

IMPROVING

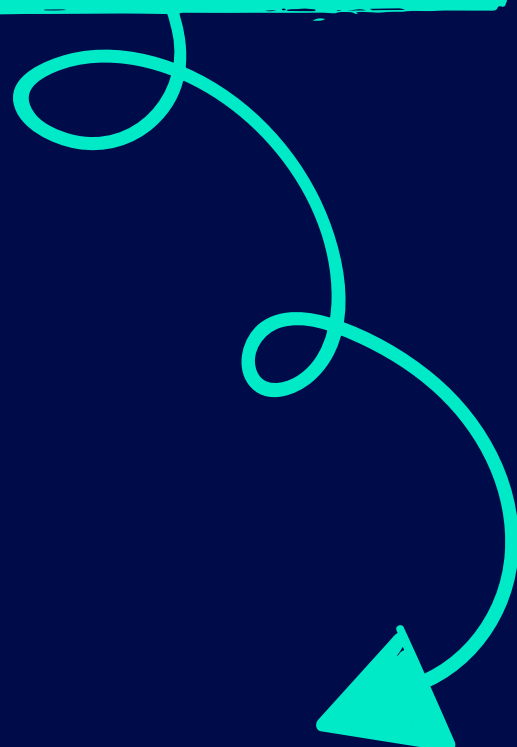
**YOUNG PEOPLE'S
ACCESS TO CANCER
CLINICAL TRIALS**

**TEENAGE
CANCER
TRUST**



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EXECUTIVE SUMMARY

Cancer kills more teenagers and young adults in the UK than any other disease, and at Teenage Cancer Trust we are determined to change that.

Every year, 250 young people will have their lives cut short by the disease.¹ Our big goal is that by 2040, young people (aged 13-24) with cancer in the UK will have the best outcomes and quality of life in the world. To achieve this goal, it is crucial that new and better treatments for cancer continue to be developed, and that young people can access them.

New treatments are first accessed through clinical trials. Clinical trials help researchers find new and better treatments for cancer, saving or prolonging lives and reducing side effects. Much of the progress that has been made in treating cancers that affect young people has been made because of clinical trials.

Teenage Cancer Trust believes that every young person with cancer in the UK should have the opportunity to participate in a clinical trial where one is available that is suitable for them.

Over the past year Teenage Cancer Trust has sought to understand how we can achieve this ambition. We know from our experience working with teenagers and young adults across the UK that currently too many young people are unable to access clinical trials. However, we wanted to understand more about the current barriers to access and put together recommendations to address them and identify examples of best practice.

To do this we have spoken to young people, clinicians, academics, charities, and other experts in this area. In this report we also highlight some of the excellent work of other research charities and organisations and the solutions they are calling for to lead to broader improvements in clinical research. However, this report will focus on the specific barriers that young people face, based on the experiences that they and professionals they work with have shared.

Young people are not alone in not being able to access clinical trials. We know there are big challenges in accessing them for many people across the UK. However, there is some evidence to suggest young people face challenges to accessing trials. Increasing the overall number of trials active in the UK would not on its own dismantle the other obstacles currently preventing participation for many young people. Some of these factors cut across age groups; some are faced uniquely, or especially sharply, by teenagers and young adults. This is due to the types of cancer they are more likely to be diagnosed with, where their care is delivered, who delivers their care, and their life stage and experience. That is why it is so important that there is a particular focus on teenagers and young people's access to clinical trials.

Some of these barriers are easier to address than others, and there are many good examples, some of which we highlight in this report, that show progress can be made. At a national level there are also important policy developments happening across the UK that could improve the situation – but at present young people's voices and experiences are absent in many of these initiatives. Another significant challenge is a lack of consistent data on the numbers of teenagers and young adults that are offered or can access a clinical trial.

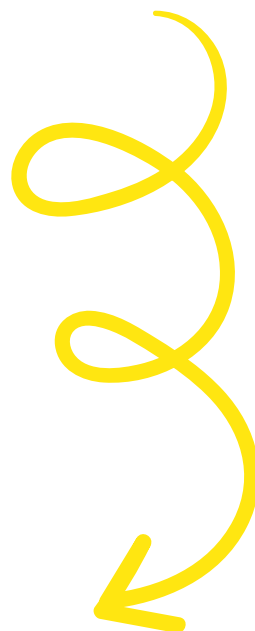
¹ Young people's cancers statistics, Cancer Research UK: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/young-peoples-cancers>

We hope this report shows is that it is possible to make a change to improve young people's access to clinical trials and why it is vital we do so. Teenage Cancer Trust wants to do what we can to make this happen, both practically through our service development and through sharing insights from professionals and the young people we work with, but we can't do it alone.

This report includes recommendations which could act as steps forward to achieve this outcome. These recommendations aren't exhaustive, and we highlight other areas for further consideration in the conclusion of this report. Some of these recommendations require change national policy change, while others are about sharing existing good practice. Our hope is that we can work with the key stakeholders - Government's across the UK, the NHS, industry, other charities, and experts in this area to deliver them, to help make our 2040 goal a reality.

To improve access for young people to innovative and potentially lifesaving treatments through clinical trials, this report makes the following priority recommendations:

- Teenagers and young adults living with cancer must be included in national initiatives to increase the availability of clinical trials.
- To effectively measure progress and address inequality, data around the numbers of young people who are offered and participate in trials – and those for whom no trial was available – must be consistently collected and transparently available.
- Healthcare professionals and young people must be able to access up-to-date and reliable information on which trials are available, regardless of where they live in the UK.
- Accessible and age-appropriate information on clinical trials should be available to teenagers and young adults to allow them to make an informed decision about their care.
- The NHS, regulators, pharmaceutical industry, and researchers should work together to identify and reduce the burdens that participating in clinical trials can place on young people, including through timely financial assistance.



