Cancer Drug Development Forum

ANNUAL CONFERENCE

Challenges, Advances, and Open Questions in Global Cancer Drug Development and Clinical Trials

3-5 February 2025
Noordwijk aan Zee, NL
Hybrid Conference

www.cddf.org

EVENT OUTLINE

The CDDF Annual Conference, scheduled from February 3-5, 2025 focusses on highly relevant topics in the development of anti-cancer drugs and offers constructive discussions with highly competent leaders in fields central to oncology drug development (patient advocates, regulators from the FDA, EMA and EU national agencies, health technology assesors, academic researchers and pharmaceutical industry). It will take a deep dive into the efforts to increase diversity, representativity and inclusion, in clinical trials as well as the latest discussions on endpoints in oncology drug development. Presentations and panel discussions will update the audience on innovative clinical trial designs and on controversial topics in diagnostics. Finally, the EU health technology assessment process with be reviewed with a focus on overcoming inequalities, Joint EMA/HTA scientific advice and patient participation.

LEARNING OBJECTIVES

- Session 1 (Joint CDDF/AAADV): Explore the open questions relating to diversity in clinical trial participation and discuss US and EU regulatory perspectives.
- Session 2: Understand the current debate on the use of endpoints in cancer drug development, the controversial perspectives on currently used endpoints as well as examples of the development of new endpoints.
- Session 3: Examine innovative cancer clinical trial designs that are fit to generate efficient but also robust evidence including use of external control data, EU initiative to advance conduct of innovative trials, case studies as well as HTA and academic perspective.
- Session 4: Discover and engage in the discussion of controversial topics on diagnostics in the development of anti-cancer treatments, incl. precision cancer diagnostics, regulatory guidance of laboratory-developed tests, an update on IVDR regulation.
- Session 5: Review the EU health technology assessment process and discuss inequalities of the approval process in the EU, understand lessons learned in the Joint EMA/HTA scientific advice process, and discuss the impact of patient participation in HTA processes

PROGRAM COMMITTE

- Committee chair: Axel Glasmacher (CDDF, DE)
- Co-chair: Jaap Verweij (CDDF, NL)
- Kim Lyerly (AAADV, US)
- Pio Zapella (Debiopharm, CH)
- Birgit Wolf (Bayer, DE)
- Lidia Zielinska (MPNE, PL)

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 advocates.

CONFERENCE VENUE

Van der Valk Palace Hotel Noordwijk
Pickeplein 8, 2202 CL Noordwijk, Netherlands

HYBRID CONFERENCE

The conference 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

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PROGRAM

Day 1 : Monday, 3 February 2025

SESSION 1: CDDF/AAADV JOINT SESSION ON DIVERSITY IN GLOBAL DRUG DEVELOPMENT	
Session Chairs: Kim Lyerly (AAADV, US); Axel Glasmacher (CDDF, DE)	
12:00 - 12:50	Lunch
12:50 - 13:00	Welcome note and learning from 2024 activities Axel Glasmacher (CDDF, DE)
13:00 - 13:15	Introduction to the session Kim Lyerly (AAADV, US); Axel Glasmacher (CDDF, DE)
13:15 - 13:35	What does diversity involve clinically? Marie von Lilienfeld-Toal (Univ. Bochum, DE)
13:35 - 13:45	CDDF Diversity Consensus Initiative Fergus Sweeney (CDDF, IE)
13:45 - 14:05	Fostering Diversity in Drug Development: Collected experience and new Developments Tamy Kim (FDA, US)
14:05 - 15:00	Panel Discussion Guest Panelists: • Khullat Munir (Patvocates, DE) • Pio Zapella (Debiopharm, CH) • Denis Lacombe (EORTC, BE) • Mark Fleury (American Cancer Society, US) • Terrell Baptiste (Gilead, US) • Victor Gîrbu (Patient Advocate, RO)
15:00 - 15:40	Coffee Break

SESSION 2: ENDPOINTS IN DRUG DEVELOPMENT: PROGRESS AND CONTROVERSIES

Session Chairs: Jaap Verweij (CDDF, NL); Lidia Zielinska (Melanoma Patient Network Europe, PL)

