



The future of cancer therapy

CDDF & EORTC MULTI-STAKEHOLDER WORKSHOP

Health Technology Assessment in Cancer Drug Development



EXECUTIVE SUMMARY

5-6 OCTOBER 2026
HYBRID, BRUSSELS (BE)



CDDF & EORTC Multi-Stakeholder Workshop

Health Technology Assessment in Cancer Drug Development

5-6 October 2026 , Brussels (BE)

With the EU Health Technology Assessment (HTA) Regulation applying to cancer medicines since January 2025, the Cancer Drug Development Forum (CDDF) and the European Organisation for Research and Treatment of Cancer (EORTC) joined forces to help stakeholders navigate the rapidly evolving HTA landscape in Europe and understand what it means for cancer care.

In line with this goal, a hybrid workshop on HTA in cancer drug development was held on 5–6 October 2026 in Brussels, bringing together experts from regulatory agencies, HTA bodies, the pharmaceutical industry, academia, healthcare providers, policymakers, and patient groups. Participants explored the practical implications of Regulation (EU) 2021/2282 and Joint Clinical Assessments, while examining the methodological foundations underpinning HTA processes. Over two days, the programme featured five sessions with interactive panel discussions, offering unique opportunities for candid dialogue and networking. This executive summary captures the key insights that emerged from these discussions across the different stakeholder perspectives.



SESSION 1: SETTING THE SCENE: HTA LANDSCAPE AND SOCIETAL NEEDS



KEY TAKEAWAYS

- Health technology assessment (HTA) in the European Union offers robust evidence generation, transparency, and connectivity. Since the HTA Regulation began applying in 2025, 15 Joint Clinical Assessment (JCA) procedures have been performed, with 4 published and 4 discontinued.
- Oncology is a central driver of rising pharmaceutical expenditure across countries, with high budget impact and high uncertainty.
- Regulatory frameworks tend to prioritise speed of access, while pivotal trials minimise the risk of a negative result (e.g. by selecting doses and durations of treatment that are as high as reasonably possible), leading to increased uncertainty.
- Missing data are a key challenge at many levels of the HTA process; for example, the data physicians need to treat patients optimally are often unavailable. However, it is important to recognise that there is no such thing as the 'perfect' dataset and data are only useful if they can change treatment decisions and outcomes.
- While there are tools to collect patient-reported outcomes (PROs) and to assess patient quality of life (QoL), these are not currently well incorporated into trials. There is a need to re-engineer the end-to-end process from access to development, structuring the role of HTA and healthcare in this process.



SESSION 1: SETTING THE SCENE: HTA LANDSCAPE AND SOCIETAL NEEDS



NEXT STEPS

- HTA can accelerate and improve access through earlier alignment between stakeholders on evidence that can support timely, affordable access.
- Optimisation trials should be considered an integral part of drug development.
- Tackling uncertainties remains a concern, and recommendations include to randomise as early as possible, to adopt a shared estimand framework, and to ensure timely access to patient-level data.
- There is a need to make European drug development more competitive in the face of international competition from the US, China, and other parts of Asia.

SESSION 2: IMPLEMENTATION OF HTA REGULATION: PRACTICAL LEARNINGS



KEY TAKEAWAYS

- The objective of the HTA Regulation, to build a framework for a single assessment based on questions from all 27 HTA bodies, has been met.
- Lessons learned from JCAs to date stem from 15 JCA procedures, of which 4 were published and 4 were discontinued.
- Current challenges include meeting the timelines for all parties (including HTA assessors, industry, clinicians, patients, and the European Commission); the relative difficulty in predicting and understanding the HTA bodies' expectations; and the completeness of JCA dossiers, particularly in terms of the complete presentation of available evidence, assessable and verifiable justification for missing data, and other decisions by the health technology developer (HTD) in the dossier.
- A more collaborative approach among stakeholders will help ensure all expectations are met.
- The inclusion of patients at all stages of the HTA process, and recognition of their involvement, requires further development.
- Transparency and connectivity are key developments of the HTA Regulation, as the outcomes of JCA assessments will be publicly available (including JCA reports, summary reports, technical and factual accuracy checks, comments on missing data, and the submitted JCA dossier).

SESSION 2: IMPLEMENTATION OF HTA REGULATION: PRACTICAL LEARNINGS

NEXT STEPS

- Continued engagement, collaboration, and feedback from all stakeholders will be key for future JCA assessments.
- The impact of JCA reports on national HTA assessments will be an interesting aspect to monitor in the future.



