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Investigator Participation in Clinical Research: An Examination of Barriers and Facilitators in the Indian Clinical Trials Settings

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Abstract

Background: This study aims to improve clinical research by identifying the barriers and facilitators for investigators conducting trials. We explore investigator demographics, challenges faced, and factors promoting engagement. Additionally, we examine how investigators' background influences their experiences with both barriers and facilitators, ultimately aiming to foster a patient-centric clinical trial ecosystem.

Methods: A quantitative, exploratory study investigated barriers and facilitators in clinical trials among 132 investigators in India. A self-designed questionnaire captured experiences with challenges, strategies, and facilitators. Pilot testing ensured tool validity and reliability. Ethical considerations were addressed, and data analysis will identify key factors impacting investigator engagement. This study aims to improve the clinical research ecosystem in India.

Results: The study aims to identify the facilitators and barriers experienced by the research investigators. An online questionnaire survey was used in this cross-sectional investigation. The study's population consists of 132 respondents, with 68 (51.5%) males and 64 (48.5%) females. Clinical Research Coordinators (CRCs) (41.7%), Research Associates (RA's) (27.3%), Supporting staff (19.7%), Co-Investigators (Co-I) (6.8%), and Principal Investigators (PIs) (4.5%) which were the majority of respondents. The most common barriers found among the principal investigators regarding the limited resources ($p=0.014$) towards the clinical trials. Inadequate training ($p=0.461$), Complex regulations ($p=0.625$), and Communication barriers ($p=0.853$) did not seem like barriers to the clinical research staff. Whereas some of the staff faced barriers ($p=0.118$) with the complex regulations and Inadequate training on the other hand most of the respondents considered the same statements as facilitators ($p=0.963$) with their daily working activities.

Conclusion: The Barriers and Facilitators experienced by the clinical investigators, It was found that there is no difference in viewpoint. As per the results, Research associates agreed more with the facilitators and the principal investigators faced barriers.

Keywords: Clinical Trials, Barriers, Facilitators.

Introduction

Clinical trials were initially conducted as comparative studies without prospective randomization. In 1747, Lind examined the effects of various treatments on 12 patients who had scurvy symptoms. The largest improvement was shown in those who consumed oranges and lemons, which are pure forms of vitamin C. [1]

Similar comparative studies on the effectiveness of medicines or vaccinations in the treatment of smallpox, diphtheria, and cholera were carried out throughout the 1800s.[1] Studies on the prevention and treatment of infectious diseases make up the majority of the 1900s literature. With the British Medical Research Council's (MRC) first placebo-controlled randomized clinical trial, the design of clinical trials entered a new, gradually more scientific phase. This study, which was published in 1948, looked at how streptomycin affected tuberculosis, and it seemed to the initial study to randomly assign patients to control and interventional arms.[2]

To draw correct inferences about prevention and overall survival from the data, an efficient trial must tackle highly focused questions or set of concerns, use a logical and practical method to obtain a valid answer, include investigators with major experience in clinical care as well as a research approach, and be carried out over a suitable period. Because full adherence to the protocol is essential, it must include a documented protocol that outlines a particular plan for action for completing the research and is easy to understand by all involved investigators.[1]

Clinical trials are essential for evaluating the effectiveness, safety, and side effects of new treatment options, The development of new treatments, tests, and medical equipment depends mainly on clinical trials. Regulatory bodies require a series of research studies to be carried out and outcomes analyzed before a new treatment can be introduced for public consumption because there is no other way to demonstrate the efficacy and safety of new therapeutic modalities for human use or their equivalence or superiority over existing therapy[3]. Collaborations between doctors and researchers may improve the applicability of study results and the acceptance of research findings across populations. There are various perceived hurdles to conducting clinical research.[4] Previous research has identified the primary issues as a lack of cash, time, and resources in an already overburdened healthcare system.[3]

