Clinical Trial Coordinators – A Vital Sign of a Good Clinical Trial

Clinical trial coordinators (CTCs), also known as nurse coordinators, research coordinators, clinical coordinators, or study coordinators, are considered the hub of the clinical research enterprise and are critical to the execution of a successful clinical trial. In fact, it has been said that, “The daily conduct of any clinical trial lives or dies on the performance of the CTC”. They often manage the majority of the day-to-day tasks associated with conducting a clinical trial and function as the glue that binds many of the pieces together. This chapter will outline many of the CTC’s tasks and show how these duties contribute to the uniqueness and importance of the CTC’s role in the efficient and responsible execution of a clinical trial.

An Evolving Role: Assistant to Research Colleague

Up until the past few decades, principal investigators (PIs) routinely took on the roles of researcher, trial manager, and patient-care provider simultaneously. The delegation of duties to the investigator’s subordinates (particularly those pertaining to trial management and patient care) were an inevitable development in the evolution of clinical trial administration as the complexity of the clinical trial increased. The CTC, once viewed only as an assistant, is more often being viewed as a colleague, as they take on more research-oriented and managerial tasks. The consequences of this change have been a demand for greater and broader expertise among senior nurses and a redefinition of roles for most or all of the trial team, including the PI. It is important to note, since the clinical trial team dynamic is still evolving to this day and teams and trial sites differ, that the CTC’s role is still not clearly defined in the medical community.

However, it is expected that the CTC will be a highly trained and experienced person, often a master’s prepared, clinical nurse specialist, who is nationally certified in his or her field of practice. The Association of Clinical Research Professionals (ACRP) offers a Clinical Research Coordinator (CRC) certification program. Since 1992, nearly 12,000 CRC certifications have been earned worldwide (ACRP Web site: http://www.acrpnet.org). Also, training workshops are available for CTCs through the Society of Clinical Research Associates (SoCRA). These workshops aim to improve overall understanding of the clinical trial process, including regulatory guidelines, good clinical practices, the intricacies of human subject protection, and the various aspects of informed consent.

Getting Started

Even before the initiation of a study, a seasoned CTC may aid the PI in assessing a sponsor’s proposed protocol, and providing feedback on the clinical and logistical feasibility. Having the CTC review the details of the protocol can have a positive impact on trial efficiency. A physician eager to conduct research on a particular topic may not focus on whether his or her practice has the necessary equipment or recruiting capability to serve as a trial site. CTCs, with so much time spent “in the trenches,” may be more apt to catch potential complications before they become actual problems during execution. For example, the CTC may recognize that the sponsor’s design of a data collection form may be overly elaborate, and can work with the sponsor to address the issue. Additionally, the CTC often has a significant role in preparing the institutional review board (IRB) or other ethics committee submission documents.

Subject Recruitment and Enrollment

After the protocol has been IRB approved, the CTC takes on the task of managing the subject recruitment process. It has been shown that the involvement of a CTC strengthens subject recruitment
numbers. CTCs often are the ones to conduct eligibility screenings, and it is usual for about 1 in 4 potential subjects who are screened via telephone to meet the criteria and actually become study participants. For potential study subjects identified by the CTC via telephone, an in-person interview is scheduled. At the interview, which the CTC usually conducts, the nature of the research is discussed, informed consent is obtained, and a health history is documented. In some cases, CTCs make assessments of the subject.

At sites where multiple clinical trials are conducted simultaneously, a CTC’s duties can become even more complicated. These trial sites, which can be private institutions that exist solely for conducting studies or are hospital affiliated, may create a central office that is responsible for employing and assigning CTCs to the individual studies being conducted at the facility. Thus, a CTC may not work with the same investigators and staff for each trial, and must be able to adapt to different specialties, protocols, processes, and personalities. Cooperation between research personnel is essential for these trials to reach adequate enrollment numbers. A CTC, therefore, may be asked to help identify potential subjects for a trial that is being managed by one of his or her colleagues.

Subject Protection: A Job for an Interpreter

CTCs, who are the link between the subject, the investigator, and the nursing staff, are uniquely positioned to protect subjects. Much of the subject’s knowledge of the study comes from the CTC, starting during the recruitment process, continuing with informed consent, through the treatment period, and not ending till after exit examination and follow-up. The importance of establishing and maintaining relationships with subjects is not to be overlooked. Simply having a casual conversation with a subject might make the difference between someone who completes the study and one who drops out.

Absolutely vital to the CTC’s job is functioning as an interface between the investigator and the trial subjects. Through interaction with the subject, the CTC is privy to information that the investigator may not possess. The CTC is the most likely person to whom the subject will express his or her concerns about the trial. Also, subjects are more likely to report symptoms to the CTC than to the PI. Direct interaction with both subjects and trial team members make the CTC the most successful patient advocate on the staff. One need not wonder why the presence of a CTC improves subject retention rates.

