Review Article

A Brief Review on Good Clinical Practice and its Training Methods

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Abstract

The field of clinical research continues to advance, and for ethical conduct of research, researchers need to have a strong foundation in good clinical practice (GCP). GCP guidelines are internationally recognized standards that govern the conduct of clinical trials, ensuring the protection of human subjects and the generation of reliable data. However, novice researchers or postgraduate medical students who would delve into research activities may face difficulty getting avenues for GCP training. Hence, in this brief review article, we discuss the significance of GCP in the field of clinical research with a glimpse of its history, development, and key principles. We provide a list of online courses, benefits, and disadvantages of those courses, and a list of organizations that conduct GCP workshops or continued medical education programs in India.

Keywords: *Clinical trial, education, ethics, GCP, medical, research*

Introduction

Ethical conduct in clinical research is of paramount importance, ensuring the protection of human subjects and the reliability of scientific data. Novice researchers (e.g., researchers after graduation, postgraduate students) often take their first steps in the realm of clinical trials without basic knowledge of research ethics and good clinical practice (GCP).[1] Lack of awareness or incomplete knowledge about GCP guidelines can lead to serious consequences, such as compromised participant safety, unreliable study results, or even regulatory non-compliance.[2]

Many times, young researchers or newly joined postgraduate students may face challenges to attend a workshop or continuing medical education session about the GCP as, in India, these sessions are rarely organized for students.

In this context, the primary objective of this review paper is to bridge the knowledge gap and empower novice authors with a clear understanding of basics of GCP principles. To facilitate accessibility and convenience, the paper will highlight the availability of self-paced online GCP courses. These courses offer novice authors the flexibility to learn at their own pace, allowing them to fit GCP training into their busy schedules.

What is GCP?

GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human participants. GCP guidelines cover various aspects of clinical trial conduct as shown in Table 1.[3,4]

Glimpse of history

Unethical trials or studies might have been present since historical times. That is why, in 450 BC, the Hippocratic oath was introduced to promote better medical treatment [Figure 1].[1] Physicians all around the world might have treated patients with drugs that they believed would work or conducted research on vulnerable humans. Many might have consumed remedies like Grandma's Secret or Dr. Bull's Cough Syrup, which contained morphine. To reduce the use of unapproved drugs, the United States Food and Drug Administration (US FDA) Act was introduced in 1938. However, this act primarily focused on regulating drugs and not on research.[1,5,6]

During World War II, in Nazi concentration camps, German physicians conducted inhumane experiments on humans. Recognizing the need to put an end to such unethical practices, the Nuremberg Code was introduced in 1947. The code emphasized that research should be based

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Table 1: Core components of good clinical practice

Theme	Brief
Ethics	"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 applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants"
Consent	"Informed consent is an integral feature of the ethical conduct of a trial. Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed"
Review	"Clinical trials should be subject to an independent review by an institutional review board/independent ethics committee (IRB/IEC)"
Scientific	"Clinical trials should be scientifically sound for their intended purpose and based on robust and current scientific knowledge and approaches"
Expertise	"Clinical trials should be designed and conducted by qualified individuals"
Quality	"Quality should be built into the scientific and operational design and conduct of clinical trials"
Justification	"Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected"
Clarity	"Clinical trials should be described in a clear, concise and operationally feasible protocol"
Reliability	"Clinical trials should generate reliable results"
Documentation	"Roles and responsibilities in clinical trials should be clear and documented appropriately"
Compliance	"Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be stored, shipped, handled and disposed of in accordance with the product specifications and the trial protocol"

The themes were generated by the authors and not endorsed by ICH. The brief was sourced from ICH Harmonised Guideline - Good Clinical Practice (GCP) E6 (R3) available at https://ich.org/page/efficacy-guidelines; accessed on 03 August 2023

on scientific principles and that participation in research should be voluntary. In 1948, the United Nations adopted The Universal Declaration of Human Rights.

However, researchers or physicians might not have been well-trained about the ethical conduct of research or may have ignored it. The Tuskegee syphilis study and the Thalidomide tragedy further highlighted the urgent need for comprehensive regulations and ethical guidelines. The Tuskegee Study, conducted from 1932 to 1972, involved the unethical withholding of treatment for syphilis in African American men to study the disease course in detail. In 1962, the Thalidomide tragedy observed 10,000 babies born with limb deformities due to the unapproved use of thalidomide during pregnancy. Hence, the Kefauver-Harris Amendment was introduced to ensure that all drugs be passed by the US FDA before use in humans. In 1964, the Declaration of Helsinki was developed by the World Medical Association (WMA).[1,5,6]

In 1979, the Belmont Report was issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which stressed "respect," "beneficence," and "justice" in recruiting human participants for research. Concurrently, the World Health Organization (WHO) played a pivotal role in establishing ethical guidelines for clinical trials. The WHO's early efforts culminated in the publication of the first International Ethical Guidelines for Biomedical Research Involving Human Subjects in 1982.

