

GOOD CLINICAL PRACTICE: GUIDE TO MEDICAL RESEARCHER

Md Mahtab Uddin Hassan¹

To produce safe doctors and future scientist is the goal of medical education. The medical teachers in one hand is involved in teaching and on the other hand they are expected to do research in various field of medical science to generate the evidence. WHO defines clinical trial as: any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, e.g. drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care. GCP (Good Clinical Practice) is defined as: an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

The purpose of GCP is

- Assurance that the data and reported results are credible and accurate.
- Assurance that the rights and confidentiality of trial subjects are protected.

Looking back to the history, the first attempt to regulate the Ethics of medical research was Nuremburg code in 1947, which revealed unethical research by medical profession during nazi period in Germany. Nuremburg code was a directive for human experiments which emphasized that the voluntary consent of the human subjects is essential, which is now called as informed consent. The thalidomide tragedy in 1956-1961 (which was used as anti emetic for morning sickness and near about 12000 birth deformities) triggered review of practices in Europe & declaration of Helsinki in 1964 was adapted. Helsinki declaration in 1964 formally adopted the Nuremburg code and ethical principles of carrying out a research. The key elements of Helsinki declaration was: Informed consent, Protection of patients' rights, Scientific/medical basis, Risk benefit, Protocol and Ethical approval. In the year 1996 international conference on GCP was held and which was consistent with principles of the declaration of Helsinki and unified standard has been setup which provides mutual acceptance of clinical trial data by the regulatory authorities.

Finally the principles of GCP in medical research is being adapted.

The Principles of GCP are

- 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 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/favourable opinion.
- 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 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.

1. Professor & Head of Medicine
Chittagong Medical College, Chittagong

This is very important that every medical researcher should have GCP training before doing a research (General GCP training and GCP training according to that particular research)

References

1. Nuremburg Code : <http://ohsr.od.nih.gov/guidelines/nuremberg.html>
2. Declaration of Helsinki <http://www.wma.net/en/30publications/10policies/b3/index.html>
3. International conference on harmonization of technical requirements for registration of pharmaceuticals for human use. Guideline for good clinical practice 1996; E6(R1)