This study is essential because clinical trials are the cornerstone of medical progress, yet their effectiveness in India is hampered by various obstacles. By exploring the perspectives of clinical trial investigators and research staff, this research aims to pinpoint the specific challenges hindering these trials, such as difficulties in recruitment and resource allocation. Furthermore, the study seeks to uncover facilitators that can streamline operations and improve the overall conduct of clinical trials. By addressing these critical aspects, the research hopes to contribute to a more optimized clinical research ecosystem in India. This includes informing policy changes and improvements to infrastructure that will better support efficient clinical trials. Ultimately, the study seeks to foster a culture of sharing best practices, leading to high-quality and patient-centric research. This, in turn, will contribute to significant advancements in healthcare and the expansion of medical knowledge.

This current paper's objective is:

1. To identify barriers and facilitators of clinical trials among investigators in selected research centers.
2. To find out the relationship between barriers and facilitators of clinical trials among investigators.
3. To find out the association between Barriers of clinical trials among investigators with their

selected demographic variables.

4. To determine the association between Facilitators of clinical trials among investigators with their selected demographic variables.

Methods

This study employed a quantitative approach with an exploratory research design to investigate barriers and facilitators of clinical trial conduct among investigators at selected Indian research centers.

Participants: A purposive sample of 132 clinical investigators from 45 research centers participated. Inclusion criteria specified participants holding roles in clinical research and actively involved in at least one ongoing clinical trial or academic study. Exclusion criteria ensured participants were not students, interns, or unaffiliated with clinical research activities.

Data Collection: A self-structured questionnaire served as the primary data collection tool. Data was collected by using an online questionnaire, meticulously crafted to align with research objectives, and captured insights on challenges faced, strategies employed, and perceptions of facilitators in clinical trial execution. The structured format ensured uniformity in responses. Content validity was established through expert consultation and a pilot study (n=10) conducted at a reputable research center in Ludhiana, Punjab. The pilot study assessed tool feasibility, participant availability, and data collection time. The final questionnaire demonstrated high reliability (r=0.980) using the split-half method.

Ethical Considerations: Written consent was obtained from all participants after providing a detailed explanation of the study's purpose and maintaining confidentiality. Ethical approval was granted by the College research committee and Desh Bhagat University ethics committee.

Data Analysis: Summarize investigator demographics (age, gender, role, experience) and other relevant variables (resource availability, communication barriers, trial complexity, ethical considerations). Explore potential relationships between barriers/facilitators and investigator demographics using appropriate statistical tests chosen based on data distribution (e.g., chi-square for categorical data, correlation for continuous data). Significant associations will be identified for further interpretation.

Results

Frequency and percentage distribution of sociodemographic characteristics of investigators of selected research centers.

Table-1 Genders participating in the study

N=132

Gender	Frequency (F)	Percentage (%)
Males	68	51.5
Females	64	48.5

Age		
21-25	35	26.6
26-30	57	42

31-35	15	11.4
36-40	12	9.2
41-45	7	5.4
46-50	2	1.6
51-55	1	0.8
56-60	3	2.3
Role		
Principal Investigator (PI)	6	4.5
Co-Investigator (Co-I)	9	6.8
Clinical Research Coordinator (CRC)	55	41.7
Research Assistant/Associate (RA)	36	27.3
Other Research Staff	26	19.7
Number of Trials/Study		
1	37	28
2-5	73	55.3
5<	22	16.7

Table 1 shows that the maximum (51.5%) were males and (48.5%) were females. As per the percentage of investigators according to age, the majority of the participants (N=57) (42%) belonged to the age group of 26-30 years, followed by 35 (26.6%) were of the 21-25 years age group, while only 1 participant (0.8%) belonging to the age-group of 51-55 years. Roles of the participants in clinical trial studies show that 6 participants (4.5%) are PIs, followed by 9 participants (6.8%) are Co-I, followed by 55 participants (41.7%) are CRCs, followed by 36 participants (27.3%) are RA's and 26 participants (19.7%) are other clinical staff amongst them. Frequency and Percentage distribution of clinical trials on the research investigators were analyzed and it was found that 37 participants (28%) were involved in only 1 study, followed by 73 participants (55.3%) are involved in 2-5 studies, followed by 22 participants (16.7%) are involved in more than 5 studies.

