Cancer Surrogate Endpoints Feasibility Project

Project description

Currently, the UK lags behind comparative European countries in some areas on cancer mortality, survival rates, access to and uptake of innovative cancer medicines.[1] There is a collective drive and intent across the UK cancer community to improve patient care and outcomes through earlier access to innovative therapies. However, there is often a significant delay in patients being able to access such medicines, as fewer highly innovative drugs are approved by NICE compared to low or moderately innovative ones.[2]

The ability to reliably corroborate surrogate endpoints as indicators of longer term outcome data such as overall survival is required by the National Institute for Health and Care Excellence (NICE), for assessing medicines for use in the NHS. It is particularly important for speeding access to life-extending medicines to be used early in the treatment pathway. It could take many years before evidence of overall survival from trials of innovative new treatments is available.

Janssen, the Association of the British Pharmaceutical Industry (ABPI) and DATA-CAN: The Health Data Research UK Hub for Cancer, are partnering to undertake feasibility work towards evaluating emerging cancer endpoints to measure effectiveness of cancer medicines sooner, so that patients may access medicines earlier. This feasibility project aims to build on the strength of UK healthcare data and the diverse UK population. The focus is initially on two exemplar cancer types (Multiple Myeloma and Lung Cancer), with broader learnings for other cancer types.

Organisations involved

This project is jointly funded by Janssen and the ABPI and will be delivered by DATA-CAN, working with the Health Economics Unit (HEU).

Project approach

The project involves engaging with multiple stakeholders including: UK clinical research leaders in Multiple Myeloma and Lung Cancer, data experts, NICE and patient representatives. It will entail an assessment of current UK datasets, linking and enrichment capabilities. The project aims to generate recommendations for Multiple Myeloma and Lung Cancer endpoint validation pilot studies, based on a gap analysis between evidence standards for surrogate endpoint validation and current UK datasets, plus a feasibility assessment of options to bridge the gaps. The project is designed to also highlight broader cancer data learnings to drive health data policy.

The DATA-CAN Patient and Public Involvement and Engagement group has reviewed and approved DATA-CAN's role in the project, including that patient representatives will be consulted and represented in the project governance.

The feasibility report is expected by the end of 2021.

Benefits to patients

Patients with cancers often suffer from a lack of new effective treatment options – any improvement in bringing new treatments for these patients is likely to lead to improvements in their outcomes. This project is a first step towards faster patient access to life-extending cancer treatments through reliable and accepted link between shorter term outcomes and longer-term benefit.

Item Ref: CP-242854
Date of Preparation: June 2021

Benefits to the NHS

The project will increase understanding of the quality and potential of NHS datasets for robust evidence generation in cancer. If the project contributes to surrogate endpoint validation the NHS will also benefit from a more accurate understanding of prognosis and treatment, as well as shorter-term measures as a basis for clinical decision-making. This project is also aligned with the Innovative Licensing and Access Pathway introduced by the UK Medicines and Healthcare Products Regulatory Agency to deliver earlier access to new innovative medicines.

Benefits to the pharmaceutical industry

This project is a pathfinder towards providing faster access to innovative cancer medicines, benefiting patients, industry, regulatory agencies, NICE, SMC and the wider UK cancer community. The objectives include providing increased understanding of surrogate endpoint evidence standards which in turn will support evidence-based health policy engagement for quality UK cancer data. The successful validation of surrogate endpoints in studies informed by this project will provide new target endpoints to inform the industry's R&D strategy, increasing the potential for more pragmatic, shorter and adaptive clinical trials, leading to earlier licensing of effective cancer therapies.

References

1. The Institute of Cancer Research. Cancer Drug Manifesto (2019). Available at: https://www.icr.ac.uk/about-us/policy-and-engagement/improving-drug-access/cancer-drug-manifesto Accessed: June 2021
2. Sharpe E, Hoey R, Yap C, Workman P. From patent to patient: analysing access to innovative cancer drugs. Drug Discovery Today.2020; 25(9):1561-1568