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Overview of clinical research logistics in Saudi Arabia; Barriers and difficulties facing researchers-clinical researchers' perception

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Abstract
Introduction: In reputable educational institutions, clinical research is one of educational process compartments. Internationally, research affects the ranking of universities. Research is one of main performance indicators considered in methodology of international ranking entities such as Times Higher Education World University Rankings (9).
The objective of this research is to determine the barriers and obstacles facing clinical research conducted in Saudi Arabia. We aimed to highlight the weakness points as well as the areas to improve during clinical research cycle, hence solutions could be made to boost the growth of research productivity within the kingdom.
Methodology*:* A survey was used to measure to identify the researchers' perspectives, measure their satisfaction with the clinical research aspects and pay attention to the barriers and difficulties they meet during their research work within different departments of well-known academic institution in Riyadh.
Results: The total of 192 researchers from different departments and variable career levels shared their perspectives about research current situation within the medical city and what might be the barriers of increasing the research productivity.
Conclusion*:* Clinical researchers showed high interest in conducting clinical researches and welcome working in clinical trials. As academic institution, it motivates the research conduct by applying a rewarding system for the academic staff. However, research team members could be included in a recognition system to motivate them to increase their productivity. Mostly, time is the main barrier hinders the research conduct and causes lots of delayed deliverables. Actions can be taken to improve the processes required to conduct the clinical research and reduce the time consumed in preparation for the initiation of the research, whereas time is the key player in the research production: time for getting IRB approval as well as time taken for contracting.
It is recommended to build specialized units for clinical research and support the existing research entities logistically and financially to enhance the progress of clinical research and growth of research outputs. Awareness should be raised by conducting workshops and lectures to enlighten the researchers about ethical requirements, current and updated SOPs.

Keywords: barriers, difficulties, obstacles, clinical research, clinical trials, king Saud university medical city, Riyadh, Saudi Arabia

Introduction
Nowadays, a research became an integral part of educational process and one of obligatory syllabi in medical colleges especially for the highly reputed universities. Clinical research is one of the active branches of research. Scientifically, clinical research is a systematic investigation including human subjects to gain scientific knowledge, test scientific hypothesis or understand health condition or disease [1, 2].
However, clinical trial is a scientific investigation involving human subjects, in which the human subjects are assigned prospectively to an intervention to test its effect, safety or to acquire knowledge about its pharmacological metabolism [3].
Saudi Government focused on the scientific research in its latest strategic plan; "Vision 2030". The modern vision was built to increase the international competitiveness of Saudi Arabia through diversifying the economic resources and adding new resources to the petroleum and oil mining. Vision 2030 aims to include five Saudi universities among the top 200 worldwide. Thus, it was recommended to paying more attention to scientific research and dedicating the country resources and money for the research purposes [4].
Kingdom of Saudi Arabia with its ambitious strategy and strong fund has promising future in scientific research. In the Nature Publishing Index (NPI) evaluation of high-quality research output, KSA was not listed among the highest countries in research output but mentioned as one of the five spotlighted countries to-watch in research matter [5].
According to Nature Index, Saudi Arabia took the 39th place in 2012 while in 2015, it rose to 31st place. The leading Saudi institutes achieved this progress -according to their high quality-research output- were: - King Abdullah University of Science and Technology (KAUST), King Abdulaziz University (KAU), King Saud University (KSU), King Abdulaziz City for Science and Technology (KACST); and King Faisal Specialist Hospital & Research Centre (KFSH&RC) [6].
During last decade (January 2007 to January 2017), 448 clinical trials had been registered in Saudi Arabia on Clinical trials.gov, [7]. Considering the Saudi large budget with very large healthcare expenditure and the population above 33 million, the number of registered clinical trials is lame and considerably low compared with other Middle Eastern

countries like Egypt and Israel? Previous study recommends promotion to perform more clinical trials and raising the awareness of clinical investigators about the importance of clinical trials reporting [8].

The investigators being asked to answer the survey during this study are working in King Saud University; the biggest and oldest university in Saudi Arabia and one of the most reputable universities in the Middle East.

