THE CANCER DRUG DEVELOPMENT FORUM

FACILITATE. DEBATE. ACTIVATE. INNOVATE.

Promoting Multi-Stakeholder Collaboration to Advance Oncology Therapeutics.

CDDF
Cancer Drug Development Forum

TOGETHER, WE IDENTIFY AND OVERCOME CHALLENGES IN THE **DEVELOPMENT** AND **DELIVERY** OF **CANCER DRUGS**

OUR MISSION

The Cancer Drug Development Forum (CDDF) is the leading non-competitive drug development platform in Europe whose sole objective is to stimulate discussions to advance cancer drug development and access.

HOW WE ADVANCE OUR MISSION

The CDDF provides a unique platform to facilitate collaboration between stakeholders to increase efficiency in cancer drug development.

Our integrative approach aims to bring together leading voices from academia, the pharmaceutical industry, regulatory authorities, health technology assessors, policymakers, and patient groups to improve cancer treatment.

INITIATIVES

For many years, the Cancer Drug Development Forum (CDDF) has stimulated discussions to **accelerate effective drug development** in oncology treatment and shorten time to market, and time to patient access.

CDDF offers workshops, conferences and webinars that bring stakeholders involved in cancer drug development into **a productive dialogue in a neutral, non-competitive space.**

CDDF drives multiple activities and initiatives in **close contact with regulators** from both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) and other regulatory agencies, **academic researchers** from around the globe, **pharmaceutical companies**, and **patient advocates.**

The Cancer Drug Development Forum (CDDF) Annual Conference is a unique meeting. This multi-stakeholder, interactive three days meeting offers plenary lectures with moderated discussions, including case studies and networking opportunities.

The responsive nature of the CDDF platform allows **programs to be quickly initiated or adapted to reflect current and pressing issues.** Following the outbreak of the COVID-19 pandemic, CDDF rapidly organised multiple webinars to discusss the impact of the pandemic on both cancer care delivery and clinical trial performance.

CDDF has clearly proved to be a **visionary force within the cancer drug development field** addressing topics such as immuno-oncology, real-world data in cancer drug development, and improving outcomes for children and adolescents with cancer through the **ACCELERATE platform** launched in 2013.

The CDDF continues **to pioneer progress in cancer drug treatments** through workshops exploring the potential impact of digital health and artificial intelligence on cancer patients.

CDDF publishes reports prepared from workshops discussions, conference presentations and lecture briefings **to increase knowledge of the challenges and opportunities in cancer drug development.**

CDDF WORKSHOPS PRESENT **REGULATOR, HTA, INDUSTRY, ACADEMIC** AND **PATIENT** PERSPECTIVES. EVERYONE IS GIVEN THE CHANCE TO **CONTRIBUTE**

CDDF LEADERSHIP

The CDDF is governed by a rotating board of directors dedicated to the development of cancer drugs.

These distinguished academics, representing a range of perspectives within the drug development process, are experienced pre-clinical and clinical investigators, medical oncologists, statisticians, and immunologists, who have experience working within regulatory agencies, the pharmaceutical industry and patient advocacy.

The chairperson and directors are elected for a period of three years.

CDDF BOARD OF DIRECTORS

Prof. John Smyth
Chairperson

Prof. Ruth Plummer
Deputy Chairperson

Prof. Axel Glasmacher
Treasurer

Prof. Jaap Verweij
Managing Director & Board member

Prof. Francesco De Lorenzo
Board Member

Prof. Eva Skovlund
Board member

Dr. Catarina Edfjäll
Board Member

Dr. Katrin Rupalla
Board Member

Prof. Mark Lawler
Board Member

Prof. Stefan Symeonides
Board Member

CDDF OFFICE

CDDF staff members oversee the day to day running of the organisation. The head office is located in Brussels, Belgium.

Marjorie Recorbet
Director of Operations

Magdaléna Strmeňová
Event Coordinator

Giorgia Campagnano
Event Coordinator

CDDF ACTIVITIES IN 2022

CONFERENCE

CDDF ANNUAL CONFERENCE 2022: TOWARDS A COLLABORATIVE FUTURE IN PATIENT ACCESS

NOORDWIJK AAN ZEE, THE NETHERLANDS | 7 – 9 FEBRUARY 2022

OBJECTIVES

The programme will focus on the way towards a collaborative future in patient access with a special emphasis on the following topics:

Integration of Regulatory Assessment and the Assessment of Reimbursement.

Enhancing the Future of Clinical Trials.

Lessons learned from Acceleration in Pediatric Oncology Programs.

Collaboration in the Post-Covid Regulatory Environment.

KEY TAKE-HOME MESSAGES

Clinical trial design will have to be adapted to the needs of both marketing approval assessment and health technology assessment (HTA).

Clinical trials will increasingly be patient-centric, and organized in a decentral way.

Multi-stakeholder collaboration proofs to be key in accelerating drug development.

The COVID-19 pandemic has strengthened international regulatory collaboration.

