CDDF
Cancer Drug Development Forum

CDDF MULTI - STAKEHOLDER WORKSHOP

Biomarkers and Patient's Access to Personalized Oncology Drugs in Europe

Brussels, Belgium
24 - 25 September 2018

PROGRAMME

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Day 1 Monday 24th September 2018

13:00 **Introduction**
Heinz Zwierzina (CDDF / Medical University of Innsbruck, Austria)

SESSION 1: PERSONALISED MEDICINE - THE FUTURE OF DRUG DEVELOPMENT

Co-chairs : Sonia Garcia Perez & Heinz Zwierzina

13:10 **Academic perspective on enabling precision immuno-oncology**
Zlatko Trajanoski (Medical University of Innsbruck, Austria)

13:30 **Industry perspective: the challenges & opportunities of personalized/stratified medicine from a development and patient access perspective**
Michael Zaiac (Novartis, Switzerland)

13:45 **Biotech perspective**
Kieran O'Kane (Biodesix, United States)

14:00 **Role of in vitro diagnostics in the authorization of anticancer medicines**
Harald Enzmann (bFarm, Germany)

14:15 **HTA's perspective**
To be announced

14:30 **Payer's perspective**
Anouk Waeytens (RIZIV / INAMI, Belgium)

14:45 **Patient advocate's perspective**
Francesco De Lorenzo (ECPC, Italy)

15:00 **Roundtable discussion**

15:40 Coffee break

SESSION 2: CHALLENGES FOR ACCESS TO BIOMARKERS

Co-chairs : Isabelle Huys & Michael Zaiac

16:10 **In Vitro Diagnostics (IVD) - European regulatory perspective**
Markus Paulmichl (European Medecines Agency, Austria)

16:30 **Case stories**
David Browning (Oxford Cancer Biomarkers, United Kingdom)
Kieran O'Kane (Biodesix, United States)

16:50 **HTA perspective**
Sonia Garcia Perez (AEMPS, Spain)

17:05 **Biomarker development for immunotherapy: a new chance**
To be announced

17:20 **Patient advocate's perspective**
Kathi Apostolidis (ECPC, Greece)

17:35 **Regulatory point of view: Industry perspective**
Claudia Dollins (Merck, Germany)

17:50 **Personalised cancer care: translating promise into practice - with multi-stakeholder approach**
Titta Rosvall-Puplett (Bristol-Myers Squibb, Belgium)

18:05 **Roundtable discussion**

18:45 End of Day 1

19:30 Networking Dinner at The Twelve Restaurant (Thon Hotel EU)

Day 2 Tuesday 25 September 2018

SESSION 3: THE WAY FORWARD

Co-chairs : Claudia Dollins & Tatiana Prowell

09:00 **Fostering collaboration in the era of precision oncology: academic perspective**
Tatiana Prowell (John Hopkins Kimmel Comprehensive Cancer Center, United States)

09:20 **Strategies to allow indication based payment for biomarkers**
Afschin Gandjour (Frankfurt school of Finance & Management, Germany)

09:35 **Developing practical guidance for Member States on implementing precision genomics in medical care**
Marc Van den Bulcke (Sciensano, Belgium)

09:50 **Access to biomarkers: "Are we ready for value-based precision medicine?"**
Patricia Carrigan (Bayer, Germany)

10:05 **Payer's perspective: sustainability of healthcare systems**
Annie Pannelay (United Kingdom)

10:20 **Potential of real world evidence for access to biomarkers**
Jesús María Hernández Rivas (HARMONY/ IBSAL, Spain)

10:35 **Roundtable discussion**

11:05 Coffee break

SESSION 4: NEXT STEPS

Co-chairs : Lothar Bergmann & Ivana Cattaneo

11:25 **Introduction on the EUnetHTA actions**
François Meyer (HAS Santé, France)

11:45 **The provider's point of view**
Santiago Valor (Labco, Spain)

12:05 **Multi-stakeholder approaches for addressing barriers to precision medicine: Diagnostic Quality Assurance pilot**
Lindee Goh (Tapestry, United States)

12:15 **All stakeholders' perspective on the next steps**

12:35 **Roundtable with the programme committee**

13:00 Lunch at The Twelve Restaurant (Thon Hotel, EU)

Meeting Outline

The incidence of cancer will increase within the next 5 years up to 15 million patients per year worldwide with a further increasing tendency. Therefore, there is a requirement for more emphasis on cancer prevention, research and effective anticancer drugs including a rapid licensing and market availability for the patients. In the EU, the centralized procedure (CP) of the European Medicine Agency (EMA) is mandatory for marketing authorization for innovative anticancer drugs. At variance, numerous independent healthcare systems are in operation across the EU, and each Health Technology Assessment (HTA) body follows its own methodologies and scientific value judgements in the assessment of the added value of an innovative anticancer drug. Consequently, drug access for patients differs considerably within the EU. Initiatives to improve the interface between the different stakeholders are currently on the way, but are unlikely sufficient enough to overcome these fundamental problems.

In order to accelerate drug development, reduce costs, increase efficacy and bring new and effective agents to patients as rapidly as possible, a huge clinical need remains for minimally invasive tests to determine subgroups of patients with a high probability for response to therapy. Biomarkers are characteristics that can be objectively measured and evaluated as an indicator of normal or pathogenic biological processes or of pharmacologic responses to therapeutic interventions. Therefore biomarkers hold great potential to predict clinical outcome and define a personalized treatment strategy tailored to a specific tumor.

In many instances a single marker cannot offer the necessary sensitivity and specificity. Given the complexity of the neoplastic process a panel of multiple markers is required. Consequently, many investigations now focus on the development of multiplexed assays that screen multiple genes and proteins in the same specimen at the same time.

The future will see the widespread use of biomarkers. The regulatory challenges and the hurdles such as finances, access to clinical data and reimbursement will be addressed. There is a need for a better science-based common position on methodology, greater commitments by politicians and healthcare decision makers to ensure equal access for patients across the EU to innovative antitumor medicines.

The multi-stakeholder workshop on Biomarkers and Patients' Access to Personalized Oncology Drugs in Europe is organised by the Cancer Drug Development Forum (CDDF), in collaboration with the European Cancer Patient Coalition (ECPC). CDDF is a not-for-profit association whose mission is to improve the efficiency of oncology drug development and delivery by providing a unique forum for discussion where all those involved in cancer drug development can meet to address hurdles and explore potential solutions together.

This workshop aims at giving an overview about developments in European regulatory and health technology assessment of new cancer drugs as well as at facilitating a collaborative discussion between regulatory bodies, HTA organisations, healthcare providers, academics, patients and industry on the challenges of equal access to personalized therapy within and between European countries.

Programme Committee

- Heinz Zwierzina (Innsbruck University Hospital / CDDF, Austria)
- Ivana Cattaneo (Vice-Chair EFPIA Oncology Platform / Public Affairs Director, Novartis Oncology)
- Francesco De Lorenzo (European Cancer Patient Coalition, Italy)
- Sonia Garcia Perez (AEMPS, Spain)
- Isabelle Huys (KU Leuven, Belgium)
- Annie Pannelay (United Kingdom)
- Markus Paulmichl (European Medicines Agency, Austria)

Meeting Venue

Thon Hotel EU
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Meeting Secretariat

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