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*Research Article*

# Patient's perspective on Clinical Trials in Indian Population: A Historical Comparative study

Ms. Priya Maisheri *[1]; Dr. Kaushal Kapadia[2]

1. Texila American University

2 Clinical Research Professional

*Correspondence to: Ms. Priya Maisheri, Texila American University.



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***Abstract:***

***Introduction*** *- For conducting a clinical trial successfully, patients' perspective towards it plays an important role. The patients should have a clear understanding of the reason of their participation in a clinical trial. However, there have been multiple unfortunate incidences in the past that tarnished the image of the clinical research sector in India. Since the last decade, the scenario has changed drastically with constant regulatory updates and improvements in the assurance of patient rights and safety. Nevertheless, scientific illiteracy among a major fraction of the Indian population can cause less patient recruitment and their dropout from the trial. The study aims to find out the positive or negative changes in the perception of common Indian patient population regarding clinical trials and its safety in the last 10 years considering the major regulatory changes in the Indian clinical research sector and public awareness initiatives.*

***Background information*** *– India is termed as the global hub for clinical trials. Clearly, the number of participants of trial subjects are a concern when number of trials are always on the upward curve. As part of a 2013 study, Dr. Kapadia evaluated the perception and understanding of 6122 patients on clinical research in India as potential clinical trial participants. In this study, many of the respondents were found out to be unaware of the basic principles behind ethical conduct of clinical trial, role of ethics committees, and measures taken by regulatory authorities that safeguards subject's rights, safety, and well-being. Clear lack of adequate awareness and understanding was demonstrated as the main cause behind the "guinea pig" syndrome.*

***Methodology*** *- A survey was conducted using validated questionnaires in chronic (long-term) patients groups, and the data collection was through digital or online mode to avoid manual errors and data entry discrepancy. The data collected was analyzed statistically corresponding to our test hypothesis, largely by univariate and bivariate and if appropriate a Chi-square test for association.* ***Conclusion*** *- The study helped to understand the difference in the knowledge, awareness and perception of chronic patient population on the matters of clinical research, ethical conduct of research in humans, subject rights and safety assurance, compensation laws, and trustworthiness of other stakeholders in a trial. This will also pave the way to chalk out strategies to build and enhance awareness on clinical research in Indian individuals who can be potential participants in human clinical trials.*

## Introduction

Development of new treatment and medications often arise through collaborations between different countries and regions as developing any procedure for global application requires wider applicability across different races. However, these kinds of collaboration can lead to complications in form of varied integrity of research, quality of patient care, trust of individuals in medicines etc. which may lead to conflict of interests and can reduce the confidence of individuals on clinical trials and affect their perception. This has led to substantial debate about the ethics of research in developing countries [1][2]. The controversies have been centered on three key issues; first, the quality of informed consent; second, the standard of care provided; and third, the availability of interventions proven to be useful during the course of clinical trials [3]. These longstanding issues about ethical acceptability of clinical trial conducted in developing countries.

India has successfully overcome such negative connotations and has appeared as a hub for clinical trials of international sponsors over the last decade. Fast recruitment, low cost of trial conduction, well equipped medical facilities, skilled personnel and strong information technology (IT) support have made India one of the most attractive destinations for global clinical studies. The major factors which have been driving India are as follows:

a) High enrollment rate: Enrollment rate of patients in clinical trials has been observed to be higher in India than other countries. For example, the enrollment rate in India was at 3 patients per month as compared to US' 0.3 patients during the same period [4].

b) Spectrum of disease: Wide spectrums of patients with different diseases ranging from tropical infection to degenerative disease are easily available in India. Therefore it is beneficial for sponsoring agencies for testing novel approaches.

c) Human resource and technical skills: The human resource involved in India's health care infrastructure is massive. Recent estimates have reported that India has more than 500 investigators, along with 572,000 doctors, about 43,322 medical facilities and approximately 8.7 lakh beds across both private and public hospitals [5].

d) Regulatory oversight: All clinical trials in India fall under the purview of the Drug Controller General of India (DCGI). Indian Council of Medical Research (ICMR) is another important body for providing expert advice and opinions. Other than these regulatory bodies, ethics committees are present in all premier institutions, who first examine the trial proposals before obtaining authorization from DCGI.

e) Reliable data quality: The colonial mindset of doubting research data originating from Asian countries has now been obliterated mostly and research related to Asian countries is now acknowledged and accepted by international regulatory authorities. Data is being continuously generated from India as per international standards and are regularly presented and published in international conferences and publications respectively.

