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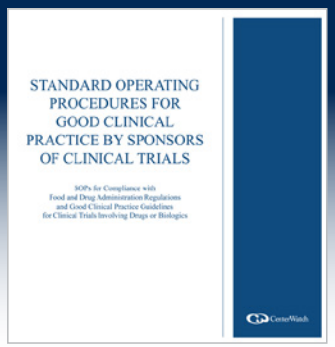

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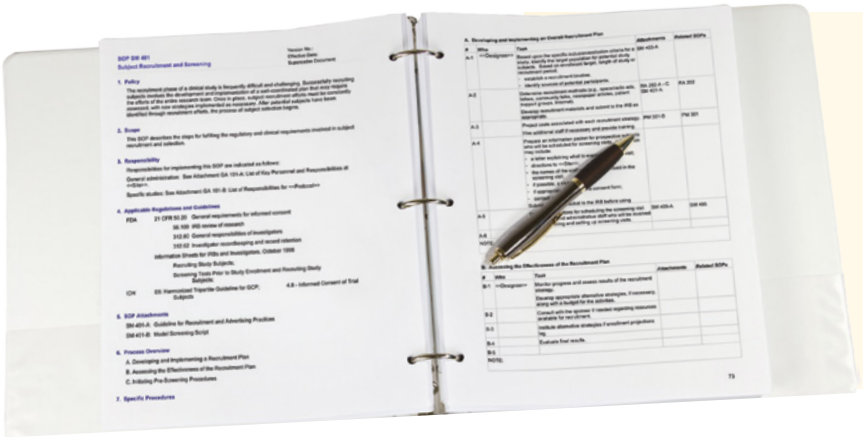

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December 2016 • Volume 30, Issue 6 • ISSN 2334-1882

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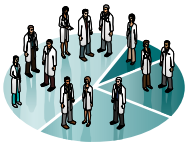
Features

PEER REVIEWED



Also in This Issue

ACRP
FOR LEARNING FOR LISTENING FOR LIFE

Clinical Researcher ISSN 2334-1882 (Print) and ISSN 2334-1890 (Online) is published bimonthly. It is provided to ACRP members by the Association of Clinical Research Professionals (ACRP). The views, research methods, and conclusions expressed in material published in *Clinical Researcher* are those of the individual author(s) and not necessarily those of ACRP.

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The Three Pillars of Hiring and Retaining the Best Billing Compliance Staff

Do you have positions "open" continuously in billing compliance? Finding someone with the expertise needed to master billing compliance rules is difficult and intense. What are the secrets to success in hiring and retaining the best staff you can in this unique area of research compliance?

Billing compliance networking has combined the insurance world, government, sponsors and sites together to have a positive influence on this distinct area of compliance.

Many administrators in billing compliance do not know what to do when they receive an unexpected resignation. Perhaps the most common reaction is to question what you should do next. You are obviously not flooded with staff knowledgeable regarding all aspects of the billing compliance. Set a strategic investment plan for growth for advancement, and your staff will limit their options for moving on.

The first pillar of hiring is to create purpose with each position. Having distinct roles and responsibilities will help create security. When working with clients all across the country, there is a significant need for focus on roles and responsibilities. Do not allow billing compliance to be done by whoever feels like doing it; set parameters and know where the duties belong. By doing so, you facilitate teamwork and lessen anxiety.

The second pillar is to create value in each position. Having upward mobility and opportunity for advancement will keep staff engaged in your department. Many times, there is no growth at a facility in research billing compliance. This is because nobody truly knows who owns the process. Set job descriptions, policies and procedures so your staff understands what is expected of them.

The final pillar is allowing your team to attend conferences, seminars and training. Establish a priority for training and your staff will respond positively. The value of training comes back to your department in many ways, including the connections formed at external events. Billing compliance networking has combined the insurance world, government, sponsors and sites together to have a positive influence on this distinct area of compliance. By attending the 11th Annual Clinical Trial Billing & Research Compliance Conference, your staff will benefit from six workshops, two full days of sessions, expert speakers and industry leaders from across the country.

Kelly Willenberg, DBA, RN, CCRP, CHRC, CHC, is the owner of Kelly Willenberg & Associates. Kelly has extensive knowledge in clinical trial management and research compliance, including all aspects of clinical trial billing compliance. She has more than 30 years of clinical research and billing compliance experience.

Learn More
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GUEST EDITOR'S MESSAGE
Paula Smailes, RN, MSN, CCRC, CCRP

[DOI: 10.14524/CR-16-4047]

The Necessity of Workforce Development for Clinical Research Professionals

Jim Kremidas, executive director of the Association of Clinical Research Professionals, has stated that, due to the lack of a standardized path into the clinical research enterprise, there is a "tremendous amount of variance in research conduct, processes, and workforce competence, which culminates in a detriment to research quality."[1] His statement hits home the necessity of why workforce development in clinical research is important and should be an ongoing priority for all clinical research professionals.

A skilled workforce is essential, and the only way it can be accomplished is through education and ongoing professional development. In an effort to bring new ideas on clinical research workforce development to our readers, this issue of *Clinical Researcher* addresses the topic from multiple angles for a wide array of clinical research roles.

Where We're Focusing

One ongoing push in the industry is the idea of having standardized competencies, which has been a focus of the Joint Task Force (JTF) on Clinical Trial Competency. The JTF's eight competency domains within a Core Competency Framework represent the key areas in which research professionals should be knowledgeable.[2] The application of these concepts to workforce development is a common theme in several of our articles this issue.

For example, one article probes the findings of a multinational JTF survey of more than 2,000 clinical research professionals who were asked to complete a self-assessment of their competence level, the significance of core competencies to their role, and need for further training. Elsewhere in this issue, Nicole Tesar analyzes workforce development within the clinical research associate (CRA) role and applies the JTF Core Competencies to the role by analyzing the key attributes of what CRAs must do to be successful. The final article addressing JTF competencies is contributed by Soumya J. Niranjan, who addresses the competencies in the context of hiring qualified staff as a starting point for building quality into a clinical research program.

Also Ahead…

There has been an ongoing rise of academic courses and degrees in clinical research, and in another of this issue's articles, we learn the paths that one can take from degree-granting programs in clinical research. Furthermore, we see how that translates to career opportunities. Unique to this article are the vignettes of several clinical research professionals and how their training, be it on the job or academic, contributed to their career success.

Meanwhile, Romiya Barry, Joe Coffie, Catherine Pui Yin Mok, and Jill Chapman take a deeper look at the role of project managers in clinical research and how the valued duties of this role aids to facilitate the planning and execution of clinical trials. As we learn from their article, good management at both the site and sponsor level leads to high-quality research.

Vipul S. Halbe and Jeroze Dalal also address the impact of risk-based monitoring on a variety of clinical research roles, such as the sponsor, data manager, study manager, auditor, monitor, investigator, site team, and regulatory authorities. This is the perfect article to demonstrate how the changing clinical research climate impacts roles and the need for research professionals to stay current with ongoing change via workforce development.

Looking to the Horizon

As we look to the future, clinical researchers must advance human health within a highly complex and rapidly changing social, economic, political, regulatory, and scientific environment.[3] The innate challenges faced by those who oversee experimentation in human subjects are quite grand—regulatory protections, changing technologies, and medical science all intersect in a fast-paced environment. Given this environment, staying abreast of job requirements in the 21st century is no easy task; however, we must not lose site of the fact that investing in our clinical research workforce is investing in our future.

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Paula Smailes, RN, MSN, CCRC, CCRP, (Paula.Smailes@osumc.edu) is a member of the ACRP Editorial Advisory Board, a training and optimization analyst for clinical research at The Ohio State University Wexner Medical Center, and a visiting professor with Chamberlain College of Nursing.

AT PRA, WE'RE FAMILY

A look inside PRA's "boomerang" phenomenon

Employees gather for a grand opening celebration.

We'll be the first ones to admit, we've had CRAs quit. They've even left PRA for other CROs. Sure, there's the allure of new opportunities, new studies, new systems. But at PRA, we've noticed one big difference. They "boomerang" back. At a rate of 6.5 former employees per month, in fact.

Believe us, we were surprised by this number too. It's not often you find an employee that has left so eager to come back. But they are.

Why?

Great question, glad you asked. The answer is simple, and we hear it overwhelmingly from our CRAs. "PRA is home, and the people here are family."

So what makes PRA home?

True, PRA is 11,000+ employees. We have offices all over the world. But there's one thing we never do. And that is forget that every single person that works here is part of the family. We don't define our employees by a number. We define them by the incredible work that they do.

PRA is home, and the people here are family.

Experience Nicole's CRA journey at DiscoverYourPRA.com.

Being a CRA asks a lot. Being a CRA means missed family dinners, missed soccer games, and just missed time. Time with loved ones, time with spouses, time with kids. And that's tough. It's more than tough. But that's why we do everything we can to give our CRAs flexibility when they need it. We try as best as we can to keep them close to home and work with their schedules so that they miss as few of those soccer games and dinners as possible. At PRA, we know how important family is, because at the end of the day, we consider every single person that works here family.

Really though, why would someone leave and then come back?

They come back because we welcome them back. We don't consider CRAs that have left to be outcasts. We know that our managers are incredibly supportive, our systems are top-of-the-line, and our teams are always there to help each other. But we also know that everyone longs to see or do something new. We don't exile someone for that. We encourage all of our employees to ask questions and challenge norms. We want our CRAs to discover, create, and most importantly, innovate. When CRAs return to PRA, we know that they've explored other places. They've worked on other studies and used new systems. We are happy to welcome back their input on how we can make PRA better.

So many people come to PRA because they want to do some good in the world. They want to go home each night knowing that they have truly made a difference in the world, while at a place they love working. So many people stay at PRA because, not only do they get to shape the future, they get to do it in a place they truly love. And we are happy to have them.

For more information, please visit DiscoverYourPRA.com

PRAHEALTHSCIENCES

[DOI: 10.14524/CR-16-4052]

CHAIR'S MESSAGE
Steven Ziemba, PhD, CCRC, CPI

Be a Part of Our Bright Future

This is the last *Clinical Researcher* message that I will share with you as chair of ACRP's Association Board of Trustees (ABoT). My year in this position has witnessed a time of celebration and accomplishment, as well as of challenge and loss.

Steven Ziemba, PhD, CCRC, CPI, (ziemba.steven@mcrf.mfldclin.edu) is the associate director of the Marshfield Clinic Research Foundation in Wisconsin and Chair of the 2016 Association Board of Trustees for ACRP.

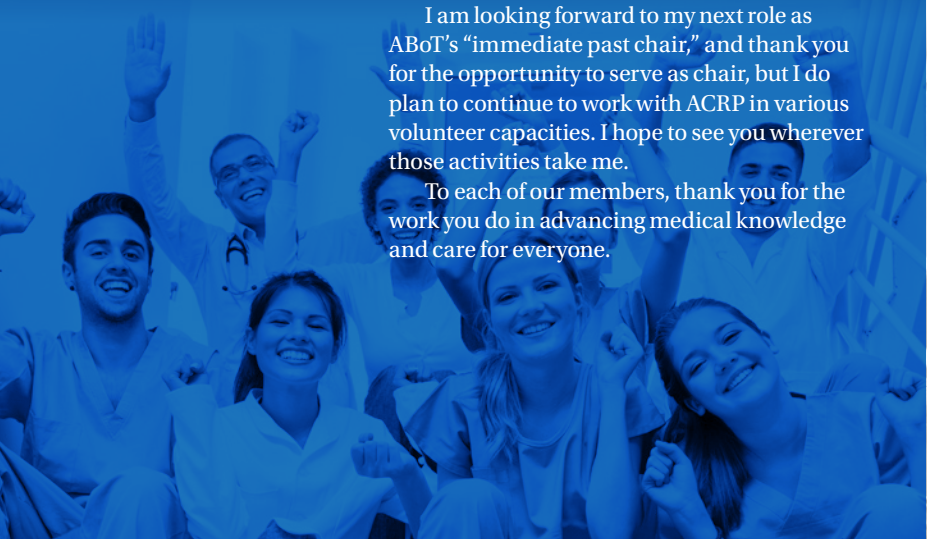
I am grateful for the time I served in this role—not only because it has been an education, but because the work of the staff and my fellow board members has shown that ACRP has a bright future. I am grateful to have been a small part of helping to develop that future. To this end, I urge our dynamic membership to also help guide the evolution of our organization.

Please consider participating through volunteerism with your local chapter or on an ACRP committee, by submitting an article to this journal, or by forwarding a nomination to the ABoT. You'll get something back in return as well, and it is something that goes beyond knowing you are helping your colleagues and your profession.

I am a believer in the value of always learning, and volunteering is a great way to acquire new skills and develop yourself as a leader. This is where volunteerism really does pay back to you, and makes it worthwhile to take the time out of your professional and personal lives.

I am looking forward to my next role as ABoT's "immediate past chair," and thank you for the opportunity to serve as chair, but I do plan to continue to work with ACRP in various volunteer capacities. I hope to see you wherever those activities take me.

To each of our members, thank you for the work you do in advancing medical knowledge and care for everyone.



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STANDARDS
Key to Preparing for the Evolving Trials Landscape

[DOI: 10.14524/CR-16-4051]

There's no replacement for getting out in the field and interacting directly with clinical trial professionals. Whether it's attending a chapter meeting, or speaking at a conference, or in any number of other ways, I value each chance to connect with our members and others who are working to make clinical trials more effective and efficient.

Jim Kremidas (jkremidas@acrpnet.org) joined ACRP as its new executive director in October 2015.

In November, I had the opportunity to speak at the Clinical Trials & IoT (Internet of Things) Forum in Cambridge, Mass. I was struck by the passion and commitment I heard from sponsor, site, and institutional review board (IRB) representatives, including many clinical research coordinators (CRCs). In each presentation, and during each conversation on a break between sessions, I was inspired to hear what was working in the field. I was even more inspired by what's coming down the pike. Technology and new ways of looking at our profession bode well for the clinical trials of tomorrow.

At ACRP, we've been working to help identify and codify those skills and experiences that make for an excellent clinical trial practitioner. While "time served" can be important, we and others believe competence is more about actual performance milestones and less about the calendar.

Today, we're stuck in something of a chicken and egg situation.

Employers have been complaining that university-prepared students are not entering the workforce with the ability to do the tasks required in their roles. At the same time, arbitrary calendar-based barriers are keeping new entrants from obtaining the experience they need to be ready to enter the workforce.

