



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

EFSPI Newsletter September 2013

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Regulatory Update

EMA data transparency

EFSPI and PSI held a workshop on Aug 22nd in London to discuss EMA's draft policy on the publication and access to clinical trial data (click [here](#) to access the materials). Perspectives from both Industry and non-Industry were provided followed by breakout discussion groups on the following topics: (i) rules of engagement; (ii) patient confidentiality; and (iii) good analysis practice. A variety of comments on the draft policy were discussed during the breakout sessions and the major comments were summarized and submitted to the EMA for consideration (click [here](#) to see the EFSPI comments). A new EFSPI/PSI data sharing working group is being set up, see [below](#) for more information.

EMA draft guideline on adjustment for baseline covariates

EMA published a draft revision of the guideline on adjustment for baseline covariates (www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?wbContentId=WC500144946). The deadline for comments is the end of 2013, but we would like to get your comments by the end of October to allow for consolidation. Please send your comments to Christoph Gerlinger (christoph.gerlinger@bayer.com).

Regulatory Committee seeks new members

The Regulatory Committee is a joint PSI/EFSPI group that coordinates PSI/EFSPI contact with Regulatory Authorities around the world and other industry organisations. It monitors and responds, where appropriate, to regulatory statistical issues within the pharmaceutical industry. Expert groups

(comprised from academia and industry) are formed on key topics to drive best practice. A major area of activity is to generate responses to draft regulatory guidelines from PSI/EFSPI members.

Additional members are being sought from the other EFSPI member associations to join the regulatory committee. If you are interested please contact Lesley France (Lesley.France@astrazeneca.com).

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[New Data Sharing Working Group](#)

Moves towards greater disclosure of data from clinical trials will have a significant impact on the pharmaceutical industry. Disclosure and analysis of these data involve many statistical issues. EFSPI and PSI are pleased to announce the formation of a new data sharing working group. The objectives will be to identify, prioritise, co-ordinate and disseminate information important to data sharing. The working group will be chaired by Uli Burger (Roche) with Sally Hollis (AstraZeneca) supporting as deputy chair.

Anyone wishing to join this EFSPI/PSI data sharing working group should contact Uli Burger (hans_ulrich.burger@roche.com) by the 18th October 2013.

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[Scientific Meetings](#)

The recent meeting held in London on September 17th about Structured Benefit-Risk Assessment was a successful day with well-known speakers and an interactive discussion at the end. All presentations can be found on our website (under 'EFSPI activities' or directly using this link: <http://www.efspi.org/index.php?p=EFSPI%20ACTIVITIES&fid=431>)

EFSPI has its next scientific meeting in November 2013:

- Survival Analyses and its applications in Drug Development on November 7th 2013 in Brussels.

This meeting aims to bring together statisticians from Pharma, academia and regulatory agencies to discuss recent advances in the application of survival methodology and important operational issues. For details on the registration process, speakers and titles of presentations, please visit the EFSPI website (<http://www.efspi.org/>).

In addition to organising the one-day scientific meetings, EFSPI is planning to organise a webinar later this year (or beginning next year, most likely on the topic of Data Sharing. More information will follow in future newsletters.

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[SIG Update](#)

The HTA SIG would like to bring to your attention that EUnetHTA, a network of HTA agencies in Europe, have published an HTA Core model for rapid relative effectiveness assessment for new

pharmaceuticals including a series of methodological guidelines. The topics covered in the methodology guidelines include: clinical endpoints, composite endpoints, surrogate endpoints, safety, health-related quality of life, criteria for the choice of the most appropriate comparator, direct and indirect comparisons, internal validity, and applicability of evidence in a relative effectiveness assessment.

Click [here](#) to access the guidelines from the EUnetHTA website.