Despite this positive attributes there are certain challenges that are present in the Indian clinical trial scenario. For example, despite having approximately 77 million diabetic patients in India [6], only about 15% of this population takes part in clinical trials. This unwillingness to participate in clinical trials is a major point of concern. Another point of ethical concern is the increasing trend of developed countries investing more and more in clinical trials carried out in developing nations like India. Lower costs and relatively naïve population of potential participants often attract pharmaceutical companies to India. The potential of ethical misconduct is greater in such a scenario, where there is a large population of mostly vulnerable poor people with low literacy and a culture of accepting authority without question. Many patients who participate in clinical trials in India are not informed about the nature of the study. Some participants often state that they do not feel free to quit the trial in fear of losing good healthcare.

## Methodology

The main goal of this study was to collect information on the factors that influence recruitment in clinical trials in India. This was accomplished by having the general population complete questionnaires outlining their viewpoints. The questionnaire asked them general questions about clinical trials and the ease of participating in them. The target population for this investigation was selected from various regions of India in order to gather a wealth of data that might be used to improve clinical trial enrolment rates. The responses recorded are compared with previous records to observe for changes since the last decade in the attitude towards clinical trials. The work presented here is an observational study focused on the comparative evaluation of change in awareness, knowledge and perception of clinical research in India, in a conveniently sampled population of patients suffering from one or more chronic illnesses, opposed to the control dataset of the Patients cohort from the 2013 study results obtained from previous study.

## Results

In order to present a comparative development of patient outlook towards clinical trials. The data generated in the present study was compared with previously published report of Kapadia, 2013. To avoid biases arising

from sample size difference, only the percentage composition has been considered.

When comparing, marginal increase in awareness is observed with 69.01% to 76.88% of participating patients on hearing about clinical research. However, there was lowering of willingness to participate in clinical trial as observed from the drop in percentage of those willing to participate from 2013 to present. Responses displayed a sharp decrease between the two time points, as the willingness to share about participation to society dropped from 57.73% to 6.54%. The response was more or less comparable between the two time points, with 66.43% and 56.84% agreeing to the fact that clinical research benefits the society. However, a sharp increase was also observed in people's opinion of clinical research harming society (from 5.13% to 31.79%.

