

EFSPI Newsletter

Quarter 2 2026



CONTENT

- Welcome
- EFSPI Council – Who we are
- EFSPI activities and updates
- ESIGs updates
- Regulatory updates
- National Groups updates
- Happy Summer Holiday!

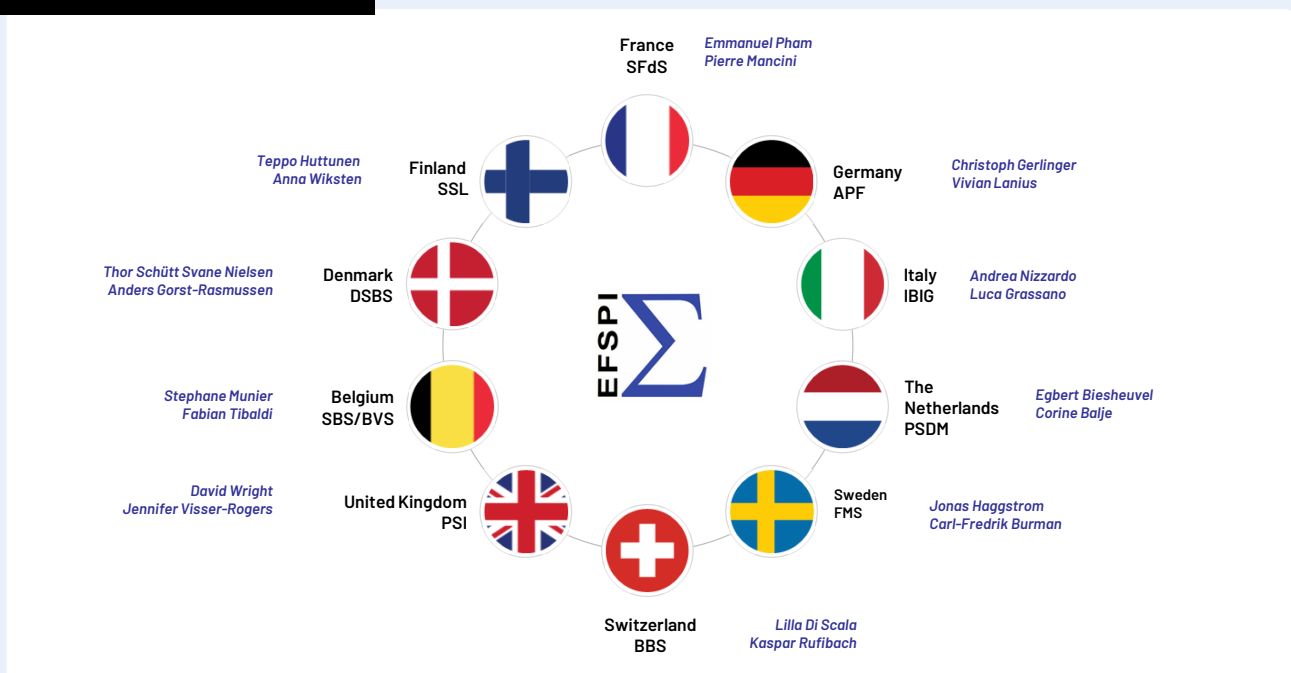
Welcome to our second newsletter of 2026!

As we move into the second half of the year, we are pleased to share this second edition of the 2026 EFSPI Newsletter. This issue brings together updates from across our community, including developments within SIG, collaborative training initiatives, and activities led by national organisations

It also reflects another active quarter for EFSPI, marked by the success of the Statistical Leaders Meeting and preparations for the upcoming Regulatory Statistics Workshop, one of the highlights of our annual calendar. We hope this edition offers a snapshot of the continued momentum within EFSPI and inspiration for the months ahead. Wishing you all a wonderful summer and a relaxing, well-deserved holiday!

EFSPI COUNCIL

Who we are



EFSPI Council Meeting – June 2026

On 12 June 2026, the EFSPI Council met virtually to review ongoing activities, discuss strategic priorities, and coordinate upcoming initiatives across the EFSPI community.

The meeting highlighted the continued momentum of the organisation and the strong collaboration between Council members, National Organisations, Special Interest Groups, and strategic working groups. A warm welcome was extended to several new representatives joining the EFSPI community, including Sue Rogers, Joana Marques Barros, and Carl-Fredrik Burman, reflecting the continued evolution and renewal of the Council.

