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

EFSPI Newsletter April 2017

In this newsletter:

CBS – Introducing the Council for Biopharmaceutical Statistics

Where Collaboration Counts

We are excited to introduce the **Council of Biopharmaceutical Statistics (CBS**); a platform that promotes communication and harmonization across leading professional statistical organisations. The CBS was initially conceived approximately 2 years ago, with the leaders from the following organisations subsequently agreeing to form a steering committee, the CBS.

Organisations participating in CBS*

- American Statistical Association Biopharmaceutical Section (ASA BIOP)
- Drug Information Association (DIA) Statistics communities
- European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)
- International Society of Biopharmaceutical Statistics (ISBS)
- Quantitative Sciences in the Pharmaceutical Industry (QSPI)
- Statisticians in the Pharmaceutical Industry (PSI)

*Other statistical organizations with a focus in the development of therapeutic drugs or devices are welcome to join.

Leaders from these organisations have been meeting on a monthly basis to: establish a charter; share the remits and responsibilities of each organization; and develop a platform to share organizational materials including those from current working/expert groups. The expected benefits of the CBS bringing together multiple professional statistical organisations include:

- Increasing collaborations between organizations, for example sharing activities, outputs and perspectives on key statistical topics
- Improving the co-ordination of scientific working groups set up in each organisation, for example scheduling workshops and agendas proposed scientific meetings and conferences
- Prioritising statistical issues that could have a large impact or influence in developing new therapeutics
- Highlighting opportunities for organizations to partner in education events and publications
- Identifying areas of consensus
- Maximising the use of resources available across the member organizations.

For more information about CBS please visit our wiki. Anyone with an interest to participate in the CBS, or with any questions can email Chrissie Fletcher (fletcher@amgen.com) or Steve Wilson (Stephen.Wilson@fda.hhs.gov).

Current CBS participants: Frank Bretz (ASA BIOP), Olga Marchenko (ASA BIOP, Safety WG), Dionne Price (ASA BIOP), Matilde Sanchez-Kam (ASA BIOP), William Wang (DIA, China), Juergen Kuebler (DIA, Europe), Jerry Schindler (DIA, Global), Bruce Binkowitz (DIA North America), Brenda Crowe (DIA, North America), Stephen Wilson (DIA, Scientific Working Group), Chrissie Fletcher (EFSPI), Jie Chen (ISBS), Anna Berglind (PSI), Naomi Givens (PSI), Tim Rolfe (PSI), Mike Hale (QSPI), Jose Phinero (QSPI), David Stock (QSPI).

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Regulatory

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. Specific focus areas include estimands, confidentiality of interim results, subgroups, transparency, and multiplicity. Materials from the first workshop can be found here.

Regulatory guidelines

There are a couple of new draft guidance's for consultation which the regulatory committee is collating comments:

- The EMA published the **Draft guideline on multiplicity issues in clinical trials** intended to provide guidance on how to deal with multiple comparison and control of

type I error in the planning and statistical analysis of clinical trials. From the points to consider document published in 2002, aspects related with multiplicity issues in safety, drug-response studies, secondary endpoints, subgroup analysis and estimation were added or updated, and statistical terms were clarified. **Erika Daly (erika.daly@iconplc.com)** is collating comments on behalf of EFSPI. If you would like to comment, please review and send any comments to Erika using the attached form by **Wednesday May 31 2017.**

- 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 using the attached form by **February 28 2018**.

In addition, please note that the FDA has published the Draft Guidance on **Delayed Graft Function in Kidney Transplant: Developing Drugs for Prevention.** The purpose of this guidance is to assist sponsors in the clinical development of drugs for the prevention of delayed graft function (DGF) in kidney transplantation and although not a stat specific guideline it discusses statistical matters. Electronic comments can be submitted at https://www.regulations.gov before **June 20, 2017**.

Regulatory Committee Goals

The regulatory committee has finalized its goals for 2017 and 2018. The committee will continue to provide a statistical viewpoint on regulatory issues, reviewing regulatory policy and guidelines, form expert groups to discuss issues with the aim of forming an industry consensus to drive debate on future regulatory policy, participate and lead cross-industry initiatives, and engage with statisticians in European regulatory agencies. The committee is contributing to the PSI conference, especially the session on regulatory hot topics scheduled on 17th May in London, as well as the 2nd EFSPI regulatory workshop in Basel October 5-6 2017.

