No time to waste – starting cancer clinical trials faster

A call to action from Cancer Research UK

July 2025

CANCER RESEARCH UK

Contents

About this report

Reference

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About Cancer Research UK

We're the world's leading cancer charity dedicated to saving and improving lives through research. We fund research into the prevention, detection and treatment of more than 200 types of cancer through the work of over 4,000 scientists, doctors and nurses. In the last 50 years, we've helped double cancer survival in the UK and our research has played a role in around half of the world's essential cancer drugs. Our vision is a world where everybody lives longer, better lives, free from the fear of cancer.

Our values

Our values help guide our behaviour and culture in an ever-changing world, building on the best of what we do today aspire to be in the future. They unite and inspire us to achieve our ambitious plans and our mission of beating cancer, together.

and what we

Executive summary

Clinical trials are essential for advancing cancer prevention, diagnosis and treatment, playing a critical role in the significant increase in cancer survival rates over the past 50 years[1]. Clinical research not only benefits current and future patients, but it also makes the UK an attractive research destination and drives economic growth. As an organisation, Cancer Research UK have a proud history of supporting many ground-breaking and practice-changing clinical trials, and we are committed to continuing support for clinical research with £200m pledged for clinical trials over the next five years.

Despite the central role of clinical research in improving patient outcomes, the UK clinical research system faces significant delays in trial set-up, affecting both commercial and non-commercial trials. These delays hinder timely patient access to life-saving treatments. Public and charity-funded trials, led by academic investigators, are particularly important in exploring treatments for areas with less commercial investment, such as rare, hard-to-treat or paediatric cancers, in addition to assessing repurposed drugs or non-pharmaceutical options like surgery and radiotherapy.

Cancer clinical trial set-up in the UK faces many challenges and is a complex process within a complex healthcare system. These challenges include regulatory approvals, contracting across multiple NHS sites with resource constraints and the need for specialised infrastructure such as radiology, pharmacy and pathology.

This report draws on insights from our own non-commercial clinical trial portfolio, to highlight key sources of delays and provides recommended actions to address these to ensure that cancer patients continue to benefit from timely, cutting-edge treatments. These include implementing an effective mechanism to coordinate NHS R&D approvals across multiple sites, publishing detailed metrics on trial set-up times for non-commercial clinical trials and improving specialist capacity for research in NHS Trusts and hospitals.

We welcome the recently announced suite of national efforts aimed at improving the UK clinical research ecosystem. However, to deliver meaningful change, these reforms must tackle the system-wide challenges and must lead to real-world improvements on the ground – engaging both the clinical research delivery workforce and patients. It is critical that non-commercial trials are not left behind in this transformation. For people living with cancer now, there's no time to waste.

1. Introduction

1.1 Importance of cancer clinical trials

Clinical trials have played a vital role in the improvement of cancer outcomes over the past 50 years. During this time, cancer care has progressed substantially, and cancer survival has doubled[1]. UK scientists have led many of the practice-changing studies which themselves have involved many thousands of cancer patients and people at risk of cancer, who have had the opportunity to participate and access novel treatments and innovations.

Cancer Research UK is the major funder of public and charity cancer research in the UK and currently supports more than 100 clinical trials. Over the next five years, we will invest over £200m in cancer trials which more than 80,000 people will participate in. As well as funding individual trials, we fund infrastructure to design and deliver trials through seven clinical trials units (£37m over five years) and 29 experimental cancer medicine centres (ECMCs funded in partnership with the National Institute for Health and Care Research (NIHR), the devolved Health Departments of Wales, Scotland and Northern Ireland and the Little Princess Trust). In addition, we fund a network of senior research nurses embedded mainly at ECMC sites to aid patient recruitment.

