



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

# EFSPI Newsletter

Quarter 2 2025



EFSPI President 2024–2025

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## Welcome to our second newsletter of 2025!

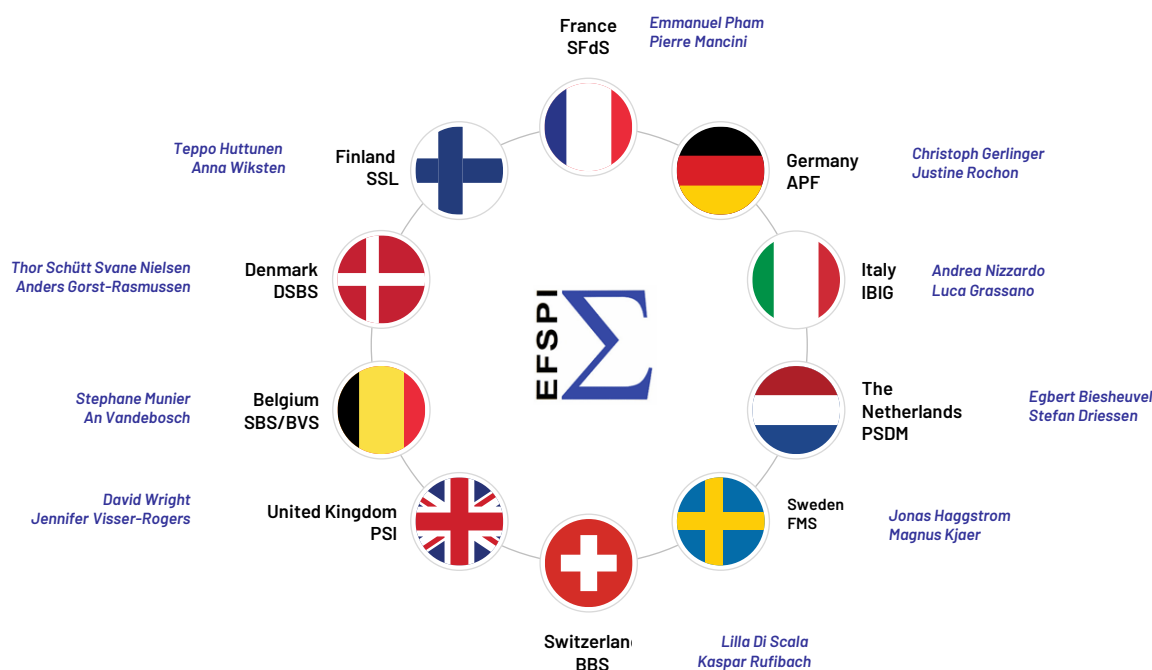
As we wrap up the second quarter of 2025, I'm excited to welcome you to the latest edition of our newsletter. A lot has happened already this year, and even more is on the horizon! We've marked a major milestone with the launch of our new website, continued our tradition with a

successful Statistical Leaders Meeting and represented EFSPI at important international events. I invite you to explore the sections ahead to learn more about these activities and what's coming next, including the special 10th edition of our Regulatory Statistical Workshop in September.

Wishing you all a pleasant and well-deserved summer break!

## EFSPI COUNCIL

## Who we are



# EFSPI Updates and Upcoming Events

## Welcome to our 2nd Newsletter of 2025!

We are delighted to bring you the latest news, achievement and upcoming events!

At the beginning of June, we officially launched our new EFSPI website. (URL remains unchanged). This is an important milestone in the journey of enhancing EFSPI's ways of communicating and we are proud of this achievement. Although the website looks similar to the previous one, the new website gives us much more control and flexibility to keep the information up-to-date.

Traditionally, we have held the Statistical Leaders Meeting in spring. Already the 16th edition which took place in Copenhagen on 12 - 13 May. You can read more about this successful meeting later in the newsletter.

Representatives of the Statistics Methods Leaders attended the Bayes workshop organised by EMA on 17 June on behalf of EFSPI. This was an excellent opportunity to highlight EFSPI's role as a stakeholder and representative of a larger community. The application of Bayesian methods in drug development is one of the four priorities of the Statistical Methodology Leaders, as mentioned in previous newsletter.

