



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Review Paper

An Overview of Clinical Trial Review Processes in India: Roles and Responsibilities of Regulatory Bodies

Sujata Samant^{1*}, Nikita Raut², Geeta Ban³, Jagdish Urgunde⁴, Vaishnavi Biradar⁵, Sakshant Shindalkar⁶, Hanuman Wable⁷, Sanket Chavan⁸, Vaishnavi Bobade⁹

¹Department of Pharmacology, Abhinav Bahu-Uddeshiya Shikshan Sanstha's Siddhivinayak College of Pharmacy, Warora, 442914, Chandrapur, Maharashtra, India.

^{2,3,4,5,7,8,9} Department of Pharmacology, Godavari Institute of Pharmacy, Kolpa, Latur, 413512, Maharashtra, India.

⁶Department of Pharmacology, Shri Sharanabasaveshwar College of Pharmacy, Vijayapura, 586103, Karnataka, India

ARTICLE INFO

Published: 03 May 2025

Keywords:

Clinical Research, Clinical studies, DCGI, DTAB, CDSCO

DOI:

10.5281/zenodo.15333182

ABSTRACT

A clinical trial is a research investigation involving human participants aimed at addressing specific health-related inquiries. When conducted meticulously, clinical trials represent the quickest and most secure means of identifying effective treatments and enhancing health outcomes. Investigational studies assess the safety and efficacy of novel therapies or new applications of established treatments within a controlled setting. Observational trials examine health-related topics within large populations in natural environments. The primary objective of clinical trials is to evaluate therapeutic effectiveness, and they represent a crucial and highly specialized type of biological assessment. In phase I, clinical pharmacologists investigate pharmacokinetics, safety, and overall effects in human volunteers. If a drug successfully meets the criteria, it progresses to phase II testing, where pharmacokinetics, safety, and therapeutic efficacy are analysed in a select group of patients by clinical pharmacologists. Following successful outcomes in phase II, hundreds of patients are assessed primarily for safety and therapeutic effectiveness by clinical investigators in phase III. Upon passing this phase, the drug receives approval and becomes available in the market. Even after market release, health professionals from various hospitals and clinics provide feedback on the drug concerning adverse drug reactions (ADRs) and efficacy during phase IV.

***Corresponding Author:** Sujata Samant

Address: Department of Pharmacology, Abhinav Bahu-Uddeshiya Shikshan Sanstha's Siddhivinayak College of Pharmacy, Warora, 442914, Chandrapur, Maharashtra, India

Email ✉: nirmalpharmasolutions@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



INTRODUCTION

Clinical trials are forward-looking biomedical or behavioral research studies involving human participants. They provide data on safety and effectiveness while addressing specific inquiries regarding biomedical or behavioral interventions, such as novel vaccines, drugs, treatment devices, or innovative applications of existing approaches^[1]. A clinical trial assesses a new medical treatment or a revised method for administering an established treatment to determine if it offers a superior strategy for preventing, screening, diagnosing, or treating a disease. Before any new medication can begin clinical trials, it must successfully complete preclinical testing. This preliminary phase includes both *in vitro* (laboratory or test tube) research and experiments on animal populations. During these investigations, a range of dosages of the investigational drug is administered to either animal subjects or *in vitro* systems to obtain initial data on efficacy, toxicity, and pharmacokinetics^[2]. As indicated by the term "clinical trials," these are sets of experiments and observations conducted in human participants for clinical research. They aim to discover new treatments, interventions, or tests that serve to prevent, detect, treat, or manage various diseases or medical issues. Clinical trials help ascertain whether a new intervention is effective, its safety, and whether it surpasses existing treatments. The World Health Organization defines a clinical trial as follows: Recently, the surge in health care expenditures in the United States has led to significant federal funding aimed at uncovering highly valuable medical treatments. Specifically, the American Recovery and Reinvestment Act of 2009 allocated \$1.1 billion for "comparative effectiveness" research to assess the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures utilized in preventing,

diagnosing, or treating diseases, disorders, and health conditions. While various study designs can fulfill these objectives, clinical trials—particularly randomized controlled trials (RCTs) continue to serve as the gold standard for comparing disease interventions. Nonetheless, executing clinical trials requires a robust strategy grounded in scientific, statistical, ethical, and legal principles^[3]. Consequently, it is essential for health care providers to grasp the foundational principles of well-conducted clinical trials to foster collaboration with patients and industry in the quest for safe, effective, and efficient therapies. We outline key concepts and the challenges encountered in the successful design and implementation of clinical trials^[4].

