



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

EFSPI Newsletter June/July 2021

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EFSPI President Update

Half-way through 2021 and after a very, short period of time Returning-to-Office I am back in the working from home mode. You may have had similar experiences. It is still all hard to predict apparently.

That is also what we see in EFSPI. In July we had our third virtual Council meeting. And when asking about plans of events for the rest of this year, only few Associations (countries) mentioned to think about, or rather hope for, a real face-to-face meeting this year.

But still in a virtual setting events can be great. This was demonstrated by the Organizers of the 12th Statistical Leaders Meeting held in June. Big compliments to Justine, Ingrid, Tina, and Chrissie for making this event still “feel” like a face-to-face meeting, really impressive! You can read about it further down in this Newsletter.

One thing that has not changed is that almost every year there is another hot topic arising. This year, I think it is two initiatives that are heavily related: Denmark’s Agency initiative DAC (Data Analytics Center) and EMA’s data initiative to access and use raw data as part of regulatory review process. In both the Stats Leaders Mtg and in the Council meeting time was spent to discuss these and it was unanimously decided to support and collaborate with these initiatives.

We think that as a Federation of statisticians that very well understand the power of data in our business' we can bring value to the table. More to come over the next period of time.

But for now, I wish you good summer holidays, wherever you are, or can be, or are allowed to be! Stay safe!

Stefan Driessen, EFSPi President

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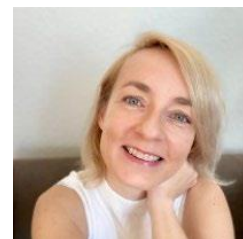


EFSPi Council News

The EFSPi Council met on the 21st July. Key topics discussed included a debrief of the recent EFSPi Statistics Leader meeting (see ESIG below), an update from the Data Science ESIG including results from a recent survey (see ESIG news below), an update of the Danish Academic Centre (DAC) and EMA data project, strategy to revamp the EFSPi website, opportunities to connect the local associations on their training activities, updates on FENStatS accreditation, and local association news.

Congratulations to **Randi Grøn**, Project Director, Analytics, Modelling & RWD at Novo Nordisk who has taken over from Chrissie Fletcher (GSK) as the **EFSPi Communications Officer**. Randi is already an EFSPi Council Member as one of the Danish representatives and she will also oversee the creation of a new EFSPi website (led by Mathew Simcock, BMS), monthly newsletters (continue to be led by Chrissie) and social media activities (led by Randi).

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EFSPi Statistics Leaders 2021 Meeting Debrief

The annual EFSPi Leaders meeting took place on the 30th June and 1st July 2021, hosted by Novo Nordisk and Lundbeck. This year, the community of EFSPi leaders met virtually for the second time in the 12 years history of the meeting. More than 30 EFSPi leaders were inspired by invited external speakers and spent two great afternoons together exchanging on four key topics.

The first topic of this year's meeting was "Career development and leadership skills for biostatisticians". After a recap of discussions at previous meetings and presentation of results of a pre-meeting survey, we discussed different career paths and explored specific skills needed to be

successful as a statistician in today's pharmaceutical industry. We were especially challenged by the question: Are we making progress and if not, why not? Second, we learnt about "Perspectives on use of clinical data in the regulatory review process and scientific advice by regulatory authorities". It was great to have members of the Danish Medicines Agency and EMA share their perspectives. The third part of the meeting was dedicated to "Data Science versus Biostatistics in the pharmaceutical industry". We heard from the Royal Statistical Society what has happened since the start of their Data Science Section in 2017, learnt about vision of Data Science from our peers and explored together challenges and opportunities of Data Science working in partnership with Biostatistics. The fourth and last topic on our agenda was about flexible workplace after Covid-19. Motivated by the results of a pre-meeting survey, we discussed what we have learnt from working remotely for an unexpected and extended period of time, what leaders feel were key concerns and potential opportunities for statisticians, and what can EFSPI do to support leaders and the broader statistical community with embracing new ways of working.

The 2021 Organising Committee would like to thank all who actively contributed to the 12th EFSPI Leaders Meeting. As Warren Bennis, the legendary pioneer of modern leadership principles stated: "Leadership is the capacity to translate a vision into reality." EFSPI leaders are committed to make things happen! We are driven by collaboration and everyone participating in our annual meeting strongly believes in the importance of our community to guide 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 Leaders) on behalf of the Organising Committee, 12th EFSPI Leaders Meeting



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Scientific



The Scientific Committee is planning for a number of events in 2021:

- An event on **COVID**, together with the ESIG on Vaccines, planned in second half of 2021.
- A meeting together with the ESIG on **Small Populations** also in the second half of 2021
- An event on **Decentralised trials** in the last quarter of the year.