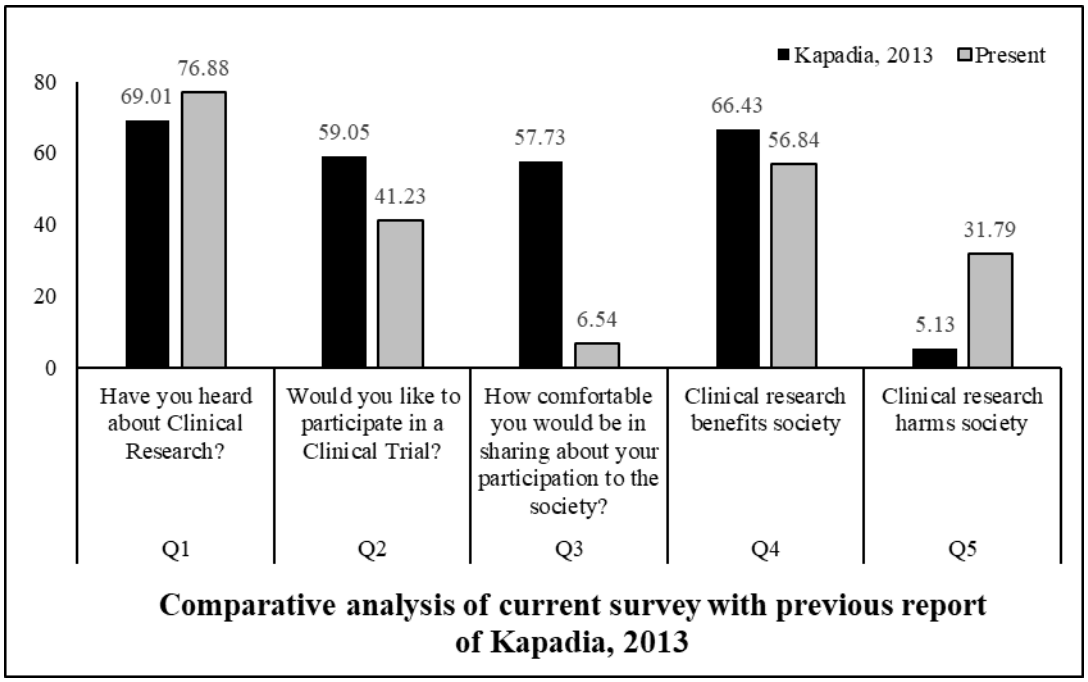


Fig 1

The response were more or less comparable, however an increase in positive responses was observed from 2013 to present. 77.26% of the participants from the current study believed that clinical research was essential for developing new treatments, which was greater than the 53.97% observed in 2013. A sharp decrease, from 72.07% (2013) to 21.19% (present) was observed in response to the notion of government always providing adequate protection to the public against unethical clinical research.

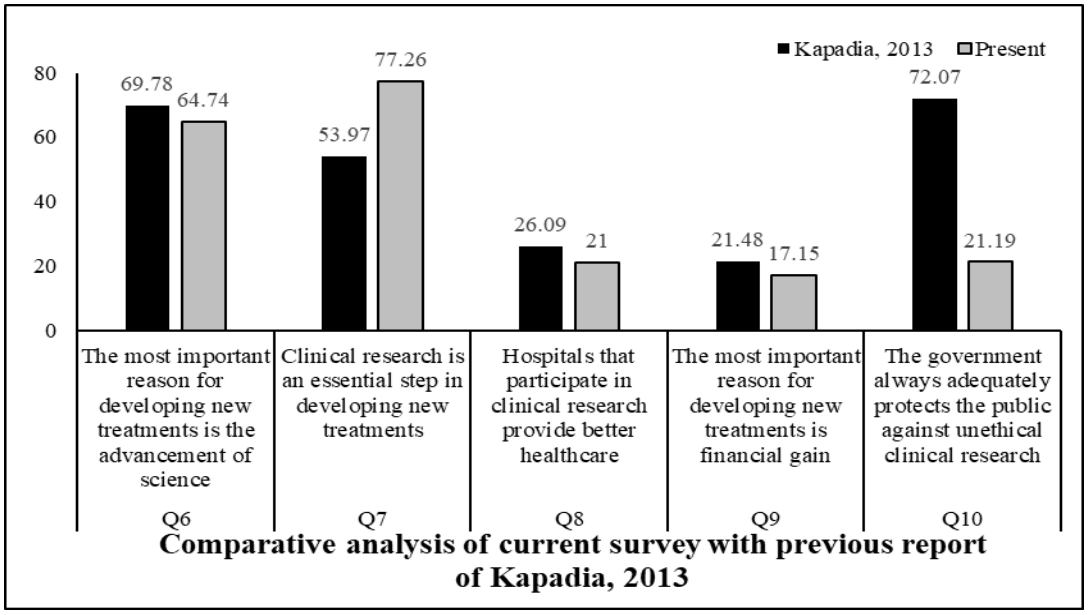


Fig 2

Similar loss of trust was observed in response, with an increase from 3.59% (2013) to 34.49% (present) when they were asked whether the doctor will continue to provide good care even if the patients did not participate in research. Responses were more or less comparable, increase in distrust was also evident, as more participants (from 21.4% to 40.66%) stated that participants were treated like human guinea pigs.

