Status as of July 15, 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, 08:30-17:30 (+1.5h 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: *<title>*, Kit Roes (Chair of MWP EMA, Radboud UMC, NL) Talk 2: *<title>*, Mouna Akacha (Co-chair EFSPI statistical methodology leaders, Novartis, CH) 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
10:45 – 12:30 (105 min)	**ICH E20 Guideline on "Adaptive Designs for Clinical Trials" – A Critical Discussion from Different Perspectives** Homework: To get most out of the session please read the *draft version* of the ICH E20 guideline on Adaptive Designs for Clinical Trials currently on public consultation Discussants will pick and discuss one or two 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: *<title/ICH guideline intro>* Frank Pétavy (EMA, NL) 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 – Dalia Dawoud, (PEHTA Consulting, UK) Moderated panel discussion with the audience, the speakers and representatives of the **ICH E20 WG**: Khadija Rantell (MHRA, UK), Hans Ulrich Burger (Medical University of Graz, DE), Jürgen Hummel (Novo Nordisk, UK), Thomas Hiemstra (Novartis, CH)

Time	Presentation
12:30 – 14:00 (90 min)	Lunch break and poster session: ESIGs and EFSPI Working Groups
14:00 – 15:15 (75 min)	**From Trials to Target Populations: Extending Evidence for Decision-Making [TBC]** Speakers will discuss issues of transportability and generalisability *Chairs:* *Anja Schiel (SAWP & MWP member, NoMA, NO), Seamus Kent (ESHPM, NL)* Talk 1: Transportability: Implications for Evidence Synthesis and HTA Decision-Making, Antonio Remiro-Azócar (Novo Nordisk, ES) Talk 2: *<title>,* Miguel Hernán (Harvard T.H. Chan School of Public Health, US) Q&A / panel discussion with the audience, the speakers <and further discussants?>
15:15 – 15:45 (30 min)	Coffee break
15:45 – 16:30 (45 min)	**China Review System Reform and Development*** *Chairs:* *NN (affiliation, country code), NN (affiliation, country code)* Talk 1: Reform of China's Drug Review System and Measures to Encourage Innovation, NN (CDE, CN) Talk 2: Development of Statistical Review in China and Framework for Guideline Systems, NN (CDE, CN) Q&A
16:30 – 17:30 (60 min)	**10th Anniversary of the EFSPI Regulatory Statistics Workshop** *Theme + Speakers TBC*
17:30 – 19:00	**Get-together** including wine tasting organised by Emmanuel Zuber (Independent consultant, CH) and Hans Ulrich Burger (Medical University of Graz, DE)

***Session to be confirmed. The program will be adapted accordingly if not confirmed.**

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 (AGES, AT), Anja Schiel (NOMA, NO), Florian Klinglmüller (AGES, AT), Florian Lasch (EMA, NL), Frank Pétavy (EMA, NL), Katharina Hees (PEI, DE), Khadija Rantell (MHRA, UK), Kit Roes (Radboud UMC, NL), Lukas Aguirre Dávila (PEI, DE), 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: *<title>*, Gabriel Westman (MPA, SE) Talk 2: *<title>,* Tim Friede, (University of Göttingen, DE) Talk 3: *<title>,* Chris Harbron (Roche, UK) Moderated panel discussion with the audience, the speakers, and Dr. Andrea Manfrin (MHRA, UK)
12:30 – 14:00 (90 min)	Lunch break
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 in several therapeutic areas with the intent to characterize the effect of treatment by combining different outcomes using Generalized Pairwise Comparisons (e.g. win statistics), Desirability of Outcome Ranking, or Ordinal Longitudinal Models for State Occupancies. Speakers from regulatory agencies as well as industry will critically discuss the need to address a well-defined clinical question of interest, pros and cons of the different approaches, and their role in regulatory decision making. *Chairs:* *Heidi Mestl (SAWP member, NoMA, NO), Patrick Schlömer (Bayer, DE)* Talk 1: Hierarchical Composite Endpoints: More Nuance, More Insight and … More Confusion?, Henrik F. Thomsen (Novo Nordisk, DK) and Mickaël De Backer (UCB, BE) Talk 2: *<title>,* Lukas Aguirre Dávila (SAWP member, PEI, DE)

Time	Presentation
	Moderated panel discussion and Q&A with the audience, the speakers and Andreas Brandt (BfArM, DE), 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. Different 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: <*title*>, Olaf Klungel (MWP member, University of Utrecht, NL) Talk 2: Target trial emulation meets clinical trial design: illustrations of use in non-randomized comparisons in clinical studies, Rima Izem (Novartis, CH) Talk 3: From a regulatory perspective: what can we gain from TTE?, Angelika Geroldinger (AGES, AT) Facilitated Q&A with the audience, the speakers <and discussant>

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: *<title>,* Nicky Best (GSK, UK) Talk 2: Bayesian Approaches in Clinical Trials: A Discussion on Regulatory Expectations, Katharina Hees and Florian Krach (PEI, DE) 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: *<title>,* Flora Musuamba Tshinanu (SAWP & MWP member, University of Namur, BE) Talk 2: *<title>,* Oliver Sailer and Valerie Nock (Boehringer Ingelheim, DE) Talk 3: ICH-M15 to support credibility assessment for Bayesian Modelling, Tobias Mielke (J&J, DE) Panel discussion and Q&A with the audience and the speakers and Norbert Benda (University of Göttingen, DE)
12:00 – 12:10	**Closure**
12:10	Lunch

Poster session of ESIGs and EFSPI Working Groups on Day 1 – Confirmed posters:

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 and Training Academy	<NN>	Jonas Häggström
EFSPI/EFPIA EIWG with phuse subteam	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
Launch & Lifecycle SIG	<NN>	*Lada Mitchell, Cornelia Dunger-Baldauf*, Jenny Devenport, Yulia Dyachkova
openstatsware / Software Engineering SIG	<NN>	Audrey Yeo, Daniel Sabanes Bove, Alessandro Gasparini
PSI / EFSPI Biomarkers SIG	<NN>	Denis Engemann
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