

EFSPi Newsletter

Quarter 3 2026



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Welcome to our second newsletter of 2026!

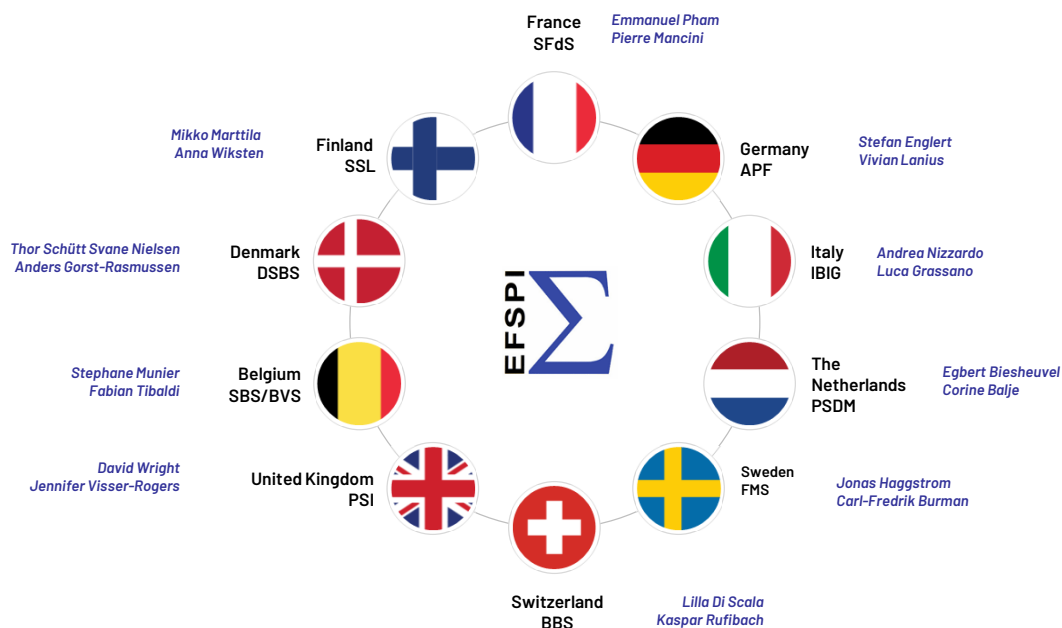
As we enter the final quarter of 2026, we are pleased to share the third edition of the EFSPi Newsletter. This issue highlights another exciting period for our community, bringing together updates from the EFSPi Council, Special Interest Groups, regulatory initiatives, and activities across our National Organisations

A particular highlight of this quarter was the successful 11th EFSPi Regulatory Statistics Workshop in Basel, which once again demonstrated the importance of open dialogue and collaboration between industry, academia, and regulators. We hope this edition provides valuable insights into our latest achievements and the many opportunities ahead.

Wishing you all an enjoyable and inspiring final quarter of the year!

EFSPi COUNCIL

Who we are



EFSPI PRESIDENT'S MESSAGE

Cool and scary - what is a good attitude and speed in exploring new areas?

This summer I had an opportunity to have a vacation in Finland. As I wanted to take the dog along, the only option was to drive, since the dog is afraid of airplanes and trains. Driving to Finland seemed like a long and exhausting trip, until my best friend said she would love to do the trip together. The long and demanding drive turned into a wonderful road trip through Germany, Denmark, and Sweden. After three days of driving we arrived at the ferry harbor near Stockholm, and my friend said, "this was so cool, I hope it had lasted longer".

Professionally and within EFSPI the most burning topic is obviously AI, and how it is changing the way we work and the opportunities we have. During the past 6 months I have had several "cool" moments, either by applying AI myself or seeing applications from others. Many of the ideas I didn't have time to explore earlier, I can now do with AI as my coding assistant. At the same time there are of course "scary" moments. How can we ensure things are correct? How will this impact our job market? How can statisticians evolve as professionals in drug development? AI is useful far beyond programming and automation: asking questions on any topic has become incredibly easy. But sometimes the answers are incorrect, with AI as well as with humans, and we need a good balance there. This is where many statisticians have a superpower: the ability to make sanity checks. Within EFSPI we are exploring this topic in several of our groups, and in council we are looking at what EFSPI can do as an association. We'd love to hear your thoughts too, please contact us with any ideas via email, LinkedIn, or in events.

