



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

EFSPI Newsletter

Quarter 2 2025



EFSPI President 2024–2025

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Welcome to our third newsletter of 2025!

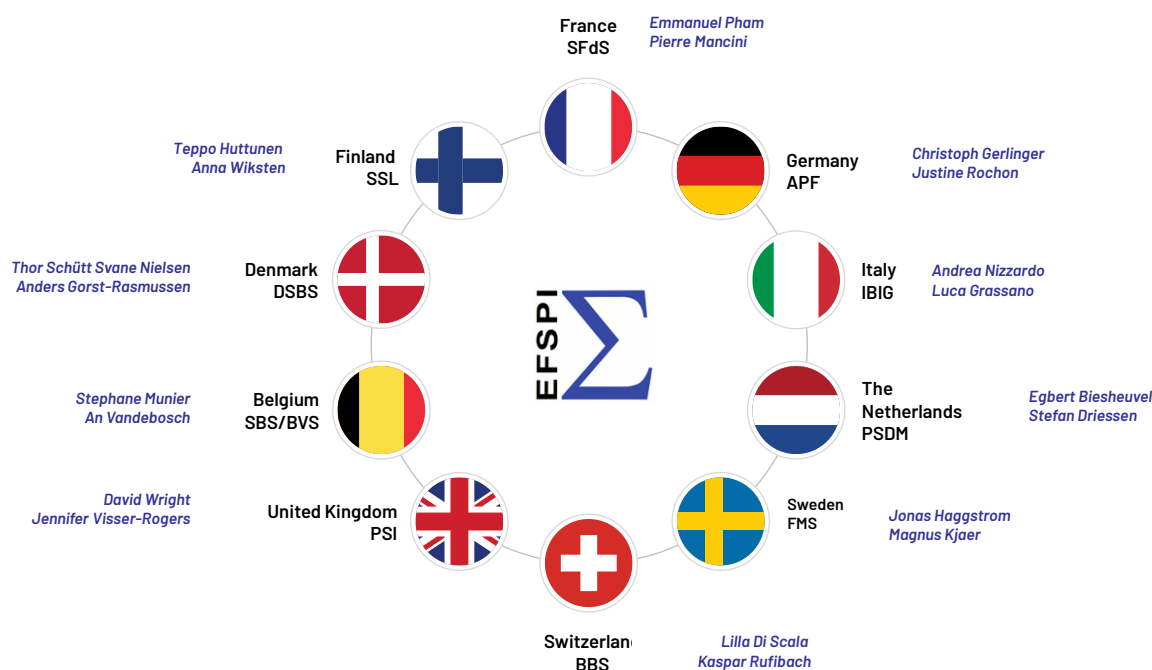
As we close the third quarter of 2025, I'm pleased to welcome you to this new edition of our newsletter. The past months have been full of activity for EFSPI, with productive discussions during our recent Council meeting in Basel and the great success of the 10th Regulatory Statistics Workshop.

Our community continues to grow and evolve, with new initiatives taking shape and exciting changes within the Council. I invite you to read on to discover the latest highlights and what lies ahead for EFSPI in the coming months.

Wishing you all an enjoyable and inspiring autumn season!

EFSPI COUNCIL

Who we are



3rd Council Meeting – Basel, September 2025

On 9 September 2025, the EFSPI Council met in Basel for its third in-person meeting of the year, just one day before the 10th EFSPI Regulatory Statistics Workshop.

It was a great opportunity to take stock of the progress made so far in 2025 and to plan ahead for what's next. The agenda covered ongoing priorities such as the continued enhancement of our new EFSPI website and the update of our Council job descriptions, ensuring clarity and continuity in the way we work together. We also discussed new initiatives that will further strengthen our federation and its visibility in the coming months, more details will follow soon!

The meeting was also marked by several important transitions within the Council, reflecting both continuity and renewal in our leadership team:

- Fredrik Öhrn has taken on the role of Regulatory Affairs Lead, succeeding Christoph Gerlinger, and will also serve as co-chair of the Regulatory ESIG. We extend our heartfelt thanks to Christoph for his many years of dedication and contribution to EFSPI, and we warmly welcome Fredrik to his new role.
- Anna Wiksten has been elected EFSPI President-Elect and will take over as EFSPI President in January 2026. Congratulations to Anna, who will bring great energy and vision to her upcoming mandate!
- Justine Rochon, our Vice President, will soon leave the Council to begin a new professional chapter in the United States. We thank her sincerely for her strong contributions to EFSPI and wish her every success in her new role abroad.
- Since our last Council meeting in June, Lilla Di Scala has taken over as Treasurer, succeeding Teppo Huttunen. A big thank you to Teppo for his work and commitment, and welcome to Lilla in her new position!