According to Times Higher Education World University Rankings, King Saud University is in the 501–600 th rank of World University Rankings 2018 and the 59 th in Asia University Rankings 2018 [9]. In Times Higher Education University Rankings, the judgment is based on 5 fundamental performance indicators, research is one of them. It assesses the research output, income and reputation for each university [10].

In this research, we aimed to investigate the confounding factors contribute in hindering the progress and growth of clinical research industry in one of the biggest countries in the Middle East. Very limited studies have been done to investigate the barriers and difficulties that clinical researcher has to deal with during the conduct of the clinical research in Kingdom of Saudi Arabia.

Study setting

King Saud University Medical City (KSUMC), Riyadh, Saudi Arabia. King Saud Medical City (KSUMC) is a tertiary care academic medical center with decades of experience in multi-facility and multi-disciplinary administration. From medical point of view, KSUMC comprises of 3 major hospitals: King Khalid University Hospital (KAUH) and King Abdulaziz University Hospital (KAUH) and Dental Hospital; and research centers: College of Medicine Research Center (CMRC), several research centers and research chairs [11].

Objective

The objective of this research is to

1. Evaluate the boundaries, difficulties and barriers facing clinical research from investigators' perspective.
2. Highlight the weakness points and areas to improve during clinical research lifecycle
3. Hence, solutions and recommendations could be made to boost the growth of research productivity within Saudi Arabia.

Targeted Population

The targeted population are investigators; research staff have an experience for at least 1 year in clinical research work. Moreover, Academic staff with experience in clinical research work are being targeted. They have to agree to answer the survey, express their opinions and share their perspectives.

Methodology

A self-developed survey was created based on the author's observations and the discussion with colleagues who are working in the clinical research field about the possible barriers and challenges facing them during their work on clinical research.

The questions are built to identify to produce a knowledge about 2 main topics:

A. Human factors

- Clinical research experience of the respondents.
- Motivation and enthusiasm to continue working in the clinical research field.

B. Work-environment factors

- Administrative authorizations required: IRB, contracting, other administrative processes
- Application and awareness of Good Clinical Practice ethics.
- Clinical research conduct: human subjects' recruitment and access to medical records.
- Services, resources and support: research clinics, statistics, scientific writing and publication process.

Survey development

- **Survey Reliability:** The reliability of the developed survey was calculated. The Cronbach's alpha score is 0.967 for overall items which reflected excellent reliability and internal consistency of the items within the survey. The reliability ranges from 0.96 to 0.97.
- **Survey structure:** The survey was divided into four parts: 1) Respondent's personal data; including name, department, job title, highest educational level, specialty & sub-specialty; and contact information. 2) Respondent's interest in continuing to do clinical research future. 3) Part 3 was measuring the respondent's experience in research generally and spotting the activity of respondent's department\ unit in research work. 4) The last part was constructed to detect the respondent's perspective regarding each phase of the clinical research cycle.
  - **Questions Types:** All questions of the survey are close-ended. The respondents are allowed to add their comments on specific questions related to the clinical research lifecycle within their institution. Dichotomous and multiple choice questions were used to measure respondents' experience, their preparedness to participate\ continue in clinical research work and their preferences. A Likert scale of 5 levels was used to measure the respondents' satisfaction. Likert scale is a rating scale named after its creator. It serves the purpose of measuring peoples' perspectives and opinions about a specific topic [12].
- **Survey distribution:** The survey has been submitted online; and the link has been sent randomly to KSU staff, distributed through emails to researchers, academic staff, research coordinators and research assistants along with invitation to agree, answer the questions and share their experiences. An internal program which is embedded in the institution system to facilitate the communication among the institution's staff, had been used to distribute the survey throughout medical city different departments.
- **Data Management and Statistical Analysis:** The responses were collected through the surveying web, tested for eligibility and filtered.

The total of 196 responses were received during a period of 6 months. After data management and exclusion of invalid responses, the remaining valid responses are 192.

