European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter

Quarter 3 2024

EFSPI President 2024–2025

CONTENT

Welcome to the 2024 third quarter edition of our newsletter!

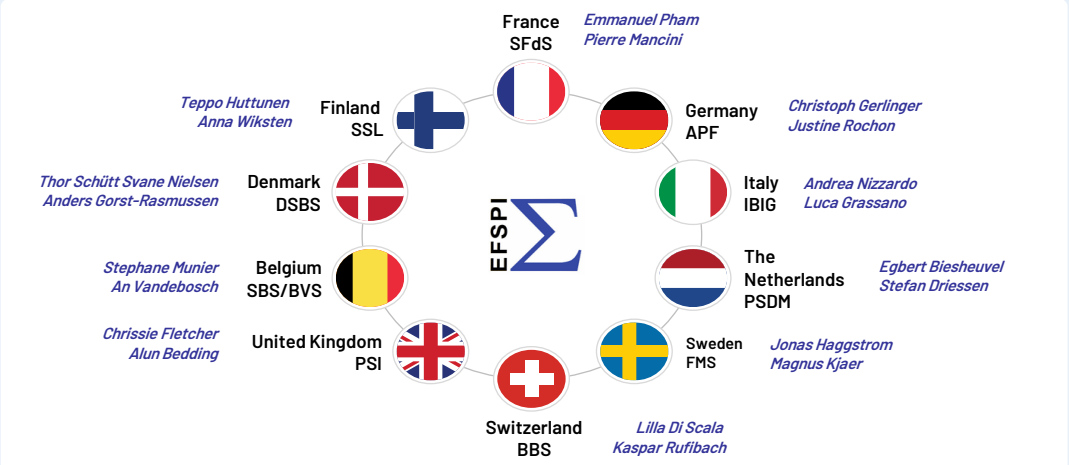
As we have ended the third quarter of 2024, we're excited to reflect on the successful events that have significantly enhanced EFSPI's visibility.
This quarter has been marked by a series of engaging and impactful initiatives, including the highly successful 9th Regulatory Statistics Workshop, which brought together industry experts and fostered valuable collaboration.

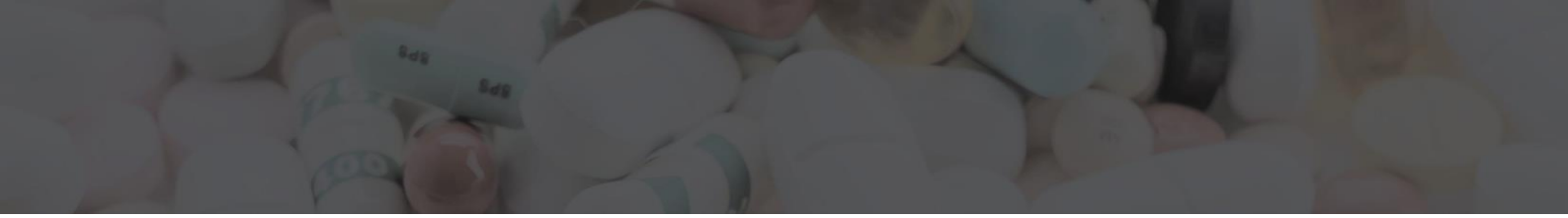
Our community's involvement continues to grow, and we're thrilled with the momentum building around these events. Additionally, our LinkedIn page has seen increased activity, and we encourage you to follow us there for real-time updates on upcoming events, initiatives, and insights.

Thank you for your continued support, and we look forward to an even more impactful final quarter.