Among the key updates discussed:

- Statistical Methodology Leaders reported significant progress on several strategic initiatives, including new publications, collaborations with regulators, and ongoing work on Bayesian methods, AI in drug development, covariate adjustment, estimands, and statistical methodology evaluation.
- Regulatory Affairs focused on defining EFSPI's future role in endorsing technical papers, with the Council agreeing to develop clear criteria and guidance for future endorsements.
- Scientific & Training Academy presented plans for a new pan-European meeting in 2027 dedicated to Statistics and Drug Development, aimed at bringing together statisticians at different stages of their careers through scientific sessions, networking, and professional development opportunities.
- Preparations for the 11th EFSPI Regulatory Statistics Workshop in Basel are progressing well, with the scientific programme nearing completion, poster submissions underway, and continued efforts to maximise participation and interaction between industry, academia, and regulators.
- A summary of the highly successful 2026 Statistical Leaders Meeting highlighted key discussions around artificial intelligence, methodological innovation, regulatory engagement, and developing the next generation of statisticians.

The Council also reviewed progress on several communication initiatives. The new EFSPI events calendar is now operational, the recently launched Jobs Board continues to grow, and the implementation of the Stripe payment platform has successfully streamlined registrations for EFSPI events.

Finally, updates from National Organisations and ESIGs once again demonstrated the breadth of scientific activities taking place across Europe, reinforcing EFSPI's mission of promoting collaboration, knowledge sharing, and innovation throughout the statistical community.

As preparations continue for the second half of the year, the Council looks forward to welcoming the community to Basel in August for another successful Regulatory Statistics Workshop and to advancing several new initiatives that will further strengthen EFSPI's role across Europe.

Towards a value proposition for statisticians and other quantitative scientists in AI-enhanced drug development

AI is reshaping drug development. In the future, it may extend to every aspect of our work, influencing workflows, functional roles and disciplines far beyond simple automation. Much has been said, ascertained and speculated, about this ongoing (r)evolution. As EFSPI's Statistical Methodology Leaders group, we propose to embrace this unique moment of opportunity and proactively shape this shift, for the benefit of the patients we serve.

To this end EFSPI have formulated six tenets:

1. As statisticians and quantitative scientists, let us actively embrace the opportunities offered by AI to automate, delegate or support a wide range of tasks.
2. Let us double down on those core strengths of ours that involve human judgement and generate the greatest value: scientific rigor, translating broad scientific questions into sound experiments, handling uncertainty, and facilitating rational, data-driven decisions.
3. Collaboration, communication and consultancy skills will remain a core capacity of impactful quantitative scientists.
4. Let us also continue to drive innovation in statistical and other quantitative methodologies beyond AI.
5. There is a tension between curiously engaging with new methodologies such as AI, and firmly holding the line of rigor and integrity of robust inference. Statisticians are experienced in living in this tension, and continuing to embrace it will be key to success.
6. Fostering the next generation of statisticians and quantitative drug developers may require a new approach.

Want to know more? Check out our viewpoint paper linked in comments. The paper reflects the consolidated opinion of the EFSPI statistical methodology leaders group and will serve as a starting point for further engagement of the group on this topic.

Thank you Marc Vandemeulebroecke for leading this effort!

Sincerely,

Mouna Akacha, Klaus Kähler Holst, Michael Krams, Baldur Magnusson, Aris Perperoglou, Kaspar Rufibach, David Wright.

EFSPI Methodology Leaders

EFSPI statistical methodology leaders have published discussion paper and made AI one of their priority topics

After its inception the EFSPI statistical methodology leaders have quickly integrated into the EFSPI ecosystem and broader drug development landscape in Europe and beyond.

The group has contributed to several EMA and EFSPI events, see here.

We also recently met face-to-face in Copenhagen (thanks to Novo Nordisk and Lundbeck for the hospitality!) to discuss the status of the five priority topics etc., see here.

The five priority topics currently being worked on are:

- Application of Bayesian methods in drug development.
- Covariate adjustment.
- Model Assumptions, Risks & Communication (ICH M15)
- Specific topics related to estimands.
- AI.

