9th EFSPI Regulatory Statistics Workshop
11-13 September 2024
Basel Switzerland

Draft program as of 5 June 2024

11th September 2024, 0830-1700 (+2h wine tasting), Day 1

Time	Duration (mins)	Presentation
8:30-8:45	15	**Opening remarks** Egbert Biesheuvel (EFSPI President, Senior Director Viatris)
8:45-10:45	120	**Session 1: Fast to market vs. robustness of the data** Talk 1: How much it matters to be first in class. And how can you catch up? Speaker: Jenny Devenport (Roche) Panel discussion with the audience
10.45-11.15	30	Coffee break
11:15-13:15	120	**Short topics** (20 mins per topic): **Present problem on 2-3 slides and receive input from a panel of regulators** *Chairs: Elina Asikanius (fimea, EMA) and Kaspar Rufibach (Roche)* Topic 1: Topic 2: Topic 3: Topic 4: Topic 5: Topic 6: Please send proposals by 15 August to hlyn@novonordisk.com
13:15-14:45	90	Lunch break and poster session: ESIGs and EFSPI Working Groups
14:45-17:00	135	**Session 2: Estimands – Celebrating the 5th anniversary of ICH E9(R1) – what have we learned and where do we need to go?** Talk 1: What has improved and what new issues did we uncover and what issues are we still ignoring? Speakers: Frank Bretz, Novartis and Rob Hemmings, Consilium Panel discussion with audience
17:00-19:00	120	**Wine tasting** organised by Hans Ulrich Burger (Roche) and Emmanuel Zuber (Novartis)

12th September 2024, 0830-1700, Day 2

Time	Duration (mins)	Presentation

8.30-10.00	90	**Session 3: How can statisticians navigate the interface between the EU Joint Clinical Assessment and EMA regulatory assessment?** Panel discussion with the audience
10.00-10.30	30	Coffee break
10:30-12:30	120	**Session 4: Patient centricity** *Chairs:* Talk 1: ICH E22 General Considerations for Patient Preference Studies. Speaker: Dr Francesco Pignatti, Rapporteur (EC) Talk 2: Industry case study. How a patient preference trial impacted the approval/SmPC. Speaker: Brett Hauber, Pfizer Talk 3: Selecting the treatment – my patient and statistician perspectives. Speaker: Anna Wiksten Panel discussion with the audience
12.30-14.00	90	Lunch break
14:00-15:30	90	**Session 5: Openstatsware - How can we build a scalable ecosystem?** Panel discussion with the audience
15:30-17:00	90	**Session 6: Regulatory updates** EMA Speaker: Kit Roes Radboud University, Netherlands Q&A

13th September 2024, 0830-1200, Day 3

Time	**Duration (mins)**	**Presentation**
8.30-9.45	75	**Session 7: Regulatory landscape in China** Q&A
9.45-10.15	30	**Coffee break**
10.15-11.45	90	**Session 8: The role of innovative statistical methods in pan-European HTA** Panel discussion with the audience
11.45-12.00	15	**Closure** Helle Lynggaard (Novo Nordisk, Local Organizing and Scientific Committee)

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Confirmed posters:

ESIG/EFSPI Working Group	**Title**	**Author(s)/Presenter(s)**
Estimand Implementation Working Group (EIWG)		
EIWG – reporting sub-team		
EIWG – estimands in non-inferiority trials		Sue McKendrick (PPD), David Wright (AstraZeneca), Helle Lynggaard (Novo Nordisk), Chrissie Fletcher (GSK) and Sunita Rehal (GSK)
Launch & Lifecycle		Jenny Devenport (Roche) and Yulia Dyachkova (Merck)
Regulatory ESIG		Alessandro Previtali (BMS), Mark Whitlock (GSK) and Yolanda Barbachano (Biontech)
Statistics Methods Leaders		