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Understanding Patients Perspective on Clinical Research in Indian Population

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Abstract

Objective: To understand patient's 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, and research professionals, etc.

Methods: India is said to be the hub of clinical research. It is also equivalently important that the Indian population remain 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: Though Central Drugs Standard Control Organization (CDSCO) – the office of the Drug Controller General (India), the supreme regulatory authority for clinical research in India, has framed necessary guidelines and schedules to oversee that clinical trials are conducted in ethical manner still the understanding of patients remains ambiguous. The data concludes that awareness about clinical research remains low. Better public awareness will help us bring new therapies to the market.

Keywords: 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 [1,2]. 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 [3]. Even though the phase of clinical trial was not in a good shape and it had affected majority 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 the U.S. i.e. 0.3 patients per month in US as against 3 patients in India during the same period [4].

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 [5].

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 and dispensaries, and about 8.7 lakh beds covering both private and public hospitals [6,7].

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 this there are EC's responsibility to scrutinize the clinical trial before providing an approval [8].

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 [5,7].

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 exposed to clinical trials [3]. 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 [9]. As per few of the investigators a major hurdle considered was "Approvals delayed from regulator authorities" [10]. It was noted that India is not the only country facing this issue but the situation is similar across all the developing countries [11].

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) to understand the research ethics in India [12]. 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. 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 freelancers. 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.

Study population

The study population was selected by convenience sampling from urban and rural locations in the states Bihar, Delhi NCR, Gujarat, Karnataka, Madhya Pradesh, Maharashtra, West Bengal, and Punjab. The participants were males and females from varied ages from 18 years to 63 years.

The questionnaire consisted of 5 sub parts viz.

Basic information: Which captured patient's 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 15th Jan 2014 to 31st 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 and 2).

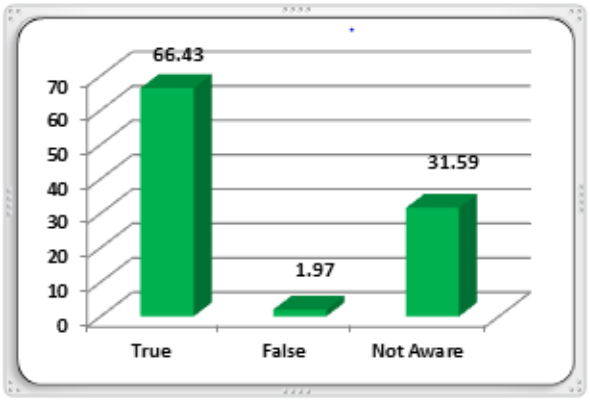

Figure 1: Clinical research benefits society; Y Axis: Percentage.

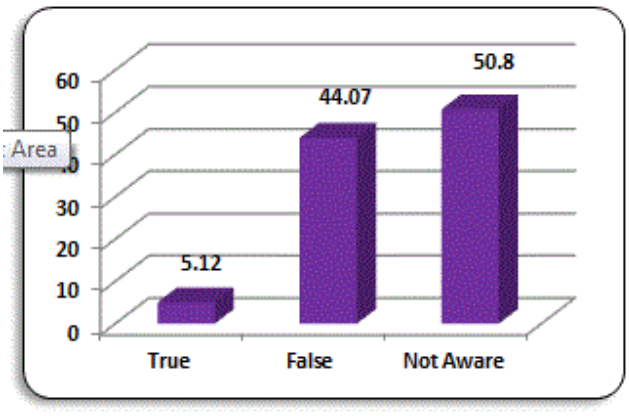

Figure 2: Clinical research harms society; Y Axis: Percentage (%).

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).

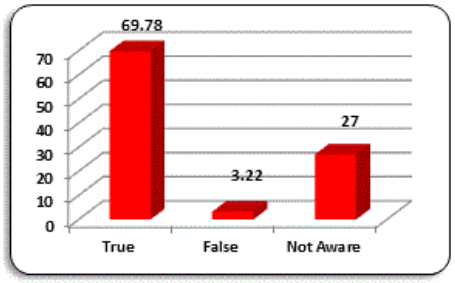

Figure 3: Clinical research is most important reason for new drug development; Y Axis: Percentage (%).

