



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

## EFSPI Newsletter June 2020

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### Update from the EFSPI President



COVID-19 keeps surprising us, or is it rather our environment, governments, institutions, communities, dealing with it? Anyhow, at least in Europe we already have some statisticians in certain countries and companies returning to the office, while a month ago that was not expected. Other countries and companies will likely follow soon, if we keep the virus away from a second wave. Even though COVID-19 might not be the immediate health threat compared to a few months ago for our work in Biostatistics still has a great impact.

You will read about that in this Newsletter again. Chrissie Fletcher has done a great job again by pulling all the important news feeds into this edition, and I thank her for doing such a marvelous job!

Everyone in our organization is running the extra mile to cover the importance of this pandemic to our businesses. Justine Rochon is organizing extra sessions with the Statistical Leaders group, Chrissie and Maylis Coste have kicked off a new COVID\_19 ESIG, Christoph Gerlinger, Egbert Biesheuvel and Hans-Ulrich Burger are working hard to still get Scientific Meetings and Regulatory workshop to you, be it in a different, virtual fashion. And finally, Teppo Huttunen with colleagues at the EFSPI Executive Office keep a close look on our expenses to pass us safely through this pandemic

financially to keep maintain supporting you all. It is a privilege to be part of and work with such a great team.

And there are many more out there that make EFSPI what it is today! If you have any ideas to support you better, please let us know, we are there for you!

Stay safe!

*Stefan Driessen, EFSPI President*

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## **EFSPI Statistics Leaders Meeting**



The 2020 EFSPI Statistics Leaders meeting will be held on the afternoon of the 23<sup>rd</sup> July as a virtual webinar. Two key themes will be discussed:

- 1) Safety analytics with a focus on how statisticians are adding value and leadership in addressing safety topics within organizations
- 2) Organisational evolution with a focus on how are statistics groups positioned within organisations and how statistics leaders are preparing for future success

A summary of the meeting will be provided in a future newsletter.

*Justine Rochon, EFSPI Statistics Leaders Chair*

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## **Regulatory**

The final points to consider on [COVID-19 and methodological issues for ongoing clinical trials](#) from EMA's Biostatistics Working Party has been published on the EMA website. In addition the FDA also released a [Guidance on Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency](#) on 17 June 2020 (which was issued as a final document, so comments are not collated).

EMA has published a discussion paper on The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes. We plan to collect comments jointly with the ESIG

on data transparency until July 10<sup>th</sup>. Please send your views to Roland Marion-Gallois ([rmariongallois@celgene.com](mailto:rmariongallois@celgene.com)) or to Christoph Gerlinger ([Christoph.gerlinger@bayer.com](mailto:Christoph.gerlinger@bayer.com)).

The EFSPI Regulatory Statistics Workshop scheduled for the 12-13<sup>th</sup> 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)**

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## **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**

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## **ESIG News**

### **Toxicology ESIG**

The next PSI Toxicology SIG webinar has been moved from 23<sup>rd</sup> June to **15<sup>th</sup> July 2-3pm BST**.

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

**Overview:** For 15 years the scientific literature has repeatedly underlined the important lack of reproducibility and replicability of studies in biomedical research. As a consequence, several scientific organisations (journal, scientific societies, universities, national agencies) have identified some root causes to this issue and proposed good research practices to improve the replicability of the results. The misuse of statistical concepts, from design of studies to analysis of data to decision-making is at the heart of the crisis, even if not the only cause. In this webinar we will explain the how to understand

the sequences of issues and how to fix it in order to drastically improve the replicability of the results. Through example 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.

#### **4 key learnings attendees will take away from this webinar:**

- The value of good design of experiments
- Consider Bayesian statistics to answer your question
- P-values is not always what you're looking for
- Adopt a life-cycle over the long-run, not just study by study

**Speaker: Bruno Boulanger, PharmaLex**

Click [here](#) to register.

**2-day workshop** – currently planned for 24 and 25 November 2020 at the Crowne Plaza Hotel, Heathrow, London.

Topics include – 4.5-hour Bayesian training course (focused on pre-clinical applications), Combining Sexes, Biomarkers in Toxicology and Measuring animal activity.

**Gareth Thomas, Toxicology ESIG lead**

#### **Data Transparency ESIG**

The Data Transparency ESIG hosted a session at the PSI Virtual Conference. The session "Data as an asset, the re-use of data" was organised in memory of Sally Hollis who was the founding co-chair of this ESIG. The topics and presenters were:

-What has changed? Why is data now an asset? Janice Branson, Novartis

-Internal Data Reuse...or what's data privacy got to do with it? Katherine Tucker, Roche

-Using real world data to drive precision medicine across the UK healthcare economy Dr Ceire Costelloe, Imperial College London

Janice and Katherine's presentations along with the panel discussion for the session will be made available via [the PSI's video on demand platform](#).

