



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

EFSPI Newsletter October 2020

In this newsletter:

[World Statistics Day](#)

[Regulatory](#) – Regulatory Statistics Workshop, meetings with regulatory statisticians, new guidelines

[ESIG news](#) – Estimands in oncology, Vaccines, ToxSIG

[Country news](#) – APF (Germany), FMS (Sweden), PSI (UK)

[Job opportunities](#)

[Follow us on Twitter and LinkedIn](#)

[And finally...](#)

World Statistics Day



The third World Statistics Day was celebrated around the globe on 20 October 2020 with the theme “Connecting the world with data we can trust”. This theme reflects on the importance of trust, authoritative data, innovation and the public good in national statistical systems. Click [here](#) to see announcements and events held to celebrate.

[back to top](#)



Regulatory

EFSPI Regulatory Statistics Workshop

The EFSPI Regulatory Statistics Workshop took place on the 12-13th October 2020 14:00-16:35 (CEST). The topics for each webinar were:

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

Approximately 500 people attended each webinar. A great range of presentations from Industry, Academia and Regulatory Agencies. The slides and summary of Q&A for each webinar can be found [here](#).

Meetings with Regulatory Statisticians

On October 2nd EMA's Biostatistics Working Party (BSWP) held a virtual stakeholder meeting with several industry trade organizations and EFSPI. Topics were the BSWP's guidance on COVID-19 implications to statistics and their draft guidance on quality attributes in CMC. Dan Evans and Bruno Boulanger presented on behalf of EFSPI. A summary of the meeting is being drafted and key highlights will be shared in future newsletters.

The regulatory ESIG will have a virtual meeting with MHRA statisticians on the 19th November 2020. If you have topics you would like us to address please contact Jürgen Hummel Jurgen.Hummel@ppdi.com or Christoph Gerlinger christoph.gerlinger@bayer.com.

New guidelines

EMA has published a draft [Guideline on registry-based studies](#) for a three-month public consultation. Please send your comments to Roland Marion-Gallois Roland.Marion-Gallois@bms.com and Florian Voß florian.voss@boehringer-ingenheim.com by the end of November 2020.

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

[back to top](#)

ESIG News

Estimands in Oncology ESIG

The oncology estimand SIG held / will hold informal TCs with the Health Authorities of the US FDA, HC + Swissmedic, MHRA, Japan, China, and Taiwan. In these TCs the WG presented a summary of the

work that has been done in the last two years and invited HAs to comment and raise points they encourage the WG to look into or where they could imagine a collaboration. Generally, these HAs very much appreciated the informal information sharing and encouraged the WG to continue its work and the interactions with authorities. The slide deck summarizing the WG's work that was presented to the HAs is available on the WG's webpage (www.oncoestimand.org) [here](#).

The SIG relevantly contributed to the recent BBS seminar "RCTs meeting causal inference: principal stratum strategy and beyond". The slide decks, a recording of the entire event, as well as a Q&A document replying to the questions raised in the chat during the event are available on the BBS webpage [here](#).

Vaccines ESIG

The webinar held on the Thursday 15th October was a great success with around 100 attendees worldwide. Two presentations were given on topics relating to methodological developments in vaccines research. Frank Harrell, Vanderbilt University presented 'Sequential Bayesian Designs for Rapid Learning in COVID-19 Therapeutic Trials'; and Dean Follmann, NIH, presented 'Statistical Aspects of COVID-19 Vaccine Trials'. If you missed the webinar, you can access the recording using this link: <https://www.psiweb.org/vod/item/psi-vaccine-sig-webinar-statistical-topics-on-covid-19-vaccine-and-therapeutic-clinical-trials>

PSI ToxSIG

The PSI ToxSIG are pleased to announce the following webinars:

Webinar: Biomarkers in Toxicology 25 November, 2020, 2 PM-3 PM

The deployment of biomarkers in drug development and diagnostics has many challenges ranging from analytical validation, in vivo study design, to the translation to human utility and financial considerations. In this webinar focus will be given to safety biomarkers. Statistical issues in data science that nonclinical statisticians might encounter along the way will be discussed.

Webinar: Combining Sexes 1 December, 2020, 2 PM-3 PM

The webinar will provide a general introduction to the topic of combining sexes for statistical analysis in Toxicology. It will also discuss guideline recommendations pertaining to this topic.

[back to top](#)

Country News

APF (Germany)

APF will have its annual fall workshop on November 27th with topics about the implications of COVID-19 on statistics. We also plan a virtual get-together on the evening on the 26th with a wine tasting. Details can be found soon on our homepage <http://www.biometrische-gesellschaft.de/arbeitsgruppen/pharmazeutische-forschung.html>.

FMS Sweden

FMS will be holding an online AUTUMN MEETING Nov 13, 2020 on the topic "Current statistical topics concerning Covid-19". Presentations will include academia (Department of Mathematics, Stockholm

University), industry (AstraZeneca) and governmental authorities (Statistics Sweden, National Board of Health and Welfare, and Public Health Agency of Sweden).

PSI (UK)

Do you have any non-statistical colleagues looking to improve their statistical knowledge?

We are delighted to announce a new collaboration between PSI and Richard Kay for his training course "Statistical Thinking for Non-Statisticians in Drug Regulation".

