

Written evidence submitted by Association of Medical Research Charities

We welcome the [Public Affairs Committee consultation on NHS backlogs and waiting time](#). Over the past year the UK's healthcare system has been put under immense pressure, which has impacted on every element of service delivery, including clinical research. Medical research is a critical part of the health and social care system, offering hope to patients across the UK and helping to attract and retain some of the most talented clinicians in the world. Our response, representing UK medical research charities, highlights the impact of the backlog on clinical research, and the measures that need to be taken to deliver on the ambition laid out in the Government's clinical research vision – [The Future of UK Clinical Research Delivery](#) – and [Life Sciences Vision](#).

Summary:

- **The pandemic, and subsequent backlog has had an adverse impact on clinical research.**

At the height of the pandemic, more than 70% of all clinical studies in the UK were paused or cancelled. While the recovery process has helped to address some of this, **a significant percentage of studies remain paused due to the pandemic** and those studies that are open are struggling to recruit patients. There is still a long way to go before the UK's clinical research activity is back to pre-pandemic levels.

- **Clinical research is a vital component of patient care**

COVID-19 has highlighted the importance of research as an integral part of the healthcare pathway. Conducting clinical research in the NHS helps to improve patient experience and outcomes, provides benefits to NHS staff and organisations, and delivers economic benefits. Failing to address the backlog in clinical research could therefore have disastrous consequence for the healthcare system more broadly.

- **The impact of the backlog is on patients, clinicians and the UK's international reputation for clinical research**

Patients are suffering through disruption and anxiety. Staff and services have been directed away from research to front line services. Finally, the UK is struggling to recover its clinical research portfolio compared to other countries

- **The pandemic has highlighted the importance of research and collaboration**

It has Improved visibility of clinical research and increased cross sector collaboration

- **The key barriers to clearing the backlog must be addressed**

Clinical research is competing for resources with wider clinical services whilst social distancing and quarantining of staff has significantly reduced clinical capacity. There are also concerns that COVID research is continuing to receive priority over non-COVID research.

- **Investment is needed to address workforce capacity across the system, whilst working to further embed clinical research into care.**

It is clear that there is only so much that can be achieved with the current workforce and infrastructural capacity. Increased support and funding to address capacity constraints are needed to develop a longer-term recovery plan. This will provide the opportunity to further embed clinical research into the NHS, including through the Health and Care Bill.

Introduction

The Association of Medical Research Charities (AMRC) is the membership organisation of the leading medical and health charities funding research in the UK. We represent over 150 medical research charities of a variety of sizes; from household names such as Cancer Research UK, Wellcome, the British Heart Foundation, and Alzheimer's Research UK to smaller charities who invest in specific areas of unmet need.

Together, AMRC medical research charities account for half (49%) of publicly funded medical research in the UK¹. In 2020, out of a total charitable investment of £2.9 billion by AMRC members, £1.7 billion went towards research in the UK. Over the past 10 years, AMRC members have consistently invested more than £1 billion in research each year - totalling over £14.5 billion.

This includes support for innovative clinical research studies within the NHS, with 31% of all non-commercial clinical research projects funded by AMRC members in 2018. In 2020, AMRC's members recruited 336,000 people into 800 clinical studies. Charities also invest in patient-centred data and digital assets including registries and biobanks, making them key partners in the clinical research landscape.

Our response will be focussed on how the backlogs have impacted on the set up and delivery of clinical research in the UK. This aims to complement responses from our members who will cover the impact on the care pathways that effects their community more broadly. We highlight examples and case studies from these charities in our response, highlighting how the pandemic has negatively impacted on the delivery of studies.

Clinical research is a vital component of patient care

Conducting clinical research, alongside the delivery of care in the NHS is an important aspect of the NHS. Not only can it improve patient experience and outcomes, but it also provides benefits to staff and organisations as well as additional economic benefits². Further details are provided below.

Benefits of conducting clinical research in the NHS

1. Patient benefits

Patients treated in clinical settings engaged with research have improved outcomes³, lower mortality rates⁴ and increased confidence in the care being delivered, with research active NHS organisations seeing improved Care Quality Commission (CQC) ratings⁵.

