



Clinical investigations and healthcare establishments

Guidance on devices which are manufactured by healthcare establishments for use on their own patients is available in the [In house manufacture](#) section.

The MHRA has identified a number of scenarios, which are arising in practice for healthcare and related establishments. We set out our view of the obligations in each of those scenarios below.

1. A healthcare establishment manufactures a medical device and sees the possibility of placing that device on the market either themselves or by selling it to another legal entity for commercial purposes.

Because the device is to be commercialised, i.e. placed on the market, it will need to comply with the provisions of the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) or the (EU) Medical Devices Regulations 2017/745 (MDR). In order to demonstrate conformity with the relevant essential requirements or general safety and performance requirements, it may be necessary for the healthcare establishment to carry out a clinical investigation. Any clinical investigation must be notified in accordance with the UK MDR 2002 (for Great Britain) or EU MDR (for Northern Ireland), even if it is carried out on patients within the same legal entity.

Where an NHS Innovation Hub is involved, it is the MHRA's opinion that a commercial application has been identified and therefore a notification to the MHRA will need to be made if a clinical investigation is necessary. The notification will need to be made prior to the clinical investigation commencing.

2. A healthcare establishment manufactures a medical device solely for use on its own patients within a clinical investigation and does not see the possibility of placing that device on the market.

Because the device is being used in-house and will not be commercialised, a clinical investigation notification to the MHRA will not be required.

3. A healthcare establishment uses a device for a purpose not intended by the manufacturer (as stated in the data supplied by the manufacturer, on the labelling, instructions for use and/or the promotional material), without the knowledge of the manufacturer.

Where a healthcare establishment uses a device within a clinical investigation on their own patients for a purpose other than that stated by the manufacturer, and without the knowledge of the manufacturer, a clinical investigation notification will not be required unless the intention of the healthcare establishment was to seek commercialisation of the device for the new intended use. However, there might be other legal consequences following from such action, such as liability for using a device for a purpose not intended by the manufacturer. Legal advice on this should be obtained.

If the action taken by the healthcare establishment involved modification of the device, it is possible that the healthcare establishment might become the manufacturer of what is now a 'new device' if their intention is to seek commercialisation of the modified device. On that basis it would be expected to notify the MHRA of any clinical investigation carried out with a view to commercialisation of that device (see scenario 1 above).

4. A healthcare establishment trials a device already on the market with regard to a new purpose (i.e. not intended by the manufacturer as stated in the data supplied by the

manufacturer, on the labelling, instructions for use and/or the promotional material) and the manufacturer is involved in that process.

Where a manufacturer is seeking to investigate a new use for a device already on the market with a view to UKCA/CE/CE UKNI marking the device for the new purpose, the MHRA considers that the clinical investigation provisions are likely to be engaged. Whether or not that is the case will depend upon the circumstances, including the nature of the study. In general, if the manufacturer is supplying the device (for free or at a reduced cost) specifically for use in the study or if they are funding part or whole of the study, it is the MHRA's opinion that the clinical investigation provisions will be engaged. The manufacturer will then be responsible for making a notification to the MHRA.

Where the study has been initiated by the healthcare establishment and the manufacturer's involvement is limited to supply of the device and/or funding, a co-sponsor agreement can be drawn up with the healthcare establishment contracting serious adverse event reporting and management of the study to the investigators.

For clinical investigations conducted in Great Britain the manufacturer will remain ultimately responsible for meeting the requirements in the UK MDR 2002.

For studies conducted in Northern Ireland the study sponsor will be responsible for submitting a clinical investigation notification to the MHRA. The manufacturer of the device will need to provide a statement that the device meets all the relevant general safety and performance requirements, apart from those to be studied in the clinical investigation.

5. A healthcare establishment is asked by a manufacturer to trial a medical device which is not yet on the market and not UKCA/CE/CE UKNI marked.

Where a manufacturer is seeking to investigate a new medical device that has not yet come onto the market and is not UKCA/CE/CE UKNI marked, we consider that the clinical investigation provisions will always need to be engaged.