

EFSPI Newsletter

Quarter 1 2026



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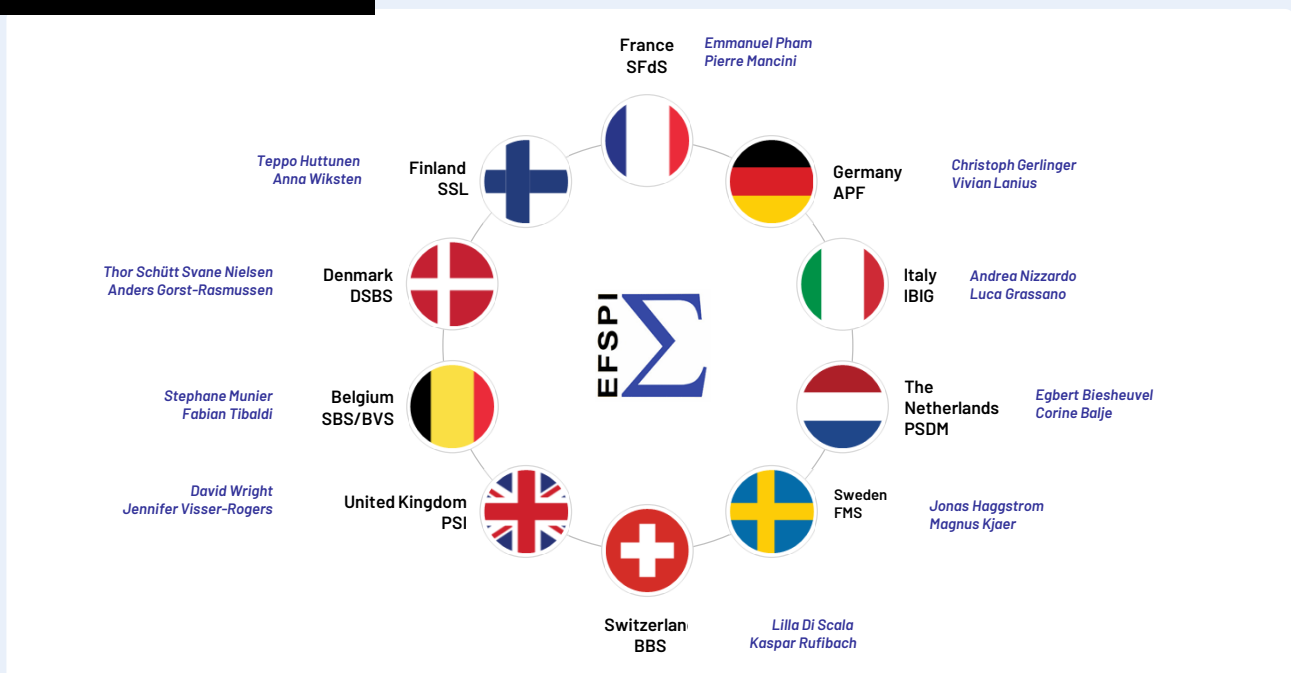
Welcome to our first newsletter of 2026!

As we begin a new year, we are pleased to share this first edition of the 2026 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 a period of transition within the EFSPI Council, with several changes and new roles shaping the future of our organisation, alongside many exciting initiatives currently in progress. We hope this edition offers a snapshot of the dynamic momentum within EFSPI and inspiration for the months ahead. Wishing you all a successful and inspiring start to the year!

EFSPI COUNCIL

Who we are



EFSPI PRESIDENT'S MESSAGE

A warm welcome to the very first newsletter of 2026!

The initial three months of 2026 have flown by, filled with many activities across the EFSPI community and plenty of learning for me as your new president. It's been inspiring to witness the enthusiasm within our groups and to observe the progress of events like EFSPI Stat Leaders and the regulatory workshop, each featuring exciting agendas. I've also greatly valued the individual conversations I've had with many members.

As president, I'm continually seeking ways to support EFSPI and its various teams most effectively, aiming to foster collaboration and forward momentum. I encourage all members to share their ideas, feedback, or questions—how can EFSPI best serve you?

I hope you enjoy this issue and let's stay connected!

Best wishes,

Anna Wiksten
EFSPI President



EFSPI ACTIVITIES AND UPDATES

Welcome to the new EFSPI council members!

Axel Krebs-Brown took over as chair of the EFSPI Scientific and Training (S&T) Academy from Jonas Häggström. Thank you to Jonas for leading the team over the past 2 years and thank you for staying with the academy to support its future work.

