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The Future of UK Clinical Research Delivery: 2021 to 2022 Implementation Plan

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Ministerial foreword

Earlier this year we, the UK government and devolved administrations, set out our bold and ambitious vision for the future of clinical research delivery. As we continue to emerge from the shadow of the pandemic, [‘Saving and Improving Lives: The Future of UK Clinical Research Delivery’](#) lays out our ambition to create a world-leading UK clinical research environment which is more efficient, more effective and more resilient, with research delivery embedded across the NHS.

By delivering on this vision, we will turn the promise of cutting-edge UK science, from genomics to novel cancer vaccines, into real improvements in disease prevention, diagnosis and treatment. This means better healthcare and better outcomes for all patients, both at home and around the world.

Today we publish our plan for 2021 to 2022, which is our launchpad to propel UK clinical research into the future. Here we detail the tangible steps we will take in the coming months, with UK-wide cross-sector partnership, to begin to turn our vision into reality. With the right investment in place, we will publish further plans in the coming years, which will build upon these strong foundations to create a fully digitally-enabled, pro-innovation and patient-centred research environment.

Our plan reflects the close collaboration that makes the UK clinical research environment so strong. Delivery will be overseen by the UK-wide Clinical Research, Recovery, Resilience and Growth (RRG) programme, which brings together partners from across industry, academia, government, universities, the NHS, regulators, medical research charities, patients and the public.

By bringing everyone together under this plan and the banner of the RRG programme, we can drive the managed recovery of non-COVID research, continue to deliver on existing commitments to improve research delivery and begin to go even further to tackle long-term barriers and embed sustainable, effective and innovative new practices across our sector.

From expediting ethical approval and study set-up, to fresh investment to digitise clinical research delivery, this plan will increase the UK’s capacity and capability to deliver cutting-edge clinical research. As a result, we will bring more research and greater investment to our shores, bolstering our economic growth, tackling health inequalities and improving the health of people right across the UK.

Importantly, our plan is part of a wider government drive to support clinical research and life sciences. We are building upon existing commitments and priorities set out in the [NHS Long Term Plan](#), the [Life Science Sector Deals](#), [A Healthier Wales](#) and the [framework for NHS Scotland](#).

We are aligning our plans for clinical research with wider government strategies to ensure the UK is at the forefront of health innovation, from the [UK Rare Diseases Framework](#) to the [Genome UK Strategy](#), which sets out how we will extend the UK’s Leadership in genomic healthcare and research.

By breaking down barriers to support research across the UK our plan will complement other initiatives to unlock the power of data to drive research. This includes those set out in the UK's [National Data Strategy](#) (NDS) published in September 2020, the recently published draft [Data Strategy for Health and Social Care](#) for England and equivalent initiatives in the devolved administrations, such as a further iteration of Scotland's health and social care data strategy.

Taking these first steps in delivering our plan will need the ongoing participation of everyone across the sector. By working together, we can begin to turn our vision into a reality – creating a clinical research ecosystem which capitalises on innovation, is resilient in the face of future healthcare crises and offers fresh hope for patients right across the country.

That is what the people of this United Kingdom deserve and what the UK government and devolved administrations will deliver.

Lord Bethell of Romford

Parliamentary Under Secretary of State for Innovation
Department of Health and Social Care



Robin Swann

Minister for Health
Northern Ireland Executive



Eluned Morgan

Minister for Health and Social Services
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Humza Yousaf

Cabinet Secretary for Health and Social Care
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Executive Summary

In March 2021, we published our bold and ambitious vision for The Future of UK Clinical Research Delivery. By working in partnership across the NHS¹, regulators, industry, medical research charities, academia and government, we can create a clinical research ecosystem which is more efficient, more resilient and more effective than ever before.

Our vision is underpinned by 5 key themes:

1. **Streamlined, efficient and innovative research** – so the UK is seen as one of the best places in the world to conduct fast, efficient and cutting-edge clinical research;
2. **Clinical research embedded in the NHS** – to create a research-positive culture in which all health and care staff feel empowered to support and participate in clinical research as part of their job;
3. **Patient-centred research** – to make access to, and participation in, research as easy as possible for everyone across the UK, including rural, diverse and under-served populations;
4. **Research enabled by data and digital tools** – to ensure the UK has the most advanced and data-enabled clinical research environment in the world, which capitalises on our unique data assets to improve the health and care of patients across the UK and beyond; and
5. **A sustainable and supported research workforce** – which offers rewarding opportunities and exciting careers for all healthcare and research staff of all professional backgrounds – across the length and breadth of commercial and non-commercial research.

This plan is our first step in making this vision a reality and will serve as a launchpad to propel UK clinical research into the future. Here we lay out the tangible steps we will collectively undertake during the coming months in close collaboration with the clinical research community and our delivery partners through the UK Clinical Research Recovery, Resilience and Growth (RRG) programme.

The RRG Programme Board brings together delivery partners from across the UK to ensure system leadership, oversight and strategic coordination of our work. Partners include the UK

¹ For the purposes of this document, all references to the NHS include equivalent bodies across the UK and devolved administrations, including HSCNI.

health departments, the Office for Life Sciences, the National Institute for Health Research (NIHR), NHS England and NHS Improvement (NHSEI), NHSX, NHS Digital, Digital Health and Care Wales (DHCW), Health and Care Research Wales, NHS Research Scotland (NRS), Health and Social Care Northern Ireland, the Health Research Authority (HRA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the Association of the British Pharmaceutical Industry (ABPI) and the Association of Medical Research Charities (AMRC).

By bringing the whole sector together under this plan and the banner of the RRG programme, we have a unique opportunity to tackle long-term barriers to clinical research delivery and to embed sustainable, effective and innovative new practices across our sector. This will increase the UK's capacity and capability to deliver cutting-edge clinical research, helping to bring more research and greater investment to our shores, bolstering our economic growth and improving the health of people across the whole of the UK.

To support the delivery of this plan, over £64m in funding has been secured. This demonstrates the UK's ongoing commitment to saving and improving lives through clinical research and means that we can take the vital first steps towards delivering on our overarching vision.

However, we know we need to go much further. Whilst delivery of our phase 1 plan is underway, we will continue to coordinate across the clinical research community to agree areas for further action. With the right investment in place, we will then publish further plans in the coming years, which will build upon the work we set out below to unleash the full potential of UK clinical research, by creating a fully digitally-enabled, pro-innovation and patient-centred research ecosystem.

