Press release

UK clinical trial approval times twice as fast with AI and reforms

Patients receive earlier access to life-saving treatments as UK trial approval times cut in half from 91 to just 41 days.

From:
Medicines and Healthcare products Regulatory Agency

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The time it takes to approve clinical trials in the UK has been cut by more than half – from an average of 91 days to just 41 days – following major reforms backed by new digital platforms at the Medicines and Healthcare products Regulatory Agency (MHRA), new research confirms.

This means patients can safely access promising new treatments – from cancer therapies to rare disease studies – several weeks sooner than before.

The progress helps support the Prime Minster's ambition to turbocharge clinical research, to fast-track clinical trials and reduce set-up time to less than 150 days by March 2026.

Findings published this week (6 October) in the British Journal of Clinical Pharmacology (BJCP), show the reforms are delivering consistently strong results, with 99 per cent of applications reviewed within statutory timelines, and most completed well ahead of target.

The study is the first comprehensive review of the MHRA's new way of reviewing trials based on their level of risk, introduced in 2023, showing how it speeds up review timelines while protecting patient safety.

A fast-track route allows some lower-risk studies to be approved in just 14 days. For example, under the 14-day notification scheme, a haemophilia A trial was able to begin several weeks earlier than expected, giving patients with this serious bleeding disorder faster access to potentially life-changing therapy.

Building on this, artificial intelligence (AI) is now being introduced to further support assessors – helping review complex data and improve consistency – while final decisions continue to rest with experienced assessors to ensure patient safety.

The reforms also support wider Government efforts to modernise the UK's research landscape through the 10 Year Health Plan – streamlining trial setup by slashing red tape, simplifying paperwork and introducing a national standardised contract to remove months of delay.

Millions of people will also be able to search for and sign up to lifechanging clinical trials, via the NIHR Be Part of Research service on the NHS App, allowing patients to browse and find the trials best suited to their interests and needs.

Health Minister Stephen Kinnock said:

“We are halving approval times and streamlining processes, so NHS patients are at the front of the queue and receiving life-changing treatments faster than ever before.

“As we shift from analogue to digital, we are harnessing AI alongside cutting red tape and reforming bureaucratic processes so patients can receive medicines in just 41 days instead of 91.

“We are getting on with modernising our NHS for patients and making it fit for the future – because when someone is fighting for their health, every day matters.”

MHRA Chief Executive Lawrence Tallon said:

“These reforms put patients first, helping them access innovative treatments sooner while maintaining the highest safety standards. They also give researchers and global companies the certainty they need to plan and invest here in the UK. By more than halving approval times through digital tools with proportionate oversight that prioritises patient safety, we are increasing the efficiency and attractiveness of the UK’s clinical trial ecosystem and reinforcing our global reputation as a leading destination for cutting-edge research.”

How digital reforms are transforming clinical trial approvals

AI is helping support clinical trial assessors, scanning thousands of pages of data to flag potential issues for human review. Two new bespoke MHRA AI tools are taking this further. The Knowledge Hub helps assessors spot common issues seen in past applications, so they can give trial sponsors clearer, higher-quality advice from the start – helping well-designed trials get underway sooner. The Good Manufacturing Practice (GMP) Compliance Checker verifies manufacturing documents in seconds instead of hours, freeing up experts to focus on complex safety assessments.

Meanwhile, digital dashboards provide real-time visibility of all active applications in the UK's trial portfolio, helping the MHRA track performance and deliver more predictable timelines.

The MHRA's Combined Review process with the Health Research Authority runs ethical and regulatory assessments in parallel, cutting duplication for researchers and industry, offering a single, streamlined route into the UK system.

Together, these tools mean the UK can maintain rigorous safety standards and handle increasingly complex studies, such as advanced cell and gene therapies or personalised treatments, without slowing down.

Proven results of a risk-proportionate approach

The BJCP analysis conducted by the MHRA in collaboration with the University of Liverpool, reviewed more than 4,600 clinical trials initial applications and amendments in the first year of the MHRA's risk-proportionate approach, launched with patient input in August 2023. Almost all initial applications (99 per cent) were completed within the statutory 30-day timeframe, and 99.9% of amendments within 35 days – with many decisions delivered well ahead of target.

Professor Andrea Manfrin, MHRA Deputy Director, Clinical Investigations

and Trials, and lead author of the study, said:

"The data confirms that our new approach is delivering for both patients and researchers, to create a system that is safe, faster, fairer and more predictable. Digital innovation and risk-proportionate oversight mean lower-risk studies can move ahead without unnecessary delay, while higher-risk trials still receive the detailed expert review they require. Researchers can know they're in good hands, with a regulator ready to support complex, next-generation therapies – and patients can be confident that safety always comes first."

Professor Sir Munir Pirmohamed, co-author of the study at the University of Liverpool, said:

"The data on the risk proportionate approach are impressive showing that 99% of clinical trial applications are being completed within the statutory timelines. This is excellent news for trialists and for patients getting access to innovative medicines. It is always going to be important to continually review how well the system is working, ensuring that patient safety is the foremost priority in the assessment of the clinical trial applications."

Building on success

The reforms deliver on government commitments in the 10 Year Health Plan for England and Life Sciences Sector Plan, and support the Prime Minister's pledge to turbocharge clinical research and cut clinical trial set-up times to just 150 days.

The MHRA is now building on this progress. Its first nationwide study of the UK clinical trial landscape also highlighted opportunities to improve diversity in research, address under-represented conditions, and attract greater international investment.

New legislation coming into force in April 2026 will embed these reforms

further. All UK clinical trials will be required to publicly register and publish their results, including easy-to-read summaries for participants. This means for the first time patients will be able to see, in plain language, what a study found – a move that could help strengthen trust in science and encourage more people to take part in research.

The legislation will also give sponsors more flexibility, by extending the deadline to respond to regulator feedback from 14 to 60 days – helping align with international trial timelines.

Together, these changes position the UK as a global leader in clinical research – offering speed, certainty and innovation while maintaining rigorous standards that protect patients and build public confidence in medical research.

Notes to editors

1. Manfrin A. et al. (2025) 'Evaluation of the MHRA's introduction of a risk-proportionate approach for clinical trials: an analysis of 4617 applications assessed between September 2023 and August 2024' British Journal of Clinical Pharmacology. DOI: 10.1002/bcp.70308.
2. Lee K. et al. (2025) 'A Multidisciplinary Approach for Developing Two Bespoke AI Tools to Support Regulatory Activities Within the MHRA Clinical Trials Unit' ASA Biopharmaceutical Report. https://asabiopreport.substack.com/p/a-multidisciplinary-approach-for?r=4mybjq&utm_campaign=post&utm_medium=web&triedRedirect=true
3. Lee K. et al. (2025).The Evolution of Digital Transformation to Support the UK Clinical Trials Regulation.: https://globalforum.diaglobal.org/issue/september-2025/the-evolution-of-digital-transformation-to-support-the-uk-clinical-trials-regulation/
4. Performance data is available at: MHRA Performance Data - GOV.UK.
5. Manfrin A. et al. (2025) 'Analysis of 4616 clinical trial initial submissions

received by the MHRA between February 2019 and October 2023' British Journal of Clinical Pharmacology. DOI: 10.1002/bcp.70061.

6. 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.
7. The MHRA is an executive agency of the Department of Health and Social Care.
8. For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

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