



EFSPi Annual Report 2002

Highlights

An enhanced and restyled website was launched in November 2002 with the help of Spadille ApS. Advertisements for jobs, journals, software and courses are being sought as a service to members and as a source of revenue.

Comments on the CPMP Points to Consider document on Baseline Covariates were submitted to CPMP in March 2002.

Dialogue is ongoing between EFSPi and regulatory statisticians to find the best way for industry statisticians to make early input to regulatory documents. A consultation process has been initiated with EFSPi member groups to develop topics for future Points to Consider papers and identify people to assist with drafting them.

Council membership

There are eleven countries within EFSPi, each represented by their national association of pharmaceutical statisticians, with a combined membership of around 2000. Members of the EFSPi Council at the end of 2002 are given in the Appendix. During 2002 resignations were received from Marie-Pierre Malice (Belgium), Stefan Driessen (Netherlands), Willi Maurer (Switzerland) and Alan Ebbutt (UK). They have been replaced by Bruno Boulanger, Kit Roes, Gerd Rosenkranz and Ann Gibb respectively. Thanks are due to the resigning members for their work on the Council, especially to Will Maurer, who was one of the founding members of EFSPi and has served on Council throughout its existence. During 2002 David Morgan (UK) was EFSPi President, with Paul Koopman (Netherlands) as Vice-President. At the Turku Council meeting in October 2002, Paul Koopman completed his term of office and Merete Jorgensen (Denmark) was elected as vice-president for 2003 and will take over as President for the 2004 and 2005 sessions.

Council meetings

Two Council meetings were held in 2002. The first took place on April 10 in Venice, in conjunction with the DIA workshop on Statistical Methodology in Clinical Research. Sixteen members (or substitutes) were present, representing 10 member groups. The second meeting was held at Orion Pharmaceuticals in Turku, Finland in October. Fifteen members were present

representing 10 member groups. Thanks are expressed to the DIA (Venice) and to Sanna Hinkka (Turku) for hosting these meetings.

Committees and working parties

1. A Committee on Regulatory Affairs is in place for review of relevant regulatory guidelines, with Karsten Schmidt (chairman), Merete Jorgensen and Francois Aubin as members.
2. The working party for development of the EFSPi website included Francois Aubin (chairman) and Antonella Bacchieri, Paul Koopman and Karsten Schmidt as members.
3. The working party on fundraising with Bernhard Huitfeldt (chairman) and Willi Maurer and Frank Langer as members, was terminated in April 2002. Its recommendation to focus on advertising on the web-site was adopted by the web-site committee.
4. The working party for the production of PR materials with Paul Koopman (chairman) and David Morgan as member produced and distributed a publicity flyer for EFSPi.
5. EFSPi currently has two special interest groups, in non-clinical statistics (ENSIGNS) coordinated by Bruno Boulanger, and in veterinary statistics (ESIGVSE) coordinated by David Smith (UK) with David Morgan as the contact person to EFSPi Council.
6. The Scientific Meetings Committee has come into operation and is chaired by Alan Ebbutt (UK). Its other members are Bernhard Huitfeldt, Ann Gibb, Sanna Hinkka from the Council, plus Steven Sharp (UK), Eric Genevois-Marlin (France) and Egbert Biesheuvel (Netherlands).

Executive Office

The Executive Office facility continues to be provided by Resources for Business of Macclesfield (UK), with Lesley Smith providing administrative support. The major focus of activities in 2002 was to complete the EFSPi archive of documents and to prepare publicity flyers.

Finances

The budget process implemented in 2000 continued to work out well. Expenditure for 2002 was in line with income, though slightly above budget due to spending on the website. The auditors (Alan Ebbutt and Karsten Schmidt) accepted the financial report for the year 2001. Changes were made to simplify the accounts by ensuring that all expenditure was reported in the year to which it related. The budget for 2003 was approved: this involves no increase in contributions from member groups.

