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

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Executive Summary

This UK-wide vision for the future of clinical research delivery is for everyone working in the NHS, for anyone thinking about getting involved in research and for all those who sponsor and support research across industry, academia and the third sector.

Clinical research is the backbone of healthcare innovation – it is the way we improve the prevention, detection, diagnosis and treatment of disease. Delivering this research depends on healthcare professionals from all backgrounds, working hand-in-hand with research participants, their families and their carers.

Here we set out our ambition to create a patient-centred, pro-innovation and digitally enabled clinical research environment, which empowers everyone across the NHS to participate in delivering research and ensures that patients from across the UK are supported to take part in research that is of relevance to them.

Implementing the vision will unleash the true potential of our clinical research environment to improve the health of us all, to capitalise on our renowned research expertise and to make the UK one of the best places in the world to design and deliver research.

The COVID-19 pandemic has hammered home the strength of our research base, through our rapid delivery of platform trials, like RECOVERY, and our leading contribution to the global vaccine effort, which is our lifeline back to normality.

Collaboration has been the foundation of our success. Our world-leading scientists and regulators have worked closely with industry and medical research charities, alongside our dedicated research workforce, including staff from across the NHS and thousands of participants from all 4 corners of the UK. We have shown that, when we come together, UK clinical research can tackle the most pressing healthcare challenges.

But we've also learned some important lessons from the pandemic about where we need to improve. For all the successes of our COVID-19 research, we have seen other research suffer. Workforce pressures and disruption to traditional delivery methods have seen study sites close or struggle to recruit during the pandemic – causing research to stall. 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, treatment types and conditions – to embed innovative approaches across our entire research ecosystem. Most importantly, the pandemic has laid bare the unacceptable health inequalities that persist across our country, which must serve as a catalyst for change.

The time to act is now. Driven by data and analytics, new technologies and treatments are transforming the way we diagnose, treat and prevent illness. We are determined that the UK is at the forefront of this healthcare revolution and our vision sets out how we will deliver a clinical research ecosystem which capitalises on innovation, delivers for all research sponsors, is resilient in the face of future healthcare crises and offers fresh hope for patients across the UK.

So, as we begin to emerge from the shadow of the pandemic, we must use this as an opportunity to learn lessons and build back better.

What we will achieve

There are 5 key themes underpinning our vision:

1. **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.
2. **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.
3. **Streamlined, efficient and innovative research** – so the UK is seen as the best place in the world to conduct fast, efficient and cutting-edge clinical research.
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.
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.

Our strategy and plans for delivery

We have plans in place to make this vision a reality. We have identified 7 areas for action, to break down traditional barriers and deliver a patient-centred and pro-innovation clinical research environment.

1. **Improving the speed and efficiency of study set-up.** This includes expediting costing, contracting and approvals, all areas we know can often delay progress. And we're going further, to actively speed up research approval and delivery. For example, the Health Research Authority has launched a rapid ethics review pilot for global clinical and phase I trials, which aims to halve the time to provide a final opinion on research applications.
2. **Building upon digital platforms to deliver clinical research.** We have seen the power of digital research platforms during COVID-19, with NHS DigiTrials supporting the rapid delivery of vaccine and therapeutic trials. We now need to build on these successes and increase the capacity for digital platforms to improve the delivery of research. This will help address other important population health burdens, such as cancer and cardiovascular disease, reduce the burden on frontline health and care staff and support research delivery for cutting-edge treatments and technologies, including genomic medicines.
3. **Increasing the use of innovative research designs.** We are seeing study teams across the country adapt research delivery methods to take advantage of virtual processes and technologies in the current environment. We need these new approaches to be adopted across commercial and non-commercial research in future. This will make research easier for people to access and will also release capacity within the NHS. By helping to deliver the best research where it is best suited, we will continue to support innovative studies for cutting-edge treatments and technologies across all phases, for all therapies and for all conditions.

4. **Aligning our research programmes and processes with the needs of the UK health and care system.** We are looking to the future health needs of the population and the health service - to better understand the demands that will be placed on it and to ensure we identify the research that is most needed to support patients and the NHS across the UK.
5. **Improving visibility and making research delivery matter to the NHS.** We are engaging with health and care staff and leadership to embed the idea that clinical research is an essential and rewarding part of effective patient care. And we are working to create the incentives and levers in the system to ensure staff feel empowered to support research and see the benefits it brings to their patients. This means capturing, monitoring and promoting research activity across the NHS – including the number of referrals to research studies, the number of participants recruited and good data collection in electronic health records. And it means building research into healthcare regulator requirements for NHS bodies and revalidation requirements for doctors and nurses.
6. **Making research more diverse and more relevant to the whole UK.** By building on centres of excellence, such as the Centre for BME Health in Leicester, we will increase support for research in more diverse and under-served populations. 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 healthcare burdens and levels of deprivation.
7. **Strengthening public, patient and service user involvement in research.** We will expand support to help sponsors easily access patient groups who can support the development of their studies. We will ensure publicly funded research models the highest standards of public, patient and service user involvement in research design and delivery, and continue to partner with other funders to improve diversity and engagement across all clinical research.

Next steps

The publication of this UK-wide vision will be followed by plans and strategies across the UK government and devolved administrations later this year, which will set out what we will deliver during 2021 to 2022.

Health is a devolved matter and therefore each individual administration has the flexibility to deliver the vision 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.

Once delivery for 2021 to 2022 is underway and our strong foundations are in place, 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.

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.

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