WEBINAR

MEASURABLE RESIDUAL DISEASE IN ACUTE MYELOID LEUKEMIA

WEBINAR | 24 FEBRUARY 2022

DR. CHRISTOPHER HOURIGAN (NATIONAL INSTITUTES OF HEALTH, US)

Measurable residual disease (MRD) in adult patients with acute myeloid leukemia (AML) undergoing allogeneic hematopoietic cell transplantation (alloHCT) has been identified as an important prognostic factor. Recent evidence demonstrates that intervention on high-risk patients testing positive may be able to reduce relapse and improve survival. Discrepancies between AML MRD detected by flow cytometry and molecular/genomic testing are possible, as illustrated by patient-personalized whole-genome-informed single-cell DNA and antibody-oligonucleotide sequencing. Finally, remaining questions regarding the clinical utility of AML MRD in alloHCT will lead to proposals for future clinical protocols.

WORKSHOP

WORKSHOP ON MEASURABLE RESIDUAL DISEASE (MRD) AND CIRCULATING TUMOR NUCLEOTIDES (CT/DNA) IN CANCER DRUG DEVELOPMENT

AMSTERDAM, THE NETHERLANDS | 25 – 26 APRIL 2022

OBJECTIVES

To address the latest developments in the use of measurable residual disease (MRD) and circulating tumour DNA as endpoints in cancer drug development.

To analyse of the rapidly evolving endpoints from all relevant perspectives.

To define a problem-solving, multistakeholder approach to the next steps and further development.

KEY TAKE-HOME MESSAGES

MRD is now established for haematological malignancies but less so for solid tumours.

Circulating tumour-nucleotides (ctDNA) is increasingly proving informative for solid tumours at least in the research setting.

The FDA is studying the use of ctDNA in relationship to the evolution of Accelerated Approval pathways.

Patients' responses to information about their MRD or ctDNA status must be sensitively recognised in order to avoid additional anxieties.

WEBINAR

CHALLENGES AND OPPORTUNITIES IN THE NEW ERA OF IMMUNOTHERAPY AND RADIOTHERAPY COMBINATIONS

AMSTERDAM, THE NETHERLANDS | 5 MAY 2022

PROF. CHARLES B. SIMONE (NEW YORK PROTON CENTER, USA)

Immunotherapy is becoming the first-line therapy for an increasing number of cancer types. However, less than 20% of patients respond to any given immunotherapy, and acquired resistance is common. A wealth of preclinical data suggested that radiotherapy synergizes with immunotherapy through several mechanisms, including enhancing tumor antigen release and presentation as well as promoting immune cell activation and infiltration. However, combining radiotherapy with immunotherapy has not been widely adapted due to clinical and regulatory challenges.

Professor Charles Simone is the national Principal Investigator of the SWOG/NRG Oncology intergroup trial combining immunotherapy and SBRT for early-stage non-small cell lung cancer and has led or been involved in several additional trials combining immune checkpoint inhibitors with radiation therapy. In this webinar, professor Simone provided insights into the following timely and critical topics.

- Are all radiation modalities the same? What is the recent development in radiotherapy?
- What is the recent development in immunotherapy including and beyond checkpoint blockade?
- Lessons learned from clinical trials of combination therapy, and what are the emerging opportunities for immune-RT combinations?

WORKSHOP

WORKSHOP ON PATIENT ACCESS AND ENGAGEMENT IN ONCOLOGY DRUG DEVELOPMENT

AMSTERDAM, THE NETHERLANDS | 19 – 20 SEPTEMBER 2022

OBJECTIVES

To appreciate and understand how patients and the patient voice are best integrated into cancer research, with particular emphasis on cancer drug development and its delivery for the benefit of patients.

To determine how patients can best contribute to regulatory decision making.

To understand the complexities of patient access to innovative medicines and reimbursement of innovative medicines and what constitutes best practice.

To be informed on the key role that data intelligence plays in the delivery of patient focused oncology medicines for the benefit of patients.

To appreciate the need and the means by which cross border access to oncology clinical trials can enhance patient access to the latest innovative medicines.

WEBINAR

DIVERSITY IN CLINICAL TRIALS

ONLINE I 26 SEPTEMBER 2022

PROF. DR. MARIE VON LILIENFELD-TOAL (UNIVERSITY OF JENA, DE) & DR. LOLA FASHOYIN-AJE (FDA, US)

Increasing clinical trial diversity in cancer trials is both a societal and scientific obligation. Underrepresentation of data from a diverse group of individuals is a barrier to understanding the safety, efficacy, and effectiveness of novel therapy in real-world populations impacted by the disease. To ensure scientific advances are beneficial and equitable to all relevant patient populations, we must consider inclusive trial designs with appropriate representation of vulnerable and disadvantaged populations. According to a recent study, minority racial and ethnic groups comprise nearly 40% of the population in the US; however, 75% of the 32,000 participants in the trials of 53 novel drugs approved in 2020 by the FDA were White.

While challenges with inequalities in patient representation in clinical trials might be different in the EU, it is nonetheless an important barrier to cancer care access. The goal of this webinar is to create awareness of why and how a lack of diversity in cancer clinical trials can ultimately hurt advancing knowledge in cancer care and patient access to innovations. In April 2022, FDA issued new draft guidance on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials that OCE Project Equity led. Our distinguished speakers will discuss missed opportunities when clinical trials are not representative of the real-world population and also missed opportunities for improving patient outcomes.

