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Understanding Clinical Trial Participants (Healthy Volunteers) Perspective on Clinical Research in Indian Population

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Abstract

Objective:

The main project is about finding perspective of Indian population (segregated into 3 categories: Patients, Healthy Volunteers, and Parents) on Clinical Research.

Design

A survey in the question-answer form was carried out including the Volunteers/Participants of Clinical research all over different regions of India. Questionnaires were filled with the help of investigators, physicians, social workers, freelancers, and research professionals, etc.

Methods

Clinical research is an important factor but it is only possible when Healthy Volunteers are participating in the clinical research. Physiological and anatomical conditions of a participant are taken in to consideration. Therefore diseases & conditions and their treatments also vary among each individual. This study has major focus on the awareness and perspective of Indian participants and their views towards clinical research. Also, participants are provided with proper treatment, confidentiality, compensation, proper treatment and knowledge as well as safety which always remain the top priority.

Results

There were 28 different parameters/data points based on which the data was collected from 1114volunteers/participants across the country. As the available data is dichotomous, a dynamic analysis was done using a percentile method.

Conclusion

In India, regulatory health authority such as the Central Drugs Standard Control Organization (CDSCO) – the office of the Drug Controller General (India), set the necessary guidelines & schedules for ethical conduction of clinical trials. This survey overall displays the analysis study all about the volunteers for clinical researches. It throws light on their understanding about 'clinical research', their beliefs, dis-beliefs about certain facts of clinical research. The whole survey was categorized into three types: Part of the population who agreed to a certain pattern of survey, one part which did not agree and the third one being unaware at all. It was observed that people who believed or thought that the facts involved were true or correct were at an appreciable percentage when compared to those who considered it as False. Whereas, the number of people who were un-aware couldn't be ignored either.

Keywords: *Clinical trials, Awareness, Volunteer/Participant Perspective, Safety, Confidentiality, Compensation, Harm /Benefit to the society, Participation, Financial gain, Collaboration.*

Introduction

In comparison with developing countries, large patient pool, diverse population, large geographical area and low cost will be the factors due to which India could become favorable country for conduction of clinical research and to attract pharmaceutical companies to carry out trials. (Bhatt A. , 2006), (De, 2005). When it was observed globally, till year 2009, success graph of clinical trials was in an inclining phase

and at the start of 2010 became it stagnant, and India also got hit due to this. (Parikh R.M., 2011). For developing countries it is essential to shape clinical trial phases, in comparison with developed countries.

There are various success factors for India with regards to clinical trials which included:

1) High enrolment rate: If we compare with U.S., enrolment rate of patients was high i.e. when 3 patients in India enrol for trials in a month, in US 0.3 patients enrol for the same period (Moin, 2013).
2) Spectrum of disease: When we consider diseases like Hepatitis B and cancer, it is essential for pharmaceutical to test the research drug in wide range of population. And in India huge diversity of patients with different diseases ranging from tropical infection to degenerative disease are easily available (Research and Markets, 2006).
3) 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).
4) Regulatory compliance: In India, clinical trials are approved by DCGI primarily. External experts and other government agencies like ICMR provide expert advice and opinion, when required. Export license is necessary for sending the samples abroad to central laboratories and IMP imported with help of import license. The whole approval procedure takes 3 months approximately and EC's carry out clinical trial examination prior approval (Das N.).
5) Reliable data quality: International regulatory authorities are now accepting research related data from all Asian countries. Sponsors are also satisfied with quality of data. Provided data is as per the international standards and also accepted at major international conferences and international journals [(Research and Markets, 2006), (N., 2006)].

Let us consider issues faced during clinical trial approval and conduction, by developing countries along with India (Fenn, 2001). India and China contribute to one third of the world's diabetic population and less than 15% of total subjects have been exposed during trials. (Parikh R.M., 2011). Non-compliance with ICH-GCP leads by untrained investigators and site staff becomes one of the major challenge and quantitative and qualitative actions were taken for the same (Bhatt A. S., 2004). If approval was delayed from regulatory authorities, it becomes a major hurdle as per few of the investigators (Jayasheel, 2010).

