

# Annual Report 1999

## **Council membership**

There are ten countries within EFSPI each represented by their national association of pharmaceutical statisticians, with a combined membership of over 2000. Contacts with representatives for national associations in Finland and Norway have been initiated to explore the interest and possibilities for a future membership. Members of the EFSPI Council at the end of 1999 is given in the Appendix.

During 1999, resignations were received from Alfredo Ardia (Italy), Maites Artes (Spain), and Eric Ludin (Switzerland) who were replaced by Bianca Francucci, Eduard Martinez, and Norbert Neumann, respectively. Thanks are due to all resigning members for their work on the Council.

During 1999 Bernhard Huitfeldt was EFSPI President, with Paul Koopman as Vice-President. According to the planned succession order their roles were turned after the Brussels Council meeting November 4, 1999.

## **Council meetings**

Two Council meetings have been held in 1999. The first one took place on April 21 in Prague, in conjunction with the DIA workshop on Statistical Methodology in Clinical Research. Eighteen members (or substitutes) were present, representing all 10 member groups. The second meeting was held in Brussels in conjunction with the DIA workshop on ICH/E10 guideline on November 4. Sixteen members were present representing all 10 member groups. Thanks are expressed to the DIA (Prague and Brussels) and to Linda Danielson (Brussels) for hosting these meetings.

## **Committees and working parties**

1. A committee is in place for review of relevant regulatory guidelines, with Karsten Schmidt (chairman), Merete Jörgensen and Francois Aubin as members. A specific working party has during the year been dealing with the review of ICH/E10 guideline (Choice of Control Group) with Karsten Schmidt (chairman), Mikael Åström and Meinhard Kieser as members (see below).
2. The working party charged with developing new directions for the future of EFSPI has continued its work during 1999 with Bernhard Huitfeldt (chairman) and David Morgan and Paul Koopman as members (see below).
3. EFSPI currently has two special interest groups, in non-clinical statistics (ENSIGNS) coordinated by Merete Jörgensen and in veterinary statistics

(ESIGVSE) coordinated by David Smith with David Morgan as the contact person to EFSPi Council.

### **Finances**

Due to the limited financial resources the Council has agreed on a financial strategy implying that expenses occurring for Council members in relation to EFSPi activities should normally be covered directly through the company at which they are employed or the member group they are representing. Under special circumstances limited funding from EFSPi could be made available through impositions from the member groups up to a committed amount for each member group. No such impositions were made during 1999. A budget for the year 2000 based on the new directions (see below) was decided and agreed upon.

### **External links**

EFSPi currently has active links with organizations including DIA (Drug Information Association) and ISI (International Statistical Institute).

EFSPi sponsored a session on Statistics in Pharmaceutical Industry at the 52<sup>nd</sup> Session of International Statistical Institute in Helsinki, August 1999 organized by David Morgan and chaired by Bernhard Huitfeldt. Talks were given by Bernhard Huitfeldt, David Morgan, Karsten Schmidt, Dieter Hauschke, and Gerd Rosenkrantz.

### **Regulatory/industry issues**

Together with DIA EFSPi has carried through a workshop organized and chaired by Karsten Schmidt in Brussels November 2-3 reviewing the ICH/E10 guideline on Choice of Control Group in Clinical Trials. This workshop was an essential part of the EFSPi review process of this draft ICH guideline. The results of this review process was summarized and submitted to EMEA/ICH office as the EFSPi consolidated comments. EFSPi participated also through Bernhard Huitfeldt in the EFPIA ICH/E10 topic group in preparing the EFPIA comments.

Other guidelines which EFSPi was engaged in reviewing were CPMP Points to Consider about "Superiority, non-inferiority and equivalence" (Alan Ebutt), the Bioequivalence guideline from FDA (Meinhard Kieser), and CPMP guideline on Multiple Sclerosis (Mikael Åström).

### **Future direction of EFSPi**

The working party for "The future direction of EFSPi" produced a discussion paper, which was discussed at the Council meeting in Prague. Generally the

recommendations and proposed actions were approved and the working party was charged with completing its work and presenting the final proposals for decision at the Brussels meeting. This was done and the suggested direction for the future of EFSPI was unanimously decided. The major decisions were as follows:

1. Implement an operational guideline for the EFSPI council
2. Implement a job description for council members
3. Establish an executive office to provide administrative support up to 20 % FTE (Full Time Equivalent)
4. Set up a yearly budget including income and expenditures to be approved by the Council in advance of the year concerned
5. Establish a time-limited non-voting associate membership
6. Propose for ratification by member groups the suggested constitution changes as a consequence of the new directions

### **EFSPI homepage**

The EFSPI homepage has been maintained with the aid of Urs Harnischmacher, a contact supplied by our former Council member Horst Nowak. It can be found at

<http://www.medizin.uni-koeln.de/projekte/efspi/index.htm>

and contains currently the Council members, the member groups of the federation, the EFSPI constitution, and some general information about the federation.

### **Qualified statistician paper**

The paper on qualified statisticians prepared by a working party within EFSPI, headed by David Morgan, has been published in the DIA Journal, vol 33, pp 407-415, 1999.

## APPENDIX

### Members of the EFSPI Council at the end of 1999

#### Belgium

Linda Danielson, UCB S.A.

Marie-Pierre Malice, Merck Sharp&Dome

#### Denmark

Karsten Schmidt, Spadille Biostatistik Aps

Merete Jørgensen, Novo Nordisk A/S

#### France

Dominique Mocatti, Laboratoires Servier

Francois Aubin, Laboratoire Fournier

#### Germany

Marlis Herbold, Hoechst Marion Roussel

Meinhard Kieser, Dr Willmar Schwabe Pharmaceuticals

#### Italy

Antonella Bacchieri, Sigma-Tau

Bianca Francucci, Novartis

#### Netherlands

Stefan Driessen, NV Organon

Paul Koopman, Kendle

#### Spain

Mariano Sust, Laboratorios Dr Esteve

Eduard Martinez, Almirall Prodesfarma S.A.

#### Sweden

Bernhard Huitfeldt, AstraZeneca

Mikael Åström, Active Biotech

#### Switzerland

Willi Maurer, Novartis Pharma Ag

Norbert Neumann F. Hoffman-La Roche AG

#### UK

David Morgan, Axess Ltd

Alan Ebutt, Glaxo Wellcome