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).

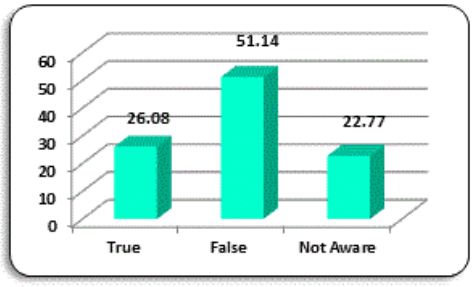

Figure 4: Better health care is provided by the hospitals that participate in clinical trials; Y Axis: Percentage (%).

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).

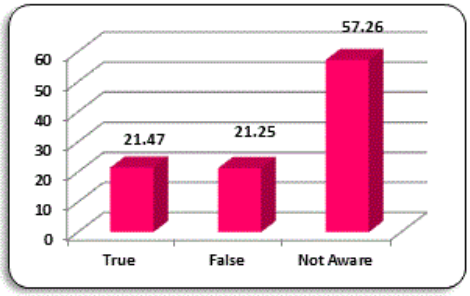

Figure 5: Financial gain is one of the major aim behind conduct of clinical trial; Y Axis: Percentage (%).

72.06% patients believed that government takes care of patients against unethical conduct of trials, 23.75% were not aware (Figure 6).

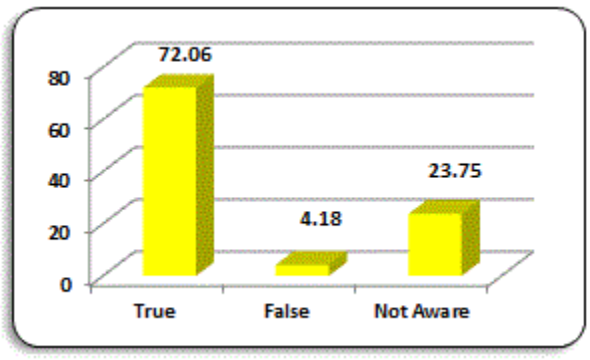

Figure 6: Government takes care against unethical conduct of clinical trials; Y Axis: Percentage (%).

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 and 8).

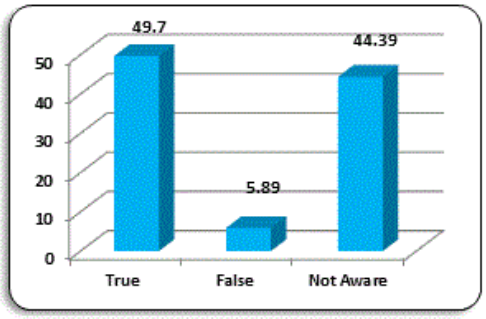

Figure 7: Pharma companies provide trusted information; Y Axis: Percentage (%).

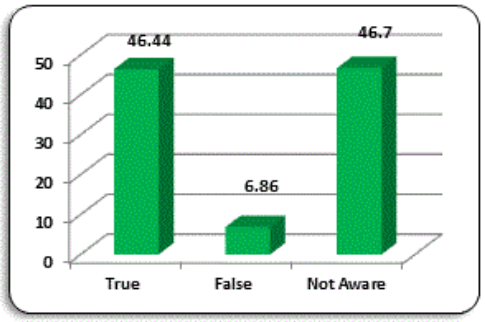

Figure 8: Academic institutions provide trusted information; Y Axis: Percentage (%).

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).

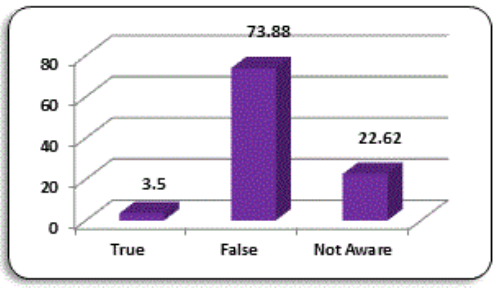

Figure 9: Investigators do not provide proper health care if your deny from participation in trial; Y Axis: Percentage (%).

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).

