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(original release date: 12/1/2015)

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, $42). 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.

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

Five Smart Strategies to Develop Your Clinical Research Career

This article focuses on five strategies to develop one's clinical research career. The strategies discussed are: **1)** keeping up with new technology, **2)** learning new regulations or guidelines, **3)** expanding networking skills, **4)** updating knowledge in a clinical specialty, and **5)** targeting volunteer efforts. By introducing career development strategies, explaining their significance, and offering methods to accomplish each step involved, this article is intended to help those seeking promotions, better jobs, or increased job satisfaction.

LEARNING OBJECTIVE
After reading this article, learners should be able to identify ways to advance their clinical research careers, develop strategies to be successful at career advancement, and describe professional development methods to assist in achieving career goals.

DISCLOSURES
Patricia Kasper, MS, CCRA:
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The Basics (and Beyond) for Making Things Better

The best way to get a promotion, find a better job, or increase satisfaction with your present job is to actively develop your clinical research career in ways that inspire you to learn and grow so you feel motivated and in control of your own career.

"There is only one corner of the universe you can be certain of improving, and that's your own self." – Aldous Huxley

The basis for advancement in any career is learning how to function effectively on the job. As you move into clinical research, there are many competencies to learn, practice, and demonstrate.

The basic competencies for a clinical research coordinator or clinical research associate/monitor are taught in classes and workshops—such as knowing that every patient needs to sign an informed consent prior to participating in a clinical trial. However, as you move into the complexities of research, it is more important to show a thorough understanding of all the permutations of each competency.

For example, a more skilled coordinator needs to know how to deal with complex consenting situations, such as those involving short forms, assents, translations, or legally authorized representatives. Demonstrating increased competency in your current position is an excellent way to advance in your career.

There are many time-consuming and expensive ways to advance your career, such as pursuing an advanced degree; however, this article focuses on five areas that are often overlooked when you are busy with your everyday job. Even targeting the small steps to keeping abreast of new technology and staying engaged with those around you can lead to big differences on the job.

Keeping Up to Date with New Technology

By learning a new technology, you become efficient and effective at your work and marketable to potential employers. The booming technological industry is churning out more tools that help clinical researchers be better, faster, and more accurate at their jobs. Here are some technologies you should learn to boost your performance:

- **Excel—**Improving your spreadsheet skills will allow you to calculate study budgets and more.
- **Microsoft Project—**Creating granular time-lines for study startup helps everyone on the site study team.
- **Electronic data capture systems—**Using these to enter data efficiently is growing as a major trend for the future of clinical trial conduct that will soon be here to stay.
- **New software for electronic informed consent—**Becoming familiar with the various new e-consent options now available will help you choose the one that offers the greatest advantages to you, your fellow researchers, and your patients.

There are many ways to keep up with technology. One handy method is viewing YouTube videos to learn a particular feature of a new software program. These two-to-four minute presentations keep your interest and teach a small skill in a short amount of time. If you are confused about a certain topic, you can go back and review the content.

There are many other ways to learn a new technology, so choose one that fits your learning style and time availability:

- Webinars are available on various topics from the Association of Clinical Research Professionals (ACRP),[1] Society of Clinical Research Associates (SoCRA),[2] and many clinical research training companies
- Online courses
- Local college classes
- Tutors may be useful for helping you learn a specific skill one-on-one
- Expert consultants may be the best way to train your team all at once on more complicated topics
- Ask a question on Ask.com

What new technology do you need to learn to stay current in your career? Write down a need and a possible opportunity to fill that need.

Learning New Regulations and Guidelines

By staying current on new regulations, you actively participate in the clinical research world and demonstrate competency to potential employers. There are always plenty of new guidance documents and regulations with which to become acquainted.

By the very nature of the pharmaceutical and medical device arena, clinical researchers work in a highly regulated environment. In fact, over the past few years, the U.S. Food and Drug Administration (FDA) has released an increasing number of guidance documents and new regulations. By checking the FDA website regularly, you will see that new guidance documents are posted often.[3] Clinical researchers need to learn these new regulations and be aware of the current thinking of regulatory agencies.

When you're reading up on new regulations, make sure you know…

- The exact citation of the regulation
- The effective date of a new guidance

- How to implement the regulations in real-life situations:
  » Will it affect an ongoing study?
  » Will it change the cost of a study?
  » Will it be a factor when starting a new study?

Here's how to stay updated with the new regulations:

- Review the new guidance list on www.fda.gov
- Listen to webinars on regulatory topics from ACRP, SoCRA, or the Drug Information Association[4]
- Take an online course on regulatory compliance
- Attend local/national meetings of professional organizations for insights from others on the latest regulations
- Invite a subject matter expert on regulatory trends to lead a team meeting at your organization

What could you do to keep up with regulations and be more knowledgeable about guidance documents? Is there a new regulation or a change in a law you've been meaning to read? Write down a need and a possible opportunity to fill that need.

Expanding Networking Skills

In order to enhance your career, networking is imperative. When you network, you are perceived as engaged, friendly, and active in the clinical research community. Furthermore, if you are friendly and open with others who are in the same profession, your opportunities expand exponentially.

These opportunities expand to jobs you have not considered and individuals who have unique perspectives on the industry. Networking is a skill, and by practicing you will become more and more skillful.

Think of networking as a way to give assistance as well as receive it. You may be asked to answer questions about how you got into clinical research. At first glance, the help that you give will not benefit you at all; but if you think about it, the goodwill you gain can only help you in the future. Ultimately, networking is all about giving forward, and you make the world a better place when you help others.

Think beyond "lunch" when planning to network. While lunch is a great way to get to know others, it can be quite hard to do if you are busy

By learning a new technology, you become efficient and effective at your work and marketable to potential employers.

QUICK TIPS

1.

Find out how much funding you have in your training budget. Talk to your manager about how you could use these funds to benefit the department and your own personal career growth.

2.

Print "business" cards with your personal e-mail and phone number so you are always ready to hand it to a potential contact. This is not associated with your current position or company, but is rather a personal contact card.

3.

