



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

EFSPI Newsletter

Quarter 4 2024



EFSPI President 2024–2025

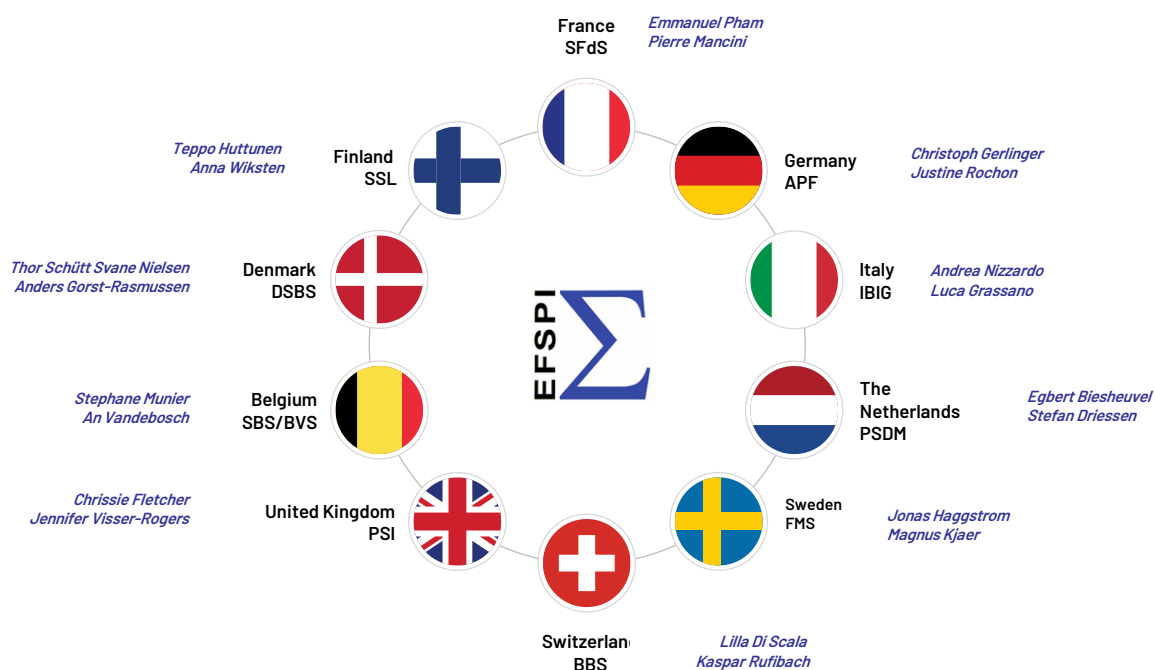
CONTENT

- Welcome
- EFSPI Council – Who we are
- Christmas greetings
- EFSPI activities and updates
- ESIGs Update
- National Groups updates

Welcome to
the 2024
fourth quarter
edition of our
newsletter!

EFSPI COUNCIL

Who we are



CHRISTMAS GREETINGS

Almost Christmas and the time of the year to finish business projects and slow down to celebrate the Christmas holidays with family and friends. Also, the time of the year to reflect. With the ongoing war in Ukraine, the situations in Gaza and Syria, I realise how lucky we are to live in free countries.

We may take this for granted, but because of this freedom we can do our daily work and in addition contribute to EFSPi as volunteer in one of the many ESIGs, the Statistical Leaders meeting, the Regulatory Statistics Workshop, Scientific and Training Academy, Regulatory Affairs, the Council, and many more

I want to sincerely thank you all for your commitment and collaborations in 2024. Without you there would be no EFSPi! And I feel honored to be EFSPi's president, with a special thanks to the Operational Board members for your support in my first year as president.

