



CDDF Annual Conference 2025

CHALLENGES, ADVANCES, AND
OPEN QUESTIONS IN GLOBAL
CANCER DRUG DEVELOPMENT AND
CLINICAL TRIALS

EXECUTIVE SUMMARY

3-5 FEBRUARY 2025
NOORDWIJK ANN ZEE (NL)



CDDF Annual Conference 2025

Challenges, Advances, and Open Questions in Global Cancer Drug Development and Clinical Trials

3-5 February 2025 , Noordwijk aan Zee (NL)

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

CDDF Annual Conference on “Challenges, Advances and Open Questions in Global Cancer Drug Development and Clinical Trials” took place on 3-5 February 2025 in Noordwijk Ann Zee (NL). It focused on highly relevant topics in the development of anti-cancer drugs and offers constructive discussions with highly competent leaders in fields central to drug development (patient advocates, regulators from the EMA and EU national agencies, health technology assessors, academic researchers and pharmaceutical industry).



SESSION 1: CDDF/AAADV JOINT SESSION OF DIVERSITY IN GLOBAL DRUG DEVELOPMENT



KEY TAKEAWAYS

- Audience is highly involved in the topic (~70%).
- More research and a better definition of diversity data points are necessary.
- Diversity research needs to focus first on large patient groups, such as sex and age.
- Diversity in clinical research is based on ICH regulations as well as FDA & EMA guidance.
- Use a large toolset to increase appropriate representation in clinical trials.



NEXT STEPS

- Answer open questions regarding diversity through science, discussion and research.
- Participate in initiatives that formulate recommendations for appropriate representation on relevant populations in clinical research.



SESSION 2: ENDPOINTS IN DRUG DEVELOPMENT: PROGRESS AND CONTROVERSIES



KEY TAKEAWAYS

- Considerations on endpoints involve complex trade-offs:
 1. The value of different endpoints is in the “eye of the beholder”.
 2. Patient preference studies should become more of a standard
 3. Focus on communication of several endpoints between all parties (more than choice of just one).
- Estimands frameworks will be necessary to be able to communicate systematically.
- There will always be a need for case by case assessments for further validation (including clinical relevance) of novel endpoints.
- The example of MRD in Multiple Myeloma demonstrates how new endpoints can be developed.



NEXT STEPS

- Is OS truly relevant still? Do we have to evaluate/validate the relevant endpoints disease by disease?



SESSION 3: OPTIMIZE EVIDENCE GENERATION AND PATIENT ACCESS WITH INNOVATIVE CANCER TRIALS (METHODOLOGY)



KEY TAKEAWAYS

- ACT EU aims to establish EU as attractive for clinical research, clinical trial methodology is a priority action area for ACT EU.
- RCTs remain the gold standard, preferred by decision-makers, even for small populations.
- External control data / borrowed data can be used when carefully planned and where RCTs cannot be performed for ethical reasons or where in rare conditions there are very few patients.
- Include the patient voice early in drug development/trial design.
- HTAs need to see data on diverse patient populations like those treated in clinical practice. The absence of these data will give rise to many questions.



NEXT STEPS

- Sponsors, and the wider research community, need to plan prospectively to ensure the availability of suitable patient data of good quality to enable construction of external (concurrent) control arms.
- More work is needed to enable high quality use of external data, for instance in the context of the European Health Data Space (EHDS), there is a need for all patient data to be carefully recorded and curated (EHDS).
- Include patient perspective more systematically in JSC/HTA process.
- Advance understanding of “pragmatic trials” and how to do better trials that represent the actual patient populations, and preferences.



SESSION 4: NAVIGATING PRECISION ONCOLOGY DEVELOPMENT IN VIEW OF NEW REGULATIONS



KEY TAKEAWAYS

- The IVDR and the FDA LDT regulations are welcomed by all stakeholders and will ensure quality diagnostics are available for patients.
- Alignment of IVDR requirements and streamlining of approval process within Europe is crucial for clinical research, especially at early stage of development, to ensure EU remains attractive.
- Combined studies drug/IVD face extended approval timelines and complex regulatory hurdles, which are impactful also for academic research, potentially leading inequities in access to clinical trials across Europe.
- COMBINE was a swift reaction from regulators, which brings all stakeholders together, with the promise of addressing the current issues in a timely manner.



