Developers guidance

# Determining whether a clinical investigation is needed for medical devices

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## This is required guidance

It is legally required and it is an essential activity.

## This Guide covers:

- Great Britain (England, Scotland, Wales)

## From:

- Medicines and Healthcare products Regulatory Agency (MHRA)



To get a UKCA mark for your medical device, you may need to prove its safety through a clinical investigation. Here's how to get the required approvals for the clinical investigation of medical devices.

# Clinical investigation of medical devices: what it is and why you need one

To apply the UKCA mark to a device, you must prove it meets the essential requirements of the Medical Devices Regulations (UK MDR 2002). To do this, you may need to provide clinical data through a clinical investigation to support the clinical evaluation process.

## A clinical investigation

A clinical investigation is a specific type of prospective clinical trial of medical devices that do not have a UKCA mark. It is done to prove the safety and performance of medical devices under normal conditions within the intended use.

## Clinical data

The clinical data you need might come from various sources. It might come from a critical evaluation of relevant scientific literature. You may be able to use clinical data from equivalent compliant devices to confirm the clinical safety and performance of your medical device.

Using clinical data and clinical evidence from equivalent devices will save you time and avoid redundant clinical investigations.

In this scenario, you'll need to show clinical, technical and biological equivalency.

Alternatively, an evaluation of the data produced by a clinical investigation or a combination of the 2 approaches can be used.

# MHRA and HRA approvals

A clinical investigation must have approval from the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) before it can start. This includes independent ethical opinion from a Research Ethics Committee.

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The MHRA assessment process takes up to 60 days with a result of objection or no objection given by the end of this period. HRA approval takes about 40 days.

# Clinical data for AI-driven digital technology

Analysis and evaluation of scientific literature are broad concepts. And in the case of AI-driven digital technology it may be difficult to use clinical data from equivalent compliant medical devices. This is because there is likely to be variation in the training data used between devices.

**So it is likely you'll need to do a clinical investigation of the medical device to answer outstanding questions about safety and performance.**

If a clinical investigation is not done, you may not be able to prove that the device meets the essential requirements. This could become a compliance issue and cause delays, prison sentences or fines.

# Getting approvals for the clinical investigation of medical devices

## Step 1:

Notify the MHRA in advance of your intention to apply for permission by emailing information to mhracustomerservices@mhra.gov.uk.

This should include:

- basic details of the device
- intended population
- type of study
- estimated timelines

Follow guidance on how to notify the MHRA about a clinical investigation for a medical device on GOV.UK.

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## Step 2:

Create your application on the Integrated Research Application System (IRAS). This is a single system for applications to both the HRA and the MHRA.

## Step 3:

Pay the fee listed in the current MHRA fees on GOV.UK.

## Useful resources:

ISO 14155:2020 Clinical Investigations of medical devices in human subjects – good clinical practice.

Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42 and 90/385 (MEDDEV 2.7/1 revision 4)

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.

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