

## 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 ie placed on the market, it will need to comply with the provisions of the Regulations. In order to demonstrate conformity with the relevant essential 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 Regulations, 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 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 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.**

Generally, a healthcare establishment will not be treated as a manufacturer of a device for the purposes of the Regulations because it uses that device for a purpose not intended by the manufacturer. This is because the Regulations do not cover the user. Similarly, where a healthcare establishment uses a device for a purpose other than that stated by the manufacturer on a trial basis on their own patients, the MHRA would not treat that as a clinical investigation 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. Also, 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 (ie 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 CE marking the device for the new purpose, the MHRA consider 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 trial. In general, if the manufacturer is supplying the device (for free or at a reduced cost) specifically for use in the trial or if they are funding part or whole of the trial, 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. In all cases the manufacturer will remain ultimately responsible for meeting the requirements in the Medical Devices Regulations 2002 for clinical investigations.

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

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