CDDF
Cancer Drug Development Forum

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

13:10 Overview of the current RWD landscape

SESSION 1: THE CURRENT POSITION AND KEY CHALLENGES

Current Attitudes and Key Challenges : Regulators & Payers Perspective

13:30 EMA

13:50 FDA

14:10 HTA

Current Attitudes and Key Challenges : Industry Case Studies

14:30 Industry case study 1

14:40 Industry case study 2
A pan-cancer registry proposal
Martina von Meyenn (Roche)

Current Attitudes and Key Challenges : Patient Perspective

14:50 Patient Perspective
Roger Wilson (Sarcoma UK charity organisation)

15:10 Coffee Break

SESSION 2: METHODOLOGICAL ISSUES

DATA COLLECTION

15:30 National Registries

15:50 Disease-based Registries:
Espen Enerly (Norwegian Cancer Registry)

16:10 Product-based Registries
Elmar Schmitt (Merck KGaA, Germany)

16:30 EH Record
Meghna Samant (Flatiron)

16:50 Data Collection Technoloigies
Cécile Ollivier (Aparito)

DATA ANALYSIS

17:10 Statistics

17:30 Big Data

17:50 What is required to build an external control

18:10 Predicting clinical outcomes and models (prediction models)

18:30 General Discussion (20`)

18:50 Welcome Drinks

19:30 Networking Dinner

SESSION 3: BREAK-OUT SESSIONS

Co-chairs: Axel Glasmacher(CDDF, DE) & Ralf Herold (European Medicines Agency, NL)

09:30 Breakout Session 1 : SPRINT Technology

09:30 Breakout Session 2 : What the industry want ?

10:30 Coffee Break

11:00 Breakout Session Report

12:00 Wrap-up and Next Steps

12:30 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.

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.
Phone: (+31) (0) 20 89 14 800

MEETING SECRETARIAT

Cancer Drug Development Forum (CDDF)
c/o BLSI
Clos Chapelle-aux-Champs 30
1200 Brussels, Belgium
Tel: +32 2 880 62 70
Email: info@cddf.org

www.cddf.org