INVOLVING AND ENGAGING PEOPLE WITH CANCER IN ONCOLOGY DRUG DEVELOPMENT

A SUMMARY REPORT ON BEHALF OF THE CANCER DRUG DEVELOPMENT FORUM

Professor Mark Lawler
Queen's University Belfast & Board of the
Cancer Drug Development Forum

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This Summary Report captures the key findings from the Cancer Drug Development Forum (CDDF)'s 'Patient Access and Involvement in Oncology Drug Development' multi-stakeholder workshop, which took place on the 19th - 20th September 2022 in Amsterdam, The Netherlands. The Report highlights the importance of Patient and Public Involvement and Engagement (PPIE) in cancer research and emphasises how involvement of people affected by cancer can help ensure a person-centred approach to developing innovative cancer medicines. Through a series of 11 recommendations that represent the key output from the CDDF Workshop, we advocate for a more patient-focussed research and innovation effort, involving people with cancer in both defining the oncology drug development agenda and ensuring its rapid and effective implementation.

A key learning from the Workshop was a realisation that involving people with cancer in research and innovation helps improve its overall quality, relevance and impact. Putting more focus on what people with cancer value (e.g. reduced toxicity, better quality of life) must inform the research questions to be asked going forward. Involving people with cancer should be considered at all stages of oncology drug development, both to ensure the relevance of the research to people with cancer and to address societal expectations around transparency and accountability. Involving people with cancer specifically in cancer clinical trial design and delivery can be a key enabler of a more efficient cancer clinical trial delivery - faster enrolment, higher retention, better compliance and clearer communication of research findings.

A number of initiatives have emphasised the importance of involving people with cancer in cancer care and cancer research agendas. The European Cancer Patient's Bill of Rights, launched in 2014, and the European Code of Cancer Practice, published 2021, both highlight that cancer patients must be active participants rather than passive recipients in their own care. Recent developments empowering people with cancer to be active participants include the Joint Declaration of the German, Portuguese and Slovenian Trio Presidency of the Council of the EU and the European Cancer Groundshot. The Trio Presidency of the EU emphasises that "patients must not be viewed as mere research objects…. they should hold an appropriate share of decision-making power in the research process." The European Cancer Groundshot calls for a "more patient-focussed, data-informed" approach to cancer research in Europe. However, despite these developments, there is still a need for studies that categorically demonstrate the value of including people with cancer in the design and delivery of new cancer medicines.

Ensuring active participation of people with cancer to inform novel more innovative approaches in oncology drug development must be pursued. Maximising the benefit of the medicines produced, so that they deliver more efficacy and address the need for safer medicines with less side effects, would address one of the key challenges that people with cancer frequently experience. The presentations, discussions and deliberations at the CDDF Workshop have led to the development of a series of recommendations, which if acted upon, would help deliver an enhanced patient-centred oncology drug development agenda that ensures benefit and produces value for patients, health services, researchers, and the private sector.

Recommendations

Recognising the absolute need for people with cancer to be involved in helping to drive oncology drug development research and its integration into clinical care, we have developed a series of recommendations:

1. People with cancer, their advocates and cancer patient organisations should be involved from the earliest stages of the oncology drug development research cycle, including helping to generate the research hypothesis, assisting in setting study goals, contributing to study design, choosing study endpoints and patient-reported outcome measures as well as preparing documents as necessary.

2. To focus on patients' unmet needs and priorities, avoid tokenism and provide balanced representation of the perspective of people with cancer, patient organisations should be involved in the PPI consultation to ensure a representative sample of people with cancer from different backgrounds contributes to oncology drug development research programmes.

3. Participation of people with cancer in cancer research for drug development should be facilitated and appropriate guidance and capacity building should be offered by pertinent national authorities to people with cancer and their advocates to enable their meaningful involvement.

4. People with cancer and their advocates who actively contribute to the study design and conduct of the research should be offered co-authorship of any resulting publications as per journal guidelines, clearly signalling the importance of involving people with cancer in research.

5. People with cancer should have access to all information to allow them to make a meaningful, informed contribution to oncology drug development and its implementation

6. People with cancer should have access to training on data protection related topics, especially in the context of increased digitalisation, and the importance of secondary use of data. Training such as the EUPATI Open Classroom or the WECAN Academy should be more frequently deployed to enhance people with cancer's technical knowledge about research and development.

7. People with cancer must be appropriately compensated for their contribution to clinical cancer research and oncology drug development.

8. In making funding research decisions, grant awarding bodies should give higher priority to research studies that provide meaningful patient involvement and patients should be involved in the grant reviewing process. Existing guidance such as from the Rising Tide Cancer Research Foundation provides a basis for research funding institutions.

9. Guidelines are needed around methodology of patient generated evidence in regulatory decision making (collection, integration, and impact), and there is also a need to increase transparency in the use of patient experience data in the regulatory decision-making process, as well as clear and communicated timelines and deadlines in R&D and regulatory processes.

10. Research is needed to evaluate barriers to participation of people with cancer in cancer research, particularly in underserved communities, and to determine how to overcome these barriers.

11. Existing frameworks on value of performance metrics and financial value should be used to assess the value and benefit of involvement of people with cancer in research.Further research investigating evidence of benefit of involving patients in oncology drug development and the design of cancer clinical trials should be undertaken to ensure that PPIE input remains relevant and impactful and proves its value for all stakeholders.

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Cancer Drug Development Forum

Prepared by:
Professor Mark Lawler
Queen's University Belfast & Board of the Cancer Drug Development Forum

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