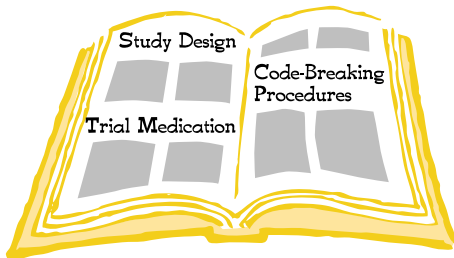


Rule 1

Obtain, Read and Adhere to the Study Protocol

* Trial Responsibilities

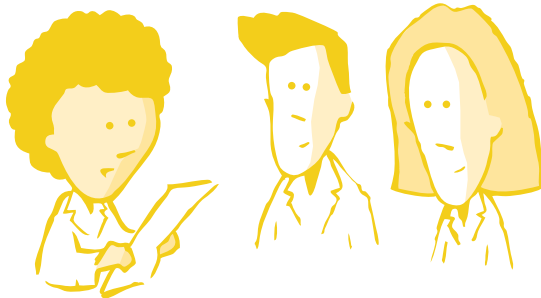
The protocol provides important information about the study design, conduct and contacts. The trial pharmacist may be asked to provide input into draft versions and comment before it is submitted to an ethics committee. Read the final version carefully, noting any relevant trial-related responsibilities and duties.



* Study Medication

Details about the study medication can be found within the protocol. This information includes

- the names of all products
- strength
- dose
- route of administration
- treatment period
- packaging
- labelling
- product accountability procedures.



* Blinding and code breaking

Blinding and code-breaking arrangements should also be described in the protocol.

* Delegation

Where delegation of responsibilities is undertaken, ensure that all co-workers are made fully aware of this.

Extracts from Relevant Guidelines

ICH GCP Guidelines

2.6

A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB) /independent ethics committee (IEC) approval/favourable opinion.

2.12

Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

4.2.4

The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.5.1

The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

4.5.3

The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.6.2

Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

4.6.5

The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

5.12.1

When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

RPS Guidelines

1. Designation of responsibility

One pharmacist should be designated to take special responsibility for clinical trials. This pharmacist or another designated by him/her should be involved in discussions of a proposed new trial as early as possible. He/she should be able to advise on many aspects of trial design, management, operation, and documentation.