Keep your resume up to date by creating a file folder (electronic or paper) where you add accomplishments every quarter. Spend a few minutes listing what you have done. Be as specific as possible and include lots of details. This way you don't forget key accomplishments, and it will be invaluable when talking about your next career move or adding to your resume.

4.

ClinicalTrials.gov is a website with a wealth of information about what trials are being conducted in different geographical areas by sites, centers, or sponsors. Look at this website and use it as another tool in your job search.

and working at great distances from those who would be most valuable for you to contact. Instead, find as many ways as possible to network.

Here are a few ways to meet new people:

- Attend ACRP Chapter meetings in your city or region; nonmembers are welcome to many chapter events (ACRP members also have access to a members-only Online Community on which they may share questions, answers, and resources related to their day-to-day duties)
- Attend national/international professional gatherings such as the annual ACRP Meeting & Expo (formerly known as the Global Conference), and consider presenting a session or workshop if you have a great topic to share
- Look for people with whom you have shared contacts and backgrounds on LinkedIn
- Explore Facebook, Twitter, Instagram, or Talkbiznow for more sources of news and views on what's happening in the clinical research enterprise

When networking, it's also important to maintain and enhance connections with your existing colleagues. Here are some ways to do this:

- Call a colleague to ask a question that falls in his/her area of expertise
- E-mail links to timely articles to colleagues who you think can use the information
- Share an interesting blog with a colleague at work as a point for discussion

Being great at networking takes practice; you have to practice meeting new people and develop a method to keep track of them all. You'll need to remember who you talked to, what you discussed, and what needs to be followed up.

Here is a system to remember everything. It's called being **"GREAT"** at networking.[5]

G = Get a business card

R = Remember key facts about the people in your network

E = Enter their names in your tracking system

A = Always follow up

T = Thank them

Let's go more in depth on each part of this system:

GET A BUSINESS CARD.

Getting someone's contact information is critical to keeping up a dynamic network. Ask for his or her card as you offer one of yours.

REMEMBER KEY FACTS.

You gain tidbits of information about friends and colleagues during your conversations. You can use these little details to keep track of what interests them. Whether it is a mutual connection or an intellectual pursuit, make a note of it. These facts are useful for follow-ups.

ENTER THEIR NAMES INTO YOUR TRACKING SYSTEM.

You can use an Excel spreadsheet to track all the contact information for each person in your network. Enter their names, nicknames, titles, companies, e-mail addresses, and phone numbers. This is also where you can enter key facts that you want to remember.

ALWAYS FOLLOW UP.

This is a critical activity if you want to have a robust networking system. If you spend the time to connect with others in your field, it behooves you to circle back with each one of them. Find an area of common interest and follow up the next day. This strengthens the connection and shows that you were paying attention.

THANK THEM.

If someone has given you advice, a connection, a good idea, or a job lead, by all means send them a thank you note; and when you thank them, do it not once but three times. First, send a quick e-mail shortly after your conversation. This sets a professional tone, and now this person has your e-mail address, too. Second, if you feel this is a great contact, mail them a letter within the next few days. Personal mail is not common these days, so it will set you apart. Finally, two weeks later, find a reason to send another e-mail that touches on a topic of mutual interest. This reinforces the connection you just made, and can be a dynamic way to stay engaged.

How could you do a better job at networking by meeting new colleagues and keeping up with current ones? Write down a need and a possible opportunity to fill that need.

Updating Knowledge in a Clinical Specialty

By keeping up to date in your clinical specialty, you demonstrate professional responsibility and become an expert at your job. Clinical researchers have a professional responsibility to understand the drugs, devices, and treatments used in their specialty, especially in terms of ensuring patient safety by knowing the signs and symptoms of potential adverse events, and the influence of

experimental products on any concomitant medication(s) that the individual needs.

As you seek to stay up to date, look for gaps in your knowledge. Then, educate yourself proactively; don't wait until the manager says you are out of touch.

For example, when moving into cardiology, you have to learn to read an electrocardiogram. You may not have this skill at the beginning, but you could learn it by taking a course through the local community college. You would buy calipers, listen to lectures, and learn all about QRS intervals and ST segments. By the end of the class, you'd be able to identify things like a 1 mm ST segment depression, and you'd feel confident, capable, and efficient.

There are many resources from which you may learn specific skills or increase your knowledge of targeted disease states. Here are a few suggestions:

- Webinars
- Local lectures
- YouTube videos
- Textbooks
- Journal articles
- Mentors

How could you keep up with your clinical specialty? Write down a gap in your knowledge and a possible opportunity to fill that gap.

Targeting Volunteer Opportunities

Volunteering is a smart strategy during your career or job hunt. Volunteering increases your network, adds to your resume, and provides additional opportunities to build new skills. It also increases your confidence because you realize you have a lot to offer.

So, how do you find the right volunteer opportunity? First, consider where your passion lies, how much time you have, and where you will meet like-minded people. Then, look for a blend of these factors.

If you like being a mentor, seeing clinical research colleagues, and increasing your leadership skills, volunteering at the local chapter of a professional organization to which you belong may be the place for you. Also, you may find a lot of connections through your activities there.

A lot of people jump into volunteering; they join an organization that has been humming along for several years and decide they have all the answers. Recently, a woman shared that she had started volunteering with a group, and at the first meeting she told the chairperson, "The title of that event

doesn't make any sense—you should change it." Of course, her comment was met with resentment, as she hadn't been on the committee for even a full day at that point. Ideally, you should start slowly and carefully in any new volunteer role.

There are many tried-and-true "dos and don'ts" to help you determine the right fit as you seek to transition into a volunteer role for an organization (see Table 1 for some examples).

TABLE 1: Factors to Keep in Mind When Looking for a Volunteer Role

DO	DON'T
Find your passion.	Let it take away from your career in time or focus.
Make it a good fit.	Take on a task that is a burden.
Get to know the organization.	Do it just to make an impression.
Start slowly.	Be inconsiderate, skip meetings, or be late.
Think about why you are volunteering.	Expect to be the boss when you're starting out.

