EU CTIMPS

If you are planning a clinical trial which involves administering medicinal products to participants, your study may fall under the EU Clinical Trials Directive. These trials are referred to as Clinical Trials of Investigational Medicinal Products (CTIMPs) and will need to meet more regulatory requirements than other kinds of clinical research projects.

Please contact the **Cambridge Clinical Trials Unit (CCTU)** in the first instance at **cctu@addenbrookes.nhs.uk**

Is my project a clinical trial?

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If you are unsure, or want to verify your decision please check the algorithm from the MHRA, see below.

It is advisable to work through this document at an early stage in planning your study.

If you believe that it is a CTIMP, your study will need approval from the Medicines and Healthcare Products Regulation Agency (MHRA) in addition to the Research Ethics Committee (REC) opinion and NHS permission.

Detailed guidance from the MHRA can be found at the link below.

Another important aspect to consider is to identify an appropriate source for your medicine that you wish to use in your trial. The medicines under investigation in your trial, the so called “Investigational Medicinal Products” (IMPs), have very specific requirements. Therefore it is important to involve pharmacy early on.

The Department of Health and the Medical Research Council provide a clinical trials toolkit which provides information on all aspects of setting up and running a CTIMP.

How do I set up a clinical trial at CUH?

First of all you need to establish who will sponsor the trial.

Will Cambridge University Hospitals sponsor my trial?

Clinical trials conducted by local investigators (Trust and University) may be sponsored by CUH or by CUH in partnership with the University of Cambridge. Please contact us as soon as possible so that we can establish sponsorship.

My trial will be sponsored by another organisation, can you help?

For those trials sponsored by other hospitals and academic institutions and where our site is just one of many taking part, please **contact** the R&D office directly.

For CTIMPs where you wish to have CUH as Sponsor (or CUH and the University as joint Sponsor) the **Cambridge Clinical Trials Unit** (CCTU) will help you with all the necessary steps for setting up a protocol, establishing necessary resources and funds, obtaining all necessary approvals, coordination and management.

Please contact the **CCTU** for further specific details.

In general, before patients can be recruited into a clinical trial the Sponsor must be satisfied that proper arrangements for all necessary regulatory requirements are in place:

- Protocol (a clinical-trial specific template is available)
- Peer review
- Ethical approval
- Clinical Trials Authorisation from the MHRA
- Pharmacy review, supply and control of the IMP (investigational medicinal product)
- The pharmaceutical company's Investigators Brochure for the drug or SmPC (Summary of Product Characteristics)
- Radiation protection
- Sponsorship and liability cover
- Tissue supply issues
- Contracts
- Safety reporting and monitoring
- Honorary contracts

These processes all take time and proper advance planning can save you time, trouble and money in the long run. Please contact therefore the **CCTU** at the very earliest stages,

preferably at the planning stages of a grant proposal.