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OPTIMISING THE VALUE OF CLINICAL RESEARCH FOR THE UK

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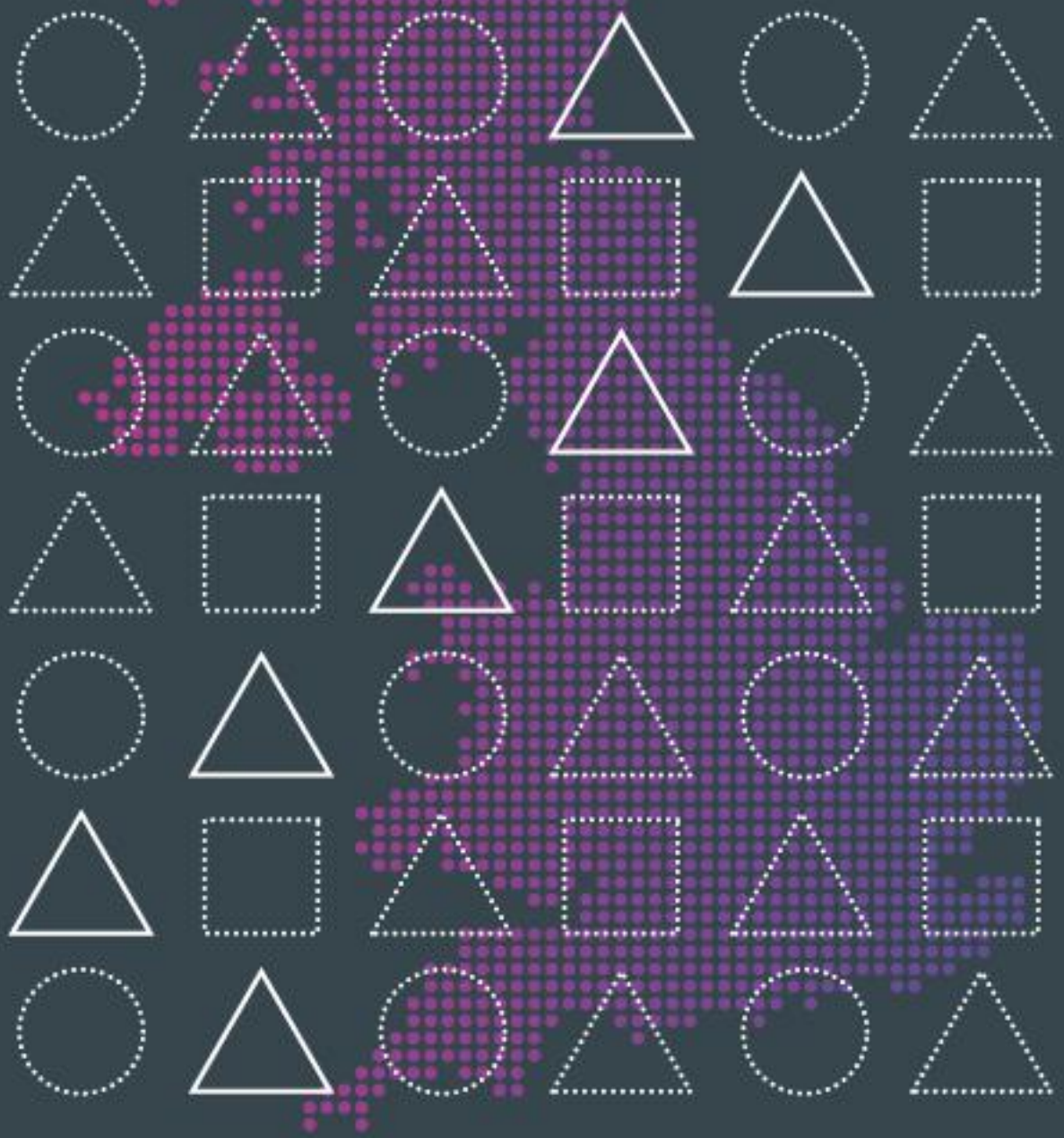

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CONTENTS

ABBREVIATIONS

AHP	Allied Health Professional
ARPA-H	Advanced Research Projects Agency for Health (USA)
CRUK	Cancer Research UK
DHSC	Department of Health and Social Care
DKFZ	German Cancer Research Centre
DSIT	Department of Science, Innovation, and Technology
HCRW	Health and Care Research Wales
HEI	Higher Education Institutions
HRA	Health Research Authority
ICB	Integrated Care Board
IUK	Innovate UK
MHRA	Medicines and Healthcare products Regulatory Authority
MRC	Medical Research Council
NIHR	National Institute of Health and Social Care Research (UK)
NHS	National Health System
NHMRC	National Health and Medical Research Council (Australia)
NMC	Nursing and Midwifery Council
OLS	Office of Life Sciences
ONS	Office for National Statistics
UKRI	United Kingdom Research and Innovation
VPAG	Voluntary Scheme for Branded Medicines Pricing and Access

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Cancer Research UK (CRUK) commissioned and funded this report. Their input throughout the project has enabled the team to identify and reach key stakeholders, and to refine the presentation of the evidence collected in the report. This report contains the views of the Transforming Evidence team, and not that of CRUK or any stakeholders or advisers consulted during this project.

We are very grateful for the insights and comments of the advisory group, Professor Steven Hanney and Dr Steve Wooding, and for the interviewees who shared their time with us. We are also grateful to our interviewees and wider network who have offered review, insights and improvements, which have all contributed to this report.

In addition to data collected, we bring our own experience in assessing, mapping, supporting and studying health research systems, from over three decades of providing leadership and advice for health care and research organisations in Australia, Canada, France, UK and US.

Throughout the project, we have worked closely with CRUK to shape the scope of the project, including identifying interviewees and discussing our emerging findings. These conversations have informed our analysis and interpretation, but the final conclusions drawn are the responsibility of Transforming Evidence, as are any errors made.

AUDIENCE AND AIMS

This report aims to share practical insights from a range of sectors and countries aimed primarily at CRUK in its current and future work: making the case for more collaboration and learning and describing what a better future might look like.

While the work that underpins this report was commissioned by CRUK, we hope the report is useful to anybody with an interest in clinical research including researchers, funders, commissioners, and staff in existing - or planned new centres – and policy and other decision-makers who want to find out more about how the UK can maximise the return on investment into clinical research and development.

INTRODUCTION

The UK has a long history of excellence in clinical research. Recently identified challenges to maintaining the quality and impact of clinical research include global systemic issues such as financial crises, ageing populations, and climate changes. Globally, clinical research has become a highly competitive arena as countries vie with one another for industry funding, rapid accruals of patients into trials, and growth and retention of qualified clinical research professionals (Benisheva et al., 2023).

The UK's clinical research is affected domestically by political and systemic issues like Brexit, NHS workforce recruitment and retention, growing health inequalities; and organisational factors such as research culture and resourcing within services. Well-documented issues like loss of NHS staff due to the Covid-19 pandemic, and increased regulatory burdens have contributed to a more complex clinical trials landscape within the UK (O'Shaughnessy, 2023, Deswal, 2023, Benisheva et al., 2023) and resulted in fewer patients having access to clinical trials (ABPI, 2022). Recruitment and development of new trials, particularly commercial trials, has waned since 2016. Yet, the Covid RECOVERY trial demonstrated the potential strength and global reach of UK clinical research (Hanney et al., 2022).

Governments, funders, industry, academia and patients want to see the quality and impact of the UK's clinical research improve. The 2024 Labour Government has health as one of its five key missions: 'Improve the NHS by reforming health and care service and reducing health inequality' (Streeting, 2024). Over the past decade, numerous reports have been published highlighting problems and outlining solutions, including Cancer Research UK: Creating time for research (Peckham S and Buckley-Mellor, 2021), the Johnson Government-commissioned review of commercial clinical trials in the UK (O'Shaughnessy, 2023) and the Sudlow review into health data use (Sudlow, 2024); policy reports such as the UK Science and Technology Framework (DSIT, 2023), the forthcoming Ten Year Health Plan (NHS, 2024) and the UK Policy Framework for Health and Social Care Research (HRA, 2023b). We have also looked at frameworks for the UK devolved administrations including the Welsh National Clinical Framework (Atherton, 2021), the Welsh Health Care and Research plan (HCRW, 2023) and the Research, Development, and Innovation Strategy from NHS Scotland (NHS, 2020).

These reports set out research agendas and, altogether, over 200 recommendations about how to improve the UK's clinical research environment (see Appendix 1). Yet although there has been dedicated time and resources devoted to highlighting some of key areas of need within the UK clinical research environment (as evidenced by continued reporting and legislative sessions), UK stakeholders have remained frustrated with a perceived lack of progress. Many good ideas have been suggested, but

less is known about how to unblock progress towards achieving the vision shared by key stakeholders.

Why does clinical research matter to the UK?

Clinical research delivers improved outcomes for patients and for the economy broadly, as well as addressing many of the challenges to the health and social care sector. Benefits are identifiable to patients, the economy (the 'health and wealth' argument), and to the wider workforce within the sector.

The UK's clinical research provides an essential evidence base for improving clinical guidelines and patient care. For example, a review of all randomised controlled trials funded and published by the UK National Institute for Health Research (NIHR) during 2006-2015 found that over 98% of clinical trials funded by the NIHR were cited in a systematic review or a policy or practice document– 68% in a policy or practice document, demonstrating the reach and potential impact of clinical work (Carroll and Tattersall, 2020). A 2020 review found that 78% of cancer REF impact cases involved citations of trial publications within policy documents (Hanna et al., 2020).

Research can identify new treatment options for patients, and, through participation in research, enable their access to drugs and therapeutics not yet part of standard care. There are direct economic gains by enabling care through research and innovation. Enrolling patients in NHS-supported trials brought an average £9,200 in income from life sciences companies and £5,800 in savings per patient (Iacobucci, 2019). Recent analyses of the NIHR Clinical Research Network found that NHS providers in England received an average of £9,200 from life sciences companies, and saved an average of £5,800 per patient (where trial drugs replaced standard treatment) (KPMG, 2019b).

The clinical research and life-sciences sector is an important one for economic growth, particularly through job creation. Clinical research raised £2.7 billion for the UK economy and created over 47,000 jobs between 2016-2019 (Iacobucci, 2019, KPMG, 2019a). The British Medical Association has found that for clinical research "every £1 invested is estimated to create a 30p return every year thereafter in the UK" (BMA, 2024, ABPI, 2024b).

Although mechanisms are not yet well-understood, research suggests that patient outcomes are improved when NHS Trusts engage in more clinical research (RCP, 2021, Boaz et al., 2024a, Boaz et al., 2024b). Providing opportunities for health and social care staff to participate in research can improve workforce morale, recruitment and retention (NIHR, 2024b).

Strengthening UK investment in clinical research also enables our participation in global networks. Participation in international collaborations such as Horizon Europe (UKRI, 2023) brings domestic and diplomatic benefits. Recent modelling estimating the economic returns of medical research in the UK found that between 17-30% of benefits realised by the UK population resulted from medical research performed in the UK, and upwards of three-quarters of clinical research benefits to the UK came from internationally funded research (Grant and Buxton, 2018).

Our task

Our aim is to summarise the current state of UK clinical research funding, governance, and policy. Drawing together literature, interviews, and key policy reports, we summarise the facilitators and barriers of good clinical research in the UK and identify promising approaches which could be adopted by the UK to support improved clinical research practice, delivery and governance. In this report we:

- map the current government structures and processes for clinical research within the UK Government and devolved administrations
- provide an overview of the health services' role in the delivery of UK clinical research
- identify the wider political issues that might impact proposed policy improvements to the clinical research environment
- identify the policy barriers and enablers to achieve a stronger research culture in the UK health service at a national, regional, and local level
- consider the role played by other sectors, including industry, academia, and charities/foundations, and evaluate how effectively these sectors work together in the UK compared to other countries.

Defining Clinical Research and Clinical Trials

Where possible, we have drawn examples from, and highlighted considerations and conclusions that are/may be specific to cancer research. This report explores clinical research within the UK, with a focus on clinical trials and cancer-focused clinical research. We heard from participants that the term clinical research can mean different things to different stakeholders and that it can be important to clarify terminology to ensure that everyone is working in alignment. For the purposes of this project, we are defining clinical research as research that seeks to "improve current treatments,

medicines and care, and develop new and better ones; diagnose diseases and conditions earlier or more accurately; and prevent people from developing diseases and conditions"[1].

Specifically, we understand clinical research that:

- actively involves people, including patients, carers and families, and is focused on improving health and care
- often happens in a hospital or GP setting but it also occurs in other places, for example in the community or people's homes
- may ask people to take a new treatment, use a device or be cared for in a certain way, or to provide information about usual care
- tests a treatment or care package, or find out more about a condition, therapy, experience or setting (HRA, 2024)(HRA, 2023c).

We understand clinical trials to be a type of clinical research, which has a comparative (often randomised) design to compare interventions in clinical practice. For example, research involving trials of surgical interventions; radiotherapy; imaging investigations; mental health investigations or therapies; physiological investigations; trials of products not defined as medicines or medical devices (for example nutritional); complementary or alternative therapies.

Our approach

In this report, we first describe the major challenges and opportunities for high quality clinical research in the UK, drawing on interviews, grey and academic literature. To do this, we combine insights from:

- Data on clinical research systems, using research funding and output databases to identify major funders of health and cancer research, and to characterise research activity
- Published research and grey literature to identify and explore different perspectives, and empirical data about challenges and enablers of effective clinical research; and

[1] https://research.uhs.nhs.uk/take-part/about-clinical-research

- Interviews conducted by Transforming Evidence between June-Sep 2024 with eighteen clinical leaders, funders, practitioners, and those involved in the organisation and delivery of care in countries of interest. We spoke with commissioners and service providers from both health and social care, to academics studying research policy, clinical trials and public administration as well as clinical academics working on cancer, and to those responsible for regulation and policy-making for clinical research. Our aim in identifying interviewees was to sample across each of our country settings to learn more about how clinical research is funded, organised and delivered; and also to think about how clinical research is part of a wider landscape of health and social care delivery.

Our aim in Part 1 is to provide an overview of the health services' role in the delivery of UK clinical research, and to identify wider political issues which influence proposed policy improvements to the clinical research environment. We identify policy barriers and enablers to achieving a stronger research culture in the UK health service at a national, regional, and local level, and consider the role played by other sectors, including industry, academia, and charities/foundations. Funders play an important role in enabling high quality research and creating opportunities to improve health and social care delivery (Bruckner et al., 2022, Gamertsfelder et al., 2024, Frick and Helzlsouer, 2024). Their functions include research governance (intelligence, resourcing, relationship management, accountability, and strategy), management (priority-setting, financing and knowledge transfer) as well as ethics, transparency, and public engagement (Smits and Champagne, 2020). Yet, to drive change, funders require – among other factors - a ready and capable research environment; an enabled and willing workforce; organisations with sufficient capacity and strategic direction; and leaders able to direct research.

In Part 2, we examine recommendations from key policy and funder strategy documents about how to improve clinical research in the UK, and five comparator nations. While many stakeholders share a common understanding of the pressures and barriers to good clinical research, there is less agreement about what the potential solutions might be. We examine which recommendations have been addressed, and how, and what alternatives might exist. We also look at issues which are important to clinical research functioning but have not been the focus of strategic actions to date. We asked senior stakeholders within cancer and clinical research networks to the applicability of recommendations across clinical research sectors. Our aim is not to produce yet more recommendations, but to indicate where progress has been made, and identify areas where, in our view, strategic work would be most valuable.

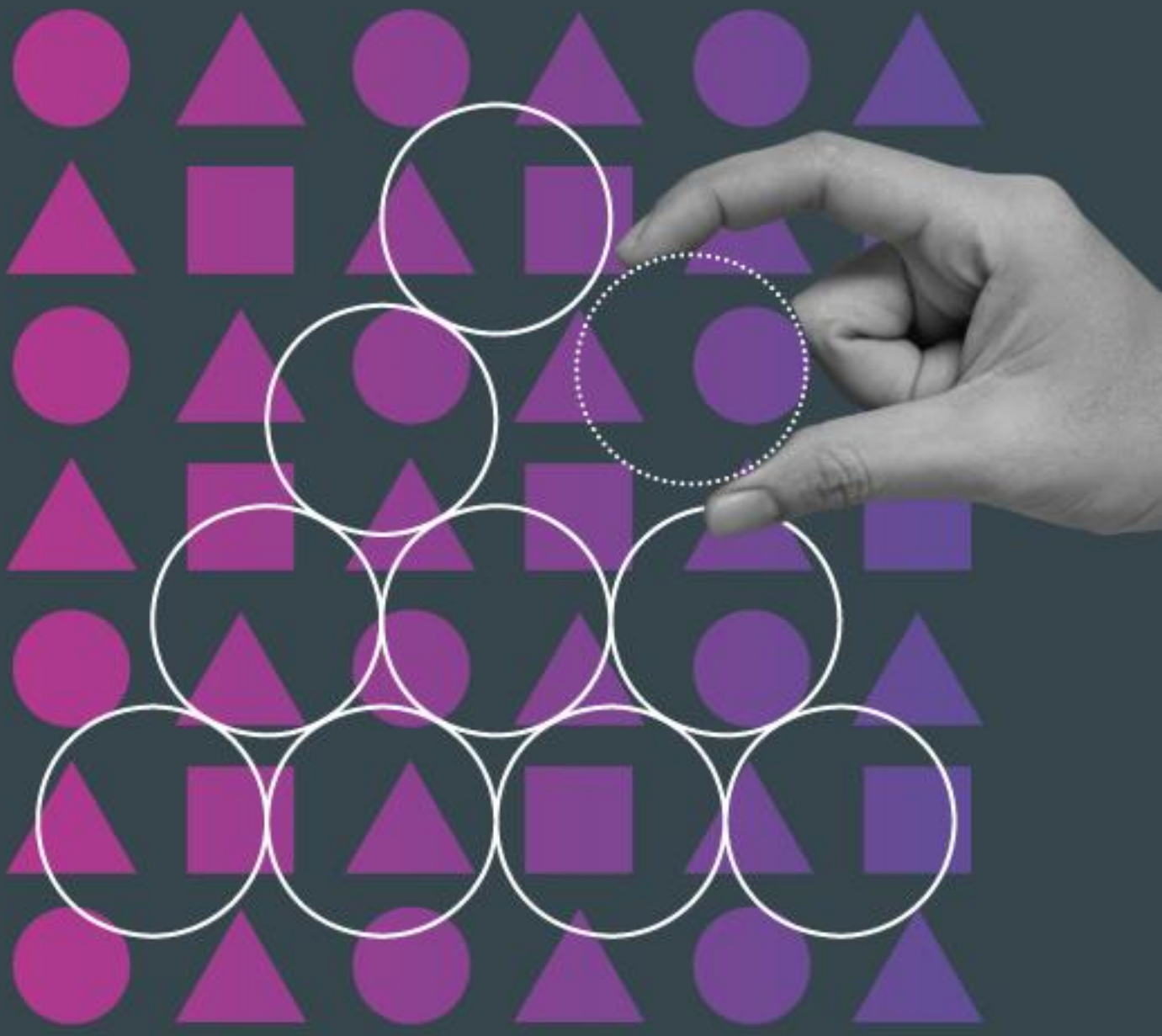
In Part 3 we present country profiles into five country settings: Australia, France, Germany, Spain and the USA. We have chosen these countries as being like the UK in important respects, yet reflecting key differences in how health care and health

research is funded, governed and implemented. All five countries are emerging or established leaders in clinical research, and four have national health systems, from which we can draw comparisons with the UK (ABPI, 2023). For each setting, we mapped the current government structures and processes for clinical research within the UK Government and devolved administrations, and evaluated how cross-sector working operates in the UK compared with these countries.

Part 4 summarises themes across these data, and identifies lessons learned to inform future clinical research policy and action. Across all the settings and countries we explored, we found *consistent challenges* to establishing an effective environment for clinical research. Interviewees looked to the UK as a centre of good practice – citing the high-profile work of Cancer Research UK and the NIHR as elements to be proud of. The key challenges identified included pressures on health and social care systems, limited workforce capacity to do research and the impacts of complex governance arrangements. The interviews, analysis of recommendations and the country case studies didn't contain a single silver-bullet strategy to transform clinical research in the UK. However, they did highlight potential solutions that might be deployed in combination to address key challenges. These included stronger leadership, infrastructure investments, incentives for collaboration (including addressing barriers to data sharing), streamlining governance arrangements and building capacity in the workforce to engage in clinical research. We also saw scope for more rigorous and transparent research prioritisation processes to ensure clinical research is focused in the right areas and mission led approaches to clinical research.

PART 1:

CHALLENGES TO ESTABLISHING A STRONGER RESEARCH CULTURE



Clinical research is an important pillar of all modern economies. Having a strong biosciences sector is important to generate knowledge about new treatment options (Hemmatian et al., 2022). Collaboration between life sciences and effective translational research offers patients access to new therapeutics. A vibrant life sciences community across public and private sectors enables recruitment and retention of a diverse and highly-skilled workforce. Yet, achieving these diverse goals remains very challenging for all the high-income countries we examined.

Across all the settings we explored, we found *consistent challenges* to establishing an effective environment for clinical research, many of which have been long identified in the academic and policy literature (Goodfellow and Mathieson, 2023).

Increased pressures on health and social care systems

The public services of most high-income countries are particularly affected by the trend towards ageing populations, with a longer proportion of life spent with one or more chronic conditions (Ellen et al., 2017). There has been a slow-down in life expectancy and the trend of infant mortality reduction is reversing (Hiam et al., 2020). Many countries have a below-replacement birthrate, leading to lower tax revenues with which to address these pressures. Tackling research, workforce, and budget deficits created by the Covid pandemic remain priorities (ABPI, 2021).

The NHS and social care systems often struggle to recruit sufficient staff to deliver excellent care, with a documented workforce gap of 8% (Lamont et al., 2024). In some places, we heard that core clinical positions remained unfilled due to local factors (e.g. hospitals being very rural and far from urban centres). This reduced the likelihood of patients having access to research studies led by these clinical experts.

Limited workforce capacity to do research

The single most frequently-mentioned factor across interviews and the literature was limited workforce capacity to do research. We heard that all clinical and social care staff are under so much pressure to deliver care, that research itself is often done last or not at all (Mahmud et al., 2018). Practice demands make it difficult for UK clinical academics to prioritise research, and there is evidence of a steady decrease in the number of clinical academics in the NHS (Lechler, 2020). The NHS struggles to recruit research-skilled staff who are often poorly integrated into the university setting. Fewer consultant jobs now ask for PhDs, a trend dating back to the 1990s (Abbasi, 2024). In addition, clinical research requires expertise in IT, logistics, management, clinical

health workforce (Knosp et al., 2022).

Adequate staff time is a necessary pre-condition for patient recruitment, perhaps particularly for minority groups, which may require additional support for trial recruitment (You et al., 2023). In the US and Canada, specialised contract research organisations (CROs) are often responsible for managing patient recruitment. Commentators identified an opportunity to upskill principle investigators in these organisations to meet concerns about ensuring diverse patient recruitment (Symes and Modell, 2020).

Covid further highlighted difficulties for professional staff wishing to build research careers, including limited time and resources, gender imbalance, career precarity and limited training and managerial support (Bentley et al., 2020, Mitchell et al., 2020, Knosp et al., 2022, Sohrabi et al., 2021). We learned that most research funding is made available to medical staff, rather than to nursing or social care stuff, or professional support staff (Schnall, 2024). Covid accelerated experimentation with skills mixing, redeployment, remote working, new clinical pathways (Lamont et al., 2024).

However, we heard that while there is data about workforce capacity, recruitment or retention, it has not been brought together in to show whether these investments are impactful. In general, we found that there was little research about how to help health organisations function well (Lamont et al., 2024). Existing research focuses on staff training and recruitment, rather than on retention and organisational capacity.

Complex governance arrangements hinder research

Clinical research and practice is an extraordinarily complex ecosystem. Analyses of what makes modern health and social care delivery effective increasingly point to the importance of taking a systemic lens. In other words, recognising that for clinical research to have any traction, all parts of the health and social care system need to be operating, and linking with each other effectively. Multiple systems and processes are already in place to provide governance and regulation to clinical research, including:

1. Peer review of research funding proposals;
2. Ethical approval of research;
3. Approval/regulation of medicines and products used in clinical trials as well as approval and licensing of drugs/devices to enter the consumer market;
4. Protection of confidential patient data,
5. Mandated trial registration on a designated trial registry.

We heard that the regulation and management of clinical trials was recognised as essential for quality assurance purposes, but typically a slow, burdensome process in every country we examined – a well-documented problem (Haynes et al., 2010), covering familiar issues such as variability in the interpretation of guidelines and policies, multiple required approvals, and lack of clear responsibilities. We heard that the UK is working hard to rectify regulator challenges, and currently has the second highest number of interventions attempting to improve the clinical trials regulatory environment after India (Crosby et al., 2022).

In the UK, the HRA and MHRA are responsible for providing regulatory oversight and approval of clinical research and medical products. While we heard that they are both operating faster and are more streamlined than they have been previously, they have been affected by high staff turnover, particularly post-Brexit. We heard that both HRA and MHRA feel that recommendations about how they should operate have been conflicting which hampers effective operations. Overall, there are good studies often waiting to start, with skilled staff, but the regulatory burdens still place the UK at a disadvantage.

Overall, trial enrolment is taking longer for all phases in all countries compared with 2019 (IQVIA, 2024a, IQVIA, 2024b), although enrolment duration has been increasing, especially in oncology with a 20% increase in months from 2019-2023. Globally, global trial activity is moving away from Europe (and towards China and North America. European countries with the highest number of trials (Spain, Germany, the UK and France) have all lost relative market share although Western Europe remains the region with the highest relative share of country-users (dropping from 32-25% over 5 years). Governance and regulation are recognised as an issue requiring global collaboration and leadership to solve.

A lack of evidence to support the system

There is a growing acceptance that to work effectively, evidence and research needs to be embedded within the system at all levels (Olsen et al., 2007). We have found that frequently, commentators identify mismatches between what health care research systems need, and what is delivered.

Research funding for health conditions does not always address the health conditions or their related side effects that are priorities of patients, professionals, or health managers (Saylor and Joffe, 2024). Studies have found that health research funding is not well aligned with the burden of disease (McIntosh et al., 2023, Gilbert et al., 2021); for example, more funding is devoted to fatal diseases, rather than on conditions and topics with the biggest day-to-day impact on health services, professionals and patients

such as headaches and migraines. Similar patterns can be observed in cancer research, with a large percentage of cancer studies and trials focusing on drug therapies and understanding cancer biology and aetiology, with fewer resources devoted to understanding how cancer patients can navigate day-to-day complexities such as housing, mobility, and other social issues (Schmutz et al., 2023, Abudu et al., 2021).

Clinical trial results may not be representative of treatment-seeking populations (Bower et al., 2020). Minority groups are often excluded from or under-represented in trial populations, both in the UK and abroad (Symes and Modell, 2020, Lopez et al., 2024, You et al., 2023, Abel et al., 2023, Gu et al., 2024). In the UK, and overseas, research funding is disproportionately allocated away from underserved communities, with richer, healthier populations having more research participation opportunities (Lopez et al., 2024, Feyman et al., 2020, Caston et al., 2022). This trend is exacerbated by difficulties finding under-represented physicians and trial investigators to pursue trials in diverse populations.

Research, industry, clinical, and patient research agendas can compete with one another for financial, staffing, and institutional resources (Saylor and Joffe, 2024). Clinical research can be established in three main ways: 1) through academic-led clinical research, which predominantly addresses researcher's priorities and can be subject to academic pressures to demonstrate scientific impact through impact evaluation activities such as the REF and funded through government, university, or charity/non-profit funders; 2) through commercial research, which commonly tends to prioritise research with the greatest potential for commercial profit; and 3) mission-oriented research, often set-up by governments and funders to centralise funding missions and strategies and steer progress in a targeted direction, such as the UK Labour Government's 2024 Health Mission, the EU Mission on Cancer in Horizon 2020 (Celis and Ringborg, 2024), or the Biden Administration's Moonshot to reduce cancer mortality by 50% by 2025 (Arteaga et al., 2023). These are increasingly seen as essential to help prioritise research, and pool limited resources across regional and national boundaries to deliver the research which is needed (Bhattacharya et al., 2021, Berns et al., 2020).

However, overall, there has been a reduction in funding available for health research. The UK Clinical Research Collaborative, which surveys health research funding for 173 public and charity funding organisations in the UK has observed "14 years of near flat funding from 2009/10 to 2022", and "a small but worrying real-terms decrease in health research funding between 2018 and 2022" (p.8) (UKCRC, 2023). This decrease comes from an observed reduction in indirect research funding that supports infrastructure and training, rather than direct research funding. The decreasing trend is most apparent among UK health charity funders: the UK CRC notes there was a loss in real terms of £208m from 2018 to 2022 (UKCRC, 2023) – likely due in part to the Covid-19 pandemic

(Griffiths 2020). Most published trials globally are supported by government (public) funding or not-for-profit trusts – particularly in cancer research where not-for-profits take a substantial role (Schmutz et al., 2019). Many countries have seen a small but steady decline in the proportion of commercially-funded studies taking place in their country (Burciaga-Jimenez et al., 2022).

Within this complex landscape, individual health and social care research organisations need to balance their own service delivery needs with other priorities, including staff training and retention, patient experience, and – often at the end of the list – research activities. The unanswered question is: what are the goals of the health and social care system, and how might research outputs and research activity help deliver them?

Sharing data, workforce capacity and infrastructure is too difficult

Funders enable creation and support of crucial research infrastructure and assets (Sudlow, 2024). These include, for example; national registries for clinical specialities, enabling analysis of career pathways and resource usage (Salluh et al., 2024); public laboratories to address questions of national priority (Hemmatian et al., 2022); data assets and national strategic resources such as Genomics England (McKibbin and Shabani, 2023); innovation hubs which focus on "incubating, developing or accelerating" products and services (Cresswell et al., 2020); journals and data repositories to support reproducible research practices (Bergeat et al., 2022); and clinical research networks, which enable multi-site collaboration around patient recruitment (Williams et al., 2022). Digitalisation, data storage and data tools are the focus for much commentary (Zayas-Caban et al., 2020). The US and the UK have strong national digital health systems strategies, which has led to increased investment, reflecting a strive for a stronger pool of professional expertise (Cresswell et al., 2020, NIHR, 2024c).

We found that investment in this type of infrastructure was very important. The US, China, France and Germany have all increased this kind of investment over the past decade, and particularly since stimulated by the Covid-19 pandemic, which raised scrutiny around the value of public R&D. Covid also reaffirmed for many nations the importance of international collaboration around therapeutics, requiring good data on where research and treatment infrastructure needs strengthening as well as good leadership (Collins et al., 2023).

Funders can incentivise good practice across the system through policies around data sharing, trial registration, open publication (Knowles et al., 2020, Bruckner et al., 2022), and support and monitoring of grantees. However, research in the US, France and across Europe suggests that funders do not always mandate best practices in data

sharing, and there is often low compliance with existing policies that could support increased transparency in data sharing and grants and trial management (Rollando et al., 2020, Knowles et al., 2020, Gamertsfelder et al., 2024). This limits the ability of funders to allocate funding in a transparent way: an essential component of effective health systems (Meadmore et al., 2020). Funders need data and tools to conduct effective programmatic review, which ought to help research planning; however existing tools are usually relatively blunt and unable to accurately surface sunk costs, return on investment, or opportunity costs (Frick and Helzlsouer, 2024).

Investment is not a straightforward recipe for success. Translation of research into innovations in service and delivery can take years, if not decades (Hanney et al., 2006). There is a lack of research about the effectiveness of innovation hubs and public laboratories in general, and a recognition that an increase in funding does not lead to an increase in supply of useful outputs in a linear fashion (36). It is also clear that the metrics used to measure performance of these different components (e.g. start-ups, universities, public labs) often mitigate against collaboration and effective systems working. For example, it is difficult to know how to balance potential workforce interest in start-ups and commercial spin-outs, which may be able to better attract a younger skilled workforce, with their relative likelihood of delivering high-quality research on par with a university-led research institute 67). Regulation and monitoring of collaboration opportunities is at times burdensome and can fail to generate more effective collaboration and competition.

The system is not incentivised to work together

Effective health systems try and improve at "individual (e.g., knowledge and skills), organisational (e.g., organisational governance arrangements, resource environments and management approaches) and network (e.g., interorganisational relationships and network-level communication and engagements) levels" (Mirzoev et al., 2022). Leadership of these 'learning healthcare systems' is no easy task but is critical to bring together knowledge about these different components (Hanney et al., 2020). This is particularly crucial when considering how to introduce and modernise health care systems which have been historically over-stretched, fragmented, are culturally risk-averse, and have poor data assets and/or data capabilities (McMahon et al., 2022).

Cometto and colleagues (2012) characterise effective health systems as those which deliver compassionate and quality care, through: advocacy and accountability mechanisms, curricular and licensing requirements, regulation mechanisms, appropriate and manageable workloads, improvements in clinical care, supervisory systems, training and mentoring, continual professional development, and individual incentives (Cometto et al., 2022). The stakeholders implied by this list of mechanisms

span the private, commercial, and public sector, and are involved in knowledge generation, clinical practice and regulation, a diverse and complicated web of co-dependencies. Understanding existing relationships between components within these systems offers ways to simplify and streamline research governance and delivery.

Finding ways for costs to be estimated, shared and planned at the system level is currently very difficult. Research activity in one site can actively harm care in another through reducing staff capacity; equally cost savings may be created through activities in one setting but realised in another with an entirely separate budget. In interviews, we heard that clinical researchers who do manage to win research funding often see that budget disappear into the overall practice budget, with no ability to reinvest in research staff and infrastructure. Thus, clinical trials units and many other clinical settings are in the position of having to balance fiscal viability and their ability to do high-quality research (Bentley et al., 2020). This leaves them vulnerable to doing research which does not necessarily benefit local populations and has perverse knock-on effects.

