

EFSPI Newsletter

Quarter 4 2025



EFSPI President 2024–2025

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Welcome to our fourth newsletter of 2025!

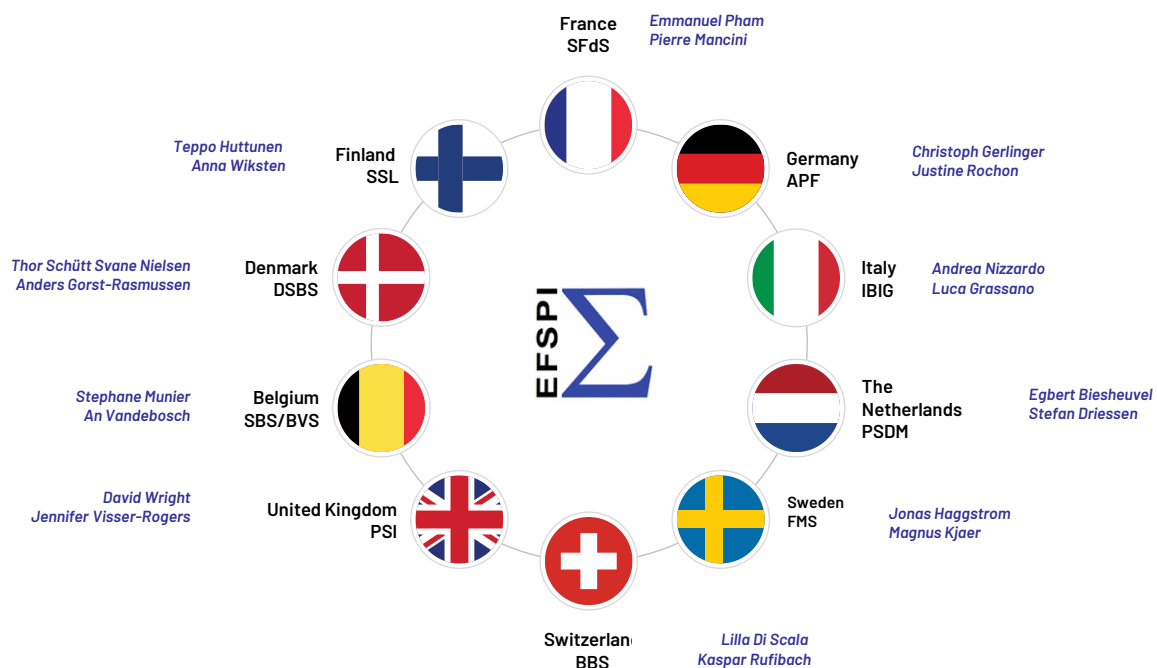
As we approach the end of the year, we are pleased to share this new edition of the EFSPI Newsletter. This issue brings together updates from across our community, including developments within Special Interest Groups, collaborative training initiatives, and activities led by national organisations.

It also reflects the continued commitment of EFSPI to fostering collaboration, learning, and scientific exchange across Europe. We hope this edition offers both a moment of reflection on the past months and inspiration as we look ahead.

Wishing you all a warm and inspiring end to the year!

EFSPI COUNCIL

Who we are



EFSPI PRESIDENT'S CHRISTMAS MESSAGE

A very warm welcome to our fourth and last Newsletter of 2025, the Christmas edition!

Just a few more days to go left to finalise projects and prepare for a well-deserved Christmas break to with family and friends. Also, a time to reflect on 2025 and look ahead to 2026. Time flies, but unfortunately not for everyone, as the war in Ukraine still continues and the situation in Gaza remains tense. I sincerely hope that 2026 will bring solutions for everyone.

In 2025, we were able to consolidate the great work we all do to promote and support statistics in the pharmaceutical industry and make an impact as a profession in global drug development.

This year, we celebrated our 10th EFSPi's Regulatory Statistics Workshop! What began as an informal initiate has grown into a well-known workshop with hot topics in a wonderful, informal and interactive atmosphere. In addition, we increased our strategic impact through our attendance at EMA meetings such as ICH E6, external controls and our influential role in the ICH E20 working group. We also maintained closer contact with the EFPIA and shared more information with our American colleagues in the ASA BIOP.

The ESIGS continue to flourish with more than 25 initiatives, and new ESIGS will be announced soon.

The annual in-person Statistics Leaders meeting demonstrates the importance of staying connected at leaders in a fast changing world.

We launched our new website, which has similar looks to the previous version, but offers much more flexibility to tailor the contents to our needs and provides storage space.

We are a healthy organization, both financially and in terms of succession planning. For example, we have Lilla di Scale as successor of Teppo Huttunen as Treasurer and Fredrik Öhrn as successor of Christoph Gerlinger as Regulatory Affairs Lead.

The above highlight some of our greatest achievements as a community and the reason why we are successful. Our success is the result of a lot of hard work of people who are passionate about statistics, and who understand the importance our profession to society, and how our work impacts people's lives.

