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

EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

MULTI-STAKEHOLDER WORKSHOP

Innovation and Access in Rare Cancers

23-24 September 2024
Amsterdam, Netherlands
Hybrid Workshop

www.cddf.org

www.eortc.org

EVENT OUTLINE

This workshop will evaluate the current state of play in terms of trials and regulatory perspectives to improve access to innovative therapies in patients with rare cancers. The workshop is being jointly organised by CDDF and EORTC, bringing together their respective expertise in the treatment, clinical trials and regulatory perspectives, and will include representatives from industry and academia as well as patient groups to explore these issues.
At this multi-stakeholder workshop, meeting delegates will have the opportunity to discuss the regulatory landscape for orphan drug indications, innovative trial designs and international programmes to help identify patients for trials and share data to build cohorts. The 1.5-day meeting consists of 3 plenary sessions and adequate discussion and networking time. Each session will also include various perspectives of academics, HTAs, regulatory agencies, patient advocates and industry and discuss challenges of improving treatment for patients with rare cancers.

LEARNING OBJECTIVES

From this interactive workshop, participants will achieve the following outcomes:

- To understand the current landscape of patient identification and profiling in rare cancers
- To explore regulatory aspects, challenges and plans for formal registration of novel agents in rare indications
- To learn about the innovative trial designs available and international efforts to improve data collection and outcomes for these patients

PROGRAMME COMMITTEE

- Committee chairs: Ruth Plummer (CDDF); Winette Van der Graaf (EORTC)
- Nina Heiss (Merck Healthcare KGaA, DE))
- Carolyn Hynes (AZ, UK)
- Simone Keller (BMS, CH)
- Ariane Weinman (EURORDIS, FR)

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.

WORKSHOP VENUE

Novotel Amsterdam Schiphol Airport
Taurusavenue 12, 2132 LS Hoofddorp, Netherlands

HYBRID WORKSHOP

The workshop will be held in Amsterdam. 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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PROGRAMME

Day 1 : Monday, 23 September 2024

SESSION 1: CHALLENGES, COLLABORATION AND NEEDS

Session Chairs: Ruth Plummer (CDDF, UK); Carolyn Hynes (AstraZeneca, UK)

12:00 - 13:00	Lunch
13:00 - 13:10	Welcome note Progamme chair
13:10 - 13:35	Keynote lecture Francesco Pignatti (EMA, NL)
13:35 - 13:55	Navigating the evolving regulatory landscape of orphan drugs in Europe Pedro Franco (Merck Healthcare KGaA, UK)
13:55 - 14:15	Arcagen (title TBC) Jean-Yves Blay (Centre Léon Bérard; UNICANCER, FR)
14:15 - 15:05	Panel Discussion
15:05 - 15:35	Coffee Break

SESSION 2: INNOVATIVE TRIAL DESIGNS

Session Chairs: Winette Van der Graaf (EORTC, NL); Simone Keller (BMS, CH)

15:35 - 15:40	Session opening
15:40 - 16:00	EORTC TRACE platform Denis Lacombe (EORTC, BE)
16:00 - 16:20	Precision oncology: a revolution for rare cancers David Thomas (OMICO, AU)

16:20 - 16:40	ACCELERATE Nathalie Gaspar (Gustave Roussy , FR)
16:40 - 17:00	EU HTA - HTA perspective Beate Wieseler (Institute for Quality and Efficiency in Health Care (IQWiG), DE)
17:00 - 17:45	Panel Discussion **Guest panelists:** • Salem Abi Nehme (BMS, CH)
18:00 - 19:00	CDDF Leadership and Industry Members meeting (internal meeting)
19:00 - 22:00	Onsite dinner (Gourmet bar & restaurant) Dinner speech by **Deborah Binner** (author of "Yet Here I am: how to survive life after death")

Day 2 : Tuesday, 24 September 2024

SESSION 3: INNOVATIVE SOLUTIONS TO IMPROVE ACCESS

Session Chairs: Nina Heiss (Merck Helathcare KgAa, DE);
Gauthier Bouche (Anticancer Fund, BE)

08:30 - 10:00	CDDF Board of Directors meeting (internal meeting)
10:15 - 10:20	Session opening
10:20 - 10:30	Testimony on the path for access (patient perspective)
10:30 - 10:40	Testimony on the path for access (medical professional pespective) Winette Van der Graaf (EORTC, NL)
10:40 - 11:00	Regulatory perspective (FDA) Timil Patel (FDA, US)
11:00 - 11:20	Opportunities and Challenges of Managing Early Access in Rare Cancers: An Industry Perspective Philipp Schlatter (Roche, CH)

11:20 - 11:40	Patient access & data collection/ownership Rachel Giles (International Kidney Cancer Coalition, NL)
11:40 - 12:00	DRUP - across countries studies Sahar Van Waalwijk van Doorn-Khosrovani (CZ Health Insurance, NL)
12:00 - 12:40	Panel Discussion **Guest Panelist:** • Paul Lacante (BMS, NL)

SESSION 4: WRAP UP AND NEXT STEPS

Session Chairs: Ruth Plummer (CDDF, UK), Winette Van der Graaf (EORTC, NL)

12:40 - 13:05	Wrap up panel discussion
13:05 - 13:10	Farewell message
13:10 - 13:40	Takeaway lunch