European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter October 2014

In this newsletter:

Regulatory Update

The EMA has announced its final policy on data transparency (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf).

EMA will publish redacted Clinical Study Reports from applications submitted after 1 January 2015. This policy will apply to clinical reports contained in all applications for centralised marketing authorisations submitted after that date. The reports will be released as soon as a decision on the application has been taken.

The public can either browse or search the data on screen, or in a more restricted procedure download, print and save the information. The reports cannot be used for commercial purposes.

In the future the EMA plans to also make available individual patient data, although the scope of this is still subject to upcoming consultations. It was clearly stated that EMA intends to publish patient data it already has and that they will not require applicants to submit patient data sets only for the purpose of publishing it.

As a reminder, EFSPI has a data transparency working group led by Uli Berger (Roche, Switzerland) and Sally Hollis (AstraZeneca, UK). The objectives are to:

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

There are 5 work streams: one is focused on providing input into EMA/EFPIA related data transparency activities, a second is developing recommendations for re-analysis practices, a third is assessing the future impact to Biostatistics with increased data transparency, a fourth is establishing what are the minimum requirements for sharing data, and a fifth is how to ensure patient confidentiality. If anyone is interested to learn more about these activities, or contribute, please contact Uli Berger (hans_ulrich.burger@roche.com) or Sally Hollis (Sally.Hollis@astrazeneca.com).

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Scientific Update

No scientific meetings are scheduled for the remainder of 2014. The planned meeting on Dose Finding Studies is postponed and will take place in the first half of 2015. In addition, EFSPI is planning for two other meetings in 2015; one meeting on Health Technology Assessments together with the BBS also in the first half year, and another meeting in the second half of 2015 (topic not yet selected).

EFSPI is providing support to the Transparency event in November organized by the BBS – see below.

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Special Interest Group (SIG) of the month – Benefit-Risk

The benefit-risk special-interest-group is a cross-pharma and academia group of statisticians working together on statistical topics related to benefit-risk. The group is chaired by Alexander Schacht (Lilly) and co-chaired by Ian Hirsch (AstraZeneca). Further members represent Amgen, Bayer, Roche, Novartis, IRIServier, Pfizer, ICON, Astellas, Abbott, GSK, and Imperial College. The main aims of the Benefit-Risk Special Interest Group are split into 5 key areas

1. To understand how best to apply Benefit-Risk Methodologies across the Pharmaceutical Industry.
2. To share examples of how Benefit-Risk has been used within pharmaceutical companies, any best practices arising from them and how they can best be used from an industry perspective.
3. To discuss and make recommendations on key methodological issues for example utility functions and weighting approaches.
4. To share external information including new developments around Benefit-Risk including those in the literature and outputs from Benefit-Risk initiatives and to produce guidance on how best they can be used within the EFSPI arena.
5. Outputs from the first 4 areas will be used to inform, educate and pass on learning for those within EFSPI and its affiliations.

In order to achieve these aims the SIG has prepared a blueprint on how statisticians can play a leading role in Benefit-Risk, summarised key Benefit-Risk publications and initiatives and collected case studies to share from companies and initiatives. This has been done with help and feedback from Statistical Leaders within EFSPI. In addition the SIG has presented and organized an "Introduction to structured Benefit-Risk" session at the Statisticians in the Pharmaceutical Industry (PSI) conference, organized a joint EFSPI/PSI one-day meeting on structured Benefit-Risk and shared outputs on the EFSPI/PSI website as well as writing a publication for summary of literature reviews and initiatives which is currently in review.

Current outputs can be found on: http://www.psiweb.org/resources/resources.

The group is open for new members to join, that would like to move forward Benefit-Risk related methodological topics.

Alexander Schacht (Chair EFSPI BR SIG Email: schacht_alexander@lilly.com)

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Other Upcoming Events

BBS

Free 'Data Transparency Seminar', Thursday, Nov. 13, hosted by Actelion in Switzerland. More details will follow and look out for flyer on BBS website (www.ceb-institute.org/bbs) or EFSPI webpage (www.efspi.org) for details on how to register.

PSI

How do Data Monitoring Committees Operate, 5 November 2014, RSS in London. Click here for more details.

A PSI Training Course: Regulatory Interactions for Statisticians, 11th-12th February 2015, London. The course objective is to inform statisticians about the likely interactions they might have with regulatory agencies, both during a submission and at other times during drug development, and give advice on how to make these interactions most effective, Click here for further details.

AFP

The German APF will host its 68th workshop on November 28th, 2014 in Munich. Topics are subgroup analyses, experiences with EMA's Missing Data Guideline, and Clinical Data Transparency. The workshop will be held in German. For details please see http://www.biometrische-gesellschaft.de/arbeitsgruppen/pharmazeutische-forschung.html.

COMET (Core Outcome Measures in Effectiveness Trials) IV Meeting

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative will hold its fourth meeting in Rome on 19th to 20th November 2014. To view the programme, click here. To register, click here.

SCT/QSPI/FDA

The Society for Clinical Trials (SCT) and Quantitative Sciences in the Pharmaceutical Industry (QSPI) are holding a meeting with FDA to present Innovations in the Science and Practice of Clinical Trials December 9-10 2014 at the Universities at Shady Grove Conference Center in Rockville, Maryland, USA. Presentations will include sessions on small trials for rare diseases and large trials for rare events, on streamlining clinical trial operations, patient group engagement and regulatory efforts to include patient preferences in decision-making and on leveraging underutilized information sources in trial planning and analysis. More details and registration are available on http://meeting.sctweb.org/qspi.

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The World of Statistics

The World of Statistics movement has grown to a total of 2,350 organizations from countries across the globe. You can view the current participant and country lists by going to The World of Statistics website. To see the full list of The World of Statistics participating organization-sponsored events and activities around the world for the remainder of 2014, click here.

The 2014 International Conference of the Royal Statistical Society (RSS) was conducted in Sheffield, England September1-4. More than 460 participants from more than 25 countries heard plenary talks from Richard Allan, Facebook; Tim Harford, BBC/Financial Times; Terry Speed, Walter and Eliza Hall Institute of Medical Research in Melbourne, Australia; and Ming Yuan, University of Wisconsin-Madison. In addition, 30 invited sessions covered a huge range of topics including new advances in multivariate modelling, data visualisation, statistical analytics challenge, quantum statistics, statistics in sport, measuring segregation, Nightingale's legacy, checking and cleaning in Big Data, megatrends in statistics, anonymisation practices for sharing data, and who's afraid of data science.

Congratulations to Craig Mallinckrodt of Eli Lilly & Company the winner of the 2014 Excellence in the Pharmaceutical Industry Award which was announced at the RSS conference. Craig's book, Preventing and Treating Missing Data in Longitudinal Clinical Trials, provides a comprehensive 'analytic roadmap' for missing data in longitudinal clinical studies. His work drew together many strands of academic research on analysis techniques and has since influenced regulators, academics and pharmaceutical companies alike in their approach to the treatment of missing data. It has also been praised for being accessible to a wide variety of researchers.

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Job Adverts

Scientific Director, Statistical Modeling (Janssen)

For all current recruitment adverts please visit the EFSPI website:
http://www.efspi.org/index.php?p=ADVERTISEMENTS&fid=9

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And finally…..

The redesign of the EFSPI website is progressing well, and we expect a go-live of the new site before the end of 2014.

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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