

EFSPi Newsletter

Quarter 2 2024

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As we move forward in 2024, we are delighted to bring you the latest updates, achievements, and events that have been driving our organization.

This quarter has been marked by remarkable advancements and collaboration, and we are thrilled to share these milestones with you.

While this newsletter serves as an additional instrument for more straightforward communication, we are excited to share that our LinkedIn page is more active than ever. We highly recommend following us on LinkedIn to stay updated on our latest initiatives, events, and industry insights.

Thank you for your unwavering support and active participation. We look forward to an enriching and productive quarter ahead.

Best Regards,
Your EFSPi President
Egbert Biesheuvel

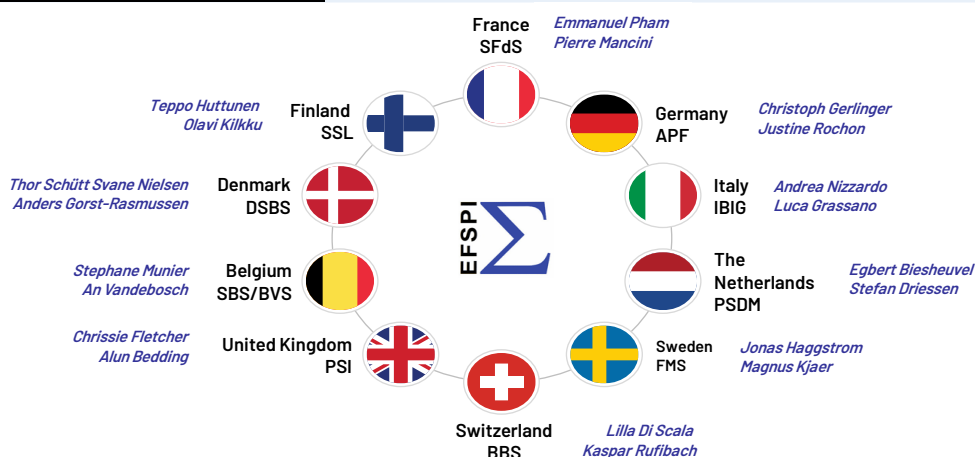


EFSPi President 2024–2025

Welcome to the 2024 second quarter edition of our newsletter!

EFSPi COUNCIL

Who we are



EFSPI 15th Statistical Leaders Meeting

Approximately 40 Statistics Leaders and guests attended the 15th EFSPI Statistics Leaders Meeting on the 4th and 5th June 2024 hosted by Bristol Myers Squibb in Boudry, Switzerland.

Three important topics were discussed with key messages as follows:

1) **Skill sets Statistical leaders need to have in the future**

Statistics Leaders have a key role to play to drive innovation, foster a growth mindset, leading diverse and hybrid teams and ensuring a strong foundation today for a fast changing R&D model needed tomorrow.

2) **How leaders are promoting innovation in drug development**

The newly created EFSPI Statistics Methodology Leaders Working Group challenged the EFSPI Statistics Leaders to embrace the two key components of innovation: the invention itself and being able to commercialise the invention so it becomes embedded and has the desired impact.

As a discipline, statisticians tend to focus more on the invention but being able to sell, advocate, and champion why the invention is needed and the value it will bring is just as important.

3) **How diversity and inclusiveness have changed Statistics departments and how leaders are leading groups**

This was the first time a session on diversity (D) and inclusiveness (I) has been discussed at the EFSPI Statistics Leaders Meeting and it was very well received. Leaders shared their experiences of creating diverse teams and how to maximise D & I in recruiting and building high performing teams. There was a key focus on culture and behaviours with NextGen Statistician guests giving superb feedback on what they have experienced thus far.

Thanks to all the session chairs, Emmanuel Zuber, and colleagues at BMS (Dr. Katrin Kupas, Roland Marion-Gallois, and Charline Meré) for their support in organising the meeting. We all enjoyed the beautiful scenery with the lake and mountains nearby.

Christine Fletcher (GSK)

EFSPI Statistics Leaders Meeting Chair



Scientific and Training Academy: Jonas Häggström as new Chair



EFSPI is thrilled to announce a significant transition within the organization.

