



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

---

# EFSPI Newsletter October 2021

## In this newsletter

[ESIG of the month](#) – Data Sharing

[Other ESIG news](#) – new Launch & Lifecycle SIG, changes in SIG chairs

[Country news](#) – APF (Germany), PSI (UK)

[Job opportunities](#)

[And finally...](#)

## **ESIG of the Month: Data Sharing**

### **Why do we have a Data Sharing ESIG?**

Clinical data has greater use beyond the original trial. These data can be used to further increase our scientific understanding of diseases and their treatment for the benefit of future patients. Dataset re-use is increasingly becoming part of good trial practice e.g. use of historical control arm data for planning, adding together the findings from many trials, and doing methodology work to improve the way we do future trials. Alongside this, clinical trial documents are increasingly required to be open to access to the public within the regulatory framework (e.g. EMA Policy 70, EU CTR). All this is challenging, as both the data privacy and the regulatory framework continue to evolve.

### **Who are we?**

This ESIG comprises statisticians (both from pharma and academia) and some policy experts who are working or have interest in the data re-use, data privacy and data sharing space.

### **What's our purpose?**

1. Promote an understanding of the challenges and responsibility organisations and statisticians have when re-using or sharing clinical data.
2. Improve understanding, implementation and data privacy concepts within the context of clinical trial data sharing.
3. Influence and shape the environment and policies regarding clinical data sharing.
4. Collaborate with other groups and stakeholders in this area.

### **Want to know more?**

Check out the [resources](#) we have on our ESIG page.

### **Would you like to join us?**

New members are welcome. If you're interested in finding out more please contact Rebecca Sudlow ([rebecca.sudlow@roche.com](mailto:rebecca.sudlow@roche.com)) or Mimmi Sundler ([mimmi.sundler@astrazeneca.com](mailto:mimmi.sundler@astrazeneca.com)) for further information.

**Rebecca Sudlow (Chair)**

[back to top](#)

## **Other ESIG News**

### **\*\* NEW special interest group: Launch & Lifecycle \*\***

The vast majority of statistical resources in the pharmaceutical industry are allocated to the clinical development plan. However, in evolving and highly competitive markets, it is increasingly important to address the evidence needs of additional stakeholders in order for patients to have access to innovative medicines. Strategic statistical input into evidence generation and communication beyond health authorities is essential to maintaining scientific integrity, promoting trust, and influencing decision making in clinical practice.

If you have a passion for generating impactful evidence to support the launch and lifecycle of innovative medicines, we invite you to join this new SIG! Please email Alexander Schacht, Chair ([alexander.schacht@veramed.co.uk](mailto:alexander.schacht@veramed.co.uk)) and Jenny Davenport, co-Chair ([jenny.devenport@roche.com](mailto:jenny.devenport@roche.com)) to join the SIG.

### **Changes in SIG Chairs**

Eloisa Brook (GSK) has taken over from Gareth Thomas (Labcorp) as the chair of the Pre-Clinical SIG. Domingo Salazar (AZ) is taking over the chair role for the Data Science SIG whilst Julia Chernova (Bayer) is on maternity leave. Josie Wolfram (Astellas) is a co-chair with Anny Stari (GSK) for the Real-World Data SIG. A new webpage has been launched for the CSM/QTL SIG <https://psiweb.org/sigs-special-interest-groups/csm-qtl-sig>.

### **Change in EFSPi Liaison role**

Gaëlle Saint-Hillary has announced she is stepping down from the EFSPi liaison role for the SIGs. Thanks to Gaëlle for her great partnership with Adam Crisp (PSI SIG liaison) for the last few years. A new EFSPi liaison role is being sought and will be announced in due course.

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-Hillary (EFSPi SIG liaison)**

[back to top](#)

## Country News

### APF (Germany)

The annual virtual autumn workshop will take place on Black Friday Nov 26<sup>th</sup> .

### PSI (UK)



PSI Conference 2022 will be held at Gothia Towers in Gothenburg, Sweden **face-to-face** from Sunday 12 to Wednesday 15 June 2022.

Abstract submission is now open! You can submit individual abstracts or abstracts for a full session. We accept abstracts on any topic but have provided a list of topics we are particularly interested in here: [Abstract Submissions \(psiweb.org\)](https://psiweb.org). The abstract templates are also available in the same location.

Abstract deadlines are:

- **10 December 2021** for oral abstract submissions
- **25 February 2022** for poster abstract submissions

Anyone selected for an oral presentation, will be eligible for **10% off the 3-day conference price**.

*David Lawrence PhD, PSI Conference Chair*



## Upcoming Events

17  
No

[PSI Sub Group SIG Webinar: Modern approaches to subgroup identification](#)

19  
No

[PSI EIWG Webinar: Estimands from trial planning to publication in medical journals: The ETHOS trial](#)

02  
Ma

[PSI Medical Statistics Careers Event](#)

## ON-DEMAND WEBINARS AND PODCASTS



### PSI VisSIG Wonderful Wednesday 20: Competing risk data example

Bodo Kirsch discusses an approach to display data on competing risks based on an issue recently published. All visualisations are available on the [Wonderful Wednesday blog](#).

[Watch here](#)

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

Gain new insights into data visualisations and learn about the regulatory perspective with this event, which provides a practical introduction to modern methods of data visualisation, including presentations from some well-known and influential speakers.



[Watch here](#)



[Preparing for a tough conversation](#)

One of the toughest discussions you can be in as a statistician is a GBA hearing in Germany. I'll be giving you some tips on what can you do to be prepared for it.

### **Statistical Unicorns**

Listen while Ena and I discuss how to improve one's career and how to make good choices that help you become more effective and have more impact at work.

### **Can introverts be good negotiators?**

Join us while I talk with Lousin Mehrabi who was selected by the Schraner Negotiation Institute as one of the 'Most Influential Negotiation Professionals Globally'!

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

*Ciao and be an effective statistician!*

*Alexander Schacht*

[back to top](#)

## **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.

[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](#)