ACRP advocates the creation of a hierarchy of competencies focused on performance, not longevity, because it will improve the quality of tomorrow's workforce. Specifically, competency should be based on a clearly defined set of standards demonstrating knowledge and skills.

At ACRP, we've been working to help identify and codify those skills and experiences that make for an excellent clinical trial practitioner.

CRCs know their work roles will change significantly in the next few years. In an ACRP job survey with more than 1,000 responses, CRCs said they expected their roles to evolve in several ways, including:

- Technology will outpace regulations
- Corrective and preventative action (CAPA)/risk evaluation mitigation will require better understanding of data management principles
- Transition from paper to electronic formats for everything
- Clinical research associates (CRAs) will become site managers

Finally, CRCs believe that this increasing complexity will come in parallel with an even greater need for trained staff. We need to lay the foundation for a new wave of CRCs and CRAs who will be able to meet and surpass the challenges ahead.

Common sense suggests that clear standards for competency will improve the workforce. However, a review of U.S. Food and Drug Administration inspection findings in 2015 offers some harder evidence that core competencies need to be more clearly defined and enforced. The most common clinical investigator deficiencies spotlighted in the review include:

- Failure to follow the investigation plan and/or regulations
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Inadequate subject protection (failure to report adverse events and informed consent issues)

To be effective and recognized in industry, competencies should be measured and assessed by a reputable organization with the credibility to make such pronouncements. Leading that charge has been the Joint Task Force for Clinical Trial Competency, composed of stakeholders in the research enterprise and organized under the sponsorship of the Multi-Regional Clinical Trials Center at Harvard University and ACRES (Alliance for Clinical Research Excellence and Safety).

ACRP wants to be your professional resource for your entire career span. As always, I welcome your thoughts and feedback on our shared mission.

Paving the Way for Workforce Innovation

James Michael Causey

[DOI: 10.14524/CR-16-4050]

The Association of Clinical Research Professionals (ACRP) recently announced that Terri Hinkley, RN, BScN, MBA, CCRC, FACRP, who had been serving as the Association's Deputy Executive Director, has now been named its Workforce Innovation Officer.

In her new position, Hinkley will lead several major ACRP initiatives to define and shape the future of the clinical research workforce and to support professionals in their career growth and development.

This new position was created in response to rapid change across the clinical research enterprise, specifically within clinical trial operations, requiring of clinical research professionals a new set of skills and competencies.

In her new position, Hinkley will lead several major ACRP initiatives to define and shape the future of the clinical research workforce and to support professionals in their career growth and development.

Key initiatives include development of the core competencies required of clinical research professionals through the Joint Task Force for Clinical Trial Competency, and development of the core competencies required for clinical research associates (CRAs) through ACRP's CRA Workforce Task Force.

Hinkley will also lead initiatives driving industry toward standardization and certification to improve trial quality by reducing variance. She sat down with *Clinical Researcher* in early November to discuss the state of the industry, and how ACRP members can play a more proactive and impactful role in managing change to the betterment of clinical trials.

Clinical Researcher: Let's talk first about your new role at ACRP. How will it benefit ACRP members?

Terri Hinkley: The title Workforce Innovation Officer is really intended to demonstrate that we're working to try to support the workforce during its entire career span.

The intention was to start focusing on what competent clinical researchers need to know. Competence is defined as the combination of knowledge, skills, and abilities. Clinical research is still very much in its infancy as a profession. In the past, clinical trials were conducted almost entirely by physicians, often in their offices or hospitals, and it was just seen as kind of an adjunct in their medical practice. What we know now is that the knowledge, skills, and abilities—the competencies required for clinical research—are very different from clinical care, and I often think of the example of myself, starting in the industry in 1995. I was a nurse. I had no idea what clinical research was, but I was trying to accomplish all these studies.

Working with the Joint Task Force, ACRP has helped to develop eight domain areas and 51 competency statements that all clinical researchers need to have. ACRP has done a lot of work to align our products and services, and everything that we do with those competencies, so that people can see how the products and services link to the competencies.

Our work is definitely needed in this area. The magnitude of the change is something that I don't think we've ever seen as an industry before. We need to help people navigate the change and recognize how roles are evolving, what clinical research is going to look like in the future, and just as importantly, how to make sure that the consequences of the changes are understood by all stakeholders.

Processes are being revised, technologies are being implemented, but we in the ACRP are representing the *people* affected within the industry as we move forward.

"Processes are being revised, technologies are being projected, but we in ACRP are representing the people affected within the industry as we move forward."

CR: How can ACRP members get involved?

Hinkley: We encourage members to reach out to us with their ideas. We want our work to reflect what they need most. One of the things that we're already doing—since September of last year—is that we put out a position paper where we stated that, instead of focusing on an arbitrary two-year experience requirement for new CRAs, we focused on competencies using the Joint Task Force competency domains. We would then be able to have a better ability to ensure that CRAs have the skills, knowledge, and abilities they truly need. We know that tenure alone does not necessarily translate into any sort of expertise.

We thought that it was time for the industry to look at this, so we formed a task force of industry representatives, experts in clinical operations, and we got them around the table and we said, "Work with us to develop entry-level competencies." They were feeling ambitious, and they decided that they actually were going to map the competencies for the life cycle of the CRA. What I mean by that is not only at the entry level, but also the intermediate, experienced, and lead CRA levels, to map what the competencies look like over time. We won't begin and end this work with the CRA role—when we move on, we're going to do CRCs, PIs, and we're going to do project managers, and we're just going to continue down this path of developing these competencies.

CR: Have you gotten any pushback on the need to define competencies and/or confusion regarding how to best define them?

Hinkley: We haven't had any pushback. Overwhelmingly, the response to this has been positive. I think clinical research professionals, the people involved in this industry, are in it because they want to make a difference. They want to bring safe and effective treatments, whether they be drugs, biologics, or devices, to patients that need them. Every single one of them is committed to that, and I think they're also committed to making sure that it's being done and in an ethical and most effective manner possible.

CR: Last question, and you kind of touched on this earlier, but can you talk a little bit more about how your own background will help you in this role, what you think you can bring to this to help change the mindset and help members maybe surf this sea change?

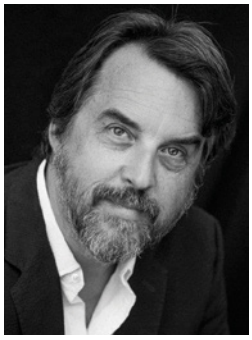
Hinkley: I think that this is really the perfect role for me in this point in my life. I've been a nurse for 30 years. I came into research, and like many from the nursing profession, I kind of fell into it. As I said before, I once honestly had no idea what clinical research was. I didn't know the path of bringing a drug to market, and I remember having a really hard time trying to differentiate what the research activities were from my nursing and my clinical care.

As I got to know more about the field, I loved it. I loved the research industry, and moved my nursing to a more part-time job and transitioned into that operations management role. I've been an active ACRP member since 1997 and obtained my CCRC in 1999. I've maintained my certification through to this day. I had the opportunity in 2013 to join ACRP and to try and bring some of that industry expertise to the staff.

Between my clinical background, my nursing background, as well as my 20 years in research, now coupled with the formal education I'm getting in my doctorate program, I understand the dynamic pieces of all of those trends. I also understand how they interrelate, and I think I can translate, through this role, what's happening in the industry into products and resources and initiatives that can be implemented and embraced by like-minded clinical researchers. Hopefully, I am able to explain it all in a way that makes sense to them, so they understand the reason for change, and to help them navigate those changes.

CR: Would you like to share any final thoughts?

Hinkley: I personally find this to be such an exciting point for clinical research. I mentioned early on in the interview that the change that's happening is unprecedented. I mean, I thought it was a big deal when we implemented electronic data capture 20 years ago, and that was a big deal for the industry, and it's nothing like what we're seeing now.



James Michael Causey
(mcausey@acrpnet.org) is editor-in-chief for ACRP.

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(original release date: 12/1/2016)

In this issue of *Clinical Researcher,* the three articles that follow this page have been selected as the basis for a Home Study test that contains 30 questions. For your convenience, the articles and questions are provided in print as well as online (members only) in the form of a PDF. This activity is anticipated to take three hours.

Answers must be submitted using the electronic answer form online (members only, $60). Those who answer 80% of the questions correctly will receive an electronic statement of credit by e-mail within 24 hours. Those who do not pass can retake the test for no additional fee.

ACRP DISCLOSURE STATEMENT

As an organization accredited by the Accreditation Council for Continuing Medical Education (ACCME®), the Association of Clinical Research Professionals (ACRP) requires everyone who is in a position to control the planning of content of an education activity to disclose all relevant financial relationships with any commercial interest. Financial relationships in any amount, occurring within the past 12 months of the activity, including financial relationships of a spouse or life partner, that could create a conflict of interest are requested for disclosure.

The intent of this policy is not to prevent individuals with relevant financial relationships from participating; it is intended that such relationships be identified openly so that the audience may form their own judgments about the presentation and the presence of commercial bias with full disclosure of the facts. It remains for the audience to determine whether an individual's outside interests may reflect a possible bias in either the exposition or the conclusions presented.

80% The pass rate for the Home Study Test is now 80% to be in alignment with ACRP professional development standards.

CONTINUING EDUCATION INFORMATION

The Association of Clinical Research Professionals (ACRP) is an approved provider of medical, nursing, and clinical research continuing education credits.

Contact Hours

The Association of Clinical Research Professionals (ACRP) provides 3.0 contact hours for the completion of this educational activity. These contact hours can be used to meet the certifications maintenance requirement. (ACRP-2016-HMS-012)

Continuing Nursing Education

The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. This activity provides 3.0 nursing education credits. (Program Number 11147-2016-HMS-012)

Continuing Medical Education

The Association of Clinical Research Professionals (ACRP) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Association of Clinical Research Professionals designates this enduring material for a maximum of 3.0 AMA PRA Category 1 Credits™. Each physician should claim only the credit commensurate with the extent of their participation in the activity.

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

[DOI: 10.14524/CR-16-0005]

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
Romiya Barry, MSc;
Joe Coffie, CCRA;
Catherine Pui Yin Mok, MSc, CCRP, CCRC:
Nothing to disclose
Jill Chapman, BHSc, CCRA:
Employee of ACRP

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.

ACKNOWLEDGEMENT AND DISCLAIMER

We sincerely thank Jovan Petty, former specialist for committees and interest groups at ACRP, for her support and coordination of this collaborative effort. All trademarked products and services mentioned in this article are the property of their respective owners. The inclusion of names of tools and management systems within this article is for illustrative purposes only, and does not serve as an endorsement by any of the authors.

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Risk-Based Monitoring:
Changing Roles, Changing Mindsets

PEER REVIEWED
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[DOI: 10.14524/CR-15-0047]

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.

ACKNOWLEDGEMENT

The authors acknowledge Dr. Saifuddin Kharawala, Dr. Archana Harshvardhan, and Ms. Zarina Irani for their valuable feedback during the development of this article.

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Workforce Development for Clinical Research Associates: Evolving Paths to Competency

PEER REVIEWED | Nicole Tesar

[DOI: 10.14524/CR-16-0021]

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

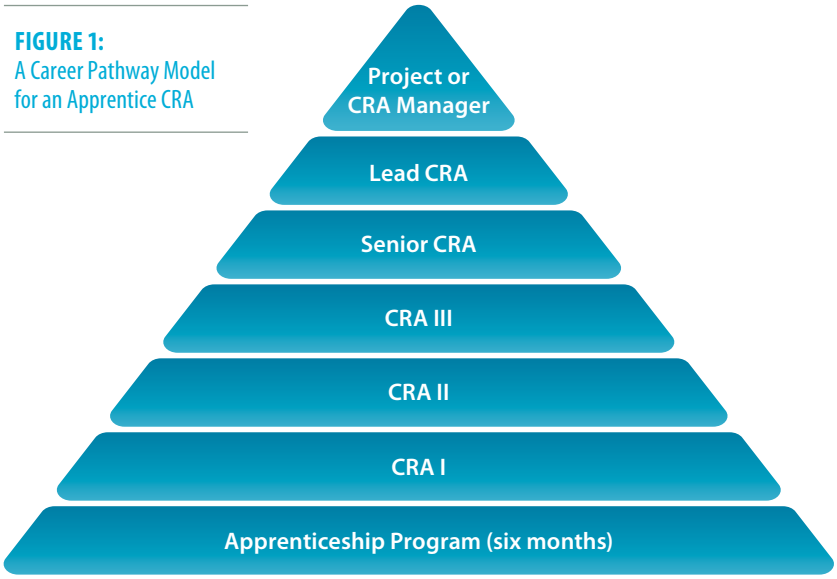
As an independent CRA, I have received LinkedIn messages, phone calls, and e-mails from many individuals looking to break into the clinical research industry. Ultimately, what they are looking for is a clear cut formula for getting their foot in the door without having direct experience. There are individuals 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

[DOI: 10.14524/CR-16-4048]

PI CORNER

Christine Senn, PhD, CCRC, CPI

QUALITY ASSURANCE

from the Independent Site Perspective

Quality assurance (QA) is a topic near and dear to my heart, having founded the Quality Assurance and Compliance program at my organization nine years ago. We started as single research site, but have since grown to nine sites across our state. The perspective gained from this growth has been illuminating; with each moment of growth, each process had to be questioned, and often needed to be improved.

Elsewhere in this issue you will read Soumya J. Niranjan's article on "Building a Quality Assurance Program: From the Ground Up." She writes from the perspective of an academic medical center, so I would like to offer the independent site perspective.

Considering the Constraints

Everything that Niranjan speaks of in terms of constraints is, indeed, a constraint at every type of site. We all have to juggle meeting enrollment goals, while often having insufficient personnel due to both the high cost of site operations and the lack of an adequately trained workforce. Add to that the well-accepted truth that trials have become increasing complex, and the industry is ripe for quality errors due simply to constraints.

I truly believe that everyone in research wants to do the best possible job. So often, though, it seems that the forces of enrollment and QA are at odds. If a site focuses on enrollment, quality may suffer. If a site focuses on quality to the detriment of enrollment, the site may not survive the financial consequences.

My opinion is that annual QA reviews are not frequent enough for almost any site. Every single entity in research—sponsors, contract research organizations, site administrators, principal investigators (PIs), clinical research coordinators (CRCs), and more—want great enrollment and great quality. How do we accomplish this?

