EFSPI

European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter December 2014

In this newsletter:

EFSPI wishes everyone a Merry Christmas

Regulatory Update

2014 has been a busy year for the PSI/EFSPI regulatory committee with the following key events:

- The committee met with CHMP's Biostatistics Working Party at the EMA in London for an in depth discussion of current biostatistics topics. This was the first time that a CHPM working party met with their scientific counterparts from industry.

- The CHMP draft guideline on subgroup analysis was released for consultation. EFSPI commented and was invited for an oral presentation of our comments at a workshop at the EMA in London. Following the EMA workshop a small working group will continue to investigate and discuss aspects relating to statistical methodology and interpretation of subgroup analysis. Of particular interest is how these approaches will relate to the criteria applied to conclude consistency across subgroups. If you have experience and expertise in subgroup analyses and are able to provide active input over the next 6-9 months, please could you contact Aaron Dane at aaron.dane@astrazeneca.com.

- EMA published its final policy on clinical data transparency. Several major comments made by EFSPI and other key stakeholders have been taken into consideration by EMA. At present, the EMA policy only concerns the publication of study reports, clinical summaries and overviews. The transparency for individual patient data will be discussed further between EMA and the stakeholders.

- An expert group on estimands has been set up to provide a discussion forum on this topic and provide input into the ICH E9(R1) working group creating the addendum to E9. The first meeting will take place in mid February 2015.

- An expert group on Post-Authorisation Efficacy Studies (PAES) has been set up to provide a discussion forum on the statistical and methodological issues pertaining to PAES. This group will collaborate with EFPIA and their working group and will support the review of the PAES guidance developed by EMA when it is released for consultation (expected in 2015). If you are interested to join this expert group on PAES please contact Hermann-Josef Huss (hermann-josef.huss@bayer.com).

In 2015, the committee is expecting the FDA draft guidance on multiplicity issues in clinical trials to be released for consultation. The CHMP's Biostatistics Working Party is also working on a Reflection Paper on Statistical Methodology for the Comparative Assessment of Quality Attributes in Drug Development which is also expected to be released for consultation.

Thanks to everyone who supported the committee and contributed to the many activities undertaken in 2014.

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Scientific Update

The EFSPI scientific committee is planning for at least three meetings in 2015; one meeting on ***Dose Finding studies in Clinical Studies*** in April; a second meeting on ***Health Technology Assessments*** together with the BBS in Basel in June 2015, and a third meeting after the summer break on ***Biomarkers & Subgroups***. In addition, we may organize a scientific meeting on ***Estimands and Sensitivity analyses*** in collaboration with the EFSPI expert group (see Regulatory update above).

If anyone has any suggestions of topics for discussion or seeks further information please email Egbert Biesheuvel (egbert.biesheuvel@ziggo.nl).

Asterix (Advances in Small Trials dEsign for Regulatory Innovation and eXcellence)

On 28 **January 2015** from 9.00 – 12.30 hrs, ASTERIX is organizing the Symposium "**Clinical development of drugs for rare diseases**" which is free of charge.

The clinical development of orphan drugs is central, with extensive attention for the patient's perspective. The symposium will conclude with a panel discussion. Our main target group includes young researchers who directly or indirectly are involved in the clinical drug development process, like statisticians.

More information and the program can be found on the website of ASTERIX – http://www.asterix-fp7.eu/news/symposium-clinical-drug-development-for-rare-diseases/. Anyone with any queries relating to Asterix please email Egbert Biesheuvel (egbert.biesheuvel@ziggo.nl).

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SIG of the month – Modelling & Simulation

Founded in 2010, the Modelling and Simulation Special Interest Group is a forum to share knowledge and understanding about statistical modelling and simulation related to pharmaceutical development.

Members of the Modelling & Simulation special interest group:

Chris Campbell (Chair)	Mango Solutions
Michael O'Kelly (emeritus Chair)	Quintiles
Vladimir Anisimov	Quintiles
Ad Theeuwes	Astellas
Vincent Haddad	Amgen
Carl-Fredrik Burman	AstraZeneca
Benoit Beck	Axiosis
Michelle Jones	Covance
Tom Parke	Tessella
Jixian Wang	Novartis

In 2014 Vladimir Anisimov organized a session at the PSI 2014 Conference called "Modelling & Simulation of Clinical Trials". This session consisted of three presentations demonstrating how understanding models through simulation can improve clinical outcomes, enhanced decision making and optimizing trial operations. Michael O'Kelly, Vladimir Anisimov and Vincent Haddad organized a one day event in conjunction with the EMA which discussed: what is needed for principled modelling and simulation; how to avoid poor, ambiguous, unclear or unstated assumptions; what kind of sensitivity analyses are needed; and what standards for modelling and simulation projects would be useful for industry and regulators. The SIG has written and is currently reviewing a Best Practice document for Modelling and Simulation, which will be published early 2015.