Finally, Jenny Devenport led the writing of the recently published manuscript Statistical Methodology Groups in the Pharmaceutical Industry. The journal (Statistics in Biopharmaceutical Research) has made this a discussion paper and invited three contributions, see here. The paper explores the setup, remit, and value of dedicated methodology groups in the pharmaceutical industry. It also examines the critical organizational considerations and success factors required to maximize their impact on decision-making and improve the speed, efficiency, and probability of success in drug development

Watch this space – more to come from this very active group!

👉 Additional information can be found here: [Statistical methodology leaders](#)

11th Regulatory Statistics Workshop

Registration is still open for the 11th EFSPI Regulatory Statistics Workshop!

Preparations are well underway for the 11th EFSPI Regulatory Statistics Workshop, which will take place on 19–20 August 2026 in Basel, Switzerland.

Over the years, the workshop has become a flagship event for the European statistical community, bringing together experts from industry, academia, HTA bodies, and regulatory agencies to discuss the most pressing challenges and emerging opportunities in pharmaceutical statistics.

This year's programme will once again feature a stimulating mix of scientific presentations and interactive discussions, including:

- Perspectives from regulators and industry experts on current statistical topics in drug development;
- The highly popular "Ask the Regulators" short topics session;
- A new interactive format where industry takes the "hot seat", allowing regulators to raise questions directly to industry statisticians;
- A forward-looking session dedicated to Synthetic Data, exploring its definitions, potential applications, and future role in drug development.

Beyond the scientific programme, the workshop continues to offer a unique environment for networking and open dialogue between all stakeholders, fostering collaboration and helping shape the future of regulatory statistics.

Basel in August also provides an ideal setting to combine scientific exchange with the opportunity to experience one of Switzerland's most vibrant cities.

We look forward to welcoming both returning participants and first-time attendees for two days of high-quality science, lively discussions, and valuable networking.

👉 Registration is now open: [Regulatory Statistics Workshop Registration](#)



Statistical Leaders Meeting

The EFSPI Statistical Leaders Meeting was successfully held in May 2026 in Munich, kindly hosted by Daiichi Sankyo.

The meeting brought together statistical leaders from across the pharmaceutical industry, with additional participation from regulatory agencies through both in-person and remote attendance.

The programme combined strategic discussions with scientific exchange, including an original host session exploring the geopolitical landscape in which the pharmaceutical industry operates, setting the scene for broader conversations on the future of our profession.

The meeting also featured an inspiring keynote presentation by Alexandre Templier, while David Wright chaired an engaging session on engagement with regulatory agencies and methodological innovation.

Several important themes emerged throughout the meeting. Participants discussed the evolving role of statisticians, emphasizing the need to strengthen our identity by connecting operational excellence with scientific leadership. There was broad consensus on the importance of engaging in multi-stakeholder collaborations, adopting a more strategic mindset, and embracing Artificial Intelligence as a powerful tool to enhance, rather than replace, statistical expertise.

Finally, considerable attention was devoted to developing the next generation of statisticians, ensuring that our profession continues to evolve and thrive in an increasingly complex environment.

Once again, the Statistical Leaders Meeting proved to be an excellent forum for exchanging ideas, strengthening collaborations, and shaping the future direction of pharmaceutical statistics.

Can't wait for the next year meeting!



Special Interest Groups (SIGs)

EFSPI Special Interest Groups (SIGs) continue to be highly active, driving scientific discussions and collaborative initiatives across many of the most relevant areas of pharmaceutical statistics.

Bringing together experts from academia, industry, and regulatory agencies, the SIGs provide an invaluable forum for sharing knowledge, developing best practices, and advancing innovative methodologies.

Following the launch of the Early Phase, Medical Devices, and Multi-Component Endpoints SIGs earlier this year, the SIG community continues to grow and expand its activities. Several webinars, publications, conference contributions, and collaborative projects are currently underway across the different groups.

EFSPI, together with PSI, is proud to support these initiatives, which continue to strengthen collaboration and innovation within the European statistical community.

We look forward to sharing updates and highlighting the achievements of the various SIGs in upcoming editions of the EFSPi Newsletter.

Anyone interested in joining one of these active groups is warmly encouraged to get involved!

