



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

EFSPI Newsletter March 2013

In this newsletter:

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

[Regulatory update](#)

[Association of the month: France and *Société Française de Statistique \(SFDS\)*](#)

[Scientific Meetings](#)

[4th EU Statistics Leaders Meeting](#)

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

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

Statistics2013 participation has passed the 1,800-participant mark and now is setting its sights on the next milestone: 2,000. Participation currently sits at 1,835 organizations and 121 countries. As a refresher, the individual participating organization count is three times the original goal of International Year of Statistics organizers. You can check out the updated participant and country lists at the [Statistics2013 website](#).

The *Significance* magazine poster promoting Statistics2013 is now available for download from the [Statistics2013 Posters section](#) of the International Year of Statistics website. At this page you will find a total of four posters for your use in promoting the International Year of Statistics to your organization’s public audiences.

Earlier this month, the International Year of Statistics honoured women worldwide and women statisticians on International Women’s Day (March 8). EFSPI is a supporter of the International Year of Statistics and this event will be promoted during the planned activities during 2013.

[back to top](#)

[Regulatory Update](#)

The EMA access to clinical trial data initiative continues to be a top priority within EFSPI. The 5 EMA advisory groups have continued discussions and the groups are close to finalizing their summaries of their topic areas: patient confidentiality; clinical trial data formats; rules of engagement; good analysis practices; and legal aspects. These summaries which will be finalized by the end of April will provide EMA with recommendations for consideration as they develop their draft policy by the end of June. Consultation on the draft policy will be open until the end of September and a final policy is due to be released by the beginning of November. EFSPI is planning to hold a 1-day joint scientific/regulatory forum to discuss the draft policy around the end of July; more information will follow in future newsletters.

EFSPI has developed a position paper summarising the key aspects important for the EU Statistical Community. The following issues are discussed:

- Anonymising data to protect patient confidentiality and the subsequent ability to re-analyse data;
- Appropriate levels of access to data for aggregate (summary) data compared to patient level data;
- Qualification of researchers request access to data and expertise to conduct analyses;
- Good scientific practice regarding the development of protocols/analysis plans for re-analysis of data; and
- Standards for data structures and documentation of supporting information.

This draft position will be reviewed by the EU Statistics Leaders and by the EFSPI Council who will seek input from their members in each country association. However, as the goal is to submit the final position paper to EMA before the end of April, there will not be a great deal of time to review and comment. The EFSPI contacts involved will do their best to incorporate as many of the comments as is possible and thank the EU Statistical community for their immediate review. The final EFSPI position paper will be published on the EFSPI website, and key highlights from the paper will be summarised in the next EFSPI newsletter.

In other regulatory news, EFSPI is anticipating EMA will release a draft guideline on subgroup analyses and FDA will release a draft guideline on multiplicity in 2013. EFSPI will co-ordinate the review of these key new guidance documents.

[back to top](#)

Association of the month: France and *Société Française de Statistique (SFdS)*

The *Biopharmacie et Santé* (B&S) Group is currently one of the "specialised groups" of the French statistical society *Société Française de Statistique* (SFdS). This society is opened to French and French-speaking statisticians. The B&S group was created in 1986 (within the former French Statistical Society *Association de la Statistique et ses Utilisateurs*), which became in 1997 the SFdS, federating ASU and two other smaller independent statistical societies. SFdS counts more than 1000 members. B&S is the biggest specialised group of SFdS, with more than 500 members interested in its activities. As any other specialised groups of SFdS, it is itself organised as a non-profit association, with an elected 10- members' board (president, secretary, treasurer and other contributing members).

The B&S group is open to all statisticians working in the pharmaceutical industry or related areas as well as in public or private, human or animal, health research institutions and universities. The diversity of the board allows interests and active sharing around statistics and related topics such as regulatory and training as examples. B&S objectives are (i) to facilitate meetings, thinking and exchanges between statisticians and statistics' users in health and drug development areas, (ii) to organize workshops, trainings, congresses and working parties, (iii) to promote the profession of statistician, and maintain links with French and European scientists and health authorities.

Since 1989 the B&S group organises in Paris an International Meeting every four years dedicated to statistical advances and innovations in drug development and health. The 7th International Meeting

- Statistical Methods in Biopharmacy, entitled "*Emerging Topics For Statistical Methodology In Clinical Drug Development*" will take place in Paris, on 16 and 17 September 2013. The scientific committee chairperson is F. Bretz and the four scientific topics are: Dose Finding, Subgroup Analysis & Identification, Quantifying Benefit-Risk and Graphical Approaches. More information on this meeting is available at <http://www.biopharma2013-sfds.fr>

During the other years, B&S has a regular one-day scientific workshop. In 2010, this workshop was international, and co-organized with EFSPi. In 2011 and 2012 the program was made of presentations from selected advanced students (master level), who had spent six months in statistical departments (in industry and/or public research institutions), and developed these hot topics. One or two yearly training sessions are generally proposed to B&S members (the two last ones covered "Dose-finding" and "Adaptative designs"). Working groups are also organised within B&S, such as "Good Statistical Practices in clinical", and "in preclinical statistics", "Medical Devices" (an EFSPi SIG) or "Genomics".

More information on SFdS and B&S is available on the B&S Website: <http://www.sfds.asso.fr/>

[back to top](#)

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). 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).

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

The Finish and Swedish associations, SSL and FMS respectively, are holding a joint workshop on **Bayesian Data Analysis, 6 - 7 May 2013 at Orion Pharma, Helsinki, Finland.** For further information please see the EFSPi website (www.efspi.org).

[back to top](#)

4th EU Statistics Leaders Meeting

The 4th EU Statistical Leaders Meeting will be held in Copenhagen (Novo Nordisk facilities) on Tuesday 18th June 2013. Key topics for discussion include EFSPi's strategic objectives for 2013-2015 (these will be presented in the April newsletter along with EFSPi Council news), benefit-risk, the EMA access to clinical trial initiative and an update of the wide range of activities that the Special Interest

Groups are engaged in. For more information about this meeting please contact Stefan Driessen (stefan.driessen@abbott.com).

The Statistical Leaders Forum has also been engaged in the discussion on the EMA Transparency initiative. In a separate meeting with the group the status of EFSPi input and review has been explained and a full review of the EFSPi position paper is planned to further strengthen our input (see also section on Regulatory Update).

[back to top](#)

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.

[back to top](#)

Chrissie Fletcher
EFSPi Communications Officer