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

EFSPI Newsletter January 2016

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New EFSPI President

It is a pleasure to be the President of the EFSPI for 2016-17. With the support of the council members, and others from the EFSPI country associations, I hope to contribute to the visibility and influence of our profession in Europe and beyond. Here are a few words about myself and my passion for biostatistics!

After graduation, I started working in cancer research (medical statistics in collaborative clinical trials) at an Italian university hospital (Parma). During these years, I had the privilege to meet global experts in medical statistics that provided me with the inspiration (and the knowledge) to continue to develop in this field. I was then offered a position at the Swiss Group of Cancer Research (Bern) and I moved to Switzerland. These were important years, leading to international experience, methodological growth (in collaboration with the Harvard School of Public Health) and publications.

At the end of 1998, I moved to the biotech world and started working at Serono in Geneva, where I stayed till mid-2009 (with positions of increasing responsibility in the Biostatistics department, last

one being head of Statistical Strategy), supporting global projects mainly in multiple sclerosis, oncology and autoimmune diseases. These were enriching years, with exposure to the methodological challenges and complexities of international drug development (mainly biologicals) and interactions with global Health Authorities. We were able to work with methodology experts from Europe and US and we could apply innovative statistical methods and solutions. And, with a strong team, we contributed to defining the strategic role of biostatistics in that organization. Then, in 2009, I had the exciting opportunity to work on the first oral drug for multiple sclerosis at Novartis. I had an amazing experience there, with a bigger group (including India and US), and a very interesting new compound which was approved at the end of 2010. Not only the project was interesting, and the team was great, I also had the privilege to be supported by Frank Bretz and his group! Afterwards, I joined Actelion, and I have been here for the last 5 years. I share this experience with colleagues, as well as some experts from the past. This is another adventure: now we work on rare diseases (including PAH) and we have the challenges to define new, relevant outcomes and optimize designs and data utilization. We still keep bringing forward the strategic value of statistics for drug development and decision making.

I look forward to utilizing my experiences gained in various leadership roles in my role as the EFSPI President. I welcome any comments and feedback of your experiences with EFSPI to date and any ideas and suggestions for where EFSPI should prioritise its efforts in the coming years. Please email me at marisa.bacchi@actelion.com.

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Regulatory

EMA are holding a Small Medium Enterprise (SME) Workshop on Biostatistics on the 5th February 2016. Industry speakers include Byron Jones (Novartis) and Oliver Keene (GSK).

EMA plans a draft reflection paper and a subsequent workshop on the extrapolation of adults' safety and efficacy data to the pediatric populations on May 17th to 18th in London (http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2016/01/WC500199753.pdf) . If you are an expert in this domain and want to contribute to the workshop of to comment the draft please contact Christoph Gerlinger (christoph.gerlinger@bayer.com).

EMA's draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development is planned for Q2. If you want to contribute to the EFSPI comments please contact Bruno Boulanger (bruno.boulanger@arlenda.com).

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Scientific

EFSPI is planning for at least three meeting events in 2016: two regular 1-day scientific events, and our 1st annual EFSPI Statistical Workshop.

1st annual EFSPI Statistical Workshop – September 12 and 13 in Basel – SAFE the DATE!

The idea for the 1ˢᵗ annual EFSPI Statistical Workshop started in 2015, and this statistical workshop being initiated in 2016 will be dedicated to the opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. We have started well in our preparations and a Scientific Committee has already been installed with representatives from all parties involved. More information will follow as soon as possible. Please mark this important date in your calendar!

Two other EFSPI scientific events are in the planning phase:

- 1-day scientific event on **June 24, Biomarkers and Subgroups in Leiden, the Netherlands** (A joined event of EFSPI and PSDM hosted by Astellas).

When biomarkers are used to identify sub-groups of patients who are likely to benefit from new therapies, a whole host of challenges arises, and many of them are of a statistical nature. In this meeting, experts from industry, academia and regulatory agencies will come together to discuss these challenges, with a focus on practical applications. Confirmed speakers include Norbert Benda (BfarM), Andrew Grieve (ICON plc), Tim Friede (University of Göttingen), Andrew Stone (Astra Zeneca), Sebastian Jobjornssen (Chalmers University) and Hans-Ulrich Burger (Novartis).

We expect to have the registration open very soon on our website.

- 1-day scientific event on **Evidence Synthesis** planned for October/November, further details to follow.

In addition, EFSPI is preparing a **webinar** before the summer break, the final topic is not yet decided. We will keep you informed as more details become available.

