



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

EFSPi Newsletter November 2013

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Regulatory Update

Data Sharing

EMA announced in November their new policy on publication and access to clinical trial data will not be finalized before the end of 2013. Further news and timings of when the final policy is expected to be available will be provided around mid-December.

The PSI/EFSPi data sharing working group had their first meeting. The working group aim:

- To identify and prospectively prioritise statistical issues in data transparency
- To co-ordinate statistical contributions to the data transparency debate
- To disseminate relevant information on the topic across the EU Statistics community
- To develop and share a vision of the potential longer term impact of data transparency

For more information about the working group contact **Uli Burger** (hans_ulrich.burger@roche.com).

EMA-HTA Parallel Scientific Advice Workshop

On the 26th November EMA held a Parallel Scientific Advice workshop with HTA bodies at EMA offices in London. The workshop began by summarizing why parallel scientific advice is needed, how parallel scientific advice can be achieved, and then a review of recent experiences and pilots using different approaches for obtaining parallel scientific advice were presented. Lessons learned to date and areas for further improvement were highlighted. Various stakeholders gave their views including representatives from regulators, HTA bodies, Industry, and patient groups. Break-out sessions focused on key elements for principles and policies for a parallel scientific advice process, science and data considerations, process and procedural aspects and special areas relating to

advanced therapeutics, orphan drugs and pediatrics. The outputs of the workshop will contribute to further enhancement and development of policies, procedures and guidelines for EMA-HTA parallel scientific advice. To view the presentations and workshop summaries, click [here](#).

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EFSPi Scientific Meetings

The recent meeting held in Brussels on November 7th about Survival Analysis was a successful day. With almost 70 participants and well-known speakers from academia, regulatory agencies and industry it discussed recent advances in the application of survival methodology in drug development and important operational issues. All presentations can be found on our website, click [here](#).

No EFSPi scientific meetings are scheduled for the remainder of 2013 and planning for meetings for 2014 is in progress.

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SIG News

The Health Technology Assessment (HTA) SIG led 2 sessions at the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) EU Conference in early November. The statistical challenges relating to network meta-analysis, treatment cross-over methods and subgroup analyses were discussed in one workshop, with the topic of integrating reimbursement needs in drug development the topic of an issue panel discussion. Both sessions were very well attended. To see presentations released from the conference, click [here](#). For more information on the HTA SIG please contact Chrissie Fletcher (fletcher@amgen.com).

The new Integrated Data Analysis (IDA) SIG held their first meeting in mid-November. The SIG are focusing on IDA in the areas of efficacy, safety, HTA and network meta-analysis and with increased availability of clinical trial data via data sharing initiatives. For more information on this SIG please contact Byron Jones (Byron.jones@novartis.com).

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Association of the month: SSL (Statistikot Suomen Lääketeollisuudessa)

Statisticians in the Finnish Pharmaceutical Industry (Statistikot Suomen Lääketeollisuudessa, SSL) is a registered association of Finnish statisticians working in the pharmaceutical industry. SSL, registered in 2001, was established to enhance biostatistics research and its practical applications and to work as a common forum for biostatisticians working in pharmaceutical companies and CROs. SSL is funded by pharmaceutical companies and CROs, and members are employees of those companies. Currently SSL has a few dozen of members. SSL organizes training for its members, co-ordinates local review of regulatory guidance documents, and communicates and collaborates with fellow organizations in other countries.

The man behind SSL and awakening of biostatistical branch in Finland is Professor Juhani Tuominen. Prof. Tuominen started and headed a two year Master's degree programme in biostatistics at the University of Turku. He had a vision to satisfy the specific need for statistical expertise in the pharmaceutical industry and to ensure a culture of continuous learning.

Despite the biometrics boom around year 2000, pharmaceutical biostatisticians remain an endangered species in Finland. The challenge is keeping the small community active. Intellectual and social regression is a real threat unless we manage to retain the drive and lively collaboration in the future also.

SSL holds biannual meetings consisting of scientific presentations, the official general meeting and a recreational part. The meetings also welcome attendees from academia, including students. Often some of the presentations are given by new graduates on their master's thesis. Every other year we co-organize meetings with our fellow-organization in Sweden (FMS). Last May Bayesian Data Analysis workshop was held in Espoo together with FMS. In recent years SSL has arranged also following workshops/courses: Statistical issues in clinical trials (2002), Introduction to CDISC (2003), Phase II clinical trial designs (2004), Adaptive designs (2007) and Nonlinear mixed models (2009).

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Update on the International Year of Statistics



There are now 2,292 organizations from 128 different countries around the globe participating in the International Year of Statistics. You can view the current participant and country lists by going to the [Statistics2013 website](#).

Optimism about the future of the discipline and profession of statistics and a keen awareness of the challenges ahead were on full display at the [Future of the Statistical Sciences Workshop](#) in London 11th-12th November. More than 100 top researchers in statistics and scientists from other fields who collaborate with statisticians examined a broad range of science across which statistics is not only applied but also is providing important guidance to developing new science and making science better.

Leading experts on statistics and data science will tell their stories about the value of statistics to science, industry, health, business and beyond during an insightful, free webcast on December 11 that will be hosted by Analytically Speaking. The event will mark the end of the International Year of Statistics.

Don't forget to view the [Activities Calendar](#) on the [Statistics2013 website](#) to see what activities are being planned for the rest of 2013 and beyond.

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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.

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