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

EFSPI Newsletter November 2019

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Women in Data

Well done to **Chrissie Fletcher**, Executive Director Biostatistics, Amgen, and **Dr Laura Bonnett**, Medical Statistician from the University of Liverpool, who have been awarded by Women in Data as two of the '**Twenty in Data and Technology 2019**'. Women in Data aims to inspire the next generation of women in fields related to Data and Technology, and connects women across different Industry sectors. Click here to view Chrissie's and Laura's videos and see the other awardees.

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Regulatory

On Wednesday 13 November the PSI/EFSPI Regulatory Committee (with representatives from Bayer, Biogen, Boehringer-Ingelheim, GSK, IQVIA, Lundbeck, Orchard, Pfizer, PHASTAR, PPD, Roche and Servier) met with the MHRA statisticians for an informal exchange of statistical topics important for both regulators and industry. There was great discussion on topics such as estimands, subgroup analyses and predefined Quality Tolerance Limits as well as quality attributes, model based dose escalation studies, real world evidence, use of historical controls and the lack of statisticians in many ethics' committees in England. Details of the discussion will be shared in a future edition of the EFSPI newsletter.

At the end of November, the FDA has released final guidance on Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry.

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Country News

AFP (Germany)

APF held the German statistical leaders meeting and the annual fall workshop on Real World Evidence end of November in Ludwigshafen. On March 16th 2020 APF is co-organizing a workshop on 'Analysis of adverse events in the context of estimands' in Heidelberg. The program can be found here: https://www.klinikum.uni-heidelberg.de/medizinische-biometrie/veranstaltungen/workshop-16-maerz-2020.

PSI (UK)

A PSI Training Course - Bayesian Practical Course using R and SAS Tuesday 18 - Wednesday 19 February 2020, Heathrow, London. This practical training course will give a deep dive into performing Bayesian analyses in R and SAS. It is aimed at statisticians who need to be able to conduct Bayesian analyses as part of their day to day work. By the end of the course participants will be able to conduct their own analyses. Click here to register.

A PSI Training Course - Practical Approaches to Designing Adaptive Clinical Trials
Wednesday 12 - Thursday 13 February 2020, London. This hands-on course will provide a deep dive into 4 software packages used to design adaptive clinical trials. The course will start by providing a general overview of adaptive designs, explaining the different type of adaptations possible and the benefits of each design. Following this, participants will be given the opportunity to have a go at designing trials in R (using RPACTS), EAST, FACTS, and nQuery. Click here to register.

Journal Club Webinar: The PSI & DIA's Journal Club presents: Subgroup Analyses

Cynthia Huber, Christoph Muysers, Bodo Kirsch & Anna Berglind

The webinar is on Subgroup Analyses and our presenters are Cynthia Huber from the Department of Medical Statistics, University Medical Centre Gottingen and Christoph Muysers and Bodo Kirsch from Bayer. The chair of the webinar is Anna Berglind from AstraZeneca. *The papers discussed were:*

* (PSI) A comparison of subgroup identification methods in clinical drug development: Simulation study and regulatory considerations – Cynthia Huber, Norbert Benda and Tim Friede
* (DIA) A Systematic Approach for Post Hoc Subgroup Analyses With Applications in Clinical Case Studies – Christoph Muysers et al.

Click here to watch the webinar.

How to lead being an introvert

Interview with Fritz Lehmann

How do you know if you are an introvert? Is it possible to lead successfully even as an introvert? Do you know how to be successful in being an introvert?

In this episode, I discuss with Fritz on how it is possible for introverted leaders to succeed in the workplace and these key points: How to assess yourself if you're an introvert; What are the strengths as introverts, which you can use to your advantage in terms of leadership; Tips on minimizing limitations being introverts; Some mindset shifts which we need to make as introverts to become leaders.

What you need to know before you try to increase productivity

Do you often find your workday spiralling out of control? Do you want to be more productive than you yesterday? Do you want to know how to improve your skill set and work performance? You are not alone. Sometimes, it's easier to wait for someone else to tell you what things you should work on rather than to assess yourself.

Focusing on continually improving your skill set will boost your confidence and help you become the best version of yourself. In this episode, Benjamin and I discuss what you need to know to increase productivity by knowing the basics of productivity and what and how to set SMARTER goals, and more.

CALC Episode 3: Get a Head Start and Map Your Route to a Career in Drug Development

Are you interested in pursuing a career in medical statistics but not sure what to do next?

You may be studying at university thinking about your future employment, or simply considering a career change. In this episode, you will learn about the different MSc courses in Medical Statistics; Funding for further study; Alternative routes into the industry; The PSI Medical Statistics Careers Event; and Searching for jobs.

Thanks to Alexander Schacht and collaborators for creating these great podcasts.

Volunteers needed

EFSPI are seeking volunteers to join an EFSPI Communications committee. If you have expertise in using a variety of communication channels and you have ideas and suggestions for how EFSPI could improve the website and its use of social media, please contact Chrissie Fletcher (fletcher@amgen.com).

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Job Opportunities

For 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.

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Chrissie Fletcher
EFSPI Communications Officer