

ANNUAL REPORT 2021 **CANCER DRUG DEVELOPMENT FORUM (CDDF)** ☑info@cddf.org ©www.cddf.org **७**@cddf_eu



CONTENTS

4	The Year in Review
6	About the CDDF
8	Organisational Structure
9	Leadership
12	CDDF Office
15	Financial Statement
18	Achievements
32	Acknowledgement of Supporters
34	CDDF in 2022: A Look Ahead
36	Appendix

FACILITATE DEBATE ACTIVATE INNOVATE

CANCER DRUG DEVELOPMENT FORUM

The Year in Review

CONTINUING TO SUPPORT DIALOGUE, COLLABORATION AND INNOVATION TO ADVANCE CANCER CARE TREATMENT

Dear CDDF community,

As you are all aware, throughout 2021, health systems worldwide continued to experience organisational challenges due to the COVID-19 pandemic, which presented increased health risks to cancer patients everywhere. Few have avoided the impact of the coronavirus disease, and the CDDF was no exception. Over the past year, however, we maintained our focus on opportunities to innovate and expand to facilitate the development of effective, accessible treatments for cancer.

We quickly responded to the increased demand from stakeholders for information on COVID-19 and its effect on cancer care. Experts in the field delivered three well attended and productive webinars on the lessons learnt from treating cancer patients during the pandemic and its impact on clinical trials involving cancer patients.

Adapting our annual conference and workshops to a virtual format and devising a schedule of webinars ensured that the dialogue on cancer drug development continued and enabled us to maintain close ties with stakeholders and expand our collaborative network. The CDDF Annual Conference 2021 on current and future challenges of innovative oncology drug development, alongside workshops on endpoints, digital tools and artificial intelligence, and gene and cell therapies, generated discussion and debate to improve understanding between stakeholders.

The CDDF acknowledges current issues in cancer drug development and continues to identify areas where progress is needed. The process of developing new medicine for patients with cancer is complex. As the population lives longer thanks to advances in disease control and greater treatment options, the number of cancer patients and health expenditure increase. Although we now have drugs that are far more selective for their given target, the scope of clinical trials to measure efficacy is reduced as patient groups are divided up. The CDDF's mission to bring together the pharma industry, researchers, regulators, health technology assessors (HTAs) and patient advocacy groups to understand and overcome these obstacles is more relevant than ever.

We are focused on accelerating timelines through clinical trial design optimisation, including patient selection, and helping regulators and HTAs understand the patient perspective on new interventions. This perspective is key to moving forward in the right direction: patient self-reported data reveal that quality of life outweighs survival at all costs for many patients. We also recognise the need to strengthen our existing affiliation with HTAs, notably to encourage closer communication between companies and regulators early in the drug development process. We are committed to fostering the valued collaborative relationships we have with all parties involved in cancer treatment.

We are looking forward to advancing these and other aspects of cancer drug development in 2022. The CDDF has scheduled an extensive programme of events throughout the year, providing the platform for in-depth discussion on issues that address stakeholders' shared goals. Our programme for 2022 includes the CDDF Annual Conference 2022, workshops on MRD and ctDNA, patient access and engagement, and tissue-agnostic drug development. For webinars, we explore a variety of topics such as MRD, "Europe's Beating Cancer Plan" and radiotherapy and immunotherapy combinations, diversity in clinical trials, IVDR implementation, and non-clinical data excellence. We plan to hold future meetings in a hybrid format, with online and in-person components, increasing the potential for participants to join us from different parts of the world.

We look forward to seeing you at these events to continue working together to accelerate cancer treatments and improve the lives of cancer patients.

Yours sincerely, Prof. John Smyth, Chairperson, CDDF







About the CDDF

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.

