Review Article

Overview of Clinical Research and its Impact in Indian Pharmaceutical Industry

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ABSTRACT

In order to better understand human health and disease, create treatments, and enhance healthcare outcomes, clinical research is crucial to the advancement of medical science. It includes a wide range of research projects, such as clinical trials evaluating therapeutic therapies and health services research meant to improve the provision of healthcare. Because of its large patient population, low cost, and skilled labor force, India is becoming more and more regarded as a potential site for international clinical trials. India conducts only 1.4% of clinical research worldwide, yet pharmaceutical corporations benefit greatly from its low prices and varied patient demographics. However, there are still ethical issues to be resolved, along with worries regarding participant safety and regulatory compliance. As a result of regulatory authorities' greater monitoring, studies have decreased. Advancement is further hampered by issues with recruitment, low public awareness, and inadequate training in research methods. India has to strengthen its clinical research infrastructure, promote patient participation, and improve its regulatory environment in order to become a global hub for clinical trials. This progress is essential to sustaining high ethical standards in research techniques and guaranteeing fair access to novel medicines. This article describes the entire situation of clinical research in India.

Keywords: Clinical research, Global Hub, Ethical Issues, Regulatory Compliance, Patient Participation, Infrastructure.

INTRODUCTION

Clinical research is a vital component of medical science that focuses on human health, disease mechanisms, and the development of new treatments. It aims to generate knowledge that will be useful for comprehending human disease, preventing and treating illness, and promoting health[1]. Clinical research and trials investigate disease features such as symptoms, risk factors, and pathogenesis whereas Clinical trials examine the potential of therapeutic medications or devices in illness management, control, and prevention[2]. It encompasses a range of investigations that involve patient interactions, diagnostic clinical materials or data, or populations falling into any of the following categories: The fields of study that comprise the following: (1) etiopathogenesis (disease mechanisms); (2) bi-directional integrative (translational) research; (3) clinical knowledge, detection, diagnosis, and natural history of disease; (4) therapeutic interventions, including the development and clinical trials of drugs, biologics, devices, and instruments; (5) health promotion and prevention (primary and secondary); (6) behavioral research; (7) health services research, including outcomes and cost-effectiveness; ; and (9) community-based and managed care-based trials[1]. To ensure accurate and validated results, it necessitates a methodical approach along with careful planning, execution, and sampling. Researchers must also possess a thorough understanding of each study methodology [3]. India is thought to be a good place to conduct international clinical trials due to its large number of patients who are not yet responding to treatment, its English-speaking medical experts, its clinical material, and its affordability[4]. It is also an integral component of evidence-based medicine, which needs the support of a strong infrastructure, particularly highly qualified clinical research personnel[5]. Clinical research can be categorized into clinical trials, which assess therapeutic interventions, and health services research, which focuses on improving healthcare delivery and outcomes[2]. The knowledge of clinical research will facilitate the discovery of drugs, devices, and vaccines, thereby improving preparedness during public health emergencies[2]. Ethical challenges are integral to clinical research, requiring adherence to regulatory standards and ensuring participant safety and rights. Only 1.4% of clinical research worldwide is conducted in India, while having 17.5% of the world's population (based on data from August 7, 2011 to August 6, 2012)[6]. Drug development research is primarily funded by the pharmaceutical industry including the process of human testing (Phase I-IV studies)[7].

HISTORY OF CLINICAL RESEARCH

The first clinical trial in history was carried out by King Nebuchadnezzar of Babylon and is documented in the Bible's "Book of Daniel". A small group of rebels who liked vegetables opposed his instructions to limit his people's diet to meat and wine. The king gave them permission to eat only water and legumes for ten days, during which time the vegetarians seemed to be getting greater nutrition[8]. For the first time in human evolution, a public health decision was determined by an unrestricted, open-ended human experiment. The comprehensive 'Canon of Medicine' by Avicenna advises studying two patients of opposing kinds and using clinical trials in their uncomplicated state. Surgeon Ambroise Pare unintentionally carried out the first clinical trial of a revolutionary therapy[8].