In August we held the annual Regulatory Statistics Workshop in Basel. The event was a success, with almost 300 in-person participants and over 700 in total! What keeps astonishing me are the lively conversations and the relevance of the topics. This is of course not a coincidence; there are amazing people behind the event. I'm truly thankful to the local team and the scientific committee for all the hard work. You can now find all the recordings and materials on the event webpage.

Back to the question of balancing between cool and scary. On my road trip, there was a moment when I drove too fast on the German highway and my friend told me to slow down. "Even if I trust you, there are many other components you can't control, and driving too fast doesn't give you time to react". She was right, and maybe that is good advice for using AI too. Let's appreciate the cool things and get excited about the opportunities but keep a speed that leaves time to react. And Let's enjoy the ride!

Anna Wiksten, President, EFSPI.



EFSPI Council Meeting – August 2026

On 18 August 2026, the EFSPI Council met in Basel, kindly hosted by Roche, with additional participants joining remotely.

The meeting provided an opportunity to review ongoing activities, discuss strategic priorities, and strengthen collaboration across the European statistical community, just ahead of the 11th EFSPI Regulatory Statistics Workshop.

The Council welcomed **Stefan Englert** as the new representative for Germany, succeeding Christoph Gerlinger, and reviewed several important developments across EFSPI's activities.

Among the key highlights:

- **Statistical Leaders Meeting:** Building on the successful meeting held in Munich, the Council discussed how to translate its recommendations into concrete actions, focusing on strategic positioning, academic partnerships, and strengthening the role of statisticians in an evolving scientific landscape.
- **Scientific & Training Academy:** Preparations continued for a new pan-European event planned for 2027, with discussions focusing on strategic thinking, Artificial Intelligence, and the future of the statistical profession.
- **Regulatory Affairs:** Updates included contributions to EMA and FDA guideline consultations, particularly on non-inferiority and equivalence, master protocols, and substantial evidence of effectiveness, alongside preparations for upcoming regulatory initiatives.
- **Regulatory Statistics Workshop:** The 11th edition attracted more than 670 registered participants, including 289 attending in person, confirming its position as a flagship event for scientific exchange across Europe.
- **Special Interest Groups:** The Council reviewed ongoing SIG activities and international collaborations, reaffirming EFSPI's commitment to supporting scientific exchange and methodological innovation.
- **EFSPI Strategy and AI:** Discussions explored how EFSPI can further support its members in navigating the opportunities and challenges of AI in pharmaceutical statistics, building on contributions from the Statistical Methodology Leaders.

The Council also reviewed updates from National Organisations, financial sustainability, and the future membership model, with particular emphasis on strengthening the value offered to the EFSPI community.

Finally, the meeting marked a moment of transition, as Christoph Gerlinger and David Wright stepped down from their Council roles. EFSPI warmly thanked them both for their valuable contributions and welcomed Anna Berglund, who will succeed David Wright as the PSI representative.

Looking ahead, EFSPI remains committed to advancing scientific collaboration, supporting innovation, and creating new opportunities for statisticians across Europe.

The next Council meeting is scheduled for 4 December 2026.

EFSPI ACTIVITIES AND UPDATES

Welcome to the new EFSPI council members!

Mikko Marttila has taken on the role of one of the EFSPI Council members for Finland, succeeding Teppo Huttunen. We sincerely thank Teppo for his contributions and commitment to the EFSPI community over the years.

Mikko is a Senior Biostatistician at Orion Pharma, where he currently supports clinical drug development in the field of oncology. He has previously held roles in biostatistics, data science, and statistical research across industry and academia, including work at the Finnish National Institute for Health and Welfare (THL) and the University of Oulu.

Mikko holds an MSc in Statistics and has a particular interest in Bayesian methods, automation and streamlining of processes, and developing open-source software.



Stefan Englert has assumed the role of one of the APF representatives for Germany, succeeding Christoph Gerlinger. We extend our sincere thanks to Christoph Gerlinger for his outstanding contributions and long-standing commitment to the EFSPI group.

Stefan Englert is a Scientific Director in the Statistical Modeling, Methodology & Consulting group at Johnson & Johnson. He has more than 12 years of experience in pharmaceutical drug development, spanning first-in-human clinical trials through regulatory submissions and post-marketing support. His work focuses on advancing drug development through innovative statistical methodology and the estimand framework, ensuring that study objectives, clinical questions, and analysis methods remain closely aligned.

He has led the development and implementation of novel statistical approaches and supporting infrastructures, including adaptive and seamless trial designs, early-phase platform studies, and generative AI-assisted solutions for clinical trial design and statistical analysis planning.