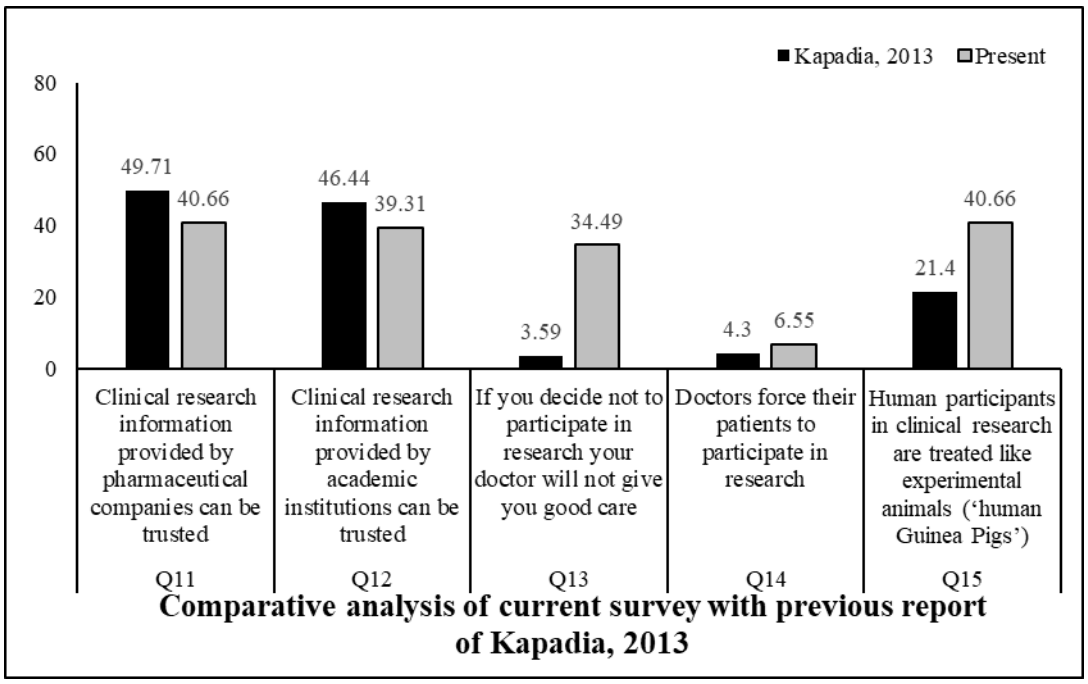


Fig 3

## Discussion

As science continues to advance and more diseases are discovered, it is important to understand how the Indian population feels about these conditions in order to determine whether or not new treatments should be developed. There is a need for both a cure and a preventative measure for every new disease. Given the current situation in which the Covid-19 vaccine has been discovered, it is important to understand how different people perceive the aforementioned statement. For example, some people believe that clinical research is only conducted for novel medications, while others hold the opinion that it is still ongoing for indications for which the standard of care is already available. The belief that the primary aim for clinical trials is to develop new medications did not change over the decade with majority believing this to be true.

Clinical research frequently chooses hospitals as its study locations. There are numerous hospitals throughout the nation where clinical research is carried out, and it is understood that all hospitals offer their services to the highest standard. In terms of infrastructure, yes, there are specific requirements that must be met when it comes to clinical research set-up, but this in no way means that the hospitals that participate in clinical research offer better healthcare facilities. This is an assumption made by people that clinical research hospitals offer superior medical care. In order to avoid additional legal requirements and additional costs, the clinical research site is only chosen after careful consideration of the overall setup and those that offer all necessary facilities on-site. However the present survey found that very few believed this notion to be true.

