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of Health &  
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Department of  
**Health**

An Roinn Sláinte  
Mánnystrie O Poustie



**CHIEF  
SCIENTIST  
OFFICE**

# **Saving and improving lives: the future of UK clinical research delivery**

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## Ministerial foreword

The past year has delivered unprecedented challenges for us all. But through these dark times, UK clinical research has provided a beacon of hope.

The tireless efforts of our healthcare professionals, researchers, participants, regulators, medical charities and industry have helped us to lead the world in COVID-19 research. From the rapid delivery of innovative platform trials, like RECOVERY, to our massive contribution to the global vaccine effort, our research ecosystem has pulled together across the UK to provide us with a route back to normality.

This is testament to our strengths. The UK has long been at the forefront of clinical research thanks to our deep scientific expertise and our dedicated research infrastructure. But the last 12 months have seen a step-change, with a heightened spirit of collaboration and innovation driving everything we have achieved.

As we look to the future, we must use these lessons from COVID-19 as a springboard to build back better. Because we stand at an inflection point for global healthcare. Driven by data and analytics, cutting-edge technologies and treatments, including precision medicines and artificial intelligence, are transforming the way we treat patients.

And this is just the tip of the iceberg. The coming years will see an explosion in breakthrough technologies which will pave the way to tackle the most pressing population health burdens and provide fresh hope to patients.

We must seize the opportunity to put the UK at the forefront of this healthcare revolution and clinical research will be the backbone of our efforts. Because research is the single most important way in which we improve our healthcare – by identifying new means to prevent, diagnose and treat disease.

Therefore we, the UK government and devolved administrations, are setting out a bold and ambitious vision for the future of clinical research delivery, which capitalises on innovation, is resilient in the face of future healthcare challenges and improves the lives of patients all over the UK and around the world.

This means embedding clinical research at the heart of patient care across the NHS, making participation as easy as possible and ensuring all health and care staff feel empowered to support research. And it means capitalising on our strengths in health data and creating new digital infrastructure to make study set-up and delivery faster, more efficient and more innovative, so that the UK remains one of the best places in the world to deliver cutting-edge research.

Our vision is ambitious – and it needs to be. As we begin to return to normality, bolstering the delivery of clinical research across all phases, all treatment types and all conditions offers a precious opportunity to improve patient care and address health inequalities - all whilst stimulating economic growth right across the UK. Most importantly, we can proceed safe in the knowledge that our world-leading scientific expertise, globally-respected regulators and unique NHS provide us with all the foundations we need to succeed.

Delivering on this compelling and ambitious vision will unleash the true potential of clinical research right across the UK, to address long standing health inequalities and improve the lives of us all, both now and in the future.

That is what the people of our United Kingdom deserve and that is what we must 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 Mental Health, Wellbeing and Welsh Language  
Welsh Government



**Jeane Freeman**

Cabinet Secretary for Health and Sport  
Scottish Government



# The value of clinical research

## Our lifeline during COVID-19

The past 12 months have held huge challenges for us all. We've lost loved ones, been separated from our family and friends, and we've seen our wonderful health and social care staff go above and beyond to keep us safe.

But throughout the COVID-19 pandemic, clinical research has provided a beacon of hope and shone a light on the vital role research plays in improving healthcare for us all.

By rapidly delivering world-leading research we have identified new tests and treatments to help tackle this deadly virus, bolstered our understanding of its transmission and created new cutting-edge vaccines which are our lifeline back to normality. And we're continuing to bring our world-leading genomics expertise to bear, to track the virus' mutations.

There has been a coordinated effort from the UK government and devolved administrations to act at unprecedented speed and ensure that the whole of the UK is at the forefront of COVID-19 research. Our achievements are thanks to the collective efforts of our world-leading scientists, regulators and universities, our dedicated frontline NHS staff<sup>1</sup> and research workforce, alongside the huge contribution from research participants, industry and medical research charities.

From the world-leading RECOVERY trial to the collaboration between Oxford University and AstraZeneca to develop one of the first COVID-19 vaccines, UK clinical research has brought much needed hope to patients, the public and NHS staff.

The spirit of collaboration shown by all those involved in this phenomenal research effort has been fundamental to our success. Regulators, the NHS and trial sponsors have worked hand-in-hand to set-up and deliver large-scale trials safely, quickly and effectively.

As we begin to emerge from the shadow of the pandemic, we must carry this spirit of collaboration with us into the future, with the UK government and devolved administrations placing clinical research front and centre of our plans to build back better.

### **Our route back to normality – discovering lifesaving COVID-19 therapies and delivering innovative vaccine trials**

The UK has led the world in COVID-19 research – through platform trials, like RECOVERY, which have been set-up in record time to identify effective treatments for the virus and through our leading role in the global COVID-19 vaccine effort.

Researchers, regulators, the NHS, medical research charities and industry have worked together across all 4 administrations – making use of new digital platforms to recruit hundreds of thousands of participants.

As a result, we were the first country in the world to identify dexamethasone as an effective treatment for COVID-19, we recruited the first global participant into the Janssen and Novovax trials and we were the first country to approve COVID-19 vaccines developed by Pfizer/BioNTech and Oxford/Astrazeneca.

Our contribution to COVID-19 research has helped to improve healthcare and save lives all over the UK and across the globe.

Read more in the [case studies section below](#).

<sup>1</sup> For the purposes of this document references to the NHS include the HSC in Northern Ireland.

## Our opportunity to grow, adapt and improve

Despite our successes during COVID-19 and the strength of our clinical research environment, the pandemic has taught us some valuable lessons about where we need to improve.

We have seen research into other conditions stall, with workforce pressures and disruption to traditional delivery methods leading study sites to close or struggle to recruit during the pandemic.

And whilst we have seen some great examples of innovative trial design and delivery, we need to go even further to support more innovative trials across all phases, all treatment types and all conditions, to help make our clinical research ecosystem more resilient.

### **Improving access and building resilience – RELIEVE IBS-D**

Irritable Bowel Syndrome (IBS) affects approximately 1 in 5 people in the UK – a third of whom experience diarrhoea-type IBS (IBS-D). The RELIEVE IBS-D study has been set up to test a new drug-free treatment for those with the condition.

When COVID-19 hit, research teams collaborated with the research sponsor, Enteromed, to develop the digital tools needed to continue this important study remotely.