¹ AMRC, Medical Research Charities: Investing in Research, (2021). URL:

<https://www.amrc.org.uk/Handlers/Download.ashx?IDMF=2d5f1e0c-39da-47f7-b7b1-4854b5ad8aff>

² NIHR, 'Embedding a research culture', Accessed: August 2021. URL: <https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/embedding-a-research-culture.htm>

³ Midlands Engine, MIDLANDS ENGINE HEALTH, Focus on: Clinical Trials, (2021).

URL:https://www.midlandsendengine.org/wp-content/uploads/ME-Health-Focus_Clinical-Trials.pdf

⁴ Downing, A., Morris, E. J., Corrigan, N., Sebag-Montefiore, D., Finan, P. J., Thomas, J. D., Chapman, M., Hamilton, R., Campbell, H., Cameron, D., Kaplan, R., Parmar, M., Stephens, R., Seymour, M., Gregory, W., & Selby, P. (2017). High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. *Gut*, 66(1), 89–96. <https://doi.org/10.1136/gutjnl-2015-311308>

⁵ Jonker, L., Fisher, S. J., Dagnan, D. (2019) Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication: Results from a retrospective cross-sectional study. *Journal of Evaluation in Clinical Practice*, 26(1), 203–208. <https://doi.org/10.1111/jep.13118>

2. NHS staff and organisational benefits

Engaging in research improves job satisfaction⁶ amongst health workers, boosts staff morale and can reduce burnout⁷.

57% of doctors surveyed by the Royal College of Physicians (RCP) said they would like to be more involved in research⁸. 67% of those surveyed said having dedicated time for research would make them more likely to apply for a role. CQC analysis also shows that staff working in NHS sites with higher clinical research activity levels are more likely to recommend their own organisation⁹.

3. Economic benefits

Clinical research represents a sound economic investment in UK intellectual capital; bringing in and developing talent; creating 'spin off' companies based in the UK; and speeding up the discovery of new medicines. The NIHR Clinical Research Network (CRN) supported clinical research activity generated £2.7 billion GVA in 2018/2019, with the estimated income for the NHS from life sciences companies totalling £355 million¹⁰.

The current position of NHS clinical research backlogs and waiting times following the pandemic.

The benefits outlined above are now at risk of being seriously undermined as a result of clinical backlogs, which could have disastrous consequences for the healthcare system more broadly. If clinical research activity continues to decline, then this will impact on patient outcomes, and the ability to attract and retain the best clinicians into the NHS. This could become a vicious circle further reducing workforce capacity and therefore reducing capacity for clinical research and general service delivery.

A significant percentage of studies remain paused due to the pandemic

At the peak of the pandemic, roughly 70% of all clinical trials on the NIHR portfolio (both non-commercial and commercial), had been paused or cancelled. Still a significant percentage of the studies remain paused whilst some have had to be stopped or cancelled completely. These figures represent significant portions of the UK's portfolio and will leave many patients without the option to take part in clinical research. This has an impact on treatment options now and in the future for patients (see case study: CRUK).

The impact has been felt across the medical research sector. Alzheimer's research UK have reported that as a result of COVID-19, 95% of dementia researchers have had their research projects or clinical trials delayed, and one in five have had research projects cancelled completely¹¹. Further to this, nearly a third (29%) of dementia researchers have had their funding suspended or cut, while 78% said future funding opportunities have decreased¹².

⁶ Wenke, R.J., Mickan, S. & Bisset, L. (2017) A cross sectional observational study of research activity of allied health teams: is there a link with self-reported success, motivators and barriers to undertaking research? *BMC Health Serv Res* 17, 114. <https://doi.org/10.1186/s12913-017-1996-7>

⁷ Shanafelt, T. D., West, C. P., Sloan, J. A., Novotny, P. J., Poland, G. A., Menaker, R., Rummans, T. A., & Dyrbye, L. N. (2009). Career fit and burnout among academic faculty. *Archives of internal medicine*, 169(10), 990–995. <https://doi.org/10.1001/archinternmed.2009.70>

⁸ Royal College of Physicians (RCP), 'Research for all? An analysis of clinical participation in research' (2020) URL: <https://www.rcplondon.ac.uk/projects/outputs/research-all-analysis-clinical-participation-research>

⁹ Shanafelt, T. D., West, C. P., Sloan, J. A., Novotny, P. J., Poland, G. A., Menaker, R., Rummans, T. A., & Dyrbye, L. N., Career fit and burnout among academic faculty. *Archives of internal medicine*, (2009). 169(10), 990–995. <https://doi.org/10.1001/archinternmed.2009.70>

¹⁰ NIHR, 'New report highlights how NIHR support for clinical research benefits the UK economy and NHS' (2019). URL: <https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/22489>

Case Study

Cancer Research UK: Cancer patients have fewer treatment options

Around 1 in 6 people with cancer are taking part in research to access new methods of care and help improve the care received by future patients.

