European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Annual Report 2013

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Highlights from the EFSPI President & Vice President

Three successful scientific meetings were held in 2013: one on Health Technology Assessment with BBS in Basel, Switzerland; one on benefit-risk with PSI in London, UK; and one on survival analysis in Brussels, Belgium. Thanks to everyone who participated and attended these meetings. All meeting materials are accessible on the EFSPI website: www.efspi.org.

EFSPI participated in the advisory groups set up by EMA early in the year to discuss key elements of clinical-trial data transparency. A position paper on key considerations relating to access to clinical trial data was published in Pharmaceutical Statistics.

EFSPI held their 4th EFSPI Statistics Leaders Meeting in 2013. There primary topic was clinical trial data transparency including a workshop on the future impact to statisticians with increased access to clinical trial data. The Medical Devices special interest group (SIG) and Benefit-Risk SIG presented their activities and a new SIG on Integrated Data Analysis was initiated.

As per the 2013-2015 strategic objectives, EFSPI have increased collaborations with EFPIA, including connecting EFSPI SIG members with related EFPIA activities in the areas of benefit-risk, modelling and simulation, and Health Technology Assessment. EFSPI are participating in an EFPIA led clinical trial design taskforce, which will contribute ideas to establishing proposals for the 'Innovative Medicines Initiative 2' consortium.

The EFSPI membership fees remained the same in 2013. The operations board monitored expenses throughout the year, and further aligned activities supported by the Executive Office relative to EFSPI business priorities.

Chrissie Fletcher (UK)
President

François Aubin (France)
Vice-President

Finance

The financial situation of EFSPI was further consolidated in 2013. Our total income was positively influenced by revenues from an increased scientific meeting activity and an unbudgeted income from web advertises. Further we have succeeded to keep our expenses below our budget expectations. Consequently our reserves are now at level comparable to the expenses of one year.

However it has been increasingly difficult to recover the membership fees from all of the national organisations. The outlook for 2014 is likely to be negatively affected by a lower meeting activity and increased expenses for the upgrade of EFSPI's web site (however the majority of this expense will be covered by the profit obtained in 2013). Therefore we can only encourage the national organisations to pay the fees in a timely manner to keep EFSPI as a financial sound organisation.

Arne Haahr Andreasen (Denmark)

EFSPI Treasurer

EFSPI Income and Expenses 2013

	Actual €	**Budget €**	Variance €
Income			
Membership Fees	12.514	12.511	3
Scientific Meetings	29.333	27.000	2.333
Recruitment Web Advertisement	1.400	-	1.400
	43.246	39.511	3.735
Expenses			
Executive Office Hours	14.612	16.500	1.888
Attending Meetings	224	500	276
Web Hosting	977	1.030	53
Office Costs	310	500	190
Bank Charges	1.578	2.000	422
Scientific Meetings	19.518	18.454	(1.064)
Scientific Meeting (2012)	162	-	(162)
	37.382	38.984	1.602
Net result for the year	5.865	527	5.338

Balance

	2013 €	2012 €
Current assets		
Debtors	1.822	2.900
Prepayments	1.381	246
Accrued Income	1.883	0
Bank - €	40.989	38.563
Bank - £ (Converted to €)	2.989	891
	49.064	42.600
Current liabilities		
Creditors	2.285	3.682
Accruals	6.148	4.151
	8.433	7.834
Revenue reserves		
Balance brought forward	34.767	31.160
Result for year to date	5.865	3.607
	40.631	34.767

Regulatory Affairs

Data Transparency: In April EFSPI has issued a position paper on EMA's data transparency initiative (http://www.efspi.org/aadocs/finalefspiposition25april2013.pdf).
We submitted comments to EMA on their draft policy in September (http://www.efspi.org/aadocs/efspicommentsonemadraftpolicy0070onpublicationandaccesstoclinicaltrialdata.pdf) and we published a viewpoint article on increased access to clinical trial data in Pharmaceutical Statistics[1] .

Guidelines: EFSPI submitted comments on the guideline on adjustment for baseline covariates. Thanks to all the individuals and associations who provided comments. The set of comments submitted can be accessed here http://www.efspi.org/aadocs/efspi__comments_adjustment_baseline_covariates_20131209.pdf. No comments on the draft CHMP qualification opinion concerning a new "statistical methodology for model-based design and analysis of Phase II dose finding studies under model uncertainty" were submitted, as we were generally in agreement with the text.

Joint EFSPI/PSI Regulatory Committee: This group monitors and responds, where appropriate, to regulatory statistical issues and generates responses to draft guidelines. Additional members are being sought from the other EFSPI member associations to join the regulatory committee. Please contact Lesley France (Lesley.France@astrazeneca.com)

Christoph Gerlinger (Germany) is the Regulatory Chair of EFSPI.

