EFSPI Newsletter

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

EFSPI President 2024–2025

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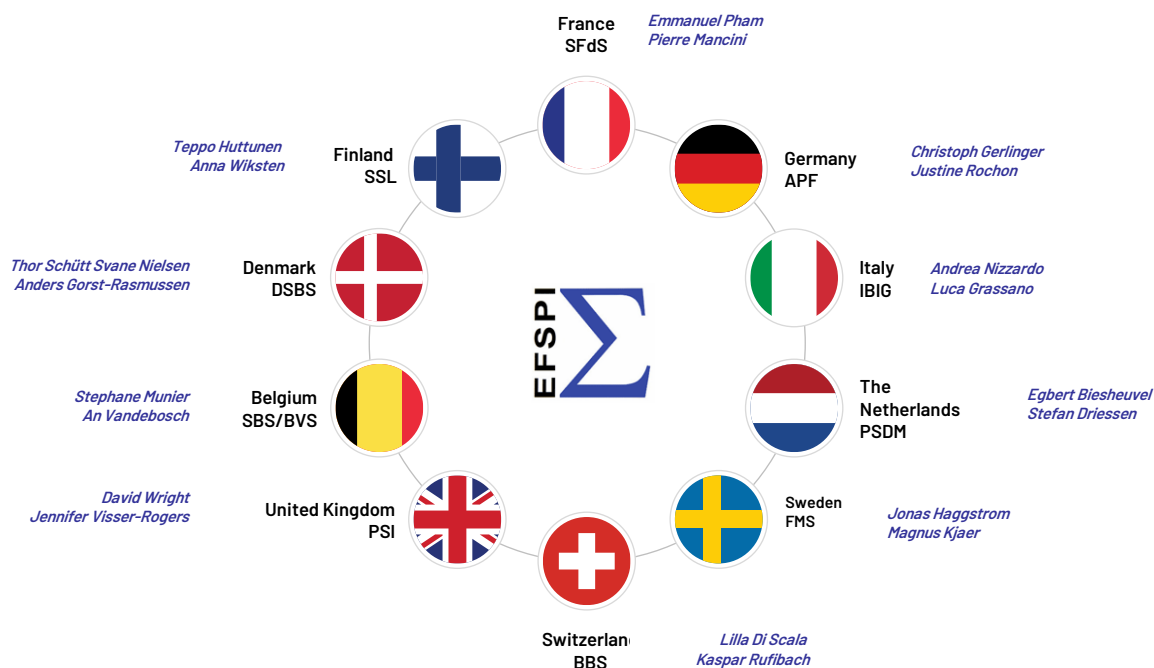- National Groups updates
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Welcome to our first newsletter of 2025!

The year is off to a dynamic start, with exciting developments ahead. We are making great progress on our new website, which we look forward to launching soon. EFSPI remains committed to driving innovation in the pharmaceutical industry, supporting open-source collaboration and contributing to key discussions shaping our field. This year will be packed with important events, from leadership meetings to regulatory workshops, providing valuable opportunities for exchange and progress. Stay tuned for more updates as we continue to advance our initiatives and strengthen our community.

EFSPI COUNCIL

Who we are

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Emmanuel Pham
Pierre Mancini

Germany
APF
Christoph Gerlinger
Justine Rochon

Finland
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Teppo Huttunen
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DSBS
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The Netherlands
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An Vandebosch

Sweden
FMS
Jonas Haggstrom
Magnus Kjaer

United Kingdom
PSI
David Wright
Jennifer Visser-Rogers

Switzerland
BBS
Lilla Di Scala
Kaspar Rufibach

EFSPI Council members and Upcoming Events

Welcome to our 1st Newsletter of 2025!

This newsletter summarizes the key updates shared via our LinkedIn page, along with additional information we discussed during the first Council meeting of 2025.

