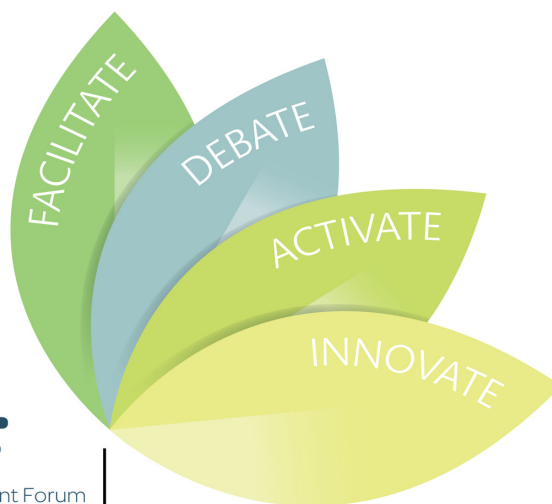




Annual
Conference
2023

CDDF Annual Conference 2023

Challenges in Clinical Trial Performance

(6-8 February 2023, 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 2023 edition, the meeting covered various important aspects in the future performance of clinical trials aiming at drug registration. The program focused on the challenges related to population diversity, the practical aspects of decentralized trials, the difficulties faced in their early career by those involved in clinical trials, and dwelled on some regulatory topics. It also provided reflections on the CDDF workshops held in 2022 and its joint activity with AAADV and ASCO to explore global collaboration in cancer drug development.

This interactive meeting generated fruitful, thought-provoking discussions and emphasized collaborative efforts among stakeholders along with the following take-home messages:



SESSION 1: DIVERSITY IN CLINICAL DATA

- There is a definite need to well define variables to capture diversity in clinical trial with the aim to ensure best possible care for everyone. Many barriers still need to be overcome to achieve the diversity goals not the least some adverse cultural barriers
- Diversity can be understood as the combination of generalisability and representativeness of the clinical trials results
- Absence of evidence for efficacy is not the same as evidence for absence of efficacy
- Improving data diversity improves AI utility and requires a strategy for (mindful) data collection, data preprocessing, multimodality, model training and evaluation to avoid bias





SESSION 3: WHAT I SHOULD HAVE ASKED WHEN I STARTED MY CAREER IN CANCER DRUG DEVELOPMENT

- It is important to early consider where you want your career to land if you are interested in cancer drug development, and plan your education and training to be prepared for a career in drug development
- Modern cancer drug development involves basic science, clinical science, and an interplay between patient needs and regulatory trajectories
- Careers in cancer drug development involve interactions between each of these constituents, but can be focused on an area or areas of personal interest and strength, combined with effective communication and management skills
- Opportunities for more formal exposure to the drug development process, in the form of workshops, internships, and post-doctoral and early career training will have a positive impact on those who experience them



NEXT STEPS

The CDDF may want to consider organizing career development activities such as training and education in cancer drug development, in cooperation with major pharma companies and/or educational institutions.





SESSION 4: DECENTRALISED CLINICAL TRIALS

- Acknowledgement of high interest from industry, academia, regulators and patient groups to adopt decentralization of cancer clinical trials to enhance equitable access, diversity of clinical trial population and patient centric drug development
- An example of the set up needed for a decentralized precision oncology trial at a leading academic network in the UK was discussed
- Regulatory representatives encouraged identifying the right type of trial to implement decentralization; perhaps pragmatic trials with simpler design or later stage trials like post marketing commitment trials rather than early- stage trials; demonstrate success in simpler trials first before moving on to complex trials
- Need to keep the legal framework in mind and legislative actions likely needed to remove hurdles and enable uptake of decentralized trials
- Opportunities to enhance inclusion of vulnerable populations like the elderly, disabled and rural populations via appropriate decentralization approaches was encouraged



NEXT STEPS

The CDDF considers following up on this topic at a webinar and/or the 2024 CDDF Annual meeting by showcasing examples of decentralized clinical trials (hybrid or fully decentralized trials) including challenges and opportunities



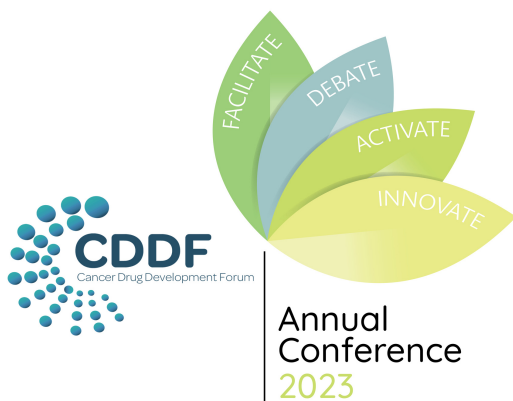
SESSION 5: OPTIMIZATION OF TREATMENT-DOSE AND SCHEDULE

- MTD is no longer the holy grail in early studies
- Initial randomized optimization studies in the pre-marketing stage can be underpowered
- Dose discontinuation should be an ultimate part of dose optimization studies



NEXT STEPS

The Cancer Medicine Forum will have further meetings on the topic. Given the many aspects, further dialogue is crucial.



