Original Article

Program management challenges of clinical studies: A qualitative critical assessment

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Abstract

Background: Organization, coordination, and discipline are required to complete any intricate operation, conducting a clinical experiment is no different. There are usually many moving components, from designing a plan, to conveying changes, to calculating risk, and excellent project management which are necessary to guarantee the study works successfully. Past evidence suggested that roadblock at any level hampers the progress of the clinical research. Understanding program management challenges hence becomes the key for timely and effective completion of clinical research. **Methods:** A cross-sectional qualitative enquiry involving stakeholders in clinical research program management. We used problem tree-based approach wherein we documented views of various stakeholders to understand the interaction, interdependence, and related interventional needs of bottlenecks for long-term research gains using modern management methods applicable in clinical settings. The best fit approach was also explored to augment maximum benefit in limited resource settings. **Results:** Non-alignment with state policy aims, a lack of effective coordination and communication among members, challenging logistic management, limited use of technology, a need for training, and an inefficient monitoring mechanism were among the major issues highlighted, and solutions were proposed. **Conclusion:** Study concludes that an Integrated Process-cum-Timeline-Based Management strategy with multisectoral emphasis is ideal for program management of clinical projects.

Keywords: Clinical research, problem solution tree, program management, qualitative research

Introduction

Clinical research studies, particularly systematic studies in human subjects (including patients and other volunteers), are required to discover or verify the effects of and/or identify any adverse reaction to investigational products in diverse population.[1] Well-designed clinical studies are essentially gold-standard randomized controlled trials (RCT) for testing the efficacy and safety of any new intervention.[2] Multistakeholders' balanced participation is the prerequisite for the smooth conduct of a clinical project as each brings a unique set of tools to bear on the critical elements of a clinical trial.[3]

The clinical research infrastructure includes all possible resources, viz. time, money, personnel, materials (e.g., medical supplies), support systems (both information technology and manpower), and a defined plan for completing the required steps in a trial. Often there are unaddressed gaps in protocol design, development, and implementation leading to ineffective program functioning of clinical studies.[4]

It hence becomes imperative to identify the bottlenecks of program management challenges of clinical studies in tertiary

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healthcare settings for qualitative augmentations in clinical research studies. The objective of this study is to enlist and analyzing the roadblock factors in the development and observance of clinical studies in addition, to also present the public health approach-based solutions for addressing thus identified bottlenecks of program management. Thus, this study has been directed to suggest research-oriented intervention measures for enhancement of quality in clinical research studies.

Methodology

Study setting: As this is a qualitative enquiry, the interviews were taken in participant's natural environment (Workplace).

Study Duration: 6-month study.

Study design: Cross-sectional study.

Sample size = 38, data saturation was applied as basis for final sample size consideration.

Sampling technique: Purposive sampling.

Study participants: Stakeholders including researchers, subject experts, field investigators, health program managers, and scientists involved in clinical research program management.

Data collection method: Group discussion (Qualitative method).

Data collection process:

Step 1- A series of group discussions were held among stakeholders to identify key root problems, and upon subsequent brainstorming and discussion, feasible solutions were suggested.

Step 2- Thereafter, clusters of area-specific issues were clubbed together and recategorized to identify major focus areas. Program-level stakeholders were then distributed to three suggested approaches and were asked to grade the individual cluster domains of concerned approach on a 5-point Likert scale based on its relevance with 1 (+) being least relevant and 5 (+) being most relevant.

Data analysis: We used thematic analysis to analyze the findings of group discussion. Key notes were made during group discussion and transcribed, and then those transcripts were analyzed for finding keywords. Codes were made and grouped to form common themes. Final themes were represented in the form of problem solution chart. Suggested approach grading was represented in tabular form.

Inclusion criteria: Stakeholders involved in clinical research project including research study subjects.

Ethical issues: Informed consent was taken from all study participants. This study was approved by Institutional Research Advisory Committee of Peoples College of Medical Sciences and Research Centre, Bhopal (Approval No-PCMS/OD/2022/738).

