



EFSPI Annual Report 2011

1. Highlights

- EFSPI reviewed draft EMA reflection papers on "*Use of active controls in clinical trials where placebo is deemed ethical*" and "*Methodological issues associated with pharmacogenomic biomarkers in relation to clinical development and patient selection*".
- EFSPI held one scientific meeting: a joint meeting with PSDM, BVS and PSI on *Advances in the Treatment of Missing Data*, in Belgium on 18 November 2011
- EFSPI organized the second session of their Statistical Leaders Meeting in June 2011 in Uxbridge UK, to continue developing the network of statistical leaders, shape and influence our professional environment and help to shape the strategy for EFSPI.
- EFSPI distributed four quarterly newsletters throughout the year.
- At the November Council meeting, Chrissie Fletcher (UK) took over the Vice-Presidency from Nigel Howitt (UK).
- Despite a small financial loss this year, the financial position at the end of 2011 remains sound.

2. Regulatory Affairs

EFSPI commented on two EMA draft guidance documents:

- The draft reflection paper on "*Use of active controls in clinical trials where placebo is deemed ethical*". EFSPI also participated in an EFPIA working group reviewing this paper.
- The draft reflection paper on "*Methodological issues associated with pharmacogenomic biomarkers in relation to clinical development and patient selection*".

The comments from EFSPI on these two documents are posted on the EFSPI website: <http://www.efspi.org/index.php?p=publications&fid=44>

Christoph Gerlinger (Germany) is the chair of the Regulatory Affairs Committee.

3. Scientific Affairs

EFSPI held one European Statistical meeting in 2011, *Advances in the Treatment of Missing Data*: a joint meeting with PSDM, BVS and PSI, in Waterloo, Belgium, on 18 November 2011. The meeting was a great success and the presentations were well received.

More information on this meeting is available on the website:

<http://www.efspi.org/index.php?p=EFSPI%20ACTIVITIES&fid=407>

Nigel Howitt is chair of the Scientific Affairs Committee.

4. Communications

Four newsletters were distributed in April, July, October and December 2011.

Communications efforts focused on updating the website with support from the EFSPI administration office, increasing communications with other organisations, and increasing advertising of EFSPI events.

The website can be found at: <http://www.efspi.org/>

Chrissie Fletcher (UK) is the Communication Officer of EFSPI

5. EFSPI Statistical 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
- Comparative drug effects & network meta-analysis
- Totality of evidence, can we make better use of resources
- Accreditation of pharmaceutical statisticians

Updates were also provided on the topics discussed at the previous meeting last year (Health Technology Assessment, Assessment of Risk Benefit, Career Paths for Statistical Leadership in the Pharmaceutical Industry).

Information on the Statistical Leaders Meeting is available at

<http://www.efspi.org/index.php?p=EFSPI%20ACTIVITIES&fid=401>

6. Special Projects

6.1 Expansion of EFSPi

The membership of EFSPi remains at 10 member countries.

EFSPi continues their efforts to identify statistical groups outside of the EFSPi regions. 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.

5.2 Special Interest Groups

During 2011, a new EFSPi SIG on Benefit-Risk was formed and two PSI SIGs (Modelling and Simulation and Epidemiology and Safety) were expanded to include EFSPi interested parties, raising the number of EFSPi SIGs to seven:

- Benefit-Risk
- Biomarker
- Epidemiology and Safety
- Health Technology Assessment (HTA)
- Medical Devices
- Modelling and simulations
- Toxicology

5.3 Accreditation of statisticians

EFSPi has considered developing a proposal regarding the introduction of a European professional level accreditation for pharmaceutical statisticians. Currently a variety of national statistical associations have accreditation for statisticians, which aims to set standards but no European system exists and no national system focuses exclusively on pharmaceutical statisticians. A European wide accreditation system would enable a standard to be defined for statisticians working in the Pharmaceutical Industry, and be based on relevant education and professional experience. This was discussed at the Statistical Leaders meeting and at the first Council meeting. Following these discussions, it has been decided not to continue working on this topic for the time being.

6. Operations Board

At the June 2011 Council meeting, Chrissie Fletcher (UK) was elected the next Vice-President and she took over the Vice-Presidency from Nigel Howitt (UK) at the December Council meeting. Nigel Howitt was thanked for his activities as a President and Vice-President. He remains on the Council as the chair for Scientific Affairs.

7. Council membership

In 2011, 10 countries were represented within EFSPi, each represented by their national association of pharmaceutical statisticians, with a combined membership of more than 2800.

During 2011, Tom Loeys (Belgium), Klaus Olsen (Denmark), Kit Roes (The NL) and Lesley France (The UK) left the Council and were replaced by Charlotte Hindsberger (Denmark), Stefan Driessen (The NL) and Chrissie Fletcher (The UK). The delegate position for Italy left vacant in 2010 was filled by Francesca Patarnello. One new delegate is to be designed by Belgium.

Members of the EFPSI Council at the end of 2011 are given in the Appendix.

9. Council meetings

Two Council meetings were held in 2011. The first took place in Uxbridge, UK on 9th June. Seven countries were represented with 11 delegates. The second was held in Oss, The Netherlands, on 6th December. Six countries were represented with 9 delegates.

Two web conferences took also place between the face-to-face meetings in March and October 2011.

10. Executive Office

The Executive Office facility is still provided by Kingston Smith (UK). Jenny Butterworth has been replaced by Julie Mellish as Secretariat for the EFSPi Association.

11. Finances

A loss of about ten thousand Euros occurred in 2011. Fortunately this loss was covered by the EFSPi reserves and the EFSPi finances remain sound. The council has reviewed options for minimising expenses in 2012 given the continued tough economic climate, and for keeping membership and meeting fees cost-effective.

12. Constitution

The EFSPi constitution has been updated to include a reference to the new treasurer role introduced a year ago, plus some minor administrative changes. The updated constitution will be submitted to each member country for formal approval.

APPENDIX: Members of the EFSPi Council at the end of 2011

Belgium

Emmanuel Quinnaux, IDDI
Vacant position

Denmark

Arne Haahr Andreasen, Andreasen Statistical Consulting
Charlotte Hindsberger, NovoNordisk

Finland

Tiina Hakonen, Encorium Oy
Toni Sarapohja, Orion Pharma

France

Francois Aubin, Cardinal Systems
Francoise Tondu, Danone Research

Germany

Joachim Roehmel, Academic
Christoph Gerlinger, Bayer

Italy

Paolo Morelli, Cros IT
Francesca Patarnello,

Netherlands

Stefan Driessen, Abbott
Egbert Biesheuvel, MSD

Sweden

Carl Fredrik Burman, AstraZeneca
Marie Göthberg, Novo Nordisk

Switzerland

Fred Sorenson, Genesis BioPharma Group
Hans Ulrich Burger, Hoffmann-La Roche

UK

Nigel Howitt, PRA International
Chrissie Fletcher, Amgen