Blood Cancer UK evidence
Lord O'Shaughnessy review of UK commercial clinical trials landscape

Context

Blood cancer is the fifth most common cancer and the third biggest cancer killer in the UK, with approximately 15,000 deaths per year. This means clinical trials to improve treatments and outcomes for people with blood cancer are crucial.

Clinical trials in blood cancer patients take on added importance as most cancers cannot be treated with surgery or radiotherapy. Over 40% of the treatments on the Cancer Drugs Fund are for blood cancer. Therefore, for many people, participating in a clinical trial will be their only and best treatment option. This means the development of new drugs and access to them, both in a clinical trial and a subsequent NHS setting, is vitally important.

Patients with blood cancer in some clinical trials have had better health outcomes than those who did not participate. Furthermore, blood cancer comprises of over 100 different types of smaller, rarer subsets which demonstrate significant unmet needs in treatments, adding to the increased importance of clinical trials access in the blood cancer community.

Trials funded by the pharmaceutical industry are more likely to focus on novel agents which show potential for improved treatments, more lives saved, and fewer side effects. Recent NICE approvals in blood cancer reflect the fact that combination treatments are most effective and so we need this throughput of new agents to combine with existing treatments to find the most effective in treating the many types of blood cancer.

Declining access to treatments through clinical research is especially concerning for the health outcomes of many, including blood cancer patients, who have limited treatment options in routine care.

Our clinical trials work.

Blood Cancer UK is a member of the Association of Medical Research Charities. We also offer a unique blood cancer clinical trials support service which was set up in June 2020 with the aim of:

- Supporting and advocating for people living with blood cancer who are enrolled on a clinical trial, for the duration of their clinical trial journey as well as offering support to their carers and relatives.
- Providing impartial advice to people undergoing treatment for blood cancer and their carers or relatives of any potential clinical trials that may be available to them, providing them with information, advocacy and liaison between clinicians and trials sites.
- Continuing to raise awareness of clinical trials in the blood cancer population.
- Ensuring we work to break down the barriers to accessing clinical trials.

Since the Clinical Trials Support Service (CTSS) began, 286 referrals have been received, and trial searches have been completed for 108 people with blood cancer. Through our searches we have documented 142 individual clinical trials and of those, 76% have been commercially led. We have successfully helped 37 people enrol onto a clinical trial for their blood cancer, 57% of those being onto commercial trials.

Recommendations for commercial clinical trials

The UK's share of global pharmaceutical R&D investment decreased from 7.7% in 2012 to 4.1% in 2019. Furthermore, the number of phase I trials initiated in the UK have fallen by 13% from 2015 to 2019, with a further 7% decrease in 2020. Although the drivers of the UK's declining clinical trials landscape have been explored by ABPI and other organisations, below are some key issues in surrounding commercial trials and opportunities to increase the attractiveness of the UK as a competitive destination for commercial clinical research.

The case for investment across the clinical trial landscape

The Government must commit to increase R&D spending and invest in the infrastructure needed to attract and deliver clinical research efficiently. Going forward, we need to ensure the life sciences sector is appropriately resourced so we can build our research capacity and cultivate a collaborative life sciences ecosystem.

The importance of a supported and sufficient research workforce cannot be overlooked. ***Future NHS workforce plans should include research commitments.*** Healthcare professionals should also be incentivised, through bodies like Health Education England, to adopt research as part of their roles and career pathways.

Additionally, the infrastructures required to efficiently run complex trials, including lab facilities, and trained staff with experience in sampling and processing of samples, is important. Equally, the capacity and capabilities of pharmacy and sterile labs are also essential for commercial clinical trials.

<u>The need for more efficient and streamlined approvals and processes.</u>
It currently takes almost twice as long to initiate a clinical trial in the UK as compared to the USA, and our clinical research is recovering more slowly than European counterparts post-Covid. Existing data highlight our European peers (namely Germany and Spain), have more trial initiations. They are also benefitting from higher patient participation meaning more patients are accessing treatments through trials, whilst the UK is underperforming in both areas.

Additionally, there is currently a lack of consistent, standardised costing and contracting processes across the UK. The resulting persistently slow and variable study set-up and recruitment timelines are pushing pharmaceutical companies to seek other countries for their trials. This variability across trial sites also slows down patient access and acts as a disincentive for trial sites is leading to clustering in a few centres and vast geographical inequalities in access.

We need a fast track, one stop, efficient ethical approval at a national level, enabling trials to open faster and patients to access drugs.

A maximum timeframe, with restrictions on negotiations to costing and contracting of commercial research, should be introduced by NHS organisations across the devolved nations.

<u>Programmes to incentivise geographical spread of trials.</u>
The Government must commit to improving geographical diversity of trials, so patients who live in suburban and rural communities have equity of access to potential new treatments.
Offering sustainable financial incentives for trial sites in underserved areas would support this.

Facilitate patient enrolment and retention.

Approximately half of all commercial trials fail to recruit to target. Late-stage clinical trials which require larger patient numbers are not being commenced in the UK. From 2019 – 2020, enrolment in commercial clinical trials in the UK has decreased by 15%. In contrast, comparable countries such as Spain and Italy have benefitted from 32% and 34% increases in enrolment respectively.

The Government must consider international insights and best practice e.g., the introduction of a quicker process for trial approval and set up in Spain.