



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

EFSPI Newsletter November 2012

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

The International Year of Statistics is just a couple of months away. The EFSPI member associations are each busy identifying planned events in 2013 where Statistics2013 can be celebrated.

More than 700 organizations—universities, research institutes, high schools, professional societies, government agencies and businesses—in nearly 100 countries are joining to celebrate and promote the importance of statistical science to the science community, businesses, governments, the news media, policymakers, employers, students and the public.

During this yearlong celebration, EFSPI and the hundreds of other participating organizations around the world will be:

- * Increasing public awareness of the power and impact of statistics on all aspects of our society
- * Nurturing statistics as a profession, especially among high-school and college students
- * Promoting creativity and development in the sciences of probability and statistics

Be sure to visit our website in the months ahead to learn more about how Statistics helps shape your everyday life: <http://statistics2013.org>. If anyone has any suggestions for how EFSPI could be involved then please contact Chrissie Fletcher (fletcher@amgen.com).

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[3rd EU Statistics Leaders Meeting](#)

The minutes of the **third EFSPI Statistical Leaders meeting** held on the 20th June in Weesp, The Netherlands are now available on the EFSPI website, click [here](#).

In there you will read that the group defined four focus areas for the short and mid term future. And for each of those specific goals were formulated that will be pursued. Read below these four areas and their goals. For more details please see the minutes on the website:

- ***NXT generation Statisticians***

To achieve that new graduates have better understanding of the whole drug development process and areas of statistical influence

- ***EU differentiators***

To maintain collective expertise and strong link between regulators, industry and cooperative group and promote advantages of EU

- ***Areas for success now***

To educate statisticians in an area such as Benefit/Risk where there is a need for quantitative valid approaches to summarize, present and communicate results across various domains to come to an overall evaluation. An area that would enable statisticians to add value beyond being a “number cruncher” and take a more strategic role while still utilizing their quantitative background.

- ***Change Management***

To increase awareness and need for change, thereby identifying the skill set needed for statisticians and leaders.

To define a vision and develop a “support package” that will enable statistical leaders to drive change in companies.

All the materials from this leaders meeting and the previous 2 leaders meetings held in 2010 and 2011 are available on the EFSPI website, click [here](#).

Please direct any comments or questions to stefan.driessen@abbott.com.

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Scientific Meetings

On September 13th EFSPI organized a one day meeting on **Modelling and Simulation**, together with the Basler Biometric Society and MSB (Modelling & Simulation Basel). Over 80 attendees with various backgrounds attended this meeting. The topic was discussed by eight presenters that included statisticians as well as other applied scientists. A lively panel discussion closed this meeting. Click [here](#) to view the agenda and presentations from the EFSPI website.

The following EFSPI scientific meetings are planned for the remainder of 2012:

- **“Are we finding the right dose(s) in phase 2” (Nov 19, 2012)**, EFSPI’s first virtual discussion on the statistical challenges of finding doses to take forward to phase 3. Perspectives from industry and from EU regulators will be provided. The webinar is free to attend. Click [here](#) for more information.

- **Subgroup analyses (Nov 30, 2012)**, this meeting will take place in Brussels. Key opinion leaders from regulatory agencies, academic institutes and industry will be speaking. The meeting is open for registration, click [here](#) to register or to see the meeting agenda click [here](#).

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Regulatory Update

No new statistical guidelines were issued since the last EFSPi newsletter. According to the published work plans of EMA and FDA the following draft guidelines are expected in 2012:

EMA

- Guideline on the Use of Subgroup Analyses in Confirmatory Clinical (EMA/CHMP/EWP/117211/2010)
Draft proposal to be developed in 2012.
- Update on Concept Paper on guideline on Adjustment for Baseline Covariates (EMEA/EWP/2863/99)
Draft proposal for the update to be published 4th Q 2012.
- Update of Points to Consider on Multiplicity Issues in Clinical Trials (CPMP/EWP/908/99)
Draft proposal for the update to be published 4th Q 2012.

FDA

- Multiple Endpoints

The EMA is holding two interesting workshops in November:

Workshop on multiplicity issues in clinical trials on Nov 16th

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/06/event_detail_000589.jsp).

The workshop's topics include usefulness and limitations of newly developed strategies to deal with multiplicity and multiplicity arising from interim decisions. Objectives are to discuss current standards and strategies to address multiplicity in clinical trials and to identify issues where guidance is missing so far. EFSPi has been invited by EMA to participate (E. Biesheuvel).

Workshop on clinical-trial data and transparency on Nov 22nd

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/07/event_detail_000656.jsp).

It is anticipated that the following questions will be among the issues debated at the workshop:

- What level of data (aggregate, patient level, ...) will be made available, and in what format?
- Which conditions have to be in place when data are made available to third parties?
- How can patient confidentiality be ensured?
- How can the highest possible quality standard of secondary data analysis be ensured, in the interest of public health?

EFSPi has been invited by EMA to participate (C. Gerlinger). Please contact Christoph (Christoph.Gerlinger@Bayer.com) if you have comments or proposals for the workshop.

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EFSPi Council News

The EFSPi Council had a teleconference on the 16th October 2012. The latest estimate of the budget for 2012 was reviewed and discussed. The number of attendees to the 1-day scientific meetings has

been lower than anticipated resulting with reduced revenue for EFSPI. A review of administrative costs for the remainder of 2012 and activities that can be supported by the EFSPI Administrative Office in 2013 is being reviewed, and further opportunities to reduce the costs and overheads of running a small number of meetings are being considered.

Actions arising from the 3rd Statistics Leaders meeting are being followed up. There is much interest in the benefit-risk SIG and how EFSPI can support their activities. Anticipated regulatory activities for 2013 were reviewed, with key guidance's anticipated in 2013 relating to subgroup analyses (EMA) and multiplicity (FDA).

The EFSPI Council is continuing to seek interest in expanding its membership to the broader statistical communities across Europe.

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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.

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