

## Original Article

# Awareness and attitude of general public about clinical trials in a developing country

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**Abstract.** Knowledge and awareness about clinical trials amongst general public is essential to improve the recruitment rate of patients. The present study was conducted to assess such aspects in semi-urban and rural India. A cross-sectional pre-validated questionnaire based assessment of views of public regarding the various aspects of clinical trials ranging from general, ethical, confidentiality and publication was conducted. Descriptive statistics was used to represent the responses in the form of proportions. A total of 400 participants were recruited for the study and 92% of the study participants opined that clinical trials benefit society while 9.7% opined that it harms the society. Nearly three-fourth (285/336, 73.8%) considered clinical research as an essential step for the development of new drugs. Surprisingly, only 118/261 (45.2%) of the study participants felt that the confidentiality of the study participants were adequately protected. Also, only 79/247 (32%) and 86/234 (36.8%) study participants were aware of compensation in case of participation in clinical trials and adverse effects respectively. To conclude, we observed an optimistic trend towards increasing awareness about clinical trials. However, more robust studies in larger groups of individuals from various strata need to be conducted to assess the attributing factors for the difference in knowledge and awareness about clinical trials.

**Keywords:** KAP, clinical research, recruitment

### Introduction

Standardizing the regulation of drugs and providing intricate training of healthcare personnel lead to better conduct of clinical trials in the Indian sub-continent in the last decade. In the past five years, the clinical investigator growth in India was found to be 14% while the same was just 9% in North America [1]. Study of registered clinical trials in the trial registry has shown that amongst the World Health Organization South East Asian Region countries (WHO SEAR), a large majority of the trials were registered by India (58.8%) followed by Thailand (32.3%) [2]. Even more appealing is the fact that the same study has also found out nearly three-fourths (73.8%) of the phase 1 studies in WHO SEAR are being carried out in India [2]. Also, additionally an increasing trend of global clinical trials is conducted in India starting from a proportion of 1% in 2005 to 25% in 2011 [3].

On the other hand, recently a series of issues have been identified related to clinical trial conduct in India especially addressing the informed consent [4]. Understanding the important principles of clinical trials by patients is crucial for resolving these issues. A study from Western part of the nation in 2012 established the fact that the awareness of

clinical trials by patients is very low [5]. Further adding to the problem is the quality of informed consent as assessed by one of the investigators in cancer clinical trials and was found to be unsatisfactory with a lot of misconceptions amongst the study participants [6]. With this background, we attempted to find out the knowledge and awareness about clinical trials from semi-urban and rural population in India.

### Method

The study was initiated after obtaining permission from institutional ethics committee between October 2014 and March 2015. The study was a cross-sectional questionnaire based analysis of opinion of general public attending a private hospital in India after obtaining their informed consent. A pre-validated questionnaire by Burt et al [7] was used in this study. Descriptive statistics was used to represent the data in proportions.

### Results

#### Demographic details

A total of 400 participants 315 (78.8%) males and 85 (21.2%) females] were enrolled in the study with a mean

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**TABLE 1**  
**RESPONSE OF THE STUDY PARTICIPANTS (n=400)**