Our key commitments within this plan are to:

- **Deliver our UK-wide programme of work to drive the managed recovery of multi-site studies over the next 12 months.** The UK remains highly active in the research and development of novel COVID-19 medicines. However, as the pressures of the pandemic ease, we will manage the recovery of research across all phases, therapy areas and treatment types, with COVID-19 becoming one speciality amongst a diverse research portfolio. Working with commercial and non-commercial funders, NIHR on behalf of the UK, will sequence the rapid recovery of selected studies across a range of conditions and ensure the UK is able to deliver the levels of activity needed to contribute to global studies.
- **Continue delivery of existing commitments to make UK clinical research delivery easier, more efficient and more effective.** We will offer an option of HRA Rapid Research Ethics Committee review as part of the roll-out of the UK Research Ethics

Committee and MHRA combined review of clinical trials of medicines. This will build upon the use of the Integrated Research Application System (IRAS) as the new digital portal for research approvals and study set-up across the UK. In addition, we will reduce the variation and time spent negotiating costs for commercial research through the National Contract Value Review, which will ensure an aligned process for contracting of research across the whole of the UK.

- **Begin to deliver ambitious new initiatives that will set us on the path towards realising our bold vision for the future of UK clinical research.** We will take the first steps towards digitising the clinical research process to make it faster and cheaper by beginning to create a holistic, data-enabled Find, Recruit and Follow-up service. Flexible workforce and delivery models will be expanded, including capacity for research in primary and community care, and the package of incentives and metrics used to drive performance across the system will be reviewed and updated. We will also support and enable the delivery and evaluation of innovative models of trial delivery, such as hub-and-spoke, decentralised models and remote participation.

Given the scope of the work and the fast pace of change in clinical research, we will keep the specifics of this plan under review via the RRG programme and we will adapt delivery as needed to ensure we meet any new challenges as they arise. The RRG programme will also hold responsibility for the monitoring and evaluation of delivery, to ensure that progress against our commitments is measured and assessed.

By delivering on this plan, we will take our first firm steps towards achieving our overarching vision – to make the UK one of the most attractive places in the world to conduct efficient and cutting-edge clinical research that unlocks the power of new treatments and technologies to revolutionise patient care.

Scope

We recognise that health policy is a devolved responsibility, where the UK and devolved administrations have distinct ownership over implementation. However, whilst there are different approaches to the delivery of clinical research across the United Kingdom, 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 peoples' lives.

We are therefore creating a joined-up system – where sponsors of both commercial and non-commercial research can easily deliver studies across the UK and patients anywhere in the country can easily participate.

To ensure compatible and consistent ways of working across England, Scotland, Wales and Northern Ireland many commitments in this plan are focussed on UK-wide implementation. Organisations such as MHRA and HRA have a UK-wide reach and as such their actions will have impacts across the UK. In other instances, actions are being led by a specific organisation on behalf of the UK, whilst other actions will be delivered through UK partnerships – recognising the different legislative and delivery contexts across the UK government and devolved administrations.

We will continue this collaborative working as part of the RRG Programme, to ensure the UK research offer remains coordinated and all parts of the country benefit from implementation.

Scotland

Scotland recognises the strength in ensuring that the UK is a cohesive and streamlined place to undertake clinical research in a global economy. We are committed to improving cross border working, ensuring compatibility and efficiency of clinical research across the UK, and in maintaining and developing our ability to attract research to Scotland and the UK.

Healthcare in Scotland is devolved to the Scottish Government. Fourteen unitary territorial Health Boards have overall responsibility for delivering service within their geographic area, and these work with a smaller number of special Health Boards that provide national services. National research support and delivery infrastructure is provided through NRS, embedded within territorial Health Boards. Study approval and delivery processes are closely aligned through NRS at both national and local levels.

NRS supports clinical research activity through partnership working between the Chief Scientist Office (CSO) of the Scottish Government and Scottish Health Boards. NRS works with Scottish Universities and other organisations to ensure that Scotland provides a highly supportive environment for clinical research. NRS is facilitated by a Central Management Team with an established Management Group and Strategic Oversight Board giving direction and support. In combination this robust governance structure allows the strategic and operational vision to be continually and consistently reviewed, improved and developed with the RRG work being incorporated into these structures.

Clinical Research Facilities (CRFs) in the main population centres cover all phases of clinical research. These act as hubs for coordination, training and peer support for research support staff to facilitate activity across Scotland - and they will engage with UK wide activities to support recruitment and delivery, such as the Patient Recruitment Centres in England.

Scotland has a developed health informatics support infrastructure, with core support provided to 4 regional Data Safe Havens supporting regulated and secure access to NHS data. These Safe Havens work in tandem with the national electronic Data Research and Innovation Service (eDRIS) and Boards to deliver research and help identify patients to take part in studies. The Scottish Health Research Register (SHARE) has consented over 280,000 people to allow their health records to be searched against eligibility criteria to enter research studies. SHARE also provides a mechanism for collection of spare blood collected through routine clinical activities, allowing large scale, rapid collection for applicable projects. NRS, through the Data Safe Havens and SHARE continue to develop to facilitate more efficient trial delivery in Scotland. Mechanisms are also being explored to further enhance the use of NHS data to support trials in Scotland and to work with equivalents in supporting UK wide trials.

Continued engagement in UK wide activities will strengthen the learning across nations, reducing duplication and increasing deliverability. Participation of NRS in sharing experiences where relevant (e.g. in relation to the National Contract Value Review project which mirrors a process already in place in Scotland), and to actively contribute to new developments will ensure compatibility across nations, even where delivery models diverge.

Strong working relationships are in place across the UK, with NRS engaged in work streams detailed within this Implementation Plan. Further detail around Scottish plans will be published in a Scottish Government Strategy for Health Research, which will encompass plans linked to the RRG work, alongside additional Scotland-specific initiatives.

Wales

Wales, through leadership from Health and Care Research Wales, is fully committed to playing its part in delivering a world-leading UK clinical research system. As an active

member of the RRG programme, Wales will work collaboratively with all partners to realise our ambitions and improve the health and well-being of the population. This vision and plan are aligned to our 'A Healthier Wales' strategy, whereby individuals are at the heart of transformation and modernisation of health and care services, and where research is embedded in high quality care.

