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A Systematic Review: Good Clinical Practice

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ABSTRACT

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 conduct of clinical research is complex and this complexity is compounded by the need to involve a number of different individuals with a variety of expertise, all of who must perform their tasks skillfully and efficiently. This article illustrates the importance of Good Clinical Practice (GCP), defines and outlines the goals of GCP, presents a historical perspective on GCP and Outlines FDA regulations relating to GCP. Ongoing research shows that whether conducting research involving a new drug, a behavioral intervention, or an interview/survey, Good Clinical Practice (GCP) provides investigators and their study teams with the tools to protect human subjects and collect quality data. In this article, the author will define GCP, explain the benefits of following GCP for all types of human research and clinical trial studies, and provide some resources to assist investigators in implementing the tenets of GCP for their own research studies. GCP is likely to follow the International Conference on Harmonization of GCP guidelines in many aspects. GCP will enforce tighter guidelines on ethical aspects of a clinical study. Higher standards will be required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities including computers. Today, the GCP are used in clinical trials throughout the globe with the main aim of protecting and preserving human rights.

Keywords: - Good Clinical Practice (GCP); ICH-GCP; Quality assurance; Inspections; Clinical trial; Human rights protection; FDA.

INTRODUCTION

GCP is a key requirement for anyone involved in the conduct of clinical research is Good Clinical Practice (GCP) training. GCP is the standard and guidelines to which all research is conducted.GCP is a set of internationally recognized ethical and scientific quality requirements that must be observed throughout the various stages of a clinical trial. Clinical trial

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following testing in laboratories and animal studies, the most promising treatments is moved into clinical trials. [1] A clinical trial is sometimes called a clinical study. [2] A clinical trial:

- Is a research study that tests how well an intervention works in a group of people
- Tests for new methods of screening, prevention, diagnosis, or therapy
- Is conducted in phases

During a trial, additional information is learned about an intervention, its risks, and its effectiveness and/or efficacy. Trials can only be conducted if there is an uncertainty about the outcome-trials cannot be conducted if the outcome is already known from a previous study. [3, 4] Good Clinical Practice (GCP) is one of the basic sets of rules for hospitals, researchers and pharmaceutical companies engaged in clinical. [5] GCP or Good Clinical Practice refers to an international quality standard provided by the ICH for regulating clinical trials that involve human subjects. GCP standards offer assurance as to the effect and safety of compounds developed in clinical trials, human rights protection of trial participants, and also define the roles of clinical research investigators, clinical trial sponsors and clinical research associates.

The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well being of the study subject. [5] It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated. It ensures that the studies are implemented and reported in such a manner that there is public assurance that the data are credible, accurate and that the rights, integrity and confidentiality of the subjects are protected. In 2005, India became fully compliant to TRIPS. Since then the policymakers have been trying to make changes in the policy framework and regulatory environment in order to promote clinical trials in India. These changes are known to have encouraged the international Clinical Research Organizations (CROs) to expand their clinical research programmers in India. India hosts nearly a fifth of all global clinical trials with a huge potential for financial and scientific gains. [6] Recently, pharmaceutical companies that are involved in clinical trials are being trailed by a growing concern over the clinical research ethics followed in India. Global pharmaceutical companies are outsourcing their projects to India for several reasons: enhancing profit, cutting the cost of drug development and speeding regulatory approval, and, fostering a less hostile environment among the world′s impoverished ill.

Clinical trials are more than 50 *per cent* cheaper in India compared to developed countries. [7,8,9] The reasons for low cost of drug development are cheap human resource, low recruitment cost and lower rate of compensation for any injury sustained or death during the research process. In fact, CROs even recruit patients without any formal assurance of compensation because a large proportion of participants in India are illiterate and lured into trials by offers of free healthcare and financial inducements. However, they are often unaware of the benefits and risks of taking part in a trial, and many may not even be able to distinguish between treatment and research. In addition, the concept of informed consent before enrolling in a trial is not very clear. [8] A clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease[25]. For any new drug to enter in clinical trial, it must pass preclinical studies. Preclinical studies involve in vitro (i.e. test-tube or Laboratory) studies and trials on animal populations. Wide range of dosages of the study drug is given to animal subjects or to an in-vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information [26].

