

# Full government response to the Lord O'Shaughnessy review into commercial clinical trials

## Ministerial foreword

We welcome the areas highlighted by Lord O'Shaughnessy in his review of commercial trials, which has brought a fresh perspective and helped us to prioritise key areas of the ongoing work to implement the vision set out in *Saving and Improving Lives: The Future of UK Clinical Research Delivery*.

The actions we are taking now to address the recommendations of the review will provide benefits for patients and the NHS across the UK, improve the environment for all types of clinical research and drive forward improvements urgently to maintain our place as one of the most attractive places in the world to conduct industry clinical trials. Our actions are supporting our fantastic life sciences sector, bringing investments into the UK and helping to build the economy. By delivering improvements across the whole clinical research pathway from early translation to late phase trials, we will ensure more people have access to innovative clinical trials that are relevant to them, and ultimately deliver better prevention, treatment, and care for all.

Since March 2021, we have taken bold action to implement our vision and recover from the impact of the pandemic on non-COVID-19 research. The strengths we demonstrated during the pandemic had a worldwide impact. We proved our ability to deliver trials that were not possible anywhere else in the world at such scale and speed. These achievements were possible due to the integration of our research delivery system within our healthcare system, as well as close working between the industry and the UK's clinical research infrastructure in the NHS and academia to deliver research in new and innovative ways. While the strengths of our system made our research response to COVID-19 possible, the system is also complex, and solutions to streamline processes and reduce bureaucracy can be difficult to achieve.

The 5 headline commitments made in the initial response to the O'Shaughnessy Review drove forward existing efforts to make progress on these long-standing issues. Through the focused and dedicated efforts of people working across the whole UK research system we have made significant leaps forward in the last 6 months:

- backlogs in research approval applications have been cleared by the Medicines and Healthcare Products Regulatory Agency (MHRA) and they have recently introduced a new notification scheme for phase 4 and low-risk phase 3 clinical trials
- barriers to the acceptance of nationally agreed costs have been removed and an approach which both increases transparency for industry and ensures full cost recovery by the NHS has been implemented

- UK performance in clinical research has exceeded pre-pandemic levels with the numbers of studies, levels of recruitment and delivery to time and target all delivering at a higher rate than previously seen
- detailed exploration of the current arrangements for identifying and contacting potential participants, and the barriers and enablers to a people-centred model has also made significant progress, with new guidance to follow by the end of 2023.

We have also taken important steps forward in addressing issues which will take longer to bear fruit. Discovery work to design an effective and efficient performance data system is moving forward at pace and will inform the design of a new system to be implemented from 2025. While maintaining pace, we should take the time to do this work well, ensuring we deliver real-time data while also reducing administrative burden and improving the data available to enable effective oversight at all levels of the UK's research ecosystem. Detailed exploration of the current arrangements for identifying and contacting potential participants, and the barriers and enablers to a people-centred model has also made significant progress, with new guidance to follow by the end of 2023.

Lord O'Shaughnessy set the bold ambition to double trial activity to get back to the pre pandemic baseline, then to double again by 2027. It is a welcome level of ambition, and we collectively share the desire to return the UK to its leadership role. We will work together across the UK to continue the timely enactment of this plan, implementing new UK performance indicators with immediate effect and progressing a range of commitments designed to enhance attractiveness as a destination for globally competitive life sciences research and our ability to deliver high quality research funded by medical research charities and UK taxpayers.

**Rt Hon Victoria Atkins MP**

Secretary of State for Health and Social Care, Department of Health and Social Care

**Peter May**

Permanent Secretary of the Department of Health, Northern Ireland Executive

**Eluned Morgan**

Minister for Health and Social Services, Welsh Government

**Michael Matheson**

Cabinet Secretary for NHS Recovery, Health and Social Care, Scottish Government

# Executive summary

In March 2021, we published our bold and ambitious 10 year vision [Saving and Improving Lives: The Future of UK Clinical Research Delivery](#). This was followed by the publication of [implementation plan for 2021 to 2022](#) and [implementation plan for 2022 to 2025](#) which set out the steps we would take to progress the vision in 2021 to 2022.

[Lord O'Shaughnessy's review of commercial clinical trials](#), commissioned in February 2023 and published in May 2023, identified key challenges in conducting commercial clinical trials in the UK and offered recommendations on how addressing them could help the life sciences sector unlock UK health, growth and investment opportunities. The [initial UK government response](#), published alongside the review, welcomed all recommendations from the review in principle, and made 5 headline commitments backed by up to £121 million. This is complemented by £10 million funding for the Medicines and Healthcare products Regulatory Agency (MHRA) to fast-track patient access to cutting-edge medical products and £175 million funding for health data infrastructure in England through the Data for Research and Development Programme.

This report sets out our response in full. It provides an update on progress made against the initial commitments and provides a prioritised response on both the remaining recommendations and the existing programme of work announced in our previous implementation plans. This document updates and supersedes our previous plans and provides renewed focus to ensure we make the progress necessary to ensure we are a global leader in the delivery of life sciences research while also ensuring continued progress towards our 10-year vision.

We have made significant progress against all 5 headline commitments and this report provides a detailed update on each. We have also completed work to successfully recover the delivery of clinical research in the NHS and have reversed the drop in commercial clinical research identified by Lord O'Shaughnessy in his review. UK performance in commercial clinical research has now exceeded pre-pandemic levels with the numbers of studies, levels of recruitment and delivery to time and target, all delivering at a higher rate than previously seen.

Figure 1: open studies delivering to time and target by month (in England)

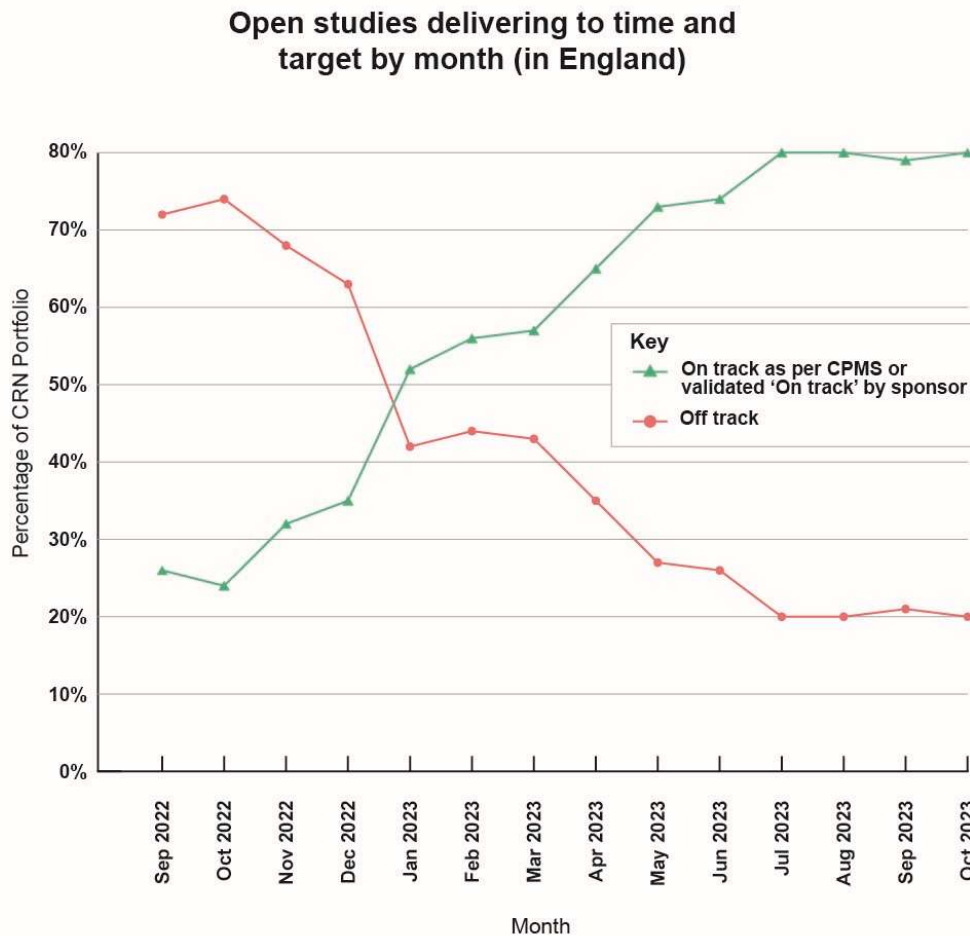


Figure 1 shows on track as per CPMS or validated 'on track' by sponsor studies increasing from 26% in September 2022 to 80% in October 2023. It shows off track studies decreasing, from 72% in September 2022, to 20% in October 2023.

