

EFSPi Newsletter December 2019



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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 SPIN.



After a long time in the making, the final [addendum to ICH E9 \(Statistical principles for clinical trials\) on estimands and sensitivity analysis in clinical trials](#) is now published! Please take a look!

This addendum presents a structured framework to strengthen the dialogue between disciplines involved in the formulation of clinical trial objectives, design, conduct, analysis and interpretation, as well as between sponsor and regulator regarding the treatment effect(s) of interest that a clinical trial should address.



The FDA has published the final [Guidance for Industry on Adaptive Design Clinical Trials for Drugs and Biologics](#).

The guidance describes important principles for designing, conducting, and reporting the results from an adaptive clinical trial. The guidance also advises sponsors on the types of information to submit to facilitate FDA evaluation of clinical trials with adaptive designs, including Bayesian adaptive and complex trials that rely on computer simulations for their design.

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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>.

IBIG (Italy)

IBIG Under 35 recently created. Members are:

- Luca Grassano, GSK Vaccines
- Daniele Bottigliengo, University of Padua
- Andrea Nizzardo, Menarini Ricerche

- Veronica Sciannameo, University of Padua

IBIG in collaboration with Politecnico of Turin will organize a Course on “Early phase clinical trials”. Prof. Thomas Jaki and Dr.Pavel Mozgunov from Lancaster University will hold the course that will take place from 6th to 8th May 2020 in Turin. More details at www.biostatistici.it

PSI (UK)

2020 PSI Conference



PSI are pleased to announce that registration has now opened for the PSI Conference 2020. The conference theme is “Shaping the Future of Statistics” and will take place in Barcelona on 7th-10th June 2020. We also have 2 excellent pre-conference courses available this year, which will take place in the afternoon of Sunday 7th June. If you would like to find out more information about these courses then please click [here](#).

Registration for both courses is available as part of the main conference registration site. Places are limited so book early to avoid disappointment and take advantage of the early bird discount! To register to attend the 2020 PSI Conference in Barcelona and book your pre-conference course place, please [click here](#). To find out more information about the Conference - such as the venue, pre-conference course information, or sponsorship, [please visit the PSI website](#)

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 RFACTS), EAST, FACTS, and nQuery. Click [here](#) to register.

Women in Data Award: Chrissie Fletcher



Two weeks ago saw the Women in Data conference held in London, and we're delighted to say that PSI's very own Chrissie Fletcher was recognised as one of their "20 Women in Data & Technology" for 2019! [Click here to view the video!](#)

"Be bold, take the initiative, step out of your comfort zone and feel proud of your achievements."
-Chrissie Fletcher

Would you be interested in working with the PSI ToxSIG Committee?

As a group of Statisticians working within Toxicology, but covering wider pre-clinical/non-clinical areas, the PSI ToxSIG committee hold regular TCs, organise up to 4 free webinars per year and run an annual 2 day workshop. Being a committee member does not take up significant time but has presented a number of advantages to both past and present committee members. The committee are currently looking for more companies to be represented on the committee. We currently have representatives from Boehringer Ingelheim, Covance, Janssen (JNJ) and GlaxoSmithKline. If you work within a related pre-clinical area and would like to be involved in this wider support network, please get in touch.

Members of the PSI Toxicology Special Interest Group committee have found this to benefit them in the following ways:

- Helps to forge partnerships with statisticians across the industry with a common goal
- Engage with some of the experts in this field
- Opportunities to be involved in writing or contributing to published papers
- Identifies who to contact when asked about an out-sourced study
- Learning on a regular basis about the work being performed in other companies
- Improving personal influencing, communication and organisational skills
- Influencing the choice of webinar topics to broaden own learning
- Promoting and increasing exposure for own Company and the innovative work performed in related areas

For more information and to express an interest in joining the committee, please email gareth.thomas@covance.com.

A PSI ToxSIG webinar - Big Data, Data Science, AI and other buzzwords: What does the Data-Driven Hype mean for Pharmaceutical Analytics?