Cancer trials are a critical component of the UK life sciences environment. They typically mark the end of the translational pathway, following years of discovery science and investment in drug or therapy development. They also serve to enhance the attractiveness of commercial investment into the UK life science sector and provide the evidence from which the NHS and the National Institute for Health and Care Excellence (NICE) can assess patient benefit. This evidence will be essential to underpin the three reform shifts that the Government's 10-year Health Plan will require – namely shifting from 'hospital to community' from 'analogue to digital' and from 'sickness to prevention'[2]. As well as leading to future breakthroughs and enabling current patients access to the latest innovations through participation in clinical trials, there are other, less obvious benefits. Evidence shows that greater research activity in the health service is associated with an overall higher quality of care, lower levels of patient mortality and improved staff recruitment and retention[3,4,5,6]. There are also substantial economic gains, including contribution to gross value added (GVA) and job creation,[7,8] with every £1 invested in cancer research generating £2.80 in economic benefits[9].

1.2 Non-commercial clinical trials have many benefits

Patient benefit

Non-commercial trials—funded and sponsored by non-commercial organisations (e.g. NIHR and Cancer Research UK) —play a vital role in advancing patient care by enabling testing of novel treatments, treatment combinations and regimens that would otherwise not happen. These studies often focus on areas that fall outside the scope of commercial interest but are of high clinical importance. This includes trials exploring treatment-sparing or dose-reduction strategies, the repurposing of existing therapies that may be cheaper or more effective than the current standard of care, and the development of surgical and radiotherapy protocols. Non-commercial research is also essential in addressing underserved areas such as rare cancers and conditions affecting children and young people, where market incentives are limited but the clinical need is high and the need for innovation is great. All of these areas are key pillars of our research strategy and clinical research statement of intent[10], and we are driving funding and support in these areas.

Clinical trials are a valuable treatment option at any stage of cancer, but for patients with later-stage disease who have exhausted all standard treatment options, clinical trials may represent the only remaining pathway to access potentially life-saving therapies. In these cases, non-commercial trials are not just a mechanism for research, but a critical route to hope and extended survival[11].

Notably, in 2023/24, over 95% of patients recruited to interventional clinical studies in the UK were recruited to trials with a non-commercial sponsor[12], clearly demonstrating the scale and impact of this vital part of the research ecosystem.

Economic benefit

Between 2018 and 2019, the National Institute for Health and Care Research's Clinical Research Network (NIHR CRN) supported both commercial and non-commercial research, generating over 47,000 full-time equivalent jobs and contributing £2.7bn in GVA. Of this, approximately two-thirds (£1.8bn) of the GVA came from commercial clinical trials funded by the life sciences industry, and it was estimated that non-commercial research supported by the NIHR CRN contributed £0.9bn in GVA and nearly 19,000 full-time equivalent jobs annually[13]. In addition, estimates from 2022-2023 suggest that every £1m spent by UK charities on medical research generates £1.83m in economic activity[14].

The strong research base built by academic clinical trials also serves to further attract industry investment, with evidence showing that public investment in research and development (R&D) stimulates further private sector investment. A 2020 government-commissioned study found that, in the long run, every £1 of

government R&D spend results in £1.96 to £2.34 in private R&D investment[15]. Furthermore, there is a mutually symbiotic relationship between commercial and non-commercial research through the pooling of resources and expertise between the two sectors.[16,17]

With the majority of patients participating in clinical trials being enrolled in non-commercial studies – and the significant impact such trials have had on clinical care and economic growth – it is clear that these trials are not only critical for patient access to potentially life-saving treatments, but also play an essential role in delivering significant economic benefits and enhancing the UK life sciences ecosystem.

Examples of the impact of non-commercial cancer clinical trials

BEACON trial (Principal investigator Dr L Moreno): In 2024, researchers found a more effective combination of drugs for treating children and young people whose neuroblastoma isn't responding to standard chemotherapies, in the international BEACON trial[18]. The data generated from the study has been incorporated into the current UK Clinical Practice Guidelines. Meanwhile, subsequent BEACON studies continue to investigate treatments to improve outcomes for patients with neuroblastoma.

Stampede (Principal investigator Professor N James): Over a period of 17 years, this trial platform has compared seven therapies and radiotherapy compared to Standard of Care. It showed improvements in survival using abiraterone, docetaxel and radiotherapy, leading to changes in treatment for many men with prostate cancer[19,20,21,22]. This trial has also been linked to the PATCH trial comparing transdermal oestradiol with LHRH analogs in prostate cancer, finding similar outcomes for the transdermal administration with an improved cardiovascular side-effect profile[23,24].

