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Research Article

PERCEPTION OF CLINICAL RESEARCH AMONG CLINICAL INVESTIGATORS IN SAUDI ARABIA

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ABSTRACT

Objective: Promoting clinical research is important, considering the shortage of clinical investigators and the increasing need for large number of multicenter studies. Participation of clinical investigators in research is crucial to achieve this goal. Saudi Arabian provinces have the infrastructure to promote the research activities. However, that is not the case, as the growth of the clinical industry is sluggish as compared with the other Middle East and North Africa region. The objective of this study was to explore attitudes of clinical investigators toward the conducting of clinical trials in Saudi Arabia and the barriers faced by them.

Methods: A questionnaire-based survey was administered to 100 clinical researchers from a different therapeutic background that has clinical research experience at least one or above. The survey was carried out in various hospitals from different province Saudi Arabia. It consisted of questions/statements on previous research experience, interests, and barriers. Responses were either yes/no answers or graded according to the five-point Likert scale.

Result: About 69.79% of the clinical research staff felt that long approval timeline from the Saudi Food Drug and Administration is the major barrier for conducting the clinical trials in Saudi Arabia. 85.41% of the responders said that lack of awareness among the research professionals and the general public is causing difficulties in the growth of the industry.

Conclusion: The majority of clinical investigators working at the therapeutic department of various academic hospitals were interested in conducting research. However, the lack of time, financial compensation, and encouragement were perceived as significant barriers.

Keywords: Clinical research, Attitude, Saudi Arabia, Barrier.

INTRODUCTION

According to the ICH-GCP E6, "good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the declaration of Helsinki, and that the clinical trial data are credible" [1]. The ICH-GCP has become the leading international guideline for the conduct of clinical trials all over the world. It has a significant impact on the globalization of industry-sponsored clinical research, since clinical trial data collected in one region is compliance with ICH-GCP and the same data can be used to file new drug applications in other regions as well. There is a persistent demand, in addition to a great need, to develop new medical treatments that are as effective and safe. Clinical trials are the mandatory bridge between the pre-clinical discovery of new medicinal products and their general uses.

In recent years, clinical research has now become a globalized phenomenon. Many of the pharmaceuticals companies are looking beyond USA and UK for conducting of clinical trials. Thus, there is a need for expanding the clinical research in developing countries, whose contribution to clinical research has remained low in proportion to their population.

Cardiovascular disease, diabetes, cancer and chronic respiratory illness, metabolic disorder, thalassemia, and sickle cell disease are widely prevalent in the Middle East and North Africa (MENA) region. Thus, in recent years there has been increased in conducting of clinical trials in MENA region [2].

Hospitals in Saudi Arabia have a good infrastructure with well-qualified physicians. Their healthcare system has been rapidly developing in the last few decades. This should increase the clinical trials in the Saudi Arabian region, but that is not the case. The gradual growth of clinical research in the region was started by performing observational studies, developed to conduct investigator-led clinical trials and then participation in renowned international multicenter trials.

According to the recent statics 2014, the number of ongoing clinical trials in Saudi Arabia is 313 (as per the clinicaltrial.gov) which are very lower as compared to number of studies conducting in Israel and Turkey [3].

Though Saudi Arabia has good infrastructure to support the research activities, but still it is unable to attract the sponsor for conducting the multicenter clinical research in the region. This can be probably due to multiple factors that may include inadequate knowledge of clinical research processes, lack of training and specialization in this field, lack of support from healthcare institutions/private industry, and governments leading to shortage of qualified clinical investigators.

Very limited or hardly any studies are carried on to understand the sluggish growth of the clinical research industry in the MENA region. This survey-based study will facilitate us to understand the major barrier in the growth of the industry.

The objective behind this survey based research study was to understand the perception of investigator for the conduction of clinical trials.

The primary objectives of the study are:

a. To understand the perception of investigators toward the clinical trials.
b. To identify the barrier faced by the clinical investigators for conducting clinical trials in their therapeutic areas.
c. To evaluated research experience and interest of clinical investigators working in the Therapeutic Department of various hospitals in Saudi Arabia.