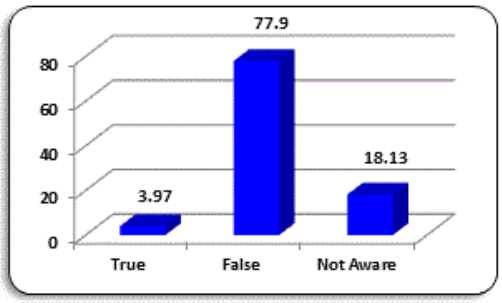

Figure 10: Doctors force their patients to participate in research; Y Axis: Percentage (%).

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).

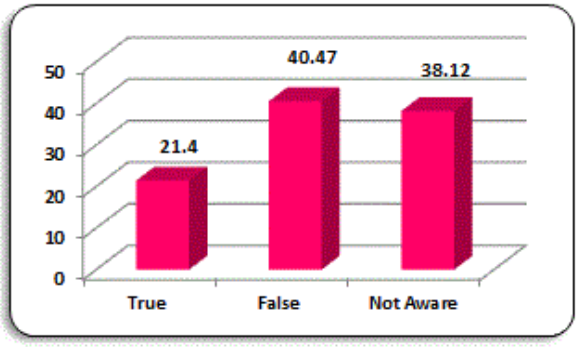

Figure 11: Humans are considered as experimental animals; Y Axis: Percentage (%).

Participation in clinical research is voluntary; 77.78% agreed, 2.14% did not agree and 20.07% were not aware (Figure 12).

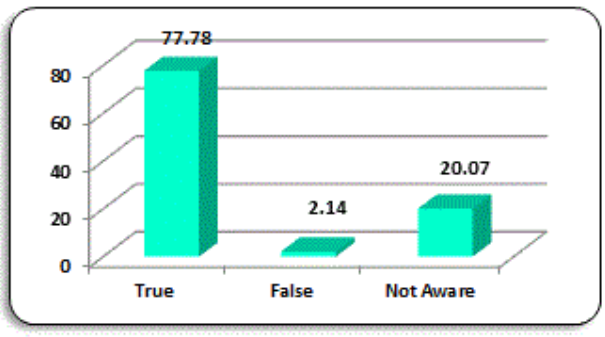

Figure 12: Voluntary participation in clinical trials; Y Axis: Percentage (%).

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).

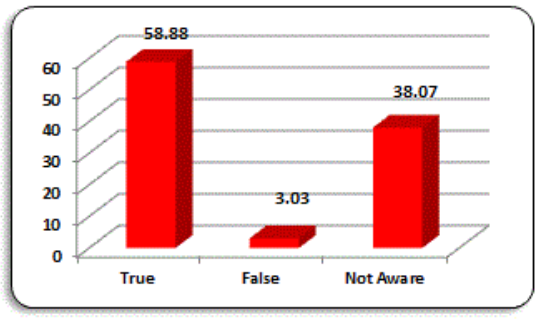

Figure 13: Adequate participation for participation; Y Axis: Percentage (%).

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).

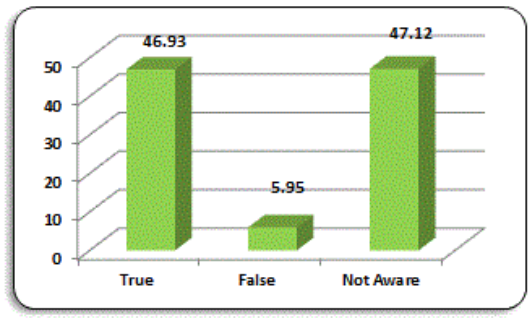

Figure 14: Adequate participation for AE's and SAE's; Y Axis: Percentage (%).

Confidentiality is of major importance; 65.30% agreed, 2.97% did not agree and the remaining 31.73% were not aware (Figure 15).

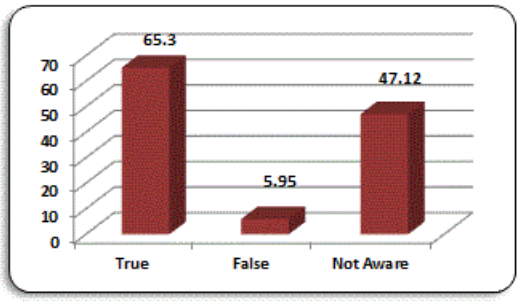

Figure 15: Subject's confidentiality is important; Y Axis: Percentage (%).