Can you identify a need in your career growth that could be augmented by volunteering at a relevant organization? Write down this need and a possible opportunity to fill that need.

Where Do We Go from Here?

Now that you've learned five strategies to develop your career, apply them to your own life before you forget! Here's a way to keep you moving: Pick two strategies that interest you and make a goal to complete them. Select a date on your calendar in about a month's time. Plan to set aside an hour of that day to make progress on your career. You could even plan to do this with a friend.

Keeping up to date with technology, understanding new regulations, networking, learning more about your clinical specialty, and volunteering are five smart strategies to developing your career. Improving these areas will make you efficient, confident, and knowledgeable. Whether you seek to gain a promotion, move into a specific job area, or become more satisfied with your position, go forth and, to quote Aldous Huxley once more, improve your own corner of the universe.

When you network, you are perceived as engaged, friendly, and active in the clinical research community.

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4. Drug Information Association. www.diaglobal.org/
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Enhancing Skills for Clinical Research Associates Through Hands-On Clinical Practicums

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Hands-on clinical experiences are considered a mainstay in the healthcare arena.[1,2] Most models used to practice hands-on clinical experiences employ the student and mentor or preceptor in a dyad clinical practicum assisting in the student's transition from academic to professional activity.[1,2]

According to Bagayoka,[3] competencies in skills are acquired through using the principles of the power of human performance. The more frequent a task is performed, the more proficient the student becomes at the task; thus, one-on-one, hands-on clinical experiences allow the students to master the skills.

During the 10-year period from 2010 to 2020, the increase in clinical trials research activity will support more than 100,000 jobs for clinical researchers, including the clinical research associate (CRA).[4] Also, as the complexity and rigor of initiating, implementing, and evaluating clinical trials increases, so do the skill sets required for CRAs.

Responsibilities of CRAs are diverse, as outlined in detail in the International Conference on Harmonization guidelines for Good Clinical Practice (ICH GCP), and crucial to the success of the clinical trial. However, two to three years of hands-on clinical trial experience is required for the CRA to develop the necessary skill set to function effectively in this position.[5-7]

In 2010, as a recipient of the National Institute on Minority Health and Health Disparities grant award, the School of Nursing at Dillard University in New Orleans, La., established the Minority Health and Health Disparities Research Center (MHHDRC) to address low participation in clinical trials and decrease health disparities. One initiative proposed by the MHHDRC was to develop a clinical research associate training program (CRATP) for post-baccalaureate nurses. The goals of the CRATP are to increase the number of minority CRAs in the state of Louisiana, especially in New Orleans, and to promote greater participation and retention of minorities in clinical trials.[8]

The CRATP Structure

Applicants who met the eligibility requirements enrolled in a year-long program that includes a 15-week didactic course followed by a 96-hour, hands-on clinical practicum over 24 weeks (see Figure 1). The program developers recognized that the CRATP needed to offer a hands-on clinical component that involved working side-by-side with preceptors to enhance the learners' skills in developing and monitoring clinical trial plans, completing source documents and case report forms, and understanding standard operating procedure requirements according to the ICH GCP.

A number of teaching institutions provide hands-on practicums through preceptorships. Researchers suggest that practical training under

Didactics (15 Weeks) + Clinical Assignments (96 Hours) = Clinical Research Associate Training Program (CRATP)
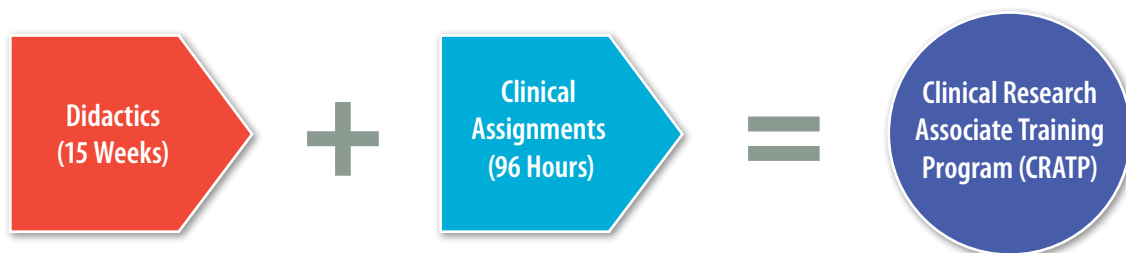
the supervision of trained preceptors help learners close the gaps between didactic skills and applied skills by increasing learner exposure to real-life settings.[9-11] However, a review of the literature revealed no clinical assignment tools used in the clinical practices or preceptorships of existing CRA training programs. The lack of such resources was the impetus behind the development of clinical assignments as a major part of the CRATP.

The coordinator of the CRA training program established an environment in which teaching-learning responsibilities are shared with learners. The learners must score 85% or higher on the didactic course midterm and final examinations to progress to the clinical component of the program. Learners self-identified any additional learning needs and developed strategies to assist with successful completion of the learning experiences.

After finishing the didactic requirements, learners complete the National Institutes of Health's module on Protecting Human Research Participants, the Collaborative IRB [institutional review board] Training Initiative (CITI) Human Subjects Training Program, and a two-day clinical orientation meeting. The orientations are conducted by clinical research professionals, including CRAs, clinical research coordinators (CRCs), pharmacists, project managers, budget managers, and data analysts.

The Preceptorship Program

The CRATP uses preceptors to implement the hands-on clinical practicum. The preceptorship program is a supervised clinical experience between a CRATP learner and a clinical faculty member at an approved clinical site, and operates according to approved guidelines developed by the CRATP coordinator with input from the clinical preceptors and the affiliated clinical site. The purpose of the guidelines is to provide the clinical preceptors with effective strategies to conduct CRA learning experiences.

