops

The regulatory committee has since January submitted comments on behalf of EFSPI on two draft guidance's: EMA's revised **Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products**; the FDA's draft guidance document on **Multiple Endpoints in Clinical Trials**. Thank you everyone who reviewed and provided comments, and thank you Maylis Coste, Bruno Boulanger, and Erika Daly for collating the comments. Bruno also represented EFSPI at the **EMA Workshop** on March 28, where some of the comments received during the public consultation for the revised first in human guideline were discussed, and where the goal was to finalize the guideline.

The **Seventh Framework Programme (FP7) small-population research methods projects and regulatory application workshop** was held at EMA on the 29th-30th March, see [here](#) for materials. The European Union funds three projects, Asterix, IDeAl and InSPiRe, within the Seventh Framework Programme (FP7) to develop new methodology on design and analysis of small population clinical trials since 2013. The projects are in their final phase and the workshop discussed their results to date. The aim is to translate and promote results and novel methodologies into tangible recommendations to advance the clinical research and development of medicines and new treatments for patients with a rare disease and personalised medicine.

Expert Working Group on Confidentiality of Interim Results

The confidentiality of interim results of on-going trials is a topic on the agenda of the EMA Biostatistics Working Party (BSWP). ICH E9 states that all staff at the investigational sites and at

sponsor (except those directly involved with the execution of an interim analysis) should remain blinded to any interim analysis results. The BSWP recognised that this advice may need to be re-evaluated, especially for some complex situations (e.g. the use of interim analyses in Cardiovascular Outcomes Trials to rule out harm or for gene therapy where the full results may not be available for 15 years).

The BSWP therefore asked the PSI/EFSPi Regulatory Committee to set up a PSI/EFSPi expert working group on this topic and to provide thoughts and recommendations. The expert working group has been formed under the leadership of Jürgen Hummel (PPD), Erika Daly (ICON) and Robin Mukherjee (Astra Zeneca), and are planning to meet face to face on 11 May with the aim to get back to the BSWP by September 2017.

2017 EFSPi Regulatory Statistics Workshop * SAVE THE DATE *****

The 2nd **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. Registration will open on the 1st June 2017. Materials from the first workshop can be found [here](#).

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Scientific

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

The first one will be a joined EFSPi/PSDM meeting on “**Statistical Aspects of Safety Data in Clinical Trials**”, to take place on Friday **June 23** in the Netherlands and we aim to focus on three areas: analyses of Adverse Events, Data Monitoring Committees and the presentation of safety data. More details will follow within a couple of weeks.

A second meeting will be on **Advances in Clinical Trial Design** and a third meeting on **Oncology**, both meetings will take place in the second half of 2017.

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EFSPi Statistics Leaders Meeting

The next **EFSPi Statistics Leaders meeting** will take place on the **4th July 2017** hosted by AbbVie in Germany. Topics being debated include the future roles and priorities for statistics groups, collaboration with academia, and data science along with updates of key EFSPi activities and future priority areas for EFSPi.

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Country News

BBS (Switzerland)

BBS Spring Seminar The use of external data for decision making May 5, 2017 Topics for discussion include: future data, uses of future data sources, case study examples, and final recommendations from the IMI GetReal initiative. Click [here](#) for more details on how to register.

PSI (UK)

Statistical Excellence in the Pharmaceutical Industry Award launched Nominations are being sought for the 2017 Award for Statistical Excellence in the Pharmaceutical Industry, jointly run by the Royal Statistical Society (RSS) and Statisticians in the Pharmaceutical Industry (PSI). The award recognises a most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. Nominees can be based anywhere in the world and do not need to be a member of PSI or the RSS. The award will be presented at the Annual PSI Conference which will be held in London from May 14th-17th, 2017. Further information and a nomination form are available on our [main website](#).