EFSPI Officers Changes and Key Roles

We are pleased to introduce the EFSPI Officers and Key Roles for the upcoming period.
Leading the organization is **Egbert Biesheuvel** (President), supported by **Justine Rochon** (Vice President).

We are happy to announce that **Lilla di Scala** will be our new Treasurer, succeeding **Teppo Huttunen**.
We extend our heartfelt thanks to Teppo for his dedication in managing EFSPI's finances since 2020, and we wish Lilla success in her new role.

Thor Schütt Svane Nielsen serves as Director (legal entity), while **Jonas Haggstrom** (Scientific Lead), **Christoph Gerlinger** (Regulatory Lead), and **Emmanuel Pham** (SIGS Lead) continue to play key roles in advancing our initiatives. The Statistical Methodology Leaders group is chaired by **Kaspar Rufibach**, while the Statistical Leaders Group is chaired by **Chrissie Fletcher**; **Andrea Nizzardo** and **Luca Grassano** continue to oversee communications. Finally, **Hayley Wheatley** represents the EFSPI Executive Office.

In addition, we welcomed **David Wright** as the new UK representative on the EFSPI Council succeeding **Chrissie Fletcher**. We sincerely thank Chrissie for her many years of dedicated service and contributions to the Council, and we wish David success in his new role.

We are making steady progress on our **new website**, which we hope to launch at the beginning of next quarter! Stay tuned for more updates!

Upcoming EFSPI Events

- **16th Statistical Leaders Meeting – Copenhagen (May 12-13, 2025)**
  Topics include academic alliances, innovative trial methodologies, and next-generation statisticians. The full agenda is available on our website.

- **10th Regulatory Statistics Workshop – Basel (Sept 10-12, 2025)**
  Preparations are well underway! We are grateful to **Vivian Lanius** for stepping in as chair, ensuring the success of this special **10th-anniversary workshop**.

Looking forward to another exciting quarter ahead!

Workshop on ICH E6 R3 at EMA

The ICH E6(R3) guideline is set to come into effect on July 23, 2025. This iteration of the guideline focuses on 11 principles of Good Clinical Practice (GCP). These principles are designed to offer flexibility and adaptability across a wide variety of clinical trials. They promote approaches that are fit for purpose, aiming to enhance the efficiency of trial design and execution.

In February, the EMA organized a two-day workshop in Amsterdam, where our former president, Justine Rochon, represented EFSPI. The workshop, conducted within the context of the ACT EU framework, aimed to accelerate clinical trials in the European Union. Emer Cooke's opening remarks set a profound tone for the event. "If you are here, it is for a good reason. It is because you are keenly aware that good clinical practice is critical for protecting patients and delivering high-quality data to inform decision-making," she said. She highlighted that the modernized ICH E6 GCP guideline emphasizes a risk-based approach to the design and conduct of clinical trials, ensuring that they are both scientifically sound and ethically robust. Furthermore, the third revision reflects a shift away from a tick-box approach towards a more thoughtful, fit-for-purpose approach, guided by the principle of risk proportionality.

The workshop aimed to:
- Offer a comprehensive overview of the significant updates in the ICH E6(R3) guideline, including those from the draft version released for public consultation.
- Outline the key concepts for modernizing Good Clinical Practice (GCP) in light of recent advancements in trial design, organization, and technology, with an aim to ensure the guideline remains relevant in the future.
- Encourage dialogue with stakeholders on the practical application of ICH E6(R3).
- The workshop was designed to engage a broad spectrum of stakeholders in the ICH E6 R3 process. This included patients, healthcare professionals, investigators, regulators, service providers, ethics committee members, academia, and the industry.

Significant updates in the new guideline include also many aspects of statistics and statistical reporting, with a specific section dedicated to statistical programming and data analysis. The essential records now contain a more precise list of documents related to statistical considerations and analysis. Additionally, the guidelines take into account the estimand framework and align with ICH E9 (R1).

Given the relevance of these updates, we highly recommend to review the workshop materials as they provide valuable insights and guidance on the application of the new principles.