The learner works directly with highly trained, seasoned practitioners. This design allows the learner to apply received content to practice, thus developing a basic level of proficiency in performing clinical activities. For example, for the first clinical assignment on "Validating the Informed Consent Form and Participating in an IRB Committee Meeting," the learner is matched with clinical preceptors at one of the six sites affiliated with clinical trial research in the greater New Orleans area.[12,13]

Preceptors are appropriately credentialed individuals with a minimum of two years of experience as a CRA, CRC, or nurse researcher who function within the scope of practice according to the U.S. Food and Drug Administration and ICH GCP guidelines. Preceptor responsibilities include:

- attending preceptor orientation;
- facilitating the learning of no more than two learners at one time;
- guiding, instructing, and overseeing learners' clinical assignment activities;
- communicating with the learner and the CRATP coordinator regarding clinical activities;
- completing the preceptor's copy of the clinical assignment sheets;
- notifying the CRATP coordinator of any discrepancies, issues, or problems; and
- providing feedback regarding CRATP strengths and challenges and suggestions for program development.

Clinical Sites

The CRATP coordinator selects and approves clinical sites to ensure the best possible experiences for all CRATP learners. Important characteristics of the clinical sites include:

- The staff recognize that the CRATP learner is in training and requires an environment that supports his/her individual learning needs.

Responsibilities of CRAs are diverse, as outlined in detail in the ICH GCP guidelines, and crucial to the success of the clinical trial. However, two to three years of hands-on clinical trial experience is required for the CRA to develop the necessary skill set to function effectively in this position.

FIGURE 2: Nursing Process for Clinical Research Associate

requirements for certification of clinical research professionals, ICH GCP guidelines, the Standards for Privacy of Individually Identifiable Health Information, the Center for Information and Study on Clinical Research Participation, U.S. and international recommendations, and the guidelines for Protecting America's Health Through Human Drugs.[5,9,14-22]

The nursing process (see Figure 2) provided the theoretical framework for the clinical assignments (see Figure 3); its cyclic continuum closes the gap between didactics and applied skills through the five sequential and interrelated constructs shown in Figure 2. The process continues until the goal is achieved.[23,24] The learner must be able to use these five problem-solving assessment skills to accurately complete the clinical assignments.

The nursing process was operationalized as follows for the CRATP clinical assignments:

- **Assessment—**CRA learners must use a systematic approach, applying classroom-acquired knowledge in the clinical setting to complete selected CRA functions related to the clinical trial. Questions enhance understanding regarding the role of clinical research organization personnel, principal investigators (PIs), and site staff.

- **Diagnosis—**The development and implementation of the protocol are vital to the success of the clinical trial. Thus, the CRA must identify, interpret, and plan for site selection based on assessment data to meet federal, state, and site policies.

- **Planning—**This step ensures that the protocol is executed correctly. For each action addressed in the protocol, the CRA develops an action plan identifying interventions for specified outcomes (checks and balances). These factors are noted in the protocol and are monitored to assure that principal investigators (PIs), adhere to GCP guidelines.

- **Implementation—**The CRA incorporates standards, guidelines, and polices based on ICH GCP, the Declaration of Helsinki, the Belmont Report, and other human subject protection guidelines to ensure that the informed consent forms are documented in a timely and organized method to ensure subject confidentiality and safety and that they meet all inclusion/exclusion criteria for enrollment in the clinical trial.

- The site is capable of meeting the objectives of the clinical assignments.
- Expert personnel are available in adequate numbers to deliver the level of instruction required by the clinical assignments.
- The staff develop an orientation to the clinical site that includes a discussion of safety regulations for the students and clients involved in the clinical trials.

Developing Clinical Assignments

The lead author (Hurst) developed nine clinical assignments reflecting professional standards for CRA education and practice in which core competencies were established. Major resources used included the Association of Clinical Research Professionals CRA certification requirements and Society of Clinical Research Associates

●**Evaluation—**The CRA ensures that the datasets are completed and maintained according to regulatory requirements. He/she also actively participates in internal and external audits.[5,25]

The second clinical assignment seen in Figure 3 provides an example of how the nursing process functions in the development of this clinical activity. The CRA learner must progress through each concept in the evaluation of a potential clinical trial site. The learner must collect the appropriate data—both subjective and objective—to answer the question; analyze the data based on a set of guidelines or within a set of parameters; set a goal that is measurable; and implement a plan of action.

The learner cannot move to the planning phase unless the correct diagnosis has been made. The five components of the nursing process allow the CRA learner to use critical-thinking and problem-solving techniques to achieve specified learning objectives that mimic the environment in a real-world setting. Clinical assignments also require learners to engage in challenging pre- and post-work activities to enhance their learning experience.
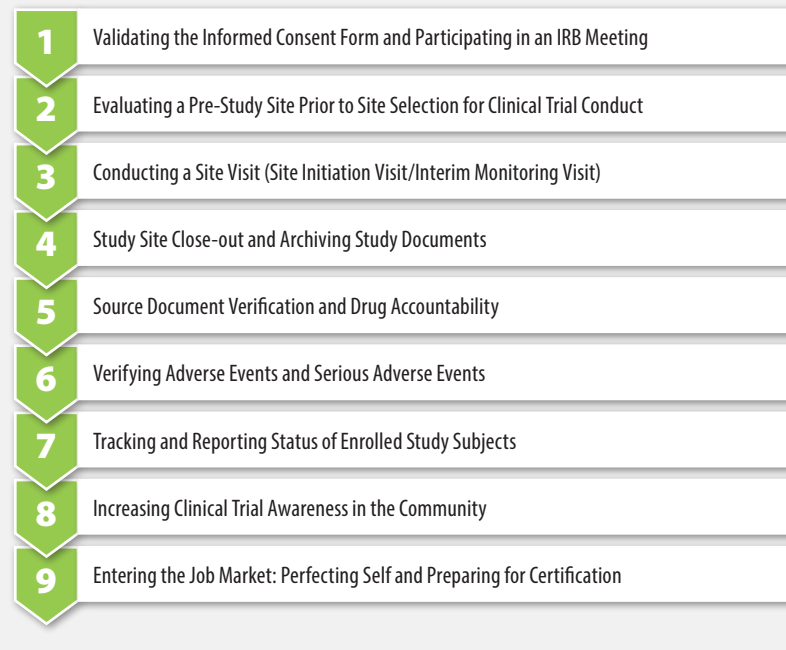
Clinical Assignment Content

The first seven clinical assignments in Figure 3 coincide with specific skills required by the organizations that offer certification programs for CRAs. Clinical assignments eight and nine enhance the learner's teaching and learning skills and provide strategies for career building. This article discusses only the first seven assignments, which involve activities—from simple to complex—that challenge the learner. The objectives for each assignment identify the learner outcomes.