What Is Clinical Research?

Clinical research is a methodical investigation involving human subjects aimed at generating data to discover or validate clinical pharmacological aspects, including pharmacodynamics and pharmacokinetics, as well as potential adverse effects, with the goal of assessing the safety and effectiveness of new drugs. A clinical trial represents a specific form of clinical research that adheres to a predefined protocol. By participating in clinical trials, individuals can take a more proactive role in their healthcare, gain access to innovative treatments, and contribute to the advancement of medical research^[5]. These trials are conducted with actual patients following a specific plan designed to assess cancer therapies, the safety of new medications, and the effectiveness of various treatments in humans. They help determine the drug's efficacy across different phases as outlined in the trial. The clinical study adheres to a protocol that outlines eligibility criteria for participants. Clinical trials typically consist of four phases. Preclinical studies encompass *in vitro* (i.e., laboratory or test tube) investigations and trials involving animal subjects



(Figure no. 1). Various dosages of the investigational drug are administered to animal subjects or an in vitro model to gather preliminary

data on efficacy, toxicity, and pharmacokinetics, guiding pharmaceutical companies in their decision to proceed with further testing^[6,7].

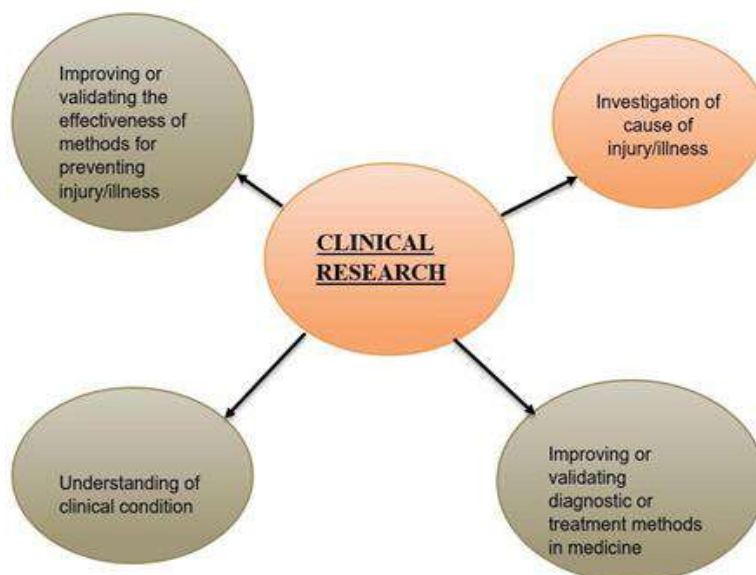


Figure No. 1: Clinical Research

Phase 0 (Microdosing Study): Recently termed Phase 0, this designation pertains to exploratory trials involving first-in-human evaluations as guided by the U.S. Food and Drug Administration's (FDA) 2006 recommendations on Exploratory Investigational New Drug (IND) studies. The primary objective of Phase 0 trials is to hasten the development of promising pharmaceuticals or imaging agents by determining at an early stage whether these substances interact with human subjects as anticipated based on preclinical data. Key characteristics of Phase 0 trials involve administering single sub-therapeutic doses of the investigational drug to a limited group of participants (10 to 15) to collect preliminary insights regarding the agent's pharmacokinetics (the body's handling of the drug) and pharmacodynamics (the effects of the drug within the body)^[8]

Phase 1 clinical trial (Human Pharmacology and Safety): In this phase, a cohort of healthy individuals, typically numbering between 20 to 80,

is selected to receive the drug. The focus here is on assessing both the efficacy of the drug and any potential adverse effects it may cause in patients^[9].

Phase 2 clinical trial (Therapeutic Exploratory): This stage involves approximately 100 to 300 participants. It primarily investigates the drug's effectiveness in diagnosing specific medical conditions among individuals. While ongoing safety assessments are performed, the emphasis shifts towards evaluating the side effects experienced by participants^[10].