However, there were inconsistencies in ethical research across the globe that needed harmonization. Hence, the International Council for Harmonisation (ICH) emerged as a key organization in the development of GCP guidelines. In the early 1990s, the ICH initiated the process of harmonizing guidelines from different regions to create a unified framework. This effort resulted in the introduction of the ICH-GCP guidelines in 1996. By 1997, many countries had adopted these guidelines as law, ensuring strict compliance with the guidelines.[1,5,6]

In India, the Indian Council of Medical Research (ICMR) released a policy statement on ethical considerations in research involving human subjects in 1980. However, during the 1970s and 1980s, controversial research practices were prevalent, including a study conducted in New Delhi where 1158 women with cervical dysplasia were left untreated to observe the progression to cancer. The study was published in 1997 and was criticized at the population level.[7] In response to such issues, the ICMR revised its policy documents in 2000 and again in 2006. The latest update, titled "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants," is current until 2017. It is important to note that this guideline is not limited to clinical trials, but is applicable to all research. For clinical trials, India follows the GCP guidelines.[8,9]

Who should have knowledge of GCP?

GCP training is recommended for various individuals involved in the planning, conduct, and oversight of clinical trials.[3,10]

Principal investigators who lead clinical trials and are responsible for the overall conduct and oversight of the study should undergo GCP training. This includes medical doctors, scientists, and other professionals who are actively involved in the design, implementation, and analysis of clinical trials. It should be started in the first few months of postgraduate training as they enter the world of research activity from the first year of study [see "Update for postgraduate students" at the end of this article].