OUR WORK IN THIS AREA

Teenage Cancer Trust offers unique care and support, designed for and with young people. We fund specialist nurses, youth workers and hospital units in the NHS, so young people have dedicated staff and facilities to support them throughout treatment.

How we developed this paper

During 2023, we have reviewed the existing academic literature on young people's access to clinical trials and engaged with stakeholders from NHS England, NHS Wales, and the Chief Scientist Office in Scotland. Other stakeholder engagement and insight gathering has included colleagues from other charities such as Blood Cancer UK, Sarcoma UK, Cancer Research UK, and the Experimental Cancer Medicine Centre (ECMC) network and industry representatives from the Association of the British Pharmaceutical Industry. We have gathered insights from Teenage Cancer Trust lead nurses and research nurses from Cancer Research UK. Most importantly, we have spoken with young people with experience of cancer, running surveys to gather their insights, discussing findings with our Youth Advisory Group, and collecting their stories, presented in this report in a series of case studies.

In this report, we will focus on cancer clinical trials, but at some points we will refer to clinical research. Clinical trials are a specific kind of clinical research, designed to test certain treatments or other specific interventions or therapies. Clinical research is broader than this and according to the Health Research Authority related to 'projects which aim to find out more about an illness, condition, treatment, therapy, or care by directly involving people'.²

Based on our work to date we have been able to make the recommendations that are included in this report. However, we also identified other potential barriers that need to be looked at further by us and other partners - these are referenced in the conclusion of this report.

² <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/people-centred-clinical-research/what-clinical-research-and-why-are-we-focussing-it/>

THE CURRENT CONTEXT

Broader challenges to accessing trials

In the 2000s, the UK's reputation as a reliable destination for cancer research was such that the country was hailed as the 'cancer clinical trials recruitment capital of the world'.³ Today, however, the UK underperforms relative to global competitors in the time it takes to get a commercial trial approved, set up and to the point where recruitment can begin: according to the latest available data covering a sustained period, the median time between an application being submitted to the regulator and the first patient receiving a dose is 247 days, far longer than the turnaround times in most comparator countries – both Australia (182 days) and Spain (197 days) post median times of under 200 days, while the United States has a turnaround time of just 155 days.⁴

The UK also underperforms in terms of recruitment. Over the past five years, there has been a 44% decrease in the numbers recruited to industry-led trials in England. Combined, the relative delays in setting up trials and the failure to meet recruitment targets on time has driven a deterioration in global boardroom confidence in the UK as an attractive location for conducting

clinical research.⁵ Notwithstanding the impact of the COVID-19 pandemic, these factors go some way to explaining why, over the past five years, there has been a 48% decrease in total number of industry-sponsored oncology trials in the UK.⁶

Clinical trials originate in either the commercial or non-commercial (sometimes called academic) sectors. Commercial trials are typically run by pharmaceutical companies, with the aim of developing a treatment that can be taken to market. They tend to be larger than academic trials and might take place across multiple countries at the same time. Non-commercial trials are usually carried out by clinicians or researchers associated with universities or hospitals and funded either by those institutions, charities such as Cancer Research UK or public research funding bodies like the National Institute for Health and Care Research (NIHR). Young people are more likely to be recruited to non-commercial trials.⁷

The box below sets out several recommendations put forward by clinical research charities including Cancer Research UK and the Association of Medical Research Charities to improve the clinical research environment, for commercial and non-commercial trials.

³ United Kingdom becomes the cancer clinical trials recruitment capital of the world. *J Natl Cancer Inst.* 2007; 99: 420-422

⁴ Life science sector data, 2022. Office for Life Sciences, Department for Science, Innovation and Technology, Department of Health and Social Care, and Department for Business, Energy & Industrial Strategy. Published 21 July 2022

⁵ "Unpredictable set-up timeframes reduce the time global industry clinical trials have to recruit in the UK, contributing to the UK's poor performance in trial recruitment and reducing industry's confidence in placing trials in the UK." Commercial clinical trials in the UK: the Lord O'Shaughnessy review. 26th May 2023

⁶ Rescuing patient access to industry clinical trials in the UK, ABPI. Published 20 October 2022

⁷ Clinical trials in cancer: Barriers in access to clinical trials, especially in light of the Covid-19 pandemic, the Institute of Cancer Research. December 2021

Cancer Research UK, Longer, better lives: A manifesto for cancer research and care⁸

The UK Government should set an ambition, in its first 100 days, to lead the G7 in research intensity and set out a plan to get there through increased investment and making the UK an attractive research destination.

Within a year of a general election, the UK Government should work with industry, research funders and research charities to set out a plan to, at least, close the more than £1bn funding gap for cancer research over the next decade.

Association of Medical Research Charities, Life Sciences Manifesto⁹

A renaissance in UK clinical trials

Recent challenges with NHS trials must be reversed. An immediate priority is addressing delays with approvals and study set-up times. Longer-term, the UK should capitalise on the opportunity to build a world-leading regulatory framework and become a destination of choice for high-quality trials.

Harnessing the power of NHS data

The potential of patient data to transform research and care must be unlocked urgently by facilitating access to high-quality data and improving data linkage. This can only be delivered with meaningful public engagement, ongoing dialogue, and transparency. Charities can act as trusted advocates, but ultimate responsibility lies with government and the NHS.

Meaningful involvement of people across the UK

The NHS should ensure that clinical research is representative by involving people from all UK communities and regions and covering all conditions and disease areas. Charities can play an important role in helping deliver a system that prioritises inclusion and is committed to reducing health inequalities.