Phase 3 clinical trial (Therapeutic Confirmatory): Enrolment increases to around 1,000 to 3,000 subjects during this phase. The investigation continues to assess both safety and effectiveness, but now includes a broader demographic and various dosages. If regulatory bodies, such as the FDA, approve the drug based on favourable trial outcomes, it moves forward to the final phase^[11].

Phase 4 clinical trial (Post Marketing Surveillance): Following FDA approval, the drug undergoes further evaluation across diverse populations to confirm its safety and effectiveness.

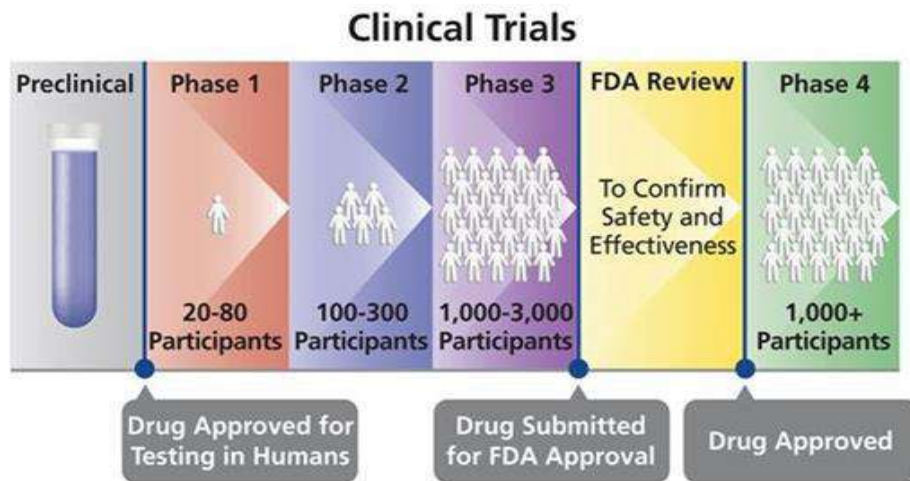


Figure No. 2: Phases of Clinical Trials^[12]

Many individuals choose to participate in clinical trials due to the lack of efficacy in existing medications or treatments. Others may enrol if no available cure exists for their condition. Participants often gain exposure to innovative therapies that have yet to reach the market. Additionally, some engage in these studies to assist researchers in advancing their investigations. Numerous research initiatives target the prevention of specific diseases, including hereditary conditions, particularly in healthy populations^[7,13].

Steps in a Clinical Trial

- The participant receives an explanation of the trial, followed by additional information being collected from them.
- The next step involves obtaining the participant's signature on consent form.
- undergo a screening to determine their eligibility the study.
- selected, the is scheduled for a baseline visit, the appointment, during which physical and cognitive are performed. Subsequently,

participants placed into either the experimental or group.

- Any adverse effects or complications experienced by the participant must be communicated to the research team.
- Participants are required to attend regularly scheduled visits at the research centre, allowing researchers to assess physical and cognitive responses as well as monitor treatment-related side effects^[14].

Clinical Trials in India

India is seen as a prime location for conducting international clinical trials, with approximately 20% of all global trials occurring within its borders. As the second most populous nation, India holds significant potential for advancing global drug development initiatives. The country offers numerous advantages, including extensive patient populations, a well-educated workforce, a wide array of diseases, reduced operational costs, and lower drug prices compared to developed nations. Furthermore, a favourable economic landscape and a strong intellectual property framework contribute to India's appeal. The

widespread use of English facilitates the establishment of clinical sites. The Drugs Controller General of India (DCGI) serves as the equivalent of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The DCGI is the federal authority overseeing pharmaceutical matters in India, comparable to the FDA commissioner. India adheres to Schedule Y for drug trials, which aligns with the IND regulations set forth in 21CFR:312. Unlike the FDA, the DCGI does not operate through multiple divisions to regulate different product types^[15,16].