ICH-GCP:

The objective of this ICH GCP Guideline [6] is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The International conference on harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) [7,8] is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO). This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects [9]. The objective of such harmonization is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health [10-12]. Clinical studies should be carried out according to International Conference on Harmonization (ICH)/WHO Good Clinical

Practice standards [13]. This provides a unified standard for the European Union (EU) [14, 15], Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organisation (WHO). Thus, any country that adopts this guideline technically follows this same standard. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

ICH GCP GUIDELINES:

The principals of ICH GCP --

1. Clinical trial 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 requirement.

2. 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.

3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

6. 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.

7. 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.

8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks.

9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.

10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement.

12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approval protocol.

13. Systems with procedures that assure the quality of every aspect of the trial should be implanted[29].

INTERNATIONAL CONFERENCE ON HARMONIZATION GUIDELINES:

In Recognition of the international market place for pharmaceutical and in an effort to achieve global efficiency for both regulatory agencies and the pharmaceutical industry, the FDA, counterpart agencies of the European Union and Japan and geographic representatives of the pharmaceutical industry formed a tripartite organization in 1991 to discuss, identify, and address relevant regulatory issues. This organization, named the international conference on Harmonization of Pharmaceuticals for Human Use (ICH) has worked toward harmonizing, or bringing together, regulatory requirements with the long-range goal of establishing a uniform set of standards for drug registration within these geographic areas. With ICH success, duplicative technical requirements for registering Pharmaceuticals would be eliminated, new drug approvals would occur more rapidly, patients' access to new medicines would be enhanced worldwide, the quality, safety, and efficacy of imported products would be improved, and there would be an increase in information transfer between participating countries. The ICH's work toward uniform standards is focused on three general areas, quality, safety and efficacy. The quality topic includes stability, light stability, analytical validation, impurities, and biotechnology. The safety topics include carcinogenicity, genotoxicity, toxicokinetics, reproduction toxicity and single and repeat dose toxicity. The efficacy topics include population exposure, managing clinical trials, clinical study reports, dose response, ethic factors, good clinical practices, and geriatrics. For each topic, relevant regulations are identified, addressed and consensus guidelines developed. The intension is that these guidelines will be incorporated in to domestic regulations. In the United states the resulting guidelines are published in the Federal Register as notices, with accompanying statements indicating that the guideline should be "Useful" or "considered" by applicants conducting required studies or submitting registration applications.

Examples of specific ICH developed guidelines:

1. Stability testing of new drug substances and products
2. Validation of analytical procedures for Pharmaceuticals
3. Impurities in new drug substances and products
4. General consideration for clinical trial [32].

Principles of GCP:

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.

2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.

3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.

5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.

7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.

Overview of the Clinical Research Process

Key trial activities include:

1. Development of the trial protocol

2. Development of Standard Operating Procedures (SOPs)

3. Development of support systems and tools

4. Generation and approval of trial-related documents

5. Selection of trial sites and the selection of properly qualified, trained, and experienced investigators and study personnel

6. Ethics committee review and approval of the protocol

7. Review by regulatory authorities

8. Enrollment of subjects into the study: recruitment, eligibility, and informed consent

9. The investigational product(s): quality, handling and accounting

10. Trial data acquisition: conducting the trial

11. Safety management and reporting

12. Monitoring the trial

13. Managing trial data [16-18]

14. Quality assurance of the trial performance and data

15. Reporting the trial

Common GCP Issue During Clinical Studies

Informed consent

1. Length of consent form

2. Copy to patients

3. Documentation - of contacts, in source files etc.

4. Translations

5. Ethics committee approval and information to ongoing patients

6. Witness

Recruitment and study procedures

Screening procedures before consent

1. Incomplete laboratory workup per protocol

2. Inclusion/Exclusion exceptions not discussed with medical monitor

3. Patient visits outside the protocol allowed window

4. Advertisements not approved by sponsor/ethics committees

5. Difficulties in enrollment - action from investigator and sponsor.

Monitoring

Source data problems

1. CRF completion quality

2. Study team-training issues

3. Incomplete essential documentation

4. Monitoring frequency issues

Clinical trial supplies

Randomization errors

1. Accountability problems

2. Improper storage conditions

3. Compliance issues

4. Blind breaking issues

Safety reporting

Unreported SAEs

1. Delayed reporting of SAEs

2. Documentation in source files of AEs and SAEs

3.SAE reporting to institutional ethics committee

Additional safety information to ongoing/new patients-consent addenda/amendments.

