

# **UNDERSTANDING PATIENTS PERSPECTIVE ON CLINICAL RESEARCH IN INDIAN POPULATION**

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## **ABSTRACT**

### *OBJECTIVE*

To understand patients' perspectives on clinical research in India

### *DESIGN*

A questionnaire based survey was conducted in different parts of India, covering all kind of population. Questionnaires were filled with the help of investigators, physicians, social workers, freelancers, research professionals, etc.

### *METHODS*

India is said to be the hub of clinical research. It is also equivalently important that the population in India are well aware about the basics of clinical research so that individuals are not treated as "guinea pigs" and the research is conducted with full ethics and good clinical practice. The study was undertaken to analyze the perspective and awareness of clinical research amongst Indian population.

### *RESULTS*

There were 20 different parameters/data points for which the data was collected from 6122 patients across the country. As the available data is dichotomous a dynamic analysis was done using a percentile method.

### *CONCLUSION*

Clinical trials in India are conducted in ethical manner but still the understanding of patients remains ambiguous. The data concludes that awareness about clinical research remains low. Awareness will help us bring new therapies to the market.

## KEY WORDS

Clinical trials, Indian Scenario, Awareness, Patients Perspective, Ethics, Subjects Confidentiality

## INTRODUCTION

India today is said to be the hub of clinical research, considering its large patient pool, diverse population, large geographical area and low cost to be incurred for the conduct of clinical trials compared to that of the developed countries, hence India has been considered as an attractive destination for clinical drug trials. (Bhatt A., 2006), (De, 2005) Clinical trials globally were found to be in an inclining phase till year 2009; towards the start of 2010 it became stagnant. This was not only the scenario globally, but it also affected India to a greater extent. (Parikh RM, 2011;) Even though the phase of clinical trial was not in a good shape and it had affected major of the developing countries; developed countries were still continuing the trials at the same pace.

There are several success factors for India in the world of clinical trials such as high enrollment rate: India is said to enroll patients in clinical trials at much higher rate as compared to that of US i.e. 0.3 patients per month in US as against 3 patients in India during the same period (Moin, 2013). Spectrum of disease: India is said to be the hub of diseases with the wide range covering from tropical infection to degenerative disease, hence it becomes to be a good scope to the sponsor companies to test their research drug in a variant population for the diseases like Hepatitis B and cancer and so on. (Research and Markets, 2006) Human resource and technical skills: India is known to have more than 500 investigators, in addition to over 572,000 doctors, about 43,322 hospitals & dispensaries, and about 8.7 lakh beds covering both private and public hospitals. (A.R.) (N., 2006) Regulatory compliance: Regulator authority of India i.e. The DCGI who is primarily responsible for approvals of clinical trials. It also depends on external experts and other government agencies like ICMR for expert advice and opinion. Export licenses for sending the samples abroad to central laboratories and also an import license which is required to import IMP is necessary. This all takes approximately 3 month for the complete approval. In addition to there are EC's responsible is to scrutinize the clinical trial before providing an approval. (Das) Reliable data quality: International regulatory authorities now are ready to accept data from all Asian countries especially for pivotal studies. Clinical trial sites in and across Asian countries are said to provide genuine and accurate data and sponsors today are satisfied with the quality of data that is been provided. These data match the international standards and are accepted at major international conferences and international journals. [(Research and Markets, 2006), (N., 2006)]

It is understood that India and China contribute one third of the world's diabetic population, even then less than 15% of the diabetic subjects from India and China are explored to clinical trials. (Parikh RM, 2011;) Challenges such as untrained investigators and site staff which would be one of the major parameter contributing to the non-compliance with ICH-GCP, there were many quantitative and qualitative actions taken. (Bhatt A. S., 2004) As per few of the investigators a

major hurdle considered was “Approvals delayed from regulator authorities”. (Jayasheel, 2010)It was noted that India is not the only country facing this issue but the situation is similar across all the developing countries. (Fenn, 2001)

To understand the perception on clinical research from various stake holders several studies have been published covering specific parameters as per the plan, like in India a survey was conducted amongst investigators (with a small sample size i.e. of 29 investigators) was conducted to understand the research ethics in India. (Bindra, 2010) CISCRP had conducted a survey amongst 1000 patients in 2008 to understand their attitude and perception about clinical trial, as it is very important to know what perception or a mind-set an individual has (part of Discussion). In order to understand the perception of Indian population towards clinical research this study was undertaken.