In publishing this plan, we note that the UK has longer-term and bigger ambitions in the clinical trials arena, including substantially increasing and improving the number and quality of commercial clinical trials undertaken in the UK. This government response has focused on fixing the core drivers and enablers - we will continue to drive forward implementation and return to each Life Sciences Council with an update on current performance metrics, and future ambitions.

We have also announced the commencement of a new NIHR Research Delivery Network (RDN) for England from April 2024. A large-scale programme of transformation work is already underway to build on strengths of the NIHR Clinical Research Network and develop new services and functions to ensure the new RDN can respond to, and support, the needs of health and care research delivery, including for commercial companies. The RDN will work closely with research and innovation teams across the NHS in England, the life sciences industry, charities and other research funders and researchers to support their work in planning, placing and delivering studies within the health and care system. Recognising that sponsors, sites and research funders are responsible for the delivery of individual studies, the RDN will focus on portfolio monitoring, identifying and resolving strategic challenges for the research system in England. It will also ensure the system is able to achieve its ambitions around diversity in populations taking part in research, study methodology and the settings in which research takes place. The Department of Health and Social Care (DHSC) will ensure robust oversight of the RDN including accountability for

performance through a series of stretching, objective key performance indicators (KPIs) and rigorous financial governance.

This response has been developed by the cross-sector [UK Clinical Research Recovery Resilience and Growth Programme](#) in consultation with stakeholders from across the clinical research ecosystem including industry, medical research charities, academia, the NHS and patients and the public. Our plan is centred around the 5 overarching themes identified in the vision:

- **streamlined, efficient and innovative research**, so that the UK is seen as one of the best places in the world to conduct cutting-edge clinical research, driving innovation in healthcare
- **clinical research embedded in the NHS** so that research is increasingly seen as an essential part of healthcare to generate evidence about effective diagnosis, treatment and prevention
- **a sustainable and supported research workforce** to ensure that healthcare staff of all backgrounds and roles are given the right support to deliver clinical research as an essential part of care
- **research enabled by data and digital tools** to ensure the best use of resources, leveraging the strength of UK health data assets to allow for more high-quality research to be delivered
- **people-centred research** to make it easier for patients, service users and members of the public across the UK to access research and be involved in the design of research, and to have the opportunity to participate

Our plan also sets out new UK performance indicators which will be implemented with immediate effect. Underpinning the 5 themes, the performance indicators are designed to improve the speed and predictability of commercial research in the NHS while protecting our strong non-commercial sector. Our aim is for the UK to be known for fast review and set up of studies, high quality delivery and delivering ambitious levels of recruitment to industry studies. While delivering for industry, this also responds to the public's appetite to participate in research of relevance to them, as demonstrated by the high levels of participation in COVID-19 research, registration on the Be Part of Research registry and the recruitment of over 70,000 people into research studies every month over the last year.

Figure 2: monthly commercial recruitment and commercial collaborative recruitment

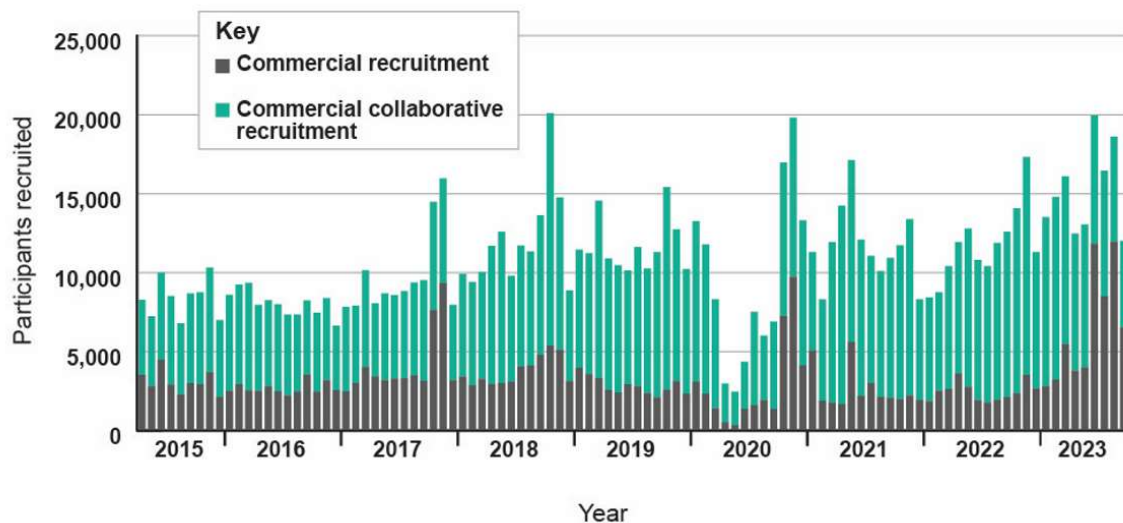


Figure 2 shows that in the last year recruitment to commercial and commercial collaborative studies in England has been steadily increasing.

## Governance

While many actions are already underway, in publishing this response we can fully move forward with the operational delivery and monitoring of the commitments we have made. Overall delivery of the plan sits with DHSC and the devolved administrations. However, this plan is system-wide and therefore there are many accountable partners who have responsibility for the performance and delivery of specific commitments including NHS England and other relevant arm's length bodies. For example, the MHRA and Health Research Authority (HRA) are accountable for performance against the 60-day approval turnaround key performance indicators and NHS trusts are contracted by commercial companies to successfully recruit to and deliver trials.

Reporting of the key performance metrics in this plan and co-ordination of delivery of the will be overseen through the UK Clinical Research Recovery Resilience and Growth (RRG) programme, organised by DHSC, with reporting to the Life Sciences Vision Delivery Board and Life Sciences Council (overseen jointly with the Department of Science, Innovation and Technology) and other groups with responsibility for health research such as the [Office for Strategic Coordination of Health Research](#) (OSCHR). The programme will monitor and drive progress towards the commitments in this plan, to ensure they are having the intended benefits on the delivery of commercial clinical research and across the whole clinical research ecosystem. Where components of the action plan are specifically linked to missions in the [Life Sciences Vision](#), then governance will follow existing reporting lines, in addition to the overarching oversight, managed through the Office for Life Sciences.

In addition to the monthly publication of updates on the UK performance indicators, we will publish quarterly progress updates on the commitments in this plan and regular communications to ensure stakeholders across the system are well informed about progress, impact and the ways in which the changes we are implementing will affect them.

# UK-wide approach

Health policy is a devolved responsibility, where each of the UK administrations has distinct ownership over their respective health systems. However, we are committed to delivering on a vision with a UK-wide reach and in pursuit of a common goal: to create a seamless and interoperable service across the UK to support clinical research delivery, shaping the future of healthcare and improving people's lives.