Table-2 Communication Barrier and Facilitators

	Mean	**Std. Deviation**
Team's ability for communication in the context of clinical research-**Facilitator**	3.947	0.702

Designated research staff members on-site, such as a Principal Investigator, Co-Investigator, and Clinical Research Coordinator make research smooth- The **Facilitator**	4.160	0.605
Level of education and expertise of the clinical research team or Clinical Research Coordinator when it comes to obtaining informed consent from patients- **Facilitator**	3.856	0.743
Family involvement in recruiting patients has a significant impact on the recruiting process in clinical trials-**Facilitator**	3.223	0.950
That effective coordination and interaction within the research team on-site can significantly enhance collaboration and productivity- **Facilitator**	3.992	0.818
Language acts as a barrier in conducting the activities in clinical trials (for example- while consenting and data collection)- **Barrier**	3.561	0.943

Table 2 shows that the participants (M=3.95, SD=0.70) believed that the study teams' capacity to communicate in the context of clinical research was good. They concurred that when the research team members assigned jobs on-site, the research went more smoothly (M=4.16, SD=0.61). When it comes to getting patients' informed consent, they believed that the research team's level of education and expertise was important (M=3.86, SD=0.74). They concur that language is a significant impediment to conducting research (M=3.56, SD=0.94). They expressed a neutral impression of the role that families play in clinical research trial recruitment (M=3.22, SD=0.95). They agreed that efficient communication and collaboration among the study team on-site can greatly improve teamwork and output (M=3.99, SD=0.82).

Table-3 Complex Regulations Barriers and Facilitators

	Mean	Std. Deviation
Experienced any significant barriers or challenges in obtaining ethical approvals from the Ethics Committee for initiating clinical trials on-site- **Facilitator**	3.023	0.903
Any significant barriers encountered when reporting Serious Adverse Events (SAEs) and Adverse Drug Reactions (ADRs) in drug trials- **Barrier**	3.030	0.924
The amount of data collection serves as a barrier in clinical research- **Barrier**	3.280	0.911
Concerns from the perspective of patients or caregivers regarding the frequency of visits in clinical trials- **Barrier**	3.273	0.989
Any obstacles related to the length of the study/clinical trial- **Barrier**	3.167	1.028
Any notable concerns when patients were assigned to the placebo group- **Barrier**	2.833	0.974

Table 3 shows that the study team occasionally encountered obstacles when trying to get ethics committee approval to start clinical trials on-site (M=3.02; SD=0.90). They thought that there were obstacles to reporting SAEs or ADRs during drug trials (M=3.03; SD=0.92). The study team has a slight challenge due to the volume of data collected during clinical trials (M=3.28, SD=0.91). Concerns about the number of visits required for clinical trials from the standpoint of patients or carers acted as a moderate barrier (M=3.27, SD=0.98). A moderate hurdle for the research team is the length of the study or trial (M=3.16, SD=1.02). When patients were assigned to the placebo group, there was some ambiguity (M=2.83, SD=0.97).

Table-4 Inadequate Training Barriers and Facilitators

	Mean	Std. Deviation
The impact of patient inclusion and exclusion criteria in clinical trials- **Facilitator**	3.221	0.853

The adequacy (S.I.V., Monthly visits, Online training sessions) of clinical trial management in providing training to the clinical research staff-facilitator	3.591	0.847
Any common barriers encountered during sample collection and invasive procedures in drug trials- **Barrier**	3.359	0.920

Table 4 shows that the participants' opinions on whether or not patient inclusion and exclusion criteria had a major impact on clinical trials were neutral (M=3.22, SD=0.85). The respondents felt that educating the clinical research personnel was adequate for managing clinical trials (M=3.59, SD=0.85). They claim that there was uncertainty experienced during invasive procedures and sample collection in drug trials (M=3.35, SD=0.92).