Best Regards,
Your EFSPI President
Egbert Biesheuvel

EFSPI COUNCIL Who we are

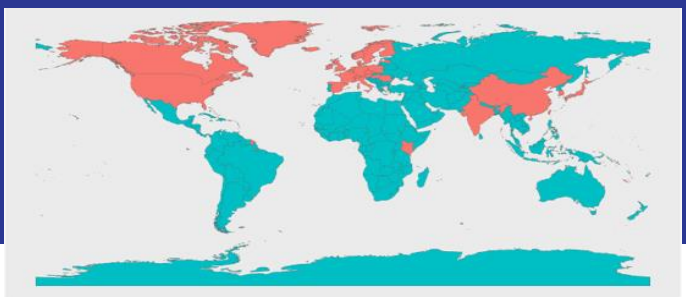




9th EFSPI Regulatory Statistics Workshop

The 9th EFSPI Regulatory Statistics Workshop held in Basel from September 11-13, 2024, was a resounding success, attracting an impressive turnout of over 774 participants (450 virtual, 324 F2F) from across the globe. Attendees included a strong mix of representatives from pharmaceutical companies, regulatory agencies, CRO, Biotech, Academia, and consulting firms, creating a richly diverse audience of statisticians and experts in regulatory science. Regulatory professionals from leading authorities like the EMA, FDA, MHRA, and PEI joined industry professionals from over 20 countries, making this workshop one of EFSPI's most internationally representative events to date.

This year's agenda covered a broad spectrum of critical topics. The opening session sparked engaging discussions on the balance between swift market access and robust data, a theme that resonated widely with participants. Subsequent sessions included rapid presentations on various statistical challenges and feedback from regulatory panels, a reflective celebration of the 5th anniversary of the ICH E9(R1) Estimand Framework, and an in-depth exploration of the evolving regulatory landscape in China. Participants also examined patient-centered approaches in drug development, discussed innovative methodologies in EU HTA, and evaluated the role of open-source statistical software in regulatory processes. The final day closed with sessions on advanced methodology in HTA, highlighting the forward-thinking aspects of this year's program.



Throughout the workshop, attendees engaged in lively panel discussions and posted updates on LinkedIn, further amplifying the event's reach and real-time impact. The enthusiastic participation and high level of interaction confirmed the event's status as a premier forum in the field of regulatory statistics.

We are deeply grateful to the organizing committee and all attendees for their invaluable contributions. As we look ahead, we invite everyone to join us in celebrating the 10th anniversary of this workshop next year—a milestone that promises an even greater exchange of ideas, insights, and innovation. Mark your calendars for what is sure to be an exceptional event on 10-12 September 2025!

Kaspar Rufibach
Helle Lynggaard
EFSPI

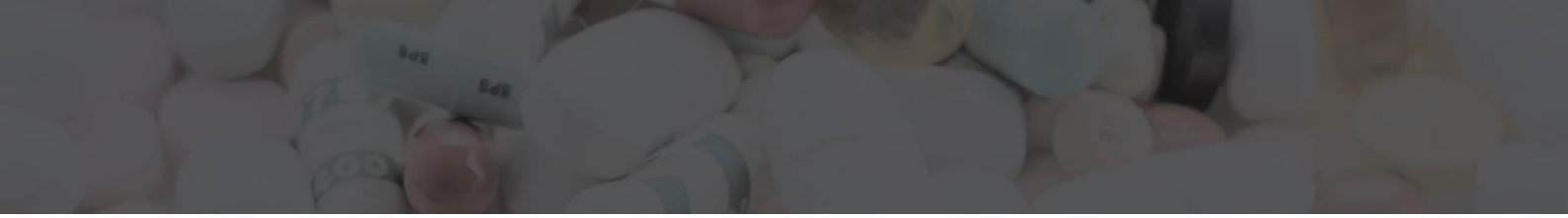
Past events? Click here

EFSPI and ASA Strengthen Transatlantic Ties

EFSPI is delighted to have played an active role in the ASA's Regulatory-Industry Statistics Workshop (RISW) 2024, an event that reinforced the growing collaboration between statisticians in the EU and U.S. Representing EFSPI were prominent leaders: former EFSPI President Justine Rochon, soon to join the ASA Biopharmaceutical Section Board, Emmanuel Zuber, co-chair of EFSPI's Statistics Leaders Meeting, and Mouna Akacha, head of EFSPI's Methodology Leaders group.

These dedicated members actively contribute to EFSPI's mission of advancing statistical expertise and innovation, and their presence at RISW highlighted EFSPI's commitment to building a stronger global statistical community.
This collaboration with the ASA Biopharmaceutical Section was instrumental in creating valuable connections and shared insights, furthering EFSPI's mission of knowledge exchange across borders. Justine Rochon shared a heartfelt message with RISW attendees, reflecting the positive spirit of partnership that drives our joint endeavors. With Justine set to join the ASA Biopharmaceutical Section Board from 2025 to 2027, we are confident that this partnership will grow even more impactful.

