



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

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## EFSPI Newsletter August 2020

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### **Regulatory**

The EFSPI Regulatory Statistics Workshop is taking place as virtual sessions on the 12-13<sup>th</sup> October 2020 14:00-16:35 (CEST). The topics for each webinar are as follows:

**Webinar 1: Data monitoring committees – evolving their role in a changing drug development landscape**

**Webinar 2: Estimands – emerging questions now that we are using the framework**

Already 300+ participants are registered. Click [here](#) to view the program and to register.

*Christoph Gerlinger (EFSPI Regulatory Chair), Jurgen Hummel (PSI Regulatory Chair)*

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## **ESIG News**

### **Estimands in Oncology ESIG**

The oncology estimand SIG has submitted another paper: Bornkamp et al (2020): Principal Stratum Strategy: Potential Role in Drug Development (2020). Submitted, <https://arxiv.org/abs/2008.05406>. The paper makes the case that there are several relevant questions in drug development that can be formulated as principal stratum estimands. While not related to the primary objective of the trial questions of principal stratum type can still play an important role to characterize how the drug works in relevant subpopulations defined by post-randomization events. The paper lists examples and discusses estimation under various assumptions. We believe that this strategy discussed in the ICH E9 estimand addendum will become more important for drug developers in the future. Our paper contributes to bridging the gap between the causal inference / epidemiological literature where this method has been introduced two decades ago and pharmaceutical drug development. The paper comes with a [markdown file](#) that provides implementations for principal stratum estimands motivated by the principal ignorability assumption. The paper was written as a collaboration of statisticians from several companies within the oncology estimand working group.

Registration for the upcoming BBS webinar "RCTs meeting causal inference: principal stratum strategy and beyond" is still open: [BBS causality estimands.pdf](#)

In September and October, the WG has arranged for TCs with six HAs globally to share the results that the WG has generated over the last few years. For anyone interested in these results we invite you to check out our webpage: [www.oncoestimand.org](http://www.oncoestimand.org).

*Kaspar Rufibach, Roche*

### **Vaccines ESIG**

The Vaccines ESIG would like to highlight the following meeting on vaccine development:

## **NISS-Merck Virtual Meet-up on Issues in Vaccine Development**

**September 16, 2020 11-12:30 EDT**

The National Institute of Statistical Science (NISS) and Merck are sponsoring a Virtual Meet-Up on Vaccine Development.

With the COVID pandemic having such a profound effect, everyone is hoping for a highly protective and safe vaccine soon. Yet most have little understanding of the difficult road for discovery and development of a vaccine. In this meet-up we will discuss some of the challenges of vaccine development and novel ways those challenges can be met.

[Register for this event here!](#)

*Fabian Tibaldi, GSK*

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## **Country News**

### **AFP (Germany)**

The APF meeting on November 27<sup>th</sup> and the German Statistics Leaders meeting on November 26<sup>th</sup> will not take place as face to face meetings. Options to hold virtual sessions are in discussion and further details will be provided in due course.

### **BBS (Switzerland)**

BBS are holding a seminar on [RCTs meeting causal inference: principal stratum strategy and beyond](#) on the 7<sup>th</sup> September 2020, 14:00-17:00 CET. Please register (which is free) via this link.

### **IBIG (Italy)**

IBIG are hosting the following webinars: Every Friday h. 10,00 – 12,30 (CET)

| <b>Date</b> | <b>Topic</b>                                                                                |
|-------------|---------------------------------------------------------------------------------------------|
| 2 October   | Quantitative Decision Making (QDM) in the Clinical Drug Development                         |
| 9 October   | SAS, R, Python – Differences, Similarities and Potentialities of Widely Used Stats Software |
| 16 October  | Clinical Trial Management during the COVID-19 Pandemic – Guidelines and Practical Impacts   |
| 23 October  | Taxonomy of Subgroup-related Analyses and Issues in Clinical Trials                         |
| 30 October  | Data Visualization for a Better Communication with Non-Stats People                         |

On the 7<sup>th</sup> October 2020, h. 10.00 – 17.30 CET: 7<sup>th</sup> Italian CDISC User Group Network have their Annual Meeting.