As a result, not only was the research able to carry on, but the new virtual approach opened-up participation to more people all over the UK and significantly bolstered recruitment. A single site using the virtual method recruited 67% faster than all 28 sites using a traditional approach.

Read more in the [case studies section below](#).

We cannot ignore the impact the pandemic has had on researchers and healthcare workers many of whom have worked flat out over the past 12 months. As we move forward, we must focus on our workforce, to ensure it is resilient and supported to continue delivering world-leading research.

The virus has particularly impacted people living in areas of high deprivation, people from ethnic minority backgrounds, older people, men and those with a learning disability.

We must use these lessons as a catalyst for change.

As we move forward, we must focus on our workforce to ensure it is resilient and supported to continue delivering world-leading research. Tackling health inequalities and supporting under-served populations must also be central to our recovery and restoration of non-COVID-19 services, including clinical research. We want every community to take the opportunities to get involved – from those in rural settings, to ethnic minorities, who have traditionally been under-served by research.

We need to work with these groups to ensure they feel confident and comfortable to participate. And we need to address the mismatch between research activity and disease prevalence, to align clinical research with the areas of greatest need. Together we can level up healthcare and improve outcomes for everyone right across the UK.

## Our hope for the future

The pandemic has showcased the clear link between research and better outcomes – for individuals and the NHS.

Our response has demonstrated the strength of our clinical research ecosystem and our unique ability to deliver innovative research to a high standard, at scale and at speed - for the benefit of everyone. We've achieved things none of us thought possible, all while continuing to deliver exceptionally high standards in clinical research and the highest possible levels of patient safety. We now need to seize this momentum and look to the future.

Clinical research is the single most important way in which we improve our healthcare – by identifying the best means to prevent, diagnose and treat conditions. So, we need to bolster delivery of innovative research across all phases, all conditions and right across the UK, as we work to rapidly restart our non-COVID-19 research portfolio and build back better.

Research is also vital in determining what doesn't work, so we can improve best practice and focus resources on providing healthcare that delivers the greatest benefit to patients. And research extends beyond clinical trials for new medicines to cover a range of activities – from a study into a new approach to radiation therapy, to work to explore how a particular disease could be prevented, or even an investigation to help mitigate the side effects of a new treatment.

Clinical research is all around us and helps to improve the quality of healthcare patients receive. Crucially, these benefits are felt by everyone, not just those participating in research. For example, data shows NHS trusts that are highly research active have better outcomes for patients across their services.<sup>2</sup>

As we look to tackle today's major healthcare challenges, including the worrying rise in long-term conditions, such as obesity, diabetes and mental health, we must double-down on our commitment to clinical research.

This is how we will identify the best treatments, the best technologies and the best techniques to improve the lives of our children and our grandchildren - whilst also ensuring we are ready to deal with any future global health crisis.

### **Tackling global healthcare challenges – The Genetic Links to Anxiety and Depression study**

Depression and anxiety are the most common mental health disorders worldwide and 1 in 3 people in the UK will experience symptoms during their lifetime.

The Genetic Links to Anxiety and Depression (GLAD) study aims to find out how genes and our environment act together to bring about anxiety and depression, to identify effective treatments and improve the lives of people experiencing these conditions.

GLAD is led by the NIHR Mental Health BioResource and researchers at King's College London, in collaboration with researchers at Ulster University, University of Edinburgh, and Cardiff University. Using novel digital recruitment methods, including social media, the study is already halfway to recruiting its overall target of 40,000 participants.

Read more in the [case studies section below](#).

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<sup>2</sup>Jonker L and Fisher S. J. The correlation between National Health Service trusts' clinical trial activity and both mortality rates and care quality commission ratings: a retrospective cross-sectional study. *Public Health*. 2018; 157:1-6.

## Our chance to help others

Clinical research is widespread, diverse and open to us all. Sometimes research needs to be conducted in specialist academic facilities, but very often it takes place right alongside delivery of routine care in the NHS and the wider health and care system.

In England, the NHS is supported by the National Institute for Health Research (NIHR) alongside other networks delivering research. As one of the largest national clinical research funders in Europe, NIHR provides the staff, facilities, training and technology that enables research to thrive.

In Wales, the NHS is supported by Health and Care Research Wales (HCRW), which promotes and supports health and care research, to ensure it is of the highest international scientific quality, is relevant to the needs and challenges of health and care in Wales and that it makes a difference to policy and practice in ways that improve the lives of patients, people and communities.

In Northern Ireland, Health and Social Care Research is supported through the Health and Social Care Research and Development Division (HSC Research and Development) of the Public Health Agency, to deliver on the 10-year Strategy, 'Research for Better Health and Social Care'. This strategy sets out how the health, wellbeing and prosperity of the Northern Ireland population will benefit from excellent, world-renowned health and social care research, that is led from Northern Ireland.

In Scotland, NHS Research Scotland (NRS) supports clinical research activity, through partnership working between the Chief Scientist Office of the Scottish Government and Scottish Health Boards. NRS works with Scottish Universities and other organisations to ensure that Scotland provides the best environment to support clinical research.

Together this creates a dedicated UK-wide infrastructure. Alongside support from national and local governments, the NHS, universities, regulators, industry and medical research charities, the UK is therefore well-placed to deliver world-leading clinical research, which transforms lives, promotes economic growth and is accessible to researchers and participants across the UK.

### **Improving outcomes for all - OPTIMAS**

Every year, around 30,000 people in the UK suffer a stroke due to atrial fibrillation - an abnormal heart rhythm.

Whilst new anticoagulant (blood thinning) treatments are available, we still don't know when it's best to prescribe them to prevent a further stroke. The OPTIMAS (OPTimal TIMing of Anticoagulation after Stroke) trial is looking to answer this important question.

Taking place in over 70 hospitals across the whole of the UK, researchers, clinical teams and participants involved in OPTIMAS are helping to improve the medical care for future stroke survivors all over the world.

Read more in the [case studies section below](#).

All clinical research can be valuable, whether it a clinical trial to test the effectiveness of a treatment or a questionnaire to understand patients' experience. Research which is robustly designed and delivered helps to bolster our understanding of what works and what doesn't - so that healthcare continues to evolve, and patient outcomes continue to improve.

Opportunities to get involved are all around us. Research is happening in NHS sites across the UK and hundreds of thousands of people take part every year. Over 1 million participants



joined a research study during 2018 to 2019<sup>3</sup> and over a million more participants have now taken part in COVID-19 research<sup>4</sup>. For those outside of hospital settings there are a host of other opportunities to get involved and support research, through GP practices, dentists, community and home-based care.