Before, During, and After

Our front-line people are obviously expected to focus on both; however, we recognize that they are the only people who can ensure high enrollment. Knowing that cognitive difficulty arises when people hold two goals in mind simultaneously, we have both real-time and after-the-fact QA procedures in place. In real time, some of these include:

- Every informed consent form (ICF) is reviewed by a separate person in the clinic (before the subject begins any trial procedures) to ensure the ICF is complete.
- Two people (a CRC and an investigator) have to independently sign off on the inclusion/exclusion criteria before randomization, because while one person can miss a detail, two missing the same detail is unlikely.

After-the-fact reviews include more people. This is where the Quality Assurance and Compliance Committee comes into play. A committee doesn't have to be big; at smaller sites, it can even be one person or can include people from the physician's practice who are not involved in research. The key is finding people who can see *trends*. Individual errors can be easily pointed out, but it is finding trends and using them as learning opportunities that lead to targeted re-training.

Our after-the-fact procedures include:

- Reviewing every delegation of authority log quarterly (and comparing it to the current U.S. Food and Drug Administration Form 1572 and training logs)
- Reviewing every monitoring visit follow-up letter for "major errors" and trends

We also perform many trials that require separate, unblinded staff. In these cases, PIs are held responsible for data that they cannot see. To protect our PIs, a QA reviewer (who is not directly involved in clinical activity) reviews all investigational product (IP) and dispensation logs after the first patient randomizes, and then monthly thereafter.

How Major is Major?

Meanwhile, you might be wondering what a "major error" is. This is the crux of what the QA reviewer needs to know. In our definition, a major error is:

- any error with the ICF or ICF documentation process
- inappropriately randomizing a subject
- mis-dosing a subject
- any error that hinders the sponsor's ability to analyze its endpoints
- any major documentation error (such as not reporting a serious adverse event in a timely fashion, failure to maintain quality IP logs, or site personnel performing duties without being on the delegation log for that duty and/or not having documented training)

When a QA reviewer determines that a major error has occurred, the CRC has two weeks to write a detailed corrective and preventative action plan to address the situation. The most appropriate site staff member must then re-train the staff who made the error.

Ongoing errors of the same type can result in disciplinary action, but we find that this usually is not necessary, because people truly want to do a good job, and they will work very hard to provide the best data possible. Making the same mistake repeatedly may be a signal that the person either cannot understand the concepts of quality trial conduct, or they do not care enough about quality data to warrant being part of your team. Keeping metrics to ensure you have the right people on your research team is a topic for another day, though.

I truly believe that everyone in research wants to do the best possible job. So often, though, it seems that the forces of enrollment and QA are at odds.

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OPINION:

What Do the U.S. Election Results Mean to the Clinical Trials Industry?

David M. Vulcano, LCSW, MBA, CIP, RAC

[DOI: 10.14524/CR-16-4053]

Undoubtedly, the actions and inactions of the U.S. Congress have direct and indirect effects on the clinical trials industry. Also undoubtedly, anxiety is heightened at times after elections, especially when they result in changes of the administration.

Times like these result in the struggle between those on their way out having last-minute opportunities to complete or build immunity into their previous efforts, those incoming into the system preparing new efforts, and those who will carry over between administrations trying to find their place in it all. While the upcoming lame duck Congressional session still may try to address several lingering bills that affect the clinical trials industry (e.g., 21st Century Cures Act, Right to Try Act, Medical Innovation Act, Reciprocity Ensures Streamlined Use of Lifesaving Treatments [RESULT] Act of 2015, etc.) all eyes seem to be turning away from the legislative branch and toward the executive branch of government as President-elect Donald Trump prepares to take office.

We Don't Know What We Don't Know

While there are many unknowns to sort out, one certainty that the change of leadership will bring calls into question the longevity of the Patient Protection and Affordable Care Act (PPACA) (plus the Senate's "fix-it bill" entitled Health Care and Education Reconciliation Act [HCERA] that passed little more than a week later, or together commonly known as "Obamacare"). The repeal of this piece of legislation (with or without replacement) and/or its defunding, has been a highly touted campaign staple of many representatives (including President-elect Trump) who were elected or re-elected this cycle. Therefore, just as we analyzed the act upon its passage in 2010, it bears reanalyzing for the reverse reason—what goes away in the event of a repeal and/or defunding.

Whether you get a repeal without replacement, a repeal and replacement, a "tweaking," or a defunding, if you run a business you need to seek advice. As a business, there will be a shift in all of the requirements, tax credits, and penalties surrounding your provision of health insurance to employees. There are also other operational requirements that may or may not affect your business (e.g., PPACA Section 4207 requiring companies of more than 49 employees to provide for up to one year post-partum a private place other than the bathroom for nursing mothers).

The potential general business impacts are far outside our focus, which herein will be on the sections whose repeal or defunding will likely affect clinical trials operations and business planning. Also beyond the scope of this article is the impact on the repeal or defunding of the sections pertaining to general healthcare operations, such as the Hospital Value-Based Purchasing Program described in PPACA Section 3001, the development of

Accountable Care Organizations as described in PPACA Section 3022, and other sections. Each organization will determine how it may restructure to meet any new paradigm, and how clinical trial operations fit in.

What we will focus on are the sections that will have the most direct impact on the clinical research industry, what would likely happen in the event of a repeal or defunding of the PPACA, and what you may be able to do about it if you choose. Each section of the PPACA (or the HCERA if relevant) is provided to you for your reference to read and make your own determinations.

Multiple Sections Affecting Insurance Coverage

Likely most of what you know about the PPACA overall relates to how individuals obtain private insurance. Repealing the PPACA will undoubtedly cause insurance migration and benefit restructuring for those affected by a hodgepodge of provisions such as i) eliminating the required provision of "adult child" coverage until the age of 26 (PPACA Section 10201); ii) elimination of pre-existing condition limitation clauses (PPACA Section 1101); iii) elimination of annual and lifetime coverage limits (PPACA Section 10101); iv) elimination of the "individual mandate" to have health insurance coverage or pay a tax (PPACA Section 1501); and v) elimination of the "Cadillac Plan" tax (the 40% tax on the provisions of an insurance plan determined "excessive" by the federal government) (PPACA Section 9001).

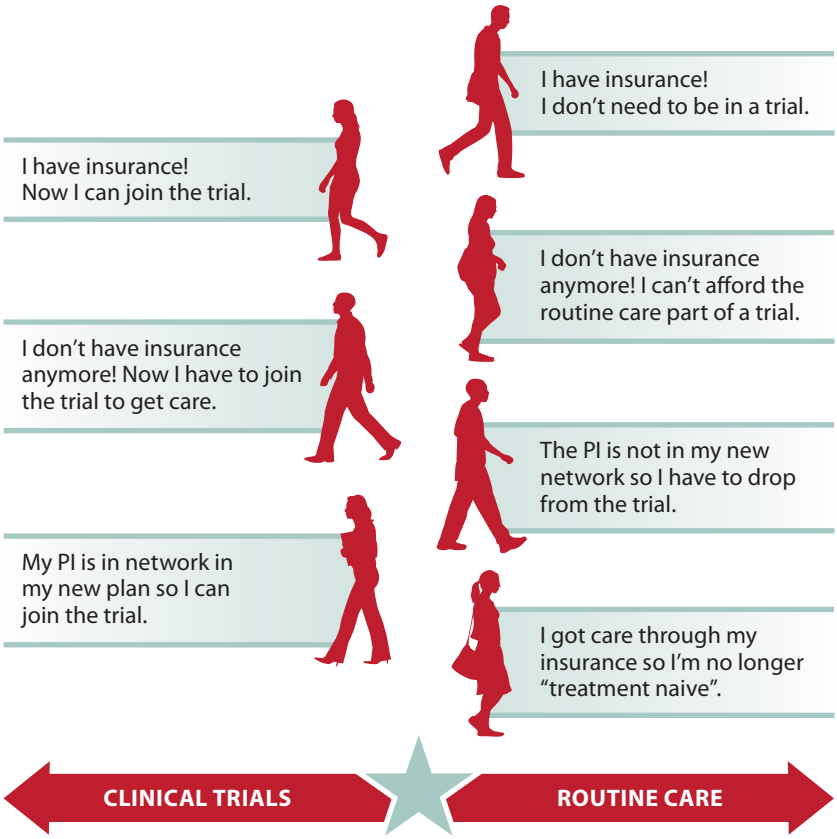
About 32 states expanded their Medicaid programs to individuals earning up to 133% poverty level income via PPACA Section 1331. Under this program, the increased cost to the state was covered under PPACA by the federal government until 2016, after which the states would have to pick up the increase on their own. As state Medicaid programs have a federal matching component, repeal or defunding of the PPACA jeopardizes that matching funding of the expanded Medicaid, thus significantly increasing the state's financial obligation to where it may not be affordable. Thus it would appear that, to the extent that the Expanded Medicaid component is not sustainable without the federal match, the states would revert back to traditional Medicaid. This would disenroll anyone on Expanded Medicaid so that they would have to obtain health insurance on their own (e.g., through their employer).

One of the hallmarks of the PPACA, spread across multiple sections, was the establishment of health insurance exchanges so that individuals could have a state marketplace to purchase an individual health insurance policy and obtain federal subsidies for its cost. Unlike the Expanded Medicaid program that a majority of states opted into, most states did not opt into running their own exchange, thus the burden fell on the federal government to run (or assist in running) many of the exchanges. With the repeal or defunding of the PPACA, this hallmark component of the act will arguably go away, as there will be no method of operating it and/or no federal subsidies for the individuals. The result will be that those individuals purchasing their insurance coverage through an exchange will have to obtain insurance via another mechanism (i.e., Medicaid, employer-based insurance, etc.).

To summarize the impact of the three paragraphs above, the repeal and/or defunding of the PPACA will likely cause insurance migration among tens of millions of Americans. Given the fact that enrollment and retention in many clinical trials is affected directly or indirectly by an individual's insurance status, it challenges research site leaders to think about their patient population, how they will shift, and how this shift will affect recruitment and retention for the kinds of trials that they do. Figure 1 shows some potential reason individuals migrate toward or away from clinical trials, based on their insurance status either initially or midway through the trial.

Be sure to tell your federal representatives now, rather than later, what you liked about the PPACA, what you wish would go away completely, and how you would make it better.

FIGURE 1: Some Reasons Why Individuals Migrate Toward or Away from Trials



The repeal and/or defunding of the PPACA will undoubtedly cause insurance migration among tens of millions of Americans. Given the fact that enrollment and retention in many clinical trials is affected directly or indirectly by an individual's insurance status, it challenges research site leaders to think about their patient population, how they will shift, and how this shift will affect recruitment and retention for the kinds of trials that they do.

PPACA SEC. 6002: Transparency Reports and Reporting of Physician Ownership or Investment Interests

Many people do not realize that the language that was once known as "The Physician Payment Sunshine Act" actually passed congress as part of the PPACA. The Sunshine Act failed to pass Congress twice as stand-alone legislation, and eventually made it through as a bolt-on section of the PPACA. Although it is often called the "Sunshine Act" in the vernacular, it is officially called "Open Payments" by the Centers for Medicare and Medicaid Services (CMS), its administering body, as its requirements go beyond just physicians and just payments. Thus, being hardwired in the PPACA, if there is a complete repeal of the PPACA or even a defunding of CMS's ability to coordinate the Open Payments program (i.e., the website, collection of data, etc.), the Sunshine Act requirements go away.

Supposing it goes away, unless renewed as part of a replacement for the PPACA or via a third try as stand-alone legislation; the stakeholders will be left without all the positives and negatives this effort has brought. This is not to say that a private effort could not take place to do this on a national level, nor is it to say that states will not create or expand their own version of the law for state reporting (and certainly both could be done as well). Needless to say that if you believe there is merit to gathering and posting this information, you have a great opportunity to revamp this entire process in the event of a repeal of the PPACA.

PPACA SEC. 6301: Patient-Centered Outcomes Research

This section amends the Social Security Act by adding a section to create and fund the private/public partnership known as the Patient Centered Outcomes Research Institute (PCORI). While many clinical research institutions are familiar with PCORI, more can be learned at www.pcori.org.

The agency and its funding mechanism (Patient Centered Outcome Research Trust Fund) was created by the PPACA. Since its inception, PCORI has created its board, hired staff, and funded many studies (you can see the reports on its website). The trust fund gets funded from a combination of federal dollars (~$150 million/year from the U.S. Treasury plus ~$85 million from the Federal Hospital Insurance and Federal Supplementary Medical Insurance) and private dollars via a required contribution from private insurers (the Patient Centered Outcome Research Fee) of $2 per year per covered life in 2013 and increased annually for inflation, which is bringing in approximately $220 million/year.

There is no immediate cash flow danger, as the FY2014 report stated PCORI had approximately $626 million cash on the bank for operations and study funding. Nevertheless, even if the above estimated numbers are a little off, a complete repeal or defunding of the legislation that created and provides the funding mechanisms could affect the financial health and/or the sustainability of this organization. If you desire to maintain or change anything about PCORI or its funding, please contact your legislators.

PPACA SEC. 7002: Approval Pathway for Biosimilar Biological Products

The repeal or defunding of this section (also called "Biologics Price Competition and Innovation Act of 2009") presents some strange questions. Through this section of the PPACA (again at the risk of oversimplifying the issue, as there are lots of caveats in this section), Congress formalized the creation of a biosimilar approval pathway for the U.S. Food and Drug Administration (FDA). Although FDA was kind-of-sort-of doing this already, amending federal law in this manner gives the agency the legal backing to do what it does—essentially the legislative branch of government (both the House of Representatives and the Senate) backing and providing additional structure for the executive branch's (i.e., FDA's) efforts here.

Many clinical trial sites have conducted biosimilar approval studies. This section of the PPACA gave the legislative authority for FDA to create the approval pathway, as well as to provide the exclusivity incentives (similar to that of drugs) necessary for the innovators. In this case, the exclusivity periods for biosimilars are essentially 12 years for the innovator product, an optional six-month pediatric extension, and then one year for the first biosimilar competitor product. A complete repeal of the PPACA would eliminate this provision, and the legislative backing for the FDA. Therefore, it challenges the system on if, when, and how we continue to do biosimilar studies. It's possible that FDA can continue as it did as long as it remains unchallenged; however, regulatory experts will have to sort this out.

