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 advancement in 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 several years, the Cancer Drug Development Forum (CDDF) has focused on developing initiatives that **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 **collaboration 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) Spring Conference is a unique annual 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 a webinar to discuss the potential impact of the virus on both cancer care delivery and clinical trial performance.

Since its inception, CDDF has 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
Board Member and Managing Director

Prof. Francesco De Lorenzo
Board Member

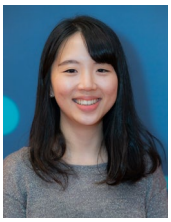
Prof. Eva Skovlund
Board Member

Dr Catarina Edfjäll
Board Member

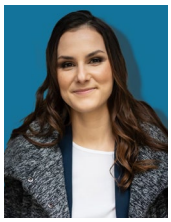
CDDF OFFICE

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

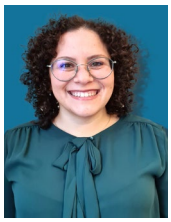
Marjorie Recorbet
Director of Operations



Hyunmin Park
Association Coordinator



Magdaléna Strmeňová
Event Coordinator



Giorgia Campagnano
Event Coordinator

CDDF ACTIVITIES IN 2021

VIRTUAL CONFERENCE
CDDF 12TH SPRING CONFERENCE

VIRTUAL CONFERENCE | 8-10 FEBRUARY 2021

OBJECTIVES

To understand the pitfalls in the European HTA process leading to current inequality in patient access.

To move the debate on endpoints in cancer clinical trials, digital tools and the use of artificial intelligence in cancer drug development forward constructively.

To understand current differences in global regulatory approval and HTA approaches and discuss the potential for harmonisation.

To raise awareness on novel methods in clinical oncology imaging, and discussion on their application as biomarkers in the drug development process.

To address regulatory guidance: EMA regulatory strategy 2025; envisioning product development for 2025; Industry perspectives on innovation and current topics in oncology.

KEY TAKE-HOME MESSAGES FROM THE CONFERENCE

The multi-stakeholder set-up is considered as one of the assets of CDDF meetings.

Active involvement of the patient voice and the patient-centred approach, are crucial. Continued training of patient advocates is important.

Tumour agnostic aspects will be the center of many future activities.

Real time oncology review (FDA-RTOR) was enthusiastically welcomed. Lessons can also be learned from the rolling reviews of COVID-vaccine trials.

The development of a Forum to discuss unequal access to drugs, received a lot of support.

ONLINE WORKSHOP

ENDPOINTS IN CANCER DRUG DEVELOPMENT

ONLINE WORKSHOP | 26 - 28 APRIL 2021

OBJECTIVES

To understand past achievements and current challenges in the definition and assessment of endpoints.

To update knowledge on novel endpoints, such as measurable residual disease and circulating tumour nucleotides, and identify possible pathways for validation.

To understand strategies and overcome obstacles to increase the use of patient-reported outcomes in cancer drug development.

To develop awareness of the need to use endpoints in expedited regulatory pathways.

KEY TAKE-HOME MESSAGES

The anticancer drug development- as well as treatment paradigm, is based on the notion of impacting tumor growth.

The magnitude of drug impact on tumour growth that is considered to represent clinical benefit, may be a matter of communal agreement based on clinical practice and summary understanding, rather than on conclusive scientific inference.

Tailored PRO design is expected to become the norm.

Attention should be given to maintain a level of standardization‘ The ‘core + extension + i’em list’ model may be a good solution.

WEBINAR

LESSONS LEARNT FROM COVID-19: "A CANCER INSTITUTE'S EXPERIENCE IN THE OPERATIONAL CANCER PERFORMANCE DURING THE COVID-PANDEMIC"

WEBINAR | 7 MAY 2021

PROF. JEAN-YVES BLAY (CENTRE LÉON BÉRARD, FRANCE)

The COVID-pandemic has had a major impact on cancer patients, on their treatments but also on the running of cancer clinical trials. How often did appointments have to be cancelled? How did one deal with required care, and have the threats of severe viral pneumonia affected the options for cancer care? How did all of this affect the running of pivotal clinical trials? These are just a few operational questions that Prof. Jean Yves Blay addressed during the discussion.

