



EFSPI Newsletter August 2015

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Regulatory

Christoph Gerlinger from Bayer has recently taken over to chair the EFSPI/PSI Regulatory Committee. A huge thanks to Lesley France from AstraZeneca who successfully chaired the committee for a number of years.

The regulatory committee commented on the FDA's draft guidance on "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff" (see http://www.efspi.org/EFSPI/Publications/Regulatory_Comments/EFSPI/Publications/Regulatory_Comments.aspx). Special thanks to Jürgen Hummel who took the lead for this guidance.

The regulatory committee will meet with MHRA statisticians on Sep 14th and with EMA's BSWP Oct 9th. The BSWP suggested discussing the measurement of treatment benefit in a survival setting; in particular, treatment estimators, OS/PFS consistency, and definition of data maturity. We are looking for volunteers to contribute ideas on this topic. Please contact Christoph Gerlinger (christoph.gerlinger@bayer.com) or Lesley France (Lesley.France@astrazeneca.com) if you like to volunteer.

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EU Statistics Leaders 2015 Meeting

Twenty-six people from 10 different countries representing 24 pharmaceutical companies and CROs attended the 2015 EFSPI Statistics Leaders Meeting, which was held in Brussels and hosted by MSD on the 1st July 2015. The agenda allowed for follow up and discussion on important developments from previous years, for example updates from the Benefit Risk and Real World data Special Interest Groups (SIGs), and the Data Transparency Working Group. New topics discussed included a proposal

to initiate a new SIG on Small Populations, and a discussion on Estimands relative to the ongoing work underway by the ICH E9 working group who are developing an addendum to E9.

The Data Transparency Working Group, set up by EFSPi and PSI, is finalizing a series of 4 papers for publication in the areas of: (1) A primer on data sharing for researchers working with patient level data sets; (2) Ensuring patient confidentiality; (3) Best practices for analyses of shared data; and (4) How data sharing is impacting the role of statisticians. The general feeling is the important role and impact of biostatistics in this area is significantly contributing to improving the reputation of the industry and increased data transparency. The working group was asked to monitor any emerging reports in the literature of analyses conducted summarising the progress all data owners are making with sharing data. The increased opportunity for the EFSPi/PSI Regulatory Committee to interact with the regulatory statisticians in Europe on key statistical issues was explained. As noted [above](#), a couple of meetings with regulatory statisticians in Europe are planned for the second half of 2015. The Regulatory Committee are still open for new members to join, especially from mainland Europe, anyone interested can contact Christoph Gerlinger (christoph.gerlinger@bayer.com).

A new EFSPi Small Populations SIG was proposed. It will have close contact with several other industry/governmental projects such as [ASTERIX](#), [IDEAL](#), and [INSPIRE](#). An announcement for volunteers to join this new SIG will be made in the EFSPi September newsletter. The impact of Real World Data to drug development and the role of statisticians in this area were extensively discussed. Compared to 2014 it seems that more companies are getting active in this area and the general feeling was that biostatisticians should get themselves involved. There is clear need for best practices, technical and leadership expertise that EFSPi can support. The Benefit Risk SIG presented its achievements over the last year and focused in the discussion on ways to increase the contribution of statisticians in this area within companies, as well as to increase the impact of the SIG and its work within EFSPi. Development of leadership and influencing skills will be key for statisticians in this area. Estimands was presented as a new topic and new framework for improved clinical trial planning, conduct, analysis and interpretation. The concept of estimands was explained and examples given as well as its context to the missing data problem and sensitivity analyses. More examples will help to better understand the underlying definition and issues but also to explain it in due time with clinical colleagues.

All the materials from the meeting will be posted on the EFSPi website and will be accessible [here](#). Thanks to Stefan Driessen for leading the organisation of another successful EFSPi Statistics Leaders meeting, and to William Malbecq and MSD for hosting the meeting.