33

COLLABORATION IS THE KEY TO IMPROVING OUTCOMES FOR CANCER PATIENTS

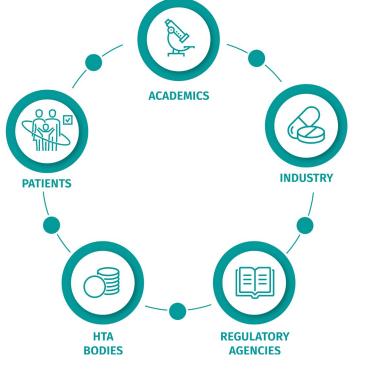
CDDF offers workshops, conferences and webinars that bring stakeholders involved in cancer drug development into a productive dialogue in a neutral, non-competitive space

HOW WE ADVANCE OUR MISSION

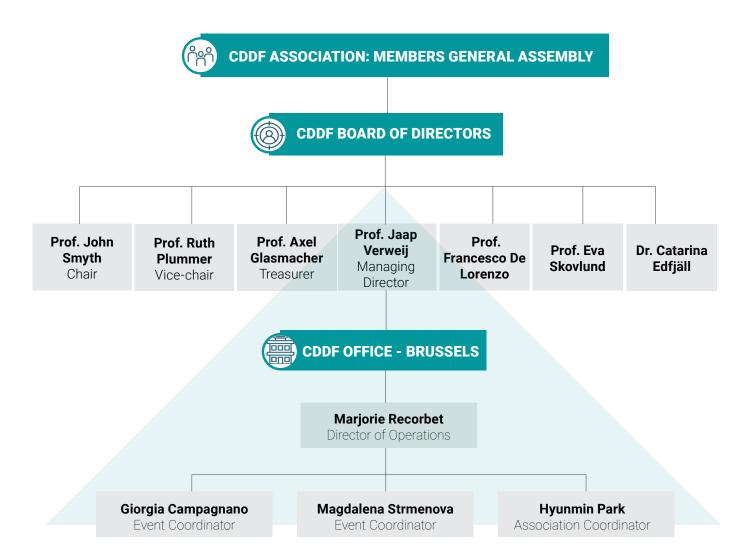
The CDDF provides a unique platform to facilitate collaboration between stakeholders to increase efficiency in cancer drug development. Our integrative approach brings together leading voices from academia, the pharmaceutical in-

dustry, regulatory authorities, health technology assessors, policymakers, and patient groups to improve cancer treatment.

To facilitate collaboration, the association has established a series of meetings, workshops and webinars to address current challenges and explore opportunities in oncology drug development. The CDDF meetings aim to increase understanding between the various stakeholders, and to try to identify areas where further progress can be made.



Organisational Structure



Leadership



CDDF Board of Directors

The CDDF is governed by a rotating board of directors dedicated to the development of cancer drugs. These distinguished academics are experienced pre-clinical and clinical investigators, medical oncologists, statisticians, and immunologists representing a range of perspectives within the drug development process. They have experience working within regulatory agencies, the pharmaceutical industry and patient advocacy. The chair-person and directors are elected for a period of three years.

Members of Association

Members of the CDDF are committed to accelerating oncology drug development and delivering optimal treatment to cancer patients. Members have the right to attend General Assembly meetings, which take place once a year and are the association's sovereign authority. At these meetings, Members monitor, assess and guide CDDF's work programme, organisational directions and best practices.



MEMBERS
OF THE
ASSOCIATION



7 CDDF BOARD OF DIRECTORS



4 CDDF Office Staff Members

FACILITATE DEBATE ACTIVATE INNOVATE



CHANGES IN BOARD COMPOSITION

In accordance with the CDDF Articles of Association, a Member of the CDDF Board of Directors is appointed for a period of three years. The mandate of the member is renewable. This rotation policy serves to develop robust governance practices within the CDDF and encourages a dynamic and diverse composition of the Board of Directors. In 2021 no change was made to the board composition.

CONFLICTS OF INTEREST

In accordance with the Articles of Association, Board members have declared any potential conflicts of interest. The disclosure forms are provided in the appendix (page 36).



BOARD OF DIRECTORS



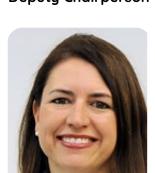
John Smyth
Chairperson



Jaap Verweij
Managing Director



Ruth Plummer
Deputy Chairperson



Catarina Edfjäll
Board Member



Axel Glasmacher
Treasurer



Eva Skovlund
Board Member



Francesco De Lorenzo Board Member

CDDF Office

OFFICE STAFF MEMBERS



Marjorie Recorbet
Director of Operations



Giorgia Campagnano Event Coordinator



Magdalena Strmenova Event Coordinator



Hyunmin Park

Association Coordinator

The CDDF office, located in Brussels, is comprised of four part-time staff members.