EFSPI looks forward to future collaborations with the ASA, creating opportunities for shared learning and progress in regulatory statistics. Here's to even closer ties and more successful joint events that continue to enhance the global landscape of statistical science!



Q3 2024 EFSPI Council meeting

EFSPI is thrilled to share some insights from our recently concluded Q3 EFSPI Council meeting. As per our annual tradition, we held the meeting face-to-face in Basel, fostering a sense of unity and collaboration among our members.

The meeting was a whirlwind of insightful discussions and updates. We had the privilege of hearing from various National Organisations, each sharing their unique perspectives, progress and future events. The upcoming Regulatory Statistics Workshop was certainly a hot topic, promising to be an event filled with knowledge sharing and innovation in the next couple of days.

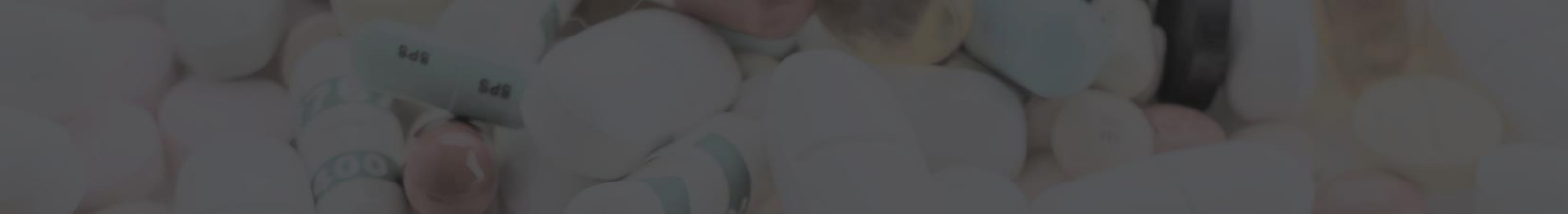
Our ESIGs (click here), Scientific & Training Academy were also in the spotlight, showcasing their recent achievements and future plans. The enthusiasm and dedication of these teams are truly inspiring!

We also delved into the exciting world of the BBS – Basel Biometric Society NextGen, discussing its potential and the opportunities it presents. Updates regarding the EFSPI's contributions to regulatory interactions were also presented, highlighting the increased relevance of the federation in this context.

Last but not least, we received updates from the Communication Office, keeping us connected and informed. Their tireless efforts in boosting the EFSPI presence on social media and digital channels are greatly appreciated.

As we move forward, we are excited about the progress we've made and the opportunities that lie ahead.

Stay tuned for more updates!!



EFPSI New Website

EFSPI is thrilled to announce that we are unveiling a completely redesigned and upgraded website, created in collaboration with the talented team at Fluidamente.
The new EFSPI site is built to be more attractive, dynamic, and incredibly user-friendly, designed with you in mind!

