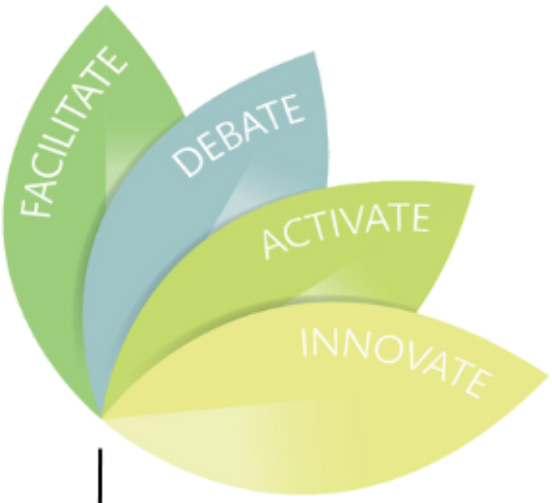


CDDF
Cancer Drug Development Forum

Annual Conference 2024

CDDF Annual Conference 2024

Changing Paradigms to Accelerate Drug Development

(5-7 February 2024, Noordwijk, NL)

EXECUTIVE SUMMARY

Cancer Drug Development Forum (CDDF)

info@cddf.org

www.cddf.org

The Cancer Drug Development Forum (CDDF) Annual Conference is a unique multi-stakeholder meeting that brings together leading voices from academia, the pharmaceutical industry, regulatory authorities, and patient advocacy groups with the aim of improving cancer treatment.

In its 2024 edition, the meeting explored and analyzed **innovative approaches** to accelerate oncology drug development, considering the **changing paradigms and regulatory environment** in the field. The program focused on **real world evidence**, **decentralized care and trials,** impact of r**ecent regulatory changes**, **diversity in clinical trials**, and **drug and biomarker combinations** in oncology. It also provided reflections on the CDDF workshops held in 2023 and its joint activity with AAADV and ASCO to explore global collaboration in cancer drug development.

The interactive forum facilitated fruitful discussions and thought-provoking dialogue among stakeholders, emphasizing the importance of collaborative endeavors.
Key takeaways are presented as follows:

TAKE-HOME MESSAGE

SESSION 1: REAL WORLD EVIDENCE

- There has been **rapid growth in the availability of RWD**, accompanied by efforts across regulators, academics, data holders, and the pharmaceutical industry to advance appropriate uses whilst working through the strengths and limitations of RWD. Great progress has been made with RWD, however we have **significant work and much required alignment amongst key stakeholders**.

- **Commitment to continuous data improvement and collection** is an important step in maximizing the utility of RWD to generate RWE for patient-centred regulatory decision. **RCTs** provide defined data, and the premise of RWD through **pragmatic trials and robust RWD collection aid decision making**, looking at the “totality of data”.

- The **evolution of registries, Darwin EU and OPTIMA** were extensively reviewed, providing insights on how these databases have advanced the RWD field. **Harmonisation and robustness of data collection within member states and globally** continues to be required to ensure robust RWD to support decision making.

SESSION 3: DECENTRALIZED CARE AND TRIALS

- The **Covid-19 pandemic** has ushered in a period of rapid change. However, as we look ahead, there appears to be **little indication that we will be capitalising on the lessons learned during this time**.

- The FDA has released a **draft guidance on decentralised trials**. The incorporation of elements from this guidance into trials will vary depending on the context, with a focus on enhancing patient involvement and facilitating access to new medications.

- Various **digital solutions platforms** are currently in development, with a specific emphasis on **patient-centricity** aimed at improving the patient experience, reducing costs, and lowering carbon emissions, all while **expediting project timelines**.

- There is **strong patient support for digital solutions** such as wearables.

- It is crucial to **design technology with a focus on the perspective of patients and caregivers.** The widespread acceptance of these innovations will largely depend on ensuring a positive and meaningful patient experience.

- It may be necessary to **maintain both traditional and digital options** to accommodate the diverse needs of all patients.

TAKE-HOME MESSAGE

SESSION 4-1: IMPACT OF RECENT REGULATORY CHANGES

- **Project Frontrunner** is an **accelerated approval pathway for a therapy in relapsed/refractory settings** that demonstrate an advantage over available therapy. FDA is looking forward to **engaging with stakeholders to discuss considerations for trial design and trial setting** that is most appropriate for the initiative (case-by-case basis discussions since one-size does not fit all).