Result

We did nine group discussions which included a total of 38 stakeholders from various domains of program management. We ensured participation from all level stakeholders with maximum participation (n = 17) from program implementers [Table 1].

Problem Identified:

After thorough group discussion with stakeholder groups, the key identified problem themes were non-alignment with state policy priorities, lack of effective coordination and communication among the members, difficult logistic management, limited use of technology, need for training, and inefficient monitoring system [Figure 1].

Proposed solutions:

For each highlighted problem themes, solutions were also suggested during the group discussion; those include identifying essential areas of study based on research gaps, setting priorities based on actual research needs, and having clearly stated research questions and research objectives.

Examples:

Problem 1: Ineffective coordination and communication

Solution 1: It suggested to be handled by utilizing central cloud-based platforms such as shared cloud storage folders, mobile applications, and email trails to keep everyone up to date about current happening on and to maximize intellectual contributions.

Problem 2

Another significant issue was a lack of adequate stock management, which resulted in pilferage and unnecessary delays in the process.

Solution 2:

Table 1: Group discussions held among various homogeneous groups

Stake-holders group discussion	No of group discussions	Total participants
Beneficiaries	02	08
Program planner	01	04
Program implementers	04	17
Program monitors	01	05
Program evaluators	01	04
Total	09	38

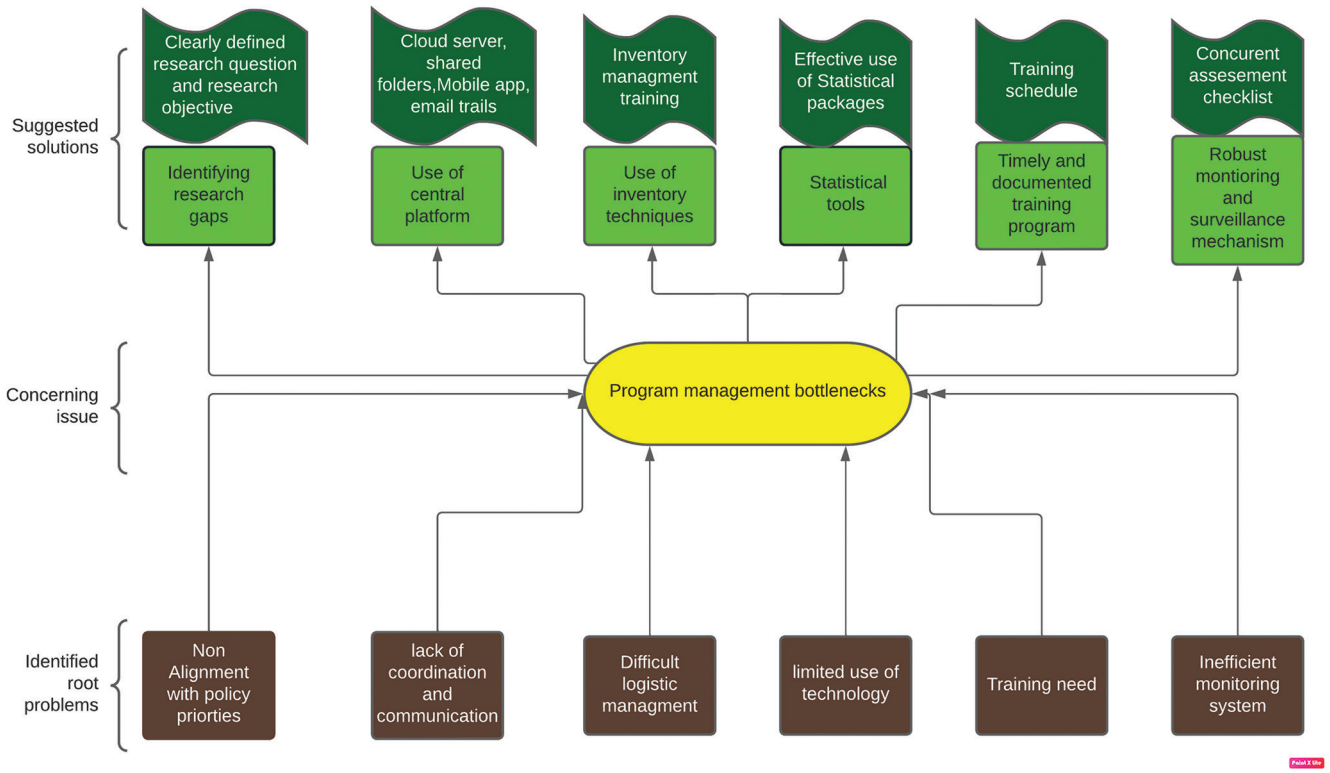

Figure 1: Problem-solution tree diagram

This can be overcome by implementing scientific inventory management methods, first by training concerned employees in various inventory management methods, and then by effectively implementing inventory management strategies for effective stock management [Figure 1].

Problem 3

One of the major barriers in the trial program administration was the lack of use of modern statistical techniques for data management.

Solution 3: Suggestions to overcome this were use of the most up-to-date statistical tools throughout the data management process, right from data collection to analysis, interpretation, and dissemination.

One of the important areas indicated for improvement was training, which was highlighted to be addressed through a time-bound training program and targets, as well as standard modules for training the stakeholders involved. Above all, a reliable monitoring system was emphasized to be essential for any program's successful functioning. This forms an integral component of program management chain [Figure 1].

We identified three approaches based on findings of group discussion keeping problem solution tree in mind and distributed the stakeholders among these approach groups and then asked to grade the individual domains and selected the best possible approach.