With the Welsh integrated health board model across primary/community and secondary care, Wales has real opportunities to offer. Working closely in partnership with our NHS leaders, and building on developments that have evolved over the last year, the Wales Study Support Service, which provides a One Wales 'front door', will now continue to support coordinated set-up, delivery and oversight of clinical research in Wales. In addition, Health and Care Research Wales will provide national coordination for the implementation of the actions within this plan, working collaboratively with organisations in Wales and across the UK.

Digital Health Care Wales is a new special health authority that was created on 1 April 2021. DHCW will take forward the digital transformations needed for better health and care and lead the delivery of national programmes to establish a modern technology enabled healthcare environment. Building on the existing digital research strengths in Wales (e.g. the Secure Anonymised Information Linkage Databank (SAIL)), DHCW will be a pivotal partner in supporting the delivery of this plan through supporting initiatives to make study set-up and delivery faster, more efficient and more innovative.

Health and Care Research Wales will also partner with Health Education and Improvement Wales (HEIW) to realise ambitions in developing and supporting our workforce in Wales, through structured research career pathways and in recognising dedicated time for research for health and care professionals.

New investments have been made in Research, Innovation and Improvement Co-ordination Hubs, focussed on driving the adoption and spread of proven innovations and new models of care. In addition, the Intensive Learning Academies are developing management and leadership roles across targeted themes linked to innovation adoption and transformation – with a strong emphasis on 'case study learning' that will translate research into better outcomes for patients.

The UK clinical research delivery vision and actions will also be a key feature in the forthcoming Health and Care Research Wales 3-year strategy.

Northern Ireland

Northern Ireland (NI) is committed to full participation in the delivery of the UK-wide vision for the future of clinical research and is already fully involved in many of the UK-wide work streams. Implementation of the vision is a shared goal across the UK, however, with

differences in scale or potentially between legislative frameworks, some variations may exist as outlined within this plan. In a number of instances, local solutions have been put in place in Northern Ireland that are compatible with those in other administrations, and aim to provide a seamless experience for those placing research studies at any site across the UK. Northern Ireland recognises the value of a UK-wide approach to clinical research and is working toward collective and compatible solutions in partnership with colleagues.

Health and Social Care in Northern Ireland is delivered by 5 geographical Health & Social Care Trusts, the NI Ambulance Service, an independent Primary Care sector and a mixture of statutory and independent care organisations. Delivery of clinical research is undertaken through the Northern Ireland Clinical Research Networks, with two Clinical Research Facilities and a single Clinical Trials Unit. NI has put in place a Clinical Research Recovery, Resilience and Growth (NI CRRRG) Taskforce to develop a local Implementation Plan for the delivery of the vision, which will complement this document.

Northern Ireland is yet to implement legislation governing the secondary use of health data. However, this has not prevented NI from becoming a full member of the UK Health Data Research Alliance, working towards optimal benefit from shared data across the UK. To date NI has expanded their safe haven data access through the Honest Broker Service, which will soon be offered remotely, in partnership with SAIL in Wales. NI is also a partner in the HDRUK core data studies around COVID-19 and is working towards full implementation of secondary uses of data legislation in the coming months, which will provide more scope for participation in the digital actions described in this document. Data will also be a major area of focus for the NI CRRRG Taskforce.

A significant joint investment from Treasury and the NI Executive in clinical research is anticipated in NI, via regional City Deal initiatives in the two main cities, Belfast and Derry. It is expected that the City Deals will bring a collective and collaborative focus on clinical research and digital health, between the two Universities and Health and Social Care, as well as engaging local industry, driving innovation and attracting significant grant income and inward investment.

England

In England, we are fully committed to supporting the delivery of the actions within this implementation plan, which will provide important foundations for future activities to build towards the delivery of our overarching vision.

As a vital first step towards creating a fully data-enabled clinical research delivery environment, we are beginning to develop a 'Find, Recruit and Follow-up' service – to make it easier than ever for researchers to connect with the digital tools and platforms that will expedite research recruitment, set-up and monitoring.

Creating this service will be a major move towards unlocking the power of data to drive research, alongside NHSX's Health and Social Care Data Strategy and the [National Data Strategy \(NDS\)](#), published in September 2020. Respondents to the [NDS consultation](#) confirmed that the framework set out in the NDS is fit for purpose and that government must now take action to ensure that we make the most of data's many opportunities.

In addition to UK-wide work on managed recovery, NIHR will also take forward further initiatives in England to diversify our research portfolio and increase system capacity. By further bolstering the 5 Patient Recruitment Centres, NIHR will make it easier and more efficient to deliver late-stage commercial research – making the UK more attractive and allowing more people to participate in research that is of relevance to them. NIHR's Clinical Research Network (CRN) will also expand their existing infrastructure in primary and community care and invest in boosting their research capacity through support for a flexible workforce and the increased use of varied delivery models for innovative research.

NHS England and NHS Improvement (NHSEI) will work closely with Primary Care Networks (PCNs) and Integrated Care Systems (ICSs) to explore how they can be empowered to support research in their local area whilst sharing best practice nationally. This collaborative working will ensure the NHS in England can embed research and innovation, both within local communities and on a national scale, to drive improvements in patient care.

The NHS Innovation Service will be established and use 'demand signalling' to effectively communicate the needs of the NHS in England. Researchers and innovators will be supported to rapidly research and develop new treatments, technologies and techniques with the potential to address these pressing healthcare challenges, to get proven solutions into the hands of the healthcare staff and patients who need them.

Together these activities in England, complemented by initiatives of the devolved administrations and in conjunction with the UK-wide actions for 2021 to 2022, represent a vital first step to the full realisation and implementation of our vision in future years.

We will pioneer England initiatives whilst continuing to actively support the wider programme of work that will lay the foundations to create a UK-wide clinical research ecosystem which is more efficient, more effective and more resilient than ever before.

Managed Recovery

As we emerge from the shadow of the pandemic and look to the recovery of non-COVID clinical research, we have heard clearly from research funders, sponsors and the NHS that a time-limited managed approach to the recovery of multi-centre studies is essential to our future growth. Stakeholders need increased certainty about when research delivery will restart, so that the UK can continue to make an active and leading contribution to global studies.