We are grateful to the ASA Biopharmaceutical Section for giving us the opportunity to introduce EFSPI to their community. Justine Rochon wrote a wonderful article on EFSPI's contribution to the Evolving Role of Statisticians in the Pharmaceutical Industry. A great opportunity to make EFSPI visible outside of Europe.

In September we will celebrate our 10th Regulatory Statistical Workshop. Please make sure to register in time if you wish to attend this special edition in person, as the capacity of the auditorium in Basel is limited and registrations are going fast.

Please check our website or follow us on LinkedIn to stay up to date on our latest initiatives, events and industry insights. We look forward to an enriching and productive quarter ahead.

Sincerely,  
Your EFSPI President  
Egbert Biesheuvel

# 16th EFSPI Statistics Leaders Meeting –

Copenhagen, May 2025

The 16th annual EFSPI Statistics Leaders Meeting took place on 12–13 May 2025 at Ferring Pharmaceuticals' scenic site in Copenhagen, Denmark. Co-hosted by five Danish companies—Ferring, Novo Nordisk, Leo, Lundbeck, and Zealand Pharma—the meeting welcomed around 40 Statistics Leaders and guests, including five inspiring NextGen Statisticians.

The agenda featured two insightful keynote presentations: Aaron Mitchell (ZS) explored “The In-Silico Revolution in R&D”, and David Martin (Novartis) spoke on “Accelerating Patient-Focused Drug Development.” Both talks highlighted the growing impact of digital innovation and patient-centered approaches in shaping the future of drug development.

Three key topics anchored the discussions:

- 1. Academic Alliances: Universities and Pharma Nurturing NextGen Talent:** Participants reflected on how Pharma and academia can partner to nurture the next generation of statisticians. NextGen Statisticians shared their career journeys, and ideas were exchanged on how EFSPI and industry leaders can help shape education programs and attract talent to the field.
- 2. Innovative clinical trial methodologies and their adoption - Priorities and Opportunities:** The EFSPI Methodology Working Group presented their top four priorities, with a call for joint action to drive wider adoption of innovative methods that can accelerate drug development and improve regulatory and reimbursement outcomes.
- 3. Irrelevant and out of touch?:** This session allowed the Stats Leaders to focus on themselves and learn from each other in ensuring as leaders they remain relevant, retain a level of authenticity and continue to be curious in their career journeys. A provocative discussion pursued with lively debate and impactful stories shared.

A heartfelt thanks to all speakers, session chairs, the five host companies, and the organizing team, Emmanuel Zuber, Kyle Raymond, Anna Karina Trap Huusom, and Sonja Paulsen, for making this meeting a success.

The beautiful setting and walking tour of Copenhagen added a special touch to an already enriching event.

Chrissie Fletcher,  
EFSPI Statistics Leaders Meeting



# 10th Regulatory Statistical Workshop

### Register Now!

We are excited to invite you to the 10th EFSPI Regulatory Statistics Workshop, taking place from 10–12 September 2025 at the Biozentrum in Basel and online.

This special anniversary edition brings together experts from regulatory agencies, industry, and health technology assessment bodies to explore the most pressing strategic statistical topics in drug development.

The program, carefully curated by the scientific committee, features high-quality presentations designed to stimulate meaningful discussion and debate, both during sessions and through informal networking opportunities.

As in previous years, attendees can submit a real-world challenge to be considered for the popular "short topics" session, where selected problems are discussed with a panel of esteemed regulators.

If you have a topic in mind, please send your proposal to Vivian Lanius (vivian.lanius@ucb.com) *by 11 August 2025*.

Whether you plan to attend in person or virtually, please register thoughtfully, indicating your preferences for each day to help us create the best experience for all participants.

Visit the conference website for the draft program, registration details, and FAQs.

👉 click [here](#)

We look forward to welcoming you in Basel or online!



10th Anniversary  
of the  
EFSPI Regulatory Workshop



# EFSPI Launches New Website!

We are pleased to share that the new EFSPI website is now live at [www.efspi.org](http://www.efspi.org)!

