



CDDF & AAADV Joint Multi-Stakeholder Workshop

CHALLENGES IN THE LANDSCAPE OF
A GLOBAL DEVELOPMENT STRATEGY,
INCLUDING PATIENT ACCESS



EXECUTIVE SUMMARY

30-31 MARCH 2026
HYBRID, BRUSSELS (BE)



CDDF & AAADV Multi-Stakeholder Workshop

Challenges in the Landscape of a Global Development Strategy, Including Patient Access

30-31 March 2026 , Brussels (BE)

Cancer Drug Development Forum (CDDF) Multi-Stakeholder Workshops are neutral, non-competitive meetings that address topical issues and recent innovations in oncology drug development with the aim of improving cancer treatment. The workshops facilitate multi-stakeholder discussion and collaboration, bringing together leading voices from academia, the healthcare industry, regulatory authorities, and patient advocacy groups.

In collaboration with the Accelerating Anti-cancer Agent Development & Validation (AAADV), the CDDF hosted a multi-stakeholder workshop titled “**Challenges in the Landscape of a Global Development Strategy, Including Patient Access**” on 30–31 March 2026 in Brussels. This joint meeting explored the current state of global clinical oncology trial development and the evolving regulatory environment. It convened leading experts and key stakeholders from Europe and worldwide to share their diverse experiences and insights in global clinical trials.

The interactive workshop fostered productive discussions and yielded the following key takeaways, highlighting the importance of collaborative efforts among all stakeholders:



SESSION 1: NAVIGATING THE REGULATORY MAZE: TOWARDS GLOBAL HARMONISATION



KEY TAKEAWAYS

- Patient preference studies inform on patients' acceptance of specific treatment effects/attributes, promoting a systematic approach to studying the heterogeneity of preferences in a population, and should be a 'non-negotiable' addition to clinical development plans.
- Although data from multi-regional clinical trials (MRCTs) should assess treatment effects in the overall population, there is currently no legislative mandate for proportionate and representative trial enrolment.
- The low participation of underrepresented populations in clinical trials remains a systems issue due to structural, operational, cultural and trust barriers.
- Regional heterogeneity can affect the study design, monitoring, analyses, interpretation and reporting, therefore context and absolute metrics both matter when assessing treatment effects across populations in global clinical trials.
- Bridging studies (e.g. country-specific extension study or a region-specific cohort) should be considered to reduce approval timelines and patient access.



SESSION 2: ENDPOINTS AND PATIENT VOICE: CORNERSTONES OF SUCCESSFUL GLOBAL DRUG DEVELOPMENT AND REIMBURSEMENT



KEY TAKEAWAYS

- Patient-reported outcomes (PROs) often fail to be methodically collected, and even when they are, these rarely get reported nor do they have much impact on decision-making about treatment access.
- Although PROs are generally only assessed at later stages of drug development, implementing PRO data collection from early-phase trials, including dose optimisation, is crucial for a patient-centric approach.
- There is an urgent unmet need to harmonise oncology PRO metrics and reporting across studies to enable indirect comparison of treatments options, so that patients can better assess the benefit-risk trade-offs involved.
- Condition-specific PROs co-created by patients, alongside the generic quality of life assessments, can help capture the totality of the data and differentiate treatment options.





SESSION 3: EXPEDITING THE ROAD TO PIVOTAL TRIALS

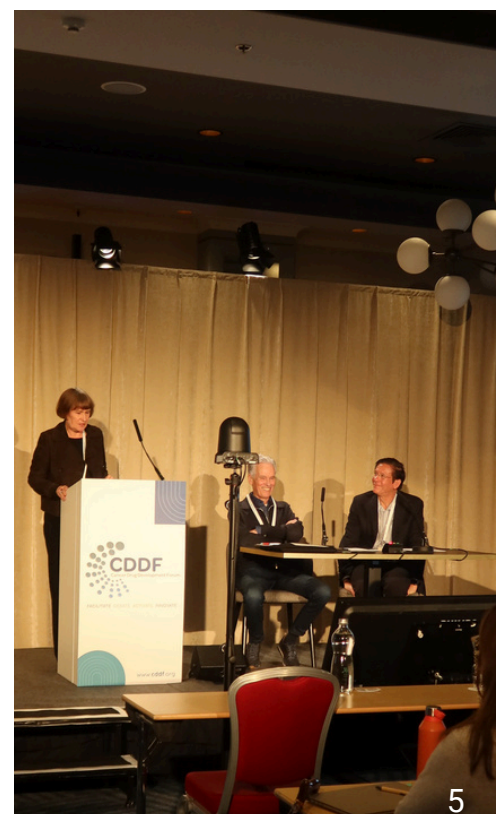


KEY TAKEAWAYS

- The oncology drug development landscape has changed dramatically over the last 20 years with global shifts in early-stage development including a proliferation of endpoints, more master protocols for basket, umbrella and platform trials, and pre-specified adaptations.
- Combination strategies in first-in-human early-phase trials can facilitate the development of new therapies by assessing the contributions of components early on.
- It is essential to seek scientific advice from regulatory authorities and health technology assessment organisations alongside patient consultation from the earliest stages of drug development to design smarter trials and expedite access.