EMPLOYMENT DETAILS

Jaap Verweij, Managing Director

Consultancy contract until 2 September 2022

► Marjorie Recorbet, Director of Operations

2.5 days/week contract

► Giorgia Campagnano

4 days/week contract

Magdalena Strmenova

4 days/week contract

► Hyunmin Park

1 day/week contract



Financial Statement

REVENUE AND EXPENSES IN THE 2021 FISCAL YEAR

+ Total Revenue

€ 632,812

€ 438,877

☑ Balance

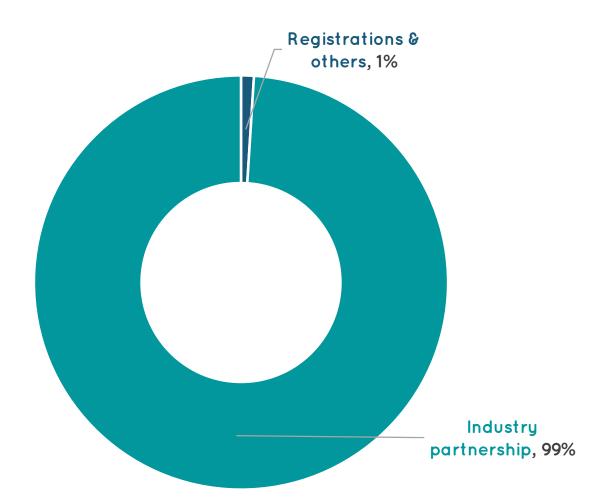
€ 193,934*

* Due to the COVID-19 pandemic all CDDF workshops had to be conducted as virtual instead of face-to-face meetings. This has reduced the planned expenses significantly and led to a positive balance not foreseen in the approved budget. The CDDF will apply these funds to future activities according to its articles of association.

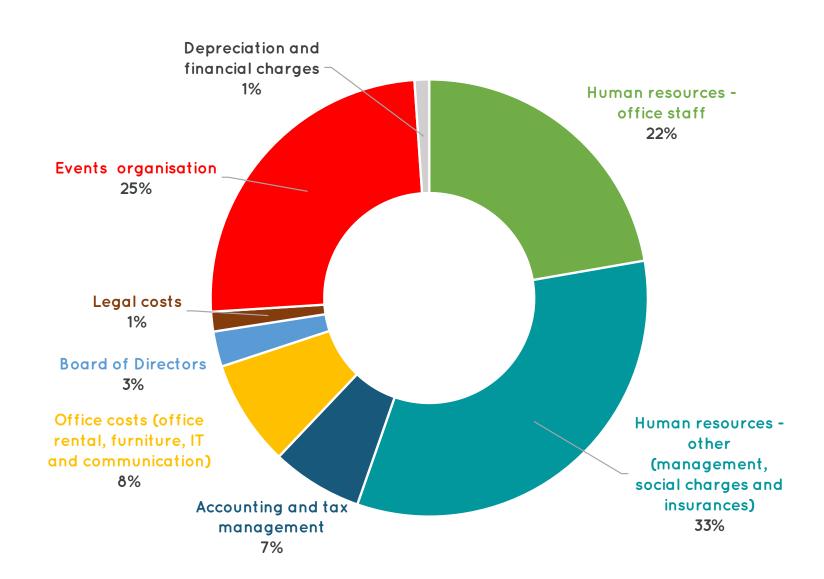




TOTAL REVENUE 2021



TOTAL EXPENSES 2021



OVERVIEW OF ACTIVITIES

In 2021, the CDDF adapted its annual conference and workshops to a virtual format and devised a schedule of webinars to ensure continued dialogue and maintain close ties with stakeholders during the COVID-19 pandemic. The change in the meeting format allowed for greater flexibility, increasing the potential for participants to join CDDF meetings anywhere.

