Launch of clinical trial reforms

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Patients in the UK to get access to new treatments faster and still safely under new clinical trial regulations coming into force on 28 April 2026.

The Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) are introducing the largest package of reforms in over 20 years. This will include faster assessment of first in human trials and the introduction of notifiable trials, a fast-track route to allow lower-risk trials to start sooner and modification to be approved quicker, whilst maintaining the highest safety standards.

The reforms will make it simpler to start lower-risk studies, strengthen support for early-stage research and embrace new approaches, including use of early safety data from overseas studies which meets UK standards and computer model simulations which can help to predict how new medicines may behave before they are tested in patients.

The regulators have already made headway towards delivering more streamlined and efficient approvals, which has contributed to exceeding the government’s ambitious target to reduce clinical trial set-up times to 150 days as part of its 10-year plan for the NHS. Latest figures show the contribution of the MHRA and HRA reducing set-up times from 169 days to just 122 days for studies going through combined safety and ethical review. The combined review process conducted by MHRA and HRA takes an average of 41 days, less than half of the time it took a few years ago.

This is good news for patients and researchers, enabling new trials to be set up more quickly and improving patient care. Innovations include the Route B substantial modification pathway which was successfully piloted from October 2025 to March 2026 and received strong support from the research community. It offers a faster, risk proportionate way to assess certain substantial modifications that do not introduce new safety concerns.

During the pilot, applications were processed in an average of just seven calendar days. Over half of registrations came from commercial sponsors, demonstrating strong industry engagement. From 28 April 2026, Route B will be legally mandated as part of the new regulatory framework. Under Route B, eligible modifications are automatically approved unless concerns are raised within calendar 14 days to inform the sponsor that a full assessment is being undertaken.

Working in partnership, the MHRA and HRA have sought the views of patients, researchers, doctors and industry to inform and develop the new framework. The regulations have the safety of trial participants firmly at their heart. They will broaden access and ensure greater transparency, including making registration of clinical trials and publication of summary results a legal requirement for the first time.

Dr Zubir Ahmed, Health Innovation and Safety Minister, said:

“This is a landmark moment for patients, researchers, and our thriving life sciences sector that will make a real, tangible difference for thousands of people waiting for new treatments.

“By introducing faster routes for lower-risk trials, embracing modern technology, and making the system simpler to navigate, we are reinforcing the UK’s position as one of the most attractive places

in the world to invest in cutting-edge research.

“The government set itself an ambitious target to cut clinical trial set-up times to 150 days — and I’m proud to say we’ve gone further and faster than that. We have driven those times down to just 122 days from 169 this time last year for commercial trials, meaning patients across the UK are getting the latest, most innovative treatments sooner than ever before.”

MHRA Chief Executive, Lawrence Tallon, said:

“These reforms to clinical trial regulations are a boost both for patients and industry investment in R&D in this country. They will help to make the UK a more attractive, internationally competitive destination for both commercial and non-commercial clinical research. Most importantly, patients will benefit from earlier access to the latest, innovative medicines.

“We have listened carefully to the needs of patients, clinicians, researchers and industry to ensure we are delivering the most efficient, streamlined approvals process without compromising safety.”

Chief Executive of the HRA, Matt Westmore, said:

“The updated regulations will bring greater transparency, faster approvals for clinical trials and simpler approaches for low-risk trials – making it quicker and easier to set up and run trials while placing patients at the centre of medical research.

“Not only will the new framework speed up vital research that could lead to innovative and improved treatments for patients, but it will support a streamlined, joined up and proportionate clinical research system. The reforms are designed to speed up access to new medicines and boost the UK life sciences economy by making it easier to do research that people can trust.”

The MHRA Clinical Trials (CT) Hub provides clear, practical guidance to help sponsors apply the new regulations. It brings together guidance and recorded webinars in one place. Guidance has been shaped by extensive feedback from both commercial and non-commercial stakeholders. You can stay up to date with developments by registering to ‘Get emails about this page’ on each set of guidance that you’re going to use.

Notes to editors

- The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

- The MHRA is an executive agency of the Department of Health and Social Care.

- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

- About the Health Research Authority (HRA): We are an arm’s length body of the Department of Health and Social Care (DHSC), which means the Government has devolved some of its responsibilities to us. Our vision is for high quality health and social care research today,

which improves everyone’s health and wellbeing tomorrow. We help realise this by making it easy to do research that people can trust. You can find out more about what we do at hra.nhs.uk

https://www.gov.uk/government/news/launch-of-clinical-trial-reforms