

EFSPI Newsletter July 2011



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2nd EU Statistics Leaders Meeting

A very successful second meeting of Statistical Leaders within Europe took place on the 8th June. Twenty-one leaders came together to discuss:

“Model-based drug development” The leaders agreed on the need to encourage and embrace estimation and the use of models to aid internal and external decision making. To support this it was agreed that EFSPi would develop a forum to share modeling and simulation methods, code and R tools on the EFSPi website. The EFSPi will investigate organizing scientific meetings to support the application of these techniques and encourage broader membership of the PSI Special Interest group for modeling and Simulation.

“Comparative drug effects & network meta-analysis” This is an area of considerable activity across the industry. EFSPi will use the website to highlight ‘hot topics’ and areas of interest to the Pharmaceutical Statistics community. The HTA network and sig are seeking to connect with various initiatives and external bodies. EFSPi will investigate the possibility of running a virtual meeting on this subject.

“Totality of evidence, can we make better use of resources” It was agreed that there is a place for the use of observational data, but this will not replace randomized control trials. Well designed observational studies are seen to be of particular value in understanding safety issues, aiding study design and increasing understanding of disease areas. There is a growing trend for more companies have statisticians involved in observational data analysis. EFSPi are seeing opportunities to support this area via Special Interest Groups, and communication of information.

“Accreditation of pharmaceutical statisticians” There was a lively debate on accreditation and key areas of discussion, where the definition of ‘Pharmaceutical Statistics’ the desire to avoid duplication with other bodies by some form of mutual recognition and the potential benefit of accreditation. The EFSPi council agreed to summarize the current position and use that information in contacts with other professional bodies.

Updates were also provided on the topics discussed at the previous meeting last year: The **EFSPi/PSI Health Technology Assessment (HTA) SIG** have been busy writing 3 manuscripts for the Pharmaceutical Statistics journal on key hot topics, including network meta-analyses, subgroup analyses in HTA, and utility measures used in economic modeling. Confirmation was obtained at the meeting that an **EFSPi benefit-risk SIG** will be initiating soon under the leadership of Ian Hirsch (AstraZeneca). Companies have also committed to continue supporting the development of materials on **Career Paths for Statistical Leadership in the Pharmaceutical Industry**, led by Hans-Ulrich Burger (Roche).

All the materials for the first and second EFSPi Statistics Leaders meeting can be accessed via the EFSPi website: www.efspi.org under “EFSPi Activities/Statistics Leaders Meetings”.

A huge thank you to Lesley France (email: Lesley.France@AstraZeneca.com) for organizing the EFSPi Statistics Leaders meeting.

Highlights of the EFSPi Council Meeting

The EFSPi council meeting took place on 9th June 2011. Seven countries were represented by 11 delegates

Chrissie Fletcher was appointed the next Vice-President, effective at the next EFSPi Council meeting in December 2011. A big thank you to Nigel Howitt for finishing his Vice-President role. Nigel is remaining on the council as the chair for Scientific Affairs.

Kit Roes and Lesley France are standing down from the EFSPi Council. A tremendous thank you to Kit for dedicating the last 9 years to the council, and to Lesley for dedicating the last 6 years to the council. Kit was instrumental for his work on Scientific Affairs and representing EFSPi on the EFPIA efficacy working party in addition to his involvement as the President and Vice-President on the Council. Lesley championed the concept, planning, and successful implementation of the EFSPi Statistics Leaders meetings, and introduced an efficient review process across EFSPi for new draft regulatory documents in addition to Chairing Regulatory Affairs.

Following the presentation by Egbert Bieheuvel on the "Accreditation of pharmaceutical statisticians" project, including the feedback from the discussion at the Statistics Leaders Meeting, it has been decided not to continue working on this topic for the time being.

New EFSPi Special Interest Groups (SIGs)

EFSPi are pleased to announce a new SIG on Benefit-Risk will be formed. Those individuals who previously volunteered to join this SIG will soon be contacted to participate in a SIG kick-off meeting. Additional individuals are also welcome to volunteer, interested parties should contact Ian Hirsch (email: Ian.Hirsch@AstraZeneca.com).

EFSPi are also pleased to announce the current PSI SIGs on Modelling & Simulation, and Epidemiology & Safety will be expanded to include EFSPi interested parties. Anyone wishing to join either of these SIGs can contact Michael O'Kelly (email: michael.okelly@quintiles.com) for the Modelling & Simulation SIG, and George Quartey (email: george.quartey@roche.com) for the Epidemiology & Safety SIG.

Scientific Affairs

The European Statistical meeting on **Advances in the Treatment of Missing Data** is being organized by EFSPi, SBS/BVS (Belgium) and PSDM (Netherlands) and PSI (UK). The meeting will be held in Brussels on Friday 18th November 2011. Presenters include: Geert Molenberghs, Mike Kenward, James Roger, David Wright (MHRA), Michael O'Kelly. Please make a note in your calendars. Registration for the meeting (via the EFSPi website) will open in July.

Regulatory Affairs

The European Medicines Agency and the [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance](#) (ENCePP) have published the [ENCePP guide on methodological standards](#)

[in pharmacoepidemiology](#), an important tool that reviews and gives direct electronic access to the main existing methodological guidance for research in pharmacoepidemiology and pharmacovigilance.

Other News

If you want to hire a statistician, EFSPI is offering the first three adverts free on its website. If you are interested, go to the "Advertisements" area on the EFSPI website at www.efspi.org and view the "Job Postings" for more information.

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 at www.efspi.org.

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