Knowing that I will not be complete, I nevertheless want to share some highlights that demonstrate our enthusiasm, commitment and drive to keep EFSPi successful and to strengthen our impact as statistical community: we have a newly formed Statistical Methodology Leaders group to highlight and lead methodological topics, strengthened our collaboration with the ASA BIOP to partner, share and learn from each other, the new website that is almost ready, the newly established Scientific and Training Academy, the closer connection to the Next Gen group, and new ESIGs on Causal Inference, AI/ML, Patient Focused Drug Development, CMC and others.

In 2025, we will continue all the good things of this year, based on our belief that successes will be created together as a community. In addition, we will celebrate our 10th Regulatory Statistics Workshop in September, launching our new website, activating a calendar of events, and expanding our partnership with the ASA BIOP, and closer connection to our next gen statisticians. We will keep you updated.

Please enjoy reading this newsletter!

Wishing you all a very nice holiday break with family and friends and all the best for a healthy 2025!

Egbert Biesheuvel,
President EFSPi.



EFSPI Council members - United Kingdom: Jennifer Visser-Rogers as new representative



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

Professor **Jennifer Visser-Rogers** is taking over the role of UK representative, succeeding Alun Bedding who has served with exceptional dedication.

We are deeply grateful to Alun for his invaluable contributions and commitment to the EFSPI group.

Few words about Jennifer: Jennifer is an accomplished consultant with a broad portfolio of achievement. Jennifer made the move into industry after a career in academia which included the University of Oxford where she was Director of Statistical Consultancy Services. She has a strong record in the development of novel methodologies in the design and analysis of clinical trials, working alongside other statisticians, clinicians, data scientists, industry experts, and regulators.

More recently, Jennifer has applied her expertise to industry, leading research teams in the CRO space and remaining at the forefront of innovation. She has experience of growing expert strategic consulting groups, developing some of the most influential and talented thought leaders.

A popular science communicator, Jennifer has made numerous media appearances and regularly works with journalists and government to improve the understanding of statistics. She was the 2020 winner of the annual HealthWatch award and named one of the Twenty Women in Data and Tech in 2024 by Women in Data®. A former Vice President of the Royal Statistical Society, Jennifer is the President of the International Biometrics Society, British and Irish Region, Director for Communications and External Affairs for Statisticians in the Pharmaceutical Industry, and Vice Chair of the Florence Nightingale Museum.

Welcome on board, Jennifer!

Q4 2024 EFSPI Council meeting

EFSPI Council Meeting Highlights – December 6, 2024 The recent EFSPI Council Meeting, held virtually, brought together members to discuss key updates and plans for the future.

The meeting began with a warm welcome to a new council member, whose fresh perspectives are expected to enrich the team's work.

Finance was a focal point of the closed session, with updates shared on the progress of the regulatory workshop. The group also addressed the need to fill a key position, fostering a productive conversation about future steps.

During the open session, representatives from national organisations shared updates on their ongoing activities and achievements, which underscored the diversity and vitality of the broader community. Communication strategies were another significant topic of discussion, with plans to enhance the website taking center stage. A new communication package was also introduced, which is expected to be a goal for the next year.

The council then turned its attention to nominations for an important scientific advisory board, with a productive discussion that will inform upcoming decisions. Updates from recent regulatory meetings provided valuable insights into developments affecting the community and sparked meaningful exchanges among participants.

After a brief break, the session resumed with an update on the regulatory workshop, highlighting its importance in addressing current challenges. The NextGen initiative was also discussed, with a focus on its progress and potential for fostering engagement within the community. Updates from the Scientific Committee and Training Academy followed, showcasing recent activities and plans for advancing professional development and scientific collaboration.

Special Interest Groups were another topic of interest, with updates emphasizing their collaborative efforts and the progress being made on various projects.

Discussions on honorary memberships explored ways to recognize significant contributions within the community, while broader leadership initiatives aimed at supporting the statistical field were also reviewed.

The meeting concluded with reflections on the discussions and an open forum for additional topics or ideas. Administrative matters, including legal and financial updates, were addressed to ensure smooth operations, and next steps were outlined to keep the council's momentum going.