When discussing research, the general public assumes that it takes place in laboratories, and when discussing drug testing, one would assume that some animal experimentation has taken place. However, the clinical development of the specific drug and consequently the clinical research involving trials in humans play a crucial role when discussing the drug development process. People believe that clinical trials only serve to turn humans into experimental subjects. If this perception persists, it will be more challenging to conduct clinical trials ethically, and compliance levels will also decline. The participant were thus asked to rate the statement "Clinical research is an essential step in developing new treatments" as true, false, or not aware. To this more number of participants chose the option of ‘true’ as compared to ten years ago. Once again this may be attributed to the awareness generated among the general public due to the pandemic.

Is the development of new medications primarily motivated by financial gain? Idealistically, the answer to this question should be NO, as the goal of developing new drugs is to benefit society. If there is an approved treatment for a particular disease, developing a new treatment may be done for reasons such as increased speed

of efficacy, long-term safety, cost considerations, etc. This question was asked as part of a questionnaire to determine how people felt about money in general. If people felt that money was the main concern, then fewer people would participate in clinical trials, and everything that falls under the research umbrella would appear to be unethical. Hence, most participants did not consider the statement to be true in 2013 as well as in the current study.

Each nation has a local regulatory body that oversees the approval and moral execution of clinical trials. The local regulatory authority is in charge of routine inspections. The rights, safety, and well-being of the subjects are the responsibility of the ethics committee, but regulatory authorities also share this duty. Human subjects taking part in clinical trials must be shielded from unethical practices. Although regulatory authorities set the necessary rules, which aid in the ethical conduct of clinical trials and the protection of trial subjects, ethics committees adhere to them in order to protect the trial subjects. With regard to the protection of test subjects, India has already undergone a number of amendments, and many more are to come. In recent times, multiple inspections have been conducted at most sites to check for trial subjects' safety and ethical conduct of clinical trial. However, it is equally important for the general public to be aware of the activities taken up by local regulatory bodies as correct awareness about the about mentioned discussion will help to build up the confidence of the research participants. All participants completed a questionnaire that included a question about whether the statement "The government always adequately protects the public against unethical clinical research" was true, false, or not aware. The trust for government seems to have taken a downward trend from 2013, with much less amount of participants believing this to be true.

Participants of clinical trial often claim that complete information was not made available to them. This has become a crucial factor that have caused serious problems in India in past occasions. The risks involved were not mentioned in the information that was provided. Inspection revealed that informed consent was not given and that the subjects were unaware of their participation in clinical trials. They were also unaware of the potential benefits and risks associated with this participation. Because they are the ones on whom trial subjects rely for information, the sponsor or the institution/hospital conducting the trial academic institutions must provide accurate and comprehensive information to the trial subjects. Understanding how much trust trial participants have in them regarding the information provided will help in developing positive relationships with trial participants and maintain subject retention, which also contributes to a high enrolment rate. For each of the three participant types, there were two questions on the questionnaire that asked whether they knew the answer or not. "Clinical research information provided by pharmaceutical companies can be trusted," and "Clinical research information provided by academic institutions can be trusted," were the claims. In response

to these statements, the percentage of participants believing the statements to be true were comparable between the years.

## Conclusion

The present study was conducted through a questionnaire survey involving patients participating in clinical trials. The objective of the study was to understand perspective of patients' with any chronic disease/disorder on conducting a clinical trial and its corresponding ethical standards in Indian landscape. This was done by comparing with previously published data of same level. Null hypothesis of the study stated that, there is no change in the overall awareness and perception of the conduct of clinical research in Indian patients since 2013. Alternative hypothesis was presented stating, there is a change in the overall awareness and perception of the conduct of clinical research in Indian patients since 2013. In order to test these hypotheses, data generated in this study was compared with data published by Kapadia, 2013.

After comparing the data generated from the current study with the previous report, no statistically significant difference was found between the patient's perspectives observed between the two time points. However, sole reliance on statistics can often be misleading. In the present scenario in many cases the patients showed greater awareness compared to the 2013 report. Greater doubt was also observed in certain cases. Therefore it should be concluded that there is some difference between the results observed in the current study with that of the 2013 data. Although, null hypothesis cannot be statistically rejected, but based on observed data trends it can be concluded that the alternative hypothesis is closer to the true scenario.

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