Axel works at Merck Healthcare KGaA in Darmstadt, Germany, where his main focus is on early phase and PK studies in healthy volunteers. In previous roles, he worked at GSK, Novartis, Syne qua non and Astellas. He was a member of the PSI Scientific Committee from 2007 to 2012 and joined the EFSPI Scientific Committee in 2013. The S&T Academy's replaced the Scientific Committee in 2023, broadening the scope to support EFSPI members' professional development, and to promote the appropriate and effective use of statistical methods in the pharmaceutical industry.



2026 will be a transition year for the Academy, as it rebuilds its activities which had come to an almost complete standstill during the pandemic. Plans for the coming years are ambitious yet realistic, and the Academy members look forward to welcoming many of you to 1-day meetings, training events, and webinars. Stay tuned and watch out for announcements!

As of 2026, **Corine Baljé Volkers** has taken on the role of one of the EFSPI Council members for the Netherlands, following Stefan Driessen's tenure. We sincerely thank Stefan for his many years of dedication, insight, and contributions to the EFSPI community.

Corine is the Founder and Managing Director of Clin Q, a specialized CRO providing programming and statistical support to (small) pharmaceutical, biotech, and medical device companies. She draws on 30 years of experience across diverse roles, all with a strong focus on statistics. Corine holds a master's degree in Mathematics with a specialization in Statistics and is a Certified Biostatistician.



Her expertise spans clinical trial design and analysis (Phase I-IV, and animal (toxicity) studies), DSMB, statistical training, and audits. She also continuously contributes to various publications, and is very interested in AI developments in the field of programming and statistics.

Beyond her leadership at Clin Q, Corine serves on the board of the Netherlands Pharmaceutical Statistics and Data Management (PSDM) group

Welcome to the new EFSPI council members!

Vivian Lanius assumed the role of one of the APF representatives for Germany, succeeding Justine Rochon. We extend our sincere thanks to Justine for her outstanding contributions and long-standing commitment to the EFSPI group.

As a Statistical Methodology Lead, Vivian supports the implementation of innovative statistical methods to advance drug development at UCB in Monheim. Her work is guided by a strong emphasis on clearly defining the scientific questions of interest and ensuring that study design and methods are closely aligned with overarching study objectives.

Vivian began her career in drug development as a trial statistician at Schering AG/Bayer AG after completing her PhD at the University of Dortmund.

Alongside her core responsibilities, she served as a co-organizer of a winter-semester lecture series in Berlin dedicated to methods and applications in biostatistics.

She is an active member and sub-team lead of the EFSPI/EFPIA Estimand Implementation Working Group (EIWG), currently represents UCB in the EFSPI Statistical Methodology Leaders group, and serves as Chair of the EFSPI Regulatory Statistics Workshop.



Fabian Tibaldi is an accomplished senior leader with over 25 years of experience in pharmaceutical biostatistics and vaccine development. He has a proven track record of delivering high-quality statistical analyses and successful regulatory submissions, including for Shingrix and Cervarix vaccines. After completing his PhD in Biostatistics from the University of Hasselt in Belgium, he joined Eli Lilly and later GSK Vaccines Belgium. He is passionate about scientific excellence, maintaining deep expertise in clinical trial methodology and regulatory frameworks. His extensive contributions include over 150 peer-reviewed publications and the supervision of more than 25 master's theses.



His specialties include Bayesian statistics, adaptive designs, complex clinical trials, and vaccine efficacy modelling, reflecting a strong commitment to advancing biostatistical science and public health. Additionally, he serves as a visiting professor at KU Leuven in Belgium and the University of Siena in Italy, where he contributes to the Master of Vaccinology program. He also chairs the PSI Vaccines Scientific Group, collaborating with representatives from various institutions and organizations worldwide. He serves as second representative for Belgium on the EFSPI Council.

EFSPI Council Meeting – March 2026

On March 13, 2026, the first EFSPI Council meeting of the year took place virtually, bringing together representatives from across Europe to discuss ongoing activities and future priorities.

The meeting covered a wide range of key topics, including updates from National Organisations, ESIGs, Regulatory Affairs, and preparations for upcoming events such as the Regulatory Statistics Workshop and the Statistical Leaders Meeting.

Among the main highlights:

- Progress on financial operations, including advancements in banking and transfer options, with the introduction of a Danish bank account and the implementation of Stripe for credit card payments
- Updates on the Scientific & Training Academy, including new leadership and the definition of a two-year strategic plan for 2026–2027
- First updates from the newly established EFSPI Senior Community, marking an important step in strengthening engagement across different career stages

In addition, the Council discussed communication activities, including website developments and upcoming newsletters, as well as ongoing collaborations and methodological initiatives.