7ᵗʰ EU Statistical Leaders meeting 2016

The next EU Statistical Leaders Meeting will take place on the **5ᵗʰ July 2016**. The meeting will be held in France, kindly hosted by Sanofi. Possible themes for the meeting include: modeling in drug development, personalized medicine and biomarkers, risk-based monitoring, data science, leadership skills for statisticians, and statisticians' engagement in regulatory policy and in public-private initiatives.

We are very much looking for people that want to sit in the Organizing Committee and help with the agenda and the set-up of the meeting. If you are interested, please contact Stefan Driessen (**stefan.driessen@abbott.com**).

Other Events

PSI (UK)

PSI Careers Fair - The Careers and Academic Liaison Committee (CALC) are planning the annual Careers Fair Event on Wednesday 3rd February 2016, to be hosted at the University of Reading. As

well as MSc students, the invitation is extended to final year BSc and PhD students with an interest in pharmaceutical statistics and statistical programming.

PSI Structured Benefit-Risk Assessment – Methodology and Practice - this 2 day training course taking place in the London Heathrow area on the 8th-9th March 2016 includes a practical workshop whereby participants will critically evaluate the benefit-risk balance of medicinal and healthcare product(s) in a robust and transparent manner. Keynote speakers include Prof Deborah Ashby (Imperial College) and Prof Larry Phillips (LSE). More information can be found here and go to www.psiweb.org to register.

PSI/RSS 2016 Award for Statistical Excellence in the Pharmaceutical Industry launched - Nominations are being sought for the PSI/RSS Award for Statistical Excellence in the Pharmaceutical Industry. The award recognises a most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. For more details please see http://www.statslife.org.uk/news/2631-2016-award-for-statistical-excellence-in-the-pharmaceutical-industry-launched#.Vo_c-0sDi-E.twitter. Nominations can be made until midnight on March 31st 2016.

The **PSI 2016 annual conference** will be taking place on 22nd- 25th May 2016 at the Pullman Hotel, Berlin. The theme of the 2016 Conference is "Promoting Statistical Insight and Collaboration in Drug Development" and registration will open soon. Sessions will include an update on estimands, subgroups, dose exposure modelling, decision criteria, use of biomarkers in translational activities, clinical registries and many more with speakers from industry, academia and regulatory agencies. The deadline for poster abstracts is 29 February 2016 - please visit the website for more information. http://www.psiweb.org/events/2016-conference/2016-conference-abstracts. For further information please go to http://psiweb.org/events/2016-conference.

As part of the PSI conference in Berlin this year, an interactive careers seminar for students local to the Berlin area will take place on Wednesday 25th May 2016 at the Pullman Hotel (Berlin). This event is aimed at students studying mathematics and statistics courses. We welcome BSc, MSc and PhD students with mathematics/statistical elements that would be interested in learning about statistics within the pharmaceutical industry. If you have contacts in the Berlin area in Maths & Statistics departments we would be grateful if you could let them know of this event. Any interested students can register to attend this event **for free** using this link: www.surveymonkey.co.uk/r/ZTM5K55. Places are limited and registration **by 31st March 2016** guarantees a place at the seminar. Registration will close on 30th April 2016.

The World of Statistics

The World of Statistics is comprised of 2,378 organizations across the globe. You can view the current participant and country lists involved in the World of Statistics by going to The World of Statistics website. To see the events and activities planned for 2016, click here.

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Get the latest news and updates about EFSPI by following us on Twitter at @EFSPItweet. Also, when you use Twitter to spread the word about EFSPI, be sure to use the hashtag "#EFSPI". You also can follow developments in EFSPI via Linkedln.
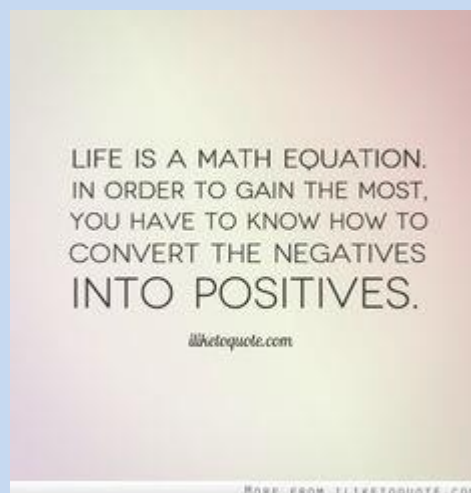
And finally.....

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.

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.

Enjoy this quote (courtesy of http://math.sfsu.edu/beck/quotes.html):

LIFE IS A MATH EQUATION. IN ORDER TO GAIN THE MOST, YOU HAVE TO KNOW HOW TO CONVERT THE NEGATIVES INTO POSITIVES.

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Chrissie Fletcher
EFSPI Communications Officer