- **Statistics:** Statistical software: Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 22 software (SPSS Inc., Chicago, IL, USA) which was used for statistical analysis.

Statistical Method

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 22.0 software (SPSS Inc., Chicago, IL, USA) which was used for statistical analysis.

We calculated the frequencies and percentages for all nominal variables and mean ± SD (stander deviation) for numerical variables (total score of some variables).

We used Fisher's exact test to compare between different opinions of Q2: the interest in participating in clinical trials in future and Q6: the experience of working in clinical trials.

Also, we calculated Pearson's correlation coefficient to find the relationship between different variables.

We considered there was a statistically significant difference when P-value less than 0.05(P-value < 0.05).

Ethical consideration

No personal or private information were required nor included in the analysis, names and personal identifiers were concealed and coded during analysis. Only the participants' qualifications satisfaction and their perspective are needed. So we believe no ethical approval is required.

Results and findings

A total of 196 responses were received, after data management and exclusion of invalid responses, the remaining are 192 responses. So, (97.96%) responded and answered the questions related to clinical research and clinical trials.

Fisher's exact test has been used to estimate the statistical significance. There is a significant difference among the results since P-value < 0.05 (P = 0.024).

A. Respondents information

The most responses are from clinical department of the medical city (59.37 %), academic departments (19.79%) and research centers and research chairs of KSUMC (7.81%).

Regarding the educational levels, (19.79 %) of respondents were PhD holders, (20.31%) Masters holders, (15.1%) had fellowship and (5.73%) are board certified (Canadian, American and Arab Board), while (4.17 %) have both fellowship and board. (20.83%) of them hold bachelor degree in their specialties.

B. Respondents' career levels & experience

Figure 1 shows the categorization of participants according to their professional roles and career levels. In managerial positions: Chairmen represented (7%) of participants, Unit heads (12%) and principal investigators (11.3%). In executive positions (working in the core of research conduct): investigators (15.5%), consultants and researchers (21.10%), consultants (6.3%), CRAs (3.5%) CRCs were (5.6%) and research assistants (17.6%). (Fig 1)

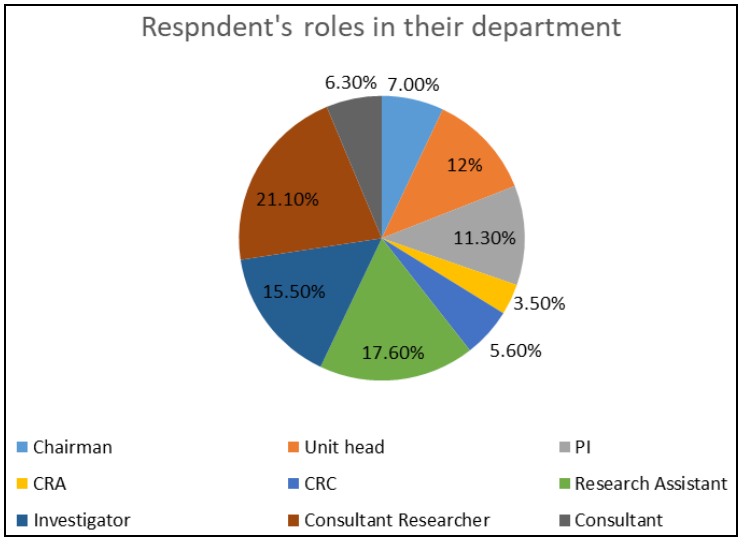

Fig 1: Respondents' Roles within Their Institutions.

- Out of 166 who responded to question asked about their past experience in clinical trials, 44.6 % of respondents had not participated in clinical trials before while 55.4 % did.
- We investigated the respondents' desired field of research in future. Among 4 types of research, the epidemiological retrospective studies got the most responses by (40.1%) followed by Prospective observational clinical trials (37 %), Prospective interventional clinical researches by (31.8%) and Translational research (19.8 %).

C. Willing to participate in clinical trials in future

(92.9%) of valid responses showed respondents' willingness to take part in clinical trials in future while (7.1%) did not want to participate in clinical trials.