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).

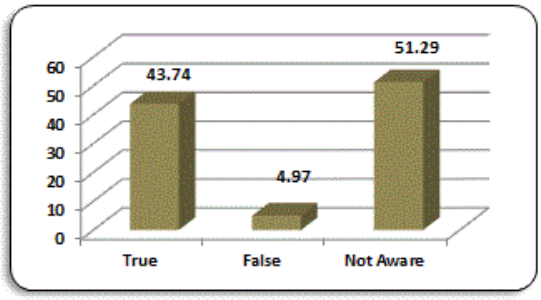

Figure 16: Subject's confidentiality is protected in an appropriate manner; Y Axis: Percentage (%).

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).

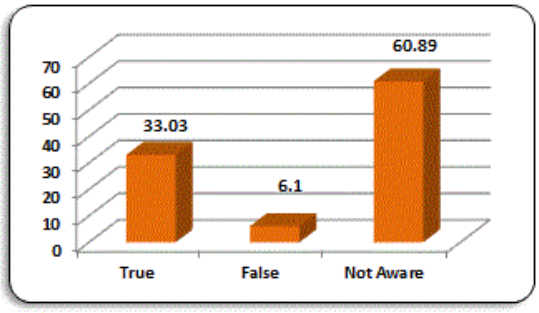

Figure 17: Results are made available to public; Y Axis: Percentage (%).

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).

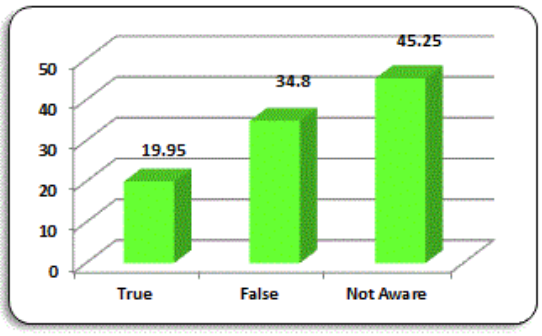

Figure 18: Altruism is the only reason for subject's participation; Y Axis: Percentage.

46.40% of patients agreed that the information provided to participants is adequate and sufficient, 45.41% were not aware of it (Figure 19).

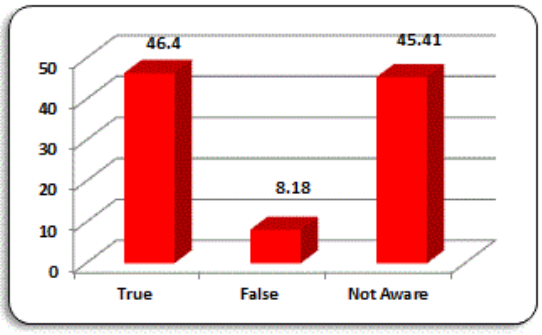

Figure 19: Appropriate information is provided to subject who participate in trials; Y Axis: Percentage (%).

Discussion/Conclusion

This survey has helped us in understanding the awareness and attitudes of patients perspective on clinical research across the country. It also depicts 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. As main discussed in the 2013 study paper regarding the higher rate of patient recruitment in India than the US, a striking question appears whether these participating patients are well aware of the pros and cons of participation in a study. The varied profile of diseases diagnosed and the vast healthcare setup network available for research purpose definitely draws huge amount of sponsor attention to this country, as we find in the 2006 report by Research and Markets. Still there is a pothole in terms of the quantum of participation in clinical trials on the side of the patients and their families, as Parikh reports in 2011 study on trends of study participation. Patient recruitment and retention is one of the key important aspects for successful clinical trial. The clear ambiguity in

the current study highlights that the lacunae mainly lies with the unaware quanta of the population in this country. 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 in an individual who is participating in a trial. The study team needs to be sure that a participant is aware of the approving authorities and also has trust in them, as they are also the ones who are responsible for patients' rights, safety and well-being.

In a concluding note, the current study underlines that 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 maintained in adequate manner, and also the data that can reveal subject's 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" in clinical research.

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