



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

EFSPI Newsletter January 2021

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New Year Remarks

Dear colleagues,

I do not know about you, but although I know that 2021 has come, for me it very much feels like 2020 still. Due to lack of usual festivities and gatherings with family and friends the holidays had to be spent with only few beloved ones and more in-house than outside. So, when 2021 working life started again with having to perform only few steps into the home office again, it did not feel like a fresh new start. Nevertheless, it is, and it will be.

This week the EFSPI Council met in a 4 hours web-ex (with a 30 mins break!) and talked about that. All the ten National Associations presented what they still organized for their members and how that was received. Common themes were that all quickly adapted by moving to online conferences and webinars and that was well received. They also liked that more than before participation was open for meetings outside of their own country. However, they also mentioned that there is currently also something like a “web-ex fatigue”. Hence in the plans for this year all the Associations but also EFSPI acknowledges that we need to think a bit better about the format; make it more interactive (using the various tools out there), shorter, and with sufficient number and length of breaks, to break the monotonicity that creeps in with too many back-to-back virtual meetings. Another common theme is that all hope for face-to-face meetings again (at least locally) in second half of this year. Whether that is possible we will have to see, but at least for the EFSPI Regulatory Statistics workshop the organizing committee is asked to also still consider that in one way or another.

Financially, we did not have a severe hit last year because all kind of events were cancelled timely and replaced by on-line meetings that were hosted by companies (for which our thanks). As many societies also EFSPI realizes that in these times more than ever before we need to have a good



website to serve you. Therefore, the Communications group led by Chrissie Fletcher will work out a proposal for substantial improvements to be implemented this year. Another area where we expect to see greater and better coverage this year are the ESIGs (European Special Interest Groups). Did you know that there are eighteen (18!) ESIGs already? There will be a meeting of all ESIG leads in February and we are excited to hear about their plans for the coming period. We will let you know in our upcoming Newsletters.

So, lots of plans again, and with agility we hope to navigate through the challenges that the pandemic will surely pose to us, to serve you with the content you like to see. And that is the last theme to mention; with the web-ex fatigue in mind, we want to strive for quality, not for quantity.

EFSPI hopes you will have a successful and COVID-19 free 2021!

Stay Safe,

Stefan Driessen, EFSPI President

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Regulatory



Thanks to those who provided comments on the EMA guideline on **Registry based studies**. The collated comments have been posted on the Regulatory ESIG webpage (PSI website).

Comments are being consolidated on the EMA draft guideline on the **Evaluation of anticancer medicinal products in man** by the Estimands in Oncology ESIG and will be posted to the Regulatory ESIG webpage (PSI website) in due course.

The [ICH Reflection paper on patient-focused drug development](#) was released for public consultation on the 10th December 2020. This Reflection Paper identifies key areas where incorporation of the patient's perspective could improve the quality, relevance, safety and efficiency of drug development and inform regulatory decision making. It also presents opportunities for development of new ICH guidelines to provide a globally harmonized approach to inclusion of the patient's perspective in a way that is methodologically sound and sustainable for both regulated industry and regulatory authorities. Please send your comments, if you have any, using the EMA comments [template](#), to [Anna Berglind](#) and/or [Véronique Robert](#) by 26 February 2021.

An EFPIA-led workshop on complex and innovative clinical trials is being planned for Q3-Q4 2021. The purpose of the workshop is to share case studies, discuss stakeholder views (regulatory, HTA, ethics committees, Industry and patients) on technical, operational/implementation and regulatory process aspects pertaining to complex clinical trials. Opportunities for creating a regulatory framework for complex innovative trials, including a pilot process, building on what has been

learned from the ongoing Complex Innovative Design Pilot process FDA will be discussed. Further details will be shared in due course, please contact Chrissie Fletcher (chrissie.a.fletcher@gsk.com) for more details.

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

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Scientific

Upcoming webinar on **Wednesday March 3** on **Statistical Leadership**

Everybody seems to talk about leadership these days. Apparently, it is no longer enough to be good at your job as a statistician – you have to be a statistical leader to get on!

We have organised a conversation with Chrissie Fletcher and Andy Grieve. More information can be found on the flyer below and registration is open on the PSI website (www.psiweb.org).

If you are thinking about your personal development and want to go into 2021 with a bit of a boost, then please attend this webinar.

| | |
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| Register: www.psiweb.org/events/psi-events | |
|  PSI & EFSPI Joint Event | <h2>Let's talk about statistical leadership</h2> |
| | Wednesday 3rd March - 12:00 GMT |
| | <ul style="list-style-type: none">• What makes a statistical leader?• Strategic and visionary thinking for statisticians• Influencing without authority• The importance of good communication• The value of networking |
| <p><i>"We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients"</i></p> |  Chrissie Fletcher |
| |  Andy Grieve |

In addition, the Scientific Committee is planning for a number of events in 2021. Although none of them have a confirmed date, these are our intended meeting in preparation for 2020:

- A joint EFSPI/BBS virtual event on **Health technology Assessment**, in June.
- An event on **COVID**, together with the SIG on Vaccines, planned in second half of 2021.
- A meeting together with the SIG 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

Click [here](#) to view information about all current ESIGs.

