



EFSPI Annual Report 2008

Highlights

- EFSPI continued its strategy to organize joint meetings with its national groups. A joint conference with PSI was held in May 08 in Brussels and a joint 1 day meeting on Non-inferiority was held in Nov 08 in Verona. Both events were very successful.
- EFSPI reviewed Reflection Paper 'Recommendation for revision of the points to consider on missing data' and the CHMP Guideline on the Investigation of Bioequivalence
- The Regulatory Review process has been streamlined to avoid repetition. The goal is to provide one set of consolidated and focused comments, which represent the overall European Statistical Community.
- PSI and EFSPI published in BMJ calling for the Regulatory Agencies in Europe to increase their statistical support. This letter was then followed by a session at the PSI/EFSPI conference in May 2008 to discuss the topic in detail - with the CHMP Chair Eric Abadie and a senior EMEA official Hans-Georg Eichler in attendance
- A new constitution was agreed by the EFSPI Council in order to streamline EFSPI business and to indicate EFSPI's position as a non-profit organization
- Financial position at end of 2008 remains sound

Regulatory affairs

There were two statistical documents reviewed by EFSPI during 2008. They were the Reflection Paper 'Recommendation for revision of the points to consider on missing data' and the CHMP Guideline on the Investigation of Bioequivalence. The review of the Bioequivalence document involved a pan European expert review committee of all the submitted comments, enabling EFSPI to submit a high quality set of consistent comments.

Kit Roes is now a member of EFPIA and he is investigating how we can develop best review practice across the industry ensuring appropriate statistical review of comments on documents with substantial statistical content.

In 2009 we are preparing for the revisions to the CHMP document on missing data and the CDER Adaptive Designs and Non-Inferiority Guidances that are expected to be issued during 2009.

Scientific Affairs

EFSPI continued its new strategy to organise joint meetings with its national groups. The joint PSI/EFSPI meeting in Brussels was the highlight of the year. The conference attracted a broad

European audience and was rated very positively by its participants. Following a commentary in the Lancet, non-inferiority designs were debated in Italy. Together with the Italian national organisation (BIAS), the "European Statistical Meeting on non-inferiority" was held on November 20th in Verona with participants from industry, regulatory and academia. It provided definite openings to bridge the apparent opposing views at the start.

Furthermore, preparations started for upcoming 2009 meetings. These may include a joint meeting with MHRA, a joint meeting with the Finnish and Swedish national groups and with the Swiss national group.

Web-facilities

The new website became live in early 2008. It looks very professional and is easier to maintain. EFSPI's website is an important asset, which offers easy access to information and important links for our member organisations. The site can be found at: <http://www.efspi.org/>

External Affairs

There were no changes in EFSPI which still represents 10 member countries. However, changes were made to the EFSPI constitution to make it easy for country to become initially involved affiliate members. More efforts need to be made in 2009 to extend out-reach to potential new member states, either as full or affiliate members. A poster summarizing the objectives of EFSPI, and advantages associated with membership, was prepared and displayed at the ISCB meeting in Copenhagen, and is planned to be displayed at future statistical meetings / conferences in order to help spread the word and raise awareness about EFSPI.

Qualification Affairs

EFSPI's paper on "Qualified Statisticians in the European Pharma Industry: Present and Future Directions" was accepted by DIA's Journal and will be published in the future.

Lack of statisticians employed by EU Regulatory Agencies

In February 2008, PSI and EFSPI published in the BMJ calling for the Regulatory Agencies in Europe to increase their statistical support [Hughes S et al. European regulatory agencies should employ full time statisticians. BMJ 2008; 336: 250.]. This letter was then followed by a session at the PSI/EFSPI conference in May 2008 to discuss the topic in detail - with the CHMP Chair Eric Abadie and a senior EMEA official Hans-Georg Eichler in attendance. As a next step to this initiative, a joint PSI/EFPSI position paper was developed on the topic. The paper was subsequently endorsed by EFPIA. PSI/EFSPI have sent the position paper to EMEA and have requested a meeting with the EU Agency Heads at a forthcoming Heads of Agencies meeting on the topic.

Council membership

In 2008, 10 countries were represented within EFSPI, each represented by their national association of pharmaceutical statisticians, with a combined membership of around 2800. Members of the EFPSI Council at the end of 2008 are given in the Appendix.

Council meetings

Two Council meetings were held in 2008. The first took place Brussels, Belgium in May (held in conjunction with the Joint Conference) and the second was held in Verona, Italy in November (held in conjunction with the 1 day meeting). A total of 12 council members (excluding RfA) attended the June meeting, representing 10 countries. Similarly, 11 council members attended the December meeting, representing 10 countries.

Constitution

The new constitution was agreed by the EFSPI Council. It was developed to streamline EFSPI business and to indicate EFSPI's position as a non-profit organization. The organization now has an Operational Committee, which meets via TC on a monthly basis to move the organization forward.

Executive Office

The Executive Office facility continues to be provided by Resources for Associations at Macclesfield (UK). Jenny Butterworth is now in place as the Association Manager for EFSPI.

Finances

EFSPI finances have much improved in recent years. The accounts for 2007 are not yet final, but a reasonable surplus is anticipated following two successful scientific events (Conference in May and 1-day meeting in November).

It was agreed by the council to increase the overall income from membership fees in 2009 by 5%.

APPENDIX: Members of the EFSPI Council at the end of 2008

Belgium

Emmanuel Quinnaux, IDDI

Tom Loeys, Merck

Denmark

Arne Haahr Andreasen, Andreasen Statistical Consulting

Klaus Olsen, Larix

Finland

Britt-Marie Lindström, Oy 4Pharma Ltd

Toni Sarapohja, Orion Pharma

France

Francois Aubin, Cardinal Systems

Francoise Tondu, Danone

Germany

Joachim Roehmel, Academic

Christoph Gerlinger, Bayer

Italy

Francesca Patarnello, GlaxoSmithKline

Paolo Morelli, Cros IT

Netherlands

Gonnie van Osta, Schering-Plough

Kit Roes, Schering-Plough

Sweden

Carl Fredrik Burman, AstraZeneca

Mikael Astrom, AstraZeneca

Switzerland

Gerd Rosenkranz, Novartis Pharma AG

Fred Sorenson, Analytica International, European Office

UK

Nigel Howitt, PRA International

Lesley France, AstraZeneca