PPACA SEC. 9008: Imposition of Annual Fee on Branded Prescription Pharmaceutical Manufacturers and Importers and HCERA SEC. 1405: Excise Tax on Medical Device Manufacturers

To the extent that increased taxes on pharmaceutical and device manufacturers have negative impacts on research and development (R&D) funding, the corollary is (hopefully) true—that if you reduce taxes on these organizations, they would have more money for R&D. Setting aside prognostication on what will

happen with business taxes through changes to the Internal Revenue Service code, in the event of a repeal of both the PPACA and the corollary HCERA, two taxes will certainly go away.

The PPACA (originally and as amended by HCERA) sets a tax on pharmaceutical manufacturers based on a percentage of sales of branded prescription drugs (excluding orphan drugs) to specified government programs (i.e., Medicare, Medicaid, Veterans Affairs, Tricare, etc.). At the risk of oversimplifying the formula and eliminating the description of a sliding scale for companies with less than $400 million in revenue, the tax levied on manufacturers is that they pay their percentage (of their sales to specified government programs) of the amount the government wants per year (a base rate of $4 billion in 2017, $4.1 billion in 2018, and $2.8 billion in 2019 and thereafter). For example (and again oversimplifying a bit), if a sponsor has 2% of the government's pharmaceutical purchases, it would owe $80 million in 2017 (2% of the base rate). The HCERA bill also slightly amended this section by adding what is essentially a joint and several liability clause to this section, so that if a company goes out of business that year, everyone else essentially has to pitch in to cover the lost percentage.

For device manufacturers, the PPACA originally had a similar tax calculation model (a percent of sales multiplied by a base amount), but the HCERA bill completely overhauled that section and replaced it with a simple flat tax of 2.3% of the price of all taxable medical devices sold (a "taxable device" as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, except items such as eyeglasses, contact lenses, hearing aids; and other devices to be determined by the secretary of the U.S. Department of Health and Human Services using the criteria of "generally purchased by general public at retail for individual use").

Most major pharmaceutical and device manufacturers stated the impact of these taxes on their annual reports to be in the tens to hundreds of millions of dollars. To the extent that these dollars, or at least a percent of them, are reinvested in R&D, it would mean resources for clinical trials and related investments. Of course, as is the case with removing any collected tax, addressing where the money is spent (in this tax case, it's to help pay for Medicare Part B), there are no easy answers. There are always trade offs.

PPACA SEC. 10103: Coverage for Individuals Participating in Approved Clinical Trials

While Medicare has been required to cover the routine care costs of qualified clinical trials since 2001, there was no such federal requirement for private insurers to do so until the PPACA. While many states required similar coverage for cancer-related clinical trials, the addition of this section in the PPACA created a federal floor for the mandated insurance coverage of routine care costs of qualifying trials.

Essentially, with some grandfathering and some exclusions, an insurer could not deny, limit, or impose additional conditions on coverage for the routine patient costs for items and services furnished in connection with a qualifying trial (for cancer or other life-threatening diseases), nor could they discriminate on the basis of an individual's participation in a trial. While the caveats of this provision include details on handling in-network versus out-of-network coverage as well as out of state coverage, it would all be moot in the event of a repeal (noting that defunding alone would not have an impact here). In the event of a repeal of the PPACA, unless replaced this federal floor goes away, and thus any requirements imposed on the private insurance carriers for covering the routine care costs would revert back to the individual states. Approximately 39 states have laws requiring coverage (mostly for cancer clinical trials) and the others have no such requirement, leaving it up to the free market to decide.

A related additional item to think about here is that one of President-elect Trump's campaign positions to help lower healthcare insurance costs was to eliminate the state-line boundaries of health insurance to increase national competition. While there are challenges in accomplishing this, should it occur it will require the sorting out of how to amalgamate the varying state laws when these traditional boundaries are eliminated. Granted there will be many other items in this vortex, nevertheless this is one that is deeply important to those conducting oncology studies and others that blend routine and conventional care into the research protocols.

Conclusion

There will undoubtedly be changes to come, but the dealings with the PPACA legislation will be high on everybody's watch list. We have an unprecedented opportunity to help guide this wind of change in our favor. Be sure to tell your federal representatives now, rather than later, what you liked about the PPACA, what you wish would go away completely, and how you would make it better. One thing is certain…what does not change is our need to efficiently provide quality data on time and at low cost while protecting the rights and well-being of the research volunteers. Always focus on that, despite where any of these winds of change take you.

Lastly, always remember to be stubborn on your vision but flexible with the journey.

> To the extent that increased taxes on pharmaceutical and device manufacturers have negative impacts on research and development (R&D) funding, the corollary is (hopefully) true—that if you reduce taxes on these organizations, they would have more money for R&D.

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[DOI: 10.14524/CR-16-0020]

Academic Preparation in Clinical Research: *Experience from the Field*

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Joe Benner, MACPR, RAC, CCRP
Kathryn Jelinek, MACPR, CCRP
Rebecca Namenek Brouwer, MS
Beth Casey, BSHS, RN
Jennifer Lanter, MSPH, RN, CCRC
Marjorie V. Neidecker, PhD, MEng, RN, CCRP

In 2012, the Institute of Medicine published a seminal work outlining an approach to transform the clinical trials landscape in the United States. This work emphasized a greater need for education and training for all levels of clinical researchers, inclusive of investigators and the wide range of professionals employed across the enterprise.

Why is this important? In clinical decision making, the number of facts considered in the treatment of a patient has steadily increased from an estimated 25 facts per decision in 2000, to 80 facts per decision in 2010, to an amazing 1,000 facts per decision by 2020, mostly due to the exponentially increasing amount of data and decision-points in genomics, genetics, and proteomics.[1,2] These decision factors are in keeping with published literature on the complexities of clinical trials in the current decade.[3]

THE NEW REALITY

Complexity is our new reality, and innovations in clinical trial design, development, and implementation will require a workforce that is able to keep pace. The harmonization of overall clinical and translational science competencies with those defined by the Joint Task Force (JTF) for Clinical Trial Competency will ensure this workforce is well prepared for the challenges ahead in the next decade of clinical research.[4]

Some professional organizations are embracing the formal structuring of current and emerging roles to reflect core competencies for clinical research professionals.[4,5] In response, academic and formal training programs and policies have emerged to fill this need.

TABLE 1: Clinical Research Site Role Opportunities

Role Category	Sample of Job Titles
Regulatory Affairs	• Regulatory Coordinator
	• Senior Regulatory Coordinator
	• ClinicalTrials.gov Coordinator
	• Regulatory Affairs Compliance Officer
Study Coordinator	• Clinical Research Specialist
	• Senior Clinical Research Specialist
	• Clinical Research Coordinator
	• Senior Clinical Research Coordinator
	• Research Program Leader
	• Associate in Research
	• Project Coordinator
	• Project Manager
	• Clinical Research Nurse
	• Senior Clinical Research Nurse
Data Management	• Data Entry Operator
	• Data Coordinator
	• Senior Data Coordinator
Grants and Contracts	• Data Processing Specialist I and II
	• Programmer Analyst
	• Sponsored Programs Analyst
	• Budget Analyst
	• Research Billing Associate
	• Contract Analyst
	• Program Manager I and II
	• Grants and Contracts Specialist
	• Grants and Contracts Officer
	• Conflict of Interest Administrator
	• Associate Director of Sponsored Projects
	• Director of Sponsored Projects
IRB Administration	• Protocol Analyst I and II
	• IRB Regulatory Specialist
	• Regulatory Compliance Manager
	• Assistant Director of IRB
	• Director of IRB

Note: This is an abbreviated sampling of job titles per role category derived from a search of research positions at several AMC sites, and is not intended to be an exhaustive list.

However, an individual with a goal of working in the clinical research field has many pathways from which he or she can choose.[6] Most position postings in clinical research prefer an applicant to have earned a bachelor's degree and have the requisite years of "experience." This is a challenge for those new to the profession, who are faced with the necessity of gaining experience in order to enter the field.

Individuals considering the clinical research profession may ask, "Are there ideal paths to success?" and "How have others advanced in this profession?" Academic programs and clinical research internships can help open doors to new opportunities.

This article introduces competency-based approaches for clinical research education, training, and progression, and shares vignettes about the career paths of a variety of clinical research professionals.

THE CLINICAL RESEARCH SITE

Clinical research sites employ a wide spectrum of individuals. In the mid-1980s, academic medical centers (AMCs) were structured such that principal investigators (PIs) would hire nurses and data entry clerks to manage their clinical trials. Back then, it was common for administrative assistants or PIs to submit protocols and informed consent forms to the relevant institutional review boards (IRBs), and sometimes to serve as the study coordinator. Even IRBs were supported by only a few staff members.

To be sure, clinical research studies were once far less complex. Notably, at that time few clinical research sites operated outside AMCs, and very few contract research organizations (CROs) were in existence.

Today's AMC research sites employ a broad range of clinical research staff (see Table 1), and IRBs have expanded with a wide range of positions. Moreover, companies in the private sector now have staff holding positions and responsibilities in the field that are very similar to those found in AMC-based study sites.

However, a significant problem exists in the current research environment; two job postings with the same title may have very different requirements and responsibilities. Further, there is a lack of training consistency and progression plans for these roles. These gaps burden human resource departments, whose staff may have a general lack of understanding about the value of research operations and the role of clinical research as the lifeblood of an AMC.

Most position postings in clinical research prefer an applicant to have earned a bachelor's degree and have the requisite years of "experience." This is a challenge for those new to the profession, who are faced with the necessity of gaining experience in order to enter the field.

STORIES FROM THE FIELD

The vignettes presented here highlight the journeys taken by some of the authors of this article in their clinical research careers. The stories explore how these individuals broke into the clinical research field, their education and training experiences, and how their roles progressed.

A CLINICAL RESEARCH NURSE STORY

Carolynn J. became a clinical research nurse coordinator after working for two years in a coronary care unit at a university hospital in the mid-1980s. Prior to a clinical research role, she had no prior knowledge of or coursework related to clinical research as a professional pathway. As she received training in an on-the-job fashion, her coordinator job duties changed from those of a clinical research nurse to a research nurse coordinator, and later from those of a study coordinator to a program manager.

Within five years, Carolynn ascended to a role as a research nurse manager and was administrator of a National Institutes of Health (NIH)–funded coordinating center, with duties in project management and monitoring. She also worked as a research director for a private practice group supervising a range of staff.

Carolynn is a member of multiple clinical research professional associations. She added a Master of Science in Public Health (MSPH) degree in epidemiology to her BSN ("because no clinical research degrees were accessible to me at the time") and, in 2014, a Doctorate in Nursing Practice (DNP). She states, "At the beginning of this clinical research journey, I had a thirst for knowledge about the role and sought journal articles to find out more. When I landed upon clinical research professional organizations, I immediately joined. I purposefully sought ascending degrees that would enhance my knowledge of research and mentored many individuals in the role. This is a fantastic area to work in. There are so many directions I could go in this profession, and now I have options to generate and lead research projects and consult, in addition to my teaching role in the university. This way I can contribute to improving our enterprise!"

A CLINICAL RESEARCH TRAINER STORY

Kathryn J. entered the clinical research field at an academic institution 25 years ago, after first attending medical school for a year but having then experienced a change of heart. She had majored in natural science in her undergraduate work with a lifelong goal of attending medical school and becoming a pediatrician. After the first year of medical school, she reconsidered her ultimate career and family goals.

Knowing that she wanted to stay in the healthcare field, Kathryn discovered the wide world of clinical research. She started working in the field as a data coordinator, gaining experience with managing data on paper case report forms. She continued to progress through various research roles, such as a Phase II grant lead site coordinator, a protocol compliance auditor, and a regulatory manager. Each of those roles provided an opportunity to learn about different facets of clinical research, but not necessarily the "why" behind those facets. All of the training came in the form of on-the job experience.

While serving as a clinical research manager, Kathryn had the opportunity to continue to expand her experience with regulatory responsibilities (such as IRB submissions, study registration, study monitoring, etc.) and clinical responsibilities (such as patient recruitment, informed consent, completing data both electronically and on paper, etc.). This position also introduced her to the business side of clinical trials, such as developing study budgets, assisting with clinical trials agreements, and invoicing for study payments. While in this position, a new graduate program in clinical research became available. This provided the opportunity to expand her knowledge about clinical research operations in a formal setting.

Kathryn's journey has been an exciting one, but she acknowledges that, "While hands-on experience is a necessity in the clinical research arena, the evolution of official academic education in this field will lead to better prepared clinical research staff more quickly."

A REGULATORY AFFAIRS PROFESSIONAL STORY

Joe B. is excited by the convergence of scientific challenges, advancement in medicine, and regulation in clinical research. As an undergraduate student in the biological sciences, he entered the profession through diverse research assistant positions at an AMC. His involvement in data and specimen management and clinical activity with research participants fostered his appreciation for the spectrum of good practices.

Joe's career continued at a pediatric hospital, with new regulatory responsibilities. "Interfacing with patients and subjects revealed the broad effects of regulatory activity on medicine and healthcare," he says. "I discovered my passion to help people by working to expedite the process of clinical development and improve medical treatment options. I felt more than excited. I was driven."

Through a regulatory position in oncology, Joe later focused on industry and investigator-initiated clinical trials. He continued to learn by exposure on the job, and through regulatory and clinical research publications. There were many avenues to explore, and he quickly recognized that an advanced degree and professional credentialing in regulatory affairs were key to transitioning into the next phase of his career. Diving in, he earned both over the next few years; the results were tremendous, because they opened doors to new job opportunities in the field.

The curriculum of a graduate degree expanded the scope of Joe's expertise. It spanned across the field of clinical research to incorporate communication, leadership, and management. In global product development, changing regulations and environments require an ability to adapt and effectively communicate. The graduate program accelerated the learning curve and prepared Joe to collaborate across organizational functions. It enabled him to take on responsibilities that are integral to regulatory affairs, but would have otherwise taken years of experience to navigate.

A RESEARCH BILLING AND COMPLIANCE OFFICER STORY

Jennifer L. started her career as a nurse. After a couple of years, she was offered a position as a cardiology clinical research coordinator. Like many in this position, she had no prior knowledge of clinical research as a career and her training came on the job. Fortunately, she loved the job, and she developed a passion for learning about the entire clinical research enterprise.

After becoming a Certified Clinical Research Coordinator (CCRC®), Jennifer developed a regulatory specialist role and eventually became director of her unit. After eight years, she was provided an opportunity to help open a Clinical Research Center focusing on investigator-initiated and NIH-funded studies. This was a great opportunity to round out her experience, which had been mostly pharmaceutical studies to that point, and it allowed her time to obtain her MSPH with a focus on clinical investigation.

