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Project Managers Influence Parallel Planning and Collaboration Between Sites and Sponsors

PEER REVIEWED | Romiya Barry, MSc | Joe Coffie, CCRA | Catherine Pui Yin Mok, MSc, CCRP, CCRC | Jill Chapman, BHSc, CCRA

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Clinical research is a dynamic field. Changes in regulatory requirements, market demands, and clinical practice can affect clinical project design and study timing. To plan and execute a clinical trial today can take years and cost hundreds of millions of dollars, but what is most at stake is the relevancy of the drug or device to the intended patient or user.

LEARNING OBJECTIVE
After reading this article, participants should be able to explain what parallel planning is in project management, provide examples of how it can be implemented in a clinical trial, and use it in their trials.

DISCLOSURES
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Nothing to disclose
Jill Chapman, BHSc, CCRA:
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It is critical that studies are conceptualized, initiated, and reported efficiently. Successful trials must be both scientifically sound and managed according to best practices, but it has been reported that many clinical trials fail to deliver because of the lack of a structured, practical, systematic approach to trial management.[1] A robust clinical project plan can have a powerful impact on increased efficiency in all phases of clinical trial development and implementation; this can be supported by a strong, collaborative approach in project management.

Parallel Planning in Project Management

Many business and project management systems are available on the market. However, while the use of tools like SAP Business ByDesign, Microsoft SharePoint Server, ProjectManager.com, ALLEGRO® CTMS, and others may garner different results for different users, the importance is having effective project leadership—whether identified by title or delineated based on the responsibilities of a person's role—at the sponsor/contract research organization (CRO) and clinical site levels.

A representative for each entity involved in the study should be responsible for initiating, planning, executing, and monitoring the project plan on his/her respective side of the overall project. These project leads (project managers) ensure that the tasks are carried out appropriately and according to the plan. Project management systems are great tools for ensuring both parties (sponsor/CRO and site) have the opportunity to review tasks associated with the project.

The project managers at the sponsor and site also are responsible for communicating with one another about their respective project plans using a pathway that can be documented for each study. This communication pathway facilitates the parallel planning approach. In current practice, it is often the case that a sponsor shares its study timeline with the site during the investigator meeting or site initiation visits, but regularly fails to actually discuss the timeline and plans for executing the study.

Use of project management systems can be optimized in a parallel planning approach by inputting site start-up timelines and enrollment rate projections (as two examples). With this information in hand, the sponsor can then look at the overall study in a "big picture" view and make informed decisions that may impact the study. For example, a particular region has one site that can be ready for a site initiation visit early, but is not expected to be a high-enrolling site, and the remaining 10 sites will be ready three months later. The sponsor may decide to delay study launch in that entire region until the time that all sites are expected to be ready. In so doing, the personnel resource requirements would be optimized, and sponsor/CRO resources would thus be directed to the other regions that are expected to be ready sooner.

Study Timelines: A Shared Responsibility

Utilizing a consultative approach by involving all stakeholders as early in the project development as possible takes into account the perspectives of the sponsor, the CRO, and the investigative site, thus reducing chances of decreased scientific relevance resulting from changes in standard-of-care that occur while the clinical project is in development. Clinical trials guided by strong communication between sponsors and sites are more successful and enjoyable, as they contribute to "pride in ownership."

All stakeholders should prospectively establish a clear understanding of each party's responsibilities and of the expectations for the conduct of the project. Often, face-to-face communications about study data quality are important steps to starting on the right foot or for getting a fledgling project on the right track.

Both sponsor/CRO and site clinical trial project managers are challenged to balance project needs, each other's requests, and the site's abilities in implementing new initiatives for a particular study. One approach to gain efficiency and increase power in planning is to use parallel planning rather than a common "authoritative" approach whereby the sponsor tells the CRO and sites what needs to happen and when.

In a parallel planning approach, each aspect of the clinical trial project plan is reviewed simultaneously from the perspectives of the site and the sponsor. This approach could foster more openness about the schedule and timeline risks, empower the site to positively influence the study schedule, and promote a collaborative culture of a shared project.

Ideally, a sample of sites should be used in parallel planning from the very beginning of the trial (from the feasibility stage). When conceptualizing a project and reading the study design synopsis, project managers at both the sponsor/CRO and the site may use a checklist to determine if the project is "Feasible, Achievable, and Believable" (see Table 1).

The early discussion phase between the sponsor and site about study feasibility is ideal for beginning parallel project planning. When planning the project, research team members from both the site and the sponsor/CRO should understand the required study coordination activities ranging from the project's conception to site initiation. During this time, leaders from both parties should discuss and make a go/no-go decision so resources can be focused where needed.

Outlining and following the study-related processes and procedures at each entity could allow for identification of parallel processes and help identify any early roadblocks. By establishing

TABLE 1: Shared Project Concept Review

	PROJECT MANAGER	
	Sponsor	**Site**
Is this study Feasible?	Define reasonable eligibility requirements and sample size for the protocol synopsis.	Confirm the site has an adequate targeted patient population that correlates with the protocol eligibility requirements.
	Clearly state the objectives and required activities of the protocol, limiting optional study activities unrelated to the objectives.	Understand if the study procedures can be performed appropriately with special attention to procedures outside the standard of care at the site.
	Specify equipment requirements that may not be standard or in routine use at studies sites (e.g., research equipment vs. clinical equipment).	Consider if any special equipment is needed to perform the study procedures described in the protocol.
	Determine with biostatistics and medical director if the study is similar to previous investigations; provide rationale for repeating the study or modifying the study design based on results of the previous evaluations.	Evaluate the rationale of the study design with respect to clinical practice at the site.
Is this study Achievable?	Propose a detailed, fair market value budget that captures the cost of procedures in the protocol.	Does the protocol include the cost of all activities and manpower required to support the protocol?
	What are the anticipated regulatory challenges for study approval in each study country?	What local ethical considerations are required for this study or were required for similar studies in the past?
	Are there temporal factors that could influence the study conduct, such as seasonal effects?	
	What is the overall timeline and what are the milestones each stakeholder needs to achieve?	
	Identify plans that can be put into place to mitigate threats and capitalize on opportunities.	
Is this study Believable?	How will the results be used?	Can the results be used for internal institution education, published in peer-reviewed literature, or disseminated to study participants?
	Are the study endpoints and expected results supported by medical advisors?	Are results relevant to clinical practice? Could these results advance medicine?
	Do the study endpoints and expected results support the user need requirements?	For patient-centered studies, are results relevant to patient needs?
	Are the study endpoints and expected results comparable to similarly available medical products?	Do the endpoints and expected results promote community public health?
	Do the study endpoints and expected results meet the expectations of regulatory approvers?	
	Is the protocol designed to be statistically credible?	