Types of Clinical Trials

1. **Treatment Trials:** Aim to assess experimental treatments, novel drug combinations, or innovative surgical and radiation techniques.
2. **Prevention Trials:** Investigate improved methods to prevent diseases in individuals who have never been afflicted or to prevent recurrence in those previously affected. This includes exploring pharmaceuticals, vitamins, vaccines, minerals, or lifestyle modifications.
3. **Diagnostic Trials:** Focused on developing better diagnostic procedures or tests for specific diseases or conditions.
4. **Screening Trials:** Evaluate the most effective ways to detect specific diseases or health issues.
5. **Quality Trials (Supportive Care Trials):** Aim to enhance comfort and improve the quality of life for individuals dealing with chronic illnesses^[17,14].

Function of DCGI

The full form of DCGI is Drugs Controller General of India. The GI leads the Central Drugs Standard Control (CDSCO), which operates under the Government of India. This authority is tasked with granting licenses for specific categories of drugs within India. Additionally, the DCGI establishes necessary standards and quality measures for pharmaceuticals overseeing their sale, import, manufacture, and distribution within country. One of its primary objectives is to ensure consistency in the enforcement of the Drugs and Cosmetics Act. Topics related to significant political matters are crucial for the UPSC examination, with relevant content included in the General Studies Paper-II syllabus. This article will delve into the background of the Drugs Controller General of India (DCGI), covering its overview, responsibilities, functions, regulations, and committees. The DCGI undertakes various responsibilities within the health sector. What is the Drug Controller General of India (DCGI)? The DCGI heads the Central Drugs Standard Control Organization (CDSCO), which falls under the Ministry of Health and Family Welfare. The authority derives its powers from the Drugs and Cosmetics Act established in 1940. This position plays a vital role in India's healthcare system, particularly in the approval of drugs and vaccines. Recently, the DCGI was instrumental in the approval process for COVID vaccines. It establishes the required standards and quality benchmarks for pharmaceuticals, overseeing their sale, importation, manufacturing, and distribution in India. Furthermore, it regulates both medical and pharmaceutical standards. The DCGI also functions as the appellate authority for determining the quality of drugs^[1,18,19] (Table no. 1).



Table No. 1: Drugs Controller General of India (DCGI)

Title	Description
Current DCGI (2023)	Dr. Rajeev Singh Raghuvanshi
Ministry Concerned	Ministry of Health and Family Welfare – Dr. Mansukh L. Mandaviya
Act	Drugs and Cosmetics Act, 1940

Responsibilities of the DCGI

- The DCGI is responsible for preparing and upholding the necessary reference standards for medications.
- It ensures consistent application of the Drugs and Cosmetics Act of 1940.
- The DCGI conducts training programs in this domain, specifically for the Drug Analysts at State Drug Control Laboratories and affiliated institutions.
- Additionally, the DCGI assesses cosmetics as part of a survey sample received from the Central Drugs Standard Control Organization.
- Serving as the central licensing authority under the Medical Device Rules of 2017, the DCGI manages the licensing of medical devices that are governed by this legislation.
- It grants approvals for drugs in accordance with the Drugs and Cosmetics Act.
- The DCGI oversees the implementation of clinical trials and establishes standards for pharmaceuticals.
- It also ensures quality control for drugs imported into the nation.
- The organization coordinates the efforts of various state drug control agencies.
- Furthermore, it is tasked with registering foreign manufacturers that produce drugs and medical devices for importation into India^[20,21].

Drug Technical Advisory Board (DTAB):

Ex-Officio Members:

1. Director General of Health Services (Chairman)

2. Drugs Controller, India
3. Director of the Central Drugs Laboratory, Calcutta
4. Director of the Central Research Institute, Kasauli
5. President of the Medical Council of India
6. President of the Pharmacy Council of India
7. Director of Indian Veterinary Research Institute, Izatnagar
8. Director of Central Drug Research Institute, Lucknow

Nominated Members:

1. Two individuals appointed by the Central Government.
2. One representative from the pharmaceutical industry nominated by the Central Government.
3. Two individuals holding the position of Government Analyst under this legislation.

Elected Members:

1. One individual elected by the Executive Committee of the Pharmacy Council of India.
2. One individual elected by the Executive Committee of the Medical Council of India.
3. One pharmacologist elected by the Governing Body of the Indian Council of Medical Research.
4. One individual elected by the Central Council of the Indian Medical Association.
5. One individual elected by the Council of the Indian Pharmaceutical Association.

Functions:



1. To provide technical advice to the Central and State Governments.
2. To perform additional functions as designated by this Act^[22,23].