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Scientific

EFSPi is organising two scientific events in the second half of 2015:

- **28th September – European Statistical Meeting on Estimands**, Hertfordshire (UK)
Are you estimating what you think you are? De-mystifying Estimands

(Early bird registration before 4th of September)

Please [click here](#) for more information

- **12th November – European Statistical Meeting on Dose Selection in Late Phase Clinical Development, Brussels**

In this meeting we will hear from EU regulators and experts in this field as well as presentations of case studies of the evolving methodology in this area
More information on this conference as well as registration process will open soon.

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Other Events

PSI

The PSI/EFSPi Toxicology SIG will be holding their next 2 day meeting on the 13th and 14th October 2015, near Heathrow airport. Current hot topics that may be up for discussion include: Analysis of large datasets (eg telemetry data), analysis of anti-drug antibody assays, experimental design, benchmark dose approaches and updates on approaches to conducting carcinogenicity studies. If you would like to register interest for this meeting, please contact Gareth Thomas, PSI ToxSIG Chair ThomasG@UKorg.huntingdon.com.

2015 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop

The ASA Biopharmaceutical Section FDA-Industry Statistics Workshop is sponsored by the ASA Biopharmaceutical Section in cooperation with the FDA Statistical Association. Each year, approximately 800 regulatory, academia and industry colleagues gather together to share insights into key trends in statistical topics relevant to pharmaceutical and medical device development. The 2015 Workshop takes place September 16-18 in Washington D.C. at the Marriott Wardman Park. The plenary includes presentations and panel discussion on The Future of Precision Medicine. As part of the plenary program, Susan A. Murphy, Professor of Statistics and Professor of Psychiatry at the University of Michigan, will discuss the use of mobile devices in micro-randomized trials. For more information click [here](#).

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The World of Statistics

The World of Statistics movement has grown to a total of 2,366 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 events and activities planned for 2015, [click here](#).

Two data visualization competitions are being held to commemorate World Statistics Day 2015. The first is sponsored by the United Nations Statistics Division (UNSD) as part of its plans for the October

20 global celebration of statistics. The other is sponsored by Wiley and its Statistics Views program. [Go to its website](#) to learn more about the event and be sure to go back periodically for updated information. The United Kingdom's Royal Statistical Society (RSS) this month launched [two free online courses for journalists](#) on statistics and science. The journalism e-learning modules takes journalists through a range of real-life scenarios related to statistics, surveys, scientific research and uncertainty.

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Job Opportunities

Opportunities exist for a Biostatistical Specialist. For all current recruitment adverts and more information on how to submit recruitment adverts, please visit the EFSPI website: [Job postings](#). If you are currently seeking to hire a statistician and wish to post a job advert, EFSPI are offering one free advert for every 3 adverts posted on the website.

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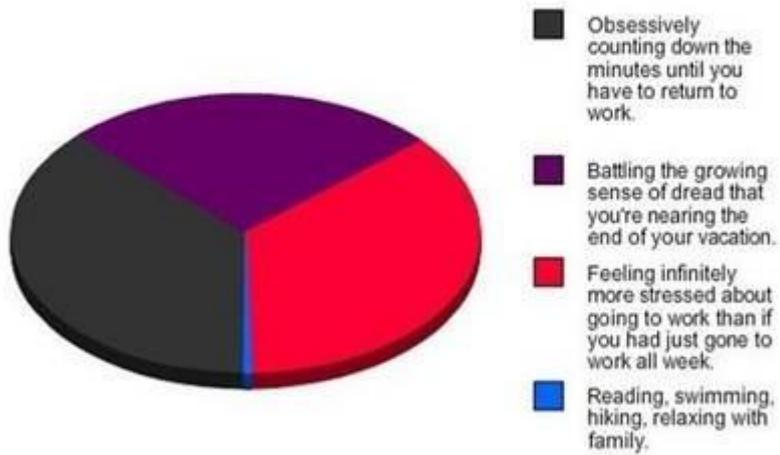
And finally.....

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.

Fun picture of the month (thanks to www.thiscanbeweird.quora.com):

How You Pass The Time On Vacation



I hope everyone had an enjoyable vacation!

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Chrissie Fletcher
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