



CDDF

Cancer Drug Development Forum

FACILITATE. DEBATE. ACTIVATE. INNOVATE.

MULTI-STAKEHOLDER WORKSHOP

**Enabling smarter clinical trials to
optimise patient care**

Deploying data to design and deliver
better trials

17 November - 18 November 2025

Brussels, Belgium

Hybrid Workshop



www.cddf.org

EVENT OUTLINE

TBC

LEARNING OBJECTIVES

- TBC

PROGRAMME COMMITTEE

- Programme co-chair: Fergus Sweeney
- Programme co-chair: Mark Lawler
- Nafsika Kronidou-Horst (Roche, CH)
- Natacha Bolaños (Lymphoma Coalition, ES)
- Javier Jimenez (PharmaMar, ES)

TARGET AUDIENCE

The target is a multidisciplinary audience of academia representatives, EU and US regulatory bodies (EMA, FDA, National Agencies), pharmaceutical Industry, HTAs and patient advocate.

WORKSHOP VENUE

Sheraton Brussels Airport Hotel
Brussels National Airport, Brussels, 1930 Belgium

HYBRID WORKSHOP

The workshop will be held in Brussels. However, participation online via the Brella event platform will also be possible. Only approved participants will receive the link and log-in details to access the virtual platform.

CONTACT

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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](#)

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](#)



A background image showing several hands in white lab coats, suggesting a medical or clinical setting. The hands are of different skin tones, and one hand is wearing a gold ring. The image is slightly blurred, focusing on the hands in the foreground.

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 TBC
10:30 - 10:45	TBC
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