At this moment all these events are planned to be online, but as soon as we have more concrete information, we will share with you via the Newsletter and our website.

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ESIG News



Regulatory ESIG

We welcome Rima Izem from Novartis Switzerland as new member of the regulatory ESIG. Rima brings a unique experience to our ESIG as she previously worked at FDA for ten years.

The FDA has released a new draft guidance [Randomized Trials Guidance: Adjusting For Covariates](#), a revision of the previous 2019 draft version. The new draft guidance includes more detailed recommendations and discusses use of nonlinear models in addition to linear models. The ESIG provided comments, thanks to all who contributed and to Florian Voß for collating the comments.

**** Reminder ** 6th EFSPi Regulatory Statistics Workshop**

We are happy to announce the 6th EFSPi regulatory statistics workshop. We plan webinar sessions on three days:

Monday, 13rd September 2021, 14.00-17.00 CET

Tuesday, 14th September 2021, 11.00-14.00 CET

Wednesday, 15th September 2021, 9.00-12.00 CET

The topics that we will discuss include:

- 1. Complex innovative designs: Where is their place in drug development?*
- 2. Real-world data - using their potential.*
- 3. Decentralized trials: What is the impact on evidence generation?*

More details are available

here: https://www.efspi.org/EFSPI/Events/Regulatory_Meetings/6th_efspi_workshop_on_regulatory_statistics.aspx

Kaspar Rufibach, on behalf of the local organizing and scientific committee.

**** Reminder ** Accelerating Complex Clinical Trials in Europe and beyond workshop**

A multi-stakeholder workshop to develop shared solutions for the use of complex clinical trials to optimise drug development in Europe. 5 October 2021, 14:00 - 19:00 CET and 6 October 2021, 14:00 - 18:30 CET

Complex Clinical Trials (CCTs) have the potential to accelerate drug development and enable patients to get timely access to transformative therapies. The main objective of this workshop is to develop shared solutions addressing key challenges with CCTs, discuss global implications of CCTs, identify emerging best practices to facilitate the use and acceptance of CCTs to multiple stakeholders, and identify synergies with existing initiatives such as IMI EU-PEARL and CTTI. The workshop will include a mix of plenary and break-out sessions involving representatives from Industry, regulatory agencies, HTA agencies, academia, patient advocacy and ethics committees. The number of attendees participating in the break-out session discussions will be limited with priority given to those with expertise and experience of CCTs. All attendees registering for the workshop will be able to listen to the live break-out session discussions. Click [here](#) to see more details and to register, and identifying delegates to participate in the break-out sessions will be based on those registered by mid-August.

Chrissie Fletcher on behalf of the EFPIA Complex Clinical Trials Team

Meeting with Biostatistics Working Party

The Regulatory ESIG is planning to meet with the Biostatistics Working Party on the 29th October 2021. This annual meeting will be similar to the one held in 2020 with multiple associations and professional groups coming together to discuss statistical topics. The Regulatory ESIG suggested three topics for discussion

- The Danish Data Analytics Centre and the future plans of BSWP to analyse data
- Decentralised trials
- Use of historical / synthetic control arm data

The SIG are waiting for the BSWP to confirm the agenda.

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

HTA ESIG

The German subgroup of the HTA ESIG has posted a preprint on “Patient-reported outcomes in the context of the benefit assessment in Germany” on arXiv: <https://arxiv.org/abs/2107.03249>. The preprint is currently peer-reviewed by the HTA ESIG and the EFSPI council.