Delivering clinical research is reliant on us all working together to play our part - from participants and health care professionals, through to researchers, regulators and government. Whilst we absolutely need specialist researchers and dedicated research teams, research relies on the involvement of participants, volunteers and NHS staff who provide day-to-day patient care – whatever clinical speciality they work in and whatever their job is. This can be as simple as talking about a research opportunity, right through to participating in the trial of a new medicine.

There are different ways in which participants can benefit from taking part in a research study. Participation may provide access to new treatments or it may help participants to learn more about their condition, whilst closer monitoring of participants by healthcare professionals also helps to improve outcomes. And research is a way for people to play a vital role in helping others, both at home and abroad. Those that do become involved in clinical research, will be guided by a robust, regulated and confidential process, with participation informed at every stage.

Studies happening locally or for specific conditions can be found using [Be Part of Research](#) – an online tool which can help everyone to find out about health and social care research taking place across the UK.

For NHS and other health and care staff, whilst there is not always an immediate benefit for their patients, supporting research makes an invaluable contribution to the health of future patients across the UK and the wider world. Studies have also shown that all patients have better health outcomes in research active hospitals, even if individual patients are not part of research<sup>5</sup>.

And the support is there to help our staff to take part - with clear processes to follow, training to help get started and learning and development opportunities available to increase involvement over time.

As research activity becomes increasingly embedded into the NHS and across all health and care settings, we will all have more opportunities to do our part. The more we all participate in research, the more healthcare progresses, and the more lives we can improve – both now and in the future.

## Our time to act is now

We are seeing a step-change in global healthcare. Driven by data and analytics, a host of new technologies and treatments, from advanced therapies to artificial intelligence (AI), are transforming the way we diagnose and treat patients – and what we have seen is just the tip of the iceberg.

The next few years will see an explosion in these technologies and treatments. Cutting-edge diagnostics will help deliver a healthcare system focussed on early intervention, where people

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<sup>3</sup> <https://www.nihr.ac.uk/news/number-of-participants-in-nihr-supported-research-exceeds-one-million-for-the-first-time/22543#:~:text=The%20number%20of%20participants%20in,the%202018%2F19%20financial%20year.>

<sup>4</sup> [https://www.nihr.ac.uk/news/uk-covid-19-research-passes-one-million-participants/27215?utm\\_source=twitter-research&utm\\_medium=social&utm\\_campaign=covid&utm\\_content=1millionnews](https://www.nihr.ac.uk/news/uk-covid-19-research-passes-one-million-participants/27215?utm_source=twitter-research&utm_medium=social&utm_campaign=covid&utm_content=1millionnews)

<sup>5</sup> Ozdemir B.A, Karthikesalingham A, Singha S, Poloniecki J. D, Hinchliffe R. J and Thompson M. M. Research Activity and the Association with Mortality. *PLoS ONE*. 2015; 10.

understand risk, plan-ahead and take ownership of important decisions about their future health.

Meanwhile, AI and our understanding of genomics will help identify more innovative therapies which will pave the way to tackle the most pressing population health burdens and provide fresh hope to patients across the UK and around the world, including those with rare diseases.

Clinical research is the key to delivering on the promise of this new era, by helping to develop and test the best treatments, technologies and techniques which will deliver benefits to patients and their families.

With these foundations in place, we can ensure the UK is at the forefront of this healthcare revolution. We are at the leading-edge of genomic medicine, prevention and screening, and we are making great advances at embedding these innovations across the NHS to improve the health of our entire population.

Our clinical research is also world-leading, with 12% of global trials for cutting-edge cell and gene therapies already taking place in the UK, representing the largest advanced therapy cluster in Europe. This delivers direct benefits for patients, with the NHS being the first national healthcare system in Europe to introduce a novel CAR-T, Kymriah, as an innovative treatment for cancer.

### **The power of innovation and collaboration – the National Lung Matrix Trial**

The National Lung Matrix Trial (NLMT), is the largest precision medicine study in the world. Participants with non-small cell lung cancer are genetically screened to understand more about their tumour type and matched to the most promising potential treatment.

NLMT shows the power of collaboration, through the UK's integrated health research system. Led by the University of Birmingham's Clinical Trials Unit and funded by Cancer Research UK (CRUK), the trial is supported by CRUK's Stratified Medicine Programme 2, the CRUK/NIHR Experimental Cancer Medicine Centres, Pfizer, AstraZeneca and Mirati Therapeutics Inc, alongside NHS organisations across the UK and devolved administrations.

Read more in the [case studies section below](#).

We need to double-down on our commitment to support innovative clinical research for all cutting-edge treatments and technologies and across all conditions, to ensure the UK remains a globally-leading destination for research investment and delivery.

### **Transforming psychotherapy using new technologies – gameChange**

Psychosis affects thousands of people every year, many of whom fear everyday social situations.

gameChange is an early-phase study evaluating whether a new immersive virtual reality (VR) psychotherapy can help patients engage in more everyday social situations and experience fewer and less severe psychiatric symptoms.

The therapy itself provides sophisticated simulations of the real-life situations that patients find troubling. Patients with strong fears are much more likely to test them in VR but, importantly, the learning then transfers to the real world.

Read more in the [case studies section below](#).

Investing in UK clinical research also offers a fantastic opportunity to bolster our economy, by supporting thousands of high-value jobs across the UK and attracting millions in private investment.

For example, from 2016 to 2019, clinical research supported by the NIHR generated an estimated £8bn of gross value added and supported over 47,000 full-time equivalent jobs across the UK.<sup>6</sup> And for every £1 the government spends on research and development, via NIHR, we generate over £19 in total economic returns – the highest return on investment for any public service. Similar analysis across devolved administrations shows health research creates jobs and generates a consistent return on investment<sup>7,8</sup>.

As we begin to re-open our economy and build back better, clinical research therefore offers a vital opportunity to improve patient care, address health inequalities and boost our future health resilience, all whilst stimulating economic growth right across the UK.

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<sup>6</sup><https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/22489>

<sup>7</sup>[https://healthandcarereseearchwales.org/sites/default/files/2020-10/impact\\_value\\_research\\_supported\\_NHS\\_organisations\\_Wales\\_2020.pdf](https://healthandcarereseearchwales.org/sites/default/files/2020-10/impact_value_research_supported_NHS_organisations_Wales_2020.pdf)

<sup>8</sup> <https://research.hscni.net/impact-hsc-rd-division-funding>

# Our vision for UK clinical research delivery

Our vision is ambitious, and it needs to be.

