CDDF
Cancer Drug Development Forum

CDDF Multi-Stakeholder Workshop

THE CRITICAL ROLE OF BIOMARKERS IN DELIVERING DRUG DEVELOPMENT-RELATED PRECISION ONCOLOGY

13-14 NOVEMBER 2023, NL

EXECUTIVE SUMMARY

CANCER DRUG DEVELOPMENT FORUM (CDDF)

CDDF Multi-Stakeholder Workshop

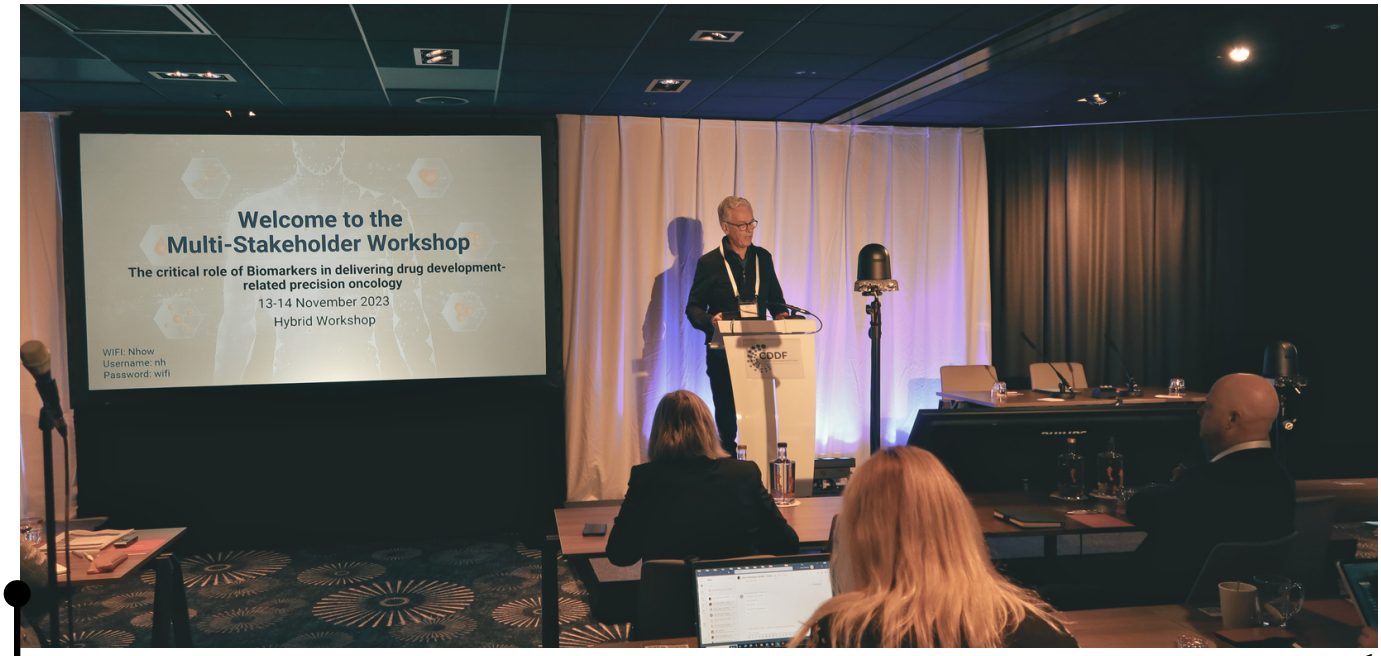
The Critical Role of Biomarkers in Delivering Drug Development-Related Precision Oncology

(13-14 November 2023, NL)

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

The workshop on "The Critical Role of Biomarkers in Delivering Drug Development-Related Precision Oncology" took place on 13-14 November in Amsterdam (NL) to discuss **how biomarker use could best be implemented in drug development** based on available insights from **all relevant stakeholders**. A quality team representing many of the key players in this rapidly evolving field explored and evaluated various **challenges and opportunities surrounding biomarkers** in oncology drug development and the trials designed to obtain marketing approval in selected populations.

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



SESSION 1: SETTING THE SCENE OF BIOMARKERS

KEY TAKEAWAYS

- Biomarkers are critical in the diagnosis of cancer, in defining prognosis and in prediction of response to and potential toxicities of precision therapies.
- Timely precision genomic testing should be embedded within health systems to provide equal access to targeted treatment option for all patients.
- Biomarker-driven research can lead to faster, more effective and cost efficient drug development
- Patients must be at the centre of biomarker-driven precision oncology.