To understand the perception on clinical research, various studies published from stake holders help, which covers specific parameters as per plan. In India, survey with small sample size i.e. of 29 investigators was conducted to understand research ethics in India (Bindra, 2010). Also, in 2008, CISCRP conducted a survey amongst 1000 patients for understanding the attitude and perception of patients about clinical trial. Hence, this survey majorly focuses on the perception of child participants and their parents regarding clinical research.

Methodology

Questionnaire was prepared based on above objective, for the child participants and parents who were thought to be eligible for clinical trials. Investigators, social workers and free lancers approached and communicated with the child participants and parents. 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. Survey will be conducted for the patient's (calculated number of patient's) who are suffering from chronic diseases. Major 'A' class cities of India will be covered for completing the target population and also would help in covering major regions of India. Some additional surveys would be conducted with the help of same questionnaire in rural India to have the information on awareness of Pan India. The objective of the research project is to understand the perspective of Indian patient's on clinical research; the project will be a survey based project.

Study Population: In this survey, the study population was selected by convenience sampling from different locations in the states Bihar, Delhi NCR, Gujarat, Karnataka, Madhya Pradesh, Maharashtra,

West Bengal, and Punjab. The study majorly focused on the parents whose children are going to be participating in the clinical trials.

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 1180 parents across India starting from 15th Jan 2014 to 31st Aug 2014. The study was approved by ethics committee.

Statistical analysis was carried out for which total number of participants was divided into different sub-groups so as to make comparison between them. The sub-groups were differentiated as per various factors such as sex of patient, general awareness towards clinical research, and ethics in clinical research.

Results and Discussion:

Overall data was collected from the Healthy volunteers of different regions, which have been analyzed on the basis of different parameters. This sub group analysis is majorly concentrating on Healthy volunteers. As in how healthy actually are the volunteers. Now lets have a look at the statistical data that was obtained from the survey:

The population out of 1114, who actually heard about the term 'Clinical Research' came to 84.65% and the rest 15.35% did not hear about it.

About participation in the clinical trials, it was found that out of 1114, 81.33% were ready to participate while 18.67 were not.

When it was asked to those 1114 people that though being a healthy individual, whether they were ready and comfortable in taking medicines without having any kind of disease, just 43% of the population turned out to be positive whereas, the rest 57% were not comfortable doing it.

Among the total population of 1114, when it came to knowing or believing the benefits that were obtained from Clinical Research to the society, 86.80% people positively knew about it and they admitted it. But, 13.20% of them weren't aware of the fact what Clinical Research has benefitted to the society. Fortunately no-one denied the fact.

On the same page, when the opposite of the above statement was surveyed: Clinical Research Harms Society. 15.71% found it true, whereas a major category of 60.50% stood firm that it did not harm the society. 23.79% were neutrally not aware of the subject.

On asking the population if they believed if the important reason for the development of new treatments was the advancement of science, 71.27% assertively said it was true. 8.26% said it was false, whereas 20.47% weren't aware.

Among the population of 1114, 82.14% believed that Clinical research was an essential step in the development of newer treatments. 17.86% of them were not aware of this developmental step though.

When it came to Hospitals that participated in the clinical research provided better health care or not? We obtained the most distributed results out of all other survey topics. Like 52.33% believed that the hospitals did provided better healthcare. 23.52% denied this statement and 24.15% were neutral as they were not aware.

Was financial gain the most important reason behind the development of new treatments? Only 13.91% agreed to this statement whereas, 46.05% did not and 40.04% were not familiar to the fact.

Out of 1114 people, when it was surveyed what the felt about the protection given to the public by the government against unethical clinical research, 53.68% undoubtedly agreed to this whereas, 3.77% were against this. 42.55% were not known about this issue.

On surveying about the trusting factor on which the pharmaceutical companies could be trusted on the clinical research information provided by them it was found that approximately 60% that is 59.96% of the population thought it was true whereas, 5.30% denied the fact and 34.74% were unaware.

