Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/14566
DOI URL: http://dx.doi.org/10.21474/IJAR01/14566

RESEARCH ARTICLE

GOOD CLINICAL PRACTICE IN PHARMACOVIGILANCE

Rajni Devi, Anjana Devi, Sanjay Kumar, Kamal Jeet, Tanuj Sharma, Sumanshu Sharma, Anjali Dhiman and Manish Kumar

School Of Pharmacy, Career Point University, Hamirpur, Himachal Pradesh, INDIA 176041.

Manuscript Info

Manuscript History
Received: 20 February 2022
Final Accepted: 24 March 2022
Published: April 2022

Key words: -
Good Clinical Practices, CDSCO, Clinical Research, Human Experimentation

Abstract

Clinical research is a mechanism or a process that provides convincing evidence that the new treatments or therapies suggested are safe and effective. The ultimate aim of clinical research is the identification and discovery of contemporary diagnostic methods as well as the establishment of advanced standards of medicine. Good Clinical Practice (GCP) is an ethical and scientific quality standard for designs, operations and recordings involving the participation of human subjects. Accompanying the Guidelines pledges to the public that the ethics, integrity and welfare of humans participating in the trials are protected. India has experienced distinct opportunities for clinical trials for clinical trials compared to ethical patients, major medical institutions with fewer and more equipped investigators and fewer patient voices than regulated countries, with larger patient counts. However, our Indian guidelines were needed to ensure a uniform standard of clinical research across the country and to provide data for registration for new drugs before use in the human population in India. Junction's guidelines were developed by a complete committee set up by CDSCO with clinical experts. This article explains the importance of good clinical practice from an Indian clinical research perspective, while defining and outlining the goals and objectives of the GCP. It addresses the historical events that led to the emergence of good clinical practices and examines the current scenario with respect to the application of GCPs in clinical trials in India. Finally, the article addresses the challenges to maintaining a best and competitive system and will suggest a way forward to increase the credibility and efficiency of good clinical practice in clinical research.

Introduction:-

Good Clinical Practice (GCP) is an internationally accepted ethical, scientific quality standard for the design, conduct, record and report of clinical trials involving the participation of human subjects. It covers all aspects and aspects of clinical trials, from the stage when the trials are started, to the level where clinical trial results are reported.

Compliance with these principles provides assurance that the rights, safety and welfare of subjects participating in clinical trials are protected, and that data generated from clinical trials are reliable. The GCP statute dates to one of

Corresponding Author:- Rajni Devi
Address:- School of Pharmacy, Career Point University, Hamirpur, Himachal Pradesh, INDIA 176041.

the oldest traditions in medicine, the Hippocratic Oath, which is primarily known for the principle that no harm was done to the subject. However, modern medical research requires a more efficient set of guidelines to facilitate the ethical as well as scientific responsibilities of healthcare professionals. Whereas medicine, and GCP is an important requirement for personnel involved in conducting clinical studies and can be termed as a standard by which all research is conducted. The GCP's most fundamental ideology is that in research on humans, science and society are of interest as a collective.

The well-being of the subject studied should never take priority. Therefore, it is considered necessary for the International Council to revise clinical trials, the ICH/ which are the two most prominent principles set forth by the 3,4 GPP guidelines as clinical practice standards;

• Safety of human subjects

•Authenticity and reliability of biomedical data produced.

These guidelines are refined and intended to ensure that clinical studies are ethically and scientifically safe and sound and that the properties of the drug or drug substance under investigation are properly documented.