This meeting reaffirmed the collective commitment to advancing the goals of the EFSPI community, and we look forward to continued collaboration and progress in the in the next year!

EFSPI ESIG Leaders Meeting A Constructive and Reflective Gathering

The recent ESIG Leaders Meeting, held on November 28th, was a truly constructive event, full of meaningful discussions and valuable reflections. This meeting brought together the leaders of EFSPI's 24 active ESIGs, providing a platform to explore ways to enhance their contributions, increase the visibility of their work, and ensure the scientific value of their activities is recognized appropriately.

Participants celebrated the achievements of the ESIGs and shared insights into their experiences, fostering an atmosphere of collaboration and mutual learning. A key focus of the discussions was identifying strategies to better highlight the impactful work of each group and to ensure it receives the recognition it deserves within the scientific community.

The meeting also provided an opportunity to strategize for the future, emphasizing the importance of continued innovation and collaboration. Leaders left the meeting feeling inspired and motivated to further EFSPI's mission by strengthening the contributions of their groups and showcasing the value they bring to the field.

We extend our heartfelt thanks to all who participated and look forward to seeing the positive outcomes of these discussions in the months ahead. Together, we continue to drive progress and excellence in statistical science.



NATIONAL GROUPS UPDATE

Arbeitsgruppe Pharmazeutische Forschung



Annual APF Meeting 2024: Advancing Drug Development for Rare Diseases

Staburo GmbH extends heartfelt thanks to everyone who attended the Annual APF Meeting 2024 on November 29 in Munich.

The event showcased a wealth of insights, collaborations, and innovations in the realm of drug development for rare diseases.

The day began with an inspiring opening statement from State Minister Gerlach and Prof. Dr. Anne-Laure Boulesteix, President of the German Region of the International Biometric Society (IBE LMU). Their words set the tone for a dynamic gathering of experts, researchers, and professionals dedicated to advancing treatments in this vital field.

Keynote Talks: Esteemed speakers, including Dr. Michael Kunz, Dr. Martin Oliver Sailer, Prof. Dr. Franz König, Dr. Tim Friede, Dr. Tobias Bluhmki, and Dr. Katrin Kupas, shared their knowledge and strategies, sparking meaningful discussions.

Working Group Updates: The APF working groups presented updates on their ongoing projects, highlighting progress and challenges.

APF Board Elections: Congratulations to the newly elected APF board members: Dr. Frank Langer, Dr. Thomas Bregenzer, Dr. Frank Fleischer, Dr. Cornelia Kunz, Susanne Schäfer, Dr. René Kubiak, and Dr. Jens-Otto Andreas. A special thank-you to Prof. Dr. Christoph Gerlinger for his steadfast support since 2009. We hope to see him at future events!

Panel Discussion: The concluding panel discussion featured Hans-Jürgen Lomp, Prof. Dr. Franz König, Prof. Dr. Tim Friede, Dr. Katrin Kupas, Dr. Tobias Bluhmki, and Dr. Tobias Mielke. Their dialogue fostered collaboration and explored innovative solutions. Networking and

Closing: The event wrapped up with an informal get-together and a lively beer tasting session, providing participants with the opportunity to forge new connections and exchange ideas in a relaxed setting.

Thank you to all speakers, panelists, and attendees for making this event a resounding success. Your contributions continue to drive innovation in the field of rare diseases. We look forward to future gatherings and furthering this essential work together!

NATIONAL GROUPS UPDATE

Italian Biostatistics Group



What an incredible success at the IBIG Forum 2024!

The pre-courses and the forum have been a fantastic achievement this year, thanks to all of you!

We had an outstanding turnout, with 63 biostatisticians, 7 PhD students, 6 professors, and 4 statistical programmers in attendance, representing diverse sectors: 34 from Pharma, 25 from CRO/consultancy, 13 from academia, 7 from research institutes, and even 1 from a health authority. With nearly equal representation—41 women and 39 men—the diversity and inclusiveness of our community continue to grow.

