



European Federation of Statisticians in the Pharmaceutical Industry
Representing Statistical Associations in Europe

EFSPI Annual Report 2012

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Highlights from the EFSPi President & Vice President



Three successful scientific meetings were held in 2012: one on Benefit-Risk Assessment Methodology with the FMA and DSBS,, one on Modelling and Simulation with BBS and the Modelling and Simulation Basel group and one Applications to Longitudinal Data and one on Subgroup Analyses.

A first webinar was conducted “Are we finding the right dose(s) in phase 2?” It was a success with about 100 lines dialled in.

EFSPi was invited by EMA and participated actively in two workshops, one on multiplicity issues in clinical trials and one on clinical-trial data transparency.

Our membership fees were increased with 5% from 2011, but still they cannot cover our ordinary administration costs. During the first half of the year our administrative costs clearly exceeded the budget, consequently the costs were monitored more closely and the administrative support refocused during the second half of the year. By the end of the year the actual budget aligned close to the planned target.

Thanks to efforts to contain costs, and a refocus of the administrative support activities during the second half of the year, by the end of the year the actual budget aligned close to the planned target.

EFSPi held their 3rd EFSPi Statistics Leaders Meeting in 2012. Over 25 attended the meeting . An overview of all existing SIGs (Special Interest Groups) was given as well as the achievements and the plan forward for the new SIG Benefit-Risk. The final paper on “Career Path” was presented, which was the result of an initiative from an earlier Stats Leader Meeting. Most of the time, dedicated to discuss the rapidly changing environment for the community of EU pharmaceutical statisticians. The interactive workshop resulted in the identification of four focus areas with definitions of objectives and action plans: NXT generation Statisticians, EU differentiators, Areas for success now and Change Management All the materials from the EU Statistics Leaders Meetings are available on the EFSPi website: <http://www.efspi.org/index.php?p=EFSPi%20activities&fid=399>

Finance

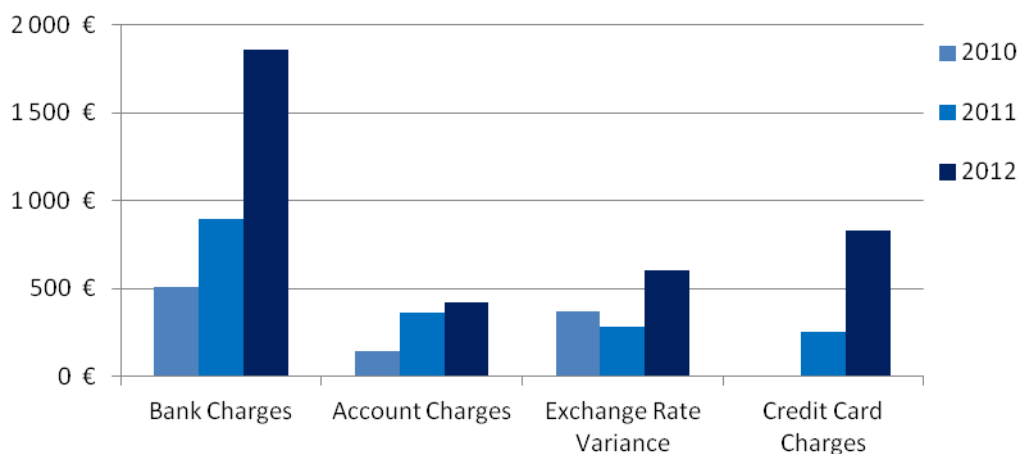
Our membership fees were increased with 5% from 2011, but still they cannot cover our ordinary administration costs. During the first half of the year our administrative costs clearly exceeded the budget, consequently the costs were monitored more closely and the administrative support refocused during the second half of the year. By the end of the year the actual budget aligned close to the planned target.



Our two first scientific meetings generate only very limited revenues, whereas the last meeting at the end of the year made up for that. In total 2012 resulted in a small profit for EFSPI. The general financial status of EFSPI is thus more or less unchanged with net assets comparable to one year expenses.

As the revenues from the scientific meeting are crucial for the balance of the budget we still need high attention on this in the coming meetings, especially catering and venue costs need to be monitored. Although EFSPI strive to cooperate with the member organisations in an atmosphere of trust and accountability, agreement on the basic elements of the meeting budget needs to be established between boards of the cooperating organisations early in the process.

In general the introduction of credit card payment has successfully shown to reduce both the efforts in tracing debtors and resulting bad debt from the scientific meetings. The CC payments do though come with increased payment charges. These have in 2012 been placed on the general account for bank charges. Consequently this account has increased considerable from 2010 before the CC payments were introduced (se figure). In the future the direct CC charges will be included as cost related to the scientific meetings, whereas the general charges for the CC payment system will remain within the account for bank charges.