Delivering clinical research across health and social care is more important than ever – as new technologies and treatments emerge, we continue to adapt to the challenges of an ageing population and as patients, quite rightly, demand new healthcare options and better outcomes.

To support our bold vision, we have identified 5 key themes which underpin the improvements we will take forward in the coming years. Together, this will ensure we continue to lead the world in clinical research delivery, the NHS is able to tackle the healthcare challenges of the future and patients across the UK and around the world will benefit from better health outcomes.

## Clinical research delivery embedded in the NHS

Health and care staff have long recognised and supported the value of clinical research in driving up standards and improving the quality of care across the health and care system. However, NHS staff are not always able to deliver research as part of their day-to-day activities. Research can also be seen as ‘someone else’s business’, reserved only for clinical academics and specialist research teams.

This has to change. Whether helping to deliver a clinical trial, supporting patients and service users to access the latest research opportunities, or adapting current practices in line with new findings – delivering research is everyone’s business across the NHS.

**Our vision is to create a research positive culture across the NHS and all health and care settings, where all staff feel empowered and supported to participate in clinical research delivery as part of their job.**

## Patient-centred research

Patients and participants are the foundation of clinical research. Without them research can’t happen and healthcare can’t improve.

But although we have infrastructure and systems supporting clinical research across the UK, access is not universal. We must ensure all patients, their families and their carers are empowered to directly and proactively explore research opportunities and to make informed decisions about participating in the research that is of relevance to them.

To get there, we need to integrate research delivery into day-to-day care and make use of new technologies to recruit people ‘where they are’ – so participation is as easy as possible. This means designing studies which minimise the number of hospital or GP visits and which make use of virtual delivery models, allowing as much of the research as possible to take place close to home.

Across the UK the journey towards integrated care is well underway. In England, the Integrated Care Systems (ICSs) are partnerships between organisations to coordinate services and deliver healthcare in a way that improves population health and reduces inequalities between different groups within their region. Research and innovation should be considered as key contributors to this planning and coordination of services, ensuring equal access to research across an ICS footprint.

Patients and service-users must also be routinely involved in the design of clinical research, to ensure outcomes match their needs and studies are designed with real participants and the realities of their daily lives in mind. We are committed to finding new ways of engaging directly with all communities. This will result in fewer people finding themselves left out of research planning, help to bolster participation amongst under-served and diverse groups, and help tackle health inequalities.

**Our vision is to make research open to everyone and to make participation in research as easy as possible.**

## **Streamlined, efficient and innovative clinical research**

Patients and service users want faster access to better treatments and better healthcare. And those sponsoring and delivering research want it to take place where these benefits can be realised as quickly as possible.

We therefore need to deliver more streamlined and more efficient clinical research – which allows more people to participate and to access new or improved treatments, technologies and techniques. This will help to ensure the UK remains an attractive place to deliver cutting-edge research – all whilst protecting research quality and patient safety.

We've seen the power of what we can achieve in response to COVID-19, with the rapid set-up and delivery of platform trials, to explore new uses for existing medicines. This has allowed us to trial multiple treatments in parallel – increasing the speed with which we can identify and rollout improvements to patient care.

Most importantly, this has all been achieved within existing regulations and guidance and without loss of rigour. The secret has been flexibility, collaboration and innovation in research design, set-up and delivery.

We need to carry this approach through into the future of all clinical research, with everyone making use of new and innovative approaches and by working together across research sponsors, regulators, government and the NHS, to support rapid set-up and delivery.

**Our vision is for the UK to be seen as the best place in the world to conduct streamlined, efficient and innovative clinical research.**

## **Research delivery enabled by data and digital tools**

Digital systems underpin the delivery of modern clinical research. They help to design and deliver protocols, identify and recruit research participants and support public involvement, engagement and awareness.

And these systems go hand-in-hand with accessible, interoperable and high-quality health data – to better understand disease and unlock advances in the future of patient care.

Fortunately, the UK enjoys unique research advantages, due to our ability to access information from across different health and social care settings. We've seen the power of what these data and digital systems can achieve during COVID-19 – with the UK vaccines registry, developed by NHS Digital (NHSD) and NIHR, offering people from all corners of the UK the opportunity to participate in landmark vaccine trials.

In addition, NHSD's Trusted Research Environment (TRE) for COVID-19 increased research capacity, by allowing researchers to access clinical data to interrogate specific research questions at speed – all whilst ensuring the highest levels of data protection and guaranteeing patient privacy.

But whilst positive steps have been taken, we need to go much further and faster to unleash the true potential of data-enabled clinical research delivery.

We need to scale current platforms, creating the mechanisms to connect eligible patients with opportunities to participate in clinical research of relevance to them. And we will work on improving interoperability between systems, to support clinical research delivery, at both a national and local level. This will be key to improve accessibility for research across our different data assets which include OpenSafely, NHS's DigiTrials, NWeHealth, Clinical Practice Research Datalink (CPRD), UK BioBank, NIHR Bioresource, Genes and Health and Genomics England, as well as Wales' SAIL databank, delivered in partnership with Digital Health and Care Wales, and the other Health Data Research hubs, like DiscoverNow. Similar initiatives in Scotland include SHARE, Generation Scotland, Precision Medicine Scotland, The Scottish Biorepository Network, eDRIS and the Scottish Data Safe Havens.

We can create a truly digitally-enabled and future-ready clinical research environment.

This will act as a vital enabler to deliver faster, more efficient and more innovative clinical research - which increases access and brings new gene sequencing, cell-based therapies, precision medicines, digital tools and artificial intelligence to bear to tackle the NHS's most pressing healthcare challenges.

**Our vision is for the UK to have the most advanced and data-enabled clinical research environment in the world – where we can capitalise on our unique data assets to deliver improvements to the health and care of patients across the UK and beyond.**

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

We have an excellent clinical research delivery workforce, and the wider NHS has stepped up during COVID-19 to implement world-leading research, which has helped save countless lives across the globe.

We have seen how hard healthcare workers have worked to take care of us throughout the pandemic, whilst also answering critical research questions.

We are working hard to strengthen the UK's research delivery workforce and make research in the NHS more resilient, across both commercial and non-commercial research. This is fundamental to our success – because it is the research delivery workforce who recruit participants, deliver research protocols, and ensure all the study data is collected.