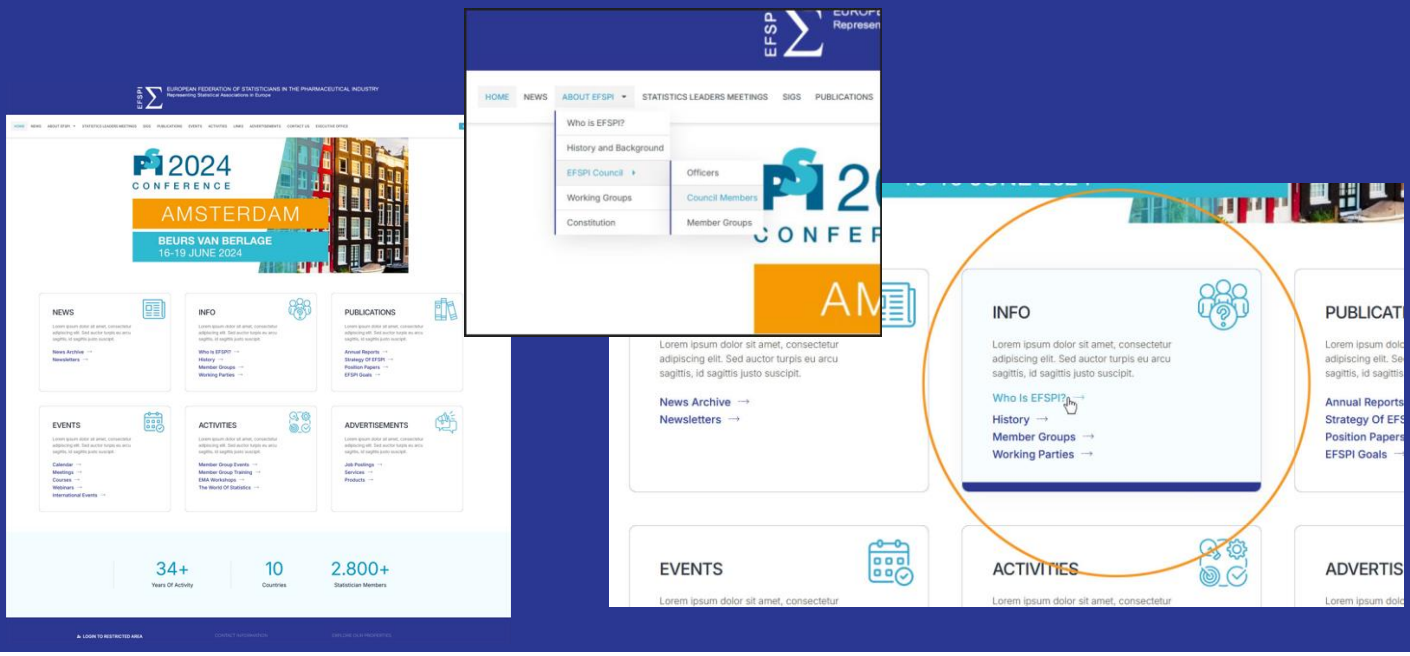
Our upcoming website will not only feature a fresh, modern look but will also make it easier than ever to access key information. Whether you're looking for the latest event details, organizational updates, or essential documents like this newsletter, everything will be just a few clicks away.

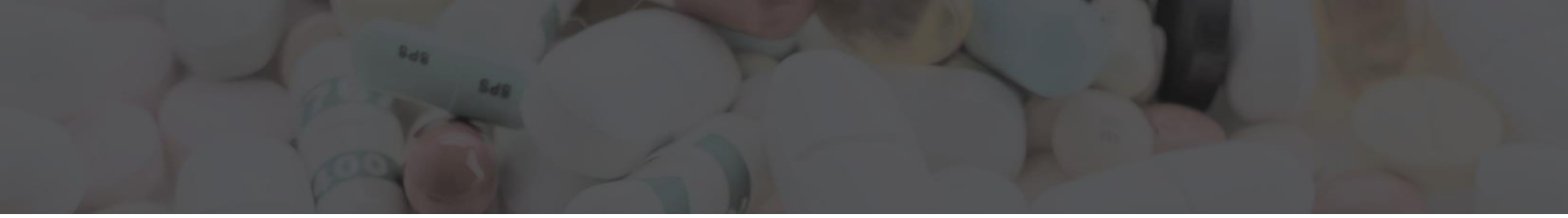
New Functionality Highlights:

- ❑ Event Management: Stay updated on all EFSPI events with streamlined registration and scheduling options.
- ❑ Materials Storage: Access a centralized library of resources, ensuring that important documents and materials are always at your fingertips.
- ❑ Working Group Repository: The new website will include restricted-access sections where each working group can safely share and store materials. These dedicated areas will make it simple and secure for groups to collaborate and manage their documents with ease.

We're putting the finishing touches on the new site and can't wait for you to experience it.

Stay tuned to our LinkedIn page for updates and be among the first to explore the new EFSPI website when it goes live!





ESIGs UPDATE

Pre-Clinical SIG WG

Webinar: Driving Efficiency in R&D – SVEM and Advanced DOE for Preclinical Toxicity Testing.

The Pre-Clinical SIG (click here) organized a successful webinar focusing on innovative strategies to improve efficiency in pharmaceutical R&D, particularly in preclinical toxicity testing. As advancements in AI, lab automation, and closed-loop optimization continue to enhance productivity, the need to minimize experimental runs remains crucial, especially in ethically sensitive areas such as animal testing.

