

## Original Research Article

# Obstacles in conducting clinical trials in the Saudi Arabia

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### ABSTRACT

**Background:** Conducting clinical research in accordance with the standards of regulatory authorities and within the guidelines of the good clinical practice (GCP) is a matter of concern. It has been noticed that some increment in the conduction of clinical trials outside USA and European countries in the last two decades. The main objective of this study is to identify the magnitude of some obstacles that affect the conduction of clinical trials in accordance with the GCP.

**Methods:** Developing questionnaire in accordance with the criteria of the GCP would make assessment on how to buildup infrastructure including policy and procedures of the research institution. Recommendation of the study is to perform this questionnaire every other year to assess the progress and development of the research institution.

**Conclusions:** To identify good clinical researchers, what sort of obstacle(s) regarding conducting clinical trials, and from these obstacles how to resolve it and build up infrastructure for the research institution and also to establish the strategic plan for the research institution.

**Keywords:** Clinical trial, Clinical research, Good clinical practice, Obstacles

### INTRODUCTION

Conduction of clinical trials become more popular in the developing countries under the regulation and instruction of regulatory authorities, this is to identify pharmacokinetic, pharmacodynamics and adverse drug reaction for an investigational drug.<sup>1</sup>

Pharmaceutical and medical companies provide clinical researchers with different set(s) of tools to support the essential component to conduct clinical research. The essential resources to form the infrastructure for conducting clinical trials workplaces are (manpower, recruitment process, support resources, material, library..), support staff (qualification, training, experience, workload, etc), time, financial support, patients (commitment, awareness, etc), communication (consultation, cooperation, informatics, etc), Research management and administration support.<sup>2</sup>

Clinical trials can be classed according to whether these trials are considered therapeutic or non-therapeutic trials. It can also be classified according to their objectives to interventional, prevention, observational, and diagnostic and screening trials. Our main concern in this study is those studies supported with pharmaceutical companies for investigational drugs. The main objectives of these trials are to optimize the quality use of investigational drugs, to support and promote the safe and ethical use of investigational drugs and to apply the principles of best good clinical practice. In the past these clinical trial are limited to the European Countries and North America, recently it has been obvious that we have in the Kingdom of Saudi Arabia (KSA) increasing year by another year. This increment in clinical trials needs to be in organized and deal with in compliance with the International Conference on Harmonization– Good Clinical Practice (GCP), and Clinical Trials Requirements Guidelines of the Saudi Food and Drug Authority (SFDA).<sup>3</sup>

Increasing the concept of clinical research among the community is a matter of concern. This matter may slowdown the process of registration where pharmaceutical industries are trying to increase the transparency of clinical trials among the community by promoting healthcare researchers to get convenient and comprehensive clinical trials information. Conduct clinical trials outside the USA and European countries will reduce the operation cost, and will give the opportunity for a large number of patients within a short period of time where the standards and regulations of GCP should be applied (clinical, salaries, rental).<sup>4</sup>

Thousands of clinical trials used to be conducted annually but the share Asia about 10% this number usually goes to East Asia, where the share of KSA is less than 0.5%.<sup>5</sup> In the past, conducting of these trials in the KSA usually as a relationship between pharmaceutical companies and the clinical researchers without rules and regulation until the SFDA intervene and give permission to create contract research organization (CRO) to work as a moderator between the clinical researchers and pharmaceutical companies in parallel with GCP guidelines. This is the case in Japan and South Korea where both countries started recently practicing clinical trials according to GCP standards.<sup>6,7</sup>

Several CROs were getting their recognition from the SFDA, provide clinical-study and clinical-trial support for investigational drugs and/or medical devices in compliance with GCP standards. The usual procedure that a CRO has a direct connection to an outsider pharmaceutical company where they need to reach a phase 3 or phase 4 (so far, in the KSA, it happened that we recorded only one case as phase 2 for a pre-existed drug). This CRO also has a link with one or more clinical researcher where they can recruit a good number of patients to participate in conducting a clinical trial. Usually, these clinical trials were conducted as a multicenter study, supported financially by the pharmaceutical company under a unified standard.

The impact of this study is to identify the obstacles that the clinical researchers are facing every day and also to be the essential bricks to build up the infrastructure of health research institution in the development countries. This will end up with vast increment in the share of conducting clinical trials in the developing countries. The authors have excellent backgrounds about the clinical trials, and they recognize the obstacles that stop some clinical researchers not to conduct clinical trials. Hence, we would like to know the magnitude of the available obstacles and if there are more obstacles, also, to know how potential are these obstacles that may stop clinical researchers. This information will give us a vision on how to overcome it, how to build up the infrastructure for a research institution and how to improve conducting of clinical trials in the future.

