



# EFSPI Annual Report 2007

## Highlights

- Successful meeting held with BBS on Adaptive Designs.
- EF SPI and PSI wrote an open letter to EU Regulatory Agencies concerning the lack of statisticians employed by the EU Agencies.
- New website is complete and is close to release
- Financial position remains sound

## Regulatory affairs

There were no major statistical documents issued that EF SPI reviewed during 2007. Attempts were made to review several disease area and safety documents but it proved difficult to obtain a representative review across Europe. As a result it has been decided to concentrate our efforts on statistical documents.

On a more positive note Merete Jørgensen represented EF SPI at the EMEA meeting on the Clinical Trials Directive and we were also represented at the EMEA meeting on Adaptive study Designs.

In 2008 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 2008.

## Scientific Affairs

EF SPI's new strategy is to organise joint meetings with its national groups, and it no longer contributes to the DIA Statistical Workshops. In June 2007, EF SPI held a joint meeting with the BBS on Adaptive Designs in Basel. The meeting was a great success and was well attended by 75 delegates and presenters. It was also profitable for the two organizations and BBS are very keen to arrange future meetings with EF SPI.

Preparations for the joint conference with PSI in Brussels in May 2008 are also going well. EF SPI is also helping in the organisation of a joint meeting with PSI on Missing Data, and is looking to arrange another joint meeting in 2008.

## **Web-facilities**

The website is now complete and will become live early 2008. The new site looks very professional and will be much easier to maintain. It is also possible to advertise on the site. EFSPi's website is an important asset, which offers easy access to information and important links for our member organisations.

## **Qualification Affairs**

Zoe Williams attended the second Council Meeting to gain feedback on her "Qualification of Statisticians" paper. Zoe hopes to finalise this in early 2008. The paper will be submitted to the Pharmaceutical Statistics with a view to publication.

## **Lack of statisticians employed by EU Regulatory Agencies**

PSI and EFSPi wrote an open letter to the regulators which highlighted the need for more statisticians to be employed by the EU Regulatory Agencies. This has been submitted to the BMJ (British Medical Journal) for publication. Many of the council members signed the open letter including the President and Vice-President. It should be published in early 2008.

## **Council membership**

In 2007, 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 2007 are given in the Appendix.

Merete Jørgensen stood down from the Council and was thanked for her long standing, exceptional and valuable contribution to EFSPi over a very long period of time, including her successful Presidency.

At the December 2007 Council meeting, in Reading UK, Nigel Howitt took over the Presidency from Kit Roes, and Kit became the new Vice-President.

## **Council meetings**

Two Council meetings were held in 2007. The first took place Lorrach, Germany in June (held in conjunction with the Adaptive Designs Meeting in Basel) and the second was held Reading UK in December. A total of 10 council members (excluding RfA) attended the June meeting, representing 7 countries. Similarly, 11 council members attended the December meeting, representing 7 countries.

## **Constitution**

In order to streamline our business and to indicate EFSPi's position as a non-profit organization, the constitution has been revised. It should be finalized in early 2008. 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). Laura Kennedy and Helen King from RFA were replaced by Dan Hollingshurst during summer 2007.

## **Finances**

The accounts for 2006 were prepared by Page Kirk chartered accountants and approved by the honorary auditors. The account advised that EFSPi were not liable for Corporation Tax.

Income in 2006 well exceeded budgeted income mainly due to income from the successful Adaptive Randomisation course and the increased surplus from the joint meeting with PSI. Budgeted income for 2006 was €15742, actual income was €33120 leaving a surplus carried forward to 2007 of €16931. EFSPi closed 2006 with cash in hand of €21291.61. The accounts for 2007 are currently being prepared.

A new fee structure for the national organisations has been proposed for 2008. The total revenue from the fees will increase by 3%.

## **APPENDIX: Members of the EFSPI Council at the start of 2007**

### **Belgium**

Cecile Dubois, UCB S.A. Cecile Dubois  
Catherine Legrand, Merck Sharp & Dohme (Europe), Inc.

### **Denmark**

Merete Jorgensen, Novo Nordisk A/S  
Arne Haahr Andreasen, Andreasen Statistical Consulting

### **Finland**

Britt-Marie Lindström, Oy 4Pharma Ltd  
Toni Sarapohja, Orion Pharma

### **France**

Florence Casset-Semanaz, Glaxo Smith Kline Serono  
Francois Aubin, Laboratoires Fournier

### **Germany**

Joachim Roehmel  
Frank Langer, Lilly Deutschland GmbH

### **Italy**

Francesca Patarnello, GlaxoSmithKline

### **Netherlands**

Gonnie van Osta, Organon  
Kit Roes, Organon

### **Sweden**

Carl Fredrik Burman, AstraZeneca  
Mikael Astrom, Clinical Data Care

### **Switzerland**

Gerd Rosenkranz, Novartis Pharma AG  
Fred Sorenson, Analytica International, European Office

### **UK**

Nigel Howitt, PRA International  
Lesley France, AstraZeneca