GOOD CLINICAL PRACTICES

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Definition

- Good Clinical Practice (GCP) is defined as a ‘standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected’

GCP

- Are mainly focused on the protection of human rights in clinical trial.
- Provide assurance of the safety of the newly developed compounds.
- Provide standards on how clinical trials should be conducted.
- Define the roles and responsibilities of -
  - Clinical Sponsors,
  - Clinical Research Investigators,
  - Clinical Research Associates, And
  - Monitors.

- GCPs are generally accepted, international best practices for conducting clinical trials and device studies
- They are defined as an international ethical and scientific standard for designing, conducting, recording and reporting trials that involve the participation of human subjects
- Compliance with GCPs provide public assurance that the rights and safety of participants in human subject research are protected and that the data that arises from the study is credible

Good Clinical Practice Guidelines

- 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 requirements
- 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
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society
- The available non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial

- Clinical trials should be scientifically sound, and described in a clear, detailed protocol
- A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion
- 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

- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks
- Freely given informed consent should be obtained from every subject prior to clinical trial participation
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification

- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements
- 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
- Systems with procedures that assure the quality of every aspect of the trial should be implemented

Good Clinical Practices (GCP)

1. PROVISIONS AND PREREQUISITES FOR A CLINICAL TRIAL
   - 1.1 Justification for the trial
   - 1.2 Ethical principles
   - 1.3 Supporting data for the investigational product 1.4 Investigator and site(s) of investigation
   - 1.5 Regulatory requirements
2. THE PROTOCOL
3. PROTECTION OF TRIAL SUBJECTS
   - 3.1 Declaration of Helsinki
   - 3.2 Ethics committee
   - 3.3 Informed consent
   - 3.4 Confidentiality

4. RESPONSIBILITIES OF THE INVESTIGATOR

4.1 Medical care of trial subjects

4.2 Qualifications

4.3 Selection of trial subjects

4.4 Compliance with the protocol

4.5 Information for subjects and informed consent

4.6 The investigational product

4.7 The trial site

4.8 Notification of the trial or submission to the DRA

4.9 Review by an ethics committee

4.10 Serious adverse events or reactions

4.11 Financing

4.12 Monitoring, auditing and inspection

4.13 Record-keeping and handling of data

4.14 Handling of and accountability for pharmaceutical products for trial

4.15 Termination of trial

4.16 Final report

4.17 Trials in which the investigator is the sponsor

5. RESPONSIBILITIES OF THE SPONSOR

5.1 Selection of the Investigator(s)

5.2 Delegation of responsibilities

5.3 Compliance with the protocol and procedures 5.4 Product information

5.5 Safety information

5.6 Investigational product

5.7 Trial management and handling of data

5.8 Standard operating procedures

5.9 Compensation for subjects and investigators 5.10 Monitoring

5.11 Quality assurance

5.12 Study reports

5.13 Handling of adverse events

5.14 Termination of trial

6. RESPONSIBILITIES OF THE MONITOR
   - 6.1 Qualifications
   - 6.2 Assessment of the trial site
   - 6.3 Staff education and compliance
   - 6.4 Data management
   - 6.5 Case-report forms
   - 6.6 Investigational product
   - 6.7 Communication
   - 6.8 Notification of the trial or submission to the regulatory authority
   - 6.9 Reports

7. MONITORING OF SAFETY
   - 7.1 Handling and recording adverse events
   - 7.2 Reporting adverse events

8. RECORD-KEEPING AND HANDLING OF DATA
   - 8.1 Responsibilities of the investigator
   - 8.2 Responsibilities of the sponsor and the monitor
   - 8.3 Archiving of data

9. STATISTICS AND CALCULATIONS
    - 9.1 Experimental design
    - 9.2 Randomization and blinding
    - 9.3 Statistical analysis

10. HANDLING OF AND ACCOUNTABILITY FOR PHARMACEUTICAL PRODUCTS
    - 10.1 Supply and storage
    - 10.2 Investigational labelling and packaging
    - 10.3 Responsibilities of the investigator
    - 10.4 Responsibilities of the sponsor and the monitor
11. ROLE OF THE DRUG REGULATORY AUTHORITY
    - 11.1 General responsibilities
    - 11.2 On-site inspections

12. QUALITY ASSURANCE FOR THE CONDUCT OF A CLINICAL TRIAL