

## European Federation of Statisticians in the Pharmaceutical Industry

President:  
Bernhard Huitfeldt  
AstraZeneca R&D Södertälje  
Biostatistics & Clinical Information Systems  
S-151 85 Södertälje  
Sweden  
Tel: +46 8 553 27 385; Fax: +46 8 553 28 884  
e-mail: bernhard.huitfeldt@arcus.se.astra.com

Vice-President:  
Paul Koopman  
Kendle, Biometrics  
Bolognalaan 40  
3584 CJ Utrecht  
Netherlands,  
Tel: +31 30 258 4632; Fax +31 30 251 5141  
e-mail: koopman.paul@kendle.com

# Annual Report 1998

## Council membership

There are ten countries within EFSPI, each represented by their national association of pharmaceutical statisticians, with a combined membership of over 2000. During 1998 the membership status of Spain was changed from observer status to full membership status. Members of the EFSPI Council at the end of 1998 is given in Appendix A.

During 1998, resignations were received from Annick Leroy and William Malbaeck from Belgium, who were replaced by Linda Danielson and Marie-Pierre Malice. Dominique Serrurier from France sadly died in 1998 and was replaced by Francois Aubin. Mick Godley from UK resigned and was replaced by Alan Ebutt. Thanks are due to all for their work on Council, especially to Mick Godley who also served as Vice President and President 1995-98.

During 1998 Bernhard Huitfeldt was EFSPI President, with Mick Godley and Paul Koopman as Vice-Presidents.

## Council meetings

Two Council meetings have been held in 1998. The first took place on April 22 in Amsterdam, in conjunction with the DIA workshop on Statistical Methodology in Clinical Research. Thirteen members were present, representing all 10 member groups. The second meeting was held in Rome, Italy on October 9. Nine members were present representing 6 member groups. Thanks are expressed to the DIA (Amsterdam) and to Antonella Bacchieri, Sigma Tau (Rome) for hosting these meetings.

## Working parties

1. 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.
2. A working party has been set up for review of relevant regulatory guidelines. Willi Maurer accepted to chair this group with Karsten Schmidt, Merete Jörgensen and Dominique Serrier (later replaced by Francois Aubin) as members. A special working party was established for

dealing with the review of ICH/E10 guideline (Choice of Control Group) with Karsten Schmidt (chairman), Mikael Åström and Horst Nowak (later replaced by Meinhard Kieser).

3. A working party to suggest directions for the future of EFSPi has been in place during 1998 with Bernhard Huitfeldt as chairman and David Morgan and Paul Koopman as members (see below).

### **Finances**

The Council has an agreed financial strategy implying that Council members' expenses are normally covered through their individual companies or own national associations. Under special circumstances limited funding from EFSPi will be available through support from national associations. No such situation occurred in 1998.

### **External links**

EFSPi currently has active links with organisations including DIA (Drug Information Association) and ISI (International Statistical Institute). Together with DIA EFSPi is planning a workshop reviewing the ICH/E10 guideline on Choice of Control Group. EFSPi was also supporting the organisation of the workshop on non-clinical statistics in Nice, December 1998 with Merete Jørgensen as the chairperson for the program committee. EFSPi is organising a session on Statistics in the Pharmaceutical Industry at the 52<sup>nd</sup> Session of International Statistical Institute in Helsinki, August 1999 organised by David Morgan. An entry about EFSPi has been included in the Encyclopedia of Biostatistics written by Mick Godley.

### **Regulatory/industry issues**

During 1998 EFSPi has been engaged in commenting draft versions of ICH/E10 through participation in the EFPIA ICH/E10 topic group by Bernhard Huitfeldt. The collection of comments to the FDA guideline about Bioanalytical procedures have been organised by Merete Jørgensen from the EFSPi council.

### **Future direction of EFSPi**

In an attempt to review its activities and consider long-term aims and objectives EFSPi conducted a survey among the national associations to assess the role of EFSPi within these and to collect information about the expectations on EFSPi from the national associations. Based on this information and on internal EFSPi Council considerations a working party was established to prepare a discussion paper including a "business diagnosis" and suggestions for a possible change of direction of EFSPi for the future. This activity is ongoing and the results will be reported in the next annual report.

### **EFSPi homepage**

The first version of the EFSPi homepage has been developed with the aid of our former member Horst Nowak and can be found at <http://www.medizin.uni-koeln.de/kai/imsie/homepages/Urs.Harnishmacher/efspi/index.htm>

It currently contains the Council members, the National associations 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 completed and accepted for publication in the DIA Journal. It will appear in the second issue of 1999.

## APPENDIX A

### Members of the EFSPi Council at the end of 1998

#### Belgium

Linda Danielson, UCB S.A.  
Marie-Pierre Malice

#### 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  
Alfredo Ardia, Zambon Group SpA

#### Netherlands

Stefan Driessen, NV Organon  
Paul Koopman, Kendle

#### Spain

Mariano Sust, Laboratorios Dr Esteve  
Maites Artes, Laboratorio Astra Espana

#### Sweden

Bernhard Huitfeldt  
Mikael Åström

#### Switzerland

Willi Maurer, Novartis Pharma Ag  
Eric Ludin, F. Hoffman-La Roche Cie. AG

#### UK

David Morgan, Axess Ltd  
Alan Ebutt, Glaxo Wellcome