In summary….

Consistently identified challenges included:

- Increased pressures on health and social care systems, including ageing populations, increasing multimorbidity, workforce recruitment and retention,
- Limited workforce capacity to do research
- Overly complex governance arrangements for clinical research, mitigate against effective systems functioning,
- A lack of relevant evidence to support an effective health research system.
- Sharing data, people, and infrastructure is too difficult
- Components within the system are not incentivised to work together

PART 2:

WHAT'S BEEN RECOMMENDED, AND WHAT RESPONSES HAVE BEEN MADE

Policy recommendations can only be successful at enacting meaningful, on-the-ground change, if they are accompanied by specific and actionable plans for implementation. Implementation plans should include details of the roles and responsibilities of organisations participating in each recommendation concrete and measurable actions that can be taken by each party, and a timeline for activity completion. These plans are valuable if designed with an evaluation plan in mind, so that implementation progress can be measured and held accountable. Implementation guidance for recent UK clinical research recommendations is currently limited: not all published recommendations are feasible, many may overlap, and most lack attached funding and a dedicated plan for implementation and evaluation (HMG, 2022).

This means that while reports on the state of the sector may enjoy visibility among clinicians and policymakers, reasonable next steps for action and identifying who should take on these next steps remains unclear. As the UK seeks to better understand how to implement the proposed policy recommendations for clinical research, it may choose to examine how other countries have handled similar political, economic, and competitive pressures to maintain and grow a successful clinical research environment. In this section, we assess progress to date across existing recommendations to improve the clinical research environment in the UK, drawing on learning from overseas.

We analysed 20 documents from government, charity or professional associations to identify: 1) recommendations for the UK clinical research environment; 2) plans for implementation of such recommendations; or 3) progress made against such recommendations. Of these reports, three focused on plans for implementation of clinical research recommendations: the Future of UK Clinical Research Delivery 2022-2025; the Northern Ireland Implementation Plan for Clinical Research, Recovery, Resilience and Growth; and Research matters: our plan for improving health and care research in Wales.

We found over 200 individual recommendations contained within these reports, with many echoing each other. Each report tended to engage with different sets of stakeholders as they identified recommendations, suggesting that while there is broad consensus for action these recommendation-building activities are not being conducted in strategic alignment.

To conduct our analysis, we compiled a list of all recommendations from each of the 20 documents and noted the type of document they came from (a document issuing recommendations, a document indicating plans for implementation of one or more recommendations, and a document reporting on progress made on the implementation of such recommendations). We then organised recommendations into themes. For each theme we grouped recommendations into subcategories and tallied the number of documents that had issued one or more recommendation in each subcategory. Finally,

we provided a colour shading to indicate if any of the recommendations were in-progress:

- Shaded rows, used to indicate where an implementation or a progress document discussed the recommendation subcategory
- Non-shaded rows, used to indicate where no implementation or progress documents discussed the recommendation subcategory.

Our full methodology for the recommendations analysis can be found in Appendix 2. A detailed recommendations table that lists specific recommendations for each theme and subcategory by document is available in Appendix 5.

An overarching theme of this analysis is that many more recommendations have been produced than have been implemented or have associated plans for implementation. Indeed, interviewees expressed "recommendation fatigue" – the sense that there were so many recommendations being produced by different organisations that it is was difficult to know where to begin, and concern that these documents, mostly without associated plans for implementation would be unlikely to get off the ground.

1. A research-ready NHS
2. Incentivising and enabling a research-active workforce
3. Creating the right data infrastructure
4. Improving how clinical trials are set-up and run
5. Making the most of commercial investment
6. Funding the right research for the UK

In the sections below, we present relevant recommendations under each theme. We describe progress to date in the UK and explore ways our comparison countries have tackled these issues. Rather than offer further recommendations for practice, we summarise outstanding opportunities for strategic action.

1. A research-ready NHS

The first theme that emerged from our recommendation analysis was the importance of building a research-ready NHS, designed to embed and employ research at all levels of the NHS – from contacts with primary care to participation in NHS-led clinical trials. Recommendations in this theme focused on; 1) performance metrics; 2) public engagement, clinician engagement and patient recruitment; 3) building capacity; 4) access to medicines and technology/Delivery of Care; 5) coordination/collaboration; 6)

finance; and 7) accreditation for research.

Table 1. Recommendation Topic Areas for Theme 1:
A Research-Active NHS

Topic area	# of docs
Performance metrics: metrics for NHS research engagement and impact	9
Build capacity: invest in local capacity; invest in workforce capacity; build capacity for services and resources; central fund essential radiotherapy for clinical trials capacity	7
Public engagement, clinician engagement and patient recruitment: public campaigns to enhance research engagement; support researchers as they involve the public; provide a common approach to contacting patients and use an innovative approach through data; local NHS R&D offices should survey research awareness and activity of staff; consider EDI and PPI	6
Access to medicines and technology/Delivery of Care: access to medicine post EU exit; access to medicines following trials; access to vaccines; improve delivery of cancer care	5
Coordination/collaboration: study collaboration; collaboration between academia, industry and NHS	2
Finance: develop better models for transferring funds between NHS bodies	1
Accreditation for Research: national accreditation for radiology, radiotherapy and laboratories	1

Overall, we heard from our UK and international interviewees that the NHS is considered a very good place to do research. It was felt that the UK has many useful mechanisms to enable research to be embedded successfully in the NHS. These include the presence of a national funder dedicated to applied research (NIHR), research capacity-building and training; the Royal Colleges and Faculties who advocate and plan for workforce recruitment, training and retention; and the ability to create job plans for (mostly medical) practitioners which have research time built in. These mechanisms were not typically present in our comparison countries, and international interviewees and data highlighted their existence as an advantage for the UK. However, we should note that these were described as levers which could be pulled, rather than as

mechanisms operating at maximum impact.

We found that recommendations about *Performance metrics*, appeared in 9 of the 20 documents. In response to the O'Shaughnessy Review, the UK government has begun posting the UK Clinical Research Delivery Performance Indicators Report monthly, which highlight nine UK-wide key performance indicators, such as "proportion of open studies on track, delivering to time and target" and "be part of research monthly registrations". While these provide a high-level snapshot of UK clinical research activity, we heard both that these UK-wide indicators are quite broad and that more targeted KPIs would be helpful, that there were few suggestions or consensus about what additional metrics would look like. Although a popular topic, we found that this national effort had not resulted in funders, trusts, or delivery settings instituting KPIs to measure or incentivise research activity or engagement. In our interviews, we heard that there were too many other pressures on practice settings for current research metrics to have any traction; and that research time and activity was therefore always the first to be squeezed and the last to be prioritised. There still seems to be limited progress making research activity a priority for NHS trusts.

Building capacity was an equally common theme amongst recommendations. In Spain, they have independent not-for-profit foundations to facilitate research activities on behalf of hospitals. These external foundations used to facilitate research activities could alleviate some of the workload burdens of NHS Trusts, as well as provide visibility to key research staff at the Trust-level. However, separating research and clinical activities in this way has costs, as well as benefits.

Recent announcements by the Department for Health and Social Care indicate how seriously they are taking this issue, with £300m announced in July 2024 to support clinical trials centres across the UK[2], creating sustainable infrastructure and enabling a more productive environment to get research up to speed when new projects start. Specific examples of research capacity-building mentioned by interviewees included investment towards local NHS capacity, improving access to medicines which has been affected by Brexit and related supply-chain issues, and radiotherapy and imaging capacity. Overall, interviewees felt that the UK had an advantage with NIHR able to fund a workforce sustainably, rather than relying on a tariff per patient or a standing charge per study as was the case elsewhere.

Although most recommendations focused on performance metrics and capacity-

[2] https://www.nihr.ac.uk/news/nihr-welcomes-ps300m-investment-clinical-trials-infrastructure-bringing-new-medicines-patients-across-uk

building, we found most progress had been made on *public and clinician engagement with research*. There has been significant work to involve the public in research design and planning with funders, and to raise awareness of research improving patient recruitment rates (e.g. the Be Part of Research App). However, while bringing patients into research is always present in recommendation documents, organisations vary in their ability to do this well, creating inequities in patient access to research. We heard that that there was a real opportunity to build on the public's interest in research heightened during Covid but that more work is needed to develop impactful narratives for connecting patients to research. There are ongoing public consultations on proposals for legislative changes for research including public involvement, patient recruitment are ongoing across the devolved nations, with Wales particularly active.

Access to medicines and therapeutics is often mentioned as a benefit of research participation, as patients gain access to otherwise unavailable therapeutics. We heard that again, Covid had demonstrated that participation in trials enabled patients nation-wide to access important treatments, often more swiftly in district general hospitals than in the larger teaching hospitals. We heard that for many clinical researchers, patients having access to cutting-edge research should be seen as a normal part of clinical care, to enable access to drugs which were otherwise unavailable. This was predominantly a theme amongst interviewees from countries where public health care systems did not have an evidence-informed health care rationing service such as that provided by NICE.

Coordination and collaboration came up as a theme in nearly every interview we conducted, although only two recommendation documents tackled this issue. We heard that the research environment within and around the NHS was a very busy space. Fragmented and distributed research portfolios increase the cost of doing research, and lead to small, low-powered trials and studies which often struggle to recruit effective numbers of patients. We learned that piecemeal research funding creates an unstable career pathway for researchers, limiting capacity.

Financing research is (another) complex issue. Before the reforms of the 1970s and 1980s, the NHS had protected research budgets to pay for long-term research staff and support. Finally, we heard that the Covid crisis precipitated work on accrediting clinical research, needed to train and develop the competencies of the workforce assuring high quality work (Lemaitre et al., 2021).

2. Incentivising and enabling a research-active workforce

The second theme was around envisioning a modern, research-ready workforce and

specifically considering what steps should be taken to incentivise and enable a research-active workforce, which fell into six groups: 1) dedicated staff time for research; 2) training and career pathways; 3) equality and diversity issues; 4) long-term workforce plan; 5) staff recruitment and retention; and 6) immigration.

Table 2. Recommendation Topic Areas for Theme 2:

Incentivising and enabling a research-active workforce

Topic area	# of docs
Training and career pathways: develop new pathways for training; increase access to training; new fellowship opportunities; create infrastructure for training; strengthen role of research as part of revalidation requirements	12
Dedicated staff time for research/raising the visibility of research within the NHS: funding time for research; job-type specific recommendations; strategies for success	11
Equality and Diversity Issues: collect data to improve EDI; provide support for EDI	5
Staff recruitment and retention: increase funding; develop new strategies; improve data collection	4
Long-term workforce plan: utilise the current long term workforce plan and plan for the next one	3
Immigration	1
Training and career pathways: develop new pathways for training; increase access to training; new fellowship opportunities; create infrastructure for training; strengthen role of research as part of revalidation requirements	12

Despite repeated concerns from interviewees that the UK clinical workforce is under significant pressures to deliver care and conduct research, we found that internationally, the UK is well regarded for its clinical research. Environmentally, challenges were common across all the countries we examined, with workforce issues and resourcing of everyday practitioner pressures particularly affecting the UK. In terms of workforce size and capacity, the UK is in a strong position but sometimes fails to make the most of existing skills and mechanisms, although since Brexit there had been a steady reduction in the number of international clinical staff, and many trained

doctors and other health professionals have left the UK.

Twelve recommendation documents discussed *training and career pathways* to improve workforce capacity, and eleven documents discussed ways to enable dedicated research time for staff. Within the implementation documents in the analysis, we found less discussion about plans for future work that would address recommendations about EDI, recruitment and retention, a long-term workforce plan, or immigration. We found two documents which reported that some progress had been made in the UK in the form of new strategy documents to link non-research staff with opportunities to link patients to research, a research strategy for allied health professionals, a NHS England strategy for research for nurses, new data collected to understand the scope of the nursing and midwifery profession, and professional accreditation schemes for clinical research practitioners and associate principal investigators. Unlike some countries, England, Wales and Scotland have a mechanism to dedicate clinical time to research through allocation of supporting professional activities (SPAs) in job plans, often individually negotiated. National guidance about SPAs and performance frameworks for all staff involved in research would help to embed research more effectively in normal practice. Flexibility between clinical work and academia should include better integration of research into NHS organisations (BMA, 2024).

Evidence from the literature suggests that finding opportunities for those at the beginning of their careers increases the likelihood that these staff remain research-active through their careers (Heggeness et al., 2023). However, teaching and management career pathways are much more clearly articulated and supported by professional bodies such as the Royal Colleges. Creating a similarly articulated and accredited scheme for a wider range of health and social care research careers would be welcomed (Faulkner-Gurstein et al., 2019). Trainees were supported by academic faculties, but largely around teaching-based or management-based careers, rather than academically-focused careers.

The role of universities was important here in training medical staff, but interviewees felt that universities could do more to support flexible exchange between practice and academic settings. Several new fellowship schemes have been recently introduced for clinical staff, such as the HEE/NIHR Advanced Clinical and Practitioner Academic Fellowship (ACAF) Scheme, which replaced the Clinical Senior Lectureship scheme in 2022[3] and now "includes salaried clinical service or practice time to help embed clinical/practitioner academic roles within organisations". International fellowships are

3. www.nihr.ac.uk/news/nihr-announces-changes-integrated-clinical-and-practitioner-academic-ica-programme

seen as a way for clinicians to develop their research and clinical practice, but – particularly since Brexit- these were increasingly rare and difficult to manage. The recently launched Health and Care Research Wales Faculty[4] may be a good program to scale nationally through its aims to provide coordination and oversight of research award schemes, monitoring of EDI across research careers, and training.

We heard from our interviewees that there was significant appetite for portfolio careers bridging practice and research, which improved morale and retention. This was the case for international interviewees too. In Spain, we heard that there was a very limited career pathway for clinicians' post-qualification, so research offered a way to gain increased recognition and status. We learned that people able to work in multiple settings tend to be more innovative, and have better interpersonal skills (Cresswell et al., 2017).

University- and funder-led opportunities for non-medical staff (including nurses, allied health professionals, social care professionals, biomedical scientists and technicians) are much more limited (Schnall, 2024, Hays and Beverly, 2021). These professionals tended to be poorly represented in comparison with medical staff in policy debates, although the NIHR is increasing its capacity-building initiatives within these sectors – although a new project in Wales is aiming to develop an action plan to increase research capacity and capability across the allied health professions, nursing and midwifery.[5] We heard that there was an opportunity to think about the skills mix available to health and social care settings, and potentially new types of roles such as research nurse practitioners. These non-medical staff need more training in research capabilities, as well as leadership and induction in to effective health care systems (Hays and Beverly, 2021). All of this is predicated on having sufficient practice staff to deliver excellent care, which is the bedrock for quality research.

3. Creating the right data infrastructure

The third theme focused on creating the right data infrastructure to enable a research-ready NHS. (NB: public trust in data and usage is addressed in theme 6. Key investments have been made to support NHS health data infrastructure, with the data strategy for Health and Social Care England published June 2022 (DHSC, 2022) and the recent Sudlow review found that there is great potential in the existing data assets held

4. healthandcareresearchwales.org/faculty

[5] https://healthandcareresearchwales.org/health-and-care-professionals/priority-project

across the four nations. However, overall, this was an area with limited progress.

TABLE 3. RECOMMENDATION TOPIC AREAS FOR THEME 3:
Creating the right data infrastructure

Topic area	# of docs
Infrastructure and technology development: ensure the UK's health data offer is globally competitive; improve infrastructure; eliminate infrastructure maintenance backlog; better utilise infrastructure; use and develop new technology to improve research capabilities	7
Data system governance: improved data management and governance; partnerships for data access	4
Performance metrics: develop performance metrics for infrastructure	3
Databases and datasets: recommendations for the EDGE database in Scotland; better use of data/research delivery enabled by data and digital tools; data for participant recruitment and engagement	3
Genomic data for research	1

We heard that internationally and in the UK the importance of having a globally-competitive health data offer to enable high-quality research by both public and commercial partners is well recognised. For example, the US allocates $14.9 billion to public labs with 141.5bn in total, and the NCI has recently announced a new deputy directorship for Data Science and Strategy (NCI, 2024). The French National Centre for Scientific Research (CNRS) is made up of 10 research institutes and receives 80% of all public R&D funds from gov (i.e., centralised and concentrated). Germany has federal and state sponsored labs: Helmoltz Association of German Research Centres, Max Planck and Fraunhofer Institutes (decentralised and distributed). China is currently going from 200 to 700 national labs administered by the Chinese Academy of Sciences (Hemmatian et al., 2022). A good data environment is likely to improve the speed and quality of care and improve research (Leon et al., 2020). Better data would enable more effective portfolio review, reducing the duplication of research and waste in the current systems globally (Arteaga et al., 2023). Using these assets can be tricky; Internationally seen as unique and valuable resources, interviewees were sometimes surprised to learn that their mandates were more limited in scope. We learned there was limited development of laws to enable international collaboration or manage asymmetric access to these resources (McKibbin and Shabani, 2023).

There is an opportunity to think more about how to digitalise clinical trials. At present,

different trials use different interfaces and software, which create unnecessary barriers to research participation. Covid provided a strong impetus to think through how to enable collection of structured, patient reported outcome data and aggregating across sites, to support more pragmatic, large-scale trials (Richesson et al., 2021).

In the UK, sites, sponsors and funders have access to and shared different trial data. In Spain a different approach had been taken to bring all three stakeholders together in a twice-yearly meeting to ensure data comparability and compatibility. This requires coordination and investment of people's time and resource but is necessary to generate useful data. We heard that the UK government views the transparency and usefulness of data as a real priority and publishes a monthly UK Clinical Research Delivery Monthly Performance Indicators Report[6] to track progress of KPIs outlined in the O'Shaughnessy Review on a national platform. The Sudlow review also indicates that more coordination and joint working would allow data access to be streamlined, and improve standards and use (Sudlow, 2024).

Internationally, this is a growing trend, as trials using secondary data to identify and recruit patients, or to explore clinical outcomes can be much larger and cheaper than standard studies (Horvath et al., 2017, Inan et al., 2020). The German National Tumour Centre Network is developing a single data platform to share research and clinical data. Commentators flag the potential for AI in harnessing real-world data (Arteaga et al., 2023). However, increased technology use will require upskilling the workforce and providing appropriate equipment. Additionally, electronic health records need standardisation (around data collection and quality assurance) to be useful (Richesson et al., 2021).

Significant investments and strategies have been produced in recent years, including NHS DigiTrials and digital platforms for Be Part of Research and NIHR BioResource (Boutros et al., 2024). Data assets like Genomics England are seen as a valuable and unique resource for the nation. We heard that internationally, the perception is that the UK clinical research workforce is not currently maximising the potential contribution this and other assets such as national clinical registries could make to the UK's research profile (Salluh et al., 2024). As one interviewee put it, "I haven't seen a [] coordinated integration of national genomics initiatives with clinical trials activity and pharmaceutical development".

Health data is frequently collected but needs to be made visible and accessible. One

6. www.nihr.ac.uk/thefutureofukclinicalresearch/home/news-updates/performance-indicators-report

useful example was the SAIL databank in Wales, which holds pseudo-anonymised NHS records and is available to swiftly estimate patient group size and disease burden. Wales is working to connect this with NHS Digital and support a workforce to maximise the value, thinking through the workforce implications. For example, if a potential trial population could be identified through the SAIL database, patient contact and recruitment would likely be done by GPs.

The UK encourages the collection of race/ethnicity and SES data from trial participants but does not have policies in place to mandate this data collection, which is bring considered in the USA.. Enforcement of data collection could improve patient enrolment from diverse populations and ensure that UK clinical research is beneficial to all patients. NIHR's current Research Inclusion Strategy is currently focused only on collecting diversity data grant applicants (NIHR, 2024d). Other European countries in our sample struggled with this issue as well. Australia has recognised this issue as a key opportunity for improving diversity and inclusion in trials and their trials registry, the Australian New Zealand Clinical Trials Registry (ANZCTR) is "scoping options to capture data on sex and gender diversity in a standardised way" (Seidler et al., 2023).

In 2023, Wales launched Treialon Cymru[7] to "provide opportunities across the whole of Wales for people to engage in trials". This allows a national discussion bringing together trial staff and stakeholders together, bridging across silos, and has resulted in two NIHR/UKRI submissions per year for large scale clinical trials in high-priority areas within Wales, two cohorts per year of associate members, to link people working in Welsh health and social care to a clinical trial unit to provide learning experience and monthly virtual and regional in-person events that provide information sharing about trials . However, while a beneficial strategy for Wales, devolution of healthcare in the UK may have led to fragmentation and differences in approaches and priorities.

We also learned that there are opportunities to think about data infrastructure as it relates to data on the clinical workforce and how individuals progress within various career pathways. We learned that some countries such as Sweden have much better data and registries about clinical workforce and career pathways (Lamont et al., 2024), giving them better information for workforce planning and forecasting.

Covid-19 demonstrated that innovative agreements around data-sharing could be mobilised at speed. The RECOVERY trial showed that regulations could be lifted without increasing risk to patients or professionals, although many of the benefits do not seem to have been sustained. Pragmatic trials do require a workforce to manage and run

[7] https://www.cardiff.ac.uk/centre-for-trials-research/about-us/treialon-cymru

them (Parker et al., 2024). Recognising that many of regulatory barriers to data sharing are in place for ethical and privacy-related reasons, Wales has been engaging in public consultations around the use of health data and public willingness to use health data to identify and contact patients for research. Wales and Northern Ireland are exploring longer-term solutions around expanding secondary-use legislation for data sharing/patient identification for trials. In the US, permits have been altered enabling waived consent for pragmatic trials where there is minimal risk (e.g. ongoing practice) (Symons et al., 2020). Internationally, we heard there was an appetite for cross-border agreements on the ethics of data use, especially secondary data use which is becoming more important for e.g. pragmatic trials (Symons et al., 2020, Richesson et al., 2021). Australia and Ireland have recently successfully worked together to adapt frameworks for health and social care data.

Finally, we observed that there are opportunities for funders and publishers to play a larger role in the conversations around infrastructure and information sharing in clinical research. Funders could encourage open data sharing and publication, but do not always do so (Bergeat et al., 2022, Bruckner et al., 2022)– although this seems to be changing (Rahaman, 2023). NIH and NUMH policies in the US were particularly identified as burdensome for researchers but may improve transparency and reporting (Kane et al., 2021). While increased compliance with data sharing provisions could add to clinician, funder and publisher workloads in the short-term, these initiatives offer the promise of greater transparency and improved facilitation of research in the long-term.

4. Improving how clinical trials are set-up and run

The fourth theme that emerged from our recommendations analysis focused on improving how clinical trials are set-up and run across the UK. Recommendations emphasised a preference for novel, innovative ways of working that tried new methods and data sources to achieve goals (AAMRI, 2021). Across all 6 themes, this is the area where most progress has been reported (as evidenced by the UK Clinical Research Delivery KPI reports). Despite increased activity addressing this theme, there remain outstanding questions about the overall comprehensiveness and utility of focusing on clinical trial reporting as means to measuring progress within the overall clinical research landscape.

Table 4.

Improving how clinical trials are set-up and run

Topic area	# of docs
Set-up: improve the speed and efficiency of study set-up; address	10

Topic area	# of docs
prioritisation and capacity; commission on sustainable biomedical research; reverse the decline in industry clinical trials	
Costing and contracting at the trial level: mandate a single negotiation and sign-off process of costing and contracting to improve trial set-up; incorporate best practices from the NCVR; review and improve study costing processes and timeline; develop Scotland cost-savings	5
Performance monitoring/portfolio management: develop performance indicators for trial performance and access to care in trials	4
Patient recruitment: pathway from genomic testing to trials; recruitment should harness data; common framework for approach; establish targets	4
Regulatory/governance: new operating model; updated guidance; collaboration; develop a new centralised approach research governance in Northern Ireland	3
Registries: develop new national registries; improve usability of existing registries	2
Networks: clinical trials accelerator networks; primary care research networks; use NCRI networks; build strong highly coordinated strategic partnerships across the whole research community	2
AI: government and regulators should develop a strategy for the use of AI in clinical trial design and regulation	1

We learned that there have been significant efforts to reduce the regulatory burden that can hinder clinical research (GCSA, 2023); and streamline the administrative bureaucracy to enable researchers to address identified health issues more rapidly and responsively (van Teijlingen et al., 2008). In fact, the UK Clinical Research Delivery program states that the sector "is no longer in recovery, given huge progress with:

- Global and European 'Firsts' provide an indication of an agile and efficiently running clinical trials system characterised by streamlined set-up and recruitment processes. In 2023/24, the NIHR achieved 2.5 times more 'First Global/European Patients' than the year before.
- Studies are back on track. The proportion of studies on the NIHR portfolio

delivering to time targets is in line with our KPI target of 80%.

- Recruitment is buoyant. Overall recruitment, and recruitment into commercial contract studies on the NIHR Portfolio continues to exceed pre-COVID-19 levels.
- NHS Contracting has been standardised. The UK has introduced the National Contract Value Review (NCVR) which standardised processes for costing and contracting. 100% of NHS trusts in England accept the local price generated as part of the NCVR process for late-phase studies without further negotiation following resourcing agreement by the lead site.
- Regulators are on target. The Medical and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) are broadly delivering combined review within the 60 day target set out in the UK Clinical Research Delivery Performance Indicators Report and backlogs have been cleared." (HMG, 2022)

Although the UK may no longer be in a state of clinical trial recovery, there are ample opportunities to strengthen the systems involved in trial set up, approvals, and portfolio management. Indeed, this remains a common scenario worldwide. All countries in our sample reported challenges navigating complex domestic and international protocols for clinical trial set up, approvals, and ongoing management. In addition to the national level approvals that trials must achieve, sponsors must navigate a complicated landscape of local site approvals for each hospital/clinical site/university that is participating in the trial. Additionally, trials face lengthy approval processing times, which can ultimately delay patient opportunities to participate in potentially lifesaving clinical research.

Governments and agencies are all aware of this issue and are trying different approaches to tackle this problem, including:

- In the UK, a large new investment of £300m has been recently announced, which will increase the available trial infrastructure in the UK (ABPI, 2021, ABPI, 2024a). This investment will help develop twelve regional commercial delivery centres for fully funded commercial trials and supporting non-commercial studies, as well as funding for hospital-based pharmacies, via a 5- year VPAG agreement. These new commercial research delivery centres will provide infrastructure, facilitate single contracting and provide a chance to upgrade clinical equipment and research facilities. Similar initiatives for non-commercial trials could be transformative.
- Germany has recently passed legislation to standardise research contracts to speed up ethical and regulatory approvals and introduced approval by single ethics boards rather than regional ones for multicentre studies.

- The Australian Clinical Trial Alliance (ACTA) aims to improve clinical trials, Solving this issue has been a government priority, and the development of the National One Stop Shop has been envisioned as a solution that will simplify regulation and funnel all trial approval processes through a central virtual processing centre. This will provide a single portal for handling clinical trial documents for registration, ethics and regulatory approval. However, while a central ethics approval can occur, the regulatory approval for each site has been harmonised rather than centralised.
- The US Advancing Clinical Trials Readiness project, launched in 2023, through the Advanced Research Projects Agency for Health (ARPA-H), with the goal of enabling "90% of all eligible Americans to take part in a clinical trial within a half hour of their home" (ARPA-H, 2023). This project will involve stakeholder outreach and planning to "build faster, less expensive trials with decentralised processes".

Within the UK, the MHRA and HRA are working much more efficiently, although a long-term solution may still be in development. Following the O'Shaughnessy review, trial metrics and automatic trial registration are being implemented. Internationally there was a perception that the UK regulatory bodies needed more effective data generation about trial performance from NICE.

Ethical approval for clinical research typically takes place at local or regional levels for each country in our sample; sponsors are directed to seek ethical approval from the review site closest to the site of the trial. In the United States and Germany, multisite clinical trials require ethical approval for each participating site, which can add significant burdens (time, money, coordination) to sponsors running multisite trials, as the processes and protocols for ethical approval can vary within and between countries. A common European ethical and legal framework for conducting clinical research would be valuable.

In contrast, the United Kingdom, Australia, France, and Spain have adopted unified approaches to multi-site ethical approvals taking place within the country. Multi-site trials with led by England and Wales can use single applications to the HRA. Trials with sites led by Northern Ireland or Scotland need to seek ethical approval via the HSC Research and Development Division of Northern Ireland[8] or the NHS Research Scotland

[8] https://research.hscni.net/hsc-rd-approvals-service

Coordinating Centre[9], respectively. Australia's NHMRC has developed a National Certification Scheme to permit multi-centre research to undergo a single ethical review. In Spain, Royal Decree 1090/2015 (effective May 2016) updated guidance to allow for a single ethical approval to apply to all study sites within Spain.

Internationally, we observed that our comparison countries are also looking for a strategic national view of how to mitigate common challenges in setting up clinical research and gaining central control of a silo-ed field. We heard that cross-European networks were helpful for coordination of large studies, particularly in rare patients and there is appetite for similar coordinating bodies following the Covid pandemic (Yajima et al., 2022). However, regulation of trials internationally needed to consider ethical issues; for example, the displacement of poorly-regulated trials to more resource-poor settings (Aguilera et al., 2020).

It remains difficult to gain oversight of the overall UK clinical trials portfolio, although some resources exist: funders publish monthly updates (e.g. NIHR), and Wales has a live tracker of clinical trials. We heard there are a multitude of trials under way at any one time, working with a range of different stakeholders. We learned from our interviews that a key element of research priority setting is first understanding and maintaining central control of a country's research grants and trials portfolio, with the goal of understanding: a) what research topics are being covered, and in which locations; b) an awareness of how these topics are aligned with stated research priorities as well as disease burden; c) and an understanding of opportunities for potential domestic, international, and industry collaborations. We heard that maintaining this level of detailed oversight of a research portfolio at an individual funder level is difficult but important, and that virtually none of the countries in our sample had this level of comprehensive portfolio review happening at a national level.

Wales are taking a 'One Wales'[10] approach to coordinate research across the country, which includes nationally coordinated site identification, rapid feedback from clinical specialty leads and delivery experts, enhanced study set-up, a single price for Wales, a single review of contracts and a single study-specific point of contact for sponsors. The approach also enables all recruitment from individual studies from the whole of Wales,

[9] https://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions

[10] https://healthandcareresearchwales.org/about/news/wales-wide-approach-deliver-research

or a referral pathway for research that crosses organisational boundaries.

Patient recruitment remains a major factor in the speed of trials. Being slow to recruit could mean that patient quotas get filled by international partners, leaving the UK with 'zombie' trials and no benefits. Metrics around patient recruitment can have the unintended consequence of focus on quantity rather than quality and usefulness of research.

Much of the policy focus in the UK and internationally has been around focusing on Phase 3 commercial trials. In the UK, we heard that the O'Shaughnessy review had highlighted issues relating particularly to Phase 3 trials, and that the main improvements had been for this tranche of studies. particularly for setting up commercial studies. There have been fewer reports focusing on non-commercial trials, which while sharing many regulatory frameworks, do differ in terms of their usual sponsors, contracting, and timelines.

Clinical research networks support the delivery and organisation of clinical research and are present in each of the countries in our report. In the UK, there are national research networks, such as the NIHR Research Delivery Network[11], which brings together 12 regional research delivery networks, the UK Clinical Research Facilities Network[12] which connects 54 clinical facilities networks across the UK and Ireland, and the UK's Experimental Cancer Medicine Centres (ECMCs)[13], which link 17 adult centres and 12 paediatric centres nationally. The network system has undergone recent transformations - in 2024, the NIHR Clinical Research Network transformed into the NIHR Research Delivery Network, to better implement the 'Future of UK Clinical Research Delivery' vision (HRA, 2023a).

It is difficult to establish the impact of these networks. The clinical research networks in the UK appear to operate a bit differently than networks in other countries: networks in Australia, France, Germany, Spain, and the United States are more focused on supporting academic clinical research at local sites whereas the UK clinical research networks have a greater emphasis on healthcare delivery.

[11] https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/research-delivery-network

[12] https://www.ukcrfnetwork.co.uk/about-us/crfs/

[13] https://www.ecmcnetwork.org.uk

5. Making the most of commercial investment

Overall, we heard that commercial research activity brings benefits to the UK, in terms of improved access to therapeutics for patients and job creation, but the breadth of the potential commercial offer was under-explored.

Overall, we learned that the potential benefits of engaging with industry research had not been articulated as clearly as they might be. Commercial studies are beneficial but also have costs. Questions most often addressed by commercially-funded trials do not overlap significantly with questions of importance to patients, communities, practitioners or service managers. There is a tension between what industry-led science can do (generate innovations in treatments) and what services need (new treatment and care options appropriate for local settings).

For example, commercial interests may not be interested in funding trials which compare drugs from two different companies or would not want to support a trial focused on a drug with an expired patent. Industry metrics focus on high patient recruitment, which drives research towards urban centres (Bentley et al., 2020). While industry funding can be seen as "net new" money into the UK clinical research system, pharma companies often focus on drugs that are too expensive to be placed on the NHS formula (Bentley et al., 2020). In Spain, this tension has been addressed by co-locating academics and industry in Barcelona's Hub and incentivising them to work together; Spain and France has recently established the Servier Research and Development Institute in Paris-Saclay which co-locates industry and academia. Industry investments in these initiatives demonstrate their perceived success.

Table 5. Recommendation Topic Areas for Theme 5:
Making the most of commercial investment

Topic area	# of docs
Income, investments, and financial incentives at the level of trade/industry: trade, investment, incorporate commercial innovation into universities	6
Income, investments, and financial incentives at the portfolio level: improve use of capital budgets; invest in decentralised clinical trials; reinvest trial income; incorporate best practices in research finance into its upcoming research guidance for ICs; rethink value of long-term investments in prevention	4

Globally, there is a perception that health research systems are overly-reliant on industry for funding clinical trials, although opinion is split on whether this investment

effectively subs cooperative or academic trials, or instead reduces capacity for these to be conducted (Bentley et al., 2020). Northern Ireland is actively researching issues around trial income generation and reinvestment, which we heard in interviews would be useful to surface the hidden benefits of commercial research. We heard that a standing contribution from industry to support data and research infrastructure would make the contribution of commercial partners more visible. We heard it is currently difficult to estimate the economic benefits of new commercial investments, in term of tax revenue, earnings, as well as savings within the health and social care sector.