Table-5 Limited Resources Barriers and Facilitators

	Mean	**Std. Deviation**
Assess the workload imposed on clinicians and researchers during the conduction of clinical trials- **Barrier**	3.629	0.823
The space (eg. OPDs, Closed rooms, IPDs, etc.) of taking consent or patient study visits affects the study quality- **Barrier**	3.364	0.813
Any barriers in extracting data from medical records, including both paper and electronic records, in clinical research- **Barrier**	2.932	1.013
Satisfaction with the budget allotted to sites for clinical trials- **Facilitator**	3.394	0.808

Table 5 shows that the limited resources barriers and facilitators. Participants in clinical trials reported a heavy workload (M=3.62, SD=0.82). The area used to collect patient Informed Consent Forms (ICF) (M=3.36, SD=0.81) and extract data from medical records (M=2.93, SD=1.0) had a moderate effect on the study process. The participants' satisfaction with the funding designated for clinical trial locations was modest (M=3.39, SD=0.81).

Table-6 Relationship between barriers and facilitators of clinical trials.

	Facilitators	Barriers
Facilitators	1	0.095
Barriers	0.095	1

Table 6 shows the correlations between barriers and facilitators. Regarding the facilitators and barriers experienced by the research personnel, there is a positive correlation in the viewpoint. As per the results, Research associates agreed more with the facilitators and the principal investigators faced barriers.

Table-7 Association between barriers of clinical trials among investigators with their demographic variables.

N=132

Demographic characteristics	N	Mean	Std. Deviation	F	P value
Genders					
Males	64	3.25	0.40	0.23	0.822
Females	64	3.23	0.50		
Number of Trials					
1	37	3.14	0.38	1.63	0.199
2-5	73	3.30	0.44		
>5	22	3.22	0.56		
Roles of investigators in clinical trials					
Principal Investigator	06	3.47	0.42	1.88	0.118
Co-Investigator	09	3.36	0.44		
Clinical Research Coordinator	55	3.12	0.41		
Research Associate	36	3.31	0.53		
Other supporting staff	26	3.31	0.39		

Table 7 shows the association of barriers with selected demographic variables among investigators. By using the ANOVA test it was found that there was no significant association of barriers and selected demographic variables (Gender, Number of trials, Roles of investigators in clinical trials).

Table-8 Association between facilitators of clinical trials among investigators with their demographic variables.

N=132

Demographic characteristics	N	Mean	Std. Deviation	F	P value
Genders					
Males	68	3.62	0.24	0.59	0.558

Females	68	3.59	0.33		
Number of Trials					
1	37	3.61	0.29	0.17	0.847
2-5	73	3.59	0.25		
>5	22	3.63	0.39		
Roles of investigators in clinical trials					
Principal Investigator	06	3.52	0.23	0.15	0.963
Co-Investigator	09	3.58	0.25		
Clinical Research Coordinator	55	3.61	0.27		
Research Associate	36	3.61	0.29		
Other supporting staff	26	3.60	0.36		

Table 8 shows the association of facilitators with selected demographic variables among investigators. By using the ANOVA test it was found that there was no significant association between facilitators and selected demographic variables (Gender, Number of trials, Roles of investigators in clinical trials).