The Drugs Consultative Committee (DCC):

This body serves as an advisory group established by the central government.

Constitution:

- Two representatives from the Central Government
- One representative from State Government

Functions: To provide guidance to the Central Government, State Governments, and the Drug Technical Advisory Board on any matters that promote consistency across India in the enforcement of this Act. Additionally, there exists a separate body known as "The Ayurvedic, Siddha, & Unani Drugs Consultative Committee," established under Section 33 D of the Act.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO):

Functions of CDSCO: The Central Drugs Standard Control Organization (CDSCO), functioning under the Directorate General of

Health Services within the Ministry of Health & Family Welfare of the Government of India, serves as the National Regulatory Authority (NRA) of India. Its headquarters is located at FDA Bhawan, Kotla Road, New Delhi 110002, and it also operates six zonal offices, four sub-zonal offices, thirteen Port offices, and seven laboratories throughout the nation. The Drugs & Cosmetics Act of 1940 and the accompanying rules from 1945 have assigned various regulatory responsibilities to both central and state authorities regarding the oversight of drugs and cosmetics. CDSCO is committed to enhancing transparency, accountability, and consistency in its operations to guarantee the safety, effectiveness, and quality of medical products that are manufactured, imported, and distributed within the country. Under the Drugs and Cosmetics Act, CDSCO oversees the approval of new drugs, the execution of clinical trials, establishes standards for drugs within the nation, and coordinates the activities of State Drug Control Organizations by offering expert advice aimed at achieving uniformity in the enforcement of the Drugs and Cosmetics Act. Additionally, CDSCO, in collaboration with state regulators, is responsible for issuing licenses for certain specialized categories of critical drugs, including blood and blood products, IV solutions, vaccines, and sera^[24,25].

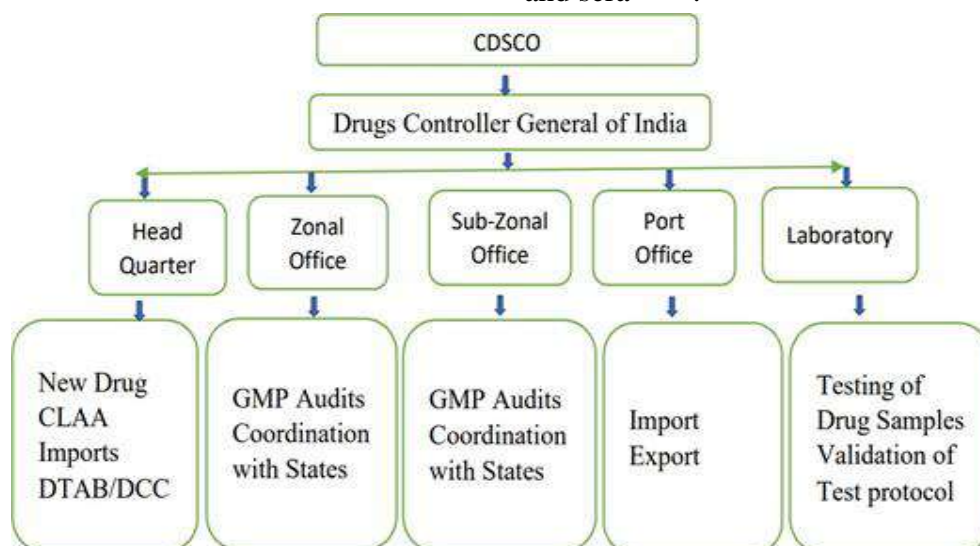


Figure. No.3: Central Drugs Standard Control Organization (CDSCO)

Regulatory Process

Each nation maintains its own regulatory authority to enforce laws and guidelines pertaining to drug marketing. Therefore, a regulatory process is essential for individuals, organizations, sponsors, or innovators to obtain approval for a drug's market entry, commonly referred to as the drug approval process. Typically, the stages involved in drug approval include: submitting applications for clinical trials, obtaining marketing authorization, and conducting post-marketing studies^[26,27].