- Two presentations from members of FDA and MPA addressed expedited approval pathways in the respective regions. Questions discussed included h**ow bridge the differences in patient population** and, at times, **benefit-risk between late line studies and confirmatory studies in earlier lines**.

- **EU CTR** has delivered on i) **harmonization of part 1 requirements**, ii) **clarity & predictability of assessment timelines**, iii) **structured data requirements in CTIS** and, iv) **Pan-European approvals.** Sponsors embrace the new regulation, however, **further enhancements are needed** (eg. CTIS, further harmonization of the assessments, more flexibility of submission pathways) to make Europe a competitive place for clinical research.

- **EU Pharmaceutical Legislation**: The proposal is under consultation and it is **unclear whether it will be passed by the European Parliament in this current period.** The most controversial part is the **changes to the market exclusivity rules** and quite **diverse changes and amendments** currently being discussed. From patients' point of view, there is a concern that the definition of unmet medical need might not include their perspective. In the discussion, the point was made that narrow definitions of key terms may turn out to be too restrictive in the future when scientific innovation changes context.

TAKE-HOME MESSAGE

SESSION 4-2: DIVERSITY IN CLINICAL TRIALS

The panel discussion focused on **two questions** regarding **the efforts to better represent relevant minority populations** that are not yet sufficiently included in clinical trials.

The first was to **assess the current status of effort to achieve better diversity and inclusion in Europe**.

- What the **European populations are not adequately represented** in pivotal oncology clinical trials? What markers of geographic ancestry, socio-economic or functional status do we need?
- **Health literacy** is an important and underrated aspect of access to clinical trials and advanced cancer care.
- There is a strong need to **establish a detailed epidemiological understanding of the target population** already at start of drug development.

The second question addressed **the challenges that will occur when the data of additional subgroups becomes available**.

- The panelists agreed on the **dangers of uncontrolled interpretation of subgroups with both false negative and false positive conclusions**.
- Regulators pointed out that these have occurred in the past and were discussed in the assessment reports.
- **Possible variations in activity or safety** should be spotted as early as possible and context provided to facilitate the correct interpretation of these findings.
- For some populations, e.g. the frail elderly, **separate trials** might be necessary to assure the safe use of innovative treatments.

TAKE-HOME MESSAGE

TAKE-HOME MESSAGE

SESSION 5: DRUG AND BIOMARKER COMBINATION

- **Academic platform Trials/cross-Europe collaboration** via consortia such as PRIME-ROSE is a route to validate activity and lead to extension of licence in rare cancers.

- The **complexity of exploring optimal dose, impact of biomarker expression**, as well as **combination of agents** (modified by target expression) requires careful consideration with respect to drug development.

- **IVDR related obstacles** to clinical trials need to be resolved as soon as possible.