Assessed parameters (Number of participants who responded to each of the questions)	Responses of the participants [n (%)]
Clinical research benefits society (n=363)	Y – 334 (92)
	N -29 (8)
Clinical research harms society (n=329)	Y – 32 (9.7)
	N – 297 (90.3)
Scientific advancement is the most important reason for developing new drugs (n=357)	Y – 343 (96.1)
	N – 14 (3.9)
Clinical research is an essential step in developing new drugs (n=336)	Y – 285 (73.8)
	N – 51 (26.2)
Hospitals that participate in clinical research provide better healthcare (n=272)	Y -189 (69.5)
	N-83 (30.5)
The most important reason for developing new drugs is financial gain (n=305)	Y-82 (26.9)
	N-223 (73.1)
The government always adequately protects the public against unethical clinical research (n=271)	Y-144 (53.1)
	N-127 (46.9)
Clinical research information provided by pharmaceutical companies can be trusted (n=261)	Y-179 (66.5)
	N-82 (33.5)
Clinical research information provided by academic institutions can be trusted (n=274)	Y-210 (76.6)
	N-64 (33.4)
If you decide not to participate in clinical research your doctor will not give you good care (n=347)	Y-81 (23.3)
	N-266 (76.7)
Doctors force their patients to participate in clinical research (n=359)	Y-44 (12.3)
	N-315 (87.7)
Human participants in clinical research are treated like experimental animals (n=338)	Y-35 (10.4)
	N-303 (89.6)
Participation in research is entirely voluntary (n=356)	Y-309 (86.8)
	N-47 (13.2)
Volunteers in clinical research get adequate compensation for their participation (n=247)	Y-79 (32)
	N-168 (68)
Participants in clinical research get adequate compensation for any adverse outcomes (n=234)	Y-86 (36.8)
	N-148 (63.2)
Confidentiality is a matter of importance to research participants (n=333)	Y-235 (70.6)
	N-98 (29.4)
Confidentiality of research participants is adequately protected (n=261)	Y-118 (45.2)
	N-143 (54.8)
All the results of the clinical trials are made available to the public (n=231)	Y-70 (30.3)
	N-161 (69.7)
Altruism is the only valid reason for participation in clinical research (n=331)	Y-173 (52.3)
	N-158 (47.7)
Volunteers in clinical research get adequate information about the research they participate in (n=316)	Y-180 (57)
	N-136 (43)

(SD) age of 30.7 (11.1) years. Of the 400 participants, 168 (42%) had done under-graduation, 149 (37.3%) did complete only school education, 78 (19.5%) had a post-graduation degree and 7 (1.2%) hold doctorate degree.

### Response to the questionnaire

Of the 363 participants who responded to the question on whether clinical research benefits the society, 334 (92%) were affirmative while 32/329 (9.7%) opined that clinical research harms the society. Details of responses to other questions are mentioned in Table 1. Close to three-fourth (285/336, 73.8%) said that clinical research is an essential step in the development of new drugs. Surprisingly, only 118/261 (45.2%) of the study participants felt that the confidentiality of the study participants were adequately

protected. Also, only 79/247 (32%) and 86/234 (36.8%) study participants were aware of compensation in case of participation in clinical trials and adverse effects respectively.

### Discussion

The present study has been conducted to assess the knowledge and awareness of general public about clinical trials from semi-urban and rural regions in India. By and large a positive attitude was found towards their thinking about clinical trials indicating a promising trend as compared to the results of the previous studies done in the same arena with a similar objective.

The primary reason for outsourcing clinical trials to India is cheap and rapid recruitment rate. But there were

many recent concerns regarding the uproar that emerged with some of the clinical trials where the victims' (patients) relatives were of the opinion that they were not informed that a trial is being conducted while the investigators argued that they did inform the same to the patient/relatives [8].

Although ethics committee and informed consent serve as two pillars for conducting an ethical research, a huge responsibility vests with the investigators in ensuring that the study participants clearly understand the basic tenets of clinical trials. But the studies that had assessed the knowledge and awareness of clinical trials in Indian population were conflicting. Burt et al [7] evaluated 175 adult and elderly Indians in Delhi and found out that the participants were aware of essential elements of clinical trials such as purpose, value and voluntary nature of participation but unsatisfied and mistrust with the way of conducting and reporting clinical trials in the country. On the contrary, Joshi et al [5] conducted a similar study in the Western India and found out that 90% of the study participants were completely unaware of clinical trials. Although we found out that the participants had fair general knowledge regarding clinical trials as well as the ethical aspects, more efforts are needed to strengthen their understanding regarding the issues of compensation and maintenance of confidentiality.

To conclude, we observed an optimistic trend (to an extent of around 92%) towards increasing awareness about clinical trials as compared to previous studies. However, only nearly half of the study population felt that confidentiality of the participants were adequately protected. More robust studies in larger groups of individuals from various strata need to be conducted to assess the attributing factors for the difference in knowledge and awareness about clinical trials.

### Conflict of interest

The authors declare that they have no competing interests.

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