Christoph Gerlinger on behalf of the German Subgroup of the HTA ESIG

Estimands in Oncology ESIG

On invitation of the PSI EIWG the oncology estimand SIG offered two PSI trainings on "Estimands in Oncology - How and Why". The target audience were statisticians and partner functions such as Clinicians, Investigators, Regulatory Experts, Medical Writers, or Ethics Committees and with >250 attendees both webinars were well attended. The group managed to make these events quite interactive, as witnessed by the many questions from the audience that were discussed either during the presentation or in the chat. The slide deck as well as a recording are available on the PSI webpage: <https://www.psiweb.org/vod/item/psi-eiwg-webinar-estimands-in-oncology---how-and-why>

Kaspar Rufibach (aspar.rufibach@roche.com)

Data Science ESIG

Data Science is a big area where experts with various quantitative methods and skills are required to collaborate, and statisticians are an integral part of this field. We recently conducted a survey which showed that our cross-industry colleagues involved in Data Science activities work across a broad range of functions from Research to Clinical Development, to Safety, and Marketing and on a broad range of tasks from visualisation and model building (inferential and predictive) to software and application development. There are many current challenges such as a deficit of understanding of what is comprised of Data Science to structural organisational, to practical such as access to the right data or developed processes. While there are many challenges, there are also many opportunities where statistical expert input can make a difference. When taking a pro-active stance, statisticians can make an impact by engaging with various stakeholders and building bridges between various mindsets, by bringing rigour in model building and validation, methodology development and by putting right data and right methods in specific scientific context.

The Data Science ESIG aims to build up communication channels between stakeholders, facilitate open discussions, share examples from real practice and encourage our cross-industry colleagues to contribute to urgently required best practices. Your expertise matters and is very welcome.

Julia Chernova (julia.chernova@bayer.com)

Please look out for updates and other ESIG news at <https://www.psiweb.org/sigs-special-interest-groups/sigs>

Adam Crisp (PSI SIG liaison) and Gaëlle Saint-Hilary (EFSPi SIG liaison)

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Country News

APF (Germany)

The 3rd International Biometric Society-Germany Region "Academia meets Industry" event, this year taking place on

October 7/8, 2021, again in a virtual setting. The intention of this interactive workshop is to bring together researchers from industry with researchers and students from academia. Participants are invited to exchange and evaluate possible collaborations, especially regarding joint supervision of BSc, MSc, and/or PhD theses. Please register using this link <https://forms.office.com/r/fB4f6sdjxC> by September 17, 2021.

PSI (UK)

MEETINGS, WEBINARS AND COURSES



PSI Leading for Impact Workshop

10:00-12:00

Who is this event intended for? Anyone in a role that contains or will contain an aspect of leadership, be it project leadership, managing a team or advising more junior statisticians or programmers on a study.

What is the benefit of attending? You will come away with a plethora of techniques to use in your day to day leadership role as well as finding out how to overcome your own personal challenges in this context.

[Register now...](#)



PSI Training Course: Repeated Measured and Mixed Models Module

10:00-12:30 & 14:00-16:30 on both days

Who is this event intended for? Statisticians working on clinical trials, who already have a good understanding of linear and generalised linear models and want to further their knowledge of repeated measures and other clustered data.

What is the benefit of attending? By the end of the course attendees will know how to analyse repeated measures of patients through time or other clustered data in randomised clinical trials and associated observational studies.

[Register your interest](#)

Podcasts & Webinars



[PSI VisSIG Wonderful Wednesday 17: Psychometric data example](#)

Abi Williams presents the visualisations of the SDQ-12 in conjunction with different anchor measures. For this challenge very different plot types have been proposed. All visualisations are available on the Wonderful Wednesday blog.

[Watch here](#)



PSI Journal Club Webinar: The use of External Controls in Clinical Trials

Watch Chris Harbron (Roche) and Margaret Gamalo (Pfizer) present their recent work. The webinar will be chaired by Elizabeth Williamson (London School of Hygiene and Tropical Medicine).

[Watch here](#)



Taking on leadership roles outside of statistics

In this episode, special guest Shanthi Sethuraman joins us. Learn while she shares with us her vast experience in the pharmaceutical industry collected over 25 years. She held various positions inside and outside of statistics organization.

The analysis of adverse events done right – SAVVY

When I started my career as a statistician in the clinical world, I was wondering about safety analysis. I thought it's always the same – count the patients with an event – job done! Then just repeat. But it's not that simple! Join us for an interview with Kaspar Rufibach and Jan Beyersmann while we deep dive into the SAVVY collaboration.

Why spend part of your career, as a pharmaceutical statistician in the non-clinical areas?

Why spend part of your career in non-clinical statistics? What are the advantages? What is the importance of having a variety of tools? In this episode, Sam and I talk about the advantages of spending time in the non-clinical areas and other important points.

Listen to these episodes and share them with your friends and colleagues.

Ciao and be an effective statistician!

Alexander Schacht

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Job Opportunities

Opportunity for a [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.

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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 Newsletters

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