The workshop materials, including video recording and the slides, can be found on the event page here.

The final ICH E6(R3) guideline can be accessed here.

EFSPI statistical methodology leaders update

In January, the EFSPI statistical methodology leaders met for their yearly face-to-face meeting at Merck in Darmstadt. Twelve members took two days out of their busy schedule to travel to Germany.

Topics discussed were:

- **Achievements** - While this group is only in effect for a bit more than one year achievements are manifold: presentations and industry at two EMA multistakeholder workshops on behalf EFPIA, building a network of methodology leaders within Europe, and fostering thinking about invention, innovation, adoption and impact through roundtables, webinars, podcasts, etc.

- **Determination of priority topics** - four priority topics were identified for which dedicated subteams are having internal discussions and work on list of questions. The idea is to be prepared for discussions with regulators once there are opportunities, e.g. within EMA multistakeholder workshops. The four topics are (1) application of Bayesian methods in drug development (2) covariate adjustment (3) a framework to appraise statistical methods building on ICH M15 and (4) specific topics related to estimands. These topics are aligned with both EFSPI and EFPIA and input from further stakeholders, e.g. the EFSPI / PSI SIGs, is sought as well.

- **Training offers** - Building on the first webinar "From Statistical Innovations to Common Practice: How to innovate with impact?" the group plans to continue a webinar series sharing examples of successful commercializations of statistical inventions.

- **Career development for methodologists** - Different models were discussed and we plan to have a discussion with the EFSPI statistical leaders how we can best collaborate to continue to build a network of methodologists.

- **Interaction with statistical engineering colleagues** - The group will seek alignment with openstatsware on implementation of software for the four priority topics and will explore further opportunities for collaboration between the two groups.

- **Library of commercialisations** - A library of successful commercialization examples of statistical inventions has been initiated. These examples will be worked up so that they can be shared with the community to help discussions on methods within companies, e.g. to get partner functions on board for certain statistical methods, not the least in a regulatory context.

Don't miss the EFSPI Statistical Methodology Leaders's <u>webpage</u>!

BBS NextGen Mentoring Scheme
A Successful Kickoff!

We are excited to share the successful launch of the BBS NextGen Mentoring Scheme, marked by an engaging kickoff event that highlighted the value of mentorship!

The event began with Guillaume Desachy drawing a creative analogy, comparing mentorship to the "castle card" in Uno Disney—a symbol of hidden potential and accelerated growth.

Alun Bedding, ICF ACC, then shed light on the nuances of coaching, providing practical advice on selecting the right coach and understanding the distinct roles of mentoring, coaching, and therapy. His insights reminded us that each approach serves a unique purpose in personal and professional growth.

Attendees actively participated in interactive discussions, sharing experiences and tackling real-world challenges together. The collaborative energy was inspiring, showcasing the power of shared wisdom.

A few of our community members shared their mentoring experiences:
*   Zeyneb MHEDHBI shared how a recent mentorship experience through a BMS program opened new doors and helped her navigate her path in pharma statistics.
*   Kévin Vervier reflected on the impact of peer mentoring, including his experience mentoring a disabled student through the myAbility Social Enterprise GmbH Talent program at Novartis.
*   Jenny Devenport introduced us to three mentoring archetypes— the All-in Advisor, the Good Idea Fairy, and the Hero You Shouldn't Refuse—each bringing unique value to the mentoring experience.
*   Achim Güttner encouraged us to adopt a "Lemur-like" mentoring style—socially active, curious, and engaged.

This event reinforced that while mentors are invaluable, the true impact comes when individuals take ownership of their development. Bring your goals, embrace feedback, and remember—you are the architect of your own growth! Additionally, we officially launched the BBS mentoring program at this event. In March , the mentors and mentees have been matched, and then they will meet for the next 4 to 6 months.

A special thank you to Novartis for hosting the event, our insightful speakers, and the dedicated organizing team: Youyou H., Olympia Papachristofi, Kristina Weber, Lukas Widmer, and Manuela Zimmermann.

