

Glisland® Training Series:

Good Clinical Practices

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Clinical Trials

1. What are clinical trials?

Biomedical or health-related research studies in human beings that follow a pre-defined protocol (ClinicalTrials.gov).

2. What is a clinical trial protocol?

A carefully designed study plan on which all clinical trials are based to safeguard the health of the participants as well as answer specific research questions.



Type of Clinical Trials

1. Treatment trials
2. Prevention trials
3. Diagnostic trials
4. Screening trials
5. Quality of Life trials



Phases of Clinical Trials

1. Phase I Trials

Studies on a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

2. Phase II Trials

Studies on a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

3. Phase III Trials

Studies on a large groups of people (1,000-3,000) to confirm the effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

4. Phase IV Trials

Post marketing studies delineate additional information including the drug's risks, benefits, and optimal use



Good Clinical Practice Regulations

1. What are Good Clinical Practices (GCPs)?
 - They are collection of regulations, requirements and policies that govern clinical research involving human subjects.
 - They are rules applying to the design, conduct, recording and reporting of clinical trails.
 - They define the responsibilities of the sponsor, the investigator, the study monitor and the IRB (Institutional Review Board).
 - They are applicable to all clinical studies of FDA-regulated products.



Key GCPs Requirements and Guidances

1. Regulations:

- Protection of Human Subjects (45 CFR Part 46 and 21 CFR Part 50)
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- Institutional Review Boards (21 CFR Part 56)

2. Guidances:

- ICH E6 *GCP Consolidated Guidance* (FR, 9 May 1997)
- ICH M4 *Common Technical Document (CTD)*
- ICH E3 *Guideline on the Structure and Content of Clinical Study Reports*
- GHTF STEP program



GCP Regulation History

1. Nuremberg Code of Ethics of 1947
2. Declaration of Helsinki of 1964
3. Kefauver-Harris *Drug Amendments* of 1962
4. FDA adopted Declaration of Helsinki informed consent in 1966 and made subsequent regulatory changes in 1967
5. *Medical Device Amendments* of 1976
6. FDA published regulations concerning Institutional Review Board (IRB) and informed consent in 1981
7. FDA published the Financial Disclosure by Clinical Investigators regulation in 1999



The Principles of ICH GCP

1. Be consistent with Declaration of Helsinki principals and regulatory requirements
2. Weigh risks against benefit for the trial subject and society
3. The rights, safety, and well-being of trial subject vs. interests of science and society
4. Adequate available nonclinical and clinical information to support proposed trial
5. Scientifically sound, clear, detailed protocol.
6. IRB/IEC approval of protocol



The Principles of ICH GCP

7. Medical care and medical decisions
8. Qualification of investigator
9. Informed consent
10. Handling clinical trial information
11. Privacy and confidentiality rules
12. GMP requirement for investigational products
13. Quality assurance



Sponsor

- Definition:

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
- Responsibilities:
 1. Quality Assurance and Quality Control
 2. Medical Expertise
 3. Trial Design
 4. Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring
 5. Investigator Selection
 6. Notification/Submission to Regulatory Authority(ies)
 7. Others



Investigator

- Definition:

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

- Requirements and Compliance:

1. Qualification and Agreements
2. Adequate Resources
3. Medical Care of Trial Subjects
4. Communication with IRB/IEC
5. Compliance with Protocol
6. Records and Reports
7. Others



Human Subject

- Definition:

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

- Special group protection (45 CFR Part 46):

1. Pregnant Women, Human Fetuses and Neonates
2. Prisoners
3. Children



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