While the web address remains unchanged, the site has undergone a complete redesign to deliver a more modern and user-friendly experience.

This launch marks an important step in EFSPI's ongoing efforts to strengthen communication and better support our members across Europe.

We extend our sincere thanks to everyone who contributed to this initiative, and a special thank you to FluidaMente – Web Marketing Agency, our development partner, for their excellent collaboration throughout the process.

We invite you to explore the new site and discover its improved features and layout!

Warm regards,

Andrea Nizzardo & Luca Grassano  
EFSPI Communication Officers



# Building Bridges: Communication Across Academia, Industry, and Regulators

## Registration is Now Open!

BBS NextGen Event – “Building Bridges: Communication Across Academia, Industry, and Regulators”  
The BBS NextGEN committee is excited to invite you to our upcoming event on Tuesday afternoon, 9th September 2025!

The event is right before the EFSPi (European Federation of Statisticians in the Pharmaceutical Industry) regulatory workshop. So if you are already in town, consider joining us!

### **Theme:** Communication Across Academia, Industry, and Regulators

Join us as we explore how statisticians can step beyond technical conversations to enhance their impact by building bridges with clinicians, engaging meaningfully with regulators, and playing an active role in decision-making processes.

### **Networking Opportunity**

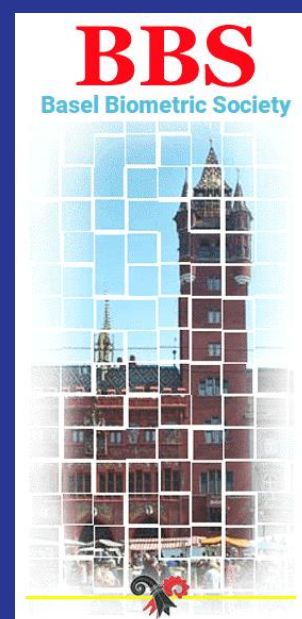
The event will be followed by an informal dinner: an ideal chance to connect, exchange ideas, and expand your network in a relaxed setting.

Participation is free, but spots are limited!

Registration is now open: First come, first served!

👉 click [here](#)

BBS NextGen events are open to all, regardless of age or experience. Whether you're early in your career or simply passionate about supporting the next generation, you are warmly welcome.



# Spotlight on Collaboration: EFSPI Featured by ASA Biopharmaceutical Section

We are proud to share that EFSPI was recently featured by the ASA Biopharmaceutical Section in a spotlight article recognizing our ongoing contributions to the evolving role of statisticians in the pharmaceutical industry.

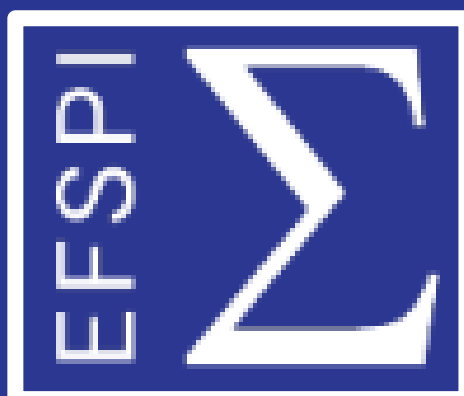
In a time of rapid transformation, driven by innovation, artificial intelligence, and the need for strategic evidence generation, statisticians are stepping into increasingly pivotal roles. From regulatory science to health technology assessment, our discipline is helping shape the future of drug development.

This international recognition is a testament to EFSPI's mission of fostering collaboration and knowledge exchange across Europe and beyond. Since 1992, we have united ten national statistical societies and a growing community of around 4,000 professionals across the continent. Our work continues to promote excellence, innovation, and impact in pharmaceutical statistics.

We are grateful to the ASA Biopharmaceutical Section for this opportunity to extend our visibility outside Europe, and for the collaborative spirit we share. We also encourage our members to follow and engage with ASA Biopharmaceutical Section for global insights and initiatives.

A special thank you to **Justine Rochon** for her excellent article on "The Evolving Role of Statisticians in the Pharmaceutical Industry: EFSPI's Contribution to Excellence", which you can read [here](#).

Together, we strengthen our global community and support the advancement of our profession!



