

Introduction to a Good Clinical Practice

Presented by

Ugochukwu Dorothy Amara

Assistant Director Of Nursing

Continuing Education & Research
Unit,

Department of Nursing,

NAUTH Nnewi

What is Good Clinical Practice (GCP)?

- GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies
- Good Clinical Practice is an international quality standard, which governments can then transpose into regulations for clinical trials involving human subjects. (Wikipedia)

- Good clinical practice is the international ethical scientific and practical standard to which all clinical research is conducted. It also provides a framework of principles which aims to ensure the safety of research participants and the integrity and validity of data.

Objectives:

- Define Good Clinical Practice (GCP)
- Outline the goals of GCP
- Provide a historical perspective on GCP
- Outline FDA regulations relating to GCP in medical device research

Why is GCP important?

- GCP compliance provides public assurance that the rights, safety and well-being of human subjects involved in research are protected

Reasons for GCP

- Increased Ethical Awareness
- Improved Trial Methods
- Clinical Trial Concept Better Understood
- Public/Political Concern over Safety Aspects
- Frauds and Accidents during Trials
- Growing Research and Development Costs
- Increasing Competition
- Mutual Recognition of Data
- New Market Structure

What are the goals of GCP?

- To protect the rights, safety and welfare of humans participating in research
- To assure the quality, reliability and integrity of data collected
- To provide standards and guidelines for the conduct of clinical research
- Good Clinical Practice = Ethics + Quality Data

What are the foundations for the ethical conduct of clinical research?

- The Nuremberg Code (1947)
- The Declaration of Helsinki (1964)
- The Belmont Report (1979)
- International Conference on Harmonization (ICH-GCP) (1996)
- International Standards Organization (2001)
- Code of Federal Regulations

GCP: A Historical Perspective

- Nuremberg Code (1947)
 - Voluntary participation
 - Informed Consent
 - Minimization of risk

GCP: A Historical Perspective

- Declaration of Helsinki (1964)
 - Well-being of subject takes precedence
 - Respect for persons
 - Protection of subjects health and rights
 - Special protection for vulnerable populations

GCP: A Historical Perspective

- Belmont Report Ethical Principles (1979)
 - Respect for Persons
 - Informed consent
 - Protection of vulnerable populations
 - Beneficence (maximizing benefits & minimizing harms and wrongs)
 - Non-maleficence (doing no harm)
 - Justice
 - Fairness

The International Conference on Harmonization (ICH-GCP)

- GCP is an international quality standard that is provided by the International Conference on Harmonization(ICH)
- Goals: Harmonize technical procedures and standards; improve quality; speed time to market
- In 1997, the FDA endorsed the GCP Guidelines developed by ICH
- ICH guidelines have been adopted into law in several countries, but used as guidance for the FDA in the form of GCP

International Standards Organization

- ISO 14155: Clinical Investigation of Medical Devices for Human Subjects
 - Assists sponsors, monitors, and clinical investigators in the design and conduct of device clinical investigations
 - Assists regulatory bodies and ethics committees in their roles of reviewing clinical investigational plans

What constitutes Good Clinical Practice in device research?

- IRB-approved protocol
- Valid Informed Consent
- Monitoring Plan
- Adverse Device Effect Reporting [Adverse Event (AE) or Serious Adverse Event (SAE)]
- Proper documentation
- Valid data collection/reporting procedures

What are the 13 principles of ICH-GCP?

- Ethics:
 1. Ethical conduct of clinical trials
 2. Benefits justify risks
 3. Rights, safety, and well-being of subjects prevail
- Protocol and science:
 4. Non-clinical and clinical information supports the trial
 5. Compliance with a scientifically sound, detailed protocol

What are the 13 principles of ICH-GCP? (contd.)

- Responsibilities:
 6. IRB/IEC approval prior to initiation
 7. Medical care/decisions by qualified physician
 8. Each individual is qualified (education, training, experience) to perform his/her tasks
- Informed Consent:
 9. Freely given from every subject prior to participation

What are the 13 principles of ICH-GCP? (contd.)

- Data quality and integrity:
 10. Accurate reporting, interpretation, and verification
 11. Protects confidentiality of records
- Investigational Products
 12. Conform to GMP's and used per protocol
- Quality Control/Quality Assurance
 13. Systems with procedures to ensure quality of every aspect of the trial

Protection of Human Subject using GCP-Principles

- *Respect for Persons*: This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from research subjects (or their legally authorized representatives)
- *Beneficence*: This principle requires that researchers maximize benefits and minimize harms associated with research. Research-related risks must be reasonable in light of the expected benefits.
- *Justice*: This principle requires equitable selection and recruitment and fair treatment of research subjects.

Who is responsible for GCP compliance?

- Sponsors
- Clinical Investigators (CIs)
- Independent Ethics Committees (IECs)
 - Institutional Review Boards (IRBs)
- Contract Research Organizations (CROs)
- Research nurses
- Clinical Research Coordinators (CRCs)
- Clinical Research Associates (CRAs)
- Medical monitors
- Data entry personnel
- Others

Samples of Case Report Form(CRF) used in Clinical Trial

- 21 CFR 11 –Electronic Records & Signatures
- 21 CFR 50 –Protection of Human Subjects
- 21 CFR 54 –Financial Disclosure
- 21 CFR 56 –Institutional Review Boards
- 21 CFR 812 –Investigational Device Exemptions
- 21 CFR 814 –Premarket Approval of Medical Devices

Summary

- Good Clinical Research Practice (GCP) is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects.

- Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected and respected, consistent with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines, and ensures the integrity of clinical research data.

- The responsibility for GCP is shared by all of the parties involved, including sponsors, investigators and site staff, contract research organizations (CROs), ethics committees, regulatory authorities and research subjects

*THANKS FOR
LISTENING*