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[Association of the month: PSI \(Statisticians in the Pharmaceutical Industry\)](#)

Statisticians in the Pharmaceutical Industry, PSI, is a long established (>30 years) organisation with membership consisting mostly of professional statisticians working within the industry. It is run and administered on a voluntary basis by a Board of Directors elected by the membership. Its primary goal is to lead and shape statistical science in drug development and deliver relevant, high quality services to its membership:

- **An annual conference and regular one day scientific meetings, webinars and training courses**
These cover classic technical topics such as multiplicity, practical introductions to increasingly common must-have skills such as network meta-analysis or predictive inference, practical case studies and breaking hot topics such as data sharing. Next year's conference will be held in easy-to-visit London and will soon be open for registration
- **Regulatory insight and input**
Our regulatory affairs committee keeps abreast of new and emerging regulatory developments, meets with the regulators for their insight and provides the statistical industry view on upcoming guidelines
- **The journal *Pharmaceutical Statistics*, associated Journal Club and members' newsletter SPIN**
Pharmaceutical Statistics is an academically reputable forum to publish the great work of statisticians in industry and welcomes and supports contributors. The journal club discusses valuable scientific papers in regular TCs and each quarterly SPIN keeps the community abreast of all the important member news, events and gossip
- **Promotion of the statistics to students, the industry and the public**
We give talks at schools, universities and national science fairs, run an annual Careers Fair where graduate students meet potential employers, run an outreach program to small pharma and provide a statistical briefing service for the lay media
- **Support for communities within the community**
Our Special Interest Groups support statisticians to make contacts with others working in the same speciality and work together to advance the science. The groups cover a range of topics including biomarkers, benefit/risk, health technology assessment and modelling and simulation.

As of 2013 PSI has around 850 members, of whom just over 100 are actively involved in the committees and special interest groups that deliver services for its membership and advance the application of statistical science in industry.

We are always looking for volunteers to join our committees and for partnerships to expand the value and reach of our work. Special Interest Groups, many initiated by PSI, are now all hosted jointly with EFSPI, as is the Regulatory Committee. Our Journal Club has been run with organisations like the DIA and our briefing service for the lay media is run with the Science Media Centre.

To join, volunteer or find further information go to the PSI Website: <http://www.psiweb.org> or email chair@psiweb.org.

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

A variety of statistical events and activities are planned for the remainder of 2013. To see the complete list of activities for 2013, [click here](#).

A new Photo contest for secondary-school students (grades/years 7-12) around the world was launched on September 9 and the deadline for entries is November 1. For more information, click [here](#).

All are welcome to join the RSS professional statisticians forum (telephone and web-based meeting) being held at 2-3.30pm GMT on the 25th November. Harry Southworth (AstraZeneca) will be presenting on "Introducing a novel statistical approach into an established business area". More details can be found at www.rss.org.uk/psf

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[First European Winner of RSS Award](#)

Congratulations to Dr Björn Bornkamp from Novartis in Basel, Switzerland who has been announced as the winner of this year's RSS/PSI award for Statistical Excellence in the Pharmaceutical Industry.

Dr Bornkamp is an Expert Statistical Methodologist at Novartis and was nominated for his work on developing innovative statistical dose-finding methodology, in particular the development of the R package DoseFinding which has so far been downloaded more than 1,000 times in 2013.

Professor Dr Frank Bretz, who is the Global Head of the Statistical Methodology group at Novartis, and who submitted the nomination, said that Dr Bornkamp had 'worked tirelessly to develop a first-class software package that is not only an essential tool at Novartis, but one that is accessible from the Comprehensive R Archive Network (CRAN) and thus broadly available to the entire pharmaceutical statistics community'.

Dr Bornkamp obtained his PhD in Statistics from Dortmund University of Technology in 2009, studying Bayesian nonparametric shape constrained inference, and joined the Novartis Statistical

Methodology group in Basel in 2010. He was presented with the award at the ceremony in Newcastle on Tuesday, 3 September during the Royal Statistical Society's annual conference.

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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 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.

To view previous newsletters please see the EFSPi website in the "News" area.

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