The meeting once again highlighted the strong engagement of the EFSPI community and the continued commitment to collaboration, innovation, and knowledge sharing across Europe.

Please also note that the EFSPI head office in Sheffield has recently moved to: Fountain Precinct, Balm Green, Sheffield S1 2JA

We are also thrilled to announce that EFSPI has officially launched a brand new **job board** on our website!

This dedicated platform is designed to connect talented professionals with exciting opportunities in our field. We invite our community to visit the job board and, even better, to submit any relevant job vacancies from your organizations. More details are available on our website [here](#).

EFSPI ACTIVITIES AND UPDATES

EFSPI Scientific and Training Academy

In February 2026, the EFSPI Scientific and Training Academy successfully delivered a three-part webinar series on “Statistical Considerations in Oncology Study Designs”, organised in collaboration with EFSPI national groups from Finland (SSL), Germany (APF), and Italy (IBIG).

The series brought together experts from industry and academia to discuss key methodological challenges and practical considerations in oncology trials.

The first webinar, “Dose Finding in Oncology” (10 February, hosted by SSL), featured **Teppo Huttunen**, who presented the BOIN design for identifying Maximum Tolerated Dose (MTD) and Optimal Biological Dose (OBD) in early development, and **Pierre Colin**, who discussed dose-optimisation strategies in late-phase development.

The second session, “Development of Combination Treatments in Oncology” (18 February, hosted by APF), included contributions from **Burak Kuersad Guenhan** on dose-escalation trials for combination therapies, **Johannes Weirather** presenting a late-phase development case study, and **Stephan Wojciekowski**, who provided insights into the FDA draft guidance on cancer drug combinations.

The final webinar, “Adaptive Designs in Oncology” (26 February, hosted by IBIG), showcased innovative approaches with presentations from **Alessandra Serra** on adaptive biomarker-based designs, **Maria Vittoria Chiaruttini** on safety-driven response-adaptive randomisation in non-inferiority trials, and **Marco Ratta** on seamless phase 2/3 designs using multi-criteria decision analysis.

This series represents a strong example of cross-country collaboration within EFSPI, combining expertise from different national groups to deliver high-quality training to the wider statistical community.

👉 Materials from the webinars are available at: [Past Events – Efspi](#)



EFSPI Methodology Leaders

In this first quarter of 2026, we would like to celebrate the key achievements of the EFSPI Methodology Leaders group over the past year.

Among the main highlights:

- Three presentations at the EFSPI Regulatory Statistics Workshop, including the four priority topics, credibility frameworks/assumptions, and Bayesian methods
- Contributions to the EFSPI Statistical Leaders Meeting, with presentations on the group's priority topics
- Co-organisation of the BBS / EFSPI webinar "From Statistical Innovations to Common Practice: How to innovate with impact?"
- Collation and submission of comments on the draft ICH E20 guideline via EFSPI
- Contributions to EMA workshops on External Controls and Bayesian methods
- Strengthened collaboration with EFPIA Clinical Trial Innovation Pillar, EFSPI Regulatory SIG, and participation in discussions with MHRA
- Continued impact across the community, with knowledge sharing within companies and alignment of priorities across organisations

We are also pleased to highlight the submission of the article: "Statistical Method Groups: Driving Innovation and Collaboration in Pharmaceutical Statistics" — Devenport et al. (2026).

Looking ahead, the group will continue to drive impactful initiatives and contributions for the scientific community in 2026, starting with the annual face-to-face meeting in Copenhagen in April.

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

11th Regulatory Statistics Workshop

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

Join us in Basel on 19–20 August 2026 for this year's EFSPI Regulatory Statistics Workshop, bringing together experts from regulatory agencies, industry, and health technology assessment bodies.

The workshop will focus on today's most pressing strategic statistical topics in drug development, with a carefully curated program and outstanding invited speakers selected by the scientific committee. Expect high quality presentations designed to stimulate lively discussion and debate.

📍 The venue at Basel Biozentrum, combined with extended breaks between sessions, offers excellent opportunities to network, exchange ideas, and engage directly with regulatory colleagues, who are highly accessible throughout the event.

👉 The draft program, registration details, and FAQs are available on the conference website [here](#)

🔔 When registering, first select face-to-face or virtual. Please be mindful of meal / event selections to help ensure accurate numbers for catering and the best experience for all participants.

💡 As in previous years, participants are invited to submit a problem proposal for the popular "Short Topics" session. Selected submissions will be discussed with a panel of highly esteemed regulators.

📧 Proposals should be sent to **Vivian Lanus (Vivian.lanus@ucb.com)** by 19 June 2026.

