



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

EFSPI Newsletter August 2021

In this newsletter

[Scientific](#) – Let's talk about career development
[ESIG of the month](#) – Pre-clinical
[Other ESIG news](#) – Regulatory
[Country news](#) – APF (Germany), PSI (UK)
[Job opportunities](#) – Senior Manager, Biostatistics
[And finally...](#)

Scientific

There is an upcoming **free** webinar on **Friday October 8** on ***Let's talk about Career Development.***

Traditionally, statisticians think of our career paths as being more or less linear. Taking more senior roles and move from one company to another, but it is common for us to take on a similar role to the one we had before. We have organised a conversation with *Karen Facey* and *David Wright* to give you a different perspective on career development. Whether your career is going just fine, or whether you think you could do with some food for thought for your next development plan discussion – join us and listen to some inspiring reflections on career development. More information can be found on the website and registration will open soon.

In addition, the Scientific Committee is planning for a webinar on Decentralised Trials on a date in late Autumn to have a follow on to the session on Decentralised Trials of the Regulatory Workshop on September 13th ([EFSPI](#)) that focusses on more examples from industry of statistical issues associated with DCTs. More information will follow in the next newsletter.



Egbert Biesheuvel, EFSPI Scientific Committee Chair

[back to top](#)

ESIG of the Month

Pre-clinical ESIG

The Toxicology SIG has been renamed as the **Pre-clinical SIG** to encourage wider participation. We would like to attract Statisticians working within the wider Research and Discovery phases of Industry (including efficacy models) to join the SIG, in addition to our current participants from the Regulatory and Investigative Toxicology/Safety Assessment areas. Joining our affiliates list is free and easy, just email gareth.thomas@covance.com. Members of our affiliates list receive early announcements of our upcoming events and have a greater chance to input into and shape our annual workshop (when such events can safely return), as well as our webinars and general discussions.

We also encourage and invite anyone working in the Pre-clinical area to join our small committee. Our committee is made up of 7 Statisticians working within Pre-clinical (from Astra Zeneca, Boehringer Ingelheim, Covance, GSK, JnJ and Novartis). We meet regularly (via webex) to discuss any hot topics, plan our webinars/workshop and generally support each other. We like the committee to remain fresh and to represent as wide a cross-section of industry as possible, so please get in touch if you would like to join or if you know someone working in these areas, particularly whose Company is not yet represented, please pass this on to them.

Objectives

To provide a forum to discuss and advance statistical topics related to Research, Discovery, Regulatory and Investigative Toxicology and to promote the involvement of Statisticians in these areas.

Who we are

Our membership consists of statisticians at CROs, pharmaceutical companies and academia who are working in areas such as:

- Discovery
- Good statistical practice in in-vitro, ex-vivo and in-vivo assay development
- Reproducibility and Translation from pre-clinical to clinical
- Toxicogenomics
- Genetic Toxicology
- Acute Toxicology
- General Toxicology
- Eco-Toxicology
- Toxicokinetics
- DMPK / Pharmacokinetics
- ECG
- Immuno Toxicology
- Histopathology
- Pharmacology
- Developmental and Reproductive Toxicology
- Carcinogenicity

We discuss diverse topics ranging from Dog Telemetry data analysis to Decision Trees, from Bayesian methods to dealing with irate study directors, and have a list of over 50 affiliates on our e-mail distribution list.

What we do

We currently organise 3 webinars a year (5 during 2020 to substitute not having a face-to-face workshop) and also an annual 2-day face-to-face workshop (viruses allowing). We are hoping to run our next workshop in 2022. Between these events the committee works hard to progress discussions on hot topics, prepares joint publications (having had 3 published to date) and are currently working on a paper aimed at scientists working within the Pre-clinical area. This paper is currently going through legal review within our Companies before being submitted. Please get in touch if you are interested in hearing more and/or getting involved.

Gareth Thomas, Pre-clinical ESIG Chair

[back to top](#)

Other ESIG News

Regulatory ESIG

Upcoming workshops and webinars

**** Reminder ** 6th EFSPi Regulatory Statistics Workshop**

Monday, 13rd September 2021, 14.00-17.00 CET

Tuesday, 14th September 2021, 14.00-17.00 CET

Wednesday, 15th September 2021, 9.00-12.00 CET

The topics being discussed include:

- 1. Complex innovative designs: Where is their place in drug development?*
- 2. Real-world data - using their potential.*
- 3. Decentralized trials: What is the impact on evidence generation?*

There are approximately 1000 delegates already registered to attend the workshop, from a wide mix of countries and regions, and including statisticians, clinicians and other stakeholders. More details are available [here](#) to see the full program and register.

