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How to Stimulate the Performance of Clinical Research Coordinators

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Abstract

A mutual Dilemma for site management organizations continues to be finding experienced clinical research coordinators. The success of clinical trials depends profoundly on clinical research coordinators as they play a key role in the executions of trial procedures. Therefore, the demand for experienced and qualified clinical research coordinators is extremely high. This article will describe the duties of clinical research coordinators, discuss how to stimulate their performance, and explore the training impact on CRCs.

Keywords: *Clinical Trial; Clinical Research Coordinator; Research Nurse; Study Coordinator; Duties; Challenges; Performance; Training Impact.*

The typical duties of clinical research coordinator (CRC)[1]

The CRC also called: clinical research nurse, research nurse coordinator, nurse research, study coordinator, or research assistant. Also, it is not required that the CRCs must have a healthcare background. However, most of the coordinators are nurses or medically oriented personnel. CRCs may be employed in various settings, including medical practice conducting clinical research, site management organizations, academic sites, and university hospitals.

The CRC is responsible for coordinating and implementing a diverse range of study-related activities, including administrative, clinical or nursing care, subject safety, data collection, electronic data entry, manage submissions and reports to IRB, and maintain communications with stakeholders.

Figure 1. Typical duties of CRCs (If/when delegated by principal investigator) [1]

Typical Duties of CRCS		
Screen patients and conduct assessments	Maintain site investigator/ regulatory files	Supervise other CRCs and/or ancillary personnel
Consent subjects	Order labs and assessments from other care units	Attend site initiation visits (SIVs) or study meetings at startup
Assist with enrolling subjects	Schedule subject procedures and appointments	Attend calls or meetings during the study
Collect data at procedures and follow-up visits	Conduct product accountability activities	Interface with recruitment support vendors
Enter data in EDC systems	Treat subjects during follow-up	Serve as point of contact between sponsor and investigator for study updates
Resolve data discrepancies and queries	Send de-identified consent forms and medical records to sponsor if requested	Manage submissions and reports to IRB
Host monitor visits and complete requested tasks	Send records from investigator files to sponsor for trial master file (TMF)	Communicate with sponsor/CRO on investigator's/ investigators' behalf

Clinical research involving human subjects has become an increasingly complex environment in which to work and be successful. [2] As Figure 1 indicates, CRC is one of the study team who is working directly under supervision the investigator and acting as a liaison between CT players. The

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job description and workload of CRC vary across institutions; however, the burnout is common in CRCs Job dissatisfaction including perceived daily work overload, low endurance, and nurturance personality traits were associated with high exhaustion. These issues may lead to destructive implications on productivity of overall clinical trial activities that may lead to financial, professional and ethical challenges. [3-4]

Stimulating the performance of CRCs

Clinical research is integral to the advancement of medical knowledge and health support services. Successful clinical trials are dependent upon a number of factors; however, none may be more important than understanding the wants and needs of those intimately involved in trial implementation. Site staff, including principal investigators (PIs) and study coordinators (SCs), must dedicate a significant amount of time, energy, resources to ensure trial success, and overall staffing requirements are one of the most expensive aspects of a clinical research program. Study nurses, for example, contribute greater than 30% of their overall time to any given clinical trial[5]

The multilateral nature of CTs requires specialized skills in the areas of the clinical conduct of studies, regulatory compliance, human subject protection, financial control, and overall data and quality management. Therefore, it's not only important to have well-coordinated clinical research experts, but also skills-based team stratification. For instance, a licensed research nurse is best utilized to enroll patients, coordinate clinical aspects, and execute the protocol procedures of the study, rather than spending time completing documentation required by the Institutional Review Board (IRB) or tending to other regulatory matters. In turn, and to ease the jobs of CRCs, the latter should be handled by a trained regulatory or compliance expert. Also, personnel trained in research billing and financial aspects of CTs should be handling budgeting, invoicing, billing, and financial reporting. [6] This type of team hierarchy allows individuals to become experts in specific areas, decrease the CRC's daily work overload, and increase the overall performance.

From the initial phases of trial set-up and protocol review to the final stages of patient retention, training should be made available to all staff and predominantly to CRCs, ensuring that it is tailored to their role and position and also in accordance with Good Clinical Practice guidelines.[6] Moreover, training should be offered via a number of formats to ensure that various learning styles are considered.

A CRC will progress from novice to expert when exposed to a dedicated support system (e.g., a mentor, a network of coordinators, educational resources, etc.). The opportunity to discuss confusing issues, experiences in problem solving, and sharing best practices can be powerful both professionally and personally. There are several internal and external resources available to enhance the CRC' skills and knowledge; these include clinical research professional organizations and academic institutions that offer continuing education and certifications. Also, CRCs must be encouraged to attend applicable, topic-related conferences, webinars, case studies and online courses.

Moreover, the option of conducting a virtual trial or even incorporating simulated clinical trial site into site management organizations may be appropriate training techniques. Simulation places the learners in an active role within the learning environment where the trainee is able to concentrate on practicing without any anxiety that may be associated with the real clinical setting. In the simulation setting, learners are able to learn by experience. Learners focus on a particular situation, assessing, problem solving and making decisions regarding the trial procedures in a realistic, yet simulated environment.

The training impact on CRCs and on overall study processes

A clinical trial can be a long journey that is filled with frequent challenges, therefore competency-based training and professional development is crucial[7] the success of the clinical trials often relies on the CRC's work as a vital member of the clinical research team. The development of competency and decision-making skills is influenced by many factors, including effectiveness and confidence in the ability to accomplish a task or self-efficacy that is believed to increase an individual's abilities to be successful in a task. Confidence in clinical skills or during clinical trial processes may directly influence CRC's capabilities to care for the patients safely, to execute the trials effectively, and to provide quality data properly.

Conclusion

Study Coordinator is the center of clinical trial activities and serves as the main contact or liaison person for human subjects, sponsors, clinical research organizations, ethical review boards, and other stakeholders. Therefore, the role of study coordinators must not be underestimated, and either hidden or imperceptible. Also, the duties and its related challenges of clinical research coordinator must be well-described in order to implement competency-based training and professional development programs. Well-established clinical trial institutions with an adequate trial infrastructure, an attractive clinical research environment, and effective hands-on clinical trial skills will impact positively on clinical research coordinators, minimize staff turnover, and boost the whole clinical trial operations thereafter.

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