⁸ Longer, better lives: A manifesto for cancer research and care, Cancer Research UK: <https://www.cancerresearchuk.org/about-us/we-develop-policy/manifesto-for-cancer-research-and-care>

⁹ AMRC Life Sciences Manifesto: <https://www.amrc.org.uk/amrc-manifesto-for-life-sciences>

CHAPTER 1

Increasing available clinical trials

When speaking with health professionals, the biggest barrier to access they shared was a lack of available trials. This was backed up in our conversations with charities and other experts in this area.

This is particularly concerning as cancer remains the largest disease-related killer of young people in the UK: each year, every year, 2400 young people will be told they have cancer. Each year, every year, 250 young people will have their lives cut short by the disease.¹⁰

There are some specific reasons why young people are less likely to be able to access a clinical trial. These include:

- Cancer type - they are more likely to experience rare and less common cancers.
- The small size of the population relative to others.
- Age - being too old for paediatric trials or too young for adult ones.

Cancer type

The pattern of cancers affecting teenagers and young adults is different from those impacting children and older adults – they are more likely to experience less common and rare cancers. This provides a challenge as overall there are less trials available for rare cancers.¹¹

For adults the most common cancer are lung, breast, and bowel cancers. For young people, aged between 15 and 24, they are lymphomas, germ cell tumours (including testicular cancer), skin cancers, brain and spinal cord, leukaemia, and sarcomas.¹²

While many of the cancers commonly experienced by young people are highly treatable and have high survival rates. There are some that are desperately in need of new treatments to improve survival - these include brain cancers and soft tissue sarcomas.¹²

Small population size

The rarity of these cancers in the general population is exacerbated by the small size of the teenage and young adult patient group which limits projected returns on investment and has been reported to make trials in these disease areas unattractive to pharmaceutical developers.¹³ For a patient population as small as this age group, this places even greater pressure on study sites; for a cancer clinical trial likely to recruit a very small patient population,¹⁴ there may be only a handful of sites across the UK, necessitating greater travel for young people who live far away from an open site.

Age limits on trials

Where a trial is available for a young person's cancer type and is currently recruiting, they might find that they can't access it due to their age. The National Cancer Research Institute's Teenage, Young Adults and Germ Cell Tumours Group has previously identified the age parameters applied to cancer clinical trials as an obstacle to recruiting young people, with adult studies routinely setting a lower age eligibility of 18 years. The group further found that there was "rarely any scientific rationale for this and that it had grown out of the historical boundaries around paediatric and adult cancer care."¹⁵

¹⁰ Young people's cancers statistics, Cancer Research UK: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/young-peoples-cancers>.

¹¹ <https://www.cancerresearchuk.org/about-cancer/rare-cancers>

¹² Based on data from 1997-2016. <https://ukhsa.blog.gov.uk/2021/03/15/cancer-in-children-and-young-people-what-do-the-statistics-tell-us/>

¹³ Fern LA, Lewandowski JA, Coxon KM, Whelan J; National Cancer Research Institute Teenage and Young Adult Clinical Studies Group, UK. Available, accessible, aware, appropriate, and acceptable: a strategy to improve participation of teenagers and young adults in cancer trials. *Lancet Oncol.* 2014 Jul;15(8):e341-50. doi: 10.1016/S1470-2045(14)70113-5. PMID: 24988937.

¹⁴ "A cancer is rare if it affects a child or teenager. Cancer only affects a very small number of in children and teenagers. This means any cancer in a child or teenage is a rare cancer." Macmillan Cancer Support, Rare cancers. <https://www.macmillan.org.uk/cancer-information-and-support/rare-cancers>

¹⁵ Eliminating age restriction in cancer clinical trials, 2018. Teenage, Young Adults and Germ Cell Tumours Group, National Cancer Research Institute. <https://www.ncri.org.uk/eliminating-age-restriction-in-cancer-clinical-trials/>

“After a year in Bristol, I was stable but there were no signs of improvement despite me trying two different treatment courses, so it was decided that I should be treated at The Royal Marsden as they had a clinical trial which could help me. The Royal Marsden is around four and a half hours away, compared to Bristol being two hours away, but it is one of only three hospitals in the world delivering the clinical trial.”

George

(19), aged 17 when he was diagnosed with Neuroblastoma

If a trial originates in adult care settings, those aged 17 and under may be ineligible simply because they are the wrong side of a cut-off point which itself may have no medical or clinical justification; the opposite can also be true for those aged 18–24 who may have ‘aged out’ of paediatric trials they might otherwise have benefited from. While some funders of clinical trials in the UK, such as Cancer Research UK, have longstanding policies of asking researchers to provide medical justification for any age criteria they apply on their trials, it remains unclear how regularly or convincingly this is provided.¹⁶

There is work going on to address unnecessary age limits on trials. The Fostering Age Inclusive Research (FAIR) Trials Working Group – part of the global ACCELERATE forum of academics, industry representatives, patient advocates, and regulators to find innovative treatments for young people with cancer – is working to remove age barriers to trials.

Those trials which actively avoid unnecessary age barriers and are inclusive of young people in patient enrolment are given a FAIR trials stamp. They are also examples of innovative trial designs that are trying to break down age barriers, as seen in the case study on DETERMINE below.

There is a need for continued focus on this area and discussion about what are appropriate age limits. One proposal from the FAIR trials working group is that lower age limits for adult early phase trials should as standard be reduced to 12 years old,¹⁷ a stance which is echoed by existing advice from the United States Food and Drug Administration (FDA).¹⁸

¹⁵ Eliminating age restriction in cancer clinical trials, 2018. Teenage, Young Adults and Germ Cell Tumours Group, National Cancer Research Institute. <https://www.ncri.org.uk/eliminating-age-restriction-in-cancer-clinical-trials/>

¹⁶ Since June 2013, CRUK’s Cancer Clinical Trials Awards and Advisory Committee has asked for the specific justification for both upper and lower age limits. Their funding applications also state that: “Please note that if a lower age limit for studies involving adults is deemed essential it should normally be set at 16 rather than 18 years. Low incidence of patients aged 16 and 17 is not sufficient reason alone for selecting a lower age criterion of 18 years.”

