



EFSPI Annual Report 2009

1. Highlights

- EFSPI reviewed CHMP Guideline on the Investigation of Bioequivalence and Guideline on the Missing Data in Confirmatory Studies.
- EFSPI held a European Statistical Meeting on Meta Analysis with BBS, which was very successful
- EFSPI formed a permanent Scientific Committee to better support the organization of our Scientific Meetings.
- An e-mail broadcaster is being purchased to better advertise our activities to a larger audience.
- EFSPI is organizing a Statistical Leaders Meeting in 2010, to address statistical challenges and help to shape the strategy of EFSPI
- Following lobbying from EFSPI and PSI, concerning the lack of statisticians employed by EU Regulatory Agencies, a HMA Strategy Paper II was requested at the Heads of Agencies Meeting.
- PSI and EFSPI's paper, "Statistical resource needs to be increased in the European regulatory agencies" was accepted by Pharmaceutical Statistics.
- EFSPi's paper on "Qualified Statisticians in the European Pharma Industry: Present and Future Directions" was published in DIA's Drug Information Journal in September 2009
- Nigel Howitt's Presidency has been extended to autumn 2010. Francois Aubin was elected as the new Vice-President.
- The number of council meetings has been increased to improve communication and to gain more momentum.
- Financial position at end of 2009 remains sound

2. Regulatory affairs

The new regulatory review process is working well. Lesley France has formed a network of reviewers from the main European National groups. These are supplemented by ad-hoc Experts. The goal is to provide one set of consolidated and focused comments, which represent the overall European Statistical Community, thereby increasing their impact.

The main documents reviewed during 2009 were the CHMP Guideline on the Investigation of Bioequivalence and Guideline on the Missing Data in Confirmatory Studies.

The review of the Bioequivalence document was submitted in early 2009. Christophe Sauce kindly coordinated the review on behalf of EFSPI. The review committee supporting Christophe was made up of the following: Tarmo Laine, Jurgen Hummel, Yolanda Kranz, Stefan Klein, and Lesley France. The comments can be found on the EFSPI website. We were pleased to see that many of our recommendations were accepted, which subsequently led to changes in the document.

The review of the Missing Data document was coordinated by Pierre Verweij. An expert panel was formed to review and filter the comments from the EFSPI national groups. This consisted of Kit Roes, Stig Johan Wiklund, Yolande Kanza, Prof Mike Kenward, Lesley France and Pierre Verweij. The engagement of Prof Kenward in the process was extremely valuable and helped improve the overall quality of the comments. The comments are again available on EFSPI's website.

In terms of the future, the recent announcement of the Biostatistics Advisory Committee for the European regulatory authorities provides an opportunity to meet and discuss the way statisticians working within the industry can interact with this group. An article outlining the remit of the committee will appear in the March edition of the PSI SPIN, and there is a meeting on this subject within the joint MHRA/EFSPI meeting in London in March.

With regards to our future work plan, the FDA issued their guidance on both Non-Inferiority and Adaptive Designs in February 2010. Bernhard Huitfeldt will be the rapporteur for the Non-Inferiority document and Carl Fredrick Burman the rapporteur for the Adaptive Design. In addition, on March 26th there will be a DIA symposium in Silver Spring, MD (Washington, DC area) to provide an overview and an opportunity to discuss the Adaptive Design draft guidance document.

3. Scientific Affairs

EFSPI organized a European Statistical Meeting on Meta Analysis with BBS. The meeting was held in Basel in June 2009. A total of 67 paying delegates attended. Presenters included: Steven Julious (University of Sheffield), Anne Whitehead (University of Lancaster), Tomasz Burzykowski (IDDI Belgium), Sarah Hollis (Astra Zeneca, UK), Guido Schwarzer (University of Freiburg). Stephen Senn (University of Glasgow) and David Wright (MHRA) provided a Panel Discussion.

Due to the continued successes of our Scientific Meetings a permanent Scientific Committee was formed in the autumn of 2009. The members include: Carl-Fredrik-Burman (AstraZeneca, Sweden), Nigel Howitt (PRA International, United Kingdom), James Matcham (Amgen, United Kingdom), Emmanuel Quinaux (IDDI, Belgium), Kit Roes (University Medical Center Utrecht, Netherlands), Pierre Verweij (MSD, Netherlands).

The committee will strategically focus on providing a European platform for scientific exchange and standards for (pharmaceutical) statistics, across industry, academia and regulatory authorities. The Committee is expected to provide input to the long term direction of EFSPI in this respect, as well as ensure and coordinate execution of scientific meetings. Scientific meetings will continue to be held in collaboration with one or more of our affiliated national

organisations and other stakeholders, such the EMA, MHRA, and sister statistics societies. This ensures relevant impact, both at European as well as national level.

In 2010, joint Statistical Meetings are planned with MHRA (Statistics at the frontier of drug Development), BBS (Early Oncology Studies) and SFdS B&S (autumn meeting). EFSPI has also approached EMA about holding annual joint Statistical meetings.

4. Web-facilities

The website has been updated regularly throughout the year.

The restricted access area was activated for council members and archive documents are now available on-line.

At the November Council Meeting, the decision was taken to implement an e-mail broadcaster feature to the website. Each visitor can voluntarily add his/her e-mail address to an email list that can be used to broadcast information to the entire email list (information is in HTML format and can include pictures, links and text formatting). Each email will have an "Unsubscribe Me" link auto-added to the bottom which if clicked will stop recipient from receiving emails any longer. This feature should be available beginning of 2010. This will allow EFSPI to reach a larger audience.

The site can be found at: <http://www.efspi.org/>

5. External Affairs

The membership of EFSPI remains at 10 member countries. The Operations Board was also reorganized and External Affairs is no longer included.