The partnerships and collaboration which enabled our success during the pandemic will remain vital as we recover from it. The NIHR CRN, on behalf of the UK, are leading discussions with commercial and non-commercial funders to develop operational plans for a managed recovery of clinical research. This will be undertaken by the Managed Recovery Operations Group and overseen by the RRG programme, with input from NHS R&D leaders and a range of wider stakeholders².

This approach will see COVID-19 studies become one speciality amongst a diverse research portfolio. Targeted support will also enable NHS sites to recover research activity and generate the income needed to maintain and rebuild our expert research delivery workforce, while also supporting research staff as they recover.

To begin to recover research across all phases, therapy areas and treatment types, we commit to support the following actions:

Activity	Impact
<p>The NIHR CRN is working across the UK in partnership with the research funders, the devolved administrations and other stakeholders, to identify the most pressing studies that require support to recover.</p>	<p>By delivering on urgent commercial studies, we can demonstrate that the UK is recovering from the impact of the pandemic and remains an attractive location to place global studies.</p>
<p>This includes an initial tranche of urgent commercial studies being put forward by companies, with the process to be repeated in future phases as capacity within the system increases.</p>	<p>Commercial research activity will also generate critical funding for NHS organisations, which is necessary to maintain our expert workforce and clinical research infrastructure into the future.</p>
<p>The NIHR CRN, on behalf of the UK, will lead the implementation of a managed recovery of our non-commercial research</p>	<p>By adopting a partnership approach and sequencing studies based on shared needs of a wide range of stakeholders, we will support a sustainable UK wide recovery</p>

² <https://www.nihr.ac.uk/researchers/managing-research-recovery.htm>

<p>portfolio including multi-site studies over the next 6-12 months.</p> <p>This will be agreed with input from stakeholders, including funders, sponsors, and NHS research and development leaders.</p>	<p>and allow for plans to be adapted as the system recovers.</p>
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Action Area 1 – Improving the speed and efficiency of study set-up

We know some research in the UK still takes too long to get off the ground. By simplifying and streamlining the route to study set up, incorporating greater transparency and consistency in research approvals and by expediting the processes for costing and contracting, we can reduce these delays and speed up all aspects of study set-up.

Our ambition is that the UK will become the premier destination for streamlined, transparent and efficient research – by removing unwarranted variation and setting up studies in record time. This will bring fresh business and investment to the UK to bolster economic growth and job creation. More importantly, it will set the pace for innovation and ensure research translates into improved patient care.

As our first step to make the UK the best place to deliver innovative, streamlined, effective and efficient research, we commit to support the following actions:

Activity	Impact
<p>NHSEI, NIHR and HRA will work with devolved administrations to design and implement a national contract value review process for commercial contract research.</p> <p>This will work with existing support available in Scotland with the aim of creating an aligned UK service.</p>	<p>By reducing variation and time spent negotiating costs for commercial research across the UK, we will make study set-up more efficient and predictable.</p>
<p>HRA, through the UK contracts group, will expand the range of model UK contracts agreed with industry and the NHS.</p> <p>This will include templates to support innovative trial delivery through hub and spoke models.</p>	<p>By increasing the model contract offering we will make research contracting faster and simpler for decentralised trials and other innovative models</p>
<p>HRA, working with relevant partners, will streamline and accelerate the UK ethics review service.</p> <p>This will involve offering rapid REC review as an option for clinical trials across the UK, including Phase I trials in healthy volunteers.</p>	<p>By ensuring REC review is not a barrier to fast and efficient research set-up, we will support faster approval of new research studies in the NHS and across the UK, whilst maintaining high ethical standards for research.</p>

<p>HRA will continue work on developing IRAS as a UK portal for research approvals and ongoing study oversight, streamlining approval processes, improving communication with digital interfaces and workflow tools.</p>	<p>By improving the processes and systems which support research, we can make study set-up more efficient and transparent.</p>
<p>NIHR, working with the devolved administrations, will ensure development of digital solutions that link research approvals portals with delivery management systems where linked systems are not already in place.</p>	<p>By supporting greater digitalisation of the research ecosystem, we will remove red tape and make it easier to track progress of studies and research portfolios.</p>
<p>The UK government and devolved administrations will ensure late-phase commercial clinical research is delivered through efficient and responsive models.</p>	<p>By making delivery of late-phase commercial clinical research easier and more efficient, we will provide people across the UK with the opportunity to access research opportunities that are of relevance to them and increase the UK's attractiveness as a destination for late-stage research investment.</p>
<p>The Innovative Licencing and Access Pathway (ILAP) will continue to provide an integrated UK approach to accelerate time to market.</p> <p>ILAP will also facilitate patient access to medicines by delivering tools and advice for companies on clinical trial design, to ensure optimal data is generated for both regulatory approval and health technology appraisal from its partners across the UK.</p>	<p>By implementing ILAP we will ensure speedier UK-wide approval processes and easier access to support along the development pathway for new treatments.</p> <p>This will provide increased clarity for innovators and companies regarding the data and evidence they need for licencing and health technology assessment.</p>
<p>MHRA will continue to develop proposals to improve and update the regulation of clinical trials, while maintaining alignment with global standards.</p> <p>This includes legislative changes to the Medicines for Human Use (Clinical Trials) Regulations 2004, using powers under the Medicines and Medical Devices Act 2021.</p>	<p>By improving clinical trial regulations, we can ensure better research transparency, risk proportionate safety requirements, greater accessibility for patients, and streamlined approvals for faster research delivery.</p> <p>In addition, this will help drive more effective delivery of trials, informed by global best practice and harmonisation of regulatory requirements in key areas such as terminology.</p>
<p>MHRA will further develop combined review with HRA and devolved administrations on research for both medicines and medical</p>	<p>By introducing greater combined working, we can streamline UK-wide processes and reduce bureaucracy for researchers</p>