TABLE 2: Guiding Principles for Sponsor/CRO and Site Collaborations

Recommendations for the Sponsor/CRO	Recommendations for the Site
GET STAKEHOLDERS ON THE SAME PAGE	
• Write a well-summarized project synopsis that can be distributed to internal and external team members	• Discuss the protocol with the entire team/staff and obtain feedback
DEFINE OBTAINABLE GOALS WITH SPECIFIC TIMELINES	
• Create a project plan that includes dates for deliverables from the sponsor, CRO, and site • Ask the site for timelines to meet the project goals	• Ask for project timelines • Request sponsor's/CRO's expectations for milestones in the phases prior to, during, and after the study conduct
IDENTIFY RESOURCES NEEDED TO ACHIEVE GOALS	
• Be specific on the sponsor/CRO responsibilities • Provide specific examples of support that are available to the site if needed • Prepare a detailed, fair market value study budget • Communicate the expectations the sponsor/CRO has for the site in terms of time, personnel, facility, and budget	• Review schedule of events of the protocol and confirm that all necessary resources are available • Ensure study budget accounts for all financial burdens
GET STAKEHOLDER BUY-IN	
• Document agreement on the goals with all stakeholders • Identify areas of disagreement as potential risks to the project and create a risk management plan	• Review tasks and delegation with impacted staff
REASSESS STAKEHOLDER UNDERSTANDING	
• Prepare efficient and effective investigator meetings • Conduct site initiation visits that include re-training and review of the goals and timelines	• Ensure all concerns are addressed by sponsor • Ensure all impacted/assigned staff are present at the site initiation visit or investigator meeting when possible • Ensure absent staff are trained on their study responsibilities

A robust clinical project plan can have a powerful impact on increased efficiency in all phases of clinical trial development and implementation; this can be supported by a strong, collaborative approach in project management.

deadlines for completion of critical tasks, the impact of delayed or missed targets on subsequent activities can be minimized. For example, Cheng et al. found that trials that did not have a patient enrolled within the first two months of trial activation were significantly less likely to achieve the minimum accrual target, despite the length of time the trial remained open.[2]

By including constraints on when it is acceptable to achieve the critical task of "first patient in" for a study, the risk posed by poor enrollment to a site's performance—and to overall study enrollment—may be identified earlier in the initiation phase. The above-mentioned study found that, as the two-month mark in an active trial was approached, the project managers at the sponsor and site could review if their collaboration on the study was still Feasible, Achievable, and Believable. If both parties were still willing to move forward, then a working plan could be put into place.

Continued engagement is crucial for mitigating reduced enthusiasm about the trial. Throughout the course of the project, the clinical project managers should complete quarterly or biannual reviews of the final plan. These periodic reviews provide an opportunity for discussion on whether changes are required to the parallel plan, based on the status of the project and possible future impacts to the project timeline.

Developing and Defining Meaningful Metrics

Sponsors and CROs should set expectations, but also should ask site personnel how they view their own current levels of quality and how they feel these levels can and should be measured. This is a conversation worth having up front, and not an item to be buried in an investigator pre-qualification questionnaire or site qualification checklist. According to one source, "the quality of our decisions depends at least in part on the quality of the information on which we base them,"[3] so communicating the standards and metrics for evaluation allows site staff to focus on critical elements for study management and adapt the methods as needed.

In a survey of Society for Clinical Research Sites members, less than 50% of respondents reported strong agreement that sponsor/CRO teams effectively communicate their expectations regarding quality to sites.[4] In recent years, new initiatives and guidance documents have been introduced as a method for sponsors and CROs to enhance and evaluate site performance, quality, and sustainability as a means of improving the quality of clinical trials.

Care should be taken to ensure that site quality and performance metrics are not defined solely from the industry's perspective. Sponsors should not create program-level metrics that do not fit with a specific project at the risk of inundating the top-performing sites with unnecessary requests and requirements just to meet poorly designed metrics—especially ones that are disruptive to research processes at sites that have been proven to work well.

To combat the "metrics mania," some sites have instituted their own metric systems to evaluate sponsors. However, similarly, the ability to act on some of the metrics is limited because they are not associated with actual steps in the project plan upon which the sponsor can improve.

Overall, metrics should be value-added and meaningful to both the sponsor and the site. A simpler, more focused initiative may be for project managers to identify areas of concern at their own organizations and at partner organizations.

Co-Managing Study Changes

Parallel project planning would also identify any flexibility in the project plan for expansion of time, costs, or scope. Due to the dynamism of the medicine, new information may be published or learned from clinical practice that could severely impact the study endpoints, or even introduce new concerns about risks to participant safety and data reliability.

Similarly, regulatory changes can have a huge impact on project plans. Even changes aimed at improving the efficiencies of clinical trial operations, such as the adoption of electronic data capture or risk-based monitoring, may result in undesirable outcomes to the study operations when inappropriately initiated in the study plan. Unless experienced at a great frequency, changes at a site level (e.g., staff turnover, new contract negotiation processes, etc.) may have a smaller impact on the overall project timeline.

Project plans are often inflexible to changes or expanded project scopes, yet project amendments still occur in response to new information. These changes affect the work of all stakeholders; however, it is often the case that the overall project plan is only adjusted to reflect the additional work required from one group.

Since the sponsor usually develops the original project timeline, adjustments to the schedule generally are made only for activities internal to the sponsor's operations. In some cases, the impact of the change comes in terms of extra effort by the site to maintain the expectation for the duration of work. In a parallel planning model, the impact on the amount of effort and the duration of work for both the sponsor and the site would be captured in the updated timeline.

When the details of changes in a study's scope and operational models are not communicated prior to implementation, the activities needed to support the changes may not be fully accounted for in the time, budget, and resource allocation of the project plan. Additionally, standard operating procedures (SOPs) often cannot be adapted easily to unique situations that may present during the course of the project.

