Department for Science, Innovation & Technology

Department of Health & Social Care

Office for Life Sciences

Independent report

Government response to the Lord O'Shaughnessy review into commercial clinical trials in the UK

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Foreword

Rt Hon Steve Barclay MP Secretary of State for Health and Social Care and Rt Hon Chloe Smith MP, Secretary of State for Science, Innovation and Technology

The UK has an exceptional life sciences sector, and its continued growth – underpinned by our Life Sciences Vision – is a fundamental pillar of the UK's ambition to become a science superpower. A key driver of this growth is clinical research, which is an essential step in developing the next generation of medicines and medical technology, harnessing the power of the UK's research infrastructure and delivering benefits to patients and the public worldwide.

The UK demonstrated the power of clinical research during the pandemic through the participation of over 2 million people in COVID-19 trials of treatments and vaccines for COVID-19 across the UK. The collaboration that arose between the government, the life sciences sector and the NHS drove one of the greatest joint missions in history. The UK became the first country in the world to approve and administer a COVID-19 vaccine and the first to identify an effective treatment, dexamethasone, helping to save lives all over the world.

Despite this remarkable success, the Association of the British Pharmaceutical Industry (ABPI) has reported a 44% decline in the number of commercial clinical trials initiated in the UK between 2017 and 2021, dropping the UK from 4th to 10th in global rankings for phase 3 industry clinical trials (https://www.abpi.org.uk/publications/rescuing-the-uk-industry-clinical-trials/). This has been exacerbated by international competition and a domestic pivot towards COVID-19 research during much of that period, which has impacted set-up and recruitment times for other research.

As the sector enters a new age, where rapid advancements in technologies and digital tools are opening doors to expedite processes, the UK has the unique opportunity to use its strengths and regain its position as a global leader in commercial clinical trials. We must act now to boost the clinical trials landscape, ensuring it has the right foundations and allowing the UK population to access ground-breaking treatments that can dramatically improve standards of care.

We are therefore delighted that Lord O'Shaughnessy has undertaken a detailed review of the UK's commercial clinical trials landscape and has rightly concluded that there is significant work to do. We welcome all of Lord O'Shaughnessy's recommendations, and, as a first step, will work to deliver 5 upfront commitments, backed by £121 million. These commitments will make approving and setting up trials quicker, make it easier for people to find trials and to contact patients who could benefit from ground-breaking treatments, and create exemplars for delivering trials in key areas, such as cancer and infectious disease, to improve our delivery of all trials.

We look forward to working closely with colleagues across government, the sector, the health system and with patients to deliver this ambitious response, and will follow this response with an implementation update to address the other recommendations by autumn 2023. Finally, we would like to thank Lord O'Shaughnessy, and all of those who contributed to his work across the UK clinical research landscape, for his review.

Introduction

In February 2023, the government announced an independent review, led by Lord James O'Shaughnessy, into the UK commercial clinical trials landscape. The review aimed to support the life sciences sector to unlock UK growth and investment opportunities and suggest resolutions to the key challenges in conducting commercial clinical trials in the UK.

The review ran from February to May 2023, deep-diving into the commercial clinical research landscape through 6 workshops with stakeholders across the clinical trials system, including industry leaders, medical research charities, academia, the NHS, regulators and other partners in clinical trials. These intensive workshops worked to identify barriers to the set-up and delivery of commercial phase 3 and 4 studies, with a broader exploration into the environment for earlier phase research. The process highlighted a high degree of consensus concerning areas of UK success, and where action is needed to further competitiveness and resolve key challenges. The government is grateful to all stakeholders for their comprehensive work to inform this report.

Lord O'Shaughnessy has made 27 recommendations addressing 8 problem statements. Problem statements 1 to 4 span set-up and approval processes, a lack of transparency and data about UK commercial clinical trials activity, a lack of accountability at every level for underperformance in clinical trials and how clinical research should be systemically prioritised by or within the NHS.

Problem statements 5 to 8 point to a lack of incentives for doctors, nurses and NHS organisations to take part in clinical research, especially when it is commercially funded; a low-profile for clinical research in conversations between doctors and patients, especially for marginalised and disadvantaged communities; a failure to take advantage of the NHS's considerable data assets; and finally, despite the opportunities clinical research provides for delivering population-scale trials, UK primary care is a negligible provider of clinical trial activity.

To address these issues, decisive action is needed to build on the existing initiatives being undertaken to revitalise clinical research, including commercial studies.

The following government response makes several commitments, accepting a suite of review recommendations, the implementation of which will begin immediately. In addition, the government response notes where further work is required to explore remaining recommendations, ahead of a full implementation update in autumn 2023.

Government response

Regaining the UK's position as a global leader in commercial clinical trials is critical to delivering the ambitions set out in the Life Sciences Vision and positioning the UK as a science superpower. Delivering this, while maintaining our strong performance in academic trials, is a crucial way in which we can improve healthcare for patients – by widening access to innovative treatments and technologies – as well as driving up life sciences investment.

The O'Shaughnessy review recommended a series of measures to help us achieve this goal by using regulatory, funding and policy levers to reinvigorate trial activity and create an environment where innovative commercial clinical trials can flourish. The government welcomes all recommendations from this review, in principle, and will consider delivery of all recommendations.

As an immediate first step, the government is making 5 headline commitments, backed by up to £121 million. These headline commitments will improve the speed of commercial clinical trials in the UK. In addition, we will take forward the foundational actions that will be adopted as part of the government and the health system's on-going work to support commercial clinical trials. Finally, the government will provide an implementation update in the autumn, which will outline progress against these commitments as well as responding in full to the remaining review recommendations.

