United Nations
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GENERAL ASPECTS AND PRINCIPLES OF ICH-GCP (GOOD CLINICAL PRACTICE)

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DEFINITION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

GOOD CLINICAL PRACTICE ICH

INTRODUCTION

1. GLOSSARY
2. THE PRINCIPLES OF ICH GCP
3. ETHICS COMMITTEE
4. INVESTIGATOR
5. SPONSOR
6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)
7. INVESTIGATOR'S BROCHURE
8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL

ICH-CGP PRINCIPLES

A) ETHIC GUARANTEE

- 2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

- 2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

ICH-CGP PRINCIPLES

- 2.3 The rights, safety, and well-being of trial subjects are the most important considerations and should prevail over interests of science and society.

- 2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

ICH-CGP PRINCIPLES

B) TECHNICAL-SCIENTIFIC GUARANTEE

- 2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- 2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- 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.

ICH-CGP PRINCIPLES

- 2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

- 2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

- 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.

ICH-CGP PRINCIPLES

C) PROCEDURAL GUARANTEE

- 2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- 2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement.
- 2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

GOOD CLINICAL PRACTICE ICH

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INDEPENDENT ETHICS COMMITTEE (IEC)

- An independent body (a review board or a commitee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

INDEPENDENT ETHICS COMMITTEE (IEC)

RESPONSIBILITIES:

- An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be payed to trials that may include vulnerable subjects. The IEC should obtain all relevant documents related to the trial.

- The IRB/IEC should review a proposed clinical trial and document its views in writing for the following:
  - Approval/ favourable opinion
  - Modifications required prior to its approval/ favourable opinion
  - Disapproval/ negative opinion; and
  - Termination/ suspension of any prior approval/ favourable opinion.

- The IRB/IEC should consider the qualifications of the investigator and should conduct continuing review of each ongoing trial at least once per year.

INDEPENDENT ETHICS COMMITTEE (IEC)

COMPOSITION, FUNCTIONS AND OPERATIONS:

- The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

a) At least five members.
b) At least one member whose primary area of interest is in a nonscientific area.
c) At least one member who is independent of the institution/ trial site.

- Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/ provide opinion on a trial-related matter.

INDEPENDENT ETHICS COMMITTEE (IEC)

A list of IRB/IEC members and their qualifications should be maintened.

- The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

- An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

INDEPENDENT ETHICS COMMITTEE (IEC)

- Only members who participate in the IRB/IEC review and discussion should vote/ provide their opinion and/ or advise.
- The investigator may provide information on any aspect of the trial, but should not participate in the deliberation of the IRB/IEC or in the vote/ opinion of the IRB/IEC.
- An IRB/IEC may invite nonmembers with expertise in special areas for assistance.