Various preparatory activities lead learners into the specific learning assignment (see sample clinical assignment 3 in Figure 4). Activities prior to actual clinical assignments include a variety of assessments that the learner conducts by collecting data from the clinical sites, the preceptor, and the didactic modules. The learner analyzes the data and uses the components of the nursing process to achieve the desired outcomes of the clinical assignment.

The learner must complete a summary of the clinical assignment activities and strategies used to complete the objectives within 48 hours of the learning activity, and must successfully complete the learning activities prior to moving to the next

FIGURE 3: Clinical Assignment Activities

1. Validating the Informed Consent Form and Participating in an IRB Meeting
2. Evaluating a Pre-Study Site Prior to Site Selection for Clinical Trial Conduct
3. Conducting a Site Visit (Site Initiation Visit/Interim Monitoring Visit)
4. Study Site Close-out and Archiving Study Documents
5. Source Document Verification and Drug Accountability
6. Verifying Adverse Events and Serious Adverse Events
7. Tracking and Reporting Status of Enrolled Study Subjects
8. Increasing Clinical Trial Awareness in the Community
9. Entering the Job Market: Perfecting Self and Preparing for Certification

clinical site. The preceptor validates if the activities have been successfully completed.

The CRATP Evaluation

An internal self-study of the CRATP is conducted every two years. One component involves meeting with program directors, coordinators, course facilitators, and preceptors.

In 2011, the first seven clinical assignments were developed. After the program's two-year evaluation, the clinical assignments were refined and expanded, so that learners enrolled in the CRATP must now complete nine clinical assignments. Preceptors reported being pleased with clinical assignments, the preparation of students, and the enhancement of students' clinical skills through their participation in clinical experiences.

Overall, CRA learners in the program's third and fourth cohorts (years 2012 and 2013, respectively) when surveyed stated that the majority of the clinical assignments were appropriate and enhanced their knowledge of activities to be performed by the CRA. More positive comments were stated by the CRA learners who planned for

FIGURE 4: Clinical Assignment 3
Conducting a Site Visit (Site Initiation Visit/SIV or Interim Monitoring Visit/IMV)

CRA: Clinical Rotation Experience #3 – 8 Hours

STUDY PERSONNEL: CRA, CRC, or Study Manager

CLINICAL SITES: CTRC, EXCELth Primary Care, Inc., Minority–Based Community Clinical Oncology Program MB COOP, Ochsner Clinical Trials Unit

CLINICAL OBJECTIVES FOR CRATP STUDENTS:
1. Adhere to all relevant policies and procedures while visiting the study site
2. Follow prescribed procedures notifying study site of monitoring visit
3. Follow federal guidelines and regulations when conducting the monitoring visit
4. Notify all parties of identified noncompliance issues

STUDENT ACTIVITIES:
1. Prepare agenda for SIV or IMV
2. Include appropriate personnel to include in the meeting, i.e., PI, CRC, pharmacist
3. Develop a checklist to use during the visit and correlate questions with each person
4. Assemble necessary documents and monitoring tools, i.e., subject enrollment status sheets, monitoring guidelines
5. Conduct an initial site visit   Yes ☐   No ☐
   a. Train personnel on study protocol
   b. Perform an inspection/inventory of investigational product and other supplies
   c. Discuss enrollment/recruitment strategies/enrollment logs
   d. Prepare study SIV or IMV
   e. Review regulatory binder/trial master file for completeness
6. Conduct a periodic monitoring site visit   Yes ☐   No ☐
   a. Perform administrative duties
      1. Ensure adequacy/validity of investigational product and other study supplies
      2. Evaluate subject enrollment status
      3. Assess protocol adherence
      4. Evaluate informed consents, review any protocol amendments
      5. Evaluate subject safety, i.e., appropriate staff, facilities, review lists of subjects screened at site, etc.
      6. Assess collection, storage, and shipment of biological samples
      7. Assure proper investigational product storage conditions
      8. Verify investigational product accountability records
      9. Review study files at site for completeness and accuracy
      10. Review case report forms and source documents for completeness and consistency
      11. Identify and report significant adverse events to appropriate staff
      12. Review safety reporting requirements initiation and follow-up
      13. Confirm subjects' investigational product compliance
      14. Identify study site deficiencies, provide continuing training, and implement corrective action
      15. Sign and date monitoring log
      16. Assess enrollment issues
      17. Prepare the monitoring visit report initial or follow-up
      18. Coordinate audit activities
   b. Notify appropriate agencies of potential fraud and misconduct

STUDENT MATERIALS: Study grant/protocol, form 1572; study instruction manual, subject log/binders; regulatory binder/trial master file; site visit report form SIV or IMV.

the clinical experiences and had support from their employees to pursue this activity, which describes nearly all of the students involved. Only 2% of the CRA students, who experienced problems with scheduling clinical experiences, showed less appreciation for the clinical assignments.

Limitations

Although based on a number of national organizations' guidelines and policies, the clinical assignments were specifically developed for the exclusive use of the Dillard University CRATP (single-center study). Further, the clinical assignments have construct and content validity, but have not been rigorously tested beyond this group.

CRATP – Next Steps

The use of clinical assignments offers a missing link toward developing the skill set for beginner CRAs. Currently, there is no widespread use of hands-on practicum tools for beginning CRAs in the workplace. Using expert CRAs and the clinical assignments for hands-on practicums has been effective in the CRA training program at Dillard University MHHDRC in Louisiana. Based on the results of the use of clinical assignments with hands-on clinical trial experts, preceptors indicated enhanced student knowledge and student outcomes in the clinical trial research.

The program is innovative and its continued use is earmarked for our next steps. In the next two to five years, Dillard University is looking forward to sustaining the program with a focus on affiliating with leading local clinical research facilities to establish externship programs. The externship programs will offer a means to job placement for new CRAs.