Discussion

Out of 132 participants, 51.5% (N=68) are males and 48.5% (N=64) are females, Belongs to the different age groups whereas 26.6% (N=35) participants belonged to the age group of 21-25 years, followed by 42% (N=57) belonging to the age-group of 26-30 years, followed by 11.4% (N=15) belonging to the age-group of 31-35 years, followed by 9.2% (N=12) belonging to the age-group of 36-40 years, followed by 5.4% (N=07) belonging to the age-group of 41-45 years, followed by 1.6% (N=2) belonging to the age-group of 46-50 years, followed by 0.8% (N=1) belonging to the age-group of 51-55 years, followed by 2.3% (N=3) falling in the age group of the population who was in between 56 to 60 years of age. Out of 132 participants, 4.5% (N=06) participants are PIs, followed by 6.8% (N=09) are Co-I, followed by 41.7% (N=55) are CRCs, followed by 27.3% (N=36) are RA's and 19.7% (N=26) are other clinical staff amongst them. The population in this study has a diverse experience in clinical studies as out of 132 participants 28% (N=37) participants are handling only one study, followed by 55.3% (N=73) are handling 2-5 studies, followed by 16.7% (N=22) are handling more than 5 different studies.

The study objectives, there are 4 main objectives first is the communication barrier, according to a study by Restifo and Phelan conducted in 2011[5], it was found that the communication barrier between clinicians and researchers impacts the study findings there is no shared value system, even when it comes to knowledge and ignorance. Both seemingly shared basis for life-science knowledge, masks widely diverse perspectives and rewards within their professions and in society. In the findings of this study, most of the participants have the opinion that the research team's ability to communicate in the context of clinical research was good (M=3.95, SD=0.70). They agreed that the research team members made the research smooth when they designated jobs on-site (M=4.16, SD=0.61). They considered the Level of education and expertise of the clinical research team when it comes to obtaining informed consent from patients was very important (M=3.86, SD=0.74). The studies show that language acts as a barrier between the subject and the clinicians or researchers, the study participants have agreed that language acts as a significant barrier in the research operations[6,7] (M=3.56, SD=0.94). They had a neutral opinion regarding family involvement in the recruiting processes of clinical research trials (M=3.22, SD=0.95). They had agreed

that effective coordination and interaction within the research team on-site can significantly enhance collaboration and productivity (M=3.99, SD=0.82).

The second objective is complex regulations, as per the study given by Muthuswamy in 2013[8], Sometimes the research team experienced barriers in obtaining approvals from the ethics committee for initiating the clinical trials on-site (M=3.02, SD=0.90). they had a neutral opinion that reporting SAEs or ADRs in drug trials they encountered barriers (M=3.03, SD=0.92). The amount of data collected in clinical trials serves as a mild barrier for the research team (M=3.28, SD=0.91). The studies defined the concerns from the perspective of patients or caregivers regarding the frequency of visits in clinical trials as a moderate barrier[9,10] (M=3.27, SD=0.98). The length of the study or the trial acts as a moderate barrier for the study team (M=3.16, SD=1.02). There was an uncertainty noted when patients were assigned to the placebo group (M=2.83, SD=0.97).

The third objective is Inadequate training, Educating the research team is the essential step towards the successful completion of the trial. The participants had a neutral opinion that the inclusion-exclusion criteria of patients significantly impacted the clinical trials[11,12] (M=3.22, SD=0.85). As per the opinion of the participants, providing training to the clinical research staff was adequate in clinical trial management (M=3.59, SD=0.85). According to them, there was uncertainty encountered during sample collection and invasive procedures in drug trials (M=3.35, SD=0.92).

According to the fourth objective of the study which is the limited resources that affect the quality of the trials, it has been found that during the conduction of clinical trials, a heavy workload was reported by the participants[13,14] (M=3.62, SD=0.82). The space of taking consent forms from the patients (M=3.36, SD=0.81) and extracting data from medical records moderately impacted the study procedures (M=2.93, SD=1.01). The participants were moderately satisfied with the budget allotted to sites for clinical trials (M=3.39, SD=0.81).

