![European Federation of Statisticians in the Pharmaceutical Industry - Representing Statistical Associations in Europe](logo)

EFSPI Newsletter March 2022

In this newsletter

Welcome

A warm welcome to the March 2022 EFSPI Newsletter!

From now on I will serve as editor of the EFSPI newsletter. First of all, my sincere thanks go to all of you for subscribing to our newsletter. But I also want to express a special thanks to Chrissie Fletcher who served as the editor for the EFSPI newsletter for many years. Creating a newsletter and delivering something to the readers month in, month out takes some time and energy. Many thanks for the excellent content and for presenting the relevant information in a way that was engaging and inspiring.

Dear EFSPI community, **I value your feedback, so let me know what you think!** I would like to learn from you how I can further transform our newsletter to become even more effective in meeting your needs. How helpful are our newsletters to you? Do they cover what you are interested in? Which topics would you like to read about in the newsletter? What should we start, continue, or stop doing?

In the meantime, we publish our newsletter (and more!) on our EFSPI LinkedIn account. You can take a look and engage with the posts by following us here, reacting, commenting or sharing the posts. I very much look forward to interacting with you!

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EFSPI Council news

Please join me in congratulating Emmanuel Pham as the new EFSPI eSIG liaison!

The European Special Interest Groups (eSIGs) are at the heart of our statistical communities, supporting scientific debate and collaboration across scientific disciplines, industry societies and countries/regions. The EFSPI Council and PSI Board together support and sponsor the eSIGs, including agreeing on the creation of new eSIGs and ensuring the eSIGs have tools and platforms to enable them to work efficiently and effectively.

In his new role, Emmanuel will represent EFSPI in supporting the eSIGs, seeking opportunities to improve how eSIGs operate and manage their activities, enable the eSIGs to have broad engagement within and outside of the statistical community, and help eSIGs to promote and communicate their activities and deliverables. As EFSPI eSIG liaison, Emmanuel will form the eSIG oversight committee with the PSI eSIG liaison.

Emmanuel is taking over the EFSPI eSIG liaison in April 2022 after contributing to the federation for more than 7 years as EFSPI Council member and serving as president of the Biopharmacy and Santé group of the Société Française de Statistique (SFdS) for many years.

The EFSPI Council meets four times a year. The first EFSPI Council meeting took place virtually at the end of January 2022, the second one is planned as a virtual event at the end of April 2022. We hope to eventually meet in person in the second half of this year. In July, we will combine our EFSPI Council with the Annual EFSPI Statistics Leaders meeting while in September, we plan to combine it with the Regulatory Statistics Workshop.

The EFSPI Operations Board decided to meet bi-weekly from March on in order to become even more responsive to changes happening between the EFSPI Council meetings and to better prepare and follow up on relevant topics from all the member groups that EFSPI is representing.

If you want to learn more about the EFSPI Council and the EFSPI Operations Board, please visit our EFSPI website.

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ESIG of the month

The Launch and Lifecycle (LnL) ESIG is our ESIG of the month!

The purpose of the LnL ESIG is threefold:

- to provide a platform for statisticians from sponsors and CROs working in the launch and lifecycle management to help each other in areas of pre-competitive collaboration

- to shape the industry to increase the influence of statisticians in launch and lifecycle and show 'how good looks like' for the work of statisticians

- to drive scientific projects and innovation forward related to the field of launch and lifecycle.

Learn more about the LnL SIG [here](#). As the biggest need for the members right now seems to be informal exchange on experiences in the LnL area, the ESIG currently runs biweekly meetings among the members. These meetings prove to be very helpful to learn from each other. Contact [Jenny Devenport](#) and [Alexander Schacht](#) to join the ESIG.

Last but not least, join the Launch and Lifecycle session at the PSI 2022:

Is medical affairs the wild west of statistics? The surprising truth about statisticians in phase IV!

Join this session to learn about the reality of how statisticians provide value to patients in this area.

During the session, you will get a better understanding of the purpose and objectives of the LnL ESIG. Despite it being formed only late in 2021, this ESIG has already gained significant momentum and achieved some of its goals. The ESIG members will share with you where statisticians can help beyond clinical development, regulatory approval and HTA submissions by explaining the landscape of the business and its specific complexity. Examples of the context, study designs, and strategic opportunities in the phase IV area will help you to grasp the impact of statisticians in this interesting are. Before closing the session with a panel discussion, the last presentation of the session will focus on the skill sets and knowledge areas which enable statisticians to be successful in the LnL area. The presentation will also cover results from a survey run by the LnL SIG about these topics.

