

**Apply for ethical approval:** The Regulations state that trials of medicinal products should be reviewed by a recognised NHS Research Ethics Committee (REC) before commencing. For more queries about ethics submission to the East London & The City Research Ethics Committee, please contact Dr Helen Cadiou on 020 7882 7272.

**Apply for Trust approval:** Under the Research Governance Framework, NHS Trusts are required to record and formally approve all research involving Trust patients, staff or their tissue, samples or data before the research may commence. If your trial involves BLT patients, you should first send a copy of Parts A,B & C of the ethics form, the patient information sheet / consent form, a copy of the protocol and a completed Data Protection Act (DPA) form (available from the R&D Office website) to the R&D Office for project registration.

On receipt, the R&D Office can organise sponsorship, trial agreements and indemnity for your project (if you are a BLT or QMC employee). For more information about registering your project with R&D, please contact Helene Provstgaard on 020 7882 7261.

**Seek Peer review:** Under the Research Governance Framework, all research involving the NHS should receive a peer review prior to commencing to ensure that the proposal is of high quality. If research has no funding attached to it or is funded by a charity or research council then you should contact the relevant BLT Directorate Peer Review Committee.

The R&D Office have produced a template peer review form and guidance on this process. Please see the R&D Office website for more information about the peer review system.

**Funding applications:** If you are planning on applying for funding whether from a commercial source or a non-commercial source (such as a research council or a charity) you should contact the Research Grants Dept in the R&D Office for information and advice. All research incurs some cost and Research Grants are able to provide detailed costing figures and also provide a contract negotiation service for commercially funded research.

**Apply for a EudraCT number:** EudraCT is a database of all clinical trials of medicinal products being carried out within the European community. All trials must obtain a unique number, the EudraCT number which should be included on applications to the MHRA and ethic forms. To register your trial and obtain a number, please go to [www.eudract.emea.eu.int](http://www.eudract.emea.eu.int)

**Apply for a Clinical Trial Authorisation (CTA):** If your trial is being sponsored by BLT or Queen Mary College, you will need to complete the CTA form prior to starting the trial for approval by the MHRA. The CTA form is available from the MHRA website. The form should be completed and returned to the MHRA for approval together with a fee.

#### References & useful contacts

- Medicines & Healthcare products Regulatory Agency (MHRA) - [www.mhra.gov.uk](http://www.mhra.gov.uk)
- Clinical trials toolkit - [www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk)

**For more information about carrying out a trial in BLT, please contact:** Johanna Piper, Research Governance & GCP Manager (BLT), E-mail: [johanna.piper@bartsandthelondon.nhs.uk](mailto:johanna.piper@bartsandthelondon.nhs.uk) Tel: 020 7882 7274.

Or Siobhan Lim, Research Governance & GCP Manager

## The UK Medicines for Human Use (Clinical Trials) Regulations 2004



## What are the Clinical Trials Regulations?

The UK Medicines for Human Use (Clinical Trials) Regulations (2004) implement the EU Clinical Trials Directive in the UK. The Regulations are a legal requirement introduced in an attempt to harmonise the administration of clinical trials across the EU. The Directive was transposed into UK law on 1st May 2004.

The Regulations outline the statutory controls which define how clinical trials should be carried out. The legislation covers all studies which are undertaken to ascertain the efficacy or safety of a medicinal product in human subjects.

The main addition to previous clinical trials regulations is that researchers planning trials must obtain authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA).

## Why have new Regulations been introduced?

The Regulations will ensure that the rights, safety and well-being of clinical trial participants are protected by requiring sponsors of trials to be responsible for designing, conducting, recording and reporting clinical trials according to internationally recognised principles of Good Clinical Practice (GCP).

The Regulations also protect public health by ensuring that the results of clinical trials are collected, recorded and analysed in accordance with GCP so that they can be audited and verified before being used to impact on public health.

## What are the key elements of the Clinical Trials Regulations?

**Ethics:** All clinical trials must have ethical approval prior to commencing and must adhere to the principles of the Declaration of Helsinki, 1996.

**Sponsorship:** All trials need a sponsor to take overall responsibility for the commencement, management and completion of the trial. The Regulations allow a group to collaborate to take on and share these responsibilities.

**Good Clinical Practice:** There now a legal requirement to conduct trials in accordance with internationally recognised principles of GCP to help to ensure that all UK trials are conducted to high standards and that the risks to trial participants are minimised.

**Good Manufacturing Practice (GMP):** All trials should be compliant with GMP principles to ensure that medicinal products are produced, labelled and controlled to appropriate quality standards. This standard aims to ensure that trial participants are not exposed to poor quality medicines.

**Informed consent:** The Regulations contain provisions for the protection of adults incapable of giving informed consent. The Regulations also provide additional protection to minors (i.e. persons under the age of 16 years of age) who are being considered for a clinical trial.

**Trial risk vs trial benefit:** A trial must only be undertaken if the expected benefit to patients and public health outweigh or justify the possible risk to patients.

**Clinical Trial approval:** All clinical trials require authorisation from the MHRA before they commence. In addition, trials must be registered on the European database by obtaining a EudraCT number.

**Clinical trial inspections:** The MHRA can request a compulsory inspection of a trial site at any time either to assess compliance with GCP/GMP or to assess trial management and data reliability.

**Pharmacovigilance:** The Regulations outline the procedures for recording and reporting adverse events or suspected unexpected serious adverse reactions (SUSAR's).

## Do the new Regulations affect my trial?

The scope of the new Regulations for clinical trials of medicines is broad as they encompass trials that include a medicine in any of the treatment or control arms. In addition, any trial that will generate information on the safety or efficacy of a medicine, even if it is standard treatment or in the control arm will also fall under the Regulations. Trials of new biological entities based on anti-bodies, DNA and other biotechnology products are included, as are vitamins and food products that claim medicinal benefits. The Regulations also apply to clinical trials involving healthy volunteers (Phase I trials).

## Exceptions to the Regulations

Trials of interventions such as surgery and psychological treatments where patients may also be receiving medicines as part of standard clinical care do not fall under the Regulations.

## What should I do if I am planning a clinical trial of a medicinal product involving BLT patients?

**Identify a sponsor:** It is a legal requirement that all clinical trials falling under the Regulations has a sponsor in place. If your trial is funded by a commercial company, it is expected that they will be the sponsor. If your project has non-commercial funding or has no funding,, please contact Helene Provstgaard for more assistance on 020 7882 7261. If the funding body is unwilling to be a sponsor and you are either a BLT or a QMUL employee, it is likely that your employer will sponsor the trial.