After two years as a nurse manager with the research center, Jennifer followed her boss to Columbus, Ohio to manage his clinical research program. Regrettably, her boss was not satisfied with the transition and left Ohio shortly after arriving. With her experience she was able to secure a new position working for a Hospital Billing Office as a manager in research billing and compliance. She developed a Research Billing Office and was promoted to a director position, in which she was able to learn about the revenue cycle while educating researchers and hospital staff about research and research billing.

Jennifer's research experience opened an opportunity to assume additional responsibility over the Revenue Cycle Clinical Support (RCCS) department. RCCS completes clinical pre-certifications and denials, many of which are considered experimental and not medically necessary. Her research education has opened many opportunities—not only in clinical research, but in healthcare in general.

A CLINICAL RESEARCH ASSOCIATE (CRA) AND CONSULTANT STORY

After working as a staff nurse in multiple critical care settings, Beth C. transitioned in 1987 to a clinical research nurse position at an AMC to coordinate a large, global NIH trial. Her training was largely on the job. Over the next decade, she worked as a research nurse coordinator in multiple therapeutic areas, including HIV/AIDS, transplant, and oncology.

During the early 1990s, clinical research certifications emerged along with coordinator training programs. Achieving ACRP's CCRC certification, in tandem with multitherapeutic experience, helped with Beth's career advancement to a research site management position. Meanwhile, pursuing a graduate nursing path in the 1990s did not much aid anyone interested in clinical and translational research, but focused more tightly on nursing research.

"As time passed, the emerging requisite knowledge of complex protocol development and patient safety issues, intensifying competency requirements, and burgeoning local and international regulations often received short shrift in curriculums for medicine, nursing, and allied health programs." Ultimately, pursuing an academic degree in clinical research contributed to Beth's career advancement in site management, pharmacovigilance, project management, and CRA roles.

Beth also had increased opportunities to serve as a consultant on issues related to site development/training needs, operations and quality management, medical data and safety review, and pharmaceutical development. She feels the most significant trend is the demand for high-quality, value-based execution of trials at all levels, saying, "The use of informatics has accelerated quality and pace in the industry. Sponsors in pharma and biotech no longer support 'accident forgiveness' with costly outcomes from untrained investigators/site staff and those actually managing the trials on the sponsor's behalf (CROs, vendors, CRAs, project managers, operations leads, etc.). Highly competent, educated, and well-trained research professionals and those responsible for oversight must produce quality from the first patient first visits to the final analyses."

CLINICAL RESEARCH COMPETENCIES: CURRENT APPLICATIONS

Competency-Based Approach to Academic Education

In an effort to generate an evidence base for clinical research curricula, leaders of the Consortium of Academic Programs in Clinical Research (CoAPCR) conducted a literature search of adopted clinical research core competencies from nursing, physician, and professional association groups. The findings were further discussed and harmonized in a gathering of clinical research stakeholders led by the JTF and culminating in the publication of "Harmonized Core Competencies for Clinical Research Professionals."[4]

Eight competency domains and 51 core competencies have been adopted by CoAPCR, and have become the basis for curriculum development and curriculum restructuring across several academic programs in clinical research. A competency-based accreditation pathway for these academic programs is evolving for a 2017 launch.

Competency-Based Approach to Clinical Research Training

After the JTF disseminated the "Core Competencies" in 2014, the Association of Clinical Research Professionals concentrated its training and development program to focus on competency domains, and has mapped its certification exams to the clinical research core competencies.

Moreover, several AMCs have begun to restructure their training programs using the core competencies as a roadmap for the curricula and assessing content knowledge. A focus group comprised of 62 AMC sites funded by NIH's Clinical and Translational Science Awards (CTSA) program mapped the core competencies for clinical investigator and study coordinator roles.[7] This work led to the establishment of multiple assessments of competence that have been made publicly available at www.ctsa-gcp.org.

Since many individuals continue to enter clinical research roles with no relevant education or training, these proactive contributions to competency-based training can inform site training and policies for onboarding and continuing education of research personnel.

After the JTF disseminated the "Core Competencies" in 2014, the Association of Clinical Research Professionals concentrated its training and development program to focus on competency domains, and has mapped its certification exams to the clinical research core competencies.

Competency-Based Approach to Clinical Research Human Resources

Duke University conducted a study to apply a competency-based approach to reconfigure job classifications for clinical research staff. Small working groups of research staff, followed by a widely deployed stoplight evaluation, were used to gain consensus on competencies in each job classification. Agreed-upon competencies were matched to jobs from entry level to leadership levels using a tool they designed in REDCap™. This has resulted in improved definition and organization of job descriptions, and in a competency-based objective approach for progression.

Rebecca Namenek Brouwer, associate director for research operations in the Duke Office of Clinical Research, a unified research support office,[8] reported that mapping under way with more than 700 clinical research staff was expected to be completed by the close of 2016.[9] This groundbreaking work demonstrates that the gaps in job titles, descriptions, and progression can be remedied with a competency-based approach.

CONCLUSION

Individuals pursuing interests in clinical research have multiple doorways by which to enter the field, and many different possible career ladders to climb as they explore it. Competency-based approaches to human resources in clinical research will help to better define the field and mechanisms for advancement.

The professionalization of clinical research careers suggests that the field's educational pathways offer opportunities for expanding knowledge, skills, and attitudes that are based on competencies. Becoming a competent professional would also include such elements as membership in professional associations, dedication to continuing professional education, openness to mentoring, and achievement of certification.

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OPERATING ASSUMPTIONS
Ronald S. Waife

[DOI: 10.14524/CR-16-4054]

Visiting the URGENCY ROOM

One of my friends in the biotech industry explained the business with this metaphor: Working in biotech was like running full speed at a brick wall, and at the last possible second, the brick wall would disappear, only to be replaced by another brick wall farther ahead.

While common enough in small, entrepreneurial companies, any sense of speed, focus, and anxiety is rarely found in Big Pharma.

Those brick walls, of course, represented critical milestones, such as another round of venture funding, or a research result, a regulatory filing, and so on. It was the idea of running full speed that stayed with me. While common enough in small, entrepreneurial companies, any sense of speed, focus, and anxiety is rarely found in Big Pharma, despite lip service to the contrary. Where is the sense of urgency in clinical development?

Organizing for Complacency

This is not to say that we do not all work hard. It is not to say we don't care about the progress of our work, but it is to say that at most pharmaceutical companies, on a day-to-day basis, we have neither the energy, direction, nor discipline to conduct our operations urgently. The truth is, there are many reasons to do so, including deadlines, stock options, competition, everyday failures, demanding bosses—not to mention the patients with few, unsatisfactory options waiting for our new therapies.

Some of us (people and companies) certainly may start with enthusiasm. However, particularly at the clinical stage, so many factors build up to weigh us down—the myriad inherent delays, the disappointing scientific results, the bureaucracy of corporations and regulations, the unavoidable time intervals of research itself. This is all true, but that's what we are here for—"that's why they call it work."

Most companies have institutionalized processes for complacency, rather than for urgency. Some have become standard behavior since they are so familiar:

- Slow contracting with contract research organizations (CROs)
- Slow payments to vendors and investigators
- Slow information technology projects that are completed years after originally estimated
- Slow adoption of already-approved process changes
- Slow responses to poor performance metrics
- Slow reporting of information requested by operational staff from report programmers
- Slow protocol development
- Slow document review and approval
- Slow study start up

How many of these do you take for granted, and assume they are inevitable? But they are not inevitable; they are all human-driven! These are not immutable laws of nature; these activities are slow because we allow them to be! There is nothing standing in the way of speed except the lack of will, the lack of urgency.

Just Do it

Another anecdote: During the beginning of one of my first consulting assignments, I mentioned to my client (a junior vice president) that my invoice hadn't been paid. He stood up, told me to wait there, and left his office for about 20 minutes. He came back with a paper check and handed it to me, apologizing. Well, I was spoiled for life, but the point is, of course it's possible to get a check cut, a report run, a contract signed, a meeting scheduled! It just takes a person to do it.

Not all delays—maybe not even most—are caused by perverse obstinance. Think of the many things that fill our days instead of urgent work—e-mails, meetings back-to-back and triple-scheduled, teleconferences where you can't hear what most of the people are saying. It's all too easy for our days to slip away.

What most of us are *not* doing is comparing our tasks, our to-do lists, or our schedules to the most important work list of all: What are the goals of my organization, my department, my project? How is what I am doing right now serving those goals? What does deciding this issue, or reading this e-mail, have to do with moving closer to these goals?

Getting There from Here

Changing an environment from complacency to urgency requires some bravery and lots of leadership. Let's look at some examples:

- You've been in a team meeting all morning, getting close to the end of a long project that's intended to develop a new set of evaluation criteria for your CROs. The leader asks if all are in agreement, and one key member says, "Maybe, but I have to check with my boss. We'll get back to you."
- You're working with a statistician on completing the final study report analysis for a trial. It's not due until next month, but you're very nearly done and it would be advantageous to get it submitted early. You call her up for the third time that day, and find out she's gone home, and will be on vacation for two weeks—something she neglected to tell you about.
- You got approval to add someone to your staff at the beginning of the year, but the human resources office still hasn't send you qualified resumes. When you pick someone to interview, it takes weeks to schedule her (or she has already found another job). When you try to take matters into your own hands, you are scolded for not following procedures.
- You've finally scheduled a teleconference with a key opinion leader who is very hard to reach. You need the data manager in on the call, but he is in another building on campus and says it's too far to walk. You could tie him into the telecon, but he points out (correctly) that his accent is too thick to be well understood over the phone.
- Marketing has been warning for years that you need real-world patient experience data to be competitive with your new allergy medication, but the competition's success hasn't changed the regulatory office's skepticism about using electronic clinical outcome assessment in the study. Instead of engaging with data management on the issue, the regulatory office keeps asking to see one more demo from one more vendor.

I am sure you can provide many examples from your own organization. What's missing in each of these situations is someone to speak up—not to argue the issue, but to remind all involved that we are holding up the improvements, the decision, the work. Everyone on the team needs to understand that the work is urgent; we needed to hire that new person yesterday, we needed that new software yesterday, we needed those data yesterday, we needed those sites ready for first-patient-initiated yesterday. Further, once having spoken up, we need to pursue the resolution to a quick closure, using whatever channels of authority are necessary.

Equally essential is the commitment and vocal backing of executive leadership to make clear that urgency is an organizational value and priority.

Follow the Example

To a healthcare team in your local Emergency Department, questions of priority, focus, and speed are regularly and clearly answered. They know how to triage, how to follow emergency care protocols, how to choose and listen and analyze and solve with calm, professional urgency. We all need this essence—to triage our work lives and cut through the low priorities; and we need to encourage our colleagues to do the same, so we can bring our collective focus and precious energy to the meaningful work our companies and organizations are doing.

This is why we chose this profession; let's do it with urgency.

What most of us are *not* doing is comparing our tasks, our to-do lists, or our schedules to the most important work list of all: What are the goals of my organization, my department, my project?

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Global Self-Assessment

of Competencies, Role Relevance, and Training Needs Among Clinical Research Professionals

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[DOI: 10.14524/CR-16-0016]

Competency-based education and training has been defined and applied by several groups in the clinical research enterprise,[1–4] mostly through an approach focused on specific roles (e.g., investigator, pharmaceutical physician, or clinical research nurse). However, the Joint Task Force for Clinical Trial Competency (JTF) aligned and harmonized the many role-centered statements into a single framework of eight domains and 51 associated core competencies defining professional competence throughout clinical research roles.[5] The resulting JTF Core Competency Framework (CCF) has been widely published, presented at scientific meetings, and applied by numerous organizations worldwide.

The Association of Clinical Research Professionals concentrates the elements of its Career Development Pathway, its professional certification programs, and its annual Meeting & Exposition structure based upon the CCF. Further, the Consortium of Academic Programs in Clinical Research and its member institutions have adopted the CCF to guide curriculum development and inform accreditation criteria for academic programs in clinical research.

The CCF is also being used to redefine job descriptions and support workforce development initiatives. For example, the Clinical and Translational Science Award (CTSA) Consortium has embraced the CCF as a structure for investigator and coordinator training.[6]

The JTF conducted a multinational survey of clinical research professionals, requesting that participants self-assess their competence levels and assess the significance of the specific core competencies to their current professional activities, as well as their perceived need for further training to enhance the performance quality of their roles. This survey was a first attempt to validate perceptions of competence and relevance of competencies by clinical research professionals, and further assesses self-reported learning needs for each competency.

Methods

Survey Tool and Participant Recruitment

An electronic survey tool was developed (through the online SurveyMonkey™ platform) for ease of digital distribution and response. The questionnaire included a demographic component and an assessment of perceived competence, relevance, and educational need across each of the CCF's 51 competencies.

Individuals working in clinical research, inclusive of the roles of principal/co-principal investigator (PI/CoPI), clinical research associate (CRA), clinical research coordinator/nurse (CRC/CRN), data management (DM) professional, educator/trainer, pharmaceutical physician/medical director, regulatory affairs (RA) professional, and research administrator (including clinical research/project manager [RM/PM]) were targeted as survey participants.

The researchers used a snowball sampling approach to survey dissemination that included outreach through personal/professional contacts, e-mail listservs, presentations, and social media. The active collaboration of professional associations was also sought.

The survey was launched on December 12, 2014, and was formally closed on July 1, 2015. Participation in the survey was anonymous, with the SSL (Secure Sockets Layer) feature of SurveyMonkey protecting participant confidentiality.

The survey tool was pilot tested at the University of Michigan[7] and granted expedited approval by the Eastern Michigan University Human Subjects Review Committee. Further, the University of Michigan (U-M) Institutional Review Board issued a "not regulated" determination for U-M's role in analysis of de-identified data.

Demographic parameters collected in the initial segment of the survey are described in the survey tool, which can be found at www.coapcr.org/committees. Because this survey was devised as a snowball sample, population denominators could not be estimated.

In the survey's invitation and introduction, competencies were defined as the "knowledge, skills, attitudes, and behaviors necessary for a particular set of tasks or objectives in a specific function." Competence was defined as "the array of abilities across multiple domains or aspects of professional performance in a certain multidimensional and dynamic context." A competent professional was defined as "one possessing the required abilities in all domains in a certain context at a defined stage of education or practice."[8]

Respondents were asked to rate their own level of competence for each of the 51 core competencies, and the significance of each core competency to their current role using a five-point scale of 0–4 (see Figure 1).