To do this sustainably, we need to ensure support is available where it is most needed, including primary and community settings, so we can deliver research 'where people are' and actively engage with under-served communities.

We need to develop new non-clinical research delivery roles as the practice of delivering and supporting clinical research evolves over time and ensure that there are a range of attractive career paths for highly skilled research practitioners and support staff.

We also need to support healthcare professionals to develop research skills relevant to their clinical role and to design studies in ways which ensure delivering research is a rewarding experience, rather than an additional burden. For example, NIHR's Associate Principal Investigator scheme is providing basic research skills to trainee doctors who have supported research during the pandemic.

Finally, digitisation and better use of data will also help to reduce the pressure on researchers and healthcare staff. By transforming research delivery through digital innovation, we can save time and money, whilst empowering researchers to work together effectively.

**Our vision is for a sustainable, supported research delivery workforce – offering rewarding opportunities for all healthcare staff and exciting careers for those from all professional backgrounds who lead research.**

# Our strategy and plans for delivery

Sitting underneath these 5 key themes, we need to develop focussed strategies and plans for delivery. These will be published in due course, beginning with plans for activity during 2021 to 2022. Further activity to deliver the vision will be dependent on further multi-year investment across the UK, as part of future fiscal events.

We have identified 7 specific areas for action, each of which is informed and aligns with one or more of the key themes. These actions will break down some of the barriers that prevent, delay or disincentivise research across the UK and build upon existing commitments, such as those in the Life Science Sector Deals, A Healthier Wales and the NHS Long-Term Plan.

By bringing this activity together under a set of cohesive delivery plans and strategies, we will be able to go even further and faster to achieve our vision for the future of UK clinical research delivery.

## Improving the speed and efficiency of study set-up

Firstly, we know that research can still take too long to get off the ground, with unnecessary delays and unwarranted variation at different stages continuing to cause frustration.

Which is why we will improve the speed and efficiency of study set-up. This includes expediting costing, contracting and approvals, all areas we know can delay progress.

To that end, we have restarted work on the National Contract Value Review to streamline the process of setting-up multiple research sites in the NHS – this mirrors support already in place in Scotland.

And we're not just avoiding delays, we're going further to actively speed up research approval. For example, the Health Research Authority (HRA) have launched a rapid ethics review pilot for global clinical and phase I trials, which aims to halve the time taken for approval of research applications.

## Building upon digital platforms to deliver clinical research

Secondly, we have seen the power of digital research platforms during COVID-19, with [NHS DigiTrials](#) and [CPRD](#) supporting the rapid delivery of vaccine and therapeutic trials across the UK. And we have invested in a range of digital platforms and high-quality data assets which are also providing valuable services to support research delivery.

We will be working together across the UK with the key partners for these digital platforms to ensure that they aid the acceleration of research delivery, including NHS DigiTrials, NHSD, Digital Health Care Wales, Scottish Health Research Register (SHARE), eDRIS, Digital Health and Care Northern Ireland and the Northern Ireland Trusted Research Environment.

We need to build on individual successes and increase the capacity for DigiTrials and other digital services to support delivery of other priority research, which can help to address important health burdens, such as cancer and cardiovascular disease, alongside pioneering research into cutting-edge treatments and technologies. And we need to support all researchers to easily identify and connect with the services best-placed to support their study.

Together, these approaches will help sponsors to quickly find eligible participants and translate this into improved recruitment performance for research across all different phases, treatment

types and conditions. It is the first step on our journey to create a truly data-enabled digital research environment, with the tools to support feasibility, recruitment and follow-up.

## **Increasing the use of innovative research designs**

Never before have innovative research designs been so widespread and so necessary. During the pandemic, we have seen teams across the country adapt their research designs to take advantage of virtual processes and innovative technology so they can start or continue their studies. For example, the University of Birmingham's Dare2Think clinical trial is using CPRD's digital trials infrastructure to recruit 3,000 patients across England with atrial fibrillation, using remote eConsent and data-enabled follow-up methods.

These innovative approaches help build system resilience and move recruitment away from frontline NHS services – freeing up NHS staff to work on the research that really needs their involvement, such as clinical trials for cell and gene therapies, AI-enabled diagnostics or other cutting-edge treatments and technologies.

We need all research sponsors to consider how they can embed these lessons into business as usual, so that the best research is taking place where it is best suited across the ecosystem. And we need to build upon the fantastic response we have seen from the UK regulatory system throughout the pandemic – to get innovative trials of the ground in record time. The Medicines and Healthcare Products Regulatory Agency (MHRA) is leading the charge, with the launch of the new Innovative Licensing and Approvals Pathway to smooth the journey from clinical trials through to standard of care – with closer collaboration and planning between the agencies involved in each step.

We now need to capitalise on this momentum to ensure innovation is embedded into the future design and delivery of all research – so our system is more resilient, more efficient and more effective.

## **Aligning our research programmes and processes with the needs of the UK health and care systems**

During the pandemic, clinical research with the greatest importance to public health has been COVID-19 related. But this won't always be the case.

Moving forward, we need to ensure we focus our attention and our efforts on research which aims to address the most pressing population health needs for people across the UK, whilst continuing investigator-driven research to help generate new and innovative delivery models.

Being clear about the links between the clinical research we are delivering and the benefits to patient outcomes, both now and in the future, helps to engage people in research and see it as part of their job.

And we are looking to the future of our health services to better understand the demands that will be placed upon them - to ensure we identify the research that is most needed to sustain the NHS.

This will also help industry, medical research charities and others to know what new products and evidence our healthcare systems most need, which will support the rapid uptake and spread of these new treatments, technologies and techniques across the NHS, once they are approved.



## **Improving visibility and making research matter to the NHS**

The public and healthcare staff have never been so aware of clinical research and the value it can bring to patients. We need to capitalise on this momentum and ensure we recognise and value all the activities which contribute to the delivery of research. We are engaging with health and care staff to embed the idea that research is not a burden - but an essential and rewarding part of effective patient care.

At the same time, we also need to make research matter to the NHS – to ensure staff see the benefit for their patients and feel empowered to support research, however they play their part. This means capturing, monitoring and promoting support for research across the NHS – for example, the number of referrals to research studies, the number of participants recruited to trials and good data collection in electronic health records.

