



EFSPI Newsletter May 2014

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Regulatory Update

The final EMA policy on clinical trial data transparency is still pending. Some aspects of the EMA's proposed final policy have been discussed in viewpoint articles, see for example <http://www.bmj.com/content/348/bmj.g3432>. It appears many of EFSPI's concerns regarding data privacy have been taken into consideration.

The EFSPI/PSI regulatory group is currently consolidating your comments to EMA's draft guidance on subgroups. Our comments are due by the end of July but we aim to submit them before the summer holiday season.

The EFSPI/PSI health technology assessment group is currently assessing EMA's draft best practice guidance for pilot European Medicines Agency health technology assessment parallel scientific advice procedures, see http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500166226

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SIG of the month: Toxicology

The Toxicology SIG has now been running for a number of years, having formed in 2006, and continues to provide a forum to communicate amongst statisticians working in this area. Our objective is to form a consensus on the best statistical practice in various areas of Toxicology.

The Toxicology SIG Steering Team consists of five members:

Name	Company
Gareth Thomas	Huntingdon Life Sciences – Committee Chair
Helena Geys	Johnson & Johnson
Philip Jarvis	Novartis
Sarah Kirk	AstraZeneca
Jim Saul	Covance

We have run 2 day workshops every 18 months and have discussed a wide variety of topics including:

The analysis of organ weight data
Genetic Toxicology data
Pathology data
Safety Pharmacology Telemetry Studies

In March 2013 we ran a two day workshop at Theobald's Park, Hertfordshire. There were 11 attendees as well as a guest speaker. The agenda focused on four hot topics currently in Toxicology: Combining Safety Pharmacology endpoints in Toxicology studies, Recommendations on the use of Historical Control Data, Combining sexes in analyses and what micro sampling can bring to Toxicology studies. Our next workshop is planned for October 2014. Three members of the SIG also ran a parallel session at the recent PSI Conference.

If we feel there is a subject area that warrants publication then we will endeavor to publish a paper in the Pharmaceutical Statistics Journal.

If you would like to be added to our affiliate's mailing list, of which we currently have 40 members, or are interested in attending our workshop in October, please email me:

Gareth Thomas

Chair, Toxicology Special Interest Group

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Scientific Update

EFSPi is planning for two scientific meetings in 2014. The first meeting will focus on HTA and is planned for late September or early October. Details about the exact date, location and layout of the program will be available soon. The second meeting will focus on dose finding studies, including modelling approaches like MCP-Mod, and is planned for November.

As mentioned in the previous newsletter, the Scientific Committee is looking for new candidates who are willing to join our committee. We organise European Scientific meetings and provide a platform for key opinion leaders from regulatory, academia and industry to speak and we have a

successful track record (http://www.efspi.org/index.php?p=EFSPI_ACTIVITIES&fid=19). If you are interested or want to know more, please contact our chair Egbert Biesheuvel (Egbert.biesheuvel@merck.com)

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The World of Statistics

The World of Statistics movement has grown to a total of 2,375 organizations from 129 countries. 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](#).

Past, Present, and Future of Statistical Science, commissioned by the Committee of Presidents of Statistical Societies (COPSS) to celebrate its 50th anniversary and the International Year of Statistics, was published in April by Taylor & Francis/CRC Press. Through the contributions of a distinguished group of 50 statisticians, the book showcases the breadth and vibrancy of statistics, describes current challenges and new opportunities, highlights the exciting future of statistical science, and provides guidance for future statisticians. Contributing authors are past COPSS award honorees. [Click here to read the open-access version of the book](#).

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Job Adverts

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.....

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.

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

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Chrissie Fletcher
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