Egbert Biesheuvel is currently working on a project to identify statistical groups outside of the EFSPI regions, with a view to future expansion, following recent political union in the EU.

6. Special Projects

6.1 EFSPI Statistical Leaders Meeting

EFSPI is starting a forum for Statistical Leaders within the Industry to discuss future challenges and identify areas where EFSPI can support pharmaceutical statistics.

The Pharmaceutical Industry is a constantly changing and as it does there is a need for the statistical community to re-evaluate the way it seeks to shape and influence the external environment. In recent years we have seen, increased regulation requirements, increased need to demonstrate cost benefit, more demand for quantitative evaluation of risk and benefit and increased off-shoring of routine statistical work to low cost economies. EFPSI has identified an

as yet untapped opportunity to work with senior statistics leaders drawn from across our industry to address strategic challenges, and it believes that working with this group can further improve the impact and standards of pharmaceutical statistics in Europe. Moreover, bringing such a group together on a periodic basis could powerfully amplify the impact of EFPSI in important areas. No current forum exists for Statistical Leaders and we wish to change this.

We see four key areas where such a group could potentially help shape the contribution of statistics and statisticians in our industry over the longer term.

- Education & Continuing Professional Development
- Methodology Development & Identification of Best Practice
- Regulatory and Industry policies
- Effective working with differing resourcing models

The organising group for the meeting consists of: Stephen Pyke, Thorkild Nielsen, Per Larsson and Lesley France. The meeting is planned to be in Berlin on 26th May. The programme is under development for the first meeting and will include:

- Professional Development for Statisticians
- Evaluation of Patient Risk
- Statistical Contributions to Health Technology Assessments.

We are in the process of inviting approximately 30 leaders from across Europe to participate in the first meeting. If this is successful we hope to make this an annual event.

6.2 Lack of statisticians employed by EU Regulatory Agencies

As a follow on from our BMJ letter last year, PSI and EFSPi developed a joint position paper in February 2009 calling for more statistical resource in the EU Regulatory Agencies. This position paper was endorsed by EFPIA and has since been submitted for publication to Pharmaceutical Statistics. Using this position paper, PSI and EFSPi submitted the topic as an agenda item for discussion at a Heads of Agencies meeting. This discussion took place in July and we have recently received feedback on the content of that discussion. The discussion was positive with EMEA Executive Director championing our position and specific actions have been proposed. A HMA (Heads of Medicine Agencies) Strategy Paper II was requested to consider, not only how we are dealing with statistics, but with data and data quality in the HMA strategy paper.

For clarification, the Task Force on the HMA Strategy Paper II is a new taskforce of the Heads of Medicines Agencies which will be dedicated to strategic issues. Their Strategy Paper I looked at the future of the EU Medicines Regulatory Network and was adopted November 2007. It covered themes such as communication & information, scientific resources, scientific assessment process, pharmacovigilance, inspection, lab control & enforcement, and IT information systems.

Clearly, the current state of play will not change overnight. However, we look forward to observing how this topic evolves in the HMA Strategy Paper II in due course, and the EFSPI and PSI Boards will monitor progress.

6.3 Qualifications Paper

EFSPI's paper on "Qualified Statisticians in the European Pharma Industry: Present and Future Directions" was published in DIA's Drug Information Journal in September 2009 (Volume 43, Number 5, September 2009, 573). The paper compares the responsibilities, qualifications, training, continuing professional development (CPD), and professional certification of statisticians in the pharmaceutical industry across Europe.

7. Operations Board

Nigel Howitt's Presidency has been extended to autumn 2010. Francois Aubin was elected as the new Vice-President in November 2009, and will subsequently become the next President. Kit Roes was thanked for his significant contributions as President and Vice-President. Kit remains on the Board as the chair of the Scientific Committee. Lesley France remains as chair of the Regulatory Committee.

8. Council membership

In 2009, 10 countries were represented within EFSPI, each represented by their national association of pharmaceutical statisticians, with a combined membership of more than 2800. Members of the EFPSI Council at the end of 2009 are given in the Appendix.

9. Council meetings

Two Council meetings were held in 2009. The first took place Basel, Switzerland in June to coincide with the Meta-Analysis Meeting. The second was held in Reading, England in November. The majority of countries attended each meeting and a quorum was achieved.

To improve communication and to build momentum, the number of council meetings will increase from 2 to 4 in 2010 (2 face-face and 2 web conferences).

10. Executive Office

The Executive Office facility is now provided by Kingston Smith from Macclesfield (UK), following a recent takeover. Jenny Butterworth continues to be our Association Manager and is supported by Sally Ross.

11. Finances

EFSPI finances remain sound. As such, it was agreed not to increase the overall income from membership fees in 2010.

APPENDIX: Members of the EFSPI Council at the end of 2009

Belgium

Emmanuel Quinnaux, IDDI

Tom Loeys, Merck

Denmark

Arne Haahr Andreasen, Andreasen Statistical Consulting

Klaus Olsen, Larix

Finland

Britt-Marie Lindström, Oy 4Pharma Ltd

Toni Sarapohja, Orion Pharma

France

Francois Aubin, Cardinal Systems

Francoise Tondu, Danone

Germany

Joachim Roehmel, Academic

Christoph Gerlinger, Bayer

Italy

Paolo Morelli, Cros IT

1 vacancy

Netherlands

Kit Roes, Julius Cente, University Medical Center Utrecht

Egbert Biesheuvel, MDS

Sweden

Carl Fredrik Burman, AstraZeneca

Mikael Astrom, AstraZeneca

Switzerland

Fred Sorenson, Genesis BioPharma Group

Hans Ulrich Burger, Hoffmann-La Roche

UK

Nigel Howitt, PRA International

Lesley France, AstraZeneca