
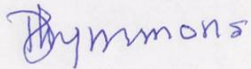




The University of Manchester

Standard Operating Procedure

Number:	UM/UoM Pharmacy Support of CTIMPs/SOP24/1.1		
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1.0	Jun 2018	First Draft
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1.0 Background

The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document.

Regulation 3, as amended by Statutory Instrument 2006/1928, requires that research which falls under the regulation has a “Sponsor”. As stated in the Regulations, the Sponsor “in relation to a clinical trial, [is] the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial”. Therefore all proposed research which falls within the scope of the Regulations must have a confirmed Sponsor.

As sponsor the University of Manchester will ensure that appropriate written arrangements are in place before any trial is given Sponsor green light. As part of this sponsor pharmacist oversight of clinical trials of investigational medicinal products (CTIMPs) is provided.

1.1 Purpose

This SOP describes the process by which the University of Manchester will ensure that there is appropriate oversight of the pharmacy related aspects of the trial from a Sponsor point of view. This is not the same as the day to day management of pharmacy related aspects of the trial, which is the responsibility of the clinical trials lead pharmacist at each site.

1.2 Procedure

This SOP only concerns studies that fall into (or potentially fall into) the category of a CTIMP or a clinical investigation of a medical device, as defined by the Clinical Trials Regulations.

1.3 Role of the Chief Investigator and Sponsor Trial Lead Pharmacist

The CI is expected to identify and detail all the relevant pharmacy-related support required for the setting-up and running of a CTIMP. The University expects the CI to work closely with a UKCRC registered clinical trials unit (CTU) (or equivalent) to ensure that all pharmacy areas where the support required, by the CI and the trial team, are identified, detailed and costed appropriately. This will include (but it not confined to) all aspects of IMP management (including the purchase, packaging, labelling, distribution, and quality control of active drugs and placebo).

1.3.1 The University will support the CI with identifying pharmacy related activities at the pre-funding stage by providing access to a Sponsor Lead Pharmacist. The role of the Sponsor Lead Pharmacist is not the same as the role of the Site Trial Lead Pharmacist. The Site Trial Lead Pharmacist should be approached via the lead NHS Trust R&D in the first instance. If no agreement is reached between the University and the lead NHS Trust R&D the Sponsor may outsource this activity subject to a financial agreement being reached with the lead Trust and research team

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1.4 Costs of IMP management

The CI must ensure that all the costs related to Trial and Sponsor Lead pharmacist, site pharmacies and IMP management have been obtained and included in the funding application by the relevant Research Support Manager. This may include identifying potential vendors in order to obtain costs. The CI must share this information with the Sponsor, CTU and the Sponsor Lead Pharmacist before submitting a funding application.

1.5 Role of the sponsor Lead Pharmacist

The role of the Sponsor Lead Pharmacist is to oversee all activities related to IMP management for quality assurance to the Sponsor (see Appendix 1). The role of the Sponsor Lead Pharmacist will be described in the Pharmacy Delegation of Duties for Individual Trials (see Appendix 2). Further details can be found in Appendix 3.

1.6 Delegation of Duties

The University expects a Pharmacy Delegation of Duties for Individual CTIMPs to be agreed with the lead NHS R&D Trust for each CTIMP (variable depending on the specific requirements of the CTIMP) as detailed in Appendix 2.

2.0 References:

[UK Policy Framework for Health and Social Care Research](#) UK Clinical Trials Regulations 2004/2006