CDDF Multi-Stakeholder Workshop

Dose Optimization in Early Oncology Drug Development

(3-4 April 2023, NL)

EXECUTIVE SUMMARY

Cancer Drug Development Forum (CDDF)

info@cddf.org
www.cddf.org

CDDF Multi-Stakeholder Workshop

Dose Optimization in Early Oncology Drug Development

(3-4 April 2023, NL)

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

The workshop on "**Dose Optimization in Early Oncology Drug Development**" took place on 3-4 April in Amsterdam (NL) to discuss how dose optimization in the future could be implemented in early drug development based on new methodologies, considering the views of all relevant stakeholders.

The program focused on the challenges of dose optimization, project Optimus and other regulatory initiatives, methodological approaches, and options for the path forward in this field. It generated **interactive, open dialogue** with various actors in this area and discussed how to move forward in dose optimization. The workshop highlighted **collaborative efforts** to address the topic along with the following key takeaways:

KEY TAKEAWAYS

- **Consensus** that dose selection needs to be optimised during early drug development in oncology, major concerns are additional complexity, time and expense added, but that the benefit will be an optimised benefit-risk of the treatment for patients.

- **One size will not fit all:** The dose selection strategy needs to be adapted tothe mechanism of action, tumour biology, the intended indication and patient population and the modality of the products. Preclinical, tumor biology and PK/PD models can help to guide trial designs, selection of the starting dose and dose increments.

KEY TAKEAWAYS

- The dose selection strategy needs to be underpinned by **data enrichment strategies:** Data from preclinical tumour evolution, preclinical in vitro and in vivo studies as well as PK/PD modelling, ideally with a biomarker of target engagement.

- Patient heterogeneity and tumour biology cause significant **complexity** as the 'optimal' dose and schedule may vary from patient to patient, from tumour site to site in same patient and over time as treatment induces cancer adaptations.

- The dose selection from the initial trial can be supported by **new methodologies** like advanced statistical analyses, early measures of efficacy, e.g. Time to Tumour Growth or ctDNA kinetics.

TAKE-HOME MESSAGE

KEY TAKEAWAYS

- The existing EU anti-cancer guideline provides high level considerations on optimising dose selection strategies, which are generally aligned with the FDA draft guidance on Project Optimus.
- There must be a stronger emphasis on long-term **tolerability** in the age of molecular targeted agents that are often used for prolonged periods of time. The sole focus on Dose-Limiting Toxicity as with cytotoxic agents is no longer adequate.
- **Patient-reported outcomes** can be great of value to assess the tolerability profile of an agent during dose finding. Validated libraries are available.

TAKE-HOME MESSAGE

CDDF
Cancer Drug Development Forum

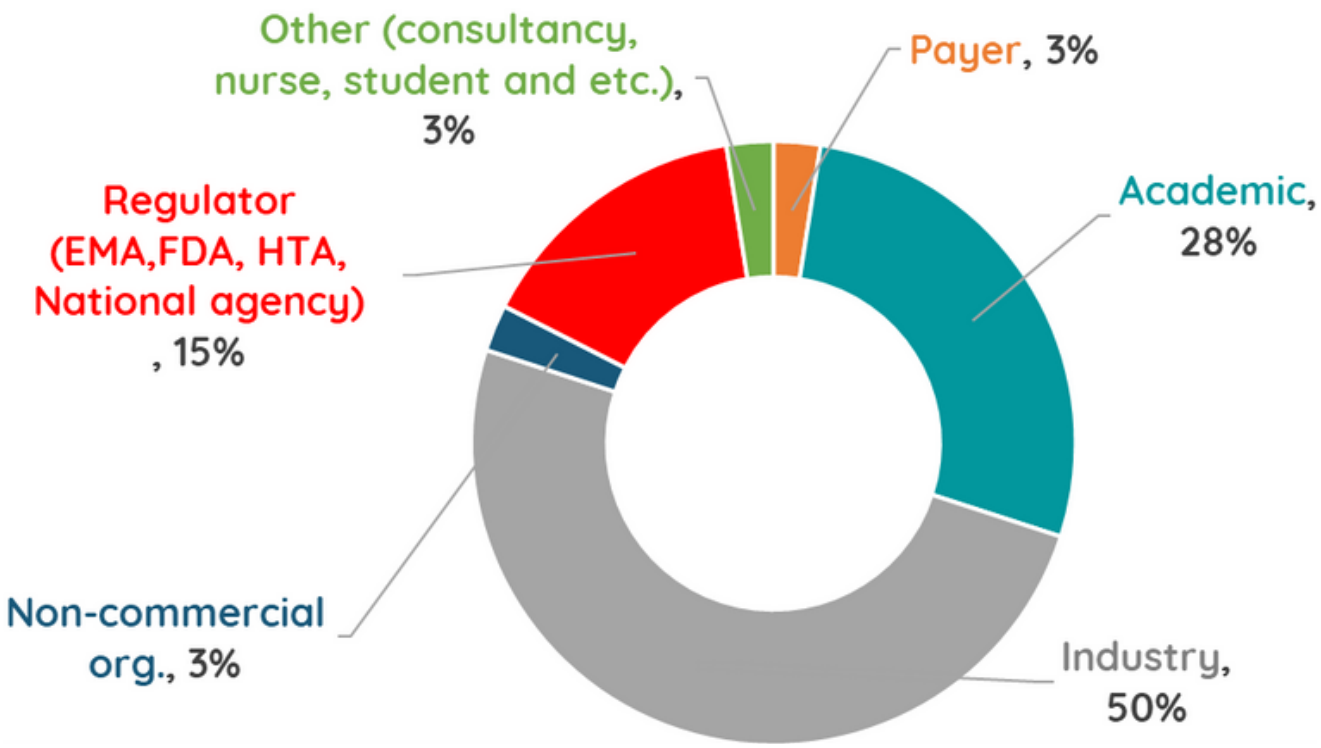
Meeting recordings and presentation slides are available to CDDF Members and regulators via the CDDF intranet platform (https://cddf.org/member-access/)