<p>devices, through established and defined collaborative clinical trial (medicine) and clinical investigation (devices) reviews.</p>	<p>conducting research with medicines and medical devices.</p> <p>This will also benefit UK companies conducting phase I trials in healthy volunteers for global sponsors.</p>
<p>The Experimental Cancer Medicine Centre (ECMC) Network, with support from MHRA and HRA, will deliver a pilot to set-up Phase I oncology trials within 80 days of IRAS submission.</p>	<p>By expediting recruitment to phase I experimental cancer trials, we will help ensure the UK remains a globally competitive location to trials of innovative and experimental treatments – particularly for ground-breaking cancer research.</p>
<p>The RRG Programme will ensure strategic coordination of work to improve the speed and efficiency of the UK clinical research ecosystem, supporting progress and ensuring alignment of current initiatives, as well as identifying key areas for improvement and investment necessary to fully realise the overarching vision.</p>	<p>By continuing to work together in partnership the RRG members will coordinate activity across the UK, ensure we remain on track to deliver on our overarching vision and communicate a clear and consistent message to commercial and non-commercial researchers.</p>

Action Area 2 – Building upon digital platforms to deliver clinical research

We have high-quality data assets and have invested in a range of digital platforms which are already providing valuable services to support research delivery. Whilst the value of these platforms has been demonstrated during COVID-19, the pandemic has also highlighted the need for further development and more cohesion across the data landscape. We now need to increase the scale and interoperability between systems, to support feasibility assessments, improve diverse recruitment and to reduce the burden and costs of clinical research delivery, at both a national and local level. Different legislative frameworks within each UK administration means tailored solutions will be required in each case. However, we are committed to ensuring a seamless and joined up UK-wide approach to research sponsors.

To progress this, in 2021, we are beginning to develop a data enabled ‘Find, Recruit, and Follow-up’ service, to make it easier, faster, and more effective to deliver clinical research. This includes making it easier for researchers to identify and use the most appropriate data and digital tools to deliver their study through study support services. Such tools include Clinical Practice Research Datalink’s (CPRD) Speedy Patient Recruitment Into Trials (SPRINT) and NHS DigiTrials, which use data to deliver studies from feasibility and recruitment, to monitoring participant outcomes during and after the study completes.

These actions will lay the foundations for a fully data-enabled clinical research environment that will, in turn, support increased recruitment, more diverse participation and the rapid development of new technologies, treatments and techniques - from precision medicines to AI-enabled diagnostics - which can help to tackle the NHS’s most pressing healthcare challenges.

As the first step towards a more cohesive data-enabled digital research environment, we commit to support the following actions:

Activity	Impact
The RRG programme will work across the UK to develop a seamless UK-wide system of digital platforms for research sponsors, ensuring they can bring research, particularly those studies with a digital component, to any part of the UK effectively.	By joining up the UK systems we will bring increased diversity in research sponsors and research sites. This will ensure patients and researchers across different parts of the UK are not disadvantaged by location, especially for digitally enabled trials

<p>The RRG programme will work with funders, researchers and volunteers to understand the various registries across the UK that allow for people to register their interest in being part of research.</p> <p>These include the Covid Vaccine Registry, other condition specific registries and more generic registries like Our Future Health.</p>	<p>By understanding the UK registry landscape, we will identify ways to make the ecosystem more efficient whilst developing better links and interdependencies that will reduce confusion for researchers and volunteers - resulting in increased opportunities for people to be part of research.</p>
<p>HRA and NIHR CRN, working with the devolved administrations, will establish guidance and support services that facilitate data-enabled recruitment and help researchers understand, navigate and use data services as part of effective study delivery. Initially, this will focus on mature, large-scale data and digital infrastructure and expand in future years.</p>	<p>By making it easier to navigate and access our NHS data and digital platforms, as well as offering guidance on effective and appropriate use, we will increase researcher confidence, enable more innovative study design and support more efficient study delivery.</p>
<p>We will further develop the capabilities of specific data and digital services to enhance UK capability for clinical research delivery, including:</p> <p>CPRD, working across the UK, will fully launch SPRINT (Speedy Patient Recruitment Into Trials) – a data-enabled patient find and recruit service for commercial studies in any setting.</p> <p>NHS DigiTrials in England will automate and develop the sophistication of their feasibility, recruitment and outcomes services to increase both capacity and speed.</p>	<p>By ensuring secure and appropriate use of national data sets we can speed up set-up, recruitment and follow-up further enabling innovative trial design and delivery.</p> <p>This will lay the foundations to connect services across the UK in future years and also support increased access to research and improved diversity of study participants.</p>

Action Area 3 – Increasing the use of innovative research designs

Innovative study designs have never been so widespread and so necessary throughout clinical research. Changing the way we design and deliver studies will allow us to build system resilience and increase system capacity, by freeing up NHS and research delivery staff to work on the activities that really need their involvement and skills.

Our commitments will support researchers to design their studies in more innovative ways through detailed guidance, expert advice, evaluation and showcasing the delivery of such approaches in practice. We will also increase our understanding of the barriers to implementation of innovative approaches through new methodology research. And we will use this improved understanding as a basis for the design of interventions in the next phase of the programme to enable a step change in study design, delivery and evaluation.

As the first step to deliver faster, more efficient and more innovative clinical research in the UK, we commit to support the following actions:

Activity	Impact
<p>MHRA will further enhance their early engagement support for researchers. This includes joined-up advice from NICE, SMC and HRA alongside a robust 'pre-assessment service' and establishment of guidance from MHRA/NICE on innovative trial designs, as an ILAP tool.</p>	<p>By bolstering early regulatory engagement we can help more researchers with their study designs, to ensure they align with the UK-wide regulatory review processes for faster decisions and the use of more innovative designs.</p>
<p>NIHR and HRA, working with MHRA and the devolved administrations, will undertake a programme of work to assess and develop capability to support virtual and decentralised trials, including delivery of pilot projects.</p>	<p>By boosting our capacity to support novel study designs we will increase future system resilience and widen access to research amongst a broader range of prospective participants, to increase access for patients with the greatest health need.</p>
<p>NIHR and devolved administrations will continue work to share examples and learning from the implementation of innovative design and delivery of clinical research, to help these approaches to become business as usual.</p>	<p>By building awareness and confidence across the clinical research ecosystem we will increase the use of innovative research designs and delivery methods.</p>

<p>The RRG Programme will lead work to understand the barriers and enablers facing researchers in delivering patient centred, innovative research designs as standard, and use this as a basis for the design of interventions that will enable a step change in practice.</p>	<p>By continuing to work together, RRG members will develop an informed and evidence-based approach to enable sustainable change across the UK research, health and care communities.</p>
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Action Area 4 – Aligning our research programmes and processes with the needs of the UK health and care systems

COVID-19 has created a completely new set of needs in our health and care system. While this has generated significant demand for research evidence and new products and treatments, it has also demonstrated the critical link between clinical research and improved patient care. Aligning programmes with current and future demands for UK health services will enable us to direct clinical research capability towards the most pressing challenges facing the NHS – to bring the greatest benefits to patients across the UK and around the world.