James Lind is credited as being the first medical professional in the contemporary age to carry out a controlled clinical study. As a surgeon on a ship, Dr. Lind (1716–1794) was horrified by the high scurvy mortality rate among the men. He organized a comparison study evaluating the best treatment options for scurvy. All the necessary components of a controlled trial are included in his detailed account of the trial[9]. When the term "placebo" was originally used in clinical trials; it meant that patients would feel better rather than worse. It was first used in the early 1800s. When Austin Flint treated 13 patients with a botanical extract rather than a recognized medication in 1863, it was the first clinical research to compare an inactive treatment to an active one. In order to investigate patulin treatment for the common cold, the Medical Research Council carried out the first double blind comparison experiment with contemporaneous controls in the general population in 1943–1944. Despite the strict controls that prevented doctors and patients from knowing the medication, the data analysis did not reveal any protective effects of patulin[9]. Although the idea of randomization was initially presented in 1923, the UK's Medical Research Council carried out the first randomized control study including streptomycin for pulmonary tuberculosis in 1946. Unlike other modern research, which is ad hoc in nature, the experiment, chaired by Sir Geoffrey Marshall, had a methodical data collection process and enrollment criteria. The experiment was a model of careful planning and execution, with specialists blinded to the patient's treatment assignment doing objective measurements like interpreting x-rays. Randomization was introduced by Sir Austin Bradford Hill, who also explained this novel statistical technique in the 1948 seminal BMJ publication. By using a statistical series based on random sampling numbers, the trial decided whether to treat a patient with bed rest alone (C case) or with streptomycin and bed rest (S case). This approach is still revolutionary in the field of controlled trials and has had a tremendous impact on clinical care[9].

Guidelines for using human subjects in medical research were developed in 1964 and are known as the Helsinki Declaration. The Nuremberg Code had a bearing on it since it stressed the significance of informed consent in research. With its most recent edition in 2008, the Helsinki Declaration has undergone repeated updates. A key component of the 1966 International Covenant on Civil and Political Rights was the freedom to refuse medical or scientific treatment. Since the Food and Drugs Act of 1906, the 1862-founded FDA has become a law enforcement agency. As more scientific fields and technologies are incorporated into medication research, the ethical and regulatory framework for human experimentation is constantly changing[9].

Through an amendment to the Drugs and Cosmetics Act's Schedule Y, the Indian government liberalized the license granted to international pharmaceutical corporations conducting clinical trials in India in 2005. With cooperation from the Department of Science and Technology (DST) and the World Health Organization (WHO), the National Institute of Medical Statistics (NIMS) of the Indian Council of Medical Research officially inaugurated the Clinical Trials Registry - India (CTRI) on July 20, 2007. As of June 15, 2009, the Indian government mandated that all clinical trials conducted within the nation be registered. Before beginning the trial procedure, the researchers should register the clinical study with the ICMR Clinical Trial Registry, according to a notification issued by the Drug Controller of the Government of India (DCGI)[10].

In India, clinical research opportunities began in the early 2000s, particularly with regard to conducting market-driven international clinical trials (CTs), which included international bioequivalence studies[11].

INDIAN SCENARIO VS. GLOBAL SCENARIO

India has recently witnessed a notable expansion and advancement in the field of clinical research. As a venue for these trials, India offers many benefits. Since trials account for about 40% of the costs associated with drug research, it is believed that the large pharmaceutical corporations will greatly benefit from India's large reservoir, which is 60% less expensive than industrialized nations. With over a billion people living there, its largest asset is perhaps its population[10,12]. For example, India offers a large testing population for international pharmaceutical companies and Indian outsourcing firms due to its 70 million heart patients, 40 million asthmatic patients, 35 million diabetic patients, 8–10 million HIV positive individuals, 8 million epileptic patients, and 3 million cancer patients4. Furthermore, there is a growing trend among Indians to experience the same illnesses as Americans and Europeans, for which pharmaceutical companies are desperately trying to discover treatments. It also has an advantage over the majority of developing nations due to its advanced hospitals, many of which have English-speaking medical staff[10]. Companies in the biotechnology and pharmaceutical industries are practically under pressure to shorten their development times due to reduced funding and resource availability. By recruiting a large number of sites outside of major markets, India allowed patients with cancer, diabetes, hypertension, asthma, tropical infections, and degenerative disorders to have greater access to treatment[11]. The second important reason was the significant cost savings achieved through labor cost and scale efficiencies. Thirdly, well-trained investigators and support personnel for clinical trials and IT management; the former have undergone substantial training in good clinical practice (GCP) and other Indian norms of good practice[11].

Here, major clinical studies had been initiated by all international corporations. This is because of a number of other advantageous elements, including broad networks and hospitals across India, precisely specified Standard operating procedures (SOPs) to adhere to good practices (GXPs), a database of investigators in a range of therapeutic disciplines, etc[11]. Trials must be conducted flawlessly, which requires resourceful, expertise-focused locations as well as skilled, well-trained, and experienced investigators. Only qualified and knowledgeable staff members should conduct

formal training and testing in research methodology, GCP, good laboratory practice, documentation, and regulatory affairs for individuals working as investigators, monitors, trial designers, statistical analysts, and other related roles[11,13].