While the GCP was only a recommendation in the commercial studies on which it was initiated, over the years, the importance of the GCP has grown significantly, and more than one came into force in STEM 2004, a European Union Directive Danish law, which said GCP was no longer such a recommendation, but a valid requirement when carrying out clinical trials on new drugs and medical products. For medical devices following clinical trials, it was necessary to comply with the ISO standard: DS/EN 14 155 which is found to be equivalent to the GCP for medical devices. [1-6]

Why Pharmacovigilance Is Needed: -

The processes involved in the clinical development of drugs are illustrated in Figure 1. Once put on the market, a drug leaves the safe and secure scientific environment of clinical trials and is legally free for consumption by the general population. At this point, most drugs will only be tested for short-term safety and efficacy on a limited number of carefully selected individuals. Some subjects as few as 500 in some cases, and rarely more than 5000, will receive the product before its release. So, for good reason, it is essential that new and clinically still-developing treatments are monitored due to actual and post-medical release of the condition. More information is generally needed regarding use in specific population groups, especially children, pregnant women, and the elderly, and the efficacy and safety of older ingredients, especially in combination with other medicines. Experience has shown that many adverse effects, interactions (i.e., with foods or other medicines) and risk factors only come to light in the year following drug release. [7-9]

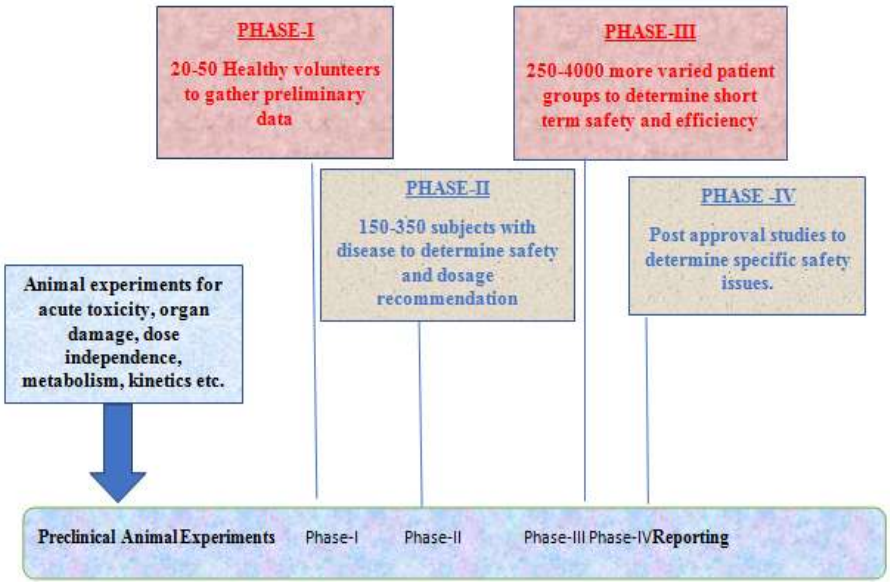

Fig. 1: - Clinical Development of Medicines.

History Of Good Clinical Practice: -
It may be necessary to understand the background of the development of the ICC-GCP principles. The current form of the GCP has been developed through a constitution and a constitution, as discussed below. [10-14]

The Federal Food and Drug Act 1906: -
The object of this act was to prevent the manufacture, sale or distribution of consonant or wrong brand or drugs. However, the act was compromised because of a great declaration that the manufacturer had made in relation to the drug, not to mislead the Court, that the act was not extended to cosmetics and was considered dangerous drugs was not given the right to restrict the use.

Sulphanilamide Tragedy 1937: -
Sulphanilamide, a drug used to treat streptococcal infections, was shown to have a therapeutic effect and was used safely for a short period in tablet or powder form. Various scientific investigations proved that sulphanilamide would dissolve in diethylene glycol. The company control laboratory conducted tests on the mixture for taste, appearance and aroma, and the product was later marketed as the "elixir of sulphanilamide". Immediately, the company made the elixir in large quantities and shipped shipments to all countries. A complication that was local engraftment was not tested for its integrative toxicity. No studies were conducted on the pharmacological activity of the new nectarine preparation and therefore due to this negligence, there was a failure to identify the distinguishing feature of the solution. Diethylene glycol, a chemical commonly used as an antifreeze, is believed to be fatal, killing around 100 people with some drug that was clearly unsafe. This event prompted the enactment of the Food, Drugs and Cosmetics Act 1938, which extended the authority to regulate drugs.