The Association of Clinical Research Professionals concentrates the elements of its Career Development Pathway, its professional certification programs, and its annual Meeting & Exposition structure based upon the CCF.

Statistical Analysis Methods

As part of the analysis plan, the researchers translated results for "perception of competency" that included combined responses of 0, 1, and 2 from the competency key into a composite score of "0" (e.g., "less than competent"), and translated combined responses of 3 or 4 into a composite score of "1" (e.g., "competent"). This scale was also used for "perception of relevance to role."

FIGURE 1: Competence and Role Relevance Scales

Competence Key

0	Never been exposed to this content
1	Aware of the content, but never needed to become further informed
2	Exposed and sufficiently aware of content that I can look up what might be necessary for my role
3	Competent – Able to interpret or discuss concepts and use knowledge to solve simple problems based on application concepts
4	Mastery – Able to apply knowledge to complex problems, integrate information, and create solutions

Role Relevance Key

0	Unnecessary, no relevance to my role
1	Has some relevance to my role, but not my responsibility
2	Relevant to my role, but not a major component
3	Significant to my role and part of my job responsibilities
4	Major part of my responsibility or supervisory expectations

Moreover, for presenting "competence" or "relevance" scores by domain across roles, education, or experience, the researchers defined that a mean value of 0.6 or more implies "more competent" or "more relevant," and a mean value of less than 0.6 implied "less competent" or "less relevant."

Similarly, for measures of competence and relevance across roles and specific core competencies within a domain, the researchers defined that a score of 60% or more implies "more competent" or "more relevant" and a score of less than 60% implied "less competent" or "less relevant."

It may be viewed as a limitation of this study that the authors made this decision somewhat arbitrarily, but it provided a means of discussing potential educational need. For the questions "need for additional education/training" per domain or core competency, "1" indicated "yes" and "0" indicated "no."

The current levels of competence, significance to role, or need for training/education were analyzed across whole domains using one-way analysis of variance (ANOVA) or the Kruskal-Wallis test. A chi-square (X2) test was used to evaluate the current level of competence or significance to role for each 51 individual core competencies. Statistical analyses were performed using SAS software, Version 9.4 (SAS Institute Inc., Cary, N.C.).

Results

Survey responses were received from 2,194 professionals from across the globe. A total of 1,738 respondents completed the demographic component of the survey and at least one response to the competency/relevance/training need component. Of those respondents, 1,584 were designated as DM, RA, CRC/CRN, CRA, RM/PM, or PI/CoPI; regional responses from this total are shown in Figure 2.

The roles of PI/CoPI and CRA had the highest self-perception of competence (in seven and six domains, respectively). Most members of the clinical research team indicated they believed they were competent in the domains of "Ethical and Participant Safety Considerations" and "Clinical Trials Operations."

TABLE 1: Self-Perceived Level of Competence in JTF Domains by Role

Domains	Competence/Role (mean value)					
	DM (n = 47)	RA (n = 90)	CRC/CRN (n = 559)	CRA (n = 177)	RM/PM (n = 357)	PI/CoPI (n = 354)
Scientific Concepts and Research Design	0.3	0.3	0.3	0.4	0.4	0.8
Ethical and Participant Safety Considerations	0.4	0.7	0.7	0.7	0.7	0.8
Medicines Development and Regulation	0.3	0.5	0.4	0.5	0.5	0.5
Clinical Trials Operations	0.4	0.6	0.6	0.8	0.7	0.8
Study and Site Management	0.3	0.4	0.5	0.6	0.7	0.7
Data Management and Informatics	0.7	0.4	0.6	0.7	0.6	0.7
Leadership and Professionalism	0.4	0.5	0.6	0.6	0.7	0.8
Communication and Teamwork	0.5	0.5	0.6	0.6	0.6	0.8

Note: ANOVA p<0.0001 between roles across all domains at 5% significance. Shaded area ≥ 0.6, "competent."

TABLE 2: Self-Perceived Level of Relevance to Role by Domain

Domains	Relevance/Role (mean value)					
	DM (n = 47)	RA (n = 90)	CRC/CRN (n = 559)	CRA (n = 177)	RM/PM (n = 357)	PI/CoPI (n = 354)
Scientific Concepts and Research Design	0.2	0.2	0.2	0.4	0.3	0.7
Ethical and Participant Safety Considerations	0.3	0.6	0.7	0.7	0.5	0.8
Medicines Development and Regulation	0.2	0.4	0.3	0.5	0.4	0.5
Clinical Trials Operations	0.4	0.5	0.6	0.8	0.6	0.8
Study and Site Management	0.2	0.3	0.6	0.6	0.7	0.7
Data Management and Informatics	0.7	0.2	0.6	0.6	0.5	0.7
Leadership and Professionalism	0.4	0.4	0.7	0.6	0.7	0.8
Communication and Teamwork	0.4	0.4	0.6	0.6	0.6	0.8

Note: N = 1584. ANOVA p<0.0001 between roles across all domains at 5% significance. Shaded areas ≥ 0.6, "relevant."

TABLE 3: Self-Perceived Competence in the Five Core Competencies of the "Scientific Concepts and Research Design" Domain

Core Competency	Competence/Role (%)					
	DM	RA	CRC/CRN	CRA	RM/PM	PI/CoPI
Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as they relate to medicines discovery and development	29.6	28.3	28.6	41.9	39.5	76.6
Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature	40.7	30.4	31.3	37.2	38.4	83.4
Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design	29.6	23.9	27	29.1	38.9	64.7
Design a clinical trial	37	37	22.9	31.8	39.1	69.6
Critically analyze study results with an understanding of comparative effectiveness	37	31.1	21	40.7	35.5	83.7

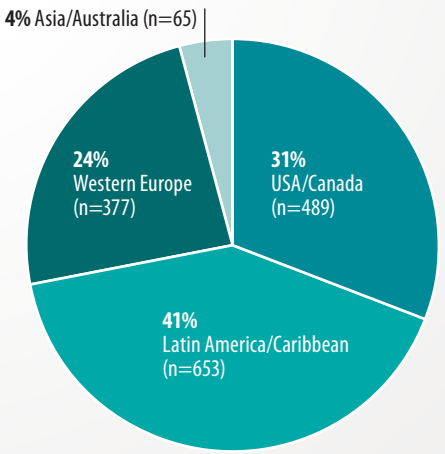
Note: Chi-Square, p< 0.0001 between all roles and competency. Shaded areas > 60%, "competent."

TABLE 4: Self-Perceived Relevance in the Five Core Competencies of the "Scientific Concepts and Research Design" Domain

Core Competency	Relevance/Role (%)					
	DM	RA	CRC/CRN	CRA	RM/PM	PI/CoPI
Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as they relate to medicines discovery and development	22.2	21.3	30.6	51.2	28.6	73
Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature	22.2	21.3	22.9	38.4	26.1	80.8
Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design	25.9	17	24.4	29.1	33.2	69.6
Design a clinical trial	25.9	25.5	20.3	29.4	26.2	68.1
Critically analyze study results with an understanding of therapeutic and comparative effectiveness	25.9	12.8	15.9	32.6	25.5	79.6

Note: Chi-Square, p< 0.0001 between all roles and competency. Shaded areas > 60%, "competent."

FIGURE 2: Survey Responses by Country/Geographic Region (N = 1,584)



Perceptions of Competence and Relevance

The self-perceived level of competence for survey participants by domain and role is shown in Table 1. The roles of PI/CoPI and CRA had the highest self-perception of competence (in seven and six domains, respectively). Most members of the clinical research team indicated they believed they were competent (e.g., mean value of 0.6 or above) in the domains of "Ethical and Participant Safety Considerations" and "Clinical Trials Operations."

The perceptions of competence in the domains of "Leadership and Professionalism" as well as "Communication and Teamwork" were high (> 60%) for most of the roles with the exception of DM and RA. Only the PI/CoPI role showed mean values of "competent" (≥ 0.6) in the domain of "Scientific Concepts and Research Design." Furthermore, the mean value for all roles showed perceived lack of competence (< 0.6) in the domain of "Medicines Development and Regulation."

The perceived relevance of each domain by role is shown in Table 2. All roles but PI/CoPI perceived a low level of relevance to role for the "Scientific Concepts and Research Methods" domain. A low level of relevance (< 0.6) of the "Medicines Development and Regulation" domain was observed for all roles, including CRA and PI/CoPI.

Diving deeper into self-perceived "competence" or "relevance" response levels by role for each of the specific core competencies for the "Scientific Concepts and Research Design" domain, data are shown in Tables 3 and 4, respectively. The PI/CoPI role had mean competence and relevance scores > 60%, compared to all other roles scoring well below 60% for competence and relevance for each competency in this domain.

TABLE 5: Percent of Self-Perceived Competence in "Medicines Development and Regulation" Domain

Core Competency	Competence/Role (%)					
	DM	RA	CRC/CRN	CRA	RM/PM	PI/CoPI
Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices, and biologics	40	56.5	46.7	55.8	54.5	54.5
**Describe the roles and responsibilities of the various institutions participating in the medicines development process	40	58.7	40	53.5	53.7	55.9
*Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products	32	34.8	25.1	44.2	40.3	53.5
*Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices, and biologics and ensures their safety, efficacy, and quality	28	67.4	37.7	47.7	55.2	45.8
Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product	36	65.2	39.8	50.6	57.2	58.9
Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	40	69.6	53.2	52.9	61.2	60.2
*Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products	20	30.4	18.5	43.7	27	41.8

Note: For competencies tagged as (*) – Chi Square, $p < 0.0001$; for competencies tagged (**) – Chi Square $p < 0.005$ across roles. Shaded areas > 60%, "competent."

TABLE 6: Self-Perceived Competence in Domain by Academic Degree

Domains	Competence/Role (mean value)						
	No Post-Secondary Degree (n=35)	AS/AD (n=92)	Diploma (n=119)	BA/BS (n=312)	Post – BA/BS Certificate (n=133)	Masters (n=462)	Doctorate (n=330)
*Scientific Concepts and Research Design	0.2	0.2	0.3	0.3	0.3	0.5	0.7
*Ethical and Participant Safety Considerations	0.5	0.6	0.6	0.7	0.6	0.7	0.8
Medicines Development and Regulation	0.3	0.4	0.4	0.4	0.4	0.5	0.5
Clinical Trials Operations	0.6	0.6	0.6	0.7	0.7	0.7	0.8
Study and Site Management	0.5	0.7	0.6	0.5	0.7	0.6	0.6
Data Management and Informatics	0.5	0.5	0.6	0.6	0.6	0.6	0.6
Leadership and Professionalism	0.6	0.6	0.6	0.6	0.7	0.7	0.8
*Communication and Teamwork	0.5	0.5	0.5	0.5	0.6	0.7	0.7

Note: Domains tagged (*) ANOVA $p < 0.0001$ across domain and degree earned at 5% significance level. Shaded areas ≥ 0.6 "competent."

TABLE 7: Self-Perceived Relevance to My Position of Domain by Academic Degree

Domains	Relevance/Role (mean value)						
	No Post-Secondary Degree (n=35)	AS/AD (n=92)	Diploma (n=119)	BA/BS (n=312)	Post – BA/BS Certificate (n=133)	Masters (n=462)	Doctorate (n=330)
Scientific Concepts and Research Design	0.3	0.2	0.4	0.2	0.3	0.4	0.6
Ethical and Participant Safety Considerations	0.6	0.7	0.6	0.6	0.6	0.7	0.7
Medicines Development and Regulation	0.4	0.4	0.4	0.3	0.4	0.5	0.4
Clinical Trials Operations	0.6	0.7	0.7	0.6	0.7	0.7	0.7
Study and Site Management	0.5	0.7	0.7	0.6	0.6	0.6	0.7
Data Management and Informatics	0.6	0.6	0.6	0.5	0.6	0.6	0.6
Leadership and Professionalism	0.6	0.7	0.7	0.6	0.7	0.7	0.7
*Communication and Teamwork	0.6	0.6	0.6	0.5	0.6	0.6	0.7

Note: Domains tagged (*) ANOVA $p < 0.0001$ across domain and degree earned at 5% significance level. Shaded areas ≥ 0.6 "competent."

There was a consistent low level of perceived competence across most roles for the seven competencies in the domain of "Medicines Development and Regulation" (see Table 5). However, the self-perceived competency for the RA role (> 60%) is seen in three of the seven competencies in this domain. The core competence related to safety reporting requirements was rated in the "competent" range for the PI/CoPI, PM/RM, and RA roles.

When analyzing self-perceived competence and relevance by domain and academic degree level, the domain "Scientific Concepts and Research Design" again lags in perceived confidence across all degree levels, with the exception of the doctorate level. There is a consistent low level of confidence (< 0.6) across all degree levels in the "Medicines Development and Regulation" domain. Similar findings are shown for perceived relevance in these two domains (see Tables 6 and 7).

The domain "Communication and Teamwork" was self-perceived at the competent level for those possessing a postbaccalaureate degree or above; however, relevance for this domain was perceived as high (≥ 0.6) for all degree levels, with the exception of those with a baccalaureate degree, which scored at 0.5.

Levels of perceived competence and relevance to role by years of experience in the clinical research enterprise were also analyzed (see Tables 8 and 9). With the exception of the two domains, "Scientific Concepts and Research Design" and "Medicines Development and Regulation" (both averaging < 0.6), there are increasing levels self-perceived competence with years of experience. For all domains, self-assessed competence increases as professionals have six to 10 years of experience; thereafter, self-assessed competence levels off.

Self-assessment of relevance to the role does not rise with increasing experience, however. The perceived relevance of the domain to the role is virtually the same in those with less than two years of experience as for those with more than 20 years of experience.

Perceptions of Learning Needs

The perceived need for additional education/training is reported as an average percentage of "yes" responses with each of the competency domains, broken down by role. For the purposes of this paper, we have highlighted percentages > 50% in Table 10. The lowest perceived need for training was expressed by the PM/RM role. The roles of CRA and PI/CoPI expressed a need for additional education/training at rates > 50% for all domains.