We heard that commercial research is valued not just around treatments, but also in prevention, by addressing chronic diseases which over time have the biggest impact on the health care system. We heard that commercial research is often viewed as just pharmaceutical companies conducting – often oncological – drugs trials. This perception may be underestimating the potential range of contributions from industry. For example, data analytic skills, service interfaces and technological capabilities including AI which could answer patient-relevant questions are more frequently found in industry than in the public sector. There is great potential to expand the ways new technologies (e.g. cloud-based structures AI, machine-learning) contribute to health research; capabilities for which probably currently rest with industry (Salluh et al., 2024). We also heard that while cancer may attract most industry-led research and innovation, ultimately these advances will benefit all patient groups and other disease groups. However, we heard that it is important for the UK health and social care sector to better articulate why commercial research is needed, and what specific needs commercial partners are best placed to address. Both Wales and the UK government are working to improve industry engagement.

To make industry involvement work well, we heard again that a healthy data environment was essential, demonstrating that we could identify relevant patients at speed and scale. To reach all parts of the UK, resources would be needed to support standardisation across trusts to improve industry engagement.

6. Funding the right research

The sixth and final theme that emerged from the recommendation analysis was to fund the *right* research that improves the lives of the UK's patients, communities, and the health and care sector broadly.

Overall, we heard that research funders and future investments needed to be more strategic and aligned with UK health priorities (which themselves needed better articulation). We learned that the main funders in the UK (MRC, CRUK, WT, UKRI, NIHR) are not in alignment on funding priorities which creates difficulties.

Table 6. Recommendation Topic Areas for Theme 6:
Funding the right research

Topic area	# of docs
Increased funding: target funding for key areas	8
Develop a research culture/enhance leadership: strengthen research culture; statement by leadership; enhance leadership	8
Build a strategy/define research priorities: conduct a review to explore future research scope and priorities; produce and implement a Scottish Cancer Research Strategy; improve the evidence base for the need for a research strategy/refresh; collaborate on research strategies for Wales; align our research programmes and processes with the needs of the UK health and care systems	7
Academic research infrastructure funding: sustain and maintain academic research infrastructure funding and capacity	1
Increased funding: target funding for key areas	8

Defining research priorities appears to be an organic, ad-hoc process. We heard that the research agenda for clinical research in the UK is powerfully influenced by universities and academics. Pharmaceutical companies have strong lobbying arms within governments and can represent a valuable source of "net-new" money for life sciences portfolios. However, the commercial sector focuses primarily on disease areas and treatments which stand to raise the highest profits. The non-commercial and charity sector plugs a lot of research gaps which commercial industry does not address. Yet, there are still gaps, such as around workforce skills and capacity research.

We heard that academics are not always good judges about what matters to patients, and what improvements they think will impact their lives. Preventing cancer and managing life with disease rank high as priorities for persons living with and beyond cancer, however these topics are often less funded than research on cancer treatments, biology, and early detection and diagnosis. A 2021 analysis of research from 120 cancer research funders belonging to the International Cancer Research Partnership (a partnership covering many of the world's largest cancer research funders - including CRUK) found that in 2018, cancer funders' research portfolios focused on treatment (29%), cancer biology (26%), early detection, diagnosis, and prognosis (15%), cancer aetiology (12%), before cancer control, survivorship, and outcomes (9%), and prevention (9%) (Abudu et al., 2021). A 2023 European study found

that only 4% of 1477 European cancer funders support research into primary prevention, and only 1% fund implementation studies (Schmutz et al., 2023, Abudu et al., 2021).

The prevailing view was that there should not be a competition between research topics and agendas, but the overall capacity for research should be increased. We head that a diverse research portfolio is important to address NHS needs – the challenge remains about how to do this well. In practice, this probably means identifying areas within the overall research agenda for different actors to tackle (e.g. incentivising commercial companies to explore drugs to address dementia and obesity, or to provide data-enabled technologies). At present, financial concerns drive portfolio management more than clinical, professional or patient need – even research quality (Bentley et al., 2020).

At present, research capacity does not allow all potential studies to run effectively. We heard that mission-led funding was often successful at incentivising research activity in areas of national priority, both in the UK, but also in Australia, Canada and the US. However, we heard that funding for clinical research was in general somewhat fragmented. There was appetite for a forum which consolidated and prioritised at a national level. We heard from interviewees that in the UK, if investigators can find funding and can meet the ethical and governance approvals, trial portfolios are not scrutinised for fit and need with patient or other priorities. While ethical and governance approvals provide oversight of ethics and patient safety, they do not necessarily provide feedback on the merits of research design and overall project utility. There are currently no national-level central controls in the UK or in any of our comparator countries for permitting/restricting clinical trials by priority topic level or by feasibility of achieving outcomes.

In the UK, the MRC, Innovate UK, and the NIHR all have strategic priorities set by central government. In practice, prioritisation of funding happens at two levels: assignment to mission-led calls in which tenders specify topics and disease areas; and within responsive mode calls which are mostly clinical academic led. We heard in our interviews that most of these schemes benefit medically-trained professionals, rather than Allied Health Professionals. These research programmes are adopted by Higher Education Institutions (HEIs) or practice settings on a case-by-case basis, depending on local capacity. There appears to be no forum to enable the use of local or regional health priorities by health and social care settings, or to put it another way, there is no consistent forum through which prioritisation of research activity happens at local, regional or national levels.

In comparison countries, cancer research has a dedicated government office with public funding (i.e. Cancer Australia, French NCI, Spanish NCI, US NCI, German DKFZ). These typically come with National Cancer Plans for articulating research priorities. These can enable the sharing of knowledge and resources between research centres (Arteaga et al., 2023) – but only where backed by a full implementation plan. However,

we heard that in all countries, more needed to be done to connect research infrastructure with communities of need. Several important stakeholders told us that research priorities ought to focus on issues affecting the greatest number of people. This is of course not a straightforward calculation, with rarity and severity of disease not correlated with prevalence. Yet there are too many examples where patient priorities or disease burdens are simply not correlated with research activity.

Local fora such as the Integrated Care Boards (ICBs) and national strategies (One Wales) appear to be a potentially useful mechanism to bring together stakeholders to prioritise and deliver clinical research useful to local footprint. Where this is working well, we heard it takes very skilled and intensive management of relationships. For example, in Wales, there is one person in contact with all the R&D directors on a regular basis. This transforms performance management from a top-down metrics exercise to a discussion and a negotiation about realistic targets. Overall, the consensus seems to be that rationing and targeting research to the most appropriate settings would be welcomed by managers, patients and researchers.

We didn't see any evidence of national committees to assess prioritisation of clinical research projects, trials, or funding against a national priority list of research topics within our review. We found a few examples of research prioritisation being undertaken at the funder level. Recently, Morton et al. of the Australian Clinical Trials Alliance's Research Prioritisation Reference Group have published their work to identify current examples of research prioritisation that could apply to clinical trials, such as the James Lind Alliance's priority setting partnership exercises, the Delphi method, or a weighted ranking approach (101). They note that there is a current trend for priority setting efforts to emphasise the inclusion of patient and stakeholder preferences for research priorities. This work was used to inform the Australian Clinical Trials Alliance's comprehensive Research Prioritisation Framework for Clinical Trials Networks and Funders[14]. Morton and colleagues observe that there is an appetite for a ranking methodology that could accommodate the preferences of different stakeholders and criteria but a lack of methodology available to pursue this type of priority setting exercise. Taylor et al. (also part of the ACTA) have since developed a "multi-criteria tool for evaluating research proposals that reflects stakeholders' preferences" (Taylor et al., 2023). Even these dedicated experts have not finalised a methodology, in part because they aren't able to draw upon an existing one – a chicken-and-egg problem.

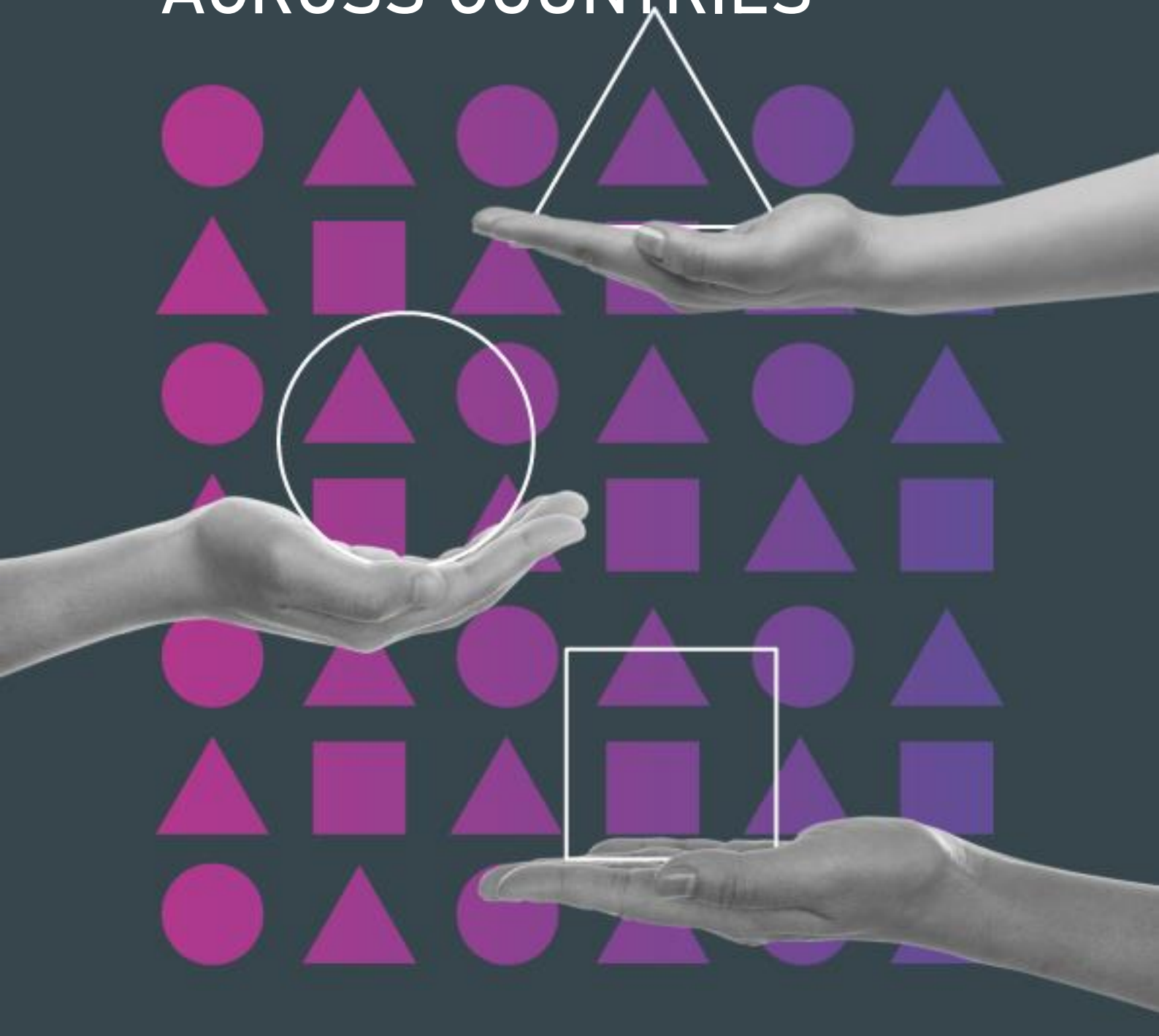
Research leadership and culture were frequently mentioned in recommendations

[14] https://anzmusc.org/wp-content/uploads/2020/02/Professor-Rachael-Morton-ACTA-Framework.pdf

documents, but we did not identify any significant progress towards implementing these. While research leadership has been identified as a transformative element within health services (Flinders, 2020) It is worth noting that in the UK, the next round of the Research Excellent Framework will include an assessment of research culture within each research organisation. However, there is an opportunity to strengthen research culture (including in the ways noted above around KPIs, workforce capacity and training, protected budgets and time) within the NHS, and to support sector leadership on research. Whichever is the goal of any future roadmap, the UK needs to consider how to structure its clinical research so that it can be a leader in this space.

PART 3:

COMPARING ACROSS COUNTRIES



When we began our interviews, we expected to hear about concrete initiatives used to improve clinical research from UK interviewees and some key success stories from our comparator countries. We anticipated that our contacts from comparison countries would be able to share ways of working that produced key wins for clinical research.

Instead, we found much more equivocal views about how the UK should respond to the challenges which were common to all countries in our sample (see Table 1). Interviewees did not feel that any country in particular had a better approach than others, and successful initiatives were often very context-dependent. Although there are interesting ideas to explore, there were no obvious 'quick wins' which could be easily transferred to the UK. See Appendix 3: Country Reports for full details.

Table 1. Countries included in Comparison Analysis

Country	Healthcare system
UK	The UK has a single-payer healthcare system comprising NHS England, NHS Wales, NHS Scotland and Northern Ireland's HSC.
Australia	Australia has universal health coverage that is regionally administered, with the option to buy additional private coverage.
France	France has universal health coverage with the option to buy additional private coverage.
Germany	Germany has mandatory health insurance, offering statutory (subsidised) insurance or an option for private coverage (not-subsidised). The government does not directly provide healthcare and facilities and providers treat all citizens regardless of insurance type.
Spain	Spain has a single-payer healthcare system. Healthcare is delivered regionally and coordinated nationally.
United States	The US has a mixed funding system with no universal health coverage. There are some federal public coverage options restricted by age (Medicare) or income (Medicaid), sometimes supplemented by states. The Veteran's Administration is the only national healthcare provider.

Among the UK interviewees we heard more fundamental discussions about how the UK could and should structure its clinical research enterprise to maximise scientific knowledge, NHS benefits, and economic wealth. All interviewees wanted to spend less time discussing the details of recommendations and more time outlining the need for a culture shift within clinical research funding and delivery.

Our international interviews shared stories of their successes, but also highlighted their many challenges, pointed out facets of the UK system that they wished to adopt, and explained that often important policy wins were the result of unique circumstances rather than a prescribed series of steps that could be easily replicated in the UK. They were also often positive about the UK's clinical research environment, its many strengths and levers which - while not always being used as effectively as they could be – nevertheless represent a competitive advantage.

In this chapter, we summarise some key characteristics across our international comparisons, and highlight 'Strategies for success?' which are innovative ideas from countries attempting to improve their clinical research environment.

Key trends in clinical research funding

Globally, the UK is regarded as being a strong competitor in clinical research, delivering high impact research outputs and having a high share of trial patients overall. Participation in research enables doctors and patients to access cutting-edge treatments, technologies and drugs, and research-active health organisations tend to have better staff retention and improved patient outcomes (HRA, 2023a, NIHR, 2024b). Research is seen as a "core function of health and social care" (HRA, 2023b).

Clinical research is an important sector within the overall R&D landscape. The overall spend on R&D in the UK has been estimated by the Office for National Statistics at £59.5 billion (latest estimates from 2022. 2.6%, of GDP of which 0.13% for health). It is difficult to estimate R&D spend by industry and commercial organisations on health-related R&D. The latest ONS release estimates that £9bn spent by pharmaceuticals product group (17.9% of all UK business R&D). AstraZeneca and GSK were responsible for over 90% of this spend, manufacturing and testing drugs (ONS, 2024). In early 2024 the UK government announced a £400 million investment to boost clinical trial capacity within the UK, indicating the importance of health research to improving the health and wealth of the nation (ABPI, 2024a), primarily to support commercial trials.

In terms of patients recruited to clinical trials, the UK recruits around 350k patients per year into clinical trials (NIHR, 2024a), with about 2.6% of the global patient population recruited to commercial trials in 2022. The UK performs well in share of patients recruited compared with other European countries, with the USA and China recruiting the highest numbers of patients globally.

Clinical research is funded by a diverse portfolio of public funders, non-profit funders, academic funders, and industry funders (see Table 2: NB: Coverage of international funders in Dimensions Analytics varies with some countries under-represented).

Table 2. Public vs charity funding among top 10 funders for clinical research, total for 2018-2022, Dimensions Analytics (USD)

Country	Public Funding	Charity
UK	$104.7 B	$2 B
Australia	$2.4 B	$35.2 M
France	$281.6 M	$4 M
Germany	$635.4 M	$528 K
Spain	$311. 9 M	NA
United States	$199 B	$7.9 B

Across all countries in our sample, public funders provided the most funding for clinical research. Much of the health and cancer research in the UK is funded by the National Institute for Health Research (NIHR) and the Medical Research Council (MRC), together with UKRI collaborators. In addition to their regulatory missions, the FDA in the US and the MHRA in the UK also provide some funding for special research projects such as innovation research and regulatory science projects. The charity sector, particularly Cancer Research UK (CRUK), funds and enables important research, with over £1.9 billion offered in total by the Association of Medical Research Charities. As with most clinical research, charity funding was significantly affected by Covid, with long-term impacts on scientific capacity (Griffiths et al., 2020). Overall, there has been a decline in foreign direct investment in UK research, with similar decreases seen in USA (OLS, 2024).

Strategy for success?

France	France's Health Innovation Agency provides support to 100 projects annually through three support programmes: the "priority access" programme to bring innovations to market, the "off-framework" programme bringing new innovations to market that currently fall outside of regulatory guidelines, and the "scaling up" programme for demonstrated safe and effective innovations.

All countries in our sample except the UK have dedicated government cancer research funding organisations, although size, scope, and influence vary. A publicly-funded agency dedicated to a single health topic area can be a useful forum for articulating government research priorities for a health topic area, developing strategies, and

convening other research, healthcare delivery and industry partners around key areas for coordination and collaboration of research activities. Alongside this dedicated funding, Australia, France, Germany, Spain and the US all had national cancer research strategies linked to their national cancer research funding agencies, often covering care delivery as well as clinical cancer research.

Table 3. National clinical research plans and cancer strategies

UK	The Life Sciences vision (2018), the Future of UK Clinical Research (2021), detail the importance and role of clinical research for national health and wealth.	The UK has cancer strategies for England, Northern Ireland, Scotland, and Wales. These have short sections on research.
Australia	Australian Medical Research and Innovation Strategy 2021-2026 covers clinical research broadly. A National Health and Medical Research Strategy has been in development from May 2024.	10-year Australia Cancer Plan, which includes a section on research launched in 2023.
France	A landmark Health Innovation 2030 plan, with an associated 7.5B euros.	National 10-year 2021-2030 Cancer Control Strategy, which emphasises the role of research in meeting goals.
Germany	2024 Medical Research Act aims to speed up trial approvals through reorganisation of regulatory agencies, the establishment of a new federal ethics committee and standardising contracts.	A 10-year plan: National Decade Against Cancer (2019-2029) that is led by the DKTK.
Spain	Spanish Science, Technology and Innovation Strategy 2021-2027 mentions clinical research and innovation	A dedicated cancer research and delivery strategy, Estrategia en Cáncer del Sistema Nacionalde Salud 2021.
USA	The US has recently launched a “whole-of-government approach to bolster clinical trial capacity in the United States”, the Clinical Trials Readiness Initiative.	The most recent National Cancer Plan was developed in 2023

The most recent UK cancer strategies arose from the NHS in England and the devolved administrations. In February 2025, DHSC launched a new call for evidence to inform an updated national cancer plan[15]. The UK was the only country in our sample that had national strategy focused solely on clinical research (The Future of UK Clinical Research Delivery), although all countries had recent broad health strategies or policy visioning documents that covered pharmaceutical or clinical research.

Governance and coordination of clinical research

As noted above, significant mission-focused funding has been announced in the UK, as well as the US, Canada and several other high-income countries. For example, Australia has allocated $5 billion in mission-oriented funding for cancer research between 2020-2030 (Gilbert et al., 2021). The EU's mission on Cancer has a total budget of 119 million euros. While we heard frequently that additional funding for all parts of the clinical research system would be useful itself, more coordination and better governance is needed to maximise the value of these investments (Arteaga et al., 2023).

Governance is about the relationships between regulatory, funding, practice and research organisations. Countries have different organisations that fund research, govern/regulate research, and set research policy, though these organisations and functions sometimes overlap. Governance of clinical research typically covers:

- Peer review of research funding proposals;
- Ethical approval of research;
- Approval/regulation of medicines and products used in clinical trials as well as approval and licensing of drugs/devices to enter the consumer market;
- Protection of confidential patient data, which is sometimes handled separately.
- Mandated trial registration on a designated trial registry.

Countries were generally working toward simplification of regulatory processes, though these efforts involved navigating various mandates of different agencies, providing new funding to tackle these problems, and often, developing new legislation to support this work, such as the Medizintforschungesetz (MFG), the new German Medical Act (2024). France is aiming to coordinate a European-wide

[15] https://www.gov.uk/government/calls-for-evidence/shaping-the-national-cancer-plan/shaping-the-national-cancer-plan

regulatory framework for clinical research to match the speed of new innovations.

In each country we heard there was ample opportunity for these organisations to work in a more coordinated fashion (see Table 4).

Table 4. Coordinating and regulatory networks

UK	The UK Clinical Research Collaboration (2004) was established to reengineer the UK's clinical research environment. The NIHR Clinical Research Delivery Network (2025) supports better clinical research. The Office for Strategic Coordination of Health Research (OSCHR) and the Health Research Authority (HRA) also work to improve health research in the UK.
Australia	The not-for-profit Australian Clinical Trials Alliance (ACTA) is a national alliance representing coordinating trial centres and clinical quality registers, investigator-led clinical trials and clinical trial networks of all therapeutic areas. The Australian Health Research Alliance brings together 14 National Health and Medical Research Council (NHMRC) Research Translation Centres
France	The French Clinical Research Infrastructure Network (F-CRIN) is a comprehensive organisational network that spans 19 medical fields and includes clinical research an investigation networks, platforms and coordination units.
Germany	The DKTK, the German Cancer Research Centre, helps to manage the Germany Cancer Consortium, an academic-focused clinical cancer research network. The KKS Network (KKSN) is a network of 28 academic coordinating centres for clinical research studies across Germany. It operates as a non-profit organisation with "the aim of strengthening patient-oriented clinical research"
Spain	The National Institute of Health Carlos III (ISCIII) has 32 associated Biomedical Research Institutes (BRI) that provide coordination for research activities alongside Spanish National Health System hospitals and primary care centres, and facilitate collaboration among academia, public and non-profit research and industry.
USA	The US has several clinical trials networks that support research across disease areas within the US. Including the NCI National Clinical Trials Network (NCTN) and the NIH Pragmatic Trials Collaboratory, which supports academic-led clinical trials.

In practice, clinical research networks often play an important role in coordinating clinical trials and research efforts and connecting clinical researchers to governments, policy makers, and patients. For example, Spain, Germany and France participate in the European Clinical Research Infrastructure Network, which assists with the coordination and management of multinational clinical trials in Europe. Following Brexit, the UK left this network although collaborations may still be possible.

Strategy for success?

France	To ensure that government is working in a coordinated fashion toward a common goal, France has set up an interministerial steering committee "for the purposes of sharing clinical research objectives, coordinating the various actions decided upon and assessing their progress shared indicators and dashboard"[16].

The long-term advocacy efforts (Celis and Ringborg, 2024) and sustained expert input and infrastructure (Arteaga et al., 2023, Berns et al., 2020) required to enable this kind of international coordination and strategic collaboration should not be underestimated. Simply adding new funding at various points in the clinical research pipeline would not go as far without coordinated efforts to make sure that organisations are incentivised to work toward common goals. Adding new money for additional trials does not help if there is not adequate infrastructure and staffing in place (and coming down the training pipeline) to run the trials. We heard that Spain has a very coordinated national health system that "comes after years of collaborative work between health authorities, research hospitals, patients and pharmaceutical companies"[17].

These networks also help develop national strategy and implementation. For example, in coordination with the Health Innovation Agency, F-CRIN has undertaken two recent scoping projects looking at how real-life health data can be used in clinical research and how clinical trial methodologies have evolved over time. This type of collaboration can offer policymakers important information about how the overall clinical research system can be better supported and streamlined.

Delivery of cancer research is often arranged through dual funding or co-location of research and care. In Australia, clinical trials units or clinics are often co-located next to or nearby existing hospitals. This arrangement allows for dedicated beds to be

[16] www.info.gouv.fr/upload/media/content/0001/10/440a92a17aa78c3b5585acaf780189a16fb394d2.pdf

[17] https://distefar.com/en/spain-a-clinical-trials-powerhouse/

maintained for clinical research patients separate from regular hospital operations, but close enough to allow research patients access to support staff and services that may be needed for research. The French Clinical Investigation Centres are jointly managed by the Ministry of Health and Prevention and INSERM to ensure that research agendas align with care priorities.

While the UK is in a good position with national funders able to support long-term activity, globally we found that there is often insufficient funding for trials infrastructure and staff retention (Bhattacharya et al., 2021). International interviewees mentioned the sustained funding available through MRC and NIHR for research infrastructure as a major advantage for the UK. This was not the case in Australia, where most of the research workforce were employed on temporary project-based contracts, leading to a patchy and transient workforce which in turn led to increased costs such as re-recruitment at the start of every research project. Being able to retain a critical mass of skilled people meant that health and social care settings were ready to start new trials quickly and at scale.

Managing clinical research portfolios

However, finding ways for clinical, patient and researcher priorities to be aligned with research priorities seemed to be a challenge for all countries. At present, there does not seem to be any obvious mechanisms or forum to regularly review funding portfolios, nationally or internationally to assess fit with stakeholder needs, or to spot opportunities for collaboration and reduction of waste and duplication. Individual countries do sometimes run portfolio reviews, such as Australia's Deepening our Understanding of Quality in Australia (DUQuA), but these are usually partial and not linked back to funder prioritisation processes (Braithwaite et al., 2020).

Strategy for success?

Australia	The ACTA has established a Research Prioritisation Reference Group have recently published work to identify current examples of research prioritisation methodologies that could be apply to clinical trials, such as the James Lind Alliance's priority setting partnership exercises. This work was used to inform the Australian Clinical Trials Alliance's comprehensive Research Prioritisation Framework for Clinical Trials Networks and Funders to explore ways to prioritise trials based on priority topic areas and stakeholder preferences.

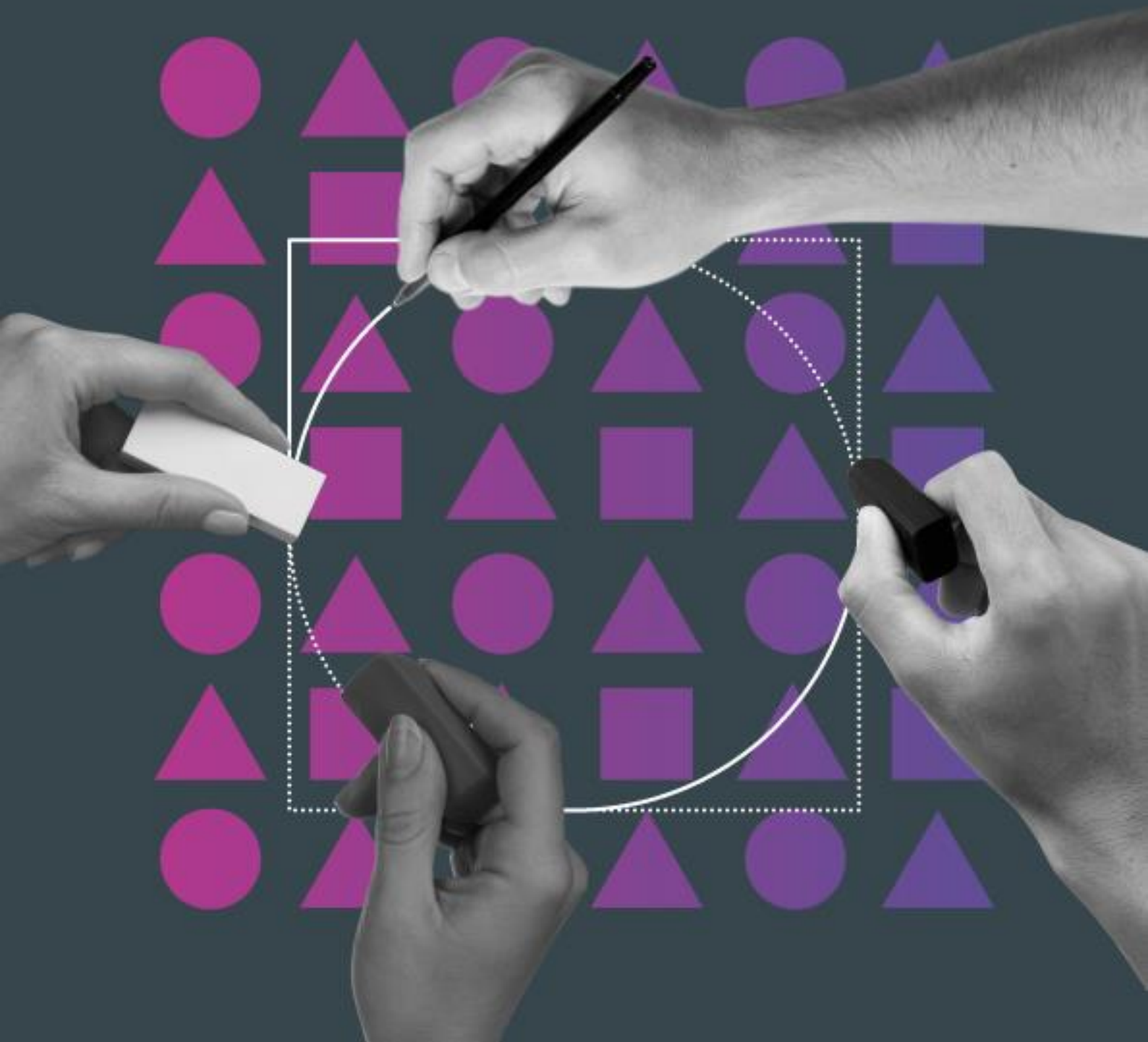
UK	In the UK, the Areas of Research Interest offer a useful mechanism for policy and practice organisations to articulate their evidence needs, improving coordination with research funders and providers.

More common may be funder-level portfolio reviews of funded research; however, these exercises can be siloed and not well-publicised. A greater focus on national-level portfolio review, while notably more complex, could provide opportunities to think strategically about what progress has been made to date, and where the greatest investments in research funding, infrastructure, and training could be placed to best achieve meaningful, patient-oriented scientific impact.

This seems like an area with potential for swift improvements, especially with the grown and innovation in AI tools. For example, in the UK, all government departments, and increasingly other parts of the public sector, produce regularly-refreshed statements of evidence needs, call Areas of Research Interest. These statements can be categorised and, using large language models, mapped against existing funding portfolios to identify topics where there are gluts and gaps in the evidence base (Oliver et al., 2025). In turn, this information can be used to prioritise and shape future funding calls and programmes. Even without prompts like these explicit statements of knowledge need from service providers, more can be done to mobilise existing evidence, through better management of funder portfolios and greater use of evidence synthesis and knowledge exchange.

PART 4:

LESSONS LEARNED



We hear a consensus that the UK is a promising environment for clinical research with a strong track record and internationally recognised institutions. Going forward there isn't one single strategy that will achieve the step change needed. Our analysis contain detail on potentially useful next steps under each of the themes emerging from existing recommendations. In addition to these themes, we found that not all issues raised in the literature and in interviews were addressed by recommendation documents. In this final section, we pull together the major lessons across all themes, and across our data sources.

In our analysis, we found that the UK has made some headline commitments around raising the visibility of research within the NHS and building small-scale training pathways for staff but that large-scale solutions remain the most likely to enact meaningful change. In our view, the scale of the problems identified do not match the scale of proposed solutions. For example, the recent focus on national KPIs for commercial clinical trials has highlighted progress that MHRA and HRA have made to speed up trial approvals and streamline set-up processes. However, the interviewees we spoke with largely felt that these activities, while necessary, only represent a small part of the larger "puzzle" to solve (i.e., workforce development, questions about emphasis on commercial rather than non-commercial research, increased research funding, making research accessible to all).

While there is evidence of some progress being made in
4 out of 6 major recommendation thematic areas,
this work is not being addressed evenly.

Ongoing work has only been reported for
8 of 32 recommendation subtopic areas.

However, with a change of government, there is an opportunity to think more broadly and strategically about how to grow the UK clinical research portfolio…notably, these broad strategic areas are not currently being addressed (at all or to the same degree) within implementation plans.

Clarifying our goals for research in the NHS

Overall, we heard different views about the value of research for the NHS and social care sector. Some felt that participation in research activity benefited patients and clinicians directly. Others spoke about moral imperatives to enable universal research participation, with exclusion (through lack of resources) driving greater health inequalities. Still others felt that research was a costly and burdensome activity which ought to be concentrated of areas with greatest capacity.

We heard conflicting views about whether the NHS should be more research active. On one hand, the idea that being treated in a research-active practice setting is common, and there seems to be some agreement in the literature that patient outcomes are improved where professionals can be research-active. However, we also heard that there was a limit to the amount of research capacity, and rather than an 'everyone, everything, everywhere all at once' approach, a more effective strategy would be to concentrate research activities around areas where there is expertise and volume of patients to generate high-quality data. The systems incentives seemed to be directing NHS Trusts to participate in as many research studies as possible, rather than thinking strategically about what would be most useful, and effective locally. Several interviewees emphasised that research in the health and social care sector required research activity within and beyond hospital settings. Primary and community settings as well as social care environments were highlighted as critical to ensuring inclusive research participation. There is a considerable way to go for non-hospital settings to be considered as central to clinical research activity.

Overall, a shared vision for what research can deliver needs to be better articulated and shared so that all parts of the system can work together collaboratively to deliver this goal.

