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International Standards Related to Clinical Research

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Introduction

The standard to which clinical trials must conform is called 'good clinical practice' (GCP). GCP is defined as a standard that ensures in the first place adequate protection of subjects participating in clinical trials. Furthermore, GCP facilitates good science and ensures that all trial activities and data are meticulously documented and reported. The latest GCP guideline was developed by the International Conference on Harmonization (ICH) and was first published in May 1996. The GCP guideline is underpinned by ethical principles that have their origin in the Declaration of Helsinki from 1964, which has been modified over the years (last revision in October 2000). Beside GCP as an internationally accepted standard, clinical trials must comply with the local law of the country where the study is being conducted.

Summary of Responsibilities of Clinical Site Staff

According to ICH GCP 4.1.3, an investigator should be aware of and should comply with GCP and further applicable regulatory requirements. This includes, besides adequate resources and specific medical care for trial subjects, knowledge about the following:

- communication with the ethics committee;
- clinical study protocol;
- investigational product;
- randomisation and unblinding procedures as defined for the study;
- informed consent procedure;
- records and reports;
- responsibilities related to safety aspects.

Detailed Actions

Before the start of the study

- Familiarise yourself with GCP and local legal requirements.
- Familiarise yourself with the investigational product (Clinical Investigator Brochure) and ensure suitable storage after having received it.
- Read study protocol and sign it, if you agree to its content.
- Start communication with the ethics committee (see guide 2).
- Familiarise yourself with the study randomisation procedure and any procedures to be followed for necessary unblinding (for general information, see guide 13).
- Prepare yourself for the oral information of subjects before obtaining their consent.
- Look at the case report forms (CRFs) – practise completion to identify problems.
- Be aware of your responsibilities with respect to safety reporting as written in the study protocol and ICH GCP guideline.

Familiarise yourself also with section 4 of the ICH GCP guideline.

Ask sponsor's staff for a copy of the GCP guideline or print it yourself from e.g. the EMEA website:

www.emea.eu.int/index/indexh1.htm#

You should pay special attention to bullet point 4.

A copy of the Declaration of Helsinki should always be included in the study protocol.

During the study

- Enroll subjects strictly in accordance with the study protocol, after informed consent has been obtained.
- Ensure that the investigational drug is dispensed strictly according to the randomisation scheme, and do not open the study codes unless absolutely necessary for safety/medical reasons.
- Complete CRFs carefully and legibly and keep all source documents.
- Report serious adverse events immediately to the sponsor.

After completion or termination of the study

- Ensure that all CRFs are fully completed and signed. Check if corrections have been done properly (dated and initialed).
- Inform ethics committee about completion of the clinical study.
- Store the trial files carefully and arrange for archiving as agreed with the sponsor.

Hints and Tips

- Before the start of the study, organise a meeting with the study staff involved at your site to discuss the study in detail. Consider if it might be useful to appoint a study site co-ordinator.
- Make yourself available for contact by study subjects and the study monitor. As the responsible investigator at the site, you should keep your staff informed about progress and any changes.
- Provide a small card or a sticker to the study subjects. Ask them to carry it with them so they can be identified as study participants.
- Prepare yourself for regular monitoring visits by knowing the status of the study (number of subjects recruited etc.), by being aware of adverse and serious adverse events and by making available all records needed for checking and verifying data.
- Organise subject visits; try to ensure they are timely.
- At the end of the study, thank subjects for their participation.
- Before initiating any publication, discuss it with the sponsor.

Related Guide(s)

- 2 Clinical Research and Ethics Committees
- 5 Clinical Study Protocol
- 6 Case Report Form and Its Completion
- 8 Documentation and Archiving
- 11 Subject Information and Consent
- 13 Randomisation and Blinding
- 14 Investigational Product
- 15 Safety in Clinical Studies

Action Item List

(to be completed
as appropriate)

Action item	Done/Initials
1. Familiarise yourself with GCP.	
2. Familiarise yourself with the medicinal product (Clinical Investigator Brochure) and ensure suitable storage after having received it.	
3. Read study protocol and sign it, if you agree to its content.	
4. Start communication with ethics committee according to procedures outlined in guide 2.	
5. Familiarise yourself with the study randomisation procedure and any procedures to be followed for necessary unblinding.	
6. Prepare yourself for the informed consent process.	
7. Look at the CRFs and practise completion to identify problems.	
8. Be aware of your responsibilities with respect to safety reporting as written in the study protocol.	
9. Enroll subjects strictly in accordance with the study protocol after informed consent has been obtained.	
10. Provide a small card or a sticker to the study subjects. Ask them to carry it with them so they can be identified as study participants.	
11. Ensure that the investigational drug is dispensed strictly following the randomisation scheme, and do not open the study codes unless absolutely necessary for safety reasons.	
12. Complete CRFs carefully and legibly and keep all source documents.	
13. Report serious adverse events immediately to the sponsor.	
14. Ensure that all CRFs are fully completed and signed, and that corrections have been done properly.	
15. Inform the ethics committee about completion of the clinical study.	
16. Store the trial files carefully and arrange for archiving as agreed with the sponsor.	