4. Updates to investigators' brochure

PHASES OF CLINICAL TRIAL

Before pharmaceutical companies start clinical trials on a drug, they conduct extensive pre-clinical studies[27].

Pre-clinical studies

Pre-clinical studies involve in vitro (i.e., test tube or laboratory) studies and trials on animal populations. Wide-ranging dosages of the study drug are given to the animal subjects or to an in-vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information and to assist pharmaceutical companies in deciding whether it is worthwhile to go ahead with further testing.

Phase 0

Phase 0 is a recent designation for exploratory, first-inhuman trials conducted in accordance with the U.S. Food and Drug Administration's (FDA) 2006 Guidance on Exploratory Investigational New Drug (IND) Studies Phase 0 trials are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was anticipated from preclinical studies. Distinctive features of Phase 0 trials include the administration of single sub therapeutic doses of the study drug to a small number of subjects (10 to 15) to gather preliminary data on the agent's pharmacokinetics (how the body processes the drug) and pharmacodynamics (how the drug works in the body).

Phase I

Phase I trials are the first stage of testing in human subjects. Normally, a small (20-80) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. These trials are often conducted in an inpatient clinic, where the subject can be observed by full-time staff. The subject who receives the drug is usually observed until several half-lives of the drug have passed. Phase I trials also normally include dose-ranging, also called dose escalation, studies so that the appropriate dose for therapeutic use can be found. The tested range of doses will usually be a fraction of the dose that causes harm in testing. Phase I trials most often include healthy volunteers. However, there are some circumstances when real patients are used, such as patients who have end-stage disease and lack other treatment options. This exception to the rule most often occurs in oncology (cancer) and HIV drug trials. Volunteers are paid an inconvenience fee for their time spent in the volunteer centre. Pay ranges from a small amount of money for a short period of residence, to a larger amount of up to approx £4000 depending on length of participation.

There are different kinds of Phase I trials:

1**. SAD**

Single Ascending Dose studies are those in which small groups of subjects are given a single dose of the drug while they are observed and tested for a period of time. If they do not exhibit any adverse side effects, and the pharmacokinetic data is roughly in line with predicted safe values, the dose is escalated, and a new group of subjects is then given a higher dose. This is continued until recalculated pharmacokinetic safety levels are reached, or intolerable side effects start showing up at which point the drug is said to have reached the Maximum tolerated dose (MTD).

2**. MAD**

Multiple Ascending Dose studies are conducted to better understand the pharmacokinetics & pharmacodynamics of multiple doses of the drug.

Phase II

Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects. Phase II studies are sometimes divided into Phase IIA and Phase IIB. Phase IIA is specifically designed to assess dosing requirements (how much drug should be given), whereas Phase IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)). Some trials combine Phase I and Phase II, and test both efficacy and toxicity.

Phase III

Phase III studies are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions. It is common practice that certain Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency. While not required in all cases, it is typically expected that there be at least two successful Phase III trials, demonstrating a drug's safety and efficacy, in order to obtain approval from the appropriate regulatory agencies (FDA (USA), TGA (Australia), EMEA (European Union), etc.). Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details,

and shelf life. This collection of information makes up the "regulatory submission" that is provided for review to the appropriate regulatory authorities in different countries. Most drugs undergoing Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines, but in case of any adverse effects, being reported anywhere, the drugs need to be recalled immediately from the market. While most pharmaceutical companies refrain from this practice, it is not abnormal to see many drugs undergoing Phase III clinical trials in the market.