Early identification of procedures for co-managing study changes could minimize such barriers to the study's progress as described here. These procedures may include mechanisms for revising and updating SOPs expeditiously, so they can be readily implemented during the conduct of the clinical trial. This level of engagement requires communication skills and a clear communication plan to ensure information from both parties is being delivered efficiently and conveyed effectively.

Leading a Collaborative Partnership

It is critical that the project managers from both the sponsor and the site provide strong leadership, set the tone for shared collaboration in the projects, and resist the urge to show off their authority to one another. With a historic culture of having "sites as customers" and the "customer is always right" mentality, shifting to the "sites as suppliers" concept and following the practices of supply management require a focus on finding balance in the relationship.

A post in response to the recent "Site Empowerment Series" of webinars from Forte Research Systems stated that "one of the easiest ways to improve site-sponsor relationships is for sites to take control."[5] Reading past that bold—and somewhat aggressive—statement, the content of the webinar series supports shared collaboration, by which the clinical project is a partnership between the site and the sponsor that is founded on open communication and transparency in the planning, conduct, and reporting of the study.

Conclusion

Good management at both the sponsor and site level is essential to the delivery of high-quality trials. More specifically, sites that are (or want to be) known as being committed to providing quality data have high-performing clinical project managers, and their counterpart project managers with at least equal skills on the sponsor/CRO side likewise contribute greatly to the successful delivery of clinical programs.

Using a few guiding principles for early engagement can lead to a culture of shared collaboration on the clinical project (see Table 2). Far from being a "team of one," successful clinical trial project managers have the ability to work effectively with each other and with all of a study's stakeholders to define the clinical program requirements, shape the output of projects, and drive successful outcomes.

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Risk-Based Monitoring:
Changing Roles, Changing Mindsets

PEER REVIEWED
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The adoption of any new concept or technology in organizations is generally slow and usually meets with some resistance from the intended end-users. Some of the issues with adoption of new technologies are the users' comfort level (mindset), the time needed to make changes, the costs involved, the strength of the proof of value/concept presented to users, the ultimate level of user acceptance, and the performance and reliability of the technology itself, including the factor of whether it will continue to provide value to the organization.[1]

Risk-based monitoring (RBM) is still a relatively new method of performing clinical trial monitoring. It uses a combination of modern technology and protocol information to define study risks and analyze the frequency and type of monitoring to be conducted for a given trial.

RBM is supposed to provide a more structured and proactive approach for monitoring to generate higher quality data without compromising subject safety or data integrity. This in turn is expected to lead to better acceptance of data by regulatory authorities.

As RBM continues to be promoted as the new best practice in monitoring of clinical trial data, just as with any other new technology it is likely to face resistance to its widespread adoption. In fact, one of the biggest challenges in adopting RBM appears to be changing approaches/attitudes on the part of those who are directly or indirectly involved in monitoring of clinical trial data.

Let's have a look at the three prime stakeholder groups impacted by the use of RBM—sponsors, investigators/site teams, and regulatory authorities—and some of their representatives.

LEARNING OBJECTIVE
After reading this article, participants should be able to understand the different stakeholders and their responsibilities in successful implementation of risk-based monitoring.

DISCLOSURES
Vipul S. Halbe, MSc, CCRA, CAPM;
Jeroze Dalal, PhD:
Nothing to disclose

Sponsors

A sponsor is an individual, company, institution, or organization responsible for the initiation, management, and/or financing of a clinical trial.[2] Sponsors may be considered the primary stakeholder where the process of conceptualizing, implementing, and sustaining RBM is concerned.

When RBM was still in infancy, its proof of value had yet to be harnessed on a large scale.[3] Even now, the sponsor's return on investment for RBM may be slow. For a sponsor, proactive planning of all processes to be followed in the trial is extremely important, as one of the main sources of risk in a trial using RBM is associated with insufficient consideration of the details surrounding the study population and investigational product.[3]

It is also important to have a system for continuous review, and to fine tune the executed plan for ensuring optimum results. Some operational challenges the sponsor may face in implementing RBM can include the need to review and create a robust monitoring plan, standard operating procedures (SOPs) dedicated to RBM, and electronic data capture systems (including metrics and reports).[4]

Although a sponsor may have initial apprehensions about adopting RBM, it is noteworthy that some important mortality outcome studies using RBM have generated credible and valuable results, despite having very few onsite monitoring visits.[5]

Within the category of sponsors as the main entity, four main functions that need to adapt to RBM methodologies are in the realms of the data manager, project manager, monitor, and auditor.

DATA MANAGER

The data manager for a sponsor is primarily responsible for providing the framework for how study data should be entered into the case report form (CRF) and ensuring that the received data are analyzable. Historically, a data manager's work has been essentially limited to the "back end" of the study (i.e., cleaning the data entered into the CRF as the source data are verified by the monitor at the site).

In scenarios using RBM however, data managers are among the most important players. As RBM includes use of software technology, data managers must not only learn nuances of new technology, but also ensure an automated, error-free run during the actual trial conduct. RBM puts data managers on the front line in the quest for high-quality data, as they are the ones having large amounts of data fed to them (usually in real time) for sorting and identifying trends that affect the study.

In some settings, data managers may be in a position to make the call on deciding how monitoring visits for a particular site should be conducted, based on risks that have been identified up front and then tracked during the course of the study. This will require them to be more vocal in their communications, as well as to spot trends at a much faster rate for effective resolution. Thus, the domain of data monitoring may be integrated with data management over time. In other words, the data manager's role could evolve to include responsibilities of a monitor, and even those of an auditor.

Another important, and often overlooked, aspect of the data manager's functions in light of RBM is the responsibility for facilitating effective competency to ensure minimal data entry errors. Since RBM is a concept based on identifying, assessing, monitoring, and mitigating risks to the quality and safety of studies, strong systems for training and other foolproofing methodologies need to be in place to minimize chances of error, before removing the need for actual monitoring visits.

PROJECT MANAGER

A project manager is an individual whose main responsibility is to ensure day-to-day management of the trial at the operational level.

Typically, a project manager's role has been oriented toward study/project management on the basis of information provided by the monitor through review of monitoring visit reports. Within the context of RBM, the project manager needs to consider inputs not just from the monitor, but also from the data manager (for metrics/hard facts and figures, such as quality metrics). The project manager's role will also extend to data monitoring to ensuring that the monitoring activity plan for each site is followed efficiently.