Tuesday 14 January 2020 14:00 - 15:00 GMT

Speaker: Richard Pugh (*Mango Solutions*)

The last 15 years has seen a massive shift in the role of data and analytics, driven by the increased hype around big data, data science, machine learning and AI. This presents both challenges and opportunities for analytic teams. This webinar will strip back the hype to look at what these buzzwords really mean and talk about the impact this is having on the role, remit and operating model of analytic teams in the life sciences industry.

This webinar is organised by the Toxicology Special Interest Group. [Find out more about their objectives.](#)

PSI New Starters Half-Day Networking Event



Thursday 6 February 2020 13:30 - 17:30 GMT

Location: King's College London, Waterloo Campus

An opportunity to meet statisticians from across the pharmaceutical industry in a relaxed and informal setting. An exciting program of events and a chance to work in small groups on a data analysis challenge. Lunch provided. Click [here](#) to register.



Visit the Video-on-Demand Platform here!





PSI Webinar: Longitudinal modelling: Time to take the next step?

José Pinheiro, Björn Bornkamp, Tobias Mielke, France Mentré, Rob Hemmings

The purpose of this webinar is to explore the use of longitudinal modelling across drug development, highlighting its opportunities (such as usage as primary analyses, or for improved decision making at interim analyses) and caveats. One important aspect to be discussed is the evaluation of the efficiency of (parametric) longitudinal modelling versus standard cross-sectional approaches, and factors based upon which one approach might be preferable over the other. Click [here](#) to watch.



Quantitative Decision-Making SIG Webinar: SWOT Analysis for role of Pre-Clinical Statistician

Véronique Robert, Guido Thömmes, Oliver Sailer

Quantitative methods to support decision-making in clinical drug development already exist but may be unknown or unused by pharmaceutical companies. We performed a survey among pharmaceutical companies, targeting people with different profiles (statisticians, non-statisticians and decision-makers) working at different stages of the clinical development (study level, development level or portfolio level). This survey allowed us to analyse which quantitative methods are known, which quantitative methods are used (or not), what benefit is expected from this kind of methods, and what are the needs for a larger use of quantitative methods to support decision-making. It permitted to understand the gaps and some of the issues associated to the use of such methods in drug development. The webinars are intended to share the learnings from the survey and to promote different quantitative methods for decision-making. Click [here](#) to watch.



How to get into the flow and reach peak performance

Do you want to have fun at work?
Do you want to experience satisfaction?
Do you want to get things done at work?

Getting into flow is about these things. Today, we will speak about a research on how to get into the flow and reach your peak performance.

How to leverage time-boxing to reduce overwhelm being a statistician

Batch processing and scheduling tasks to fight procrastination

Do you know how to make a good to-do list?
Do you know how to set priorities versus the time it takes?
Do you have a problem with over-committing?

One of the most effective skills you can have in life is effective time management. According to Michael Hyatt: "What gets scheduled gets done." If you're not managing your time well, there's no way you're going to reach your goals at work and the life outside of it. In today's episode, we discuss time boxing and batch processing.

CALC Episode 4: Be Significant: What employers look for

So, you want to be a statistician in the pharmaceutical industry?
You want to drive drug research and development, but you are wondering what employers look for in the perfect candidate?

You are in luck – PSI [CALC](#) are here to share their top tips on how to be the ideal candidate. In this episode, learn about: Entry Requirements; Technical and soft skills you'll need to demonstrate; Writing the perfect CV

*Go ahead, listen to this episode and be an effective Statistician!
Alexander Schacht*

10% discount on the early bird rate available for the following courses:



Register your interest now to receive updates, hear when registration opens and receive a discount on the early bird rate (where applicable)!

Future Events

- Training Course: PK Methods and Regulatory Considerations
- Training Course: R for SAS user
- PSI One Day Meeting: Missing Data
- PSI Scientific Committee One Day Meeting: Non-proportional hazards and applications in immuno-oncology

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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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Follow us on Twitter and LinkedIn

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 LinkedIn.

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And finally.....

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To view previous newsletters please see the EFSPI website in the "[News](#)" area.

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Chrissie Fletcher
EFSPI Communications Officer