Formative and summative evaluation of the CRA training program at Dillard University is conducted annually and every two years, and the trended data (qualitative and quantitative) are used to develop hands-on clinical experiences for the CRA learner, to make changes in the program, and to continue positive relationships with the clinical preceptors and sites. These practices are consistent with the literature and other programs that require clinical experiences.[5,12,15,20,22] The authors strongly believe that the novel approaches discussed in this article will lay a foundation for further development and acceptance of hands-on clinical assignments for training CRA workforces.

The authors strongly believe that the novel approaches discussed in this article will lay a foundation for further development and acceptance of hands-on clinical assignments for training CRA workforces.

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The Professionalization of Research Coordinators

PEER REVIEWED | Erika J. Stevens, MA
Esther Daemen, BSN, PG, PMP, MBA

As the number of global clinical trials continues to rise, so does the need and demand for qualified research support personnel, which further drive expectations for clearly established job functions. Variability in the assigned roles and responsibilities among clinical research coordinators (CRCs) creates opportunity to provide clarity in defining the profession.

HS

LEARNING OBJECTIVE
After reading this article, learners should be able to explain the profession-alization of the clinical research coordinator (CRC) position by using national demographic benchmark trends among CRCs and clearly defining position expectations.

DISCLOSURES
Erika J. Stevens, MA;
Esther Daemen, BSN,
PG, PMP, MBA:
Nothing to disclose

This article identifies current leading practice roles, responsibilities, and scope of practice for CRCs. Understanding national demographic benchmark trends among CRCs and clearly defin-ing position expectations provides insight into the professionalization of the CRC position. The ability to establish a clearly defined roadmap for the CRC—one based on a thorough understanding of the role's salient competencies—better enables job performance and provides opportunities for career advancement and credentials to those in the profession.

Trends of Note

The growth rate of clinical trials in the United States was 35% from 2008 to 2013.[1] The largest growth globally occurred in China at 80%. Data illustrated in Table 1 highlight global geographic areas with vast growth in clinical trials.[1]

Meanwhile, the number of people working in clinical research continues to rise.[2] Over the past decade, research and development (R&D) employment shows a strong secular growth trend, increasing by 26%, while total U.S. employment

grew only 1%. Over this period, R&D employment increased to nearly 120,000 new jobs.[2]

CRC Responsibilities

The CRC (also referred to as clinical trial admin-istrator, clinical trial nurse, and other terms) role is not described or defined in regulations or in the Good Clinical Practice (GCP) E6 guideline of the International Conference on Harmonization. Nevertheless, the CRC role merits attention due to its importance in the realm of clinical trials, as coordinators conduct important tasks delegated by principal investigators (PIs) at research sites.

Throughout this article, we will refer to the role as CRC for clarity and convenience. A CRC is tasked with supporting trial activities, such as coordinating study visits, maintaining study source documentation, and reporting adverse events experienced by study subjects.

Over time, the assigned job tasks expanded to include regulatory management, contract nego-tiation, budget development, training, and more. In a survey conducted among institutions that had received Clinical and Translational Sciences Awards (CTSAs) from the National Institutes of

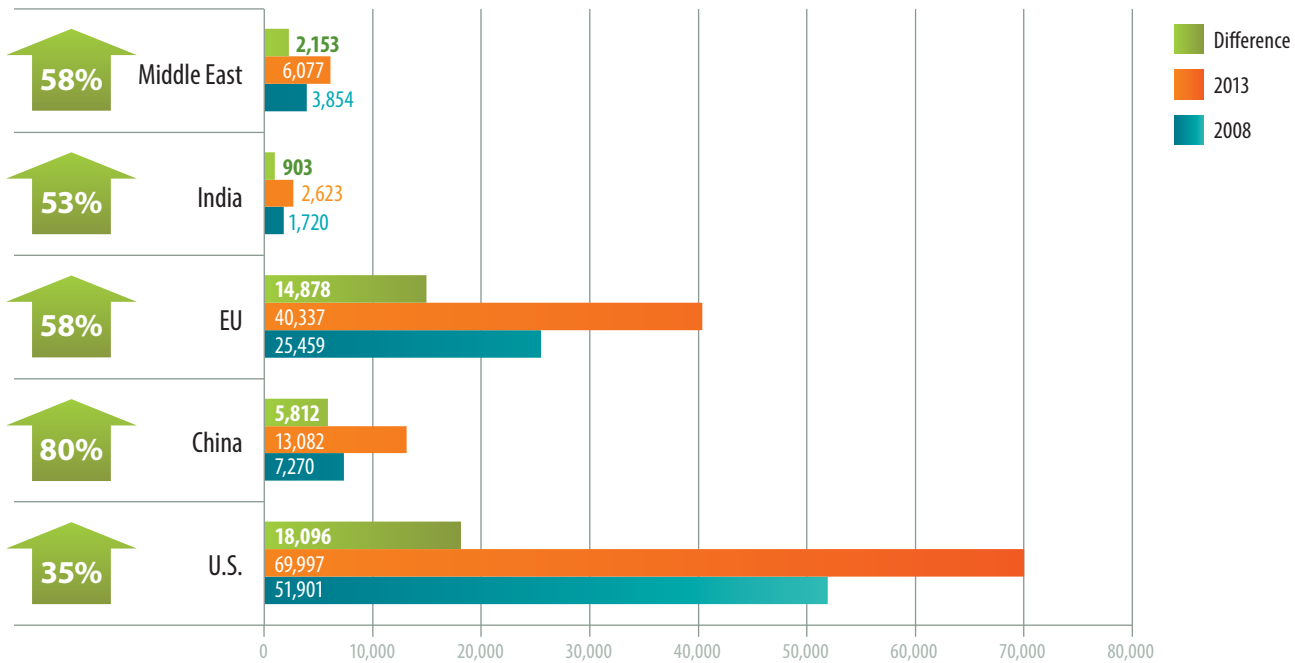**TABLE 1:** Growth in Clinical Trials by Nation/Region, 2008 to 2013[1]

	Difference	2013	2008
Middle East (58%)	2,153	6,077	3,854
India (53%)	903	2,623	1,720
EU (58%)	14,878	40,337	25,459
China (80%)	5,812	13,082	7,270
U.S. (35%)	18,096	69,997	51,901

Health, 50% of CRCs self-reported managing more than 15 job responsibilities (see Table 2).[4]

The expanding scope of tasks assigned to CRCs challenges expectations and responsibilities of the role. Defining and measuring capabilities for the CRC further promotes the profession.