It has been a pleasure and an honor to serve as EFSPi's president in the previous two years, and I'm pleased to hand over to Anna Wiksten, who will be our next president by the 1st of January 2026!

Please enjoy reading this newsletter!



EFSPI PRESIDENT'S CHRISTMAS MESSAGE



Wishing you all a very nice holiday break with family and friends and a healthy 2026!

Welcome to the new EFSPI president!

Dear EFSPI community,
I'm honored to serve as EFSPI president for the coming two years and to introduce myself to the European statistics community.

My journey with statistics and statistical communities started 20 years ago when I started to study statistics at University of Turku, Finland. From beginning I was fascinated by statistics and the opportunities it gives to model real life phenomena in many fields of science. The warm welcome in our student association made those years very happy and special. There I learned how valuable it is to have a community of like-minded people to solve statistical problems together.

Throughout my career, I have gained experience in statistics, statistical programming, and business development within a CRO, as well as late-stage drug development and statistical methodology for a global pharmaceutical company. I am currently an HTA and medical affairs statistician at Bristol Myers Squibb. I'm the Chair of SSL (Finnish country organization) and represent Finland in the EFSPI council. I get excited on many things, and if I feel my work is contributing to the core purpose of our industry - developing drugs - I happily move across roles and areas. Beyond statistics and drug development, I'm interested in organizational psychology and the impact it makes on our performance and wellbeing.

It is a great honor to serve EFSPI and I'm thankful for all the people working in different groups and making EFSPI a vibrant community. As president, I am dedicated to improving our infrastructure and promoting collaboration and learning for all members.

Before starting my tenure, I'd also like to express my sincere gratitude for the current president Egbert Biesheuvel for his leadership in the council the past 2 years and for the excellent onboarding during the past months.

I wish a wonderful holiday season for all our members and happy new year!

Sincerely,
Anna



EFSPI Scientific and Training Academy

The EFSPI Scientific and Training Academy is pleased to announce a mini-series of webinars on "Statistical Considerations in Oncology Study Designs", to be held in February 2026. There will be three sessions, each one organized by a country organization:

- Dose Finding in Oncology, hosted by SSL (Finland), on 10-Feb-2026, 13:30 – 15:00 (CET)
- Development of Combination Treatments in Oncology, hosted by APF (Germany), during the week beginning 16-Feb-2026 (date and time to be confirmed)
- Adaptive Designs in Oncology, hosted by IBIG (Italy), during the week beginning 23-Feb-2026 (date and time to be confirmed)

Participation is free of charge; however, registration is required for each session.

Details, including confirmed speakers and titles of the talks will be available on the EFSPI LinkedIn page shortly.

This mini-series is a great example of the added value created when national groups collaborate across borders, combining local expertise and perspectives to deliver a high-quality training offering to a broader European audience.



11th Regulatory Statistics Workshop

Apply to Join the Scientific Committee for the EFSPI Regulatory Statistics Workshop

Do you want to contribute to the scientific program of the EFSPI Regulatory Statistics Workshop?

The EFSPI Regulatory Statistics Workshop is a bespoke annual meeting that attracts an ever-growing number of participants. With recent workshops, we reached the venue's maximum capacity for face-to-face attendees. Additionally, several hundred colleagues joined us virtually from around the world.

The success of the workshop hinges on the Scientific Committee. Each year, under the leadership of our chair (currently: Vivian Lanius) the committee engages in in-depth discussions to design a strategic program. The committee is composed of regulatory and industry colleagues in approximately equal numbers. General principles for the composition of the Scientific Committee are summarized in the slide deck linked in the comments.

We are inviting applications for new members of the Scientific Committee. We are looking for individuals who:
Are willing to learn about the unique culture that has been built over a decade in organizing the EFSPI Regulatory Statistics Workshop.

Have extensive drug development and regulatory interaction experience with a statistics background, particularly senior individuals working on projects (project or compound statisticians).

Can devote time to about 4-6 preparatory TCs, put together sessions, plan and chair sessions, propose short topics, and attend the workshop in person (next workshop: 19-20 August 2026 in Basel).

The general selection criteria are (for details, check out the slide deck):

- Balanced representation of EFSPI regions.
- Maximal one member per company.
- Diversity in terms of age, gender, region, organization size, areas of expertise.

It is important to recognize that the work in the Scientific Committee is a very collaborative effort – contributing to the Scientific Committee is not about you and your career, it is about contributing to the continued success of the EFSPI Regulatory Statistics Workshop.

Industry Scientific Committee Members are generally elected for two years, with the potential to apply for a one-year extension.



If interested, please submit a short statement until 05th November 2025 with your background and what you would like to bring to the Scientific Committee to Vivian Lanius, vivian.lanius@ucb.com.

Special Interest Groups (SIGs) – Updates and New Initiatives

On 10 December, EFSPI held the Annual ESIG Leaders Meeting, bringing together leaders from across all Special Interest Groups to reflect on ongoing activities, welcome new members, and discuss future directions.