Jonas Häggström is taking over the role of Chair of the Scientific and Training Academy, succeeding Egbert Biesheuvel who has served with exceptional dedication and leadership.

We are deeply grateful to Egbert for his invaluable contributions and commitment to the Academy. His leadership has been instrumental in shaping the Academy.

As we welcome Jonas into his new role, we are confident that he will bring fresh perspectives and innovative ideas to continue the Academy's mission.

Few words about Jonas: Jonas Häggström, Swedish council representative in EPSI. Currently Jonas is at Cytel as the Vice President of Global Health and Advanced Analytics and has been practicing statistics for over 20 years, with experience in working across all phases of drug development, with emphasis on Global Health, Neurosciences, Oncology, Rare Diseases, and Immunology.

We look forward to this new chapter in the Academy's journey under Jonas's leadership. Please join us in congratulating Jonas on his new role and thanking Egbert for his remarkable service!



EFSPI ACTIVITIES: WHAT'S NEXT?

9th EFPSI Regulatory Statistics Workshop Registration open!

EFSPI is happy to announce that registration for the **9th EFPSI Regulatory Statistics Workshop**, taking place **11-13 September 2024** in beautiful **Basel**, Switzerland, is open!

Registration link: http://www.efspiworkshop.org/registration_faq.html

You can find the topics that will be discussed at the meeting on the workshop website. The program will be continuously updated with more details, so please remember to check it out regularly.

Meeting info: <http://www.efspiworkshop.org>

We continuously strive to develop the workshop further!

This year we extend the workshop by a half day to allow room for a dedicated HTA session.

Still, registration fees remain at the same decent level as in the previous years.

For the first time, we will also have a patient talking to the audience.

We look forward to having you with us again this year!

EFPSI New Website

EFSPI is getting a fresh new look with a revamped website, thanks to our collaboration with the web agency "Fluidamente."

The new site will be more dynamic and user-friendly, making it easier to access EFPSI event info, organization details, and documents like this newsletter!

We're working hard to get it up and running ASAP! Keep an eye on our LinkedIn page for updates and be one of the first to check out the new EFPSI website when it goes live!

ESIGs UPDATE

Estimands in Oncology WG

In 2024 Estimands in oncology working group will release a series of short videos! In the videos the members of the WG will not only summarize key messages of their manuscripts, but also provide some personal reflections and learnings on the group's journey.

Three videos were already released!

In the first one, Evgeny Degtyarev and Kaspar Rufibach, the co-founders and co-leads of the WG, kick it off with a conversation about the group's beginnings and their learnings.

In the second part of their conversation, Evgeny Degtyarev and Kaspar Rufibach share their advice for future initiatives revealing their main 4 learnings.

In the third short video of the series, the PRO Taskforce shared its learnings of how it started and built on issues and learnings from the whole working group and the application to specific topics relating to PRO endpoints in oncology. Rachael Lawrance chaired the taskforce and explained the groups achievements as a taskforce and their next steps evolving into a broader PSI/EFSPI SIG (PFDD) for the future.

Keep an eye on EFSPI, PSI and ASA Linkedin pages, as they will be posting the next videos soon!

NATIONAL GROUPS UPDATE

SFdS Biopharmacie et Santé



Precision medicine holds great potential for improving health and health care, yet a gap remains between the growing number of statistical strategies and their implementation in clinical settings. Strategies to bridge this gap are context-dependent.

The webinar on June 26th, organized by SFDs Biopharmacie et Santé, focused on individualized treatment rule characterization via surrogates for the value function.

It was hosted by Nicolas Savy, Assistant Professor at the Toulouse Institute of Mathematics, University of Toulouse III, and featured Nikki Boatenhamer Freeman, Assistant Professor of Biostatistics and Bioinformatics at Duke University and a member of the Duke Clinical Research Institute.

NATIONAL GROUPS UPDATE

PSI



PSI 2024 Conference was held in Amsterdam, 16-19 June.

A huge thank you to the PSI Scientific Committee for all their hard work in organising an incredible conference!