List of our 27 SIGs



- *Artificial Intelligence/ Machine Learning (AI/ML)*
- *Application & Implementation of Medical Statistics (AIMS)*
- *Benefit-Risk*
- *Biomarkers*
- *Causal Inference*
- *Central Statistical Monitoring*
- *CMC*
- *Data Science*
- **Early Phase (*NEW*)**
- *Historical Data*
- *Health Technology Assessment (HTA)*
- *Launch & Lifestyle*
- **Medical Devices (*NEW*)**
- **Multi-Component Endpoints (*NEW*)**
- *Neuro Estimands*
- *Onco Estimands*
- *Openstatsware*
- *Patient Focussed Drug Development (PFDD)*
- *Pre-Clinical*
- *Quantitative Decision Making*
- *Randomisation*
- *Regulatory*
- *Real World Data (RWD)*
- *Small Populations*
- *Treatment Effect Heterogeneity*
- *Vaccines*
- *Visualisation*

“We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients.”

REGULATORY UPDATES

Draft FDA guidance: Master Protocols for Drug and Biological Product Development

FDA has published a draft guidance on Master Protocols for Drug and Biological Product Development (Link in comment) which is now open for comments.

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



Click [here](#) to read it!

Please provide consolidated comments by 10th August 2026 from your organisation to:

- Teresa Barata (Teresa.Barata@Roche.com)
- Elisabeth (Els) Coart (ecoart@argenx.com)
- Stefan Hantel (stefan.hantel@boehringer-ingenelheim.com)

For comments, use the following form!

We look forward to receiving your comments!



Click [here](#) for the Form!



NATIONAL GROUPS UPDATE

A Busy Year Across Our National Groups!

The Statistical National Groups continue to be at the heart of our community, with an impressive programme of scientific meetings, training courses, workshops, and networking events taking place throughout the year. Their activities reflect the diversity and vitality of the European statistical community, covering topics ranging from artificial intelligence and Bayesian methods to Real-World Evidence, oncology, and modern clinical trial methodology.

Below is a selection of some of the key initiatives that have already taken place or are planned for the remainder of 2026.

We encourage all EFSPI members to explore the LinkedIn pages and websites of the individual National Groups to stay up to date with their latest activities, discover new opportunities for collaboration, and register for events of interest!

Belgium (SBS/BVS)



- 13–17 July: UCouvain Summer School on AI and Python
- 14 September: KU Leuven workshop on Non- and Semi-parametric Inference in Contemporary Statistics

Denmark (DSBS)



- Successful Annual Meeting held in May, focusing on the new regulatory guidance on Bayesian methods with practical examples from Danish pharmaceutical companies.
- 23 September: Course on Indirect Treatment Comparisons
- 19–20 November: Joint DSTS/DSBS Meeting
- Planning has also started for the 2027 DSBS/FMS Joint Meeting.

Finland (SSL)



- The Annual Spring Seminar, dedicated to AI and Automation, attracted more than 40 participants.
- During the Annual Meeting, Petri Niemelä was elected as the new Chair, while Anna Wiksten continues to serve on the Board

NATIONAL GROUPS UPDATE



France (SFdS)

- 1 September: Conference "From Biostatistics to AI in Healthcare" in Paris.
- 5–6 November: Annual Biopharmacy & Health meeting.
- Preparations have also begun for a new SnB Conference planned for 2027.



Germany (APF)

- The first face-to-face German Statistics Leaders Meeting was successfully held in Freiburg.
- 5 November: German Statistics Leaders Meeting.
- 27 November: 80th APF Workshop, including a dedicated session on Artificial Intelligence.



Italy (IBIG)

- Preparations are well underway for the IBIG Forum 2026 in October, including pre-forum courses and sessions focused on topics selected by the community.
- Additional initiatives planned throughout the year include university seminars, the CDISC Italian User Network, the IBIG Journal Club, and a free one-day statistical seminar.



The Netherlands (PSDM)

- 4 November: Third Annual PSDM Face-to-Face Networking Event.
- The society is also progressing with its name update to Programming, Statistics & Data Management (in Life Sciences), while maintaining its well-established acronym and logo.



United Kingdom (PSI)

- The PSI Conference 2026 successfully took place in Belfast in June.
- Further scientific meetings, webinars, and training opportunities are available throughout the year via the PSI website.

HAPPY SUMMER HOLIDAY!



SUMMER BREAK, STATISTICAL STYLE!