EFSPI Income and Expenses 2012

	Actual	Budget	Variance
Income			
Membership Fees	12514	12511	3
Scientific Meeting Benefit & Risk	5175	12000	-6825
Scientific Meeting Modelling & Simulation	8000	8000	0
Scientific Meeting Subgroup Analysis	10880	10000	880
Recruitment Web Advertisement	700	0	700
	<u>37269</u>	<u>42511</u>	-5242
Expenses			
Executive Office Hours	15225	14500	-725
Attending Meetings	416	1000	584
Web Hosting	1009	1030	21
Office Costs	218	1800	1582
Bank Charges	1856	1000	-856
Scientific Meeting Benefit & Risk	5085	7000	1915
Scientific Meeting Modelling & Simulation	6004	5500	-504
Scientific Meeting Subgroup Analysis	3858	5500	1642
Anticipated Revenue Sharing	290	5000	4710
Bad Debt Provision	-300	2500	2800
	<u>33662</u>	<u>44830</u>	11168
Net result for the year	<u>3607</u>	<u>-2319</u>	5926

Balance

	2012	2011
Current assets		
Debtors	2900	2488
Sundry debtors	0	133
Prepayments	246	519
Bank - €	38563	47559
Bank - £ (Converted to €)	891	4069
	<u>42600</u>	<u>54768</u>
Current liabilities		
Creditors	3682	3454
Accruals	4151	20153
	<u>7834</u>	<u>23608</u>
Revenue reserves		
Balance brought forward	31160	37749
Result for year to date	3607	-6588
	<u>34767</u>	<u>31160</u>

Arne Haahr Andreasen (Denmark) is the Treasurer of EFSPI

Regulatory Affairs

No regulatory guidelines were commented upon in 2012.

EFSPI was invited by EMA to the workshop on multiplicity issues in clinical trials on Nov 16th, 2012 and to the workshop on clinical-trial data and transparency on Nov 22nd, 2012. We participated actively in both workshops.

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



Scientific Affairs

EFSPI held three successful European Statistical meeting in 2012:

- Benefit-Risk Assessment Methodology, a joint meeting with the FMA and DSBS, in Malmo, Sweden on June 7
- Modelling and Simulation and applications to longitudinal data, a joint meeting with the BBS and MSB in Basel, Switzerland on September 13 and
- Subgroup analyses in Brussels, Belgium on November 30

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>

A pilot webinar was conducted on November 19 focused on "Are we finding the right dose(s) in phase 2?". Perspectives from industry and EU regulators were provided and with close to hundred lines calling in it was a successful pilot. A next webinar is planned for 2013.

Egbert Biesheuvel (MSD) has replaced Nigel Howitt as chair of the Scientific Committee.



Egbert

Statistics Leaders Meeting

In 2012 the 3rd EFSPi Statistics Leaders Meeting was held in Weesp, The Netherlands.



Over 25 representatives from all the EFSPi countries representing many EU pharmaceutical companies attended the meeting facilitated by Abbott. The general purpose of the meeting is to continue to develop a network of statistical leaders, to shape and influence our professional environment and to help to shape the strategy for EFSPi. In this third meeting, an overview of all existing SIGs (Special Interest Groups) was given as well as the achievements and the plan forward for the new SIG Benefit-Risk. The final paper on “Career Path” was presented, which was the result of an initiative from an earlier Stats Leader Meeting. Most of the time, however, was dedicated to discuss the rapidly changing environment for the community of EU pharmaceutical statisticians. Firstly a thought provoking note was given on this topic followed by an intensive workshop. What was clear to the Statistical Leaders Forum is that the EU pharmaceutical statistical community will need to adapt and find ways and areas so that it can demonstrate its added value in the exciting area of developing and improving therapeutics.

The interactive workshop resulted in the identification of four focus areas with definitions of objectives and action plans (for more details please see the minutes on the website):

NXT generation Statisticians

To achieve that new graduates have better understanding of the whole drug development process and areas of statistical influence

EU differentiators

To maintain collective expertise and strong link between regulators, industry and cooperative group and promote advantages of EU

Areas for success now

To educate statisticians in an area such as Benefit/Risk where there is a need for quantitative valid approaches to summarize, present and communicate results across various domains to come to an overall evaluation. An area that would enable statisticians to add value beyond being a “number cruncher” and take a more strategic role while still utilizing their quantitative background

Change Management

To increase awareness and need for change, thereby identifying the skill set needed for statisticians and leaders. To define a vision and develop a “support package” that will enable statistical leaders to drive change in companies.

