


Standard Operating Procedure

Number:	UM/UoM CTU Selection /SOP15/3.0		
Title:	Selection and Overview of a Clinical Trials Unit		
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1.0 Background

The University of Manchester in its role as Sponsor of a clinical trial of an investigational medicinal product (CTIMP) has ultimate responsibility for the trial. The University may delegate defined functions related to a clinical trial of an investigational medicinal product (CTIMP) or a trial of a medical device to a UKCRC registered clinical trials unit (CTU). The guidance in this SOP may be used as a benchmark to assess the suitability of a CTU for involvement in a particular trial.

2.0 Purpose

To ensure legal and good clinical practice (GCP) compliance, both the University in its capacity as the Sponsor of a CTIMP/medical device trial and the Chief Investigator (CI) need to have oversight of all functions and activities delegated to a CTU. The CTU will be considered to be legally responsible when agreeing to undertake functions and activities on behalf of the University, and must therefore comply with relevant legislation, good clinical practice, and guidance required by the Medicines Health Regulatory Agency (MHRA) and the Research Ethics Committee (REC).

3.0 Procedures

3.1 Selection of Clinical Trials Unit

The process for adequately assessing and documenting the suitability of a CTU may vary according to the level of risk-based function and activity likely to be undertaken. The CI should assess a CTU for suitability using one or more of the following criteria:

1. Confirmation that the CTU has current UKCRC registration. The University is only able to Sponsor a trial if it is run via a UKCRC registered CTU.
2. Positive past experience with the CTU
3. Recommendation of the CTU from credible source (e.g. MAHSC Partner and experienced Chief Investigator or research team)
4. Review of the quality management system and written procedures (including organisational charts)
5. Evidence of experience of the CTU in running other clinical trials in the same clinical area or using the same methodology as the proposed trial

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The final decision on the selection of the CTU must be approved by the University Clinical Trials Management Group (CTMG) before the University will agree to sponsor the trial.

3.2 Working with a selected CTU prior to submitting funding application

Once a CTU has been selected, the trial functions that will be carried out by this unit must be clarified and documented in a delegation of responsibilities log. Such aspects include, but are not limited to, methodology input, trial statistician, pharmacovigilance, randomisation, data collection, database provision, monitoring etc. Further to this, costings should be negotiated with the CTU and factored into the funding application.

3.3 Contract

Once a CTU has been selected and funding secured a contract must be put in place by the University to cover the activity and payment of the CTU with respect to the trial in question. The contract should contain information relating to the delegated functions and activities as well as the required standards for the work and how these will be monitored. Advice will be sought from the University Contracts team to ensure compliance with local requirements. In addition to trial specific activities, it is expected that the CTU will be contracted to manage the following responsibilities on behalf of the sponsor as detailed in parts 4 and 5 of the UK Clinical Trial Regulations 2004:

Under Part 4: Good Clinical Practice and Conduct (GCP):

1. Put and keep in place arrangements to adhere to GCP
2. Ensure investigational medicinal products (IMPs) are made available to subjects free of charge
3. Take appropriate urgent safety measures (if no other person is specified to do so)

Under Part 5: Pharmacovigilance:

1. Keep records of all adverse events reported by investigators
2. Ensure recording and prompt reporting of Suspected Unexpected Serious Adverse Reactions (SUSAR's)
3. Ensure investigators are informed of SUSAR's
4. Ensure all SUSAR's including those in third countries are entered into a European database
5. Provide annual list of suspected adverse reactions and a safety report for a CTIMP study

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A copy of the signed and dated contract (and any subsequent amendments) must be filed in the trial master file.

3.4 Oversight of the Clinical Trials Unit

The CTU will be expected to communicate regularly with the CI and provide regular reports to the Sponsor regarding trial progression and important trial related issues in order to meet its contractual, legislation, good clinical practice, and MHRA/REC requirements.

The University may delegate a minimum level of pre-defined oversight of the activities of the CTU with respect to the trial to the CI which will be detailed in an agreement.

Where concerns arise regarding the conduct of the CTU, the University CTMG must be informed at the earliest opportunity.

4.0 References:

- Directive 2001/20/EC
- Directive 2005/28/EC
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 1928)
- MHRA Good Clinical Practice Guide, 2012

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