We look forward to welcoming you in Basel or online for two days of insightful discussions and meaningful connections!



Special Interest Groups (SIGs)

EFSPI Special Interest Groups (SIGs) continue to play a central role in advancing statistical thinking across the pharmaceutical industry.

Covering a wide range of the most relevant and “hot” topics currently under discussion, these groups reflect the vibrancy and engagement of our community, as well as the importance of collaboration among experts from academia, industry, and regulatory bodies.

We are particularly pleased to highlight the launch of three new SIGs in 2026:

- Early Phase
- Medical Devices
- Multi-Component Endpoints

These new groups further strengthen our ability to address emerging challenges and opportunities in the field.

EFSPI, together with PSI, is proud to support and sponsor these initiatives, which foster knowledge sharing, innovation, and cross-functional collaboration across Europe.

Anyone interested in contributing to one of these groups is very welcome to join and become part of this active and growing community.

List of our 27 SIGs



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

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

REGULATORY UPDATES

FDA Draft Guidance on “Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval”

The FDA has released a draft guidance titled “Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval,” which is now open for public comments.

The PSI/EFSPI Regulatory SIG is gathering feedback from interested parties to submit to the FDA.



Click [here](#) to read it!

FDA Draft Guidance on “Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products”

FDA recently published draft guidance on the Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products, 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!



NATIONAL GROUPS UPDATE

PSI



The countdown to PSI Conference 2026 is ON! 🎉

Mark your calendars for June 14-17, 2026 at the ICC in Belfast, Northern Ireland.

Dive into expert talks, networking galore, and workshops on the latest in pharmaceutical statistics!



Basel Biometric Society



BBS
Basel Biometric Society

The Basel Biometric Society successfully hosted a face-to-face course delivered by Stephen J. Ruberg in Basel on March 25th: "Does This Treatment Cause That Outcome: A Practical Guide to Estimand Thinking."

The course provided valuable insights for clinical trial practitioners, helping statisticians and clinicians better understand and apply the estimand framework.

Participants explored how to align important clinical questions and objectives with appropriate study design, analysis approaches, and interpretation of results.

The session fostered thoughtful discussion and meaningful engagement across stakeholders, contributing to a clearer and more consistent application of estimand thinking in clinical research.

NATIONAL GROUPS UPDATE

Italian Biostatistics Group



IBIG Forum 2026 – Call for Abstracts & Posters!

 October 21–23, 2026
 Sapienza University of Rome

Following a highly successful community survey, which gathered strong engagement and valuable feedback, the main themes for this year's Forum have been defined as:

- Operational Issues in RCTs and Observational Studies, including sample size re-assessment, operational challenges, and practical case studies
- Early Phase Studies, with a focus on topics such as the FDA Optimus Project and dose optimisation strategies
- Real-World Evidence, including AI/ML applications, Target Trial Emulation, and External Controls

The Call for Abstracts for both talks and posters is now open, inviting contributions from across the community.

Submissions are encouraged on methodological challenges, case studies, innovative approaches, and practical solutions to real-world problems.

Selected speakers will be granted free access to the Forum, while poster presenters will benefit from a discounted registration fee.

This initiative aims to make the Forum increasingly practical, interactive, and representative of the evolving biostatistics landscape.

The IBIG Steering Committee welcomes contributions and is available to support interested participants throughout the submission process.

We look forward to your contributions and to seeing you in Rome!   

DID YOU KNOW?

Women's Day Tribute: Gertrude M. Cox, Pioneer of Applied Statistics



To celebrate Women's Day, we highlight the remarkable contributions of Gertrude Mary Cox (1900–1978), a trailblazer in applied statistics and a key figure in the development of modern statistical practice.

Gertrude Cox is widely recognized as one of the founders of modern experimental design and applied statistics. She played a pivotal role in bringing statistical methods from theory into real-world applications, particularly in agriculture, industry, and public policy.

At a time when few women were active in the field, Cox co-founded the Department of Experimental Statistics at North Carolina State University, one of the first of its kind. Her work helped shape how statisticians collaborate with scientists to design experiments and interpret data effectively.

Cox was a strong advocate for interdisciplinary collaboration, emphasizing the importance of statisticians working closely with subject-matter experts. She also contributed significantly to statistical education, mentoring generations of statisticians and promoting the practical use of statistical thinking.

In recognition of her impact, she became the first female president of the American Statistical Association (ASA) in 1956, marking a historic milestone for women in statistics.

Her legacy continues today through the widespread use of experimental design principles and the strong connection between statistics and applied sciences.

As we celebrate Women's Day, we honor her pioneering spirit and her lasting influence on the role of statistics in solving real-world problems.