We need to identify and create the incentives and levers in the system to ensure we enable different ways of working – both in individual organisations and collaboratively across the system. For example, through a strengthened research delivery focus in healthcare regulator requirements for NHS bodies and through revalidation requirements for doctors and nurses.

## **Making research more diverse and more relevant to the whole UK**

COVID-19 has demonstrated the need to engage diverse populations in clinical research - to ensure research cohorts reflect the populations that will benefit from new treatments. But this goes beyond the pandemic. Making research more diverse is critical to addressing persistent health inequalities. By building on centres of excellence, such as the Centre for BME Health in Leicester, we will increase support for research in more diverse and under-served populations.

We will also ensure that, wherever possible, research is delivered where the patients with the greatest need are located. This means increasing the capacity and confidence to deliver research in areas with the highest disease burdens and levels of deprivation. By boosting capacity and actively reaching out to engage more diverse communities, through trusted channels, we can ensure we better serve the healthcare needs of everyone across the UK.

## **Strengthening public, patient and service user involvement in research**

Finally, involving patients, service users and the public in the design of the research is critical.

Patient and public contributions are invaluable, providing insights from their lived experience and alternative views to those of research teams or NHS staff. Patients are also able to make judgements based on their understanding of their condition and may have different aspirations and thoughts about health outcomes that health care professionals and researchers may not have considered.

Patient and public involvement is now recognised in industry standards, building on a strong record of patient involvement in medical research charity and publicly funded research.

We'll expand support to help sponsors easily access patient groups who can support development of their studies. And we will ensure that publicly funded research models have public, patient and service user involvement in research design and delivery at their heart, in line with the highest UK standards. This will ensure patients and the public feel empowered and that they have a voice in the research that affects them.

# Where we go from here

## Moving forward together

Together, we need to create a resilient and future-proofed research environment, which is focussed on tackling the most pressing healthcare burdens for people across the UK and is ready to ensure everyone can benefit from advances in cutting-edge healthcare.

To demonstrate our ongoing commitment and to build on our achievements to date, we have worked with the clinical research community to design this vision for the future of UK clinical research delivery.

The vision will be underpinned by future strategies and detailed plans, which will provide more information about the specific steps we will take within each administration to achieve the high-level aims set out above.

## Our approach across the UK

Our vision for clinical research builds on our proven ability to work together, across the research community and from all 4 corners of the UK, in pursuit of a common goal – to create a clinical research delivery ecosystem which will shape the future of healthcare and improve people's lives for years to come.

The UK has built and nurtured a culture of close collaboration and partnership between government, universities, industry, the NHS, regulators and medical research charities. And these have been further strengthened during our response to COVID-19.

We have drawn upon this network to develop and test this vision, undertaking a detailed programme of engagement with stakeholders from across the clinical research landscape, including health and care staff, patients, industry, research charities, academia and the NHS.

We have formed the sector-wide UK Clinical Research Recovery Resilience and Growth (RRG) Programme to deliver the vision, supported by the UK government and devolved administrations. Partners in this work include the Department of Health and Social Care, the Office for Life Sciences, UK Research and Innovation (UKRI), NHS England and NHS Improvement (NHSE/I), NHS Wales, NHSx, NHS Digital, Digital Healthcare Wales, the NIHR Clinical Research Network, HCRW, Department of Health Northern Ireland, HSC Research and Development, HRA, the Chief Scientist Office and the MHRA.

The Programme is supported by an Advisory Group including representatives from industry, medical research charities, NHS Research and Development, representatives of the research delivery workforce across NHS settings, patient and public representatives, the Royal College of Physicians and Royal College of Nursing, NIHR, NHS Research Scotland, HCRW, universities, the Medical Research Council and NHSE/I regions.

## Wider policy alignment

Our vision for clinical research delivery complements wider work to support clinical research in the round, including academic research and research design, and builds upon existing commitments in the [NHS Long-Term Plan](#) and [Life Science Sector Deals](#).

In addition, our vision is a vital part of the wider strategy to improve the health of people right across the UK, and to ensure we continue to lead the world in the development and delivery of cutting-edge treatments and technologies.

The vision complements the UK [Rare Diseases Framework](#), which outlines the government's priorities for improving the lives of people living with rare diseases over the next 5 years, as

well as the [Genome UK Strategy](#), which sets out how we will extend the UK's Leadership in genomic healthcare and research.

In addition, the NHSx Health and Social Care Data Strategy, due to be published later this year, will set out the vision and plan for revolutionising how we use health and care data in England. The strategy will specifically cover how safe access to high quality data can support research, to develop new therapies and new approaches to keeping people healthy and living independently. The vision is also aligned with the [National Data Strategy \(NDS\)](#). Published in September 2020, the NDS sets out government's ambition to unlock the power of data use in order to drive innovation and secure the next scientific breakthrough.

We also recognise the importance of capitalising on clinical research to ensure all patients get access to the best proven treatments and technologies. Which is why the Accelerated Access Collaborative (AAC) was established to drive proven health innovations into the hands of the patients and healthcare professionals who need them right across the UK. The AAC's first annual report [Our Year in Focus](#), shows that during 2019 to 2020 the AAC helped to provide more than 700,000 patients with access to proven health and care innovations, resulting in an estimated 12,000 fewer hospital admissions and 125,000 fewer days spent in hospital, with total savings to the NHS of over £50m.

In Wales, several new collaboration initiatives have been established under the auspices of 'A Healthier Wales', to support the commitment to building joint health and care research, innovation and improvement capacity. 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.

So, we all need to continue to work together. Because when world-leading research delivers cutting-edge innovations into the hands of dedicated healthcare staff, everyone wins.

## Phased implementation

Our UK-wide vision for clinical research will be delivered in 2 key phases.

### Phase 1

Phase 1 is this document – the Future of UK Clinical Research Delivery alongside our underlying action plans and strategies for improvements to be delivered during 2021 to 2022 – which will be published later this year.

The vision sets out our 5 underpinning themes and 7 priority areas for action, to create a world-leading clinical research delivery environment. These are shared by the UK government and devolved administrations and provide a strategic direction for our work on clinical research delivery, to improve the health of people across the UK.

Health is a devolved matter and therefore each individual administration has the flexibility to deliver the aims of the framework in the way which is most effective for their population.

However, all 4 administrations are committed to working together collaboratively and, wherever possible, we will pool our collective efforts and take a UK-wide approach.

### Phase 2

This is the next step in our journey. Once delivery in 2021 to 2022 is underway, we will then lift our gaze and set our sights even higher.

