Status as of August 07, 2025	• This is a **draft program subject to changes**, updates will be posted on a regular basis. • This year we'll celebrate the **10th anniversary** of the EFSPI regulatory statistics WS. To mark this milestone, we have planned a special commemoration on Day 1.

10th EFSPI Regulatory Statistics Workshop

10-12 September 2025

Basel Switzerland

Day 0: 09th September 2025, 19:00-22:00

19:00 – 22:00	**Pre-Conference Regulatory Dinner** *All regulators and HTA assessors* are cordially invited to this (self-paid) event, organized by Benjamin Hofner and Heidi Mestl. For more information and registration please visit **link**.

Day 1: 10th September 2025, 08:30-17:00 (+2h get-together)

Time	Presentation
08:30 – 08:45 (15 min)	**Opening Remarks** Egbert Biesheuvel (EFSPI President, Viatris, NL)
08:45 – 10:15 (90 min)	**"Overture": Strategic Priorities in Pharmaceutical Statistics** Speakers will discuss 1. Regulatory priorities in Europe 2. Industry view on regulatory priorities in Europe *Chairs: Bergrún Magnusdottir (IMA, IS), Pierre Mancini (Sanofi, FR)* Talk 1: Kit Roes (Chair of MWP EMA, Radboud UMC, NL): *<title>* Talk 2: Mouna Akacha (Co-chair EFSPI statistical methodology leaders, Novartis, CH): *<title>* Q&A with the audience, the speakers and regulatory agency representatives: Andrea Manfrin (MHRA, UK) and Rafael Sauter (Swissmedic, CH)
10:15 – 10:45 (30 min)	Coffee break

Day 1: 10th September 2025, 08:30-17:00 (+2h get-together) *<continued>*

Time	Presentation
10:45 – 12:30 (105 min)	**ICH E20 Guideline on "Adaptive Designs for Clinical Trials" – A Critical Discussion from Different Perspectives** Homework: Please read the *draft version* of the ICH E20 guideline on Adaptive Designs for Clinical Trials currently on public consultation to get most out of the session. Discussants will pick and discuss 1 or 2 topics that they found the most thought-provoking. *Chairs: Fredrik Öhrn (J&J, SE), Kit Roes (Chair of MWP EMA, Radboud UMC, NL)* Talk 1: Frank Pétavy (EMA, NL), Khadija Rantell (MHRA, UK): *<title/ICH guideline intro>* Talks 2 – 5: ICH E20 guideline on adaptive designs for clinical trials: my reflections as a statistician working in … Academia – Christopher Jennison (University of Bath, UK) Industry – Silke Jörgens (J&J, DE) Regulatory assessment – Maria Grünewald (MPA, SE) HTA assessment – Seamus Kent (ESHPM, NL) Moderated discussion with the audience, the speakers and representatives of the **ICH E20 WG**: Hans Ulrich Burger (Medical University of Graz, DE), Jürgen Hummel (Novo Nordisk, UK), Thomas Hiemstra (Novartis, CH)
12:30 – 14:00 (90 min)	Lunch break and poster session: ESIGs and EFSPI Working Groups
14:00 – 15:30 (90 min)	**From Trials to Target Populations: Extending Evidence for Decision-Making** Speakers will discuss issues of transportability and generalisability *Chairs: Anja Schiel (SAWP & MWP member, NoMA, NO), Seamus Kent (ESHPM, NL)* Intro Seamus Kent (ESHPM, NL) Talk 1: Antonio Remiro-Azócar (Novo Nordisk, ES): Transportability: Implications for Evidence Synthesis and HTA Decision-Making Talk 2: Miguel Hernán (Harvard T.H. Chan School of Public Health, US) *<title>* Q&A and moderated discussion with the audience and the speakers
15:30 – 16:00 (30 min)	Coffee break
16:00 – 17:00 (60 min)	**10th Anniversary of the EFSPI Regulatory Statistics Workshop** *Theme + Speakers TBC*
17:00 – 19:00	**Get-together** including wine tasting organised by Emmanuel Zuber (Independent consultant, CH) and Hans Ulrich Burger (Medical University of Graz, DE)