The session will be chaired by Jenny Devenport (Roche) and Alexander Schacht (Veramed).

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Other ESIG news

Re-Launch of the Biomarkers ESIG

The goal of the EFSPI/PSI Biomarkers ESIG is not only to explore the hot topics of the moment when it comes to analysing biomarkers data, but also to increase the interactions with other disciplines, be they medicine, biology, or academic research.

Whether you work in pre-clinical or clinical development, whether you handle untargeted or targeted biomarker data, we want to hear from you! The more diverse the group, the more ideas will flow so please don't be shy and contact Nicole Kraemer or Guillaume Desachy to join our ESIG.

Pre-Clinical ESIG

The main objective of the Pre-Clinical ESIG is to provide a forum to discuss and advance statistical topics related to Research, Discovery (including efficacy models), Regulatory and Investigative Toxicology/Safety Assessment and to promote the involvement of Statisticians in these areas.

The Pre-Clinical EFSPI/PSI ESIG has the following virtual activities planned in 2022:
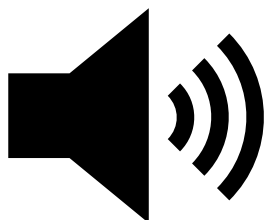
Item	Date	Title/Info	
Webinar	12th April	Optimal Experimental Design in Pre-Clinical Dose Response Studies. Dr. Tim Holland-Letz, DKFZ	For more information and to register click here and see poster attached.
Webinar	21st June	Regression to the mean, dilution and bridging studies illustrated in R. Dr. Bernard Francq, GSK	See website for updates.
Workshop	19th/20th September	1.5 days including a short course on the application of Bayesian Methods in a Pre-Clinical Environment by Bruno Boulanger.	See website for updates.
Webinar	4th October	Therioepistemology: Rethinking how we conduct animal-based experimentation Dr. Brianna Gaskill, Novartis	See website for updates.

If you wish to be the first to hear about our events, then join the Pre-Clinical ESIG mailing list by emailing Eloisa Brook.

Local Association of the month

APF (Germany): We are happy to share with you some feedback from the APF-Statistical Leaders Workshop "Open-source R-packages for innovative, GCP-compliant reporting"!

On March 29, the German-based APF-Statistical Leaders Working Group hosted a 2-hour virtual meeting on "Open-source R-packages for innovative, GCP-compliant reporting – available building blocks & initiatives". This event had been set up specifically for Statistical Leaders and Statistical Programming Leaders from Pharma Companies, CROs and Academic Institutes. The purpose of the meeting was to inform and discuss the amazing progress of the open-source movement in pharma and to present strategies for applying open-source R in the analysis and reporting of clinical trials.

Overall, the meeting was a big success, with 60+ Statistical- and Statistical Programming Leaders participating from various EU-countries and US. The presentations informed about the current strategic directions taken at Roche and Boehringer Ingelheim, as well as provided a summary of existing across-industry collaborations. This was complemented by an overview on open-source building-block packages like Admiral, rtables and NEST. A core part of the meeting was dedicated on viable organisational strategies to start the transition from an existing, mostly SAS-based proprietary clinical reporting environment (CRE) to an open-source/R-based CRE. This crucial topic was addressed using concrete recommendations, including a demo of the R-package suite NEST, which Roche, together with other companies, plans to release as open-source later in 2022. Finally, methodology statisticians from Roche, BI and GSK presented examples of advanced statistical packages in R, together with their perspective on the importance of collaboration between industry and academia to jointly build innovative open-source analysis software.

The meeting also included five 30min breakout-sessions – moderated by presenters and subject matter experts – intended to discuss further the transitioning process towards an open-source/R-based CRE. Break-out session topics included (1) Pharmaverse & R-validation hub, (2) Admiral, (3) NEST-collaboration, (4) Advanced statistical methods, and (5) Dynamic data visualisation and other innovative R packages. The meeting concluded with feedback from the beak-out sessions, emphasising some **key messages**:

- The open-source/R collaboration between Pharma, CROs and Academia to generate the elements of a clinical trial reporting environment has great promise to be a game-changer.
- The intent of open-source/R collaboration is to innovate and transform the existing proprietary static workflows into a seamless integration of interactive data exploration with reproducible and traceable analysis and reporting.
- Major R-based building-block frameworks and platforms are available or will be released as open-source very soon. This allows interested organisations to jump-start the transition.
- Contribution and commitment of all organisations are welcomed and needed.
- We need more meetings of this kind to promote exchange between organisational leaders and to learn from each other.