Kaspar Rufibach, on behalf of the local organizing and scientific committee.

**** Reminder ** Accelerating Complex Clinical Trials in Europe and beyond workshop**

A multi-stakeholder workshop to develop shared solutions for the use of complex clinical trials to optimise drug development in Europe. 5 October 2021, 14:00 - 19:00 CET and 6 October 2021, 14:00 - 18:30 CET

Complex Clinical Trials (CCTs) have the potential to accelerate drug development and enable patients to get timely access to transformative therapies. The main objective of this workshop is to develop shared solutions addressing key challenges with CCTs, discuss global implications of CCTs, identify emerging best practices to facilitate the use and acceptance of CCTs to multiple stakeholders, and identify synergies with existing initiatives such as IMI EU-PEARL and CTTI. The workshop will include a mix of plenary and break-out sessions involving representatives from Industry, regulatory agencies, HTA agencies, academia, patient advocacy and ethics committees. Click [here](#) to see more details and to register.

Chrissie Fletcher on behalf of the EFPIA Complex Clinical Trials Team

First Announcement: Joint Webinar by PSI, EFSPi & ASA BIOP on Complex Innovative Designs

21 October 2021: 14.00 – 16.00 (British Summer Time)

The event is intended for statisticians involved in the design of clinical trials in all therapeutic areas, from industry, CROs and academia. The audience will gain insight into regulatory considerations for complex innovative designs and their use in practice. Registration is free and now open :

<https://psiweb.org/events/event-item/2021/10/21/default-calendar/joint-psi-efspi-asa-biop-webinar-complex-innovative-designs>

Meeting with Biostatistics Working Party

The Regulatory ESIG is planning to meet with the Biostatistics Working Party on the 29th October 2021. This annual meeting will be similar to the one held in 2020 with multiple associations and professional groups coming together to discuss statistical topics. The Regulatory ESIG suggested three topics for discussion

- The Danish Data Analytics Centre and the future plans of BSWP to analyse data
- Decentralised trials
- Use of historical / synthetic control arm data

The SIG are waiting for the BSWP to confirm the agenda.



Christoph Gerlinger (EFSPi Regulatory Chair) and



Jurgen Hummel (PSI Regulatory Chair)

Please look out for updates and other ESIG news at <https://www.psiweb.org/sigs-special-interest-groups/sigs>



Adam Crisp (PSI SIG liaison) and



Gaëlle Saint-Hilary (EFSPi SIG liaison)

[back to top](#)

Country News

APF (Germany)

The 3rd International Biometric Society-Germany Region "Academia meets Industry" event, this year taking place on October 7/8, 2021, again in a virtual setting. The intention of this interactive workshop is to bring together researchers from industry with researchers and students from academia. Participants are invited to exchange and evaluate possible collaborations, especially regarding joint supervision of BSc, MSc, and/or PhD theses. Please register using this link <https://forms.office.com/r/fB4f6sdjxC> by September 17, 2021.

PSI (UK)

PSI award winners



PSI is delighted to announce three people who have been recognised in 2021 for their contributions to PSI. Find out more about their achievements on the website.

- Lisa Hampson - PSI / RSS Award for Statistical Excellence in the Pharmaceutical Industry
- Lyn Taylor - PSI Mick Godley Award
- Ray Harris - PSI Honorary Member

[Find out more](#)


Apply now to be part of the PSI mentoring scheme!



The PSI Professional Development Committee are excited to introduce a mentoring scheme with members already signing up! Mentors and mentees will be matched based on years of experience, personal goals and the sector they work in (unless otherwise requested). Find out more about the scheme from the link below.

[Register now](#)

MEETINGS, WEBINARS AND COURSES



**17 & 24th
Sep**

PSI Scientific Meeting: Generating Insights through Modern Applications of Data Visualisation

13:00-17:00

Who is this event intended for? Anyone interested in data visualisation in the pharmaceutical industry.

What is the benefit of attending? Gain new insights into data visualisations and learn about the regulatory perspective. With no technical or coding knowledge assumed, a variety of practical workshop exercises will bring to life many of the concepts learned in part one.