NEXT STEPS

- Promote patient education on importance of precision oncology and its impact on patient care.
- Encourage collaboration between academic, industry and regulatory agencies to generate the data required to support implementation of biomarker-driven precision care.
- Derive evidence base to support implementation of ctDNA approaches to enhance the cancer treatment pathway.

SESSION 2: BIOMARKER BASED AUTHORISATION & REIMBURSEMENT

KEY TAKEAWAYS

- More data are required to better inform the selection of clinically-relevant cut-off points.
- Precision oncology currently accounts for more than a third of new FDA drug approvals, but regulatory approval for Companion Diagnostics (CDx) poses certain challenges.
- Health Technology Assessment (HTA) bodies should incorporate the test-treatment combination within cost-effectiveness analyses.
- In the Netherlands, a tripartite national committee, comprising health professionals, health insurance companies and patient advocates, helps selected appropriate testing and reimbursement of biomarker approaches.
- Increased transparency regarding testing, has the potential to diminish practice variation and enhance patient access to biomarker-informed precision oncology.

SESSION 3: THE COST OF NOT USING BIOMARKERS

KEY TAKEAWAYS

- Genomic testing rates are lower than anticipated in lung, colorectal and ovarian cancers, diseases for which there are clear data on the benefit of application of targeted therapy approaches.

- Multi-pronged strategies are needed to deliver precision medicine, including mechanisms to streamline testing delivery, access and reimbursement.

- Collaboration of patient advocacy, medical specialists, insurers, politicians and national health authorities has resulted in reimbursement of whole-genome sequencing for patients with cancer of unknown primary (CUP) in the Netherlands, and a network of CUP clinics to support genomic testing.

- Increasing access to broad biomarker sequencing panels and repeat testing can help address spatial and temporal heterogeneity across tumours.

SESSION 4: IN VITRO DIAGNOSTIC REGULATION (IVDR)

KEY TAKEAWAYS

- It is important to consider the real world setting for biomarker-informed treatment.
- We need to ensure that IVDs are constantly refined and that the quality of tests provided is high.
- From a regulatory perspective, the IVDR adds complexity to clinical trials and to approval of drugs with CDx.
- We need to reduce complexity and harmonize approval procedures so that broad access to biomarker testing in Europe is facilitated.
- Notified bodies are deeply involved in discussions with the EMA through pre-submission meetings and the consultation procedure, so as to ensure rigour but also facilitate approvals.