The way clinical trials are conducted has significantly changed throughout time. Early on, most clinical trials were carried out in academic medical facilities. To test these compounds, however, a growing number of patients with a greater spectrum of ailments had to be enrolled as the pharmaceutical industry expanded and new therapeutic molecules were found. This demand was too great for academic medical centers to handle alone. The requirement was subsequently met by the emergence of Clinical/Contract Research Organizations (CROs)[14]. Ethics committees oversee clinical trials at locations where human subjects are protected locally. In addition to capturing the current problems that ECs are facing, the poll poses significant queries about the administrative load on the EC, the ease of doing research, and the supervision of authorized research[15].

Indian Regulatory Authorities for Clinical Research are Drugs Controller General of India(DCGI), Indian Council for Medical Research (ICMR), Central Drugs Standard Control Organization (CDSCO), Genetic Engineering Approval Committee (GEAC), Department of Biotechnology (DBT), Atomic Energy Review Board (AERB), Bhabha Atomic Research Centre (BARC), Drugs Consultative Committee (DCC), Central Drug Laboratory (CDL), Central License Approving Authority (CLAA), Drug Technical Advisory Board (DTAB)[16].

All throughout the world, more than 3000 multi-center studies are conducted. Few multi-center dental studies have been conducted and published in India, particularly within the dentistry community[14].

A study held in 2020 shows that Out of all the trials that were recovered, 220 were found to be relevant for analysis. Drugs made up the majority of the experimental goods (55%) and were followed by vaccines (38.2%). Chemotherapy for cancer (19.8%) was the most prevalent therapeutic class of medications, followed by chemotherapy for antimicrobial infections and endocrinology (18.2% each). The measles, mumps, and rubella vaccine (15.5%) was the second most common vaccine, behind the influenza vaccine (21.4%). Ninety-one percent of the Phase 1 trials were sponsored primarily by the pharmaceutical sector. Two tertiary care medical colleges (cumulatively 9%) and three private nonacademic institutes (cumulatively 31%) made up the top five locations where the majority of the Phase 1 studies were carried out[17].

Recruiting enough patients to test the medications that come out of pharmaceutical corporations' laboratories is becoming increasingly difficult. Prior to authorizing the commercialization of an investigational medicine, the Food and medicine Administration needs data from an average of over 4000 patients. In the US, 86% of clinical studies fail to recruit the necessary number of participants and are delayed by an average of 366 days. Less than 5% of people are willing to participate in clinical trials[12,18] .

In Finland, RECs were governed by a law pertaining to medical research; in the other nations, RECs were governed by numerous laws and regulations, with extra rules relating to drug trials. There was a REC control body in the USA and England. All nations had lay members who were willing to join, with different payment plans. Patient protection was the primary ethical criterion, although there were variations in other criteria as well (research advancement, results availability, payments, and precise compliance with laws). Administrative responsibilities had been assigned to RECs in every nation. The mandate, practical arrangements, managing multi-site research, explicitness of proportionate handlings, evaluating scientific quality, decision-making timelines, project monitoring, role in institute protection, handling conflicts of interest, managing projects without informed consent, and quality assurance research varied by country.

The division of labor for verifying formalities among secretariats and REC members differed. Quality assurance for REC work was carried out thoroughly in England, somewhat thoroughly in the USA, and not at all in Finland[19]. 83 (76.1%) of the 109 Brazilian doctors surveyed, the majority of whom were oncologists, were employed by research centers. Only 31.2% of patients were invited to participate in clinical trials, nevertheless, with less than 1% of them accepted. Limited trials, a shortage of skilled labor, protracted regulatory approval procedures, and patient awareness are some of the obstacles to research. Of those who were not involved in research, 96.1% showed interest, 31.8% made an attempt, and 62.4% knew very little about how trials are conducted[20].

In the past six years, there has been a notable surge in phase 1-3 drug and biologic trial counts in China and India, with 62% of trials funded by universities and hospitals, 36% by industry, and 1% by the US National Institutes of Health and other federal agencies. As of May 18, 2014, industry financed 60% of trials in India, while universities and hospitals sponsored 68% of trials in China. There is a notable disparity in trial sponsorship between China and India: in China, 68% of trials are sponsored by universities or hospitals, whereas in India, industry funds 60% of trials. Diabetes, stomach, liver, and respiratory cancers are expected to be the top causes of mortality in 2030. These conditions account for 80% of phase 1-3 trials funded by both business and academic institutions. The majority of phase 1-3 drug and biologic trials in China and India, according to data from ClinicalTrials.gov, are not carried out by international pharmaceutical companies or industries[21].