## **METHODOLOGY**

Focusing on the above objective, a questionnaire was prepared for the patients who were deemed eligible for clinical trials. The patients were approached and communicated through investigators, social workers and free lancers. Data was collected on a printed questionnaire; simultaneously a website was created for collection of the data, for which every individual collecting the data from the patients were provided with the login id and password, thereby ensuring consistency and confidentiality. The questionnaire consisted of 5 sub parts viz.

*Basic information-* which captured patients demographic details and information such as source of income, education, locality, etc. no information was captured which could reveal patients identity.

*General information-* which captured basic awareness of a patient on and about clinical research

*Trust in Clinical Research-* this section focused on the government support and information sharing by the pharmaceuticals and the academic institutes who conduct clinical trials

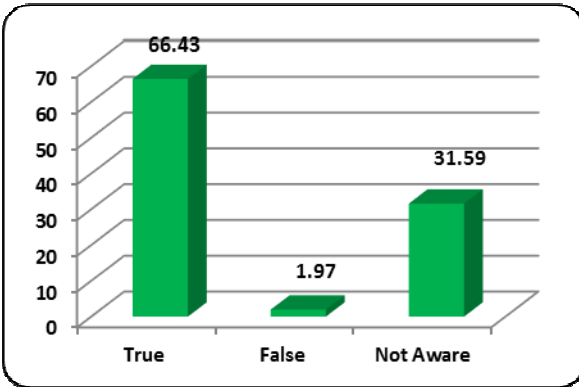
*Ethics-* here the focus was completely on patient’s safety like behavior of the doctor, compensation, voluntary participation, confidentiality of the participant etc.

None of the questions were open ended, all were with the specific option which are further discussed in the results and discussion below. Data were collected on 6122 patients across India starting from 15<sup>th</sup> Jan 2014 to 31<sup>st</sup> Aug 2014. The study was approved by ethics committee.

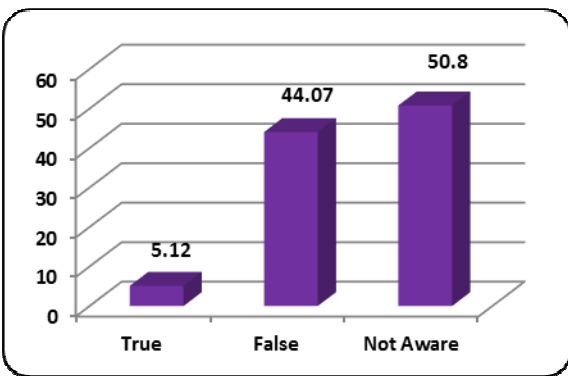
## **RESULTS**

Survey was conducted across India to get the overall data of 6122 patients. Data obtained with the help of investigators, physicians, free lancers, social workers, etc.