SESSION 3: HTA REGULATION AND METHODOLOGICAL FOUNDATIONS



KEY TAKEAWAYS

- Alignment is needed between PICO, the evidence generated, the analytical methods used, and the information provided in the dossiers.
- Stakeholders should plan early (e.g. with proactive PICO simulations), talk early (via Joint Scientific Consultations to de-risk the development plan through formal dialogue before studies are locked), design 'JCA-ready' trials that answer the needs of HTA bodies (by creating an integrated evidence plan and designing trials that can support multiple estimands), and master the methodology (by leading the scientific narrative and rigorously justifying the use of advanced methods such as matching-adjusted indirect comparison, for example).
- Having a responsive HTA means giving equal floor time to patients.



NEXT STEPS

- There is a need for more HTA-JCA-HTD alignment slots to help align on evidence early.
- Relevant PICOs should be made transparent as early as possible.



SESSION 4: LOOKING AHEAD: PREPARING FOR FUTURE INNOVATION



KEY TAKEAWAYS

- The European Medicines Agency (EMA) has a robust system and strategy for performing horizon scanning (over a timescale of 3 to 10 years) to proactively prepare for forthcoming challenges and opportunities, to support the regulatory approval process, and to foster scientific excellence to evaluate medicines.
- The Member State Coordination Group on HTA (HTACG) are responsible for the preparation of reports on emerging health technologies. These reports are prepared by the HTACG's Subgroup for the Identification of Emerging Health Technologies (EHT SG) with a time horizon of 10 years and are based on information from various sources, including EHT SG members, the Medical Device Co-ordination Group (MDCG), and the EU-Innovation Network. The reports highlight emerging trends, including innovative health technologies and approaches/tools with a major impact, as well as therapeutic areas, drug classes, medical device/in vitro diagnostics, or any other relevant areas of particular interest.
- Patients should be at the core of all activities, and not just there as part of a box-ticking exercise.
- Geography matters when navigating policy. The European Union is good at regulating new health technologies, but there is a lack of consistency in other geographical areas. It is important to recognise that China has transitioned from a regulatory follower to a counterparty, with 20% of global drug development.
- The question remains as to whether the HTA JCA and EMA centralised procedures are truly aligned.

SESSION 4: LOOKING AHEAD: PREPARING FOR FUTURE INNOVATION

NEXT STEPS

- Understanding the reasons for the discontinuation of JCAs and unexplained evidence gaps will be important.
- The HTA Regulation is here to stay, and it will be important to reduce duplication of efforts and improve the speed of access to new health technologies.
- The HTA regulation does not come in isolation, but rather as part of an evolving regulatory environment to which it must also contribute; there is thus a need to be watchful about other regulations, such as the EU pharmaceutical legislation, that will have an impact on timelines.





