

EFSPI Annual Report 2001

Highlights

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

A position paper on the ICH E10 guideline “Choice of Control Groups in Clinical Trials” was endorsed by the Council and published in the DIA Journal (vol 35 (2001/4), 1147-1156).

Finland has been accepted into membership of EFSPi.

The internal organization was further strengthened, with the establishment of an executive office and description and documentation of the functions of the Council of EFSPi. Preparations to enhance external visibility were continued and a restyled and enhanced homepage is under construction.

Council membership

In September, Finland was accepted into EFSPi membership. There are now 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 2001 are given in the Appendix. During 2001 a resignation was received from Eduard Martinez (Spain) whose replacement was still open at the end of the year. Thanks are due to the resigning member for his work on the Council. During 2001 Paul Koopman (Netherlands) was EFSPi President, with David Morgan (UK) as Vice-President. According to the planned succession order, Paul Koopman and David Morgan changed roles at the Paris Council meeting in September 2001, where David Morgan was installed as president for the period 2001-2003.

Council meetings

Two Council meetings were held in 2001. The first took place on April 4 in Vienna, in conjunction with the DIA workshop on Statistical Methodology in Clinical Research. Thirteen members (or substitutes) were present, representing 9 member groups. At this meeting a re-design of the Homepage by Spadille ApS (Denmark) was agreed and preliminary discussions took place on funding, visibility, operation of the regulatory affairs committee and on strategy. The second meeting was held at Laboratoires Fournier in Paris in September. With the consent of the absent member groups, Finland was accepted into membership of EFSPi and the new Finnish council members attended the meeting. Ten members were present representing only 7 member groups as a number of council members had to announce their absence at short notice due to travel restrictions by their companies following the terrorist attacks on September 11. Despite the fact that the meeting was not quorate, it was decided to continue the meeting and to arrange for an additional teleconference halfway the next council meeting in order to set formalities as

needed. The main issue at the meeting was the report from the working party on the “Future of EFSPi”, and it was decided to install a new committee on Scientific Meetings and a new Working Party on Qualifications and Training of Statisticians. Thanks are expressed to the DIA (Vienna) and to Francois Aubin (France) 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. A specific working party has prepared a position paper on ICH E10 for publication in the DIA Journal.
2. The working party charged with identifying new areas for strategic concern for EFSPi has completed its work at the end of 2001 with David Morgan (chairman) and Linda Danielson and Paul Koopman as members.
3. The working party established to discuss the upgrading of the EFSPi website with Francois Aubin (chairman) and Antonella Bacchieri, Paul Koopman and Karsten Schmidt as members, produced a report on the re-design of the website by Spadille ApS that was accepted, and gave initial feedback to the designers.
4. The working party on fundraising with Bernhard Huitfeldt (chairman) and Willi Maurer and Frank Langer as members produced a first discussion paper that was well received and that has led to further actions to be taken by them.
5. The working party for the production of PR materials with Paul Koopman (chairman) and David Morgan as member produced overhead transparencies and DIA slides and made specific proposals for a poster, a flyer, a banner and badges.
6. EFSPi currently has two special interest groups, in non-clinical statistics (ENSIGNS) coordinated by Merete Jorgensen (Denmark) and in veterinary statistics (ESIGVSE) coordinated by David Smith (UK) with David Morgan as the contact person to EFSPi Council.

Executive Office

The executive office was established in 2000 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. This arrangement is working well in practice. For efficiency reasons, the responsibility for the office was transferred from Jayne Fox who resides at RfB’s Cambridge office to Lesley Smith at RfB headquarters at Macclesfield. In relation to the office, a paper was accepted defining the content and nature of the archive, and this is now being implemented.

Finances

The budget process implemented in 2000 worked out well and was further streamlined in 2001. An arrangement was made to secure cash flow. A start was made to create a working capital with the surplus of the year 2000. Auditing was introduced and the auditors (Alan Ebbutt and Karsten Schmidt) reported to accept the financial report for the year 2000.

External links

For a long period, EFSPI has had active links with organizations including DIA (Drug Information Association) and ISI (International Statistical Institute). Recent contacts were continued 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) and JMA (Japan). A directory on external relations was made for regular communications.

Regulatory/industry issues

EFSPI made consolidated comments on the CPMP guideline on Bioavailability and Bioequivalence (rapporteur: Paul Koopman) and on the CPMP Points to Consider on "Validity and Interpretation of Meta-Analyses, and one Pivotal Study" (rapporteur: Stefan Driessen), on "Missing Data" (rapporteur: Eduard Martinez) and on "Multiplicity Issues in Clinical Trials" (rapporteur: Linda Danielson).

A position paper on the ICH E10 guideline "Choice of Control Groups in Clinical Trials" by Bernhard Huitfeldt, Linda Danielson, Alan Ebbutt and Karsten Schmidt was endorsed by the Council and published in the DIA Journal (vol 35 (4) 1147-1156).

EFSPI homepage

The original EFSPI homepage was slightly updated and has then been transferred to the new address www.efspi.org. An enhanced and restyled homepage is under construction by Spadille Aps.

EFSPI visibility

The strategy for a publicity approach that had been adopted in 2000, both at an international scope and at a national scope of the member groups, has been followed through. The production of PR materials has commenced.

A meeting was jointly organized with Henry Stewart Conference Studies in London in September on Requirements for Control in Clinical Trials. EFSPi provided Chairman and one speaker and negotiated a 20% discount for members of national associations.

A proposal was developed for a session on the Education and Training of Statisticians at the 2003 ISI conference in Berlin, but the proposal was not accepted.

APPENDIX: Members of the EFSPI Council at the end of 2001

Belgium

Linda Danielson, UCB S.A.

Marie-Pierre Malice, Merck Sharp & Dohme

Denmark

Karsten Schmidt, Spadille Biostatistik Aps

Merete Jorgensen, Novo Nordisk A/S

Finland

Sanna Hinkka, Orion Pharma

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

Stefan Driessen, Solvay Pharmaceuticals

Paul Koopman, Solvay Pharmaceuticals

Spain

Mariano Sust, Laboratorios Dr Esteve

Sweden

Bernhard Huitfeldt, AstraZeneca

Mikael Astrom, Clinical Data Care

Switzerland

Willi Maurer, Novartis Pharma Ag

Norbert Neumann F. Hoffman-La Roche AG

UK

David Morgan, Ingenix Pharmaceutical Services

Alan Ebbutt, Glaxo Smith Kline