This year, we were also honored to welcome numerous high-level speakers, including several international experts who enriched the scientific content of the forum and raised the bar even higher.

The Steering Committee is deeply grateful for the enthusiasm and energy that all of you brought to these three days. Thanks to each of you, our group has grown significantly, and together, we have reached new heights!

Though IBIG Forum 2024 has wrapped up, our journey is far from over! Our drive to organize more events and initiatives is stronger than ever! But to do that, we need your help. Let us know what topics you'd like to explore and which areas you'd love to dive deeper into. We're here for you, so please reach out with your ideas and feedback to make our community even more vibrant!

A huge thank you to Chiesi Group for hosting us this year and to SIMeF ETS - Società Italiana di Medicina Farmaceutica ETS for their constant support and commitment to our initiatives!

Sincerely,

The IBIG Steering Committee

Marco Costantini, Giulia Zigon Andrea Nizzardo, Andrea Vele, Luca Grassano, Daniele Bottigliengo, Veronica Sciannameo, Elisa Rizzo, Stefano Vezzoli, Gabriele Filippo Di Domenico, Arturo Lanzarotti, Fabio Montanaro



NATIONAL GROUPS UPDATE

SFds Biopharmacie et Santé



SnB2025 Conference - Paris, Oct 8-10, 2025

"Advancing drug development through innovative designs and efficient data use"



On behalf of the Organizing Committee and the Scientific Committee, we are delighted to invite you to Paris for the 10th International Meeting on Statistical Methods in Biopharmacy. The SnB2025 Conference organized by the Statistics and Biopharmacy group of the SFds (French Society of Statistics) will be held in Paris 8-10 October 2025. It is a unique event, usually 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. The theme of this year's conference is "Advancing drug development through innovative designs and efficient data use". Multiple topics will be concerned such as challenges in small population trials, novel endpoints, use of external data, data visualisation, causal inference and bayesian approaches.

The conference venue is the Salon de l'Aveyron auditorium, located in Paris Bercy. The City of Paris is especially renowned for its museums and architectural landmarks (such as the Louvre which was the most visited art museum in the world in 2019), historical district along the Seine classified as a UNESCO Heritage Site, and many other monuments such as the popular Eiffel tower.

We are convinced that the SnB2025 will be as attractive scientifically as the city of Paris is charming. Therefore, mark your calendar now! Looking forward to meeting soon at the SnB2025

Estelle Lambert (Chair, Organizing committee) , Annette Kopp-Schneider (Chair, Scientific committee)

Pharmaceutical Statistics and Data Management



On 26th November 2024 PSDM organized their first so called 'Networking event'. The main purpose of this meeting was the local networking to stay connected, rather than having one main theme, and that worked very well. Together with a variety of presentations by and for the members of PSDM with topics of interest to data managers, programmers and statisticians this led to a successful event with around 30 people.

Presentations are available on our website [PSDM Networking Event 26 November 2024 – Pharmaceutical Statistics and Data Management](#)

This formula of a Networking event will be repeated in 2025.

CHRISTMAS GREETINGS



Dear EFSPI Community,

As this year draws to a close, the EFSPI Council would like to express its heartfelt gratitude to each of you for your continued support, enthusiasm, and engagement.

Your participation and affection have made this another truly remarkable year, and we feel privileged to have such an inspiring and vibrant community. We are already looking forward to the upcoming year, brimming with fresh ideas, exciting initiatives, and innovative opportunities that we hope will captivate, inspire, and involve you even more.

Wishing you and your loved ones a joyous holiday season and a prosperous New Year filled with happiness, health, and success.

Warm Regards,
EFSPI Council



Andrea Nizzardo, Luca Grassano
EFSPI Communication Officers