Following approaches were identified:

1. Pre-identified Intervention Tool-Based Management: Here the concept is to ensure easy and efficient logistic management and greater emphasis laid on preparation including training of the manpower
2. Integrated Process-cum-Timeline-Based Management: It is a comprehensive management approach with added component of stringent monitoring and supervision.
3. Outcome-based management approach: Here the greater emphasis is on the outcome with ease of availability of vital records, statistical computing, and early and effective dissemination of the results obtained.

Following the division of the stakeholders into the three method groups, a 5-point Likert scale was used for their expert grading on individual selection criteria. The results of are reflected in Table 2.

As shown in Table 2, the "Integrated Process-cum-Timeline-Based Management" was selected as the best-suited approach with maximum scores. The trans-disciplinary stratified discussion forum clarifies the spectrum of focused reform and also provides an insight towards addressing the problems in to thorough coherent, concentric, and energy-centric reforms. The high emphasis area in category 1 included stakeholder partnership and replicability with 3 points each out of 5, whereas the input–output analysis was the only approach cluster emphasized in category 3.

Although category 1 has the highest replicability, the aspects of feasibility evaluation and targeted areas cannot be ignored. The

Table 2: Problem tree-based comparative analysis of the three shortlisted approaches and selection criteria

Domains	Approach categories		
	1	2	3
	Pre-identified Intervention Tool-Based Management	Integrated Process-cum-Timeline-Based Management	Outcome-based management
Target population	+	+++	++
Target area of work	++	+++	++
Stakeholder partnership	+++	+++	+
Input-output analysis	++	+++	+++
Evaluation specification	++	+++	+
Stream lining of policy initiatives	+	++	++
Address cross-cutting issues	++	++	++
Feasibility of activities	++	+++	+
Replicability	+++	++	+
Total	18	24	15

Integrated Process-cum-Timeline-Based Management approach not only highlights the importance of analysis, evaluation, replicability but also value the selection of target population and selection of the area of work based on identification of real research gaps.

Discussion

Defining the trend

As evident from the results obtained, the roadblocks in program management can be encountered at all steps. Addressing these bottlenecks, roadblocks, and inertia for multifaceted and stream-specific targets needs time-bound, techno-intensive, and modern management technique-assisted changes for cumulative gains in the long term. However, it is worth mentioning, based on qualitative inputs herein received, that the programmatic management challenges of clinical studies are also inherently dependent on the concept, design, development, and resulting finalized protocol with its adherence in word and spirit by all the stakeholders.

