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Press release

MHRA highlights “remarkable” progress and launches real-world data consultation on International Clinical Trials Day

“…the MHRA is once again taking a global lead” says Lord O’Shaughnessy

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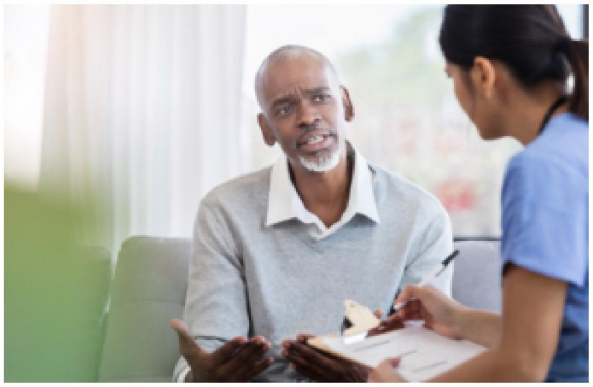

Major progress has been made in delivering a more efficient and adaptable regulatory framework for clinical trials, the Chief Executive of the Medicines and Healthcare products Regulatory Agency (MHRA) has reflected on International Clinical Trials Day.

New regulations (https://www.gov.uk/government/news/clinical-trials-regulations-signed-into-law) – which represent the most significant update to the UK clinical trials landscape in 20 years – are designed to put participants firmly at the centre of how trials are run, while supporting faster, more streamlined approvals, making it easier to test new treatments in the UK.

Lawrence Tallon, MHRA Chief Executive said:

“I’ve experienced first-hand the life-changing impact clinical research can have on patients and their families. This, combined with the benefits it brings to the economy, is why it’s so important we ensure the UK is one the most attractive places in the world to conduct trials.

“The UK is already a research powerhouse driven by innovation, with one in eight trials in the UK testing treatments in humans for the first time.

“But we want to go further. Last month, we began implementing the most significant update to UK clinical trials regulation in over two decades. These reforms will address the research sector’s need for a more risk-proportionate regulatory framework for clinical trials and will help get cutting-edge new treatments to the NHS as quickly as possible.”

Lord O’Shaughnessy, former health minister, senior partner at Newmarket Strategy and author of the landmark report (https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report) into the UK commercial clinical trials landscape said:

“The progress the MHRA has made in the two years since I published my review has been remarkable. Despite its global reputation for excellence, by 2023 trial approval set up times had slipped badly.

“The MHRA is now delivering consistently good approval times while introducing further reforms to add speed and flexibility to the process.

“With a clear mandate from the Prime Minister to reduce trial set up times to 150 days – which would be genuinely world-leading – the MHRA is once again taking a global lead.”

Professor Sir Martin Landray, Chief Executive of Protas, said:

“I am delighted with the progress the MHRA has made to deliver an efficient and coordinated regulatory process for clinical trials.

“Innovation in clinical trials is much needed if we are to find better ways to prevent and treat the growing burden of common and life-threatening diseases. The UK can be in pole position to lead the charge, and regulatory enlightenment is a key part of this journey.”

Developed in partnership with the Health Research Authority (HRA), and shaped by feedback from patients, researchers, doctors, and industry, the new regulations will take full effect from April 2026, following the 12-month implementation period.

To ensure these substantial reforms are phased in effectively, the MHRA and Health Research Authority (HRA) will be producing updated guidance.

Already, the MHRA and HRA have launched a pilot Inclusion and Diversity Plan (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/increasing-diversity-people-taking-part-research/developing-our-inclusion-and-diversity-plan-and-supporting-guidance/). Shaped by input from over 300 researchers, it offers practical guidance to help sponsors design more representative studies, to ensure that trials represent the populations they are designed to treat.

In the meantime, the MHRA has embedded improvements in processing clinical trial applications into standard working practice, with 100% of clinical trials and investigations applications having been handled within statutory timescales since September 2023.

Combined Review approval time with the Health Research Authority is now at 60 days or less for all trials, with an average time for Combined Review determination (including questions raised) of 40 days in March 2025.

Launch of consultation on use of real-world data

Beginning on International Clinical Trials Day, the MHRA is launching a six-week consultation (https://www.gov.uk/government/consultations/mhra-draft-guideline-on-the-use-of-external-control-arms-based-on-real-world-data-to-support-regulatory-decisions) on the use of real-world data for external control arms of clinical trials, which has the potential to help accelerate the approval of treatments, especially in cases when randomised controlled trials may not be ethical or feasible. It is another example of the work the MHRA is doing to support the set-up of innovative trials.

Real-world data refers to information that is collected from patients during the course of their normal clinical care. Data can include electronic health records (EHR), disease and patient registries, and patient reported outcomes (PRO) data, alongside data from other sources. Once this data is analysed, the information is referred to as real-world evidence (RWE).

The new guidance is for those planning a clinical trial which may include a real-world data external control arm with the intention of using the trial to support a regulatory decision on a medical product. This means that a control arm of the study would use data from patients not part of a specific clinical trial.

To access the guideline and participate in the consultation, please visit the MHRA website (https://www.gov.uk/government/consultations/mhra-draft-guideline-on-the-use-of-external-control-arms-based-on-real-world-data-to-support-regulatory-decisions).

Notes to editors

- Today (20 May 2025) is International Clinical Trials Day, which recognises the day the first randomized clinical trial began in 1747. As part of celebrations, the MHRA is proud to support the National Institute for Health and Care Research (NIHR) in its #BePartofResearch campaign (https://bepartofresearch.nihr.ac.uk/)
- The Lord O’Shaughnessy review (https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review) into UK commercial clinical trials made 27 recommendations where action should be taken by the government and delivery partners, including the Medicines and Healthcare products Regulatory Agency (MHRA), to address key challenges and transform the commercial clinical trials environment. The Government has committed to implementing his recommendations in full.
- The real-world data guidance is one of a series of guidelines (https://www.gov.uk/government/publications/mhra-guidance-on-the-use-of-real-world-data-in-clinical-studies-to-support-regulatory-decisions) on the use of real-world data for supporting regulatory decisions
- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

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