Interlace (Principal Investigator Dr M McCormack): This trial compared induction chemotherapy prior to chemoradiotherapy in locally advanced cervical cancer with chemoradiotherapy only. The results showed a progression free survival of 73% and overall survival of 80% at five years in the trial arm compared to 64% and 72% in the other group[25].

1.3 Non-commercial trials are taking too long to set up

The UK has an incredible track record in the delivery of high-quality, cutting-edge and well-governed studies, ranging from first-in-human to late phase registration trials. Despite the huge value of cancer clinical trials, we believe that the UK is still being held back from delivering its full potential as a global leader. The system created has historically enabled the delivery of both commercial and non-commercially sponsored trials. However, the pathway to set up a trial remains disproportionately complex and, unfortunately, as some areas of the pathway are improved, delays in set-up are simply pushed into other domains.

This means that set-up times for both commercial and non-commercial clinical trials are unacceptably slow and not competitive internationally. The O'Shaughnessy review[26] of commercial clinical trials found that UK clinical trials are carried out twice as slowly as in the US and a third slower than those in Australia and Spain. This review highlighted that the lengthy set-up process led to delays in patient access to new treatments, making the UK less attractive for international research. Whilst the review's primary focus was on commercial trials, the delays and bureaucratic processes highlighted in the report also have significant implications for non-commercial trials, as these operate in the same regulatory and set-up environment. These challenges are evident within our own portfolio and have been echoed by other non-commercial clinical research funders, as well as in the broader literature[27,28].

The O'Shaughnessy review[29] also provided comprehensive recommendations to improve commercial clinical trial delivery, which currently make up around 46% of interventional clinical trials in the UK (commercial contract and commercial collaborative trials)[30]. It is encouraging to see the progress being made to meet some of these recommendations, especially with regards to the significant improvements in approval times from the Medicines and Healthcare products Regulatory Agency (MHRA)[31] and the introduction of the National Contract Value Review (NCVR) which was successfully piloted in the ECMC network[32] and aims to standardise and expedite the costing and contracting processes for commercial clinical research within the NHS.

As set out in section four, we believe learnings from the impacts of improved coordination and targeted investment can be applied to bring the same innovative approach to other parts of the pathway in order to finally deliver transformational improvements in set-up times.

The rest of the world is not standing still in this regard, and we know trial set-up can be slower in the UK than in other countries. We must ensure the UK speeds up and retains its position as a world-leading and competitive site for cancer clinical trials.

2. Cancer Research UK clinical trials portfolio

2.1 Set-up data for Cancer Research UK clinical trials portfolio

Why do we monitor clinical trial set-up times?

Cancer Research UK funds around half of the public and charity-funded cancer research in the UK[33]. This includes support for a broad portfolio of clinical trials at all phases, spanning multiple cancer types (common and rare), modalities (e.g. new drugs, radiotherapy, surgery and screening interventions), population types (children to adults) and crossing international borders. We also provide endorsement for approved clinical trials funded elsewhere that run through our CTU network; endorsement utilises our peer review process. Since 2010, we have monitored the set-up times[i] for trials we fund or endorse to identify issues and ensure patients can be recruited as soon as possible after a trial has been funded. We have set an expectation that all trials should have their first site open within 12 months of receipt of the grant award. This is monitored through our Clinical Research Monitoring Panel.

What do our analyses show

Median Trial Set Up by report year[ii]

Review year	Time period in analysis	Median (months)	Proportion opening within 12 months	Proportion opening within 18 months
2019/2020 report	2011-2017	17.4 months		
2020/2021 report	2015-2019 (n=47)	13.9 months	40%	64%
2023/2024 report	2018-2022 (n=44)	**20 months**[11]	25%	48%
2024/2025 report	2019-2023 (n=48)	**20 months** (is underestimation – rounded to the latest date for studies NYO (May 2025)	19%	45%

i At Cancer Research UK we define this as the time period between the issue of the Grant Award Letter to the Host Institution and the date of first trial site opening

ii Our internal trial set up reports analyse medians across a number of years (rather than year-on-year) because the total n number of our trials on a per-year basis is not large enough to be statistically robust, so we've historically compared how the cohort median shifts each year.