From thought-provoking presentations to engaging discussions between colleagues, the PSI conference is always a valuable platform for our community to connect and share their latest findings in the field!

We are grateful for the scientific committee's dedication and expertise in making this conference a success also this year!

This year, we had the privilege of having our EFSPi Council members, Christine Fletcher and Alun Bedding representing PSI/UK, Lilla Di Scala and Kaspar Rufibach from BBS/Switzerland, and Justine Rochon from APF/Germany, attend the PSI2024Conference in Amsterdam. They were joined by Helle Lynggaard, the Chair of the EFSPi Regulatory Statistics Workshop, and Mouna Akacha, Cornelia Ursula Kunz, and Kaspar Rufibach, who are the driving forces behind the EFSPi Methods Leaders Group.

Their participation underlines the power of collaboration and the importance of a unified community in our field. It's inspiring to see such dedicated leaders attending the conference, being approachable, and coming together to share knowledge, drive innovation, and strengthen the future of our community.



NATIONAL GROUPS UPDATE

Basel Biometric Society



BBS
Basel Biometric Society

BBS organized a seminar on **Essentials of Medical Data Sharing and Privacy – Maximize the use of data**

To unlock innovation in the life science space, sharing data among public and private institutions is critical. With a diversity of approaches and tools available, it is not always easy to create a fit for purpose solution for a specific data sharing situation at hand.

The seminar by BBS aimed to provide practical guidance to select a possible data sharing approach for a given problem statement. Statistical, technological, legal and policy considerations were discussed for a spectrum of data sharing approaches by academic, industry and regulatory experts in the field of data sharing.

Italian Biostatistics Group



IBIG

The IBIG Working Group is pleased to announce the successful completion of the seminar "**Introduction to Causal Inference in Clinical Research**," held on June 14th at the University of Rome.

Causal inference has become increasingly important with the recent introduction of the concept of estimands in clinical trials (as per the ICH-E9 R1 guidelines). The seminar aimed to provide an initial conceptual framework, with some discussions on intercurrent events and analysis strategies.

The event featured presentations by Veronica Ballerini (University of Florence), Roberto Rocci (La Sapienza), and Fabrizia Mealli (European University Institute).

All set for the **BIG Forum 2024!**

Mark your calendars for October 29-31 in Parma, where this year's event will be hosted by Chiesi Italia.

We are thrilled to welcome several international speakers/teachers this year, and as always, the event will kick off on the first day with two pre-forum courses:

- Approaches to use historical information for the design and analysis of clinical trials and their applications
- Optimizing the Programming of ADaM CDISC Datasets for the Implementation of Estimands Framework

The Forum continues with two more days of engaging sessions on:

- Innovation in Statistics
- Statistics & Regulatory
- Design & Analysis of Early Phase Studies

Find the full agenda and more details for the registration on the IBIG LinkedIn page!

DID YOU KNOW?

International Clinical Trials Day



On May 20th, we honored the International Clinical Trials Day, a day dedicated to raising awareness and recognizing the tireless efforts of everyone involved in clinical trials. This date pays tribute to one of the first randomized clinical trials, initiated on the same day in 1747 by James Lind (1716–1794).

Representing 10 statistical associations across Europe, we at EFSPI are committed to maintaining professional statistical standards, especially in the context of clinical trials and their methodologies. Quantitative decision-making is an integral part of clinical trials, but the quality of the analysis and interpretation of the evidence are directly tied to the quality of the data. Healthcare professionals, researchers, and all staff at clinical trial facilities work tirelessly each day to gather and provide high-quality data that meets the objectives set out in the clinical trial protocol. Their role is fundamental in the process, often undertaken in demanding circumstances.

We also want to acknowledge the patients who participate in these trials. Their trust, courage and resilience are vital to the progression of medical science. Their participation in clinical trials paves the way for improved treatments and therapies, ultimately enhancing patient care worldwide.

We invite you to take a moment to reflect on the importance of clinical trials and express your gratitude for those who dedicate their days to this important work. Their contributions are key to improving patient outcomes.

See you at the next quarterly newsletter!

Andrea Nizzardo, Luca Grassano
EFSPI Communication Officers