The Nuremberg Code,1947: -
It was designed because of the immoral and horrific experiments that were carried out by a German scientist in Nazi war camps on a person alive during World War I. The Nuremberg Code established the need for informed consent and clearly designed scientific experiments for the benefit of human participants so that they could be withdrawn from the experiment at any time.

Thalidomide Disaster Of 1962: -
Thalidomide was first marketed in West Germany in 1957 under the trade name Kontaren. In 1962, a sleeping pill was manufactured and became widely used in several countries, being investigated for use in the United States. Australian obstetrician Dr. William McBride discovered that the drug could be used to treat morning sickness in pregnant women. He began prescribing medication to his pregnant patients and set a trend. Those children had severe birth defects that were probably due to consumption of the harmful compound that was delivered. They later found that the drug was captured by a pregnant woman during the first trimester of pregnancy causing serious injury to the foetus. Children were born without birth or any serious deformity.

Declaration Of Helsinki: -
The World Medical Association developed the Declaration of Helsinki in 1964. It constitutes the basic structure of the ethical principles that follow the Inch-GCP guidelines we are practicing today. The purpose behind the Declaration of Helsinki is to advise physicians who are engaged in clinical trials and its focus was the responsibilities of an investigator to protect the rights of human volunteers participating in clinical trials. The 10 register is regarded as a humanitarian point of view even though the Declaration of Helsinki is the responsibility of the World Medical Association.

Partners In Pharmacovigilance: -
Management of risks associated with the use of drugs calls for close and effective collaboration among the key players in the field of pharmacovigilance. The continued commitment of such cooperation is critical if challenges are to be formally met in the future, and if the discipline is to continue to develop and flourish. Those responsible who must jointly anticipate, describe and respond to the ever-increasing demands and expectations of the public, health administrators, policy officials, politicians and health professionals. However, this is very unlikely to happen in the absence of sound and comprehensive systems that make such collaboration possible. Constraints include a lack of training, resources, political support in general, and scientific infrastructure in particular. Understanding and dealing with them is a necessary condition for the future development of science and the practice of predictions.

Pharmacovigilance In National Drug Policy: -

The provision of good quality, safe and effective medicines and their proper use is the responsibility of national governments. Establishment of a National Medical Regulatory Agency and designated a

Centres for the study of adverse reactions are central to the achievement of these tasks. Multidimensional cooperation is of great importance; In particular, there needs to be links with various departments of the Ministry of Health and also with other stakeholders, such as the pharmaceutical industry, universities, non-governmental organizations (NGOs) and those professional associations that have responsibility with medicines and drugs.

Principles Governing Good Clinical Practice: -

The formulation of the GCP guidelines not only wanted to protect the rights and safety of study subjects, but also to serve the interests of all parties involved in clinical research. The basic principles governing the concept of GCP are as follows: -[15-18]

1. Assist on a global scale, to aid and stimulate the attainment of an authorized standard for the conduct of clinical research studies on humans.
2. Assist clinical research editors to assess the acceptability of research submitted for publication, and to enable veterinary personnel who may affect the use and registration of certain medicinal products.
3. To provide a general summary and any other necessary advice on the how-to and how-to of clinical research in a humanely accepted form.