The meeting provided an overview of newly approved SIGs for 2025, alongside introductions of new leaders joining existing groups. Participants also received an update on the revised SIG Committee Operating Guideline, originally established in 2019 and now refreshed to better support the evolving SIG landscape. In addition, the session introduced EFSPI's DEIB Representative, highlighting how Diversity, Equity, Inclusion, and Belonging can be further embedded into SIG activities. An open discussion also took place on the new Teams collaboration area, gathering feedback from SIG leaders on opportunities to enhance cross-group interaction and knowledge sharing.

Two new SIG proposals were presented, reflecting both the growth and the scientific breadth of the EFSPI community:

- **Early Phase ESIG**

This newly proposed ESIG focuses on early phase clinical trials, a critical stage in drug development where sound statistical methodology is essential to ensure appropriate dose selection, schedules, and combinations. By bringing together statisticians from industry and academia, the group aims to improve the design and analysis of early phase studies, ultimately reducing the risk of suboptimal treatments progressing to later phases.

Key objectives include promoting best practices through training and publications, sharing real-world experience across stakeholders, and fostering a collaborative and supportive community.

- **Multi-Component Endpoints ESIG**

A second proposal introduced a SIG dedicated to multi-component endpoints, addressing the growing need for methods that better capture complex clinical outcomes. The group aims to explore structured approaches beyond traditional composite endpoints, with a focus on definition, analysis, interpretation, and alignment with the estimand framework.

This SIG seeks to stimulate open scientific debate, methodological development, and collaboration across industry, academia, and regulatory bodies through case studies, reviews, and training activities.

These discussions highlighted once again the central role of SIGs within EFSPI as engines of methodological innovation, collaboration, and community building. Further updates on the new SIGs and upcoming activities will be shared in the coming months.

The updated SIG Committee Operating Guideline is now available on the EFSPI website: [LINK](#)

EMA draft “Guideline on non-inferiority and equivalence comparisons in clinical trials”

EMA has published a draft guidance “**Guideline on non-inferiority and equivalence comparisons in clinical trials**”



Click [HERE](#) to read it

The draft guideline is now open for comments!

The PSI/EFSPI Regulatory SIG is collating comments from interested parties to provide to EMA.

Please forward consolidated comments from your organisation to Helle Lynggaard (hlyn@novonordisk.com) and to Florian Voss (florian.voss@sanofi.com) by 15 March 2026, using the form as specified on the EMA website.



Click [HERE](#) to download the form



NATIONAL GROUPS UPDATE

Italian Biostatistics Group



IBIG Forum 2025 – What a success!

We did it! Three incredible days of biostatistics, innovation, and networking here in the beautiful city of Naples have come to an end, and what an edition it's been!

This year, we really put you to the test... not just with statistics, but with food! 🍷 🍴
Between the scientific sessions and our very generous lunches, we might have created the perfect conditions for a classic postprandial nap, but once again, you amazed us with your enthusiasm, energy, and curiosity from start to finish.

We're so proud of what we've built over the years as the IBIG community, a growing network of Italian biostatisticians that's becoming increasingly dynamic, connected, and visible.

Your engagement pushes us to keep raising the bar: to connect professionals across companies and universities, to share ideas and best practices, and to make IBIG a truly vibrant and recognizable presence in Europe.

As always, we like to end by saying: the best is yet to come!

📅 For now, mark your calendars: October 21–23, 2026, because we've already started working on the next IBIG Forum 2026!

Stay tuned here on LinkedIn for updates on all upcoming IBIG events and initiatives, and once again, thank you from the entire IBIG Steering Committee for making this Forum truly unforgettable!



NATIONAL GROUPS UPDATE

Pharmaceutical Statistics and Data Management



On 25th November PSDM organized their 2nd networking event.

The main purpose of this meeting was the local networking to stay connected, rather than having one main theme for the event, and that worked very well.

Together with a variety of presentations by and for the members of PSDM, being interest to data managers, programmers and statisticians this lead to a successful event with almost 50 people.

Slides are available on our website [PSDM Networking Event 25 November 2025 – Pharmaceutical Statistics and Data Management](#)



CHRISTMAS GREETINGS



As we come to the end of another year, the EFSPI Council would like to sincerely thank all of you for your continued engagement, commitment, and support throughout 2025. Your active participation, open exchange, and collaborative spirit are what make EFSPI such a strong and vibrant community.

This year has been marked by important milestones, inspiring discussions, and meaningful connections across our network. As we look ahead to the new year, we are excited about the opportunities it will bring and the initiatives we will continue to develop together to support innovation, learning, and collaboration within our community.

We wish you and your loved ones a joyful holiday season and a New Year filled with health, happiness, and success.

Warm Regards,
EFSPI Council



Andrea Nizzardo, Luca Grassano
EFSPI Communication Officers