Previous analyses showed that for trials funded or endorsed by Cancer Research UK between 2011 and 2017, the median trial set-up time was 17.4 months. This realisation led to proactive interventions, and as a result, for the period between 2015 and 2019, the trial set-up time reduced to 13.9 months, almost meeting our 12-month target. However, in our most recent analysis covering 2019 to 2023, the

median trial set-up time had increased to 20 months.

This period does of course overlap with the disruption caused by the Covid-19 global pandemic, which will have had some impact on these times due to prioritisation of Covid-19 studies, as well as during the well-documented MHRA approval backlog that was subsequently addressed by the end of 2023[34].

The COVID-19 pandemic placed enormous strain on the clinical research system in the UK[35], causing well-documented, widespread delays to the set-up and delivery of non-commercial clinical trials. However, while the pandemic understandably disrupted the system, it also exposed longstanding inefficiencies in the set-up of non-commercial trials—challenges that have persisted beyond the immediate crisis. Even as the research landscape begins to stabilise, many of the issues that delayed trials during the pandemic remain deeply embedded. Inconsistent local processes, duplicated reviews and complex approval pathways continue to hinder timely trial activation.

This is echoed by our own portfolio. Looking year-on-year[iii], of trials funded in 2020, 29% were open within 12 months, whereas for trials funded in 2022 and 2023, none opened within 12 months. In 2023, widespread delays were often linked to internal reorganisation within the MHRA, which caused significant bottlenecks. These have since cleared, and improvements have been made in terms of the speed of this stage of approvals, although there remains concern around the sustainability of maintaining this.

The proportion of trials opening within 18 months of funding also paints a troubling picture, at 57% of those funded in 2020, falling to 50% in 2021 and just 14% in 2022. On a more positive note, there are now early signs of recovery in our latest analysis—57% of trials funded in 2023 opened within 18 months, and two trials funded in 2024 have opened between 9 and 13 months, but the rest remain unopened.

Despite these encouraging early signs, the majority of non-commercial cancer trials continue to experience unacceptably long set-up times. Since 2021, we have had to pause funding for half of our newly awarded clinical trials while set-up delays are addressed—an unsustainable situation that risks undermining research delivery and delaying access to innovative treatments for patients.

Trial set up by year of funding[iii]

Year of 1st GAL (funding received)	%age studies open within 12 months	%age studies open within 18 months	Estimated median (this includes studies that have not yet opened but calculated to the cutoff date May 2025 – for this reason these median times will be an underestimation of reality)	
2020 (n=7)	29%	57%	15 months	
2021 (n=15)	27%	50%	21 months	*1 trial NYO
2022 (n=7)	0%	14%	27 months	*3 trials NYO
2023 (n=8)	0%	57%	17 months	*3 trials NYO

iii The year on year median set-up times are not statistically robust due to low n numbers per year, but we have included them here to provide a sense of what trial set-up looks like year on year.

What are the key challenges to set up of non-commercial cancer clinical trials in the UK?