While the core principles of the UPC are given above, give a brief overview of the GCP's essence, which provides a highly specific set of core principles, established in 1995, that give a comprehensive idea of the GCP's intentions and objectives. Is. These main principles are given below:

1. Ethical principles established by the Declaration of Helsinki must be strictly followed when conducting research in human subjects. Three ethical principles, justice, respect for the public and the beneficiary, will be considered above all other GCP principles.
2. All research involving human subjects must have scientific reasoning and be informed in a detailed, comprehensive protocol.
3. Any proximate risks and potential side effects along with the potential benefits should be reported to the test subjects.
4. Clinical studies involving human involvement will only be performed if the expected benefits from the studies outweigh the potential risks.
5. Intended research can only be undertaken after advances from an Institutional Review Board or an independent ethics committee.
6. The protocol will be approved before starting the clinical trial.
7. Voluntary informed consent will be obtained from trial participants in accordance with national requirements. In paediatric or geriatric patients or after the test subject is not able to give consent himself, a consent form can be obtained from a legally authorized representative.
8. Research studies, in the form of human studies, should continue as long as the risk-benefit analysis remains appropriate and favourable.
9. Medical care of research subjects will be the responsibility of qualified medical personnel (doctors, dentists etc.)
10. Those who work on clinical trials as well as the other personnel involved to conduct the tests will have qualified qualifications as well as be sufficiently experienced.
11. All research data must be gathered and generated and stored to ensure accurate reporting, validation and analysis.
12. Good manufacturing practices will be strictly enforced in terms of product manufacturing, handling and storage.
13. Strategies will be put in place to execute procedures that ensure the competence of every aspect of the clinical trial.

Responsibilities Of Ethics Committee: -

A body of Standard Operating Procedures (SOPs) and fundamental principles should be prepared by the Institutional Ethics Committee. This should include nominations, representatives of the workplace and quorum requirements, terms and conditions. Official procedure, informational forms, case-in-case inclusion/exclusion criteria and other source documents regarding the test are reported. Standard operating procedures should be checked and reviewed regularly. Reviews conducted by the Ethics Committee may be free from bias and influence of any kind. The

committee should primarily focus on securing the rights, dignity, safety and welfare of the research subject participating in the proposed clinical trials. The committee should ensure that the inspection mechanism is in place (examining site visits, internal audits, ongoing tests). All source documents relating to the test performed must be retained for a minimum of 5 years after its completion. [19-20]

Responsibilities Of Sponsors: -

A person or organization that takes responsibility for initiating, managing or funding a clinical trial is known as a sponsor. When a sponsor transfers clinical trial data to a scientific body or contract research organization (CRO), stringent measures will be in place to ensure that any transfer of data is well recorded and documented. It is the responsibility of the sponsor to ensure that investigators performing experiments on humanity are qualified, trained, experienced in conducting tests. Approval to conduct clinical trials must be obtained from the Drugs Controller General of India (DCGI) and the Institutional Ethics Committee.

Responsibilities Of Investigators: -

A clinical investigator involved in a trial is responsible for ensuring that an investigation is conducted in accordance with a signed investigator statement, investigation plan and applicable regulations to safeguard the safety, dignity and well-being of potential researchers. Sponsor and Investigator should assign protocol, SOP, safety, audit process monitoring and trial related responsibilities prior to the start of the trial. An informed consent from each research` participant is a mandatory requirement for a clinical trial. The investigator is expected to report any serious adverse events that occurred during the trial within a given timeline. The protocol should be carefully followed by the investigator, ensuring that all individuals conducting the study are made aware of the obligations and are trained. Investigator is not allowed to conduct more than three tests at a time. [21-22]

Conclusion: -

Despite its 40-year history, pharmacovigilance remains a dynamic clinical and scientific discipline. It is playing an important role in meeting the challenges resulting from the increasing range and power of drugs, all of which carry an indispensable and some unexpected possibility of loss at times.

Good clinical practice in India has come a long way, from mere conceptual concepts to having a well-organized and systematic set of guidelines. He has helped establish and maintain the highest standards regarding the planning and conduct of clinical trials. The Indian GCP Guidelines for Clinical Diagnostic Trials are now at par with the International GCP Guidelines. However, given the vastness of the country and the enormous population size, the need for attention and impartial supervision by efficient and regulated bodies is paramount. It should also be noted that a transparent monitoring system will be in place, which can be assured to bring the results of clinical trials under the domain of RTI. Right to Information Act. The emphasis is on upgrading the already existing infrastructure and control measures through a comprehensive and coordinated program of clinical research education, creating a clinical trial environment of zero-tolerance for non-compliance with GCP guidelines.

