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Collection

Medicines: clinical trials hub

Legal framework, regulatory requirements, and supporting guidance needed to design, apply for, conduct, modify, close, and comply with UK legislation for clinical trials for medicines in the UK.

From: **Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)**

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Contents

UK Legislation

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 came into force 28 April 2026.

The Medicines for Human Use (Clinical Trials)Regulations 2004 (https://www.legislation.gov.uk/uksi/2004/1031/contents)

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (https://www.legislation.gov.uk/uksi/2025/538)

The Human Medicines Regulations 2012 (https://www.legislation.gov.uk/uksi/2012/1916/contents)

Regulatory Framework

Important Note: This guidance is designed to assist sponsors and investigators in complying with their duties in relation to clinical trials. This page includes links to pages containing general guidance only. It must not be regarded as a definitive interpretation of the Regulations or a substitute for the regulations.

The MHRA cannot provide a definitive interpretation of the law; only the courts can do this. If in doubt you should seek your own legal advice.

International guidance

ICH Efficacy Guidelines (https://www.ich.org/page/efficacy-guidelines)

Other relevant guidance

Health Research Authority (https://www.hra.nhs.uk/)

MHRA guidance

The amended Clinical Trials Regulations took full effect on 28 April 2026. As such, this guidance should now be considered effective and is no longer in draft.

Clinical trials for medicines: Compliance with ICH E6 good clinical practice (GCP) in the United Kingdom
(/guidance/clinical-trials-for-medicines-compliance-with-ich-e6-good-clinical-practice-gcp-in-the-united-kingdom)
28 April 2026 Guidance

Clinical trials for medicines: guidance on quality and risk proportionality
(/guidance/clinical-trials-for-medicines-guidance-on-quality-and-risk-proportionality)
28 April 2026 Guidance

Clinical trials for medicines: International Council for Harmonisation (ICH) annotations
(/government/publications/international-council-for-harmonisation-ich-e6r3-annotations)
28 April 2026 Guidance

Clinical trials for medicines: Clinical Trials Regulations transitional arrangements
(/guidance/clinical-trials-for-medicines-clinical-trials-regulations-transitional-arrangements)
28 April 2026 Guidance

Clinical trials for medicines: Declaration of Helsinki and Clinical Trial Regulations alignment
(/government/publications/clinical-trials-for-medicines-declaration-of-helsinki-and-clinical-trial-regulations-alignment)
28 April 2026 Guidance

Clinical trials for medicines: MHRA phase I accreditation scheme
(/guidance/clinical-trials-for-medicines-mhra-phase-i-accreditation-scheme)
6 March 2026 Guidance

Medicines: get scientific advice from the MHRA
(/guidance/medicines-get-scientific-advice-from-mhra)
4 March 2026 Guidance

Applying for clinical trial approval

Clinical trials for medicines: apply for approval in the UK
(/guidance/clinical-trials-for-medicines-apply-for-approval-in-the-uk)
28 April 2026 Guidance

Clinical trials that include an in vitro diagnostic device
(/government/publications/clinical-trials-that-include-an-in-vitro-diagnostic-device)
9 March 2026 Guidance

Clinical trials for medicines: notifiable trials
(/guidance/clinical-trials-for-medicines-notifiable-trials)
28 April 2026 Guidance

Common issues identified during clinical trial applications
(/government/publications/common-issues-identified-during-clinical-trial-applications)
28 April 2026 Guidance

Clinical trials for medicines: expert advice
(/guidance/clinical-trials-for-medicines-expert-advice)
28 April 2026 Guidance

IMPs & NIMPs

Clinical trials for medicines: labelling
(/guidance/clinical-trials-for-medicines-labelling)
28 April 2026 Guidance

Clinical trials for medicines: non-investigational medicinal products
(/guidance/clinical-trials-for-medicines-non-investigational-medicinal-products)
28 April 2026 Guidance

Clinical trials for medicines: good manufacturing practice and radiopharmaceutical investigational medicinal products
(/guidance/clinical-trials-for-medicines-good-manufacturing-practice-and-radiopharmaceutical-investigational-medicinal-products)
28 April 2026 Guidance

Clinical trials for medicines: Diagnostic Radiopharmaceutical Investigation Medicinal Products and Good Manufacturing Practice requirements

(/government/publications/clinical-trials-for-medicines-diagnostic-radiopharmaceutical-investigation-medicinal-products-and-good-manufacturing-practice-requirements)

28 April 2026 Guidance

During the clinical trial

Clinical trials for medicines: collection, verification and reporting of safety events