We will publish detailed plans for the future, which will deliver on our vision and unleash the true potential of UK clinical research.

## Next steps

This vision is part of a coordinated and coherent programme of work to ensure the recovery, resilience and growth of UK clinical research delivery. This encompasses the support, processes and infrastructure that enable research delivery, and the aspects of research design, management and oversight which impact on the potential to improve.

In developing our plans and strategies for 2021 to 2022, we will continue to work closely with the clinical research community, via the RRG programme, to ensure commitments are appropriate, actionable, and measurable.

Together we can create a research delivery environment that improves patients' lives, levels up economic opportunity across the UK and bolsters our health resilience, all whilst addressing health inequalities.

This is what the UK needs, what patients deserve and what we must deliver.

## Case studies

### Discovering lifesaving COVID-19 therapies in record time – RECOVERY

RECOVERY, led by the University of Oxford with funding from UKRI's Medical Research Council (MRC) and the NIHR, is the world's largest randomised controlled trial for COVID-19. Set-up in record-time in the early stages of the pandemic, RECOVERY identified the first proven treatment for the virus and has provided other vital evidence about which treatments work and which don't.

In just 9 days the RECOVERY trial protocol was written and approved, and the first participants were recruited. The trial is designed and run in a way that makes it easy for both patients and the NHS to get involved – with over 38,000 patients in 177 hospitals across all 4 corners of the UK having taken part.

It was RECOVERY which successfully identified dexamethasone as a cheap, effective and widely available treatment for COVID-19. This vital treatment has cut mortality rates by as much as one-third in COVID-19 patients needing ventilation and helped to save lives all over the world.

Since then, RECOVERY has continued to produce ground-breaking research, showing that Tocilizumab reduces the need for a mechanical ventilator and also shortens the time COVID-19 patients spend in hospital. Equally important, RECOVERY has shown several treatments, such as convalescent plasma, don't work.

Using a platform approach the study is able to trial multiple therapies simultaneously, meaning researchers can easily stop trialling treatments that show little or no effect and re-focus their efforts on the most-promising candidates. This has proven vital at a time of intense pressure on the NHS and healthcare services all over the globe.

All of this wouldn't have been possible without our investments across the UK - in the people, processes and systems needed to deliver high quality health research. In particular, NHS health-data systems, including NHS DigiTrials, have helped to reduce the burden on front-line delivery teams, as minimal demographic and consent data could be collected at a patient's bedside and then integrated with routine NHS information on treatment, diagnosis, COVID-19 tests, clinical results and survival – to provide the full range of data needed to deliver the trial.

You can find out more about RECOVERY [here](#).

### Our route back to normality – The UK's role in innovative COVID-19 vaccine trials

Developing a new vaccine is a complex process which can often take over a decade. But in the last year, we have seen new, safe and effective COVID-19 vaccines developed, trialled and rolled-out at phenomenal speed.

The UK has been at the forefront of this global effort, playing a pivotal role in numerous vaccine trials. We recruited the first global participants in the Janssen and Novavax trials in Dundee and Blackpool, and we were the first country in the world to approve the COVID-19 vaccines developed by Pfizer/BioNTech and Oxford/Astrazeneca.

These amazing feats have been possible thanks to the UK's close collaboration with industry, dedicated research delivery staff and, most importantly, participants nationwide who took part

in trials. Our national COVID-19 Vaccine Registry, made up of over 450,000 volunteers across the UK, allowed researchers to rapidly identify and recruit a diverse range of participants to the vaccine trials, to test whether they were safe and effective.

In addition, the SIREN and Vivaldi studies have researched infection rates among healthcare and care home workers, producing real world data which demonstrates that vaccines are highly effective in slowing the spread of COVID-19 and preventing serious infection. Through these and other studies we are now able to track the long-term impacts of vaccines in the real world.

Thanks to the hard work of our researchers, research delivery teams and regulators, alongside the fantastic support from trial participants, the world now has new tools to tackle the pandemic and offer hope for a brighter and safer tomorrow.

You can find out more about COVID-19 vaccine research and how to sign up to participate [here](#).

## **Improving access and building resilience – RELIEVE IBS-D**

Irritable Bowel Syndrome (IBS) affects approximately 1 in 5 people in the UK – a third of whom experience diarrhoea-type IBS (IBS-D). Symptoms have a huge impact on quality of life, with patients often suffering debilitating abdominal pain and bloating.

The RELIEVE IBS-D study has been set up to test Enterogel – a new drug-free treatment that is taken orally. By adopting an entirely virtual approach to trial this promising new treatment, the study is a major step forward in developing the UK's capacity and capability to conduct virtual clinical research.

RELIEVE IBS-D was originally designed to run across 28 hospitals, GP practices and private clinics in England, with participation limited to those in these catchment areas. However, to enable the research to continue during the COVID-19 pandemic, teams at the Newcastle Hospitals NHS Foundation Trust and the NIHR National Patient Recruitment Centre in Newcastle collaborated with UK company Enteromed to develop the digital tools needed to continue this important research remotely.

The new virtual approach opened-up participation to people across the UK, with patients in England, Wales, Scotland and Northern Ireland taking part from the comfort of their own homes. And this has significantly bolstered recruitment, with a single site using the virtual method recruiting 67% faster than all 28 sites using a traditional approach.

You can find out more about the RELIEVE IBS-D study [here](#).

## **Tacking global healthcare challenges – the Genetic Links to Anxiety and Depression Study**

Depression and anxiety are the most common mental health disorders worldwide and, in the UK, 1 in 3 people will experience symptoms during their lifetime. The Genetic Links to Anxiety and Depression (GLAD) study aims to find out how genes and environment act together to bring about anxiety and depression.

GLAD is led by the NIHR Mental Health BioResource and researchers at King's College London, in collaboration with researchers at Ulster University, University of Edinburgh, and Cardiff University. By improving understanding of the risk factors for depression and anxiety, the study is aiming to identify effective treatments and improve the lives of people experiencing these conditions.

The study is the largest ever of its type and uses novel digital recruitment methods, including social media and other online forums, to help identify anyone who has experienced clinical anxiety or depression and wants to take part. Potential participants can easily register on the study website and send saliva samples back in the post for analysis.

As a result, more than 8,000 people registered on the website within 24 hours after launch and by the end of week one that figure had grown to almost 15,000. Interest in the research has continued to grow and over 20,000 participants enrolled in the first year, which is halfway to the overall study target of 40,000 people.