Cancer Research UK (CRUK) had to pause 95% of their clinical trials during the peak of the pandemic. These disruptions were caused by the need for researchers to minimise the number of patients visiting hospitals, as this increased COVID-19 infection risk. At the same time, clinical staff usually dedicated to research needed to support frontline services as part of the NHS's response to COVID-19.

COVID-19's impact extends beyond disrupting today's cancer trials – it also threatens tomorrow's cancer research. CRUK expect to fund fewer new trials this year.

The reduction in the number of clinical trials will reduce care options for cancer patients, potentially forcing some to consider palliative care instead. This will significantly impede efforts to improve UK cancer outcomes in the long term.

Part of the problem is caused by clinical studies competing with other parts of the healthcare system to conduct research related care activities. For example, AMRC members have noted that the growing backlog of planned surgery operations¹³ have severely impacted on their ability to deliver clinical research in arthritic patient populations. There have also been significant impacts on cancer research, with bottlenecks in radiology services¹⁴ impeding the delivery of research.

Studies that are open are struggling to recruit patients

Longer waiting times have an impact on recruitment to clinical research. Patients often have a very narrow window in which they are eligible for a particular trial or study. For example, if a patient's cancer progresses beyond a certain point, this may make them ineligible for a trial that may give them access to a potentially life saving treatment. For many patients, clinical trials can offer another line of treatment where there would otherwise be none, for others clinical research is simply a way to help others in trying to better understand their disease and improve care pathways.

Even for those studies which are open, recruitment to non-COVID research remains much lower than pre-pandemic levels. Recruitment can vary between months, but recruitment in the UK has been consistently low for non-COVID research since January 2020. CRUK have reported that although there has been progress, recruitment rates remain at approximately 68.5% of pre-pandemic levels (as of September 2021). If studies are not able to recruit to target, then they are forced to either extend the study timelines, which will come at a cost, or to fund clinical research in another country that may be a better place to reach recruitment

¹¹ Alzheimer's research UK, Translating Science into Breakthroughs: The future of late-stage dementia clinical trials in the UK, (2021). URL: <https://www.alzheimersresearchuk.org/wp-content/uploads/2021/05/FUTURE-OF-CLINICAL-TRIALS-FINAL.pdf>

¹² Alzheimer's research UK, Translating Science into Breakthroughs: The future of late-stage dementia clinical trials in the UK, (2021). URL: <https://www.alzheimersresearchuk.org/wp-content/uploads/2021/05/FUTURE-OF-CLINICAL-TRIALS-FINAL.pdf>

¹³ Carr, A., Smith, J. A., Camaradou, J., Prieto-Alhambra, D., Growing backlog of planned surgery due to covid-19 (2021) URL: <https://www.bmj.com/content/372/bmj.n339>

¹⁴ The Royal College of Radiologists, New RCR census shows the NHS needs nearly 2,000 more radiologists (2021). URL: <https://www.rcr.ac.uk/posts/new-rcr-census-shows-nhs-needs-nearly-2000-more-radiologists>

targets. The latter would likely reduce inward investment for the UK. For a specific example of issues with recruitment and the impact see case study: Parkinson's UK.

Case Study

Parkinson's UK: Long-term health studies face disruption from COVID-19 crisis

Longitudinal studies that test health outcomes in specific groups over time, such as patients with Parkinson's, are facing disruption from the coronavirus crisis. Two studies funded by Parkinson's UK, called Tracking-PD and Parkinson's Discovery Cohort, work by assessing participants at regular intervals over many years to understand how Parkinson's Disease progresses.

