

# EFSPI Newsletter October 2011



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## EFSPI Council News

In September 2011 EFSPi has written to numerous national statistical associations to invite them to join EFSPi as part of its efforts to increase the membership of EFSPi. Currently 10 national statistical associations are EFSPi members, see website for further information:

<http://www.efspi.org/index.php?p=information+on+EFSPi&dw=member+groups>

Whilst EFSPi agreed in July not to pursue an accreditation scheme for Pharmaceutical Statisticians, discussions are ongoing with other associations who have accreditation schemes, such as the RSS in the UK, and ASA in the US, to understand how the schemes operate and to continue to gather information. If anyone has any specific opinions, please contact Egbert Biesheuvel [Egbert.biesheuvel@merck.com](mailto:Egbert.biesheuvel@merck.com).

## EU Statistics Leaders Meeting Materials

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 EFSPi Special Interest Groups (SIGs)

As a reminder anyone wishing to join the new SIG on benefit-risk, currently being formed, please contact Ian Hirsch (email: [ian.hirsch@AstraZeneca.com](mailto:ian.hirsch@AstraZeneca.com)).

Anyone wishing to join any of the following EFSPi/PSI SIGs can contact the respective SIG leader:

Modelling & Simulation SIG, leader= Michael O'Kelly (email: [michael.okelly@quintiles.com](mailto:michael.okelly@quintiles.com))

Epidemiology & Safety SIG, leader= George Quartey (email: [george.quartey@roche.com](mailto:george.quartey@roche.com))

Health Technology Assessment SIG, leader = Chrissie Fletcher (email: [fletcher@amgen.com](mailto:fletcher@amgen.com))

## Upcoming Scientific Meetings

The upcoming meeting in Advances in the treatment of missing data (18-Nov-11) is nearly fully booked, last few places remaining.

For 2012 the following meetings are being planned:

Benefit and risk (June 2012)

Modelling & simulation (Sept 2012)

Subgroup analyses (Nov 2012)

## Regulatory Update

EFSPI commented on the EMA's Reflection paper on methodological issues associated with pharmacogenomic biomarkers in relation to clinical development and patient selection. Many thanks to Jon Blatchford, UK, Niclas Sjögren, Sweden, Richard Vonk, Germany, Kristian Madsen Windfeld, Denmark, and their countries' contributors for providing their comments and for the final round of discussions. The comments are posted on the EFSPI website:

<http://www.efspi.org/index.php?p=publications&fid=44>.

In November the EMA will be holding a workshop that will discuss the role of subgroups in the assessment of clinical trials, discuss standards and methods for planning conducting and reporting 'confirmatory' as well as 'exploratory' subgroup analysis. EFSPI has been invited and will participate.

In late November/Early December the EMA and EFPIA are sponsoring a workshop on modelling and simulation to discuss the role and scope of modelling and simulation in drug development, both from the developer's and the regulator's perspectives. Representation from the EFSPI/PSI modelling and simulation SIG will be participating in this workshop.

## 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](http://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](http://www.efspi.org).

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