CDDF
Cancer Drug Development Forum
FACILITATE. DEBATE. ACTIVATE. INNOVATE

CDDF
MULTI-STAKEHOLDER
WORKSHOP

26 - 28 APRIL 2021

Endpoints in Cancer Drug Development

Online Workshop

PROGRAMME

www.cddf.org

WELCOME NOTE

On behalf of the Cancer Drug Development Forum, its partners, and the organizing committee Axel Glasmacher, Denis Lacombe, Ralf Herold, Chitkala Kalidas, and Claudia Hey, we would like to welcome you to the 2021 CDDF Multi-Stakeholder Workshop: Endpoints in Cancer Drug Development.

Due to the continuing threat of the COVID-19 pandemic and its impact on our ability to travel, after thoughtful discussions, we decided to move our workshop into a fully virtual meeting. The safety and well-being of our speakers and attendees are our priority. The virtual meeting will allow us to safely serve our participants and provide new opportunities for knowledge exchange, engagement, and interaction. The dates of the workshop are 26-28 April 2021 and half-day sessions are scheduled to deliver the agenda in more digestible segments.

During the workshop, we will address the current challenges with the definition and contextualization of endpoints in drug development and commercialization. We will focus on a problem-solving aspect through debates and multi-stakeholder panel discussions.

We are looking forward to the discussions with you, and to fulfill our mission to facilitate cancer drug development.

CDDF Team

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ONLINE WORKSHOP
26-28 APRIL 2021

EVENT OUTLINE

This workshop is aimed at all relevant stakeholders in cancer drug development, patients, academic researchers, regulatory agencies and pharmaceutical companies. It will address the latest developments in the use of endpoints in cancer drug development. It focuses on the assessment within the context of other data from clinical trials and looks to define a problem-solving, multistakeholder approach to the future development of endpoints. The workshop will focus on discourse-inducing presentations and interactive panel discussions.

PROGRAMME COMMITTEE

- Ralf Herold (EMA)
- Denis Lacombe (EORTC)
- Axel Glasmacher (CDDF)
- Chitkala Kalidas (Bayer)
- Claudia Hey (Merck Healthcare KGaA)

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.

EVENT PLATFORM

The workshop will be held online via the unique event platform (as the CDDF Spring Conference 2021). Only approved participants will receive an information including the link to the platform and log-in details closer to the date.

CONTACT

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PROGRAMME

DAY 1 – MONDAY 26 APRIL 2021

16:00 - 16:15	Opening of the meeting, introduction to the meeting objectives Axel Glasmacher (CDDF, DE)
WHEN OVERALL SURVIVAL CANNOT BE THE PRIMARY ENDPOINT	
Session Chairs: Denis Lacombe (EORTC, BE) & Ralf Herold (EMA, NL)	
16:15 - 16:25	Introduction by the chairs, voting Denis Lacombe (EORTC, BE) & Ralf Herold (EMA, NL)
16:25 - 16:45	Reflection on the challenge Axel Glasmacher (CDDF, DE)
16:45 - 17:00	Discussion of presentation
17:00 - 17:10	Break
17:10 - 17:40	Pathway towards solutions (20+10 min) *Industry speaker*: Chitkala Kalidas (Bayer, USA)
17:40 - 17:55	Pathway towards solutions (10+5 min) *Industry speaker:* Elmar Schmitt (Merck Healthcare KGaA, DE)
17:55- 18:25	Pathway towards solutions (20+10 min) *Regulatory agency speaker:* Filip Josephson (EMA, SWE)
18:25 - 18:55	Breakout groups: Discussion, questions for the panel
18:55 - 19:25	Break
19:25 - 20:10	Panel & Audience Discussion Moderator: John Smyth (CDDF) Panellists: Vishal Bhatnagar (FDA), Filip Josephson (EMA, SWE), Elmar Schmitt (Merck Healthcare KGaA, DE), Chitkala Kalidas (Bayer, USA), Axel Glasmacher (CDDF, DE), Ralf Herold (EMA, NL), Denis Lacombe (EORTC, BE), Hans Scheurer (MPE, NL)

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DAY 2 – TUESDAY 27 APRIL 2021

ENDPOINTS IN EXPEDITED APPROVAL PATHWAYS	
Session Chairs: Axel Glasmacher (CDDF, DE) & Serban Ghiorghiu (AstraZeneca, UK)	
17:00 - 17:10	Opening of the meeting, introduction to the meeting objectives Axel Glasmacher (CDDF, DE), Serban Ghiorghiu (AstraZeneca, UK)
17:10 - 17:30	Patient perspective (15+5 min) Hans Scheurer (MPE, NL)
17:30 - 17:50	Regulatory perspective(15+5 min) Vishal Bhatnagar (FDA, USA)
17:50 - 18:10	HTA perspective (15+5 min) Carole Longson (NICE, UK)
18:10 - 18:40	Breakout groups: Discussion, questions to the panel
18:40 - 19:10	Break
19:10 - 20:00	Panel & Audience Discussion (with focus on problem solving, case stories) Moderator: Axel Glasmacher (CDDF, DE), Filip Josephson (EMA, SWE) Panellists: Serban Ghiorghiu (AstraZeneca, UK), Vishal Bhatnagar (FDA, USA), Carole Longson (NICE, UK), Hans Scheurer (MPE, NL)

DAY 3 – WEDNESDAY 28 APRIL 2021

PRO ENDPOINTS – REVIEW OF STRATEGIES	
Session Chairs: Anne-Sophie Darlington (EORTC, UK) & Michael Zaiac (Novartis, CH)	
17:00 - 17:10	Opening of the meeting, introduction to the meeting objectives Anne-Sophie Darlington (EORTC, UK), Michael Zaiac (Novartis, CH)
17:10 - 17:30	Patient Perspective (15+5 min) Jayne Galinsky (MPE, UK)
17:30 - 17:50	Regulatory Perspective (15+5 min) Vishal Bhatnagar (FDA, USA)
17:50 - 18:10	Industry Perspective (15+5 min) Paul Kamudoni (Merck Healthcare KGaA, UK)
18:10- 18:20	Break
18:20- 18:40	HTA Perspective (15+5 min) Leeza Osipenko (London School of Economics, UK)
18:40 - 19:00	Academic Perspective (15+5 min) Corneel Coens (EORTC, BE)
19:00 - 19:20	Breakout groups: Discussion, questions to the panel
19:20 - 19:40	Break

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19:40 - 20:35	Panel & Audience Discussion (with focus on problem solving, case stories) Moderator: Jaap Verweij (CDDF, NL) Panellists: Filip Josephson (EMA, SWE), Anne Sophie Darlington (EORTC, UK), Michael Zaiac (Novartis, CH), Jayne Galinsky (MPE, UK), Vishal Bhatnagar (FDA, USA), Paul Kamudoni (Merck Healthcare KGaA, UK), Leeza Osipenko (London School of Economics, UK), Corneel Coens (EORTC, BE)
20:35 - 20:40	Farewell Axel Glasmacher (CDDF, DE)

NOTES