Running for eight years and costing millions of pounds, the research will be disrupted by missed study visits that will negatively impact the quality of the data researchers get. It is not a case of just pausing and then resuming after the crisis. Most importantly, there is a huge cost to patients that rely on the outcomes of these trials, left waiting for improved health outcomes, care, and quality of life.

This also has an impact on recruitment, with many patients' conditions progressing and potentially falling outside of the eligibility criteria to take part in clinical research. This is something that will have impacted on all areas of research.

Patients are suffering through disruption and anxiety

The above data is stark and has led to disruptions to clinical research care pathways for thousands of patients, whilst many more have missed out on the opportunity to take part in research completely. See case study: MS society.

Breast Cancer Now found that of the patients surveyed who were receiving or expecting to receive treatment as part of a clinical trial during the pandemic, just under a quarter (22%) had experienced disruptions¹⁵.

Many patients are feeling both 'anxious' and 'frustrated' at the current state of care, including around clinical research^{16, 17}. 70% of stroke survivors are feeling more worried about their health, and 72% are worried about what the future holds¹⁸. Similar findings were present in a Myeloma UK survey: 33% of myeloma patients felt their mental health was more difficult to manage during the COVID-19 pandemic, compared to usual¹⁹. These feelings are unlikely to be unique to the patients responding to these surveys and would be expected across a variety of vulnerable disease groups.

¹⁵ Breast Cancer Now. PRESS PLAY: Getting and Keeping Breast Cancer Services Back on Track, (2020).

URL: https://breastcancernow.org/sites/default/files/final_breast_cancer_now_press_play_report.pdf

¹⁶ Cancer Research UK. Cancer Research UK Cancer Patient Experience Survey 2020: The impact of COVID-19 on cancer patients in the UK, (2020). URL: https://www.cancerresearchuk.org/sites/default/files/pes-covid_2020.pdf

¹⁷ Stroke Association. Stroke Recoveries at Risk: How the Covid-19 pandemic has affected stroke survivors' lives and recoveries, (2020). URL: https://www.stroke.org.uk/sites/default/files/campaigning/jn_2021-121.1_-_covid_report_final.pdf

¹⁸ Stroke Association. Stroke Recoveries at Risk: How the Covid-19 pandemic has affected stroke survivors' lives and recoveries, (2020). URL: https://www.stroke.org.uk/sites/default/files/campaigning/jn_2021-121.1_-_covid_report_final.pdf

¹⁹ Myeloma UK. The Myeloma UK Patient, Family and Friends COVID-19 Survey (2), (2020). URL: <https://www.myeloma.org.uk/wp-content/uploads/2020/10/Myeloma-UK-Patient-Family-COVID-19-Survey-2-Summary.pdf>

Case Study

The MS Society: Disruptions hit vulnerable groups and the innovation pipeline they depend on

The MS Society continues to face a drop in income due to COVID-19, which will directly affect research into multiple sclerosis. Some of their clinical trials and studies have been paused during the pandemic, and this has had a knock on impact on the pipeline for potential treatments for Multiple Sclerosis (MS).

During the pandemic around 70% of their university research programmes have had to slow or stop altogether, creating a delay and funding gap. The gap in funding and delay to vital research puts at risk the development of new life-changing treatments, without which people with MS in the future could find themselves more reliant on the social care and welfare systems.

Staff and services have been directed away from research to front line services

The redeployment of clinical research staff has only exacerbated disruption issues, and left research patients with less support than they had before. A Breast Cancer Now survey of Clinical Nurse Specialists (CNSs) found that only 35% felt that they had enough time to offer each secondary breast cancer patient the opportunity to discuss their wider concerns and needs in the weeks following diagnosis, and just 31% had the time to offer this as treatment changes or the cancer progresses²⁰. The pandemic will have only made such issues worse, with over 400 Macmillan NHS professionals being deployed elsewhere²¹.

Although clinical research staff are now returning from redeployment, the picture is still patchy, with COVID research representing a significantly large new research discipline that is taking up a substantial amount of capacity within a system that was already very overstretched. Without the capacity and workforce to engage with patients and carry out research, recruitment rates will remain low.

The UK is struggling to recover its clinical research portfolio compared to other countries

The latest COVID-19 impact report from Medidata²² shows that recruitment of patients to clinical research in the UK has continually fallen behind our European counterparts (see Figure 1).

