

## **EFSPI Annual Report 1997**

### **Council membership**

There are ten countries within EFSPI, each represented by their national association of pharmaceutical statisticians, with a combined membership of over 2000. Each national association has two representatives on the EFSPI Council. Membership at the end of 1997 consisted of the following

#### **Belgium**

Annick Leroy, Bristol-Myers Squibb  
William Malbecq, Merck Sharp and Dohme

#### **Denmark**

Merete Jorgensen, Novo Nordisk  
Karsten Schmidt, Spadille Biostatistik

#### **France**

Dominique Moccatti, Servier  
Dominique Serrurier, Pasteur Merieux Connaught

#### **Germany**

Marlis Herbold, Hoechst Marion Roussel  
Meinhard Kieser, Dr Willmar Schwabe Pharmaceuticals

#### **Italy**

Alfredo Ardia, Zambon  
Antonella Bacchieri, Sigma-Tau

#### **Netherlands**

Stefan Driessen, Organon  
Paul Koopman, Kendle

#### **Sweden**

Mikael Astrom, Ferring AB  
Bernhard Huitfeldt, Astra Arcus – EFSPI President

#### **Switzerland**

Eric Ludin, Hoffman La Roche  
Willi Maurer, Novartis

#### **UK**

Mick Godley, Zeneca – EFSPI Vice-President  
David Morgan, Hoechst Marion Roussel

## **Spain** (observer status)

Maite Artes, Astra

Mariano Sust, Laboratorios Dr Esteve

During 1997, resignations were received from Jean-Christophe Lemarie (France), Ad Theeuws (Netherlands), Marco Girelli (Italy), Erik Cobo (Spain), John Shelton (UK) and Horst Nowak (Germany). Thanks are due to all for their work on Council, especially to Horst for his efforts over many years, having been one of the founder members of Council.

## **Officers**

During 1997 Mick Godley was EFSPI President, with Karsten Schmidt as Vice-President. For 1998-9 Bernhard Huitfeldt will be President, with Mick Godley as Vice-President until end-1998.

## **Council Meetings**

Two Council meetings have been held in 1997. The first took place in April in Nice, France, in conjunction with the DIA Clinical Statistics conference. Ten members were present, representing 7 member groups. The second meeting was held in Sodertalje, Sweden in October 1997. Thirteen members attended, representing 8 country groups. Thanks are expressed to the DIA and to Astra Arcus for hosting these meetings.

## **Working parties**

- The work of the EFSPI-sponsored working party looking at the issue of Certification of the 'Qualified Statistician' is nearing completion; Council has endorsed a draft report and the final report will soon be completed and submitted for publication. This reflects a lot of hard work by the working party. Led by David Morgan. The task of achieving a European consensus regarding the definition of the academic qualifications and experience required of a statistician in the pharmaceutical industry is a challenging one.
- In addition Council established a Working Party, chaired by Karsten Schmidt, to review and make comment on ICH E9.
- EFSPI currently has two special interest groups, in non-clinical statistics (ENSIGNS) and in veterinary statistics (EISGVSE).

## **Finances**

Council agreed a financial strategy for EFSPI. Council Members' expenses are normally covered through their individual companies or own national organisations. Under special circumstances limited funding from EFSPI will be available. No such situations occurred in 1997.

## **External Links**

EFSPI currently has active links with organisations including FDA (US Food and Drug Administration), PhRMA (US Pharmaceuticals Research and Manufacturing Association,

especially their Biostatistics Subsection), DIA (Drug Information Association) and ISCB (International Society of Clinical Biostatistics). Entries were made in the EU directory and the ISI annual publication. An entry for the forthcoming Encyclopaedia of Biostatistics was also submitted. EFSPi are looking to establish a homepage on the Internet.

## **Regulatory/industry issues**

Much effort was focused on reviewing and commenting upon a number of regulatory guidelines. These documents included CPMP guidelines on Influenza vaccines, Anti-bacterial Medicinal Products, Medicinal Products for Children and Medicinal Products in the Treatment of Alzheimer's disease. Most notable of all these documents were those deriving from the International Conference on Harmonisation (ICH), in particular documents E9 "Statistical Principles in Clinical Trials" and E10 "Choice of Control Groups in Clinical Trials". Extensive comments on the former guideline were submitted to both the EFPIA and via the national industry associations. Bernhard Huitfeldt was the EFPIA topic leader for E9 and the document was the subject of a two day workshop shaped by EFSPi Council members, attended by around 200 delegates and held under the auspices of the DIA. Industry's input to E9 is now complete and the guideline should shortly progress to ICH Step 4 and subsequent implementation by the US, European and Japanese regulatory authorities.

## **Meetings**

EFSPi does not itself put on scientific meetings, but provides input to DIA statistical activities, with much involvement in the Clinical Statistics meeting (as noted above), and ENSIGNS members leading the committee planning the Non-Clinical Statistics meeting to be held in Nice in November 1998.

## **Strategy**

With the intense activity of developing ICH E9 now over, the EFSPi Council is now taking the opportunity to review its activities and consider long-term aims and objectives. As the regulation and marketing of pharmaceutical products becomes more European and less national, the need for a clear voice for professional statisticians at European level is becoming more important. EFSPi's task is to bring together the views and activities of the national organisations and ensure that we can achieve more together than we can individually.