Stefan is actively engaged in methodological research. He leads the Engagement Sub-Team of the EFSPI/EFPIA Estimand Implementation Working Group (EIWG), contributes to multiple professional initiatives, and is an active lecturer in biostatistics at the University of Heidelberg, Germany.

His research interests include the estimand framework, adaptive clinical trials, early oncology development, and the application of artificial intelligence in pharmaceutical research and development.

Artificial Intelligence in Drug Development

Artificial Intelligence continues to be one of the most prominent topics across the pharmaceutical and statistical communities, with growing interest in its potential to transform many aspects of drug development.

Recognising the strategic importance of this rapidly evolving field, EFSPI has increased its focus on AI-related activities during 2026, fostering discussions on both current applications and future opportunities for quantitative scientists.

AI is increasingly influencing areas such as evidence generation, clinical trial design, data analysis, modelling and simulation, knowledge management, and scientific communication. At the same time, the growing adoption of these technologies highlights the need for robust statistical thinking, methodological rigor, and critical evaluation of results to ensure that innovation is accompanied by scientific reliability and transparency.

As the field continues to evolve, EFSPI aims to support its members by facilitating knowledge exchange, encouraging collaboration across industry, academia, and regulatory stakeholders, and helping statisticians navigate the opportunities presented by AI-enabled methodologies.

Through these efforts, EFSPI seeks to contribute to the responsible and effective integration of artificial intelligence into the future of medicines development.

11th EFSPI Regulatory Statistics Workshop: Another Great Success!

The 11th EFSPI Regulatory Statistics Workshop, held on 19–20 August 2026 in Basel, once again brought together more than **670 registered participants**, including **289 attending in person**, from regulatory agencies, industry, academia, and HTA organisations.

Over two days of stimulating presentations, lively debates, and valuable networking opportunities, the workshop reaffirmed its position as a unique forum for open dialogue and collaboration within the European statistical community.

This year's programme covered a broad range of timely and relevant topics, including innovative clinical trial designs, novel patient-relevant endpoints, evolving regulatory guidelines, and the implementation of Joint Clinical Assessments under the EU HTA framework.

Particular attention was also given to the new draft EMA guideline on Non-inferiority and Equivalence, recent developments in baseline covariate adjustment, and the opportunities and challenges associated with synthetic data.

One of the highlights was the introduction of a new interactive format, where regulators posed questions directly to industry statisticians, complementing the traditional Ask the Regulators session. This innovative approach sparked engaging discussions and reinforced the workshop's distinctive spirit of open and constructive exchange.

Throughout the event, a common message emerged: meaningful scientific progress requires innovation, clear communication, mutual trust, and continuous dialogue between stakeholders.

Beyond the scientific programme, the workshop once again provided an invaluable opportunity to reconnect with colleagues, establish new relationships, and strengthen the European statistical community.



EFSPI ACTIVITIES AND UPDATES

A heartfelt thank you to all speakers, panellists, and participants for their valuable contributions, and especially to the dedicated volunteers who made this event possible!

Special thanks to our Local Organising Team:

Muriel B., Rima Izem, Almut Mecke, Tobias M., Jenny Devenport, Julie Jones, Vivian Lanius, Helle Lynggaard, Egbert Biesheuvel, and Kaspar Rufibach.

And to our Scientific Committee:

Elina Asikanius, Julie Jones, Jenny Devenport, Claudia Dallinger, Katrin Kupas, Vivian Lanius, Helle Lynggaard, Heidi Mestl, Anouk Neven, Khadija Rantell, Lukas Aguirre Dávila, Egbert Biesheuvel, Jan Lucca Bilek, Andreas Brandt, Sandro Gsteiger, Robert Hemmings, Benjamin Hofner, Seamus Kent, Florian Klinglmueller, Pierre Mancini, Kaspar Rufibach, Rafael Sauter, and Patrick Schloemer.

Looking Ahead to 2027: Join the Scientific Committee!

Preparations are already underway for the 12th EFSPi Regulatory Statistics Workshop, planned for 15–17 September 2027 in Basel.

Would you like to help shape the next edition? We are inviting expressions of interest from industry statisticians to join the Scientific Committee, contributing to the development of engaging, discussion-focused sessions on emerging regulatory and HTA topics.

Interested? Send a brief expression of interest to vivian.lanius@boehringer-ingelheim.com by 31 October 2026.

We look forward to continuing these inspiring conversations in 2027!