¹⁷ FAIR (Fostering Age Inclusive Research) Trials Initiative, SIOP Europe (European Society for Paediatric Oncology). 18th February 2020: <https://siope.eu/news/fair-fostering-age-inclusive-research-trials-initiative/>

¹⁸ Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials: Guidance for Industry, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), Oncology Center of Excellence (OCE). March 2019

CHAPTER 1

Increasing available clinical trials

The need for better data

In England, the NHS Long Term Plan included a target of enrolling 50 per cent of young people onto clinical trials by March 2025,¹⁹ which is referenced in the Teenage and Young Adult service specification published in 2023.²⁰ However, at present there is no national data for this target.

In the nations there are also aspirations to see more young people enrolled on clinical trials. For example, in Scotland the cancer strategy for children and young people states: “All children and young people should be enrolled on a clinical trial where possible”.²¹ However, again at present there is also no data available to show progress.

Having data on young people’s access to clinical trials across the UK, including if there is no trial available, is vital to be able to identify and address current inequalities in access.

Current government initiatives

In the last year, there has been renewed focus on boosting clinical research with a number of initiatives aimed at improving the UK’s clinical trials landscape: the O’Shaughnessy Review,²² commissioned by the Government to address challenges in conducting commercial trials in the UK, contained a number of recommendations to enhance the country’s reputation as a centre of excellence for commercial clinical trials. This complements the emphasis on research and development in the Science and Technology Framework²³ published in March 2023 and the decision to re-join Horizon Europe²⁴ - the EU’s funding program for research and innovation - taken in September.

In England, in addition to the references in the NHS Long Term Plan and the Teenage and Young Adult service specification on clinical trials, the Major Conditions Strategy, with a focus on enhancing research opportunities within the NHS, will soon be published. Action is also underway in the devolved nations: in Scotland, the Chief Scientist Office has begun work to close inequities of access to cancer clinical trials;²⁵ the Welsh Government in 2022 published CreSt, the first national cancer research strategy for Wales, to increase the depth and reach of research activity in the country;²⁶ and in Northern Ireland, the Cancer Strategy for 2022–2032 includes an acknowledgement of the current lack of available of trials for teenagers and young adults.²⁷

¹⁹ “We will actively support children and young people to take part in clinical trials, so that participation among children remains high, and among teenagers and young adults rises to 50% by 2025.” The NHS Long Term Plan, NHS England. June 2019

²⁰ Teenage and Young Adult Cancer Service Specification, NHS England.

²¹ Collaborative and Compassionate Cancer Care: cancer strategy for children and young people 2021–2026

²² Commercial clinical trials in the UK: the Lord O’Shaughnessy review. Department of Science, Innovation and Technology and Department of Health and Social Care

²³ UK Science and Technology Framework, Department of Science, Innovation and Technology

²⁴ United Kingdom joins Horizon Europe programme, European Commission. 4th December 2023: https://ec.europa.eu/commission/presscorner/detail/en/IP_23_6327

²⁵ Improving equity of access to cancer clinical trials in Scotland, Chief Scientist Office, Scottish Government. 13th February 2023

²⁶ CreSt: the cancer research strategy for Wales, Wales Cancer Research Centre

²⁷ A Cancer Strategy for Northern Ireland 2022–2032, Northern Ireland Department of Health

Innovation in clinical trials – the DETERMINE study

Moving beyond the traditional divide between paediatric and adult drug development – which can leave adolescents waiting years for trials to open – will require a culture shift among investigators, pharmaceutical companies, and regulators. Such a shift may require the academic sector to take a lead in demonstrating the feasibility of such an approach before the more risk-averse commercial sector follows, and the DETERMINE trial offers an illustration of how to remove age barriers at the level of study design. DETERMINE is led by the University of Manchester and is sponsored and managed by Cancer Research UK's Centre for Drug Development, in partnership with multiple pharmaceutical partners. DETERMINE is a platform trial examining the use of licensed medicines in unlicensed indications, covering rare cancers (and common cancers that have rare genetic aberrations). If positive data emerges, approval for drugs can be accelerated through the Cancer Drugs Fund for these patient groups who often have few options. It has been awarded the FAIR for AYA (Adolescent and Young Adult) stamp in recognition of a good model of age inclusivity led by academics and supported by pharmaceutical companies.²⁹

Recommendations

The importance of clinical trials is firmly on the policy agenda of all four nations of the UK. Teenage Cancer Trust is concerned, however, that in the welcome drive to improve the clinical research landscape, the needs of young people risk being overlooked. If we are to make the most of these opportunities, these strategies must be developed and implemented in a way that accounts for the specific challenges faced by young people living with cancer.

Teenagers and young adults living with cancer must be included in national initiatives to increase the availability of clinical trials.

To effectively measure progress and address inequality, data around the numbers of young people who are offered and participate in trials – and those for whom no trial was available – must be consistently collected and transparently available.

To help deliver this:

- The UK Government, working where relevant with governments in the devolved nations, should work to implement the recommendations of Lord O'Shaughnessy's review into commercial clinical trials in the UK,³⁰ in a way that accounts for the unique needs of teenagers and young adults with cancer and the challenges they face in accessing research.
- No young person with cancer should miss out on the chance to participate in a clinical trial only because of their age. Any age limits must have a medical justification. A shift is required so that eligibility criteria instead reflect the age incidence of the disease.
- The work by ACCELERATE and the FAIR Trials initiative, highlighted above, represents important progress; however, it is important that this work continues to be prioritised and considered in broader discussions at a national level about access to trials and appropriate age limits.

