

Annual Report 2000

Highlights

In order to strengthen the internal organization, an executive office was established and functions of the Council of EFSPI were described and documented. Related hereto, a contribution fee system has been implemented.

A major development in 2000 was that EMEA asked EFSPI directly for input in the Meta-analysis Point-to-Consider guideline. As this has not happened before, this is a real breakthrough, which demonstrates that EFSPI is gaining visibility and can do more for the profession than the national member associations can do individually.

Collective comments from the national member associations were submitted to EMEA for three CPMP draft guidelines and words of thanks were received from EMEA.

The DIA workshop on Non-Clinical Statistics in Montreux has been organized under the auspices of the EFSPI.

Council membership

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

During 2000 a resignation was received from Meinhard Kieser (Germany) who was replaced by Frank Langer. End 2000, a resignation was received from Dominique Moccatti who is replaced per January 1, 2001 by Florence Casset-Semanaz. Thanks are due to all resigning members for their work on the Council.

During 2000 Paul Koopman was EFSPI President, with Bernhard Huitfeldt as Vice-President. According to the planned succession order, David Morgan replaced Bernhard Huitfeldt after the London Council meeting October 20, 2000.

Council meetings

Two Council meetings have been held in 2000. The first one took place on April 12 in Barcelona, in conjunction with the DIA workshop on Statistical Methodology in Clinical Research. Fifteen members (or substitutes) were present, representing all 10 member groups. At this meeting a revision of the Constitution was agreed and job descriptions for the president/vice-president were accepted. The second meeting was held at Glaxo Wellcome in London. Fourteen members were present representing all 10 member groups. At this meeting, job descriptions for committee/working party chair and for network coordinator were accepted.

Thanks are expressed to the DIA (Barcelona) and to Alan Ebbutt (London) for hosting these meetings.

Committees and working parties

1. A permanent Committee on Regulatory Affairs is in place for review of relevant regulatory guidelines, with Karsten Schmidt (chairman), Merete Jørgensen and Francois Aubin as members. A specific working party is active to prepare a position paper on ICH E10.
2. The working party charged with developing new directions for the future of EFSPI has completed its work early 2000 with Bernhard Huitfeldt (chairman) and David Morgan and Paul Koopman as members.
3. A new working party has been installed to discuss the upgrading of the EFSPI website with Francois Aubin (chairman) and Antonella Bacchieri, Paul Koopman and Karsten Schmidt as members.
4. By the end of 2000, new working parties have been installed on fundraising, producing PR materials and to identify new areas for EFSPI concern, resp.
5. EFSPI currently has two special interest groups, in non-clinical statistics (ENSIGNS) coordinated by Merete Jørgensen and in veterinary statistics (ESIGVSE) coordinated by David Smith with David Morgan as the contact person to EFSPI Council.

Executive Office

As a consequence of the “future direction” paper, an executive office was established to provide administrative support up to 20% FTE. A contractual agreement was made with Resources for Business (RfB), a UK-based company that provides these kind of services. Jayne Fox of RfB resides at their Cambridge office and is appointed as EFSPI Executive Officer. This proves to be a good provision. In relation to the office, a paper was accepted that defines the content and nature of the archive.

Finances

In order to fund the operation of the Executive Office, approval of a yearly budget was implemented for the Autumn Council Meeting. Related hereto, a policy for division of the contribution for EFSPI by the member groups was approved, based on a general portion and parts proportional to the group size and ability to pay fees. In addition, the policy on reimbursement of costs by Council Members that are not foreseen in the budget was revised correspondingly. Besides, the principle was agreed to create a working capital.

External links

For a longer period, EFSPi has active links with organizations including DIA (Drug Information Association) and ISI (International Statistical Institute). The ENSIGNS network worked closely together with DIA in the organization of the European Workshop on Non-Clinical Statistics, 14-15 September in Montreux, where Merete Jørgensen acted as program chair.

Contacts were made to investigate further cooperation with the IFAPP (International Federation of Associations of Pharmaceutical Physicians) and the BDMSC (Biostatistics and Data Management Steering Committee) of PhRMA (US Pharmaceutical Manufacturers).

Regulatory/industry issues

EFSPi made consolidated comments on the CPMP guideline on Multiple Sclerosis (Rapporteur: Mikael Åström - AktiveBiotech) and on the CPMP Points to Consider on “Superiority, Non-inferiority and Equivalence (Rapporteur: Alan Ebbutt – GlaxoWellcome) and on “Validity and Interpretation of Meta-Analyses, and one Pivotal Study” (Rapporteur: Stefan Driessen – Solvay Pharmaceuticals).

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 could be found at www.medizin.uni-koeln.de/projekte/efspi and has been transferred to the new address www.efspi.org that is maintained by the Executive Office.

The homepage contains currently the Council members, the member groups of the federation, the EFSPi constitution, and some general information about the federation. A further upgrade is under discussion.

EFSPi visibility

A strategy for a publicity approach has been adopted, both an international scope and at a national scope of the member groups. As a first step, the logo has been restyled and a budget created for the production of PR materials.

APPENDIX

Members of the EFSPI Council at the end of 2000

Belgium	Linda Danielson, UCB S.A. Marie-Pierre Malice, Merck Sharp&Dohme
Denmark	Karsten Schmidt, Spadille Biostatistik Aps Merete Jörgensen, Novo Nordisk A/S
France	Dominique Moccatti, Laboratoires Servier Francois Aubin, Laboratoires Fournier
Germany	Marlis Herbold, Aventis Pharma Germany GmbH Frank Langer, Lilly Deutschland GmbH
Italy	Antonella Bacchieri, Sigma-Tau Bianca Francucci, Novartis
Netherlands	Stefan Driessen, Solvay Pharmaceuticals 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, Ingenix Pharmaceutical Services Alan Ebbutt, Glaxo Wellcome