Vaccines

EXPERT WORKSHOP ON VACCINES FOR AMR PATHOGENS

The COMBINE project is part of the IMI AMR Accelerator. In this project, the consortium wants to address questions regarding the optimization of preclinical and clinical studies in the development of antibiotics, vaccines and other therapies to tackle AMR resistant pathogens. This workshop will provide an open discussion forum to identify, propose and prioritize specific challenges, success and risk factors in the development of vaccines against nosocomial AMR pathogens. Click [here](#) for more information and to register.

Fabian Tibaldi (GSK)

HTA

Effective January 2021, Lara Wolfson (MSD) has taken over from Chrissie Fletcher (GSK) as the new chair of the HTA ESIG. Thanks to Chrissie Fletcher for chairing the HTA ESIG for the last 10+ years and since it was created in early 2010. HTA continues to be a key focus area for statisticians.

Lara and Chrissie are currently working on updating the HTA ESIG webpage sharing latest news and important links.

Chrissie Fletcher (GSK) and Lara Wolfson (MSD)

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Communications

Welcome to Randi Gron (Novo Nordisk) and Mathew Simcock (BMS) who have formed a new Communications Team with Chrissie Fletcher (GSK) for EFSPI. Randi will lead EFSPI's communications in social media, Mathew will lead the revamp of EFSPI's website, and Chrissie will continue to lead the monthly newsletters and connect EFSPI with other associations.

Please send in your requests to join the EFSPI group on LinkedIn and I look forward to your posts, sharing information, seeking feedback and contributing to discussion topics. A new EFSPI Statistics Leaders LinkedIn group has recently been formed to allow more regular communication within this community.

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Country News

PSI (UK)

Abstract Submission OPEN for the PSI Conference 2021



The PSI Conference will be held online from 21 to 23 June 2021. Submissions are now being accepted for contributed oral or poster abstracts. Abstracts on any topic are accepted, and topics of particular interest include Bayesian, COVID-19 (developing treatments and implications on drug development), data science and its application, data visualization, estimands (methods, theory and case studies), innovative trial design, personalised medicine. The deadline for oral abstract submissions is **12 March 2021** and for poster abstract submissions is **26 March 2021**. Anyone selected for an Oral presentation will be eligible for **50% off the conference registration fee**.

[Find out more](#)

MEETINGS, WEBINARS AND COURSES



PSI Webinar: Wearable Technologies

14:00-16:00

Who is this event intended for?

Anyone working with digital health data; Clinician, Regulator, Investigator, Academic, Ethics Committee, Statistician, Data Scientist.

What is the benefit of attending?

Understand the benefits of continuous digital health data but also its challenges in terms of processing and analysis.

[Register now...](#)



PSI Leadership Event: Lunchtime conversation with C. Fletcher & A. Grieve

12:00-13:00

Who is this event intended for? Any statistician thinking about their personal development.

What is the benefit of attending? Hear Chrissie and Andy's thoughts on what makes a statistical leader, strategic and visionary thinking for statisticians, influencing without authority, the importance of good communication, and the value of networking.

[Register now...](#)



PSI Medical Statistics Careers Event 2021

All day

Who is this event intended for? This event is aimed at students with an interest in the field of Medical Statistics, for example within pharmaceuticals, healthcare and/or medical research.

What is the benefit of attending? Learn more about the types of opportunities available within medical statistics and have the chance to network with potential employers.

[Register now...](#)

Podcasts & Webinars



[PSI VisSIG Wonderful Wednesday 11: Prediction of binary outcome](#)

Bodo Kirsch presents ways to explain the possible impact of risk factors on a binary outcome with means of graphical displays and tools. Very different approaches have been sent in to solve the challenge of last month.

[Watch here](#)



[Knowledge sharing and what it means for you](#)

Knowledge sharing is close to my heart and Nelson, who is a very knowledgeable statistician, has shared a lot of articles in LinkedIn and on his website. Listen while we talk about these.

[How to best visualize uncertainty](#)

Our job as statisticians focuses primarily on the analysis and communication of uncertainty in its many aspects. In this episode, I think of uncertainty as the variability in the population we are studying, the uncertainty around estimates, or the model uncertainty, which we might capture via looking into various models.

[Do you want to think and act more strategically?](#)

Outside of statistics departments, we are often seen as tactical and operational implementers. This branding makes it hard for statisticians to be included in strategic discussions. This limits our ability to influence the organizations and projects. I'm long on a journey to fight against this branding. Listen to this episode while Swarna, a long-term listener of the effective statistician,

shares with us ways to think and act more strategically.

Listen to these podcast episodes now and share it with others who might learn from it.

Ciao and be an effective statistician!

Alexander Schacht

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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.

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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 Communications Officer

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