



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

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## EFSPI Newsletter April 2020

In this newsletter:

[Update from EFSPI President](#)

[Regulatory](#) – update on COVID-19 guidance and regulatory statistics workshop

[Scientific](#) – update on meetings scheduled for 2020

[ESIG News](#) – estimands in oncology, new COVID-19 ESIG, DIA COVID-19 stats webinar

[Country news](#) – BBS (Switzerland), PSI (UK)

[Women in Data 2020](#) – \*\* reminder \*\* open for nominations

[Volunteers needed](#) – \*\* reminder \*\* join EFSPI website and social media committee

[Job opportunities](#) – Statisticians for Clinical Development

[Follow us on Twitter and LinkedIn](#)

[And finally...](#)

### Update from the EFSPI President



Last month we said, “It is an unprecedented and challenging time for everyone” and with all the changes in the world that has not changed. I hope you, your family, relatives and friends are keeping well during the coronavirus pandemic. And that you can still make the best of it, may be living in much different ways than you experienced before. Nevertheless, I feel fortunate to still have a job and be able to work from home compared to those who have unfortunately lost their job, have experienced a sudden reduction in income, or to the hero’s who work in the “frontline” in hospitals and nursing homes. All very, very challenging.

For EFSPI there will also be some challenges ahead. At the end of April, the EFSPI Council met virtually to discuss the impact of COVID-19 on our business and plans for this year. The situation is not easy as the stage of the pandemic is different across the countries in our federation and the current measures enforced by the respective governments varies as well. Whilst some countries are considering relaxing some measures, the social distancing is something that will be with us for a much longer time. This is a key factor the Council will take into account in thinking over the events we have planned for this year, such as the scientific events, the Statistics Leaders Meeting and the

Regulatory workshop. There is no easy solution, but we will let you know as soon as possible what alternative plans we can move forward with.

Many of you will be engaged in assessing the impact of the COVID-19 pandemic to ongoing and future clinical trials. In a record time many regulatory agencies have issued new guidance to address the many challenges created, including a draft Points to Consider paper issued by the EMA Biostatistics Working Party. The Regulatory Committee was quick to seek your input, and thanks to all those who provided comments. The EFSPi comments were collated with five (!) other organizations resulting in a united commentary that reinforced key aspects and at the same time will help the regulators be efficient to consider the feedback.

New times, new ways, let's see how things will pan out for all of us and let's also embrace the good things that will come to us in these difficult times.

Stay tuned and Stay safe!

Stefan

[back to top](#)



## **Regulatory**

The regulatory committee collected comments to EMA's draft "Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials". To ease the administrative burden to EMA we joined several other stakeholders including EFPIA and submitted joint comments. These will be published on our website. Special thanks to all colleagues who participated.

Many regulatory and health technology bodies like FDA, EMA, or NICE are currently publishing adhoc guidance's in response to the pandemic. In short, the key issue for statisticians is we need to thoroughly document the COVID-19 related issues such as the impact to estimands and missing data and plan to conduct analyses that will help describe the impact of the pandemic to trials and their interpretation.

The EFSPi Regulatory Statistics Workshop scheduled for the 12-13<sup>th</sup> October 2020 in The Netherlands will not proceed as a face to face meeting. Options to hold virtual sessions are being explored. Further details will follow in subsequent newsletters.

[back to top](#)



## **Scientific**

The Scientific Committee has revised its plans for meetings given the impact by COVID-19. The dates of these meetings will be confirmed in subsequent newsletters and on the EFSPi website. However, these are the meetings planned for 2020:

- A free webinar on **Leadership skills of a statistician**. Rather than a course, the focus will be more on an overview of skills needed to be impactful, and the link to communication and the core of our profession.
- A free joint BBS/EFSPi/PSI webinar organized together with the European SIG "**Estimands in Oncology**" on this topic in Basel, scheduled for the afternoon of 29<sup>th</sup> June 2020.
- A free joint EFSPi/BBS webinar on **Health Technology Assessment**, looking back at '10 years of HTA' and looking forward, scheduled for the afternoon of 30<sup>th</sup> June 2020.
- A free webinar on **Vaccines**, jointly organized with the Belgian Association (SBS/BVS) and the ESIG on Vaccines, to take place in Q4 2020.
- A meeting, likely a webinar, together with the ESIG on **Small Populations** may be held in Q4 2020.

[back to top](#)

## **ESIG News**

The Estimands in oncology ESIG has compiled a first version of a slide deck discussing the impact of the COVID-19 pandemic on estimands in oncology trials. The deck summarizes discussions of industry colleagues from the entire working group (currently at 36 members representing 22 companies). The deck can be downloaded on the group's webpage: [tinyurl.com/oncoestimand](https://tinyurl.com/oncoestimand).

The ESIG consider this deck a "living document" and anticipate to update it over time. Anyone with comments can email Kaspar Rufibach ([kaspar.rufibach@roche.com](mailto:kaspar.rufibach@roche.com)). The ESIG will be developing a manuscript using this content for a special issue dedicated to COVID-19 in the Statistics in Biopharmaceutical Research journal.

### **New COVID-19 ESIG**

There are numerous statistical challenges to consider for clinical trials impacted by the COVID-19 pandemic and in designing and analysing clinical trials for new medicines to treat the COVID-19 infection. If anyone is interested to join a new COVID-19 ESIG then please email Chrissie Fletcher

([chrissie.a.fletcher@gsk.com](mailto:chrissie.a.fletcher@gsk.com)) by Friday 15<sup>th</sup> May.

