



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

EFSPI Newsletter July 2012

In this newsletter:

[EFSPI celebrates 20 years](#)

[EFSPI supports 2013 as the International Year of Statistics](#)

[3rd EU Statistics Leaders Meeting](#)

[Scientific Meetings](#)

[Regulatory update](#)

[EFSPI Council News](#)

[And finally.....](#)

[EFSPI celebrates 20 years](#)

Congratulations to EFSPI which is **20 years old**. EFSPI was founded on August 3, 1992 by 7 countries and currently has 10 national organisations that are members: Belgium (SBS/BVS), Denmark (DSBS), Finland (SSL), France (SFdS B&S), Germany (APF), Italy (BIAS), Netherlands (PSDM), Sweden (FMS), Switzerland (BBS) and UK (PSI). Collectively the national organisations within EFSPI serve approximately 2800 statisticians and statistical programmers.

The **objectives** of EFSPI are:

- To promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry
- To offer a collective expert input on statistical matters to national and international authorities and organisations
- To exchange information on and harmonise attitudes to the practise of statistics in the European Pharmaceutical Industry and within member groups

These objectives are met through the activities led by the Scientific Committee, the Regulatory group, and the individual national associations. In recent years, the annual EFSPI Statistics Leaders meeting has further extended the networking and exchange of information across EFSPI. Enabling national associations in Europe to collaborate, debate important scientific issues and promote the statistical profession is at the heart of EFSPI and **thanks to all** who have participated and supported EFSPI.

[EFSPI supports 2013 as the International Year of Statistics](#)

EFSPI is pleased to announce their support to 2013 as the International Year of Statistics. The International Year of Statistics ("Statistics2013") is a worldwide celebration and recognition of the contributions of statistical science. Through the combined energies of organizations worldwide, Statistics2013 will promote the importance of Statistics to the broader scientific community, business and government data users, the media, policy makers, employers, students, and the general public. Up to July 20 2012, there are 570 organisations from 89 countries signed on as participating organizations.

EFSPI and the national organisations are planning potential celebratory events and more information about these will be forthcoming later in 2012. If anyone has any suggestions for specific events then please contact Chrissie Fletcher (fletcher@amgen.com).

More information about this initiative can be found here: <http://statistics2013.org>. Take a look at the activities page (<http://statistics2013.org/activities.cfm>), there is already at least one activity scheduled for every month during 2013. One event includes an international video contest which aims to celebrate the positive impact of statistical science around the world.

3rd EU Statistics Leaders Meeting

Over 25 representatives from all the EFSPI countries and major pharmaceutical companies attended the **third EFSPI Statistical Leaders meeting** held on the 20th June in Weesp, The Netherlands. The general purpose of the meeting is to continue to develop a network of statistical leaders, shape and influence our professional environment and help to shape the strategy for EFSPI. In this third meeting, the achievements and the plan forward for the new SIG Benefit-Risk was presented, that was set up as a result of the meeting last year. An overview of all existing SIGs was presented as well as the final paper on "Career Path", which is again a result of a previous year initiative. A thought provoking note was given on the world for statisticians beyond clinical trials, which very well touched upon the theme of this year's meeting, our mutual future.

We see at present a lot of challenges in the EU pharmaceutical statisticians environment and it is not so clear what the best way is to address those by the various stakeholders; the companies, EFSPI, the Statistical Leaders Forum, and last but not least, the statisticians themselves. An intensive workshop in the afternoon was dedicated to get this on our radar screen and objectives and action plans for the short and longer term were defined. We will come back to that in a subsequent Newsletter and will be interested to hear from you; your feedback, comments, and willingness to participate. What is clear is that we will need to adapt and find ways and areas so that we can demonstrate our added value in the exciting area of developing and improving therapeutics.

All the materials from this leaders meeting and the previous 2 leaders meetings held in 2010 and 2011 are available on the EFSPI website:

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

If you have any specific questions or comments relating to this then please email

Stefan Driessen: stefan.driessen@abbott.com

Scientific Meetings

We are pleased to announce that **Egbert Biesheuvel** (MSD) is the new chair of the Scientific Affairs Committee. We also would like to thank **Nigel Howitt** (PRA) for chairing this committee over the last years in an excellent way.

The joined Benefit-Risk Assessment Methodology Workshop of EFSPi, FMS and DSBS in Malmo on June 7 had almost 50 participants. The opinions from key note speaker Larry Philips, different European regulators as well as practitioners in this field and the closing panel discussion made it a successful meeting

The following EFSPi scientific meetings are planned for the remainder of 2012:

- **Modelling & Simulation** (Basel, Sep 13, 2012), partnering with the Modelling & Simulation SIG and BSS. The meeting will discuss the role of M&S in drug development as well as applications of M&S to longitudinal data. <http://www.efspi.org/aadocs/efspibbsmsflyerprogramme2.pdf>

- **Subgroup analyses** (Nov 30, 2012), this meeting will take place in Brussels. Key opinion leaders from regulatory agencies, academic institutes and industry will be speaking. <http://efspi.org/aadocs/subgroupsflyer3.pdf>

Both events are open for registration (<http://www.efspi.org/>)

Regulatory Update

The EMA published two concept papers (outlines of guidelines to be drafted) that might be of special interest to you.

- 1) **Concept paper on extrapolation of efficacy and safety in medicine development**
(http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129285.pdf) Deadline for comments is Sep 30th, 2012.
- 2) **Concept paper on the need for a guideline on multiplicity issues in clinical trials**
(http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/05/WC500127901.pdf) Deadline for comments is Aug 30th, 2012.

The European Medicines Agency is hosting a one-day invitation-only workshop on multiplicity issues in clinical trials. The workshop will be held on 16 November 2012 at the EMA in London, UK.
(http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/06/WC500128996.pdf)

EFSPi has been invited to participate and will of course do so.

EFSPi Council News

The EFSPi Council had a face to face meeting on the 21st June 2012. The final accounts for 2011 showed EFSPi made a loss of approx €6.5k. In order to minimise any future losses, EFSPi are investigating holding scientific meetings at cheaper venues and in more central locations. In addition, outstanding debts have been substantially reduced.

EFSPi are planning a webinar on dose finding in phase 2. The meeting will take place in October or November. The aim of the webinar is to discuss recent case studies assessing the extent of dose finding in phase 2 and the challenges of choosing optimal dose(s) for phase 3. The perspectives from Industry and from the regulators will be provided, and key recommendations and best practices for improving phase 2 drug development programs will be highlighted.

The EFSPi Council is continuing to seek interest in expanding its membership to the broader statistical communities across Europe.

And finally.....

If you are currently seeking to hire a statistician and wish to post a job advert, see the "Advertisements" area on the EFSPi website at www.efspi.org and view the "Job Postings" for instructions. EFSPi are offering one free advert for every 3 adverts posted on the website.

To add your e-mail address to the EFSPi mailing list, click on "Sign up to our newsletter" on the homepage of the EFSPi website at www.efspi.org.

To view previous newsletters please see the EFSPi website www.efspi.org.

Chrissie Fletcher
EFSPi Communications Officer