WEBINAR

ACCELERATING PATIENT ACCESS TO NOVEL ANTI-CANCER DRUGS

WEBINAR | 21 JUNE 2021

PROF. DR. HAIKO BLOEMENDAL
(CENTER FOR ONCOLOGY, RADBOUDUMC UNIVERSITY MEDICAL CENTER, NL)

It often takes (too) long for innovative anti-cancer drugs to be reimbursed by insurers, thereby denying patients access to these drugs. With the intent of systematically collecting data on the safety and efficacy of novel anti-cancer drugs awaiting approval and implementation in the Dutch healthcare system, the Dutch Society of Medical Oncology, together with HTA bodies, developed a program to shorten the time between EMA approval and reimbursement by insurers.

WEBINAR

LESSONS LEARNT FROM COVID-19: "TREATMENT OF CANCER PATIENTS DURING THE SARS-COV2 PANDEMIC: LEARNINGS AND OUTLOOK AFTER 18 MONTHS"

WEBINAR | 13 JULY 2021

PROF. DR. MARIE VON LILIENFELD-TOAL (JENA UNIVERSITY HOSPITAL, DE)

Prof. Dr. Marie von Lilienfeld-Toal had given her first talk on "Treatment of Cancer Patients during the SARS-CoV2 Pandemic: Implications for Clinical Trials" at the CDDF webinar in April 2020. For this webinar, she presented and discussed learnings and outlook for clinical trials in oncology after 18 months from the outbreak of the global pandemic.

WEBINAR

LESSONS LEARNT FROM COVID-19: "HOW TO ANALYSE CLINICAL TRIAL DATA COLLECTED DURING THE PANDEMICS"

WEBINAR | 23 SEPTEMBER 2021

DR. JAN BOGAERTS (EORTC, BE)

The COVID pandemic has affected clinical trials in several ways, ranging from accrual numbers to protocol deviations to being a competing risk factor in the patient's outcome. We discussed how methodologists may consider the task of analyzing data in presence of the impact of COVID, using ideas from the new paradigm of estimands. We also looked into a number of ideas ranging from analysing the data "as is" to far-reaching efforts to consider COVID a confounder that needs to be eliminated from the analysis.

WORKSHOP

DIGITAL TOOLS AND ARTIFICIAL INTELLIGENCE IN ONCOLOGY DRUG DEVELOPMENT

ONLINE WORKSHOP | 27 – 28 SEPTEMBER 2021

OBJECTIVES

From this interactive workshop, participants achieved the following outcomes:

To understand the current landscape of use to digital tools in cancer drug development.

To explore regulatory aspects, challenges and plans for formal registration of digital tools from trial data.

To learn about the various digital options to support trials and improve data collection and outcomes.