CDDF Meetings **CDDF** Annual Conference 2021 **Multi-Stakeholder** Multi-Stakeholder **Multi-Stakeholder** Workshop Workshop Workshop Endpoints in Cancer Gene and Cell Digital Tools and Artificial Intelligence Drug Development Therapies in in Oncology Drug Oncology Development Online Online Online 26-28 April 29-30 November 27-28 September 2021 2021 2021

© CDDF Webinar Series - Lessons Learnt from COVID-19

Lessons Learnt from COVID-19 Lessons Learnt from COVID-19

A Cancer Institute's
Experience in
the Operational
Cancer Clinical Trial
Performance during
the COVID-Pandemic

7 May 2021

Treatment of Cancer Patients during the SARS-CoV2 Pandemic: Learnings and outlook after 18 months

13 July 2021

Lessons Learnt from COVID-19

How to Analyse Clinical Trial Data Collected during the Pandemic

23 September 2021

Q CDDF Webinar Series - other topics



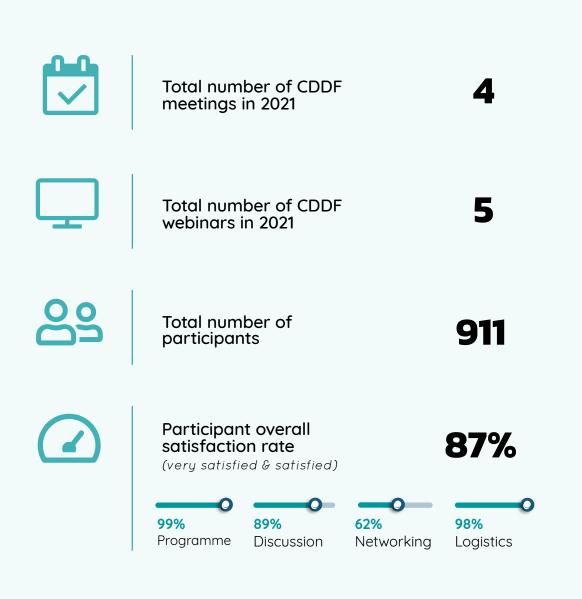
CDDF Webinar

Accelerating
Patient Access to
Novel Anti-Cancer
Drugs

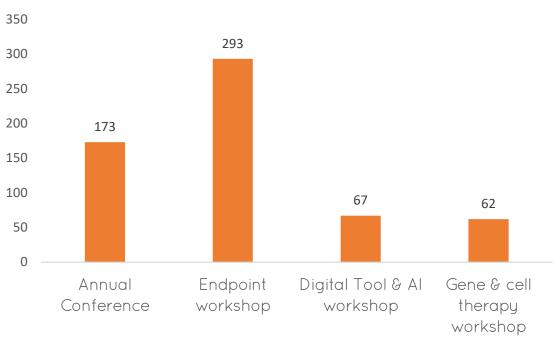
21 June 2021



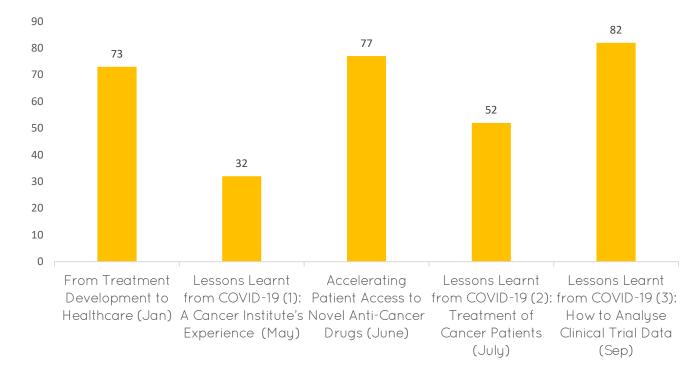
OVERVIEW OF ACTIVITIES



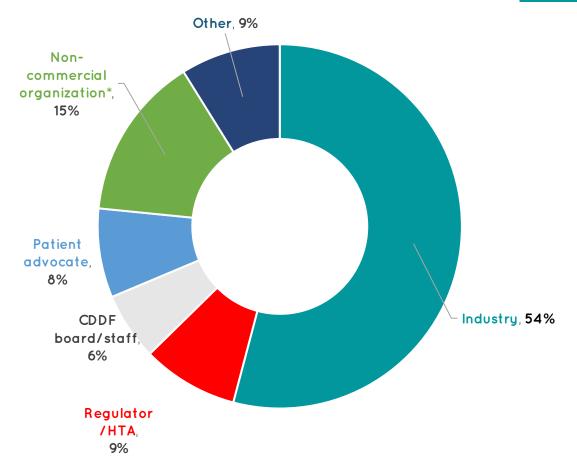
Number of Participants per Meeting



Number of Participants per Webinar

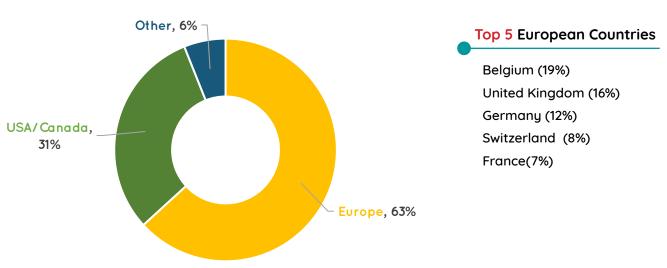


☐ Categories of Webinar Participants

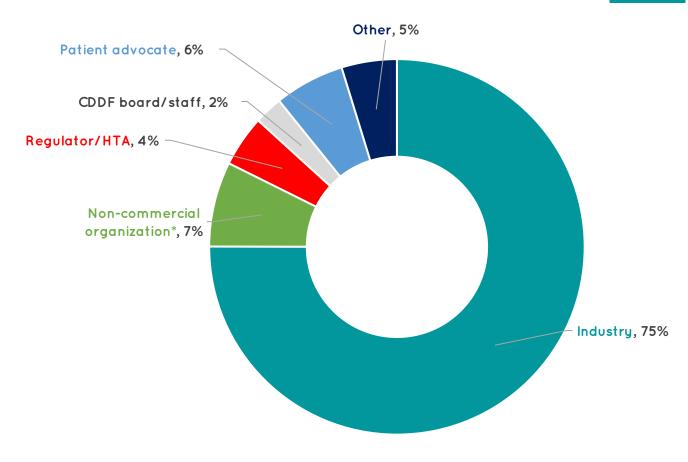


Non-commercial organization*: academic/foundation/charity/association

☐ Countries of Webinar Participants

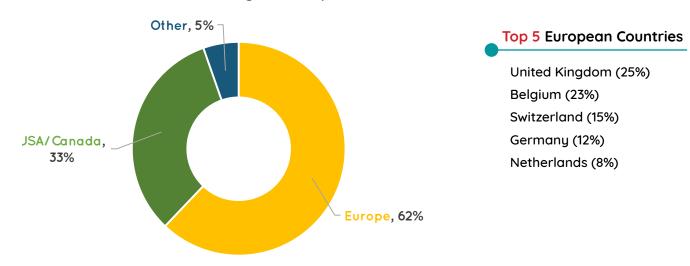


☐ Categories of Meeting Participants



Non-commercial organization*: academic/foundation/charity/association

☐ Countries of Meeting Participants







CDDF Annual Conference 2021

Current and Future Challenges of Innovative Oncology Drug Development

Online, 8-10 February 2021

The CDDF annual conference 2021 focused on the latest and future challenges of innovative oncology drug development, emphasising patient access, cancer drug development in a global setting, advances in imaging and hot regulatory topics such as patient preferences and RWD. This interactive meeting offered plenary lectures with moderated discussions, including case studies, as well as networking opportunities. These valuable discussions demonstrated the importance and effectiveness of multi-stakeholder collaboration, especially when patients are actively involved in the conversation.

Digital Tools and Artificial Intelligence in Oncology Drug Development 27 - 28 September 2021 ONLINE WORKSHOP

CDDF Multi-Stakeholder Workshop

Digital Tools and Artificial Intelligence in Oncology Drug Development

Online, 27-28 September 2021

With the increased use of digital tools in clinical trials, this multi-stakeholder workshop sought to evaluate opportunities for and discuss the regulatory perspectives of using digital tools and AI in cancer drug development. The meeting covered diverse topics, reviewing practical examples of digital tools and AI used in clinical trials to stimulate discussion in the panel sessions. It provided meeting delegates with the opportunity to assess digital options to support design trials and improve data collection and outcomes.