These changes once again demonstrate the dynamic and diverse character of the EFSPI Council, bringing together representatives from different national organisations and reflecting the collaborative spirit that defines our federation.

Meeting in person in Basel was not only productive but also energising. It reminded us how much can be achieved when ideas are shared face-to-face, and how valuable our community is, driven by enthusiasm, professionalism, and a shared passion for advancing pharmaceutical statistics across Europe.

It was wonderful to reconnect, exchange ideas, and celebrate the continued growth and vitality of the EFSPI community!

3rd Council Meeting – Basel, September 2025



10th Regulatory Statistics Workshop

From 10 to 12 September 2025, EFSPI celebrated a very special milestone: **the 10th edition of the EFSPI Regulatory Statistics Workshop**, held at the Biozentrum in Basel and online.

This anniversary edition gathered an impressive 648 participants from 33 countries, including over 60 representatives from regulatory competent authorities. Once again, the workshop confirmed its position as one of the leading forums in Europe for open scientific exchange between regulators, industry, and academia in the field of pharmaceutical statistics.

Over two and a half days, participants took part in a rich and diverse programme that sparked discussion, learning, and collaboration. The sessions covered a wide range of key topics shaping the future of regulatory statistics, from strategic priorities and adaptive designs to transportability and generalisability, target trial emulation, AI in clinical trials, hierarchical composite endpoints, Bayesian methods, and assumptions in drug development.

Each session fostered lively dialogue and critical thinking, reflecting the workshop's unique ability to bring together diverse perspectives under a shared goal: advancing innovation and sound statistical practice in the regulatory landscape.

The workshop was not only about science but also about community. The atmosphere was vibrant and friendly, with plenty of opportunities for networking, idea sharing, and informal exchanges. The famous pink bottles made their return, symbolising the workshop's collaborative spirit and the joy of reconnecting in person after months of preparation.

As part of the 10th anniversary celebrations, participants looked back at how far EFSPI and the workshop have come, from their roots in the DIA Statistics Workshop of the 1990s to today's dynamic and inclusive event that continues to grow year after year. Looking forward, we also caught a glimpse of the future shape of the workshop, which aims to become an even more interactive space for open dialogue, innovation, and balance between regulatory and industry statisticians.

A heartfelt thank you goes to everyone who made this milestone possible: the scientific and local organising committees, the chairs and panelists, and especially Vivian Lanius, whose leadership, commitment, and collaborative spirit were instrumental to the success of this edition. And, of course, a huge thank you to all participants for their enthusiasm, curiosity, and dedication, which make this event so special every year.

After two and a half days full of inspiring talks, engaging debates, and new connections, we can proudly say that this 10th edition has exceeded all expectations.

We are already looking forward to seeing you again for the 11th EFSPI Regulatory Statistics Workshop, which will take place on 19–20 August 2026 in Basel.

Until then, let's keep the conversation alive, together we continue shaping the future of pharmaceutical statistics!



10th Regulatory Statistics Workshop



NATIONAL GROUPS UPDATE

Italian Biostatistics Group



IBIG – RCT Day 2025, Milan

In September 19th we met at PoliHub – Milan, with the patronage of Politecnico di Milano, for a full day on “The Evolving Field of Design and Analysis of RCTs”.

The event was a real success, we even reached the maximum number of registrations! 🎉
This truly made us proud and showed once again the enthusiasm of the IBIG community!

A huge thank you to all speakers for their excellent contributions, and to all participants for making the discussions lively and inspiring.

🇮🇹 A quick snapshot of our participants: About 75% women and 25% men. Mostly from Biostatistics, Medical Affairs, Clinical Operations, and Quality Assurance. With strong presence from companies like Italfarmaco, Latis, Bayer, Menarini, IQVIA, Medineos, and many more.

We are proud to see such an engaged and diverse community, and we'll continue to create events with content that matters to you.



NATIONAL GROUPS UPDATE

Italian Biostatistics Group



IBIG

IBIG – Forum 2025, Naples

The Italian Biostatistics Group (IBIG) is getting ready for its flagship event of the year: the IBIG Forum 2025, which will take place on 22–24 October 2025 in Naples.

The three-day programme will start with two pre-courses on simulating complex trial designs and regulatory pathways for FDA submissions, followed by two full days of scientific sessions and discussions.