Similarly, when it was interrogated that Clinical research information provided by the academic institutions could be trusted or not, it came out that 65.71% believed the academic institutions with this regards and 34.29% were not aware of this situation.

Moving ahead to the next but interesting topic of survey, which was: 'If decided not to participate in the research your doctor would not give good care to you'. In this expectedly only 6.10% population among the 1114 people said it was true. 46.32% were against the fact and 47.58% were not even aware.

Another most interesting yet popular subject, Doctors forced their patients to participate in research, on surveying this out we found that 3.50% still thought that they did force! Whereas, 70.83% genuinely declined this and 25.67% were not familiar with this area.

The most threatening myth of the clinical researches, Human participants in the clinical research are treated as experimental animals like Guinea pigs. From total of 1114 people, 58.08% people refused to have being said this. Whereas, according to only 9.61% it was true and 32.32% were not aware.

Moving to another survey topic, Participation in survey is entirely voluntary, 72.44% spontaneously agreed to this and 1.53% refused to this whereas, 26.03 were not aware of this fact.

Another topic in the survey which was: Volunteers in clinical research get adequate compensation for their participation. According to the survey, 53.95% of the population among the 1114 people believed it to be true. Another 46.05% of the population did not know about it and no part of the population disbelieved it.

Similarly, the participants in clinical research get adequate compensation for any adverse outcomes. Out of 1114 people 38.42% believed it as true, 11.31% denied it and 50.27% did not know about this.

When survey was performed regarding the confidentiality, as in the topic was Confidentiality a matter of importance to the research participants, 65.71% positively agreed to it. 34.29% were not aware of the fact.

Confidentiality regarding the participants won over the protection of this confidentiality. Meaning that when a survey was carried out to analyze that how many people thought that this confidentiality was adequately protected, only 56.37% of the population thought it was protected. Rest 43.63% did not even know about it.

As the survey was nearing its end, the topics of survey were more sensitive and of much importance. The next topic was whether all the results of clinical research were made available to the public or not! Some people, actually very less amount of people thought that real results were hidden or not all the results of the research were disclosed to the public. But 55.57% of the people thought that only the real and all the results were shown to the public. Still 39.05% were not aware.

Disinterested and selfless concern for the well-being of others which means nothing but Altruism, was this only main reason for the participation in the research? 26.30% thought it was correct. 28.19% thought it was false and 45.51% did not have any idea about this statement.

Among the 1114 people 59.52% of the people thought that all the volunteers get adequate information about the research they participate in. On the other hand, 38.87% were unaware of the fact and only 1.62% thought it was not true.

Among the last two topics of the survey, when these 1114 people were asked what was the impact on clinical research regarding collaborations with non-Indian industry or academic partners, according to 41.56% of people it had a good impact. For 24.42% of the people it had a bad impact and 5.30% people had a neutral opinion. Percent of people who were not aware was 28.73%.

Coming to the last topic of this survey, which was at this time fairly the same topic but the answer was expected in quantity unlike the previous one (quality wise). This time 50.36% people thought it had a large impact, 22.17% thought it was a moderate consequence and 27.47% thought it had a minimal impact on the clinical research.

Conclusion

This survey overall displays the analysis study all about the volunteers for clinical researches. It throws light on their understanding about 'clinical research', their beliefs, dis-beliefs about certain facts of clinical research. The whole survey was categorized into three types: Part of the population who agreed to a certain pattern of survey, one part which did not agree and the third one being un-aware at all. It was observed that people who believed or thought that the facts involved were true or correct were at an appreciable percentage when compared to those who considered it as False. Whereas, the number of people who were un-aware couldn't be ignored either. We need to take more steps in order to negotiate the number of people coming into the category of 'Un-awareness'. From this survey it can be said that there is a mature understanding in the people when it came to the effects on the society caused by Clinical research. For example: 86.80% of the population considered it true when they were asked if they thought Clinical Research benefitted the society.