There are also online courses available on Define-xml and CDISC Submission Ready Document:

Part 1: 9<sup>th</sup> September 2020, h. 9.30 – 13.00

Part 2: 16<sup>th</sup> September 2020, h. 9.30 – 13.00

See [here](#) for more details.

# MEETINGS, WEBINARS AND COURSES

## PSI Webinar: Using visualisation to help make decisions

3<sup>rd</sup> September 14:00 - 15:30

### Who is this event intended for?

Anyone who is interested in data visualisation.

**What is the benefit of attending?** The audience will gain insight into how data visualisations are being used to aid clinical research.

[Register now...](#)

## PSI Webinar: Patient preference studies

13<sup>th</sup> Oct 14:00 - 15:30

### Who is this event intended for?

Anyone keen to learn about patient preference studies and their application.

**What is the benefit of attending?** Learn what a patient preference study is & how it can inform regulatory decision-making.

[Register now...](#)

## PSI Webinar: Master protocols - theory, application & regulatory considerations.

23<sup>rd</sup> Sept 14:00 - 16:00

### Who is this event intended for?

Statisticians, academics & generally everybody interested in the topic.

**What is the benefit of attending?** The audience will gain insight into design & regulatory considerations, and the conduct of clinical trials with a master protocol.

[Register now...](#)

## Future events

Register your interest to determine what topics you'd like to see in future PSI events!

Our most recently proposed Event:- [EFSPi/PSI Webinar: why is leadership important for me as a statistician?](#)

[Register](#)

# Podcasts & Webinars



## PSI VisSIG: Wonderful Wednesday Webinar 6

In this month's webinar, we discussed an exacerbation example data set. The challenge was to produce a data visualisation incorporating the information on the number of exacerbations observed. The discussed visualisations included a straightforward and clear presentation of the number of exacerbations, a Power BI app, longitudinal plots, and a display of patient-level outcomes.

[Watch here](#)



### [My personal lessons from using various data visualizations](#)

In this episode, I'll be sharing with you what I have learned from the past year about visualization as I worked a lot of these – the exploratory and explanatory visualization. These kinds of visualization helped me a lot to open new doors and made me amazingly easy to stand out from other statisticians.

### [How to run effective meetings, even if you are just a participant](#)

What are typical meetings you would be invited to as a statistician? Study meeting? Project meetings? Team meetings?

In this episode, I talk about the important questions that we need to answer and the points we need to consider to ensure an effective meeting and the steps you can follow and what can you do if these steps are not followed in a meeting you're invited to.

### [Everything you need to know about matching adjusted indirect comparisons](#)

What can we do about indirect comparisons to make it better and more efficient rather than using the usual technique? What are the indirect comparisons in terms of the efficacy of different drugs?

In this episode, Daniel and I talk about these questions and discuss about Bucher vs MAIC, Methodik MAIC, and NICE technical document

*Listen to these podcast episodes now and share it with others who might learn from it.*

*Ciao and be an effective statistician!*

*Alexander Schacht*

[Listen here](#)

## **SFdS (France)**

The Yearly Biopharmacy & Health congress, joint meeting SFdS, SFB and GDR Santé, 1-2 Oct 2020, in CNAM and Virtual Weblink: [https://www.sfds.asso.fr/fr/biopharmacie\\_et\\_sante/480-actualites/](https://www.sfds.asso.fr/fr/biopharmacie_et_sante/480-actualites/)

The International congress "Statistics and Biopharmacy" 20-22 Sept 2021.

"The **SnB2021** Conference organized by the Statistics and Biopharmacy group of the [SFdS](#) (French Society of Statistics) will be held in Paris 20-22 September 2021. It is a unique event organized every four years integrating multiple perspectives on innovative applied statistical research for the drug

development and an excellent opportunity to meet colleagues from academia, regulatory agencies and pharmaceutical companies". Website: <http://www.snb2021.paris/Home.aspx>

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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.....**

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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