Personalised Medicine: Statistics for Companion Diagnostics Webinar Thursday 4th May 14:00 - 15:30 UK time. Personalised medicines - which are designed to treat particular groups of patients - are becoming increasingly prominent. In order to identify patients suitable for treatment a companion diagnostic assay is often needed. The Personalized Medicines Coalition (PMC) recently published an article stating that 25% of NME approved by FDA in 2016 included a companion diagnostic. This webinar will introduce and examine some of the considerations required for statisticians working in the field of companion diagnostics and will include information from an FDA (CDRH) speaker and perspectives/ case-studies from representatives from both a pharmaceutical company and a diagnostic company. Please [click here](#) for more information.

PSI Conference 2017, 14th – 17th May 2017 at the Grange Hotel, London. The theme will be “Celebrating 40 years of promoting statistical insight”. Two keynote speakers include Richard Stephens and David Spiegelhalter, more details can be found on the [website](#). We are also excited to be able to offer the choice of two pre-conference training courses. We also have a number of other plenary and parallel sessions with speakers from industry, academia and regulatory agencies, including Lisa LaVange (Director of the Office of Biostatistics in the Center for Drug Evaluation and Research at the USA FDA).

Estimating Sample Sizes in Clinical Trials Training Course 28 - 29 Jun, 2017, London UK. The course describes calculations for sample size estimation in the design of clinical trials. It will be highlighted how the objectives of a clinical trial will impact on sample size calculations. The course is a practical course and all methods will be illustrated with examples and case studies. Please click [here](#) for more information and to register.

View the replay of the recent webinar by the Benefit-Risk Special Interest Group This webinar is now online and can be viewed [here](#). You can find the abstracts of the presentations with bios of the speakers [here](#).

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.

SSL (Finland)

SSL is organizing Spring meeting on Regulatory statistics, headlined by Christoph Gerlinger, 20th April in Turku. Statisticians in the Estonian pharmaceutical industry are also invited to the meeting. Presentations of the Machine Learning webinar are available on SSL's website <http://sslry.fi/ajankohtaista/>.

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Other news/events

International Biometrics Society (IBS) Channel Network Conference 2017 April 24-26, 2017 The 2017 Channel Network Conference of the International Biometric Society (IBS) will take place at Hasselt University, Campus Diepenbeek, Belgium. This biannual conference is organized by the IBS regions Belgium, France, Great-Britain/Ireland and the Netherlands. This conference aims at gathering biostatisticians to discuss the newest statistical methodology for the analysis of biological and medical data. It is a 3-day conference with 2 courses, invited and contributed sessions. Usually, around 150 researchers from both academia and industry participate in the conference. Final registration is 14th April 2017. Click [here](#) for more details.

InSPiRe Conference 26-28 April 2017 The **InSPiRe** (Innovation in Small Populations Research) project brings together international experts in innovative clinical trial design methodology from across the globe. It focusses on the development of novel methods for the design and analysis of clinical trials in rare diseases or small populations defined, for example, by a rare genetic marker. This conference will present key results from the InSPiRe project and bring together international experts in innovative clinical trial design and analysis to present recent advances in the methodology for clinical trials in small populations. In addition to a series of plenary invited talks, the conference will include two pre-conference courses and poster presentations. Final registration closes 21 April 2017. Click [here](#) for more information.

International Clinical Trials Methodology Conference (ICTMC) 2017 / Society of Clinical Trials Annual Meeting 8th – 10th May 2017 Liverpool, UK The event brings together international colleagues working in clinical trials, including trialists, methodologists, clinicians and allied health professionals. The programme will include three Keynote lectures, and a range of sessions designed to stimulate discussion and engagement during this unique event. Click [here](#) for more details.

Bayes Pharma 2017 Conference The Bayes Pharma 2017 conference is scheduled for 22-25 of May 2017 and will take place at the Faculty of Pharmacy, University of Castilla-La Mancha, Albacete, Spain. The conference is supported by the International Society for Bayesian Analysis (ISBA), Royal Statistical Society (RSS) and the Adolphe Quetelet Society. A web page offering more information on the Bayes Pharma 2017 conference is available at <http://www.bayes-pharma.org>.

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Job Postings

Opportunities exist at the [University Ziekenhuis Brussels](#). 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, 187 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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Chrissie Fletcher
EFSPI Communications Officer