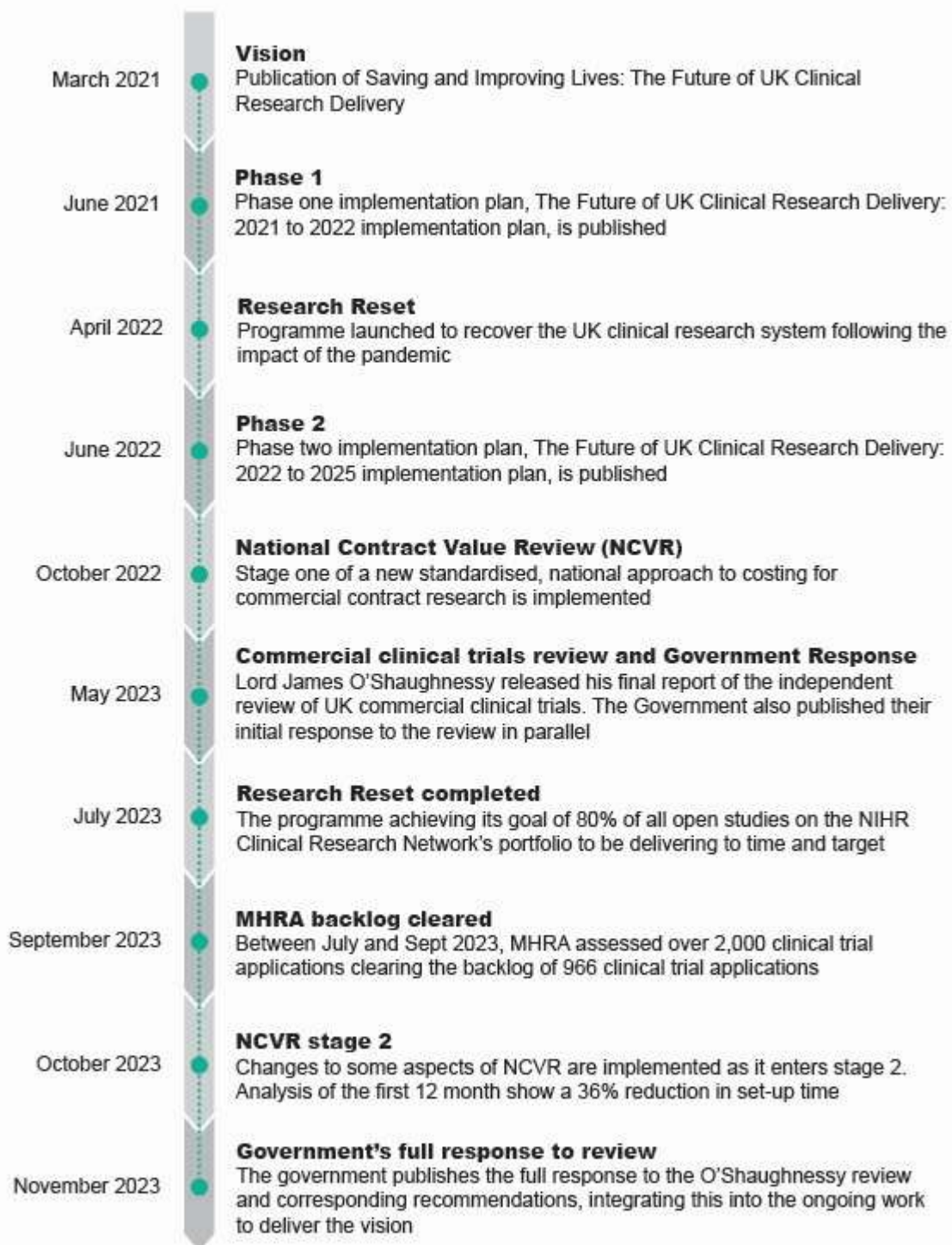
We are therefore further strengthening a joined-up system, where sponsors of both commercial and non-commercial research can easily deliver studies across the UK and people can participate easily. To ensure compatible and consistent ways of working across England, Scotland, Wales and Northern Ireland many commitments in this plan are focused on UK-wide implementation. Organisations such as [MHRA](#) and systems such as IRAS ([Integrated Research Application System](#)) have a UK-wide reach and their actions will have impacts across the country. In some instances, actions are being led by a specific organisation on behalf of the UK, while others will be delivered through UK partnerships - recognising the different legislative and delivery contexts across the UK government and devolved administrations.

## Scope

The needs of UK citizens and our health research system are broad and diverse. We are committed to maintaining a rich and balanced portfolio of early and late phase studies in rare and common diseases, ranging from complex, intensive studies in small, highly targeted populations to pragmatic population health research in large cohorts, using a range of methodologies and methods as appropriate to the research questions.

Our vision focuses specifically on the future of UK clinical research delivery. Other types of research, including social care and public health research, are vitally important to provide the evidence necessary to support policy making and service delivery in these areas. Many partners involved in delivering this clinical research plan also support a broader programme of research activity, and other work programmes are underway to enable their development. We expect that many of the improvements we make in the clinical research environment will have benefits for other kinds of research and will work across our organisations and with wider groups of stakeholders to ensure the lessons are shared.

Figure 3: timeline of activity from publication of the vision to this response





# 1. Progress since the initial response in May 2023

As an immediate first step towards the response to the O'Shaughnessy Review, the UK government made 5 headline commitments backed by up to £121 million, together with a foundational action to develop SMART objectives for all the ambitions in the clinical research vision, [Saving and Improving Lives: The Future of UK Clinical Research Delivery](#), (the vision). These headline commitments remain the core priorities in our overall response to improve the delivery of commercial clinical trials in the UK - ensuring more people across the UK can access new treatments being assessed in clinical trials more quickly.

We have made significant progress in the first 6 months of implementation and, in addition, completed work to recover clinical research performance to pre-pandemic levels, announced the launch of a new Research Delivery Network for England, and implemented a new MHRA notification scheme for clinical trial application approvals. We will continue to build on this, at pace, to increase the speed and predictability of commercial research further while ensuring the continued success of non-commercial research. In the section below, we update the progress and actions against the recommendations prioritised in the initial response.

## 1.1 Develop and publish SMART metrics for all the ambitions in the clinical research vision Saving and Improving Lives: The Future of UK Clinical Research Delivery

### Recommendation 1

#### Vision theme: cross-cutting

In the initial response, we committed that the UK Clinical Research Recovery, Resilience and Growth (RRG) programme would develop SMART objectives for all the themes in the vision and report these regularly to the Life Sciences Council. These are set out in detail in the full response and integrated with other recommendations, in section 2.1.

## 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 coordinated 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.

Figure 4: cumulative applications processed by week since July 2023

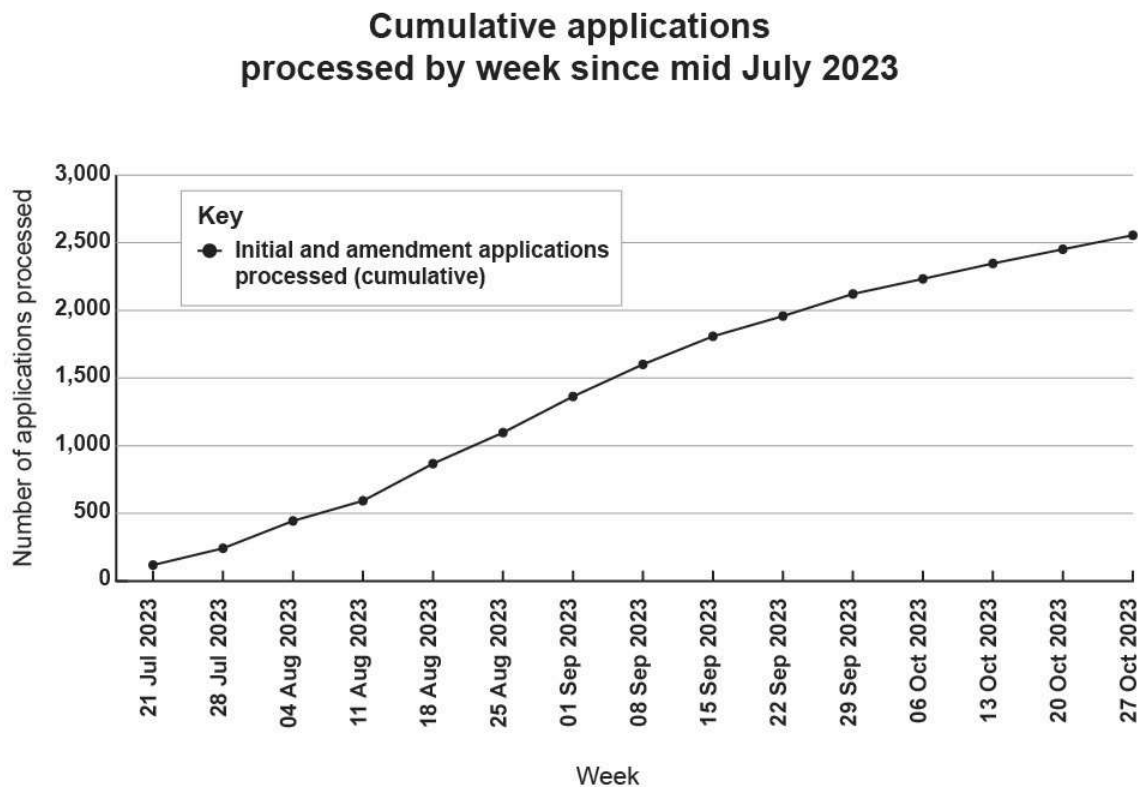


Figure 4 shows initial and amendment applications processed cumulatively increasing from near 0 on the week of 21 July 2023, to near 2,500 on the week of 27 October 2023.

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.

## 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.

## Return to pre-pandemic levels of performance and activity

The Research Reset programme was established in March 2022 to recover the UK's capacity to deliver clinical research due to the impact of the COVID-19 pandemic. While our response to the pandemic demonstrated the UK's ability to deliver high-quality, impactful studies at scale and speed, research in other areas was reduced as a result.

DHSC and NHS England led work across the UK system to achieve 80% of all open studies on the NIHR Clinical Research Network (CRN) portfolio delivering on time and to target by the end of June 2023. Industry studies recovered at an even better rate, with 83% delivering on time and to target by the end of June, and we are delivering higher levels of activity than we were prior to the pandemic, addressing concerns highlighted in the O'Shaughnessy Review about the drop in levels of UK clinical trials.