D. (97.9%) of respondents who are experienced in conducting clinical trials are interested to continue doing clinical trials. However, 90% (63) of respondents who are non-

experienced in clinical trials showed eagerness to take part in clinical trials in future.

Table 1: shows the cross tabulation between the responses on past experience in clinical trials and those on future willingness to conduct clinical retrials.

Table 1: Cross-tabulation between past experience in doing clinical trials and future interest in taking part in Clinical Trials in future.

			Q2-Interest in Clinical Trials Participation (Future)		Total
			No	Yes	
Q6-Did you participate in CTs before?	No	Count	7	63	70
		% within Q6-Did you participate in CTs before?	10.0%	90.0%	100.0%
	Yes	Count	2	85	87
		% within Q6-Did you participate in CTs before?	2.3%	97.7%	100.0%
Total		Count	9	148	157
		% within Q6-Did you participate in CTs before?	5.7%	94.3%	100.0%

E. Research role the respondent will fit in

Candidates had been given the freedom to choose the research role they think they will fit in perfectly. (30.7%) chose to do investigator's role, (22.9%) clinical research associates (CRA), (14.1%) research assistants, (9.9%) clinical research coordinators (CRC) and (1.0%) research nurse.

Researchers' perspective

Our study sought to measure the candidates' evaluation on overall clinical research stages starting from administrative authorizations, ethical approval, logistical facilities and availability of required resources for clinical research conduction. Moreover, they were encouraged to add their comments on each assessment in order to create a comprehensive view of what is really happening during the clinical research within their healthcare institution.

In evaluation of the difficulty of IRB approval, out of 115 responses, reasonable choice was mostly responded (35.7 %), followed by moderately difficult (33.9 %), difficult to extremely difficult (6.1% and 1.7% respectively) and very easy (5.2 %). The remaining (17.4%) were non-response.

Time for getting IRB response is moderately correlated with difficulty of IRB approval (0.6) p-value <0.0001. (26.3 %) assessed time of IRB as slightly longer than scheduled, within the timeframe (25.4%), moderately long (21.9 %), too long (7 %), and quick (1.8 %).

When asking for assessment of current process of contracting in case of dealing with external research sites, variable responses has been received from 115 respondents (59.9%) of total responses. Out of 115 responses, their assessments were (27 %) difficult, (7%) extremely difficult, (9.6%) reasonable, (28.7 %) moderate and (0.9%) very easy. (27%) is non-response percentage. Furthermore, most responses found the time of contracting moderately to slightly longer than scheduled (27.8% and 18.3% respectively), within the timeframe (13%), too long (10.4%) and quick (1.7%). Contacting stage is highly correlated to time of contracting (0.824) (P-value is highly significant p < 0.0001).