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



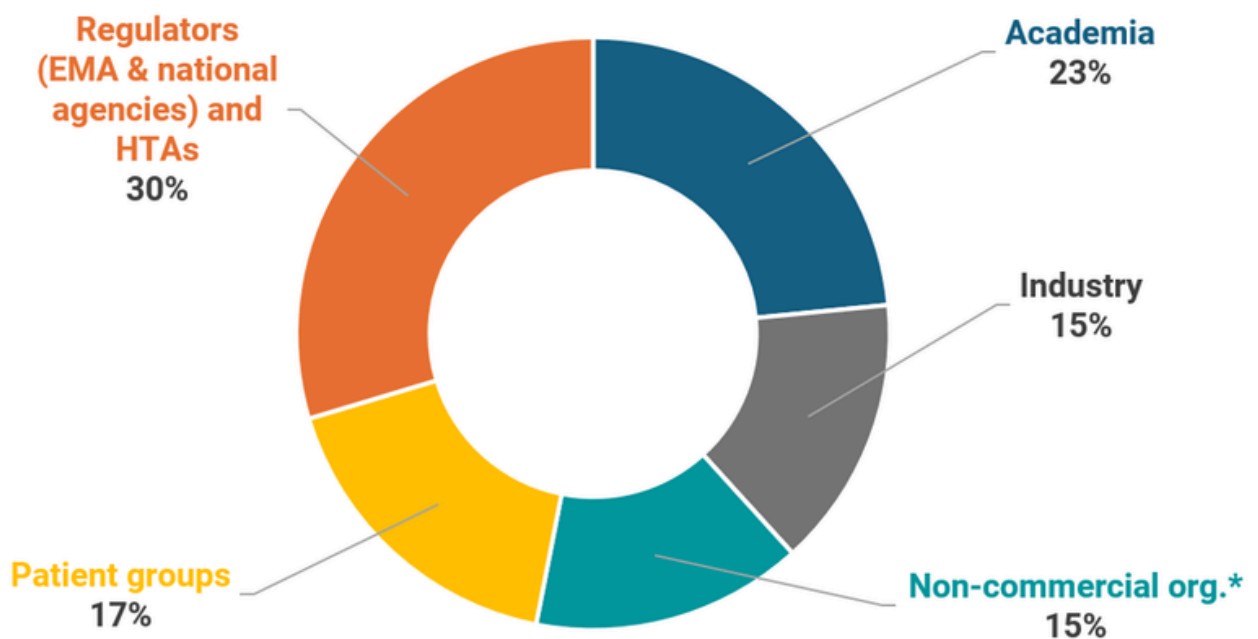


AUDIENCE AT THE CDDF WORKSHOP

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**.



Onsite Participants & Speakers



**including European Commission, associations, foundations*

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

71

**IN-PERSON
ATTENDEES**

99

**ONLINE
ATTENDEES**



WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"It is very important that CDDF brings us together because especially nowadays with everything that is happening in the world, **we cannot afford not to talk to each other**. This is why it is **important to have also uncomfortable conversations** about the evidentiary requirements. Are we asking the right questions when it comes to drug development? Are we sending the right signals to the market? Do we know enough about the drugs that are getting approved in Europe? All of these questions are extremely important, especially for us as public healthcare payers, because they help us really with our decision-making."

Yannis Natsis (BE)

**Director, European Social Insurance Platform & Coordinator,
Medicine Evaluation Committee**

"It really provides us with an opportunity and a dedicated time to think about what HTA is all about and the big picture conversations. I think that all of us who work in the HTA space, sometimes, we get into the nitty-gritty of the daily work and life that's linked to HTA, and I think that the workshop is **an opportunity for us to all take a step back and be reminded of why we do this work**, which is a great and wonderful opportunity."

Josephine Mosset (BE)

Head of Policy, Cancer Patients Europe

"This was really a much needed discussion — **open, transparent discussion with all the stakeholders** that are involved with the EU HTA regulation, the commission, HTA bodies, patients, clinicians and industry, and that we were able to **share our learnings, our challenges**, and hopefully that will lead to **a better system for the future**."

Sacha Wissink (NL)

Therapeutic Area Lead, Ex Dir, Oncology/Devices Regulatory Affairs Europe, MSD

"The beauty of these two days is that we could really have all the opinions in one unique place so that we can **try to see how we can move forward, taking into account the interest and the needs of all the stakeholders**, towards a better Europe for better care for patients."

Denis Lacombe (BE)

EORTC Director General

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.

CDDF'S UPCOMING ACTIVITIES

MULTI-STAKEHOLDER MEETINGS & LIVE WEBINAR

Cancer Drug Development Forum (CDDF)

ANNUAL CONFERENCE 2027

**How can we
accelerate cancer
drug development
and access for EU
patients ?**

8-10 February 2027
Antwerp, Belgium



[Programme](#)

[Registration](#)



CDDF & AAADV JOINT WORKSHOP

**Innovation in
Acquisition,
Analysis and Use
of Real-World Data**

19 - 20 April 2027
Brussels, BE (hybrid)



[Programme](#)

[Registration](#)

LIVE WEBINAR



LIVE WEBINAR

**"Compassionate Use and EAP
for Cancer Drugs – From
Fragmentation to a Common
Framework in Europe under the
New Legislation"**

Ramona Reichenbach (Novartis)
François Houyez (Eurordis)

26 October 2026
16:00-17:00 CET, Online



[Webinar Outline](#)

[Registration](#)

Visit the CDDF website for more updates
on upcoming activities. www.cddf.org



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

Cancer Drug Development Forum (CDDF)

Registered office: c/o BLSI, Clos Chapelle-aux-Champs 30, 1200 Woluwe Saint Lambert, Belgium
Register of legal entities: the French Speaking Enterprise Court in Brussels
Enterprise number: 738.523.752

✉ info@cddf.org

🔍 www.cddf.org