European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Annual Report 2015

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Highlights from the EFSPI President & Vice President

2015 was another busy year for EFSPI. The new EFSPI website was released in Q1 2015 with a new look and improved functionality.

The regulatory committee continued to review draft guidelines, including the new draft FDA guideline on Adaptive Designs.

Three scientific meetings were held focussing on Health Technology Assessment (HTA), estimands and dose escalation to support late phase development.

The EFSPI Statistics Leaders meeting was well attended, and for the first time delegates were charged a small fee to attend. The additional income supports the administation costs for running EFSPI allowing EFSPI membership fees to be retained at current levels. Key topics discussed at the meeting included data transparency, real-world data, benefit-risk and estimands.Two new Special Interest Groups (SIGs) were established, one on the Application and Implementation of Methodologies in Statistics (AIMS) and one on Small Populations. An expert group on estimands was also formed.

EFSPI became an official body by becoming registered in Denmark.

Chrissie Fletcher (UK)	Marisa Bacchi (Switzerland)
President	Vice-President

Finance

EFSPI generated a small surplus in 2015, slightly less than planned. The website development work was completed as planned. The bank reserves remained constant since 2014.

EFSPI Income and Expenses 2015

	Actual €	**Budget €**	Variance €
Income			
Membership Fees	12.514	12.514	0
Scientific Meetings	19.530	27.000	(7.470)
EFSPI Statistics Leaders Meeting	5.070	4.875	195
Recruitment Web Advertisement	2.800	700	2.100
	39.914	45.089	(5.175)
Expenses			
Executive Office Hours	15.067	14.000	(1.067)
Attending Meetings	467	650	183
Web Development & Hosting	5.454	4.250	(1.174)
Office Costs	1.044	960	(84)
Bank Charges	3.838	2.000	(1.838)
Scientific Meetings	4.902	18.000	13.098
EFSPI Statistics Leaders Meeting	1.347	868	(479)
Incorporation	750		(750)
Anticipated revenue sharing	2.939		(2.939)
	37.468	41.478	4.010
Net result for the year	2.446	3.611	(1.165)

Balance

	2015 €	2014 €
Current assets		
Debtors	1.142	450
Prepayments	383	398
Accrued Income	5.190	
Bank - €	39.122	39.102
Bank - £ (Converted to €)	3.225	214
	49.062	40.164
Current liabilities		
Creditors	2.015	833
Accruals	5.280	10
	7.295	843
Revenue reserves		
Balance brought forward	39.322	40.6317
Result for year to date	2.446	(1.310)
	41.767	39.322

Birgitte Biilmann Rønn (Denmark)

EFSPI Treasurer

Regulatory Affairs

2015 has been a busy year for the PSI/EFSPI regulatory committee with the following key events:

- The US Institute of Medicine published a report on “Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk”.

- An expert group on estimands met to discuss the concept paper for the addendum to ICH E9. The expert group concluded it will be important to communicate and educate both statisticians and non-statisticians in the concepts, terminology and consequences of the choice of estimands for a clinical trial.

- The US Food and Drug Administration (FDA) issued a draft guidance on adaptive designs.

- The committee met with MHRA statisticians in London. Topics discussed included modelling and simulation, subgroup analyses, post-authorisation efficacy studies, methods for dose response evaluation, parallel scientific advice involving regulators and/or payers, data transparency, use of Bayesian approaches in confirmatory trials, comparison between Europe and US of initiatives aimed to accelerate the development of promising new medicines and biosimilars.

- The committee met with EMA’s Biostatistics Working Party (BSWP) in London. Topics discussed were subgroup analyses, quality attributes, measuring treatment benefit in a survival setting, the ICH E9 Addendum on estimands and sensitivity analysis, and multiplicity.

- EMA published draft guidance on post approval efficacy studies.

Christoph Gerlinger (Germany)

Regulatory Chair

Scientific Affairs


Egbert

EFSPI held three European Statistical meeting in 2015:

- A joint meeting with BBS on Health Technology Assessments held in Basel on the 23rd June
- A joint meeting with PSI on Estimands hosted by GSK in the UK on the 28th September.
- Dose Selection in Late Phase Clinical Development hosted by BMS in Brussels on the 12th November.

PSI/EFSPI also held a benefit-risk webinar in June that discussed latest methodology as well as sharing case studies of B-R assessments.

All presentations can be found on our website ('EFSPI international events'): http://www.efspi.org/index.php?p=EFSPI+activities&fid=19

Egbert Biesheuvel (the Netherlands)

Scientific Chair

Statistics Leaders Meeting

Twenty-six people from 10 different countries representing 24 pharmaceutical companies and CROs attended the 2015 EFSPI Statistics Leaders Meeting, which was held in Brussels and hosted by MSD on the 1st July 2015.