CDDF MULTI-STAKEHOLDER WORKSHOP Endpoints in Cancer Drug Development 26 - 28 April 2021 ONLINE WORKSHOP

CDDF Multi-Stakeholder Workshop

Endpoints in Cancer Drug Development

Online, 26-28 April 2021

This workshop addressed the latest findings on endpoints in cancer drug development. It focused on the assessment within the context of data from other clinical trials to define a problem-solving, multi-stakeholder approach to establishing future endpoints. The workshop provided presentations and interactive panel discussions to encourage debate as well as networking opportunities. The workshop provided a platform to connect stakeholders from all relevant areas fostering collaborative efforts to understand better and improve the science and practical use of endpoints.



CDDF MULTI-STAKEHOLDER WORKSHOP

Gene- and Cell Therapies in Oncology

29 - 30 November 2021 **HYBRID WORKSHOP**



CDDF Multi-Stakeholder Workshop

Gene and Cell Therapies in Oncology

Online, 29-30 November 2021

This multi-stakeholder workshop outlined how to generate the gene and cell "cancer killer," presenting challenges in assessing and marketing these therapies. It examined how to improve patient access to treatment and future perspectives of this innovative therapeutic approach. Each session included viewpoints from academics, regulatory agencies, patient advocates and industry to debate the issues and potential of gene and cell therapies in oncology.





operational cancer clinical trial performance during the COVID-pandemic

Prof. Jean-Yves

07 May 2021



Lessons Learnt from COVID-19

A Cancer Institute's Experience in the Operational Cancer Clinical Trial Performance during the COVID-Pandemic

7 May 2021

The CDDF held a series of live webinars on lessons learnt from COVID-19, exploring how the pandemic had affected clinical trial performance and assessment from different stakeholder perspectives. Prof. Jean-Yves Blay (Centre Léon Bérard, FR) presented the first topic in the series, "A Cancer Institute's Experience in the Operational Cancer Clinical Trial Performance during the COVID-Pandemic".

Prof. Blay explained the COVID-19 impact on the accrual of newly diagnosed patients in 2020 and 2021, with biases for some specific isotypes. He pointed out that delays in diagnosis impacted the clinical presentation of patients, affecting potential long-term curability. After the presentation, the speaker and participants joined an interactive panel discussion chaired by Prof. Jaap Verweij (CDDF, NL) and Prof. Axel Glasmacher (CDDF, DE).

COLLABORATION IS THE KEY TO IMPROVING OUTCOMES FOR CANCER PATIENTS



CDDF WEBINAR SERIES

Lessons learnt from COVID-19

Treatment of Cancer Patients during the SARS-CoV2 Pandemic: Learnings and Outlook after 18 months

Prof. Marie von Lilienfeld-Toa

13 July 2021 17:30 - 18:30 (CEST).



Lessons Learnt from COVID-19

Treatment of Cancer Patients during the SARS-CoV2 Pandemic: Learnings and Outlook after 18 Months

13 July 2021

Prof. Marie von Lilienfeld-Toal (Jena University Hospital, DE) delivered the second edition of the CDDF webinar series, Lessons Learnt from COVID-19. Her lecture focused on the gained knowledge and outlook for cancer patient treatment 18 months after the outbreak of the SARS-CoV2 pandemic. The speaker presented examples and cases to highlight the direct and indirect effects of the pandemic on cancer care. Prof. Axel Glasmacher (CDDF, DE) chaired the interactive discussion that followed.

CDDF WEBINAR SERIES Lessons learnt from COVID-19

How to Analyse Clinical Trial Data Collected during the Pandemic

Dr. Jan Bogaerts

23 September 2021 18:00 - 19:00 (CEST)



Lessons Learnt from COVID-19

How to Analyse Clinical Trial Data Collected during the Pandemic

23 September 2021

The third webinar in the series focused on statistical challenges caused by the pandemic. Dr Jan Bogaerts (EORTC, BE) discussed how methodologists might approach the task of analysing data within the context of COVID-19's impact. He suggested concepts from the new paradigm of estimands, outlining several ideas ranging from analysing the data "as is" to far-reaching efforts to consider COVID-19 as a confounding variable requiring elimination from the analysis. This insightful lecture was followed by a discussion session moderated by Prof. Ruth Plummer (CDDF, UK).