²⁹ DETERMINE Precision Medicine, Cancer Research UK

³⁰ Commercial clinical trials in the UK: the Lord O'Shaughnessy review. 26th May 2023

CHAPTER 2

Improving the visibility of suitable trials

It can be difficult for clinicians to find reliable, up-to-date information about active clinical trials, and for young people themselves to know about opportunities that could be available to them.

Some specific barriers we identified included:

- A lack of dependable and up-to-date source of information of active clinical trials.
- Age limits on current programmes to increase awareness of clinical trials.

Challenge: Lack of dependable and up-to-date source of information on active clinical trials

In England, Scotland and Wales, it is already NHS policy that each young person with cancer should be discussed at multidisciplinary team (MDT) level in relation to potential involvement in clinical trials but, considering the issues around data collection and reporting detailed above, it is not clear how frequently this occurs in practice. It was suggested in our conversations that the presence of a Teenage and Young Adult research nurse within a multidisciplinary Team could improve discussions around clinical trials and is something that should be explored further.

In the East Midlands Clinical Research Network (CRN), Jenny Salmon acts as a dedicated Teenage and Young Adult Research Nurse Champion, linking research teams across the region with the TYA clinical team to improve visibility of and access to clinical trials for young people. With a brief to help the East Midlands TYA service reach the target of 50 per cent enrolment by 2025, Jenny provides the crucial link between research teams across the region and the TYA clinical team. She works closely with Teenage Cancer Trust Lead Nurse Jamie Lawson to identify the number of young people going into trials, and attends the TYA multidisciplinary team meetings each week to recommend available trials. To do so, Jenny has developed the CRN East Midlands MDT Tool. Updated every month, the tool allows both the MDT and research teams to efficiently identify if any trials are available and suitable for each young person in their care.

The East Midlands model is replicated in many areas of the country, and TYA Research Nurse Champions meet regularly to share best practices.



A barrier to this happening more frequently is the lack of information on what trials are available and suitable for young people. Information on open clinical trials does exist, but at present it is not universal, and available to everybody that could benefit from it. For example, at present there is no single, dependable, and up-to-date database of active clinical trials. In interviews conducted for this report, we heard from health care professionals that methods for identifying trials in fact vary from NHS Trust to NHS Trust; in many cases, clinical teams are reliant on the US-based ClinicalTrials.gov database which can lack accurate and up to date information.³¹ This can leave patients dependent on their clinician already knowing which trials are available, who in turn may only be knowledgeable about their disease area.

This challenge can be compounded when clinical staff are time-poor or operating in environments where resources are already stretched: in such instances, clinicians may tend towards a 'utilitarian' approach aimed at benefiting the greatest number of patients with each intervention, making the administrative demands of searching for and enrolling a patient on to a trial an additional demand on staff time.³²

Challenge: Age limits on current programmes to increase awareness of clinical trials

Be Part of Research is a UK-wide programme run by the NIHR and the devolved administrations in Scotland, Wales and Northern Ireland. Accessible through the NHS app and as an online service, the programme acts as a research registry for patients to log their information and be notified of any potential research relevant to them. At the moment, the service is only available to people aged 18 and over.

In terms of increasing young people's awareness of clinical trials specifically there is potential to learn from innovation in other countries. In Australia, Canteen - an Australian not-for-profit that provides support young people aged 12-25 impacted by cancer - has supported the creation of an App - the ClinTrial Refer AYA App. The app enables young people, and clinicians, to easily access information on suitable trials.³³

³¹ An article in the British Medical Journal stated that it will 'always be incomplete... first, individual studies may be missing from the database and, second, study information may be missing from the records.' How to avoid common problems when using ClinicalTrials.gov in research: 10 issues to consider BMJ 2018;361:k1452

³² Hart, R.I., Hallowell, N., Harden, J. et al. Clinician-researchers and custodians of scarce resources: a qualitative study of health professionals' views on barriers to the involvement of teenagers and young adults in cancer trials. *Trials* 21, 67 (2020). <https://doi.org/10.1186/s13063-019-3942-y>

³³ <https://www.clintrialrefer.org.au/2022/02/17/clintrial-refer-client-youth-cancer-services-canteen/>

CHAPTER 2

Improving the visibility of suitable trials

Innovation – trial funding tool for clinicians

EC Trial Finder is web-based tool for clinicians and nurses to search for early-phase clinical trials by cancer type or molecular aberration and age eligibility, pulling up a list which can then be filtered by further criteria, such as the location of the treating site. After testing across the Experimental Cancer Medicine Centres (ECMC) Network on several metrics – how widely it would be used, whether it would aid in visibility and accelerate referrals and recruitment – the EC Trial Finder has been highly effective and is now being rolled out nationwide. NHS healthcare professionals across the UK can now use EC Trial Finder to search trials open in the ECMC network, and it is planned that additional clinical sites will be able to list their trials on the tool in the coming months. While it can be labour-intensive keeping the database up to date, EC Trial Finder data coordinators update their trial portfolio monthly to ensure only currently available trials are shown.

Recommendations

Healthcare professionals and young people must be able to access up-to-date and reliable information on which trials are available, regardless of where they live in the UK.

To help deliver this:

- As recommended by the O’Shaughnessy review,³⁴ the UK Government, in collaboration with the devolved administrations in Scotland, Wales and Northern Ireland, should explore the development of a single, UK-based clinical trials database. Any database must contain relevant information on age criteria for trials.
- Experiences of barriers to access clinical trials and strategies developed within MDTs to overcome them should be more routinely shared across centres.
- Look at opportunities to learn from innovation in other countries such as the ClinTrialReferApp in Australia.
- Public awareness campaigns aimed at increasing participation in research, like Be Part of Research, must cover the teenage and young adult age group, drawing on the expertise of organisations like Teenage Cancer Trust to develop best practice in communicating with young people.

