



## EFSPI Newsletter June 2013

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### [Regulatory Update](#)

#### **EMA transparency initiative**

EMA has published its draft policy

([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2013/06/WC500144730.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf))

and comments are due by 30<sup>th</sup> September 2013. A joint EFSPI/PSI meeting to discuss the draft policy will take place at the Royal Statistical Society in London on August 22<sup>nd</sup> 2013. In order to facilitate the discussions at this meeting, the number of participants will be limited to ~60. Further details of the meeting will be announced in the July newsletter. If you would like to participate in the workshop please send an email to Egbert Biesheuvel ([egbert.biesheuvel@merck.com](mailto:egbert.biesheuvel@merck.com)) by the 15<sup>th</sup> of July 2013.

#### **FDA transparency initiative**

The FDA has posted questions for consideration on their proposal to release masked individual patient data ([www.regulations.gov/#!documentDetail;D=FDA\\_FRDOC\\_0001-3962](http://www.regulations.gov/#!documentDetail;D=FDA_FRDOC_0001-3962)). The deadline for comments is Aug 5<sup>th</sup>.

EFSPI will be collating comments on both of these initiatives. The EFSPI Council representatives from each country association will be the points of contact for collating comments in each country. A separate email will be sent within each association with the contact names and timelines for submitting comments.

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

Wiley has created a new statistics information hub, [www.statisticsviews.com](http://www.statisticsviews.com), which aims to bring statistics together with free access to exclusive feature articles, news items, details of forthcoming events, society details and much more. Throughout 2013 StatisticsViews.com will be updated with news related to the International Year of Statistics.

To celebrate 2013 and the International Year of Statistics, Wiley has created an opportunity for statisticians around the globe to sample much of its statistics book and journal content. Use this link [www.wiley.com/go/iys](http://www.wiley.com/go/iys) to get free access for the duration of 2013 to over 150 classic journal articles & book chapters, free trial access to over 20 statistics journals and free issues of Significance magazine to read on a mobile app.

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## [Scientific Meetings](#)

EFSPI is organizing two scientific 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/>).

In addition, EFSPI and PSI are planning a meeting in the summer to discuss the **draft EMA policy on publication and access to clinical trial data**. For more information, please see the [Regulatory Update](#).

A very successful and well attended meeting on **Health Technology Assessments** took place on 4<sup>th</sup> June 2013 in Basel. A summary of the meeting and all presentation slides can be found on both the BBS site (<http://www.ceb-institute.org/bbs/?p=506>) and EFSPI (<http://www.efspi.org/index.php?p=EFSPI+activities&fid=19>) websites.

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>)

JAMA (Journal for the American Medical Association) have released an updated publication policy where they will now evaluate and consider for publication clinical trials that are analysed by statisticians employed by or contracted by the study sponsor without requiring independent statistical analysis by an academic biostatistician. Click [here](#) to see the updated policy.

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

A successful 4<sup>th</sup> EU Statistics Leaders meeting took place in Copenhagen at Novo Nordisk on the 18<sup>th</sup> June 2013. Twenty-three leaders from 9 different countries and 20 institutions attended. The strategic objectives for EFSPI for 2013-2015 were presented, followed by the introduction of the Medical Devices SIG. A useful summary of the recent changes and trends relating to Medical Devices was presented along with the key areas of focus for the SIG, including the regulatory framework and how statistics is contributing to this evolving field. The Benefit-Risk SIG presented on the progress they have made since the last meeting, including the development of a roadmap that will describe and link the numerous Benefit-Risk initiatives currently underway and will give statisticians material to increase their capabilities in the area. An update was provided for all the other SIGs, and it is clear there is a significant amount of important activities being pursued by the SIGs, including meetings, handbooks and best practices.

The EMA's Clinical Trial Data Transparency initiative was extensively discussed: GSK and Roche shared details of the strategies their companies are taking with regard to transparency, and four breakout sessions focussed on what impact transparency will have on the EU statistics community in the future.

A further summary of the actions arising from this 4<sup>th</sup> leaders meeting and access to the materials will be available in the July newsletter. In the meantime, 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**

The PSI/EFSPI SIG Biomarkers announced that there will be a two day introductory course to the use of Biomarkers in pharmaceutical drug development. The course will provide an overview of general statistical principles in the development of biomarkers and biomarker-based classifiers and in the design and analysis of biomarker studies. Practical examples will be given in R. The PSI is organising the course in conjunction with the SIG.

**Statistical Issues in the Use of Biomarkers - 25-26 September 2013, Sunningdale Park, Ascot, Berkshire - **REGISTRATION OPEN****

Please [click here](#) for further information and to register for the course.

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## Association of the month: Germany and APF

The Arbeitsgruppe Pharmazeutische Forschung ([APF](#)) is a working group within the German Region of the International Biometric Society. Founded in 1978, the APF is aiming to establish contacts between biometricians who work in, or for, the pharmaceutical industry. Through this group an exchange of information on statistical methodology and development of new methods, particularly concerning their practical application, is expected to be much faster. In addition, information on regulatory requirements, guidelines and scientific meetings is distributed and discussed within the group.

About 330 statisticians are currently member of the APF. All biometricians who work in, or for, the pharmaceutical industry can become a member of the APF.

Regular workshops are organized annually in autumn. Presentations, preferably concerning practical aspects, are given by members or invited guests from Industry, Academia or Regulators. The next workshop is planned for 29<sup>th</sup> of November in Darmstadt. The topic will be "Phase II in Oncology". Furthermore, the group is actively taking part in facilitating session at the annual meetings of the International Biometric Society, German Region, e.g. the APF planned and chaired a session at the 59th Biometric Colloquium in Freiburg on "**Data Monitoring Committees for Confirmatory Adaptive Clinical Trials**".

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## EFSPI Council News

The Council met face to face following the EFSPI Leaders meeting and welcomed Birgitte Billmann Ronn who has replaced Charlotte Hindsberger as the 2<sup>nd</sup> Denmark council representative. EFSPI thanks Charlotte for her contributions to EFSPI over the last few years. Egbert Biesheuvel from the Netherlands was voted in as the next Vice-Chair for EFSPI which will be effective following the next face to face council meeting in December. A second council member is being sought to shadow the current EFSPI Treasurer in order to ensure a smooth succession plan for this key role. There was endorsement by the Council to improve the EFSPI website and investigate options and associated costs. Francois Aubin is leading the activities for the website, where volunteers are requested to form a small website working group.

EFSPI are investigating the possibility of becoming a formal legal entity. Having an official legal status is becoming increasingly important and a requirement to participate in consortia led projects, for example projects funded by the EU Commission.

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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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