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Scientific

The Scientific Committee is planning for three 1-day scientific meetings in 2017.

The first one will be a joint EFSPI/PSDM meeting on "**Statistical Aspects of Safety Data in Clinical Trials**", to take place on Friday **23 June** in the Netherlands. This meeting will focus on three areas, analyses of Adverse Events, Data Monitoring Committees and the presentation of safety data. Information on confirmed speakers and topics can be found here. Registration for this event is open – use this link to register.

A second meeting will be on **Oncology and Survival Analyses** planned for November in Brussels. A third meeting joint with PSI on **HTA** is planned for the fourth quarter of 2017. More information will follow in future newsletters.

(The planned meeting on Advances in Clinical Trial Design has been rescheduled to early 2018.)

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EFSPI Statistics Leaders Meeting

For the 8th time EFSPI will have its EU Statistics Leaders Forum in 2017. This time in Ludwigshafen, Germany, kindly hosted by AbbVie. The program has been finalized and all session chairs confirmed and it is expected to be a great event again for the Statistics Managers in EU pharma to interact, network and discuss the strategies and choices to be made for the future.

This year the meeting will discuss the role of statistics in decision making, increasing collaboration with Academia, and revisit the workshop outcomes of 2016 to further define strategic directions for EFSPI, the leader's forum and for the statisticians working in the pharmaceutical industry in general. This year time will be devoted to the rise of "Data Science" and there will be a workshop discussing the current developments and how this might affect our environment. We expect over 30 participants again this year and look forward to a very good and interactive meeting.

For those less familiar with this meeting: this one-day meeting organized by EFSPI will consider and discuss the (new) developments in the area of Pharmaceutical Statistics. The forum of Statistics Leaders based in Europe explores how it can best develop our profession and direct and engage itself optimally for the challenges that lie ahead, including the interaction with other professional bodies. The outcome of the meeting will also help direct the strategy for EFSPI.

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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Country News

APF (Germany)

The German Statistics Leaders Meeting took place on Friday, April 28th 2017. Topics discussed included: R in clinical development, software in adaptive designs, continued education in statistics, and data visualization. The fall meeting of APF is planned for Friday, November 24th 2017.

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)

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.

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Other news/events

Completion of IMI GetReal

The GetReal project (www.imi-getreal.eu) completed at the end of March 2017 and has released its policy recommendations relating to real-world evidence. A new RWE Navigator is the best way to view the wide variety of deliverables produced by GetReal. The policy recommendations fall into a number of categories:

- integrity, quality, access and privacy protection of RWD sources;
- guidance on RWE study design, evidence synthesis and interpretation in decision making;

- standards for decision makers' use of RWE in decision making;
- RWE training and education;
- broader involvement of stakeholders, especially patients and healthcare professionals, in RWE generation and use of RWD;
- an emphasis on a joint (regulatory/HTA/payer) scientific advice process; and
- creation of a standing, pan-stakeholder, forum and linking with ongoing initiatives.

More detail on the recommendations can be found on the GetReal website: http://www.imi-getreal.eu/News/ID/80/Policy-recommendations-from-WP1-Policy-Expert-Group-online.

In 2016 a series of webinar's were held presenting the focus areas of GetReal, see the 'Webinar's tab from the GetReal home page to view these webinars and access the presentations.

A report summarising ***Methodological guidance, recommendations and illustrative case studies for (network) meta-analysis and modelling to predict real-world effectiveness using individual participant and/or aggregate data*** is available, click here. A new tool for conducting evidence synthesis and benefit-risk analyses, ADDIS, has been released, click here for more information.

Further dissemination and rollout of new tools, methods and best practices from GetReal is planned during 2017. Anyone wanting more information or has questions about GetReal can contact Chrissie Fletcher (fletcher@amgen.com).

Other Events

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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The World of Statistics

The World of Statistics is comprised of 2, 188 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.

The Statistical Excellence Award for Early Career Writing recognizes the ability of early career statisticians to tell data-driven stories in an entertaining and thought-provoking way. Organized by the Royal Statistical Society (RSS), this award is intended for students or anyone within the first 10 years of their statistical career – whether studying, recently graduated or already working. Entries must be received by midnight on May 29, 2017.

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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 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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Chrissie Fletcher
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