Headline commitments

Substantially reduce the time taken for approval of commercial clinical trials, with the goal of reaching a 60-day turnaround time for all approvals

The first 'problem statement' within the review sets out the challenges associated with commercial clinical trial set-up and approval processes, which are 'slow and bureaucratic compared to other countries'. To address approval times, the review makes 2 recommendations targeted at the UK regulators. As a first step, the government accepts the recommendation to rebuild capacity and deliver reduced turnaround time for all approvals within statutory timelines – led by Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) and backed by £3 million Department of Health and Social Care (DHSC) funding over 3 years. This is in conjunction with the announcement made by the Chancellor at the March 2023 Budget to provide £10 million over the next 2 years to MHRA to help bring innovative new medicines and medical technologies to UK patients more quickly.

The MHRA has established a task and finish group with industry trade associations to reduce the backlog of delayed applications and is committed to making regulatory decisions within statutory timeframes, working towards all new fully

compliant clinical trial applications received from 1 September 2023. An update on progress will be provided in the autumn.

Deliver a comprehensive and mandatory national approach to contracting

To tackle delays in set-up and address the challenge around bureaucracy in undertaking commercial clinical research, the review makes a recommendation to build on and expand the existing National Contract Value Review (NCVR), which was set up through the Future of Clinical Research Delivery: 2021 to 2022 (https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery-2021-to-2022-implementation-plan) implementation plan.

The government accepts this recommendation and reinforces its commitment to a mandatory national approach to costing and contracting, led by NHSE England, with an enhanced service to be delivered from October 2023. This new approach allows organisations to agree contract values once with a lead site on behalf of the whole NHS; a site-specific multiplier will ensure full cost recovery for all trusts and increased transparency for industry; and an unmodifiable financial appendix will be added to the existing suite of nationally mandated contracts, developed and agreed with the sector.

Further to this, the NHS England-led programme will explore the expansion of the scope of NCVR to include early phase studies and advanced therapy medicinal products (ATMPs) from October. The NCVR delivery partners, HRA, National Institute for Health and Care Research (NIHR) and DHSC, will also establish a working group to agree and implement national commercial clinical trials contracting documents and technical review processes, backed by an additional £15.75 million over 3 years provided by the NIHR.

The group will also explore (i) extension to existing indemnity arrangements to cover all risks associated with operating clinical trials, and (ii) measures that could be used to incentivise NHS sites to accept mandatory national contracting provisions. An initial review and plan will be completed by the autumn.

Provide ‘real-time’ data on commercial clinical activity in the UK

To address the lack of transparency and data about commercial clinical trials, as outlined by the second problem statement, the review made 2 recommendations. The government recognises that NIHR currently collects and manages clinical research performance data, with around 6,000 clinical trials currently included on the NIHR Clinical Research Network’s portfolio. In addition, the NHS-NIHR’s Be Part of Research platform helps the public, patients and clinicians find out about health and social care research taking place across the UK, including commercial trials.

However, these existing arrangements can be further enhanced to improve transparent and easy access to data and information. The government therefore accepts both recommendations, with delivery to begin immediately, and backed by £81 million over 3 years, provided by the National Institute for Health and Care Research. This will benefit all NIHR Clinical Research Network portfolio research from all funding sources, and ensure that transparency and accessibility for patients, clinicians and research funders is enhanced.

In the immediate term, while the systems to deliver this commitment in full are in development, we will continue monthly reporting of key performance indicators building on the approach implemented in Research Reset. Discovery work for collection and publication of clinical trials performance data has begun and will complete by winter 2023. Discovery work and development of a UK-wide plan to further develop Be Part of Research as the UK trial directory will also be complete by autumn 2023.

Establish a common approach to contacting patients about research

The review's seventh problem statement covers health data and notes how it can be used to give patients the opportunity to participate in clinical trials of innovative treatments. The review puts forward 2 recommendations, including establishing a common approach to contacting patients to take part in research and achieving greater data usage for research delivery in a way that commands public trust.

The government accepts both recommendations. The HRA will work closely with its Confidentiality Advisory Group, the National Data Guardian, the Information Commissioner's Office, DHSC and NHS England to establish measures that streamline the processes to approach patients about research.

This group will also establish the means by which the public should be consulted and identify whether legislation is needed to establish clinical research as part of direct care, making it easier to provide innovative treatments to patients. We will report on the outcomes of this work by Autumn 2023. This will be supported by up to £1 million funding through the NIHR Policy Research Programme to aid implementation.

Establish clinical trial acceleration networks (CTANs)

The review notes that regaining the UK's global leadership position requires restoring more 'traditional' clinical trial activities, but also recommends accelerating new and innovative ways to deliver trials.

The government accepts this recommendation and commits £20 million over 2 years to establish 2 to 3 clinical trial acceleration networks, most likely in the research areas of infectious disease vaccines, cancer and dementia.

This funding will be used to deliver innovative, efficient and effective approaches for clinical trials, enabling the UK to lead globally on the delivery of high-quality

research. These networks will support emerging place-based knowledge clusters to ensure that research delivery is spread both nationally and at a local level. We will plan to use the CTANs as exemplars for the development and spread of new approaches for the benefit of the whole clinical research system.

Foundational actions

Alongside the 5 headline commitments set out above, the government also accepts in principle the foundational actions set out by the review. The UK Clinical Research Recovery, Resilience and Growth (RRG) Programme will develop SMART objectives for commercial clinical research and report these regularly to the Life Sciences Council.

Implementation update

Through the government response, we have committed up to £121 million over 3 years and agreed to take forward 5 headline commitments, underpinned by the foundational actions recommended by the review. Progress against these actions will begin immediately, with reporting on progress to be made to the Life Sciences Council. A full implementation update on this progress will be published in autumn, where the government will also set out a comprehensive response to the review, outlining further detail where appropriate alongside decisions on the recommendations not covered in this response.

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