



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

## EFSPI Newsletter May 2013

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### [Update on "Statistics2013" and the International Year of Statistics](#)

The number of participating organisations in the International Year of Statistics currently stands at 1,947 organizations from 122 countries worldwide. The [Statistics2013 website](#) is filled with information and resources including recent and upcoming events, and tools to help educate the public about how statistics improves their lives, the work of statisticians as well as careers in the statistical sciences.

A workshop on the Future of the Statistical Sciences Workshop will be held on November 11 and 12 in London, United Kingdom. The aim is to bring together statisticians from around the world, scientists who collaborate with statisticians, science writers and representatives from funding agencies. If you know of an outstanding statistician deserving of recognition for his or her work, you can nominate the person for the Statistics2013 Statistician Job of the Week, see the website for more details.

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### [EFSPI 3-year Strategic Plan and 2013 Goals](#)

The 3 year strategic plan for EFSPI for 2013-2015 has been finalized and is available on the [EFSPI website](#). The 3 priority areas of focus are summarized below:

1. Represent the association members of EFSPi and provide a united and respected voice on key scientific, regulatory and statistical issues in drug development
2. Enhance the profile of EFSPi in Europe and strengthen alliances and collaborations with other professional bodies within Europe
3. Set and promote professional standards in Europe for the application, understanding and communication of statistics in drug development

Goals for 2013 can also be viewed on the [EFSPi website](#). The goals will be updated during the year as needed.

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## Regulatory Update

The EMA's transparency initiative reached its first milestone. The results from the five advisory groups have been finalized and are available on EMA's website: ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\\_topics/document\\_listing/document\\_listing\\_000368.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000368.jsp)). In general, there was little consensus between the diverse stakeholders ranging from academia to industry.

EFSPi developed a [position paper](#) on access to clinical trial data to EMA for consideration. EFSPi supports the EMA transparency initiative and we highlighted in the position paper that different levels of access will help to preserve patient confidentiality; the process of analyzing clinical trial data is complex and requires qualified and experienced individuals; data anonymisation will protect patient confidentiality but may prevent results to be reproduced and may limit further analyses; and access to data be granted in the format used in the original analyses. EFSPi supports further guidance on technical aspects relating to re-analyses and secondary analyses would be useful.

The next step will be EMA drafting the policy on access to clinical trial data, which is expected by June 30<sup>th</sup>. The consultation period will be until end of September. EFSPi plans to hold a scientific meeting to discuss the draft policy towards the end of the summer, see the [Scientific update](#) below.

EFSPi commented on the FDA' enrichment guidance (<<add link to EFSPi website>). Special thanks to all who contributed and in particular to Francis Lynn, Leslie France and Jürgen Hummel who collated the comments.

The German HTA body IQWiG is updating their methods paper in several steps ([https://www.iqwig.de/download/13-04-18\\_Entwurf\\_Aktualisierung\\_Allgemeine\\_Methoden\\_4-0.pdf](https://www.iqwig.de/download/13-04-18_Entwurf_Aktualisierung_Allgemeine_Methoden_4-0.pdf)). Unfortunately the 42-page draft version of the first update is only available in German.

Three EFSPi colleagues attended the recent FDA/DIA Statistics Workshop held in Washington DC, US 29<sup>th</sup> April to 1<sup>st</sup> May 2013. This was an excellent meeting covering an overview of PDIFA V commitments, missing data, statisticians as leaders, dichotomising continuous measures for primary endpoints, benefit-risk, Health Technology Assessment and comparative effectiveness research, companion diagnostics, meta-analysis for safety data, pre-competitive collaboration, overview of the draft FDA guidance on enrichment populations, and the international year of statistics. There was excellent discussion amongst the attendees which included many statisticians from the various FDA centers, and representatives from Industry and academia.

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## Scientific Meetings

EFSPi is organizing three scientific meetings in 2013:

- **Health Technology Assessments on June 4, 2013 in Basel.** This joint meeting with the BBS will highlight, together with case studies, some of the key statistical challenges by representatives from academia, HTA bodies/regulators and industry. Please look at the EFSPi website for more information on the program, speakers and how you can register for this event. (<http://www.efspi.org/>)

- **Structured Benefit-Risk Assessment on September 17, 2013 in London.** This joint meeting with the PSI will give the latest information around structured Benefit-Risk assessments from academia, industry and regulatory perspectives. For more information, please visit the EFSPi website for more information (<http://www.efspi.org/>). This event is open for registration; see also the PSI website ([https://services.psiweb.org/site/events/events\\_summary.asp](https://services.psiweb.org/site/events/events_summary.asp)).

- **Survival Analyses on November 2013 in Brussels.** More information will follow.

In addition, EFSPi is planning to organise a meeting towards the end of the summer to review the draft EMA policy on access to clinical trial data. For more information, please see the [Regulatory Update](#).

Other Scientific Meetings organised by local national member organisations can be found on the *Calendar of Events*. (<http://www.efspi.org/index.php?p=calendar+of+events&fid=17>)

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## 4<sup>th</sup> EU Statistics Leaders Meeting

EFSPi is organizing the fourth Statistical Leaders Meeting in Copenhagen at Novo Nordisk on June 18. Forty four leaders from 10 different countries have been invited. In follow up of last year they will review and discuss recent developments in the EU statistical community and jointly try to manage the change for the good of our profession and work capacity. The SIG Benefit Risk, identified as key area of attention, will present progress on the roadmap to

be developed. The new topic of EMA's Clinical Trial Data Transparency initiative will be extensively discussed: EMA's considerations, EFSPi's position statement, individual companies' policies will be presented and elaborated on. Both short term consequences and long term expectations will be debated.

In case, you have any specific questions that you would like to see addressed by this group **please contact Stefan Driessen (stefan.driessen@abbott.com).**

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## **Association of the month: Denmark and the Danish Society for Biopharmaceutical Statistics (DSBS)**

The Danish Society for Biopharmaceutical Statistics (DSBS) was formed in March 1992 as an independent non-profit association. About 150 statisticians, representing 18 companies, are currently members of the society. DSBS aims to promote the exchange of information between professional statisticians working for the pharmaceutical or biotech industry in Denmark and abroad and to support and maintain a high level of scientific knowledge within the community. This is done by organising courses, scientific meetings and workshops for the members. Last year a course "Sample Size Determination in Clinical Trials and Meta-analysis Using Individual Patient Data" was held in January while a workshop was held jointly with the Swedish organisation, FMS, titled "Benefit-Risk Assessment Methodology Workshop, Statistical Issues in Medical Statistics".

This year, the international year of statistics, a half day scientific meeting has been held in January titled "The statistician in a regulated and global industry - Experiences and challenges" and a mini seminar is planned in connection with the Annual General Meeting on May 23.

Further information on the society can be found on the website [www.dsbs.dk](http://www.dsbs.dk).

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## **EFSPi Council News**

EFSPi finances remain on budget. The council is considering options and associated costs for upgrading the website as the website platform is now several years old. The contract with the Executive Office is due for renewal at the end of 2013 and a careful review is ongoing of the admin support required to ensure EFSPi runs successfully at a cost that is affordable relative to the activities being undertaken.

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## 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](http://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.

To view previous newsletters please see the EFSPi website in the "News" area.

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Chrissie Fletcher  
EFSPi Communications Officer