Significant learnings have been taken from Reset, including the introduction of a new approach to performance monitoring by NIHR and the introduction of new terms and conditions for NIHR CRN support. The expectations and requirements set out in the new terms and conditions enable the NIHR to effectively monitor and manage a national portfolio of health and care research across England on behalf of DHSC. They represent good portfolio management practice. In Scotland, NHS Research Scotland (NRS) is a partnership between Health Boards and the Scottish Government's Chief Scientist Office (CSO) investing in the infrastructure to promote and support high quality health research, monitoring and managing outcomes, including working in cooperation with partners across the UK. These approaches enable effective allocation of resources to ensure as many studies as possible can be delivered and provide evidence to improve care and outcomes for UK citizens. In Wales, through Health and Care Research Wales and its NHS partners, active monitoring of NHS R&D funding and study delivery is in place. In Northern Ireland, portfolio studies are delivered and monitored by the Northern Ireland Clinical Research Network, reporting to the HSC R&D Division.

Building on work to address open studies, we have turned our focus to studies in set-up, setting a new goal to have no studies on the NIHR CRN portfolio that are more than 90 days past their planned opening date by the end of 2023. This complements work to clear approvals backlogs.

We are also introducing new system wide UK Performance Indicators to ensure we maintain the performance achieved and go further in key priority areas.

## 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.

Figure 5: cumulative Be Part of Research registrations by month and method

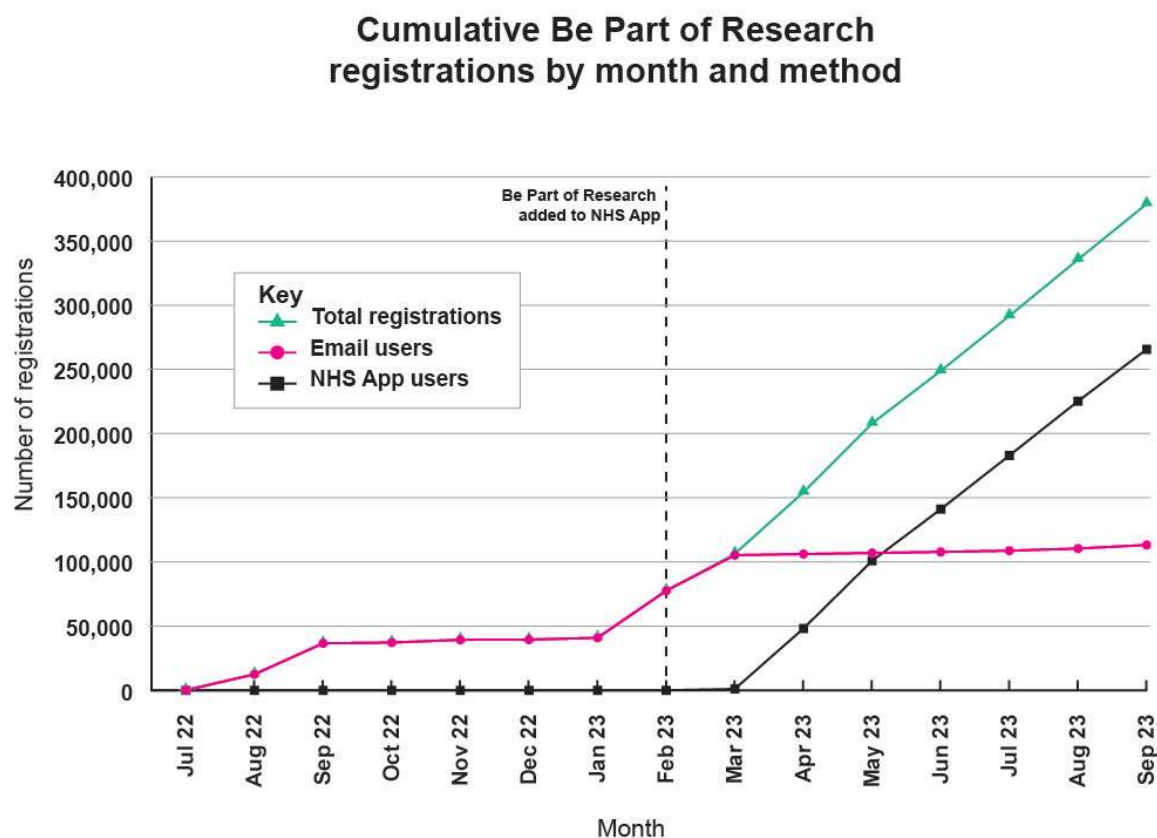


Figure 5 shows email users increasing from 0 in July 2022, to over 100,000 in September 2023. Be Part of Research was added to the NHS App in February 2023. NHS App users increased from 0 in March 2023, to over 250,000 in September 2023. Total registrations increased from 100,000 in March 2023, to over 350,000 by September 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.

## **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.

## 2. Our next steps

Over the next 2 years, we will continue to implement in full the 5 headline commitments announced in May 2023, make progress in tackling all the problem statements identified by Lord O'Shaughnessy, and continue work underway to improve the UK environment for all types of clinical research. We have reprioritised previously published implementation plans considering Lord O'Shaughnessy's recommendations and feedback from a broad range of stakeholders, and this plan supersedes and replaces them while not losing the ambition and vision set out in *Saving and Improving Lives: The Future of UK Clinical Research Delivery*. In the following section we set out SMART metrics in greater detail for all the ambitions set out in [Saving and Improving Lives: The Future of UK Clinical Research Delivery](#), addressing recommendation 1 of the O'Shaughnessy Review.

### 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.

Table 1: UK Performance Indicators: achieving globally competitive timelines

	UK Performance Indicator	Baseline	Measure	Time	Achieve or maintain
All	Proportion of studies receiving combined regulatory review achieved within 60 days, measured	Not applicable – new	99%	All new fully compliant initial applications	Maintain

	from IRAS submission to combined MHRA and REC regulatory decision			received from 1 September 2023	
C	Proportion of studies open to recruitment within 60 days of HRA approval letter or equivalent process used by the devolved administrations	Not applicable – new	90%	November 2024	Achieve
C	Proportion of studies recruiting first participant within 30 days of sites opening to recruitment, except where this is not expected in the study milestone plan (for example, rare diseases studies)	Not applicable - new	90%	November 2024	Achieve

Table 2: UK Performance Indicators: contracting and delivery

	UK Performance Indicator	Baseline	Measure	Time	Achieve or maintain
All	Proportion of open studies on track, delivering to time and target	79%	80%	Ongoing	Maintain
C	Proportion of NHS trusts in England who accept the local price generated as part of the NCVR process for late-phase studies without further negotiation following agreement of the resource required by the lead site	74% in July 2023	100%	December 2023	Achieve

Table 3: UK Performance Indicators: levels of recruitment

	UK performance indicator	Baseline	Measure	Time	Achieve or maintain
All	Recruitment to all studies is maintained	61,000 (note 1)	70,000 or more per month (note 2)	Ongoing	Maintain
C	Recruitment to all commercial studies to be monitored, with data on trial phase to be provided subsequent to implementation of digital infrastructure.	3,200 (note 1)	Reported per month	Ongoing	Achieve

Notes for tables 1 to 3:

'All' indicates a measure that applies to all studies

'C' indicates that it applies to commercial contract studies only

note 1: average per month in England only from 2015 to 2020

note 2: rolling average across the previous 12 months

Table 4: commercial contract study delivery timeline based on UK Performance Indicators

Indicator	60 days	60 days	30 days	Ongoing
Total time	60 days	120 days	150 days	Ongoing

From IRAS submission	To HRA approval letter or DA equivalent, confirming successful combined review	From HRA Approval letter or DA equivalent, to first site open to recruitment	First participant within 30 days of first site opening to recruitment	80% or more of studies on track
Achieved	September 2023	November 2024	November 2024	June 2023

**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.

## 2.2 Streamlined, efficient and innovative clinical research

### Recommendations 23, 24 and 25

In addition to progress achieved since our initial response in May 2023, and achievement of the UK performance indicators, we will continue to drive forward activity to streamline and speed up the delivery of innovative clinical studies.

- HRA will continue work to develop IRAS as a UK portal for research approvals and ongoing study oversight, streamlining approval processes, improving communication with digital interfaces and workflow tools.
- As set out in the government response to the public consultation on legislative proposals for clinical trials published in March 2023, with HRA the MHRA will develop and lead implementation of secondary legislation to improve and strengthen our clinical trials environment. These changes will help deliver the vision of a more proportionate, streamlined, flexible and effective clinical research environment, putting patients at the heart and the UK at the forefront of innovative regulation for clinical trials (subject to Parliamentary approval).
- Complementing approaches used by the devolved administrations, in April 2024 NHS England will publish research finance guidance to support NHS organisations to realise the financial benefits of undertaking commercial clinical trials and support capacity and capability building to increase commercial research activity.
- To address delays to set up that fall outside of costing and contracting processes, by March 2024, DHSC, devolved administrations, NHS England, HRA and NIHR will update guidance and implement processes to improve site and sponsor engagement prior to submission of regulatory applications and the progress of study set-up to meet UK Performance Indicators.
- Using the funding announced in the initial government response to the O’Shaughnessy Review, from April 2024 DHSC and HRA will expand the cohort of professionals across the UK providing pharmacy technical review and support uptake of these national reviews in local practice.

