



EFSPI Annual Report 2010

1. Highlights

- EFSPI reviewed FDA Guidelines on Adaptive Design Clinical Trials for Drugs and Biologics and Non-Inferiority Clinical Trials.
- EFSPI held three scientific meetings:
 - Joint meeting with MHRA, Statistics at the frontier of drug development, March 2010 in London
 - Joint meeting with BBS, Innovations in Early Oncology Studies, June 2010 in Basel.
 - Joint meeting with SFdS-Biopharmacie et Santé, European Statistical Meeting, November 2010 in Paris
- EFSPI organized a Statistical Leaders Meeting in May 2010 in Berlin, to develop a network of statistical leaders, shape and influence our professional environment and help to shape the strategy for EFSPI.
- Chrissie Fletcher (UK) took over the newly created role of 'Communication Officer'
- Arne Andreasen (Denmark) took over the newly created role of EFSPI Treasurer
- François Aubin (France) took over the Presidency from Nigel Howitt (UK), who became the new Vice-President.
- Financial position at end of 2010 remains sound

2. Regulatory Affairs

The new regulatory review process (with a network of reviewers from the main European National groups, supplemented by ad-hoc experts) has proven to work well.

During 2010, EFPSI provided consolidated responses to two FDA documents:

- *Adaptive Design Clinical Trials for Drugs and Biologics*. Carl Fredrick Burman kindly coordinated the review on behalf of EFSPI
- *Non-Inferiority Clinical Trials*, which review has been coordinated by Bernhard Huitfeldt

Christoph Gerlinger (Germany) has replaced Lesley France as chair of the Regulatory Affairs Committee.

3. Scientific Affairs

EFSPI held three scientific meetings:

- Joint meeting with MHRA, Statistics at the frontier of drug development, 29-30 March 2010 in London
- Joint meeting with BBS, Innovations in Early Oncology Studies, 24 June 2010 in Basel.
- Joint meeting with SFdS-Biopharmacie et Santé, European Statistical Meeting, 18-19, November in Paris

Nigel Howitt has replaced Kit Roes as chair of the Scientific Affairs Committee.

4. Communications

A new 'Communications Officer' role was established in September 2010 with the remit to:

- Distribute quarterly newsletters (coordinated around council meetings)
- Roll out and utilize e-mail broadcaster to advertise EFSPI events
- Ensure the website remains up to date and assess opportunities to increase advertising
- Liaise with other organisations

Chrissie Fletcher (UK) took over this role in October 2010 and following the Council meeting held in November 2010, a newsletter for Q4 2010 was distributed. A key focus in 2011 will be to update the website with support from the EFSPI administration office, increase communications with other organisations, and increase advertising of EFSPI events.

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

5. Special Projects

5.1 Expansion of EFSPI

The membership of EFSPI remains at 10 member countries.

EFSPI is currently working on a project to identify statistical groups outside of the EFSPI regions, with a view to future expansion, following recent political union in the EU.

Egbert Biesheuvel (The NL) is leading this project for EFSPI

5.2 EFSPI Statistical Leaders Meeting

EFSPI held its inaugural Statistical Leaders Meeting in Berlin on 26th May 2010. The organising group for the meeting consisted of: Stephen Pyke, Thorkild Nielsen, Per Larsson and Lesley France. The purpose of the meeting was to develop a network of statistical leaders, shape and influence our professional environment and help to shape the strategy for EFSPI. Many statistical leaders from Pharmaceutical and CRO companies attended. The main topics for the event were:

- Professional Development for Statisticians
- Assessment of Risk Benefit
- Health Technology Assessment (HTA)

A second meeting is planned on 7th June 2011

5.3 Special Interest Groups

EFSPI has decided to promote international participation to its national member associations SIGs. Following this decision, four SIGs have expressed their interest in opening to other country participants:

- The PSI SIG on Health Technology Assessment (HTA) SIG. Anyone interested in joining this SIG can contact Chrissie Fletcher (email: fletcher@amgen.com).
- The PSI SIG on benefit-risk
- The PSI SIG on Modeling and simulations
- The SFdS SIG on Medical Devices

EFSPI members wishing to become members of these SIGs should contact the EFSPI administrative office: EFSPI@kingstonsmith.co.uk

5.4 Accreditation of statisticians

EFSPI is looking into setting up an accreditation scheme for pharmaceutical statisticians in the EU. A working group has been set up, chaired by Egbert Biesheuvel (the NL). A proposal is currently being developed.

6. Operations Board

At the November 2010 Council meeting, in Paris France, François Aubin (France) took over the Presidency from Nigel Howitt (UK), who became the new Vice-President.

Two new board positions were opened to improve operations:

- Treasurer: Arne Andreasen (Denmark) volunteered to become the EFSPI Treasurer
- Communications Officer. Chrissie Fletcher (UK) was assigned as the first Communications Officer.

7. Council membership

In 2010, 10 countries were represented within EFSPI, each represented by their national association of pharmaceutical statisticians, with a combined membership of more than 2800. Members of the EFPSI Council at the end of 2010 are given in the Appendix.

9. Council meetings

Two Council meetings were held in 2010. The first took place Basel, Switzerland in June to coincide with the European Statistical Meeting on Oncology, co-organised with BBS. The second was held in Paris, France, in November, just before the Joint European Statistical Meeting with

SFdS-Biopharmacie et Santé. The majority of countries attended each meeting and a quorum was achieved.

Following the decision taken in 2009, the number of council meetings was increased from 2 to 4 in 2010, with two web conferences in addition to the two face-to-face meetings. The web conferences were introduced as a means of improving communication to the council members outside of the council meetings.

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

EFSPi finances remain sound. As such, it was agreed not to increase the Membership Subscription fees in 2010.

APPENDIX: Members of the EFSPI Council at the end of 2010

Belgium

Emmanuel Quinnaux, IDDI

Tom Loeys, Merck

Denmark

Arne Haahr Andreasen, Andreasen Statistical Consulting

Klaus Olsen, Larix

Finland

Tiina Hakonen, Encorium Oy

Toni Sarapohja, Orion Pharma

France

Francois Aubin, Cardinal Systems

Francoise Tondou, Danone Research

Germany

Joachim Roehmel, Academic

Christoph Gerlinger, Bayer

Italy

Paolo Morelli, Cros IT

1 vacancy

Netherlands

Kit Roes, Julius Center, University Medical Center Utrecht

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

Lesley France, AstraZeneca