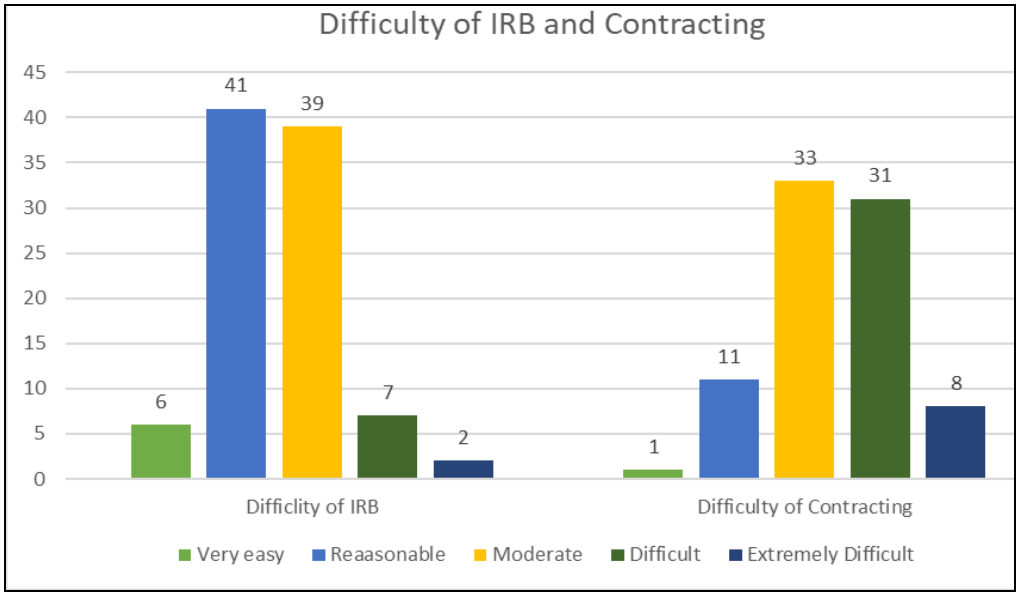

Fig 2: Difficulty IRB and contracting processes.

Total of 86 responses has been received on assessment of investigators' career path within the institution. Among 5 satisfaction levels, satisfaction was chosen the most (32.6 %), non-satisfaction (29.1%), moderate satisfaction (20.9%), slight satisfaction (15.1%) then complete satisfaction (2.3 %). See figure 3.

We found 40.1% of respondents shared their perspectives on adherence to GCP within King Saud University. The satisfaction rate was (11.7%) complete and (31.2%) satisfied. (20.8%) were moderately satisfied. Whereas (14.3%) slight satisfied and (22, 1%) not satisfied.

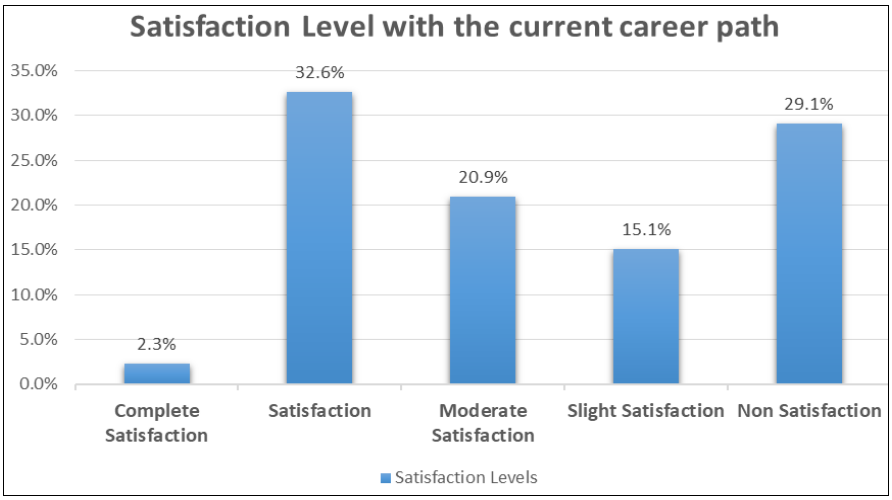

Fig 3: Respondents' Satisfaction with Career Path for Investigators

Total 87 responded to questions about the easiness of administrative authorizations and access to patients' medical records. For assessments of administrative authorizations, the choice which has been responded the most was non-satisfaction (29.9%). (13.8%) of 87 are slightly satisfied, (21.8%) moderately satisfied, (26.4%) satisfied and (8%) completely satisfied. See figure 4.