## **Artificial intelligence (AI)**

AI is being developed for use across many areas of the healthcare system but is at different stages of development in different areas.

MHRA and HRA will develop guidance and advise on AI in clinical trial design. The HRA will explore opportunities to make use of AI and related technologies as it develops its new version of IRAS.

## **2.3 Clinical research delivery embedded in the NHS**

### **Recommendations 9, 10, 11, 12, 14, 16, 17, 23 and 26**

Our aim is to create a step change in the delivery of clinical research in the NHS, so that research is increasingly seen as an essential part of healthcare, and research delivery is delivered in ways that maximise the use of established care pathways where possible and appropriate. This will improve our ability to deliver studies and help support implementation of proven approaches as standard of care.

## Delivering research in primary care

Research is effectively being delivered in primary care and there is strong potential for an increase in this research activity. Eighteen per cent of commercial recruitment in England in the 2022 to 2023 FY was from general practice (GP) sites, with a further 186 GP sites acting as participant identification centres. The potential of primary care to deliver commercial research has been recently demonstrated with the [HEART](#) and HARMONIE studies, as well as studies to support the development of vaccines for COVID-19.

Almost a quarter (21%) of all research participants in England in a combination of commercial and non-commercial studies this year (2022 to 2023) were recruited in primary care locations. However, only approximately 10% of the open studies on the NIHR portfolio are running in a primary care location. All studies should consider whether primary care is an appropriate location during the study design and funding process.

More than 90% of consultations and direct experience in health and care happens in primary care and GP sites. By offering more studies in primary care, we are widening the opportunity for patients and citizens to participate in health and care research and improving access for our underserved communities, increasing diversity in studies. Eleven per cent of the commercial recruitment in England in the 2022 to 2023 FY was from the primary care speciality. To address the needs of the population, research needs to take place in the primary care setting, delivered by healthcare professionals across the primary care speciality.

The new Research Delivery Network will continue to develop capacity and capability for research in primary care. In addition, the clinical trials delivery accelerators in dementia and vaccines will support delivery of research in primary care, the community (such as pharmacies) and at home.

- The General Medical Council (GMC) have published an updated version of [Good medical practice](#), the professional standards for all doctors in the UK, which comes into effect on 30 January 2024. The standards have a stronger focus on supporting the delivery of research by all doctors including an expectation that doctors should tell patients about opportunities for them to participate in appropriate research.
- As detailed earlier, the contract for the new NIHR Research Delivery Network (RDN) will begin in 2024. Building on the strengths of the NIHR Clinical Research Network and the progress made through Research Reset, the RDN will support the successful delivery of high-quality research, as an active partner in the research system and work strategically to increase the capacity and capability of the research delivery infrastructure for the future.
- The NIHR CRN has begun work to transition to new ways of operating in the RDN and will fully implement the new approach to performance monitoring initiated through Research Reset by March 2024. It will also work with partners to develop an improved national process for faster industry site selection, which promotes the delivery of research in suitable sites across the whole of England. Details of the new approach will be published by March 2024, with full implementation of changes in place by October 2024.
- DHSC is currently reviewing the NIHR patient recruitment centres (PRCs), which provide dedicated staff and facilities for commercial research, using stakeholder feedback and key performance indicators to evaluate achievements of the scheme so far. Based on these findings, we will explore an enhanced scheme which builds on

the successes of the pilot scheme launched in 2020 and applies lessons from this further iteration to provide an even better service for industry. We will complete this review and publish an update on our approach by March 2024.

- As part of the new PRC scheme, DHSC is planning to establish PRCs in primary care and community settings, as well as expanding centres in NHS trusts, to create additional capacity and grow expertise to deliver commercial trials, as these are already identified as areas for further investment. We will launch the new competition in 2024.
- DHSC and the devolved administrations will work with the Community Healthcare Alliance of Research Trusts (CHART), UK Research and Development (UKRD), the NHS R&D Forum, NHS England, ICBs and devolved equivalents to identify opportunities to make it easier for GPs and other primary and community care services to deliver research.
- The Association of Medical Research Charities (AMRC), DHSC and NIHR are working together to explore opportunities to promote the benefits of clinical research to people working in the health and care system, patients and service users and the general public. Further details will be published by March 2024.
- Wales are working with their NHS independent board members research champions from each of the NHS organisation, their national CEO R&D champion, and R&D directors, as part of the implementation of the NHS R&D framework published in July 2023 to embed and integrate research into the NHS, raise its profile and tackle system wide issues.

## **2.4 A sustainable and supported research delivery workforce**

### **Recommendations 13, 14, and 22**

The UK clinical research delivery workforce is critical to the achievement of our vision. Healthcare and research staff of all backgrounds must be offered rewarding, challenging and exciting careers within clinical research, so that the most talented people can be brought into clinical research - including research delivery and R&D management - as a life-long career. This will help to bolster the capacity of the clinical research system and support a motivated and sustainable workforce.

- NHS England's Long Term Workforce Plan, published in June 2023, recognises the importance of research and the current contribution of clinical academics, as well as in training the future healthcare workforce. NHS England has committed to work with partners to explore how best to address the issues raised around research workforce careers.
- DHSC will develop and publish a workforce plan in support of the vision for clinical research delivery during 2024. This will set out workforce needs to be addressed in order to deliver the 10-year vision in full by 2031, and highlight actions needed in the medium term (from 2025 onwards) to progress this.
- Welsh Government will publish a nurses and allied health professionals (AHPs) research action plan in 2024 where workforce will be a key pillar.



- In Northern Ireland, the AHP Research and Innovation Strategy 2023 aims to build research capacity in the AHP workforce.
- NHS England will publish a multi-professional practice-based research capability framework for the healthcare professions by spring 2024. The framework elaborates incremental research capability development across 4 levels of practice (entry, enhanced, advanced and consultant) for the professions other than medicine and dentistry. It is intended to promote and encourage involvement in and with research as an integral component of practice for all health and care professionals, regardless of the setting in which they work. Application of the framework by individual practitioners, service and department managers, service providers and education and training providers will facilitate tangible improvements in practice-based research capabilities among the health professions and make a significant contribution to embedding research delivery across the NHS.
- In England, the NIHR is expanding its Development and Skills Enhancement Award in both the scope and the number of awards to be funded in future. This award is now open to anyone looking to develop their career in research who has been awarded a PhD, whereas previously it had just been open to existing NIHR Academy Members with a sole focus on supporting the development of careers leading research. This expansion will mean the award is open to a much wider range of people and will help support career development across a broader range of research careers including research delivery careers. In addition, the Development and Skills Enhancement Award has a particular highlight around supporting the career development of individuals looking to lead and conduct clinical trials. The NIHR is also investing an additional £30 million a year to boost research careers for health and care professionals. This funding is supporting training and career development opportunities across all career stages, from internship schemes aimed at sparking an interest for research in people early in their clinical careers, to more senior awards aimed at better embedding research within NHS and care settings. As part of this investment the focus is expanding from solely clinical academic careers to the whole range of careers in research, including within research and clinical trial delivery.
- NIHR will establish a 'commercial trial exemplar site' scheme in 2024, recognising excellence in the delivery of commercial research. This will enable sites to demonstrate their suitability for placement of commercial research and provide industry with a mechanism to differentiate between sites for placement of studies. The scheme will be designed to incentivise excellence in delivery including in areas that enhance UK attractiveness for the placement of global research.
- DHSC and the health departments in other parts of the UK will continue to provide funding for NHS support costs via the NIHR Clinical Research Network and equivalent mechanisms across the UK. From October 2024, the NIHR Research Delivery Network will implement a new approach to funding which increases the flexibility with which NHS support costs funded by DHSC can be used for the delivery of research in the NHS while still operating in line with guidance on appropriate cost attribution. This will support NHS sites' ability to expand the range of skilled staff available to support research delivery and enable them to deliver research in innovative ways. The new approach will also increase sites' accountability for adherence to national policies and procedures designed to improve the delivery of the national portfolio of studies and increase UK attractiveness for placement of global studies.

## 2.5 Research delivery enabled by data and digital tools

### Recommendations 6, 15, 17, 19, 21 and 25

Investing in data and digital tools and making ethical use of them increases the efficiency and effectiveness of the clinical research process. These tools also improve our ability to widen access to research opportunities, increase the resilience and sustainability of the healthcare system, and reduce the burden on the NHS workforce.

Minimum viable products have been developed in a range of areas, in some cases establishing data-enabled research delivery for studies in real time for the first time. We will continue to build on these services. We will continue work to refine the use cases for each service ensuring we minimise duplication and enable researchers to access the services of greatest relevance to them. This will enable us to set out the case for the implementation of such approaches at the scale necessary to impact on a large proportion of the research portfolio in the future.

