Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Application to MHRA for Clinical Trials Authorisation**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Draft v 2.0
Draft v 2.0	7/03/11	Update following GCP Inspection	Final v 2.0
Final v 2.0	20/08/2012	Periodic Review	Final v 3.0
Final v 3.0	06/10/2014	Periodic Review	Final v 4.0
Final v 4.0	19/09/2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for applying to the Medicines and Healthcare products Regulatory Agency (MHRA) for authorisation to undertake a Clinical Trial.

2. Introduction

The European Directive 2001/20/EC requires that before an Investigational Medicinal Product (IMP) Trial may commence, it receives authorisation from a Competent Authority. Within the United Kingdom the MHRA is the Competent Authority and it is responsible for ensuring that medicines and medical devices are safe.

An IMP is defined in the Directive as *"a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form".* Therefore, an authorised medicinal product used as a comparator in a clinical trial is an IMP. (Article 2 (d) European Directive 2001/20/EC).

A Clinical Trial is defined in the Directive as *"any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects to one or more investigational medical product(s), and/or to identify any adverse reactions to one or more investigational medical product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy". This definition includes pharmacokinetic studies.* (Article 2(a) European Directive 2001/20/EC).

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A useful 'clinical trial algorithm' has been produced by the MHRA to assist with deciding if a CTA is required. This can be accessed via the MHRA website: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

Should you be in any doubt about whether your planned study is a CTIMP the MHRA must be consulted and a copy of correspondence retained.

Any research fulfilling this definition requires a Clinical Trials Authorisation (CTA) from the Competent Authority in the Member State in which the research is being carried out.

3. Scope

The SOP applies to clinical trials where the University has accepted the role of Sponsor.

4. Responsibilities

4.1 Chief Investigator

Must establish whether or not regulatory authorisation is required for their study and ensure that this is in place prior to the commencement of a trial.

4.2 Sponsor

To ensure that the appropriate regulatory authorisation is in place.

5. Procedure

5.1 Allocation of an EudraCT number

The Sponsor is responsible for obtaining a unique EudraCT number from the EudraCT database. This number must be included on all trial applications and on other documents relating to the trial, as necessary. In order to obtain a EudraCT number, follow the procedure outlined in the MHRA website https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

5.2 CTA Application Form

The CTA application form should uniquely identify the clinical trial and the organisation(s) and key individuals responsible for the conduct of the trial. The CTA can be completed using the form on the Integrated Research Application System (IRAS) www.myresearchproject.org.uk or through the European Clinical Trials Database http://ec.europa.eu/health/files/eudralex/vol-10/application-form2009_en.pdf
In order to complete an application you will require your allocated EudraCT number, and then proceed to:
https://eudract.ema.europa.eu/eudract-web/index.faces. Full guidance notes for completing the CTA application form can be found on the MHRA website:
https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
The form should be completed by the CI/PI as they should have the most knowledge about the proposed research area and the proposed IMP to be used.

5.3 Supporting Documentation

The type of supporting data that needs to be sent with a CTA application form depends on the type of application (i.e. phase I, phase II IMP-Trial). This is explained on the MHRA's website:
https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
It may not be obvious as to which category your study will belong to. Therefore, applicants should, if required, contact the Clinical Trials Unit in the MHRA, using the contact details listed in 5.5 below.

5.4 Fees

There are fees incurred for obtaining a CTA from the MHRA and for the ongoing management of a Clinical Trial. Fees differ depending on the type of clinical trial application. Information on fees can be found at:
https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

5.5 Where and how do I apply to the MHRA?

The MHRA provides clear and current guidance on its website as to what is required in an application and the format in which documents should be presented. It is important that complete applications are submitted in order for your application to be valid. Applications are submitted using the Common European Submission Platform (CESP) by using the following the link:
https://cespportal.hma.eu/Account/Login?ReturnUrl=%2f

6. References

Medicines and Healthcare products Regulatory Agency website, accessed 22 July 2008, 7 March 2011, August 2012 and September 2016
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EudraLex - Volume 10 Clinical trials guidelines, Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial (last accessed September 2016)

7. Appendix

None.