Our commitments, initially being progressed by NHSEI, will help us to better understand these demands, both now and in the future, so that we can work with industry, medical research charities and public funders to pioneer research into the latest treatments, technologies and techniques. This will support the rapid uptake and spread of these innovations across the NHS, once they are approved.

We will also initiate a programme of work to develop, sustain and support our research delivery workforce in the NHS – by developing new professional roles, by expanding our flexible workforce and delivery models, and by increasing capacity for research in primary and community care.

As the first step to ensure world-class research is aligned to the greatest needs of the UK healthcare systems, we commit to support the following actions:

Activity	Impact
NIHR, on behalf of the UK, will develop the professional identity, standards and regulatory accountability for Clinical Research Practitioners and further develop the Associate Principal Investigator role.	By building and securing a sustainable research workforce and by ensuring more people within the NHS are able to support research, we will bolster overall system capacity. In addition, by making research roles more appealing, the NHS will be better able to attract and retain the best talent and to open research to all healthcare staff.

<p>The use of flexible workforce and delivery models will be increased – particularly to support research delivery in primary and community care. Further strategies to boost capacity and expand to other research settings will be explored across the whole of the UK.</p>	<p>By using more flexible workforce models and boosting capacity in non-traditional research settings we will increase system capacity across the wider NHS and support wider access to research amongst all prospective participants.</p>
<p>The RRG Programme will provide strategic coordination of initiatives around embedding research in the NHS and workforce, ensuring alignment across initiatives and identifying areas which require improvement and investment to fully realise our overarching vision.</p>	<p>By continuing to work together in partnership the RRG members will coordinate activity across the UK, ensure we remain on track to deliver on our overarching vision and communicate a clear and consistent message to commercial and non-commercial researchers.</p>

Action Area 5 – Improving visibility and making research matter to the NHS

As highlighted in our vision, NHS sites that are active in clinical research see improved health outcomes not just for those participating in research, but for all patients. In addition, investment in clinical research leads to economic benefits for the NHS that can support frontline services including the development and retention of the workforce.

But despite these many benefits, research delivery is not as visible across the NHS as it should be. While we capture a lot of data about the research activity taking place across the UK, the metrics we apply in monitoring performance – and their consequences – can have unintended results which move us away from the aims of the vision rather than towards them.

Our commitments in the coming year will ensure we better understand these data, considering the impact current metrics, measures and incentives have on performance, and using this to drive new approaches. We will also increase awareness of research amongst NHS leaders and work with regulatory bodies to embed research in standards for registered professionals.

As the first step to embed research as an essential and rewarding part of effective patient care, we commit to support the following actions:

Activity	Impact
<p>Across the UK we will make clear to all staff the different ways they can get involved in research and increase awareness of the value of research and innovation amongst staff and NHS Leaders.</p> <p>This includes promoting evidence that research active settings have lower mortality rates and increased staff retention.^{3 4}</p>	<p>By promoting the benefits of research and having this acknowledged by senior NHS leaders, we will increase staff engagement in research delivery and bolster overall system capacity.</p>

³ <https://pubmed.ncbi.nlm.nih.gov/29438805/>

⁴ <https://onlinelibrary.wiley.com/doi/10.1111/jep.13118>

<p>Across the UK the NHS will facilitate recognition of the professional contribution of nurses, midwives, allied health professions, pharmacists and healthcare scientists to the research workforce, and the value of research and innovation amongst NHS leaders, making clear to these professions the different ways they can get involved in research</p>	<p>By acknowledging the important role of all health and care professionals in research delivery and by embedding research within the roles of all professions, we can help to ensure all health and care staff are supported to get involved in research and further boost overall system capacity.</p>
<p>NIHR, on behalf of the UK, will engage with regulatory bodies for registered professionals around the inclusion of research delivery activity in standards and revalidation requirements.</p>	<p>By ensuring research becomes embedded within the role of registered professionals across the UK we will increase participation and embed research as a core part of the job for all health and care staff.</p>
<p>The RRG Programme will lead work to review and refine the package of metrics, measures and incentives to drive the behaviours and ultimately the performance needed to realise the vision.</p> <p>This will include recognition and promotion of the range of activities which enable effective research delivery in addition to recruitment, and workforce involvement in research across multidisciplinary teams.</p>	<p>By adopting an informed and evidence-based approach across the UK, we can enable sustainable change across the NHS and wider research community to support clinical research delivery across all phases, settings and specialties.</p>
<p>Based on the outputs of the RRG programme’s work, we will explore ways in which metrics and reporting can increase the visibility of research across the NHS and strengthen the incentive for trusts and boards to support clinical research.</p>	<p>By increasing research visibility and providing NHS leaders with detailed insights into health and social care research performance, we will be able to effectively demonstrate the positive impact research has on patient outcomes, improvements in patient care and as a source of NHS revenue.</p>
<p>Based on the outputs of the RRG programme’s work, we will review and amend existing performance reporting requirements, including the UK’s Performance in Initiating and Delivering (PID) research metrics for clinical trials, high level objectives and other metrics used across the UK.</p>	<p>By transforming the way we capture research activity we will increase the visibility of a range of research delivery within the NHS - enabling all staff and leaders to recognise its value.</p> <p>This will reinforce the value of research and support further delivery across the NHS, leading to better overall outcomes for researchers, sponsors, delivery teams, participants and all patients.</p>

Action Area 6 – Making research more diverse and more relevant to the whole of the UK

We are committed to diversifying research demographics and democratising research access, particularly for communities under-served by research. We will learn from centres of excellence to understand the practices and approaches which increase confidence and willingness to participate in research and identify the mechanisms that can appropriately increase their use and access across the research ecosystem. We will also improve data collection on diversity, to monitor progress and focus further activity.

This will help us to form an accurate picture of the diversity of research participants, building on our understanding of how clinical research can increasingly be utilised to address health inequalities and improve health outcomes for everyone across the UK and around the world. This approach will empower researchers to fulfil their duty in carrying out representative research, providing detailed insights as to where barriers persist and highlighting effective techniques to bolster research participation amongst communities.