The webinar explored how cutting-edge statistical Design of Experiments (DOE) techniques, including Definitive Screening Designs (DSDs) and Orthogonal Minimally Aliasing Response Surface (OMARS) designs, are revolutionizing the exploration of complex systems with fewer experiments. The session also introduced Self-Validated Ensemble Modelling (SVEM), a new analytical method applying machine learning principles to small data sets from designed experiments, providing robust models even with limited data.

A case study on preclinical toxicity testing of an oncology drug formulation illustrated these methods in action. This (simulated) study examined how formulation factors like the concentrations of Erlotinib, Cisplatin, and Dexamethasone, along with pH and particle size, influenced toxicity and efficacy outcomes in a rat model. Key responses measured included tumor inhibition rate, survival rates, and a spectrum of toxicity indicators, encompassing hepatic, renal, cardiac, and hematological effects.

Participants left the session with a deeper understanding of how advanced DOE and SVEM can drive efficiency and improve data quality in preclinical research, setting a foundation for more ethical and productive R&D practices in pharma

NATIONAL GROUPS UPDATE

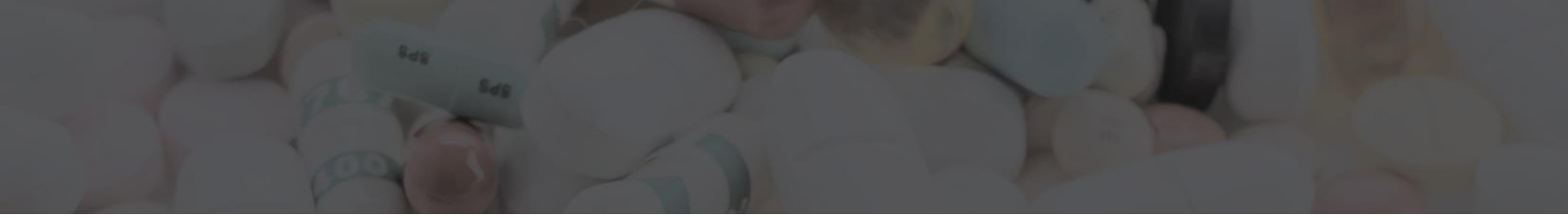
Italian Biostatistics Group

IBIG Forum 2024 (29-31 October): A Huge Success!

IBIG Forum 2024 brought together a vibrant community of biostatisticians, PhD students, professors, and programmers from diverse sectors. With strong gender balance and an impressive lineup of expert speakers, the event set a new standard for collaboration and knowledge-sharing in our field.

Thanks to all participants for their enthusiasm, and to Chiesi Group and SIMeF ETS for their invaluable support.

Stay tuned for more highlights in the Q4 EFSPI newsletter!



NATIONAL GROUPS UPDATE

PSI

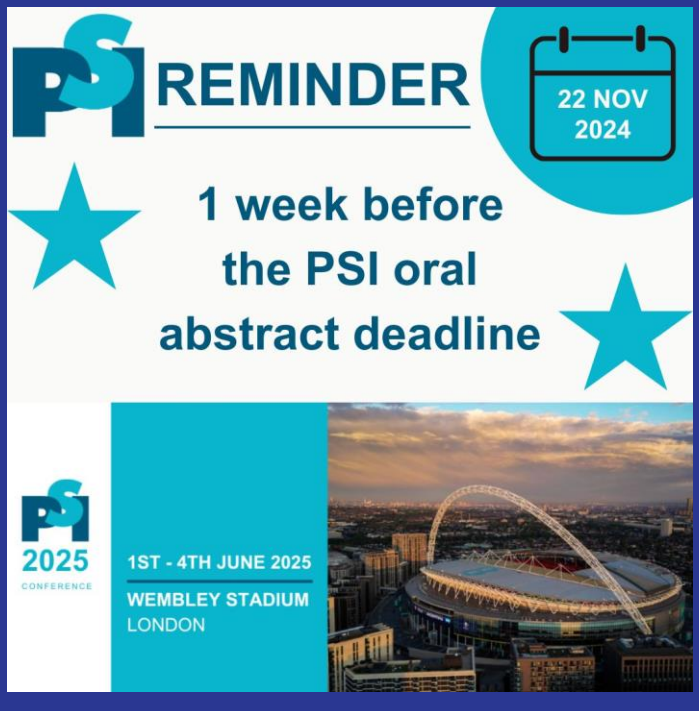
Deadline for abstract submissions for the PSI Conference 2025 : 22 November 2024