CDDF
Cancer Drug Development Forum

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

CDDF Cancer Drug Development Forum

FACILITATE DEBATE ACTIVATE INNOVATE

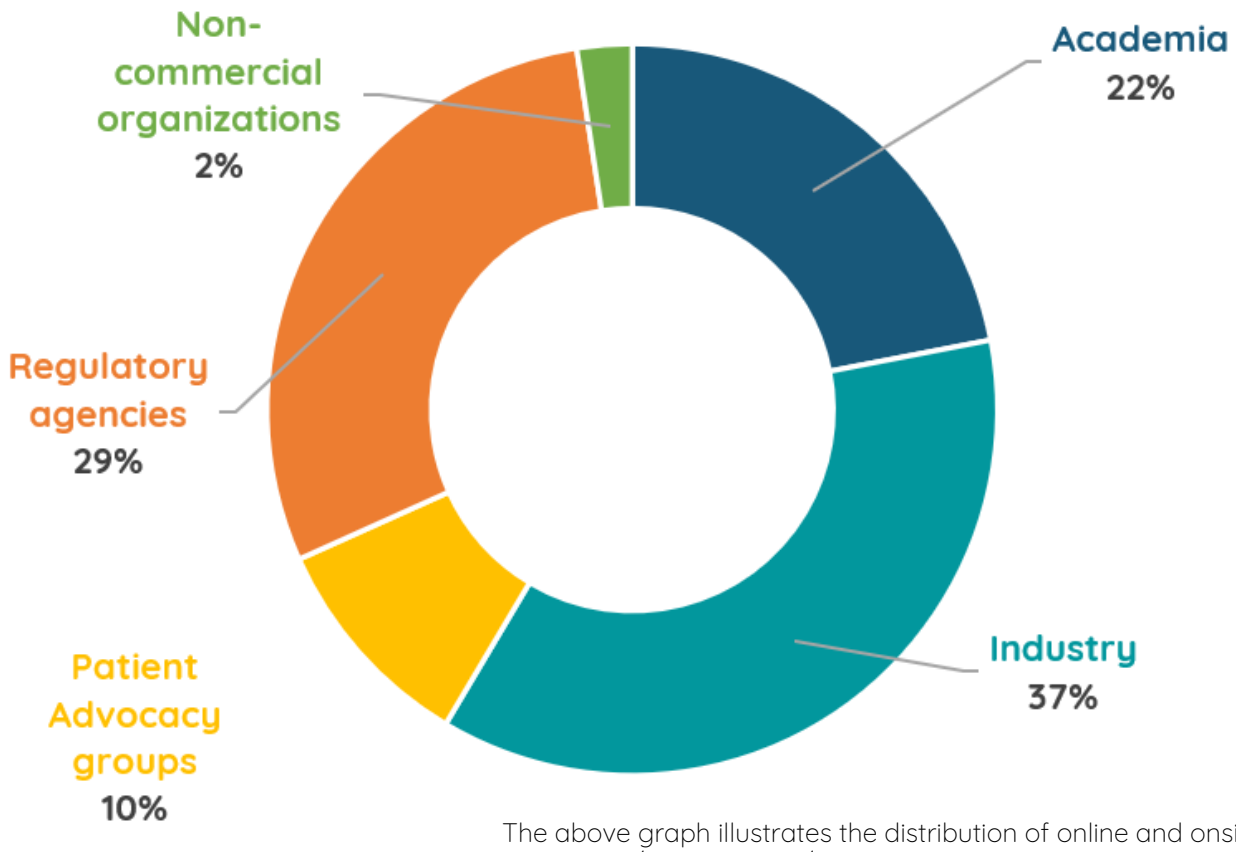
Annual Conference 2024

Collaboration and open dialogue among all stakeholders are key to accelerate the development and delivery of oncology drugs

AUDIENCE AT THE CDDF ANNUAL CONFERENCE 2024

CDDF's meetings present **a wide range of prespectives** 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 above graph illustrates the distribution of online and onsite speakers/chairpersons/panelists along with onsite attendees.

152
ONLINE ATTENDEES

82
IN-PERSON ATTENDEES

WHAT PARTICIPANTS SAY ABOUT THE ANNUAL CONFERENCE?

"I liked the lively discussions where people were not shy and coming forward with their thoughts and views. That gave me lots to think about on my journey home."

Richard Price
European Cancer Organisation (ECO), BE

"I learned so much and I really value the thoughtful and deliberative nature of the sessions. It honestly was one of the best conferences I've attended in a long time."

Debbie Keatley
Independent Cancer Patients' Voice (ICPV), UK

"We are extremely aware of the significance of having multi-stakeholder discussions about important topics in oncology. I think CDDF is an excellent forum to reach a number of different audiences and spread the message about many initiatives that we have at the agency."

Francesco Pignatti
European Medicines Agency (EMA), NL

"The conference is very accessible, open and intimate and makes it easy to go talk to anybody and network. Discussions are packed with information and to the point."

Ruth Curley
Ryvu, PL

"What I like most at the meeting is facilitated dialogue and collaboration among stakeholders involved in oncology drug development."

Dana Gabriela Marin
National Agency for Medicines and Medical Devices of Romania

"It was nice to see at the conference that we all agreed that we need to work on diversity in clinical trials in Europe and advanced ourdiscussions on how we do it. Hopefully there will be more coming potentially with a pilot."

Katrin Rupalla
Johnson & Johnson, CH

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 UPCOMING DISCUSSIONS

Multi-Stakeholder Workshop (Hybrid)
Clinical Research in Central and Eastern Europe

15 – 16 April 2024
Krakow (PO)

Multi-Stakeholder Workshop (Hybrid)
Innovation and Access in Rare Cancers

23 – 24 September 2024
Amsterdam (NL)

CDDF Live Webinar
Cancer Medicines Forum

25 June 2024. 16:00-17:00 CEST
Online

ESMO-CDDF joint session
Regulatory Challenges in Clinical Cancer Drug Development

16 September 2024, 08:30-10:00 CET
CC5 – Zaragoza Auditorium, Barcelona (ES)

ACKNOWLEDGEMENTS

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

Visit the CDDF website

Follow us on LinkedIn

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

www.cddf.org
Info@cddf.org