³⁴ Recommendation 6 - Building on near real-time activity and performance generated according to the above recommendation, UK governments should create a UK phase 1 to 4 clinical trial directory – called ‘clinicaltrials.gov.uk’ – to create a single source of activity for patients, clinicians, researchers and potential trial sponsors. <https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report>

CHAPTER 3

Improving communications with teenagers and young adults about clinical trials

Teenagers and young adults often must make a decision about whether to participate in a trial quickly, and often at a time when they are having to come to terms with a cancer diagnosis and absorb other complex information about their disease. As such, not understanding what a trial is and the value of participating in them can be a significant barrier to participation.

This can be due to:

- A lack of confidence from health professionals to communicate with young people.
- The types of information available on clinical trials.

Challenge: A lack of confidence from health professionals to communicate with young people

For many young people, the first port of call for information around clinical trials will be the medical professionals overseeing their clinical care.³⁵ Some of those professionals, such as the clinical nurse specialists funded by Teenage Cancer Trust, will have training and experience in the specialist care of young people with cancer; other, non-medical roles, such as our own youth support coordinators, will also have a background in meeting the unique psychosocial needs of this age group. Other roles, however, will not have a specific training on working with teenagers and young adults and our conversations found that some professionals have less confidence in communicating with teenagers and young adults than with older age groups or with the parents of younger children,

something that is also backed up by existing research.³⁶ This is something that could act as a barrier to conversations about clinical trials.

Our conversations found differing approaches to relaying information about trials:

- Some teams will inform their young patients about clinical trials – what they might involve and the possible benefits of participation – even if one is not currently available.
- Others choose not to discuss them until they become aware of a trial for which their patient might be eligible.

There are merits to each approach: on the one hand, introducing the concept of trials early gives the young person time to absorb the information they are receiving. Waiting until a trial becomes available, however, avoids raising false hope of participation and enables information to be tailored and precise.

While approaches may vary – and can and should be tailored to the circumstances of each individual young person and the judgement of the professionals who work with them – the principle of most importance is that such conversations must take place.

“I was constantly informed, told why I was doing it, told the pros and cons of it and it was fully left up to me to make the decision so there was no pressure at all.”

Alice

(23), aged 22 when she was diagnosed with Hodgkin lymphoma

³⁵ Pearce S, Brownsdon A, Fern L, Gibson F, Whelan J, Lavender V. The perceptions of teenagers, young adults and professionals in the participation of bone cancer clinical trials. *Eur J Cancer Care (Engl)*. 2018 Nov;27(6):e12476. doi: 10.1111/ecc.12476. Epub 2016 Mar 3. PMID: 26936110.

³⁶ ‘Health professional perceptions of communicating with adolescents and young adults about bone cancer clinical trial participation’. *Support Care Cancer* 27, 467–475 via <https://link.springer.com/article/10.1007/s00520-018-4337-4>.

CHAPTER 3

Improving communications with teenagers and young adults about clinical trials

“[My] immunotherapy involves Nivolumab which is in clinical trial stage for Hodgkin’s. It has very good statistics and there aren’t many spaces on the trial, and so my consultant identified me as a possible candidate even before I finished the last lot of chemo. They knew that it might be needed, and I am glad they were so proactive as otherwise I might not have had a space on the trial.”

Lucy

(26), diagnosed with Hodgkin lymphoma

In Newcastle-upon-Tyne, Teenage Cancer Trust Lead Nurse Karen Hamlen and Cancer Research Nurse Consultant Ben Hood worked with young people to produce informational materials to shed light on clinical trials, as well as genomics and biobanking. The resulting Teenage and Young Adult Research (TYAR) project was conceived as a way of addressing the concerns young people raise about prospective participation in clinical trials, in language, formats and at times that are most accessible to them.

After identifying the need to produce these materials, the team sent letters to all young people who had been through the multidisciplinary team at any point over the preceding five years. The team wanted to give every eligible young person the chance to take part in the project, to avoid the risk of putting together a potentially unrepresentative group comprised of only the most engaged, ensuring their TYA Research Group reflected the diversity of young people with cancer.

At initial meetings, the team ran scenarios asking the group to imagine they were being offered the chance to participate in a trial: what questions would they need answering to feel comfortable enrolling? Queries emerged regarding the amount of extra time they would need to spend in hospital and whether they would need to repeat aspects of treatment that had been unpleasant, such as additional biopsies.

After establishing the kinds of concerns young people want addressed, the group then considered what formats they would prefer materials to be presented in, with widespread agreement that long, paper copies of information were unappealing. Instead, the young people involved in the TYA Research Group preferred “quick and snappy” resources which they could access at times of their choosing and through the technology they are most familiar with; among the innovations the Group has introduced is making their materials accessible through QR codes, for young people to engage with at their own convenience.

Once on the site, young people have the choice of viewing bite-size pieces of content explaining important aspects of clinical trials in language tailored to their age group – not overly dry and technical, but not ‘overcorrected’ and too childish either. Content produced for the site includes bespoke interviews with doctors and researchers, conducted by young people, with each video focusing on a single topic to allow every young person to readily identify the most relevant clips for them. Each piece of content uploaded to the site is tested with the group to ensure it is age-appropriate and informative, with animations created to visually explain some of the harder-to-grasp concepts. The group also identified peer-to-peer support as a great help in making decisions around clinical trials, and so the TYAR project includes interviews with young people who have taken part in clinical trials, sharing their insights and experiences.