You can find out more about the study on the GLAD website [here](#).

## **Improving outcomes for all – the OPTIMAS trial**

Every year, around 30,000 people in the UK suffer a stroke due to atrial fibrillation – an abnormal heart rhythm. For most of these people, anticoagulant (blood thinning) medication is the best way to prevent a further stroke, but we still don't know how soon after a stroke the medication should be started.

Historically, taking anticoagulant medication early after a stroke has been considered to increase the risk of potentially harmful intracranial bleeding – when a blood vessel within the skull ruptures or leaks, causing damage to the brain. For this reason, many clinicians delay anticoagulation for up to 2 weeks after the stroke has occurred. However, during this time, there is a risk a patient may experience a further stroke – a terrifying reality for hundreds of people across the UK every year.

Although the practice of delayed anticoagulation is supported by several current guidelines, these are based largely on historical and observational data in patients treated with Warfarin – an older anticoagulant with a much higher risk of causing bleeding.

Newer direct oral anticoagulants (DOACs) are increasingly used in modern clinical practice, and more recent studies suggest that early DOAC use is associated with a low risk of intracranial bleeding – whilst delays increase the risk of a further stroke.

So, starting DOAC medication early might be safe and effective. But a randomised controlled trial comparing early and delayed treatment is needed to answer this important question.

Led by University College London and funded by the British Heart Foundation, the OPTIMAS (Optimal TIMing of Anticoagulation after Stroke) trial is seeking to do just that. OPTIMAS is taking place in over 70 hospitals across the whole of the UK. By working together, the researchers, clinical teams and patients will help to improve medical care for future stroke survivors all over the world.

You can find out more about OPTIMAS [here](#).

## **The power of innovation and collaboration – the National Lung Matrix Trial**

Non-small-cell lung cancer accounts for over 80% of lung cancer cases and the disease kills over 35,000 people in the UK every year. Genetic subtypes of this cancer have been identified and, through the National Lung Matrix Trial (NLMT), researchers are testing new, targeted drugs and novel treatment combinations faster than in traditional trials.

NLMT is the largest precision medicine trial in the world. Patients who sign up to take part are genetically screened to understand more about their tumour type and whether they possess the relevant genetic signatures to be matched to a targeted treatment. The trial's adaptive

approach makes it possible for new drugs and combinations to be added as soon as they become available, or to be retired quickly and easily if evidence suggests they aren't effective.

NLMT shows the power of collaboration through the UK's integrated health research system. Led by the University of Birmingham's Clinical Trials Unit and funded by Cancer Research UK (CRUK), the trial is supported by CRUK's Stratified Medicine Programme 2, the CRUK/NIHR Experimental Cancer Medicine Centres, Pfizer, AstraZeneca and Mirati Therapeutics Inc, alongside NHS organisations across the UK.

Since NLMT opened to recruitment in May 2015, hundreds of patients have been recruited to over 20 different study arms testing 8 different targeted treatments.

You can find out more about the National Lung Matrix trial on the University of Birmingham's website [here](#) and in Nature [here](#).

## **Transforming psychotherapy using new technologies - gameChange**

Psychosis affects thousands of people every year, many of whom fear everyday social situations. This can lead to extreme isolation and poor physical and mental health. One study is looking to develop a powerful new treatment, by using highly scalable and personalised innovation in virtual technologies.

With funding from NIHR, gameChange is an early-phase study to evaluate whether a new immersive virtual reality (VR) psychotherapy can help patients engage in more everyday social situations and experience fewer and less severe psychiatric symptoms.

In designing the study, researchers collaborated with those who have experience of psychosis – with participants working side-by-side with the computer programmers creating the VR therapy. The therapy itself provides sophisticated simulations of the real-life situations that patients find troubling. Patients with strong fears are much more likely to test them in VR but, importantly, the learning then transfers to the real world.

One of the most innovative features is a virtual therapist – a friendly computer-generated avatar, voiced by a real person, that carefully guides the patient through the therapeutic work, helping them practise techniques to overcome their difficulties. In effect, the treatment is automated, making it a low-cost yet effective complement to existing care.

You can find out more about gameChange [here](#).



# Glossary

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

**Accelerated Access Collaborative** – brings together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking new treatments and technologies which can transform care.

**Artificial intelligence** – describes a range of techniques that allow computers to perform tasks typically thought to require human reasoning and problem-solving skills.

**Cell and gene therapies and cell-based therapies** – involve extracting cells, protein or genetic material (DNA) from the patient (or a donor), and altering them to provide a highly personalised therapy, which is re-injected into the patient.

**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 ensure better 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.

**DataLoch** – a Scottish health data repository created jointly by NHS Lothian, Borders and Fife and the University of Edinburgh.

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

**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 Welsh organisation that funds and supports health and social research in Wales. It aims to provide collective oversight of research to ensure it is of the highest international scientific quality, is relevant to the needs and challenges of health and care in Wales, and makes a difference to policy and practice in ways that improve the lives of patients, people and communities 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). Its work is

based on the principle that the best health and social care must be underpinned by knowledge, based on well conducted research, which can then be applied in the delivery of care.

**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.

**iCAIRD** – a pan-Scotland collaboration of 15 partners from across industry, the NHS, and academia working to establish a world-class centre of excellence focusing on the application of artificial intelligence to digital diagnostics.

**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 Research (NIHR)** – is a UK government agency which funds research into health and care, and is one of the largest national clinical research funders in Europe.

**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 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 by the Prime Minister in summer 2018, will be spent over the next 5 years.

**NHSx** – is a joint unit bringing together teams from the Department of Health and Social Care and NHS England and Improvement 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** – is part of the Department of Health and Social Care and the Department for Business, Energy and Industrial Strategy. OLS champions research, innovation and the use of technology to transform health and care services.

**Platform trials** – allow for the evaluation of multiple treatments or interventions during a clinical trial, using interim evaluations and addition of new interventions.

**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.

**Royal College of Nursing** – is the world's largest nursing union and professional body. It represents more than 450,000 nurses, student nurses, midwives and nursing support workers in the UK and internationally.

**Royal College of Physicians** – a British professional membership body dedicated to improving the practice of medicine, chiefly through the accreditation of physicians by examination.

**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 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.

**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 seven disciplinary research councils including MRC, as well as Research England and Innovate UK.

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Science, Research and Evidence Directorate

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