Basic statistical skills are more vital than ever, and this course will enable non-statisticians to understand the fundamentals of statistics for clinical trials in the pharmaceutical industry. Learners who sign up to this course through PSI will receive a special discount. Sign up below!

[Find out more](#)

Volunteer for PSI Leadership Team

We are looking for an enthusiastic volunteer to join the Leadership Workstream. They will be responsible for leading the planning and designing on the PSI website, working with the rest of the team to drive the thinking on content.

[Contact us](#)

2021 Conference - POSTPONED

Due to the ongoing situation relating to the COVID-19 (coronavirus) pandemic, PSI has taken the difficult decision to postpone the Annual Conference which was due to take place in Gothenburg on 20 – 23 June 2021 to the new date of 12 - 15 June 2022. While this is disappointing news for all involved, the well-being of our delegates and sponsors is our most important consideration.

MEETINGS, WEBINARS AND COURSES



Joint PSI, EFSPi & ASA BIOP Webinar: Estimands

14:00 - 16:00

Who is this event intended for? The event is intended for statisticians involved in the design of clinical trials (particularly Phase II and III) in all therapeutic areas, from industry, CROs and academia.

What is the benefit of attending? The



PSI Journal Club: Bayesian Methods

16:00 - 17:00

Who is this event intended for? Active journal subscribers or anyone wishing to learn more about the application of Bayesian methods.

What is the benefit of attending? Gain insight into the use of Bayesian approach in

audience will gain insight into the use of estimands in practice and regulatory considerations.

[Register now...](#)



Register your interest to help determine future topics.

Our most recent proposal:- EFSPi/PSI Webinar: why is leadership important for me as a statistician?

[Register here](#)

design & analysis of paediatric cancer clinical trials, and estimation of group means.

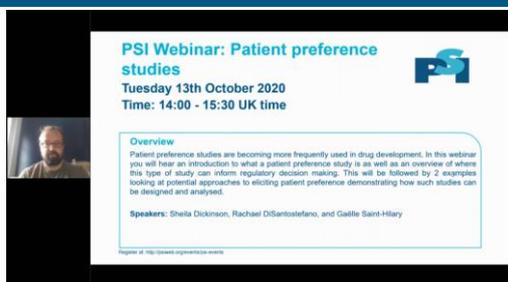
[Register now...](#)

Stay tuned - more events to be announced soon!

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 the health and wellbeing of its delegates, so we continue to monitor the situation closely and refer to Governmental advice. This may mean a delay in some F2F events being re-scheduled, but we will publish new dates as soon as possible.

Podcasts & Webinars



[PSI Webinar: Patient Preference Studies](#)

In this webinar you will hear an introduction to what a patient preference study is as well as an overview of where this type of study can inform regulatory decision making. This will be followed by 2 examples looking at potential approaches to eliciting patient preference demonstrating how such studies can be designed and analysed.

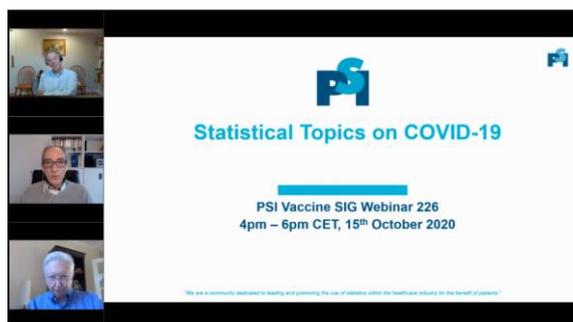
[Watch here](#)



[PSI VisSIG Wonderful Wednesday 8](#)

Abi Williams presented data visualisations on co-occurrence of adverse events. How to display events that occur at the same time in the same patient and highlight differences of treatment or gender? A variety of very different approaches was discussed.

[Watch here](#)



[PSI Vaccine SIG Webinar: Statistical Topics on COVID-19 vaccine and therapeutic clinical trials](#)

The Vaccine SIG is proud to bring you this webinar, which features two presentations on topics relating to methodological developments in vaccines research. We are delighted to be joined by Frank Harrell who will present 'Sequential Bayesian Designs for Rapid Learning in COVID-19 Therapeutic Trials'; and also by Dean Follmann, who will present on 'Statistical Aspects of COVID-19 Vaccine Trials'.

[Watch here](#)



[What statisticians can learn from "The Art of Action"](#)

Stephen is the author of The Art of Action and has a background in consulting and history. Based on this knowledge, he wrote a couple of books about history and leadership. Business can learn a lot from this area. I'm talking about the military space as armies were the biggest organizations needing strong leadership for thousands of years.

[How understanding the bigger picture boosts your career](#)

Throughout the leadership program, this topic comes up again and again. In this episode, I am sharing about my experience I had earlier in my career when I was working on a lot of different publications with different physicians responsible for these studies.

[Getting to YES: Negotiation skills for everyday](#)

If you enjoyed the last book review, you'll surely enjoy this one as well. This is much more practical than the last one. Getting to Yes is a very fundamental book that everybody should read. You will see from our discussion the AHA moments Stuart had by reading this book and the important points I've learned.

*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](#)

[back to top](#)

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.

[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](#)