



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

## EFSPI Newsletter May 2021

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### **EFSPI Social Media**

The EFSPI communications team has started to use the EFSPI LinkedIn group as an addition to our website. The LinkedIn group will be used for posting news and information around upcoming events, the monthly newsletter, surveys, eSIG news etc.. The communications team invite you all to join the group [EFSPI|LI group](#) and help us grow the EFSPI network.

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### **Scientific**



The Scientific Committee is planning for a number of events in 2021:

- A joint EFSPI/BBS virtual event on **Precision Medicine and Health technology Assessment, 28<sup>th</sup> June 3-5pm CET**. Click [here](#) to get more information and to register.
- An event on **COVID**, together with the ESIG on Vaccines, planned in second half of 2021.
- A meeting together with the ESIG on **Small Populations** also in the second half of 2021
- An event on **Decentralised trials** in the last quarter of the year.

At this moment all these events are planned to be online, but as soon as we have more concrete information, we will share with you via the Newsletter and our website.

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## ESIG News



## Regulatory ESIG

### **6<sup>th</sup> EFSPi Regulatory Statistics Workshop**

We are happy to announce the 6th EFSPi regulatory statistics workshop. We plan webinar sessions on three days:

Monday, 13rd September 2021, 14.00-17.00 CET  
Tuesday, 14th September 2021, 11.00-14.00 CET  
Wednesday, 15th September 2021, 9.00-12.00 CET

The topics that we will discuss 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?

More details are available

here: [https://www.efspi.org/EFSPi/Events/Regulatory\\_Meetings/6th\\_efspi\\_workshop\\_on\\_regulatory\\_statistics.aspx](https://www.efspi.org/EFSPi/Events/Regulatory_Meetings/6th_efspi_workshop_on_regulatory_statistics.aspx)

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

### **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. Attendees for the break-out sessions are requested to have expertise or experience of CCTs. Two of the break-out sessions will discuss statistical considerations relating to CCTs. Click [here](#) to see more details.

***Chrissie Fletcher on behalf of the EFPIA Complex Clinical Trials Team***

### **Meeting with Biostatistics Working Party**

The Regulatory ESIG is planning to meet with the Biostatistics Working Party on the 29<sup>th</sup> 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. Further details will follow.

### **Other Regulatory News**

On the 11<sup>th</sup> May 2021 the FDA adopted the final [E9\(R1\) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials: Guidance for Industry](#).

The FDA has released a new draft guidance [Randomized Trials Guidance: Adjusting For Covariates](#), a revision of the previous 2019 draft version. The new draft guidance includes more detailed recommendations and discusses use of nonlinear models in addition to linear models. If you wish to contribute to the commenting please contact Jürgen Hummel ([Jurgen.Hummel@ppdi.com](mailto:Jurgen.Hummel@ppdi.com)) or Christoph Gerlinger ([christoph.gerlinger@bayer.com](mailto:christoph.gerlinger@bayer.com)).

The FDA has issued [guidance](#) to provide recommendation to sponsors of master protocols evaluating drugs and biological products for the treatment or prevention of COVID-19. The guidance primarily focuses on the design, conduct, and statistical considerations of master protocols intended to generate or contribute to substantial evidence of effectiveness and adequate characterization of safety of drugs for the treatment or prevention of COVID-19.

***Christoph Gerlinger (EFSPi Regulatory Chair), 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)***

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## **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.

### **DSBS (Denmark)**

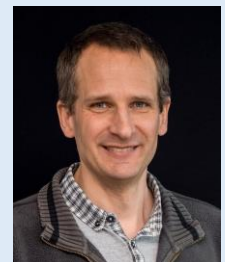
On 29 April 2021 the Danish Society for Biopharmaceutical Statistics (DSBS) held the annual meeting including two scientific talks, all in a virtual format. The overall theme for the two scientific talks was: "COVID-19 vaccines, the regulatory process and what comes next". The invited speakers were Kirstine Moll Harboe, Chief Medical Officer at the Danish Medicines Agency and Jens Nielsen, Senior Scientist at Department of Infectious Disease Epidemiology and Prevention, Statens Serum Institut.

