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Good Clinical Research Practices

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Abstract: ***This article highlights the importance of Clinical Practice in Research. Good Practice Clinical Practice is a process that incorporates established and scientific quality standards for design, ethics, recording and reporting of clinical research involving the participation of human studies. The GCP provides valuable clinical training to research groups involved in clinical trials of drugs, biologics, and devices, as well as those who participate in behavioural interventions and social science research studies. Participants are respected and protected, and that the data produced is reliable and accurate.***

Index Terms - Ethics, Human Rights, Privacy, Testing, GCP, Quality, Research, Compliance

I. INTRODUCTION

Medical research is needed to determine the safety and effectiveness of certain health and medical products and procedures. Much of what is known today about the safety and effectiveness of certain products and treatments comes from randomized clinical trials designed to answer important scientific questions and health care. Randomized controlled trials form the basis of "evidence-based medicine", but such research can only be relied upon if it is conducted in accordance with the collection principles and standards called the "Clinical Research Practice" (GCP).

A good practice of clinical research based on major international guidelines, including GCP guidelines published after 1995, such as the International Conference on Harmonization (ICH):

• describes the clinical research process as it relates to health and medical products, and identifies and describes each common function in multiple studies and the parties responsible for it;

• linking each of these processes to one or more GCP Policies.

• define each GCP Policy and provide guidance on how each Policy is applied and applied in general terms;

• Guide specific international guidelines or other guidelines that provide more detailed advice on how to comply with the GCP.

International Committee on Harmonization of Good Clinical Practice (ICH-GCP)

The ICH Guidelines are a set of guidelines to ensure that safe, effective and high quality medicines are developed and properly registered. These guidelines have been approved by authorities around the world. The level of design, ethics, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials ensures that the reported data and results are reliable and accurate, and that the rights, integrity, and confidentiality of trail subjects are protected. Quality and scientific ethical standards for designing, performing, recording and reporting tests involving the interaction of human subjects to ensure the rights, safety and well-being of the subjects being tested are protected. Verify the reliability of clinical trial data.

The ICH guidelines are divided into four sections below and the ICH title codes are provided according to these sections.

Quality Guidelines:

The achievements of harmonization in the Quality Area include important developments such as the conduct of sustainability studies, clarification of appropriate pollution control parameters and the appropriate compliance with medical standards based on Good Practice (GMP) for disaster risk management.

Safety Guide:

Q ICH has developed a complete set of Safety Guidelines to identify potential risks such as carcinogenicity, genotoxicity and reprotoxicity. The most recent success has been the non-clinical trial trial for QT extension period: one of the most important causes of drug withdrawal in recent years.

Operational Guidelines:

The work done by the ICH under the heading Efficiency is concerned with the design, conduct, safety and reporting of clinical trials. It also incorporates the novel types of drugs found in biotechnological processes and the use of pharmacogenetics / genomics techniques to produce better targeted drugs.

Multidisciplinary Guidelines:

Those are the divisive topics that do not fit into one of the categories of Quality, Safety and Efficiency. Includes ICH medical terminology (MedDRA), Common Technical Document (CTD) and the development of Electronic Transmission Control Standards (ESTRI).

HISTORY OF HISTORY

In 1947, the Nuremberg Code was created as a result of illicit and horrific experiments conducted during World War II in Nazi military camps by German doctors, after which they were tried and prosecuted in the Nuremberg Military Court. This code refers to the need for a scientific basis for research on human subjects and the voluntary consent and protection of participants. The Universal Declaration of Human Rights (December 10th 1948) was adopted by the United Nations after World War II and reaffirmed the humanitarian nature of medical research.

The archive is summarized as follows:

460BC:	Hippocrates' oath
1930	U.S. Food, Drugs and cosmetic Act
1947	Nuremberg Code
10 Dec 1948	Declaration of Human Rights
1962	Kefauver-Harris Amendment
1964	revised 2000: Proclamation of Helsinki
1979	Belmont Report
1982	International guidelines for biomedical research involving human studies
1996	ICH-GCP guidelines issued
1997	ICH-GCP guidelines become legal in some countries

In 1964, the Declaration of Helsinki was established by the World Medical Association, which formed the basis for the ethical principles underpinning the ICH-GCP guidelines we have today. The purpose of this declaration is to protect human rights and this is evident in its introduction

In 1962 the world was again shocked by the severe paralysis of the child's legs related to the use of maternal thalidomide. In fact, this drug reaction was only found after the birth of 10,000 babies in more than 20 countries around the world. In response, Kefauver-Harris Amendments were passed that required the FDA to test all new drugs for safety and efficacy.

Another important step in the development of the ICH-GCP guidelines was the Belmont Report released in April 1979 by the National Commission for the Protection of Human Subjects for Environmental and Behavioural Research. The principles of this report are as follows:

1. Respect for the People: This principle recognizes the dignity and freedom of all human beings. Requires informed consent from research studies (or their authorized representatives)

2. Beneficence: This principle requires researchers to maximize profits and reduce research-related harm. Research-related risks should be moderate in view of the expected benefits.

Justice:

This policy requires equal selection and recruitment and proper management of research studies. In 1982, the World Health Organization (WHO) and the Council of International Organizations for Medical Sciences (CIOMS) released a book entitled 'International Guidelines for Biodiversity Research involving Human Studies'. This document was released to help developing countries apply the principles of the Helsinki Declaration and the Nuremberg Code. Throughout the world, many organizations and committees have issued various directives and guidelines on the same subject, and a decision was made to integrate all these guidelines into one universal guide.