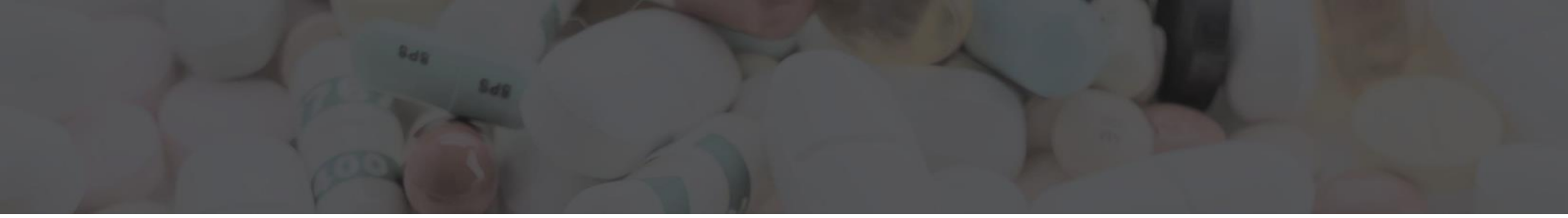
Abstracts are accepted on any topic, however a list of topics we are particularly interested in is provided below for guidance:

- AI/Machine Learning
- Bayesian
- Causal Inference
- Complex trial designs including adaptive designs
- Data visualisation and animation
- Estimands: methods, theory and cast studies
- Health Technology Assessment
- Master protocols and platform trials
- Non-technical: leadership
- Non-technical: soft skills
- Patient reported outcomes/Patient centred drug development
- Rare diseases and special populations
- RWD
- Use of external data
- Use of Opensource software e.g. R/Python in Industry

Remember, anyone selected for an Oral presentation, will be eligible for 10% off the three-day conference price!

Conference registration will open at the end of the year, we hope to see you at Wembley!





NATIONAL GROUPS UPDATE

Pharmaceutical Statistics and Data Management

PSDM Networking event at Astellas in Leiden (NL) on Tuesday 26 November!
The PSDM board invited you to a networking event hosted at Astellas Pharma in Leiden, the Netherlands. Get together with Data Managers, Programmers and Statisticians who work in clinical research in the Netherlands.

There will be presentations on relevant topics like working with Git, Statistical Computing Environments, external controls, and of course plenty of time to network.

Registrations are open! Please click here for more info!

Basel Biometric Society

Patient-Focused Drug Development: The Role of Patient Preference Studies

The Basel Biometric Society recently hosted a successful virtual event on "Patient-Focused Drug Development: The Role of Patient Preference Studies."

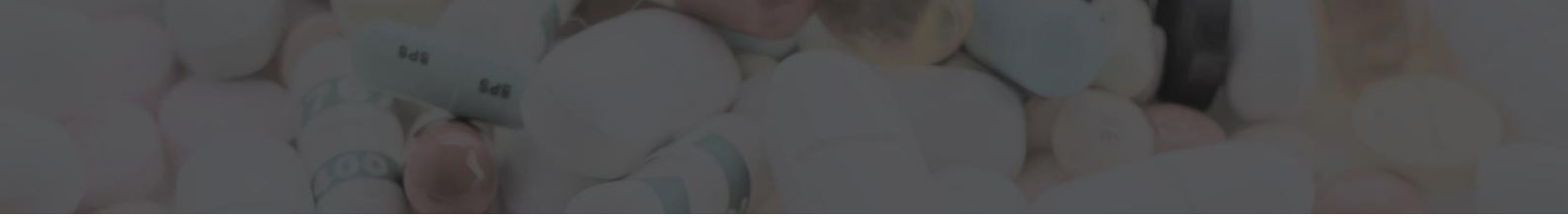
The event explored key themes such as integrating patient-centered approaches into drug development, understanding their regulatory role in pivotal studies, and their impact on HTA submissions.
The critical question of how statisticians can contribute to patient preference studies was also discussed.
A big thank you to the speakers and organizers!