Regulatory Framework

Drugs Sector

The current Indian legal framework governing the manufacture, sale, import, export, and clinical

research of drugs and cosmetics is established by the following legislation:

1. The Drugs and Cosmetics Act, 1940
2. The Pharmacy Act, 1948
3. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
4. The Narcotic Drugs and Psychotropic Substances Act, 1985
5. The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
6. The Drugs (Prices Control) Order, 1995 (under the Essential Commodities Act)
7. The Industries (Development and Regulation) Act, 1951
8. The Trade and Merchandise Marks Act, 1958
9. The Indian Patent and Design Act, 1970
10. The Factories Act (effective April 1, 1949)

Table NO. 2: List of CDSCO Offices and Laboratories in India

Zonal Offices	<ul style="list-style-type: none"> • Mumbai • Kolkata • Chennai • Ghaziabad • Ahmedabad 	<ul style="list-style-type: none"> • Hyderabad • Chandigarh • Goa • Jammu • Bangalore
Port Offices	<ul style="list-style-type: none"> • Ahmedabad • Kolkata Port • Kolkata Air Cargo • Chennai Port • Chennai Airport • Bangalore • Hyderabad 	<ul style="list-style-type: none"> • Goa • Kochi • Delhi • Mumbai Air Cargo • Nhava Sheva, Mumbai • Mumbai Custom House
Central Drug Testing Laboratories	<ul style="list-style-type: none"> • Central Drug Laboratory, Kolkata • Central Drug Laboratory, Kasauli • Central Drug Testing Laboratory, Mumbai • Central Drug Testing Laboratory, Chennai 	<ul style="list-style-type: none"> • Central Drug Testing Laboratory, Hyderabad • Regional Drug Testing Laboratory, Guwahati • Regional Drug Testing Laboratory, Chandigarh

FUTURE PERSPECTIVE:

Clinical research serves as the only method for assessing the efficacy of any chemical compound

and its potential for biological treatment. The expanding global landscape increases demand for such research, and only clinical trials can meet this



need. The future of clinical research is focused on various diseases, necessitating multiple drugs for the safety and well-being of humanity, making it a critical field. India is recognized as an optimal location for clinical research trials within the pharmaceutical sector. The demand for skilled professionals in clinical research is growing rapidly, leading to numerous job opportunities in this field that offer significant career advancement potential.

- Different career Opportunities
- Clinical Research Coordinator (CRC)
- Clinical Research Associate (CRA)
- Clinical Trial Monitor
- Research Nurses or Site Managers
- Data Manager
- Clinical Research Scientist
- Biostatistician
- Clinical Quality Assurance Auditor
- Clinical Safety Analyst
- DCGI Committee
- CDSCO Member

CONCLUSION:

Clinical trials for new medications operate under the regulations set forth by ICH and GCP. These trials involve human volunteers to confirm the beneficial attributes of new drugs. Following preclinical development, an investigational new drug proceeds through clinical phases I, II, III, and IV. Each phase offers a comprehensive analysis of the pharmacokinetic and pharmacodynamic characteristics, as well as any potentially harmful or beneficial side effects, adverse reactions, and post-marketing surveillance assessments.

REFERENCES

1. Ramakrishna G, Shalini MB, Bonthagarala B, Sindhu YR. COMPARATIVE STUDIES FOR FILING AND MARKETING AUTHORIZATION OF GENERICS IN EUROPE, UNITED STATES & INDIA.
2. Thorat SB, Banarjee SK, Gaikwad DD, Jadhav SL, Thorat RM. CLINICAL TRIAL: A REVIEW. 1(2).
3. Kandi V, Vadakedath S. Clinical Trials and Clinical Research: A Comprehensive Review. Cureus [Internet]. 2023 Feb 16 [cited 2025 Apr 21]; Available from: <https://www.cureus.com/articles/128436-clinical-trials-and-clinical-research-a-comprehensive-review>
4. Samala VR, C KK, P V. Phases of clinical trials: a review. *Asian J Hosp Pharm.* 2022 Jan 24;09–13.
5. Chidambaram AG, Josephson M. Clinical research study designs: The essentials. *Pediatr Investig.* 2019 Dec;3(4):245–52.
6. Samala VR, C KK, P V. Phases of clinical trials: a review. *Asian J Hosp Pharm.* 2022 Jan 24;09–13.
7. Tiwari A, Joshi M, Kamleshdashora. Clinical Trials: A General Review. 2016 Jan 5;22131
8. Kummur S, Rubinstein L, Kinders R, Parchment RE, Gutierrez ME, Murgu AJ, et al. Phase 0 Clinical Trials: Conceptions and Misconceptions. *Cancer J.* 2008 May;14(3):133–7.
9. Ivy SP, Siu LL, Garrett-Mayer E, Rubinstein L. Approaches to Phase 1 Clinical Trial Design Focused on Safety, Efficiency, and Selected Patient Populations: A Report from the Clinical Trial Design Task Force of the National Cancer Institute Investigational Drug Steering Committee. *Clin Cancer Res.* 2010 Mar 15;16(6):1726–36.
10. Torres-Saavedra PA, Winter KA. An Overview of Phase 2 Clinical Trial Designs. *Int J Radiat Oncol.* 2022 Jan;112(1):22–9.
11. Hoering A, LeBlanc M, Crowley JJ. Randomized Phase III Clinical Trial Designs for Targeted Agents. *Clin Cancer Res.* 2008 Jul 15;14(14):4358–67.



