

EVENT OUTLINE

The Cancer Drug Development Forum (CDDF) Annual Conference is a prestigious event that unites leaders in the field of oncology drug development. Scheduled from 5th to 7th February 2024, this conference will offer a hybrid format, allowing participants to attend either in person or virtually. The event brings together medical researchers, pharmaceutical industry representatives, regulatory authorities, and patient advocacy groups for engaging discussions and networking opportunities.

LEARNING OBJECTIVES

- Explore and analyze innovative approaches to accelerate oncology drug development, considering the changing paradigms in the field.
- Understand the impact of recent regulatory changes on the development and approval of oncology drugs.
- Examine the use of real-world evidence and its significance in shaping future oncology care.
- Discuss decentralized care and clinical trial strategies, drawing from lessons learned during the COVID-19 pandemic.
- Evaluate the potential of drug and biomarker combinations and their regulatory acceptance.
- Address challenges and opportunities in utilizing companion diagnostics in oncology drug development.
- Discover advancements in master protocols, platform trials, and blood-based biomarkers for early patient testing.
- Engage in forward-facing discussions on the future of global regulatory collaborations in oncology drug development.

PROGRAM HIGHLIGHTS

Day 1: Innovative Approaches in Oncology Drug Development

- Keynote Address: Changing Paradigms to Accelerate Oncology Drug Development.
- Panel Discussion on the Impact of Recent Regulatory Changes in Oncology.
- Real-World Evidence in Shaping Oncology Care: Case Studies and Insights.

Day 2: Decentralized Care and Clinical Trials

- Learnings from COVID-19: Adapting Clinical Trials for Decentralized Care.
- Patient Perspective: Enhancing Safety and Diversity in Decentralized Trials.
- Accelerating Drug Development: Strategies for Faster and Efficient Trials.

Day 3: Drug and Biomarker Combinations in Oncology

- Novel-Novel Combinations: Regulatory Acceptance and Dose Optimization.
- Challenges and Opportunities with Companion Diagnostics in Drug Development.
- Advancements in Master Protocols, Platform Trials, and Early Patient Testing.
- The Future of Global Regulatory Collaborations in Oncology.

PROGRAM COMMITTE

- Committee chair: Ruth Plummer (CDDF, UK)
- Axel Glasmacher (CDDF, DE)
- Hemal Morjaria (Johnson & Johnson, UK)
- Jose Vicente-Garcia (AstraZeneca, UK)
- Hans Scheurer (Myeloma Patients Europe, NL)

TARGET AUDIENCE

The target is a multidisciplinary audience of academia representatives, EU and US regulatory bodies (EMA, FDA, National Agencies), pharmaceutical Industry, HTAs and patient advocate.

CONFERENCE VENUE

Alexander Hotel

Oude Zeeweg 63, 2202 CJ Noordwijk, Netherlands

HYBRID CONFERENCE

The workshop will be held in Noordwijk aan Zee. However, participation online via the Brella event platform will also be possible. Only approved participants will receive the link and log-in details to access the virtual platform.

CONTACT

Cancer Drug Development Forum (CDDF)

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PROGRAM

Day 1: Monday, 5 February 2024

SESSION 1: REAL WORLD EVIDENCE

Session Chairs: Hemal Morjaria (Johnson & Johnson, UK); Hans Scheurer (MPE, NL)

12:00 - 12:50	Lunch
12:50 - 13:00	Welcome note Ruth Plummer (CDDF, UK)
13:00 - 13:15	Regulatory Perspective on Opportunities for Oncology RWE Donna Rivera (FDA, US)
13:15 - 13:30	Regulatory Perspective Francesco Pignatti (EMA, NL)
13:30 - 13:45	Payer's Perspective Carole Longson (Carole Longson Consultant, UK)
13:45 - 14:00	Project Darwin EU Peter Rijnbeek (Erasmus Medical Center, NL)
14:00 - 14:15	Academic perspective Peter Mol (University Medical Center Groningen, NL)
14:15 - 14:30	Project Optima James N'Dow (University of Aberdeen, UK)
14:30 - 15:10	Panel Discussion
15:10 - 15:40	Coffee Break

