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MHRA's regulatory renaissance: Why the UK is now a strategic hub for early clinical trials

A KEY QUESTION

Why has the UK emerged as a strategic hub for early-phase clinical trials?

KEYWORDS Early-Phase Research, Phase I Clinical Trials, MHRA, Study Efficiency, Optimized Study Location

The strategic importance of regulatory efficiencies

In the race to bring new therapies to market, time is the most critical concern. For sponsors, delays anywhere in the development cycle are a concern, especially those that are out of the immediate control of the development team. One such area is in regulatory approvals, where delays can derail development timelines, inflate costs and impact investor confidence. Another area is in import/export rules. And still another is in participant availability.

Historically, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) faced scrutiny for approval delays—particularly in the wake of the UK's "Brexit" from the European Union, and also from the impact of the COVID-19 pandemic.

However, the situation has shifted dramatically. Today, the MHRA is recognized for its predictable timelines, streamlined processes, digital innovation and sponsor-centric reforms that have repositioned the UK as a premier destination for Phase I clinical trials.

The UK also enjoys an abundance of participants. The NIHR report that, as of August 2024, over 528,000 people have signed up, and about 50,000 had already participated in studies.[1] Little wonder why the UK is now considered among the most attractive global locations for such studies.

MHRA's transformation: From backlogs to benchmarks

The MHRA's turnaround is a testament to its commitment to the industry. In 2023, the agency took steps to address the backlog of regulatory approvals, clearing the backlog of Clinical Trial Applications (CTAs), and restoring confidence in its operational capacity.

Sponsors now benefit from consistent delivery of statutory timelines—30 days for initial review and less than 60 days for final decisions[2]—making the UK one of the most predictable regulatory environments globally. MHRA timeline performance data is regularly published, giving sponsors the ability to view up to date trends. MHRA Performance Data - GOV.UK.

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Combined review and integrated ethics

One of the most impactful reforms has been the introduction of the Combined Review process, which integrates ethics and regulatory approvals into a single streamlined pathway. This innovation has significantly reduced duplication and administrative burden for sponsors, replacing what was once a fragmented system with a unified approach that accelerates timelines and improves predictability.

Under this model, sponsors submit a single application that is jointly assessed by the MHRA and a Research Ethics Committee, ensuring that regulatory and ethical considerations are addressed in parallel, delivering an efficiency gain that has positioned the UK as a leading destination for early-phase trials. For organizations navigating complex first-in-human studies, this integrated review speeds up approvals.

Fortrea has embraced the Combined Review framework to help sponsors capitalize on these benefits. With extensive experience in submitting CTAs under this process, Fortrea's regulatory team facilitates the proper preparation of applications, with the aim of reducing risk and avoiding delays.

Digital acceleration and AI tools

The MHRA has embraced digital transformation with tools like Knowledge Hub and GMP Compliance Checker, which use AI to automate document handling and compliance verification.

Real-time dashboards and automated workflows have reduced variability and increased transparency, allowing sponsors to track progress and respond proactively.[3]

Global acceptability and strategic value

MHRA approvals are globally respected, thanks to alignment with ICH and FDA standards.[4,5] The International Recognition Procedure (IRP) and the Innovative Licensing and Access Pathway (ILAP) further enhance the UK's appeal by facilitating international collaboration and faster access to global markets.[6]

Operational efficiency and site readiness

The voluntary MHRA Phase I accreditation scheme is a rigorous program for the most advanced clinical research units, in particular for those conducting first in human (FIH) trials. The program is intended to ensure that Phase I trials are conducted in a manner that ensures the highest level of safety and to increase public trust in the regulation and conduct of these trials.

Accredited entities must exceed the basic good clinical practice (GCP) standards by having additional procedures that include the highest standards for avoiding harm to trial subjects and for handling any medical emergencies.

Fortrea's CRU in Leeds, UK has been accredited since the inception of the MHRA program. The award-winning research unit represents a state-of-the-art facility, backed by a team with 35+ year's operating history. It is supported by world-class scientific infrastructure and is widely recognized as an outstanding and sophisticated clinical research unit.

Fortrea's site in Leeds has demonstrated the ability to deliver 12-week start-up timelines, helping to offer sponsors speed without compromising quality. Combined with favorable cost structures and experienced personnel, the UK presents a compelling operational proposition.

Legislative reform and future outlook

Looking ahead, the MHRA is preparing for further legislative reforms in April 2026, including mandatory public trial registration and extended sponsor response timelines. These changes reflect a commitment to transparency, accountability and continuous improvement—hallmarks of a modern regulator.

Conclusion: The UK advantage for early-phase sponsors

The MHRA's transformation has redefined the UK's role in global clinical research. For pharmaceutical sponsors, the combination of regulatory reliability, digital innovation and strategic alignment can make the UK an ideal location for Phase I trials.

At a time of political and economic uncertainty in key research territories and patient scarcity in others, this alignment with ICH and FDA make the UK an ideal location for clinical research.

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