Together, we're shaping futures, one mentoring session at a time!

Happy International Women's Day !

At EFSPI, we are very thankful for the many female colleagues who are making an impact in our industry. Your hard work, dedication, and leadership are very important in shaping the future of healthcare, and we want to celebrate this with you!

We are also happy to share that **Justine Rochon**, our former president of EFSPI (2022-2023), has been recognized in the Reuters Events: Trailblazing Women in Pharma 2025 list.

This important list highlights ten women who are not just inspiring and leading by example but are also making a big difference. The theme for this year's International Women's Day, "Accelerate Action" aligns well with the achievements of these trailblazing women.

We encourage you to look at the list and join us in celebrating the amazing work of women in pharma. Check out the nominees in the report here.

Reuters Events

TRAILBLAZING WOMEN 2025
PHARMA

A celebration of trailblazing women inspiring the pharmaceutical industry

We need to invest in women's potential, not as charity, but as a strategic move. The change we need isn't in women, but in the systems that surround them.

Justine Rochon
Boehringer Ingelheim

EFSPI Supports Open-Source

EFSPI is committed to fostering an environment where innovation thrives, and we believe that collaborative efforts in the open-source arena are enablers to achieving this vision.

EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

EFSPI

January 2025
EFSPI Supports Open-Source

On behalf of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI), we would like to express our support for efforts to advance open-source collaboration in statistical engineering and clinical reporting.

As statistical leaders within the pharmaceutical industry, we understand the critical importance of innovation and efficiency in statistical methodologies and processes that drive clinical development. The challenges we face in scaling and adopting innovative approaches often lie in navigating complex data environments, ensuring reproducibility, and fostering cross-company collaborations that facilitate faster, more efficient decision-making. In this context, the role of collaborative, open source initiatives such as Openstatsware and Pharmaverse is key.

Cross-company collaborations like Openstatsware and Pharmaverse offer unique opportunities to harmonize methodologies, standardize practices, and create accessible platforms for innovation in statistical analysis. These initiatives provide a foundation for collective progress across the industry, enabling pharmaceutical companies, regulators, and academic institutions to work together more effectively in advancing statistical practices and clinical reporting. They allow for the exploration of new ideas and methodologies that might otherwise be overlooked, fostering a culture of open dialogue and collaboration among all stakeholders.

EFSPI is committed to fostering an environment where innovation thrives, and we believe that the collaborative efforts in the open-source arena are enablers to achieving this vision.

Arbeitsgruppe Pharmazeutische Forschung

German Statistics Leader Meeting

The upcoming German Statistics Leader Meeting is scheduled for May 9, 2025, in Frankfurt at Sanofi! Stay tuned for updates on the agenda and additional details as the event approaches.

We'll be sharing more information soon, so make sure to keep an eye on the APF webpage and our LinkedIn page for the latest news and announcements.

Don't miss the chance to connect with fellow leaders in the field and explore key topics shaping the world of statistics!

Italian Biostatistics Group

Get ready for a year full of events and initiatives at IBIG!

We are thrilled to announce a series of webinars dedicated to **R programming**, with a focus on specific libraries like *gMCP, rpact*, and *subscreen*, which are designed for planning and analyzing clinical studies.
Whether you're a beginner or an advanced user, these webinars will provide valuable insights and practical applications.

Of course, we are also working hard to bring you our **annual IBIG Forum** and the pre-forum courses on 22-24 October 2025. While the agenda is still being finalized, we can already give you a sneak peek: we are about to confirm one of our pre-forum courses, "*A Practical Introduction to Simulating Complex Trial Designs*". Stay tuned!

