



European Federation of Statisticians in the Pharmaceutical Industry
Promoting Professional Standards in Europe

EFSPI Newsletter April 2012

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Scientific Meetings

The following EFSPI scientific meetings are planned in 2012:

- Benefit and Risk Assessment Methodology Workshop (June 7, 2012), partnering with the Swedish Society for Medical Statistics (FMS) and the Danish Society for Biopharmaceutical Statistics (DSBS). For registration and more information on this workshop , please see the EFSPI website www.efspi.org.
- Modelling & Simulation (Sept 13, 2012), partnering with the Modelling & Simulation SIG.
- Subgroup analyses (Nov 30, 2012), this meeting will take place in Brussels. Key opinion leaders from regulatory agencies, academic institutes and industry will be speaking.

Regulatory Update

The FDA has published their workplan for 2012:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079647.pdf?source=govdelivery>. A new guideline on multiple endpoints is planned.

The EMA has released a new concept paper on the need to revise the points to consider on adjustment for baseline covariates:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/02/WC500123464.pdf

EU Statistics Leaders Meeting

The 3rd EU Statistics Leaders meeting will cover areas relating to risk-benefit, observational research, and the impact of the evolving R&D business model to the EU statistical community. If anyone has any specific questions relating to these areas for consideration then please email Stefan Driessen: stefan.driessen@abbott.com.

A reminder that all the materials from the previous 2 EU Statistics Leaders meetings held in 2010 and 2011 are available on the EFSPi website:

<http://www.efspi.org/index.php?p=EFSPi%20activities&fid=399>

Update on Special Interest Groups (SIGs)

The new Benefit-Risk SIG recently had their kick-off meeting in Feb 2012 and is currently organising the next meeting where key topics for future meetings will be decided. Therefore new members are still welcome, so please contact Ian Hirsch (email: Ian.Hirsch@AstraZeneca.com) if you are interested in joining this SIG.

Anyone wishing to view any materials from any of the SIGs please see the EFSPi website www.efspi.org.

News from National Groups

The PSI Introduction to Industry Training Course is now accepting applicants for the 2012/2013 session. The course is open to both statisticians and statistical programmers in the pharmaceutical industry. The next course starts in October 2012, and there are limited places available. Application forms must be received by 1st June 2012. For further information or an application form please see the PSI website: <http://www.psiweb.org/index.php?p=resources&fid=25> or contact Helen Christie at helen.christie@ppdi.com for more information.

For further news from each national organization, please see the EFSPi website: www.efspi.org.

EFSPi Council News

The EFSPi Council had a teleconference meeting on the 1st March 2012. The EFSPi constitution was reviewed and updated.

The "Who's EFSPi" slide deck is available on the EFSPi website www.efspi.org. The information provides a summary of the mission and vision of EFSPi, which country associations are members of EFSPi, who sits on the Council and the specific roles individuals have which support EFSPi.

In late 2011, EFSPi along with PSI have initiated a new collaboration with a US-based Statistics group, QSPI. QSPI stands for 'Quantitative Sciences in the Pharmaceutical Industry'. They are associated to the Society of Clinical Trials (SCT) and were previously known as the PhRMA BDMTG (Biostatistics and Data Management Technical Group). EFSPi and QSPI are keen to identify areas for collaboration, for example, engaging in the review or new or updated regulatory guidelines. A representative from QSPI will participate in the next EFSPi Council meeting and provide an update on the key goals and activities QSPI will be focusing on in 2012.

Also in late 2011, EFSPi along with PSI have initiated a new collaboration with ISPOR, the International Society of Pharmacoeconomics and Outcomes Research. There are ongoing discussions to identify opportunities for the societies to collaborate, which could include areas relating to scientific meetings and training courses. The HTA SIG has been working with some ISPOR members on specific activities. This outreach by EFSPi and PSI to ISPOR is aimed at seeking areas of mutual interest across both societies given the increased collaboration in Pharmaceutical companies between Health Economics/Outcomes Research and Biostatistics disciplines. More details will follow in future newsletters.

Carl-Fredrik Burman (FMS representative) has stepped down from the council after serving 7 years. EFSPi greatly appreciates the contributions Carl-Fredrik has made over this significant time period. John Adler will be replacing Carl-Fredrik. EFSPi would also like to thank the contributions of Franseca Patarnello (BIAS) and Tom Loes (SBS/BVS) who also have stepped down from the Council, and welcome their replacements, Giampaolo Giacobelli and An Vandenbosch respectively.

Other News

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 at www.efspi.org.

To view previous newsletters please see the EFSPi website www.efspi.org.

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