CDDF WEBINARS ON OTHER TOPICS



From Treatment Development to Healthcare: Is the Continuum Becoming a Reality?

28 January 2021

Dr. Denis Lacombe (EORTC, BE) presented the lecture, "From Treatment Development to Healthcare: Is the Continuum Becoming a Reality?" He suggests that the process of treatment development in healthcare needs reforming. Delivering datasets informative to patients, doctors, HTA bodies and investors should be integral to the process of providing treatment to healthcare systems to address the efficacy-effectiveness gap. Re-engineering the process while integrating new solutions for data access is bound to methodological and economic challenges amongst others, which was addressed at the Webinar.

Following the lecture, Prof. John Smyth (CDDF, UK) and Prof. Jaap Verweij (CDDF, UK) moderated a lively discussion with the speaker and a multi-stakeholder audience.

Accelerating Patient Access to Novel Anti-Cancer Drugs

21 June 2021

Prof. Haiko Bloemendal (Center for Oncology, Radboudumc University Medical Center, NL) outlined the program developed jointly by the Dutch Society of Medical Oncology and HTA bodies to shorten the time between EMA approval and reimbursement by insurers. He discussed systematic data collection on the safety and efficacy of novel anti-cancer drugs awaiting approval, implementation in the Dutch healthcare system and improving patient access. This informative talk was followed by a panel discussion moderated by Prof. Jaap Verweij (CDDF, NL) and Prof. John Smyth (CDDF, UK).



The CDDF believes that collaboration is key to its mission. In 2021 it established and maintained close collaborations with the following organizations representing various perspectives in cancer drug development:



The future of cancer therapy

EORTC

The European Organisation for Research and Treatment of Cancer (EORTC) and the CDDF continued their active collaboration through a series of clinical cancer research-related workshops and webinars covering all aspects of cancer treatment, from early drug development to accessing therapeutic modalities.

October 2021

Prof. Ruth Plummer, CDDF board member, served on the programme committee at the "Innovations and Biomarkers in Cancer Drug Development" (IBCD) conference in October 2021. Prof. Jaap Verweij and Prof. Eva Skovlund represented the CDDF in the meeting's scientific committee.

AAADV

The CDDF continued its close collaboration with the Accelerating Anticancer Agent Development and Validation (AAADV), exchanging best practices and information on cancer drug development in the U.S. and Europe to achieve the shared mission of delivering effective cancer treatment to patients.

September/October 2021

Prof. Jaap Verweij, CDDF Board Member, was invited to the programme committee at the 17th Annual AAADV workshop in September-October 2021. He spoke at and moderated the "CDDF-AAADV Satellite Session on Global Pediatric Neuro-Oncology Network", providing valuable scientific input to facilitate useful discussions.





28 (CDDF, UK).







Federation of European Academies of Medicine (FEAM)

Prof. Jaap Verweij on behalf of the CDDF and the Royal Dutch Academy of Science attended the FEAM Forum Annual Lecture in November 2021 where multistakeholders gathered to discuss accelerating EU drug development. He presented the key note lecture, "Efficiency gains through innovation in medicines development: How can science contribute?" and participated in a panel discussion.





EMA & FDA

The CDDF continued its ongoing collaboration with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), providing regulatory voices to CDDF's multi-stakeholder meetings. The EMA and FDA presented the regulatory perspective on diverse topics in cancer drug development and facilitated constructive discussions among CDDF stakeholders.

FACILITATE. DEBATE. ACTIVATE. INNOVATE.

Promoting Multi-Stakeholder Collaboration to Advance Oncology Therapeutics



WECAN

The Workgroup of European Cancer Patient Advocacy Networks (WECAN) has collaborated closely with the CDDF since 2019. The WECAN and its representatives have served in various roles at CDDF meetings, assisting the CDDF to incorporate the patient perspective into ongoing discussions.

Prof. Jaap Verweij, CDDF Board Member, spoke at the 11th SPAEN (Sarcoma Patients EuroNet - Member of WECAN) Annual Conference in April 2021, which gathered international, leading sarcoma experts and patient advocates representing organisations covering all subtypes of sarcomas. He presented informative, scientific evidence on patient involvement in clinical research.