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

AUDIENCE AT THE CDDF WORKSHOP ON DOSE OPTIMIZATION

The 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.**

Speakers & Onsite Participants



272
ONLINE ATTENDEES

33
IN-PERSON ATTENDEES

WHAT PARTICIPANTS SAY ABOUT THE WORKSHOP?

"There was a lot of great dialogue and engagement from the audience. I really liked the range of questions that were asked and the different perspectives that were included."

Hillary Stires
Friends of Cancer Research, US

"What was interesting and very pleasing for me was that various stakeholders were present at the meeting. It was good to hear all stakeholders working together to get something for patients' benefits"

Benoy Daniel
MHRA, UK

"The value of this workshop is to be able to have a conversation with all different stakeholders and informative interactions and also to be able to discuss some concerns in depth that we all have in our respective roles"

Josephson Filip
Swedish Medical Products Agency (MPA),SE

"It was very interesting to see everyone come together and share their perspectives because in everyday life, we sometime get too focused on our own perspectives and lose sight of the big picture. Every stakeholder, at the end of the day, focus on the same goal to improve efficacy and tolerability for patients"

Lisa Vervueren
National Institute for Health and Disability Insurance (NIHDI), BE

"It was interesting to hear some of the key considerations from multi-stakeholder perspectives on opportunities and further refinements when it comes to dose optimization. This is an incredible opportunity especially after the recent draft guidance of FDA related to Project Optimus"

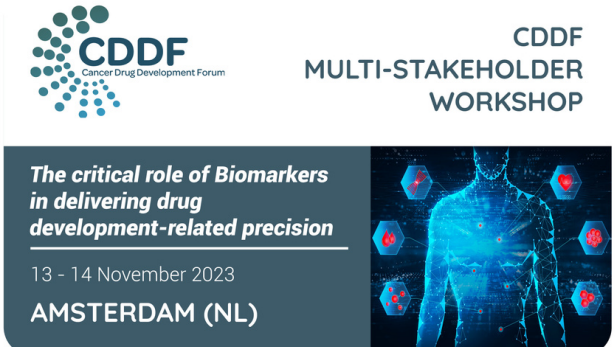
Divya Samineni
Roche, US

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 MULTI-STAKEHOLDER COMMUNITY

Multi-Stakeholder Workshop (Hybrid)
Innovative Oncology Trial Designs

18 – 19 September 2023, Amsterdam (NL)



Multi-Stakeholder Workshop (Hybrid)
The Critical Role of Biomarkers in Delivering Drug Development-Related Precision Oncology

13 -14 November 2023, Amsterdam (NL)

WEBINAR TOPICS FOR 2023 +

- Decentralized care
- Europe's Beating Cancer Plan
- EU clinical trials regulation
- EU HTA regulation
- Clinical research in Central and Eastern Europe
- Preventive cancer care
- COVID-19 and impact on cancer patients, treatments and developments

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