TABLE 8: Self-Perceived Competence in Domain by Years of Experience

Domain	Competence/Years of Experience (mean value)				
	< 2 (n=125)	2–5 (n=316)	6–10 (n=459)	11–20 (n=459)	>20 (n=156)
Scientific Concepts and Research Design	0.3	0.3	0.4	0.5	0.5
Ethical and Participant Safety Considerations	0.6	0.6	0.7	0.8	0.8
Medicines Development and Regulation	0.4	0.3	0.4	0.6	0.5
Clinical Trials Operations	0.5	0.6	0.7	0.8	0.7
Study and Site Management	0.4	0.5	0.6	0.7	0.7
*Data Management and Informatics	0.5	0.5	0.6	0.7	0.6
Leadership and Professionalism	0.5	0.6	0.7	0.8	0.8
*Communication and Teamwork	0.5	0.6	0.6	0.7	0.7

Note: ANOVA, $p < 0.0001$ or < 0.001 (*) across all domains and years of experience. Shaded areas ≥ 0.6, "competent."

TABLE 9: Self-Perceived Relevance to My Position by Domain by Years of Experience

Domain	Relevance/Years of Experience (mean value)				
	< 2 (n=125)	2–5 (n=316)	6–10 (n=459)	11–20 (n=459)	> 20 (n=156)
Scientific Concepts and Research Design	0.3	0.3	0.4	0.4	0.4
*Ethical and Participant Safety Considerations	0.6	0.6	0.6	0.7	0.7
*Medicines Development and Regulation	0.4	0.3	0.4	0.5	0.4
*Clinical Trials Operations	0.6	0.6	0.7	0.7	0.7
*Study and Site Management	0.5	0.5	0.6	0.7	0.6
Data Management and Informatics	0.6	0.6	0.6	0.6	0.6
*Leadership and Professionalism	0.6	0.6	0.7	0.8	0.7
Communication and Teamwork	0.6	0.6	0.6	0.6	0.6

*Note: *ANOVA, $p < 0.005$ for these domains. Mean values ≥ 0.6, "relevant."*

TABLE 10: Self-Perceived Need for Additional Education/Training in Domain by Role

Domain	Need for Education/Training (%)			
	CRC/CRN	CRA	RM/PM	PI/CoPI
Scientific Concepts and Research Design	48	57	44	61
Ethical and Participant Safety Considerations	48	52	44	51
Medicines Development and Regulation	50	58	38	58
Clinical Trial Operations	45	52	36	53
Study and Site Management	56	57	48	62
Data Management and Informatics	45	53	36	60
Leadership and Professionalism	55	62	52	62
Communication and Teamwork	48	57	45	57

Note: Shaded areas ≥ 50%.

Discussion

The increasing complexity, growth projections, and personnel needs of the clinical research enterprise have been widely reported; there is a need to expand and better qualify the clinical research workforce to meet those needs. The Institute of Medicine projected these factors and initiated a call for development of the entire clinical research workforce.[9]

Today, there are reported shortages of CRA personnel.[10] As this growth and complexity has occurred, working groups in nursing, medicine, and clinical research have sought to understand and categorize the requisite knowledge and skills needed to meet the demands. The JTF CCF emerged as a harmonization of those efforts.

Academic programs in clinical research are seeking to prepare an educated workforce by utilizing the JTF CCF to develop curricula that are responsive to needs of the enterprise using a competency-based education approach.[11,12] Support for education and professionalization of clinical research professionals have been widely promoted, but gaps remain.[13,14]

The results of this survey illustrate gaps in perceived competence and relevance in the domains associated with drug, device, and biologics development and in the domain of "Scientific Concepts and Research Design," the basis of clinical research studies.

Leaders at academic medical center sites are beginning to pattern their curricula to the JTF CCF, and even to explore how the JTF CCF may inform job descriptions and progression pathways; however, consistency in site onboarding training and ongoing training of clinical research staff are lacking.

In presenting preliminary data from the JTF survey, this paper represents a first attempt to measure perceived competence and relevance of the domains and competencies of the JTF CCF across multiple roles. It also serves to assess and present perceived learning needs across roles for the JTF CCF domains and competencies.

The results demonstrate variations in the respondents' perceived competence or perceived relevance of domains/competencies for their roles.

Competence and relevance gaps are suggested for two key JTF domains. Across all roles, the scores for competence and relevance were perceived as low for the "Medicines Development and Regulation" domain. Likewise, similar gaps were seen for the "Scientific Concepts and Research Design" domain, with the exception of in the PI/CoPI role.

With the exception of "Ethical and Participant Safety Considerations" and "Clinical Trials Operations," there were low perceived competence and relevance across all domains for the RA role. The DM role perceived competence and relevance in data management, yet had lower scores across all other domains in both areas.

Perceived competence increased with years of experience and with postsecondary education. Moreover, the domains "Medicines Development and Regulation" and "Scientific Concepts and Research Design" showed increases at the Masters degree level. Results also suggest that most clinical research professionals, including those in the PI/CoPI role, perceive a need for additional education/training.

The limitations inherent in this survey include the fact that it was disseminated broadly using a snowball method. Therefore, conclusions cannot be generalized to larger populations; however, they are suggestive based on the responses of participants.

Moreover, there was significant survey fatigue across respondents in the survey, due to the length and design of the survey tool. Many respondents did not complete the entire survey, which is a recognized limitation of long surveys.[15]

Finally, measuring perceptions of competence and relevance can be fraught with bias, as often those who are less experienced or educated may inflate their perceptions. At the same time, those who have higher education and experience may realize the breadth of knowledge yet to be gained, and rate themselves as requiring more education to meet competency demands.[16,17]

Considering the rising complexity of the clinical research enterprise—and the need for an interdisciplinary team approach to managing studies across medical disciplines and across clinical research personnel roles—more focused approaches to job descriptions, role responsibilities, and educational pathways are warranted. Despite a low perceived relevance of some domains by role of some respondents, the levels of decision-making and requisite needs of today's research enterprise suggest that a minimum entry level of education should be defined and required, and that intentional onboarding and staged education and continuing professional development in each domain should occur—even at the lowest role level.

Clinical research professionals, including PIs/CoPIs, should be educated and trained across all domains at levels in keeping with their responsibilities. The current International Conference on Harmonization E6 Good Clinical Practice training of both new and experienced investigators and staff should be generally perceived as a "floor," not a "ceiling," for the knowledge necessary to conduct a safe and accurate clinical trial.[18] While all domains should be included in curricula, increased content that focuses on "Scientific Concepts and Research Design" and "Medicines Development and Regulation" is indicated.

It would appear that, in today's clinical research enterprise, the time honored "learning on the job" is no longer sufficient to produce a qualified clinical research professional and ensure proper conduct of research and protection of human participants.

Conclusion

The results of this survey illustrate gaps in perceived competence and relevance in the domains associated with drug, device, and biologics development and in the domain of "Scientific Concepts and Research Design," the basis of clinical research studies. However, it also provides an opportunity for further explorations on core competence for clinical research professionals.

The workforce needs are ever expanding; the model for hiring in the field is still based upon experience, not necessarily competence, and there are no entry-level educational requirements. Professional certifications exist for those who have achieved a defined professional experience level in a clinical research area; however, validated, evidence-based competency measures for the workforce have been lacking.

The JTF CCF has gained acceptance as an important response to the necessity for better definitions of the basic competencies for clinical research professionals. This work is not done; new stakeholders are joining the JTF. Therefore, additional core competencies are likely to emerge.

As the clinical research enterprise embraces the professionalization of roles, this survey not only identifies potential needs, but also stimulates conversations about minimal education requirements; definition of roles; standardization of job titles at ascending levels of competence; policies for staff training; and potential new research on the application of these core competencies.

This paper presents only one portion of the data gleaned from the JTF survey. Results that assess regional differences of respondents may identify learning needs in specific geographic areas.

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ON THE JOB
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[DOI: 10.14524/CR-16-4049]

Clinical Technology Designed to Unite

The life sciences industry invests more than $55 billion in technology today—$35 billion specifically on software and services,[1] and it is having a profound effect globally. Technology is a catalyst to bring us all together—especially in research and development (R&D), where it enables greater efficiency and collaboration. As clinical trials go global and companies continue to outsource critical functions, technology becomes more important in optimizing stakeholder communications and data management processes throughout the drug development lifecycle.

To help streamline the processes of functional groups and address emerging requirements of global clinical trials, companies have added off-the-shelf software or tacked on new capabilities in a piecemeal fashion over the years.

"The ability to leverage information across an increasingly broad ecosystem of internal and external stakeholders is urgent. Connections between data, partners, patients, providers, and payers are key to clinical discovery," said Jennifer Goldsmith, a senior vice president for a cloud technology solutions provider to the life sciences industry, during her keynote presentation at the recent Veeva 2016 R&D Summit held in Philadelphia. "They enable richer, data-driven insights that speed the process of bringing drugs to market. The companies that focus on combining data-driven insights with stronger human connections will drive new ways of thinking in product development."

Seeking Unification

While most life science companies already use technology to enable business functions, disparate software and legacy technology are more of a hindrance than a unifier. To help streamline the processes of functional groups and address emerging requirements of global clinical trials, companies have added off-the-shelf software or tacked on new capabilities in a piecemeal fashion over the years. As a result, teams are stuck trying to leverage a mix of non-integrated systems to manage trials.

It's not unheard of for clinical operations today to use as many as 20 different non-integrated systems to manage global trials—from electronic data capture (EDC) systems and study start-up applications, to clinical trial management systems (CTMSs) and electronic trial master files (eTMFs).

Despite all of these technologies, most study managers rely heavily on manually compiled spreadsheets to get a singular view of the status of trials across a study or a portfolio of studies. According to a recent survey, more than 90% of study managers export data from a CTMS or EDC system, and manually roll them into a central spreadsheet with data from other systems.[2]

"Clinical operations in every part of the world are hindered by a tangled web of disparate legacy systems," said Michael McKelvey, president of inVentiv Health Clinical. "Interoperable technology is the foundation for unifying clinical processes—saving time, resources, and even lives. It could be transformative and set the direction for the future."

Indeed, instead of streamlining processes, some technology solutions are adding costs and complexity by requiring staff to spend significant time handling clinical data. System set-up, ongoing maintenance, inflexibility, and a lack of integration among important clinical systems slow trials down dramatically while hindering sponsors' ability to get clean data quickly to make informed decisions during trials.

Wanted: Clear Vision

The primary challenge for executives is the uncertainty that results from a lack of transparency. Gaps in the various handoffs across key processes and a lack of system interoperability prevent them from knowing if the clinical studies are performing to plan. They lack visibility of potential challenges, such as lagging patient enrollment, sites that require additional support, or compliance risks that may exist. Ultimately, this prevents teams from investigating and mitigating issues in real time.

"The clinical development process is highly inefficient due to a number of factors, including the inconsistent use of a large number of incompatible technologies," said Ken Getz, associate professor at Tufts University School of Medicine and chairman of the Center for Information and Study on Clinical Research Participation. "Transparency, compatibility, and integration are critical factors driving technology adoption among clinical research professionals, patients, and the broader healthcare environment."

Unifying clinical technology can have a positive impact that ripples throughout the entire organization. For example, uniting three clinical systems can reduce by 60% the number of steps in the end-to-end processes of creating a protocol, collecting essential documents, supporting the submission, and finalizing the clinical study report; or from an average of 26 steps to just eight.

With all stakeholders working on the same platform, team members can dramatically reduce the tedious back-and-forth, logging in and out of different systems, and downloading and uploading the same documents multiple times from multiple places. When systems are interconnected, information automatically flows between them seamlessly.

Collaboration that Counts

Unifying clinical technology is also crucial for stakeholders to enable efficient collaboration on activities that drive product faster to market. Uniting all clinical applications on one platform supports a faster and more standardized methodology of creating, collecting, and submitting necessary documents in finalizing a clinical study. Integrated processes reduce data entry while providing a timeline of interactions that make data audit ready.

Advanced Clinical, an award-winning clinical development organization, uses a modern eTMF solution that's part of an integrated cloud suite to accelerate information sharing with sites and sponsors and improve overall visibility. Serving as a single source to share documents, the eTMF application enables more efficient collaboration among investigating sites, allowing automatic acknowledgement of receipt of documents and electronic sign-off after review. A reliable audit trail also supports compliance.

"In the past, we used e-mail, shared docs, and spreadsheets to exchange and track data with clinical sites, sponsors, and other stakeholders. Without integrated applications, sites operated in silos and could not readily collaborate on documentation or easily share data," noted Jessica Vicari, director of regulatory start-up and document management at Advanced Clinical.

One multinational developer, manufacturer, and marketer of life-enhancing medical technologies that recently attended the Veeva R&D Summit also leverages an integrated eTMF application to oversee and track activities with its different shareholders. "Rather than ship boxes of information and manage documents on spreadsheets, our cloud-based eTMF enables our stakeholders to easily upload and manage data using fast electronic processes," explained the company's clinical research associate manager. "A continuously updated TMF serves as a single source of truth for sponsors, contract research organizations, and sites."

All for One, and One for All

With EDC, CTMS, and other processes built into one common platform, companies have the capacity to improve trial processes by speeding workflows and enabling real-time feedback. An integrated process ensures that the most current documents and operational data automatically appear in the various clinical applications with the correct metadata associated with them as it happens.

Technology that unifies documents, workflows, and people on one platform streamlines end-to-end clinical trial processes by eliminating the need to manually move documents and operational data, which can get out of sync within a team. It also cuts costly, time-consuming reconciliation of documents and data between various systems by clinical monitors. It removes the complexity of multiple points of data entry and the tedious logging in and out of different systems for clinical trials.

With one view of data across clinical trials, stakeholders have greater visibility and can collaborate better together. Standardized and automated methodologies support a seamless and paperless flow of information to take drugs to market faster and at less cost.

We live in an age when we can have information almost immediately and are always connected. Want to know the weather forecast? There's an app for that. Want to find an address to a restaurant? Just ask "Siri" and she'll tell you.

Whether in the consumer world or business, technology investment globally continues to sky rocket. In life sciences, technology is bringing us closer together in very dramatic ways. However, it could also have a different effect if we don't continue finding new ways to connect all of these systems efficiently. Nowhere is this more crucial than in clinical operations. Now is the time to come together, unifying our systems for the greatest impact.