The UK has made progress in August, whilst France, Spain and Italy struggle with a rise in COVID-19 cases, but it is clear that these countries are able to recover at a faster pace.

The UK is a global competitor for investment into clinical research and as recruitment activity in the UK stagnates, progress is made overseas which in turn damages the long-term investment prospects in the UK. This will impact on the UK's attractiveness as a destination for international investment for clinical research, but it may also see UK based charities

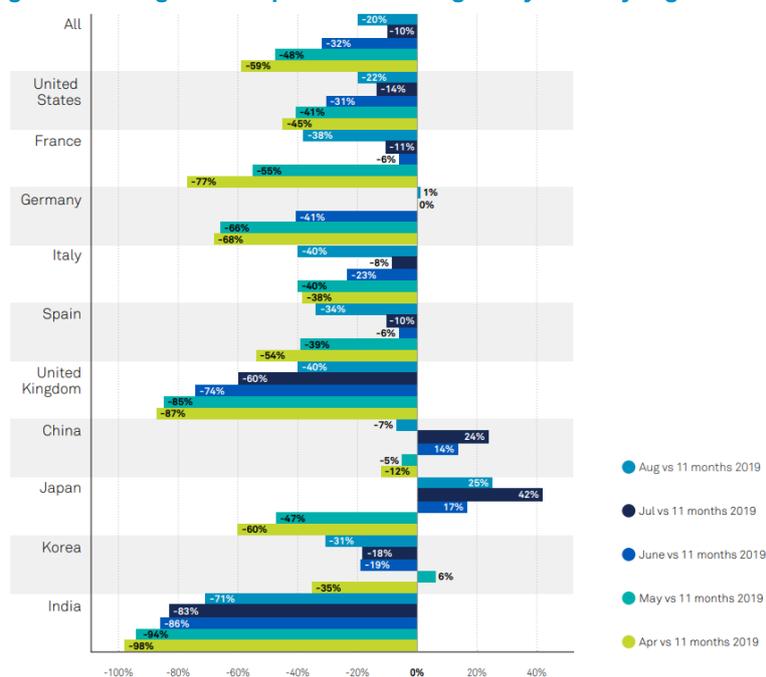
²⁰ Breast Cancer Now. PRESS PLAY: Getting and Keeping Breast Cancer Services Back on Track, (2020). URL: https://breastcancernow.org/sites/default/files/final_breast_cancer_now_press_play_report.pdf

²¹ Breast Cancer Now. PRESS PLAY: Getting and Keeping Breast Cancer Services Back on Track, (2020). URL: https://breastcancernow.org/sites/default/files/final_breast_cancer_now_press_play_report.pdf

²² Medidata. COVID-19 and Clinical Trials: The Medidata Perspective, (2021). URL: https://www.medidata.com/wp-content/uploads/2021/06/COVID19-Response9.0_Clinical-Trials_2020921_v2-1.pdf

looking to collaborate and fund research in other countries that have the capacity to deliver on recruitment targets. The potential for a knock-on effect on skills and expertise is significant, as talent could be lost to countries who recover at a quicker pace.

Figure 1: Change in new patients entering study-sites by region²³



The pandemic has highlighted the importance of research and collaboration

Whilst the pandemic has put a huge amount of strain on already overstretched healthcare and research systems, it has also increased the visibility of research as an integral part of the healthcare pathway and provided a starting point for increased collaboration.

Improved visibility of clinical research

Innovative trials like RECOVERY allowed clinicians to quickly and safely test the efficacy of multiple treatments against COVID-19²⁴. This trial – delivered in the NHS – led to the identification of dexamethasone, an inexpensive and widely available steroid, as an effective treatment for COVID-19 patients, and has been estimated to have saved around one million lives²⁵. This highlights the importance of further integrating clinical research into all parts of the NHS.