As the first step to ensure research is more diverse and reflective of all communities, we commit to support the following actions:

Activity	Impact
NIHR, on behalf of the UK, will work with existing centres of excellence and other partners to develop systems and processes that enable health research to be directed to and supported within areas and communities traditionally under-served by research (e.g. by deprivation, ethnicity or geography) to tackle health inequalities.	By enabling under-served communities to access research, we will help to broaden recruitment, ensuring that people with the greatest health need can be supported through research. Helping researchers to drive improvement in the diversity of research cohorts will lead to more inclusive research and address disparities between research activity and the prevalence of certain diseases, leading to better healthcare provision for all.
NIHR, NHS Digital and the devolved administrations will scope the use of national datasets to analyse the diversity of research participants.	By gathering this data, we will improve our understanding of the diversity of participants in research, including in under-served groups. Research designs, methodologies and support can then be adapted appropriately to ensure all

	prospective participants have the opportunity to get involved.
MHRA and HRA will lead the development of guidance to increase diversity in studies.	By creating clearer guidelines, regulators will increase confidence within the research community and enable researchers to take action to address the current imbalance for under-served communities and groups.
HRA will automatically register clinical trials in a public registry, unless the sponsor has permission to delay this to a later stage, starting with trials of medicines.	By removing the need for registration, this reduces the burden on sponsors and trial managers. A single source of information for all UK clinical trials will support work to increase participation in research.
Where not already in place, the UK will work to develop and strengthen the ecosystem that will allow people to indicate their interest in taking part in research and explore ways to sustain high quality engagement over time.	By providing people with a range of options to participate in research, we can increase the number and diversity of potential participants by ensuring that different options meet the needs of different groups in different contexts.
The RRG programme will map activity aimed at increasing the diversity of people taking part in research across the sector and facilitate joint working in this area.	By reducing duplication of efforts across research organisations we will enable coordinated and targeted interventions to increase diversity of people taking part in research.
The RRG Programme will lead work in addressing the barriers and enablers of behaviour change needed to deliver patient centred, innovative research designs.	By supporting a sustainable change towards greater diversity in clinical research, researchers will be empowered and informed to carry out research with more representative participant cohorts as standard practice, resulting in improved health outcomes.

Action Area 7 – Strengthening public, patient and service user involvement in research

The UK is world-leading in public, patient and service user involvement in clinical research. We recognise and value the unique insights that patients, carers and the public can contribute to the design and delivery of clinical research. This makes studies more effective, more relevant and often more cost effective.

Our commitment is to continue to set the global standard for good practice in public involvement in research design and management. This will ensure the public, patients and service users feel increasingly empowered to contribute to clinical research, and that researchers are supported to work effectively with them.

As the first step to expand public, patient and service-user involvement in research, we commit to support the following actions:

Activity	Impact
NIHR and devolved administrations will build on their local and regional capacity to work on community engagement with patients and communities to shape priorities and study designs for research.	By working with local communities, we can help to ensure patients and the public across the UK feel empowered to get involved in research and that they have a voice in the research that affects them.
The UK will increase opportunities for researchers to access patient expertise by further developing services connecting researchers with patients.	By helping sponsors to easily access patient groups across the UK who can support development of their studies, we can ensure publicly funded research demonstrates the highest standards of public, patient and service user involvement.
The UK will work to address practical barriers to enable increased and easy-to-administer involvement of the public, working with key partner organisations.	By working with the public and community organisations across the UK, we can address and overcome barriers, such as pragmatic processes for payment for public involvement activities, resulting in increased public engagement in research.
The RRG Programme will draw on this work to address the barriers and enablers of behaviour change needed to deliver	By furthering progress towards public, patient and service user involvement in clinical research delivery, researchers will

<p>patient centred, innovative research designs.</p>	<p>be empowered to carry out more patient-centred and innovative research designs, resulting in improved efficiency, costs and relevance of studies.</p>
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Governance and future actions

As set out in ‘The Future of UK Clinical Research Delivery’, the implementation of our UK-wide vision for clinical research will be delivered in 2 key phases:

Phase 1 is delivery of this implementation plan for 2021 to 2022. This detailed plan is fully funded and has been developed by the UK government and devolved administrations in collaboration with the clinical research community and our delivery partners, through the UK Clinical Research Recovery Resilience and Growth programme.

The RRG Programme Board brings together the delivery partners across the UK to provide system leadership, oversight and strategic coordination of the work to realise our shared aspirations for UK clinical research delivery. Partners in this work include the UK health departments, the Office for Life Sciences, the NIHR, NHSEI, NHSX, NHS Digital, DHCW, Health and Care Research Wales, NRS, Health and Social Care Northern Ireland, the HRA, the MHRA, the ABPI and the AMRC, as well as representatives from the MedTech Industry.

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

The Programme is supported by an Advisory Group including representatives from industry, medical research charities, academia, NHS Research and Development, representatives of the research delivery workforce across NHS settings, patient and public representatives, UK Research and Innovation (UKRI), the Royal College of Physicians and Royal College of Nursing’s Research Nurse Subcommittee, NIHR, and NHSEI regions.

An Oversight Group, chaired by the DHSC Minister for Innovation and composed of senior representatives from our partner organisations, industry, medical research charities, the NHS and academia, provides strategic direction and coordination.

Phase 2 is the next step in our journey. Once delivery in 2021 to 2022 is underway, we will continue to coordinate across delivery partners and the clinical research community to develop ambitious future strategies and plans in support of the key themes and areas of action within the vision.

In preparing for Phase 2 we will consider new investment, future fiscal events, emerging scientific advances and wider changes to the clinical research landscape to set our sights

towards a multi-year implementation plan, which can deliver on our vision and unleash the true potential of UK clinical research.

Most notably, we will continue to focus our efforts to embed clinical research across the NHS, by bolstering system capacity and nurturing a research-positive culture where all staff are supported to participate in research delivery. We will also work to identify the research that is most needed and align research programmes with current and future demands for health services. This will ensure we support sustainable change across the UK research community, so that the NHS is well equipped to meet the healthcare challenges of the future and that people across the UK continue to benefit from the latest improvements in healthcare delivery.

Glossary

A Healthier Wales – published in June 2018, is the Welsh Government’s long-term plan for health and social services in Wales.