Problem tree approach-setting priorities

The challenges of clinical studies are to be addressed with great care, concern, and continuity without disruptions to reap the fruits of quality conduct. The modernization and sustenance of processes for program management also need due attention, especially at all levels of intervention including administration, management, and public health action. Completion of all tasks related to clinical studies in a defined time frame, quality focus, and efficiency can be understood through shared learning of various research teams at different levels of planning-cum-implementation mechanisms.[5]

The analysis of the problem tree, therefore, guides for all-inclusive research orientation, analytical approaches, and design-specified issue-faced resolution of challenges encountered during strata-wise progress in observance of clinical studies.

It has been noted and widely discussed that there is ample requirement for setting priorities for the researched molecules in the larger interest of the target population including the deprived people of a developing country.[6]

Getting research done and not being able to put the expected benefits of clinical studies to use is a challenge that necessitates speed, accuracy, involvement, participation, dedication, determination, zeal, enthusiasm, and a people-centered approach to converting findings into community-oriented benefits.[6] Feasibility and priority foci are also essential factors in achieving research objectives.

Stakeholder's partnership

Although equal emphasis has been laid on stakeholder's partnership in the "pre-identified intervention tool-based management approach" and "Integrated Process-cum-Timeline-Based Approach", there is observed lesser emphasis upon it in the "outcome-based management approach." It illustrates that stakeholder partnership is an important tool, especially in the planning and implementation phase of any program. The herein evidenced highest emphasis on target population, target area, partnerships, input–output analysis, emphasis on evaluation techniques, and feasibility of performance is driving for resolution of programmatic management challenges in varied settings of geopolitical, social, financial, linguistic, and cultural environment.[7]

It is felt the need of program managers that the comprehensiveness of a goal-orientated approach requires the repair of gaps in the equated distribution of resources among various components of the program managers. As a consensus, the challenges of clinical trials pose enormous challenges at institutional, departmental, and investigator levels. Addressing challenges have also to be in line with the national priorities, expected research gains, and alleviating the suffering of masses to prevent morbidities and mortalities.[4]

Capacity building and multisectoral coordination

The capacity building of multilevel initiatives associated with manpower is critical to adherence and observance of guidelines

in terms of feasibility analysis, appropriate documentation, and corrective action for the failure encountered at various levels of governance and clinical management for the entrusted study.[8]

Involvement of a spectrum of departments, agencies, and hospital management necessities requires an integrated approach to developing and implementing various clinical studies, especially randomized controlled trials. The need for a command system, planning processes adherence to the operational manual, arrangement of logistics, and administrative-cum-financial management are essentially required to be integrated into the research studies formats for appropriate, timely, complete, and coordinated systems to be actively placed.[8]

The role of knowledge creator, knowledge integrator, and knowledge leverage has been identified to have a larger role in devising research and developmental model of any research-orientated, research focused and research based addressing the foreseeable requirement of the healthcare sector in larger, wider, and defining perspective.[9]

Prior resource assessment

The challenges of writing study protocol should also be dealt with caution as it has an impact on the study design costing and implementation procedure. The developing countries have their challenges of logistics, staff, structural support, and resources for well-designed multicentric clinical studies.[10]

There is a strategic developmental need for undertaking clinical trials from various perspectives of barriers and facilitators to their conduct by academic, clinical, and established healthcare settings while ensuring fulfillment of programmatic requirements of the implementing agencies. It will act as a boost to augment the health-related outputs and provide answers to the roadblocks of clinical treatment and care.[11]

Record-based monitoring

The question about the ability of a clinical trial to be transformative for translational medicine remains unanswered due to deficiencies in facilities, the incompletion of timeline-based tasks, and challenges related to structural reforms required for bringing about such changes.[12] Igniting the spark of translating research into action through policy revisions brings in the dreamt reforms into existing health preferences.[13]