Last but not least, this year IBIG has strengthened its collaboration with academia!
We are excited to be part of a series of seminars for Master's students in Biostatistics at the University of Milano-Bicocca. These seminars will cover topics such as:
• Adaptive designs in clinical trials
• Comparative effectiveness research in observational studies
• The ICH E9 guideline: statistical principles for clinical trials and the estimand framework
• Multiplicity and multiple testing in clinical trials: regulatory perspectives from EMA and FDA

Stay connected with us on our LinkedIn page to keep up with the latest news about our 2025 events!

The IBIG Steering Committee

SFdS Biopharmacie et Santé

Statistics & Biopharmacy conference - SnB 2025

Join us for the 10th SnB in Paris from Wednesday 8 to Friday 10 October 2025.
The conference program will include four plenary sessions

Session 1: Modern clinical trials: the challenges of small populations and novel endpoints
- Nigel Stallard (Warwick Medical School): Advances in statistical methods for clinical trials in rare diseases: an overview
- Mia Tackney (MRC, University of Cambridge): Eight Methodological Questions for Digital Outcome Measures

Session 2 & 4: Use of external information to improve decision making I & II
- Simon Wandel (Novartis): The Good, the Bad and the Ugly: Experiences When Utilizing External Information in Clinical Trials
- Kit Roes (Radboud University Medical Center Nijmegen): Regulatory view on use of external information: Considerations from design to assessment
- Andrea Callegaro (GSK): Covariate-adjusted Robust Mixture Prior approach in clinical trials with historical controls
- Beate Wieseler (IQWiG): Health Techology Assessment view on use of external information

Session 3: Improving statisticians' communication and coding skills
- Daniel Sabanés Bové (RCONIS): Why we Need to Improve Software Engineering in Biostatistics - A Call to Action
- Fanny Chevalier (University of Toronto): Data Insights: Bridging the Gap Between Numbers and Knowledge

There will also be one pre-conference course "Applied Modelling in Drug Development - Flexible regression modelling in Stan via brms" and one post-conference course "Good Software Engineering Practice for R Packages". There will be plenty of networking opportunities with other delegates and sponsors during multiple social events.
Poster and oral presentation abstract submissions remain open until 10 May 2025. Further information can be found here.

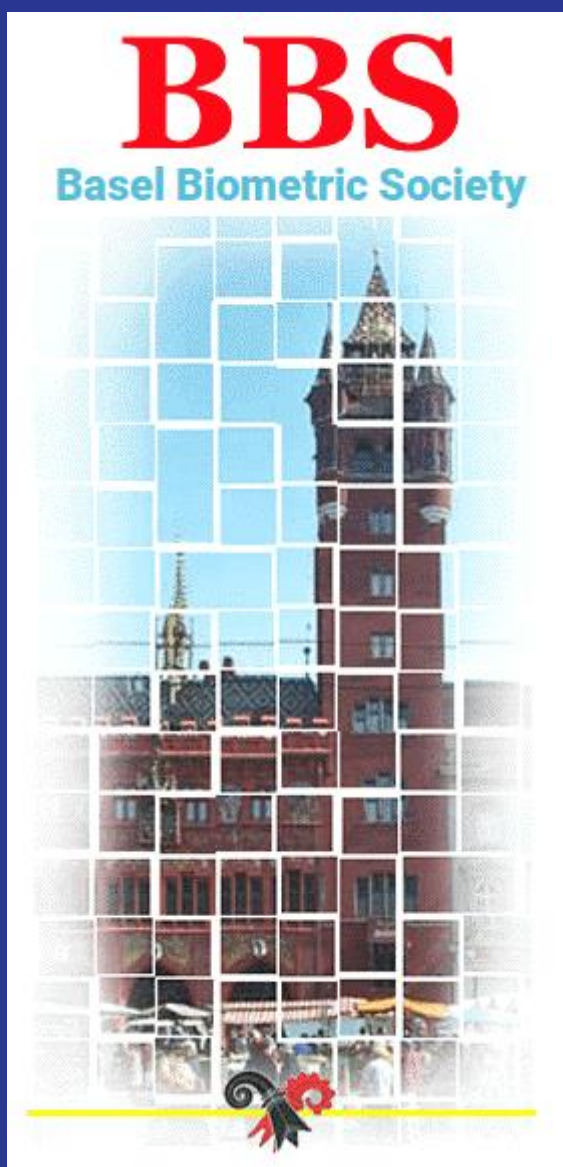The Local and Scientific Organizing Committees are looking forward to welcoming you in Paris !