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[1] Fletcher C, Driessen S, Burger HU, Gerlinger C, Biesheuvel E; EFSPI.
European Federation of Statisticians in the Pharmaceutical Industry's position on access to clinical trial data.
Pharm Stat. 2013 Nov;12(6):333-6.

Scientific Affairs


Egbert

EFSPI held three successful European Statistical meeting in 2013:

- Health Technology Assessment, a joint meeting with the BBS in Basel, Switzerland on June 4. With more than 115 participants from various backgrounds a well received and successful meeting on this developing topic.
- Structured Benefit-Risk Assessment, a joint meeting with the PSI in London on September 13. An informative and enjoyable one-day meeting that gave opportunity to mix with counterparts from across Europe. Examples included the IMI PROTECT Work Package 5.
- Survival Analysis and its applications in drug development in Brussels, Belgium on November 7. A well organised meeting with a mixture of interesting topics and a lively panel discussion closed the one-day event.

Each meeting had various speakers from academia, regulatory bodies and industry and all presentations can be found on our website ('EFSPI international events'): http://www.efspi.org/index.php?p=EFSPI+activities&fid=19

In addition, EFSPI and PSI organised a workshop on EMA's Clinical Trial Data Transparency draft policy in London on August 22. This workshop discussed the draft policy, highlighted key challenges in this area and had stimulating breakout sessions that generated comments on the draft position paper. Presentations of this workshop can be found on our website: http://www.efspi.org/index.php?p=EFSPI%20ACTIVITIES&fid=430.

In 2013, the Scientific Committee consisted of the following members:

- Francois Aubin, Cardinal Systems, France
- Egbert Biesheuvel, MSD, the Netherlands (Chair)
- Carl-Frederik Burman, Astra Zeneca, Sweden
- Nigel Howitt, PRA International, UK
- James Matcham, Amgen/Astra Zeneca, UK
- Emmanuel Quinaux, IDDI, Belgium
- Pierre Verweij, MSD, the Netherlands

Egbert Biesheuvel (the Netherlands)

Statistics Leaders Meeting

Statistics Leaders Forum call – February 2013

In February a teleconference was held with 23 EFSPI leaders to give feedback on the June 2012 meeting as well as to discuss the agenda for 2013. Also the trending topic of Transparency was put on the agenda which led to a lively discussion demonstrating a very interested Forum. Ultimately this led to making it the main topic for the 2013 meeting.

EFSPI Position on Clinical Trial Data Transparency – March, April 2013

The Statistics Leaders received the draft EFSPI position paper for review and approval. Over 15 members responded and their comments were collated, categorised and prioritized before subsequent discussion and incorporation by the authoring group into the final position paper.

EFSPI Statistics Leaders Meeting – June 2013

In 2013 the 4th EFSPI Statistics Leaders Forum Meeting was held in Copenhagen, Denmark, kindly hosted by Novo Nordisk.

Twenty-three leaders from 9 different countries and 20 pharmaceutical companies attended. The strategic objectives for EFSPI for 2013-2015 were presented followed by several sessions on Special Interest Groups (SIG). The new SIG Medical Devices was introduced with a useful summary of recent changes and trends in this area with opportunities for statisticians and EFSPI to contribute to the developing regulatory framework. The Benefit Risk SIG presented on the progress since the last meeting with the development of a roadmap describing and linking in to the numerous Benefit-Risk initiatives currently underway. It is well under way to give statisticians material to increase their capabilities in the area to lead and contribute to benefit-risk projects within their company. Nevertheless, it is a two-way street and the SIG would greatly benefit from more cases studies to further develop best practices. The session was closed by an overall update on all SIGs from which it became clear that there is a significant amount of important activities underway, including meetings, useful handbooks and best practice documents. The idea to start a new SIG on Integrated Data Analyses was well received.

The EMA's Clinical Trial Data Transparency initiative was extensively discussed: status updates were provided on emerging trends by the regulators including EMA and FDA, and emerging positions by Industry Associations including EFPIA and EFSPI were summarised. GSK and Roche shared details of their company's strategies with regard to transparency and

four breakout sessions elaborated on what impact transparency is anticipated to have on the EU statistics community in the future. The general message of the Statistical Leaders to EFSPI was that it should focus on good statistical principles and seek opportunities to highlight these. Ideally EFSPI should strive to develop one industry position on the important principles regarding access to data and data anonymisation. Furthermore, it would be good for EFSPI to consider developing or collaborating on guidance for secondary and/or re-analysis of study results. Finally, the Statistics Leaders acknowledged transparency is a new and important area for the statistics community, which will bring challenges and opportunities.