External links

EFSPI maintained its active links with DIA (Drug Information Association). Contact was also maintained with ISI (International Statistical Institute), IFAPP (International Federation of Associations of Pharmaceutical Physicians), the BDMSC (Biostatistics and Data Management Steering Committee) of PhRMA (US Pharmaceutical Manufacturers) and JMA (Japan). A directory of external relations was made for regular communications. ISI had sought input from the pharmaceutical industry for a meeting on revision of the ISI declaration on ethical issues affecting statisticians, but it was not possible to identify a speaker. Contact has been made with the European Network of Business and Industrial Statisticians (ENBIS), with a view to obtaining funding from the EU.

Regulatory/industry issues

Comments on the CPMP Points to Consider document on Baseline Covariates were submitted to CPMP in March 2002. There was strong representation from EFSPI Council in the session on regulatory issues at the DIA Clinical Statistics conference in April. A revised EFSPI procedure for making comments on regulatory documents was agreed by Council. The Regulatory Affairs Committee is engaging in dialogue with regulatory statisticians to find the best way for industry statisticians to make early input to regulatory documents. A consultation process has been initiated with EFSPI member groups to develop topics for future Points to Consider papers and identify people to assist with drafting them.

EFSPI website

An enhanced and restyled website was launched in November 2002 with the help of Spadille ApS. Advertisements for jobs, journals, software and courses are being sought as a service to members and as a source of revenue.

EFSPI visibility

The strategy for publicity adopted in 2000 has been followed through. A publicity flyer (a folded A4 leaflet) has been produced and distributed to individual members of all national groups. A short article about EFSPI was requested by the Quality Assurance Journal and will be published in 2003.

Scientific Meetings Committee

The Scientific Meetings Committee was set up under the Chairmanship of Alan Ebbutt (UK) and with representation from Finland, France, Netherlands, Sweden and UK. The Committee is

working to define an EFSPI policy on meetings. It has been agreed that EFSPI will work only with not-for-profit organizations. Council accepted an invitation by PSI to organise a session at their 2003 conference.

Networks

The EFSPI non-clinical network (ENSIGNS) was involved in a DIA meeting on statistical methods in the non-clinical area, held in Barcelona on 26-27 Sept 2002. The meeting was successful though attendance was lower than hoped. Bruno Boulanger (Belgium) was organiser of that meeting and has now taken over as Co-ordinator of ENSIGNS. There has been no activity with the veterinary network (ESIGVSE).

Glossary

CPMP	Committee for Proprietary Medicinal Products (of the EU)
DIA	Drug Information Association
ENSIGNS	European Network of Special Interest Groups in Non-clinical Statistics
ESIGVSE	European Special Interest Group in Veterinary Statistics and Epidemiology

APPENDIX: Members of the EFSPI Council at the end of 2002

Belgium

Linda Danielson, UCB S.A.

Bruno Boulanger, Eli Lilly

Denmark

Karsten Schmidt, Spadille ApS

Merete Jorgensen, Novo Nordisk A/S

Finland

Sanna Hinkka, Orion Pharmaceuticals

Eliisa Loyttyniemi, Oy Contral Pharma Ltd

France

Florence Casset-Semanaz, Glaxo Smith Kline

Francois Aubin, Laboratoires Fournier

Germany

Marlis Herbold, Aventis GmbH

Frank Langer, Lilly Deutschland GmbH

Italy

Antonella Bacchieri, Sigma-Tau

Bianca Francucci, Novartis

Netherlands

Paul Koopman, Solvay Pharmaceuticals

Kit Roes, Organon

Spain

Mariano Sust, Laboratorios Dr Esteve

Sweden

Bernhard Huitfeldt, AstraZeneca

Mikael Astrom, Clinical Data Care

Switzerland

Gerd Rosenkranz, Novartis Pharma AG

Norbert Neumann, F. Hoffman-La Roche AG

UK

David Morgan, Ingenix Pharmaceutical Services

Ann Gibb, Parexel