The challenges get enhanced in the scenario of rapid conduct of the study, emergency needs, and changing threats of disease agents, especially during pandemic management priorities across wide geographic areas.[14] Wide horizons of multidisciplinary team-based research initiatives have a definite edge over unicentric research due to a larger representation of varied research expertise, experience, and involvement.[15] Keeping the records of the clinical studies safe and secure for a long time requires careful planning, delegation, and responsibility sharing as per the agreed protocol of research conduct. Analyzing the big data related to medical research poses intrinsic challenges related to the completeness, purity, continuity, and differentiability of data.[16]

Interdisciplinary research focus has become pivotal for bringing about social change for the elimination of diseases through the application of comprehensive resource allocation in science, epidemiology, clinical intervention healthcare systems epidemiology, program implementation, and social sciences.[17]

The upgradation of the research program depends on enhanced research training, sharing of experiences, and establishment of facilitatory support networks, which ensures the use of skilled personnel and strength and facility for conduct of high-end research.[18] Global requirements of the researched molecule and its related marketing, distribution, and availability also pose great challenges at different levels including political will, technical excellence, managerial skills, and regulatory requirements.[19]

Advantage of technological advancement

Using recent advances in medical sciences and healthcare services, biostatistics, internet technologies, and specific software-based devices have changed the horizon of healthcare research in multidisciplinary streams. Newer methods for conducting clinical studies have included teleconsulting and virtual randomized clinical trials (vRCTs) to address the challenges related to informed consent procedures in clinical studies, thereby reducing cost, time, and the need for the physical presence of the participant.[20]

As evidenced by various trials conducted for developing a vaccine, drug, or appropriate intervention, the advantage of technological progress so far in computer sciences and public health interventions has reduced the timing and required energy for translational of completed research into a public benefit.[21] Despite the supremacy of the human mind, the role of artificial intelligence in future research shall have far-reaching goals and will contribute immensely. The channelization of health data ensures upscaling of the planned initiatives and has multifold benefits while using these datasets for drawing inferences.[22]

The use of operational research has contributed to management, system, and implementation reforms as its inferences direct the monitoring and evaluation teams, guide the program managers, and provide adequate insight to the policy planners for efficient and effective utilization of available resources in the larger benefit of the general population.[23]

Perks and challenges of developing nations

It is easy to conduct a clinical trial in a developing country due to the visible stages of various diseases; however, there are enormous challenges in obtaining informed consent, adhering to norms, health infrastructure deficiencies, and other unavoidable resource constraints. Thus, the parallel and effective mechanisms are warranted for intrinsic and extrinsic support systems to be

placed for quality outputs of extensive and extended clinical studies of higher order. Challenges of conducting research are not only limited to the development of a product but also post-development processes including permissions, surveillance, distribution, and acceptance of the research undertaking for appropriate gains to alleviate the pain and suffering of the diseased population.[24]

The new initiatives for clinical research in a country scenario also include developing a national-level review board, protocol development mechanisms, protocol adherence monitoring system, and appropriate checks for evidenced-based outcomes in clinical research.[25] Design-based conduct and quality adherence to clinical study are important pillars for outcome reliability.[26] The focus on quality output gets itself identified on the higher horizon in the times of excellence, quality, and repeatability of research inputs.[27]

Limitation

Since it is a qualitative enquiry, the findings are subjective to experience of the stakeholders involved in the process. Data specific to the project must be collected from stakeholders for individualized research inputs.

Conclusion

To conclude clinical trial program management is critical to maintaining steps of trials on schedule and within budget, but project managers are not always provided with the resources they need to succeed. A successful clinical trial relies on effective and well-structured project management. Many different factors and moving pieces make up project management. The study also concludes that concentric continued and focused management is the key to resolving bottlenecks of program management challenges in clinical research studies. However, the analysis of bottleneck for solution indicates comprehensive management-cum-evaluation approach to be best suited among other grouped approaches.

Ethical approval: This study was approved by Institutional Research Advisory Committee of Peoples College of Medical Sciences and Research Centre, Bhopal (Approval No-PCMS/OD/2022/738).

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Conflicts of interest

There are no conflicts of interest.

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