Survey on Meeting – July 2013

A small survey was held amongst the participants with ten responders (43%).

The meeting was rated overall as good (80%) or excellent (20%). Attendees felt there was sufficient time for discussion (90%) and like the format (100%). The seven sessions were rated and ranged from 3.8 to 4.9 on a 5-point scale, with the EMA Transparency update scoring highest. All responders replied that they would attend again the following year.

EFSPI Updates – October, December 2013

The outcome of the meeting and survey were fed back to the EFSPI Council and communicated in EFSPI Newsletters. The EFSPI Council was pleased to see that the topic of transparency has been picked up very well by the community with active engagement and contribution from the Stats Leaders forum into commenting on the draft policy.

Statistics Leaders Forum

Presently the Statistics Leaders Forum consists of about 45 active members from all EFSPI countries and from a wide range of EU pharmaceutical companies, or affiliates of ex-EU companies. It is for the third year led by Stefan Driessen (stefan.driessen@abbott.com), and before that for two years by Lesley France.

All material from the EU Statistics Leaders Meetings held in 2010, 2011, 2012, and 2013 are available on the EFSPI website:
http://www.efspi.org/index.php?p=EFSPI%20activities&fid=399.

Stefan Driessen (the Netherlands)

Communications

Monthly newsletters were distributed in 2013, allowing each of the EFSPI country associations to be "Association of the month" ansummarising their activities. The monthly newsletters are favoured over the previous quarterly newsletters, and enables EFSPI members to be kept up to date in a more timely fashion on key regulatory news, on upcoming scientific events, of the work being undertaken by the Special Interest Groups, latest news from the local statistical associations and advertising job opportunities.

The website continues to be a useful source of information. However, it will be undergoing a revamp in 2014. The Council have approved a plan to upgrade the software and revitalise the look and feel of the website. The current website address is http://www.efspi.org.

Chrissie Fletcher (UK) is the Communication Officer of EFSPI.

Operations Board Summary

The Operations Board had eleven teleconference meetings over the year, during which all ongoing and future activities were reviewed and issues discussed.

The board is composed of: Arne Haahr Andreasen (Treasurer), François Aubin (Vice-President), Egbert Biesheuvel (Scientific Affairs), Stefan Driessen (Statistical Leaders Meeting and SIGs), Chrissie Fletcher (President), Christoph Gerlinger (Regulatory Affairs), Julie Mellish (Executive Office).

Council Membership

In 2013, 10 countries national associations of pharmaceutical statisticians from 10 European countries were represented within EFSPI, totalising a combined membership of more than 2200.

During 2013, Birgitte Biilmann Rønn took over from Charlotte Hindsberger for Denmark, Marisa Bacchi took over from Fred Sorenson to represent Switzerland and Kevin Carroll replaced Nigel Howitt for UK. Françoise Tondu (France) also left the Council, her successor Maylis Coste joined the Council in early 2014.

Members of the EFPSI Council at the end of 2013 are listed in the Appendix.

Council Summary

Two Council meetings were held in 2013. The first took place in Copenhagen, Denmark, on 19th June. Eight countries were represented with 11 delegates. The second was held in Louvain-la-Neuve, Belgium, on 4th December. Twelve delegates, representing nine countries were present.

In addition to the two face to face meetings, two web conferences were held on 13th March and 8th October 2013.

At the June 2013 Council meeting, Egbert Biesheuvel was elected to become the new Vice-President, according to the EFSPI Constitution. At the December 2013 Council meeting, Francois Aubin withdrew as Vice-President and Egbert Biesheuvel became Vice-President.

Executive Office

The Executive Office facility continues to be provided by Kingston Smith (UK). Julie Mellish is the Secretariat for EFSPI.

Appendix: Council members at the end of 2013

Belgium
Emmanuel Quinnaux, IDDI
An Vandenbosch, Janssen

Denmark
Arne Haahr Andreasen, Andreasen Statistical Consulting
Birgitte Biilmann Rønn, Novo Nordisk

Finland
Tiina Hakonen, Oncos Therapeutics
Toni Sarapohja, Orion Pharma

France
Francois Aubin, Cardinal Systems

Germany
Frank Langer, Lilly
Christoph Gerlinger, Bayer

Italy
Paolo Morelli, Cros IT
Giampaolo Giacovelli, Rottapharm Madaus

Netherlands
Stefan Driessen, Abbott
Egbert Biesheuvel, MSD

Sweden
John Adler, AstraZeneca
Marie Göthberg, Novo Nordisk

Switzerland
Hans Ulrich Burger, Hoffmann-La Roche
Marisa Bacchi, Actelion Pharmaceuticals

UK
Chrissie Fletcher, Amgen
Kevin Carroll