Some of the important metrics that a project manager must pay attention to cover type of visit, number of queries, time onsite, noncompliance, and monitoring action items open/closed.[3] Further, project managers play a major role as coordinators/mediators between data managers and monitors. In fact, owing to there being so much overlap in the roles of data manager and project manager, there is a possibility that these roles may be combined into a single staff position in RBM studies.

MONITOR

A monitor is an individual who oversees the progress of the clinical trial at the investigative site level, and who ensures that the trial is conducted, recorded, and reported in accordance with the protocol.[2]

The monitor's role in RBM is modified greatly compared to the case if he/she is used to performing 100% source data verification and making frequent onsite visits. A traditional monitor often verifies 100% of a study's data, however there is no guarantee that this practice improves data integrity or an investigator's oversight. As a result, there is a requirement to fine tune monitoring to address keys risks associated with the study.

One focal point of RBM is to tackle study-critical data first, along with any changes to those data that may lead to changes in the study's outcome.[6] The monitor needs to adjust to the fact that the way data will be monitored will not be solely his/her call, but may come to be influenced more than is now common by the data manager, who is remotely located and generally does not contact the site. This may sound like a negative, but should actually be considered an added weapon available in the monitor's arsenal.

One of the biggest challenges in adopting RBM appears to be changing approaches/attitudes on the part of those who are directly or indirectly involved in monitoring of clinical trial data.

RBM puts data managers on the front line in the quest for high-quality data, as they are the ones having large amounts of data fed to them (usually in real time) for sorting and identifying trends that affect the study.

To further elaborate on this point, a monitor is only exposed to the data generated from his/her site; as a result, that monitor is only privy to those limited trends. In RBM, trend analyses covering all sites will be carried out at a central level with the help of computerized systems. Such analyses may identify issues even before their occurrence; this can only help the monitor to be better prepared for mitigating risk or totally preventing risk factors from becoming problematic.

The monitor would be required to unlearn legacy methods used in the past, and to adopt such new monitoring practices as using a combination of onsite and offsite visits, relying on remote contacts, and sometimes having no ongoing contact for certain sites. In this environment, communication skills will play a wider role in RBM, as the monitor is expected to relay information to the site and see to it that the proper outcomes occur without making frequent face-to-face, onsite visits.

Communication is also key to the process of the monitor receiving information about the monitoring activity plan from the data manager. A monitor becoming familiar with RBM will require not just training, but cooperation and support from the data manager, study manager, and members of the site team.

AUDITOR

An auditor is a sponsor representative who performs a systematic and independent examination of trial-related activities and associated documents to ensure that they were recorded, analyzed, and reported accurately according to the trial protocol, the sponsor's SOPs, and applicable regulatory requirements.[2]

To improve overall quality and confidence in the RBM model, an evolution in the quality management mindset is required. Auditing a study employing RBM may be challenging, and will certainly require a completely different approach than has been the case historically. The following list gives some of the main reasons for this state of affairs:

- Data reviewed during an audit may not match the RBM plan fixed for a particular site/study. To eliminate bias from an audit perspective, it is also vital that the audit plan and RBM plan are prepared independently of each other.
- There are multiple overlapping responsibilities among the data manager, study manager, and monitor roles. Hence, it is necessary to identify in advance who will provide corrective and preventive actions (CAPAs) for any given type of observation.
- Continuous trend analysis is an innate process within RBM. Thus, RBM also overlaps the domain of the audit function, which may lead an auditor to change his/her processes regarding what to audit, how to audit, and even whom to audit.

Given these factors, two main aspects that an auditor needs to review in an RBM environment are as follows:

- An auditor needs to ensure that the RBM processes—especially those followed to mitigate risks—are set up adequately at the start of the study.
- During the active part of the study period, an auditor needs to confirm that all of the planned processes are actually working in practice (i.e., are the monitoring activities being conducted as per the prescribed monitoring plan). There have been instances in which the auditing team has observed that, despite having the availability of centralized/remote monitoring activities, the monitors have fallen back on conventional methods of monitoring.[7] This makes the intentions behind using RBM techniques counterproductive, since monitors will still be reviewing voluminous amounts of data at reduced efficiency, with little or no impact on data quality. The primary root cause of this issue is again resistance to change in mindset.

Investigators/Site Teams

An investigator conducts the clinical trial at a site, and is usually supported by a team comprised of medical and nonmedical staff.

For the investigator and his/her team, RBM still means following the study protocol, conducting the informed consent process, recruiting patients, maintaining study drug supplies, attending to source documentation, making safety reports, updating CRFs, and other tasks. What changes for the site team members is how their data are monitored/audited by the sponsor.

In RBM, more remote/offsite monitoring may be undertaken instead of onsite visits made. Hence, for RBM to be successfully implemented, it is essential that sites attend to the aforementioned unchanged activities in a timely manner and without any compromise in quality.

RBM shifts much of the onus of data integrity and quality back to the investigators and their teams. Site staff must consider the offsite visits/contacts as seriously as the onsite ones.

Moreso than a sponsor, the investigator has the best opportunity to mitigate risk to the subject and, in turn, to the study.[3] This, in a way, impacts sponsors as they identify potential sites for studies in which RBM will be adopted. In RBM, sponsors may opt for sites with a track record or reputation for compliance with protocols and safety measures. This may lead to more stringent filtration of sites for selection, which will in turn challenge the best-performing sites to recruit more patients and simultaneously maintain high standards of quality.

Regulatory Authorities

These are legal governmental agencies whose members formulate the rules and regulations associated with pharmaceutical products in their own countries. All stakeholders are required by law to follow these rules while performing clinical trials within those countries.[2]

Regulatory agencies such the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) already have created guidance/position papers on the RBM approach[8,9] that endorse RBM and encourage sponsors to adopt it in new studies. Sponsors of multinational trials for which data are expected to be submitted to the FDA and EMA are already implementing RBM.

Although the FDA and EMA are globally influential agencies, they surely do not govern countries beyond their jurisdiction. This leaves many countries around the world where clinical trials are being conducted using the International Conference on Harmonization's Guideline for Good Clinical Practice E6[2] as guidance on RBM. There remains a need to sensitize and educate other regulatory authorities for a globally standardized RBM adoption.