SESSION 2: REFLECTIONS ON CDDF WORKSHOPS AND JOINT ACTIVITIES

15 minutes lecture + 5 minutes Q&A

Session Chairs: Ruth Plummer (CDDF, UK)

15:40 - 15:45	Session opening
15:45 - 16:05	Workshop on dose optimisation in oncology drug development Axel Glasmacher (CDDF, DE)
16:05 - 16:25	Workshop on innovative oncology trial designs Rosa Giuliani (CDDF, IT)
16:25 - 16:45	Workshop on the critical role of Biomarkers in delivering drug development-related precision oncology Mark Lawler (CDDF, UK)
16:45 - 17:05	2023 AAADV-ASCO-CDDF joint workshop Kim Lyerly (AAADV, US)
17:30 - 18:30	CDDF Leadership and Industry Members meeting (internal meeting)
19:00 - 22:00	Offsite dinner

Day 2: Tuesday, 6 February 2024

SESSION 3: DECENTRALISED CARE AND TRIALS

Session Chairs: Ruth Plummer (CDDF, UK); Jose Vicente-Garcia (AstraZeneca, UK)

10:30 - 10:35	Session opening
10:35 - 10:55	Learnings from COVID-19 - academic perspective Richard Sullivan (King's College London, UK)
10:55 - 11:15	Regulatory perspective (FDA) Timil Patel (FDA, US)

11:15 - 11:35	How to run a decentralised clinical trial - industry perspective Luis Garcia-Gancedo (AstraZeneca, UK)
11:35 - 11:55	Patient perspective on safety in decentralised clinical trials Hans Scheurer (Myeloma Patients Europe, NL)
11:55 - 12:35	Panel Discussion
12:35 - 14:45	Offsite lunch

SESSION 4: IMPACT OF RECENT REGULATORY CHANGES

15 minutes lecture + 10 minutes discussion

Session Chairs: Axel Glasmacher (CDDF, DE); Sushmita Sen (Roche, CH)

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14:45 - 14:50	Session opening
14:50 - 15:15	Project Frontrunner: Changes to Accelerated Approval Lola Fashoyin-Aje (FDA, US)
15:15 - 15:40	Expedited approval pathways in the EU Filip Josephson (Lakemedelsverket, SE)
15:40 - 16:05	EU CTR implementation: Opportunities and challenges Christopher Price (Merck Healthcare KgAa, DE) & Siard Houtzager (Johnson & Johnson, NL)
16:05 - 16:30	EU Proposed Pharmaceutical Legislation Richard Price (European Cancer Organisation, BE)
16:30 - 16:45	Coffee break
16:45 - 17:45	Panel Discussion on diversity in clinical trials Moderators: Axel Glasmacher (CDDF, DE); Sushmita Sen (Roche, CH) Guest Panelists: Harald Enzmann (CHMP, DE) Craig Tendler (Johnson & Johnson, US) Hans Wildiers (UZ Leuven, BE) Rachel Giles (International Kidney Cancer Coalition, NL) Marie von Lilienfeld-Toal (Ruhr University, DE) Lola Fashoyin-Aje (FDA, US)
19:00 - 22:00	Onsite dinner

Day 3: Wednesday, 7 February 2024

SESSION 5: DRUG AND BIOMARKER COMBINATION

Session Chairs: Ruth Plummer (CDDF, UK); Filip Josephson (Lakemedelsverket, SE)

08:30 - 10:00	CDDF Board of Directors meeting
10:30 - 10:35	Session opening
10:35 - 10:55	Master protocols and platform trials - academic perspective Sarah Halford (Cancer Research UK, UK)
10:55 - 11:15	Novel - novel combination Hilke Zander (Paul-Ehrlich-Institut, DE)
11:15 - 11:35	IVDR regulations Marie Claire Beurier (Roche, CH)
11:35 - 12:15	Panel Discussion
12:15 - 12:40	Wrap up panel discussion Panelists: Ruth Plummer (CDDF, UK) Axel Glasmacher (CDDF, DE) Jose Vicente Garcia (AstraZeneca, UK) Hemal Morjaria (Johnson & Johnson, UK) Hans Scheurer (MPE, NL) Filip Josephson (Lakemedelsverket, SE)
12:40- 12:45	Farewell message
12:45 - 13:10	Takeaway lunch