References

[1]. A.R., C. (n.d.). Clinical trials: present and future in India. Retrieved February 2015, from Pharmainfo.net: http://www.pharmainfo.net

[2]. Bhatt, A. (2006). Winds of Change - Evolution of clinical drug trials in India. Pharma Times(38:), pp. 19-20.

[3]. Bhatt, A. S. (2004, Feb 26). Indian clinical research odyssey. Pharma Biz(Chronicle specials). Retrieved January 2015, from http://saffron.pharmabiz.com/article/detnews.asp?articleid=20742&sectionid=50

[4]. Bindra, S. K. (2010). Survey on perceptions of indian investigators on research ethics. Perceptives in Clinical Research, 1:, 94-7.

[5]. Das, N. (n.d.). Outsourcing clinical trials to India. Chillibreeze Solutions Pvt. Ltd. Retrieved February 2015, from http://www.chillibreeze.com

[6]. De, M. (2005). India, ideal destination for clinical trials. CurrSci, 89:597.

[7]. Fenn, C. W. (2001). The contemporary situation for the conduct of clinical trials in Asia. Int J Pharm Med(15:), 169-73.

[8]. Jayasheel, B. (2010). Issues regarding delay in regulatory approvals carrying out clinical trials in India. Regulatory Affairs Journal Pharma, 1-4.

[9]. Moin, D. (2013). Clinical trials and safety reporting under Schedule Y. Retrieved February 2015, from Pharmabiz: http://www.pharmabiz.com.

[10]. N., V. (2006, June 1). Conducting clinical trials in Asia. Retrieved February 2015, from http://www.actmagazine.com

[11]. Parikh RM, G. M. (2011;). Trend of clinical drug trials in type 2 DM over last decade. Percept Clin Res, 2:, 64-6.

[12]. Research and Markets. (2006). India: pharmaceutical and biotechnology opportunities. India: Pharmalicensing Ltd. Retrieved January 2015, from http://www.researchandmarkets.com

Works Cited

[1]. A.R., C. (n.d.). Clinical trials: present and future in India. Retrieved February 2015, from Pharmainfo.net: http://www.pharmainfo.net

[2]. Bhatt, A. (2006). Winds of Change - Evolution of clinical drug trials in India. Pharma Times(38:), pp. 19-20.

[3]. Bhatt, A. S. (2004, Feb 26). Indian clinical research odyssey. Pharma Biz(Chronicle specials). Retrieved January 2015, from http://saffron.pharmabiz.com/article/detnews.asp?articleid=20742&sectionid=50

[4]. Bindra, S. K. (2010). Survey on perceptions of indian investigators on research ethics. Perceptives in Clinical Research, 1:, 94-7.

[5]. Das, N. (n.d.). Outsourcing clinical trials to India. Chillibreeze Solutions Pvt. Ltd. Retrieved February 2015, from http://www.chillibreeze.com
[6]. De, M. (2005). India, ideal destination for clinical trials. CurrSci, 89:597.
[7]. Fenn, C. W. (2001). The contemporary situation for the conduct of clinical trials in Asia. Int J Pharm Med(15:), 169-73.
[8]. Jayasheel, B. (2010). Issues regarding delay in regulatory approvals carrying out clinical trials in India. Regulatory Affairs Journal Pharma, 1-4.
[9]. Moin, D. (2013). Clinical trials and safety reporting under Schedule Y. Retrieved February 2015, from Pharmabiz: http://www.pharmabiz.com.
[10]. N., V. (2006, June 1). Conducting clinical trials in Asia. Retrieved February 2015, from http://www.actmagazine.com
[11]. Parikh RM, G. M. (2011;). Trend of clinical drug trials in type 2 DM over last decade. Percept Clin Res, 2:, 64-6.
[12]. Research and Markets. (2006). India: pharmaceutical and biotechnology opportunities. India: Pharmalicensing Ltd. Retrieved January 2015, from http://www.researchandmarkets.com