10th STATISTICS & BIOPHARMACY CONFERENCE

Advancing drug development through innovative designs and efficient data use

Paris

8 - 10 October

Basel Biometric Society

Exciting Events from the Basel Biometric Society (BBS)!

The Basel Biometric Society (BBS) has been active in organizing insightful events to foster knowledge-sharing and innovation in the field of biostatistics. Here's a quick look at two recent events that took place:

Webinar: From Statistical Innovations to Common Practice
How to Innovate with Impact?On March 19th, BBS hosted a thought-provoking webinar on implementing statistical innovation effectively within organizations. The event provided valuable insights on identifying and overcoming barriers to the implementation of statistical methods. Industry and regulatory experts shared their experiences on how to make statistical innovation a strategic and impactful aspect of drug development. Attendees gained practical perspectives on driving meaningful change and advancing statistical practices within their organizations.

F2F event: Basel Biometric Society Meeting on Covariate Adjustment in Clinical Trials
Covariate adjustment is a well-known method in statistical modeling, yet its application in clinical trial analysis remains limited. The BBS organized a half-day meeting to address this topic, offering both theoretical and practical views on covariate adjustment. The meeting included case studies and discussions on aligning with FDA and EMA guidance for adjusting covariates in clinical trials. It was a valuable opportunity to understand the practicalities and regulatory perspectives of this approach.

To stay updated on future events in 2025 and to explore more about the BBS initiatives, visit the group's LinkedIn page.

Don't miss the chance to engage with the vibrant community of statisticians!

Women's Day Tribute: Florence Nightingale, Pioneer of Healthcare and Statistics

To celebrate Women's Day through the story of a remarkable woman who transformed healthcare and statistics, we honor **Florence Nightingale** (1820–1910).

Widely recognized as the founder of modern nursing, her contributions extend significantly into the realm of statistics, where she applied her analytical skills to address public health issues.

Born into an affluent British family, Nightingale received a comprehensive education, which was uncommon for women of her time. Her passion for mathematics and statistics became evident early on, and she later utilized these skills to effect substantial reforms in healthcare.

During the Crimean War (1853–1856), Nightingale led a team of nurses to the British military hospital in Scutari (now Üsküdar in Istanbul). She encountered deplorable conditions: overcrowding, poor sanitation, and inadequate supplies. Recognizing that disease was a more significant cause of mortality than battlefield injuries, she meticulously collected data on death rates and their causes. By analyzing this information, she identified unsanitary conditions as the primary contributor to high mortality rates.

To communicate her findings effectively, Nightingale employed statistical diagrams, including the "coxcomb" or polar area diagram. This innovative visualization illustrated the impact of improved sanitation on reducing death rates, making complex data accessible to both policymakers and the general public. Her work in this area is considered pioneering in the field of data visualization.

Beyond her wartime efforts, Nightingale's statistical acumen influenced broader public health reforms. She conducted extensive studies on sanitation in India, advocating for improvements that would reduce disease and mortality. Her reports combined statistical analysis with compelling narrative, emphasizing the necessity of sanitary reform in colonial and domestic contexts.

In recognition of her contributions to statistics and public health, Nightingale became the first female member of the Royal Statistical Society in 1858 and later an honorary member of the American Statistical Association.

Florence Nightingale's legacy endures in both nursing and statistics. Her application of statistical methods to healthcare demonstrated the power of data in informing policy and improving patient outcomes. As we celebrate Women's Day, we honor her pioneering spirit and the lasting impact of her work on science and society.

Andrea Nizzardo, Luca Grassano