Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
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Faculty webinar: Forthcoming changes to clinical trial legislation and approvals processes

Cat Johnston, GCP Training Manager

Gurmel Bachu, Approvals Manager

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NIHR | National Institute for Health and Care Research

The UK Clinical Trials regulations and Good Clinical Practice (GCP) are changing

Version 1.3 May 2025

Background on the Clinical Trial Regulations and GCP - This is where we are

The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended)

Clinical trial regulations govern the design, conduct, and reporting of trials

ICH GCP E6 R2

GCP ensures ethical standards, participant safety, and data integrity

Background on the Clinical Trial Regulations and GCP - This is where we are going

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Clinical trial regulations govern the design, conduct, and reporting of trials

ICH GCP E6 R3

GCP ensures ethical standards, participant safety, and data integrity

What do you need to know?

- The Medicines for Human Use (Clinical Trials) Regulation 2004 is being revised.

- ICH GCP E6 **R3** will be implemented in the regulations above.

28 April 2026

ICH GCP E6 (R3) Principles will be legally required to be complied with for all trials of medicinal products as per the UK Clinical Trial Legislation from this date.

Why are the regulations being updated?

- To ensure we include all participants and promote the inclusion of underserved populations in clinical trials, aiming to increase diversity.

- To ensure patients and their safety are at the focus of all clinical trials and bring the benefits of clinical trials to everyone.

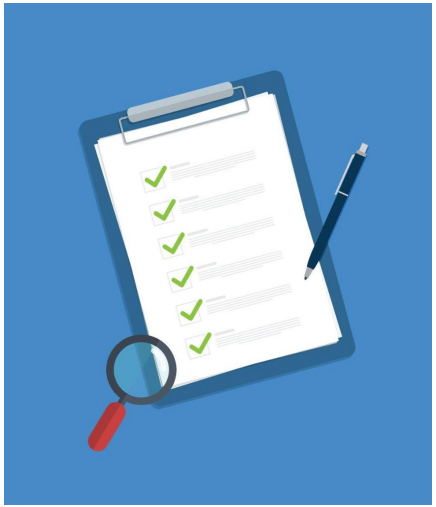
Why are the regulations being updated?

- To create a proportionate and flexible regulatory environment.
- To cement the UK as a destination for international trials.
- To provide a framework which is streamlined, agile and responsive to innovation.

Reasons for the updates

Risk-based	Innovation	Consistency	Flexibility
Efficiency	Data-integrity	Technology	Inclusion

Revision changes at a glance



- Approvals
- Transparency
- Safety Reporting and Pharmacovigilance
- Consent

This revision supports a more streamlined and flexible approach to the regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants.”

COMING SOON:
Proposed Guidance topics from the MHRA and HRA

Broad

- ➔ Implementation of ICH (GCP) E6 (R3) principles
- ➔ Risk proportionality and risk assessment
- ➔ Sponsor responsibilities & oversight

Specific

- ➔ Archiving
- ➔ Labelling
- ➔ Radiopharmacy

Explanatory

- ➔ Regulatory actions
- ➔ Declaration of Helsinki

Changes in our landscape

Updates in our definitions and terminologies

- Subjects → Participants
- Trial Site → Trial Location
- Amendment → Modification
- Essential Documents → Essential Records

Critical to Quality Factors (CtQ)

Critical to Quality Factors focus attention on the aspects of a trial that have the greatest impact on participant safety, data integrity, and the credibility of the results.

Critical to quality factors are intrinsic to risk proportionality.

Who can be an Investigator

- A doctor
- A registered nurse / midwife
- A dentist
- A pharmacist
- An optometrist
- A person registered in the Health and Care Professions Council register as a member of a relevant profession
- A registered chiropractor
- A person registered under the Anaesthesia Associates and Physician Associates order

Relevant professions registered with HCP Council:

- Arts therapist
- Chiropodists
- Clinical scientists
- Dietitians
- Medical laboratory technicians
- Occupational therapists
- Orthoptists
- Paramedics
- Physiotherapists
- Prosthetists and orthotists
- Radiographers
- Speech and language therapists

Who can act as an investigator (continued)

In accordance with Regulation 3B of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025;

> 3B. The investigator, in relation to a clinical trial, shall be a health care professional who is appropriately trained to undertake that role in a clinical trial."

This individual will need **appropriate support for any medical decisions in regards to the trial.**

Timings matter

- Extension of urgent safety measure reporting to 7 days (but expect initial phone call within 24 hours)
- Lapse of clinical trial approval - After 24 months if trial has not recruited
- Retention of trial master file and medical records required for 25 years
- Request for further information deadline - 60 days from when notice given
- Register trial in public database before first participant recruited or 90 days after approval
- Publish trial summary of results within 12 months of conclusion of the trial

The importance of Risk

The Declaration of Helsinki and GCP

The Declaration of Helsinki is the ethical foundation and forms the ethical basis for Good Clinical Practice (GCP)

1. *Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants.*

Declaration of Helsinki

- Uses “human participants” over “subjects”; stronger protections for vulnerable groups.
- Promotes meaningful community involvement.
- Recognises electronic and ongoing consent.
- Emphasises scientific rigour, ethical oversight, and open data sharing.
- Pushes for equity in research benefits and broader inclusion.
- Addresses AI, data privacy, and digital ethics.

GCP training updates…

The proportionate approach to GCP

Introduction to GCP and GCP Refresher

Awareness

- Research Practice in Clinical Settings
- Research Practice in Wider Health, Care and Community Settings

- Wales – Research Awareness Factsheet

Fundamentals

- Fundamentals for Labs
- Fundamentals for Investigational Medicinal Products

What courses need to be updated in the NIHR?

- GCP Courses - 3
- Informed Consent - 5
- Research Practice - 2
- Fundamentals - 2

What can you do

- Visit the NIHR Learn GCP Page for information.
- Read the revised Clinical Trial Regulations, ICH R3, MHRA, and HRA guidance.
- Attend webinars and discussions to stay informed.
- Assess current trials to determine regulatory applicability.
- Train staff on new requirements.
- Ensure change control processes are in place.

Key Takeaway

Use the lead time before implementation to;

- read up,
- review processes,
- make necessary adjustments,
- ensure compliance,
- work with sponsors to develop consistent approaches to working.

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Useful links

- Guidance on changes to the clinical trials regulations - Health Research Authority
- Medicines: clinical trials hub - GOV.UK (draft MHRA guidance)
- Revised Clinical Trial Regulations
- ICH R3