## ***Aim of the study***

### *Primary aim*

To know more about the magnitude and how potential are the obstacles of conducting clinical trials in KSA. Moreover, to know more obstacles if it has not mentioned in the questionnaire.

### *Secondary aim*

- Explore more information on how to conduct clinical trials in KSA.
- How to process new clinical trials in the future.
- The possibility to find a faster mechanism to process clinical trials.
- To have an idea about the active research institution and the most active clinical researchers and their attitude.
- To make a good control on conducting clinical trials by GCP standards.

## **METHODS**

### *Development of a questionnaire*

We had developed a questionnaire based on the author's experience in conducting clinical trials in KSA. Authors identify most of the obstacles yet, they would like to know more idea about how potential are these obstacles may stop clinical researchers to conduct clinical trials.

A questionnaire has been developed to have more ideas about the obstacles concerning:

1. Institution; availability of the infrastructure and the operation procedure.
2. IRB; availability the policy and procedure and the length of procedure for approval.
3. Availability of research specialists; regarding research coordinator, technician, nurses, biostatistician and other.
4. Clinical researchers; training and experience, time, incentive and others.
5. Study subjects; their commitment, their knowledge about research culture and the conception research, difficulty to recruit patients and insurance.
6. Financial support; availability and smoothness of process.
7. Logistics; availability and smoothness of process.
8. Communication; availability of cooperation between clinical research, research administration and other collaboration.
9. Research administration; bureaucracy to get approval and legality issues.
10. Publication; skills in writing and editing and the experience in publication.

The questionnaire started by what we meant by clinical researchers and targeted only clinical researchers. It allows clinical researchers to express what are the main obstacles and allow them to give digital number to express their agreement or disagreement each of the obstacles that may stop them to show the magnitude and how potential of each obstacle.

## **DISCUSSION**

Conducting clinical research for investigational drugs is necessary to establish the pharmacodynamic, pharmacokinetic and side effect of the new medication. The main principle of GCP guideline is that the researchers should be in compliance with the GCP standards to assure the rights, safety and well-being of trial subjects are protected where the involvement of participation of human subjects. From another point, the advantages of these researches is to establish the safety and compare the effectiveness of similar products.

To evaluate and identify strategies for enhancing the effectiveness and efficiency of clinical trials, a public workshop to discuss their clinical trial successes and failures, the challenges they face in conducting clinical research, and strategies for improving the efficiency of clinical trials while maintaining the highest standards for the data generated. Efforts spent to discover the main challenges and boundaries against processing of clinical research and to generate ideas for improving the clinical research, and biomedical research.<sup>9,10</sup> The first step to build the infrastructure is to find out what are the obstacles and what are the magnitude of each obstacle.<sup>11</sup>

### ***Institution; availability of the infrastructure and the operation procedure***

This is the concern of most of research institution that they do not have policies or mechanisms and how to build up the infrastructure. Another matter is how to improve these policies and procedure (if there is any).<sup>12</sup> Most of the clinical trials used to be conducted in a tertiary care hospital where the availability of researches, research clinic and most importantly the availability of patients' recruitment procedures.

### ***IRB; availability the policy and procedure and the length of procedure for approval***

Most of the clinical researchers' concern is the lengthy procedures for most of the IRB committees. Although most their procedures deal with checklist, with "prompt reporting", hence the time consume to have the IRB approval is still under the expectation of pharmaceutical companies and some clinical researchers. GCP standards stated that IRB should review the research proposal in "a reasonable time" with no limited time for the length of the procedure for approval. Therefore, there should be a time limit to give a decision from the IRB so that the

investigators and pharmaceutical companies get a power of encouragement to do their research.

### ***Availability of research specialists; regarding research coordinator, technician, nurses, biostatistician and other***

With the availability of courses, workshop and spreading knowledge, this will strengthen the skills and knowledge for high professional research specialists to cover for high the demand. The availability of these specialist will facilitate the work and gives the opportunity to the clinical researchers to produce with highest quality and quantity. It has been noticed that the department with more than one clinical research support produces more research outcome, represented by number of publication and number of research conducting. This point could be applied for the clinical and biomedical research.