Increased cross sector collaboration

NIHR in collaboration with the Recovery, Resilience and Growth (RRG) programme (through which the [Future of UK Clinical Research Delivery](#)²⁶ paper was developed) have

²³ This graph was produced by Medidata and has been taken straight from the following report: Medidata. COVID-19 and Clinical Trials: The Medidata Perspective, (2021). URL: https://www.medidata.com/wp-content/uploads/2021/06/COVID19-Response9.0_Clinical-Trials_2020921_v2-1.pdf

²⁴ RECOVERY, Accessed: August 2021. URL: <https://www.recoverytrial.net/>

²⁵ NHS, 'COVID treatment developed in the NHS saves a million lives', (2021). URL: <https://www.england.nhs.uk/2021/03/covid-treatment-developed-in-the-nhs-saves-a-million-lives/>

²⁶ Department for Health and Social Care (DHSC). The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan, (2021). URL: <https://www.gov.uk/government/publications/the-future-of-uk-clinical->

implemented a Managed Recovery process to help speed up the delivery of clinical research.

The RRG programme involves stakeholders from across the sector and has been instrumental in making progress on reducing clinical research backlogs. However, there is still a long way to go before the UK's clinical research activity is back to pre-pandemic levels.

NHS and care service reforms to help deal with the backlog

There is currently a myriad of issues that are impacting on the UK's ability to deliver clinical research for patients. The biggest barriers to reducing clinical research backlogs are outlined below:

- NHS resource for clinical research competing with resource for clinical services
- Impact of social distancing and quarantine on staffing
- Where sites were able to restart non-COVID-19 research, there are concerns that COVID-19 studies are continuing to receive priority status. Whilst this is now an important research area that must be resourced, it is important not to forget research into other conditions.

The Department for Health and Social care paper 'The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan' outlines a number of key action areas that will help to better deliver clinical research in the NHS, and ultimately reduce the backlog. However, in order to make progress we must first increase workforce capacity and further embed clinical research into the NHS.

Workforce capacity needs to be increased to address the backlog in clinical research

We recognise and applaud the tireless efforts of those working within the healthcare and research delivery system. Clinicians on the ground have put everything in to dealing with this pandemic, whilst key organisations such as NIHR, NHS England, and those in Devolved Nations have done their best to support the recovery process.

However, it is clear that there is only so much that can be achieved with the current workforce and infrastructural capacity. The clinical research activity data presented in this paper suggests that the system is over capacity and in need of increased support and funding in order to develop a longer-term recovery plan.

Cancer research UK's insightful report 'Creating Time for Research' outlines the key barriers to addressing these issues within the NHS. The report found that dedicated time for clinicians to conduct research is too inaccessible and too inadequately supplied²⁷. This means that health service staff are forced to conduct research in their own time. This is not sustainable, especially in an environment where burnout amongst NHS staff is at 'emergency levels'²⁸.

The UK is almost entirely reliant on the NHS to conduct clinical research, and when backlogs build up within standard of care pathways, these have significant impacts on our ability to conduct research, improve patient care, and bring novel treatments into the NHS.

[research-delivery-2021-to-2022-implementation-plan](#)

²⁷ Cancer Research UK. Creating Time for Research, (2021). URL:

https://www.cancerresearchuk.org/sites/default/files/creating_time_for_research_february_2021_-_full_report-v2.pdf

²⁸ Iacobucci, G., Staff burnout: MPs demand "total overhaul" of NHS workforce planning, (2021). 373, doi: <https://doi.org/10.1136/bmj.n1461>

Embedding clinical research into the NHS will help improve the quality of care delivered by Integrated Care Systems (ICSs)

Clinical research is too often seen as an added extra that is less essential to the wider healthcare system. However, as the pandemic showed with trials such as RECOVERY, this is not the case. By embedding research into all parts of the UK's health and social care system, patients will gain easy access to high quality clinical research and clinicians will be afforded more opportunities to engage and contribute to medical advancements in the UK. The opportunity is considerable and one that the UK is well placed to take with a single payer system and a new Health and Care Bill²⁹ that encourages more collaboration.

This will require supporting the commitments made in the '[Future of UK Clinical Research Delivery](#)' paper with a funding uplift for NIHR, but also further commitments to ensure that clinical research is a core feature and function of newly established ICS's. There must be research representatives on both Integrated Care Boards and Integrated Care Partnerships to ensure a more joined up approach to care and clinical research. Furthermore, the new Health and Care Bill should mandate that Integrated Care Systems ensure that NHS organisations for which they are responsible conduct and resource clinical research.

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²⁹ Health and Care bill. URL: <https://bills.parliament.uk/bills/3022>