



## EFSPI Newsletter July 2013

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### [Regulatory Update](#)

EMA published its draft policy on publication and access to clinical trial data for consultation on the 24<sup>th</sup> June 2013 and comments are due by September 30<sup>th</sup> 2013. EFSPI has issued a position paper on EMA's data transparency initiative and will be submitting comments on the draft policy on behalf of the EU Statistical community. The comments are currently being collated within each EFSPI member association.

EFSPI / PSI are hosting a ***European statistical workshop on Thursday 22<sup>nd</sup> August 2013 at the Royal Statistical Society (RSS) in London*** to discuss key elements of the draft policy. Various speakers will highlight key challenges in this area from different angles to stimulate the discussion in breakout sessions. In order to facilitate the discussions at this meeting, the number of participants will be limited to ~60. This meeting is now open for registration. Please go to: [www.efspi.org](http://www.efspi.org).

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### [Scientific Meetings](#)

In addition to the statistics workshop noted above, EFSPI is organizing two other meetings in the remainder of 2013:

- **Structured Benefit-Risk Assessment on September 17, 2013 in London.** This joint meeting with 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 and its applications in Drug Development in November 2013 in Brussels.** This meeting aims to bring together statisticians from Pharma, academia and regulatory agencies to discuss recent advances in the application of survival methodology and important operational issues. For more information, please visit the EFSPI website (<http://www.efspi.org/>).

The next **PSI Pharmaceutical Statistics journal club** takes place on the **1<sup>st</sup> August 2-3.30pm BST**. Please see the flyer for more information: [http://www.efspi.org/index.php?p=CALENDAR\\_OF\\_EVENTS&fid=17](http://www.efspi.org/index.php?p=CALENDAR_OF_EVENTS&fid=17). 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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## [EU Statistics Leaders Meeting](#)

The fourth EFSPI Statistical Leaders meeting was held June 18, 2013, in Copenhagen, Denmark. 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 and to develop collaboratively good statistical practice in Medical Devices. 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. 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 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; Two companies, GSK and Roche, shared details of their company 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.

All the presentations will be available on the EFSPI website (<http://www.efspi.org/>). Detailed minutes of the meeting will also be available when they are finalized. For any queries relating to this meeting **please contact Stefan Driessen ([stefan.driessen@abbott.com](mailto:stefan.driessen@abbott.com))**.

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## SIG Update

EFSPi are pleased to announce the formation of a new SIG on **Integrated Data Analysis**. The new SIG will be led by Byron Jones from Novartis, Basel, and has the following aims:

1. To create a forum for individuals interested in integrated data analyses to share experiences, develop best practices, work with experts in the field and collaborate with other interested parties on integrated data analysis in drug development.
2. To be aware of regulatory initiatives of relevance to integrated data analysis and to assess their potential impact on industry practice.
3. To develop an industry position on how data in the private and public domains should be integrated and presented, particularly with respect to how such data will be considered by regulatory agencies.
4. To form working groups to review current methodology and practice, and where necessary develop new methods or practices for the integration of data, in the areas of
  - a. Efficacy Data in Phases II and III;
  - b. Safety Data (maintaining links with the Epidemiology and Safety SIG);
  - c. Health Technology Assessment and Network Meta-Analysis (maintaining links with the Health Technology Assessment SIG);
  - d. Trial results made public as a result of greater data transparency on the part of the industry.
5. To write position papers on the topics identified in 4. and engage in public debate by making presentations at public meetings and conferences.

Byron is looking for volunteers to actively contribute to this new SIG. If anyone wants to learn more about the SIG or to volunteer, please contact him at [byron.jones@novartis.com](mailto:byron.jones@novartis.com).

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## Association of the month: FMS (Föreningen för Medicinsk Statistik)

The Swedish Society for Medical Statistics, FMS (Föreningen för Medicinsk Statistik) is a subsection of the Swedish Statistical Society (Svenska Statistikfrämjandet), an association for all fields of statistics and statisticians: medicine, industry, surveys and official statistics, education and research. Statisticians as well as users of statistics and other "friends of statistics" are welcome as members.

FMS organizes statisticians within the medical area, i.e. in the pharmaceutical industry as well as in other medical research, public or private, and in biostatistical research and education. The main objective of FMS is to stimulate the development and promote the use of new and established statistical methods within the medical sector as well as within the areas of pharmaceutical industry and public health.

To achieve this, FMS organizes courses and scientific meetings, typically 2-4 meetings each year. Regular such meetings are the combined spring/annual meeting and a fall meeting. Every other year we co-organize meetings with our sister-associations in Denmark (DSBS) and Finland (SSL). The most recent collaborations were a workshop on Bayesian data analysis in Espoo, Finland, organized together with SSL this year, and a workshop in Malmö (Sweden) 2012 on Benefit-risk assessment methodology organized together with DSBS and EFSPi.

In addition to organizing meetings, FMS distributes information on scientific meetings, courses, EFSPi information etc. FMS also promotes discussions on applications or statistical issues through articles in Qvintensen, a quarterly magazine published by the Swedish Statistical Society.

FMS has almost 300 members and was founded in 1987; we recently celebrated our 25th anniversary.

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

New items are being added daily to the [Activities Calendar](#) on the [Statistics2013](#) website. This list is an excellent place for finding activities which you can participate to celebrate Statistics2013. It also is a great place to see what other organizations around the world are doing to mark the celebration.

The [Statistics2013 website](#) is filled with information and resources—particularly the [posters](#) and the [downloadable flyer](#)—to educate the public about how statistics improves their lives, the work of statisticians as well as careers in the statistical sciences. Think about how you might be able to use these resources as part of celebrating Statistics2013.

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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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