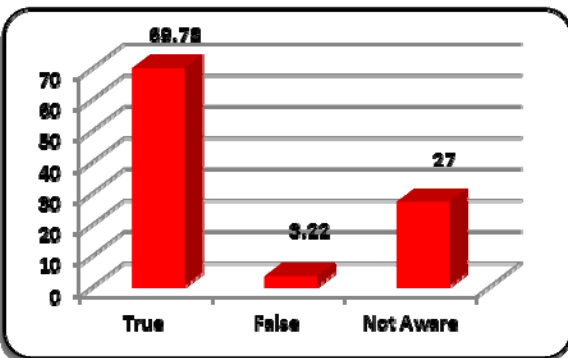
66.43% of patients stated that Clinical research benefits society while 5.12% stated that it harms the society, similarly 31.59% were unsure of any benefits. (Figure 1 & 2). 69.78% of patients agreed that clinical research is one of an important reason for developing new treatment, 3.22% did not agree to the same and 27% were not aware (Figure 3). 53.96% agreed that it is essential for new treatment development while 43.09% were not aware. Better health care is provided by hospitals that participate in clinical research. 51.14% believed that it is false, 26.08% said it to be true and 22.77% of them were unsure (Figure 4). Financial gain is one of the reason for new treatment development: 21.47% considered it to be true, 21.25% and 57.26% considered it to be false and were not aware respectively (Figure 5). 72.06% patients believed that government takes care of patients against unethical conduct of trials, 23.75% were not aware (Figure 6). 49.70% and 46.44% patients believed that information provided by pharma companies and academic institutions respectively can be trusted 44.39% and 46.79% said that it cannot be trusted (Figure 7 & 8). Doctors do not take proper care if you deny from participating in clinical trial; 73.88% did not agree with this and 22.62% were not aware about it (Figure 9). Only 3.97% of patients said that investigators force subjects for their participation, 77.90% did not agree and remaining 18.13% were not aware (Figure 10). 40.47% of patients denied that a tendency exists for humans to be considered as experimental animals, 21.40% agreed to it while the remaining 38.12% were not aware about the scenario (Figure 11). Participation in clinical research is voluntary; 77.78% agreed, 2.14% did not agree and 20.07% were not aware (Figure 12). Adequate compensation is given to subjects for participating in trials; 58.88% agreed, 3.03% did not agree and 38.07% were not aware (Figure 13). 46.93% patients agree that the AE's and SAE's are compensated, 5.95% did not agree and the remaining 47.12% were not aware (Figure 14). Confidentiality is of major importance; 65.30% agreed, 2.97% did not agree and the remaining 31.73% were not aware (Figure 15). 43.74% of patients confirmed that the confidentiality is adequately protected, 51.29% were not aware and 4.97% did not agree to it (Figure 16). 60.89% of patients were not aware about the publication of the clinical trial results and it to be made aware, 33.03% agreed that it is made available and the rest 6.10% did not agree (Figure 17). 19.95% of patients opined that altruism is the only reason for participation, 34.08% did not think so and 45.25% were not aware of it (Figure 18). 46.40% of patients agreed that the information provided to participants is adequate and sufficient, 45.41% were not aware of it (Figure 19).



**Figure 1: Clinical research benefits society**



**Figure 2: Clinical research harms society**



**Figure 3: Clinical research is most important reason for new drug development**

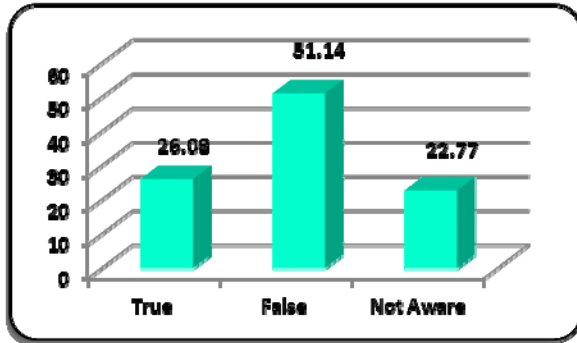


Figure 4: Better health care is provided by the hospitals that participate in clinical trials

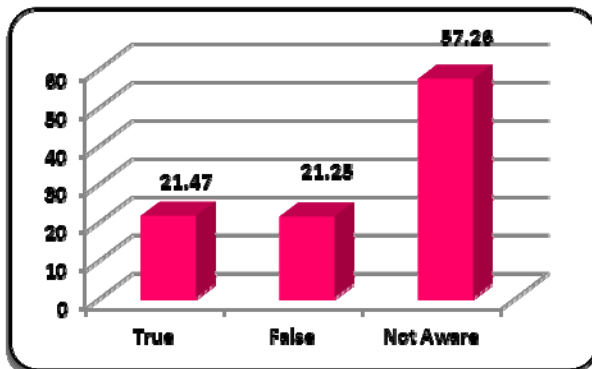


Figure 5: Financial gain is one of the major aim behind conduct of clinical trial