Look out for more insights in the upcoming Q4 EFSPI newsletter!!

! Not only statistics !

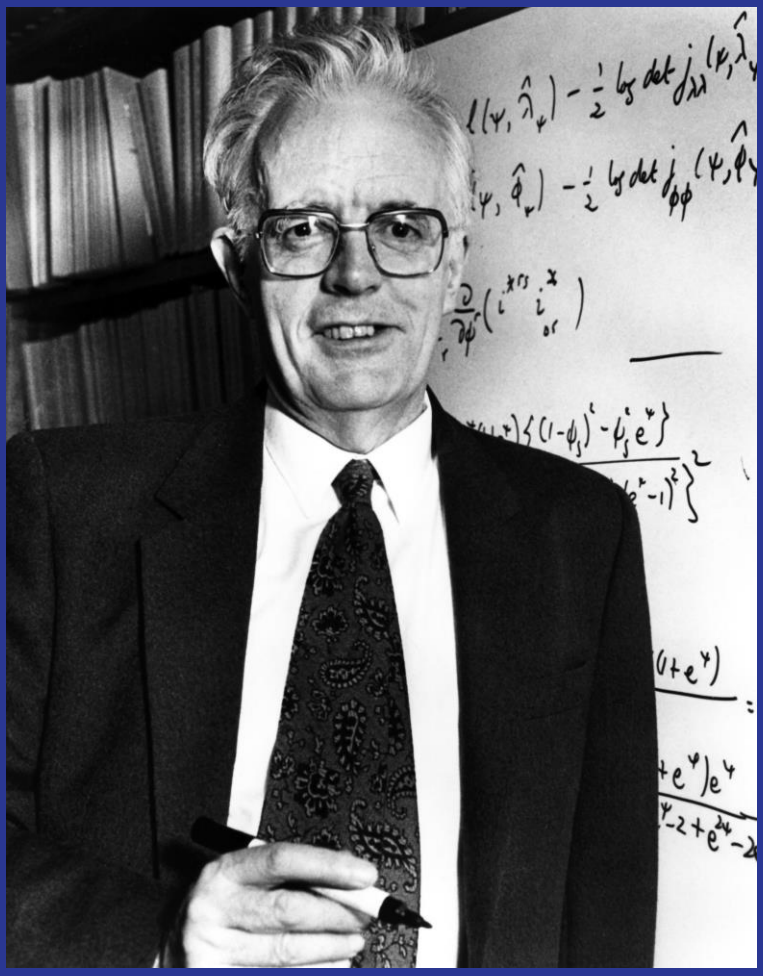
If you were in Basel for the 9th EFSPI regulatory workshop, you also had the chance to join BBS for an informal dinner at KLARA, BBS' usual lunch place!

It was an excellent opportunity to connect and exchange with the community!



DID YOU KNOW?

David Cox's birthday anniversary



David Cox, born on July 15, 1924, was a highly influential statistician known for his groundbreaking work in survival analysis, regression modeling, and clinical research.

He was best known for developing the Cox proportional hazards model in 1972, which revolutionized survival data analysis by assessing the relationship between survival time and predictor variables. This model has become a cornerstone in clinical research, especially in evaluating the effectiveness of treatments and understanding patient survival. Cox also made significant contributions to regression analysis, particularly in handling censored data, which arises when the event of interest is not observed for all subjects.

His techniques have improved the accuracy of conclusions drawn from clinical trials and observational studies. Additionally, his work in multivariate analysis and experimental design has greatly impacted the field of medical statistics, enabling researchers to analyze complex data involving multiple variables and treatment groups. Cox's methods have been pivotal in clinical research, especially in clinical trials, where understanding survival and time-to-event data is critical.

His model allows researchers to adjust for confounding factors like age, sex, and treatment type, helping isolate the effects of key variables on patient outcomes.

His contributions to both theoretical and applied statistics continue to influence modern statistical practices, particularly in medicine, epidemiology, and public health.

In summary, David Cox's work, especially the Cox proportional hazards model, has had a lasting impact on statistical and clinical research. His legacy as one of the most influential statisticians of his time remains vital in the analysis of clinical trials and survival data..

See you at the next quarterly newsletter!

Andrea Nizzardo, Luca Grassano
EFSPI Communication Officers