METHODS

Study tools

A questionnaires based survey were followed for acquiring the information from the clinical researchers from the different therapeutic background, having more than 1 year of experiences in their therapeutic department. The use of questionnaires based methodology facilitates to acquire the objectives of this study without any bias. The questionnaires were designed in such a way that the maximum information is directly obtained from the medical professionals involved in the study.

The questionnaires designed for the study include the demographic data of the professionals and the barriers faced by the professional's i.e., ethical barriers, administrative barriers, and cultural barriers.

Study area

The survey was carried out in various hospitals from different provinces of Saudi Arabia.

All the prepared questionnaires for clinical research professionals contain closed-ended. The responses were recorded either yes/no answers or graded according to the five-point Likert scale.

Sampling method and size

Around 110 clinical research professional gave consent to be part of this survey-based study but only 96 gave their response. The questionnaires were prepared in English language. The various professionals participated in the survey were prior informed that the study is carried out, purely for academic purposes and full confidentiality of the data given by the participants will be maintained. The participants were asked to rate their knowledge. The respondents were even asked to register their names if they were willing to participate in conducting of ethical clinical trials in their department.

Study duration

A survey was carried out from March 2014 to September 2014. The survey was carried out in a very flexible manner, those who were unable to give their opinion during the face-to-face meeting on the paper; their opinion was recorded through phone and mail. Before initiation of the telephonic recorded of the survey, a copy of the questionnaires was mailed to them in order to get their consent for the participation.

Frequent reminder mails were sent to all the participants so that the survey was completed within the time limit.

Collection of data and analysis

The data acquired from the questionnaires based survey was statistical analysis through the help of Microsoft Office Excel. Charts, graphs, and table were used for interpretation of the acquired data from the survey form.

Ethics Committee (EC) approval

No personal information was asked from the participants thus need for EC approval is not required.

RESULT

Around 110 clinical researchers were asked to give their views but we received only 96 responses from the clinical investigators of Saudi Arabia.

Characteristics of investigators

As an introductory question, the clinical investigators were asked upon the demographic question, which includes age, sex, and knowledge about the clinical research field. More number of males than females participated in the studies this may be due to the law where it constraints the women to work in the male dominating society. The age of the participations was of the mid-age range, which shows that they were highly experienced and qualified in their therapeutic areas. When they were questioned on the certification in clinical research, the mixed response was received. Still there is need of education for most of the clinical Investigators in the clinical research field. The result is shown in Table 1 and Fig. 1.

Further, the questionnaires were divided into three sections in order to know the perspective of the clinical researchers toward the clinical research.

The three sections were an ethical barrier, research barrier, and cultural barrier (Figs. 2-4). The results for each section are explained further.

Ethical barrier

Ethics forms backbone of the clinical research. Institutional Review Board (IRB) and EC approval and Saudi Food Drug and Administration (SFDA) approval are mandatory to conduct clinical research. However, at the same time they can be a major hurdle in the smooth conduction of clinical trials because of the long approval timeline. In order to understand the role of IRB/EC and regulating agency, a question was asked to the professionals stating that whether these two regulating bodies are creating barrier in conduction of the clinical trials in MENA region. 69.79% of the clinical research staff felt that long approval timeline from the SFDA is the major barrier for conducting the clinical trials in Saudi Arabia. Surprisingly, 82.29% of the clinical research professionals said that hospitals in Saudi Arabia have an IRB/EC and also 67.70% said that the approval timeline is not long. These indicate toward the positive future of the clinical research industry in Saudi Arabian provinces.

Administrative barriers

Administrative plays an important role in smooth and proper conduct of the clinical trials. A question was asked in order to evaluate the components responsible for creating a barrier in the smooth conduction of clinical trials in the administrative part. The result received state that 53.12% and 59.37% of the responded felt that the shortage of human resource and lack of the hospital and institutional support are the major barriers in the conduction of the clinical trials. All Rhabdoid tumors, 62.6% of nurses and 30.8% of physicians thought that lack of encouragement were also an important factor ($p<0.001$ among the three groups). Other barriers stated by respondents included lack of training in research and presence of only one biostatistician in the department. These also stated that if proper education, support is provided to the clinical investigator than there are chances of growth of industry in the Saudi Arabian region.

