



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

EFSPI Newsletter March 2020

The EFSPI Council wish you, your family, your friends and your colleagues are all keeping well during the coronavirus pandemic. It is an unprecedented and challenging time for everyone. As noted below, many meetings and events planned in the coming weeks and months have been postponed, and the decision on whether some events can continue is still being discussed. Please check the EFSPI website for latest news on future events and any new updates will be shared in subsequent newsletters.

We know that many of you are now working from home and we sincerely hope that you will be able to stay safe and healthy in that environment as well while trying to keep on working. We also know that a lot of you are engaged and involved in the consequences of the COVID-19 pandemic to clinical studies and possibly even in new studies in the development of drug treatments, diagnostics and/or vaccines to counter the life-threatening virus. We wish you all the successes in these endeavours where the pharmaceutical industry can help beat this virus.

But foremost: Stay Safe!

EFSPI Council

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Regulatory

A number of regulatory agencies have issued guidance in response to the impact of COVID-19 to clinical trials and clinical research. This includes [FDA](#), [EMA](#), [CTFG](#) and others. Colleagues are advised to check the regulatory agency websites to obtain the latest guidance.

The EMA Biostatistics Working Party (BSWP) has released a draft '[Points to consider on implications of Coronavirus disease \(COVID-19\) on methodological aspects of ongoing clinical trials](#)'. Comments are due by the 25th April (4-week consultation period). If anyone has any comments, please use the comments template using the link in the draft guidance, and email your comments to Dan Evans (daniel.evans@pfizer.com) and Christoph Gerlinger (christoph.gerlinger@bayer.com) by **EOB Friday 10th April 2020**.

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Scientific

The Scientific Committee is planning for a number of events in 2020. Some of the dates for these meetings may be impacted 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 one-day meeting on Soft 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 joint BBS/EFSPi/PSI seminar will be organized together with the European SIG "[Estimands in Oncology](#)" on this topic in Basel, currently scheduled for the 29th June 2020.
- A joint EFSPi/BBS meeting on [Health Technology Assessment](#), looking back at '10 years of HTA' and looking forward. This 1-day meeting is currently scheduled for the 30th June 2020 in Basel.
- A meeting on Vaccines, jointly organized with the Belgian Association (SBS/BVS) and the SIG on Vaccines. The aim is to have a combination of a course and a scientific meeting, which will take place in October near Brussels.
- A meeting together with the SIG on Small Populations in the second half of 2020

Defining Multimorbidity in Clinical Trials

Multimorbidity, the presence of two or more health conditions rather than a single standalone health condition, is very common and a major issue in healthcare globally. Patients with multimorbidity are less likely to receive guideline-recommended treatments and many clinical guidelines are equivocal on the applicability of trial findings to multimorbid patients. To help to address this uncertainty, the International Research Community on Multimorbidity (IRCMo - <http://crmcspl-blog.recherche.usherbrooke.ca/>) are seeking to develop standards for measuring and reporting on multimorbidity in clinical trials of drug interventions. They are looking for interested partners in either academic or industrial settings. If you might be interested in getting involved, please email definingmultimorbidity@glasgow.ac.uk

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ESIG News

Data Transparency

Check out the publication from Data Sharing ESIG member Janice Branson on "*Evaluating the re-identification risk of a clinical study report anonymized under EMA Policy 0070 and Health Canada Regulations*" published [here](#).

The ESIG are continuing to prepare for the PSI Conference where we will be hosting a session in memory of Sally Hollis on "Data as an asset: the re-use of data".

Any interest to join this ESIG please contact Rebecca Sudlow (rebecca.sudlow@roche.com).

Vaccines

Fabian Tibaldi from GSK has taken over as the chair of the Vaccines ESIG for 2020. The ESIG are planning a session at the FDA workshop in September 2020. An EFSPi workshop is also being planned for October in Leuven (Belgium). For more information about the Vaccines ESIG please visit the SIG website: <https://www.psiweb.org/sigs-special-interest-groups/vaccines>.

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Country News

IBIG (Italy)

The planned training course on Early Phase Clinical Trials held by Prof. Thomas Jaki and Dr. Pavel Mozgunov (Lancaster University) originally scheduled to take place in May has been postponed. The revised dates will be confirmed in subsequent newsletters and on the EFSPi website.

PSI (UK)

2020 PSI Conference

The PSI Board of Directors are currently discussing and looking into a few different scenarios around the PSI 2020 Conference and we will look to update delegates and sponsors as soon as possible. Should the situation change we will contact all registered participants and partners, as well as updating the conference website, PSI eNews and in subsequent EFSPi newsletters.

MEETINGS, WEBINARS AND COURSES

Please Note: 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 Video on Demand](#)

Following its recent upgrade, why not take a look at our Video on Demand platform and catch up on previous events and webinars? You can also now share individual video links, so make sure your colleagues check it out too!

Enhance your online learning today with our recorded event and webinar content.

[Click here to watch](#)



[Data visualization – the often overlooked basics \(Episode 1\)](#)

Why is visualization so important?

How do you determine the goal of visualization?

In today's episode, I review the different things you need to consider in creating an effective data visualization when presenting.

[Problems for statisticians to take on](#)

Many statisticians stay in the statistics department for their entire careers but not Stephen Pyke.

He shared some important learnings from his career during the PSI strategy day in 2019 and we discuss the main points of his presentation and the takeaway learnings for every statistician – even if you don't work in a large pharma company.

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](#)

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Women in Data



**** Reminder **** As discussed in the February newsletter 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 8th May 2020.

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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).

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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.

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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.

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Chrissie Fletcher
EFSPI Communications Officer