SESSION 4: NAVIGATING PRECISION ONCOLOGY DEVELOPMENT IN VIEW OF NEW REGULATIONS



NEXT STEPS

- The real issue is what actually determines drug prices—it's no longer about willingness to pay, but about the ability to pay.
- Societal needs should play a key role in drug development, but the industry alone can't bear that responsibility. In some cases, drug development must prioritize societal benefit over business interests.



SESSION 5: EU HTA REGULATIONS - STAKEHOLDER COLLABORATION TO IMPROVE PATIENT ACCESS



KEY TAKEAWAYS

- Care is more than just drugs.
- The elephant in the room, what actually determines the costs of drugs versus what the market can bare (it isn't a willingness to pay anymore but an ability to pay).
- More inclusion of patients in all decisions the different stakeholders make but keep in mind that sometimes one-size-fit's all doesn't exist.
- Societal needs should be an important driver of drug development but that cannot be seen as a sole responsibility of the industry. Quite the opposite, If we want to drive drug development from that perspective we need to acknowledge that sometimes there is no 'business mode' but only a 'societal mode'. This is a shared responsibility.





SESSION 5: EU HTA REGULATIONS - STAKEHOLDER COLLABORATION TO IMPROVE PATIENT ACCESS



NEXT STEPS

- Provide a forum that enables cross-stakeholder discussions on evidence generation requirements from all Stakeholder perspectives.
- Learn from examples of studies not exclusively focusing on evidence generation for approval only, but incorporate the needs of downstream decision makers.

Meeting recordings and presentation slides are available to CDDF Members, regulators, patients and academics via the CDDF intranet platform (<https://cddf.org/member-access/>)

