

What is a Competent Authority?

A Competent Authority (CA) is the body which has the authority to act on behalf of the government of a member state to ensure that the requirements of the Medical Devices Directives are carried out in that particular member state. In the UK this is done by the Medicine and Healthcare Regulatory Agency (MHRA).

When should a Competent Authority be informed of a Medical Device Clinical Study?

Competent Authority **approval** must be obtained **before** the **commencement** of the Clinical Investigation. In general, Competent Authority submission and approval for a Post-Marketing Surveillance (PMS) Study is not required.

Competent Authority Submission

The Competent Authority (MHRA) application form can be found on the MHRA website: www.mhra.gov.uk. The application form, including a section for Research Ethics Committee approval, can also be found at www.myresearchproject.org.uk using the Integrated Research Application System (IRAS). The following documents are usually required for submission:

- The final approved **Clinical Investigation Plan** including any appendices and amendments.
- A final approved **Clinical Investigator's Brochure**, including any amendments.
- A **signed statement** from the manufacturer ensuring "that the device in question **conforms** to the **Essential Requirements** except with regard to those aspects of the device that are to be investigated and that in respect of those aspects, every precaution has been taken to protect the health and safety of the patient".
- A copy of the **Patient Information Sheet, Informed Consent Form** and **GP letter**.
- Any other information given to the subject like **product leaflets, questionnaires** and **diary cards**.
- Details for **compensation** or treatment in the case of injury/death of a subject and any **insurance** or **indemnity** provided to

cover the liability of the Clinical Investigator and Sponsor.

- Details of the **financial arrangements** between the Sponsor and the Clinical Investigator, other hospital departments or the subjects.
- **Curriculum vitae** of the Clinical Investigator.
- **Application fee**. Fees for the MHRA range from £2,700 for Class I, Ia, IIb (other than long term implantable) to £3800 for Class IIb implantable or long term invasive devices, Class III and active implantable. The fee should be provided by the Sponsor in advance of the submission deadline.
- Completed Competent Authority **application forms (PCA1 and PCA2)**.
- **Research Ethics Committee** approval.

It should be noted that **6 copies** of each document must be supplied to the MHRA. Submission should be via the MHRA portal or electronically stored on disc, not on paper.

Competent Authority Approval

Research Ethics Committee approval is normally required before Competent Authority approval, but in the UK, both may be submitted in parallel. CA approval will take the form of a letter. However this may stipulate certain conditions to be met or further information to be supplied prior to giving approval. The timescale for a decision may be up to 60 days.