Day 2: 11th September 2025, 09:00-17:30

Time	Presentation
09:00 – 11:00 (120 min)	**Short Topics**: **Present a problem on 2-3 slides and receive input from a panel of regulators** (20 mins per topic; only F2F presenters allowed) *Chairs:* *Elina Asikanius (MWP member, fimea, FI),* *Kaspar Rufibach (Co-chair EFSPI statistical methodology leaders, Merck KgaA, CH)* Panelists: Angelika Geroldinger and Florian Klinglmüller (AGES, AT), Anja Schiel (NOMA, NO), Florian Lasch and Frank Pétavy (EMA, NL), Katharina Hees and Lukas Aguirre Dávila (PEI, DE), Khadija Rantell (MHRA, UK), Kit Roes (Radboud UMC, NL), Maria Grünewald (MPA, SE), Tommi Nurminen (fimea, FI), Xiaofei Liu (BfArM, DE) Additional panelists (topic-dependent): Flora Musuamba Tshinanu (University of Namur, BE), Gabriel Westman (MPA, SE), Olaf Klungel (University of Utrecht, NL), Seamus Kent (ESHPM, NL) Topic 1: < … > Topic 2: < … > Topic 3: < … > Topic 4: < … > Topic 5: < … > Topic 6: < … > Note: You can submit a problem and, if selected, you can discuss it with a panel of highly esteemed regulators. Proposals should be sent to Vivian Lanius, Vivian.lanius@ucb.com, no later than 11 August 2025.
11:00 – 11:30 (30 min)	Coffee break
11:30 – 12:30 (60 min)	**From Black Box to Pandora's Box: Navigating AI in Clinical Trials** *Chairs:* *Florian Klinglmüller (MWP member, AGES, AT), Jenny Devenport (Roche, CH)* Talk 1: Gabriel Westman (MPA, SE): *<title>* Talk 2: Tim Friede (University of Göttingen, DE): *<title>* Talk 3: Chris Harbron (Roche, UK): *<title>* Moderated discussion with the audience, the speakers, and Andrea Manfrin (MHRA, UK)
12:30 – 14:00 (90 min)	Lunch break

Day 2: 11th September 2025, 09:00-17:30 *<continued>*

Time	Presentation
14:00 – 15:30 (90 min)	**Characterizing the Effect of Treatment Using Hierarchical Composite Endpoints – Risks and Benefits of Win Statistics and Beyond** HCEs are proposed across therapeutic areas with the intent to characterize treatment effects by combining different outcomes using Generalized Pairwise Comparisons (e.g., win statistics), Desirability of Outcome Ranking, or Ordinal Longitudinal Models for State Occupancies. Speakers will discuss the importance of a clear clinical question, methodological strengths and limitations, and their role in regulatory decision making. *Chairs: Heidi Mestl (SAWP member, NoMA, NO), Patrick Schlömer (Bayer, DE)* Talk 1: Henrik F. Thomsen (Novo Nordisk, DK) and Mickaël De Backer (UCB, BE): Hierarchical Composite Endpoints: More Nuance, More Insight and … More Confusion? Talk 2: Hierarchical composite endpoints - time to untie the not's? Lukas Aguirre Dávila (SAWP member, PEI, DE) Moderated discussion and Q&A with the audience, the speakers, Andreas Brandt (BfArM, DE) and Anja Schiel (SAWP & MWP member, NoMA, NO)
15:30 – 16:00 (30 min)	Coffee break
16:00 – 17:30 (90 min)	**Keeping it Real or Losing Control? Adventures in Target Trial Emulation** Goal: to explore how Target Trial Emulation (TTE) can improve transparency and methodological rigor when designing, evaluating, and assessing clinical trials incorporating observational data. Stakeholders will gain insights into regulatory expectations, industry experiences, and how TTE enhances alignment and communication between regulators and pharmaceutical companies. This includes how TTE clarifies assumptions, addresses biases, and facilitates robust sensitivity analyses and evaluation criteria through structured links to randomized trials. *Chairs: Florian Klinglmüller (MWP member, AGES, AT), Julie Jones (Novartis, CH)* Talk 1: Olaf Klungel (MWP member, University of Utrecht, NL): *<title>* Talk 2: Rima Izem (Novartis, CH): Target trial emulation meets clinical trial design: illustrations of use in non-randomized comparisons in clinical studies Talk 3: Angelika Geroldinger (AGES, AT): From a regulatory perspective: what can we gain from TTE? Moderated discussion and Q&A with the audience and the speakers