Anyone wishing to learn more about the modelling & simulation SIG can contact Chris Campbell (ccampbell@mango-solutions.com).

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Other Upcoming Events

PSI

PSI Training Course: Regulatory Interactions for Statisticians, 11th-12th February 2015, London. The course objective is to inform statisticians about the likely interactions they might have with regulatory agencies, both during a submission and at other times during drug development, and give advice on how to make these interactions most effective, Click here for further details.

PSI Training Course: Cross-over trial in Clinical Research, 4th – 5th March 2015, Heathrow, London. The emphasis is on practical matters: how should one plan and analyse cross-over trials if one is genuinely interested in finding out the effects of treatment. The approach is grounded in practical pharmacological considerations and unrealistic approaches to adjusting for carry-over will be avoided. The examples are all genuine. Click here for further details.

2015 PSI Conference: Relevant Applications in a Changing Environment, 10th - 13th May, London. Registration is now open (early bird registration until the 16th February 2015); if you wish to find out more please click here.

German Region of IBS

61st Conference of IBS, German Region, 15th- 19th March 2014 with sessions on Benefit-Risk Assessments. For more information click here.

DIA/FDA

DIA/FDA statistics forum, Apr 20 - Apr 22 2015, Bethesda, US. Featured topics include Biosimilars/Analytical Similarity Adaptive Design, Bayesian Working Group Feedback, Sentinel Initiative and Postmarketing Surveillance, Statistical Issues Related to Health Technology Assessment, Subgroup Analysis, Benefit-Risk, Estimands and Sensitivity Analyses, and FDA and Industry Town Hall. For more information click here.

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The World of Statistics

The World of Statistics movement has grown to a total of more than 2,356 organizations from countries across the globe. You can view the current participant and country lists by going to The World of Statistics website. To see the events and activities planned for 2015, click here.

The 2015 Channel Network Conference, the biennial conference organized by the Belgium, France, Great Britain/Ireland and the Netherlands regions of the International Biometric Society, will be held April 20-22 in Nijmegen, the Netherlands. The meeting will examine the newest statistical methodology for the analysis of biological and medical data. Registration details and additional information about the 5th Channel Network Conference can be found here.

The American Statistical Association's (ASA) outreach group Statistics Without Borders (SWB) recently joined with the Royal Statistical Society's (RSS) Statisticians for Society (SFS), an initiative that enables statisticians to support charities and other socially useful initiatives on a pro bono basis. Visit the SWB website to get involved.

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Council News

The second face to face Council meeting took place at Orion based in Helsinki, Finland. Mark Morris (PSI) has joined the committee replacing Kevin Carroll. Birgitte Bilmann Ronn (Denmark) is taking over as EFSPI Treasurer from Arne Haahr Andreasen (Denmark). Arne has been treasurer for 6 years and has significantly improved the oversight and financial planning processes supporting EFSPI during this time. Arne will be remaining on Council.

The Special Interest Groups (SIGs) have been very active in 2014. Information about each SIG has been provided on a monthly basis throughout the year. Please refer to previous newsletters on the EFSPI website for information about SIGs, including contact details for SIG leaders. All of the SIGs welcome new members at any time, and individuals who may be interested to join a SIG do not need to be an expert in the topic area(s). Individuals who are motivated to learn about a topic and are keen to actively engage and collaborate with colleagues are very welcome to join a SIG.

The Council wish to thank Francois Aubin for leading the activities relating to the redesign of the EFSPI website. The new website design is a significant improvement over the previous one, with Council members now having more direct control over the content management for the website. The costs of the redesign also remained within the agreed budget. The new website will be launched in early 2015.

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And finally.....

If you are currently seeking to hire a statistician and wish to post a job advert, see the "Advertisements" area on the EFSPI website at www.efspi.org and view the "Job Postings" for instructions. EFSPI are offering one free advert for every 3 adverts posted on the website.

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.

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EFSPI Communications Officer