12. ICH_E6(R3)_Step4_FinalGuideline_2025_0106.
13. Mahan VL. Clinical Trial Phases. *Int J Clin Med*. 2014;05(21):1374–83.
14. Shreyash Koli1* SP. Effectiveness Of Clinical Method Evaluation. 2024 Jan 16 [cited 2025 Apr 13]; Available from: <https://zenodo.org/doi/10.5281/zenodo.10517844>
15. Ccoonnffeerreennccee A, Ssoocciieetty IP, Ssoocciieetty IP. Clinical trials in India: Pangs of globalization.
16. Selvarajan S, George M, Kumar Ss, Dkhar S. Clinical trials in India: Where do we stand globally? *Perspect Clin Res*. 2013;4(3):160.
17. Grimes DA, Hubacher D, Nanda K, Schulz KF, Moher D, Altman DG. The Good Clinical Practice guideline: a bronze standard for clinical research. *The Lancet*. 2005 Jul;366(9480):172–4.
18. Pandiri D. Protection of Subjects and Regulation of Clinical Trials in India.
19. Kumar A, Kumari S. Regulatory Guidance for Conducting Clinical Trials in India. 2025;2(1).
20. Annapurna SA, Rao SY. New drug and clinical trial rules, 2019: an overview. *Int J Clin Trials*. 2020 Oct 20;7(4):278.
21. Evangeline L, Mounica N, Reddy VS, Ngabhushanam M, Reddy N, Bonthagarala B. Regulatory process and ethics for clinical trials in India (CDSCO).
22. Bhalke PD, Dhewale S. DRUG REGULATORY AGENCIES IN INDIA AND U. S. A. 13(9).
23. Pawar N. A Review on: Indian Pharma Regulatory System and List of New Drugs Approved By Central Drugs Standard Control Organization in the Year 2021 Till Date.
24. Panda T, Lala PK, Manoharan K, Jinson J, George M. Evaluation of the current status of ethics committees in India using the National Accreditation Board for Hospitals and Healthcare Providers, Central Drugs Standard Control Organization (CDSCO), and Department of Health Research databases. *Perspect Clin Res*. 2025 Apr;16(2):75–80.
25. Ashok Kumar P, Dhanush K P, Darshan G V, Vikas S, Rakshith B M, Manoj Kumar M C. Recent advancement in regulatory requirements on hypertension in India as Per CDSCOIN comparison with Australia. *World J Adv Res Rev*. 2024 Sep 30;23(3):2979–89.
26. Chowdhury N, Joshi P, Patnaik A, Saraswathy A. Administrative structure and functions of drug regulatory authorities in India.
27. Pharmaceutical Regulatory Affairs: An Overview of Global Regulatory Frameworks and Emerging Trends. 2024;.

HOW TO CITE: Sujata Samant*, Nikita Raut, Geeta Ban, Jagdish Urgunde, Vaishnavi Biradar, Sakshant Shindalkar, Hanuman Wable, Sanket Chavan, Vaishnavi Bobade, An Overview of Clinical Trial Review Processes in India: Roles and Responsibilities of Regulatory Bodies, *Int. J. of Pharm. Sci.*, 2025, Vol 3, Issue 5, 329-339. <https://doi.org/10.5281/zenodo.15333182>