Conclusion

Our study revealed limited resources as a critical barrier for Principal Investigators (PIs). Complex regulations, inadequate training, and communication gaps did not significantly hinder clinical research staff. While some staff found these challenging, most viewed them as learning opportunities. This highlights the need for role-specific support. Initiatives for PIs addressing resource limitations and staff development programs on regulations and training could be beneficial. Future research with larger samples could delve deeper into these themes and explore additional factors influencing investigator participation in clinical trials.

Results

The response rate was 100% out of 132 respondents, with 68 (51.5%) males and 64 (48.5%) females. CRCs (41.7%), RAs (27.3%), Supporting staff (19.7%), Co-I (6.8%), and PIs (4.5%) were the majority of respondents. The most common barriers found among the principal investigators regarding the limited resources (p=0.014) towards the clinical trials, Inadequate training (p=0.461), Complex regulations (p=0.625), and Communication barriers (p=0.853) did not seem like barriers to the clinical research staff, Whereas some of the staff faced barriers (p=0.118) with the complex regulations and Inadequate training, on the other hand, most of the respondents considering the same statements as facilitators (p=0.963) with their daily working activities.

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Conflict of Interest

There was no conflict of interest observed while doing this study.

References

1. Jenkins J, Hubbard S. History of clinical trials. Semin Oncol Nurs. 1991 Nov;7(4):228–34.
2. Streptomycin Treatment of Pulmonary Tuberculosis. Br Med J. 1948 Oct 30;2(4582):769–82.
3. Roberts R, Perry N, Phillips A, Richardson D, Soni S. Clinical research should be a priority in the NHS - but what do genito-urinary medicine clinic staff think? Int J STD AIDS. 2015 Feb;26(2):107–12.
4. Unertl KM, Fair AM, Favours JS, Dolor RJ, Smoot D, Wilkins CH. Clinicians' perspectives on and interest in participating in a clinical data research network across the Southeastern United States. BMC Health Serv Res. 2018 Jul 20;18(1):568.
5. Restifo LL, Phelan GR. The cultural divide: exploring communication barriers between scientists and clinicians. Dis Model Mech. 2011 Jul;4(4):423–6.
6. Slade S, Sergent SR. Language Barrier. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 [cited 2024 Apr 25]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK507819/
7. Al Shamsi H, Almutairi AG, Al Mashrafi S, Al Kalbani T. Implications of Language Barriers for Healthcare: A Systematic Review. Oman Med J. 2020 Apr 30;35(2):e122.
8. Muthuswamy V. Ethical issues in clinical research. Perspect Clin Res. 2013 Mar;4(1):9.
9. Mahmud A, Zalay O, Springer A, Arts K, Eisenhauer E. Barriers to Participation in Clinical Trials: a Physician Survey. Curr Oncol. 2018 Apr 1;25(2):119–25.
10. Williams J, Craig TJ, Robson D. Barriers and facilitators of clinician and researcher collaborations: a qualitative study. BMC Health Serv Res. 2020 Dec;20(1):1126.
11. Passmore SR, Farrar Edwards D, Sorkness CA, Esmond S, Brasier AR. Training needs of investigators and research team members to improve inclusivity in clinical and translational research participation. J Clin Transl Sci. 2021;5(1):e57.
12. Mercieca-Bebber R, Calvert M, Kyte D, Stockler M, King MT. The administration of patient-reported outcome questionnaires in cancer trials: Interviews with trial coordinators regarding their roles, experiences, challenges and training. Contemp Clin Trials Commun. 2018 Mar;9:23–32.

13. Mbuagbaw L, Thabane L, Ongolo-Zogo P, Lang T. The challenges and opportunities of conducting a clinical trial in a low resource setting: The case of the Cameroon mobile phone SMS (CAMPS) trial, an investigator initiated trial. Trials. 2011 Dec;12(1):145.
14. Adams MCB, Bicket MC, Murphy JD, Wu CL, Hurley RW. Opportunities and challenges for junior investigators conducting pain clinical trials. PAIN Rep. 2019 May;4(3):e639.