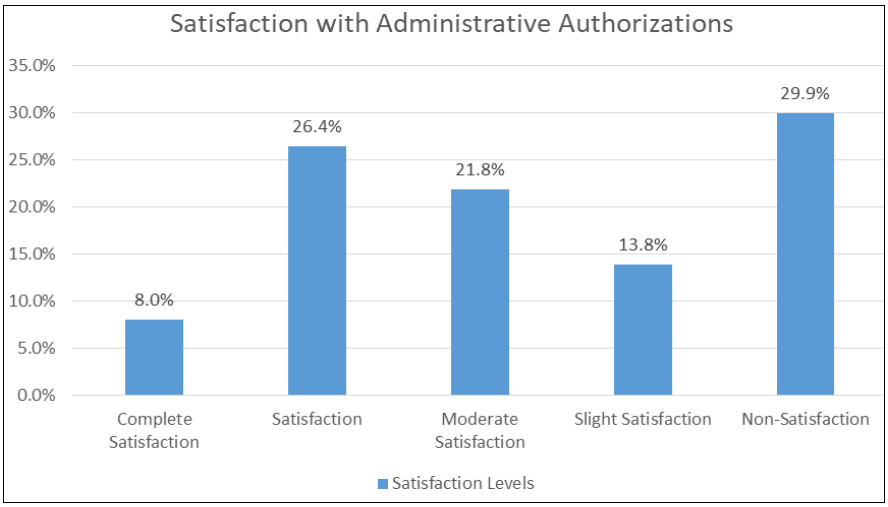

Fig 4: Respondents' Satisfaction with Administrative Authorizations within the Institution.

For access to medical records, (26.4%) were not satisfied, (13.8%) slightly satisfied, (24.1%) moderately satisfied, (26.4%) satisfied and (9.2%) completely satisfied.

Out of 86 responses to question about research clinics, (50%) not satisfied, (18.6%) and (11.6%) showed moderate and slight satisfaction; and overall satisfaction percentage of (19.8%). few responses added comments stating that clinics dedicated for research are unreachable as they are few compared to the large number of clinical researchers.

For the part assessing the statistics, 86 responded, majority of them are not satisfied (51.2%). The overall satisfaction is (23.3%) -satisfied and completely satisfied- while (16.3%) and (9.3%) have moderate and slight satisfaction respectively.

In assessing publication process, 81 researchers responded. (42%) expressed non-satisfaction while (20.9%) showed overall satisfaction, (24.7%) and (12.3%) moderate and slight satisfaction respectively.

Satisfaction on medical and scientific writing: A total of 79 responses were received. Of the total responses on medical writing, (49.4%) expressed non-satisfaction, (10.1%) and (22.8%) slight and moderate satisfaction respectively while (30.9%) showed satisfaction and (3.8%) complete satisfaction.