A Team Player

The CTC is vital to good communication between all of the trial team members. Frequently, the PI’s instructions to staff are conveyed through the CTC. This is beneficial to the PI, because he or she only has to provide instructions once, having confidence that the other staff members will be instructed accordingly. It is also advantageous for the CTC to be the one instructing staff members because CTCs understand an unusually wide range of perspectives and can anticipate concern regarding particular instructions. Every member of the team approaches his or her duties from a different perspective. For example, the PI may see the trial through the lens of an investigator; nurses may focus more on the patient-care aspects, and other team members may be concerned primarily with administrative tasks. The CTC has a hand in all of these responsibilities, and, thus, may better understand the perspectives of other trial team members, which facilitates team communication.

CTCs and the Outside World

The CTC also serves as a significant external liaison on behalf of the trial site. The CTC often is the site contact with sponsors, clinical research organizations (CROs), site management organizations
(SMOs), and even regulatory agencies. Such duties may include the transfer of data from the site to the sponsor or CRO and managing regulatory agency audits. Communication from the sponsor and these other organizations to the study site also often flows through the CTC.

**Role Interactions: Potential for Conflict?**

Despite the importance of the CTC's liaison function, one of the more often cited challenges of the position relates to role interactions. This challenge stems from a perceived conflict between research obligations and patient-care obligations. The CTC sees himself or herself as both an investigator and a caregiver. An investigator wants subjects to participate not only because he or she thinks that the subjects may benefit but, also, because he or she sees the trial as serving a greater good. A caregiver, on the other hand, is solely concerned with caring for the patient. Reconciling these duel roles is not always easy, and, some say, is not fully possible. An example may be a patient who has a condition that would make him a good candidate for a clinical trial, but the CTC doubts he understands informed consent even though he says that he does. The question becomes, “Should this patient be enrolled or not?” While the investigator may not be fully aware of the patient’s level of comprehension, the caregiver may decide not to enroll this patient even though there is no obvious objection. When the CTC is approached by those seeking treatment, he or she has to take care in communicating, sometimes continually, that the subject may or may not receive what he or she was expecting. Balancing messages of hope with messages of realism is a daily challenge for the CTC.

**The Many Duties of a CTC**

Adding to the complexity of the position, the CTC is responsible for many of the day-to-day responsibilities of running the trial. For example, the CTC manages the scheduling of initial visits, follow-up visits, and any necessary further testing; arranges the shipment of specimens to be tested; and dispenses the investigational compound. The CTC may also assist with managing the recording of trial data. All relevant trial information pertaining to a particular patient is recorded in source documents and then transferred to a case book or on an electronic handheld device, which is held in a secure area that is accessible only to authorized members of the clinical trial team. If the CTC is not responsible for the actual recording and managing of this information, he or she will likely be in charge of managing those staff that do—often nurses or data input specialists. One survey identified 128 different tasks often carried out by CTCs.

The CTC is often responsible for monitoring subject adherence, and is essential for ensuring adherence by assisting subjects who may be having trouble keeping appointments and taking study medications. Following study completion, the CTC may interpret the results of the study for the subjects, especially if continued monitoring is necessary or study medication is still being supplied to the subjects prior to marketing approval, as is common in developing countries. They may also discuss any suggested follow-up treatments that may be beneficial for the subject outside of the study setting.

**Skills**

To accomplish all of the necessary duties, the position of CTC demands many skills. For managing much of the day-to-day trial tasks, organizational and leadership skills are paramount. The CTC must be able to manage and motivate both staff and subjects. Teaching and instructional skills are necessary, considering that CTCs are required to clearly spell out complex issues, such as the intricacies of informed consent and trial protocol, to subjects who are often ordinary people with no medical or research backgrounds. CTCs also frequently train much of the clinical trial team. Therefore, not only because of their extensive liaison functions, but, as educators, CTCs are expected to be master communicators.
In addition to the managerial and interpersonal skills needed, a superior CTC also must have collected a vast amount of research knowledge. This includes research methodology, IRB and regulatory requirements, including the Health Insurance Portability and Accountability Act (HIPAA) privacy rules, and the trial site’s institutional framework. CTCs need the expertise to recognize problems involving both subjects and staff members. With advances in technology yielding an abundance of software, particular to tasks such as testing, recording clinical data, recruiting, screening, and randomizing subjects, significant computer skills are also essential.

CTCs Really ARE Vital

According to Eaton & Pratt, “The first and most important job [of PIs] is the timely, careful selection of [CTCs] and their training prior to the initiation of the trial”. This is not surprising, given the CTC’s almost ubiquitous presence during all periods of the trial. Also not surprising is that the presence of a CTC has been shown to increase overall study efficiency. Furthermore, in a survey funded by the National Institutes of Health, the majority of respondents, all clinical research professionals, responded that, out of all clinical trial team members, including the investigator, the CTC position is the most time- and work-intensive, requires the greatest technical and interpersonal skill, and, interestingly, is both the most stressful and the most satisfying. With so many CTCs regularly attending research conferences and annual scientific meetings, as well as coauthoring papers in top-tier journals, CTCs should be viewed as professional research colleagues. It has been observed that when the investigator sees the CTC as a research professional, the trial site produces higher-quality data than when CTCs are seen as merely support staff.

With changing technologies, new regulations, and an increase in complexity of drug development, the role of the CTC will continue to expand and evolve. And the importance of this member of the clinical trials team will continue to grow.

Resources