Throughout the Asia Pacific region, 77 sites were contacted for this survey. Of the 49 sites that responded to the 63 surveys, sixty-four percent said that they would be interested in taking part in clinical trials for children. 71% of the sites had experience from previous projects. Eighty

percent stated that pediatric patients must provide their consent for research to be conducted; eighteen percent to ninety-five percent stated that ethics committees will allow placebo-controlled and pharmacokinetic studies; and thirty-seven percent mentioned difficulties in dealing with this demographic [22]. Clinical trials for cancer medicines faces a number of major obstacles in Latin America and the Caribbean, including funding and support shortages, shortages of specialists, investment gaps, and regulatory delays. Despite these challenges, the distinct cancer epidemiology, dense population, and varied genetic backgrounds of Latin America and the Caribbean make the region appealing for clinical research. These areas participated in 5.5% of all cancer trials conducted worldwide in 2022, with the most active participants coming from Brazil, Argentina, Mexico, Chile, and Peru. The fact that most studies are supported by the sector shows how important foreign funding is to regional research initiatives[23].

DIFFICULTIES IN PERFORMING CLINICAL RESEARCH IN INDIA

In September 2013, the Supreme Court of India recommended stricter controls on clinical trial conduct to safeguard participant rights. This recommendation followed public interest litigation by the SwasthyaAdhikarManch, a non-governmental organization that reported unethical practices in Madhya Pradesh, such as enrolling participants without proper informed consent and inadequate compensation for trial-related injuries or deaths. In reaction to the Supreme Court's observations and directives, the Central Drugs Standard Control Organization (CDSCO) implemented a range of measures, which have been criticized for causing a notable decrease in clinical trials in India, leading both domestic and international pharmaceutical companies to seek alternative trial locations[24]. The decrease in clinical trials was linked to a rise in reported research mishaps, negative media coverage, activist protests, delays in regulatory processes, and the loss of sponsors and collaborators. During this time, there were increased efforts by regulatory bodies, research professionals, and public stakeholders to understand and address these issues[25]. Limited formal training in bioethics and research methods, combined with heavy clinical workloads and inadequate administrative support, hampers investigators. The lack of oversight for ethics committees and inadequate quality control in ethics reviews raise societal concerns about participant safety. Additionally, conducting research on irrelevant issues and failing to ensure post-trial access further contribute to public skepticism[26].

In India, unlike medical schools in developed countries like the USA and UK, there is little focus on research activities and experience. While programs like the Indian Council of Medical Research's Short-Term Studentship (STS) and the Department of Science and Technology's Kishore VaigyanikProtsahanYojana (KVPY) encourage undergraduate research, there is minimal institutional support. Research experience is not a key factor in selecting candidates for postgraduate courses (MS or MD) in India. In contrast, in the USA, research experience and published papers are crucial for postgraduate admissions, alongside strong USMLE scores. This encourages students to engage in research to enhance their chances for competitive residency and fellowship programs. In India, however, postgraduate students often complete their thesis more out of obligation than genuine interest[27].

Inadequate recruitment significantly affects the scientific and financial viability of randomized controlled trials (RCTs). Failure to meet the estimated sample size increases the risk of a type 2 error, where no significant difference between treatment groups is wrongly concluded. Adequate enrollment ensures projected retention and aids in patient data evaluation, but poor recruitment can extend the trial period, raising costs and causing uncertainty about treatment efficacy. Slow evidence acquisition can impact funding, as investors may prefer quicker, less reliable evaluation methods. Despite its importance, recruitment is often underestimated, with insufficient institutional resources allocated to it[28].

Misconduct of clinical research is seen to a great extent in India. The reasons for misconduct in clinical research range from personal motivations to professional ambitions. Financial gain and the desire for fame are common drivers. Additionally, laziness, especially in complex studies with repeated assessments, can lead to misconduct. Some researchers may fabricate results if they believe strongly in a particular outcome despite contrary evidence. Ethical training and codes of conduct cannot prevent all misconduct, which often reflects individual moral values rather than intelligence or education. The actual incidence of misconduct is likely underreported. Examples of research misconduct include falsifying data, engaging in fraud, endangering patients, ignoring adverse events, failing to obtain proper consent, and violating study protocols.

Official bodies and committees should be established in the country to investigate clinical research misconduct. Enhanced regulation and open communication among research teams about critical aspects of trials may help reduce misconduct. There should be increased awareness about misconduct in India, and similar studies should be conducted to validate these findings in other groups, expanding the participant base. Misconduct should be discussed at symposia, conferences, lectures, and other meetings. Additionally, research ethics and the principles of credible conduct should be incorporated into both undergraduate and postgraduate curricula[29].