Day 3: 12th September 2025, 08:30-12:10

Time	Presentation
08:30 – 10:00 (90 min)	**The Added Value of Bayesian Methods for Pivotal Clinical Trials – Just a Communication Issue?** *Chairs:* *Claudia Dallinger (Boehringer Ingelheim, DE), Elina Asikanius (MWP member, fimea, FI)* Talk 1: Nicky Best (GSK, UK) <*title*> Talk 2: Katharina Hees and Florian Krach (PEI, DE): Bayesian Approaches in Clinical Trials: A Discussion on Regulatory Expectations Reflections of the panelists: Aysun Cetinyurek Yavuz (MEB, NL), Simon Wandel and Frank Bretz (Novartis, CH), Frank Pétavy (EMA, NL), and Tobias Mielke (J&J, DE) Moderated discussion and Q&A with the speakers, the audience and the panelists
10:00 – 10:30 (30 min)	Coffee break
10:30 – 12:00 (90 min)	**How to Deal with Assumptions in Drug Development? What Insights Can We Gain from ICH M15?** *Chairs:* *Claudia Dallinger (Boehringer Ingelheim, DE), Rafael Sauter (Swissmedic, CH)* Talk 1: Flora Musuamba Tshinanu (SAWP & MWP member, University of Namur, BE): <*title*> Talk 2: Oliver Sailer and Valerie Nock (Boehringer Ingelheim, DE): Bridging Disciplines with ICH M15: A Case Study on Assumption Testing for Pharmacometric-Enhanced Bayesian Borrowing Talk 3: Tobias Mielke (J&J, DE): ICH-M15 to support credibility assessment for Bayesian Modelling Moderated discussion and Q&A with the audience, the speakers and Norbert Benda (University of Göttingen, DE)
12:00 – 12:10	**Closure** Vivian Lanius (UCB Biosciences, Local Organizing and Scientific Committee, DE)
12:10	Lunch

Poster session of ESIGs and EFSPI Working Groups on Day 1 (10th September 2025, 12:30 – 14:00)

ESIG/EFSPI Working Group	**Title**	**Author(s)/*Presenter(s)***
Causal Inference SIG	<NN>	*Sanne Roels*, *Alex Ocampo*, Kelly Van Lancker
CMC Statistical Network Europe SIG	Introduction to CMC Statistical Network Europe and Areas for Priority	*Beate Presser*, *Christian Schmid*, Jens Lamerz, Kevin Lief, Martin Motava
EFSPI Scientific & Training Academy	<NN>	Jonas Häggström
EFSPI/EFPIA EIWG with phuse sub-team	Estimands in Safety Analytics	*Armin Schüler*, *David Wright*, Amel Besseghir, *Khadija Rantell*, Andreas Sashegyi, Katarina Hedman, George Kordzakhia, Mike Colopy, Liangcai Zhang
Historical Data SIG	<NN>	*Oliver Sailer*, Monika Jelizarow
HTA SIG	"Adaptive Clinical Trials" – what are the challenges and opportunities from an HTA perspective?	Maximo Carreras, Chrissie Fletcher
HTA SIG	Characterizing the Effect of Treatment Using Hierarchical Composite Endpoints – Risks and Benefits of Win Statistics and Beyond in the HTA context	Fred Sorenson, Anders Gorst-Rasmussen, Shahrul Mt-Isa
HTA SIG / RWE SIG	Target trial emulation and incorporation of observational data into clinical trials from an HTA perspective	*Katrin Kupas*, Min-Hua Jen, Orlando Dohring, *Rima Izem*
HTA SIG	From Trials to Target Populations: Extending and Extrapolating Evidence for HTA Decision-Making	Ash Bullement, Peter Pemberton-Ross, Grammati Sarri, Orlando Dohring
Launch & Lifecycle SIG	<NN>	*Lada Mitchell, Cornelia Dunger-Baldauf*, Jenny Devenport, Yulia Dyachkova
openstatsware / Software Engineering SIG	openstatsguide : Checklist for good statistical software packages	*Audrey Yeo*, Daniel Sabanés Bové, Alessandro Gasparini, Nils Penard
PSI / EFSPI Biomarkers SIG	<NN>	*Denis Engemann*, Laura Schlieker, Mathias Cardner
Real World Data SIG	<NN>	Josephine Wolfram, *Rima Izem*
Regulatory SIG	<NN>	*Christoph Gerlinger, Jürgen Hummel*
Small populations SIG	The PSI/EFSPI Small Population Special Interest Group	Giles Partington, *Maeva Dupuis*, *Aysun Cetinyurek Yavuz*
Treatment Effect Heterogeneity SIG	<NN>	*Bjoern Bornkamp*, Kostas Sechidis, David Svensson, Ashwini Venkatasubramaniam