ECPC

The CDDF, with support from the European Cancer Patient Coalition (ECPC), made continued efforts to listen to and acknowledge patient views on opportunities and challenges in cancer drug development.

The CDDF co-signed the ECPC's joint letter on COVID-19 and cancer, which calls for action to identify the impact of the pandemic on cancer care and improve services to mitigate it.

Acknowledgement of Supporters

The CDDF thanks all partners and collaborators for their engagement and valued input to support the CDDF's activities in 2021.

□ CDDF INDUSTRY PARTNERS IN 2021







































□ COLLABORATORS

















CDDF in 2022: A Look Ahead

CDDF'S FOCUS IN 2022

Key discussion items in cancer drug development

The CDDF Board and Industry Partners have selected high-priority topics in cancer drug development and access. Discussion topics listed below will be explored and examined at CDDF webinars and meetings. The CDDF is committed to collaborating with diverse stakeholders to successfully develop and execute meeting programmes throughout 2022.

CDDF WEBINAR SERIES IN 2022

- MRD by NGS in Patients with AML Undergoing Allogeneic Transplantation
- : Dr. Christopher Hourigan (NIH, US), 24 February 2022
- Europe's Beating Cancer Plan
- : Dr Peter Liese (EU Commission, DE), 16 March 2022
- Radiotherapy & immunotherapy Combinations
- Diversity in Clinical Trials
- Challenges with patient access to personalized medicines in the context of in vitro diagnostic regulation (IVDR) implementation
- Non-clinical data excellence for oncology drug development

CDDF MEETINGS IN 2022





Annual Conference 2022

Towards a Collaborative Future in Patient Access

7 - 9 February 2022, Virtual Conference



Multi-Stakeholder Workshop

Patient Access & Engagement in Oncology Drug Development

19 - 20 Sep 2022, Hybrid workshop (NL)



Multi-Stakeholder Workshop

MRD and ctDNA in Cancer Drug
Development

25 - 26 April 2022, Hybrid workshop (NL)



Multi-Stakeholder Workshop

Tissue Agnostic drug development – is this the future for cancer drugs?

14-15 Nov 2022, Hybrid workshop (NL)

35





Prof. John Smyth

Pharmaceutical companies with a potential conflict of interest

 Consultancy contract with Bristol Myers Squib, Merck and Northwest Biotherapeutics

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 12 January 2022

Prof. Ruth Plummer

Pharmaceutical companies with a potential conflict of interest

- Honoraria for the last three years for attending advisory boards from Pierre Faber, Bayer, Novartis, BMS, Cybrexa, Ellipses, CV6 Therapeutics, Immunocore, Genmab, Astex Therapeutics, Medivir, and Sanofi Aventis.
- Honoraria for working as an IDMC member for Alligator Biosciences, GSK, Onxeo and SOTIO Biotech AGI
- Honoraria for delivery of educational talks or chairing educational meetings by AstraZeneca, Novartis, Bayer and BMS.
- Funds to support attendance at conferences from MSD and BMS

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 12 January 2022

Prof. Axel Glasmacher

Pharmaceutical companies with a potential conflict of interest

- Member of Board of Directors: 4D Pharma (chairperson), Active Biotech, Ryvu Pharmaceuticals, and Avencell
- Consultancy/other honoraria:: Active Biotech, Nanexa, and Cellex GmbH
- Stock Ownership (fulfilling the criterion above): 4D Pharma plc, Active Biotech, and Bristol Myers Squibb

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 12 January 2022

Prof. Jaap Verweij

Pharmaceutical companies with a potential conflict of interest

• Basilea, Boehringer Ingelheim, Deuter Oncology, Ellipses, Galecto, GenMab, Helsinn, NanoGhost, NBE and Seagen

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 13 January 2022



Prof. Francesco De Lorenzo

Pharmaceutical companies with a potential conflict of interest

No partnerships to disclose

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 18 January 2022

Prof. Eva Skovlund

Pharmaceutical companies with a potential conflict of interest

No partnerships to disclose

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 12 January 2022

Dr. Catarina Edfjäll

Pharmaceutical companies with a potential conflict of interest

- Consulting contract with Novo Nordisk
- Board member of ObsEva

Other affiliations with a potential conflict of interest

No partnerships to disclose

Last updated on 15 February 2022