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



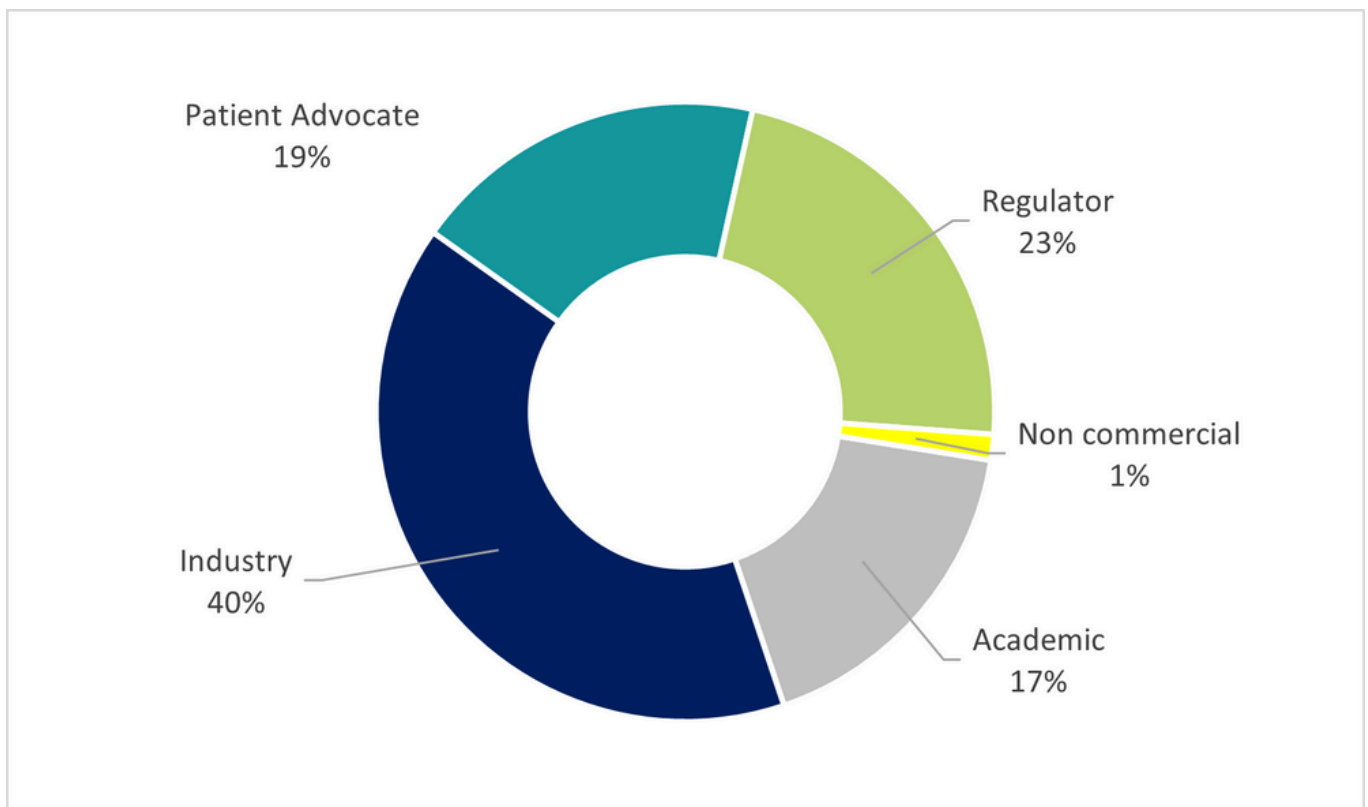


AUDIENCE AT THE CDDF WORKSHOP

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**.



Onsite Participants & Speakers



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

91

**IN-PERSON
ATTENDEES**

134

**ONLINE
ATTENDEES**



WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"I really like the sort of intimate setting that we have at these CDDF meetings where we have, of course, industry, but we also have regulators, we have very important patients, academicians, payers, where we can all have an open, honest debate and discussion in a very safe and conducive environment to really tackle what are big challenges and issues and opportunities in oncology drug development."

Dr. Harindra Abeysinghe
Johnson & Johnson, UK

"So for me, the highlights of the session were the fact that it seemed like everybody had a really open and curious approach, where there was an understanding that clinical trials are about building knowledge, and that we are all actually in this process together of growing this body of knowledge."

Mrs. Khullat Munir
Patvocates, DE

"What I particularly liked was the fact that we're getting alerted and educated about what the challenges may be, and most importantly, reflecting on Day 2, what I found particularly enjoyable was the very vibrant discussion we had with a panel of sessions, which means we can really hear all of our thoughts and start to debate and deliberate over what we will do in the future to make all of this have a successful outcome."

Dr. Navid Malik
Northwest Biotherapeutics, UK

"Developing effective therapies requires a global, multi-stakeholder effort. Integrating real-world evidence and patient perspectives is crucial, especially in precision medicine. In the end, it's about the right treatment, for the right patient, at the right time."

Mr. Szymon Bubilek
Polish Sarcoma and Melanoma
Patients Association, PL

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 MEETINGS & DISCUSSION

MULTI-STAKEHOLDER MEETINGS



MULTI-STAKEHOLDER WORKSHOP

New Modalities in Cancer Drug Development

31 March - 1 April 2025
Brussels, BE (hybrid)



[Programme](#)

[Registration](#)

Focus of Discussion

- 1 What is New in Oncology
- 2 Radiopharmaceuticals
- 3 Personalized Vaccines in Oncology
- 4 Cellular Therapies
- 5 Discussion Session on Common Challenges



MULTI-STAKEHOLDER WORKSHOP

Accelerating drug development to deliver better patient care

17 - 18 November 2025
Brussels, BE (hybrid)



[Programme](#)

[Registration](#)

Focus of Discussion

- 1 Specifics of CHMP Assessment of Cancer Drugs
- 2 Current Status and Implications of the In Vitro Diagnostics Regulation (IVDR)
- 3 Initiatives for a Joint EU HTA Assessment
- 4 Q&A and Discussion

CDDF'S UPCOMING MEETINGS & DISCUSSION

Joint Workshop



AAADV-ASCO-CDDF Workshop
Global Oncology Drug Development

15-16 May 2025, Washington D.C. (US)

[AAADV website](#)

Webinars

- 1 **EU HTA Regulations**
- 2 **Webinar series: AI and Big Data AI in drug development:**
 1. Transparency and risk assessment
 2. Modern imaging tools for response assessment
 3. AI-driven patient profiling for personalized treatment recommendations
 4. Use of AI in clinical trials
- 3 **Webinar series on ACT EU:**
 1. Overview of ACT EU
 2. Patients – CTIS

[Webinar outline](#)

**CDDF BREAKS DOWN SILOS
IN THE ONCOLOGY COMMUNITY AND
FACILIATES OPEN, MEANINGFUL
DIALOGUE AMONG ALL
STAKEHOLDERS**



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

ACKNOWLEDGEMENTS

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