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

MULTI-STAKEHOLDER WORKSHOP

The critical role of Biomarkers in delivering drug development-related precision oncology

13-14 November 2023
Amsterdam, Netherlands
Hybrid Workshop

www.cddf.org

EVENT OUTLINE

The progress in molecular biology, coupled with progress on pharmaceutical aspects, has enabled an increasing development of effective medicines, for a (sometimes highly) selected patient population with tumors defined based on so-called biomarkers. Commonly these are molecular features of a malignant disease that can be identified with an appropriate test.

The downside of this, is that a patient populations become increasingly fragmented, ultimately turning every malignant disease into a rare disease.
This creates challenges for drug development in general, and for the trials designed to obtain marketing approval in small populations specifically, and for the debate on drug-related use, -costs and -reimbursement after marketing approval.

The workshop will offer a neutral and collaborative platform for evaluation and discussion of innovation in these areas with active participants from all relevant stakeholders. Informative lectures and panel discussions open to all attendees will alternate.

The main objective of the workshop will be to formulate how biomarker use could best be implemented in drug development based on available insights from all relevant stakeholders.

LEARNING OBJECTIVES

- How to define a biomarker, and related populations within the health systems
- To align the conditions for the involved biomarker assessment in the EU
- Regulatory requirements for marketing authorizations
- Regulatory requirements for reimbursement approval after marketing authorization

PROGRAMME COMMITTEE

- Programme chair's: Jaap Verweij (CDDF, NL) & Mark Lawler (CDDF, UK)
- Richard Vart (Lilly, UK)
- Ademi Santiago-Walker (Janssen R&D, US)
- Patient advocate - Marianna Vitaloni (Digestive Cancers Europe)

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

Nhow Amsterdam RAI
Europa Boulevard 2B, Amsterdam, The 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 13 November 2023

SESSION 1: SETTING THE SCENE OF BIOMARKERS

Session Chairs: Marianna Vitaloni (DiCE, BE) ;
Jessica Vermeulen (Janssen R&D, NL)

12:00 - 12:55	Lunch
12:55 - 13:00	Welcome note Jaap Verweij (CDDF, NL)
13:00 - 13:05	Introduction
13:05 - 13:25	How can we define a biomarker - Academic perspective Nicola Normanno (INT-Fondazione Pascale, IT)
13:25 - 13:45	How can biomarkers have relevance to patients and health systems Mark Lawler (CDDF, UK)
13:45 - 14:05	Industry perspective, biomarkers & drug development Ademi Santiago-Walker (Janssen R&D, US)
14:05 - 14:40	Panel discussion
14:40 - 15:00	Coffee Break

SESSION 2: BIOMARKER BASED AUTHORISATION & REIMBURSEMENT

Session Chairs: Richard Vart (Eli Lilly, UK);
Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)

15:00 - 15:05	Introduction

15:05 - 15:25	Biomarkers and marketing authorisation of medicines in Europe Olga Kholmanskikh (Famhp, BE)
15:25 - 15:45	Biomarker based drug development and authorisation in US Reena Philip (FDA, US)
15:45 - 16:05	Biomarkers and HTA/PRA – does precision medicine lead to better access and reimbursement? Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)
16:05 - 16:40	Panel Discussion

SESSION 3: THE COST OF NOT USING BIOMARKERS

Session Chairs: Jaap Verweij (CDDF, NL);
Ademi Santiago-Walker (Janssen R&D, US)

16:40 - 16:45	Introduction
16:45 - 17:05	Precision oncology - What's holding us back? Peter Keeling (Diaceutics, IE)
17:05 - 17:25	Why patients want biomarkers Warnyta Minnaard (Missie Tumor Onbekend, NL)
17:25 - 17:45	The Clinical consequences of not-testing Rosa Giuliani (Guy's and St Thomas' NHS Foundation, UK)
17:45 - 18:15	Panel Discussion Guest panelist: Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)
18:30 - 19:30	CDDF Leadership and Industry Panel Meeting (internal meeting)
19:30 - 22:00	Welcome drink & onsite dinner

Day 2 : Tuesday 14 November 2023

SESSION 4: IVDR

Session Chairs: Mark Lawler (CDDF, UK); Claudia Popp (Roche, CH)

08:30 - 10:00	CDDF Board of Directors meeting (internal meeting)
10:30 - 10:35	Introduction
10:35 - 10:55	Challenges for biomarkers in clinical trials (patient selection, stratification, primary analysis) Roberto Salgado (EORTC, BE)
10:55 - 11:15	IVDR implementation - industry perspective Claudia Popp (Roche, CH)
11:15 - 11:35	IVDR implementation - regulatory perspective Ana Trullas (EMA) & Olga Kholmanskikh (Famhp, BE)
11:35 - 12:00	Panel Discussion Guest panelist: Heike Moehlig-Zuttermeister (TÜV Süd, DE)

SESSION 5: WORKSHOP WRAP-UP AND NEXT STEPS

Session Chairs: Jaap Verweij (CDDF, NL); Mark Lawler (CDDF, UK)

12:00 - 12:15	Wrap up & farewell message Mark Lawler (CDDF, UK)
12:15 - 13:00	Sandwich lunch and departure