WEBINAR

IMMUNOTHERAPY AND RADIOTHERAPY COMBINATIONS

ONLINE | FALL 2022

WORKSHOP

WORKSHOP ON HISTOLOGY INDEPENDENT DRUG DEVELOPMENT: IS THIS THE FUTURE FOR CANCER DRUGS?

AMSTERDAM, THE NETHERLANDS | 14 – 15 NOVEMBER 2022

OBJECTIVES

To understand the current landscape of tumour agnostic drug development.

To be able to discuss suitable trial designs to deliver such studies.

To develop an understanding of biomarker development and the need for agnostic tumour registrations.

To understand the regulatory environment around these registrations.

CDDF AGENDA 2023

CONFERENCE

THE CDDF ANNUAL CONFERENCE IN NOORDWIJK AAN ZEE

CHALLENGES IN CLINICAL TRIALS PERFORMANCE

NOORDWIJK AAN ZEE, THE NETHERLANDS | 6 – 8 FEBRUARY 2023

WORKSHOP

DOSE OPTIMIZATION WORKSHOP IN AMSTERDAM

AMSTERDAM, THE NETHERLANDS | 3 – 4 APRIL 2023

WORKSHOP

INNOVATIVE ONCOLOGY TRIAL DESIGNS WORKSHOP IN AMSTERDAM

AMSTERDAM, THE NETHERLANDS | 18 – 19 SEPTEMBER 2023

WORKSHOP

BIOMARKER WORKSHOP IN AMSTERDAM

AMSTERDAM, THE NETHERLANDS | 13 – 14 NOVEMBER 2023

In future years, CDDF will continue to encourage early dialogue between regulators, pharmaceutical companies, academics and patient advocates through working group meetings to achieve valuable input on topics such as RWE / PRO in oncology, digitalization approaches in oncology clinical trials, non-clinical data excellence for oncology drug development , equal access of oncology drugs in Europe and global development.

CDDF INDUSTRY PARTNERS' PLATFORM

WHAT IS THE CDDF INDUSTRY PARTNERS' PLATFORM?

The CDDF Industry Partners' Platform is composed of large and SME partners from the pharmaceutical industry who support the CDDF in its mission to establish a neutral space for stakeholders to facilitate discussion on innovative drug development in oncology.

The Industry Partners' Platform acts as an advisory body within CDDF. It supports the association in compliance with all relevant regulations in a manner consistent with the non-competitive, non-commercial platform that CDDF offers to all stakeholders.

WHY JOIN THE CDDF INDUSTRY PARTNERS PLATFORM?

- Stimulate advancement in oncology treatment and delivery
- Identify and overcome challenges in the development of cancer drugs
- Improve product time to market for new treatments

CONTRIBUTE TO THE **DEVELOPMENT** OF **CANCER DRUGS** AND **TREATMENT**

BECOME A PARTNER OF THE CDDF

INDUSTRY PARTNER BENEFITS

1. **Access to the CDDF Industry Partners Platform** to join pharmaceutical partners in addressing challenges in cancer drug development from a multi-stakeholder perspective.

2. **Complimentary registration for in-person participants at every CDDF hybrid event** (one for small businesses, two for medium-sized enterprises and four for large pharmaceutical companies).

3. **Livestream access** to CDDF workshops and conference.

4. **Early access to digital content** from the conference and workshops for one year before public release.

5. Professional **contribution to CDDF's scientific programme** and the chance to collaborate with stakeholders on developing content for CDDF meetings.

6. Access to a **reputable oncology network** and opportunities to connect informally with representatives from **academia, regulatory authorities, HTAs, and patient groups.**

CDDF INDUSTRY PARTNERSHIP PACKAGES

	Start-up Small business	Medium-sized enterprise	Large pharmaceutical company
Criteria	No oncology product on the market *AND* Revenues ≤ € 50 million	Either low revenues w/ at least one oncology product on the market or medium or large revenues w/ no oncology product on the market	At least one oncology product on the market *AND* Revenues ≥ € 1 billion
Annual Contribution	**€ 7 000**	**€ 18 000**	**€ 40 000**
BENEFITS			
Access the CDDF Industry Partners Platform	✓ Yes	✓ Yes	✓ Yes
Number of free registration to every CDDF event	1	2	4
Numbrer of free livestream access to CDDF workshops and conference	5	15	Unlimited
Number of employees with early access to digital content from the conference and workshops for one year before release	5	15	unlimited
Contribute to CDDF's scientific programme and coordinate event programmes	✓ Yes	✓ Yes	✓ Yes

COLLABORATION IS THE **KEY** TO IMPROVING OUTCOMES FOR **CANCER PATIENTS**

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The Cancer Drug Development Forum (CDDF)

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The CDDF is a non-profit association in the register of legal entities at the French Speaking Enterprise Court in Brussels. Enterprise number: 738.523.752

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