Collaboration and open dialogue
among **all stakeholders** is **key** to
accelerating and improving
oncology drug development
for patients



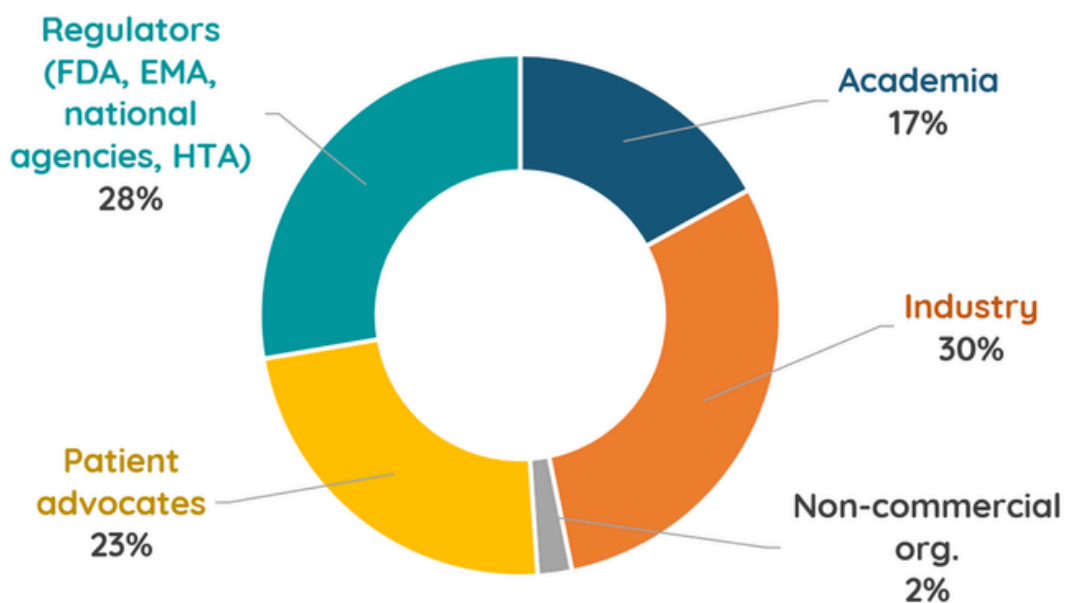


AUDIENCE AT THE CDDF WORKSHOP

The CDDF's meetings present a **wide range of perspectives** from **various stakeholders** who are involved in the development of oncology drugs. Our **multi-stakeholder, collaborative approach** facilitates a productive dialogue in a neutral, non-competitive space in order to **accelerate effective cancer drug development**.



Participants & Speakers



The graph illustrates the distribution of online and onsite speakers/chairpersons/panelists alongside onsite attendees.

51

**IN-PERSON
ATTENDEES**

89

**ONLINE
ATTENDEES**



WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"I enjoyed and learned from the discussion on **the need for and the value of patient preference studies**. It is important to continue advancements on how to do them and how to use the data from them."

Scott Evans

Professor, George Washington University (USA)

"The third session, Expediting the Road to Pivotal Trials, was the most important and beneficial for me. It was really **valuable to hear different perspectives**— from the clinician's viewpoint and from other organizational perspectives. I will definitely take a few key concepts and ideas back to Poland."

Karolina M. Nowak PhD, MBA

**Director of Innovation and Biotechnology Development Department,
Medical Research Agency (Poland)**

"For me, the highlights of Session 2, 'Endpoints and Patient Voice,' were the alignment demonstrated by the four speakers between the FDA, HTA bodies, patient-focused groups, and the private sector. We really need more **robust and highly patient-centred clinical trial designs** to get new drugs faster to the patient"

Heidi Nauwelaerts

Head of Clinical Development, Debiopharm (Switzerland)

"Even though the presentations came from **different perspectives and stakeholders**, there was **alignment**. The words **harmonization, diversity, and inclusion**—along with the necessity to bring everything together—were repeated many times and in such varied contexts. I'm actually hopeful after these sessions. Everyone from all perspectives is willing to pitch in and take the next step toward the future. "

Nadia Malliou

President, Pain Alliance Europe (Greece)

The views expressed in this page are the personal views of the participants and may not be understood as being made on behalf of or reflecting the position of the regulatory agency/agencies or organisations with which the participants are employed/affiliated.

MULTI-STAKEHOLDER MEETING



 
The future of cancer therapy

CDDF & EORTC JOINT WORKSHOP

Health Technology Assessment in Cancer Drug Development

5 - 6 October 2026
Brussels, BE (hybrid)

[Programme](#)

[Registration](#)

Session Topics

- 1 **Setting the Scene: HTA Landscape and Societal Needs**
- 2 **Implementation of HTA Regulation: Practical Learnings**
- 3 **HTA Regulation and Methodological Foundations**
- 4 **Looking Ahead: Preparing for Future Innovation**

LIVE WEBINARS



 **CDDF**
Cancer Drug Development Forum

LIVE WEBINAR

CDDF Live Webinar series – AI and Big Data AI in Drug Development: Use of AI in clinical trials

Dr. James Gulley (NIH)

12 May 2026
16:00-17:00 CET, Online

[Webinar Outline](#)

[Registration](#)

Webinars in Planning

- **AI and Big Data Series:** Transparency and risk assessment
- **CDDF Diversity Initiative paper**
- **Compassionate use/Expanded access program in Europe**
- Learnings from “Facilitating and Accelerating Strategic Clinical Trials in the EU” - **Pilot FAST EU**

Visit [the CDDF website](#) and follow us on [LinkedIn](#) to stay informed about upcoming webinars



We thank all our program committee members, speakers, panelists, Industry members, and participants for their invaluable inputs and engagement.

Cancer Drug Development Forum (CDDF)

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