Forum topics will include the future of biostatistics and regulatory innovation (ICH E20 & ICH E6[R3]), AI and machine learning in pharmaceutical research, success prediction through innovative quantitative methods, Bayesian applications to RCTs, and the transition to R and open-source technologies.

Poster sessions will also offer participants the chance to share their work and exchange ideas with peers.

With its mix of technical depth, regulatory insight, and networking opportunities, the IBIG Forum 2025 promises to be a key event for statisticians, data scientists, and clinical researchers across Italy and beyond.



Day 1 – Pre-Forum Courses

A Practical Introduction to Simulating Complex Trial Designs
Pavel Mozgunov, Dominique-Laurent Couturier (MRC Biostatistics Unit, University of Cambridge, UK)

Regulatory Pathways: Mastering FDA Submission Strategies from Statistical programming point of view
Gabriele Di Domenico, Giulia Caldarazzo (GSK Vaccines, Siena)



Day 2 & 3 topics:

Statistics & Regulatory

Quantitative Decision-Making

AI/ML

Bayesian statistics in the context of RCTs

Transitioning to R/Open-Source

NATIONAL GROUPS UPDATE

Basel Biometric Society



BBS
Basel Biometric Society

BBS – Webinar on Patient Preference Studies

On 17 September 2025, the **BBS Suisse Romande** hosted an engaging webinar titled “Patient Preference Studies: What Do We Know Now?” featuring Andrea Phillips Beyer as invited speaker.

The session offered a comprehensive overview of the latest developments in patient preference studies, bridging insights from health outcomes, regulatory policy, and quantitative research. This event once again demonstrated the strong interest of the BBS community in emerging methodological and regulatory topics that connect statistical innovation with patient-centred approaches.



NATIONAL GROUPS UPDATE

Basel Biometric Society



BBS
Basel Biometric Society

BBS – Training Course on Data Monitoring Committees

The Basel Biometric Society (BBS) will host an in-person training course on Data Monitoring Committees (DMCs) on 14–15 October 2025 at the Novartis Campus, Basel, Switzerland.

This two half-day course will provide a comprehensive overview of the purpose, structure, and operations of DMCs in clinical trials and development programmes. The agenda will cover topics such as the historical evolution of DMCs, regulatory guidance from EMA and FDA, and practical aspects including DMC charters, reporting, and meeting organisation.

The training will feature interactive sessions and case studies facilitated by experienced speakers from both academia and the pharmaceutical industry, offering insights for participants with all levels of experience. Special attention will be given to the role of DMCs in adaptive designs, accelerated approvals, and other complex settings.

👉 Please note: Capacity is limited to 40 participants, and registration is mandatory. A small registration fee (CHF 50) applies.

BBS training course on Data Monitoring Committees (DMCs)

October 14th, 13:00-17:30

October 15th, 8:30-12:00

In person only at Novartis Campus, Basel, Switzerland



Stats Word Search – A challenge for our Readers!

Take a short break and test your statistical detective skills!

Hidden in this grid are key concepts, famous statisticians, and classic terms from our field... and a secret phrase waiting to be discovered.

Can you find them all and the hidden message? 

P	D	S	U	R	V	I	V	A	L	E	U	E	N	L
E	N	P	O	S	T	E	R	I	O	R	V	A	S	I
A	A	R	G	L	O	P	E	A	N	I	I	T	C	K
R	M	F	N	A	E	D	E	R	T	S	U	Y	O	E
S	I	A	I	U	T	I	O	P	E	D	N	T	R	L
O	T	O	L	D	F	S	A	Y	E	T	A	I	R	I
N	S	T	P	I	I	D	A	N	S	T	I	L	E	H
A	E	R	M	S	A	B	T	C	I	A	N	A	L	O
V	S	E	A	E	F	I	S	H	E	R	I	S	A	O
O	N	W	S	R	T	H	S	E	Y	A	B	U	T	D
N	E	O	P	H	A	R	M	A	C	G	E	A	I	U
A	S	P	E	A	R	M	A	N	T	A	I	C	O	C
E	C	N	E	D	I	F	N	O	C	U	A	L	N	I
E	S	T	I	M	A	T	E	N	D	S	U	S	T	R
P	R	I	O	R	E	G	R	E	S	S	I	O	N	Y

adaptive

anova

bayes

bayesian

causality

confidence

correlation

estimand

estimate

fisher

gauss

likelihood

pearson

posterior

power

prior

regression

residuals

sampling

spearman

student

survival