The Data Transparency Working Group, set up by EFSPI and PSI, is finalizing a series of 4 papers for publication in the areas of: (1) A primer on data sharing for researchers working with patient level data sets; (2) Ensuring patient confidentiality; (3) Best practices for analyses of shared data; and (4) How data sharing is impacting the role of statisticians. The general feeling is the important role and impact of biostatistics in this area is significantly contributing to improving the reputation of the industry and increased data transparency.

The impact of Real-World Data to drug development and the role of statisticians in this area were extensively discussed. Compared to 2014 it seems that more companies are getting active in this area and the general feeling was that biostatisticians should get themselves involved. There is clear need for best practices, technical and leadership expertise that EFSPI can support.

The Benefit Risk SIG presented its achievements over the last year and focused in the discussion on ways to increase the contribution of statisticians in this area within companies, as well as to increase the impact of the SIG and its work within EFSPI. Development of leadership and influencing skills will be key for statisticians in this area.

Estimands was presented as a new topic and new framework for improved clinical trial planning, conduct, analysis and interpretation. The concept of estimands was explained and examples given as well as its context to the missing data problem and sensitivity analyses. More examples will help to better understand the underlying definition and issues but also to explain it in due time with clinical colleagues.

All material from the EU Statistics Leaders Meetings held in 2010 through to 2015 are available on the EFSPI website:

http://www.efspi.org/EFSPI/Statistics_Leaders_Meetings/Previous_Meetings/5th_Meeting_-_June_2014/EFSPI/Statistics_Leaders_Meetings/5th_Meeting.aspx?hkey=60573615-f29f-4c2d-96cd-a140f3c68cee.

Stefan Driessen (the Netherlands)

Statistics Leader Forum Chair

Special Interest Groups

In 2015 two new EFSPI/PSI SIGs were established: the Application and Implementation of Methodologies in Statistics (AIMS) SIG and the Small Populations SIG. The AIMS SIG will investigate new analytical tools, enhancement of existing analysis software packages and evolution of industry data standards and guidelines. The Small Populations SIG will exchange information and share case studies of statistical/methodological challenges faced in the area of small populations, collaborate and discuss strategies and methodology being applied in this area of research, create visibility on biostatistics activities for small populations, and to promote and highlight opportunities for statisticians to make a positive impact, and form a working expert group within industry identified by, and interact with the external community, like the FP7 programs (IDEAL, INSPIRE and ASTERIX).

A summary of all the SIGs active in 2015 is provided below:

- Biomarker (leader = Athula Herath, AstraZeneca)
- Benefit-risk (leader = Alexander Schacht, Eli Lilly)
- Health Technology Assessment, HTA (leader = Chrissie Fletcher, Amgen)
- Integrated Data Analysis (leader = Byron Jones, Novartis)
- Medical Devices (leader = Roland Marion-Gallois, Metronic)
- Modelling & Simulation (leader = Chris Campbell, Mango Solutions)
- Real World data (leader = George Quartey, Roche)
- Toxicology (leader = Gareth Thomas, Huntington Life Sciences)
- Application and Implementation of Methodologies in Statistics (AIMS) (co-leads = Craig McIlloney, PPD and Lyn Taylor, PRA)

Stefan Driessen (the Netherlands)

Special Interest Group Chair

Communications

Monthly newsletters were distributed in 2015. Key highlights announced during the year included local association news and upcoming events, World of Statistics latest news, and celebrating milestones such as World Statistics Day and Clinical Trials Day. All newsletters are available on the EFSPI website (see address below).

The new website was released in Q1 2015 as planned.

Chrissie Fletcher (UK)
Communication Officer

François Aubin (France)
Website

Operations Board Summary

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

The board is composed of: Marisa Bacchi (Vice-President), Biilmann Rønn (Treasurer), François Aubin (Website), Egbert Biesheuvel (Scientific Affairs), Stefan Driessen (Statistical Leaders Meeting and SIGs), Chrissie Fletcher (President and Communications Officer), Christoph Gerlinger (Regulatory Affairs), and Julie Mellish (Executive Office).

Council Membership

In 2015, 10 countries national associations of pharmaceutical statisticians from 10 European countries were represented within EFSPI, totalising a combined membership of more than 2200.

Members of the EFPSI Council at the end of 2015 are listed in the Appendix.

Council Summary

Two Council meetings were held in 2015.

In addition to the two face to face meetings, two web conferences were held.

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 2015

Belgium
Emmanuel Quinnaux, IDDI
An Vandenbosch, Janssen

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

Finland
Sami Virtanen, Orion Pharma
Teppo Huttunen, 4Pharma

France
Francois Aubin, Cardinal Systems
Maylis Coste, Servier

Germany
Frank Langer, Lilly
Christoph Gerlinger, Bayer

Italy
Paolo Morelli, Cros IT
Giampaolo Giacovelli, Rottapharm Madaus

Netherlands
Stefan Driessen, Abbott
Egbert Biesheuvel, MSD

Sweden
Mattis Gottlow, AstraZeneca
Magnus Kjaer, AstraZeneca

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

UK
Chrissie Fletcher, Amgen
Mark Morris, Conatus Pharma