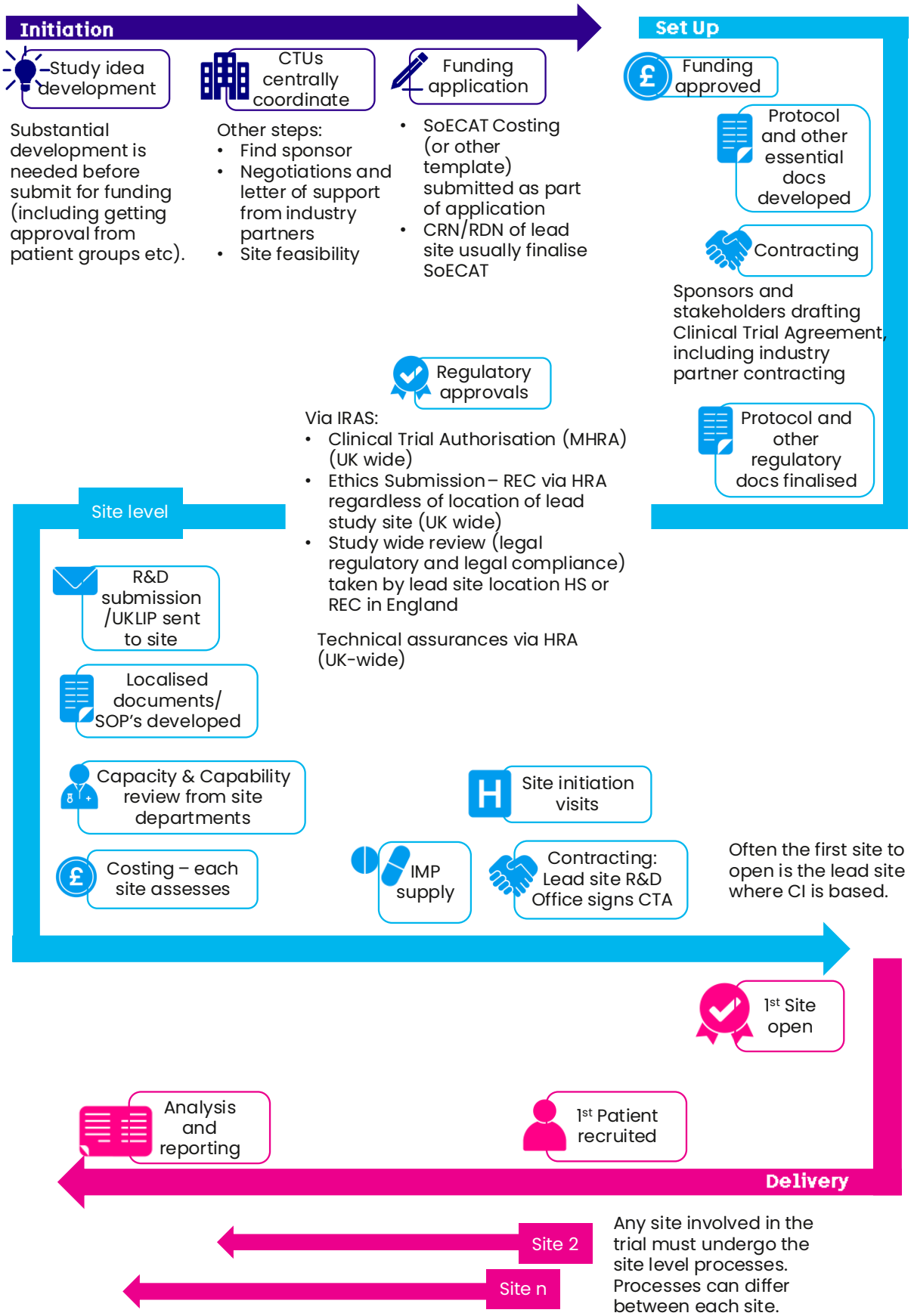
Setting up a clinical trial in the UK is a complex process, operating within a complex healthcare system, and each of the individual steps is subject to delays and complications.

The figure on page 12 illustrates the complex path to trial set-up, and all components need to be optimised to more efficiently set up trials. Following interventions to improve Research Ethics Committee and MHRA approval times, feedback from the clinical trials community indicates that the main challenges to non-commercial trial set-up are at NHS site level. These challenges fall into two broad groups:

1. Delays in NHS R&D site-level approvals, including contracts and costing particularly when approvals are needed for ionising radiation.
2. Capacity in pharmacy, radiology and/or pathology services.

These challenges are exacerbated in complex, innovative trial designs, internationally recruiting trials and rare cancer trials, all of which are priorities for Cancer Research UK, as set out in our refreshed research strategy and clinical research statement of intent[36], to drive maximum patient benefit and learn the most from our research.

These delays in the set-up of non-commercial cancer clinical trials deny some cancer patients the opportunity to participate in innovative studies, increase costs from much-needed public and charity funds, and slow the timeline to determining if an intervention is effective. An effective clinical trial system is also critical to deliver the evidence that will underpin the Government's planned shifts to reform the NHS. We call for urgent action across stakeholders, including NHS Trusts and Health Boards, UK Departments of Health and regulatory bodies, to ensure we maintain the UK's status as a global leader in clinical trials.