The U.S. Food and Drug Administration (FDA) requires investigators to confirm supervision of activities performed in clinical trials and assesses delegation in clinical trial operations. Specifically, the FDA examines qualifications of personnel performing delegated tasks.[5]

The new European Union (EU) regulation (applicable as of April 2016) will require a description of the qualification of the investigators and requires supporting documentation, such as curriculum vitae. Any previous training in the principles of GCP or experience obtained from work with clinical trials and patient care shall be described (Article M 57). Other individuals involved in conducting a clinical trial shall be suitably qualified by education, training, and experience to perform their tasks (Article 46).[6]

Defining the necessary minimum requirements to be "qualified" to perform the delegated tasks presents a challenge to the industry. What we can say for certain is that there are measures of qualification in the industry; education level is one of these measures. Taking a snapshot in the summer of 2015 of the Association of Clinical Research Professionals (ACRP) member database, which also includes details on the members of the Academy of Physicians in Clinical Research (APCR), yields information related to the highest degree completed by members showing 43.7% earned a bachelor's degree (see Table 3).[7]

TABLE 3: ACRP/APCR Membership Database Results on Highest Level of Education Completed[7]

Highest Degree Completed	Members	%
High School Diploma	781	5.7%
Associate/Two-Year	1,531	11.3%
Bachelor's	5,901	43.7%
Master's	3,476	25.7%
Doctorate	1,352	10%

TABLE 2: CTSA Research Coordinator Task Force Survey Results on Self-Reported Job Responsibilities[4] (1,597 coordinators responded to the CRC-directed survey)
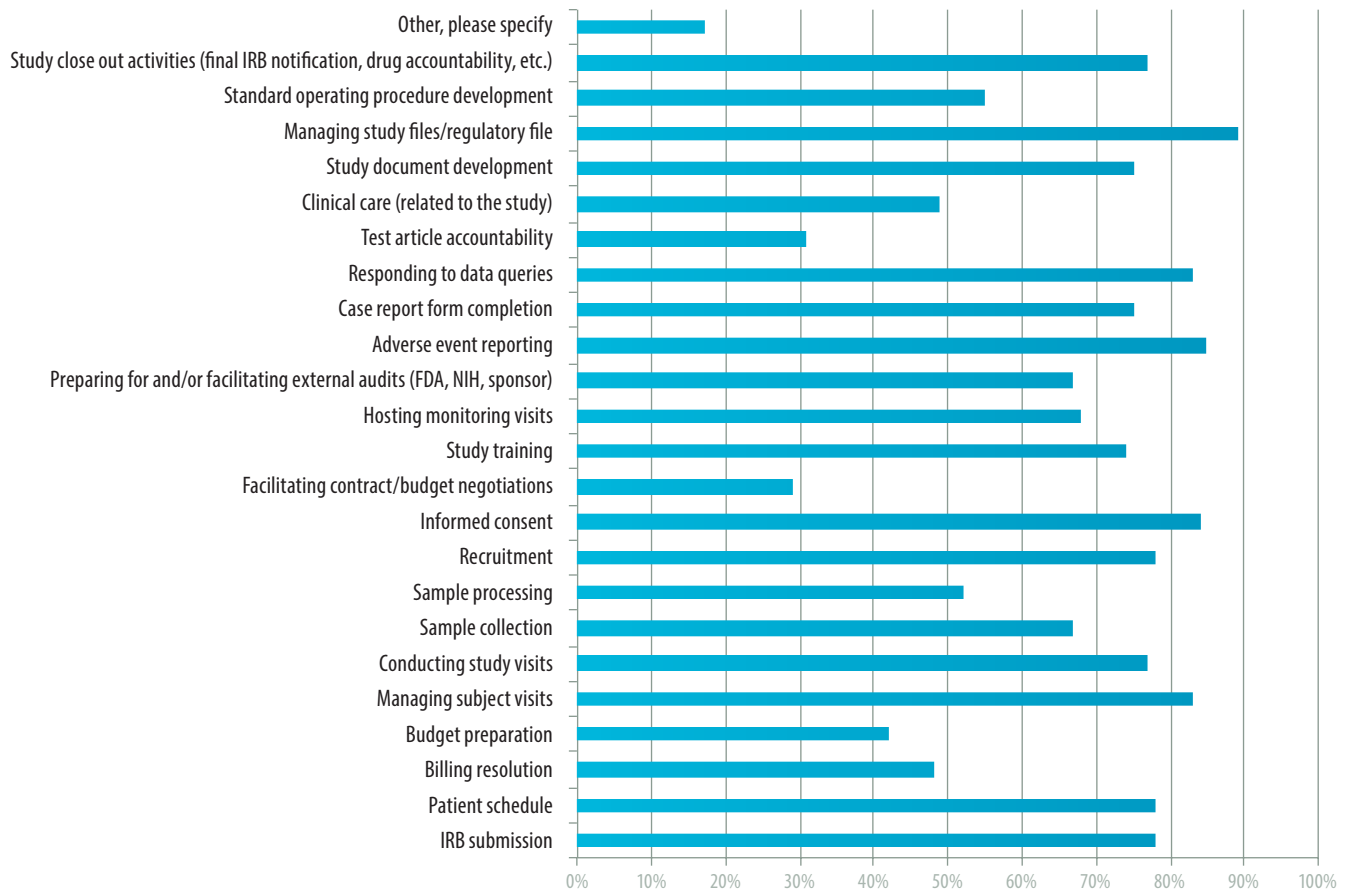
A second measure for defining competency is clinical research certification. Many professions require licensure or certification, and certification further credentials the CRC profession. Regulations require researchers to be "qualified" (meaning competent), but provide no guidance on what types of education, training, certification, license, or experience are required or what kind of proof needs to be provided for someone to qualify for a certain clinical research–related role.