A need for strategic coordination, leadership and action

We observed a clear appetite across all sectors for strategic direction to guide the next era of UK clinical research and a readiness to make meaningful, on-the-ground changes to improve patient health and the research experience. We found interviewees were eager to identify strategies to improving coordination among stakeholders to enable novel ways of working, to move beyond broad recommendations and toward actual, system-wide strengthening of the UK clinical research environment. In some areas (such as on trial regulation and set up) additional new initiatives are probably unnecessary but oversight and coordination by a system leader would be useful. In others, clear action is required.

While we have observed that progress is being made in some recommendation areas, as identified through our review of publicly available implementation documents and our conversations with government officials, we note that there remains no single convener across all stakeholder groups to ensure progress happens across the board. In Australia, a multi-sector stakeholder group called the Inter-Governmental Policy Reform Group [18]was appointed under the Ministry of Health and Aged Care, to provide policy and operational oversight of their new National One-Stop Shop for health and medical research. In India, there is a single point of contact in the national Department for Biotechnology which reviews portfolios and supports multi-institutional networks (Shenoy and Dey, 2021).

Although the UK has a centralised health system, there are lots of providers, funders and potential partners that must be coordinated to ensure high-quality research is conducted in a timely fashion. This requires policy agreements to state shared priorities agreements between funders to improve collaboration and reduce competition, ethical agreements to ensure clinical research is conducted in a highly responsible and patient-safe manner, and cross-sector collaboration frameworks between funders, industry, and health services professionals. Stakeholders were keen to emphasise their eagerness to adopt any unified strategy addressing long-term issues rather than short-term wins. Other parts of the health and social care system such as care homes are provided by a much more varied range of providers with implications for organisation and collaboration.

Across the UK, we heard that more coordination towards a shared strategy would be welcome. Specifically, 1) recommendations could be better formulated, ideally in the style of SMART goals (i.e., specific, measurable, achievable, relevant, and time-bound); and 2) recommendations could be linked to a tangible implementation strategy which could operate as a clear roadmap to success with defined roles for action. The devolved administrations of Northern Ireland, Wales, and Scotland typically had more detailed and comprehensive implementation plans of the UK-wide Future of Clinical Research Delivery visioning document. For example, the Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth articulate specific activities to be taken, along with metrics for how successful implementation of that activity should be judged, what ideal impact would look like, whose responsibilities it is to implement the activity, the perceived resources needed to complete the activity, and the suggested timing for when the activity should occur.

Having the right leadership in place is key to driving success and ensuring that

[18] https://www.australianclinicaltrials.gov.au/about/igprg

stakeholders can see themselves as having a valuable role to play in the larger research ecosystem. The clearest example of this type of coordinated research effort comes from the UK's experience with Covid-19 research. Early in the Covid pandemic, NIHR played a key role in identifying a small number of research topics as urgent public health priorities, and then stipulated "that only projects designated as Urgent Public Health studies would be eligible for NIHR support" (Hanney et al., 2022). This resulted in a coordinated research effort that ensured that the few Covid studies that did go forward would be high-powered enough to produce meaningful results quickly, and it was only possible because other investigators were forced to redeploy their efforts (that could have been spent on their own trials) in support of the high-powered trials designated as urgent health priorities.

This type of incentivised prioritisation and collaboration (through the mechanism of withholding NIHR funding to none-priority studies) could potentially bring substantial change to the UK clinical research system more broadly, although it is important to acknowledge that this system may look like rationing of research funding/projects. We heard that there was an appetite for this type of structuring from individuals in policy positions that we spoke to, but not necessarily the same level of support for this idea from individual researchers trying to compete for grants. However, it is important to acknowledge that the UK's most successful Covid trial, the RECOVERY trial, would only have been possible with this type of portfolio oversight led by NIHR. Covid-19 of course presented a very unusual set of circumstances including a large eligible population, and agreement around urgency.

Use metrics to drive better collaboration

Overall, we learned that the UK has many factors which make it a great place to do clinical research well. We have a centralised health system, dedicated public funders, internationally-recognised data assets, an excellent life sciences sector, and world-class universities. However, the system is uncoordinated and fragmented, with a poor data infrastructure and very stretched workforce and organisational capacity which hinders our ability to make the most of these assets. A theme throughout the interviews and observable in the data is the sheer complexity of the health and social care system. We have identified the key components of successful governance frameworks as:

- A national strategic plan for change with clearly articulated guiding principles for the implementation of a governance framework, realistic objectives and measurable outcomes
- A national (or bi-national, as in Europe) legislation and policy framework
- A national or central coordinating agency

- A national or central IT platform
- A national and local-site capability framework
- Independent accreditation to assess site-level providers to confirm they have implemented the nationally harmonised approach to clinical trials governance.

The UK will need to assess the extent to which it has these components, and how well they are functioning. The government's recent push to build out the NIHR RDN represents a prime opportunity to analyse the utility of these components, and we encourage NIHR/DHSC to make this opportunity available to all research stakeholders, so that this development work can be useful to funders as well as NIHR/DHSC. Next steps may involve determining which of these components should be prioritised for development and implementation and what, if anything, is still needed to fill gaps.

We heard that interventions in one part of the sector could lead to costs increasing elsewhere; that there were disincentives to supporting other parts of the system unless savings were realised within the same organisation; that career and productive incentives for academia directly mitigated against production of useful research for practice.

We heard a consensus that the NHS needs metrics for measuring NHS research and engagement to increase visibility, support, and accountability for research. One metric which has gained traction is the O'Shaughnessy goal of identifying 1 million patients taking part in research, which we heard discussed in multiple interviews. This metric, along with others from the O'Shaughnessy report tend to focus on things that can be easily measured, which while sensible, can run the risk of oversimplify problem areas and potentially creating perverse incentives. Although useful, the identification of 1 million patients willing to take part in research does not directly translate into the delivery of clinical trials. There are many ways in which metrics could be implemented – for example, linking health care funding to clinical trials metrics – but limited evidence about the effects or perverse effects these might generate. As future metrics are developed, the NHS should ensure that these metrics are productive, not overwhelming for local staff, and aligned across organisational levels and goals.

While metrics can help incentivise and lead to culture change, they can also create perverse effects and may not always be aligned with patient needs. Having a strategic vision and comprehensive implementation plan that accommodates the needs of all relevant stakeholders can ensure that included metrics can better serve the whole system.

New interventions to improve systems functioning

Current interventions in the clinical research environment tend to benefit one sector (e.g. higher education) or increase competition (incentivising commercial clinical research at the expense of non-commercial research). New initiatives should consider how they can improve delivery of a shared vision for research, by mapping out costs and benefits to all organisations in the clinical research ecosystem. Although the system is very complex, it should be possible to at least map out the various components and thus begin to understand what a functioning system would look like. Identifying an organisation that has the scope and appetite to take this work forward will be an important first step. This mapping effort will require the development of different metrics which do not focus on the optimisation of individual organisations, but rather on systems functioning itself – for example, cost savings across multiple practice settings (Cresswell et al., 2017).

One such example can be seen in the UK's national research delivery networks and clinical trial centres. We observed that the UK's national research delivery networks seem to be a very helpful element which are working well for the UK. During Covid, the US was limited in its ability to quickly recruit patients to trials due its reliance on CROs (which were not linked through national networks). In contrast, the UK was able to scale up patient recruitment to the RECOVERY trial quickly by using the national Clinical Research Network (now the RDN)(Collins et al., 2023). Additionally, networks of clinical trial centres are potentially very important to scale up multi-stakeholder collaboration, and capture inclusion of all patient groups (Batist et al., 2018). While many countries in our sample have networks of clinical trial centres at a regional or national level, the UK's additional national Research Delivery Network may be seen as a unique advantage to scale up clinical research efforts. These kind of large-scale, coordination efforts require incentivisation and provision of resources especially for low—income settings (Park et al., 2021).

A second promising idea we learned about that can be adopted at all levels of the system (academic/non-commercial, publicly funded, and commercial research) concerns mandated race/ethnicity data in trials, with additional recommendations to collect socioeconomic (SES) data from patients from the US. The UK encourages the collection of race/ethnicity and SES data from trial participants but does not have policies in place to mandate this data collection. Enforcement of data collection could improve patient enrolment from diverse populations and ensure that UK clinical research is beneficial to all patients.

Finally, we heard that a useful contribution in this space would be for a central coordinating actor to develop "scope guidelines", which set out roles for different actors, expectations, and timelines for each step along the approvals pathway. It was felt that this would address the common problem where multiple organisations or

jurisdictions had to implement the same step or policies, but did so in a variety of ways to different standards (Crosby et al., 2022). This would also help to de-risk studies for practice settings and would require work with NHS indemnity. We heard that this would need significant NHS buy-in as in practice, having single-contracting would remove the need for R&D offices to accept a centralised system.

Collaborating to deliver different research agendas

Effective health and social care systems need a wide range of evidence of many different types, to inform effective collaboration and service delivery. Evidence is needed about:

- the needs and priorities of patients, families and carers, health and social care professionals, and managers
- what works in different practice settings (evaluations, implementation studies)
- the impact of different interventions, programmes and strategies across systems
- how to best engage and work with partners across settings.

Yet, despite these being well-understood areas for research, there was consensus that the UK as a nation does not always get the research it needs to benefit patients, practitioners, the health and social care sector, or society at large. As discussed above, there are three main agendas which come into play (see Table 1).

These agendas do not typically centre the needs of patients when considering what research is most needed to improving the daily lives of patients and communities and would directly improve their lives. Several countries have mechanisms to articulate patient priorities, but these usually do not systematically feed into national funding strategies (Amano, 2019). Although academic trials often have some PPI involvement in their research, a truly patient-oriented research agenda may prioritise different research aims than an academic-led, industry-led, or even population health minded NHS agenda. Similarly, the NHS badly needs research on workforce capacity to be able to plan, train and recruit the staff it needs (Lamont et al., 2024).

Table 1

Industry and commercial

Pros	Cons
Money that comes from industry is "Net-new" money that the UK doesn't have to source from elsewhere	NHS seen as a testing ground for devices & pharmaceutical treatments which do not lead to commercially-viable options
Seeking industry collaboration is key to remaining competitive globally	Sise of the population affected by the potential drug or device to be sold is less relevant than the potential to gain a patent
Industry money can finance things the UK needs to improve clinical research (i.e., equipment, facility space, drug access)	Provision of new equipment and facilities may not match patient or clinical need

NHS

Pros	Cons
NHS-led research is useful because industry research does not always focus on areas of NHS need	There is currently no forum or mechanism for NHS to articulate its research or knowledge needs
NHS plays an important role in obtaining cost-effective drugs; industry research produces which can be expensive and cannot always be added to NHS formulary	NHS-led trials can be difficult to set up and run at sufficient scale
There is a perception that NIHR acts "slow" because it takes a critical role of reviewing added population benefit for new NHS drugs, but this can play a valuable role in managing population health	Research capacity is not always aligned with patient disease burden
	Research active trusts provide a context for other people to do research, rather than having their own research agenda

Academia

Pros	Cons
Research priorities between academia and industry are quite different and academia / clinician-lead research tends to focus on important areas that industry avoids	Research can be incremental and non-innovative
Academia plays a useful role in training clinical research workforce	Clinical research priorities are shaped by demands and incentives of academic careers and journals, not patient need
	Clinical staff find it difficult to commit time

Funders should think about how to further broaden research opportunities beyond clinical staff – perhaps particularly about how to help develop career pathways that enable people to cross sectors to pursue a research career. The research strategy that is ultimately the most beneficial to the UK could be a combination of all four research agendas and would probably require national leadership. However, acknowledgement of the agenda-setting powers of each group can go a long way to creating a shared agenda.

Across our interviews, we heard that there is ample opportunity and excitement for an next-generation UK clinical research system. Stakeholders were keen to share their personal priorities for future clinical research in the UK, and we heard that perhaps more importantly, the UK had a unique potential among the countries in our sample to enact this type of change due to the work it has already undertaken to build a health system focused on research-rich healthcare delivery. For comparison, while the US has committed significantly more funding for research and supports more research networks than other countries in our sample, it is much further behind the UK when it comes to systems structuring for healthcare and research delivery.

We heard that there are several potential areas of opportunity, although interviewees had differing views over which to prioritise: big trials with primary or community home setting; deep phenotyping for small trials; gene therapies; or personalised medicine. We recognise the need to pursue innovative research but argue that at present the ecosystem is too fragmented to organically coalesce around whichever of these is the national priority.

We also heard strong views about the role of industry-led research in our interviews:

> "The [O'Shaughnessy] review starts from a position that says "We need to make the NHS the most receptive, trouble free, straightforward environment in which industry research can be done". What it doesn't at all question is the nature of that relationship with industry… And indeed, the extent to which the research industry wants to do, is research that the NHS wants done."

Commercial companies fund and support significant amounts of health research, Yet, how these contributions are assessed and counted as part of national R&D is often unclear (Gagnon, 2023). Countries beyond our comparison group share similar challenges when it comes to balancing research funding (% from industry) with research priorities of the country (Bentley et al., 2020) – despite strong claims made about unequivocal benefits.

Research prioritisation is key

The topic of prioritisation was widely discussed, but people found it difficult to articulate practical ideas about how to improve current processes. We heard that there is no clear way to assess or select which studies ought to be progressing, and thus prioritisation happened in different places, according to different criteria, and mostly without strategic oversight. Instead, research priorities are set in an ad-hoc manner, depending on individual entrepreneurialism and activity, or the outcome of competing agendas from various funders.

Some expressed the perception that prioritisation was often resisted by academics and local practitioners for a variety of reasons. One was the perception that the NHS was able to take on all the non-commercial trials which research funders were wiling to support. This leads to a huge NHR portfolio, passing on the burden of recruiting sufficient patients and sites to individual researchers. Similarly, academics find it hard to withdraw from studies, it being difficult in practice to say that one research interest is less important than another. In group settings such as health partnerships, this can make strategic prioritisation impossible. The research community, driven and incentivised as it currently is, cannot automatically generate the research which is needed to improve how the health and social care system functions and delivers care. However, as one interviewee put it:

> "If you don't prioritise - well, you're still prioritising, but you're just choosing to prioritise in a variety of really arcane ways, which probably privilege really strong voices, probably privilege certain powerful interests and probably don't produce necessarily a very rational outcome."

We heard that this type of work would be difficult to do in practice as it would meaning saying that some research could not go forward; however, in the early days of the Covid pandemic this is exactly what happened in the UK - all non-essential trials were halted and regulatory agencies were given greater powers to mandate that institutions work together on a single trial rather than host multiple, under-powered trials. Several participants expressed this type of oversight was likely unrealistic in non-emergency circumstances but acknowledged that it did facilitate rapid, high-quality research for a priority topic.

Further, national-level portfolio review may be necessary to assess alignment of the various research portfolios with the priorities of patients, practitioners, managers, decision-makers, and these funding mechanisms are unlikely to currently deliver all the evidence required for effective health care systems (Frick and Helzlsouer, 2024). These competing research and funding agendas were observed in all countries in our sample and we repeatedly heard that these agenda required delicate handling.

In the UK, we heard about multiple organisations which perform this portfolio review role to some extent already. The NIHR Task Force helps NIHR deliver its portfolio of studies, but does not play an active role in prioritisation. The Office for Life Sciences helps connect DHSC and DSIT, and champions research an innovation, but as a government body does not have a role in funding research or selecting studies. Individual charity funders set their own funding calls and select studies to fund; however, these calls are often not made in coordination with other funders or governmental bodies and projects selected for funding are not typically evaluated against criteria of research duplication. In essence, proposing studies, prioritising them, funding them and setting strategic priorities for the nation are functions carried out by different bodies. While most funders undertake portfolio management of some kind, it is not always easy to assess the relative weight placed on financial, clinical, professional or patient concerns drive portfolio management– or research quality (Bentley et al., 2020).

A mechanism for prioritisation is needed

In terms of mechanisms, we heard that prioritisation happens in grant panels; in science advisory committees which hold concept development priorities; in local trust R&D offices who decide whether to join a study on the NIHR portfolio; within strategic funding committees. Funders hold significant responsibility for ensuring that funding strategies align with social values, which is operationalised through review criteria, training for researchers, and clear articulation of what these values are (Saylor and Joffe, 2024).

We heard that there is no single forum, at any level of jurisdiction, where the portfolio of research activity is reviewed and assessed against a set of strategic criteria. We heard that portfolio reviews are often difficult to complete, as data is held by different bodies in different formats. We are aware that NIHR regularly reviews strategic investments, such as the ARCs, and conducts condition-specific reviews. Funders sharing information with each other about portfolios can support more targeted funding to address gaps (Abudu et al., 2022); however, in practice this can be difficult to arrange. There is a need to be radical about prioritisation and think about how do things differently at a systems level.

However, ultimately this will require an effective prioritisation strategy which enables funders to target resources, and for all components of the health and social care system to work in concert to deliver needed research. An effective mechanism for prioritisation would require all relevant funders and practice settings to agree on a common prioritisation strategy. We heard competing views about what this strategy might look like, and what criteria might include. For example:

- Scientific importance of the question and methodological rigour of the study
- A return on investment in terms of cutting treatment and care costs around the system, including introducing cost-effective therapies even with increased costs.
- Potential to reduce burden of disease
- Focuses on rare diseases and the role of international collaboration in this space
- Local needs and service resource deficits
- Tackling problems which address the greatest number of people
- Opportunities to link international and national research efforts across sites to create high-powered studies?

Any such prioritisation mechanism for cancer research will likely require:

- portfolio review across public, third sector and industry. This may be something the new DSIT Metascience Unit could support, alongside NIHR and other funders.
- The NHS, practice settings and its professions need to articulate its own research agenda: an equivalent of the Areas of Research Interest for this important part of the public sector. This may be something which the Government Office for Science could take forward with public and third sector funders
- Liaising with cancer funders in other countries around scope, collaboration,

and avoidance of duplication and waste.

Whatever the mechanism, it would be useful for the UK clinical research community to articulate their varied, and common strategic goals for clinical research. Prioritisation will mean saying no to some issues. Therefore, we identify a need for strong leadership to convene the important voices to formulate a realistic strategy.

Importantly, this organisational leader must be able to articulate the costs and benefits of different choices around research investment: to make the case for what will, and what not be supported; and crucially, to explain why.

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APPENDIX 1:

LIST OF SPEAKERS AND ADVISORY GROUP MEMBERS

Advisory Group

- Emeritus Professor Stephen Hanney at Brunel University London.
  Steve has over 35 years' experience researching a range of topics, including: how to assess the impact, payback or benefits from health research; the use of research in policymaking; and how best to organise health research systems to maximise impacts and improve health and health systems. In retirement, he currently provides technical expertise to projects on an ad-hoc basis.
- Dr. Steven Wooding, University of Cambridge.
  Steven is currently Senior Research Fellow at the Research Strategy Office at the University of Cambridge where he undertakes research looking at mapping global research funding, developing metrics for communicating the value of research and understanding the effects of scale, scope, and the peer review process within the allocation of research funding. Previously, Steven served as Director of Innovation and Technology at RAND Europe and he also co-directed the Centre for Policy Research in Science and Medicine.

Interviewees and reviewers

With thanks to those who prefer to remain anonymous.

Professor John Simes, Founding Director, NHMRC Clinical Trials Centre, Australia
Professor David Thomas, CEO Omico, Australia
Professor Dorothy Keefe, CEO Cancer Australia
Fabien Calvo, Universite Paris Diderot, France
Dr Julia RItzerfeld, Head of Clinical Trials Office, DKFZ, Germany
Dr Emiliano Calvo, Director of START, Madrid
Dr. Miguel Angel Quintela, Acting Director, Spanish National Cancer Institute, Spain
Lord James O'Shaughnessy, Newmarket Strategy, UK
Aoife Regan, GOSH, UK
Kieran Walshe, Director of Health and Social Care Wales, UK
Carys Thomas, Health and Social Care Wales, UK
Sally Sheard, Professor of History of Medicine, UK
Angela Topping, Chair of NHS R&D Forum, UK
Shona Haining, Head of Research and Evidence at NHS North of England Commissioning Support Unit, UK
Giulia Cuccato, Head of Policy, Academy of Medical Sciences, UK.

APPENDIX 2:
METHODS

For the purposes of this project, we define clinical research as research that seeks to "improve current treatments, medicines and care, and develop new and better ones; diagnose diseases and conditions earlier or more accurately; and prevent people from developing diseases and conditions"[20].

Where possible, we have drawn examples from, and highlight considerations and conclusions that are/may be specific to cancer research. However, these findings are relevant across health and social care, and our interviewees were drawn from across clinical medicine, the allied health professions, adult social care, regulation, industry and academia.

Phase 1: Mapping clinical research systems in the UK and internationally

Approach: For the UK and each comparator country, we used desk research (i.e., document searching and review) to map each country's governance structure for clinical research, identifying funders of clinical research and the policy makers.

Sources of data: We drew on strategic policy, governance, and funding documents on four groups of websites, using Boolean searches to combine terms relating to clinical governance, research governance, RCTs, Trials. The following data sources are listed as examples of websites reviewed as part of our search strategy.

- Funding websites: We examined UK Funder websites (such as UKRI, NIHR, Wellcome, and CRUK) to determine which funders support clinical research and their specific areas of remit. We will use the International Cancer Research Partnership, an organisation which collects funding data from leading cancer research funders around the world, to identify UK-based cancer research funders. Currently, over 25 UK-based cancer research funders participate in the ICRP. Finally, we will use Dimensions Analytics to identify overall funding totals for UK clinical and cancer research funders to identify and rank the top clinical research funders within the UK.
- UK Policy websites: We examined strategic policy, framework, and governance documents on UK government websites and websites of devolved administrations. Examples can be found in Table 1 within the appendix.
- UK Health service websites, including but not limited to: NHS England, NHS Wales, Health and Social Care Northern Ireland, NHS Scotland, NHS HRA, NICE, and NIHR Clinical Research Network. We identified key health organisations as part of our work for objective 1. For each organisation, we

searched their websites to identify descriptions of the aims, goals and strategies, usually found in Mission statements or strategic plans.

- UK Research websites: University websites (e.g., major teaching university hospitals), professional research association websites, and related commentary on Web of Science.
- Comparator country grey literature search: Additionally, we looked for reviews and key publications from our comparator countries that highlight best practices for how the clinical research landscape in the comparator country was improved and/or maintains a high level of excellence, as well as government and/or health services websites that detail clinical research funding, priorities, and roles/responsibilities. To supplement this web searching, we contacted stakeholders from each country to ensure that we identified the most comprehensive and up-to-date summaries available. Where possible, these searches mirrored the planned approach we have for the UK (i.e., funding websites, policy websites, health services websites, and research websites).

From each document, we extracted data on:

1. The major funders of clinical research; type of funding organisations (i.e., government, charity, pharma etc.)
2. The primary funding mechanisms for clinical research (i.e., grants/ contracts/ cooperative agreements)
3. Organisations providing governance of clinical research, and how they interact with funding and policy making bodies; their role in delivering clinical research

Phase 2: Systematic assessment of enablers and barriers

To place the findings from Phase 1 into context, we identify the wider political issues that might impact proposed policy improvements to the clinical research environment through a systematic review of the literature. We examined the role of these wider political issues, such as the level of Government funding and resources, the political and public enthusiasm for clinical research, stated priorities for future research, or the impact of the UK leaving the EU within our comparison countries, to understand how these policy pressures have played a role in their clinical research environments. We identified barriers and enablers to effective clinical research, aiming to understand the role played by other sectors, including industry, academia, and charities/foundations, and

evaluate how effectively these sectors work together in the UK compared to other countries.

To help us manage the large amount of research on these topics, we focused only on systematic reviews, and on reports for key funders and stakeholders which provide usable data (e.g., for the Kings Fund and Health Foundation) addressing three questions:

1. What are key components of a clinical research system within a national health system?
2. What are the major opportunities and challenges of embedding research into the health service?
3. Which countries have been successful with embedding research into their health service, and which countries have not been as successful?

We extracted data on:

- Political or systemic barriers which influence clinical research practice, culture or governance;
- Barriers or facilitators to a strong research culture in a health service at a national, regional, and local level for the UK and for comparator countries
- Role, contributions, collaborations, and opportunities brought by industry, academia, the third sector, and government, in the UK and across comparator countries

Phase 3: Stakeholder interviews

Stakeholder interviews: To supplement published commentary around the proposed policy recommendations for the UK, we conducted stakeholder interviews from the UK and comparison countries to understand the wider political issues that can affect the proposed policy improvements to the clinical research environment. We asked interviewees:

- Who are the key players that would need to be involved in implementation?
- What resources would be needed for implementation?
- What level of funding would be needed for implementation?
- What political issues are likely to affect implementation?
- How would implementation be evaluated for progress?

All interviews were transcribed using automatic recording software, with transcripts and a thematic synthesis of the data included as an appendix to the final report. Interviews were conducted online and recorded for use within the team only. Permission was sought before quotes are used in published materials.

Phase 4: Assess the feasibility of existing recommendations

We analysed 20 documents that provided one of the following: 1) recommendations for the UK clinical research environment; 2) plans for implementation of such recommendations; or 3) progress made against such recommendations. We coded each individual recommendation by thematic area and then grouped similar recommendation topic areas into six overarching themes that best fit the key messages we found from the recommendations, literature review, and interviews.

The table below lists these topic areas by descending number of total documents from which the recommendations appeared. Recommendation topic areas shaded in yellow signify that some progress has been reported against these recommendations (as evidenced by reporting in the implementation documents), and topic areas in red signify that no progress has been reported against these recommendations (as evidenced by no reporting on these topic areas within the implementation documents). It is important to note that progress could be occurring in any of these topic areas despite not being captured in the implementation documents used in this analysis.

APPENDIX 3:

COUNTRY REPORTS

SPOTLIGHT ON: AUSTRALIA

Australia is the world's 54th most populous country with 27.1 million people. Australia has universal health coverage that is regionally administered, with the option to buy additional private coverage. Australia is a leading country for clinical research and has taken steps to enhance its attractiveness as a destination for commercial clinical trials.

How is clinical research generated?

Step 1: Obtain funding	Australia has provided over 2B USD towards clinical research grant funding from 2018-2023 through public funding from the Department of Health and Aged Care. Additional funding is available through other public and nonprofit funding sources. Australia has several offerings to boost competition and innovation in clinical research including: a competitive R&D Tax Incentive to offset R&D costs; a proposal to support domestic R&D businesses and Australian medical and biotech patents; a A$750 million Medical Research Future Fund to boost clinical trials activity over 10 years; and a A$500 million venture capital fund sponsored by government and the private sector for translating research into commercial innovations.
Step 2: Obtain regulatory approval	• Ethical approval: Human Research Ethics Committee • Medical products approval: Therapeutic Goods Administration • Data protections legislation: Health data collected during research must be stored in accordance with the Privacy Act 1988 What's new: Australia has been focused on solving regulatory burdens and approval delays through the development of the National One Stop Shop, that aims simplify regulation and funnel all trial approval processes through a central virtual processing centre.
Step 3: Trial Registration	Trials are reported to the Australia New Zealand Clinical Trials Registry; clinical trial data is readily accepted by the FDA and European Medicines Approval Agency, meaning that clinical trials in Australia do not require US FDA Investigational New Drug (IND) application approval (a process that can otherwise add delays).

How is clinical research funded?*

Funder	Type	# of Grants	Funding amount
1. Department of Health and Aged Care (DoH) Including: National Health and Medical Research Council, Medical Research Future Fund, Cancer Australia, DOH, National Mental Health Commission, National Blood Authority	public	2,463	2.19 B
2. Australian Research Council	public	236	83.0 M
3. Department of Industry, Science and Resources	public	35	49.79 M
4. National Heart Foundation of Australia	nonprofit	191	33.0 M
5. Department of Social Services	public	5	20.3 M
6. Department of Infrastructure, Transport, Regional Development, Communications, and the Arts	public	6	20.2 M
7. Department of Education	public	1	17.7 M
8. Australian Centre for International Agricultural Research	public	5	5.8 M
9. Cancer Institute of New South Wales	public	57	4.8 M
10. Garnett Passe and Rodney Williams Memorial Foundation	nonprofit	13	2.2 M

*Data reflects top 10 funders for clinical research for years 2018-2022, from Dimensions Analytics.

Strategies for success

National Plans	Currently, the Australian Medical Research and Innovation Strategy 2021-2026 is in effect and covers clinical research broadly. In May 2024, Australian Government announced they are beginning the development of a National Health and Medical Research Strategy. In 2023, Australia launched the 10-year Australia Cancer Plan, which includes a section on research.
Role of Networks	• Clinical research networks play an important role in coordinating clinical trials and research efforts across the nation and connecting clinical researchers to governments, policy makers, and patients. • The not-for-profit Australian Clinical Trials Alliance (ACTA) is a national alliance representing investigator-led clinical trials and clinical trial networks of all therapeutic areas, as well as coordinating trial centres and clinical quality registers. Individual clinical trial networks may apply for public funding, professional society/ charity funding, or industry funding to finance their networks. • In Australia, clinical trials units or clinics are often co-located next to or nearby existing hospitals. This arrangement allows for dedicated beds to be maintained for clinical research patients separate from regular hospital operations, but close enough to allow research patients access to support staff and services that may be needed for research.
Promising Ideas	The ACTA has established a Research Prioritisation Reference Group have recently published work to identify current examples of research prioritisation methodologies that could be apply to clinical trials, such as the James Lind Alliance's priority setting partnership exercises. This work was used to inform the Australian Clinical Trials Alliance's comprehensive Research Prioritisation Framework for Clinical Trials Networks and Funders to explore ways to prioritise trials based on priority topic areas and stakeholder preferences.

SPOTLIGHT ON: FRANCE

France is the world's 23rd most populous country with 66.5 million people. France has universal health coverage with the option to buy additional private coverage. France is a leading country for clinical research within Western Europe.

How is clinical research generated?

Step 1: Obtain funding	France has provided over 2B USD towards clinical research grant funding from 2018-2023 through public funding from the Department of Health and Aged Care. Additional funding is available through other public and nonprofit funding sources.
Step 2: Obtain regulatory approval	• Ethical approval: Regional Ethics Committees (Committees for the Protections of Persons, CPP). • Medical products approval: French National Agency for the Safety of Medicines and Health Products (ANSM). • Data protections legislation: Health data collected during research must meet the guidance of the French Data Protection Authority (CNIL) and follow Europe's GDPR.
Step 3: Trial Registration	Trials are reported to the EU Clinical Trial Information System, and there is also a cancer specific clinical trials registry - the INCA Clinical Trials Registry.

How is clinical research funded?*

	Funder	Type	# of Grants	Funding amount
1	Agence Nationale de la Recherche	Public	2,223	281.6 M
2	Fondation de France	Nonprofit	23	3.9 M
3	Fondation Vaincre Alzheimer	Nonprofit	1	115.0 K
4	Fondation ARC pour la Recherche sur le Cancer	Nonprofit	41	
5	International Human Frontier Science Program Organisation	Nonprofit	13	

* Data reflects top 5 funders for clinical research for years 2018-2022, from Dimensions Analytics. Only five French funders for clinical research were included in Dimensions.ai.

Strategies for success

National Plans	• France launched a landmark Health Innovation 2030 plan in 2021 with an associated 7.5B euros. • France also has a national 10-year 2021-2030 Cancer Control Strategy, which emphasises the role of research in meeting strategy goals.
Role of Networks	• Clinical Investigation Centres: The Ministry of Health and Prevention and INSERM jointly manage 36 Clinical Investigation Centres. • The French Clinical Research Infrastructure Network (F-CRIN) is a comprehensive organisational network that spans 19 medical fields and includes “17 theme-based clinical research and investigation networks, 3 networks of advanced expertise, 1 multiservice platform and 1 national coordination unit acting as

	infrastructure headquarters".[19] In coordination with the Health Innovation Agency, F-CRIN has undertaken two recent scoping projects looking at how real-life health data can be used in clinical research and how clinical trial methodologies have evolved over time.[20] • France is also a participant in the European Clinical Research Infrastructure Network, which assists with the coordination and management of multinational clinical trials in Europe.
Promising Ideas	• In order to ensure that government is working in a coordinated fashion toward a common goal, France has set up an interministerial steering committee "for the purposes of sharing clinical research objectives, coordinating the various actions decided upon and assessing their progress (shared indicators and dashboard"[21] • France aims to be a leader in the European clinical trials regulatory space, with goals to create a European regulatory framework for clinical research that matches the speed and needs of new innovations • France's Health Innovation Agency aims to provide direct support to 100 projects annually that address priorities of the agency through three support programmes: the "priority access" programme that offers support in bringing innovations to market, the "off-framework" programme that assists projects trying to bring new innovations to market that currently fall outside of regulatory guidelines and would not otherwise make it through the regulatory system, and the "scaling up" programme that offers assistance to projects that have a demonstrated safe and

[19] https://www.fcrin.org/en

[20] www.fcrin.org/nouvelles-methodologies-en-recherche-clinique/livrables-et-avancement-des-travaux

[21] www.info.gouv.fr/upload/media/content/0001/10/440a92a17aa78c3b5585acaf780189a16fb394d2.pdf

effective innovation but need help scaling their project nationally.

SPOTLIGHT ON: GERMANY

Germany is the world's 19th most populous country with 84.4 million people. Germany has mandatory health insurance and offers statutory (subsidised) insurance or an option for private coverage (non-subsidised). The government does not directly provide healthcare and facilities and providers treat all citisens regardless of insurance type.

How is clinical research generated?

Step 1: Obtain funding	Germany has provided over 575M USD towards clinical research grant funding from 2018-2023 through public funding from the Federal Ministry of Education and Research. Additional funding is available through other public and nonprofit funding sources.
Step 2: Obtain regulatory approval	• Ethical approval: German Medical Ethics Commission • Medical products approval: Federal Institute for Drugs and Medical Devices (BfArM) and the Paul-Ehrlich-Institute • Data protections legislation: Germany complies with GDPR laws dictating how personal data must be collected, processed, and stored.
Step 3: Trial Registration	Clinical trials in Germany are reported to the German Clinical Trial Registry and the EU Clinical Trial Information System.