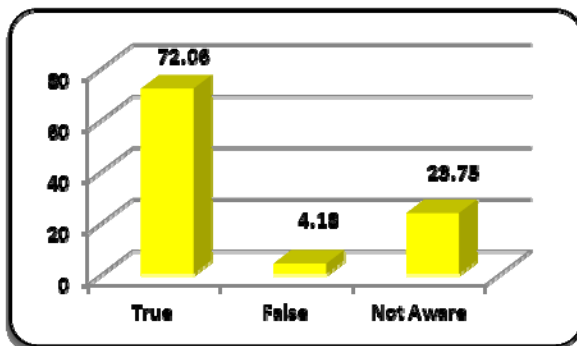
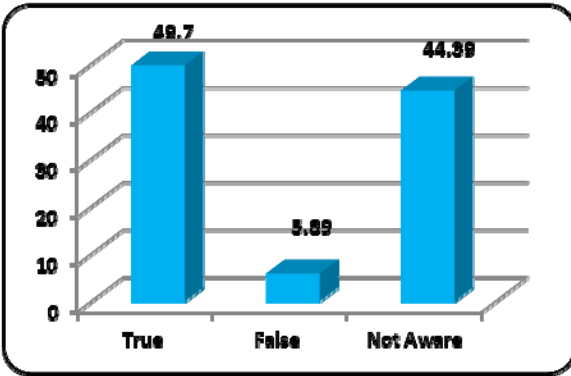
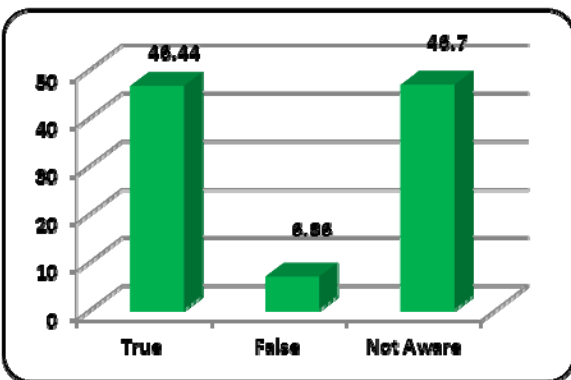


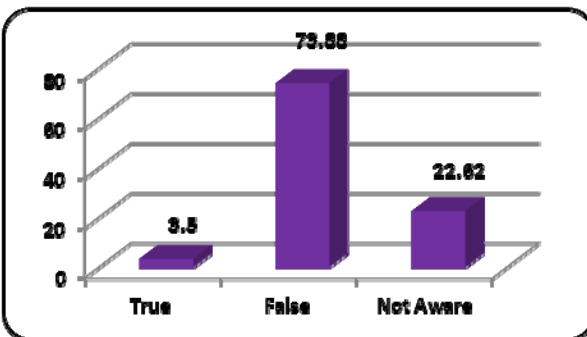
Figure 6: Government takes care against unethical conduct of clinical trials



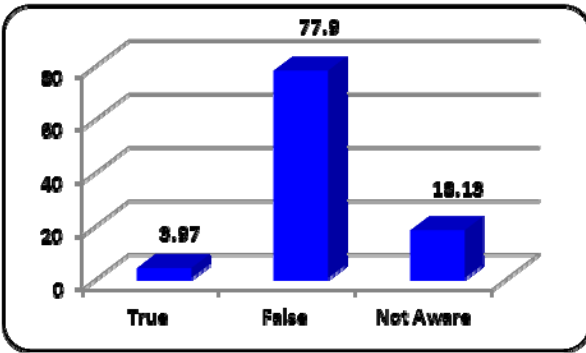
**Figure 7: Pharma companies provide trusted information**



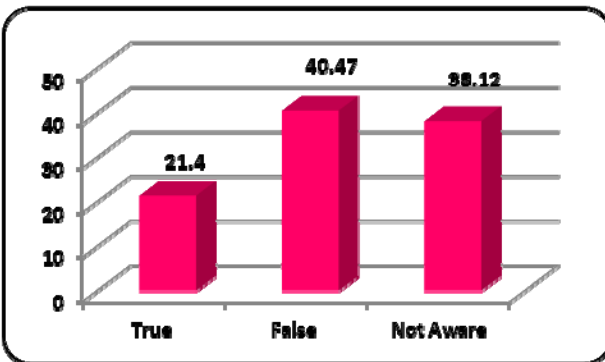
**Figure 8: Academic institutions provide trusted information**