[Register now...](#)



**29th
Sep**

PSI Leading for Impact Workshop

10:00-12:00



**27th
Sep**

PSI Book Club

PSI are starting a book club! We will be reading and discussing non-technical books which are relevant to our roles. Participants will be split into smaller discussion groups so members can network with each other and practice exercises to help implement their learnings.

Who is this event intended for? The Book Club is for PSI Members to discuss and practice learnings from a wide range of books relevant to their role and network with colleagues from the industry. Facilitators will also have an opportunity to lead and chair discussions

[Find out more...](#)



**14-15th
Oct**

PSI Training Course: Repeated Measured and Mixed Models Module

10:00-12:30 & 14:00-16:30 on both days

Who is this event intended for? Anyone in a role that contains or will contain an aspect of leadership.

What is the benefit of attending? You will come away with a plethora of techniques to use in your day to day leadership role as well as finding out how to overcome your own personal challenges in this context.

[Register now...](#)

Who is this event intended for?

Statisticians working on clinical trials, who already have a good understanding of linear and generalised linear models and want to further their knowledge of repeated measures and other clustered data.

What is the benefit of attending? By the end of the course attendees will know how to analyse repeated measures of patients through time or other clustered data in randomised clinical trials and associated observational studies.

[Register now...](#)

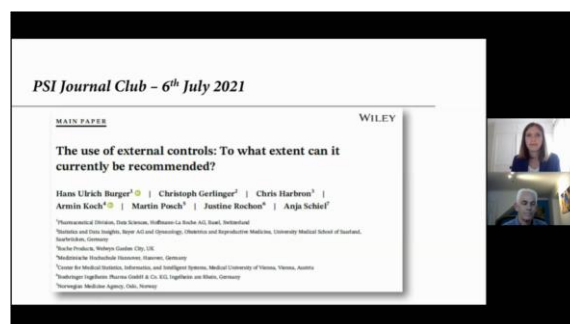
Podcasts & Webinars



[PSI VisSIG Wonderful Wednesday 17: Psychometric data example](#)

Abi Williams presents the visualisations of the SDQ-12 in conjunction with different anchor measures. For this challenge very different plot types have been proposed. All visualisations are available on the Wonderful Wednesday blog.

[Watch here](#)



[PSI Journal Club Webinar: The use of External Controls in Clinical Trials](#)

Watch Chris Harbron (Roche) and Margaret Gamalo (Pfizer) present their recent work. The webinar will be chaired by Elizabeth Williamson (London School of Hygiene and Tropical Medicine).

[Watch here](#)



[5 steps to teaching statistics well](#)

How do you create and teach effective and moving content that your audience will pay attention to and add great value to them? In this episode, Sam and I talk about the 5 steps to teaching stats and other types of content well.

[CALC Episode 6: Opportunities offered by doing a placement year in the Pharmaceutical and Healthcare industry \(Part 1 – Statisticians\)](#)

Following on from 2019's series, we again collaborate with PSI CALC (Careers and Academic Liaison Committee) to bring two new episodes, this time discussing the opportunities offered by doing a placement year in the Pharmaceutical and Healthcare industry.

[Mentor others to be mentored – Manatee Mentor](#)

Is having a mentor really beneficial? What is Manatee Mentor? What are its key features? How can this predict your professional success? Listen to our interview with Lucy Setian to find out more about Manatee Mentor - an AI-powered platform to make mentoring inclusive, affordable and accessible to all.

Listen to these episodes and share them with your friends and colleagues.

Ciao and be an effective statistician!

Alexander Schacht

[Listen here](#)

Non-PSI Events

[RSS 2021 International Conference](#)

Date: Monday 6th - Thursday 9th September 2021 | **Location:** Manchester

The annual RSS Conference provides one of the best opportunities for anyone interested in statistics and data science to come together to share knowledge and network. Registration is open with discounts for RSS Fellows and early booking.

PHUSE

Bringing people together is at the heart of all PHUSE events. We have continued to connect, share, and advance the future of life sciences through innovative work and knowledge-sharing at our virtual events.

[PHUSE / FDA CSS](#) **Date:** Monday 13th - Wednesday 15th September 2021 | **Location:** Virtual

[PHUSE EU Connect](#) **Date:** Monday 15th - Friday 19th November 2021 | **Location:** Virtual

[back to top](#)

[Job Opportunities](#)

Opportunity for a [Senior Manager, Biostatistics](#).

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.

[back to top](#)

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.



Chrissie Fletcher, EFSPI Newsletters

[back to top](#)