Regulators should make frequent contact with all stakeholders and consider their feedback on the functioning of RBM and how it can be further evolved for higher success. Regulatory agencies that have no guidance on RBM should connect with those agencies that do, and update their processes to seamlessly adapt to newer methodologies.

Conclusion

With an embrace of RBM, the clinical research enterprise is poised to become more effective in an environment geared toward doing more with less. There is no doubt that for RBM to evolve successfully, the key stakeholders involved need to adapt and simultaneously improve upon their RBM approaches in a variety of ways:

- Sponsors must accept and invest in the initial cost of setting up the infrastructure of RBM, as well as define new processes for implementation of the same.
- Sponsor-based representatives of different functions of clinical trials must step out of their comfort zones and accept the changes implicit in RBM, update their skills, and let go of some or many of their old routines.
- Investigators and site staff must ensure that they provide high-quality data without frequent intervention from the sponsors, and recognize that the data generated from their sites will be subject to scrutiny in real time.
- Regulatory agencies should perform a lead role in ensuring consistent implementation of RBM methodologies across all stakeholders and across regions.

All of these changes to individual roles will be followed with changes in mindsets to create a beneficial paradigm shift in the way clinical trials are conducted.

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Workforce Development for Clinical Research Associates: Evolving Paths to Competency

PEER REVIEWED | Nicole Tesar

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One of the greatest challenges facing the clinical research enterprise today is ensuring that a qualified, competent workforce is available to carry out its activities. Those of us already working in clinical research know that the downstream effect of having a highly qualified team is bringing new products to market quicker. The role of the clinical research associate (CRA) or monitor, like so many others in the industry, is challenging to break into, and one reason is the high standards set by employers for job entry.

LEARNING OBJECTIVE
After reading this article, participants should be able to understand the importance of having a workforce development program in place for CRAs, recognize some of the related challenges that organizations face, and describe potential models for success.

DISCLOSURES
Nicole Tesar:
Nothing to disclose

An innovative approach to hiring new entry-level CRAs needs to be created—an approach that would fill the business need and give intelligent, motivated people a chance for success in the industry. Once new staff have gained experience, thoughtful measures must also be taken to continue training and professional development that ensures ongoing career success.

Getting in the Clinical Research Door

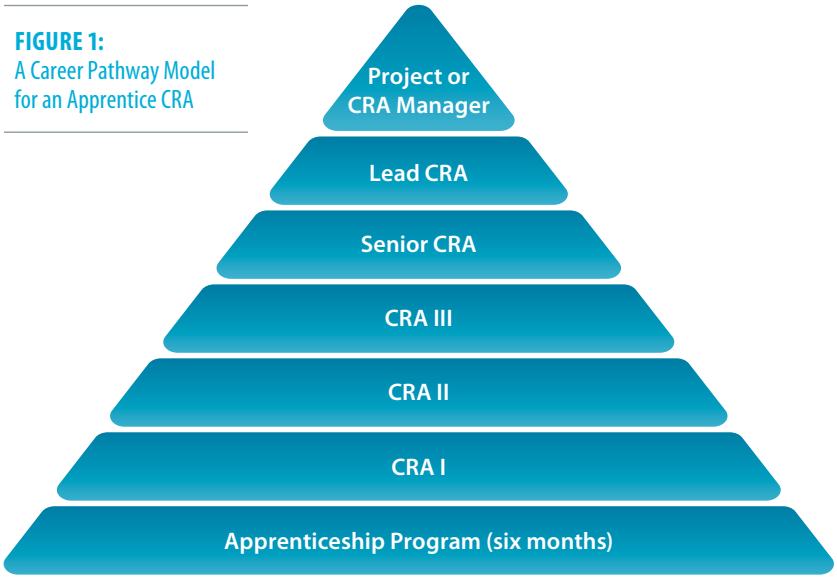
As an independent CRA, I have received LinkedIn messages, phone calls, and e-mails from many individuals looking to break into the clinical research industry. Ultimately, what they are looking for is a clear cut formula for getting their foot in the door without having direct experience. There are individuals out there with potential to be valuable assets to an organization, but they need an opportunity. Possible routes into the clinical research arena include networking, volunteering, and internships,[1] however, there is no prescribed route for CRAs.

An arbitrary requirement for CRAs to have at least two years of experience is still in place at most contract research organizations (CROs) and sponsor companies. This raises the question: To what extent are employers valuing clinical research credentials/education, and how do the employers validate that individuals with these credentials are superior to those who do not have them? Conversely, how do job seekers find those particular companies that do value them?

To help point CROs and sponsors in the right direction, in 2013 the Joint Task Force (JTF) for Clinical Trial Competency was formed to develop competencies and skill requirements for the clinical research professional. Eight competency domains are highlighted in the JTF's projects, including scientific concepts and research designs, ethical and participant safety considerations, medicines development and regulation, clinical trials operations (Good Clinical Practice [GCP]), study and site management, data management and informatics, leadership and professionalism, and communication and teamwork.[2] The goal of this group was to align both skill and competency requirements for the industry professional.

It is not uncommon for companies to want a mix of skills, degrees, and general competencies for their CRAs. For the beginner CRA, the challenge becomes how to demonstrate skills and competencies despite a lack of prior work experience. As an industry, we have an obligation to bridge the gap between the inexperienced and seasoned CRA. One possible solution to this may be an Apprenticeship Program Model.

FIGURE 1:
A Career Pathway Model for an Apprentice CRA



Apprenticeship Program Model

By utilizing apprenticeship as a workforce development strategy, an organization can promote successful outcomes for both its business and job seekers in a manner that helps it find and retain skilled workers with desired traits. Apprenticeship has been shown to be an effective solution for many federal- and state-regulated industries.[3] Research shows that, through an apprenticeship program, companies have been successfully able to recruit, train, and retain highly skilled workers.[4]

The clinical research enterprise has all of the following challenges, which make it ideal for an apprenticeship model:

- Jobs for which it is difficult to find workers with the right skills
- Positions with high turnover
- Challenges helping workers keep pace with industry and technology advances
- Difficulty in attracting new and diverse talent pools

An Apprenticeship Program Model for CRAs would involve a lower pay rate/salary initially, on-the-job training, and low-risk task assignment.

The lower pay rate/salary at the onset lends to less financial burden on the organization. If the apprentice is willing to accept lower pay, the exchange would be the opportunity of a full-fledged job upon successful completion of the program.