Association of Medical Research Charities (AMRC) – a membership organisation for health and medical charities that is dedicated to supporting medical research charities in saving and improving lives through research and innovation.

Association of the British Pharmaceutical Industry (ABPI) – is a trade association that represents the views of the pharmaceutical industry across the UK. The ABPI works in partnership with government and the NHS to make the UK the best place in the world to research, develop and use new medicines and vaccines - so patients can get new treatments faster.

Chief Scientists Office (CSO) – is part of the Scottish Government Health Directorates. CSO supports and increases the level of high-quality health research conducted in Scotland for the health and financial benefits of the population.

Clinical research – refers to all research carried out on humans (healthy or sick people). It focuses on improving knowledge of diseases, developing diagnostic methods and new treatments or medical devices to improve patient care.

Clinical Practice Research Datalink (CPRD) – is a UK government, not-for-profit research service that has over 30 years of primary care clinical data. CPRD collects anonymised patient data from a network of GP practices across the UK and supplies this for public health research.

COVID-19 – is an infectious disease caused by a newly discovered coronavirus.

Digital Health Care Wales – a new special health authority that will deliver national digital, data and technology services for health and care in Wales.

Experimental Cancer Medicine Centre (ECMC) Network – a network of 18 adult centres and 11 paediatric locations across the UK that supports over 200 world-leading scientists and clinicians involved in early phase trials and translational research to drive the discovery, development and testing of new treatments to combat cancer.

Genome UK: the Future of Healthcare – published in 2020, this UK-wide government strategy sets out the vision to extend the UK’s leadership in genomic healthcare and research.

Genomics – is the study of the body’s genes, their functions and their influence on the growth, development and working of the body – using a variety of techniques to look at the body’s DNA and associated compounds.

Health and Care Research Wales (HCRW) – is the organisation that funds and supports health and social research in Wales.

Health and Social Care Northern Ireland (HSCNI) – is the national health and social care provider for Northern Ireland. For the purposes of this document, all references to NHS include equivalent bodies across the UK and devolved administrations, including HSCNI.

Health and Social Care Research and Development – is part of the Public Health Agency, and is responsible for the administration and coordination of the HSC research and development budget on behalf of Department of Health, Northern Ireland (DoH NI).

Health Research Authority (HRA) – an arm’s length body of the Department of Health and Social Care (DHSC), which protects and promotes the interests of patients and the public in health and social care research. The HRA is responsible for research ethics approval. All medical research involving people in the UK, whether in the NHS or the private sector, must first be approved by an independent research ethics committee.

Life Sciences Industrial Strategy – published in 2017 and written by the UK Life Science’s Champion Professor Sir John Bell, the strategy provides recommendations to government on the long-term success of the life sciences sector.

Medicines and Healthcare products Regulatory Agency (MHRA) – an arm’s length body of the Department of Health and Social Care (DHSC). Before a clinical trial of a new medicine can begin the MHRA needs to review and authorise it. The MHRA inspects sites where clinical trials take place to make sure they are conducted in line with good clinical practice.

Medical Research Council (MRC) – is a part of UKRI that is responsible for co-coordinating and funding medical research in the UK. The MRC’s work ranges from laboratory research, for example on genes and molecules, right through to research with people, such as clinical trials and population studies.

National Institute for Health and Care Excellence (NICE) – a non-departmental public body of the Department of Health and Social Care in England. NICE's role is to improve outcomes for people using the NHS and other public health and social care services,

working actively with researchers, funders, charities and policy organisations to achieve high-quality, impactful research.

National Institute for Health Research (NIHR) – is a UK government agency which funds research into health and care. It is one of the largest national clinical research funders in Europe.

National Data Strategy (NDS) – published in September 2020 and with consultation across the UK, the NDS is a pro-growth strategy that aims to drive the UK in building a world-leading data economy while ensuring public trust in data use.

NHS Digital (NHSD) – is the national information and technology partner to the national health and care system. NHSD works with partners to ensure health information flows efficiently and securely.

NHS England and Improvement (NHSEI) – NHSEI lead the NHS in England and oversees delivery of the NHS Long Term Plan to improve patient care.

NHS Long-term Plan – aims to improve the quality of patient care and health outcomes. It sets out how the £20.5 billion budget settlement for the NHS, announced in summer 2018, will be allocated.

NHS Research Scotland (NRS) – is a partnership of Scottish NHS Boards and the Chief Scientist Office (CSO) of Scottish Government that promotes and supports excellence in clinical and translational research in Scotland - so patients can benefit from new and better treatments.

NHSX – is a joint unit bringing together teams from the Department of Health and Social Care and NHSEI to drive the digital transformation of care. This includes setting national policy and developing best practice for National Health Service technology, digital and data, including data sharing and transparency.

Office for Life Sciences (OLS) – is part of the Department of Health and Social Care (DHSC) and the Department for Business, Energy and Industrial Strategy (BEIS). OLS champions research, innovation and the use of technology to transform health and care services.

Precision medicine – is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.

Rare disease – is a condition which affects fewer than 1 in 2,000 people. It is currently estimated that there are over 7,000 rare diseases, with new conditions continually being

identified as research advances. 1 in 17 people are estimated to be affected by a rare disease at some point in their lives.

Rare diseases framework – published in 2021, outlines the government’s priorities for improving the lives of people living with rare diseases over the next 5 years.

Clinical Research Recovery Resilience and Growth (RRG) – is the UK-wide programme that brings together partners from across industry, academia, government, universities, the NHS, regulators, medical research charities, patients and the public. The RRG programme will oversee the delivery of the Future of UK Clinical Research Delivery vision, this plan and future publications.

Scottish Health Research Register (SHARE) – a register of over 280,000 people in Scotland aged 11 and over who have granted use of their health records to assess their eligibility for research studies, as well as ground-breaking work to carry out consented collection of left-over blood from routine clinical tests for anonymised health research.

Scottish Medicines Consortium (SMC) – is part of Healthcare Improvement Scotland and provides advice to NHS Scotland about the value for patients of every newly licensed medicine.

UK Research and Innovation (UKRI) – a non-departmental public body sponsored by the Department for Business, Energy and Industrial Strategy (BEIS). UKRI brings together the 7 disciplinary research councils including MRC, as well as Research England and Innovate UK.

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