Challenge: The types of information available on clinical trials

The way information on clinical trials is presented can also present a barrier to enrolling young people on to clinical trials. Once a trial has been identified and their clinician has identified it as suitable for a young person, the patient information sheets (PIS) they are sent before enrolment can be very inaccessible. They can be very long and the language they include can be very technical, making them difficult to understand and engage with.³⁷ On the flip side, there is some research to show that attempts to provide material in more accessible language

can be interpreted by young people as being too childish.³⁸ To avoid this ‘overcorrection’ and overlooking teenagers and young adults as a group distinct from younger children, researchers and healthcare professionals should co-produce any age-appropriate materials with young people. Teenage Cancer Trust’s information guide ‘Your Guide to Cancer’ includes age-appropriate answers to questions young people might have about clinical trials, including what they are used for, what participation might involve, and advice on how to ask questions of their doctors. The guide, written with the help of young people who have had cancer and the clinical staff who supported them, is available as a free download from the Teenage Cancer Trust website.³⁹

³⁷ “When assessed against both traditional readability criteria and health literacy-based tools, the PILs/ICFs in this study are inappropriately complex. There is also evidence of poor compliance with guidelines produced by literacy agencies. These data clearly evidence the need for improved documentation to underpin the consent process.”

O’Sullivan L, Sukumar P, Crowley R, et al. Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis. *BMJ Open* 2020;10:e037994. doi:10.1136/bmjopen-2020-037994

³⁸ Buchanan ND, Block R, Smith AW, Tai E. Psychosocial barriers and facilitators to clinical trial enrollment and adherence for adolescents with cancer. *Pediatrics*. 2014 Jun;133 Suppl 3(Suppl 3):S123-30. doi: 10.1542/peds.2014-01221. PMID: 24918211; PMCID: PMC4258829.

³⁹ Your Guide to Cancer, Teenage Cancer Trust, 2022.

CHAPTER 3

Improving communications with teenagers and young adults about clinical trials

It is important that any professional tasked with supporting a young person in their decisions around clinical trial participation feels equipped to communicate effectively with them. Informed decisions require information to be communicated in a transparent, age-appropriate, and authoritative way. In a wider context, this has been recognised in materials such as NHS England's good practice guide on communicating with different audiences to increase the diversity of people participating in research.⁴⁰

Recommendations

Accessible and age-appropriate information on clinical trials should be available to teenagers and young adults to allow them to make an informed decision about their care.

To help deliver this:

- NHS England's good practice guide on communicating with different audiences to increase the diversity of people participating in research could be expanded to include information on how to communicate with young people with cancer, covering discussions about participation in clinical trials.⁴¹ Teenage Cancer Trust is ready to offer our experience and expertise in working alongside young people to support such efforts.
- Better use could be made of the Teenage and Young Adult-specific expertise of other MDT members such as youth support coordinators could therefore be beneficial in supporting young people making a decision about involvement in a trial.

⁴⁰ Increasing Diversity in Research Participation: A good practice guide for engaging with underrepresented groups. NHS England. February 2023

⁴¹ Increasing Diversity in Research Participation: A good practice guide for engaging with underrepresented groups. NHS England. February 2023

CHAPTER 4

Giving young people the support they need to take up the offer of a trial

“ALL has one of the most complicated regimes and the consultants explained that if I wanted to be on the UKALL 2011 Trial then I would need to stay in Bristol rather than being treated closer to home because my local hospital didn’t have the trial open”

Jessica

(22), aged 20 when she was diagnosed with Acute Lymphoblastic Leukaemia

When a clinical trial is available, young people aren’t always able to take up the offer or chose not to.

This can be due to:

- Demands on time that participation in a trial would involve.
- Their mental health, and a lack of support for that.
- The costs of participation.

Challenge: Demands on time

Young people living with cancer, are still young people, and many desire to live their lives as close to ‘normality’ as possible. When illness and treatment already make it more difficult to go to school, university, or work, to see friends and do the things they enjoy, any other demands on a young person’s time will have to be carefully considered.

When trials involve travelling long distances to another hospital, or extended stays in units for routine procedures like a blood test or giving feedback – procedures that could just as readily be conducted in a GP’s surgery, a local hospital or even from home – research has shown that a young person may decide that taking part in a trial comes at too high a cost to their other important priorities.⁴²

There are two main issues to consider here. The first is that when a trial is open to young people it may only be available at a few sites in the UK, as highlighted in the case studies below, which for most young people requires travel away from their home and usual place of treatment. The second is the procedures that are required as part of a trial to monitor patient safety; and to gather necessary information on how well the treatment works. For example, in terms of patient safety, this could include the need for a young person to undertake a pregnancy test prior to starting on the trial. If these tests and procedures must happen at the trial site this can increase the time burden on young people.

“The only downside is this drug is part of a clinical trial at The Royal Marden NHS Foundation Trust hospital, so to receive it I have to make the five-hour round trip journey every week.

Verity

(23), diagnosed with ovarian cancer and DSRCT sarcoma

⁴² Pearce S, Brownsdon A, Fern L, Gibson F, Whelan J, Lavender V. The perceptions of teenagers, young adults and professionals in the participation of bone cancer clinical trials. *Eur J Cancer Care (Engl)*. 2018 Nov;27(6):e12476. doi: 10.1111/ecc.12476. Epub 2016 Mar 3. PMID: 26936110.

CHAPTER 4

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“My new team at The Royal Marsden were just as happy for me and have done everything in their power since I started in early February 2022 to make this treatment bearable, be it prescribing medication for symptom control for the autoimmune disorders I’m dealing with, arranging a taxi, or sorting out expenses for me each week with the trial company to lessen the financial load. We’ve discovered throughout my diagnosis that cancer doesn’t just take its toll physically and mentally but financially as well.”