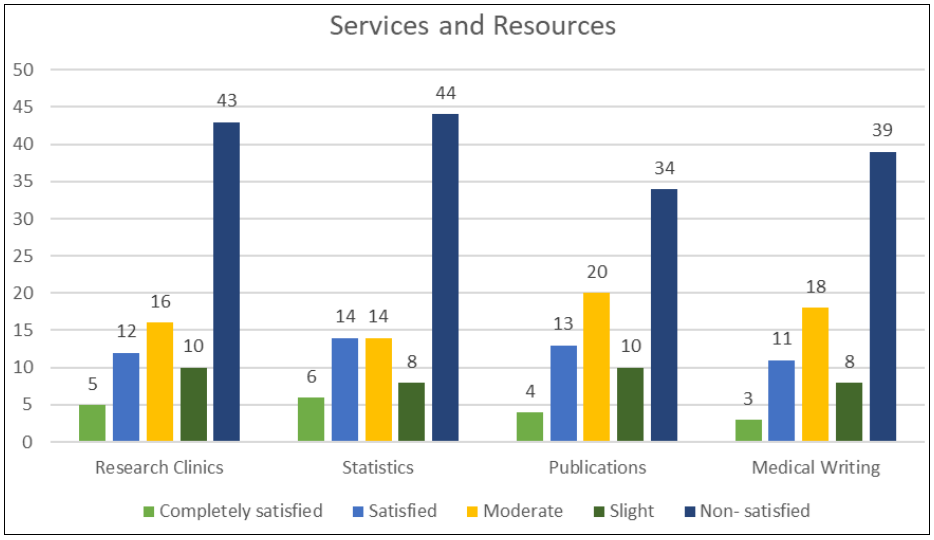

Fig 5: Satisfaction on Services and Resources of Clinical Research

Table 2: The Researchers' Perspective on Institutional Factors

Researchers Perspective				
Factor	**Positive (%)**	**Moderate (%)**	**Negative (%)**	**The Major Attitude**
IRB	40.9	33.9	7.8	Positive
Time of IRB response	27.2	26.3	28.9	Negative
Contracting	10.5	28.7	34	Negative
Contracting Time	14.7	18.3	38.2	Negative
Career path	34.9	20.9	44.2	Negative
Adherence to GCP in the institution	42.9	20,8	36.4	Positive
Administrative Authorizations	34.4	21.8	43.7	Negative
Access to medical records	35.6	24.1	40.2	Negative
Research Clinics	19.8	18.6	61.6	Negative
Statistics	23.3	16.3	60.5	Negative
Scientific Writing	17.7	22.8	59.5	Negative
Publication	20.9	24.7	54.3	Negative

Discussion

This study is mainly investigating definite factors that may hinder the growth of clinical research industry and to what extent they can affect the development of Saudi Arabia in clinical research.

Study sample are selected as active members in research from different sections and departments across King Saud University Medical City which is well-recognized and highly-reputed medical city which is known for its international ranking and productivity in research. The data was collected from diverse career levels: Chairmen, investigators, research coordinators, research assistants and consultants to have a comprehensive, detailed knowledge about the research within the institution.

Human resources capabilities and Interests

This study evaluated the qualifications, clinical research experience, future research interest of the respondents and their contentment with various processes across the clinical research lifecycle.

It was found that the respondents have proper qualifications to perform their jobs as they have high scientific degrees; PhD and Master holders, have fellowship and board certifications. 44.6% have previous experience in performing clinical trials.

When investigating about the desirable field of research, epidemiological retrospective studies was on the top, because they are easy, quick, having minimum risks and easy to write and publish. Second was prospective observational clinical trials followed by interventional clinical trials then translational research.

During this survey, we found a high interest in taking part in clinical trials among both groups: those who have previously worked in clinical trials and those who did not. This positive attitude towards clinical trials showing the attractiveness of this type of research industry probably due to its reputation as high income industry. Moreover, working in clinical trials is a big asset in researcher's resume and gives the researcher priority over other delegates [13].

Human resources are the backbone for any clinical research. This research investigated the most desired research role for each respondent, luckily, all research roles found to be attractive and could be fulfilled; except research nurse. It was the least available role. In fact, there is a shortage in nurses internationally. Saudi hospitals suffer an increased shortage in nurses due to the high demand on nursing in therapeutic and clinical settings of healthcare organizations [14].

Ethical approvals

As known, ethical approval is crucial for any clinical research to assure the safety and well-being of human subjects. Moreover, handling the IRB submission and amendments is a great step for researchers as well as clinical research organizations (CROs). Through our study, most of respondents feel are satisfied with IRB support. Some felt kind of difficulty in handling IRB submission and think of it as a burden in their way to finish their research. Furthermore, most of them think of the time taken by IRB to come to a decision as relatively longer than expected.

Logistics of the clinical research

For logistics, the contracting procedure time–when applicable-seemed to be obstacles as it takes longer than expected causing the delay in the path clinical research especially in

case of clinical trials. Whilst, contracting procedure is relatively average. Researchers also think administrative authorizations required during their work; are not as high as expected but in lesser extent than the contracting.

For most of researchers, scientific writing and publication are challenging steps. Publication is the destination that researcher looking for to document his/her work. During this survey, most of researchers saw publication as an obstacle. On the other hands, scientific writing is found to be a problem for the most of researchers. They are seeing writing in English difficult because it is not their native language. Actually, scientific writing and publication process require time and training to ease research production [15].

Services

Services like access to medical records and statistics did not reach an acceptable satisfaction level –barely reached 35.6% and 23.3% respectively- indicating that they require improvements. Furthermore, majority of researchers showed dissatisfaction on the availability and use of research clinics.

Motivations

Presence of a rewarding system for researchers and investigators motivates them to accomplish more research output. Some of respondents were satisfied with the present career path in their institutions while others were not. In fact, KSU as an academic institution, encourages its academic staff to produce researches in order to get promoted to higher academic ranking. However, research team members –the research workforce- could be included in a recognition system to motivate them to increase their productivity.