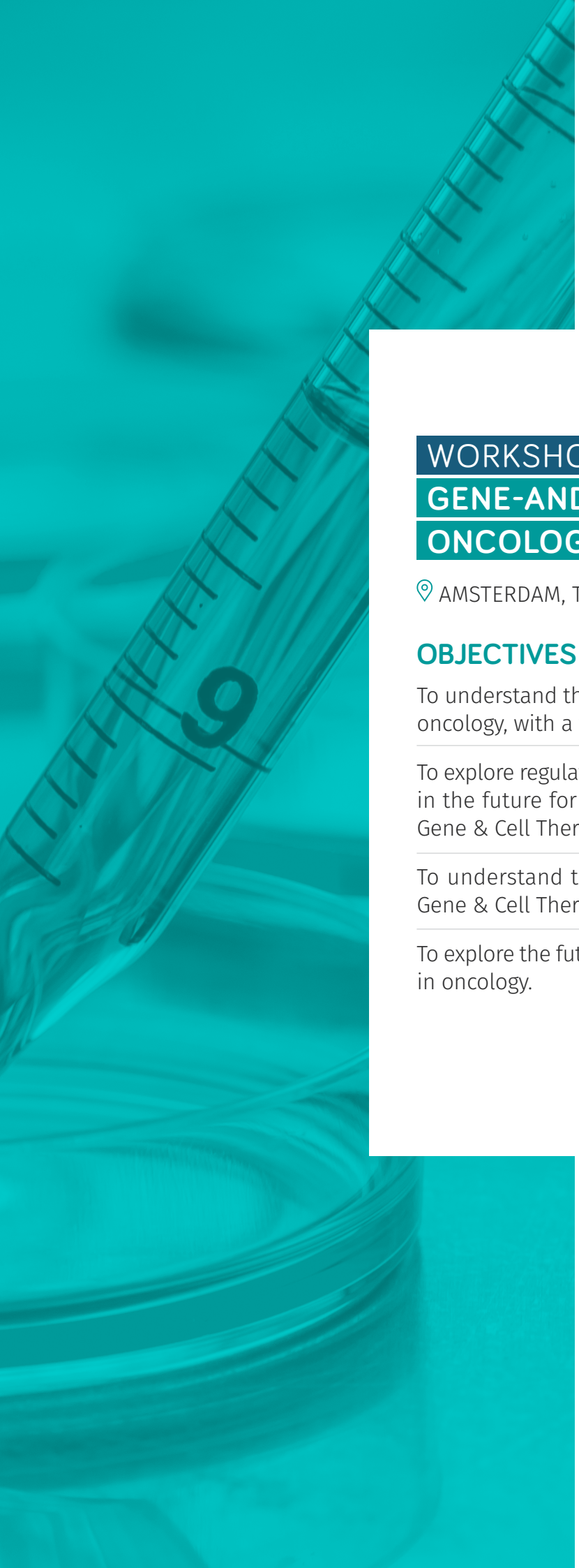
KEY TAKE-HOME MESSAGES

Healthcare systems across the world are currently transitioning to the digital acquisition, consumption, analysis and communication of data, involving patients in the direct two-way exchange of information in new ways.

Current WHO standards are defined by cytomorphology, immunophenotyping, standard chromosome banding analysis via metaphases, and normally by panel sequencing for molecular genetics.

In the digital world problems can arise as much from too few regulations as from too much.

GDPR is a core tool for the lawful conduct of clinical trials and can play a crucial role in supporting patient engagement if used appropriately.



WORKSHOP
GENE-AND CELL THERAPIES IN ONCOLOGY

AMSTERDAM, THE NETHERLANDS | 29 – 30 NOVEMBER 2021

OBJECTIVES

To understand the current landscape of Gene & Cell Therapy in oncology, with a focus on advances in drug development.

To explore regulatory aspects, challenges and pathways now and in the future for the development and approval of innovative Gene & Cell Therapies.

To understand the patient perspectives and challenges with Gene & Cell Therapies.

To explore the future perspectives related to Gene & Cell therapy in oncology.

FORTHCOMING CDDF ACTIVITIES & CDDF AGENDA 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.

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.

WEBINAR

HOW CAN WE IMPLEMENT THE RECOMMENDATIONS OF THE EUROPE BEATING CANCER PLAN? THE PERSPECTIVE OF THE EU PARLIAMENT SPECIAL COMMITTEE ON CANCER

WEBINAR | Q2

DR PETER LIESE , MED (MEMBER AND EPP COORDINATOR IN THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY)

On February 2021, the European Commission published the “Europe’s Beating Cancer Plan” to renew the EU commitment to cancer prevention, treatment and care. It is structured around four key action areas (prevention, early detection, diagnosis and treatment, improve quality of life) and it is supported by ten flagship initiatives and multiple supporting actions.

One year after the publication and in light of the recent European Parliament’s vote on the topic, the CDDF invited Dr Peter Liese to share the perspective of the European Parliament Special Committee on Beating Cancer (BECA) on how to implement the recommendations of the Europe Beating Cancer Plan.

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

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)

WORKSHOP

WORKSHOP ON PATIENT ACCESS AND ENGAGEMENT IN ONCOLOGY DRUG DEVELOPMENT

AMSTERDAM, THE NETHERLANDS | 19 – 20 SEPTEMBER 2022

WORKSHOP

WORKSHOP ON TISSUE-AGNOSTIC DRUG DEVELOPMENT

AMSTERDAM, THE NETHERLANDS | 14 – 15 NOVEMBER 2022

CDDF AGENDA 2023

CONFERENCE
THE CDDF ANNUAL CONFERENCE IN NOORDWIJK AAN ZEE

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

WORKSHOP
BIOMARKER 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
DOSE OPTIMIZATION WORKSHOP IN ASMTERDAM

AMSTERDAM, THE NETHERLANDS | 13 – 14 NOVEMBER 2023

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	Meduim-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
Free registration to every CDDF event	1	2	4
Livestream access to CDDF workshops and conference	5	15	Unlimited
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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1200 Woluwe Saint Lambert, Belgium

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