The result also demonstrated that Saudi Arabian provinces have the scope of expanding the clinical research activities in their region. Most of the clinical research professionals feel that region has enough patient pool and good infrastructure. These eventually state that the region can support the demand of the research activities in the future.

Cultural barrier

The literacy rate in the Saudi Arabian region is increasing year after year. In spite of progressing literacy rate, advances in the infrastructure development in the region, the Arab population is unaware of the newer developments in the scientific field. This may be due to various factors. To understand whether the cultural background is creating a hindrance in the growth of the research activity, a question was put forward to the participants. 85.41% of the responders said that lack of awareness among the research professionals and the general public is causing difficulties in the growth of the industry. The other significant contributing factors are long vacations and holiday on a special occasion. Nearly, 76.04% and 62.50% of the responders gave their opinion that special occasion holidays and long vacation respectively are preventing the research activity.

Being a Muslim dominating country Saudi Arabia government declares long holidays during Ramadan and Hajj month.

From the result, it can be seen that cultural factors are one of the major barrier for the growth of the clinical research field in Saudi Arabia region.

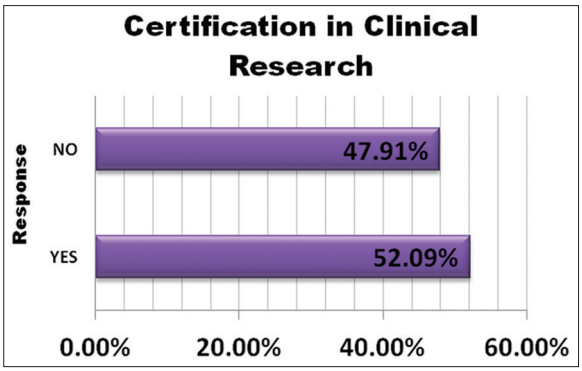

Fig. 1: Clinical investigators with certification in clinical research

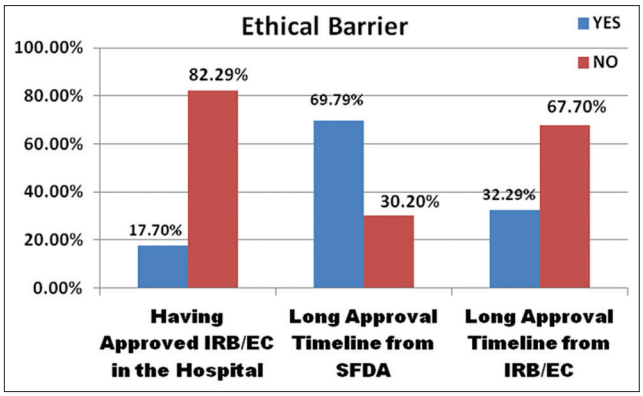

Fig. 2: Factors contributing as ethical barrier

DISCUSSION

This study evaluated the research experience, interest and barriers faced by the clinical researchers working in the Therapeutic Department of various hospitals in Saudi Arabia. From the demographic result, it was observed that most of the participants were in the average age of 44±9 which showed that they were experienced in their therapeutic area. From the survey it was observed that a very few of physician, nursing, and respiratory care staff had prior research experience while the majority of staff in these three disciplines showed high interest in participating in research in the future. In addition, these healthcare providers also indicated that they needed education on various research areas.

This survey was conducted in preparation for a departmental research course and aimed at identifying clinical researchers who were interested in clinical research and the research areas they would like to learn about.

During the survey, it was found a high interest in performing research among clinical therapeutic staff primarily hired to perform clinical work. This was likely, at least in part, due to the belief that it would enhance their future career. In a view, that research accomplishments and publications can be frequently used to gain promotion in the professional and shall improve academic status.