On a related topic, an Industry Biostatistics Consortium of Statistics Leaders (Pharmaceutical Industry COVID-19 Biostatistics Working Group), primarily in the US, was formed in mid-March with two objectives: 1) Organising a webinar in collaboration with DIA and 2) Developing a manuscript to highlight the study and data integrity issues caused by the COVID-19 pandemic for ongoing clinical trials. The DIA webinar will focus on '**Study and Data Integrity Considerations for Clinical Trials Impacted by COVID-19**' and will take place on the **13<sup>th</sup> May at 4pm UK time / 5pm CET**. There will be a short presentation followed by Q&A. To register click [here](#). The manuscript was finalised at the end of April and will be published in a special issue dedicated to COVID-19 in the Statistics in Biopharmaceutical Research journal.

[back to top](#)

## Country News

### BBS (Switzerland)

#### **Impact of COVID-19 on clinical trials, 6<sup>th</sup> May 10am-12noon CET.**

The COVID-19 pandemic hits not only societies around the world hard but also clinical trials. Trials are affected to a different degree, depending on the indication, site location, and trial stage. For some trials, the impact can be substantial. Therefore, it is time to talk about this impact and mitigation steps. The agenda includes EMA perspectives and guidance on COVID-19, Industry perspective on COVID-19, Overview of Pharmaceutical Industry COVID-19 Biostatistics Working Group, COVID-19 from the Cross-Industry Oncology Estimands Working Group and a panel discussion.

To register for this webinar e-mail Laurence Guillier [laurence.guillier@roche.com](mailto:laurence.guillier@roche.com). To send questions for the panel discussion email Hans Ulrich Burger [hans\\_ulrich.burger@roche.com](mailto:hans_ulrich.burger@roche.com).

### PSI (UK)

#### **2020 PSI Conference**

The PSI 2020 Conference has been cancelled due to the COVID-19 pandemic. PSI are exploring all possible opportunities to deliver some of the content virtually. Keep a look out for further updates via social media, the PSI website and PSI eNews.

It would be wonderful to see you all at next year's Conference, which will be held on the 20th – 23rd June 2021, in Gothenburg, Sweden.

## MEETINGS, WEBINARS AND COURSES

We would like to thank you for your patience whilst we process the events, during what is a difficult situation for all. PSI is committed to ensuring health and wellbeing of its delegates, so we continue to monitor the situation closely and refer to Governmental advice.

**Events that have been re-scheduled:**

\* [A PSI Training Course - R for SAS Users](#)

\* [PSI Toxicology SIG Workshop](#)

**Events that are yet to be re-scheduled:**

\* PSI One-Day Meeting: Non-Proportional Hazards & Applications in Immuno-oncology

\* PSI One-Day Meeting: Missing Data in Clinical Trials - Past, Present & Future



## [PSI VisSIG Webinar: Wonderful Wednesdays - Webinar 2](#)

The VIS SIG's new initiative, "Wonderful Wednesdays" is now underway. The aim of this initiative is to teach participants about visualisation principles and get them to apply what they learn to relevant examples from the field of healthcare and the development of new therapies. In this webinar we discuss the first submissions looking at some great ways to visualise a categorical response variable over time. We talk about what the SIG members like about each plot and give some pointers on areas we think could be improved.

We also introduce the second dataset about time to event analyses in a multi-arm study and invite submissions for our next challenge. Find out more [here](#).

[Click here to watch](#)





### [Covid-19 and How Charts Lie](#)

The Corona Virus being discussed across the world, with all the visualizations there, it is timely that I am speaking with Alberto Cairo. He is a visualization guru and has written the book “How Charts Lie”.

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### [Running on 2 Legs](#)

What do we need to do as statisticians in this crisis? I was asked about what we need to do to be more visible as a function? I talked about many problems in last week’s episode and that triggered some discussions about statisticians and leadership on LinkedIn. Thus, today, I’m speaking about “Running on 2 legs – my call to action for statisticians to step-up in this COVID pandemic.”

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### [Why and How to De-clutter and Simplify your Data Visualisation](#)

Do you know why is it so important to create a simple yet informative data visualization? In episode 3 of this mini-series, I discuss the impact of simplified data visualization and how to achieve it.

*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](#)

### [Introduction to Industry Training \(ITIT\) Course](#)

Next course starts October 2020. Application deadline 26<sup>th</sup> June 2020.

The 2020/21 course will include 3 sessions in continental Europe and 3 sessions in the UK. The course will aim to describe the drug development process, including sessions on drug discovery, toxicology, data management & role of the CRO, clinical trials, health technology assessment and marketing.

**PSI Member:** £1050 + VAT  
**Non-Member:** £1145 + VAT

(Non-Member rate includes PSI membership from September 2020 – December 2021)

[Click here to register](#)

[back to top](#)

## **Women in Data**



**\*\* Reminder \*\*** Women in Data have launched their Twenty Women in Data & Technology 2020 campaign, click [here](#) to watch a video and click [here](#) for more details. Given the significant talent of women in the Pharmaceutical Industry it would be fantastic to have more nominations from the EU Statistics Community. Click [here](#) to submit a nomination for the ***Twenty Women in Data & Technology 2020*** of inspirational women from your company who are known for their outstanding talent, achievement, innovation and leadership. The closing date is the 8<sup>th</sup> May 2020.

[back to top](#)

## **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 ([chrissie.a.fletcher@gsk.com](mailto:chrissie.a.fletcher@gsk.com)).

[back to top](#)

## **Job Opportunities**

Job opportunities exist for Statisticians in different levels of seniority in clinical development, click [here](#) to view the job advert. 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](#)

## **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.

[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.

[back to top](#)

Chrissie Fletcher  
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