References: -

1. Chakraborty BS. Clinical Research in India: The current scenario and prospects. Journal of advanced pharmaceutical technology and research. 2021;4(3):126-127. doi:10.4103/2231-4040.116776
2. Pooja Sharma TB. Clinical Research Environment in India: Challenges and Proposed Solutions. Journal of Clinical Research and Bioethics. 2020;5(6):1-8. doi:10.4172/2155-9627.1000201
3. Dowsett M. Clinical Trials in Oncology: Design, Interpretation, and Challenges. Live Law. 2020:1-5.
4. Thatte U, Marathe P. Ethics Committees in India: Past, present and future. Perspectives in Clinical Research. 2021;8(1):22. doi:10.4103/2229-3485.198549
5. Saxena R, Saxena P. Clinical trials: Changing regulations in India. Indian Journal of Community Medicine. 2014;39(4):197. doi:10.4103/0970-0218.143018
6. Dickens B. Ethical guidelines regarding interventions for fetal wellbeing: FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. 2006:1-120. doi: 10.1016/j.ijgo.2011.07.006
7. Merican MI. Good clinical practice: issues and challenges. The Medical journal of Malaysia. 2000;55(2):159-163.
8. Institute of Medicine (US) Forum on Drug Discovery D and T. Challenges in Clinical Research. 2010;(Dc):1-11.

9. Guideline for Good Clinical Practice E6(R1). International conference on harmonisation of technical requirments for registration of pharmaceuticals for human use. 1996:1-53. doi:10.1056/NEJMp1012246
10. Ministry Of Health and Family Welfare Government of India. Good Clinical Practice Guidelines. 2015.
11. Verma K. Base of a Research: Good Clinical Practice in Clinical Trials. Journal of Clinical Trials. 2013;3(1):1-5. doi:10.4172/2167-0870.1000128
12. Dylan Fernandes S et al. A national approach to pharmacoviligance: The case of India as a growing hub of global clinical trials. Research in Social and Administrative Pharmacy. March 2018. doi: 10.1016/j.sapharm.2018.03.061
13. Wandile P, Ghooi R. A Role of ICH- GCP in Clinical Trial Conduct. Journal of Clinical Research and Bioethics. 2017;8(1):1-5. doi:10.4172/2155-9627.1000297
14. Abraham S, Grace D, Parambi T, et al. Milestones in Development of Good Clinical Practice. 2008;9(1):1-5.
15. Vijayananthan A, Nawawi O. The importance of Good Clinical Practice guidelines and its role in clinical trials. Biomedical Imaging and Intervention Journal. 2008;4(1):1-4. doi:10.2349/biij.4.1. e5
16. Wilson BC. Good Clinical Practice – A Brief History. 2014:2-4.
17. Clinical G, Reviewed G. Good Clinical Practice Research Guidelines Reviewed, Emphasis Given to Responsibilities of Investigators: Second Article in a Series. Journal of Oncology Practice. 2008;4(5):233-235. doi:10.1200/JOP.0854601
18. Verma K. Base of a Research: Good Clinical Practice in Clinical Trials. Journal of Clinical Trials. 2013;3(1):1-2. doi:10.4172/2167-0870.1000128
19. The U, Of M, Sops WU, Gcp ICH, Gcp WHO. What' s the difference between ICH-GCP and WHO-GCP.
20. WHO. Handbook for Good Clinical Practice. 2002.
21. Protection India HS, Adequate II. Human Subject Protection in India – Is It Adequate? Need for a Level Clinical Trial Platform GCP-Compliance – Priorities. 2017;1(1):15-20.
22. Agarwal DSP. Central Drugs Standard Control Organization. http://www.cdsco.nic.in/html/GCP1.html. Accessed November 13, 2017.