## NATIONAL GROUPS UPDATE

### Italian Biostatistics Group



## IBIG Forum 2025 – Save the Date!

 October 22–24, 2025

 Naples, Università degli Studi di Napoli Federico II

We're excited to announce that preparations for IBIG Forum 2025 are well underway!

Join us in Naples this October for three days of learning, collaboration, and discussion on some of the most important and forward-thinking topics in pharmaceutical statistics.

#### ◆ Day 1 – Pre-Forum Courses

Get hands-on with two high-value courses:

- A Practical Introduction to Simulating Complex Trial Designs - *Pavel Mozgunov, Dominique-Laurent Couturier (MRC Biostatistics Unit, University of Cambridge, UK)* - Learn how to design and simulate adaptive Multi-Arm Multi-Stage (MAMS) trials using Monte Carlo simulations, including practical insights from the TREADON trial.
- Regulatory Pathways: Mastering FDA Submission Strategies from a Statistical Programming Perspective - *Gabriele Di Domenico, Giulia Caldarazzo (GSK Vaccines, Siena)* - Explore effective programming strategies for navigating FDA submission requirements, from a real-world, hands-on point of view.

#### ◆ Days 2 & 3 – Main Forum Topics

The core forum will feature expert-led sessions and interactive discussions on:

- Statistics & Regulatory
- Quantitative Decision-Making
- AI/ML in Drug Development
- Bayesian Statistics in the Context of RCTs
- Transitioning to R/Open-Source Tools

Whether you're looking to deepen your technical skills, explore regulatory challenges, or engage with peers across the industry, IBIG Forum 2025 offers something for everyone.

The full agenda will be released soon, and registration will open shortly. If you're interested in presenting, there's still time to get involved! Please contact on LinkedIn Andrea Vele, Andrea Nizzardo, Marco Costantini, or Stefano Vezzoli.

Stay tuned for more updates and we hope to see you in Naples!



# NATIONAL GROUPS UPDATE

PSI



## Registration for the PSI/EFSPI Vaccines Statistics Workshop IS NOW OPEN!

Join us for our PSI/EFSPI Vaccines Statistics Workshop on October 23rd, 2025 in Wavre (GSK site), Belgium.

This workshop will focus on statistical methodology and innovative approaches in vaccines research and development.

The PSI/EFSPI SIG Vaccines Statistics Workshop is pleased to invite researchers, statisticians, and industry professionals to submit posters for presentation at our upcoming workshop.

Poster presentation abstract submissions remain open until September 12th, 2025.

The Local and Scientific Organizing Committees are looking forward to welcoming you in Wavre, Belgium!

👉 click [here](#) for more information

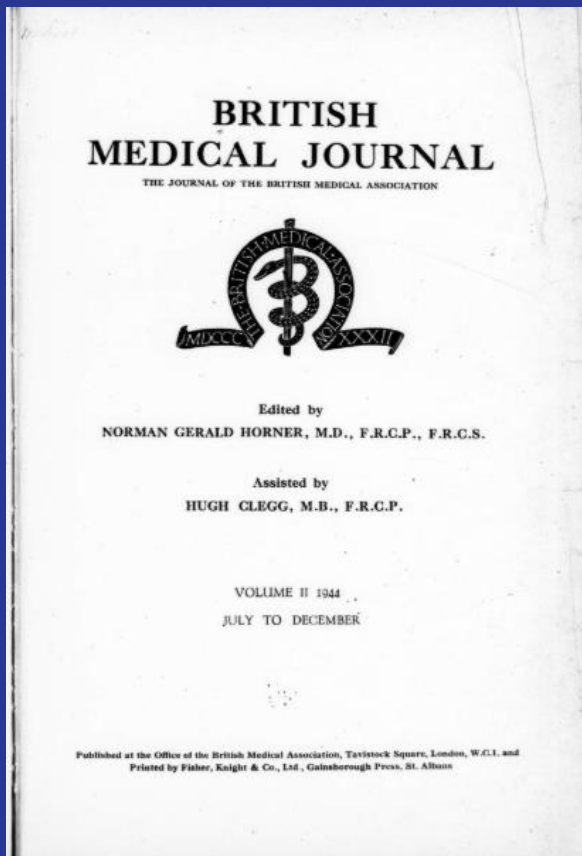
### PSI/EFSPI Vaccines Statistics Workshop