In an effort to overcome international GCP compliance in all countries, the International Conference on the Compliance of Technical Requirements for the Registration of Drugs (ICH) has issued the ICH Guidelines: Topic E6 GCP Guide. This guide was approved on 17 July 1996 and has been used in clinical trials since 17 January 1997. Participants in these guidelines were representatives from pharmaceutical authorities and companies from the EU, Japan and the United States as well as those from Australia, Canada, and Nordic. Countries and the WHO.

Objectives:

The purpose of this ICH GCP Guide is to provide an integrated standard for the European Union (EU), Japan and the United States to facilitate the uniform acceptance of clinical data by regulatory authorities in these areas. The guide was developed through an examination of the current best 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 guide should be followed when generating clinical trial data intended to be submitted to regulatory authorities.

The GCP aims to ensure that the studies are scientifically accurate and that the clinical features of the research product are well documented. The GCP guidelines include academic human rights protection and volunteers in clinical trial. High standards are required regarding comprehensive clinical protocol documentation, record keeping, training, and resources, including computers and software. Quality assurance and testing ensures that these standards are met. The GCP aims to ensure that the studies are scientifically accurate and that the clinical features of the research product are well documented.

A series of failed and ineffective clinical trials in the past was the main reason for the implementation of ICH and GCP guidelines in the US and Europe. These discussions eventually led to the development of specific regulations and guidelines, which changed the operating code of international consensus for quality research.

13 HUMAN ICH-GCP PRINCIPLES:

1. Clinical evaluation must be conducted in accordance with the ethical principles derived from the Declaration of Helsinki, and in compliance with the GCP and applicable regulatory requirements.

2. Prior to the commencement of the trial, the actual risk and disruption should be weighed against the expected benefit of each test subject and the community. The evaluation should be initiated and continued only if the expected benefits justify the risk.

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

4. The available non-clinical and health information of the research product should be sufficient to support the proposed clinical trial.

5. Clinical trials should be scientifically sound, and defined by a clear, detailed protocol.

6. The trial must be conducted in accordance with an agreement approved by the institutional review board (IRB) / independent ethics committee (IEC).

7. The medical care provided, and the medical decisions made on their behalf, topics should always be the responsibility of a qualified dentist or, where appropriate, a qualified dentist.

8. Each person taking part in the examination should have knowledge of education, training and practical skills.

9. Relevant informed consent should be obtained throughout the study before participating in clinical research.

10. All clinical trial data should be recorded, handled, and maintained in a manner that allows for its accurate reporting, interpretation and validation.

11. The confidentiality of records that identify subjects must be protected, with respect to privacy and confidentiality laws in accordance with applicable (requirements).

12. Research products must be manufactured, processed, and stored in accordance with the productive manufacturing practice (GMP). They must be used in accordance with the approved protocol.

13. Systems with procedures that ensure the quality of all aspects of the test should be used.

These principles are self-explanatory and, when summarized, simply state:

All clinical trials should be conducted in accordance with ethical principles, sound scientific evidence and detailed regulations.

The benefits of conducting tests should outweigh the risks. The rights, safety and well-being of study participants are very important and this should be maintained by obtaining informed consent and keeping it confidential. Care should be given to trained and experienced staff. Records must be easily accessible and downloaded for accurate reporting, verification and interpretation. Research products should be made in accordance with Good Manufacturing Practice.

It is also important to name GCP participants in clinical trials and their responsibilities respectively.

These are as follows:

A. Regulatory Authorities:	Review clinical data submitted and perform tests.
B. Sponsor:	A company or institution / organization that is responsible for initiating, managing and funding clinical trials
C. Project Monitor:	Usually nominated by sponsors
D. Investigator:	You are responsible for conducting clinical trials in the testing area. Team leader.
E. Pharmacist:	Responsible for the care, maintenance and disposal of research products.
F. Patients:	Human studies.
G. Ethics Committee:	Appointed by the institution or in its absence then the Health Authority in that country will be responsible
H. Major review monitoring committee:	Overseas sponsors e.g. Drug companies.

International Review Board:

It is an independent body established to protect the rights and well-being of study participants. Any clinical investigation involving a product controlled by the U.S. The Food and Drug Administration (FDA) must also be reviewed and approved by the IRB.

The IRB must have a diverse membership that includes both scientists and non-scientists. Scientists may include researchers, doctors, psychologists, nurses, and other mental-health professionals. Non-scientists may have special knowledge of a certain number of people (pregnant women, children or prisoners).

Informed Consent Form:

Informed consent is the process by which a person voluntarily agrees to participate in a research study after being fully informed of it. An informed consent document should contain all the information a participant needs to make an informed decision about participating in the study. Participant's signature confirms his or her voluntary participation in the study.

Confidentiality and Privacy :

All records of the identity, diagnosis, prognosis, or treatment of any person kept in connection with the prevention of alcohol or drug abuse, education, training, treatment, rehabilitation, or research must be kept confidential.

Participant Safety and Adverse event:

The safety of the study participants must always be protected during the study period.

Adverse Event (AE) is defined in the Clinical Practice Guidelines as any “unexpected medical event should not be related to the cause of drug treatment. Generally all AEs and SAEs

CONCLUSION

The significance of the GCP lies in the question of ‘why’ and ‘how’ the GCP test took place. To know the answer to this, we need to look at the historical context that led to the development of GCP guidelines in the United States and Europe and the establishment of the ICH. The events that led to the culmination of the ICH-GCP guidelines brought public awareness of the need to regulate and regulate clinical trials related to drugs and human subjects. Human rights abuses have played a major role and that is why the Helsinki Declaration and the Nuremberg Code remain the framework of current guidelines. The ICH-GCP guidelines are therefore regarded as the bible’s clinical trials, and have become a universal protective law.

Mankind as we know it today.

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