How is clinical research funded?*

	Funder	Type	# of Grants	Funding amount
1	Federal Ministry of Education and Research	Public	769	575.6 M
2	Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection	Public	11	24.4 M
3	Federal Ministry for Economic Affairs and Climate Action	Public	49	23.4 M
4	Federal Ministry for Digital and Transport	Public	12	10.4 M
5	Federal Ministry of Food and Agriculture	Public	6	1.2 M
6	Alzheimer Forschung Initiative	Nonprofit	7	528 K
7	Deutsche Bundesstiftung Umwelt	Public	4	433 K
8	Deutsche Forschungsgemeinschaft	Public	2,552	
9	Volkswagen Foundation	Nonprofit	45	
10	Fritz Thyssen Foundation	Nonprofit	3	

* Data reflects top 10 funders for clinical research for years 2018-2022, from Dimensions Analytics.

Strategies for success

National Plans	• In 2024, the Medical Research Act was passed, representing a major new pharmaceutical research strategy for the country. It has several aims which include speeding up ethical and regulatory approvals through a few key mechanisms including: reorganisation of the two regulatory agencies, the establishment of a new federal ethics committee which will limit the need for trials to pass through multiple local level ethics committees when the trial focuses on an urgent health need, and standardising contracts across sites. • Germany has a 10-year plan: National Decade Against Cancer (2019-2029) that is led by the DKTK.
Role of Networks	• The DKTK, the German Cancer Research Centre, helps to manage the Germany Cancer Consortium, an academic-focused clinical cancer research network. • The KKS Network (KKSN) is a network of 28 academic coordinating centres for clinical research studies across Germany. It operates as a non-profit organisation with "the aim of strengthening patient-oriented clinical research". (cite: https://www.kks-netzwerk.de/en/network/about-us/). • Germany is a participant in the European Clinical Research Infrastructure Network, which assists with the coordination and management of multinational clinical trials in Europe.
Promising Ideas	Germany has set up the Health Innovation Hub that serves an independent "think tank, sparring partner, and implementation supporter for the Federal Ministry of Health and its subordinate authorities, among others" with the goal to serve as the main point of contact between all stakeholders within the German healthcare system. (cite: https://hih-2025.de/en/about). Their remit primarily covers electronic health records, health data, digital applications for health research and AI.

SPOTLIGHT ON: SPAIN

Spain is the world's 32nd most populous country with 47.9 million people. Spain has a single-payer healthcare system. Healthcare is delivered regionally and coordinated nationally.

How is clinical research generated?

Step 1: Obtain funding	Spain has provided over 300 M USD towards clinical research grant funding from 2018-2023 through public funding from the Instituto de Salud Carlos III. Additional funding is available through other public and nonprofit funding sources.
Step 2: Obtain regulatory approval	• Ethical approval: Ethics Committee of Research with Medicines • Medical products approval: Spanish Agency of Medicines and Medical Devices (AEMPS) • Data protections legislation: In 2022, the Spanish Data Protection Authority approved the "code of conduct on the processing of personal data in the field of clinical trials and other clinical research as well as pharmacovigilance" (128, 129) which offers additional clarification on the roles and responsibilities of trial sponsors and clinical research organisations in managing patient data protections.
Step 3: Trial Registration	Clinical trials in Spain are reported to the Spanish Registry of Clinical Trials and the EU Clinical Trial Information System.

How is clinical research funded?*

	Funder	Type	# of Grants	Funding amount
1	Instituto de Salud Carlos III	Public	2411	311.9M
2	Salud Castilla y Leon	Public	79	

* Note: only two Spanish funders for clinical research were included in Dimensions.ai.

Strategies for success

National Plans	• Spain does not have a national clinical research strategy, but innovations in biomedical research are mentioned in the Spanish Science, Technology and Innovation Strategy 2021-2027. • Spain has a national cancer control strategy available here: Estrategia en Cáncer del Sistema Nacionalde Salud 2021
Role of Networks	• The ISCIII has 32 associated Biomedical Research Institutes (BRI) that provide coordination for research activities alongside Spanish National Health System hospitals and primary care centres, and facilitate collaboration among academia, public and non-profit research centres, and industry. • Spain is a participant in the European Clinical Research Infrastructure Network., which assists with the coordination and management of multinational clinical trials in Europe.
Promising Ideas	We heard that Spain has a very coordinated national health system that "comes after years of collaborative work between health authorities, research hospitals, patients and pharmaceutical companies"[22].

[22] https://distefar.com/en/spain-a-clinical-trials-powerhouse/

SPOTLIGHT ON:
UNITED KINGDOM

The United Kingdom is the world's 21st most populous country with 68.7 million people. The United Kingdom has a single-payer healthcare system that is operated across four devolved nations: England, Scotland, Wales, and Northern Ireland.

How is clinical research generated?

Step 1: Obtain funding	The United Kingdom has provided over 10 B USD towards clinical research grant funding from 2018-2023 through public funding from NIHR and UKRI. Additional funding is available through other public and nonprofit funding sources.
Step 2: Obtain regulatory approval	• Ethical approval: England and Wales submit approvals to Health Research Authority (HRA), Northern Ireland submits approvals to HSC Research and Development Division of Northern Ireland, and Scotland submits approvals to NHS Research Scotland Coordination. • Medical products approval: Medicines and Healthcare Products Regulatory Agency (MHRA) • Data protections legislation:
Step 3: Trial Registration	NIHR asks sponsors to use ClinicalTrials.gov or ISRCTN to register their trials as both are reported to NIHR's Be Part of Research program.

How is clinical research funded?*

	Funder	Type	# of Grants	Funding amount
1	National Institute for Health and Care Research Including: NIHR, NIHR Evaluation Trials and Studies Coordinating Centre and NIHR Academy	Public	3521	6.43B
2	UK Research and Innovation Including: MRC, UKRI, ESRC, Innovate UK, EPSRC, BBSRC, AHRC, NERC, and STFC	Public	5287	3.69B
3.	Gov UK	Public	417	348.9M
4.	Wellcome Trust	Nonprofit	1,024	1.41 B
5.	British Heart Foundation	Nonprofit	347	202.7 M
6.	Cancer Research UK	Nonprofit	898	129.0 M
7.	Blood Cancer UK	Nonprofit	128	90.1 M
8.	Yorkshire Cancer Research	Nonprofit	86	79.0 M
9.	Versus Arthritis	Nonprofit	151	71.3 M
10.	Prostate Cancer UK	Nonprofit	42	39.2 M

Strategies for success

National Plans	• In 2018, the UK announced the Life Sciences Vision, which covered clinical research as one of its three main themes for health research. • In 2021, The Future of UK Clinical Research Delivery was published further articulating the UK's vision for clinical research. • In 2021 and 2022, associated implementation plans were published detailing next steps for implementation. • The Future of UK Clinical Research Delivery Implementation Plan 2022-2025 • The Future of UK Clinical Research Delivery Implementation Plan 2021-2022 • The UK does not have a current national-level cancer research strategy, however there are cancer research strategies for England, Northern Ireland, Scotland, and Wales*.
Role of Networks	• NIHR Clinical Research Network ---> NIHR Research Delivery Network • Regional Research Delivery Networks • UK Clinical Research Facilities Network • Northern Ireland Clinical Research Network • Northern Ireland Clinical Trials Unit • Centre for Trials Research at Cardiff University Wales Cancer Network
Promising Ideas	• The Areas of Research Interest are a useful mechanism to surface priority evidence needs • Funding to move and build research capacity where needed

*Following our interviews, we learned of a new initiative from Wales: the Tackling Cancer Initiative, which has a key research workstream to tackle systemwide challenges through a "One Wales" approach to process and deliver cancer clinical trials, strengthening leadership, and improving patient access to studies and clinical awareness of studies.

SPOTLIGHT ON: UNITED STATES

The United States is the world's 3rd most populous country at 334.9 million people. The United States has no universal health insurance coverage, although there is federal funding available for a national Medicare program (for adults 65 year of age an older), Veteran's health, children, and low-income people (via Medicaid and the Children's Health Insurance Program). Additional public funding for insurance coverage may be available at the state level, and states direct safety-net care for the uninsured populations in their jurisdiction. Employee-sponsored private health insurance covers most of the U.S. population. The U.S. government is the world's leading funder for clinical research, and the country is a leader in industry start-ups for clinical research.

How is clinical research generated?

Step 1: Obtain funding	The United States has provided over 175 B USD towards clinical research grant funding from 2018-2023 through public funding from the NIH alone. Additional funding is available through other public and nonprofit funding sources.
Step 2: Obtain regulatory approval	• Ethical approval: Local IRB boards, all must be registered with the HHS Office for Human Research Protections • Medical products approval: FDA • Data protections legislation: Health data collected during research must be stored in accordance with the Health Insurance Portability and Accountability Act (HIPAA); in addition, "most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the FDA's human subject protection regulations (21 CFR Parts 50 and 60) (130).
Step 3: Trial Registration	All trials are reported to ClinicalTrials.gov.

How is clinical research funded?*

	Funder	Type	# of Grants	Funding amount
1	National Institutes of Health (NIH) 25 Institutes reporting clinical research grants	Public	56,842	177.5B
2	Health and Human Services (HHS) 7 Agencies or Administrations reporting clinical research grants, excluding NIH	Public	7802	13.7B
3.	Bill and Melinda Gates Foundation	Nonprofit	878	3.6 B
4.	National Science Foundation 9 Directorates reporting clinical grants	Public	4736	3.2B
5.	Patient-Centreed Outcomes Research Institute (PCORI)	Nonprofit	957	3.1 B
6.	Department of Defense (DoD) 10 Departments or Agencies reporting clinical grants	Public	1024	2.6B
7.	Department of Education (DoE)	Public	880	1.7 B
8.	Robert Wood Johnson Foundation	Nonprofit	1,511	756 M
9.	Department of Agriculture (USDA)	Public	1,196	482 M
10.	American Heart Association	Nonprofit	1,239	443 M

* Data reflects top 10 funders for clinical research for years 2018-2022, from Dimensions Analytics.

Strategies for success

National Plans	• The US does not have a formal national clinical research strategy, but has recently launched a "whole-of-government approach to bolster clinical trial capacity in the United States", called the Clinical Trials Readiness initiative.[23] • Additionally, the most recent National Cancer Plan was developed in 2023;
Role of Networks	• The US has several clinical trials networks that support research across disease areas within the US. Two trial networks of note include the NCI National Clinical Trials Network (NCTN) and the NIH Pragmatic Trials Collaboratory -this network supports academic-led clinical trials.

[23] A Stronger Clinical Trial Infrastructure for Better Health Outcomes

APPENDIX 4:

RECOMMENDATIONS ANALYSIS

Table 1. Documents included in recommendations analysis

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
Recommendation documents										
2018	1	UK Gov	Gov	Life Sciences Vision	X		X	X	X	X
2021	2	UK Gov	Gov	Saving and Improving Lives: the Future of UK Clinical Research	X	X	X		X	X
	3	CRUK	Non-profit	Creating Time for Research	X	X				X

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
	4	Senedd Cross Parliamentary Group	Mixed	Senedd Cross Parliamentary Group on medical research Report	X	X				X
2022	5	ABPI	Industry	Rescuing patient access to industry clinical trials in the UK	X	X	X	X		X
	6	CRUK	Nonprofit	Beyond Recovery	X	X	X	X		X

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
2022	7	Wales Gov	Gov	Making research careers work: a review of career pathways in health and social care in Wales		X				
	8	Royal College of Physicians	Education	Making research everybody's business	X	X				
2023	9	Lord O'Shaughnessy	Gov/ Industry	Commercial Clinical Trials in the UK: the Lord O'Shaughnessy Review		X	X		X	X
2013	10	CRUK	Non-	Longer, Better Lives	X	X	X	X	X	X

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
			profit							
	11	ABPI	Industry	Getting back on track: Restoring the UK's global position in industry clinical trials			X			
	12	Scotland Gov	Gov	Improving equity of access to cancer clinical trials in Scotland - gov.scot	X	X	X		X	X
2024	13	ABPI	Industry	2024 Manifesto or Investment, health and growth	X		X	X	X	

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
2024	14	British Medical Association	Non-profit	Medical academic workforce planning for the future		X				X

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
Implementation strategy documents										
2021	15	UK Gov	Gov	The Future of UK Clinical Research Delivery Implementation Plan 2021-2022	X					
2022	16	Wales Gov	Gov	Moving forward: a cancer research strategy for Wales		X		X	X	X
	17	Health and Care Research Wales	Gov	Research Matters: our plan for health and care research in Wales	X	X	X	X	X	X

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
2022、	17	Health and Care Research Wales	Gov	Research Matters: our plan for health and care research in Wales	X	X	X	X	X	X
	18	Northern Ireland Gov	Gov	Northern Ireland Implementation Plan for Clinical Research, Resilience and Growth	X	X	X	X	X	X
	19	UK Gov	Gov	The Future of Clinical Research Delivery: 2022 to 2025 implementation plan - GOV.UK	X	X	X		X	

Year	#	Author	Author type	Document name	A Research -Ready NHS	Incentivising and enabling a research-active workforce	Creating the right data infrastructure	Improving how clinical trials are set-up and run	Making the most of commercial investment	Funding the right research
Progress documents										
2023	20	UK Gov	Gov	Full Govt response to O'Shaughnessy Review		X				

APPENDIX 5.

RECOMMENDATIONS BY THEMATIC AREA

Theme 1: A research-active NHS

Topic area	# of docs
Performance metrics: metrics for NHS research engagement and impact	9
Build capacity: invest in local capacity: invest in workforce capacity; build capacity for services and resources; central fund essential radiotherapy for clinical trials capacity	7
Public engagement, clinician engagement and patient recruitment: public campaigns to enhance research engagement; support researchers as they involve the public; provide a common approach to contacting patients and use an innovative approach through data; local NHS R&D offices should survey research awareness and activity of staff; consider EDI and PPI	6
Access to medicines and technology/Delivery of Care: access to medicine post EU exit; access to medicines following trials; access to vaccines; improve delivery of cancer care	5
Coordination/collaboration: study collaboration; collaboration between academia, industry and NHS	2
Finance: develop better models for transferring funds between NHS bodies	1
Accreditation for Research: national accreditation for radiology, radiotherapy and laboratories	1

Theme 1. Topic 1:
Performance Metrics

Recommendations from Reports

1. Metrics for NHS research engagement and impact:

- All four national departments of health should develop a coordinated set of metrics to capture NHS research engagement and impact. These quantitative metrics should capture research's impact on patients, staff, NHS systems and cost savings. The resulting data should be incorporated into existing platforms for evaluating NHS Trusts and Health Boards.
- NHSE should develop a coordinated set of metrics to monitor and evaluate commercial and non-commercial NHS research engagement and impact at Trust, regional and national levels. This should include an annual target in the NHS mandate that is reported to parliament.
- Adopt KPIs for use across NHS Scotland, and NHS Research Scotland Central Management Team to report board level performance at regular intervals.
- NHS England and its devolved equivalents should develop metrics to better capture the impact of NHS research.
- NHSE should work with the pharmaceutical industry to co-develop research guidance and research performance metrics for ICSs
- Make research matter to the NHS to ensure staff see the benefit for their patients and feel empowered to support research, however they play their part. This means capturing, monitoring and promoting support for research across the NHS – for example, the number of referrals to research studies, the number of participants recruited to trials and good data collection in electronic health records.
- Recognise and reward trusts that engage with research and industry to improve patient care: In 2019, the NHS Long Term Plan indicated that performance on adopting proven innovations and on research would become part of core NHS performance metrics, assessment systems and benchmarking data. This provides an important mechanism for recognising research active trusts. NHSE should explore what opportunities are available to reward trusts that perform highly on these metrics, to further incentivise engagement with research. The departments of health in the other UK nations should consider what equivalent levers are available to recognise and reward research activity in Scotland, Wales and Northern Ireland.

- Monitoring and reporting research and innovation activity across the NHS, to increase transparency and allow for constructive, evidence-based improvement in places where focus on research and innovation could be increased.

2. Include clinical research in quality accreditation:

- For the Care Quality Commission (CQC): strengthen assessment of clinical research activity as a marker of high-quality care within assessment processes of trusts and ICSs: In 2019, the CQC began to take account of research when inspecting trusts by including questions about clinical research activity within its well-led framework. Recognising the positive impact that research has on patient care – and working with other stakeholders, including NHSE as it leads the development of new metrics and system oversight – the CQC should further strengthen the position of clinical research within its new regulatory model and assessment methodology to ensure that trusts and systems are encouraged to be research active.

Headline commitments from implementation documents

Metrics for NHS research engagement and impact:

- We will work across the UK administrations to introduce new metrics and measures to increase the visibility and recognition for undertaking and supporting clinical research across NHS organisations

Progress made to date

- None reported

Referring Documents

1. CRUK Creating Time for Research Report
2. CRUK Longer, better lives
3. Improving equity of access to cancer clinical trials in Scotland
4. Beyond Recovery
5. ABPI Rescuing Patient Access to Industry Clinical Trials
6. Saving and Improving Lives
7. Making research everybody's business
8. Life Sciences Vision

Theme 1. Topic 2:
Public engagement, clinician engagement and patient recruitment

Recommendations from Reports

1. Public campaigns to enhance research engagement:

- improving visibility of research within NHS
- a national participatory process should be conducted to examine how to achieve greater data usage for clinical studies in a way that commands public trust. This should seek to establish a publicly supported position around the proactive contacting of patients to take part in clinical trials and studies that could form part of their care
- an ongoing public campaign should be conducted to promote research and to generate evidence on the most effective communication methods, in partnership with medical and research charities
- the government and the NHS should work with royal colleges and unions to integrate 'research conversations' into all NHS communications and clinical interactions

2. Provide a common approach to contacting patients to participate in clinical trials, and use an innovative approach through data.

- full Integration of NIHR Be Part of Research with the NHS App should be accelerated, with enhanced opportunities to take part in clinical trials added to the platform.

3. Local NHS R&D Offices should undertake periodic reviews of research awareness and activity amongst their health service staff and patients. The resulting qualitative insights should inform local efforts to showcase research's value and increase staff engagement with research.

4. Consider EDI and PPI:

- ensure people have the opportunity to take part in research and have equitable access to clinical trials
- make research more diverse and relevant to the whole UK By building on centres of excellence, such as the Centre for BME Health in Leicester, we will increase support for research in more diverse and under-served populations.
- Increase the capacity and confidence to deliver research in areas with the highest disease burdens and levels of deprivation.

5. Clinician engagement:

   For the GMC: build on the publication of its key principles by continuing to work with partners to encourage greater participation: The GMC has published key principles describing the system changes that will help doctors and healthcare teams to engage with and support more research as part of their clinical practice. The GMC should continue to work closely with partners in the education, health and research sectors to encourage greater participation in and a more inclusive approach to research in clinical practice.

Headline commitments from implementation documents

1. Public campaigns to enhance research engagement:

- [1.1.05] Improve communication with the public about research in HSC and increase public awareness of the value of this research.
- [3.2.05] Increased, appropriate use of public "advertising" (e.g. social media) to identify potential participants for HSC research, bearing in mind the need to ensure that expectations of the public are properly managed and that these approaches to recruitment may need approval as part of the ethical approval for the trial.

2. Support researchers as they involve the public in their work.

   We will support new and existing researchers, academics and the NHS research community to communicate the impact of their work and involve the public in their research. This will include raising the profile of their research on Health and Care Research Wales communication channels, providing a bespoke media training programme, and developing our Ambassador programme for senior research leaders so they can be more effective brand ambassadors for Health and Care Research Wales

- We will work as part of the Five Nations Public Involvement Group to lead and collaborate on projects that tackle administrative and system barriers to meaningful public involvement
- We will create tools and resources to support researchers to incorporate meaningful public involvement in their work, drawing on the UK Standards as the framework for good practice
- We will expand the opportunities for more diverse population of Wales to get involved in shaping, informing, reviewing and delivering high quality research, working with local community groups and national organisations

- We will continue to implement the three year public engagement strategy we published in 2021, to promote the vital role the public play in enabling research to happen, and how they can get involved.
- We'll expand support to help sponsors easily access patient groups who can support development of their studies.
- We will ensure that publicly funded research models have public, patient and service user involvement in research design and delivery at their heart, in line with the highest UK standards.

3. Provide a common approach to contacting patients to participate in clinical trials, and use an innovative approach through data.

- [2.4.01] Ensure a coordinated approach to increase public participation and involvement in research.
- [3.2.04] Better use of routine data to identify potential participants for HSC research.
- [3.2.07] Development of methods to support econsent for HSC research.

4. Local NHS R&D Offices should undertake periodic reviews of research awareness and activity amongst their health service staff and patients.

- [1.1.05] Improve communication across the Northern Ireland health and life science ecosystem (including with and between HSC Trusts, commercial companies and universities) about HSC research and the opportunities for research to increase awareness of research.
- [2.3.02] Scope for creation of lead posts for PPI in research within HSC Trusts and primary care.

5. Consider EDI and PPI:

- [2.4.02] Align with UK work streams to identify strategies to ensure that communities traditionally under served by research have opportunities to take part in research, both as participants and PPI partners.
- [2.4.03] Work with the Community Engagement Network, PHA, community leaders, Together NI and other fora to promote opportunities for involvement and participation of people from seldom heard groups.
- [2.5.01] Ensure PPI from the start and throughout the research cycle, including the choice of the research question, design of the study, development and implementation of the study, and dissemination of its findings. This will ensure that PPI is a strong and meaningful component in any application for R&D funding as part of the RRG process and aligns with

UK standards.

- [2.5.02] Create a PPI Coordinator/lead role to increase practical training for researchers, service users and the public in implementing PPI in the research process.
- [2.5.03] Develop a mechanism to ensure that researchers can access patients, service users and public as partners and/or participants in research.
- [2.5.04] Continue to build on communications and media work around COVID19 to maintain public awareness of the importance of research with service users and public through the appointment of a dedicated communications officer.
- [2.5.05] Ensure that Northern Ireland is represented on UK working groups and commits to 4-nation initiatives on PPI (e.g. Public Standards for Involvement; NIHR/HRA Joint Statement/Payments policy).
- [3.2.06] Improved methods for identifying people in hard-toreach groups who would be potential participants for HSC research.
- Reflect the diversity of the UK's population in future clinical research – System partners, including the medical research charities, will work together to proactively increase the racial, age, gender, and geographic diversity of clinical trial participants and those in real world data sets. This will include the development of novel processes and guidance to increase uptake among traditionally underserved communities, including those in rural or small-town settings; ethnic minority groups; women; as well as children and the elderly.

Planned commitments from the Future of UK Clinical Research Delivery 2022-2025 Implementation Plan:

- Our aim will be to achieve a sector-wide, sustained shift in how studies are designed and delivered so that inclusive, practicable and accessible research is delivered with and for the people with the greatest need and in ways that enable us to tackle the greatest challenges facing the NHS. The UK's ability to deliver diverse trials and studies will also give us a competitive advantage on the global stage, attracting researchers from around the world to base their studies here:
- The HRA is leading a cross-sector project, co-produced with public contributors, to collect evidence about how high quality, people-centred clinical research is done well: finding out what matters most, what 'good' looks like and what might be making it difficult. It will make recommendations to help improve the way clinical research happens in the

UK and disseminate information about actions and resources developed by partners

- NIHR will invest in the development of skills and tools for innovative trial delivery, increasing the confidence and ability of our researchers to design and deliver studies in people-centred ways
- NHS England will launch a toolkit that could be used by researchers across the UK to help them engage more effectively with selected underserved communities. NIHR will also promote increased use of the resources developed by the NIHR INCLUDE project project which enable researchers to increase inclusion of underserved communities in their research
- NIHR and NHS Digital will develop mechanisms to monitor the diversity of people participating in NIHR Clinical Research Network portfolio studies in England in order that we can understand where improvement is needed and what action will be most effective.
- In England, the NHS Accelerated Access Collaborative will invest in demand signalling (the process of identifying, prioritising and articulating the most important research questions) and horizon scanning (the process of identifying and better understanding emerging transformational technologies of potential benefit to the NHS and our communities) to improve identification of the most needed treatments and technologies and rapidly bring these into clinical use
- In Scotland, SHIP is leading the new Scottish Health and Industry Partnership Demand Signalling Plan. This new framework will support identification and decision making around key strategic challenges and operational pressures to accelerate NHS Scotland Re-mobilisation, Recovery and Re-design, aligning with delivery of the NHS Recovery Plan 2021 to 2026, and the Life Science Vision healthcare missions
- Medical research charities play an important role in supporting people-centred research, utilising their contacts with patients and communities, and prioritising their needs when setting a research agenda. The Association of Medical Research Charities (AMRC) will be working with NIHR and NHS England to formalise this work – and will share findings once developed across the UK
- The RRG programme will ensure strategic co-ordination of this work across the UK clinical research ecosystem, supporting progress and ensuring alignment of initiatives, as well as identifying key areas where we can go further within the next 3 years.
- Work is also underway to improve access to research through digitised recruitment as detailed in the section on research delivery enabled by data

and digital tools.

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

- The MHRA ran a public consultation on proposals for legislative changes for clinical research. The proposals aim to promote patient and public involvement in clinical research, increase the diversity of participants, streamline clinical research approvals, enable innovation, and enhance clinical research transparency. The consultation sought the views of the wider public, clinical research participants, researchers, developers, manufacturers, sponsors, investigators, and healthcare professionals to help shape this important future legislation and over 2,000 responses were received
- Delivering studies such as PANORAMIC and IBS-RELIEVE has demonstrated the UK's growing ability to harness technology and conduct studies virtually and in the community
- HRA and MHRA, in collaboration with NHS Research Scotland, Health and Social Care Northern Ireland (the equivalent to the NHS in Northern Ireland), and Health and Social Care Research Wales, have published UK-wide guidance on the set up of interventional research to enable research to be delivered across organisational boundaries and to help take research to where people might find it easier to take part, for example using hub and spoke models
- The NIHR led UK Working Group on Remote Trial Delivery published a report in June, which discussed the challenges and opportunities in remote trial delivery and provided guidance for researchers
- The NIHR Race Equality Framework was piloted by industry. This self-assessment tool helps organisations to improve racial equality in health and care research
- Partners across the UK are working together to ensure patient and public involvement in research in a variety of ways including through regulation, ethics, payment for public contributors and development of new public engagement strategies. This includes the publication of a shared commitment to public involvement in research to ensure involvement is built into study design, delivery, and dissemination
- In Northern Ireland the Clinical Research Recovery Resilience and Growth Taskforce implementation plan includes a patient and public engagement

and involvement sub-group, which is focused on the development of patient and public centred priorities, and an innovation sub-group planning approaches to innovative and people-centred trial design

- In Wales, the 'Discover your Role' programme is underway, with a co-created action plan to ensure that people are at the heart of new developments in research
- The NHS Research Scotland patient and public involvement workshop series completed and reported in September 2021. Findings from the workshops and the Scottish Patient Public Involvement Survey are informing work to support greater visibility and connectivity, increased diversity and representation, and a review of the current mechanisms for pre-award funding

From the Full Government Response to the O'Shaughnessy Review in Nov 2023:

By empowering people to access research studies of relevance to them we will increase engagement and participation in research across the country and help to break down traditional barriers to accessing research based on geography. It will also support clinicians in identifying research of relevance to their patients and provide tools and information to help discuss research as part of choices about care.

For this reason, we have ambitious goals regarding registrations on Be Part of Research with our aims being:

- Leveraging key NHS platforms such as the England NHS App, we will have 500,000 people signed up to Be Part of Research by April 2024
- By March 2025, this will have increased to 1 million people
- By summer 2024, the 20 most visited condition-specific pages on the NHS website in England will feature a link to Be Part of Research, providing people who are interested in that condition the opportunity to explore the opportunities for them to take part in studies
- NHS England is also considering the most appropriate ways to build on the success of linking the NHS app to Be Part of Research
- Be Part of Research volunteers have the option to register their interest in being directly invited to participate in specific studies for which they may be eligible. Since February 2023, the service has been used by 11 studies, contacting over 20,000 volunteers leading to approximately 2,000 participant enrolments. The service has an active pipeline, with 51 studies preparing to use the service. We will continue to build on this as part of our broader efforts to develop data enabled approaches to research delivery, as set out

later in this document.

[1.5] Establish a common approach to contacting patients about research

Recommendations 18 and 20

Vision themes:

- Research delivery enabled by data and digital tools
- People-centred research

The HRA has engaged with a range of UK-wide organisations and individuals to understand current arrangements for identifying and contacting potential participants, and the barriers and enablers to a people-centred model. This has involved detailed work to establish legal positions on a variety of issues and surface differing interpretations and their implications. New guidance on specific areas has been developed based on this work with input from a range of stakeholders and is being reviewed through the Health and Care Information Governance Panel.

Final conclusions and recommendations will be published by the end of 2023. We will publish details of further actions based on the recommendations to support data-enabled delivery of research by April 2024. This will include HRA's considerations as to whether a national participatory process on patient consent is required and, if so, how this might be conducted.

Referring Documents

1. O'Shaughnessy Review
2. Senedd Cross Parliamentary Group on medical research 2021
3. Saving and Improving Lives
4. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Research matters: our plan for improving health and care research in Wales

Theme 1. Topic 3:
Build capacity

Recommendations from Reports

1. Invest in local capacity:

- The UK Government should invest in expanding the capacity of local NHS R&D offices
- The UK Government should conduct a regional review of clinical research activity. The review's findings should inform proposals for additional funding that facilitates increased research engagement within regions currently under-served by research. The review's findings should also inform revisions to existing R&D investment, with a view to making this investment more regionally equitable and unlocking research capacity.

2. Invest in workforce capacity

3. Build capacity for research:

- Such that resource is available for research and development within the genomics labs, to allow evolution of testing in line with new targets for cancer therapies.
- Build capacity in services required to support tissue testing including pathology, biorepository, tissue transportation.
- Cover a broad panel of genes required for SMC approved medicines and including targets currently under exploration in early-phase trials and targets with promising pre-clinical data.
- Consider the need for more complex tests in certain circumstances (HRD testing, fusions, structural variation, whole genome sequencing).-Establish the National Molecular Tumour Board to allow discussion of complex molecular testing results and consideration of clinical implications.
- Align a programme of education to the new strategy to improve genomic literacy across the health service but particularly within oncology, radiology (understanding tissue requirements for molecular testing), surgery, medical specialities.
- The Managed Recovery programme should take steps to prevent further disruption to cancer research, increase researchers' access to the resources needed to restart clinical trials, and set clear targets to coordinate local NHS leaders and their resources

- For the NIHR: continue to build capacity and capability for research across the whole of the NHS and care, working closely with other funders, academies and cross-funder initiatives: The benefits of clinical research are not felt equally across the UK. Access to research opportunities needs to be improved for patients and clinicians in communities that have been historically underserved. NIHR has an important role to play in developing the infrastructure and capacity necessary to increase research activity in these areas and in ensuring that this encompasses all of health and social care, and should work with other funders, academies and cross-funder initiatives such as the Clinical Academic Training Forum to achieve this.
- Ensure that grant awards and research processes recognise and support research that addresses health inequalities and other NHS priority areas: Tackling inequalities in health outcomes represents an urgent challenge for all those working in health and care. It is crucial that clinical research plays its part in reducing health inequality, the causes of which are often complex and long term. In order to facilitate this, research funders must ensure that health inequality is a priority within grant-making, and that awards, funding and subsequent research processes all address inequalities.
- Ensure that research projects that are funded are accessible and inclusive: Improving equality, diversity and inclusion within clinical research and widening participation – in terms of both who conducts research trials and who takes part in them – is essential to ensuring that the benefits of research are felt by everyone. Funders should therefore ensure that the projects they support are accessible and inclusive, and provide guidance to grantholders on how to improve inclusivity in their work, such as that available through the NIHR INCLUDE project. Patient and public involvement in clinical research is ultimately crucial to its success and the shared commitment to improve public involvement in research, supported by many UK funding bodies, provides an important standard in this regard.
- Provide support to grant-holders to reduce the environmental impact of clinical research activity: As research becomes more embedded in clinical practice, it is vital that this is achieved in a way that supports the NHS's wider net zero targets. Clinical research activity can be a significant source of CO2 emissions, with one study, based on a sample of 12 randomised controlled trials, finding that the average CO2 emission per trial was 78.4 tonnes. Funders should provide support to their grant-holders to reduce the environmental impact of their work, such as the carbon reduction guidelines developed for researchers by NIHR.
- Creating the system capacity, incentives, and enablers in the NHS to support all staff to actively participate in research and innovation programmes.

4. Centrally fund essential radiotherapy clinical trials capacity.

- Resource requirements should be confirmed separately by the national Radiotherapy Management Group.

Headline commitments from implementation documents

1. Invest in local capacity:

- [2.2.01] Undertake local mapping exercise against national opportunities to address gaps and areas of future need in research capacity.

2. Invest in workforce capacity:

- NIHR will provide investment to support NHS R&D transformation, increase research capacity including nurses, midwives and allied healthcare professionals, and provide more opportunities for rewarding careers in research

3. Centrally fund essential radiotherapy clinical trials capacity.

- Resource requirements should be confirmed separately by the national Radiotherapy Management Group.