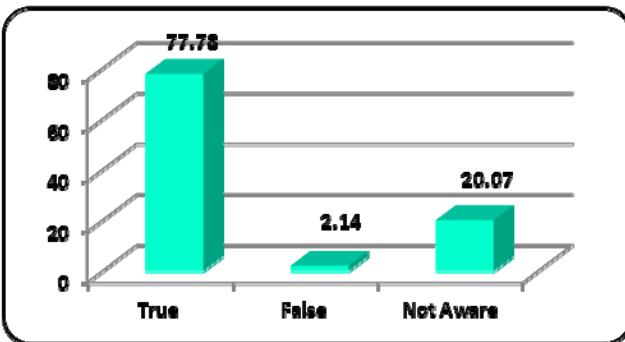
**Figure 9: Investigators do not provide proper health care if your deny from participation in trial**



**Figure 10: Doctors force their patients to participate in research**



**Figure 11: Humans are considered as experimental animals**



**Figure 12: Voluntary participation in clinical trials**



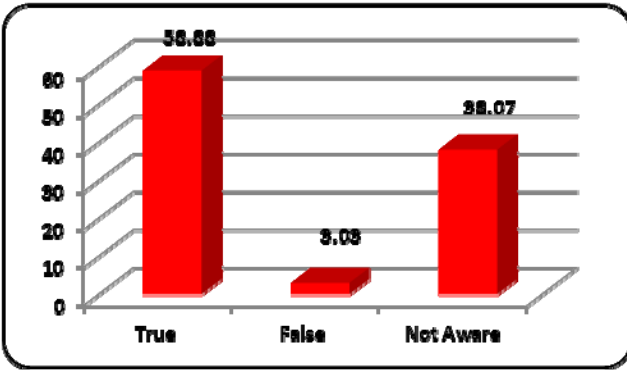


Figure 13: Adequate compensation for participation in clinical trials

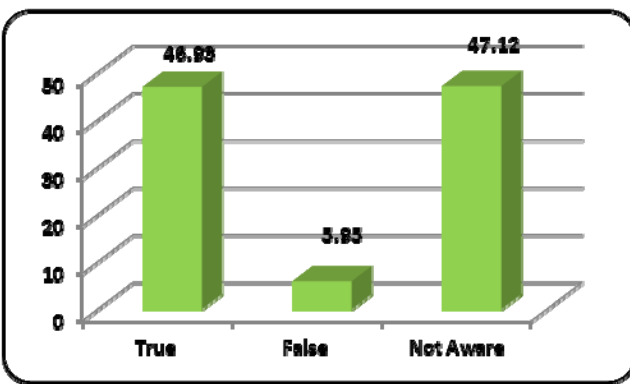


Figure 14: Adequate compensation for AE's and SAE's

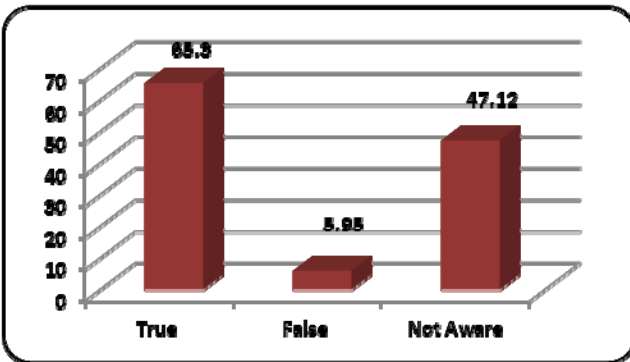


Figure 15: Subject's confidentiality is important

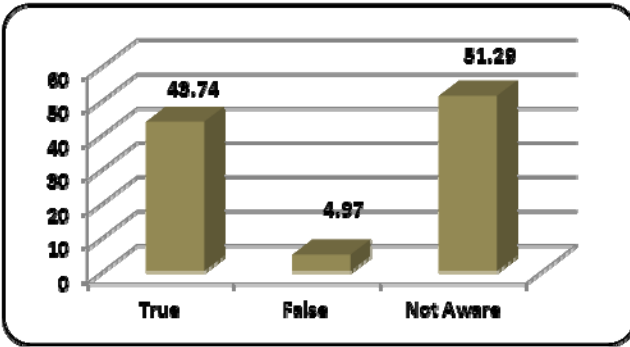


Figure 16: Subject's confidentiality is protected in an appropriate manner

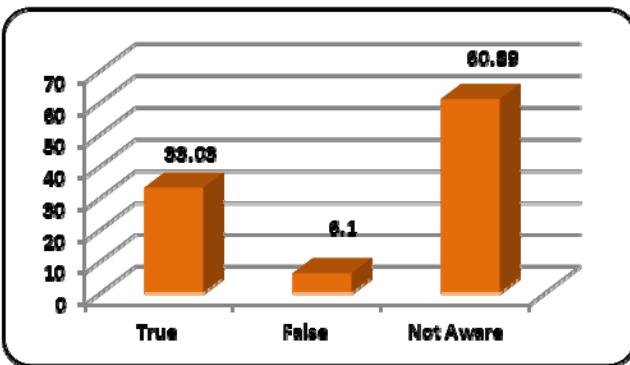


Figure 17: Results are made available to public

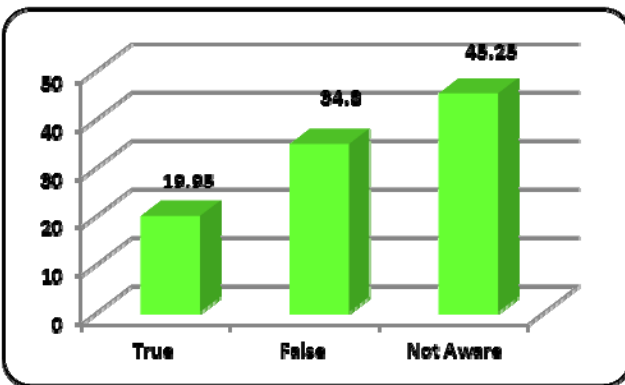
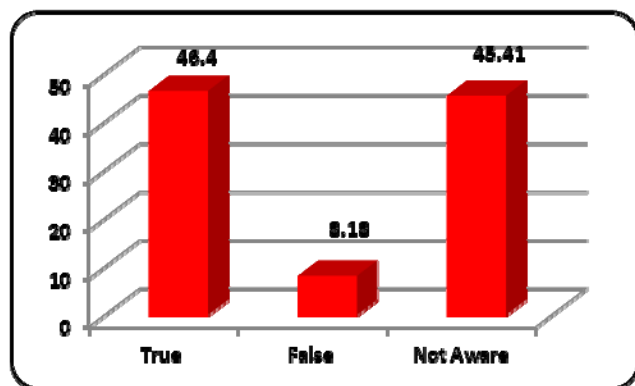


Figure 18: Altruism is the only reason for subject's participation



**Figure 19: Appropriate information is provided to subject who participate in trials**

## **DISCUSSION/CONCLUSION**

This survey has helped us in understanding the awareness and attitudes of patient's perspective on clinical research across the country. It also concludes that the understanding about clinical research is low and needs to be informed to the larger population and people in India need to be made aware on the same. Patient recruitment and retention is one of the key important aspects for successful clinical trial. Proper awareness will help achieve this. Trust is another important parameter without which enrollment and retention would not be possible, trust not only in investigators, but also important that an individual who is participating in a trial is aware about the approving authorities and also have trust in them as they are also the ones who are responsible for patients right, safety and well-being.

Trust can be built only if we are sure that the trials are conducted in an ethical manner and under appropriate applicable regulatory guidelines, confidentiality of the subjects being an important parameter is been maintained in adequate manner, and also the data that can reveal subjects' identity is appropriately maintained. Participation should be confirmed to be voluntary and no external pressure is put on an individual for participating in a clinical trial. This will help us alleviate the syndrome of "guinea pig".

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