8:50 - 9:00	Welcome
9:00 - 10:30 Session 1	<p>Chair: Ian Hirsch, AstraZeneca</p> <p><b>A Threshold of Protection Model for Monoclonal Antibody Efficacy Against SARS-CoV-2 Variants.</b> <i>Seth Seegobin, Executive Director of Biostatistics and Head of the Statistics Department of Vaccine and Immune Therapies, AstraZeneca.</i></p> <p><b>Winter is coming; forecasting the next season's wave in advance.</b> <i>Tom White, Head of Clinical Data Science, Vaccine and Immune Therapies, AstraZeneca.</i></p> <p><b>Bayesian Statistics for Age Expansion in Vaccines with Example.</b> <i>Scott Patterson, Senior Expert Statistical Scientist, Sanofi Vaccines, Sanofi.</i></p>
10:30 - 11:00	Coffee break
11:00 - 12:30 Session 2	<p>Chair: Andrea Callegaro, GSK</p> <p><b>Robust (exchangeability) Bayesian methods for vaccines targeting multiple serotypes.</b> <i>Margherita Annaratone, Principal Statistician, GSK Vaccines</i></p> <p><b>The validity of test-negative design for assessment of vaccine protection.</b> <i>Prof. Xinxue Liu, Associate Professor of Epidemiology and Health Statistics, University of Oxford.</i></p> <p><b>Within-host mathematical models to study antibody kinetics after the prophylactic Ebola vaccine in the Democratic Republic of the Congo.</b> <i>Irene Garcia-Fogeda, Steven Abrams, Stijn Vanhee, Maha Salloum, Benson Ogunjimi, Niel Hens. Researchers, University of Antwerp, Belgium</i></p>
12:30 - 14:30	Lunch Break and Poster Session
14:30 - 15:30 Session 3	<p>Chairs: Larry Molton (TBC)</p> <p><b>Adopting Estimand in Prophylactic Vaccine Trials.</b> <i>Francois Beckers, Global Head of Vaccines Biostatistical Sciences, Sanofi.</i></p> <p><b>Assumption-Lean Strategies for Handling Intercurrent Events in Randomized Trials.</b> <i>Prof. Stijn Vansteelandt, University of Gent, Belgium.</i></p>
15:30 - 16:00	Coffee break
16:00 - 17:00 Session 4 and closing	<p>Chair: Fabian Tibaldi, GSK</p> <p><b>Paradigms for the evaluation of surrogate endpoints and correlates-of-protection: vaccines, the pandemic preparedness, and beyond.</b> <i>Prof. Geert Molenberghs, Professor of Biostatistics, I-BioStat Universiteit Hasselt &amp; KU Leuven, Belgium.</i></p>
17:00	Drinks

## DID YOU KNOW?

May 1944

### Laying the Groundwork for Modern Clinical Modeling



In May 1944, the British Medical Journal published one of the first known studies to apply a form of what we now recognize as logistic regression to medical data.

Although the technique was still in its early stages, the authors sought to model binary outcomes, such as the presence or absence of disease, by relating them to patient characteristics using a probabilistic framework.

This marked a pivotal shift in statistical thinking: rather than relying solely on descriptive comparisons or linear models, the study used non-linear modeling to better reflect real-world clinical data, where outcomes are often categorical or dichotomous.

This pioneering application planted the seeds for what would later evolve into the generalised linear model (GLM) framework, formally developed in the 1970s. Logistic regression, in particular, became a core tool in epidemiology, clinical trials, and health outcomes research, enabling statisticians to quantify risk, adjust for confounders, and predict clinical events with greater accuracy.

📌 Fun fact: The term "logistic" comes from the logistic function, a type of S-shaped curve, which maps any input to a value between 0 and 1, perfectly suited for modeling probabilities.

This 1944 publication may not have named the method as we know it today, but it represents an important moment in the history of medical statistics: the beginning of a more sophisticated, model-based approach to understanding health and disease.