Progress made to date

None reported

Referring Documents

1. Beyond Recovery
2. CRUK Creating Time for Research Report
3. Improving equity of access to cancer clinical trials in Scotland
4. Making research everybody's business
5. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 1. Topic 4:
Access to medicines and technology/Delivery of Care

Recommendations from Reports

1. Access to medicine post EU exit:

2. Access to medicines following trials:

- Guarantee patients' early access to medicines by reforming the unused Innovative Medicines Fund (IMF) for England
- Adopt NICE recommendations to value patients' lives more than ever before
- "DHSC and the NHSE Accelerated Access Collaborative should routinely conduct targeted horizon scanning to identify the most impactful cancer interventions that must be prioritised for national rollout. This must involve working closely with the NHSE Cancer Programme, NHSE Screening Teams, Cancer Alliances, Academic Health Science Networks (AHSNs), clinicians, researchers and Cancer Research UK."
- Create a joined-up life sciences ecosystem with the resources and capacity to deliver rapid approvals, leading to rapid adoption and use of medicines by the NHS

3. Access to vaccines:

- Deliver key commitments in the VPAG
- Prepare the ground for a new generation of innovative vaccines and support vaccine access and uptake

4. Improve delivery of cancer care:

- To fulfil their duty as mandated by the 2022 Health and Care Act to ensure the use of evidence obtained from research in the health service, the UK Government and NHSE should direct ICBs to work with their Cancer Alliances and AHSNs to develop a coherent, shared strategy for the identification, adoption and implementation of approved cancer innovations across their geographies.
- Develop a plan to provide as much care as possible in local centres, through coordinated and resourced multicentre collaborations, and use of technologies such as NearMe, ProKnow and other Radiotherapy picture/patient archiving and communication systems.

5. Improve integration of studies into routine care

- The NIHR, MHRA and NICE and the NHS will work with universities and research sponsors to ensure studies are delivered in the most innovative and effective ways that support rapid integration into routine care pathways
- Harnessing the NHS's potential as a source of real world evidence and the use of patient registers and registries to support the development, uptake, and demonstration of the outcomes of medtech and pharmaceuticals.

Headline commitments from implementation documents

1. Access to medicine post EU exit:

- [6.1.01] Lead on a project to manage the transition to new postEU Exit IMP supply arrangements, on account of the Northern Ireland protocol, with particular focus on importation of IMPs from GB.
- [6.1.02 Work with HSC Trusts to identify clinical trials of IMPs and medical devices at risk of interruptions to supply of medications at any point during the transition period.
- [6.1.03] Work with Sponsors of commercial and noncommercial clinical trials of IMPs with Northern Ireland sites to ensure arrangements are in place for continuity of supply.
- [6.1.04] Provide communication and assurance to sponsors of Northern Ireland's continued ability to host clinical trials.
- [6.1.05] Monitor issues around supply of Medical Devices.
- [6.1.06] Monitor issues surrounding divergence of legislation between EU and GB.

2. Access to medicines following trials:

3. Access to vaccines:

4. Improve delivery of cancer care:

Progress made to date

None reported

Referring Documents

1. ABPI 2024 Manifesto for investment, health and growth
2. CRUK Longer, Better Lives
3. Improving equity of access to cancer clinical trials in Scotland
4. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
5. Life Sciences Vision

Implementing Documents

None reported

Theme 1. Topic 5:
Coordination/collaboration

Recommendations from Reports

1. Study Coordination:

   NHS England (NHSE) and the devolved administrations should establish mechanisms to improve coordination between companies and study sites.

2. Collaboration:

   Support and incentivise academic and industry partnership across and outside Wales, and engagement with research in the NHS in Wales

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

1. ABPI Rescuing Patient Access to Industry Clinical Trials
2. Senedd Cross Parliamentary Group on medical research 2021

Implementing Documents

None reported

Theme 1. Topic 6:
Finance

Recommendations from Reports

Develop better models for transferring funds between NHS bodies.

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

1. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

None reported

Theme 1. Topic 7:
Accreditation for Research

Recommendations from Reports

Radiology, Radiotherapy and laboratories should be nationally accredited. Patients would therefore be able to engage in trials in larger centres and be able to get screening and follow-up investigations locally.

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

2. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

None reported

Theme 2: Incentivising and enabling a research-active workforce

Topic area	# of docs
Training and career pathways: develop new pathways for training; increase access to training; new fellowship opportunities; create infrastructure for training; strengthen role of research as part of revalidation requirements	12
Dedicated staff time for research/raising the visibility of research within the NHS: funding time for research; job-type specific recommendations; strategies for success	11
Equality and Diversity Issues: collect data to improve EDI; provide support for EDI	4
Staff recruitment and retention: increase funding; develop new strategies; improve data collection	4
Long-term workforce plan: utilise the current long term workforce plan and plan for the next one	3
Immigration	1

Theme 2. Topic 1:
Training and career pathways

Recommendations from Reports

1. Develop new pathways for training:

- This group should undertake a crosscutting project to identify gaps in the cancer research workforce and career pathways in Wales across all disciplines.
- To deliver DCTs, the UK Government and NHSE will need to consider training and skills in future workforce planning.
- Develop an attractive training pathway for genomics-focussed clinical scientists and offer multiple career progression options after qualification.
- Review how standard care pathways can be effectively established to map new hub and spoke staff training and service model to support cancer trial delivery
- Provide a package of training and support for NHS managers and ensure the requirement to support trials is built into job descriptions and service planning.
- Develop a clear, structured, visible research career pathway for all health and social care disciplines, across all sectors and at all stages of careers
- Work with professional bodies and UK wide partners to consider opportunities for integrating research into professional training from an early stage
- Take opportunities to implement proportionate training requirements for those involved in research: It is essential that everyone who is involved in clinical research is appropriately trained to undertake the tasks required of them. Equally, training requirements must be proportionate – trusts, health boards and ICSs should take all opportunities to ensure this is the case, so that training requirements do not inadvertently become a barrier to research. As part of this, they should take account of the joint statement by the Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and administrations in the other UK nations which specifies that training in Good Clinical Practice is not required unless researchers are involved in clinical trials of investigational medicinal products (and can be proportionate even in that instance).
- Higher educational institutions should promote careers in medical education

and provide role models and mentors to inspire careers in this area.

2. Increase access to training:

- The UK Government should take steps to make clinical cancer research more accessible and inclusive by reviewing the regional distribution of research and building on its investment in widening opportunities for careers in clinical research.
- NHS England and its devolved equivalents should work with health research funders and academia to increase NHS staff's access to research training.
- Continue to collaborate with UK wide funding partners, including government funding partners, research councils and charities to ensure training and development opportunities for Welsh researchers, enabling cross funder investment where appropriate

3. New fellowship opportunities:

- Develop a national Senior Clinical Research Fellowship to rapidly build essential senior medical capacity for standard of care and cancer trials.
- Ensure the national NRS service structure has a proportionate focus on cancer given the size of the national trials portfolio that this represents. This should include consideration of a dedicated cancer fund for the NRS Fellowship Programme
- The NIHR, CSO and HSC R&D should develop new programmes modelled on the HCRW's Pathway to Portfolio Development Funding Scheme to fund small-scale projects that develop the confidence, expertise and capacity of NHS staff to deliver research.

4. Create infrastructure for training:

- Create an all Wales service to provide a package of support, guidance and training for health and social care researchers in developing their research careers for example through an integrated Health and Care Research Wales Faculty
- Review the research mentorship schemes across Wales, with a view to enhancing the provision of mentorship schemes for researchers and developing a standardised framework as part of a unified all-Wales approach
- Enable co-ordination of support for research careers across Wales, as well as enhanced collaboration amongst key stakeholders and infrastructure groups, to facilitate the development of research careers through a shared responsibility
- Coordinate and oversee a range of widely accessible (and targeted where

needed) personal research award schemes for health and social care researchers across professions and at different stages of their careers

- Progress the individualised and peer learning and development and mentorship that our health and social care personal award holders need to advance their research careers
- Foster interdisciplinary interactions and networking across the faculty community of health and social care personal award holders from all backgrounds and all areas of Wales
- Enable opportunities for the sharing of high-quality faculty research with relevant UK and international communities with a view to raising the awareness of profile of Welsh research and promoting the research career opportunities of the researchers themselves.

5. Strengthen role of research as a part of revalidation requirements/professional standards for doctors and nurses

- Health Education and Improvement Wales, working closely with Welsh Government and the NHS, will develop plans to support and facilitate the nursing, midwifery, allied healthcare professionals and health sciences professions in embracing research as part of their roles and career pathways. Through the development of competency and skills frameworks, Health and Care Research Wales is working to support the inclusion of research delivery roles
- Government, working with the Professional Regulators, will embed research and innovation in standards for registered professionals and provide the necessary support and development resources to help healthcare professionals be research active.

6. Workforce planning:

- Ensure that multidisciplinary workforce planning encompasses those who support clinical research: There have been significant pressures on the workforce that supports the delivery of clinical research for some time, as a result of the pandemic and the need to reduce waiting lists. Action is needed to increase capacity, to enable research support staff to develop new skills in areas such as digitalisation and data science that are necessary to take advantage of innovation opportunities, and to maximise the contribution that members of the wider health workforce – such as physician associates, radiology, pharmacy and laboratory staff – can play in clinical research and supporting interventional medicinal clinical trials. As a first step, trusts, health boards and ICSs should ensure that their workforce planning includes those who support the delivery of clinical research.

- The Government must increase the medical teaching workforce to meet increased teaching demands and in turn address wider medical workforce issues.

7. Support for early career researchers:

- It is vital that support for early-career researchers is made a priority by employers. This should include: the promotion of mentoring and networking opportunities throughout training and early careers; the use of role models in both education and research focused careers across all specialities; the promotion of resources to support individuals navigating complex career structures and opportunities in academia. For example, the medical academic training and careers hub, CATCH, provides information and highlights opportunities and rewards that a medical academic career can bring.
- Work with stakeholders to promote opportunities for postgraduate doctors, medical students and other health professionals to engage with research: Engaging medical students, postgraduate doctors and other health professionals in clinical research at an early stage enables them to build experience that they can draw on throughout their career. HEE and other statutory education bodies should work with stakeholders at all levels – such as deaneries locally and royal colleges nationally – to ensure that these groups can access opportunities to participate in research. Initiatives such as trainee research collaboratives, flexible portfolio training and NIHR's associate principal investigator scheme support the development of the skills and experience needed to undertake research.

8. Building an academic career within the NHS:

- More information must be provided to all clinicians about entry routes and career progression in academia.
- Attractive opportunities in academic medicine should be promoted by employers and private sector industries.
- Higher education institutes must prioritise research training and experience throughout medical school.
- Employers must ensure that clinicians wishing to undertake research are able to easily switch back to a fully clinical career - guidance and support should be clear and accessible.
- Employers must create flexible and part-time job opportunities in academia to make this an attractive career prospect.
- Schemes to support clinicians who wish to undertake academic activity

during their career should be developed.

- For example, the 'new blood' clinical senior lectureship scheme offered five years of start-up funding for NHS consultants. The scheme saw a small increase in more senior medical academic positions between 2009 and 2017.
- Flexibility between clinical work and academia should include better integration of research into NHS organisations.
- The BMA has joined other organisations in calling for amendments to the Health and Care Bill to mandate that integrated care systems ensure NHS organisations conduct clinical research and publish research plans.

Headline commitments from implementation documents

1. Develop new pathways for training:

- [2.2.02] Support professional pathways in research for all levels of HSC staff and disciplines in all settings, with agreed gateways and milestones in order to establish local research leaders.
- The RRG partners will expand the package of training programmes for the research workforce including through the RCP-NIHR Credentialing Scheme, the NIHR Associate PI scheme, the NIHR Nurse and Midwife Leaders Programme, an NHS England programme for executive nurses in Trusts and Integrated Care Systems (ICSs), and a research matron's toolkit

2. Increase access to training:

3. New fellowship opportunities:

4. Create infrastructure for training:

- We will work to develop opportunities for NHS staff to develop their research careers through the Health and Care Research Faculty and other routes, and to ensure opportunities are available to professional groups such as nurses, allied health professionals and clinical scientists who in the past have tended to have poor access to existing programmes and limited protected time for research.
- We will work with our partners to provide development opportunities and stable careers for those working in NHS R&D offices and in research delivery.

5. Strengthen role of research as a part of revalidation requirements for doctors and nurses

- Health Education and Improvement Wales, working closely with Welsh Government and the NHS, will develop plans to support and facilitate the nursing, midwifery, allied healthcare professionals and health sciences professions in embracing research as part of their roles and career pathways. Through the development of competency and skills frameworks, Health and Care Research Wales is working to support the inclusion of research delivery roles

Progress made to date

- The NIHR, working with the devolved administrations, launched a UK census for nurses and midwives working in clinical research in order to understand the truesize of this workforce. Data was also sought on location, speciality and banding or grade. It was able to identify that there are at least 7,469 research nurses and midwives across the UK and Ireland working at every level and within all areas of healthcare. This census demonstrates the breadth and depth of nurse and midwife involvement in research across the healthcare sector.
- In June 2021, NIHR on behalf of the UK launched a new UK-wide professional accreditation scheme for Clinical Research Practitioners (CRP) as part of efforts to double the number of this important workforce over the next few years. Over 1,000 members have already signed up to the CRP directory.
- NIHR also launched the UK wide Associate Principal Investigator Scheme, which aims to make research a routine part of clinical training so doctors, nurses and allied health professions can become the principle investigators of the future. Over 1,000 health and care professionals had registered for the scheme by April 2022.
- In February 2022, Wales published a vision for research career pathways that outlines recommendations to improve support and encourage more health and social care professionals to embark on research careers

Referring Documents 1. Beyond Recovery

1. CRUK Longer, better lives
2. Moving forward: Recommendations for the future of cancer research in Wales
3. Improving equity of access to cancer clinical trials in Scotland
4. CRUK Creating Time for Research Report
5. Making research careers work: a review of career pathways in health and social care in Wales
6. Saving and Improving Lives
7. Medical academic workforce planning for the future
8. Making research everybody's business
9. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 2. Topic 2:

Dedicated staff time for research/raising the visibility of research within the NHS

Recommendations from Reports

1. Fund time for research:

Generally,:

- Provide long term funding and opportunities for research careers, including protected time for clinical academics and clinicians, and continuing support for the Ser Cymru scheme to foster talent
- Invest more funding in research careers, to fill identified funding gaps in Wales, whilst quantifying the scale of disparity of funding opportunities for researchers across the UK, to enable the levelling up of investment
- Support NHS organisations and local authorities to invest in support for research careers, investing in researcher development, protected time for their researchers, research leadership posts and exploring clinical/ practice academic posts
- Through networks "Fund sessions for the 3 regional clinical leads to support each node, and matched senior management sessions to support the national cancer research champion"
- Through reinvestment revenue from industry clinical research "NHSE and its devolved equivalents should reinvest revenue generated by industry clinical research into increasing the provision of dedicated research time and research training, especially for nurses and other staff critical to delivering clinical trials."
- Fully-fund an already proposed pilot program that offers subset of NHS dedicated research time "In-line with the Academy of Medical Sciences' proposals, the UK Government and Devolved Administrations should implement fully funded pilot programmes that offer a proportion of health service staff (including those in under-represented professions) contracts that include dedicated time for research."
- Financial incentives should be introduced for GPs to take part in commercial trials

2. Job-specific recommendations:

- NHSE should work with Trusts to increase the total supply of dedicated research time in health service staff job plans, paying particular attention to professions underrepresented in research such as nurses, midwives and allied health professionals.
- Scope the number of academic honorary contracts that support cancer research to ensure that this dependency is visible and understood
- All oncologists and haemato-oncologists should be allocated at least one dedicated research DCC session within a standard 10 PA job plan.

3. Strategies for success:

- NHS England and its devolved equivalents should embed clinical cancer research into everyday practice by incorporating research into workforce strategies
- NHS Trusts and Health Boards should increase the visibility and accessibility of dedicated time for research in order to expand research engagement amongst staff, especially under-represented professions. Progress towards this goal should be locally monitored using the research metrics and reviews we also recommend, as well as periodically reviewed by national NHS bodies.
- Increase the number of research sessions across the country in all cancer centres to build a network of clinicians to coordinate research. Clinicians, nurses, physicists, radiographers and allied health care professionals who are funded to engage in research should also develop and support national networks to ensure equity of trials.
- Develop strong links between medical directors, R&D (research and development) directors and chief executives: Securing buy-in for clinical research at senior level is essential to creating a positive research environment and realising the benefits of research for patients and staff. Building relationships between medical directors, R&D directors and chief executives – within organisations and across systems – is a fundamental part of this, providing a platform to embed research in practice more widely. This is also vital for developing effective external partnerships with universities – something the Academy of Medical Sciences has identified as crucial to accelerating the translation of research into patient benefit – as well industry and other national and international partners.
- Encourage support for research to be recognised as part of direct clinical activity and reward involvement of such through local and national awards: All clinicians can play a role in supporting the delivery of clinical research as

part of their everyday practice, for example as a principal investigator in a study. One opportunity to promote this is by recognising support for research as part of direct clinical activity, given the substantial benefit that research can have for patient care and outcomes. This is something that individual trusts should consider encouraging. The contribution of clinicians who have been involved in impactful research should also be acknowledged and rewarded through local and national awards.

- Ring-fence time for research in job plans of those who want to have a substantive research leadership role: For clinicians who wish to build a career in research and take on a substantive leadership role – such as a chief investigator – ring-fencing protected time in their job plan should be considered to support their development. This will ultimately be a matter for local negotiations around job planning or with funders. A letter sent from health leaders to NHS chief executives in England in May 2022 on the release of medical colleagues for the purposes of carrying out work for the wider health system highlighted the value that time allocated in job plans to causes such as research has delivered during the pandemic. It is vital to ensure that clinical research is inclusive and that opportunities to pursue a research career are accessible for everyone, regardless of their background.

Headline commitments from implementation documents

1. Fund time for research:

- In support for NHS R&D transformation, Wales will invest in a new Health and Care Research Wales Faculty, which will include increased investment in the NHS Research Time scheme to help develop the next generation of principal and chief investigators in the NHS alongside enhanced mentorship schemes

2. Job-specific recommendations:

3. Strategies for success:

- [1.1.02] Facilitate the incorporation of research into routine practice in HSC in Northern Ireland.
- [2.3.01] The DoH should drive the requirement for research job plans for all HSC staff, including those in primary care.
- [2.3.03] DoH should ensure that Research Directors are part of HSC Trust Boards.

4. Actions proposed for Future of Clinical Research Delivery Phase 2:

- NHS England and the devolved administrations will each develop clear and tangible plans to work towards embedding responsibility and accountability for research in healthcare delivery
- NHS England and the devolved administrations will use existing legal duties and planning frameworks to promote and facilitate research. Each administration will develop assurance frameworks and use existing channels such as annual reports and joint forward plans to help cement the importance of research as a core duty. In England this will include the implementation of the Health and Care Act. Integrated Care Boards (ICBs), NHS England and the Secretary of State for Health and Social Care will all have enhanced duties to report on how they are promoting and facilitating research. NHS England will also lead development of a research framework for ICBs to help them understand and fulfil the minimum expectations around research that the Health and Care Act sets. This will herald a significant shift in how research is considered within the NHS and drive a greater responsibility for more research activity across all sites. In Wales, we will explore opportunities provided through the development of the NHS Executive in Wales to strengthen the national oversight of NHS research.

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

- The UK Research and Development (UKRD) and NHS R&D Forum, with NIHR, developed the 'Best Patient Care, Clinical Research and You' online guide that aims to help busy non-research staff become more aware of the impact of research in their trust the General Medical Council (GMC) published its position statement Normalising Research - Promoting Research for all Doctors
- The Allied Health Professions' Research and Innovation Strategy was published, addressing the key areas which impact research and innovation across all health professions in England
- The NHS Chief Nursing Officer (CNO) for England published the strategic plan for research for nurses. The plan aims to create a people-centred research environment that empowers nurses to lead, participate in and deliver clinical research that is fully embedded in practice and professional decision making
- together with existing strategies in the devolved administrations, we are

continuing the development of UK-wide support for the key professional groups

Referring Documents

1. CRUK Creating Time for Research Report
2. CRUK Longer, better lives
3. Beyond Recovery
4. Improving equity of access to cancer clinical trials in Scotland
5. Making research careers work: A new vision for research career pathways in Wales
6. O'Shaughnessy Review
7. ABPI Rescuing Patient Access to Industry Clinical Trials
8. Senedd Cross Parliamentary group on medical research 2021 Wales
9. Making research everybody's business

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research, Recovery, Resilience and Growth
2. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 2. Topic 3:
Equality and diversity issues

Recommendations from Reports

1. Collect data to improve EDI:

- DSIT should increase the value of the data collected in future versions of the R&I workforce survey by improving coverage, data collection and disaggregation to provide a comprehensive nationwide overview of equality, diversity and inclusion in research. DSIT should then publish an action plan to address the inequalities in the research workforce that have been identified.
- Local NHS R&D Offices and Human Resources departments should collaboratively consult under-represented professions to identify and address the social and cultural barriers they face to engaging with research. Progress towards this goal should be locally monitored using the research metrics and reviews we also recommend, as well as periodically reviewed by national NHS bodies.
- Develop plans to monitor equality, diversity and inclusion data amongst the researcher population, publishing data reports and action plans to help facilitate the equal representation of all groups in the Welsh researcher population
- Publish researcher equality, diversity and inclusion data and develop action plans to help facilitate the equal representation of all groups, across career stages and professions, in the Welsh researcher population

2. Improve EDI barriers:

- NHS and higher education institution employers must work to better understand and overcome the barriers faced by underrepresented groups in medical academia, specifically in senior posts. They must actively work to improve academic culture and diversify the workforce.

Headline commitments from implementation documents

1. Collect data to improve EDI:

- We will commit to publishing diversity data across the range of Health and Care Research Wales activities and monitor this on an ongoing basis to

identify areas for improvement.

2. Support for EDI:

- We will develop an action plan that will result in more inclusivity across all our activities, taking a co-creation approach in consultation with the community.
- We will create greater leadership for EDI across our work programmes and ensure it is fully embedded at policy and delivery level through our funded activities.
- We will address under-representation in our own practices e.g. on funding panels, in public involvement, in governance processes (such as advisory boards), and in the individuals and communities who participate in the research we fund or support
- We will work with other funders to learn from good working practices and ensure issues relevant to minority groups are part of research portfolios and are well embedded in the research we fund.
- We will work with partners organisations including Health Education and Improvement Wales, Social Care Wales and wider public sector partners
- (NHS, HEIs and Local Authorities) to improve representation within the workforce and develop initiatives, working practices and training to attract a more diverse range of people into research careers and wider research workforce.
- NIHR and the devolved administrations will invest in learning and support for researchers, so that they are equipped with the expertise and cultural competency to design and deliver people-centred studies to meet the needs of patients, service users and the public, including those from underserved communities and groups not traditionally served by research

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives
2. CRUK Creating Time for Research Report
3. Medical academic workforce planning for the future

Implementing Documents

1. Research matters: our plan for improving health and care research in Wales
2. Future of UK Clinical Research Delivery: 2022-2025 Implementation Plan

Theme 2. Topic 4:
Staff recruitment and retention

Recommendations from Reports

1. Increase funding:

- As a baseline, the UK Government must invest £1.5bn between 2024-29 in training the staff to fill 16,000 full-time equivalent (FTE) specialist roles in the seven key cancer professions identified in the 2018 HEE Cancer Workforce Plan, as requiring a 45% growth.
- The Government must provide make start-up funding available through such schemes to encourage movement between clinical care and academia and in turn increase the number of senior medical academics in the workforce.

2. Develop strategies:

- NHS Trusts and Health Boards should embed research into their strategies for staff recruitment and retention, and workforce development planning. These local efforts should be reinforced by ambitious national strategies for supporting clinical research that recognise the NHS as an indispensable part of the UK's research environment.
- Explore mechanisms for supporting NHS organisations and local authorities to embed research into their strategies for staff recruitment and retention, and workforce development planning, enabling the development of a nurturing research environment for health and social care professionals
- Work with universities to identify gaps in academic leadership, opportunities for joint clinical/ practice academic posts and explore solutions to enable longer term, secure employment opportunities for researchers
- Develop a unique selling point for research careers in Wales as a vehicle to attract and retain researchers, for example, focussing on a nurturing environment for researchers
- Develop a programme of work to raise awareness and the profile of research amongst health and social care professionals, their employing organisations and the regulators, promoting research careers in Wales, particularly in underdeveloped areas
- The Department for Business, Energy & Industrial Strategy must acknowledge the need for an increased medical academic workforce across all specialities and set out a detailed plan for how this will be achieved.

3. Improve data collection:

- As part of the two-yearly refresh of the plan, NHSE should improve data collection on staff leavers, with an aim to regularly publish this data by 2025 and use it to target efforts to boost retention at the issues and staff groups where they will make the most difference.

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives
2. CRUK Creating Time for Research Report
3. Making research careers work: a review of career pathways in health and social care in Wales
4. Medical academic workforce planning for the future

Implementing Documents

None reported

Theme 2. Topic 5:
Long term workforce plan

Recommendations from Reports

1. Utilise the current Long Term Workforce Plan:

- The NHS should use the upcoming NHS Long Term Workforce Plan and UK RRG Research Workforce Strategy to establish a clinical trials career path for training critical roles for research
- The UK Government should instruct NHSE to develop a specific cancer workforce plan as a companion to the NHS Long Term Workforce Plan for England, to be delivered within one year of the next general election. The plan should consider the specialties essential to the diagnosis and treatment of cancer, with an initial focus on sub-specialisms in endoscopy, pathology, radiology, tumour-specific oncologists and nurse specialists.

2. Plan for the next Long Term Workforce Plan:

- The UK Government should immediately instruct NHSE to begin the planning cycle for the 2025 Long Term Workforce Plan refresh, so sufficient preparation can be made to address weaknesses in the current plan for England.

Headline commitments from implementation documents

1. Utilise the current Long Term Workforce Plan:

2. Plan for the next Long Term Workforce Plan:

- NHS England, working with its partners is developing a comprehensive, long-term NHS workforce plan. This will include consideration of research requirements to support the delivery of high-quality care

Progress made to date

None reported

Referring Documents

1. 1. O'Shaughnessy Review
2. 2. CRUK Longer, better lives

Implementing Documents

1. Future of UK Clinical Delivery 2022-2025 Implementation Document

Theme 2. Topic 6:
Immigration

Recommendations from Reports

- By the end of the next parliament, the Home Office should reduce overall and upfront immigration costs for researchers so they are competitive with comparable leading research nations. To support this, by 2026, the Home Office should work with DSIT to initiate a review on the impact of the immigration system on the recruitment of international research staff.

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives

Implementing Documents

None reported

Theme 3: Funding the right research

Topic area	# of docs
Increased funding: increase research budgets for public and charity industry fundings; target funding for key areas	8
Develop a research culture/enhance leadership: strengthen research culture; statement by leadership; enhance leadership	7
Build a strategy/define research priorities: conduct a review to explore future research scope and priorities; produce and implement a Scottish Cancer Research Strategy; improve the evidence base for the need for a research strategy/refresh; collaborate on research strategies for Wales; align our research programmes and processes with the needs of the UK health and care systems	7
Academic research infrastructure funding: sustain and maintain academic research infrastructure funding and capacity	1

Theme 3. Topic 1:
Increased funding

Recommendations from Reports

1. Increase research budgets:

Public funding:

- Deliver long-term certainty on research funding by setting a goal for the UK to have the highest level of public R&D investment in the G7
- The UK Government must continue to support prestigious multinational research funding programmes (including Horizon Europe and successor EU framework programmes after 2027), and should join and lead the development of further global research programmes, including on cancer.
- The UK Government should set a target in its first 100 days to lead the G7 in research intensity. The Treasury and the Department for Science, Innovation and Technology (DSIT) should set out a plan for stable and sustained investment and/or fiscal safeguards to provide long-term stability to the R&D sector.
- The UK Government and Devolved Administrations should uplift long-term funding for the NIHR, CSO, HCRW and HSC R&D. At a minimum, these funding increases should be in-line with broader uplifts in public R&D investment and keep pace with future increases in inflation.
- The group should work with Welsh Government, Welsh institutions and with UK funders of cancer research to explore future opportunities for cancer funding.
- The National Institute for Health Research's annual budget should be increased from £1 billion to £1.4 billion by 2025, with proportionate uplifts for its devolved equivalents.
- Research England must increase mainstream quality-related (QR) funding in line with inflation and wider increases to R&D funding. The Charity Research Support Fund (CRSF) should also receive an uplift to ensure that government support underpins the indirect cost of charity investment in universities and enables effective partnerships.
- Match UK levels of funding in the Higher Education Funding Council for Wales research grant to universities and in the budget of Health and Care Research Wales
- Continue to maximise our engagement (alongside equivalent departments

from Scotland and Northern Ireland) with funding schemes led by NIHR in England and strongly encourage (through, for example, our core funding for research centres and units) Welsh institutions to improve their performance in securing funding from these and other UK funding sources

- Seek further opportunities for co-funding partnerships with other funders particularly where they will both meet Welsh research needs and stimulate and support the development of research capacity and capability in Wales
- The Government must prioritise the association agreement between the UK and Horizon Europe and provide clear and transparent guidance for researchers.

Charity and industry funding:

- Identify and address areas where reliance on charitable funding may affect resilience and continuity of research services.
- DSIT and the Treasury should work with charities, industry and public funding agencies to establish a Commission on Sustainable Biomedical Research. This should be tasked with developing a new long-term investment solution for late-stage basic and early-stage translational life sciences research within one year of being established, and include setting out a plan for closing the more than £1bn funding gap for cancer research over the next decade.
- The Government must ensure that some of the increased investment announced will be ringfenced to support the charity research sector and bridge the gap in research spending.

2. Target funding for key areas:

- The Department of Health and Social Care (DHSC) and equivalents in the other UK nations, DSIT and Office for Life Sciences (OLS) must work with public funders to coordinate investment in early detection and diagnosis (ED&D) research. They should also convene a cross-sector working group (to include the health service, funders, National Institute for Health and Care Excellence (NICE), industry, economists and patients) to develop a comprehensive health economics model for ED&D.
- The Department for Levelling Up, Housing and Communities (DLUHC) and DSIT should develop clear UK-wide and local strategies to grow diverse research clusters of excellence. As part of this, the UK Government should work with higher education institutions, industry and funders to seed new large-scale research institutes, including a new life sciences cluster in Scotland.

- "Provide dedicated central funding for the National Action Plan to protect the world from the silent pandemic of antimicrobial resistance (AMR)"

3. Grant funding:

- It is important that funding bodies recognise the challenges and uncertainty faced by researchers and remain flexible. This should include being receptive to cost extensions.

Headline commitments from implementation documents

To maximise the use of our research funding and the likely impact of the research we fund, we will take the following actions:

- Review and streamline the existing separate Health and Care Research Wales funding schemes, to improve the efficiency of our processes and increase the frequency of our funding calls and opportunities, while ensuring that research in areas where capacity building is crucial, such as social care, continue to be adequately protected and supported.
- Seek to add a commissioned arm to the new arrangements which can link to the priority setting processes outlined above and will ensure that we are both proactive and agile in funding research that addresses important and urgent needs from Welsh Government and the NHS and social care system in Wales.

Progress made to date

None reported

Referring Documents

1. Beyond Recovery
2. Improving equity of access to cancer clinical trials in Scotland
3. CRUK Longer, Better lives
4. Moving forward: Recommendations for the future of cancer research in Wales
5. CRUK Creating Time for Research
6. Senedd Cross Parliamentary Group on medical research 2021 (Wales)
7. Medical academic workforce planning for the future

Implementing Documents

1. Research Matters: our plan for improving health and care research in Wales

Theme 3. Topic 2:
Develop a research culture/enhance leadership

Recommendations from Reports

1. Strengthen Research Culture:

- DSIT should work with UK Research and Innovation (UKRI) to strengthen the UK's research culture. This should include action to increase the stability of roles, support sectoral mobility and ensure incentives for universities to improve research culture are considered in the development of REF2028.
- High level strategic support is needed from Welsh universities, NHS Health Boards and Trusts and Welsh Government agencies who need to work collaboratively with a collective responsibility for the future of cancer research in Wales.
- Strengthened research delivery focus in healthcare regulator requirements for NHS bodies

2. Statement by Leadership:

- A statement should be made by the NHS leadership and ministers of the UK's intention for the health service to be the world's leading platform for health R&D, and annual R&D targets should be introduced for the NHS at every level
- Making it a core expectation of the incoming Chief Executive of NHS England, as well as national, regional, and local NHS leadership and the Department of Health and Social Care that they actively support the research, innovation and uptake agenda. Forthcoming legislation will create specific duties for Integrated Care Systems in England to promote and support research and innovations.

3. Enhance leadership:

- A Wales Cancer Strategy Leadership group should be established to bring the research community together, develop costed plans and implement the key next steps. A nominated research leader should be appointed to define research priorities and act as a champion and ambassador for each of the six themes.
- NHSE and the devolved administrations should consistently incorporate research leadership into the role descriptions for NHS R&D Directors, Medical Directors, Directors of Nursing, and Chief Executives.

- Health and Care Research Wales, Health Education and Improvement Wales and Social Care Wales should work together to support the enhancement of research careers through a collaborative leadership approach
- Health and Care Research Wales should invest in a high-level leadership role to lead this area of work, raising the profile of research careers, co-ordinating national developments, Wales wide collaborations with key partners and facilitating UK wide collaboration

Headline commitments from implementation documents

1. Strengthen Research Culture:

2. Statement by Leadership:

- [2.2.03] Department of Health to endorse Chief Executives' public commitment to research and its importance in HSC Trusts.

3. Enhance Leadership:

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives
2. Moving forward: Recommendations for the future of cancer research in Wales
3. ABPI Rescuing Patient Access to Industry Clinical Trials
4. O'Shaughnessy Review
5. Making research careers work: A new vision for research career
6. pathways in Wales
7. Saving and Improving Lives
8. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research, Recovery, Resilience and Growth

Theme 3. Topic 3:
Build a strategy/define research priorities

Recommendations from Reports

1. Conduct a review to explore future research scope and priorities:

- The UK Government should work with Cancer Research UK and others in the sector to conduct a review exploring the future of cancer research.
- DSIT, DHSC and OLS must work with the wider innovation ecosystem to align priorities and strategies intended to support innovation in healthcare. This should include the development of a cross-department action plan to address the enablers (such as those set out below) to accelerate the adoption of health innovation to improve cancer outcomes.

2. Produce and implement a Scottish Cancer Research Strategy which closely aligns with the refreshed national Cancer Strategy, and the developing national Genomics Strategy. This should be co-designed by the various stakeholders in academia, government, health, industry, patient and public involvement (PPI) and the third sector.

