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Site Management Organizations Sustenance: Challenges and Potential Innovative Solutions

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Abstract

Clinical research and innovation continue to play an important role in the advancement of evidence based clinical practice regardless of its complex multi-step processes and accordingly related challenges.

Despite the adaption of technology and quality systems, site management organizations (SMOs) still face significant operational challenges to execute the studies effectively. SMOs administering various clinical trials in multiple clinical sites and operate with a vast number of clinical trial staff. Therefore, the need for effective management strategies, well trained multi-skilled staff, teamwork, and collaboration of all sites are very crucial. This review article lists most of the SMOs operational challenges as well as potential innovative solutions needed to enhance their management process.

Keywords: *Clinical Trials; Multi-Sites Trial Management; Inter-institutional Collaboration*

SMOs operational challenges

Challenges encountered multi-sites clinical trial organizations are mostly related to inadequate or even lack of inter-sites collaborations. For example, few organizations have exactly the same training requirements for coordinators and, as the number of clinical trial sites increases, these variations can present challenges in trial management. Training variability has the potential to create discrepancies among study staff regarding operating procedures, data collection, record-keeping, and reporting[1]. Moreover, this will cause more errors and poor quality of data, with a higher possibility of violations occurring, ultimately affecting subject safety[2]. Other challenges are highlighted in Table 1.

Table 1: Challenges run into multi-sites management organizations[1, 2]

Communication across multi-sites • Infrequency of face-to-face meetings • Travel time between clinics and appointments • Lack of necessary technology
Multi-institutional coordinator training • Variation in clinical research management and clinical coordinator training
Multiple record keeping methods • Non-access to inter-sites servers for clinical research personnel • Non-access to Electronic Medical Records (HER) for trial staff • Lack of common data for potential subjects • Maintenance of patient files off-site
High clinical staff/coordinator turnover • Issues around consistency of training and retraining • Reduced treatment fidelity • Potential impact on data integrity • Opportunity for missed follow-ups • Inadequate compensation and benefit packages
Subject recruitment and retention • Various levels of withdrawal • Inappropriate education plan and orientation sessions related to clinical studies

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• Substituting phone interviews for face-to-face during follow-up
Multiple Institutional Review Boards • Varying submission formats • Varying research training requirements • Variation in review criteria • Delays in the processing of submitted forms • Excessive number of deviations/violations and misreporting
Time Involvement • Extra clinical research-related work • Discussions with patients and consent interviews • Ethics submissions and approvals • Lack of dedicated time to be involved in clinical trial by investigators • Underestimate the required time to deliver research tasks
Resource issues • Financial and overall costs involved • Facilities and infrastructure (inadequate management team, administrative support, clerical activities, and technology) • Lack of skilled staff and access to relevant training • Lack of organizational networks • Subjects (insufficient number available, multi-trials competition, restricted eligible criteria)
Physician-related barriers[2, 3] • Field, setting, and academic profile of physicians • Lack of interest of physicians in the trial topic and uncertainty inherent in clinical research • Limited familiarity with research policies and protocol procedures • Disruption to clinical practice and loss of professional autonomy (role conflict of clinician and clinical researcher) • Potential side effects • Negative effect on doctor-patient relationship • Inadequate financial compensation • Attend investigator meetings
In-house study management concerns[3, 4] • Lack of project management processing vision • Inability to investigate issues in real-time • Lack of study risk management and rescue groups • Lack of knowledgeable management/leadership team and related relevant training • Absence of documented lessons learned from previous studies

Clinical trials today are more complex than ever before; unique procedures per trial have increased 46%; total procedures have increased 65%; and the number of trial days is up by 70%[8]. Thus, over the last few years, clinical research sites have incurred worsening delays in conducting clinical trials. One of the major challenges facing multi-sites trial organizations is the collaboration of all sites and their resources in a coordinated manner. If one clinical trial is conducted by setting up a nodal center and the resources arranged, the next trial starts again from scratch instead of drawing ideas and resources from the previous trial. [9] Nearly 80% of trials fail to meet milestones, thus delaying the delivery of potentially life-savings to market. Operations professionals are constantly expected to improve efficiency and productivity, to deliver cost-effective studies to deadlines and within budget, while maintaining quality and ethical standards. [10] This impose the importance of collaborative communication styles among the multi-sites and harmonize a common direct management operating procedure for each study. Therefore, at the sites management organizations, the success of any particular clinical trial study is heavily dependent on close

communication, collaboration and harmonization of all key players, including the investigators, the clinical trial staff, information technology (IT) specialists, ancillary departments (e.g., clinical laboratory, radiology, and pharmacy), IRBs, and management and administrative team. In addition to the above-mentioned concerns, lack of adequate infrastructure or resources to conduct the trial will result in poor performance, shortage of enrolment, and an unacceptable number of protocol deviations/violations.[11] These challenges are some of the major obstacles enabling clinical trials from becoming well-organized process and rise up the red flag to invent new miraculous solutions. The potential management solutions for multi-sites clinical trial organizations are presented in Table 2.