In this survey, significant number of clinical researchers alleged adequate knowledge in many research areas. Surprisingly, more than 50% of respondents reported adequate or more than adequate knowledge in many research skills. Around 52% of the respondents specified that they possess clinical research certification whereas the other 48% are not certified by the clinical research institute. This study survey did not specifically address the knowledge issue, but it was believe that in the current study clinical Investigators might have overestimated their ability to perform certain research activities and that their responses reflected their perceptions and attitudes about clinical research.

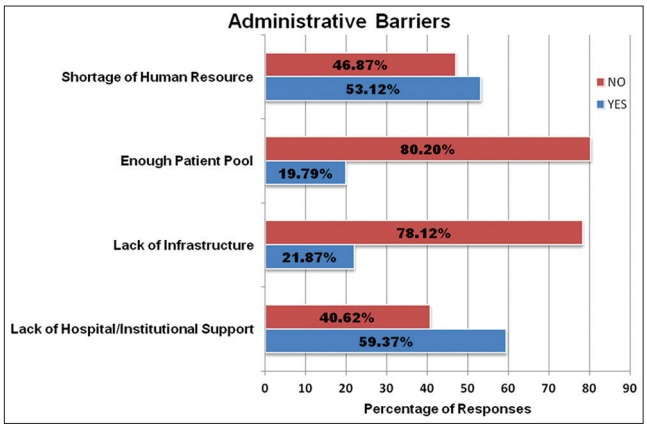

Fig. 3: Factors contributing as administrative barrier

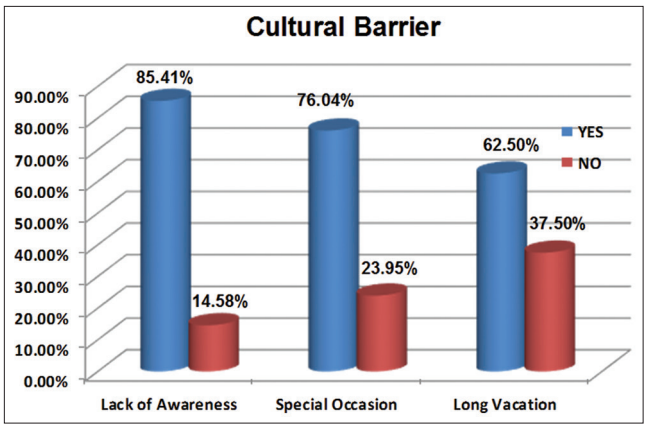

Fig. 4: Factors contributing as cultural barrier

Table 1: Demographic characteristic of investigators

Characters	
Age	44±9
No. of participants	Male=72; Female=24

Though the interest level was very high among the professional, the growth of the industry was sluggish. The obstruction in the growth of the clinical research industry in Saudi Arabia was studied with three factors ethical barrier, administrative barrier, and cultural barrier.

To facilitate participation of the clinical investigator in research, barriers should be identified and addressed. The result received from the survey was very surprising and even interesting.

Long approval timeline for the clinical study from IRB/EC and SFDA was found to be major obstacles in the clinical research activities. An average IR/EC required approximate 6 months in the approval of the clinical trials. SFDA required 180 days for approval of the international study, which is not approved by any of the international regulatory bodies, i.e. FDA, MHRA, etc. If the clinical trial is approved by any of the renowned international regulatory bodies, then SFDA takes 30 days for the approval. Thus, long approval timings had formed major obstacles in the growth. On the other hand, it was surprisingly to observe that Saudi Arabian region have well-established IRBs/ECs in their region. This point toward the bright future of clinical research in the region.

Promoting clinical research is important even in developed countries especially with the existence of worldwide shortage in clinical investigators and clinician scientists. When the participants were questioned on the administrative barrier, the same problem of

human resource shortage was observed thus making the expansion of researchers' pool more urgent in the Saudi Arabia too. Although 33.6% of the clinical investigator participated in the research, only 11.2% presented their research at national or international meetings, suggesting that the number of principal investigators was modest.