### **PSI (UK)**

#### **PSI Online Conference 2021 update**

The PSI Conference programme is now available on the website. We have 3 plenary sessions and 27 parallel sessions spread out over the three days, along with on demand content and posters. Find out more [here](#).

*Paul Terrill PhD, PSI Conference Chair*



Registration for the Online Conference includes:

- Access to:
  - exciting, relevant and up to date presentations and sessions over the three live days
  - additional on demand content
  - the latest research in the e-poster portal
- Continued access to all of the Online Conference content for at least 6 months after the conference, allowing you to view content at your leisure
- Opportunity to attend live networking sessions
- Ability to meet and engage with sponsors and exhibitors
- Ability to catch up and connect with colleagues

Companies that sponsor the 2021 PSI Online Conference will receive a large number of complimentary delegate passes that will be issued separately.

# MEETINGS, WEBINARS AND COURSES



**1<sup>st</sup> & 2<sup>nd</sup>  
June**

## PSI EIWG Webinar: Estimands in Oncology - How and Why

1 June: 15:00-16:30, 2 June: 9:00-10:30

**Who is this event intended for?** Anyone working in clinical trials: Clinician, Regulator, Investigator, Academic, Ethics Committee, Statistician.

### What is the benefit of attending?

Through a case study you will understand the benefits of using the estimand framework to describe the diversity of patient journeys addressing the right questions in clinical trials.

Please note: this event takes place on both the 1st and 2nd June but will entail exactly the same content.

[Register now...](#)



**8-10<sup>th</sup>  
June**

## PSI Training Course: Data Monitoring Committees (DMCs)

8 June: 9:00-13:00, 9 June: 14:30-16:30, 10 June: 9:00-13:00


**Who is this event intended for?** Statisticians working on clinical trials which require a DMC.

**What is the benefit of attending?** Understand the different roles and responsibilities within a DMC and have the chance to participate in a DMC within an interactive workshop.

Please note: Places for this course are limited and in high demand, so please ensure you are able to attend all sessions before booking.

[Register now...](#)

# Podcasts & Webinars



**Our Speakers**

**Dominic Magirr**  
Dominic joined Novartis's Advanced Methodology and Data Science group in February 2020. He studied statistics at Lancaster University and worked for several years at AstraZeneca in Cambridge.

**Chang Yu**  
Chang Yu is a faculty member in the department of biostatistics at Vanderbilt University Medical Center. Before joining Vanderbilt, he worked over 5 years at Merck Research Laboratories on late-stage clinical trials.

## [PSI Journal Club Webinar: Survival Analysis](#)

Watch this Journal Club webinar to hear Dominic Magirr (Novartis) and Chang Yu (Vanderbilt University) present their recent work. With the webinar chaired by Jennifer Rogers (PHASTAR).



### [PSI VisSIG Wonderful Wednesday 14: Mobile App Usage](#)

Irene de la Torre Arenas presents the results of last month mobile app data challenge. The change of individual app usage over time has been visualised in very different ways as well as its impact on individual symptoms of COPD. The discussion centre around the usability of the respective display type for the given purpose. All visualisations are available on the Wonderful Wednesday blog.



### [Welcome to Sam Gardner and insights into non-clinical statistics](#)

Let's welcome Sam Gardner as our new co-host for our podcast show!

### [Learnings about data visualisation from one year of Wonderful Wednesday Webinars](#)

The Wonderful Wednesday Webinar series was introduced in an earlier episode. In this episode, we dive deep into what has happened over one year of the Wonderful Wednesday Webinars.

### [Non-clinical pharmaceutical statistics](#)

Join us while Sam and I dive deeper into the non-clinical statistics and discuss some of the example for non-clinical statistics in the manufacturing and quality area.

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

*Ciao and be an effective statistician!*

*Alexander Schacht*

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## **Job Opportunities**

Opportunity for a [Director and Team Leader, 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.

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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.



***Chrissie Fletcher, EFSPI Communications Officer***

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