### ***Clinical researchers; training and experience and practice, time, incentive and others***

The real investment is to perform training and get experience for the clinical researchers. Investigator, should be encouraged to conduct training session, this will encourage collaboration, support the bridge builders, and will brainstorm and stimulate new ideas.<sup>13</sup> Future strategies for the clinical researcher by giving the opportunity for clinical training will support the idea for clinical research and development. Obviously this will give the chance increase the number of research funded and the support for the development.<sup>14</sup>

### ***Study subjects; their commitment, their knowledge about research culture and the conception research, difficulty to recruit patients and insurance***

Recruitment of research subjects specifically patients, could be the most difficult part of research methodology. The concept of clinical research in the KSA is very limited. Financial motivation is not a big deal for most of the patients, the concept of "participating in clinical research means a guinea pig" is still valid, and what is the direct medical benefit which is still not known. Up to date there is no company handing research insurance in the KSA, most (if not all) the tertiary care hospital in the KSA are under a government sector and it is free of charge.<sup>15</sup> Therefore, most (if it is not all) the patients undergo for the clinical trials are treating in a governmental hospital and no need to get medical insurance.

### ***Financial support; availability and smoothness of process***

The main obstacle for clinical research is how to get sponsor to provide a financial support. Financial support elements for a clinical deserve are (a) incentives for investigators and other research team, consultations (if any), (b) equipment and supplies, and (c) others (as

specific items) such as meeting, travelling, accommodation and others. The research protocol gives more detail about the budget and must be stated in writing. The process of financial support usually depends on the investigators and the impact and the significant of the research study.

#### ***Logistics; availability and smoothness of process.***

Logistics was a struggle part for the researchers, but with the available of the new technology and communication, access to logistics services including purchasing. Storing and delivering become very easy. Delivery of investigational drug during clinical trial, should go through the regulatory authorities. The process of logistics services depends on the research administration, sponsor and their interaction with the regulatory authorities.

#### ***Communication; availability of cooperation between clinical research, research administration and other collaboration***

Communication always between the investigator and (sponsor, IRB, research administration and others). Communication would be an easy part if there is a research project manager or a monitor (assigned by the sponsor). That would facilities reporting system, phone calls, expediting and make all communication to easy.

#### ***Research administration; bureaucracy to get approval and legality issues***

The main charge for research administration is how to ensure that the funds provided for research are paid and well controlled according to the policies of the research institution. Policy bureaucratization and conflict of interest are the main elements of destruction for any research organization. Conflict of interest will never be controlled completely yet; this action will make restriction which will lead to limitation in conducting research.<sup>16</sup>

#### ***Publication; skills in writing and editing and the experience in publication. With the new technology and communication***

One the main challenge for the investigators is the workflow for processing for the publication. The KSA researchers as non-native English speakers which make the process of writing is an obstacle. Another deficiently is the lack of connection which reflect in a potential obstacle in a manuscript submission.<sup>17,18</sup>

It is the responsibility of the research administration to control all the above obstacles by preparing the policies and procedure accordingly. Tactic planning to identify the impact and magnitude of any of the above obstacle give the right direction to make the road map and strategic plan for the research institution.

More obstacles and several barriers, which may stop or slow down the work process of conducting clinical research should be identified. Another problem that the authors can imagine is the increase number of the investigator. Although if the investigator number increased will strengthen the communication and will get more financial grants, hence, authors can imagine that in clinical research whenever the work team become bigger, the trouble become increased.

#### ***Recommendations***

It is recommended to perform this questionnaire to at least 50% of the clinical researchers in your institution to be the standard background, then to be performed every other year to assess the progress and improvement of the research institution. It is also possible to build up the infrastructure of a research institute including policy and procedures. Performing this questionnaire will give a hint to assess the magnitude of each obstacle, and how to establish a strategic plan for the research institution. Moreover, the following achievements could be obtained from the same questionnaire:

- Creating enthusiastic research environment will improve the quality and quantity of clinical research.
- Performing multicenter studies will increase the communication between clinical research which will increase the quality of clinical research.
- Increase the number of supporting staff (as research associate, or research coordinator etc.), this will increase the research capacity from quality and quantity view.

#### **CONCLUSION**

As a conclusion, this questionnaire will make difference for most of the research institution in how to build up the infrastructure and strategic plan with the following impacts:

1. Identify the enthusiastic, new and good clinical researchers.
2. Identify obstacle(s) regarding conducting clinical trials.
3. Build up infrastructure with clinical research capacity.
4. Establish a roadmap for the new clinical research.

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