Meanwhile, the program is comprised of a mix of classroom training, online modules, and one-on-one training with an assigned mentor. In this program model, the apprentice must pass ongoing skills and knowledge testing.

Finally, low-risk tasks would be assigned as the would-be CRAs learn more about their future role. Examples of potential low-risk tasks include taking meeting minutes during a team teleconference or organizing and filing of Trial Master File documents.

An apprenticeship program essentially involves "You do the job, and then you get the job." Candidates would begin a six-month clinical research apprenticeship, spending one-half day per week on a site visit with a more senior CRA in order to further develop core skills and observe interaction with site staff. Once hired as a CRA, the former apprentice should successfully move upward to a higher level role over time (see Figure 1).

The senior CRA position involved in such a program holds mentoring responsibilities and a decreased site load. Thus, an apprenticeship program incentivizes a potential employee with the opportunity of a job at the conclusion of a successful apprenticeship, as well as providing an opportunity for the senior CRA to grow and add new leadership skills.

However, as no training and development model is perfect, what happens if the apprenticeship program is not successful? What if apprentices decide the CRA role is just not for them? Furthermore, what happens if they are unable to meet the benchmarked requirements of the role?

One important step to reduce such risks is to ensure that the apprenticeship program is long enough. Perhaps the candidates need longer than six months to meet the required milestones. In the case of the apprenticeship model, it is critical to evaluate learned skills frequently to ensure those preset benchmarks are being met. If not, an extension of the program may be required.

Meanwhile, what if candidates decide they no longer wish to pursue the role of a CRA? If an individual has already invested time in a program, and the company has invested in training them, one positive outcome may be that while the CRA role might not be a good fit, perhaps another role can be identified as being of more interest. Part of a solid apprenticeship program would be the understanding of cross-functional roles within clinical research. If a candidate feels that his or her interest has shifted to one of those roles, the CRA apprenticeship may end; however, the potential for a different development plan could be considered to provide more exposure to the alternate role.

While the Apprenticeship Program Model represents a viable option for the novice CRA, other pathways exist to help facilitate this transition. A multiple-mentor workforce program would allow for an apprentice to be exposed to different work styles and personality types. In this model, the candidate would have mentors who are subject

As an industry, we have an obligation to bridge the gap between the inexperienced and seasoned CRA. One possible solution to this may be an Apprenticeship Program Model.

matter experts in specific cross-functional areas (e.g., data management, site management, therapeutic area training).

A learning and personal development model treats people as individuals, targets both traditional work skills and knowledge, and includes whole-person development—not just transference of skills. This model would have a secondary focus on assisting employees in identifying and achieving their own personal potential.[5] Regardless of which route is taken, the presence of a formal program is essential for success.

Training and Development for Existing CRAs

As a CRA begins to gather experience, an ongoing training and development program is necessary. This not only shows that an employer is investing in the CRA's future, but training ensures that

TABLE 1: CRA Attributes and JTF Competency Domains/Harmonized Core Competencies

CRA Attributes	Objectives	JTF Competency Domain(s)	Harmonized Core Competencies
Attention to Detail	Comprehending data completeness and deviations, review of medical records, study protocols, regulatory documents, and conducting product accountability	Data Management and Informatics; Study and Site Management	• Carefully reviewing the importance of data collection, capture, and management, as well as the ICH GCP requirements for data correction • Assist sites in the management of patient recruitment, completion of required procedures, and progress tracking
Organization	• Prepared and well-organized for site visits, training sessions, study meetings, or other type of interaction with sites or sponsor representatives • Needed to ensure maximum efficiency of a site visit and use of investigator's/study team's time • Prioritization (managing most pressing issues first)	Study and Site Management	Effectively train site staff during the site initiation visit to reduce risk and improve quality of the clinical research study at the site
Communication Skills	• Effective interaction with both internal and external colleagues; critical when writing reports and e-mails, conducting training sessions, or delivering presentations at study meetings or external events • Corresponding with cross-functional teams within the organization	Communication and Teamwork; Leadership and Professionalism	• Act as a liaison between the site and sponsor/CRO; effectively communicate the content and relevance of the required procedures • Demonstrate skill, good judgment, and polite behavior during all interactions
Regulatory Knowledge	• Excellent working knowledge of *Code of Federal Regulations,* International Conference on Harmonization (ICH) guidance on Good Clinical Practices (GCPs), and other applicable guidances and regulations • Base guidance to site personnel on these guidances/regulations and be able to direct them to the specific sources when necessary	Medicines Regulation and Development; Clinical Trials Operations; Ethical and Participant Safety Considerations	• Describe the safety reporting requirements of the site, and how that contributes to the development of new drugs, devices, and biologics • Describe the roles and responsibilities of the site staff as defined by GCP guidelines • Explain to sites how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection
Ability to Consume and Retain Information Efficiently	• May need to review hundreds of pages of medical records in order to verify trial data during a site visit • Process large numbers of e-mails, site action items, or study documents • Must quickly and effectively focus on the important information without losing sight of peripheral matters	Data Management and Informatics; Study and Site Management	Understand the typical flow of data throughout a clinical trial and the significance of data quality
Educating Teams	• Necessary for training physicians, study coordinators, and junior monitors	Leadership and Professionalism; Communication and Teamwork	Effectively train and re-train sites throughout the conduct of a clinical trial to reduce risk and improve quality at the site level
Interpersonal Skills	• Ability to effectively work with all personality types and be able to navigate such relationships in a manner that produces results and desired outcomes • Work collaboratively and respectfully with the research coordinator in order to achieve mutual goals and build rapport	Leadership and Professionalism; Communication and Teamwork	• Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research • Understand the principles and practices of leadership, management, and mentorship, and apply them within the working environment

employees are knowledgeable in the ever-changing landscape of the industry while supporting a career path for them.

Training and development of a successful CRA workforce involves a three-step process (see Figure 2). The first step is **skilling**—the basic teaching of a required skill. This initial step typically involves a structured orientation program, including training on company standard operating procedures (SOPs). SOPs standardize the required skills, and are updated frequently as regulations and company expectations evolve. SOPs ensure that the CRA is, and remains, properly qualified and trained for job roles for which he or she is made responsible.

Once skilling is established, the next step is **reskilling**, which involves re-teaching the skills that change or evolve.

