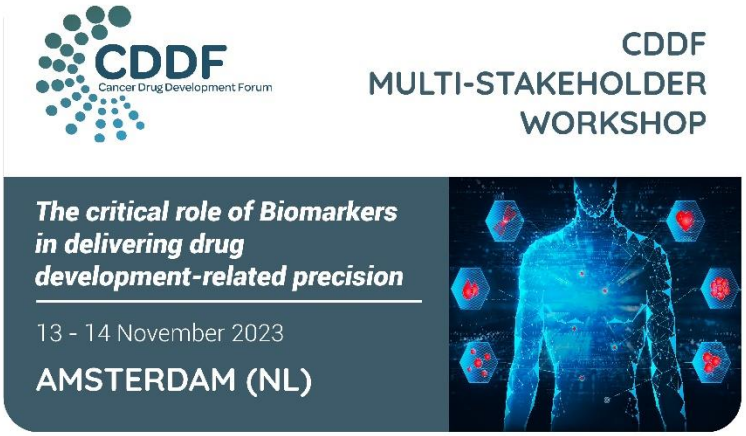

CDDF Multi-stakeholder Workshop

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

13 - 14 November 2023
Amsterdam, NL

(DRAFT PROGRAMME)

Meeting Secretariat
Giorgia Campagnano (Event Coordinator, CDDF): giorgia@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, the trials designed to obtain marketing approval in small populations in specific, and a 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. CDDF intends to publish the outcome.

LEARNING OBJECTIVES

- How to define a biomarker, and related populations within the health systems
- To alienate 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: Jaap Verweij (CDDF, NL) & Mark Lawler (CDDF, UK)
Richard Vart (Eli Lilly, UK)
Raluca Verona (Johnson & Johnson, US)
Marianna Vitaloni (Digestive Cancers Europe, IT)

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

EXPECTED NUMBER OF PARTICIPANTS:

+/- 40 onsite participants/ +/- 100 online participants

MEETING DATE:

13 - 14 November 2023

MEETING VENUE:

Nhow Amsterdam RAI
Europa Boulevard 2B
Amsterdam, The Netherlands

DRAFT PROGRAMME

DAY 1 (Monday 13 November 2023)

12:00-13:00: **Lunch**
13:00-13:05: **Welcome Note**
Jaap Verweij (CDDF, NL)

Session 1: Setting the scene of Biomarkers

Session chairs: Marianna Vitaloni (Digestive Cancers Europe, ES); Jessica Vermeulen (Johnson & Johnson, NL)

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 Stantiago-Walker (Johnson & Johnson)
14:05-14:40 **Panel discussion**

14:40-15:00 **Coffee break**

Session 2: Companion diagnostics, approval & reimbursement

Session chairs: Richard Vart (Eli Lilly, UK)

15:00-15:20 **Biomarkers and EU registration** (licensing)

15:20-15:40 **Biomarkers and US registration** (licensing)
Reena Philips (FDA, US)
15:40-16:00 **Biomarkers and HTA/PRA – does precision medicine lead to better access and reimbursement?**
Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)
16:00-16:40 **Panel discussion**

Session 3: The cost of NOT using biomarkers

Session chairs: Jaap Verweij (CDDF, NL); Raluca Verona (Johnson & Johnson, US)

16:40-17:00 **Precision oncology - What's holding us back?**

17:00-17:20 **Why patients want biomarkers**
Natacha Bolaños (Lymphoma Coalition, ES)
17:20-17:40 **The Clinical consequences of not-testing**
Rosa Giuliani (The Clatterbridge Cancer Centre, UK)
17:40-18:10 **Panel discussion**
Guest panelist: Sahar Barjesteh van Waalwijk van Doorn-Khosrovani (CZ, NL)
18:15-19:15 **Industry panel meeting (Internal meeting)**

19:30-22:00 **Welcome Drink & Networking Dinner**

DAY 2 (Tuesday 14 November 2023)

8:30 - 10:00 **CDDF Board meeting (internal meeting)**

Session 4: IVDR

Session chairs: Mark Lawler (CDDF, UK)

10:30- 10:35 **Introduction**
Session chairs

10:35- 10:55 **Challenges for biomarkers in clinical trials**
Roberto Salgado (EORTC, BE)

10:55-11:15 **IVDR implementation - industry perspective**
Claudia Popp (Roche, CH)

11:15-11:35 **IVDR implementation - regulatory perspective**

11:35-12:00 **Panel discussion**

Session 5: Workshop wrap-up and next steps

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

12:00-12:30 **Wrap up panel discussion**

12:00-12:30 **Farewell message**
Mark Lawler (CDDF, UK)

12:55-13:30 **Sandwich lunch and departure**