SCOPE AND RELEVENCE OF CLINICAL TRIAL IN INDIA

India is rapidly becoming a global hub for clinical trials, benefiting from the "India Advantage," which includes a large patient population, motivated and skilled medical and paramedical personnel, state-of-the-art hospitals, and robust IT support. Increasingly, pharmaceutical companies and clinical research organizations (CROs) are seeking to

conduct trials in India. Consequently, it is crucial that clinicians, who serve as principal investigators, are thoroughly knowledgeable about all aspects of conducting clinical trials.

Evaluating new medicines robustly is primarily done through clinical trials, essential even when numerous existing medicines are available, to ensure patients have access to better future treatments. India is rapidly emerging as a prime destination for clinical trials, offering rapid completion and reduced costs for sponsors from Canada, Europe, and the US. India's standards for conducting trials have risen to meet international requirements, positioning it to participate in more global trials.

Recently, India has been highlighted as an attractive trial location due to its large, diverse, therapy-naïve patient pool with high incidences of both acute and chronic diseases. The government of India has started supervising these clinical trials through the Drugs Controller General of India. Despite India's growing role in clinical trials, its R&D expenditure remains low compared to the US and China. The US leads in medical research due to substantial government funding and support from universities and academic institutions. The Indian government is attempting to increase overall R&D spending, with a goal to raise private sector investment to 50%. Multinational pharmaceutical companies are increasingly conducting clinical trials in India, ensuring that Indian participants receive the same treatment as their counterparts in other countries such as Europe, America, Australia, and other South Asian nations.

However, conducting clinical trials in India involves challenges, especially when dealing with vulnerable populations. These disadvantaged groups require extra care and protection in research, ensuring their rights, well-being, safety, privacy, and confidentiality. The informed consent process is crucial, particularly for these participants, impacting their understanding of the proposed study. Institutional or Independent Ethics Committee Members play a vital role in monitoring these studies to provide additional safeguards for vulnerable subjects[30].

NEED OF CONDUCTING CLINICAL TRIALS IN INDIA

Clinical trials aim to determine the safe and effective administration of new treatments to people. They build on the successes of existing treatments, aiming to improve upon them by following specific steps and protocols. Standard treatments serve as the foundation for developing potentially better therapies.

With increasing pressure to contain research and development (R&D) costs across the global pharmaceutical industry, there is a heightened focus on reducing the expenses of clinical development. Additionally, delays in development negatively impact the timely introduction of new drugs, resulting in lost potential revenues. This dual challenge has led major pharmaceutical companies to explore alternative locations for sourcing patients for their global studies. Countries like Latin America, Eastern Europe, and Asia have become areas of interest. Among Asian countries, India stands out due to its large population of treatment-naïve patients, English-speaking doctors, and a significant pharmaceutical presence known for affordable generics. India is developing competence and experience as a result of the outsourcing of research and clinical trial activities by global pharmaceutical corporations from the US and Western Europe. This shift helps India transition from being a hub for generic and specialty contract manufacturing to becoming a leader in innovative drug discovery and development, setting the stage for increased global competition[31].

An observational study reveals that while India is making progress in clinical research, it still lags behind developed countries and other Asian nations such as Japan and China. One reason for this lag is the under-registration of trials, stemming from researchers' lack of awareness about the need to register clinical trials. Additionally, patients' ignorance and fear about participating in clinical trials contribute to the issue. Previous studies have indicated that Indian patients are generally less willing to participate in clinical trials. To address this, it is essential to dispel myths about clinical trials among patients, volunteers, and the public by conducting ethically sound and well-designed trials.

Another reason for the lower number of registered trials in India is the lack of fully equipped clinical trial sites compared to other regions. Additionally, concerns about ethical principles in conducting trials and the lengthy approval process from the Drug Controller General of India contribute to the limited number of trials. For India to become a global hub for clinical trials, it needs more well-trained clinical researchers and a faster approval system for new drugs[32].

CONCLUSION

Due to its large patient population and economic advantages, India is quickly becoming a major player in the global clinical research arena. However, the nation must solve important issues including participant recruiting, ethical oversight, and regulatory efficiency if it is to improve its role. Fostering a sustainable clinical research environment requires strengthening researcher training, raising patient knowledge of clinical trials, and setting strong ethical norms. By concentrating on these areas, India may further establish itself as a leading clinical trial location, ultimately leading to better healthcare outcomes on a national and international level.

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