Potential management solutions

Table 2. Potential Management Solutions for Multi-Sites Clinical Trial Organizations. [1, 2, 3, 4, 5, 8, 9]

Challenges	Potential Solutions
Communication across multi-sites [1]	• Conduct weekly or bimonthly research meetings for the all team via phone, face-time or face-to-face. • Conduct separate coordinator meetings for clarification on minor recruitment issues.
Multi-institutional coordinator training	• Conduct coordinator cross-training • Implement simulated clinical trial site • Encourage continuing educations and online training courses
Multiple record-keeping methods	• Add study-specific templates with downloadable fields to the EHR. • Provide uniform data collection forms (paper forms w/Access database or data entry directly into netbook/laptop). • Develop a policy for obtaining and maintaining consistent access for internal personnel despite changes in compliance staff. • Implement a secure method of transporting and housing of records with PHI and maintain consistent policy.
High clinical coordinator turnover	• Secure commitment from the centralized clinical system to dedicate coordinator(s) to the project for the duration of the study period. • Conduct weekly or biweekly coordinator meetings. • Establish network relationships with HR agencies to secure staff-backup • Develop online inter-sites standard operating procedures manual. • Support Quality Assurance (internal/external audits) to assess and correct inconsistencies between sites and coordinators, and ensure data integrity. • Encourage coordinators to acquire certifications and memberships offered by various clinical research associations.
Subject recruitment and retention	• Set clear strategic monthly recruitment goals for each clinic • Monitor recruitment via ongoing progress reporting and tracking • Provide option for passive withdrawal form study • Provide option for phone follow-up instead of unnecessary in-person visit

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	• Offer educational brochures, oriented sessions and seminars
Multiple Institutional Review Boards	• Establish a lead IRB up-front with high regulatory expertise • Submit protocol forms and addendums to the same IRB • Identify the local IRBs and select the one offers express review and approvals • Maintain a single/same version of currently-approved consent form for all sites executing same study.
Physician-related barriers [2]	• Policy and procedures: • Publications of guidelines • Time management • Reimbursement • Reward and recognition • Involvement in clinical research committee. • Create internal expertise of clinical management and leadership. • Establish knowledgeable and high-skilled clinical research groups. • Networking with other clinical research organizations. • Promote evidence-driven practice. • Create internal database for potential clinical research subjects. • Rapid learning health care and research system. • Attend annual meetings offered by various clinical research associations. • Research in undergraduate medical curricula and continuing educations.
In-house study management concerns [3-4-5]	• Implement the five steps of project management for each study. • Apply project management organizational system (techniques/tools). • Identify potential risks early and control study tasks, scope, schedule, cost, communications, and quality. • Create in-house study rescue groups. • Encourage study team to participate in project management, leadership, and soft skills training.

Additionally, to the above-mentioned potential solutions, the option of incorporating simulated clinical trial site into site management organizations may be an appropriate training technique. Also, implementing of project management in clinical trial activities will enhance the process of planning, organizing, executing, analyzing, reporting, and managing the effort to accomplish successful trials in a well-structured and stimulated manner with minimal or no risks.

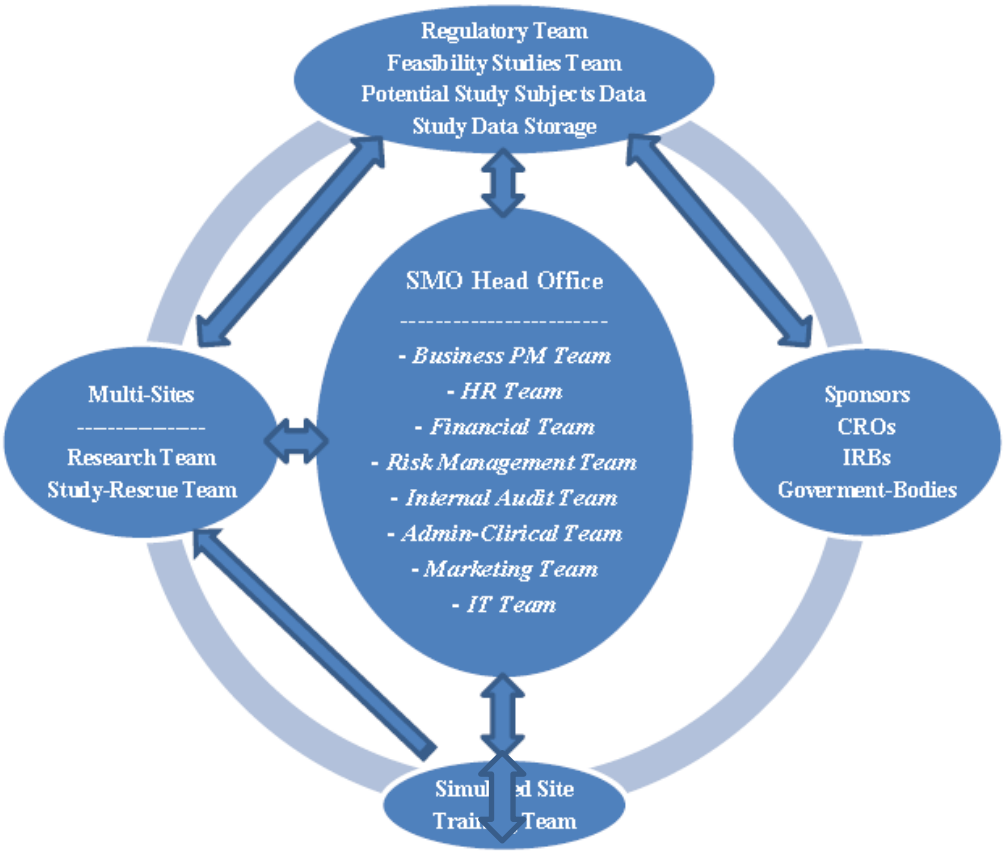

Figure 1. Proposed Innovative Multidisciplinary Research Team for Multi-sites Organizations
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Conclusion

The well-developed SMO has a potential of great advantages, such as: cost-effective way of sharing resources, cohesive highly qualified research professionals, multi-skilled administrative and regulatory team, rationalized infrastructure, standardized operations, maintain ongoing training, centralized access to data of potential trial subjects, and common data logistics. Therefore, Innovative and reconstructed model of site management organizations as proposed in Figure 1, is in profound and urgent need to ensure clinical research sustainability at the sites and must be taking into deep considerations in order to execute trials successfully to benefit the industry and humanity.

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