



CDDF MULTI - STAKEHOLDER WORKSHOP

The use of Real-World Data to Optimise Oncology Drug Development and Access

Amsterdam, Netherlands
21-22 November 2019

PROGRAMME



PROGRAMME

Day 1 Thursday 21 November 2019

- 13:00 **Welcome Note**
John Smyth (CDDF Board, BE)
- 13:15 **Overview of the Current RWD Landscape**
Nafsika Kronidou Horst (Roche, CH)

SESSION 1: THE CURRENT POSITION AND KEY CHALLENGES

Session-chairs : John Smyth (CDDF, BE) & Nafsika Kronidou Horst (Roche, CH)

Current Attitudes and Key Challenges : Regulators & Payers Perspective

- 13:30 **EMA**
Ralf Herold (European Medicines Agency, NL)
- 13:50 **HTA**
Carin Uyl-de Groot (Erasmus Universiteit Rotterdam, NL)
- 14:10  **Q&A Session / Discussion (10')**

Current Attitudes and Key Challenges : Clinicians' perspective & Industry Case Studies

- 14:20 **Clinician Perspective**
Jaap Verweij (Erasmus Universiteit Rotterdam/CDDF, NL)
- 14:40 **Industry case study 1**
Valerie Andre (Lilly, UK)
- 14:50 **Industry case study 2: A pan-cancer Registry Proposal**
Stefan Foser (Roche, CH)

Current Attitudes and Key Challenges : Patient Perspective

- 15:00 **Patient Perspective**
Roger Wilson (UK)
- 15:10  **Coffee Break (20')**

SESSION 2: METHODOLOGICAL ISSUES

Session-chairs : Eva Skovlund (Norwegian University of Science and Technology, NO)
& Ralf Herold (EMA, NL)

15:30 **Introduction to Methodological Challenges**
Eva Skovlund (NTNU, NO)

DATA COLLECTION

15:35 **Disease-based Registries**
Espen Enerly (Norwegian Cancer Registry, NO)

16:05 **Product-based Registries**
Elmar Schmitt (Merck KGaA, De)

16:30 **Data Collection Technologies**
Cécile Ollivier (Aparito, US)

16:55  Q&A Session / Discussion (15')

DATA ANALYSIS

17:10 **Statistical Considerations in Building External Control**
Chris Harbron (Roche, UK)

17:35 **Electronic Healthcare Records**
Meghna Samant (Flatiron, US)

18:00  General Discussion (30')

18:30  Welcome Drinks

19:30  Networking Dinner

Day 2 Friday 22 November 2019

SESSION 3: IDENTIFYING SOLUTIONS - BREAKOUT SESSIONS

09:00 **Identifying Solutions - Breakout Sessions**
Moderator: Gracy Crane (Roche, UK)

11:00  Coffee Break

11:30 **Consolidating Outcomes from Breakout Sessions**

12:30 **Wrap-up and Next Steps**
Chair: John Smyth (CDDF, BE)

13:00  Lunch

EVENT OUTLINE

Due to the current interest in Real World Data both from Industry but especially the EMA and FDA, the Cancer Drug Development Forum organizes a multi-stakeholder workshop on the Use of Real-World Data to Optimise Oncology Drug Development and Access on 21-22 November, 2019 in Amsterdam, NL.

The aim of the workshop is to have a multi-stakeholder discussion representing regulators, clinicians, HTA / payers, and policy makers on the challenges of developing RWD proposals in Oncology and share current experience on the best sources of RWD of high quality in Oncology Drug Development. We will discuss ways to enhance knowledge on benefit/risk as well as development and access to optimal treatment regimens.

The discussion will focus particularly on issues concerning methodology of collecting good quality and relevant information, and the specific requirement of Regulators to maximise the use of RWD in licensing decisions. We will also explore possible solutions to the current challenges and collaborative search for agreements.

PROGRAMME COMMITTEE

- John Smyth (University of Edinburgh - CDDF Board) - Programme Chair
- Nafsika Kronidou Horst (Roche)
- Stefan Schwoch (Lilly)
- Eva Skovlund (Norwegian University of Science and Technology, NTNU)

TARGET AUDIENCE

The target is a multidisciplinary audience of Patient Associations, Academia Representatives, EU and US Regulatory Bodies (EMA, FDA, National Agencies), Pharmaceutical Industry, and HTAs.

WORKSHOP VENUE & HQ HOTEL

Room Mate Aitana Hotel

www.room-matehotels.com/en/aitana/

Address: IJDok 6 1013 MM - Amsterdam, Netherlands.

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WORKSHOP ROOM

Oscar Meeting Room

MEETING SECRETARIAT

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