(/guidance/clinical-trials-for-medicines-collection-verification-and-reporting-of-safety-events)

28 April 2026 Guidance

Clinical trials for medicines: roles and responsibilities

(/government/publications/clinical-trials-for-medicines-roles-and-responsibilities)

28 April 2026 Guidance

Clinical trials for medicines: Notification of Serious Breaches of GCP or the trial protocol

(/government/publications/clinical-trials-for-medicines-notification-of-serious-breaches-of-gcp-or-the-trial-protocol)

28 April 2026 Guidance

Making changes to trials

Clinical trials for medicines: modifying a clinical trial approval

(/guidance/clinical-trials-for-medicines-modifying-a-clinical-trial-approval)

28 April 2026 Guidance

Ending a trial

Clinical trials for medicines: ending a clinical trial

(/guidance/clinical-trials-for-medicines-ending-a-clinical-trial)

28 April 2026 Guidance

Clinical trials for medicines: Archiving and retention of clinical trial records
(/government/publications/clinical-trials-for-medicines-archiving-and-retention-of-clinical-trial-records)
28 April 2026 Guidance

Compliance

Clinical trials for medicines: Good clinical practice inspections
(/guidance/clinical-trials-for-medicines-good-clinical-practice-inspections)
28 April 2026 Guidance

Clinical Trials Regulations enforcement provisions
(/government/publications/clinical-trials-regulations-enforcement-provisions)
28 April 2026 Guidance

News and blogs

Route B substantial modifications pilot: the results are in (https://mhrainspectorate.blog.gov.uk/2026/04/27/route-b-substantial-modifications-pilot-the-results-are-in/)

MedRegs blog (https://medregs.blog.gov.uk/)

Inspectorate blog (https://mhrainspectorate.blog.gov.uk/)

Launch of clinical trial reforms
(/government/news/launch-of-clinical-trial-reforms)
27 April 2026 Press release

Clinical Trials Regulations webinar recordings
(/guidance/clinical-trials-regulations-webinar-recordings)
25 March 2026 Guidance

Payments and fees

Payments for DSUR submissions by credit or debit cards can be made via our payment centre (https://products.payments.service.gov.uk/pay/8a0fe506df%0A06403a85e912be3a8ad76f).

MHRA fees
(/government/publications/mhra-fees)
21 April 2026 Statutory guidance

Make a payment to the MHRA
(/guidance/make-a-payment-to-mhra)
2 September 2025 Guidance

Archived guidance

Access previous versions of MHRA Guidance from the UK Government Web Archive (https://www.nationalarchives.gov.uk/webarchive/find-a-website/access-an-archived-page-from-a-live-website/)

Guidance - before 28 April 2026

Clinical Trials guidance that should be followed prior to 28 April 2026.

Route B substantial modification pilot
(/government/publications/route-b-substantial-modification-pilot)
21 January 2026 Guidance

Clinical trials for medicines: apply for authorisation in the UK
(/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk)
31 March 2026 Guidance

Clinical trials for medicines: manage your authorisation, report safety issues
(/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues)
9 June 2025 Guidance

Published 21 September 2023
Last updated 28 April 2026 - hide all updates

28 April 2026

This page has been updated to streamline and clarify information in light of recent changes to clinical trials legislation. Content has been reorganised, references updated, and links improved to direct users to current online guidance.

23 April 2026

Notification published of system updates and downtime, in preparation for the transition to the new Clinical Trials Regulations that are mandated on 28 April 2026.

27 March 2026

Added 'Clinical trials for medicines: guidance on quality and risk proportionality' and 'Clinical trials for medicines: guidance on compliance with ICH E6 good clinical practice (GCP) in the United Kingdom'.

9 March 2026

Added guidance document 'Clinical trials for medicines: good manufacturing practice and radiopharmaceutical investigational medicinal products'.

12 January 2026

Added 'International Council for Harmonisation (ICH) E6R3 Annotations'

12 January 2026

Added the following guidance pages to the collection:
- Declaration of Helsinki and Clinical Trial Regulations alignment
- Clinical Trials Regulations enforcement provisions
- Archiving and retention of clinical trial records

12 January 2026

Added 'Common issues identified during clinical trial applications' to the group 'Guidance - before 28 April 2026'.

1 October 2025

Added link to payment DSU Payment centre to Pay an fees section of the collection.

18 August 2025

Added new page to collection: Route B substantial modification pilot

25 June 2025

Links added for draft guidance, to support amendments that come into force 28 April 2026.

21 September 2023

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