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Building an Internal Quality Assurance Program: From the Ground Up

PEER REVIEWED

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[DOI: 10.14524/CR-16-0019]

Central to the principles of Good Clinical Practice (GCP) are steps taken to protect human subjects' rights and safety, as well as to ensure the validity and accuracy of data generated from clinical trials to support regulatory submissions.[1] In this light, any academic medical center (AMC) nurturing a research program must implement reasonable measures to safeguard compliance. This task is easier said than done, considering that research sites are challenged by several realities, including competitive enrollment among sites, high cost of site operations, shortages of qualified staff, increasing trial complexities, and lower study budgets.[2]

Thus, it is not uncommon that AMCs rely heavily on monitoring by sponsors for maintaining compliance in studies. Although only sponsors are required by the International Conference on Harmonization (ICH) guidelines to implement and maintain quality assurance (QA) and quality control systems to achieve GCP objectives,[3] it is imperative that studies are proactively audited at the site to make the research program robust and to correct problems early in the process. Better yet, potential problems would be identified even before they occur, making them audit-proof. Additionally, it takes a dedicated team to get all staff educated and on board with this process, which will ultimately prove to be critical to site success.

Developing Audit Plans

"The process of audit should be relevant, objective, quantified, repeatable, and able to affect appropriate change."

Charles D. Shaw[4]

Establishing audit plans is the first step in successfully managing an audit program.[5] An audit plan typically defines the various kinds of audits that an internal QA unit will carry out in order to assess the conduct of trials. Format, content, review, approval, and revision of the quality audit plans should be outlined in an approved operation manual that is readily available.

At the author's place of employment (an AMC-based cancer center), specific audit plans are developed based on the details of the trials for which a principal investigator (PI) has assumed responsibility. It is without doubt that spotting and mitigating any and all preventable errors is the aim of good QA procedures and training. Thus, the role of a QA program is to minimize the possibility of systematic discrepancies in treatment management among participating institutions. Therefore, the purpose of an internal audit is:

- To ensure patient safety
- To ensure protocol and regulatory compliance
- To ensure accurate data collection
- To identify problem areas
- To take corrective action when necessary
- To educate and instruct

Operationalization: Hiring the Right Staff

An essential element in operationalizing an audit program is buy-in from top managers as a sign of their commitment to quality. Thorough attention must be paid to hiring and training the right person for the job, which can help make the QA program a success from the start.

QA professionals come from a wide variety of backgrounds. It is generally recognized that at least a bachelor's degree in a science-related field is a solid basic educational requirement.[6] Additionally, it is advantageous to possess good communication skills, deductive reasoning abilities, persistence, and likeability. Thus, possessing assertive communication skills and a fine balance between conflict-seeking and conflict-avoidance is very much a desirable characteristic in a QA professional.

Being cognizant of Sonstein, et al.'s competency framework,[7] and seeking at least a few of the key competencies listed below will lay the foundation for a thriving and effective QA unit.

1. **Scientific Concepts and Research Design:** Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.
2. **Ethical and Participant Safety Considerations:** Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.
3. **Medicines Development and Regulation:** Encompasses knowledge of how drugs, devices, and biologics are developed and regulated.
4. **Clinical Trial Operations (GCPs):** Encompasses study management and GCP compliance, safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational products.
5. **Study and Site Management:** Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs).
6. **Data Management and Informatics:** Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction, and the concept of a locked database.
7. **Leadership and Professionalism:** Encompasses the principles and practice of leadership and professionalism in clinical research.
8. **Communication and Teamwork:** Encompasses all elements of communication within the site and between the site and sponsor, contract research organization, and regulators, as well as the understanding of teamwork skills necessary for conducting a clinical trial.

Accordingly, a typical QA professional has the following responsibilities:

- Troubleshoot clinical trials activities
- Track audit findings and corrective actions and their implementation to completion
- Prepare standard operating procedures (SOPs)
- Provide support for the planning and implementation of clinical programs to clinical teams from a QA perspective

SOPs and Audit Tools

Sites must actively pursue best practices in the context of ethical, safe, and effective research. In conjunction with the stakeholders responsible for quality, compliance to GCP is achieved through the development of measurable, descriptive SOPs.

ICH GCP E6 2.13[8] states that "systems with procedures that assure the quality of every aspect of the trial should be implemented," indicating that clinical trials should not be implemented without defined SOPs and quality systems. It is now common practice to have written SOPs; however, revisions to SOPs usually do not happen as regularly as would be ideal in most organizations. Thus, necessary SOP updates promote continual improvement in the conduct of clinical studies.

Once the right person is hired, audit tools that reflect specific and measurable quality indicators can be developed. It is an established fact that an audit tool will allow the site to be sure it is consistently performing at expected levels, while also providing a means to document any deviations in full compliance with quality indicators.[9]

When internal audits are conducted, auditors are not necessarily looking for problems, but rather are looking at concerns affecting their assigned sites. Deficiencies that are detected can vary from the innocuous, administrative-type errors to significant findings in which the subjects' rights, safety, and welfare—as well as data integrity—have been compromised.

Lessons Learned Mean Training Opportunities for Teams

It is a good practice to summarize audits conducted in reports to research teams, as well to provide an overall compliance audit report with key findings and deficiencies identified in each fiscal quarter to senior management. However, it is important to note that the U.S. Food and Drug Administration (FDA) will not request reports generated from a written QA program as a matter of routine, since to do so would not encourage a robust QA approach within an institution.[1]

The task of setting up, managing, and directing an operation of this nature can be challenging, and requires not only experience, technical skill, and excellent communication aptitudes, but also steadfast devotion.

All QA reports should be shared with the research group and management personnel. In addition to tracking results from internal QA auditing, feedback from external monitors during routine site visits can provide invaluable information. Furthermore, the only way a research program can grow in the right direction is when lessons learned from audits are disseminated to all research personnel in the unit; this must also include all the times "we got it right."

The Road Ahead

Depending on the volume of studies, the level of scrutiny, and the commitment from management, the number of auditors in an organization can be increased. Another possibility is that, depending on the size of the research unit, the role of the internal auditor may be expanded to accommodate additional responsibilities. For example, there may be added value in including the QA professional (keeping in mind his/her experience) to be a part of the hiring team. In the frequent context of high attrition in research units, getting the QA personnel's feedback on whether a candidate is "teachable" may be helpful.

Additionally, training and re-training responsibilities can be transferred from the hiring manager(s) to the QA professional, thereby keeping the training information more consistent. Finally, a well-established program can undertake the implementation of a quality management system (QMS) for document control, training requirements, and tracking of audit/ result trends.

The Story at One Institution

The QA program at University of Alabama at Birmingham's Comprehensive Cancer Center has two components:

- As a National Cancer Institute–designated cancer center requirement, one office tied to the QA program is a part of the institution's data safety and monitoring plan (established in 1993), and this office audits investigator-initiated trials (IITs) exclusively. All IITs are audited annually by lead physicians not involved with the relevant protocols.

  Each auditing physician is selected by the QA program director, and the number of charts to be audited is calculated by a biostatistician, who selects 10% of the protocol charts using a random number generator. The final audit reports are distributed to both the research team and the institutional review board.
- On the other hand, another internal QA office was proactively established in 2015 with an exclusive focus on industry-sponsored therapeutic clinical trials. These studies are audited by a QA professional who is hired by the cancer center, and the selection of studies is based on high accruals and new clinical research investigators. Typically, 25% of the total number of subjects accrued is selected and the subject's records are audited for GCP compliance, protocol compliance, and compliance with the research unit's SOPs.

  The audit reports are approved by the Associate Director of Clinical Research and, in this case, sent only to the research team; thus, follow up is managed within the research unit. This office plays an active role in helping the research staff prepare for all audits (sponsor and FDA), and is a part of the exit interview, as well. Moreover, this office is privy to sponsor monitoring reports and sponsor audit reports. This comparatively new office is currently managed by one person, and, keeping in mind the number of actively recruiting oncology clinical trials at the cancer center (~150 studies), its existence can be viewed as a step in the right direction.

It is also important to note that reports and correspondence related to the QA program are maintained centrally—complete with an audit trail—and are available for inspection during core grant renewals.

Conclusion

Internal QA is a nascent field that is still evolving. The task of setting up, managing, and directing an operation of this nature can be challenging, and requires not only experience, technical skill, and excellent communication aptitudes, but also steadfast devotion. The impact it can have on the research team is far reaching.

Viewing internal QA as an essential, cohesive element of research programs fosters constructive interactions between the research team and QA professional, thereby building higher standards of quality into the program. In addition to its positive effect on the research program, a well-oiled internal QA program will be well received by pharmaceutical sponsors, which has been the case at the author's AMC.

For a well-managed audit program, continuous improvement is vital to remain effective in the evolving regulatory climate.[9] Keeping in mind that being proactive is the only long-lasting solution in such a climate, audit programs should be reviewed annually, evaluated for continued effectiveness, and updated based on new regulatory development, which is critical to the quality of clinical studies.

Hence, continued improvement is crucial to ensuring compliance objectives. The ultimate barometer of internal QA success is when others' perceptions of this proactive role in quality management allow it to evolve into the friendlier and more accepted role of an internal consultant.

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[DOI: 10.14524/CR-16-4046]

The Mysterious and Sometimes Maddening Form FDA 1572

In this issue's column, the questions raise a number of issues regarding the use of the U.S. Food and Drug Administration (FDA) Form 1572, otherwise known as the "Statement of Investigator" form. Although the form has been in use for many years, it continues to generate a variety of Good Clinical Practice (GCP) compliance–related questions.

Until a 2008 draft, the FDA had not issued guidance on how to complete the form or communicated any expectations for the type of information to be included on the form. I think it is telling of the complexity of the form and the importance of the information contained therein that a simple (in design), two-page form requires a 25-page guidance document (May 2010 information sheet/guidance on "Frequently Asked Questions—Statement of Investigator (Form FDA 1572)") to explain its use.

It is telling of the complexity of the form and the importance of the information contained therein that a simple (in design), two-page form requires a 25-page guidance document to explain its use.

Q. When should the Form 1572 be used and does it need to be submitted to FDA?

A: In many cases, companies collect and submit the completed and signed 1572s to the FDA in the original Investigational New Drug (IND) application, and subsequently when new investigators are added to a study. The IND application holder does this as a convenient way of fulfilling an FDA requirement in the *Code of Federal Regulations* at 21 CFR 312.23(a)(6)(iii)(b), which calls for a clinical trial protocol submitted in an IND to provide "the name and address and a statement of the qualifications (CV or other statement of qualifications) of each investigator."

Because this has become such a common practice, some incorrectly assume that it is an FDA requirement. In fact, the IND cover form (Form FDA 1571) explicitly gives sponsors the option of fulfilling 312.23(a)(6)(iii)(b) by submitting either investigator data spelled out in this section of the CFR or completed Form(s) FDA 1572.

Several FDA officials have stated informally that companies seem to obsess over the Form 1572. Since it is not even required to be submitted to the FDA, in theory, the FDA would never even see it. In practice, most companies submit the Form 1572 along with the IND as an efficient means to provide information required under the regulation being addressed here.

The Form 1572 is signed by the investigator to provide the sponsor with information about the study and to ensure the investigator's commitment to comply with FDA's regulatory requirements. The regulations require that the investigator sign the form, thereby making the Form 1572 legally enforceable.

By signing the form, the investigator is agreeing to (among other things) follow the protocol and to comply with the applicable regulations. The FDA does note that the form and its stated commitments are "legally enforceable." The agency has noted it can initiate enforcement action and the clinical investigator can be disqualified (i.e., from performing future FDA studies) based on the commitments contained on the form.

QA Q&A CORNER

Michael R. Hamrell, PhD, RAC, FRAPS, RQAP-GCP, CCRA

Q. Should a clinical research coordinator and/or a study site's pharmacist be listed as subinvestigators in Section #6 on Form 1572?

A: The FDA addresses each of these two positions directly in its May 2010 guidance/information sheet. Whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study.

The FDA notes that a research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would typically not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a subinvestigator in Section #6. However, he/she should be listed in the investigator's study records on the site delegation log.

On the other hand, the FDA has suggested that pharmacists who undertake several different tasks that may contribute to protocol conduct should be listed in Section #6. This would include preparing the test article (in contrast to merely dispensing tablets), blinding of product, and evaluating or reporting data relative to the study activities, as well as activities such as compounding, labeling, monitoring, and reporting test article compliance data.

However, the guidance does seem to establish that research coordinators should typically be named on the Form 1572. Generally, a research coordinator plays a role in performing critical study functions and making direct and significant contributions to the data for the study. A research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572.

When there is a question of whether or not an individual who falls into this category of some other study role should be listed in section #6 of the form, the FDA would refer to any written instructions/directions from the sponsor/contract research organization (CRO), as well as to any site standard operating procedures, in considering whether the site completed the form properly. In this regard, different sponsors/CROs may have different expectations for who should be listed in Section #6 of the form.

Q. What form is used for a medical device trial to document an investigator's qualifications and compliance with the regulations?

A: Clinical trials for medical devices are covered under the Investigational Device Exemption (IDE) regulations in 21 CFR 812. These regulations do not require the use of the Form FDA 1572, which is specific for IND (drug/biologic) studies and does not apply to medical device trials.

The device regulations do require that the sponsor obtain a signed agreement from each participating investigator that includes a commitment by the investigator to conduct the investigation in accordance with the agreement, investigational plan, and other applicable regulations (i.e., GCP), FDA regulations, institutional review board requirements, and any other sponsor requirements (21 CFR 812.43(c)). There is no FDA form specified or required to document this agreement.

Medical device firms typically develop a written contract/agreement that encompasses the required language and agreements. Using the Form FDA 1572 for this purpose would not be acceptable, since it specifically references the IND regulations and Part 312.

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IN MEMORIAM

The Association of Clinical Research Professionals (ACRP) is saddened by the passing of Douglas Bryant III, JD, Board of Trustees Treasurer and Public Member.

Bryant was elected by the ACRP membership in 2014 to serve as the association's first Public Member, and was re-elected by the Association Board of Trustees (ABoT) for a second term in 2016. Bryant was subsequently elected by the ABoT to serve a one-year term as Treasurer, and was re-elected to that position in November. He has also served on ACRP's Governance and Finance committees during his tenure as an ABoT member.

Bryant is a Georgia native who attended Georgia Tech before completing his undergraduate studies at Columbus State University. He obtained a law degree from Texas Southern University School of Law and most recently practiced wealth management at the Cate Bryant Houser Group. He also served on the faculty at Troy University, and was a board member for the Columbus Regional Healthcare System and the Texas Southern University School of Law Alumni Board.

Bryant is survived by his 15-year-old daughter Kaela.

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- We are confident that we can surpass sponsors expectations relating to cost, subject enrollment/retention, and the quality of our work.

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