



CDDF
MULTI-STAKEHOLDER
WORKSHOP

19-20 SEPTEMBER 2022

Patient Access and Engagement
in Oncology Drug Development

HYBRID WORKSHOP



EVENT OUTLINE

This event has been organised by the Cancer Drug Development Forum (CDDF) to address the increasingly important topic of Patient Access and Involvement in Oncology Drug Development. Patient and Public Involvement and Engagement (PPIE) is becoming a critically important component of all aspects of cancer research and its translation into better care, but there is currently a dearth of opportunities for the cancer community (healthcare professionals, researchers, patients, industry, regulators, payers, policy makers and other relevant stakeholders) to learn about the latest developments and exemplars of best practice and to discuss and debate how patient access and involvement in oncology drug development can be enhanced to ensure a truly patient-centred approach to delivering innovative medicines.

This multi-stakeholder event (which will be informative for all the stakeholders highlighted above) will bring together experts in the field in a series of 5 sessions over two half days, delivered through a series of keynote lectures, round tables and discussion fora. The event will examine ways in which patients can be empowered to be active participants in cancer research; how we ensure that the patient voice is amplified both in the delivery of clinical oncology research and in regulatory decision making; the challenging areas of reimbursement and access to innovative oncology medicines for patients; the absolute primacy of deploying data intelligence to underpin patient focussed oncology drug discovery and development and the highly relevant but sometimes challenging area of cross border access for clinical trials in oncology.

LEARNING OBJECTIVES

- To appreciate and understand how patients and the patient voice are best integrated into cancer research, with particular emphasis on cancer drug development and its delivery for the benefit of patients
- To determine how patients can best contribute to regulatory decision making
- To understand the complexities of patient access to innovative medicines and reimbursement of innovative medicines and what constitutes best practice
- To be informed on the key role that data intelligence plays in the delivery of patient focussed oncology medicines for the benefit of patients
- To appreciate the need and the means by which cross border access to oncology clinical trials can enhance patient access to the latest innovative medicines



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PROGRAM COMMITTEE

- Committee chair: Mark Lawler (Queen's University Belfast, UK)
- Mirjam Crul (Amsterdam UMC, NL)
- Anne-Marie Baird (Trinity College, IE)
- Susan Bhatti (Merck Healthcare KGaA, NL)
- Birgit Wolf (Bayer, DE)

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.

WORKSHOP VENUE

Van der Valk Amsterdam Amstel

Joan Muyskenweg 20, 1096 CJ Amsterdam, Netherlands

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The workshop will be held in Amsterdam. However, participation online via the Brela 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)

Email: giorgia@cddf.org, info@cddf.org

Website: www.cddf.org

Address: c/o BLSI Clos Chapelle-aux-Champs 30, 1200 Brussels, Belgium

PROGRAMME

DAY 1 – MONDAY 19 SEPTEMBER 2022

SESSION 1: EMPOWERING PATIENT INVOLVEMENT IN CANCER RESEARCH

Session Chair: Hans Scheurer (Myeloma Patients Europe, NL)

13:30 - 13:40	Welcome note Francesco de Lorenzo (CDDF, IT)
13:40 - 14:10	Patient empowerment and co-creation in cancer research - the only way to go Mark Lawler (Queen's University Belfast, UK)
14:10 - 14:25	Putting patients first - the FDA perspective Vishal Bhatnagar (FDA, US)
14:25 - 14:45	Panel Discussion Moderator: Hans Scheurer (Myeloma Patients Europe, NL) Panelists: • all speakers of the session
14:45 - 15:00	Coffee break

SESSION 2: EMBEDDING THE PATIENT VOICE IN CLINICAL ONCOLOGY RESEARCH AND REGULATORY DECISION MAKING

Session Chairs: Birgit Wolf (Bayer, DE); Jan Geissler (Patvocates, DE)

15:00 - 15:05	Session opening
15:05 - 15:20	The Added Value of Patient Engagement in Early Dialogue at EMA: Scientific Advice as a Case Study Maria Mavris (EMA, NL)
15:20 - 15:35	Evidence Based Advocacy and the impact of patient evidence on decision-making processes Ananda Plate (Patvocates, DE)

15:35 - 15:50	Making scientific research understandable and accessible to the (cancer) patient and caregiver community Pooja Merchant (Bayer, USA)
15:50 - 16:30	Roundtable Moderators: Birgit Wolf (Bayer, DE); Jan Geissler (Patvocates, DE) Panelists: • all speakers of the session • Ingrid Klingmann (European Forum for Good Clinical Practice, BE) • Paul Kluetz (FDA, US)
16:30 - 17:00	Coffee Break
SESSION 3: REIMBURSEMENT AND EARLY ACCESS TO INNOVATIVE ONCOLOGY MEDICINES FOR PATIENTS	
Session Chairs: Susan Bhatti (Merck Healthcare KGaA, NL); Mirjam Crul (Amsterdam UMC, NL)	
17:00 - 17:05	Session opening
17:05 - 17:20	Early access for patients through conditional reimbursement schemes Haiko Bloemendal (Radboud University Medical Center, NL)
17:20 - 17:35	Patient Perspective on early access Stefan Gijssels (Patient Expert Center, BE)
17:35 - 18:15	Panel Discussion Moderators: Susan Bhatti (Merck Healthcare KGaA, NL); Mirjam Crul (Amsterdam UMC, NL) Panelists: • all speakers of the session
19:00 - 11:00	Onsite Dinner

DAY 2 – TUESDAY 20 SEPTEMBER 2022**SESSION 4: TURNING DATA INTO INTELLIGENCE FOR PATIENT FOCUSED ONCOLOGY DRUG DEVELOPMENT**

Session Chairs: Mark Lawler (Queen's University Belfast, UK); Kathi Apostolidis (ECPC, BE)

10:30 - 10:35	Session opening
10:35 - 10:50	Driving a data informed patient relevant agenda – lessons from DATA-CAN, the UK's Health Data Research Hub for Cancer Mark Lawler (Queen's University Belfast, UK)
10:50 - 11:05	Patient Perspective Gilliosa Spurrier-Bernard (MelanomaFrance; Melanoma Patient Network Europe, FR)
11:05 - 11:20	Industry Perspective Bartek Madej (Novartis, CH)
11:20 - 12:00	Panel Discussion Moderators: Mark Lawler (Queen's University Belfast, UK); Kathi Apostolidis (ECPC, BE) Panelist: - all speakers of the session - Mathijs Goossens (EMA, NL)
12:00 - 12:30	Lunch Break

SESSION 5: CROSS BORDER ACCESS FOR ONCOLOGY CLINICAL TRIALS

Session Chairs: Susan Bhatti (Merck Healthcare KGaA, NL); Bettina Ryll (Melanoma Patient Network Europe, SE)

12:30 - 12:35	Session opening
12:35 - 12:50	Accessing clinical trials abroad. The experience of the Melanoma Patient Network Europe Bettina Ryll (Melanoma Patient Network Europe, SE)

12:50 - 13:05	Cross-Border Access to Clinical Trials in the EU: results from an exploratory study Teodora Lalova-Spinks (KU Leuven, BE)
13:05 - 13:20	Can we improve cross-border access to clinical trials? Ingrid Klingmann (Chairman at Board of the European Forum for Good Clinical Practice, BE)
13:20 - 13:50	Panel Discussion Moderators: Susan Bhatti (Merck, NL); Bettina Ryll (Melanoma Patient Network Europe, SE) Panelist: all speakers of the session
13:50 - 14:00	Key messages, next steps and farewell