### Developing our find, recruit, and follow-up service

Since publication of our vision in 2021, we have developed minimum viable products to deliver secure data enabled study feasibility, recruitment, and follow-up within established governance and legal requirements across England and other parts of the UK.

The following minimum viable products have been developed to provide feasibility and data-enabled recruitment:

- NHS England's DigiTrials self-service feasibility tool supports researchers in determining suitable locations for their studies by establishing where the largest groupings of eligible people are based. Using this tool, feasibility queries can be run securely on England-wide patient data in a matter of minutes. Outputs of anonymised counts of data can be split flexibly to support a range of query types, for example by acute trust, deprivation deciles or GP practice. Similarly, in Wales, the feasibility data tool, hosted via the SAIL (Secure Anonymised Information Linkage) Databank, provides anonymised primary and secondary care data, available for Health and Care Research Wales Delivery team to provide insight on potential participant populations alongside site capabilities in discussions with sponsors as part of the 'One Wales' model
- [NHS England's DigiTrials recruitment service](#) also enables the NHS to more easily approach patients about research of relevance to them. A second phase of pilots is underway following the success of the first phase where 18 million people were given the opportunity to join research with over 750,000 people successfully consented into research studies. DigiTrials-type capabilities are also planned to be implemented in Wales, with a focus on opportunities for partnership to deliver studies across both services
- [MHRA's Clinical Research Practice Datalink \(CPRD\)](#) enables participating GPs to more easily identify potentially eligible patients in order to invite them to participate.
- [Be Part of Research](#) is a registry which enables people to proactively register their interest in participating in research. Over 370,000 people to have registered have joined the volunteer service to be invited to participate in specific studies of relevance to them

- As laid out in the [Data saves lives](#) strategy, to make research ready data more accessible and linkable for research purposes through access rather than sharing, the NHS England Data for R&D Programme is establishing the NHS Research Secure Data Environment (SDE) network. This interoperable network includes the NHS England Secure Data Environment, and a small number of regionally based SDEs that collectively cover all of England. By April 2025, the NHS SDE network will support over 500 users, and 450 research projects through privacy-protecting accelerated access to multimodal data, including genomics and over 45 million primary care records. This work includes collaborating with the HRA on streamlined research governance approvals for secure data environments. The network will support a range of research use-cases, including the feasibility, recruitment, and follow-up for clinical trials.
- In Scotland, data enabled delivery of research studies in Scottish health boards is supported locally by NHS Research Scotland Data Safe Havens (trusted research environments (TREs)) and across Scotland by the Scottish Health Research Register and Biobank (SHARE). SHARE is an expanding register of individuals that have agreed to medical record searching in order to match them to studies. A feasibility service and tool are also available to assess the numbers and geographic location of those registered to SHARE that match study criteria to support the design of studies. The government's [Health and social care: data strategy](#) sets out Scottish aims to support the greater use of data to support research and innovation, including through the Data Safe Havens.
- In Wales, the SAIL Databank will continue to offer and expand the most well categorised, anonymised person-level data across health and wider public sector datasets for research purposes, enabling exploration of the widest possible determinants of health.
- The proposals will be implemented through the Northern Ireland [Health and social care \(HSC\) data strategy 2022 to 2030](#). Building on existing achievements, the Northern Ireland trusted research environment (NITRE) and HSC Data Institute will widen participation in clinical trials by both clinicians and patients. This is particularly timely as NI implements a new electronic health care record in the encompass programme, which will bring together both health and social care records in a searchable format that should greatly facilitate recruitment to clinical trials and patient follow up.
- As detailed earlier, we will continue to develop Be Part of Research to enhance support for the public, patients and clinicians to find out about and access health and social care research taking place across the UK, including commercial trials. This includes a goal of 1 million people registering on Be Part of Research by March 2025 and continued development of services to support recruitment into specific studies for people who have volunteered for this part of the service.
- Subject to successful discovery work to leverage other registries to support Be Part of Research, by April 2025 local, regional and charity research volunteer registries will have the opportunity to link to Be Part of Research to form a national networked database of interested volunteers in research.
- Publicly funded NHS data providers across the UK administrations will work together to consider how activity can be expanded to include SAIL and SHARE, 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.

## Genomic sequencing

All patients receiving genomic sequencing of any kind in the UK should be offered a standard consent for engaging in research.

In 2018, NHS England established the NHS Genomic Medicine Service (NHS GMS) to support standardised, high quality and equitable access to genomic medicine across the NHS in England. This will enable the NHS to harness the power of genomic technology and science to improve the health of our population and be the first national health care system to offer whole genome sequencing as part of routine care.

A full range of genomic testing, including whole genome sequencing and non-whole genome sequencing tests, are delivered in a standardised way by a national network of 7 NHS genomic laboratory hubs (GLHs) which are commissioned by NHS England. The NHS GLHs are able to use cutting edge high throughput next generation sequencing technology which enables scientific progress in diagnostic discovery, translational research and the development of new precision treatments.

The service is actively supporting the delivery of clinical research studies in multiple different ways. Patients undergoing whole genome sequencing in the NHS GMS are currently offered the choice to participate in research and have their de-identified genomic data stored in the National Genomic Research Library, managed by Genomics England. When data was last reported, 90% of the patients who discussed participating in research gave their consent. A key consideration of the genomics data and digital framework is ensuring that a technical solution is developed for enabling a standardised approach to research and clinical consent for all patients receiving genomic testing, through enabling the collection, active management by patients, and appropriate access to standardised de-identified consented genomic data for both research and clinical purposes.

The [Accelerating genomic medicine in the NHS](#) strategy, published in October 2022, also includes key commitments with regards to research, including commitments to drive equity in access to clinical trials by aligning clinical trial targets with standard of care NHS testing to enable patients to access genomically informed clinical trials. This will require putting in place a mechanism to systematically horizon scan upcoming clinical trials to ensure the correct targets are added to the National Genomic Test Directory, while also having the data sharing infrastructure in place to share genomic data safely where appropriate and with the necessary patient consent.

DHSC is supportive of the ambition to expand the approach described above to non whole genome sequencing with work already ongoing in NHSE in conjunction with partners such as Genomics England to explore this as part of the genomics data and digital framework recognising that there are multiple elements to achieving this inclusive of changes to standard of care where implications and options for delivery need to be established. Wales is currently undertaking a genomics research review of the landscape and future opportunities, which will report end of 2023. This will shape the next steps to our offer, including how our genomic infrastructure can support research delivery.

Scotland will publish its first genomic medicine strategy in 2023, following on from a [strategic intent document](#) published earlier in the year. The initial 12-month implementation plan will focus on mapping how genomic services are currently delivered across Scotland and where

there are opportunities to integrate genomic data with other sources of Scottish health and care data to support research activity.

## 2.6 People-centred research delivery

### Recommendations 14, 18, 24 and 26

HRA published the [principles and 'hallmarks' of good people-centred research](#) on 30 October 2023 alongside resources to help share them. Their work also identifies 3 important drivers for people to take part in clinical research and a report sets out the barriers and enablers that will hinder or help the system take action to improve research in people-centred ways. Decentralised trials, with a focus on settings outside of secondary care, will enable people-centred research to be delivered.

- HRA have undertaken engagement with people across the research community including patients and the public to develop, refine and promote the hallmarks as a first step to bringing a change practice. They will publish further guidance for researchers and will work with partners across the system to identify the most impactful actions which can be taken to drive initial progress over the next 2 years. We will publish an update on our plans by March 2024.
- Clinical trial delivery accelerators will play a key role in driving forward the implementation of people-centred research delivery, ensuring the studies they support bear hallmarks of good practice and sharing the approaches and tools used to achieve this in ways that enable their effective spread across the wider research system.
- In the 2024 to 2025 FY, recognising the need for embedded, multi-organisational approaches to engagement around research, NHS England and DHSC will continue to support the ICS Research Engagement Network (REN) development programme. The REN programme develops local approaches to better enable engagement with underserved communities around research and increase opportunities and access to take part in research. By targeting strategic changes to support more diverse representation of different communities in research we will improve the potential impact and value of research for our population.