Initiation
Study idea development
CTUs centrally coordinate
Funding application
Substantial development is needed before submit for funding (including getting approval from patient groups etc).
Other steps:
• Find sponsor
• Negotiations and letter of support from industry partners
• Site feasibility
• SoECAT Costing (or other template) submitted as part of application
• CRN/RDN of lead site usually finalise SoECAT
Set Up
Funding approved
Protocol and other essential docs developed
Contracting
Sponsors and stakeholders drafting Clinical Trial Agreement, including industry partner contracting
Protocol and other regulatory docs finalised
Regulatory approvals
Via IRAS:
• Clinical Trial Authorisation (MHRA) (UK wide)
• Ethics Submission – REC via HRA regardless of location of lead study site (UK wide)
• Study wide review (legal regulatory and legal compliance) taken by lead site location HS or REC in England
Technical assurances via HRA (UK-wide)
Site level
R&D submission /UKLIP sent to site
Localised documents/ SOP's developed
Capacity & Capability review from site departments
Costing – each site assesses
Site initiation visits
IMP supply
Contracting: Lead site R&D Office signs CTA
Often the first site to open is the lead site where CI is based.
1st Site open
Analysis and reporting
1st Patient recruited
Delivery
Site 2
Site n
Any site involved in the trial must undergo the site level processes. Processes can differ between each site.

3. What needs to change

Specific asks

1. Implement an effective mechanism to streamline and accelerate NHS R&D approvals across multiple sites.
2. Publish detailed metrics on trial set-up times for non-commercial clinical trials to the Department of Health and Social Care (DHSC) Performance Indicators Report.
3. Improve specialist capacity for cancer research in NHS Trusts and hospitals.

Since the publication of the O'Shaughnessy review, there has been encouraging momentum in addressing the longstanding inefficiencies within clinical research. It is essential that non-commercial research is fully included in these improvements and not left behind. The establishment of the UK Clinical Research Delivery Group (UKCRD)[37,38], tasked with driving reform in the set-up and delivery of clinical trials, is a welcome step towards tackling some of these challenges. We welcome the recent update from the programme on single costing and contracts by the lead site[39] . Success will depend upon consistent implementation of this across trial sites and it is crucial that non-commercial research is fully included in these improvements to ensure meaningful change across both commercial and non-commercial trial set-up processes.

1. **Co-ordination of NHS R&D approvals across multiple sites**

We have reviewed with our clinical trials research community where delays most frequently occur in trial set-up. In practice, much of the current delay is due to multiple reviews by NHS R&D offices at different sites alongside the centralised review by MHRA and HRA. Sites can query protocols or costing already approved at other sites, creating delays in multiple loops of revision and amendments.

This is in no way a new issue. In 2011 the Academy of Medical Sciences report

stated that 'the governance arrangements within NHS Trusts are the single greatest barrier to health research'[40] and called for a single review for NHS R&D and coordination of oversight of arrangements for local set-up. In 2016 the HRA implemented a new process to provide a single England-wide NHS approval for interventional studies with the intention to remove the need for each hospital to assess new study applications in full. Despite this, in 2023, the review led by Lord O'Shaughnessy[41] still highlighted that 'clinical trial set-up and approval processes in the UK are slow and bureaucratic, especially compared to those in other countries. The return to usual MHRA review times[42] and acceptance of the National Contract Value Review (NCVR)[43] commercial costing templates following this report are significant but there remains to be definitive action on the problem identified that: 'too many hospital trusts, where the vast majority of clinical research takes place, carry out their own bespoke processes for the set-up and costing of trials, which adds to the time and cost of set-up'.

We consider that this remains the biggest addressable barrier and that changing to a streamlined approval across NHS hospital sites would lead to highly significant improvements to both efficiency and costs with a substantial impact on the attractiveness of the UK as a site for trials and on outcomes for patients. This is in line with the O'Shaughnessy review which recommended that a task and finish group provide a plan with measures that '…address both delays in regulatory approvals, and burdensome checks and duplicative processes at site level.'[44]

Encouragingly, as highlighted previously, some steps are now being taken to address these issues. The UKCRD programme[45] has been established to drive reform in the set-up and delivery of clinical trials. It brings together key stakeholders—government, funders and industry—and will be a key vehicle for delivering change.

