Status as of June 20, 2025	• Note this is a **draft of the program which is subject to changes**. As the content is developed updates will be posted. • We are excited to celebrate the **10th anniversary** of the EFSPI regulatory statistics meeting this year. To mark this milestone, we have planned a special commemoration on Day 1, which will reflect on the past and look forward to the future of this event.

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: *<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: Dr. 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 Clinical Trials" –** **A Critical Discussion from Different Perspectives** Homework: To get most out of the session please read the ICH E20 draft guideline on Adaptive Clinical Trials currently on public consultation *<add link>* 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) Talk 2: Academic perspective – Christopher Jennison (University of Bath, UK) Talk 3: Industry perspective – Silke Jörgens (J&J, DE) Talk 4: Regulatory perspective – Maria Grünewald (MPA, SE) Talk 5: HTA perspective – Dalia Dawoud, (NICE, 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)

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 [TBC]** Speakers will discuss issues of transportability and generalisability *Chairs:* *Seamus Kent (ESHPM, NL), Anja Schiel (SAWP & MWP member, NoMA, NO)* Talk 1: <*title*>, <speaker> (…, ..) Talk 2: <*title*>, Antonio Remiro-Azócar (Novo Nordisk, ES) Talk 3: <*title*>, Miguel Hernán (Harvard T.H. Chan School of Public Health, US) Q&A / panel discussion with the audience, the speakers <and further discussants>
15:30 – 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 (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:* *Jenny Devenport (Roche, CH), Florian Klinglmüller (MWP member, AGES, AT)* 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:* *Andreas Brandt (BfArM, DE), Patrick Schlömer (Bayer, DE), Heidi Mestl (SAWP member, NoMA, NO)* Talk 1: <*title*>, Henrik F. Thomsen (Novo Nordisk, DK) and Mickaël De Backer (UCB, BE) Talk 2: <*title*>, Lukas Aguirre Dávila (SAWP member, PEI, DE) Moderated panel discussion and Q&A with the audience and the speakers 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. 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:* *Julie Jones (Novartis, CH), Florian Klinglmüller (MWP member, AGES, AT)* Talk 1: <*title*>, Olaf Klungel (MWP member, University of Utrecht, NL) Talk 2: <*title*>, Rima Izem (Novartis, CH) Talk 3: <*title*>, Angelika Geroldinger (AGES, AT) Facilitated Q&A with the audience, the speakers <and discussant>

Day 3: 12th September 2025, 09:00-12:10

Time	Presentation
08:30 – 10:00 (90 min)	**The Added Value of Bayesian Methods for Pivotal Clinical Trials - Just a Communication Issue?** *Chairs: Elina Asikanius (MWP member, fimea, FI), Claudia Dallinger (Boehringer Ingelheim, DE)* 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) Moderated panel discussion with the speakers, Aysun Cetinyurek Yavuz (MEB, NL), Simon Wandel and Frank Bretz (Novartis, CH), and <TBC> (.., ..) Q&A with the audience, the speakers 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) Q&A / panel discussion with the audience and the speakers and Norbert Benda (BfArM, DE)
12:00 – 12:10	**Closure**
12:10	Lunch

Confirmed posters:

ESIG/EFSPI Working Group	Title	Author(s)/Presenter(s)
Launch & Lifecycle SIG	<NN>	Jenny Devenport, Yulia Dyachkova
Regulatory SIG	<NN>	Christoph Gerlinger, Jürgen Hummel
CMC Statistical Network Europe SIG	<NN>	Beate Presser, Christian Schmid, Jens Lamerz, Kevin Lief, Martin Motava
Small populations SIG	<NN>	Aysun Cetinyurek Yavuz, Giles Partington, Maeva Dupuis, Tal Otiker
EFSPI EIWG collaborating with phuse subteam	Fundamentals of Estimands in Safety Analytics	Armin Schüler, Amel Besseghir David Wright