Phase IV

Phase IV trial is also known as Post Marketing Surveillance Trial. Phase IV trials involve the safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials. Harmful effects discovered by Phase IV trials may result in a drug being no longer sold, or restricted to certain uses: recent examples involve cerivastatin (brand names Baycol and Lipobay), troglitazone (Rezulin) and rofecoxib (Vioxx)[26].

INVESTIGATIONAL NEW DRUG (IND) / CLINICAL TRIAL EXCEPTION (CTX) / CLINICAL TRIAL AUTHORIZATION (CTA) APPLICATION

INDs (in the U.S.), CTXs (in the U.K.) and CTAs (in Australia) are examples of requests submitted to appropriate regulatory authorities for permission to conduct investigational research. This research can include testing of a new dosage form or new use of a drug already approved to be marketed. In addition to obtaining permission from appropriate regulatory authorities, an Institutional or Independent Review Board (IRB) OR Ethical Advisory Board must approve the protocol for testing as well as the informed consent documents that volunteers sign prior to participating in a clinical study. An IRB is an independent committee of physicians, community advocates and others that ensures a clinical trial is ethical and the rights of study participants are protected.

NEW DRUG APPLICATION (NDA) / MARKETING AUTHORIZATION APPLICATION (MAA)

NDAs (in the U.S.) and MAAs (in the U.K.) are examples of applications to market a new drug.

Such application document safety and efficacy of the investigational drug and contain all the information collected during the drug development process. At the conclusion of successful preclinical and clinical testing, this series of documents is submitted to the FDA in the U.S. or to the applicable regulatory authorities ion other countries. The application must present substantial evidence that the drug will have the effect it is represented to have when people use it or under the conditions for which it is prescribed recommended or suggested in the labeling. Obtaining approval to market a new drug frequently takes between six months and two years [28].

TYPES OF CINICAL TRIAL:

1**. Treatment trials**

Test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

2**. Prevention trials**

Look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.

3**. Diagnostic trials**

Conducted to find better tests or procedures for diagnosing a particular disease or condition.

4. **Screening trials**

Test the best way to detect certain diseases or health conditions.

5**. Quality of Life**

Trials (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness [26]

MONITORING CLINICAL TRIALS:

The purposes of trial monitoring are to verify that:

1. The rights and well being of human subjects are protected.

2. The reported trial data are protected.

3.The conduct of the trial is incompliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

ETHICAL CONSIDERATION

An Independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non- medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by among other things, reviewing and approving /providing favorable opinion on, the trial protocol, the suitability of the investigators facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations and

regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the independent Ethics Committee to act in agreement with GCP as described in this guideline.

COMPLIANCE WITH PROTOCOL

The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which were given approval/ favorable opinion by the IRB/IEC. The investigator/ institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement. The investigator should not implement in deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval / favorable opinion from the IRB / IES of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subject, or when the change(s) involves only logistical or administrative aspect of the trial (e.g. change in monitor (s), change of telephone no.(s). The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol. The investigator may implement a deviation from, or a change of the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/ favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and if appropriate, the proposed protocol amendment(s) should be submitted.

1. To the IRB/IEC for review and approval/favorable opinion.
2. To the sponsor for agreement.
3. To the regulatory authority (IES).

ETHICAL CONDUCT

Clinical trials are closely supervised by appropriate regulatory authorities. All studies that involve a medical or therapeutic intervention on patients must be approved by a supervising ethics committee before permission is granted to run the trial. The local ethics committee has discretion on how it will supervise nonintervention studies (observational studies or those using already collected data). In the U.S., this body is called the Institutional Review Board (IRB). Most Ribs are located at the local investigator's hospital or institution, but some sponsors allow the use of a central (independent/for profit) IRB for investigators who work at smaller institutions. To be ethical, researchers must obtain the full and informed consent of participating human subjects. (One of the Rib’s main functions is ensuring that potential patients are adequately informed about the clinical trial.) If the patient is unable to consent for him/herself, researchers can seek consent from the patient's legally authorized representative. In California, the state has prioritized the individuals who can serve as the

legally authorized representative. In some U.S. locations, the local IRB must certify researchers and their staff before they can conduct clinical trials. They must understand the federal patient privacy (HIPAA) law and good clinical practice. International Conference of Harmonization Guidelines for Good Clinical Practice (ICH GCP) is a set of standards used internationally for the conduct of clinical trials. The guidelines aim to ensure that the "rights, safety and well being of trial subjects are protected". The declaration of Helsinki of the World Medical Association (1964) codifies recommendation for guidance of doctors in clinical research [31].

