



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

EFSPI Newsletter December 2012

In this newsletter:

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

[Follow up after the 3rd EU Statistics Leaders Meeting](#)

[Scientific Meetings](#)

[Regulatory update](#)

[Special Interest Groups \(SIGs\)](#)

[EFSPI Council News](#)

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

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

The International Year of Statistics launch video is now available for you to view, use and distribute. Created by SAS, the video does an excellent job portraying the many and varied ways that statistics impacts our lives. Titled *Improving Human Welfare in 2013 International Year of Statistics*, the video is accessible via the SAS YouTube channel at: <http://youtu.be/nTBZuQR7dRc>.

Please view the video, and the local association contacts can post it on their website, and e-mail the link to their members. Everyone should look for opportunities to promote it to the public, media and other external audiences in your area or country, and show it at meetings and other events.

At this moment, the video is only available in English. However, we are working with SAS on subtitling the video in several other languages, and these will be available very soon. We will send information about the availability of the subtitled versions through the regular International Year of Statistics newsletter.

If you want the video subtitled in your country’s language, please email Jeffrey@amstat.org to request a copy of the script. Click [here](#) to see the International Year of Statistics Website for more information.

[back to top](#)

[Follow up after the 3rd EU Statistics Leaders Meeting](#)

In the EFSPI Council meeting in June, there was a full review of the leaders meeting, including a discussion on the actions and proposals for EFSPI. In the October Newsletter four key areas were summarized supporting shorter and longer term goals. These were: profiling the NXT generation Statisticians, the unique selling points of the EU statistical community, targeting specific areas where

statisticians can make a difference, and increasing the awareness of managing changes and dealing with the current and future challenges in the industry and the role statisticians can or will play.

The Council has discussed the many suggestions and proposals that EFSPi should prioritize to significantly further the highly esteemed input from the Statistical Leaders group. Amongst other things the emerging area of Benefit-Risk will receive extra attention as an area where statisticians can make a difference. The progress made will be one of the topics for the fourth Statistical Leaders Meeting for which preparations are ongoing. Another important strategic topic will be the upcoming disclosure of individual patient data by EMA for which the Statistical Leaders have been asked for input and further contributions (see under Regulatory Update).

In case you have specific topics that you would like to be addressed and put to the attention of the Statistical Leaders group, please do not hesitate to bring them forward to stefan.driessenn@abbott.com.

The Statistical Leaders group is being expanded to also include the area of "Medical Devices" and to get representation of some of large companies in EU that are not yet (well) represented. Click [here](#) to review materials from previous Statistical Leaders meetings.

[back to top](#)

[Scientific Meetings](#)

On November 19th EFSPi's first webinar "**Are we finding the right dose(s) in phase 2?**" took place. Perspectives from industry and EU regulators were provided and with close to hundred lines calling in it has been a successful pilot. Click [here](#) to access the presentations and a recorded podcast on the EFSPi website.

On November 30th the EFSPi event on "**Subgroup analyses**" took place in Brussels. Close to 90 attendees attended this successful meeting. The topic was discussed by key opinion leaders from regulatory agencies, academic institutes and industry. A lively panel discussion closed the meeting. Click [here](#) to view the agenda and presentations from the EFSPi website.

EFSPi scientific meetings for 2013 are planned on the following topics:

(final dates are not available, but suggested timing is in brackets)

- Health Technology Assessments (together with BBS, June)
- Benefit Risk (together with PSI, September)
- Survival Analyses (November)

[back to top](#)

[Regulatory Update](#)

EMA has decided to make individual patients' data from clinical trials available to third parties beginning January 1st, 2014, click [here](#) for more information. The key open question is how they will do this. During the EMA's workshop on "**Release of Data from Clinical Trials**" held on the 22nd November 2012 the participants' views ranged widely from putting all raw data freely on the internet to tight access control by EMA.

EMA will establish five advisory groups of stakeholders to make proposals until April 30th 2013 on the “how”:

- * protecting patient confidentiality;
- * clinical-trial-data formats;
- * rules of engagement;
- * good analysis practice;
- * legal aspects.

EFSPI nominated Christoph Gerlinger for the “good analysis practice” group and intends to nominate senior colleagues to other groups.

EMA held another workshop on the 16th November 2012 on “**Multiplicity Issues in Clinical Trials**”, click [here](#) for more information. The workshop's topics included usefulness and limitations of newly developed strategies to deal with multiplicity and multiplicity arising from interim decisions. Objectives were to discuss current standards and strategies to address multiplicity in clinical trials and to identify issues where guidance is missing so far. Key opinion leaders from regulatory agencies, academic institutes and industry presented various aspect of multiplicity within a single clinical trial, combination of several trials and the clinical development across different regions. EFSPI was invited by EMA to participate. Click [here](#) for additional summary information.

[back to top](#)

Special Interest Groups (SIGs)

The SIG leaders had a teleconference in November 2012 to update each other on recent activities and to share best practices. Click [here](#) to see a summary of SIG activities for 2012 and to links to access the SIG materials.

[back to top](#)

EFSPI Council News

Chrissie Fletcher has taken over as the new President of EFSPI until December 2014. Francois Aubin who has effectively led EFSPI for the last 2 years becomes Vice-President. A tremendous thanks to Francois for his leadership of EFSPI and continued enthusiasm for EFSPI. Nigel Howitt is stepping down from the EFSPI Council after 9 years. During his 9-year tenure, Nigel has been a strong advocate for EFSPI, was President for 2009-2010, and he has significantly increased the profile of EFSPI. Nigel’s commitment, enthusiasm, motivation and endearment will be missed greatly. A huge thanks to Nigel for all of his efforts and support to EFSPI.

EFSPI finances are close to being on target to the planned budget set for 2012. A review of finances earlier in Q4 enabled some planned administrative costs to be saved. Membership fees for 2013 will stay at the same as 2012.

A 3-year strategic plan for EFSPI is being developed for EFSPI. It is anticipated this will be available by the end of Q1 2013.

[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.

EFSPi wishes everyone a Happy Christmas and New Year.

[back to top](#)

Chrissie Fletcher
EFSPi Communications Officer