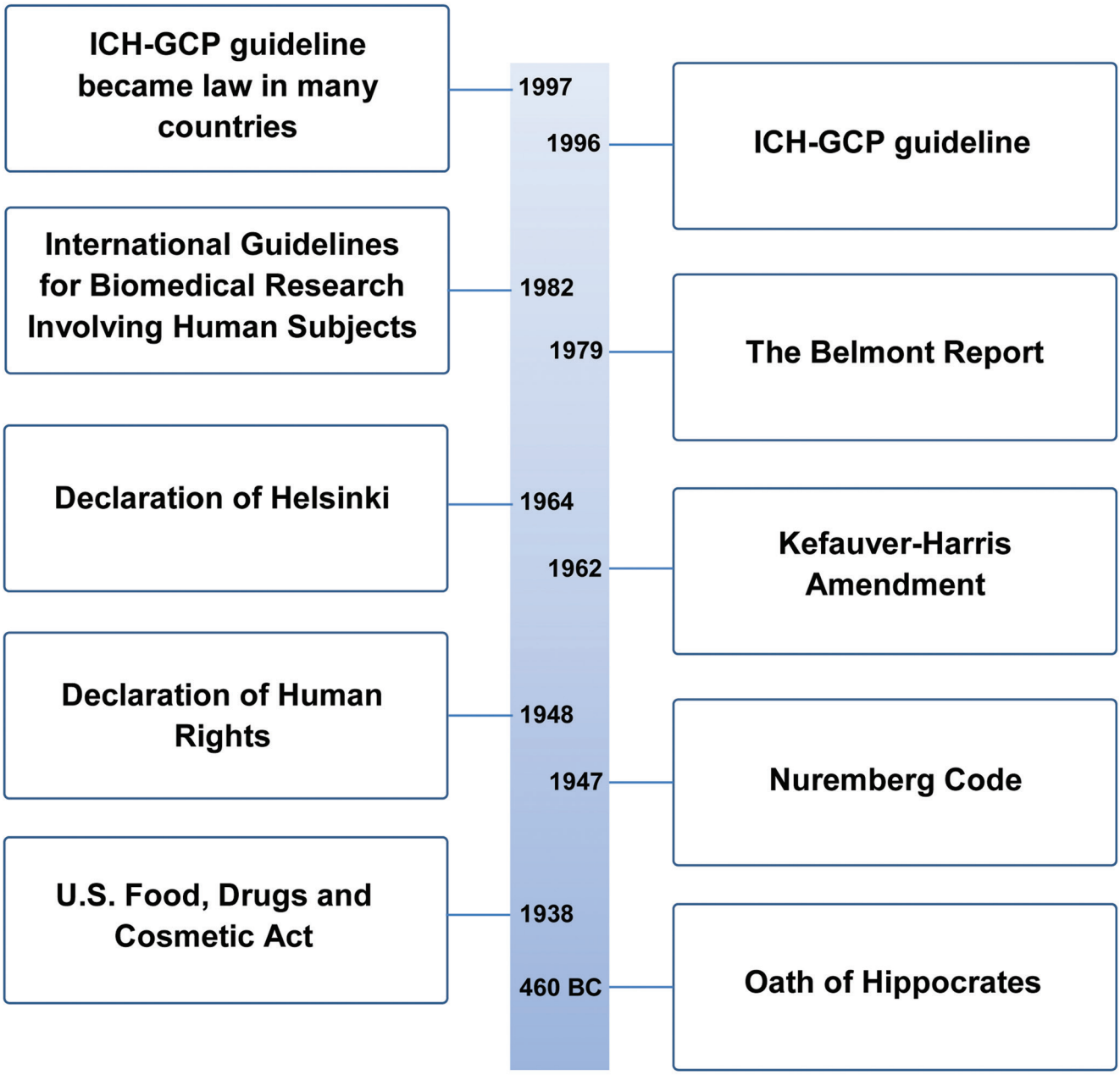

Figure 1: Historical vignette of development of ethical guidelines for conduct of research on human subjects

Study coordinators, research nurses, and other personnel involved in the day-to-day management of clinical trials should receive GCP training. They play a critical role in ensuring adherence to GCP guidelines, data collection, participant recruitment, informed consent process, and overall study coordination. Indeed, their participation is more than the principal investigator in implementing sound research practices.

Members of ethics committees, institutional review boards (IRBs), or research ethics boards (REBs) who review and approve clinical trial protocols should have a solid understanding of GCP principles. GCP training helps them evaluate the ethical aspects of proposed trials, ensuring participant rights, safety, and welfare. ICMR guideline also states that the members of IRB and Independent Ethics Committee (IEC) should have GCP training.

Individuals representing the trial sponsor, such as pharmaceutical companies, contract research organizations (CROs), or academic institutions funding the research, should have in-depth knowledge of GCP.

Regulatory authority personnel involved in reviewing and approving clinical trial applications may undergo GCP training to enhance their understanding of GCP principles. This enables them to evaluate trial protocols, data, and safety reports submitted for regulatory approval accurately.

In addition, any independent auditors and monitors responsible for assessing the compliance of clinical trials with GCP guidelines and applicable regulations should have a thorough understanding of GCP principles.

While the specific individuals who should undergo GCP training may vary based on roles and responsibilities, it is generally recommended for anyone involved in the planning, conduct, or oversight of clinical trials.

Where to get GCP training?

Any interested individual can borrow a book from the library or collect information about the GCP from the Internet. However, informal knowledge is rarely appreciated in this world. Hence, a certificate is the proof of GCP training that may be required to prove your knowledge.[11] Training or workshops are conducted for GCP in many institutions. However, young researchers and students may miss the training. Hence, in the following section, we discuss about the online training. The majority of the certificate is valid for 3 years, and learners should obtain a fresh certificate every 3 years.

Online GCP training

Several organizations offer online GCP training courses for free. Here are some websites that offer free online GCP training courses:

1. National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) is an initiative of the NIDA, which is a part of the National Institutes of Health (NIH) in the United States. You can find the courses at https://gcp.nidatraining.org/. The course is self-paced and spans about 6 hours and can be completed from anywhere. The course has a total of 12 topics based on ICH GCP Principles and the Code of Federal Regulations (CFR) for clinical research trials in the United States of America. A certificate of completion is provided immediately after completion and passing the test (minimum 80%) integrated along with the course.
2. Global Health Training Centre provides a course called ICH Good Clinical Practice E6. You can find the courses at https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/. It is a self-paced e-learning course that is based on the latest ICH Good Clinical Practice E6 (R2). It contains 10 modules and takes approximately 45–60 minutes to complete. A certificate is provided after obtaining 80% marks in the final quiz session.
3. The National Institute for Health and Care Research provides free GCP training courses for people supporting clinical research delivery at the NHS, UK universities and other publicly funded organizations in England. You can find the course at https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm. This is also a self-paced course that has a total of six modules. It approximately takes 4 hours to complete. Once the modules are completed and marked as completed, the certificate will be available to the learner.

This is a short list of websites that provide GCP training. Other websites may also be there for the same training by different providers. Be sure to review the specific details and requirements of each course before enrolling.

Online GCP training allows learners to access the training modules at their convenience, from anywhere with an Internet connection. It typically offers a self-paced learning modules, allowing participants to study at their own speed and revisit materials as needed. Many online GCP training programs are available free of charge, making them accessible to a broader audience. Online GCP training programs can be easily updated to reflect the latest regulatory guidelines, best practices, and advancements in the field. Online courses can incorporate multimedia elements, such as videos, interactive quizzes, and animations to enhance the learning experience. These engaging formats facilitate knowledge retention and understanding of complex concepts, making the training more interactive and enjoyable. After completion, participants can download or print the certificates.