Recordings of the meeting can be found here: APF – Part 1/2 and APF – Part 2/2.

Contact partners for EFSPI newsletter readers who are interested in more details are Tadeusz Lewandowski, Hans-Juergen Lomp, and Juha-Pekka Perttola.

Other Country news

SFdS (France)

The 9th Statistics and Biopharmacy (SnB) Conference organised by the Statistics and Biopharmacy group of the SFdS (French Society of Statistics) will be held in Paris September 19-21,2022. It is a unique event, usually organised 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.

The topic of **SnB2022 "When Machine Learning meets Statistics for drug development and evaluations"** will be dedicated to the new challenges in drug development associated with the need for accelerating development and the availability of big data within clinical trials and outside. Multiple topics will be concerned such as data architecture, adaptative design, high dimensional data analysis with statistical and machine learning approaches and causal inference. This will be a unique opportunity to provide a scientific forum for international exchanges on theory, methods and applications of statistical and machine learning in clinical research among statisticians from various sectors and members of other disciplines interested in this field.

More information can be found at SnB 2022 - Statistics & Biopharmacy.

IBIG (Italy)

For the second year, the Italian Biostatistics Group (IBIG) was asked to organise a series of webinars on Statistics applied to clinical trials, targeting non-statistical audience. On a monthly basis, starting in April, one-hour webinar will be offered. The IBIG Forum will be held on October 19-21, 2022. The location of the meeting is still under evaluation, and it will be selected amongst two/three cities in Northern Italy. The Forum will be back to the pre-pandemic format, with pre-congress statistics methodology course and a practical programming part followed by two-day sessions with topics ranging from quantitative decision making to estimands to innovative study designs.
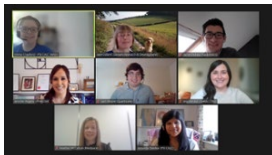
More information can be found here.

PSI (UK)

MEETINGS, WEBINARS AND COURSES:

[PSI Webinar: Novel composite estimands and their analysis](#)

ON-DEMAND WEBINARS AND PODCASTS:

PSI Conference 2021 - Watch On-Demand

All content from the PSI conference last year can be found on the website! Simply find **'PSI Conference 2021'** from the Collections drop-down menu on the [Video On-Demand](#) page, and re-live all the online sessions at your leisure.

PSI Careers Event 2022 Panel Discussion

An introduction to the Careers Event from the chair of PSI CALC, followed by a panel discussion featuring company volunteers.

[Watch here](#)

For more details, please check [PSI 2022 Conference](#)!

[Listen here](#)

How to analyse subgroups effectively using data visualisation

Subgroup analyses in combination with data visualisation is one of the hottest topics I can think about. And it hits us as statisticians during our careers again and again. Interview with Paolo Eusebi.

Measuring the impact of our research via data science on data

Publishing data is great, but we also want to measure the impact our work has beyond the additional entry in our CVs. During this episode, Mike Taylor and I discuss the tools Altmetric and Dimensions.

Things we would like to have known before we started with RWE

In this episode, Rachel Tham and I will discuss the things that we would like to have known before we started working with RWE so stay tuned to avoid mistakes we made in the past.

Listen to these episodes and share them with your friends and colleagues who might learn from it.

Ciao and be an effective statistician!

Alexander Schacht

NON-PSI EVENTS:

43rd annual conference of the International Society of Clinical Biostatistics

Date: 21-25 August 2022
Location: Newcastle upon Tyne, UK

RSS 2022 International Conference

Date: 12 September - 15 September 2022
Location: Aberdeen, UK

Job opportunities

Nowadays, job opportunities for statisticians and data scientists are excellent!

For information on how to submit recruitment adverts, please visit the Job postings on our EFSPI website. 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.

And finally

To add your email address to the EFSPI mailing list, click on "Sign up to our newsletter" on our landing page. To view all newsletters please see the "News" area on the EFSPI website. Please also follow us on EFSPI at LinkedIn for general EFSPI updates, specific news, and exciting opportunities.

And finally… EFSPI stands with the international community condemning the war and the violence in Ukraine and against its people. The news from Ukraine is truly devastating for all of us and brings a different perspective into our daily lives. Our thoughts and best wishes go out to everyone affected.

Many EFSPI members including myself have not only expressed their solidarity with the people suffering from the war but are also providing concrete help. Let's stand up together for solidarity, humanity, and peace, and let's support those who are in need within our circle of influence.

Stay well, stay safe wherever you are!

Justine Rochon, EFSPI President and Editor of EFSPI Newsletter