**Rebecca Sudlow, Data Transparency ESIG lead**

#### **Estimands in oncology ESIG (and ASA scientific working group)**

On 29<sup>th</sup> June the ESIG, together with the Basel Biometric Section, co-organized a webinar "Estimands addendum is final: Anything new for oncology?" With talks shared between statisticians and clinicians, the seminar targeted not only statisticians but also non-statisticians. With a high-profile panel (among others the current (Anja Schiel) and former (Rob Hemmings) chair of the EMA SAWP) and just short of 400 registered participants the event was a success. We had several case studies shared illustrating the benefit of the addendum as well as a panel discussion with some spicy quotes from panellists. A few of these quotes from Anja Schiel:

*The estimand discussion should not be hidden in the SAP.*

*We are running trials for patients, not statisticians.*

*Key for the success of the addendum is education.*

*An assumption being “untestable” should not be perceived as it being also “unacceptable”.*

Slides, a recording of the webinar as well as a Q&A document answering the remaining questions in the chat will be made available on the BBS (<http://bbs.ceb-institute.org/>) and ESIG ([www.oncoestimand.org](http://www.oncoestimand.org)) webpage.

The ESIG actively contributed to three further webinars:

- 6<sup>th</sup> May, BBS, E. Degtyarev: “Short overview on COVID-19 from the Cross-Industry Oncology Estimands Working Group”
- 21<sup>th</sup> May, Cytel, K. Rufibach: “Estimands in oncology”, Michelle Casey (panel discussant)
- 11<sup>th</sup> June, PSI conference webinar, K. Rufibach: “Application of the estimand framework to assess the impact of COVID-19 on clinical trials”

All these slide decks and links to recordings (where available) are also available on the group’s webpage: [www.oncoestimand.org](http://www.oncoestimand.org).

Based on a slide deck published online earlier, the ESIG has finalized a paper discussing the impact of the COVID-19 pandemic on estimands in oncology trials. The paper summarizes month-long discussion and represents a consensus opinion of the working group. It will appear in a special issue dedicated to COVID-19 in Statistics in Biopharmaceutical Research (<https://doi.org/10.1080/19466315.2020.1785543>).

Another paper with contributions from ESIG members connecting estimands and PRO was accepted by “Journal of Patient-Reported Outcomes”. Three more papers are currently under review at various journals. Details, including a link to download the COVID-19 paper, are available for download on the group’s webpage: [www.oncoestimand.org](http://www.oncoestimand.org).

The ESIG co-leads, Evgeny Degtyarev and Kaspar Rufibach, will give a course on “Answering Old Questions with New Tools: Application of the ICH E9 Addendum” at the upcoming Annual Deming conference on Applied Statistics (<https://demingconference.org/>).

Finally, the ESIG has organized various sessions with several Health Authorities globally to present the results from all the above activities and continue the dialogue that had been started earlier.

***Kaspar Rufibach & Evgeny Degtyarev, Estimands in Oncology ESIG co-leads***

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## **Country News**

### **AFP (Germany)**

The APF meeting on November 27<sup>th</sup> and the German Statistics Leaders meeting on November 26<sup>th</sup> are still scheduled as face to face meetings. If needed, a change to a virtual format will be made as late as possible without incurring cancellation fees.

## PSI (UK)

### PSI 2020 Conference - Webinar Series

#### Thank you for supporting our first virtual conference!

Whilst it wasn't the event that PSI expected to bring you in 2020, we feel like the virtual conference with 7 sessions and our annual AGM last week was a real success. We had 412 sign up in the end so very much in line with the attendance of last year's face to face conference.

We wanted to thank everyone involved; speakers, attendees, sponsors, session chairs, social activity organisers, the PSI Scientific Committee and MCI. As you can imagine a lot of work had gone into the face to face event at Barcelona and then to have to turn it around and change things at the last minute was even more work so the flexibility and willingness of everyone involved is greatly appreciated.

We are working on putting the content online for PSI members; please bear with us as this might take a few weeks, but as soon as it is available on the Video On Demand system, we will notify you.

The 2021 conference will be held in Gothenburg, Sweden at Gothia Towers between 20<sup>th</sup> and 23<sup>rd</sup> June 2021. The Scientific Committee will be putting the content outline together in July, so if you have any ideas about what you would like to see, please [contact Paul Terrill](#), the 2021 Conference Chair or [MCI](#). We hope to see you all there, face to face!

## Podcasts



### Present like a pro - 14 presentation tips

When you are presenting, you don't want the audience to feel bored and lost. But how can you deliver a knock-out presentation and wow the audience? In this episode with Benjamin, we discuss 14 presentation tips that really work and present like a pro!

### Failed study, new safety finding, mistakes – breaking bad news

As statisticians, we often need to bring terrible news to the team. We're the first to know, that a study didn't reach the primary endpoint, or that safety analyses showed some new signals, or that some analyses contained mistakes, that need to be corrected. How do you deal with such situations? Listen to this episode and learn how to break the bad news the right way!

### How to create win-win situations?

Upon observing on our daily business, we have the tendency to view situations not as win-win but as win-lose. Is it really possible to create these win-win situations? In this episode, Justine and I talk about this topic. Win-win is a situation that has the potential to be beneficial to all involved.

*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/](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>

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## **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.

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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.....**

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To view previous newsletters please see the EFSPi website in the "[News](#)" area.



***Chrissie Fletcher, EFSPi Communications Officer***

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