## Annex A: summary of recommendations and response status

	Recommendation	Status
1	Develop and publish SMART (specific, measurable, achievable, relevant and time-bound) metrics for all the ambitions in the clinical research vision Saving and Improving Lives: The Future of UK Clinical Research Delivery, and subsequent implementation plans, with owners held to account for delivery by the Life Sciences Council.	<p>Initial response and update provided in sections 1.1 and 2.1.</p> <p>SMART metrics agreed with specific milestones and timelines within each theme in section 2.</p> <p>Implementation will be led by the UK Clinical Research Recovery Resilience and Growth programme, reporting to the Life Sciences Council and other oversight bodies responsible for UK health research.</p>
2	The MHRA and HRA and other system leaders should set up a rapid 'task and finish' group to produce a plan on reducing the regulatory burden of approving trials and removing delays in set up, including with the goal of reaching a 60-day turnaround time for all approvals.	<p>Initial response and update provided in section 1.2.</p> <p>60-day turnaround time achieved by September 2023.</p> <p>MHRA and HRA task and finish group established. Reporting January 2024 to scope delivery of accelerated times.</p>
3	On receipt of this plan, additional funding should be provided by the UK government to the regulators, the MHRA and the HRA, to rebuild capacity and deliver reduced turnaround time for all approvals.	<p>Initial response and update provided in section 1.2.</p> <p>£10 million additional funding to MHRA in the March 2023 budget to bring new medicines to UK patients more quickly.</p> <p>An additional £3 million for HRA and MHRA to rebuild capacity and deliver reduced turnaround times.</p>
4	A comprehensive and mandatory national approach to costing and contracting should be developed and instigated, in partnership with industry.	<p>Initial response and update provided in section 1.3.</p> <p>Achieved for late phase commercial studies taking place in NHS trusts.</p> <p>Performance indicator of 100% adherence by sites in England by the end of 2023, building on existing 'no negotiation' approach in other parts of the UK.</p> <p>Work in progress to expand the approach to early phase and advanced therapeutic medicinal products (ATMPs) studies (first pilots will begin before December 2023).</p>

5	<p>The MHRA, 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.</p>	<p>Initial response and update provided in sections 1.4 and 2.1.</p> <p>Available data published nationally on a monthly basis.</p> <p>MHRA monthly performance data now published.</p> <p>HRA performance data published through the key performance indicators.</p> <p>NIHR monthly clinical trials data now published.</p>
6	<p>Building on near real-time activity and performance generated according to the above recommendation, UK governments should create a UK phase 1 to 4 clinical trial directory - called 'clinicaltrials.gov.uk' - to create a single source of activity for patients, clinicians, researchers and potential trial sponsors.</p>	<p>See the full response in sections 1.4 and 2.5.</p> <p>Be Part of Research already provides a single directory of clinical research studies. It provides an open access, searchable website and the option to register to volunteer to be contacted about research of relevance to you.</p> <p>Through Research Reset we have been publishing system performance measures, have developed a dashboard bringing in more system metrics and plan to make that publicly available, before moving onto the issues around tracking individual studies through the system and on 'databases' of clinical trials.</p>
7	<p>DHSC, DSIT and the NHS should set stretching annual targets for increasing commercial trials in the 4 parts 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.</p>	<p>See the full response in section 2.1.</p> <p>Industry colleagues have supported an ambition to increase recruitment to commercial clinical trials (both commercial contract and commercial collaborative models), but in the context of ensuring sustainable performance, other metrics such as study completion and choice of trials will be driven by scientific need and patient benefit.</p> <p>Within these parameters, we will continue to aim for doubling by 2025, and further doubling by 2027, monitoring to ensure that the other principles above remain extant and this does not drive perverse behaviours</p>

8	<p>A new UK-wide set of KPIs for clinical trials should be established covering all critical aspects of the approval and set-up 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 and be benchmarked against global exemplars.</p>	<p>See the full response in sections 1.4 and 2.1.</p> <p>We will address this recommendation as the new system for capturing real-time performance data is developed. The new system will be in place from the 2025 to 2026 FY.</p> <p>In the interim, using currently available data, new UK performance indicators will be implemented immediately.</p>
9	<p>In England, a new operating model for the NIHR CRN should be introduced to strengthen accountability and delivery.</p>	<p>See the full response in sections 1.7 and 2.3.</p> <p>The new Research Delivery Network will replace the CRN from 2024.</p> <p>Work has begun to transition to the new services over the next 6 to 12 months. We will monitor the impact of the new RDN to ensure the proposed changes are implemented effectively.</p>
10	<p>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&amp;D, and annual R&amp;D targets should be introduced for the NHS at every level.</p>	<p>See the full response in section 2.3.</p> <p>The publication of the report, backed by NHS England leadership and UK health ministers, reflects our commitment to the NHS as a platform for R&amp;D.</p> <p>New UK performance indicators will be implemented immediately.</p> <p>NHS England will develop a set of metrics which help ICBs and NHS providers understand their research performance and publish these by the end of financial year 2024 to 2025.</p>
11	<p>The business development service in NIHR and its equivalent bodies should be set explicit performance targets to increase the number, kind and diversity of commercial trials.</p>	<p>See the full response in section 2.3.</p> <p>Business development and industry engagement services in NIHR, the DAs and across government will seek to promote the strength and depth of the whole UK research system.</p> <p>Decisions regarding study placement sit with research sponsors and the sites they contract with. Widening access to research and increasing the diversity of studies conducted in the UK are important priorities in this document and our 10-year vision.</p>



12	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.	<p>See the full response in section 2.3.</p> <p>In April 2024, NHS England will publish research finance guidance for NHS organisations to realise the financial benefits of undertaking commercial clinical trials and support capacity and capability building to increase commercial research activity.</p> <p>Research in the NHS is conducted on a full cost recovery basis. Income generated through the delivery of commercial contract studies covers the costs of undertaking the activities required and provides additional income to build the capacity and capability for further research in the NHS.</p>
13	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.	<p>See the full response in section 2.4.</p> <p>The NHS Long Term Workforce Plan published in June 2023, commits to work with partners to explore how best to address the issues raised around research workforce careers.</p> <p>NIHR will establish a 'commercial trial exemplar site' scheme in 2024 recognising excellence in the delivery of commercial research.</p> <p>DHSC will develop and publish a workforce plan in support of the vision for clinical research delivery during 2024.</p>
14	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.	<p>See the full response in sections 2.3 and 2.4.</p> <p>AMRC, DHSC and NIHR are exploring opportunities to promote the benefits of clinical research to people working in the health and care system, patients and service users and the general public.</p> <p>Further details will be published by March 2024.</p>
15	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.	<p>See the full response in sections 1.4 and 2.5.</p> <p>There is a link on the NHS App to the NIHR Be Part of Research registration page that uses the NHS Login to pre-</p>

		<p>populate some of the registration information.</p> <p>Over 370,000 people have registered so far and we have set a goal of 1 million people registering on Be Part of Research by March 2025.</p> <p>NHS England is considering the most appropriate ways to build on the success of linking the NHS App to Be Part of Research.</p>
16	The government and the NHS should work with royal colleges and unions to integrate 'research conversations' into all NHS communications and clinical interactions.	<p>See the full response in section 2.3.</p> <p>The GMC have published an updated version of Good Medical Practice, the professional standards for all doctors in the UK, which comes into effect on 30 January 2024.</p> <p>NIHR will continue to work with royal colleges and unions to promote the delivery of research as a part of care across all professions.</p>
17	Specific targets should be introduced for the new Research Delivery Network (RDN) co-ordinating centre and regional centres to expand research to multiple sites, and to increase diversity of patients recruited.	<p>See the full response in sections 1.6, 2.3 and 2.5.</p> <p>The new RDN contract begins in October 2024.</p> <p>New KPIs will be implemented as part of the RDN's contract with DHSC to ensure the new organisation provides an improved service for its customers. This complements and supports research sponsors, funders and sites in delivering on their responsibilities to ensure individual studies are designed in the most appropriate ways to increase diversity of patients recruited.</p>
18	Agencies responsible for information governance within clinical trials should establish a common approach to contacting patients to take part in research within the current legislative framework.	<p>See the full response in sections 1.4, 1.5 and 2.6.</p> <p>The HRA have 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.</p> <p>HRA will report on its outcomes by the end of 2023.</p>

19	All patients receiving genomic sequencing of any kind in the UK should be offered a standard consent for engaging in research.	<p>See the full response in section 2.5.</p> <p>The NHS Genomic Medicine Service (GMS) is actively supporting the delivery of clinical research studies in multiple different ways. Patients undergoing whole genome sequencing in the NHS GMS are currently offered the choice to participate in research and have their de-identified genomic data stored in the National Genomic Research Library, managed by Genomics England. When data was last reported, 90% of the patients who discussed participating in research gave their consent.</p> <p>DHSC is supportive of the ambition to expand the approach described above to non-whole genome sequencing with work already ongoing in NHSE in conjunction with partners such as Genomics England to explore this as part of the genomics data and digital framework recognising that there are multiple elements to achieving this inclusive of changes to standard of care where implications and options for delivery need to be established.</p>
20	A national participatory process should take place on patient consent to examine how to achieve greater data usage for research 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 trials that could form part of their care.	<p>See the full response in section 1.5.</p> <p>Our approach to this will be informed by the outcomes of the HRA's work to consider a common approach to contacting patients to take part in research (recommendation 18).</p> <p>HRA will report on its outcomes by the end of 2023.</p>
21	The NHS England Data for R&D Programme's NHS Research Secure Data Environment (SDE) network should be rolled out, including urgent publication of guidance for NHS bodies on engaging in research with industry.	<p>See the full response in section 2.5.</p> <p>The Data for R&amp;D Programme is establishing the NHS Research SDE network. The network will support a range of research use cases, including the feasibility, recruitment, and follow-up for clinical trials.</p>
22	Financial incentives should be introduced for GPs to take part in commercial trials.	<p>See the full response in sections 1.7 and 2.4.</p> <p>In April 2024, NHS England will publish research finance guidance to support NHS organisations to realise the financial benefits of undertaking</p>