EFSPi Regulatory Statistics Workshop

12th Workshop on
15-16/17 September 2026
in Basel



REGULATORY UPDATES

Regulatory Guideline Reviews and Stakeholder Engagement

During Q3 2026, EFSPI continued its active engagement in regulatory science through the review of key consultation documents issued by both the FDA and EMA.

In collaboration with the PSI/EFSPI Regulatory SIG, EFSPI coordinated the collection and consolidation of comments from industry experts on the FDA draft guidance “Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products” and on the EMA draft Methodology Working Party (MWP) Workplan 2027-2029.

These consultations addressed a broad range of topics relevant to modern drug development, including evidence generation, estimands, modelling and simulation, synthetic data, external controls, innovative trial designs, and other emerging methodological challenges.

Through these initiatives, EFSPI provided a platform for statisticians and quantitative scientists across member organisations to contribute their expertise and practical experience to regulatory discussions. The coordinated feedback process helps ensure that industry perspectives are represented in the development of future regulatory guidance, while fostering constructive dialogue between regulators, academia, and industry.

Such activities remain a core component of EFSPI’s mission to advance statistical thinking and support the evolution of evidence-based decision-making in medicines development.

NATIONAL GROUPS UPDATE

Keeping Our Statistical Community Connected Across Europe!

As we enter the final quarter of 2026, our National Statistical Groups continue to bring the European statistical community together through scientific meetings, training courses, and networking opportunities. From Artificial Intelligence and adaptive designs to statistical methodology and professional development, the coming months offer plenty of opportunities to learn, exchange ideas, and strengthen collaborations across countries.

Here are some highlights from our National Groups, including recent activities and upcoming events. We encourage all EFSPi members to follow their National Groups' websites and LinkedIn pages for the latest updates, registration details, and opportunities to get involved!



Denmark (DSBS)

- 23 September: Course on Indirect Treatment Comparisons, delivered by Antonio Remiro-Azócar.
- 19–20 November: Joint DSTS/DSBS Meeting, hosted by Novo Nordisk, bringing together professionals and university students.
- Planning is underway for the 2027 DSBS/FMS Joint Meeting.



Finland (SSL)

- 27 October: Celebrating the 25th anniversary of SSL, with a special event dedicated to Lifelong Learning & Collaboration, featuring a contribution from EFSPi President Anna Wiksten.



France (SFdS)

- 1 September: Virtual conference From Biostatistics to AI in Healthcare, bringing together international experts.
- 5–6 November: Annual Biopharmacy & Health Meeting in Paris.
- Preparations are underway for a new SnB Conference in Paris in 2027, with the ambition of establishing a biennial event.



Germany (APF)

- 26 November: German Statistics Leaders Meeting, bringing together statistical leaders for strategic discussions.
- 27 November: 80th APF Workshop in Fulda, expected to welcome approximately 120 participants, with sessions on Artificial Intelligence and Baseline Covariate Adjustment (PROCOVA).

NATIONAL GROUPS UPDATE



Italy (IBIG)

- Preparations are entering their final stages for the IBIG Forum 2026 in October.
- The IBIG Journal Club has officially kicked off, providing a new opportunity for scientific discussion and knowledge sharing.
- Other ongoing and upcoming initiatives include university seminars, the CDISC Italian User Network, and a free one-day statistical seminar.



The Netherlands (PSDM)

- 4 November: Third Annual PSDM Face-to-Face Networking Event, featuring local speakers and opportunities for professional exchange.
- The society is progressing with its name update to Programming, Statistics & Data Management (in Life Sciences), reflecting the growing involvement of statistical programmers.



Sweden (FMS)

- Discussions are underway with the Swedish Epidemiological Society regarding a potential joint meeting.
- New opportunities for collaboration with the pharmacometrics community are being explored.
- The joint meeting with Denmark has been postponed to 2027.



Switzerland (BBS)

- 27 August: Digital Engagement Points, an in-person meeting at the University of Basel.
- 26–27 October: In-person Data Monitoring Committee (DMC) Course.
- November: Annual AI Meeting, planned in a hybrid format.
- December 1st: Hybrid seminar on Exploratory Subgroup Analyses in Clinical Trials



United Kingdom (PSI)

- 1 October: Webinar dedicated to ctDNA Data.
- 20–21 October: Training course on Adaptive Designs and ICH E20.
- Further scientific meetings, webinars, and training opportunities are available throughout the year via the PSI website.

ENJOY THE FALL SEASON!



Andrea Nizzardo, Luca Grassano

EFSPI Communication Officers

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