



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

## EFSPI Newsletter February 2013

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

The [Statistics2013 website](#) is filled with information to educate the public about how statistics improves their lives, the work of statisticians as well as careers in statistical science. **If you have not visited the site yet, take the time soon to peruse its public-oriented informational content.**

Wiley, a strong supporter of the International Year of Statistics, has developed several ways in which people worldwide can experience and try out its statistics content throughout 2013. It has created a number of offers (including *Significance* magazine), which are presented on its new statistics information hub at [StatisticsViews.com](#).

The latest International Year of Statistics newsletter is available at <http://www.statistics2013.org/files/2013/02/February-11-2013.pdf>

EFSPI is a supporter of the International Year of Statistics and this event will be promoted during the planned activities during 2013.

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### [Regulatory Update](#)

There has been a great deal of focus in January and February regarding the EMA access to clinical trial data initiative. As noted in the December 2012 newsletter, EMA have set up 5 advisory groups on the following topic areas: patient confidentiality; clinical trial data formats; rules of engagement; good analysis practice; and legal aspects. Each group will meet 3 times between January and March after which EMA will develop recommendations by the end of April. Following consultation and review during the summer, final guidance is anticipated by the end of 2013.

EFPIA have also set up working groups on these 5 topic areas. EFSPI have representation on 4 of the EMA advisory groups and EFPIA working groups. There are a number of important aspects under discussion, including who should have access to clinical trial data, how should data be made available, what data should be made available, and most importantly how will patient confidentiality be maintained. Stefan Driessen ([stefan.driessen@abbott.com](mailto:stefan.driessen@abbott.com)) is the EFSPI contact for 'patient

confidentiality'; Uli Burger ([hans\\_ulrich.burger@roche.com](mailto:hans_ulrich.burger@roche.com)) is the EFSPI contact for 'clinical trial data formats'; Chrissie Fletcher ([fletcher@amgen.com](mailto:fletcher@amgen.com)) is the EFSPI contact for 'rules of engagement'; and Christoph Gerlinger ([christoph.gerlinger@bayer.com](mailto:christoph.gerlinger@bayer.com)) is the EFSPI contact for 'good analysis plans'. Each EFSPI lead is engaging with other statisticians who are participating in the advisory/working groups and with the EFSPI Statistical Leaders to discuss the key statistical aspects. EFSPI will be developing a position and recommendations on these topics and we will share this in a future newsletter.

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## Association of the month: Italy and BIAS

The Italian association BIAS (Biometristi dell'industria Farmaceutica Associati) is organizing two events in 2013 in an effort to reach both Italian Statisticians working in the healthcare industry, and also Clinical Data Managers, SAS programmers and other roles involved in clinical research such as Quality Assurance Managers and Clinical Study Managers. As 2013 is the International Year of Statistics, the BIAS group wants to promote biostatistics and increase public awareness on its importance in clinical research.

On February 22<sup>nd</sup>, the BIAS committee is organizing a conference titled "Data Handling and Reporting in Clinical Trials with SAS". This conference covers various aspects of statistical analysis in a clinical study from a SAS programming point of view. The topics covered will focus on using data standards, the use of SAS procedures for statistical modeling, the different techniques for reporting and the strategies and techniques for QC. This is an opportunity for professionals in the industry to share experiences, challenges and solutions.

The second event of the year will be the 5<sup>th</sup> Annual BIAS Congress in September. Having great success and positive feedback in previous years, BIAS will again organize two parallel sessions joining the Biostatisticians and the Data Managers. Details on the program are still being defined, but the congress will be related to recent issues and trends in Clinical Data Management and Biostatistics. Probable topics include subgroup analysis, Bayesian methods, simulation methods and submission requirements (CDISC).

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## Scientific Meetings

EFSPI will organize 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. For more information and confirmed speakers please look at the EFSPI website ([www.efspi.org](http://www.efspi.org)). The registration process will open in a few weeks.

- **Benefit-Risk on September 17, 2013 in London.** This joint meeting PSI will give the latest information around structured Benefit-Risk assessments from academia, industry and regulatory perspectives. For more information see the PSI website ([www.psiweb.org](http://www.psiweb.org)).

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

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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 at [www.efspi.org](http://www.efspi.org).

To view previous newsletters please see the EFSPI website [www.efspi.org](http://www.efspi.org).

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