To solve the problem of clinical investigator shortage, western countries resorted to multifaceted approach. Research was promoted by the foundation of MD/PhD dual degrees, research fellowships, and various clinician-investigator programs and by the incorporation of research in specialty and subspecialty residency programs. Short and focused research courses can also boost research knowledge and experience. Sherman *et al.* found that pediatric residents who participated in a formal education process on the topic of informed consent in their residency education program positively affected residents' knowledge and attitudes about the processes and issues involving informed consent. In a controlled before-and-after study [4]. Löwe *et al.* investigated the effectiveness of a 1 year resident clinical research training program that included a weekly class in clinical research methods, completion of a research project and mentorship found that those who went through the training program had better methodological knowledge and that higher proportion of them were writing journal articles (87% vs. 36%) than those who did not [5].

From the survey, it was found that most of the investigators believed that lack of financial support and the closely linked lack of time were important factors that hindered participation in clinical research. Many institutions in Saudi Arabia had recently gained ground in organizing and supporting clinical research. Previously, research projects were the results of individual efforts. Moreover, recently many of the research had received additional support from King Abdulaziz City for Science and Technology (KACST) by providing research grants, statistical support and research coordination, thus eliminating many of the barriers that were present before.

The result from the survey also demonstrated that Saudi Arabia have potentials to be call as "hub for the clinical research field." The positive prospect of this study is that clinical investigators stated that they had enough patient pool for the participation in the clinical trials. In addition, the region also has an infrastructure that is capable to support the clinical trials in the future.

Saudi Arabian region is Muslim dominating country where most of the Arabs are followers of Islam. Ramadan and Hajj are the two most important festivals for the Islam followers. Thus, during this period government of Saudi Arabia declares long vacation. This has a direct effect on the research activities in the region. During the long vacation, the administrative activities come to a standstill. Thus, no work during the holiday time and research activities is stopped. Furthermore, another factors come into sight was the lack of awareness; this may be due to the fact that most of the people are unaware about the new emerging concept of clinical research.

To summarize the result obtained from the study, clinical professional are holding a positive attitude toward the research in the region. The major barrier faced by the professional are a lack of encouragement, clinical research knowledge, long approval timelines from regulatory authorities, lack of compensation, and many other as mentioned in this section.

The current study has several limitations. These are primarily related to the survey methodology, specifically sampling and measurement. Not all staff responded, which may have led to the overrepresentation of those who had strong opinions about clinical research. However, the relatively high response rate probably reduced this voluntary response bias. The staff knowledge that participation in the survey was voluntary and had no effect on their evaluation should have reduced socially desirable responses.

CONCLUSION

Clinical research is a globalized phenomenon where many of the pharmaceuticals companies are in need for expanding the clinical research in developing countries, whose contribution to clinical research has remains low in proportion to their population. Cardiovascular disease, diabetes, cancer and chronic respiratory illness, metabolic disorder, thalassemia and sickle cell disease are widely prevalent in the MENA region. Thus, in recent years there has been increased in conducting of clinical trials in MENA region. However, the growth is not as per the expectation. Saudi Arabia province has all the facilities to attract the sponsor but unable to do so. This study exploited the barrier faced by the clinical Investigators for conducting the clinical studies.

A survey based methodology was adopted in order to achieve the objective of the study. The participants were asked to fill the questionnaires in the face-to-face interaction. Those participants unable to give a response in personal, their response were recorded through means of email and telephone. The statistical analysis of the result was carried with the help of Microsoft excel 2007.

The result from the study found that the vast majority of clinical investigator from multiple disciplines working at the therapeutic department of various academic hospitals in Saudi Arabia were interested in conducting research and identified research areas that they need more education. These findings could result in targeted tutoring and training. Moreover, the lacks of time, of encouragement, and of financial compensation were perceived as significant barriers to participation in clinical research. Finding the appropriate incentives and addressing perceived barriers are crucial to the success and maintenance of any research program.

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