GCP adherence

The received responses on adherence to GCP ethics and certification were lower than expected. This probably was referred either to the lack of GCP knowledge or to the non-adherence to GCP among the non-responding delegates. Since GCP certification is a mandated by clinical research organizations (CROs), so researchers who had worked on clinical trials sponsored by private CROs are mandated to be GCP certified; and they will by guided through the steps of certification.

Conclusion

This study aimed to investigate the obstacles and barriers that hinder the development of clinical research in Saudi Arabia, by evaluation of several institutional intrinsic factors and determining logistical difficulties the researchers face during their work.

It was found that the delegates that perform clinical research have proper qualifications and have positive attitude towards clinical research, and clinical trials. Although, they may require training and support during getting ethical approval; and support on administrative authorizations. King Saud University does not seem have problem in human resources conducting research except for the nurses. Actually, the recommendations have been raised to assign clinical nurses especially to undertake the research in clinical research setting [16].

As known, ethical approval is crucial for any clinical research to assure the safety and well-being of human subjects. Obviously, the institutional review board of King Saud University provides the support for clinical researchers and responds to their queries; guiding them through the submission, clarifying the obscure issues and sharing the IRB policy and procedure on the institution website making it available for whoever needs. However, each institution may conduct regular lectures and workshops to raise the awareness regarding IRB submission and requirements. This will be useful especially for beginners and recently employed researchers.

Abiding to the research's schedule is very important to meet the timelines of each research project and that was an issue for the researchers. Thus, length of IRB procedure should be determined upfront; determining minimum and maximum duration to come to a decision regarding the submitted research project [17].

More attention should be paid for GCP knowledge and certification. It is preferred to invite the clinical researchers and their teams to attend in-class workshops about GCP, in which real-life scenarios are being presented and discussed. As, the theoretical knowledge of GCP is not sufficient, hence the practice of GCP in real life is more complicated [18].

Furthermore, contracting needs to be quicker and smoother stage. This could be enhanced by establishing policies for contracting and designing checklists to be checked for the contracts. The assigned individuals to finalize the contracts should have the least legal knowledge to do this task and be trained on the institutional policies.

Whereas, time is the key player in the research production; time for getting IRB approval as well as time taken for contracting. Mostly time it is the main barriers hinders the research progress and causes lots of delayed deliverables. Fund shortage and absence of clear policies, lack of communication and miscommunication between different departments come afterward.

In Saudi Arabia, to enhance conducting clinical research, it is recommended to provide the logistical support, conduct more educating lectures, make resources available for the researchers and their teams; and support the services –statistics-enhance the skills of scientific writing and provide the help in publication to support the researchers and investigators. We recommend to develop a recognition system to motivate the research team members –workforce of the research- to keep them motivated and increase their productivity. Building specialized units for clinical research to support the existing research entities logistically and financially and to enhance the progress of clinical research and growth of research outputs would be a great push to the research industry. Awareness should be raised by conducting workshops and lectures to enlighten the researchers about ethical requirements, current and updated SOPs.

Study limitations

Although the research has met its objectives, there were some unevitable limitations. First, gender and age of the delegates and how they can affect the research growth have not been investigated in this research. Second, we did not investigate the difficulty of human subject recruitment and its effect on the research progress because we mainly targeted the internal

processes of the institution. These previous factors can be subjected for further investigations.

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Conflict of Interest: None-declared.

Abbreviations

CRA : Clinical Research Associate
CRC : Clinical Research Coordinator
CRO : Clinical Research Organizations
IRB : Institutional Review Board
KACST : King Abdulaziz City for Science and Technology
KAU : King Abdulaziz University
KAUST : King Abdullah University of Science and Technology
KFSH&R : King Faisal Specialist Hospital & Research Centre
KSU : King Saud University
KSA : Kingdom of Saudi Arabia
NPI : Nature Publishing Index
PI : Principal Investigator
SOPs : Standard Operating Procedures

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