



CDDF Multi-stakeholder Workshop

Patient Access and Engagement in
Oncology Drug Development

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Disclaimer

- ML has received honoraria unrelated to this presentation from Bayer, Carnall Farrar, EMD Serono, Novartis, Pfizer and Roche

Background / Introduction

- **Multi-stakeholder event** took place on 19th – 20th September in Amsterdam
- Brought together experts in the field in a series of 5 sessions over two half days, delivered through keynote lectures, round tables and discussion fora

Learning Objectives

- To appreciate and understand **how patients and the patient voice are best integrated into cancer research**, with particular emphasis on cancer drug development and its delivery for the benefit of patients
- To determine **how patients can best contribute to regulatory decision making**
- To understand the complexities of **patient access** to innovative medicines and **reimbursement of innovative medicines** and what constitutes best practice
- To be informed on the **key role** that **data intelligence** plays in the delivery of patient focussed oncology medicines **for the benefit of patients**
- To appreciate the need and the means by which **cross border access to oncology clinical trials** can enhance patient access to the latest innovative medicines

Key Discussion Points

- The Why and the How of **empowering patient involvement** in oncology drug development research
- Ensuring that the **patient voice** is **embedded** in **clinical oncology research and regulatory decision making**
- Finding the **best path** to ensure both **early access** to, and **reimbursement** of, innovative oncology medicines for patients
- Ensuring that **appropriate data are collected** and **turned into the intelligence required** to inform patient focussed oncology drug development
- Ensuring **cross-border access** for oncology clinical trials

Take-home Message

- Patients **must be at the heart** of the oncology drug development pathway and be **active participants in all stages of the research**, from design to delivery
- **Data informed intelligence** must underpin the oncology drug development effort
- **Patients** must have **more involvement** in the **regulatory decision making process**
- **Partnership approaches** to ensure the **best value for all stakeholders** should be explored and encouraged

Recommendations I

- Absolute primacy of patient involvement
- Representation of different patient voices
- Appropriate financial compensation for patient contribution
- Co-authorship on publications that ensue from patient involvement
- Appropriate training provided

Recommendations 2

- Research to evaluate barriers to PPIE in cancer research
- Research to evaluate the benefit of PPIE in oncology drug development;
- Grant awarding bodies give higher priority to research that provide meaningful patient involvement
- Guidelines around methodology of patient generated evidence in regulatory decision making

Outcome

- Acting on the 10 recommendations will provide the impetus to deliver a truly patient-centred approach into oncology drug development and its implementation for the benefit of patients with cancer.

Next Steps

- Meeting report to be completed and made available **COMPLETE**
- White paper to be prepared **ONGOING – Near Final Draft**
- Two pager for wider distribution **to be completed following final draft**