Lastly, the third step is **upskilling**—the concept of teaching and training employees beyond their current role to position them for the next role.

Developing Soft Skills

Beyond the challenge of creating and maintaining a robust training curriculum, how best to train on soft skills is a matter to consider. Interpersonal communication and executive functioning are critical in the role of the CRA. This role involves interaction with both external partners (site staff) and internal partners (in-house team members).

CRAs often may have the basics of the communications skill set, but lack the personality it takes to balance relationships. Maintaining positive relationships is key when it comes to keeping site staff motivated and encouraged to get the work done. During the hiring process, employers need to decide what attributes are required and figure out how to not only test for aptitude, but also how to provide ongoing development of these skills.

Workforce Development in a Volatile Market

The work environment in the pharmaceutical and biotech industries these days is characterized by frequent upsizing and downsizing as a direct reflection of the ever-changing pace of product development. These conditions have led to a change in the landscape of the industry, from a primary dependence on the hiring of full-time employees to an "on-demand" approach to resourcing and the inclusion of consultants and contract workers.

FIGURE 2: Phases of Ongoing CRA Training

When considering training and development, companies are on a "slippery slope" regarding consultants/contractors, as they are only to be provided training in order to successfully complete the job to which they are contracted, and not to grow outside that role (which could be perceived as development). Developing skills and broadening one's knowledge base for future work is the responsibility of the individual in this case.

A good CRA consultant/contractor will want to continue to grow in the role. By making an investment to keep skills up to par and adding self-training to their curricula vitae/resumes (e.g., taking courses to focus on "hot" therapeutic areas or novel study designs), such CRAs understand that this will increase their marketability for future contracts. By doing this, they also show a potential client that improving and adding to their skills is important to them.

Revisiting Competency Domains and Harmonized Core Competencies

Throughout ongoing training and development of the CRA, the strengthening of attributes and skills that are essential to the role should be the ultimate goal. Many of these align with the JTF competency domains and harmonized core competencies (see Table 1).[2,6] These competencies should yield a highly proficient CRA.

Conclusion

Creating a workforce development program addresses the challenge of inexperienced CRAs not being able to break into the industry, and maintains the skill set of existing professionals. Through continuous support of the CRA's career path and ongoing development, organizations can demonstrate a vested interest in retaining the employee and, therefore, in reducing turnover. The ultimate result is an efficient and agile CRA workforce, and a clinical research industry that produces quality products for the healthcare market.

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HOME STUDY HS

The New Shape of Workforce Development

OPEN BOOK TEST

This test expires on December 31, 2017

(original release date: 12/1/2016)

Project Managers Influence Parallel Planning and Collaboration Between Sites and Sponsors

1. **What are examples of how the use of project management systems can be optimized in a parallel planning approach?**

- **A.** Preparing clinical research forms and data entry systems
- **B.** Running lab results and consulting principal investigators
- **C.** Inputting site start-up timelines and enrollment rate projections
- **D.** Negotiating contracts and enrolling study subjects

2. **Why is it important for sites and sponsors/CROs to collaborate in developing each stage of the clinical trial project plan?**

1. Establish achievable timelines
2. Foster openness to identify risks
3. Sites will determine the project schedule
4. Promote a culture of a shared project

- **A.** 1, 2, and 3 only
- **B.** 1, 2, and 4 only
- **C.** 2, 3, and 4 only
- **D.** 1, 3, and 4 only

3. **When conceptualizing a project and reading the study design synopsis, a checklist may be used by both a sponsor/CRO project manager and a site project manager. This checklist helps them better understand the project. What are the three criteria being reviewed on the checklist?**

- **A.** Planning, Executing, and Closing
- **B.** Unsatisfactory, Pass, and Good
- **C.** Behind, On Track, and Ahead of Schedule
- **D.** Feasible, Achievable, and Believable

4. **A technique for continual stakeholder engagement described in the article includes:**

- **A.** Increased onsite monitoring visits from the sponsor or CRO
- **B.** Regular reporting of project status by the sponsor/CRO to the site
- **C.** Periodic review of the project plan by the sponsor/CRO and site project managers
- **D.** Annual investigator meetings

5. **Guiding principles for sponsor/CRO and site collaborations include:**

1. Selecting the right personnel at the site and sponsor for the project
2. Communicating to internal and external stakeholders about the goals of the project
3. Documenting agreement on the goals with all stakeholders
4. Reassessing stakeholder understanding of the goals and timelines

- **A.** 1, 2, and 3 only
- **B.** 1, 2, and 4 only
- **C.** 2, 3, and 4 only
- **D.** 1, 3, and 4 only

6. **Study metrics should be developed:**

- **A.** By study sponsors only
- **B.** By study sites only
- **C.** By CROs only as a third party
- **D.** With input from all parties

7. **A suggested way of combating "metrics mania" is which of the following?**

- **A.** Sites implement metrics to evaluate sponsors
- **B.** Sponsors implement metrics to evaluate sites
- **C.** Metrics should be evaluated to ensure they add value and are meaningful to sponsors and sites
- **D.** Metrics should be standardized to ensure they are consistent across all studies, sponsors, and sites

8. **What is a drawback to the sponsor developing the original project timeline, as suggested by the authors?**

1. Adjustments to the schedule are often only made to consider sponsor's internal operations.
2. Adjustments to the schedule often do not take site operations into consideration.
3. Adjustments to the schedule often impact resourcing and work load of sites.
4. Adjustments to the schedule often increase the overall study budget.

- **A.** 1, 2, and 3 only
- **B.** 1, 2, and 4 only
- **C.** 2, 3, and 4 only
- **D.** 1, 3, and 4 only

9. **When details to a change in project scope are not well communicated, what are possible impacts to the project described in the article?**

- **A.** There should be no changes to the project plan.
- **B.** A new ethics review is required to move forward with the plan.
- **C.** The clinical trial agreement is void and the project must be re-proposed.
- **D.** Additional time, money, and resources may be required to carry out the project within the new scope.