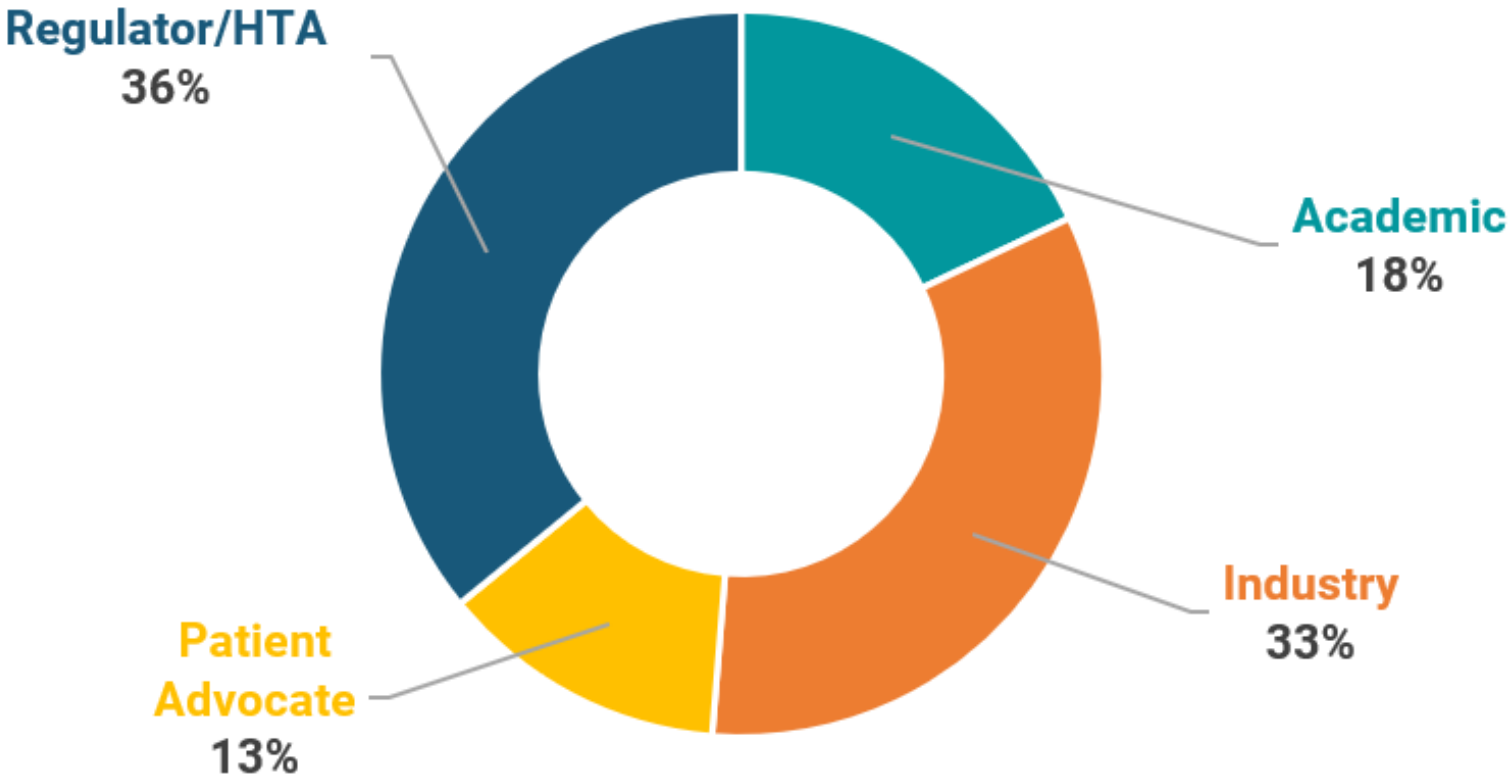
Meeting recordings and presentation slides are available to CDDF Members and regulators via the CDDF intranet platform (https://cddf.org/member-access/)

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

AUDIENCE AT THE CDDF WORKSHOP

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.**

Onsite Participants & Speakers



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

134
ONLINE ATTENDEES

42
IN-PERSON ATTENDEES

WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"The workshop session provided me with a comprehensive understanding of the biomarkers landscape in cancer research, testing, and treatment. The speakers incorporated the perspectives of all stakeholders engaged in the precision oncology pathway, covering the entire spectrum from identifying a biomarker to its application in cancer care."

Marianna Vitaloni
Digestive Cancers Europe, BE

"The value of this workshop is to enable informative sessions with stakeholders and to promote informed discussion of the challenges within our respective roles."

Ana Trullas Jimeno
The European Medicines Agency (EMA), NL

"Conversation in the room was realistic, not just about the status of technological changes that are going on in precision medicines. That brings particularly to access to these new, exciting drugs emerging from testing. When I cast my mind back to decades ago, when we were all thinking about challenges and excitement about precision medicines. One of the areas that wasn't really focused is patient access to testing. What I take away from the workshop session is that that is firmly on the agenda. I feel a realistic, collaborative sense in the room and this is the next challenge that we all need to face together."

Peter Keeling
Diaceutics, UK

"What I like most about the CDDF workshop is that it brings different stakeholders together and give them space to present their ideas. It is like every voice is heard. That is really appreciated especially today's environment."

Peter Sisovsky
State Institute for Drug Control Slovakia, SK

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

Session Topics

1. Real-World Evidence
2. Reflections on CDDF Meetings in 2023
3. Decentralized Care and Trials
4. Impact of Recent Regulatory Changes
5. Drug & Biomarker Combination

Program | Registration

Session Topics

1. Current Status of Clinical Trials in Central and Eastern Europe
2. Improving Clinical Trials in Central and Eastern Europe
3. Innovative Concepts in Central and Eastern Europe
4. Roundtable to Formulate Consensus for Next Steps

Program | Registration

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ACKNOWLEDGEMENTS

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

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Cancer Drug Development Forum (CDDF)

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