15:40 - 15:45	Session opening
15:45 - 16:05	Progress and challenges in the use of endpoints in cancer drug development Bruno Paiva (Clínica Universidad de Navarra, ES)
16:05 - 16:25	FDA Perspective on the endpoints in cancer drug development Nicole Gormley (FDA, US)
16:25 - 16:45	EMA Perspective on the endpoints in cancer drug development Francesco Pignatti (EMA, NL)
16:45 - 17:35	Panel Discussion (with 5 minutes introduction on MPAACT) Guest Panelists: • Harindra Abeysinghe (Johnson & Johnson, US) • Violeta Astratinei (MPNE, NL)
18:00 - 19:00	CDDF Leadership and Industry Members meeting (internal meeting)
19:00 - 22:00	Offsite dinner

Day 2 : Tuesday, 4 February 2025

SESSION 3: OPTIMIZE EVIDENCE GENERATION AND PATIENT ACCESS WITH INNOVATIVE CANCER TRIALS (METHODOLOGY)

Session Chairs: Fergus Sweeney (CDDF, IE); Birgit Wolf (Bayer, DE)

08:30 - 10:00	CDDF Board of Directors meeting
10:30 - 10:35	Session opening
10:35 - 10:50	ACT EU Priority Area 8 “clinical trial methodologies” Kit Roes (EMA, NL)

10:50 - 11:05	Case study: Use external data for efficient and robust evidence generation Alexandra Oger (MSD, FR)
11:05 - 11:20	Case study: Use external data for efficient and robust evidence generation Emma Clark (Roche, UK)
11:20 - 11:35	Academic perspective - Beyond randomisation Murielle Mauer (EORTC, BE)
11:35 - 12:25	Panel Discussion Guest Panelists: • Anja Schiel (NOMA, NO) • Joanna Frątczak-Kazana (Alivia, PL) • FDA perspective
12:25 - 14:30	Offsite lunch

SESSION 4: NAVIGATING PRECISION ONCOLOGY DEVELOPMENT IN VIEW OF NEW REGULATIONS

Session Chairs: Pio Zapella (Debiopharm, CH) ; Rosa Giuliani (CDDF, IT)

14:30 - 14:35	Session opening
14:35 - 14:55	Precision oncology - early development in view of the new regulations Kate Simon (Bayer, US)
14:55 - 15:15	Considerations on new regulations for Diagnostic developers Philip Febbo (Veracyte, US)
15:15 - 15:35	New regulations impact on academic research and patient care Alberto Hernando (Vall d'Hebron Institute of Oncology, ES)

15:35 - 15:55	COMBINE - updates and outcomes Ditte Zerlang Anderson (DKMA, DK)
15:55 - 16:45	Panel Discussion Guest Panelists: • Lidia Zielinska (Melanoma Patient Network Europe, PL) • Marlene Thomas (Roche, CH)
19:00 - 22:00	Onsite dinner

Day 3 : Wednesday, 5 February 2025

SESSION 5: EU HTA REGULATIONS - STAKEHOLDER COLLABORATION TO IMPROVE PATIENT ACCESS

Session Chairs: Christian Schneider (CDDF, DE); Anja Schiel (NoMA, NO)

09:25 - 09:30	Session opening
09:30 - 09:50	Inequalities in approval process in EU Carin Uyl-de Groot (Erasmus University Rotterdam, NL)
09:50 - 10:10	Lessons Learned from Joint EMA/HTA scientific advice Assia Dembri (BMS, CH)
10:10 - 10:30	Real impact of patient presence - a voice with meaning Natacha Bolaños (Lymphoma Coalition, ES)
10:30 - 10:50	HTA perspective Anja Schiel (NoMA, NO)
10:50 - 11:40	Panel Discussion Guest Panelists: • Warnyta Minnaard (World CUP Alliance, NL)
11:40 - 12:10	Learnings and next steps and closing remarks
12:10 - 13:00	Lunch