We urge that this work is completed, setting out a clear and innovative route to deliver this plan, including, if necessary, through amendments to legal responsibilities and provision of indemnity for clinical trials with NHS patient participants. This is a position we advocated for in 2023 in our Longer, better lives report: A programme for UK government for cancer research and care[46].

2. **Detailed metrics on trial set-up times for non-commercial clinical trials in the DHSC Performance Indicators Report [47]**

In order to identify and address challenges in set-up, it is important to have information on actual timescales for each stage in the pathway. It is very positive that UK-wide data on trial set-up and delivery are now being published in the DHSC Performance Indicators Report. This currently provides monthly data on timescales for MHRA/HRA approvals and trial start-up across commercial and

non-commercial trials. However, the current report provides far more detailed metrics on the start-up of commercial than of non-commercial trials. This detailed information is critical to provide accurate tracking of the impact of interventions, such as improved MHRA capacity. Our monitoring of trial set-up times inevitably lags behind such changes, so we strongly recommend that equivalent detailed metrics on non-commercial trials are included in the DHSC dashboard. The UKCRD study set-up plan commits to addressing this, and we hope for continued progress. Ideally, the data should also be broken down by disease area, allowing us to specifically assess the performance of cancer trials and allow others to assess by disease area. In addition, it's important to look beyond just the proportion of studies meeting their targets—we also need insight into median timelines and outliers to gain a more complete understanding of the current landscape.

3. **Greater investment into clinical research and specifically improving specialist capacity for research in NHS Trusts and hospitals**

In addition to duplication of checks, further delays are caused by the lack of capacity in support services often required for cancer clinical trials, particularly pharmacy, pathology and radiology. These services are often under significant pressure to meet NHS clinical care requirements. Innovative solutions to secure dedicated resources and to share these resources across trial sites are urgently needed. There needs to be greater clarity on the capacity available for research, especially where this has been funded through public infrastructure support. There is also an urgent requirement to streamline and speed up review and provision of specific trial components, particularly the use of ionising radiation and specialist pharmacy services.

More broadly, there is an urgent need to bolster the wider clinical research workforce and invest meaningfully in the infrastructure that underpins research across the NHS, to ensure the long-term viability and effectiveness of clinical research in the UK. Central to this is comprehensive workforce planning to address shortages, improve retention and build research capacity within NHS services. The recent 'Clinical researchers in the UK: reversing the decline' report[48] makes clear that the decline in the UK's clinical research workforce poses a serious threat to our ability to deliver high-quality studies. Delivery of the recommendations of this report will be key in reversing the decline of clinical researchers in the UK and will be vital to improving population health outcomes and driving economic growth.

Zooming out further, the UK must ensure that its wider life sciences strategy gives equal priority to non-commercial research. We welcome the Prime Minister's recent commitment to introduce a target aimed at accelerating clinical trial set-

up timelines—a positive and necessary step. It is also positive to see this ambition and commitment highlighted in the Life Sciences Sector Plan and 10-Year Health Plan for England. To build a strong, resilient and collaborative research ecosystem, non-commercial research must be recognised and supported as a central pillar alongside commercial studies. Only then can the UK truly lead on innovation, deliver meaningful improvements to patient care and secure its global standing in clinical research.

4. Conclusion

The UK has a world-leading science base, of which cancer research is a notable strength. We have a remarkable advantage in our national health systems and the generous commitment of so many cancer patients to clinical trials, alongside excellent research. Oncology trials are a key part of the UK clinical research ecosystem which stimulates inward investment and deliver substantial benefits to patients both here in the UK and around the world. However, there are long-recognised issues to address to ensure that the UK can deliver on the full promise of these strengths and capabilities and maximise value from investment in clinical trials. With strong leadership and determination to finally resolve difficult but surmountable challenges–such as clinical trial set-up times–we can remain globally competitive and indeed secure our future position as a world leader for cancer trials for the benefit of patients here and elsewhere.

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