However, online courses lack the face-to-face interaction and networking opportunities that can be found in offline training settings. Often, learners enroll and then lose interest in completing the course as self-motivation and discipline to complete the training are of utmost importance. Offline training may include hands-on practical exercises, such as role-playing scenarios or group activities, to reinforce learning. Online courses may have limitations in providing such practical experiences, which are better facilitated in offline settings. This lack of social connection may not suit everyone's preferred learning style, leading to a sense of detachment or reduced engagement.

It is important to note that while online courses may have these potential drawbacks, many providers strive to mitigate them by incorporating interactive elements, discussion forums, and online support systems. Participants can still gain valuable knowledge and skills through online GCP training. However, it is crucial to be aware of these potential limitations and actively address them to optimize the learning experience.

Offline provider

Several organizations in India provide GCP training. Here are some of the providers of GCP training in India. The organization may charge the learner a nominal fee.

1. Indian Society for Clinical Research (ISCR): ISCR is an organization dedicated to promoting ethical and quality clinical research in India. They offer GCP training programs for investigators, study coordinators, and other clinical research professionals. For more information, visit their website at https://www.iscr.org.

2. Indian Pharmacological Society (IPS): IPS conducts GCP training workshops and courses as part of their efforts to promote research ethics and quality standards in clinical trials. To learn more, visit their website at https://www.indianpharmacologicalsociety.org/meetings-conference.php.
3. Clinical Research Secretariat and the Department of Atomic Energy - Clinical Trials Centre (CRS and DAE-CTC), Tata Memorial Centre, conducts the Good Clinical Practice – Basic and Advanced course every year. Additional information is available at https://tmc.gov.in/. If you have difficulty finding the course details, try searching on the Internet with the institution's name and course name.

It is important to note that the availability and schedule of GCP training programs may vary, so it is recommended to visit the respective websites or contact these organizations directly for the most up-to-date information on training offerings in India. Additionally, this is not an exhaustive list, and researchers should also consider checking various government institutes, institutes of national importance, or other reputed private institutions for workshop schedules.

Download GCP document

The latest version of GCP, titled "ICH Harmonised Guideline - Good Clinical Practice (GCP) E6 (R3)," can be accessed from the official website. However, this version is still under public consultation and yet to be finalized. The previous version, E6 (R2), is also available on the website. To download it, visit https://ich.org/, hover over "Work Products," select "Efficacy Guidelines," and find "E6 Good Clinical Practice." Click on the drop-down button to access both E6 (R2) and E6 (R3).

The Indian Drug Technical Advisory Board has adopted the GCP guideline to ensure the ethical conduct of clinical studies in India. The guide can be found at https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadImmunization/Clinical.pdf.

The WHO provides the Handbook for Good Clinical Research Practice (GCP) for free from their website at https://apps.who.int/iris/handle/10665/43392. This handbook supplements the WHO's "Guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical products" published in 1995. Its purpose is to assist national regulatory authorities, sponsors, investigators, and ethics committees in implementing GCP for various types of clinical research, including industry-sponsored, government-sponsored, institution-sponsored, and investigator-initiated trials.

ICMR also provides the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants on their website, available at https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx. Additionally, they offer a concise version of the guidelines in a 28-page book titled "Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants," published in 2018. The purpose of the handbook is to provide a quick and easy reference to the ethical guidelines.

The new drugs and clinical trials rules, 2019

Indian Central Drugs Standard Control Organization under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, provides guidelines for drugs and clinical trials on their website available at https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs. This guideline discusses about the functioning of the ethics committee on clinical and drug trials.[12]

Update for postgraduate students

The draft postgraduate medical education regulations 2021 circulated by the National Medical Commission Postgraduate Medical Education Board is available at https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/final%20PGMER%20draft.pdf. This draft has a section on common course work (clause 17.14) which states that along with other courses like research methodology, basic cardiac life support, basics of management and audit, and telemedicine, the course in ethics is mandatory for postgraduate students. The courses in ethics are GCP and Good Laboratory Practices, whichever is applicable and to be completed within one year of admission. Without the certification, students will not be eligible to write university examinations. The courses are "to be conducted by the Institutes themselves or by any other method." Hence, it is presumed that an online course certificate would be valid.

Conclusion

This concise review article highlights the importance of GCP training for novice researchers and provides a list of online free courses as well as a list of organizations arranging workshops. GCP training is crucial for maintaining ethical standards, safeguarding participant rights, and ensuring the credibility of clinical research. Stakeholders should ensure that their researchers are trained in GCP. Novice researchers are encouraged to explore reputable institutions for workshop schedules as continuous learning and adherence to GCP principles are essential for responsible and high-quality clinical research, benefiting both researchers and the scientific community at large.

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Conflicts of interest

There are no conflicts of interest.

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