



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

This exciting CDDF Workshop will address how best to deploy smarter cancer clinical trials and use Real World Evidence (RWE) studies to deliver innovation and achieve better outcomes for cancer patients. It brings together key leaders in this rapidly developing field from a scientific, clinical, patient and regulatory affairs perspective. A key emphasis of the entire workshop is “What Really Matters” implementing proportionate, risk based approaches in trial design and conduct.

We will focus on turning “Data into Decisions” and emphasise the importance of implementing pragmatic approaches in cancer clinical trials and use of RWE in this rapidly revolving field. Ensuring pragmatism while driving innovation will be one of the key elements of the workshop.

We will ensure that we place the patient's opinion front and centre, that we are pragmatic and proportionate in what we present and discuss, and that we also ensure a balanced discussion where all voices are heard. Health data and its deployment will be a significant component of the workshop. Speakers will present some of the latest studies, combined with current and future thinking about how best to define and deploy the latest evidence to ensure that it becomes an integral part of how we drive innovation forward.

Fergus and I are looking forward to welcoming you to Brussels and hosting a discussion that focuses on “What Really Matters”.

LEARNING OBJECTIVES

- An appreciation of smart clinical trials and RWE studies and how they can both drive innovation and ensure better patient outcomes
- A deeper understanding of using clinical trials and studies and what they can achieve
- An appreciation of the critical importance of cancer patient co-creation and how best to empower patients going forward
- A clear vision of how best we can achieve our goals through the deployment of data – recognising that “byte to bedside” will increasingly be part of our evolving cancer lexicon

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 Brelia event platform will also be possible. Only approved participants will receive the link and log-in details to access the virtual platform.

CONTACT

Cancer Drug Development Forum (CDDF)
Email: shannon@cddf.org, info@cddf.org
Website: www.cddf.org
Address: c/o BLSI Clos Chapelle-aux-Champs 30, 1200 Brussels, Belgium

PROGRAMME

Day 1 : Monday, 17 November 2025

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

Session Chairs: Mark Lawler (CDDF, UK) & Natacha Bolaños (Lymphoma Coalition, ES)

12:00 - 12:50

Lunch

12:50 - 13:00

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

13:00 - 13:20

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

13:20 - 13:40

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

13:40 - 14:05

Fireside chat conducted by Mark Lawler with [Hugues Malonne \(FAGG-AFMPS, BE\)](#)

14:05 - 14:30

Panel Discussion
Guest panelist:
• [Zhanna Jumadilova \(Pfizer, US\)](#)

14:30 - 15:00

Coffee Break

SESSION 2: Use of pragmatic elements in clinical trials

Session Chair: Nafsika Kronidou Horst (Roche, CH)

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
[Shaun Treweek \(University of Aberdeen, UK\)](#)

15:20 - 15:35	Patient perspective Gilliosa Spurrier-Bernard (MelanomeFrance, FR)
15:35 - 15:50	Designing trials with pragmatic elements to generate high-quality real-world evidence for regulatory decisions 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 (University of Groningen, NL)
16:05 - 17:00	Panel Discussion
17:00 - 17:45	World Café
18:30 - 19:30	Industry panel meeting (Internal meeting)
19:30 - 21:30	Welcome Drink & Networking Dinner Guest speaker: • Shai Kaplan (AnuYoga, BE)

Day 2 : Tuesday 18 November 2025

SESSION 3: Driving research using health data

Session Chairs: Fergus Sweeney (CDDF, IE) & Dr Hoa Le (Daiichi-Sankyo, U.S)

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 (CTCG, AT)
10:30 - 10:45	Unlocking the Power of Real-World Data Across the Full Lifecycle of Cancer Clinical Trials Ariel Bourla (Johnson & Johnson, U.S)
10:45 - 11:00	From Patient Experience to HTA Evidence: The MyLymphoma Model for Real-World Data Generation Natacha Bolanos (Lymphoma Coalition, ES)
11:00 - 11:15	Supporting drug development through new evidence generation approaches Alison Cave (Medicines and Healthcare products Regulatory Agency, U.K)
11:15 - 11:45	Panel Discussion
11:45 - 12:30	Round table "How will the EU health data space empower cancer clinical trials in EU" Guest speaker: Alexandra Pacurariu (EMA, NL)

SESSION 4: Workshop wrap-up and next steps

Session Chairs: Fergus Sweeney (CDDF, IE)

12:30 - 13:00	Wrap up & Key takeaways Eva Skovlund (CDDF, NO)
13:00 - 13:05	Farewell message by Fergus
13:05 - 13:30	Takeaway lunch