



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

EFSPI Newsletter July 2020

In this newsletter:

[EFSPI Statistics Leaders Meeting](#) – key highlights

[Regulatory](#) – latest news on regulatory statistics workshop, comments on FDA statistics COVID-19 guideline

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

[Country news](#) – AFP (Germany), BBS (Switzerland), PSI (UK), SFdS (France)

[Job opportunities](#) – Manager Biostatistics, Senior Manager Biostatistics

[Follow us on Twitter and LinkedIn](#)

[And finally...](#)

EFSPI Statistics Leaders Meeting



The annual EFSPI Statistics Leaders meeting took place on the 23rd July 2020, hosted by Merck Group. This year, the community of EFSPI statistics leaders met virtually for the very first time in 11 years. In the new situation, the statistics leaders demonstrated that they are well prepared to deal with challenging situations and uncertainty. The meeting was a great success in terms of attendance and contents: 30 leaders and three external speakers spent five hours together in a virtual setting. We had a lot of fun trying out new ways of interactions and reflecting on relevant future-oriented topics for EFSPI. We were eventually surprised that the time flew by so fast.

The first key topic of this year's meeting was "Safety Analyses: The Cinderella of Biostatistics?". The focus of this session was on how statisticians add value and leadership in addressing safety topics within organisations. We got inspired by invited external speakers (Benjamin Hofner, Juergen Kuebler, Tim Friede) representing regulatory, industry, and academic perspectives. They emphasized not only the importance of safety for patients but also the many opportunities for further development of statisticians in the pharmaceutical industry. The second key topic of EFSPI Statistics Leaders Meeting 2020 was "Organisational Evolution" with a focus on how statistics/data sciences are positioned within organisations and how are statistical leaders preparing for future success. In order to make this session most effective, all participants were asked to complete a questionnaire

about their current and their 'to-be-state' organisations before the meeting. When looking at the responses, we found out that most of the EFSPI statistics leaders work in big pharmaceutical companies, lead cross-functional teams and focus on clinical statistics even though they expand and collaborate with new areas. With regards to the organisations of the future, the feedback showed that there is a trend to enrich the core role of clinical statisticians by skills and competencies of other data scientists, visualisation experts, and data engineers. Also new roles related to agile ways of working like product owners and agility masters seem to become more and more important in our organisations. The full results of the questionnaire will be available together with all the other meeting materials at the EFSPI website soon. In addition, our EFSPI statistics leaders continued their exchange on the impact of COVID-19 on clinical trials and projects and discussed how the EFSPI statistics leaders can contribute more to the topic of estimands. Finally, we collected many interesting topics for next year and are already looking forward to meeting all together (hopefully face-to-face) in 2021 at the latest.

The 2020 EFSPI Statistics Leaders Organising Committee would like to thank all who actively contributed to the 11th EFSPI Statistics Leaders Meeting. As an African proverb says: "If you want to go fast, go alone. If you want to go far, go together." This is us, EFSPI statistics leaders! We are driven by collaboration and everyone participating strongly believes in the importance of networking in the EU Statistics community. The EU Statistics leaders forum will continue to shape the strategy of EFSPI and motivate and inspire the current and next generations of statisticians in the pharmaceutical industry to reach their full potential. Stay tuned for upcoming EFSPI events by visiting www.efspi.org and connecting with us on LinkedIn, and Twitter at @EFSPITweet.

Justine Rochon (Chair, EFSPI Statistics Leaders)

Stefan Driessen, Armin Schueler, Maylis Coste, Hans Ulrich Burger, Chrissie Fletcher (Organising Committee, 11th EFSPI Statistics Leaders Meeting)

Stay healthy, stay well,

Justine

Justine Rochon, EFSPI Statistics Leaders Chair

[back to top](#)



Regulatory

The Regulatory Committee submitted comments on the FDA [Guidance on Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency](#). Key topics discussed included the lack of reference or alignment to ICH E9(R1) when considering changes to endpoints and analysis methods and concerns when excluding subjects from the planned analyses.

The EFSPI Regulatory Statistics Workshop scheduled for the 12-13th 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.

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

[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 the remainder of 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 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.

Egbert Biesheuvel, EFSPI Scientific Chair

[back to top](#)

Country News

AFP (Germany)

The APF meeting on November 27th and the German Statistics Leaders meeting on November 26th 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 7th September 2020, 14:00-17:00 CET. Please register (which is free) via this link.

PSI (UK)

MEETINGS, WEBINARS AND COURSES

PSI Webinar: Using visualisation to help make decisions

3rd 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

13th 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.

23rd 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...](#)

Podcasts



[PSI ToxSIG Webinar: Good statistical practices to tackle the lack of reproducibility in preclinical research](#)

In this webinar we will explain how to understand the sequences of issues and how to fix it in order to drastically improve the replicability of the results. The presentation will cover concepts such as OFAT vs DoE, p-values and Bayesian statistics and Power vs Assurance as easy opportunities to improve robustness of decisions.

[Watch here](#)



[How to play the game of business to build stronger, more innovative, and more inspiring organisations](#)

We often talk about “competing in the marketplace” – where do you think, this term is coming from? Stuart and I talk about this and his latest book about “the infinite game” – how does this apply to our industry and how this helps our industry moving forward.

[Have you ever considered a career outside of statistics?](#)

Have you ever thought of having an additional or changing career? What are the things you must prepare for when considering this? Today, we interview Lucy on how statisticians can create an impact beyond statistics. Lucy has a very inspiring career, and she has started as a statistician and got further responsibilities.

[Plotting your career and preparing the terrain](#)

For your career, have you ever thought about what mindset you should adapt to? What do you think marks a “successful” career?

Diana Stuart, who is a Senior Manager in programming, shares with us her thoughts, lessons, and her vast experience in this field and what we can do to create a robust career with all the surrounding changes.

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/

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>

[back to top](#)

Job Opportunities

Job opportunities exist for [Manager Biostatistics](#), and [Senior Manager 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.

[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.



Chrissie Fletcher, EFSPI Communications Officer

[back to top](#)