		<p>commercial clinical trials and support capacity and capability building to increase commercial research activity.</p> <p>Research in the NHS is conducted on a full cost recovery basis. Income generated through the delivery of commercial contract studies covers the costs of undertaking the activities required and provides additional income to build the capacity and capability for further research in the NHS.</p>
23	<p>New primary care research networks should be introduced to increase the proportion of commercial trials taking place in primary care and 'at home' settings.</p>	<p>See the full response in section 2.3.</p> <p>The new RDN will be established in 2024 and will continue to develop capacity and capability for research in primary care, in the community and in virtual studies.</p> <p>The new clinical trial delivery accelerators will promote ways of delivering clinical trials outside of hospital, in primary and community care for example, to improve accessibility for participants.</p>
24	<p>Regulators should produce guidance to support and promote innovative and decentralised trials.</p>	<p>See the full response in sections 1.6, 2.2 and 2.6.</p> <p>MHRA and HRA will support the design and delivery of innovative and decentralised trials through established guidance and advisory services.</p> <p>The dementia clinical trial delivery accelerator, in place from April 2024, will put these approaches into practice and provide the evidence and further guidance to enable their adoption across the system for a broad range of studies.</p>
25	<p>The government and regulators should develop a strategy for the use of AI in clinical trial design and regulation.</p>	<p>See the full response in sections 2.2 and 2.5.</p> <p>MHRA and HRA will develop guidance and advise on AI in clinical trial design.</p> <p>The HRA will explore opportunities to make use of AI and related technologies as it develops its new version of the Integrated Research Application System (IRAS).</p>

26	<p>A new 'enhanced service' option should be developed, through the proposed clinical trial acceleration networks (CTANs) to enable government and the NHS to develop an excellent process for every step of a trial for specific areas, both to further research in the selected fields and to prove the case and create an exemplar for improving the service for all trials in the future.</p>	<p>See the full response in sections 1.6, 2.3 and 2.6.</p> <p>The response takes forward the CTAN concept under a new name clinical trial delivery accelerators.</p> <p>We acknowledge that the vaccines innovation pathway (VIP) is already an accelerator and announce that a new accelerator in dementia is being implemented and will be operational from April 2024.</p>
27	<p>An action plan should be developed, to report by autumn 2023, outlining how the government and delivery partners will implement the recommendations of this review. The Life Sciences Council should provide objective accountability for the delivery of this action plan by the government and its agencies.</p>	<p>This full response is the plan that delivers on the recommendation. The UK Clinical Research Recovery, Resilience and Growth (RRG) Programme will lead implementation and report on their progress to the Life Sciences Council and other oversight bodies responsible for UK health research.</p>

## Annex B: implementation timeline

Response section	Commitment	Lead	Implementation timing
Costing and contracting	Enhanced NCVR approach introduced	NHSE	From October 2023
60-day turnaround time for all approvals maintained	MHRA launched new notification scheme	MHRA	From October 2023
UK Performance Indicators	Introduce new UK Performance Indicators with immediate effect	DHSC, DAs	By November 2023
UK Performance Indicators	Publish progress updates on a monthly basis	DHSC, DAs	From November 2023
Costing and contracting	Monitor both NHS and industry adherence to the single national review and standard contracts	NHSE	By December 2023 and ongoing
Costing and contracting	Achieve a national performance indicator of 100% of sites in England accepting the local price generated as part of the NCVR process without further negotiation, for late-phase studies and following agreement by the lead site of the resource required	NHSE	By December 2023
Costing and contracting	Enhanced NCVR approach starting to be piloted in early phase and ATMP studies	NHSE	By December 2023
Provide 'real-time' data on commercial clinical activity in the UK	New sponsor engagement tool implemented by NIHR	NIHR	By December 2023
Return to pre-pandemic levels of performance and activity	No studies on the NIHR CRN portfolio that are more than 90 days past their planned opening date	NIHR	By end of 2023
Establish a common approach to contacting patients about research	We will publish details of further actions based on the recommendations to support data enabled delivery of research April 2024	DHSC, DAs	By end of 2023
60-day turnaround time for all approvals maintained	MHRA and HRA clinical trials public consultation task and finish group starts and reports	MHRA, HRA	By January 2024
Clinical research delivery embedded in the NHS	Updated GMC Good medical practice guidance comes into force in January 2024	GMC	By January 2024
Establish clinical trial delivery accelerator	Appoint clinical trial delivery accelerator host organisation	DHSC, DAs	By February 2024

Provide 'real-time' data on commercial clinical activity in the UK	Discovery work completed in full, providing essential foundations for effective implementation	NIHR	By March 2024
Streamlined, efficient and innovative clinical research	DHSC, the DAs, NHSE, HRA and NIHR will publish guidance and implement processes to improve site and sponsor engagement	DHSC, DAs	By March 2024
Streamlined, efficient and innovative clinical research	NIHR CRN new approach to performance monitoring fully implemented	NIHR	By March 2024
Clinical research delivery embedded in the NHS	NIHR CRN fully implements the new approach to performance monitoring initiated through Research Reset	NIHR	By March 2024
Clinical research delivery embedded in the NHS	AMRC, DHSC and NIHR will publish by March 2024 a plan to work together to promote the benefits of clinical research to people working in the health and care system, patients and service users and the general public	AMRC, DHSC, NIHR, DAs	By March 2024
People-centred research delivery	HRA, DHSC, NHSE and DAs will identify actions to be taken as a result of the HRA 'hallmarks' of people centred research report	HRA, DHSC, NHSE and DAs	By March 2024
Provide 'real-time' data on commercial clinical activity in the UK	Publish implementation plan for delivery in FY 2025 to 2026, subject to business case	NIHR	By April 2024
Establish a common approach to contacting patients about research	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 April 2024	HRA	By April 2024
Streamlined, efficient and innovative clinical research	In April 2024 NHS England will publish research finance guidance	NHSE	In April 2024
Streamlined, efficient and innovative clinical research	From April 2024 DHSC and HRA, on behalf of the devolved administrations, will expand the cohort of professionals across the UK providing pharmacy technical review and support uptake of these national reviews in local practice	DHSC, HRA	From April 2024
A sustainable and supported	NHSE will publish a multi professional practice-based research capability	NHSE	By spring 2024

research delivery workforce	framework for the healthcare professionals		
Clinical research delivery embedded in the NHS	NIHR develops and implements an improved national process for faster industry site selection, details will be published by March 2024 and full implementation of changes in place by October 2024	NIHR	By October 2024
A sustainable and supported research delivery workforce	DHSC and the devolved administrations will continue to provide funding for NHS support costs via the NIHR CRN	DHSC, DAs	From October 2024
Clinical research delivery embedded in the NHS	Contract for the new NIHR Research Delivery Network begins	NIHR	In 2024
A sustainable and supported research delivery workforce	DHSC will develop and publish a workforce plan in support of The Future for UK Clinical Research Delivery	DHSC	During 2024
UK Performance Indicators	NHS England will develop a set of metrics which help ICBs and NHS providers understand their research performance	NHSE	End of FY 2024 to 2025
Research delivery enabled by data and digital tools	1 million people have registered on Be Part of Research by March 2025	NIHR, NHSE	By March 2025
People-centred research delivery	In FY 2024 to 2025 NHSE and DHSC will continue to support the ICS REN development programme	NHSE, DHSC	In FY 2024 to 2025
Research delivery enabled by data and digital tools	By April 2025 the NHS Research SDE network will support over 500 users, and 450 research projects through privacy-protecting accelerated access to multimodal data, including genomics, and over 45 million primary care records	NHSE	By April 2025
Research delivery enabled by data and digital tools	Subject to successful discovery work by April 2025 local, regional and charity research volunteer registries will have the opportunity to link to Be Part of Research to form a national networked database of interested volunteers in research	NHSE, NIHR	By April 2025, subject to successful discovery work
Research delivery enabled by data and digital tools	Continue to refine use cases and set out the case for implementation of data enabled approaches at scale in future	DHSC, DAs, NHSE, NIHR	Ongoing, to enable post-2025 response