The outcome of the Meeting was fed back to the EFSPi Council and communicated in the October Newsletter. In the EFSPi Council meeting in December priorities were determined to significantly further the input from the Statistical Leaders group. Amongst other things the emerging area of Benefit-Risk will receive extra attention from the EFSPi Council as an area where statisticians can make a difference. It will actively support the establishment of a blue print by the SIG. A status update will be on the agenda of the Meeting in 2013.

At the end of 2012 a new topic emerged, the upcoming disclosure of individual patient data by EMA. It is the intention to actively involve the Statistical Leaders Forum to help EFSPi build up its position on this topic.

The Statistics Leaders Forum nowadays consists of around 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 second year led by Stefan Driessen (stefan.driessen@abbott.com), and before that for two years by Lesley France.

A reminder that all the materials from the EU Statistics Leaders Meetings held in 2010, 2011 and 2012 are available on the EFSPi website:

<http://www.efspi.org/index.php?p=EFSPi%20activities&fid=399>

Communications

Four newsletters were distributed in April, July, November and December 2012. A special article celebrating EFSPI's 20th anniversary was distributed in August 2012. The newsletters enable EFSPI members to be kept up to date on key regulatory news, on upcoming scientific events, of the work being undertaken by the Special Interest Groups, news from the local statistical associations and job opportunities. The website continues to be a useful source of information. New for 2012 was an information pack describing the aims and objectives of EFSPI, the associations who are members of EFSPI, and a summary of the range of activities EFSPI participates in. The website can be found at: <http://www.efspi.org>.



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

Special Projects

Expansion of EFSPI

The membership of EFSPI remains at 10 member countries.

End 2011 EFSPI has written to numerous national statistical associations to invite them to join EFSPI as an effort to increase the membership of EFSPI. Despite follow-up e-mails and newsletters in 2012 none of the associations have responded to EFSPI.



Egbert

Accreditation of Statisticians

No news on the topic of professional accreditation of (pharmaceutical) statisticians on national or international level. As decided in 2011 EFSPI has not pro-actively worked on this topic in 2012 but kept looking for possibilities to collaborate in case other associations would have started activities on this topic.

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 (President), Egbert Biesheuvel (Scientific Affairs), Stefan Driessen (Statistical Leaders Meeting and SIGs), Chrissie Fletcher (Vice President), Christoph Gerlinger (Regulatory Affairs), Julie Mellish (Executive Office). At the December 2012 Council meeting, François Aubin and Chrissie Fletcher exchanged their mandate, Chrissie Fletcher became President and François Aubin Vice-President, according to the EFSPi Constitution.

Council Membership

In 2012, 10 countries national associations of pharmaceutical statisticians from 10 European countries were represented within EFSPi, totalising a combined membership of more than 2800.

During 2012, Joachim Röhmel (Germany), Francesca Patarnello (Italy) and Carl Fredrik Burman (Sweden) left the Council. They were replaced by Frank Langer (Germany), Giampaolo Giacovelly (Italy) and John Adler (Sweden) while An Vandenbosch filled the Belgian representative position that was vacant end of 2011.

Members of the EFSPi Council at the end of 2012 are listed in the Appendix.

Council Summary

Two Council meetings were held in 2012. The first took place in, UK on 21st June. Seven countries were represented with 11 delegates. The second was held in Monza, Italy, on 4th December. Eleven delegate, representing eight countries were present.

In addition to the two face to face meetings, two web conferences were held on 1st March and 16th October 2012.

At the December 2012 Council meeting, Chrissie Fletcher (UK) took over as President while François Aubin (France) became Vice-President for one year. A new Vice-President will be elected at the June 2013 Council meeting to start in December 2012.

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 2012

Belgium

Emmanuel Quinnaux, IDDI
An Vandenbosch, Janssen

Denmark

Arne Haahr Andreasen, Andreasen Statistical Consulting
Charlotte Hindsberger, NovoNordisk

Finland

Tiina Hakonen, Oncos Therapeutics
Toni Sarapohja, Orion Pharma

France

Francois Aubin, Cardinal Systems
Francoise Tondu, Danone Research

Germany

Frank Langer, Lilly
Christoph Gerlinger, Bayer

Italy

Paolo Morelli, Cros IT
Giampaolo Giacobelli, Rottapharm Madaus

Netherlands

Stefan Driessen, Abbott
Egbert Biesheuvel, MSD

Sweden

John Adler, AstraZeneca
Marie Göthberg, Novo Nordisk

Switzerland

Fred Sorenson, Xcenda
Hans Ulrich Burger, Hoffmann-La Roche

UK

Nigel Howitt, PRA International
Chrissie Fletcher, Amgen