- Future focus and investment should principally be in the six priority research themes, whilst not precluding support for new areas of potential excellence.

3. Improve the evidence base for the need for a research strategy/refresh.

4. Collaborate on research strategies for Wales:

5. Align our research programmes and processes with the needs of the UK health and care systems

Headline commitments from implementation documents

1. Conduct a review to explore future research scope and priorities:

- [2.1.01] Commission a priority setting partnership/James Lind Alliance (JLA) exercise to set priorities across the NICRN within areas of expertise and capacity, aligning with local, regional and UK priorities, to improve access for funding and ensure the necessary buy-in from the HSC Trusts and primary care researchers and industry.
- [2.1.02] NICRN to list on its website which priorities had been set and how

they ink to local and national priorities.

- [2.1.03] The Community Engagement Network within PHA and other similar forums to be approached as a resource to involve patients, service users and the public in the priority setting partnership where there are no existing clinical groups or patient and public representatives aligned to the NICRN Clinical Interest Groups.
- We will run further priority setting exercises – probably two a year – addressing the priorities of Welsh Ministers and their Programme for Government and priorities or topics which arise from our engagement with other stakeholder organisations in Wales. Topics that may be explored in 2023 include women's health and gender inequalities in research, and the integration of mental health services for children and young people.
- We will use these priority-setting processes more actively and explicitly to feed our own research commissioning programmes (see section 6 below) and to provide ideas and priorities for research to other funders.
- We will continue to engage with the funding committees and boards of NIHR programmes with which we partner and with the NIHR ideas identification and prioritisation team based at NETSCC at Southampton, to share research needs and priorities and increase the number of research questions from Wales considered for commissioned calls in these programmes.

2. Produce and implement a Scottish Cancer Research Strategy

3. Improve the evidence base for the need for a research strategy/refresh.

- [1.1.07] Provide case studies of how Northern Ireland has missed or taken opportunities to play a fuller role in HSC research locally, in the UK and internationally.

4. Collaborate on research strategies for Wales:

- We will work with NHS health boards and trusts to promote the development of their research and innovation strategies, and to co-produce a shared framework for embedding research in the NHS, whilst assessing research capacity, engagement and delivery
- We are currently engaged in early discussions with stakeholders about future collaborations on research strategies and plans in public health and in nursing and allied health professions research for Wales – similar to the work outlined above in relation to cancer, genomics and social care.
- We will establish regular meetings with key UK health and social care research funders to promote greater engagement with Welsh Government

and other stakeholders

- We will seek maximum engagement in UK level forums and discussions at the earliest stage in relation to research strategies – examples include the recently published UKRI strategy, the strategies and plans which will follow from research councils, particularly the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC) and Innovate UK; and the strategies of key charitable funders such as the Wellcome Trust, Cancer Research UK and the British Heart Foundation.
- We will work with Welsh Government colleagues who lead the university designation process (and its periodic renewal) for NHS boards and trusts to ensure that it incorporates a meaningful and ambitious set of commitments to research and innovation.
- We will co-produce, with NHS organisations and other stakeholders, a new assessment framework for research in the NHS in Wales and use it in our annual reviews of all NHS boards and trusts to support them to find an appropriate balance of embedding research in core healthcare services and reducing the burden on frontline services through different delivery models
- We will make working as 'One Wales' for research delivery the default whenever possible, focusing our research delivery investment in areas of greatest benefit and added value to Wales and working to establish a collective and planned approach to prioritising and delivering research

5. Align our research programmes and processes with the needs of the UK health and care systems

Progress made to date

None reported

Referring Documents

1. CRUK Longer, Better Lives
2. O'Shaughnessy Review
3. Improving equity of access to cancer clinical trials in Scotland
4. Moving forward: Recommendations for the future of cancer research in Wales
5. Saving and Improving Lives

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Research matters: our plan for improving health and care research in Wales

Theme 3. Topic 4:
Academic research infrastructure funding

Recommendations from Reports

1. Sustain and maintain academic research infrastructure funding and capacity

Headline commitments from implementation documents

1. Sustain and maintain academic research infrastructure funding and capacity

- We will continue to actively performance manage all current centres and units to ensure shared expectations in relation to good practice and performance, and to provide a further round (end of year 3) of feedback.
- We will develop a clear framework for assessment which we will share with all current centres and units and make available to others to inform our future funding strategy
- We will develop our plans for the next funding round, taking into consideration both the performance of currently funded centres and units and the case for investment in other areas. In so doing, we will engage with Welsh higher education institutions to understand their strategic priorities and areas of planned investment.
- We will then develop and run a new strategically-focused infrastructure funding call that will give existing and emerging groups the opportunity to apply for support beyond March 2025. That funding call is likely to take place in late 2023/early 2024 to allow adequate time for transitions in funding.

Progress made to date

None reported

Referring Documents

None reported

Implementing Documents

1. Research matters: our plan for improving health and care research in Wales

Theme 4: Making the most of commercial investment

Topic area	# of docs
Income, investments, and financial incentives at the level of trade/industry: trade, investment, incorporate commercial innovation into universities	6
Income, investments, and financial incentives at the portfolio level: improve use of capital budgets; invest in decentralised clinical trials; reinvest trial income; incorporate best practices in research finance into its upcoming research guidance for ICs; rethink value of long-term investments in prevention	4

Theme 4. Topic 1:
Income, investments, and financial incentives at the level of trade/industry

Recommendations from Reports

1. Trade:

- Strengthen global trade in life sciences outputs at the WTO by continuing to advocate for international IP frameworks
- "The UK Government must prioritise compatibility with the EU's clinical trials regulatory framework to avoid bureaucracy, cost and duplication. Reducing new frictions that undermine research collaboration should also be prioritised in the implementation review of the UK-EU Trade & Cooperation Agreement. "
- Use the full range of mechanisms in its trade policy toolkit to promote UK life science exports as a key growth sector

2. Investment:

- Deliver stability for prospective investors by providing an internationally competitive tax and fiscal incentives environment for R&D and capital investment.
- DSIT should work with the Treasury and the Department for Business and Trade (DBT) to enhance and expand government-backed schemes that encourage investment from larger investment funds into the early stages of translation to support UK-based life sciences companies. This includes, but is not limited to, collaborating with the pension industry to re-allocate pension funds.

3. Incorporate commercial innovation into universities/spin outs:

- Building on existing progress embedding commercial innovation into institutional reward systems (such as REF2028), DSIT should work with research councils and universities to better incentivise and reward individual entrepreneurs, such as in promotion criteria and grant applications.
- Joint ventures/investment from industry and pharma, including spin out companies, should be explored as additional income sources for research.

4. Other:

- Make the UK a world leader in advanced and sustainable medicines manufacturing by delivering a long-term programme of capital grants and innovation funding.
- Deliver a truly cross-departmental approach to education and skills, with regular collaboration with businesses, to forecast areas of current and future skills need
- Ensure the UK remains a financially attractive location for R&D through the UK's competitive tax environment and generous system of tax reliefs benefitting the Life Sciences industry, including R&D tax credits.

Headline commitments from implementation documents

1. Trade:

2. Investment:

3. Incorporate commercial innovation into universities:

4. Other:

- [1.1.03] Ensure that HSC research in Northern Ireland is sustainable and low carbon, uses efficient and effective methods and processes and attracts new investment.
- We will set out our industry engagement plans and will work to provide a coherent and high-quality service to industry partners wanting to undertake commercial research in Wales, so increasing the profile of Wales globally as a site that delivers reliably and effectively. We will promote and support growing collaborative NHS, academic and industry research partnerships across the UK.

Progress made to date

None reported

Referring Documents

1. ABPI 2024 Manifesto for investment, health and growth
2. CRUK Longer, better lives
3. Moving forward: Recommendations for the future of cancer research in

Wales
4. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Research matters: our plan for improving health and care research in Wales

Theme 4. Topic 2:

Income, investments, and financial incentives at the portfolio level

Recommendations from Reports

1. Improve use of capital budgets:

- DHSC and the Treasury should consult on changes to the healthcare capital allocation and approvals regime, with the aim of enabling more strategic use of capital budgets, including the role of expert organisations such as Cancer Alliances and Operational Delivery Networks (ODNs).

2. UK Government should invest in decentralised clinical trials.

3. Reinvest trial income:

- Facilitate mechanisms to enable local reinvestment of trial income, savings and core funding to feed into service design.
- income generated by commercial sponsors should be explicitly directed to units and departments leading trials in NHS sites to provide direct financial incentives to take part in commercial trials

4. NHSE should incorporate best practices in research finance into its upcoming research guidance for ICSs.

5. The UK Government must change its approach to investing in prevention, ensuring that investment decisions in England adequately capture the financial, wider economic and long-term value associated with improvements in health.

Headline commitments from implementation documents

1. Improve use of capital budgets:

2. UK Government should invest in decentralised clinical trials.

3. Reinvest trial income:

- [8.1.01] Gather information to describe challenges relating to HSC research income generation and management and reinvestment in Northern Ireland and make recommendations to overcome these issues
- [8.1.02] Implement the recommendations identified under 8.1.01

4. NHSE should incorporate best practices in research finance into its upcoming research guidance for ICSs.

5. The UK Government must change its approach to investing in prevention, ensuring that investment decisions in England adequately capture the financial, wider economic and long-term value associated with improvements in health.

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives
2. Beyond Recovery
3. ABPI Rescuing Patient Access to Industry Clinical Trials

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth

Theme 5: Creating the right data infrastructure

Topic area	# of docs
Infrastructure and technology development: ensure the UK's health data offer is globally competitive; improve infrastructure; eliminate infrastructure maintenance backlog; better utilise infrastructure; use and develop new technology to improve research capabilities	7
Data system governance: improved data management and governance; partnerships for data access	4
Performance metrics: develop performance metrics for infrastructure	3
Databases and datasets: recommendations for the EDGE database in Scotland; better use of data/research delivery enabled by data and digital tools; data for participant recruitment and engagement	3
Genomic data for research	1

Theme 5. Topic 1:
Income, investments, and financial incentives at the portfolio level

Recommendations from Reports

1. Ensure that the UK's health data offer is globally competitive

2. Improve infrastructure:

- Building upon digital platforms to deliver clinical research, including supporting NHS DigiTrials, NHSD, Digital Health Care Wales, Scottish Health Research Register (SHARE), eDRIS, Digital Health and Care Northern Ireland and the Northern Ireland Trusted Research Environment
- Consider national infrastructure support for diagnostics and aseptic pharmacy
- Development of new cancer research infrastructure should be supported, including the tripartite NHS/Academic Cardiff Cancer Research Hub providing the translational pipeline between the laboratory and clinic.
- The UK Government must provide ringfenced capital investment targeted to essential cancer infrastructure. This should be wide-ranging and engage the full range of cancer services, including diagnostics and specialist or less visible services.
- To deliver DCTs, the UK Government and NHSE will need to invest in the necessary infrastructure

3. Eliminate infrastructure maintenance backlog:

- The UK Government should eliminate the NHS maintenance backlog in England by 2030. Alongside this, to support the NHS to replace aging equipment and make long-term strategic investment, the UK Government should ensure the DHSC capital budget at least matches the EU average by population.

4. Better utilise infrastructure:

- We need to support all researchers to easily identify and connect with the services best-placed to support their work (digital platforms)

5. Use and develop new technology to improve research capabilities:

- Establishing a new Find, Recruit and Follow-Up service to expedite clinical trial set up and delivery, by supporting partner site selection, securing

access to the data needed for delivery, and by identifying the most appropriate recruitment approaches.

Headline commitments from implementation documents

1. Ensure that the UK's health data offer is globally competitive

2. Improve infrastructure:

3. Eliminate infrastructure maintenance backlog:

4. Better utilise infrastructure:

- [1.1.04] Facilitate efficient use of research infrastructure resources for HSC across Northern Ireland.

5. Use and develop new technology to improve research capabilities:

- [4.1.01] Commission citisen data and technical development work to optimise the ability of the Microsoft Analytics platform to facilitate population derived HSC research studies.
- [4.1.0] Enablement of population based epidemiological studies and interventional public recruitment studies based on ability to select at risk individuals identified within population data: Find, Recruit, Follow (FRF).
- [4.1.03] On boarding a complex data set into a flexible analytics cloud environment to provide Northern Ireland with new methodology and a more accessible environment for population health research.

Progress made to date

None reported

Referring Documents

1. ABPI 2024 Manifesto for investment, health and growth
2. Improving equity of access to cancer clinical trials in Scotland
3. Moving forward: Recommendations for the future of cancer research in Wales
4. CRUK Longer, better lives
5. Saving and Improving Lives
6. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research, Recovery, Resilience and Growth

Theme 5. Topic 2:
Income, investments, and financial incentives at the portfolio level

Recommendations from Reports

1. Improved data management and governance

- A wider review of the LPMS/research governance management systems needs to be undertaken in Scotland to evaluate the value of having one or multiple systems.
- The NHSE Data for R&D Programme's NHS Research Secure Data Environments (SDEs) Network should be rolled out, including urgent publication of guidance for NHS bodies on engaging in research with industry

2. Partnerships for data access

Headline commitments from implementation documents

1. Improved data management and governance

- [4.2.01] Build on the close links that Northern Ireland has with others in the UK e.g. NI Wales Hub & National TRE Network, HDRUK and NIHR Digital, Data and Technology (DDaT) Board.
- [4.2.02] Enactment of secondary use legislation in Northern Ireland enabling the appropriate sharing of data, where legal and, proportionate, with colleagues in the UK, and further afield to assess performance and to lead to improvements in HSC in Northern Ireland.
- We will work with HDR UK, NHS England and other partners on the further development of expectations and standards of Trusted Research Environments, and apply these to Welsh setting

2. Partnerships for data access

- We will build on the strengths of SAIL as a Trusted Research Environment and facilitate an effective partnership with the new NHS Wales National Data Resource programme to improve access to health and care data for research purposes
- We will work with DHCW as a strategic partner to support the closer integration of research and clinical systems

Progress made to date

None reported

Referring Documents

1. Improving equity of access to cancer clinical trials in Scotland
2. O'Shaughnessy Review

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Research matters: our plan for improving health and care research in Wales

Theme 5. Topic 3:

Income, investments, and financial incentives at the portfolio level

Recommendations from Reports

1. Develop performance metrics for infrastructure:

- Articulate the infrastructure requirements (staffing, systems and system integration) to provide the clinical research community with data necessary for monitoring of equity of access and other key performance metrics on an ongoing basis.
- Develop a standardised suite of performance measures for the Clinical Research Community, and simple key performance indicators (KPIs) for boards, should be agreed as part of a wider Scottish Cancer Research Strategy.
- Provide a baseline assessment of performance should be undertaken when Scotland's 2022 Census data are available
- Consider use of performance benchmarking tools to provide visibility of how regional and national performance compares with other areas. Options to consider include the National Institute for Health Research's (NIHR) INCLUDE Tool: Better Healthcare Through More Inclusive Research.

Headline commitments from implementation documents

1. Develop performance metrics for infrastructure:

- [4.3.01] Develop and implement publicfacing dashboards for research using the Microsoft Azure platform to build trust through transparency in the research and allow HSC staff to see elements of their work being displayed for the rest of the population, covering both commercial and noncommercial research.

Progress made to date

None reported

Referring Documents

1. Improving equity of access to cancer clinical trials in Scotland

1. CRUK Longer, better lives

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth

Theme 5. Topic 4:
Databases and datasets

Recommendations from Reports

1. Recommendations for the EDGE database in Scotland:

- Additional fields in EDGE should be set as mandatory fields by all cancer EDGE administrators across Scotland. This minimum dataset should be defined through stakeholder discussions.
- Define a minimum dataset and definitions of use for key items of trial information such as dates and status that should be populated across Scotland, this will facilitate use by NRS, the Networks and R&Ds.
- The Cancer Network Managers work together with EDGE to set up the background work needed to achieve this partnership level reporting access. The users then need to be advised as to the fields they need to be completing to keep this information in real-time.
- Evaluation of using EDGE as a finance tool between research staff and R&D staff across cancer trials in Scotland to ascertain if it should be implemented by all Health Board R&Ds and how it should best be implemented to achieve full benefit and reduce human error.
- Drug cost avoidance needs to be calculated across all CTIMP trials for cancer at each Health Board as a powerful tool to demonstrate the benefit of trials to health board budgets.
- Learning from support departments that have successfully used EDGE should be shared nationally to explore developing beneficial likewise solutions across the country.
- The use of EDGE across the 5 cancer centres warrants a role for national service support.
- Reduce manual manipulation to process recruitment data for ReDA and CPMS, either by the direct LPMS upload from EDGE to CPMS or have a way to auto-manipulating the data from EDGE to feed into ReDA which then uploads to CPMS.

2. Better use of data/ Research delivery enabled by data and digital tools:

3. Data for participant recruitment and engagement:

Headline commitments from implementation documents

1. Recommendations for the EDGE database in Scotland:

2. Better use of data/research delivery enabled by data and digital tools:

- [3.2.08] Better use of routine data as a source of information on the outcomes of participants in HSC research.
- [3.2.03] Better selection of outcomes to collect in HSC research (e.g., through leaner protocols and use of core outcomes sets).
- [3.2.04] Better use of routine data to identify potential participants for HSC research.

3. Data for participant recruitment and engagement:

- 4.4.01 Establishment of the NIPDP to support patient and public engagement. Themes(common to panels in other jurisdictions) might include identification of perceived benefit, social impact of digital innovation, research ethics and governance,legislative provisions for data use, creation and promotion of Open Data, data linkage methodologies and impact on population science, trusted research and digital research environments, federation of data access and registers for the public to indicate willingness to join research (see also 2.5.03).
- 4.4.02 Develop a NIPDP participation register to ensure panels may be called which are demographically targeted or diversified as necessary.
- NIHR, working in partnership with NHS England and the devolved governments, like the Scottish Health Research Register (SHARE), will continue to enhance the UK Be Part of Research platform through collaboration with other existing registries. National digital channels (for example the NHS App or NHS website) will feed into the Be Part of Research platform

Planned Phase 2 commitments from Future of UK Clinical Research Delivery 2022-2025 Implementation Plan:

- The next 3 years will see a revolution in how we use data across the health system. We will go further in utilising innovative data-driven methods and digital tools to transform the way we design, manage and deliver people-centred clinical research studies across the whole of the UK. We will achieve this by increasing the use of data and digital tools in recruitment and follow up, and by improving access to data via Trusted Research Environments (TREs: a type of Secure Data Environment, secure spaces where approved

researchers can access rich, linked datasets) and through increased partnership working across the UK health data ecosystem.

- We are very clear that the opportunity to use health data must be done in a way which is secure and trusted by members of the public, so governance and oversight processes must be both as efficient as possible and transparent, robust and trustworthy. Public trust and understanding of how data is being used to support research continues to be critical in developing appropriate activities. We will be working together to consider how to implement recommendations from the Goldacre Review, and ensuring that all work is supported by comprehensive public involvement and engagement activity.

To improve study planning, recruitment and follow-up:

- The Find, Recruit and Follow-up service will work across the 4 administrations to consider how activity can be expanded to include SAIL, Scottish Health Research Register, data infrastructure in Northern Ireland, NIHR BioResource and other key national data infrastructure, increasing opportunities for people to quickly and easily access research of relevance to them
- NHS DigiTrials and CPRD (via MHRA) will enable a significant increase in the scale of identification of people who match the eligibility criteria for specific studies in order that they can be given the opportunity to participate in research. They will also support increased use of routine healthcare data to streamline reporting of follow-up data, increasing predictability and releasing delivery capacity in the NHS
- In England, the Data for R&D Programme will invest in health data infrastructure for research and development, supported by comprehensive PPI and engagement throughout the programme, including embedded within its governance
- NIHR will invest in data and digital platforms such as Be Part of Research and NIHR BioResource, and provide the tools and support necessary to deliver virtual and decentralised studies. Increased interoperability between regulatory, NHS and NIHR platforms will enable further streamlining of processes for researchers
- In Wales, a digital recruitment programme will be developed through partnership between Health and Care Research Wales, SAIL Databank and the NHS Wales National Data Resource programme, to develop services that utilise data resources to drive research delivery. An Expert Working Group has been established to guide on the development of this ‘data for research’ programme. A pilot service has been funded to use SAIL data to provide

rapid intelligence to aid placement of research trials in Wales to support most effective recruitment

- In Scotland, scoping work and stakeholder engagement is informing plans for developments to support increased use of NHS data and digital technology to accelerate clinical trial delivery, and for further development of the Scottish Health Research Register (SHARE) to support recruitment to health research studies. We will continue to support the already established regional NHS Scotland controlled data safe havens (Trusted Research Environments) and their collaboration with the newly established Research Data Scotland to support use of data in research. We will also look for opportunities to support research and innovation as part of the forthcoming Scottish Government Data Strategy for Health and Social Care
- In Northern Ireland, the RRG Taskforce data and digital sub-group will lead work to prepare the NI data infrastructure to support digitally-enabled trials and participate in UK-wide initiatives such as the 'Find, Recruit and Follow-up' service.

To improve access to data and TREs:

- Over the next 3 years NHS England will build upon foundational investments made in 2021 and 2022 in an interoperable network of TREs. At a national level, we will expand the scale, scope and capacity of the NHS Digital TRE to enable more users to have timely and secure access to a range of national datasets. At a regional level, we will develop a small network of regional 'Sub National TREs' in England, each covering a population of more than 5 million citisens and enabling access to near real time, multimodal data particularly amenable to the development of AI algorithms
- The Data for R&D Programme within NHS England will expand the ability for researchers to access a range of rich linked genomic datasets, creating linkages across the various health data systems so that genomic data can be used to support innovation and patients and service users can benefit from the provision of innovative genomic healthcare. The Genome UK Implementation Coordination Group Data Working Group will lead work looking to link genomic datasets from across the UK, and federate these where appropriate, as set out in the Genome UK: shared commitments for UK-wide implementation 2022 to 2025
- In Scotland, we will continue to support the already established regional NHS controlled TREs and their collaboration with the newly established Research Data Scotland to support use of data in research
- In Wales, we will continue to invest and grow the internationally recognised expertise and TRE available via the SAIL Databank, offering national

population coverage and secure access to billions of person-based records

- In Northern Ireland, the Honest Broker Service and the more recently established Northern Ireland TRE will be supported to further develop secure access to data for research. This will sit alongside a sustained public dialogue and progression of the enactment of secondary uses legislation to facilitate data access for research in Northern Ireland.

Connecting these developments into a coherent UK offer will bring added benefit, therefore to unite plans:

- the RRG programme will ensure strategic co-ordination of this work across the UK clinical research ecosystem, supporting progress and ensuring alignment of initiatives, as well as identifying key areas where we can go further within the next 3 years to take steps towards fully realising our overarching vision
- an RRG data and digital subgroup will be established to enhance collaboration across the sector and ensure people across the whole of the UK benefit from research delivered using data and/or digitally-enabled approaches

The UK Clinical Research RRG programme will oversee the delivery of this plan, continuing to work in partnership with stakeholders across the sector and regularly revisit the original vision to consider any further actions needed to deliver on the 10 year vision. In doing so, we will ensure that the NHS is able to tackle the healthcare challenges of the future enabling people across the UK and around the world to benefit from better health outcomes.

Further information about the RRG programme, including our delivery partners and governance, are available on the dedicated Recovery Resilience and Growth website. Detailed summaries of our progress to date and our future plans will be published on the site on an ongoing basis, providing a central point of information and updates about the programme and our progress towards achievement of the vision. You can also sign up to receive regular email updates on our progress.

Given the scope of the work and the fast pace of change in clinical research, we will keep the specifics of this plan under review via the RRG programme and adapt delivery as needed. This flexibility will allow us to meet emerging challenges and ensure that the outcomes are aligned to the most pressing issues to realise our shared ambitions.

Progress will be measured by the RRG Programme Board and the Ministerially-chaired Oversight Group, ensuring we are delivering on the commitments set out in this plan and that they are having the intended impact on the UK clinical

research system. Specific measures for success will be published on the RRG website later in 2022.

We will publish a Phase 3 plan in 2025 to 2026 to align with the next government spending review period. The Phase 3 plan will showcase our progress and lay out the next steps needed to ensure the vision is delivered.

Achievement of our plan will require action across the whole sector, but by building on the foundations of collaboration and partnership that we have created through RRG programme we can collectively work through current challenges and see this vision become a reality.

Progress made to date

The UK's health data offering is one of our global strengths due to our national health systems and cradle-to-grave healthcare records. Investing in data and digital tools, and making ethical use of them to support clinical research, for example by making it easier to recruit and follow-up participants, increases the efficiency and effectiveness of the clinical research process. These tools also increase the resilience and sustainability of the healthcare system and reduce the burden on the NHS workforce.

Progress in Phase 1:

- The data strategy for health and social care in England was published in June 2022
- Up to £200 million committed to support NHS-led health research (subject to business case) was announced on 2 March 2022 to invest in health data infrastructure to support research and development in England, with parallel activity in the devolved governments
- The NHS-Galleri trial demonstrated the potential for the use of healthcare data to support rapid, large scale recruitment to and delivery of clinical studies in the NHS. The Accelerated Access Collaborative (AAC), led by NHS England, coordinated the design and set up of a 2 part, real-world demonstration project involving clinical data capture from NHS Digital and NIHR, and was a demonstrator for the 'Find, Recruit and Follow-up' service and NHS DigiTrials. The trial has already passed the halfway point in their recruitment of participants, with over 100,000 enrolled following the launch in autumn 2021
- Each delivery partner funded as part of year one of the 'Find Recruit and Follow-up' service launched Minimum Viable Products (MVPs) of their services including: NHS DigiTrials, which has successfully facilitated 28

active trials through its service with a further 8 in application and 12 in pre-application; NIHR CRN launched its early stage 'concierge' service, with 2 companies and 4 data service providers as early users; and HRA, which agreed an approach to review by the Confidentiality Advisory Group which will enable more efficient study set up in future. In addition, the MHRA Clinical Practice Research Datalink (CPRD) has launched SPRINT (Speedy Recruitment into Trials), a data-enabled research service that facilitates rapid feasibility and patient recruitment into industry sponsored phase 2 to 4 trials across the UK

- Making use of real-world data (RWD) in and for clinical research is now a reality, supported by MHRA's published guidance. This is the start of a series of guidelines to provide general points to consider for sponsors planning to conduct clinical research using RWD to support regulatory decision making

Referring Documents

1. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 5. Topic 5:
Genomic data for research

Recommendations from Reports

- Develop IT systems and governance systems that provide sufficient and secure storage of genomic data and that can provide controlled access to genomics data and associated clinical outcome data to facilitate translational research projects.

Headline commitments from implementation documents

None reported

Progress made to date

None reported

Referring Documents

1. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

None reported

Theme 6: Improving how clinical trials are set-up and regulated

Topic area	# of docs
Set-up: improve the speed and efficiency of study set-up; address prioritisation and capacity; commission on sustainable biomedical research; reverse the decline in industry clinical trials	10
Costing and contracting at the trial level: mandate a single negotiation and sign-off process of costing and contracting to improve trial set-up; incorporate best practices from the NCVR; review and improve study costing processes and timeline; develop Scotland cost-savings	5
Performance monitoring/portfolio management: develop performance indicators for trial performance and access to care in trials	4
Patient recruitment: pathway from genomic testing to trials; recruitment should harness data; common framework for approach; establish targets	4
Regulatory/governance: new operating model; updated guidance; collaboration; develop a new centralised approach research governance in Northern Ireland	3
Registries: develop new national registries; improve usability of existing registries	2
Networks: clinical trials accelerator networks; primary care research networks; use NCRI networks; build strong highly coordinated strategic partnerships across the whole research community	2
AI: government and regulators should develop a strategy for the use of AI in clinical trial design and regulation	1

Theme 6. Topic 1:
Set-up

Recommendations from Reports

1. Improve the speed and efficiency of study set-up:

- Set up a rapid task and finish group to reduce the regulatory burden of approving trials
- The MHRA, the HRA and other system leaders should set up a rapid task and finish group on reducing the regulatory burden of approving trials, and removing delays in setup, including with the goal of reaching a 60-day turnaround time for all approvals
- Improving timeframes for clinical trial approvals and set-up
- NHSE should develop a faster and less bureaucratic set-up process for non-commercial trials.
- The UK Government should streamline the set-up and delivery of non-commercial clinical cancer research
- Transform set-up times through expedited and standardised costing and contracting across the NHS.

2. Address Prioritisation and Capacity:

- The Research Reset initiative should accelerate prioritisation of the set-up and delivery of interventional clinical trials of new medicines and vaccines, especially global studies where the UK is competing for participation.
- Increase overall capacity to deliver clinical trials
- DHSC must urgently address capacity and resourcing issues within MHRA to speed up clinical trials approval processes for innovations and postmarket surveillance. This includes providing adequate and sustained funding for the agency via grant-in-aid to ensure capacity can keep pace with demand, and addressing staff and skills shortages through recruitment and retention measures.

3. Commission on Sustainable Biomedical Research:

- DSIT and the Treasury should work with charities, industry and public funding agencies to establish a Commission on Sustainable Biomedical Research. This should be tasked with developing a new long-term investment solution for late-stage basic and early-stage translational life

sciences research within one year of being established, and include setting out a plan for closing the more than £1bn funding gap for cancer research over the next decade.

4. Reverse the decline in industry clinical trials in the UK

5. Covid-19 Recovery:

- Fully delivering the UK Clinical Research Recovery Resilience and Growth Programme in response to the challenges created by the pandemic, including restarting non-COVID-19 research to recover to pre-pandemic levels as soon as possible and delivering a broad suite of actions to make the UK clinical research environment faster, more efficient, and more resilient.
- Supporting virtual and decentralised trial delivery; and building on the momentum of COVID-19 research, the Vaccines Registry, and advances in digital infrastructure to increase access and involvement of NHS patients and service users.
- Learn and apply the lessons from COVID-19, in terms of rapid trial start up, enrolment and delivery – and the role of Government, the NHS and NIHR in prioritising the most strategically important and impactful studies.

Headline commitments from implementation documents

1. Improve the speed and efficiency of study set-up:

- [5.1.1] Establish a new HSC R&D Approvals service as a central facility within PHA.
- [5.1.02] Appoint a new Head of HSC R&D Governance to support the Assistant Director of R&D with regional and national responsibilities, and to build on and improve collaboration with ORECNI towards the delivery of a single HSC R&D approval for Northern Ireland.
- We will reduce or remove duplication and increase speed and efficiency of study set-up and delivery processes and will monitor and review study performance metrics.

2. Address Prioritisation and Capacity:

3. Commission on Sustainable Biomedical Research:

4. Reverse the decline in industry clinical trials in the UK:

5. Covid-19 Recovery:

- [7.1.01] Put in place a COVID-19 Study Delivery Team to deliver existing and new COVID-19 studies.
- [7.1.02] Put in place additional programmed activities (PAs) for consultant physicians affording them protected time to deliver COVID-19 studies.

6. Planned Actions from the Future of UK Clinical Research Delivery 2022-2025 Implementation Document

To improve research approvals and strengthen our regulatory frameworks:

- A single UK approval service will replace HRA and HCRW Approval and equivalent process in Northern Ireland and Scotland, and site permission and confirmation processes across the UK
- MHRA will work with HRA in continuing the development of IRAS to streamline health technology and medicines research, and HRA will explore whether it is viable to embed a fast-track ethics review as part of combined review
- HRA will lead UK-wide work to further expand the suite of model agreements, including decentralised and other innovative delivery models as well as particular fields of innovative products such as Advanced Therapy Medicinal Products
- Following public consultation on proposals for legislative changes for clinical research, the MHRA is now carefully analysing the responses received, preparing a Government response and developing secondary legislation to improve and strengthen our clinical research legislation
- MHRA will support risk-proportionate trial conduct and monitoring, including through Good Clinical Practice (GCP) guidance and pragmatic investigator guidance, and will work with HRA to develop guidance on use of in vitro diagnostics (IVDs) in clinical research
- MHRA and HRA will also establish a comprehensive stakeholder reference group to assist with guidance generation on new legislation and ensure there is a common understanding of regulatory requirements that will enhance the UK's international attractiveness as a place to conduct multinational trials

To improve study set-up:

- Learning lessons from delivering COVID-19 research, we will enhance our early feedback service offer via the NIHR CRN to support study design that is optimised for delivery and explore how we can further match research delivery demand to capacity across the UK
- We will implement the UK-wide National Contract Value Review (NCVR), with the aim of expediting the costing elements of the contracting process across NHS Trusts to ensure costing does not delay study set-up. From 1 April 2022, the NCVR will begin to replace the current time-consuming process whereby each NHS organisation negotiates with each commercial sponsor for every study in order to agree bespoke contract value. The programme will be monitored throughout implementation to ensure lessons can be learnt and the process improved to ensure it achieves its aims. The existing single cost and contract review model in Scotland and across the NIHR Patient Recruitment Centres in England will integrate with NCVR as it develops, supporting more effective UK alignment and efficiency
- The Experimental Cancer Medicine Centre (ECMC) Network, with support from MHRA and HRA, will complete their pilot to set up Phase I oncology trials within 80 days of IRAS submission. Learning from this programme will be shared to enable improved set-up performance in other specialities
- RRG programme partners will identify and establish mechanisms to achieve efficient costing and contracting across other parts of the health system, supporting and enabling an increase in decentralised study designs and research taking place in primary care and community settings.
- DHSC and NHS England will lead a review of their current Excess Treatment Costs (ETC) process in England to review experiences of the policy and t explore how best we can support non-commercial research in the NHS

To make the UK offer easier to navigate:

- The RRG partners will develop a strategic plan, with input from partners and associated organisations across the UK's research infrastructure, on how we will unify, streamline and promote our services and support. We will work with others across the UK clinical research system to ensure that all companies, researchers and their teams can quickly and easily:
- Understand UK capabilities to deliver their study at all stages of the protocol development and delivery pathway
- Connect with the right part of the system to help them at the right time
- Access the network of expertise and resources available to create a

package of support to deliver studies efficiently

- MHRA, NICE, AWTTC and SMC will work with partners across the UK to develop ILAP as an effective route into the UK research system, particularly through the development of a support toolkit
- The further development of IRAS will also provide navigation and signposting through the research journey, directing applicants to relevant guidance and advice. Through interfaces with other systems it will reduce burden and duplication

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

1. In a new approach to licensing and regulation implemented by the MHRA, NICE, the All Wales Therapeutics and Toxicology Centre (AWTTC) and the Scottish Medicines Consortium (SMC), over 100 innovation passports have been issued through the Innovative Licensing and Access Pathway (ILAP), to robustly and safely support the path to market of the most innovative, transformative treatments
2. The combined review from the MHRA and the UK Research Ethics Service, in collaboration with the HRA facilitates speedier set up for clinical research trials by requiring applicants to only make a single application for both Clinical Trial Authorisation (CTA) and Research Ethics Committee (REC) approval. Since January 2022, all new Clinical Trials of Investigational Medicinal Products (CTIMPS) in the UK have been benefiting from the combined review, halving the approval time compared with separate applications over the period 2018 to 2021

From the Full Government Response to the O'Shaughnessy Review in Nov 2023:

- [1.2] Substantially reduce the time taken for approval of commercial clinical trials, with the goal of reaching a 60-day turnaround time for all regulatory approvals
- Recommendations 2 and 3
- Vision theme: streamlined, efficient and innovative clinical research

In the initial response in May, we set out how the HRA have been provided with £3 million of funding to rebuild capacity and deliver reduced turnaround time for all

approvals within statutory timelines. This is in conjunction with £10 million over 2 years to the MHRA to help bring innovative new medicines and medical technologies to UK patients more quickly.