Collaboration and open dialogue
among all stakeholders are key to
accelerate oncology drug development
and deliver optimal treatment
to cancer patients



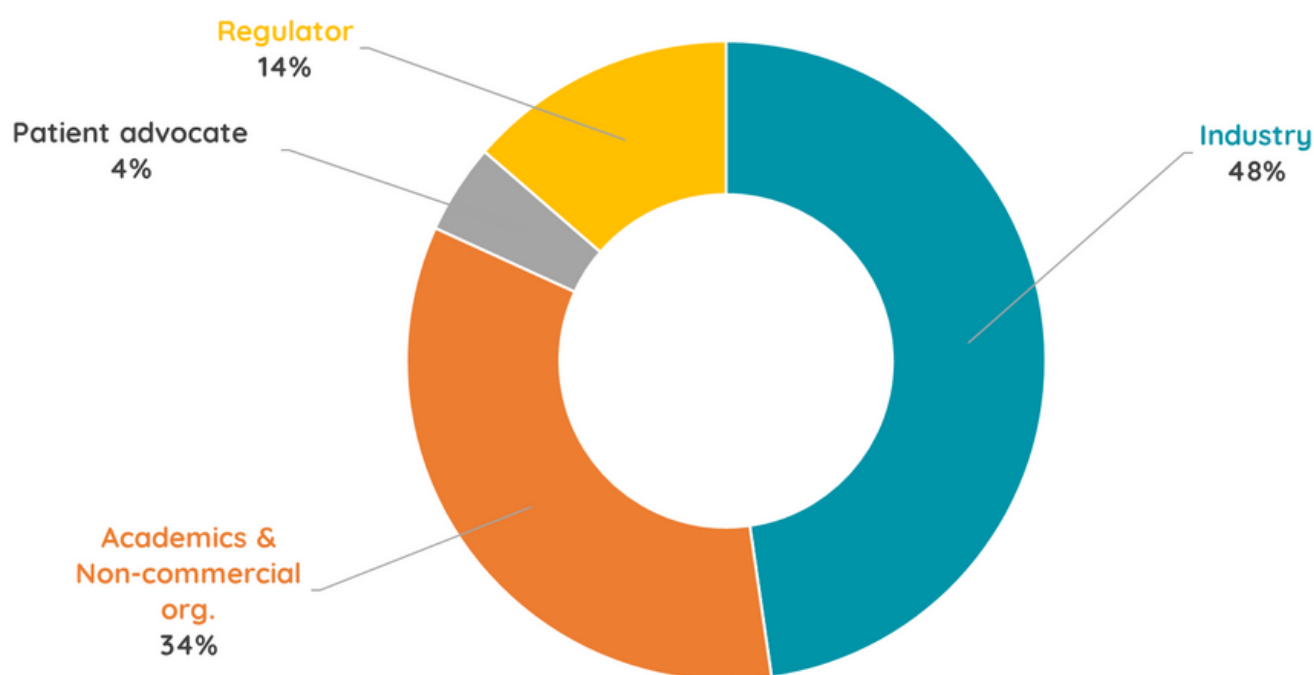


AUDIENCE AT THE CDDF ANNUAL CONFERENCE 2023

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



140

ONLINE
ATTENDEES

52

IN-PERSON
ATTENDEES



WHAT PARTICIPANTS SAY ABOUT THE ANNUAL CONFERENCE?

"I like discussions both during sessions and coffee breaks at the CDDF Annual Conference. The CDDF is great to create a very open atmosphere."

Harald Enzmann
BfArM, DE

"The conference brings together the whole cancer drug development community. It is really important because we need all stakeholders talking together to defeat cancer"

Mark Lawler
Queen's University Belfast & CDDF, UK

"The CDDF Annual Conference has lots of people from different disciplines and areas of the world. There is a constructive interaction going on here and it is easy to talk and discuss topics. I really like that."

Marie Von Lilienfeld-Toal
Clinical University of Jena, DE

"At the conference, all stakeholders involved in cancer drug development contribute their perspectives on processes to enhance and accelerate oncology drug development."

Kim Lyerly
AAADV, US

"It is an opportunity to meet colleagues and like-minded people and also listen to other stakeholders. You also get ideas from discussions in the room."

Sushmita Sen
Roche, CH

"I like the fact that the conference is not too big and there is Chatham House Rule. As the CDDF got pretty much all of the stakeholders, the CDDF have a much better dialogue. Sessions are good but dialogues afterwards are really rich"

Gilliosa Spurrier-Bernard
MPNE, MelanomeFrance, FR

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.





Join the CDDF'S OPEN DISCUSSIONS & ENGAGE WITH OUR MULTI-STAKEHOLDER COMMUNITY

CDDF Webinar

Immunotherapy and Radiotherapy Combinations Part 2: Regulatory Considerations

27 February 2023, online



Multi-Stakeholder Workshop (Hybrid) Dose Optimization in Early Oncology Drug Development

3 – 4 April 2023, Amsterdam (NL)



Multi-Stakeholder Workshop (Hybrid) Innovative Oncology Trial Designs

18 – 19 September 2023, Amsterdam (NL)



Multi-Stakeholder Workshop (Hybrid) Biomarkers in Oncology Drug Development

13 -14 November 2023, Amsterdam (NL)





**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

ACKNOWLEDGEMENTS

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