10. **This article discusses the shifting view of sites toward which of the following:**

- **A.** Sites as suppliers
- **B.** Sites as demanders
- **C.** Sites as customers
- **D.** Sites as consumers

Risk-Based Monitoring: Changing Roles, Changing Mindsets

11. **Risk-based monitoring (RBM) is a new method of monitoring:**

- **A.** Pharmacovigilance
- **B.** Clinical trials data
- **C.** Drug shipment logistics
- **D.** Vendor activities

12. **Who is NOT a main stakeholder in RBM?**

- **A.** Sponsor
- **B.** Investigator
- **C.** Patient
- **D.** Regulatory agency

13. **The sponsor's role in RBM is to:**

1. Create a robust monitoring plan
2. Establish standard operating procedures
3. Train patients on use and implementation of RBM
4. Identify potential risks in the clinical trial

- **A.** 1, 2, and 3 only
- **B.** 1, 3, and 4 only
- **C.** 1, 2, and 4 only
- **D.** 2, 3, and 4 only

14. **State the four roles within the sponsor that will need to adapt to RBM:**

- **A.** Data manager, project manager, monitor, and auditor
- **B.** Study drug supply manager, scientist, monitor, and Trial Master File manager
- **C.** Medical writer, marketing manager, sales manager, and company president
- **D.** Company president, finance manager, drug supply manager, and data manager

Find the most current online test at **www.acrpnet.org/homestudy**, including any revisions made after publication of this issue of *Clinical Researcher*.

15. **Historically, what has been the main task of a data manager?**
- **A.** Co-monitoring visits to sites with monitor
- **B.** Providing input on study drug supply
- **C.** Cleaning the data entered in the case report form
- **D.** Selection of sites for trial

16. **Traditionally, what percent of source data verification is carried out by a monitor?**
- **A.** 10%
- **B.** 50%
- **C.** 85%
- **D.** 100%

17. **The project manager will play a major role in coordination between:**
- **A.** Data manager and monitor
- **B.** Data manager and site
- **C.** Site and drug supply manager
- **D.** Data manager and regulatory authority

18. **Which of the following is NOT a challenge in auditing an RBM trial?**
- **A.** Continuous trend analysis
- **B.** Adherence to monitoring plan
- **C.** Correct identification of CAPA owner
- **D.** Selection of a site for audit

19. **RBM shifts a higher onus to the investigator for which of the following activities?**
- **A.** Data integrity and data quality
- **B.** Patient recruitment
- **C.** Patient retention
- **D.** Ethics committee notification

20. **What efforts should regulatory authorities make for successful implementation of RBM?**
1. Take active feedback from all stakeholders
2. Provide minimum or no oversight
3. Connecting with other regulatory agencies to update the process
4. Reject trials not using RBM
   - **A.** 1 and 2 only
   - **B.** 1 and 3 only
   - **C.** 2 and 4 only
   - **D.** 3 and 4 only

Workforce Development for Clinical Research Associates: Evolving Paths to Competency

21. **In clinical research, the downstream effect of having a highly qualified team is:**
- **A.** Identifying new team members
- **B.** Bringing new products to market quicker
- **C.** Decreasing training time
- **D.** Requiring less management oversight

22. **Some possible routes into the clinical research arena are:**
1. Networking
2. Volunteering
3. Surveys
4. Internships
   - **A.** 1, 2, and 4 only
   - **B.** 1, 3, and 4 only
   - **C.** 1, 2, and 3 only
   - **D.** 2, 3, and 4 only

23. **According to the Joint Task Force (JTF) for Clinical Trial Competency, the eight competency domains include:**
- **A.** Scientific concepts and research designs, ethical and participant safety considerations, federal regulations, clinical trials operations (GCPs), study and site management, data management and informatics, leadership and professionalism, and ICH Guidelines
- **B.** Medicines research and designs, HIPAA law considerations, medicines development and regulation, clinical trials operations (GCPs), study and site management, data management and informatics, leadership and professionalism, and communication and teamwork
- **C.** Scientific concepts and research designs, ethical and participant safety considerations, medicines development and regulation, clinical trials operations (GCPs), study and site management, data management and informatics, leadership and professionalism, and communication and teamwork
- **D.** Scientific concepts and research designs, ethical and participant safety considerations, medicines development and regulation, clinical research operations, study and site management, project management, leadership and professionalism, and communication and teamwork

24. **Which are some of the challenges faced by the clinical research enterprise that make it ideal for an apprenticeship model?**
1. Jobs for which it is difficult to find workers with the right skills
2. Challenges helping workers keep pace with industry and technology advances
3. Difficulty in attracting new and diverse talent pools
4. Candidates without adequate experience
   - **A.** 1, 2, and 4 only
   - **B.** 1, 3, and 4 only
   - **C.** 2, 3, and 4 only
   - **D.** 1, 2, and 3 only

25. **Examples of low-risk tasks assigned to a CRA apprentice are:**
- **A.** Getting coffee and running errands for project managers
- **B.** Taking meeting minutes during a team teleconference, or organization and filing of Trial Master File documents
- **C.** Scheduling and booking travel for the CRAs who monitor sites
- **D.** Writing CRF/eCRF guidelines and SOPs, or creating source documents for new studies

26. **What is the suggested length of a clinical research apprenticeship program?**
- **A.** Two years
- **B.** One year
- **C.** Three months
- **D.** Six months

27. **The following three-step process is included in the training and development of a successful CRA:**
- **A.** Skilling, over skilling, upskilling
- **B.** Skilling, upskilling, out skilling
- **C.** Skilling, reskilling, upskilling
- **D.** Reskilling, upskilling, over skilling

28. **Beyond a solid training curriculum and skill-based training, what is the other critical attribute that a CRA must possess but that organizations have difficulty training on?**
- **A.** Soft skills: Interpersonal communication and executive functioning
- **B.** Technical skills: Use of CTMS and web-based programs
- **C.** Organization: Creating e-mail folders and prioritizing tasks
- **D.** Regulatory knowledge: Excellent working knowledge of all applicable regulations

29. **When considering training and development, the article suggests CRA contractors can do which of the following to ensure they continue to grow in the role?**
- **A.** Request training from the CRO they are contracted to
- **B.** Read books about clinical research
- **C.** Work on multiple contracts at one time
- **D.** Take courses in a growing therapeutic area or modality

30. **Which of the following is one of the objectives of the CRA attribute: Organization?**
- **A.** Prioritization—Managing the most pressing issues first
- **B.** Correspond with cross-functional teams within the organization
- **C.** Necessary for training physicians, study coordinators, and junior monitors
- **D.** Work collaboratively with the team in order to achieve mutual goals