We have made substantial progress towards achieving our goal of a 60-day turnaround time for all regulatory approvals. The MHRA assessed over 2,000 clinical trial initial applications and amendments between mid-July and mid-September and continues work to eliminate the small number of outstanding applications as its highest priority. The MHRA's task and finish group have fulfilled their goal, with regulatory assessments now completed within statutory timeframes for all newly received, fully compliant clinical trial applications from 1 September 2023. Due to the suite of reforms implemented, applicants will continue to see improved rates of assessment in all areas.

The 60-day maximum timeline for combined review offers a single application route and co-ordinated review leading to a single UK decision for Clinical Trials of Investigational Medicinal Products (CTIMPs). A single submission through IRAS is made for both MHRA approval and a research ethics committee opinion.

Going further, the MHRA launched a new notification scheme on 12 October 2023 to enable a more streamlined and risk-proportionate approach to processing initial clinical trial authorisation (CTA) applications for some phase 4 and lower risk phase 3 clinical trials. CTA applications that meet the inclusion criteria and are submitted under the scheme will be processed by the MHRA within 14 days instead of the statutory 30 days.

Through its work to clear clinical trial application backlog and subsequent lessons learned exercises, the MHRA has identified new risk-proportionate approaches that can be applied to application assessment more broadly, for example, adapting reviews depending on the complexity of the trial, trial phase and patient population. New ways of working arising from the lessons learned have been delivered in collaboration with HRA and the National Institute for Health and Care Research (NIHR), enhancing the combined way of working that was in place, reducing time and burden to approval. While there is ambition across these pathways to reduce approval times further, we also recognise the essential attribute of predictable (rather than fluctuating) approval times, delivering within the statutory limits.

MHRA and HRA will work together with the wider community to conduct extensive stakeholder consultation for the combined review system to deliver a genuinely world leading and innovative service, with predictable and consistent delivery of trials across the UK. A workshop was held on 3 November 2023 with stakeholders from the clinical trial community as part of this process. Points raised during this meeting will be followed up in further discussions to determine the alignment of joint review.

Referring Documents

3. ABPI 2024 Manifesto for investment, health and growth
4. ABPI Getting Back on Track Report
5. ABPI Rescuing Patient Access to Industry Clinical Trials
6. CRUK Longer, better lives
7. O'Shaughnessy Review
8. Beyond Recovery
9. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth
2. Saving and Improving Lives
3. The Future of UK Clinical Delivery 2022-2025 Implementation Document
4. Research Matters: our plan for improving health and care research in Wales

Theme 6. Topic 2:
Costing and contracting at the trial level

Recommendations from Reports

1. Mandate a single negotiation and sign-off process for costing and contracting within the NHS to improve trial set-up

- NHSE and the devolved administrations should mandate rapid invoicing for all research costs, as current delays in invoicing deprive the NHS of much-needed research revenue.
- A comprehensive and mandatory national approach to costing and contracting should be developed and instigated, in partnership with industry

2. Incorporate best practices from the National Contract Value Review

3. Review and improve study costing processes and timeline

- NHSE should work at pace to ensure all NHS Trusts in England are committed to adhering to prices generated by the interactive Costing Tool for industry clinical research
- NHSE and the devolved administrations should introduce a 60-day maximum timeframe, with limited negotiation, for costing and contracting of industry clinical research.
- NHSE and the devolved administrations should commit to achieving UK-wide use of unmodified model contracts for industry clinical research.
- NHSE should develop hub-and-spoke model contracts for Integrated Care Systems (ICSs) that cover all providers in an ICS's catchment in a single contract.

4. Develop Scotland cost-savings:

- Develop a standard Scotland-wide approaches to capture drug savings and other non-financial benefits of clinical research
- Further develop the "One Scotland" model to reduce the cost of additional site setup, and enable equitable study placement, including development of "split-site" models

Headline commitments from implementation documents

1. Mandate a single negotiation and sign-off process for costing and contracting

within the NHS to improve trial set-up

2. Incorporate best practices from the National Contract Value Review

3. Review and improve study costing processes and timeline

4. Develop Scotland cost-savings:

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

1. The range of model UK contracts agreed with industry and the NHS has been expanded including the first UK-wide model Clinical Investigations Agreement (UK mCIA) for research in medical devices, and the first Model Confidentiality Disclosure Agreement (mCDA) for use by companies with potential NHS sites has also been launched
2. NHS England published refreshed guidance on Excess Treatment Costs (ETCs), expanding the framework to include studies where Clinical Commissioning Groups are the commissioner for the service where the study takes place and setting out the provider types which can utilise the national payment system in England. From April 2022 the provider thresholds for ETCs has been reduced, meaning that the number of providers who receive ETCs will increase

From the Full Government Response to the O'Shaughnessy Review in Nov 2023:

- [1.3] Deliver a comprehensive and mandatory national approach to contracting
- Recommendation 4
- Vision theme: streamlined, efficient and innovative clinical research

We have delivered on our commitment to enhance the UK-wide national contract value review (NCVR) programme and make it a truly national process for costing and contracting across the NHS. NCVR includes mandated use of unmodified model agreements to ensure a national standard approach to contracting. To deliver on our commitment to ensure both full cost recovery for the NHS and increased transparency for industry, we have updated site-specific multipliers in England. Based on feedback from NHS organisations on their reasons for varying from the national costing, for example outsourcing to third parties, the multipliers ensure these costs can be met while removing the need for site-specific negotiation and variation for each study.

This builds on existing practice in other parts of the UK where sites accept nationally agreed contract values with local multiplier applied without further negotiation.

We met our goal to introduce new multipliers in England in October 2023 and they are now used as part of the calculation to create site level prices which cannot be negotiated. Further, a new financial appendix has been added to nationally mandated standard contracts and is pre-populated with site-level budget details generated in line with the national tariff and site-specific multipliers. We will monitor both NHS and industry adherence to the single national review and standard contracts and have set a performance indicator of 100% adherence by sites in England by the end of 2023.

Since October 2022, NCVR has delivered a unified costing process with a national resource review and study costing in line with the national tariff. By July 2023, 74% of sites in England indicated that they would accept the national resource review and costing without further negotiation. Now that site-specific needs have been taken into account, 100% of sites should comply. As with any new process it may need a short time to bed in, but we expect 100% compliance across NHS sites in England by December 2023. We will monitor compliance and assess the need to take further action if non-compliance is evident following this reasonable period of time to allow the process to become embedded.

This unified negotiation process has already contributed to significantly speeding up the set-up process. In the first year the time taken from costing submission to first patient recruitment has reduced by 36% (from an average of 305 days to 194 days). The average number of trust research sites per study is 10, and in addition to faster set up, NCVR has freed up resource in sites to carry out other research activity.

Building on the learning to date we are also testing how best to expand NCVR into the costing and contracting of early phase (phase 1 and 2a) and advanced therapeutic medicinal products (ATMPs) studies. This work started in the summer and the first pilots will begin before December 2023.

Referring Documents

1. CRUK Longer, better lives
2. Improving equity of access to cancer clinical trials in Scotland
3. ABPI Rescuing Patient Access to Industry Clinical Trials
4. O'Shaughnessy Review

Implementing Documents

1. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 6. Topic 3:

Performance monitoring/portfolio management:

Recommendations from Reports

1. Develop performance indicators for trial performance:

- The business development services in NIHR and its equivalent bodies should be set explicit performance targets to increase the number, kind and diversity of commercial trials
- Establish dashboard for performance of clinical trials from set-up to impact
- The MHRA, the HRA, NIHR and its equivalent organisations across the UK should collect, consolidate and publish national monthly returns on all the clinical trials activity that is happening in the NHS, and NHS bodies and commercial sponsors should publish numbers of patients in trials on a monthly basis
- A new UK-wide set of KPIs for clinical trials should be established covering all critical aspects of the set-up, approval of and recruitment to trials, an overall measure for UK performance in clinical trials, and outcome measures for the impact of commercial trials. These KPIs should apply to all bodies involved benchmarked against global exemplars
- Improving visibility and accountability for clinical trial performance

2. Develop performance indicators for access to care in trials:

- Introduce Key Performance Indicators for access to care in trials
- Monitor performance in provision of care in both standard of care and trials settings.

Headline commitments from implementation documents

1. Develop performance indicators for trial performance:

From the Full Government Response to the O'Shaugnessy Review in Nov 2023

- [2.1] UK performance indicators
- Recommendations 1, 5, 7 and 8

To address Lord O'Shaughnessy's recommendations regarding establishing KPIs, making accountability in the system clearer and building on the common sense of

purpose and clarity established in Research Reset, we are introducing new system-wide UK performance indicators with immediate effect. These performance indicators will be ongoing and will underpin the 5 themes set out in Saving and Improving Lives: The Future of UK Clinical Research Delivery and are intended to drive short term progress towards our 10-year vision.

The NHS has responded positively to a call to action to recover the delivery of commercial contract studies during Reset, with performance in commercial trials exceeding that of the overall portfolio. We must now build on that momentum to predictably and reliably deliver commercial contract trials within globally competitive timelines. Increasing recruitment to commercial studies and doing so within globally competitive timelines delivers on our commitments to improve the UK environment for life sciences research, but it primarily benefits patients and the NHS, providing more people with earlier access to new treatments and interventions, investment in the delivery of care as part of clinical studies, and the evidence needed to improve and sustain the NHS both now and in the future.

We also plan to work further on enabling commercial collaborative trials, funded by industry (solely or in collaboration, for example with a charity) and sponsored by academic or NHS institutions. These provide a hybrid option and represent an opportunity to further embed research within normal pathways, enabling access to investigator expertise (at design and delivery stages) and bridging gaps between different models. This research supports a workforce who operate at the interface of industry, academic and clinical areas, bringing benefit to patients.

We have worked closely with industry colleagues on recruitment number targets; they have told us of their strong need for predictability and sustainability of performance, metrics beyond recruitment numbers (such as study completion), concerns over prioritisation of lower complexity, higher volume studies and realism about NHS capacity to deliver at this time. Reflecting on this feedback and concerns from industry engagement, we will continue to aim for doubling of recruitment by 2025, and then ensuring that firstly these levels are sustained, and secondly that we continue to aim for a further doubling by 2027. This will be kept under review, including the categorisation of commercial activity, to make sure that recruitment targets do not lead to perverse incentivisation. While this ambition will be supported, we will avoid penalties so as to ensure that choice of trials is driven by scientific need and patient benefit.

The UK performance indicators draw on data available through existing systems and will be updated in 2025 following both the achievement of the current indicators and the implementation of the fully fit for purpose data system required to monitor a broader range of activity.

All UK performance indicators will measure UK performance for studies on the NIHR CRN portfolio, except for regulatory approvals which will measure timelines for combined review. The indicators apply at a UK system-wide level and implementation will be overseen by DHSC, the devolved administrations (DAs) and the NHS.

2. Develop performance indicators for access to care in trials

Progress made to date

From the Full Government Response to the O'Shaughnessy Review in Nov 2023:

- 1.4 Provide 'real-time' data on commercial clinical activity in the UK
- Recommendations 5, 6, 8, 15 and 18
- Vision themes:

UK performance indicators

- Streamlined, efficient and innovative clinical research
- People-centred research

Both the learnings from Research Reset and the recommendations of the O'Shaughnessy review underlined the need to improve our systems to collect and monitor research performance data and to enable its use to drive improvements and accountability at all levels of our organisations and across the whole of the UK.

Work to collect, consolidate and publish national data on clinical research is underway. DHSC's research status reports bring together several system metrics into a single publication, providing monthly updates including total number of participants recruited, and those in commercial clinical trials. Furthermore, a dashboard of clinical research system metrics has been developed and we intend to launch a publicly available version in spring 2024.

While the dashboard represents improved transparency of research performance data, we know that we need a new system entirely to capture portfolio studies (and in time all studies) and drive accountability. This new system needs to work across all NHS organisations to collect data that NHS trusts already capture, though not in standardised ways, and collate this in a reliable way that saves rather than costs workforce time. This work involves pulling data from around 12,000 live studies. To deliver the new system, NIHR are working with organisations from across the UK ecosystem to complete essential 'discovery' work to inform the collection and publication of clinical research performance data. The aim is to identify ways to effectively track progress of a study through the UK clinical trials ecosystem and

support assessment of the international competitiveness of the UK clinical research system. It will benefit all types of research delivered in the health and care system.

The first stage of the discovery work captured the systems, data flows and 'pain points' across multiple organisations in our current approach. It also identified significant duplication of effort, a lack of shared identifiers and data standards across systems, and a lack of data to enable effective understanding and monitoring at every stage of the research delivery pathway. The second stage to explore and develop future system requirements, informed by the first, is now under way.

Discovery work will complete in full in March 2024, providing essential foundations for successful implementation. We will publish an update and an overview of key delivery milestones by April 2024. Subject to business case approval proceeding through usual government procurement routes (and proscribed timelines), the new platform will be implemented in the 2025 to 2026 financial year (FY). Regular updates and ongoing stakeholder and partner engagement will enable effective delivery and oversight as this critical system-wide project progresses.

We will continue to maximise the use of currently available monthly data in monitoring the progress of this implementation plan until the new system is in place. New UK performance indicators will continue to utilise data available to monitor studies eligible for NIHR Clinical Research Network support and equivalents used by the devolved administrations and we will learn from recognised gaps in our data to drive the development of the new systems.

Building on work completed in Research Reset, NIHR will implement a new sponsor engagement tool in December 2023. This replaces the Reset tool, implemented at speed during Reset to enable sponsors to provide assessments of study progress. Sponsor assessment is now a cornerstone of the NIHR's approach to monitoring study progress. The new tool has been designed and validated in partnership with sponsors to provide a better user experience and improved access for the people monitoring studies in sponsor organisations and on their behalf.

We also committed to further develop the UK-wide NHS and NIHR Be Part of Research platform to enhance support for the public, patients and clinicians to find out about health and social care research taking place across the UK, including commercial trials. Over 370,000 volunteers have registered with Be Part of Research to find out about research taking place across the UK, of which around 310,000 are via the England NHS App. Registration is available on the Be Part of Research homepage, the NHS.UK homepage and the England NHS App.

We will publish progress updates on a monthly basis, building on our approach in Research Reset. We will continue to monitor and publish a range of data in addition to these UK performance indicators to support their implementation, understand their

impact including on non-commercial studies, and address any unintended consequences. This will include the balance of interventional and observational studies and available data for early phase trials, and other studies not eligible for NIHR CRN support. Building on our experience in delivering Research Reset, we will also explore impactful incentives and consequences which help drive achievement of these performance indicators.

The diversity of research participants, continued growth of early phase research, commercial research income and capturing of research activity beyond recruitment and in more granular ways are essential to implementation of our vision. However, they cannot be baselined and monitored systematically within currently available data. We will use soft intelligence and partial data to monitor these areas where possible and will ensure we draw attention to them in the ongoing delivery of this implementation plan. Any incentives and consequences will also take consideration of the potential impact on these important though, at this stage, less quantifiable outcomes.

As noted previously, discovery for our new data systems will complete in full in winter 2023 to 2024, providing essential foundations for successful implementation. We will publish an update and an overview of key delivery milestones by April 2024. Subject to business case approval, the new platform will be implemented in financial year 2025 to 2026.

In addition, and working with partners, NHS England will develop a set of metrics which help integrated care boards (ICBs) and NHS providers understand their research performance across all types of research and publish these by the end of financial year 2024 to 2025. Under the Health and Care Act 2022, there is a requirement that:

Each integrated care board must, in the exercise of its functions, facilitate or otherwise promote - (a) research on matters relevant to the health service, and (b) the use in the health service of evidence obtained from research.

NHS England has issued guidance for integrated care systems (ICSs) on maximising the benefits of research. ICSs also have a duty to include research in their joint forward plans and annual reports and NHS England has a duty to assess that these duties have been discharged.

Referring Documents

1. ABPI Getting Back on Track Report
2. O'Shaughnessy Review
3. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

1. Full Government Response to the O'Shaughnessy Review

Theme 6. Topic 4:
Patient recruitment

Recommendations from Reports

1. Pathway from genomic testing to trials:

- Create a seamless pathway between genetic testing, personalised medicines access, and clinical trials
- All patients receiving genomic testing of any kind in the NHS should be offered a standard consent for engaging in research

2. Recruitment should harness data: Establish a world leading, health data-enabled patient recruitment service for clinical trials

- We will maximise our digital potential to support study set-up, delivery and access to research, by establishing a programme of work that enables the use of routine data to support research trial recruitment and delivery, shaped by public deliberation work to set expectations and approach

3. Common framework for approach: agencies responsible for information governance within clinical trials should establish a common approach to contacting patients about research within the current legislative framework

4. Establish targets:

- Specific targets should be introduced for the new RDN co-ordinating centre and regional centres to expand research to multiple sites, and to increase diversity of patients recruited
- DHSC, DSIT and the NHS should set stretching annual targets for increasing commercial trials in the 4 countries of the UK and carry out annual benchmarking exercises comparing performance against competitor countries. Central to this ambition should be the objective of doubling recruitment to commercial clinical trials within the next 2 years, with a further doubling by 2027

Headline commitments from implementation documents

1. Pathway from genomic testing to trials:

2. Recruitment should harness data:

- We will maximise our digital potential to support study set-up, delivery and

access to research, by establishing a programme of work that enables the use of routine data to support research trial recruitment and delivery, shaped by public deliberation work to set expectations and approach

3. Common framework for approach:

4. Establish targets:

Progress made to date

None reported

Referring Documents

1. ABPI 2024 Manifesto for investment, health and growth
2. O'Shaughnessy Review

Implementing Documents

1. Research matters: our plan for improving health and care research in Wales

Theme 6. Topic 5:
Regulatory/governance

Recommendations from Reports

1. New Operating Model: in England, a new operating model for the NIHR CRN should be introduced to strengthen accountability and delivery

2. Updated Guidance and Reduce Bureaucracy:

- The Medicines and Healthcare products Regulatory Agency (MHRA) and HRA should develop updated guidance to support and promote decentralised clinical trials (DCTs), incorporating lessons from the pandemic and the NIHR's scoping review.
- Develop updated guidance to support and promote decentralised clinical trials
- In line with the recommendation of the Taskforce for Innovation, Growth and Regulatory Reform (TIGRR), use the recently passed Medicines and Medical Devices Act 2021 to radically improve existing legislation on clinical trials, so that it is no longer reflects the EU's Clinical Trial Directive.
- Build on the work already started by the CEOs of UK regulators to remove unnecessary or burdensome bureaucracy associated with research approvals. For example, by actively expediting research set-up through initiatives such as the HRA's Rapid Research Ethics Committee Review.
- Further enhancing expert early advice for researchers via the Health Research Authority (HRA) and the MHRA to support efficient trial design, approval, and start-up.
- Building on the progress made by the G7 on Clinical Trial Protocols to actively champion and utilise novel clinical trial designs and regimens in the UK and internationally, to reach clinical endpoints more quickly. This will build on the UK's established leadership in areas such as Human Challenge Studies and other novel trial methodologies.
- The MHRA will also continue to advocate for and champion innovation and research friendly global regulatory standards through global regulatory fora and bilateral relationships – as well as the use of novel biomarkers or surrogate markers where the impact of treatment on disease is not well understood.
- Maintain the UK's strong Intellectual Property regime, recognising the important role this plays in securing the value of new technologies that are

trialled and tested in the UK.

3. Collaboration:

- Streamline research collaboration via the UK-EI Trade & Cooperation Agreement
- DHSC, MHRA and NICE, collaborating with NHSE, should clearly define routes to adoption from pre-market authorisation to commissioning for emerging innovations, including AI applications, digital technologies and diagnostic tests. This should involve outlining the accountabilities and responsibilities of the relevant partners, as well as evaluation criteria, evidence thresholds and cost-effectiveness requirements.

4. Develop a new centralised approach to research governance in Northern Ireland.

- [5.1.03] Through collaborative working, define roles and responsibilities within the City Deals (in particular iREACH) to ensure complementary, effective and efficient processes for the HSC R&D Approvals Service alongside the eventual internal governance structure.

Headline commitments from implementation documents

1. New Operating Model:

2. Updated Guidance:

3. Collaboration:

4. Develop a new centralised approach to research governance in Northern Ireland.

- [5.1.03] Through collaborative working, define roles and responsibilities within the City Deals (in particular iREACH) to ensure complementary, effective and efficient processes for the HSC R&D Approvals Service alongside the eventual internal governance structure.

Progress made to date

None reported

Referring Documents

1. CRUK Longer, better lives
2. O'Shaughnessy Review

3. Life Sciences Vision

Implementing Documents

1. Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth

Theme 6. Topic 6:
Registries

Recommendations from Reports

1. Develop new national registries:

- Building on near real-time activity and performance generated according to the above recommendation, the 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
- Develop national trials register with regular out puts circulated to encourage or expand recruitment circulated nationwide.

2. Improve usability of existing registries:

- Improve usability of ISRCTN registry
- The Health Research Authority (HRA), the ISRCTN registry and NIHR Be Part of Research should make it easier for sponsors to update study records, while also strengthening accountability. BMC, which manages the ISRCTN registry, will require the right level of dedicated resource to deliver such changes.

Headline commitments from implementation documents

None reported

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

- [10.] RRG partners have partnered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry to make it easy for researchers to fulfil their transparency responsibilities. Trial registration is the first step to ensuring research transparency from the outset, and from 2022 the HRA began automatic registration of clinical research with ISRCTN, taking the burden away from research sponsors and researchers

Referring Documents

1. CRUK Longer, better lives
2. Improving equity of access to cancer clinical trials in Scotland
3. O'Shaughnessy Review

Implementing Documents

1. Future of UK Clinical Research Delivery 2022-2025 Implementation Plan

Theme 6. Topic 7:
Networks

Recommendations from Reports

1. Clinical Trials Accelerator Networks:

- A new 'enhanced service' option should be developed, through the proposed CTANs, to enable the government and the NHS to develop an excellent process for every step of a trial. This will further research in the selected fields and create an exemplar for improving the service for all trials in the future

2. Primary Care Research Networks: Create new primary care research networks to increase commercial clinical trial access in easy-to-access settings

3. Use NCRI Networks

- NCRI to provide a central hub to get involved with the work of the NCRI Groups (formerly CSG's) with regular two way feedback between NCRI and wider clinical research community

4. Build strong highly coordinated strategic partnerships across the whole research community, including academia, NHS, industry and third sector requires dedicated support and focus as part of a cohesive Scottish Cancer Research Strategy.

Headline commitments from implementation documents

1. Clinical Trials Accelerator Networks:

2. Primary Care Research Networks:

3. Use NCRI Networks

4. Build strong highly coordinated strategic partnerships across the whole research community, including academia, NHS, industry and third sector requires dedicated support and focus as part of a cohesive Scottish Cancer Research Strategy.

Progress made to date

From the Future of UK Clinical Research Delivery 2022-2025 Phase 2 Implementation Plan:

In England, to support the drive to recover the portfolio, DHSC provided over £30 million of additional funding via the NIHR Clinical Research Network (CRN) in the 2021 to 2022 financial year to increase research delivery capacity, especially in community settings and with a key focus on achieving flexibility and agility in the workforce. The Welsh Government provided £1.7 million to support additional capacity in order to achieve the recovery of non-COVID-19 research, including development of research capacity outside of hospital settings. £3 million of funding from the Department of Health in Northern Ireland has been provided to support the work of a Taskforce established to address clinical research recovery in Northern Ireland

From the Full Government Response to the O'Shaughnessy Review in Nov 2023:

- [1.6] Establish clinical trial delivery accelerators
- Recommendations 24 and 26

Vision themes:

- streamlined, efficient and innovative clinical research
- people-centred research delivery

The O'Shaughnessy review notes that regaining the UK's global leadership position requires restoring more 'traditional' clinical research activities, but also recommends accelerating new and innovative ways to deliver studies. To achieve this, the review recommended the launch of clinical trial acceleration networks (CTANs) to enable the government and the NHS to develop excellence at every step of a trial, creating an exemplar for improving the service for all trials. While the O'Shaughnessy review was largely focused on commercial trials, the ambition to accelerate innovative models of trial delivery was clearly intended for both commercial and non-commercial studies. As such, our work in this area is intended to benefit all studies, irrespective of sponsor type. We committed to progressing this recommendation in our initial response published in May 2023, with a commitment of £20 million over 2 years to establish 2 to 3 CTANs.

The vision set out the innovative approaches to study delivery that we would like to see more of in the system. This includes study delivery that is closer to where people live, including virtual studies, with decentralised delivery to primary, community and social care settings. This will make research more accessible to patients and the public and better manage resource in acute care settings. Capacity constraints in the system and a lack of capability to translate existing guidance and best practice into delivery means that we are not seeing enough studies employing these innovative models.

Since the initial government response, we have undertaken significant work with stakeholders to ensure that implementation of this concept will fully address the issues

that have been identified, building on existing investments to deliver innovative, efficient and effective approaches for the delivery of clinical trials. We have heard a very wide variety of views on how accelerators might be established, with no clear consensus on an optimal model. We have modified the name to better describe what an accelerator will do, which is to accelerate innovation in the delivery of clinical trials, and will be designating 2 accelerators in defined areas. As set out in the review, these will be focused on areas of strategic importance and translated into system-wide improvements and learning.

Accelerators will comprise a dedicated multidisciplinary team (of around 20 people) embedded within existing infrastructure. They will work with trial sponsors and delivery teams to deliver studies in a way that maximises efficiency and prioritises diversity in regions, setting and trials, and to place people, regardless of their background or community in the right trials, in the right place at the right time. Technology and other novel solutions can enable sponsors and contract research organisations (CROs) to take a hybrid approach to trial design to improve patient diversity, retention and accessibility, increase study effectiveness and bring new treatments and technologies to market more quickly. By bringing together a workforce with skills in both research and health care delivery, process improvement and project management, the accelerator model will advance clinical trial design and delivery which will ultimately scale across the wider system, broadening access to research opportunities for the workforce and patients and the public.

Accelerators will assist sponsors and delivery teams by providing support and identifying opportunities to develop and apply innovative delivery methods. They will also monitor and assess how those approaches are working in real time. As a result of the improvements and efficiencies made by an accelerator, studies within an accelerator's remit should have quicker set up and delivery. Accelerators will act as continuous learning hubs and consider how to appropriately scale successful innovation across the system, taking account of the nuances of condition-specific, population-specific and regional differences.

They will test solutions to system-wide delivery problems, complementing other system improvement work set out in this response, enabling the UK to lead on the delivery of high-quality research globally. Accelerators must be able to address barriers and implement solutions that are present across the UK, some of which will be similar, but others will have key differences based upon the specific infrastructure in each nation.

Accelerators will have a specific role in spreading learning across the wider system and supporting research innovation in other disease areas. Acting as exemplars for the development and spread of new approaches for the benefit of the whole clinical

research system, they will widen access to research opportunities, speed up recruitment and increase the participation of all areas of the health and care system in delivering research. Effective partnerships between and joint leadership from industry, the NHS, academia and research funders will be vital to the success of accelerators.

To ensure pace, accelerators will be embedded in existing research infrastructure with a short process to appoint the contracted organisation who will lead the programme of work, commencing as soon as is feasible. We have taken the decision not to establish an independent body because of the resultant delays caused by the need for new legislation.

By April 2024, we will pilot a new clinical trial delivery accelerator for dementia research that will work across the UK to support the delivery of innovative clinical trials.

As acknowledged in the Life Sciences Vision and NHS Long Term Plan, dementia is one of the great healthcare challenges we face, with an estimated 944,000 people estimated to be living with dementia in the UK. Furthermore, dementia and Alzheimer's disease is the leading cause of death in the UK, with an economic cost of over £25 billion each year. From 2012 to 2022, just under 15,000 patients were recruited into phase 1, 2 and 3 dementia trials in England but there is a clear need to recruit more patients to dementia trials. Streamlined trial delivery and increased capacity across the UK in both new and existing sites will make it possible to initiate more studies in future. Delivering trials in people-centred ways through primary or community care and in care homes is highly appropriate for this clinical area.

Creating a new accelerator in an area with a ready pipeline of studies that are being provided by a mix of major commercial and non-commercial sponsors allows us to explore this as a proof of concept to inform future accelerators beyond this spending review period. Dementia is a government priority, and the work of the accelerator will build on and enhance other initiatives to improve dementia research for example through the NIHR Dementia Translational Research Collaboration Trials Network, the UK government's Dame Barbara Windsor Dementia Mission, the UK Dementia Research Institute and the Trials Delivery Framework within Dementias Platform UK. The dementia accelerator will be embedded within the UK government's Dame Barbara Windsor Dementia Mission, and will be delivered in partnership with a funder such as the Medical Research Council (MRC). We will work with stakeholders and system leaders across dementia research, on the next steps to operationalise the accelerator in dementia, harnessing their existing strengths and providing coverage across all trial phases.

As set out in the review, the UK-wide vaccines innovation pathway (VIP) provides an exemplification of many of the crucial elements of the proposed CTANs, and we are designating this existing work as a second accelerator, both to learn from the

innovative delivery models being tested and to provide any additional resources where required to ensure it is delivering the full functionality we expect from an accelerator. The VIP builds on the experience of delivering vaccine trials at scale and pace during the pandemic and will also test innovative models of trial delivery, focused on streamlining and accelerating the delivery of vaccine trials for infectious diseases and mRNA vaccines and therapeutics for cancer. The development of the VIP includes the portfolio of trials already being delivered in this area through the government's strategic partnerships with 2 major vaccine companies and the growing interest of a broader range of companies with relevant pipelines to conduct these studies in the UK.

For infectious diseases, the VIP is also looking at a range of settings for trials to take place, in particular in primary care and community settings, which should improve diversity and inclusion in studies and will support the UK's ability to deliver significant recruitment to large scale global vaccine trials. For cancer, the new mRNA therapeutics, particularly personalised vaccines, require innovative ways to embed trials in the existing care pathway so that research and treatment are fully integrated. This accelerator will align with existing funding channels and governance arrangements, but with additional reporting into the Life Sciences Vision Delivery Board.

- [1.7] A new Research Delivery Network for England
- Recommendations 9, 17 and 22

In 2024, the NIHR Clinical Research Network will transition to the NIHR Research Delivery Network (RDN). The new RDN will continue to support England's world class research system to deliver high quality research that enables the best care for the population. However, the services and ways of working for the new RDN will change to respond to strategic and stakeholder needs, incorporate learning and identify areas where the support provided to the research system could be strengthened. The RDN has been designed to be agile, adapting to the changing needs of the research system and working to deliver continuous improvements in services and outcomes. It will respond to stretching objectives and have transparent financial controls to ensure value for money.

The RDN will work closely with research and innovation teams across the NHS, the life sciences industry, charities, other research funders and researchers as an equal partner. RDN will support their work in planning, placing and delivering studies within health and care services, providing tools to monitor the delivery of individual studies. RDN will focus on portfolio monitoring, identifying and resolving strategic challenges for the research system, to ensure the system is able to achieve its ambitions around innovative study methodology, increasing the diversity of populations taking part in research and broadening the settings in which research takes place, including enabling and supporting research to move into primary and community care.

The NIHR RDN will provide funding to study sites that can be used to support the costs of research delivery across the entire study delivery pathway. It will provide financial oversight to ensure this funding is being used to support R&D activities in line with DHSC guidance on the attribution of research costs and provide dedicated support to ensure study sites are recovering all appropriate costs to sustainably fund and grow research delivery staff and facilities.

The RDN will operate as one organisation across England, with a shared vision and purpose. There will be a network of 12 regional networks, hosted by leading NHS organisations, and a co-ordinating centre, hosted by the University of Leeds. The joint leadership function for the RDN will balance regional context, expertise and relationships with national co-ordination and strategy, and involve regional leaders and DHSC policymakers. There will be greater consistency in outcomes to respond to customer needs so that all customers receive the same service regardless of where they are based.

Referring Documents

1. O'Shaughnessy Review
2. Improving equity of access to cancer clinical trials in Scotland

Implementing Documents

None reported

Theme 6. Topic 8:
Networks

Recommendations from Reports

1. AI Strategy

- The government and regulators should develop a strategy for the use of AI in clinical trial design and regulation

Headline commitments from implementation documents

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Progress made to date

None reported

Referring Documents

1. O'Shaughnessy Review

Implementing Documents

None reported