

MULTI-STAKEHOLDER WORKSHOP

Challenges in the Landscape
of a Global Development
Strategy, including patient
access

30 - 31 March 2026
Brussels, Belgium
Hybrid Workshop

EVENT OUTLINE

This workshop will evaluate the current state of development of global clinical oncology trials and regulatory perspectives. The workshop is being organised by CDDF in collaboration with AAADV, bringing together trans-Atlantic experience in clinical trials and regulatory perspectives. It will include representatives from industry and academia, regulatory agencies and health technology assessors, as well as patient advocates, to explore these issues.

At this multi-stakeholder workshop, meeting delegates will have the opportunity to discuss the regulatory issues related to innovative and adaptive trial designs and international programs.

The 1.5-day meeting consists of 3 plenary sessions, and will include adequate discussion and networking time.

LEARNING OBJECTIVES

From this interactive workshop, participants will achieve the following outcomes:

- To understand the options for global harmonization, including the challenges of balancing country enrollment and the use of non-local data for local regulatory approvals.
- To gain insights into the ICH E22 guideline on patient preferences and learn practical strategies for ensuring diversity and inclusion within global clinical trials.
- To evaluate novel trial designs and the critical role of Patient Reported Outcomes (PROs) from a patient perspective to support successful drug development and reimbursement.
- To learn how oncology trials have transitioned from chains of subsequent studies to complex, multi-functional designs, and understand the options for cohort adaptations in early-phase oncology.
- To identify the cornerstones of successful global drug development that enable faster approvals and reimbursement strategies.

PROGRAMME COMMITTEE

- Programme co-chair: Jaap Verweij (CDDF, NL)
- Programme co-chair: Kim Lyerly (AAADV, US)
- Chantal Le Floch (Pfizer, CH)
- Paul McNulty (Arvinas, UK)
- Heidi Nauwelaerts (Debiopharm, CH)
- Rachel Giles (WECAN, NL)

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

Marriott Grand Place
Rue Auguste Orts 3-7/Grand Place
Brussels, Belgium, 1000

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, 30 March 2026

Key note Lecture : ICH E22 guideline on patient preferences

Session Chairs: Jaap Verweij (CDDF, NL) & Kim Lyerly (AAADV, US)

12:00 - 13:00

Lunch

13:00 - 13:05

Welcome note
Programme chairs

13:05 - 13:25

Key note Lecture : ICH E22 guideline on patient preferences
Francesco Pignatti (EMA, NL)

13:25 - 13:40

Q&A

SESSION 1: Navigating the Regulatory Maze: Towards Global Harmonization

Session Chairs: Jaap Verweij (CDDF, NL) & Kim Lyerly (AAADV, US)

13:40 - 13:55

Balancing country enrolment requirements
Rosanno Cesari (Pfizer, IT)

13:55 - 14:10

Mathematical design challenges
Scott Evans (George Washington University DC, US)

14:10 - 14:25

Acceptance of non local data for local approval
Eva Skovlund (Norwegian Medical Products Agency, CHMP, CDDF, NO)

14:25 - 14:40	How to ensure patient diversity and inclusion in global clinical trials Nadia Malliou (Pain Alliance Europe, GR)
14:40 - 15:30	Panel Discussion
15:30 - 16:00	Coffee Break

SESSION 2: Endpoints and patient voice: Cornerstones of successful global drug development and reimbursement

Session Chairs: Heidi Nauwelaerts (Debiopharm, CH) & Rachel Giles (WECAN, NL)

16:00 - 16:05	Session opening
16:05 - 16:20	Regulatory Considerations for Use of Patient-Reported Outcomes in Oncology Vishal Bhatnagar (FDA, US)
16:20 - 16:35	FDA Project Frontrunner - Accelerating Drug Approval for Patients Jin Chen (IQVIA, US)
16:35 - 16:50	The importance of including Patient Reported Outcomes from patient perspective Alex Filicevas (World Bladder Cancer Patient Coalition, BE)
16:50 - 17:05	Patient Reported Outcomes for reimbursement and patient access Beate Wieseler (IQWiG, DE)
17:05 - 17:45	Panel Discussion
18:00 - 19:00	CDDF Leadership & Industry Members Meeting (Internal Meeting)
19:30 - 22:00	Offsite dinner

Day 2 : Tuesday, 31 March 2026

SESSION 3: Expediting the road to pivotal trials

Session Chairs: Kim Lyerly (AAADV, US) & Jaap Verweij (CDDF, NL)

08:30 - 10:00	CDDF Board of Directors meeting (internal meeting)
10:30 - 10:35	Session opening
10:35 - 10:50	How the landscape of trials has changed in the last 20 years, from a chain of subsequent studies, to 1 or 2 studies that include everything Elisabeth De Vries (UMC Groningen, NL)
10:50 - 11:05	Global Regulatory Flexibility in Oncology FIH Trials: Navigating Cohort/Trial Modifications in Early Oncology Trials Cohort Adaptations. Lynn Howie (Pfizer, US)
11:05 - 11:20	Key Considerations for HA when Reviewing Cohort/Trial Modifications versus preferring completely New Protocols in Early Oncology Trials Dr Kingyin Lee (MHRA, UK)
11:20 - 12:10	Panel Discussion

SESSION 4: WORKSHOP WRAP-UP AND NEXT STEPS

Session Chairs: Chantal Le Floch (Pfizer, CH) & Rachel Giles (WECAN, NL)

12:10 - 12:30	Wrap-up panel discussion
12:30 - 12:35	Farewell message
12:35 - 13:30	Takeaway lunch