

PROGRAMME

Day 1 : Monday, 17 November 2025

SESSION 1: Clinical trials and real world evidence: what really matters

Session Chairs: Mark Lawler & Natacha Bolaños

12:00 - 12:50

Lunch

12:50 - 13:00

Welcome note & Session introduction
[Programme chair](#)

13:00 - 13:20

Enabling Clinical Trials: Taking a proportionate approach - focusing on what really matters
[Maria Lamas \(AEMPS, ES\)](#)

13:20 - 13:40

Turning Data into Decisions: Real-World Evidence in Regulation
[Alexandra Pacurariu \(EMA\)](#)

13:40 - 14:05

Fireside chat conducted by Mark Lawler with Hugues Malonne

14:05 - 14:30

Panel Discussion

14:30 - 15:00

Coffee Break

SESSION 2: Use of pragmatic elements in clinical trials

Session Chairs: Nafsika Kronidou Horst & Kit Roes

15:00 - 15:05

Session opening

15:05 - 15:20

Matching trials aims to design decisions: how PRECIS-2 can help, and how PRECIS-3 will be better
[Prof Shaun Treweek](#)

15:20 - 15:35	Patient perspective Gilliosa Spurrier-Bernard
15:35 - 15:50	EFPIA white paper and case study in oncology Nafsika Kronidou-Horst (Roche, CH)
15:50 - 16:05	Safety data report - ICH E19 - how we streamline - example of pragmatic elements - regulatory component Peter Mol
16:05 - 17:00	Panel Discussion
17:00 - 17:45	Coffee Break
17:45 - 18:45	Industry panel meeting (Internal meeting)
19:00 - 21:30	Welcome Drink & Networking Dinner

Day 2 : Tuesday 18 November 2025

SESSION 3: Driving research using health data

Session Chairs: Fergus Sweeney & Dr Hoa Le

08:30 - 10:00	CDDF Board of Directors meeting (internal meeting)
10:10 - 10:15	Introduction
10:15 - 10:30	EMA article - clinical evidence 2030 Marianne Lunzer
10:30 - 10:45	Unlocking the Power of Real-World Data Across the Full Lifecycle of Cancer Clinical Trials Ariel Bourla
10:45 - 11:00	Natacha Bolanos
11:00 - 11:15	Digital Data Alison Cave
11:15 - 12:15	Panel Discussion

SESSION 4: WORKSHOP WRAP-UP AND NEXT STEPS

Session Chairs: Fergus Sweeney

12:15 - 12:45	Wrap up & Key takeaways
12:45 - 12:50	Farewell message by Fergus
12:50 - 13:20	Takeaway lunch