Verity

(23), diagnosed with ovarian cancer and DSRCT sarcoma

Some of the demands discussed above, especially increased intensity of treatment or prolonged hospital stays, are difficult to avoid altogether. They might be mitigated to some degree by the involvement of young people and the health professionals who work with them early in the trial design process.⁴³

An area for further consideration, as highlighted in the O’Shaughnessy review,⁴⁴ is a movement towards more decentralised trials. Following the Covid-19 pandemic there is growing interest in decentralised, remote or hybrid trials, which

take advantage of non-secondary care settings, including patients’ homes, to undertake diagnostic and treatment activities as part of a trial. Instead of travelling to This has been done successfully for cancer trials in other the countries, as shown in the case study below.

Challenge: costs of participation

Research from Young Lives vs Cancer has recently revealed the financial burden cancer places upon young people and their families: the cost of travelling to and from appointments reaches an average of £250 a month; parking and accommodation set young people back an average of £24 and £14 a month respectively. These significant outlays are set against a backdrop that can be financially devastating total additional cancer-related expenses reach an average of almost £700 a month, and earnings fall by an average of £6,000 a year for young people or their families.⁴⁵

Most trials will contain procedures for meeting subsistence costs for things like food and travel. In industry trials, these costs are met by companies who meet all research costs a hospital incurs delivering a trial in the NHS.⁴⁶ During our research, however, we heard that there can be delays in patients receiving the money, which in any case is usually paid retrospectively, leaving upfront costs to be covered by the patient. For patients with limited financial means, this can severely impact the feasibility of their participating in a trial.

⁴³ Our study... strengthens the call for the involvement of young people, and indeed professionals, in trial design at the outset.”

Pearce S, Brownsdon A, Fern L, Gibson F, Whelan J, Lavender V. The perceptions of teenagers, young adults and professionals in the participation of bone cancer clinical trials. *Eur J Cancer Care (Engl)*. 2018 Nov;27(6):e12476. doi: 10.1111/ecc.12476. Epub 2016 Mar 3. PMID: 26936110.

⁴⁴ Recommendation 24 of the O’Shaughnessy review calls for regulators to produce guidance to support and promote decentralised trials, and to at least keep pace with international bodies such as the FDA and the EMA in supporting decentralised trials.

⁴⁵ Cancer Costs, Young Lives vs Cancer, September 2023

⁴⁶ Payment guidance for researchers and professionals, NIHR. July 2023

Challenge: Mental health and its impact on trial participation

We have heard from health professionals we have spoken to during our research that poor mental health can be a barrier to accepting a trial. This link to previous research from Teenage Cancer Trust that has shown how young people with cancer often experience poor mental health through treatment.⁴⁷ Our report Not OK published in 2021 found that 87% of psychologists surveyed say current national provisions for specialist psychological support for teenagers and young adults with cancer is insufficient to meet their specific needs. It also found that just over half (52%) of young people said their mental health and wellbeing had been very poor (17%) or poor (35%).

Young people require access to psychological support at all stages of the cancer journey so that – whenever a trial becomes available – they are not prevented from taking part by mental health considerations.

Recommendations

To address the challenges outlines above:

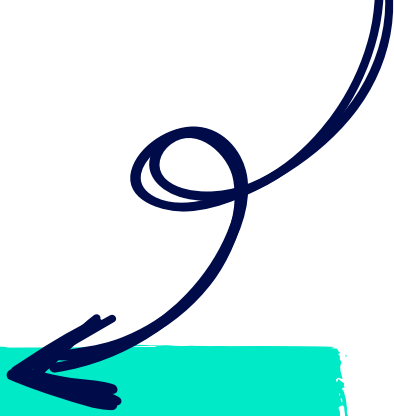
The NHS, regulators, industry and researchers should work together to identify and reduce the burdens that participating in clinical trials can place on young people, including through timely financial assistance.

To help deliver this:

- Ways to decentralise trials or aspects of them as in the Roche case study above could be considered.
- Ways to involve young people more in the design of trials could be considered.
- To improve access to specialist psychological support UK Governments must commit to providing young people with timely, high-quality support wherever they live. This will include working with the NHS, Teenage Cancer Trust, and other experts to ensure all young people can access support from specialist psychologists to help them through cancer.
- It is important to look at ways to address the additional costs of participating in trials, one way to do this, as called for by Young Lives vs Cancer is the creation of a Young Cancer Patient Travel Fund.

⁴⁷ #NotOK: Filling the gaps in mental health support for young people with cancer, Teenage Cancer Trust, 2021

CONCLUSION



In this report we make clear why it is so important to recognise the specific needs young people living with cancer face in accessing clinical trials. We also make some initial recommendations on action that could be taken to address and overcome these barriers.

Teenage Cancer Trust will use our unique experience of working with young people to provide the care and support they need, to play our part in making these recommendations happen. However, we will also need to work with other partners – Government, the NHS, other charities, regulators, and industry – to ensure that every young person with cancer in the UK can participate in a clinical trial where one is available that is suitable for them.

The barriers and solutions identified in this report are not exhaustive, there were several areas for further consideration that we have been able to mention only briefly in this report. These include the role certain staff members can play in increasing access to trials – such as research nurses, or how the primary location

of a young person care impacts access. Some of our recommendations are also broad and will require future research – such as understanding more about how a young person’s mental health impacts participation in trials.

As well as promoting the recommendations in this report, we keep gathering insight in this area, in collaboration with the partners identified above.

THANK YOU!

Finally, we wanted to thank everyone who has given their time to help us develop this report – particularly young people and the healthcare professionals who support them.



www.teenagecancertrust.org

Teenage Cancer Trust is a registered charity: 1062559 (England & Wales); SC039757 (Scotland)

