

**MRC/DH joint project to codify good practice in publicly-funded UK
clinical trials with medicines**

Workstream 4: Trial Management and Monitoring

GCP in non-commercial trials

1. GCP in non-commercial trials

There are non-commercial trials at all stages in the lifecycle of drug development and evaluation, from studies of the first use of a new compound in man to trials designed to assess the effectiveness of commonly used licensed treatments. Clearly, the potential risks to the safety and well-being of participants differ greatly across that range.

The principles of GCP are widely accepted and followed in both commercial and non-commercial trials in the UK. The main difference is that whereas commercial companies tend to use similar procedures to comply with GCP whatever the phase of the trial or type of intervention, non-commercial trials may use a variety of approaches, depending on the intervention and the design of the trial. The protection of patient rights and safety and the production of reliable results are equally important in non-commercial as in commercial trials, but because of the greater financial constraints in academic trials, the efficiency and relevance of the methods is also considered. The key is that the conduct of the trial should be fit for purpose.

2.1.1 ICH GCP Guideline

The ICH guideline provides a common standard for the mutual acceptance of clinical data by the regulatory authorities in the European Union, Japan and the United States. In its introduction it is stated that it “should be followed when generating clinical trial data that are ***intended to be submitted to regulatory authorities***” and that “the principles may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects”.

Compliance with the ICH guideline is not a legal requirement in the UK but is the standard that is expected by MHRA for clinical trials providing data for drug licensing. Although it is unusual for publicly-funded clinical trials to be used in licensing applications, when it is anticipated that the data may be used in that way it is recommended that the ICH guideline is followed.

2.1.2 MRC Guidelines on GCP

The MRC Guidelines on GCP are based on the same principles as the ICH GCP Guideline and were written specifically for effectiveness trials funded by the MRC. They have been widely adopted in the UK and must be followed in all clinical trials funded by MRC and HTA. They recommend that trials in

which the resulting data are likely to be used in licensing applications should also follow ICH GCP guidelines. However, every trial should be conducted in such a way as to produce reliable results and to protect the rights and well-being of participants.

3.0 Trial Management and Monitoring Guidance

Neither the ICH nor the MRC guidelines include advice on how to adapt the management of a trial to different types of trial and levels of risk. This is one of the main objectives of the Trial Management and Monitoring Workstream of the MRC/DH Joint Project. It should be regarded as a supplement to both ICH and current MRC GCP Guidelines. Although it was intended to meet the demands of the EU Clinical Trials Directive, it may also be applicable to intervention studies that fall outside the scope of the Directive, such as trials of surgery, physiotherapy or psychological interventions.