ROLE OF PHARMACISTS IN CLINICAL TRIALS

Pharmacists have an active role to play in research and clinical trials first of all, we provide the necessary facilities required for proper storage of the investigational medicinal products (IMPs), either in the fridge or at controlled room temperature. Regular temperature monitoring is ensured and recorded. It is also the pharmacist's duty to ensure there is constant supply of IMPs at all times, and that they are dispensed to patients accordingly. Patients are counselled on the correct use of the IMPs in addition to any written information that is provided, such as, Informed Consent Form or the Patient Information Leaflet. IMPs returns from patients are counted and documented to determine compliance to the treatment. For inject able IMPs, pharmacists will also ensure that they are prepared in accordance to the specifications stipulated in the trial, and that they are administered appropriately. Besides managing clinical trials, oncology pharmacists often run research projects that are aimed at improving outcomes in patients who receive medications, such as chemotherapy or other supportive drugs like anti-emetics, blood growth factor injections, etc. Drug Utilization Evaluations (DUEs) are research projects that are commonly conducted by pharmacists. These projects aim to facilitate rational use of drugs within our patients. Essentially, providing insights on how drugs are used in patients and observing prescribing patterns by our physicians. DUEs are sometimes considered as drug audits because pharmacists are ensuring the use of medication is appropriation In addition, pharmacists also conduct observational surveys that are aimed at investigating patients' or physicians' perspectives and attitudes towards medications. Results obtained from surveys are used to improve the services that we provide to our patients. Currently, NCC's oncology pharmacy is conducting two surveys. They are aimed at investigating patients' use of complementary and alternative medications and on patients' perspective on safe handling of oral anti-cancer drugs. Very often, pharmacy students who are adequately trained to conduct research

are assigned to survey the patients. We would like to take this opportunity to thank all our patients who have consented to participate in the survey [33]

CONCLUSION

Ongoing research shows that whether conducting research involving a new drug, a behavioral intervention, or an interview/ survey, Good Clinical Practice (GCP) [19-24] provides investigators and their study teams with the tools to protect human subjects and collect quality data. In this article, the author will define GCP, explain the benefits of following GCP for all types of human research studies, and provide some resources to assist investigators in implementing the tenets of GCP for their own research studies. This article illustrates the importance of Good Clinical Practice (GCP), defined and outlined the goals of GCP, Presented a historical perspective on GCP, Outlined FDA regulations relating to GCP. According to Van Dongen [4] ultimately it is not difficult for investigators and their study teams to follow GCP – it is simply a question of writing down procedures, documenting what is being done, and preparing for inspection. He goes on to say that there are considerable rewards, not the least of which is the confidence that the data was obtained through a GCP-compliant research study. GCP will enforce tighter guidelines on ethical aspects of a clinical study. Higher standards will be required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities including computers. The additional requirements of GCP are discussed and any advantage to the study subject. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly documented. In this paper, we address the background history and the events that led up to the formation of these guidelines. Today, the GCP are used in clinical trials throughout the globe with the main aim of protecting and preserving human rights. Quality assurance and inspections will ensure that these standards are achieved. This article reviews the impact of Good Clinical Practice (GCP) on clinical trials. A clinical trial for any new drug follows under the guidelines of ICH and GCP, clinical trial are conducted in human volunteers for confirmation of useful properties of new drug. After preclinical development, investigational new drug passes through clinical phases I, II, III and IV. These phases provide in detail explanation of pharmacokinetic, pharmacodynamic profile and side effect which may be harmful or beneficial, adverse effect and post marketing surveillance.

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