As a result, research organizations determine the requirements for their own situations, resulting, for example, in a CRC holding a research-related master's degree with one employer and a CRC completing only a few certificate courses with another employer nevertheless landing similar jobs with comparable wages. Doesn't it make more sense that the level of complexity of the actual tasks being performed by a CRC should drive the professional development (e.g., education, training, on-the-job mentorship) requirements?

This, therefore, is the environment in which we find ourselves when it comes to defining competency for the profession in order for CRCs to successfully accomplish their tasks. It is becoming an area of increased focus for the industry, but that focus will have to intensify for measurable improvements to be realized.

What Do We Mean by "Competency"?

Competencies encompass knowledge, attributes, skills, attitudes, and behaviors necessary for a particular set of tasks or objectives. Within a profession, the multidimensional abilities are defined through professional performance.[8] A competent professional is one who possesses the required abilities across domains, as defined by education or practice.[9]

FIGURE 1.
Joint Task Force Competency Domains for the Clinical Research Professional

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 biologicals are developed and regulated

4 CLINICAL TRIALS OPERATIONS (GCPs)
Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational product

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, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial

Source: Joint Task Force for Clinical Trial Competency

TABLE 4: Competencies by CRC Role (defined by Joint Task Force for Clinical Trial Competency)

DOMAIN	CRC ROLE
Clinical Trial Operations	
Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan	Optional
Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice (GCP) guidelines	Required
Evaluate the design conduct and documentation of clinical trials as required for compliance with GCP guidelines	Optional
Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials	Optional
Describe appropriate control, storage, and dispensing of investigational product	Required
Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to institutional review boards/independent ethics committees, sponsors, and regulatory authorities	Required
Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials	Optional
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	Optional
Describe the role and process for monitoring of the study	Optional
Describe the roles and purpose of clinical trial audits	Optional
Describe the preapproval and postapproval safety reporting requirements of regulatory agencies	Required
Describe the various methods by which safety issues are identified and managed during the development and postmarketing phases of clinical research	Optional
Study and Site Management	
Describe the methods used to determine whether or not to sponsor, supervise, or participate in a clinical trial	Optional
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	Optional
Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	Optional
Use elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress	Required
Identify the legal responsibilities, issues, liabilities, and account-abilities that are involved in the conduct of a clinical trial	Required
Identify and explain the specific procedural, documentation, and oversight requirements of principal investigators, sponsors, CROs, and regulatory authorities related to the conduct of a clinical trial	Optional

TABLE 5: Clinical Research Professional Development Pathway for CRCs (defined by ACRP)[9]

CONTENT AREA	DEFINITION
Human subject protection	Assurance that the rights and welfare of individuals participating in clinical trials are guaranteed according to applicable laws, regulations, and ethical principles
Management of essential documents	Preparation, maintenance, and storage of documents as defined under International Conference on Harmonization (ICH) guidelines (i.e., those documents that individually or collectively permit evaluation of the conduct of a clinical trial and the quality of data produced)
Regulatory knowledge and ethics	Awareness and understanding of the regulations and guidelines governing clinical trials
Investigative site management	Oversight of two or more clinical trials at one or more clinical research locations
Clinical trial management	Oversight and conduct of a single protocol at a single performance site
Test article accountability and management	Tracking, storage, and shipment of drugs, devices, and biologics used as part of a clinical research investigation
Project management	Oversight of two or more trials related by indication or investigational product/test article at two or more locations
Quality management	Adherence to GCP and other recognized standards and practices to develop and maintain standards in clinical research to assure human research protections and data integrity
Data management	Processes and procedures employed when handling, retrieving, monitoring, analyzing, and reporting data collected in the context of a clinical trial
Clinical research environment	Understanding the global roles, structures, and evolution of the clinical research industry and its associated functional roles and current trends
Business management skills	Operational components of clinical research, including assessment and negotiations of budgets and contracts (i.e., evaluation of patient billing compliance, insurance coverage analysis, and intellectual property management)
Interpersonal skills	Written, verbal, and nonverbal abilities to effectively communicate, manage, and influence change
Personal/professional management	Successfully managing a work/life balance
Supervisory skills	Functional role involving personnel management

The concept of competency-based learning exists across the industry, with attempts having been made to define general research-related competencies and role-specific competencies. The Joint Task Force (JTF) for Clinical Trial Competency, created and led by the Multi-Regional Clinical Trial Center at Harvard University in 2013, includes representatives from the pharmaceutical industry, contract research organizations (CROs), academic institutions, clinical research sites, and professional societies. The JTF's work resulted in the delineation of eight competency domains for the clinical research professional (see Figure 1).[10]

Detailed descriptions of each domain and the roles within are available to guide organizations with the development of competencies relevant to their area of expertise and/or roles they serve in clinical research.

The ACRP Pathway for CRCs is aligned with the competencies identified by the JTF, and offers more detailed information on what tasks a CRC should be able to conduct. Figure 1, Tables 4 and 5, and the sidebar include examples of and more insight into CRC role-related competencies, as per the JTF and the ACRP CRC pathway.

Conclusion

The CRC role remains undefined by any regulations or ICH guideline, but coordinators are responsible for increasingly important functions in the conduct of clinical trials. With expansions in assigned duties, clearly defined competencies and a related professional development pathway enable success for CRCs. Further, an understanding of the required capabilities for the role is necessary to mitigate risk, to produce quality data, and adhere to regulatory compliance within clinical trials.

Perhaps it is time for the CRC role to be recognized as an actual "profession"?

A Professional with a Good Grasp of Research Competencies Can…

➔ Apply the framework of scientific research to clinical research studies, employing principles of GCP to produce valid data

➔ Ensure that ethical principles and values are upheld in human studies research

➔ Assess and apply regulatory processes and procedures to the clinical research conduct

➔ Use statistical knowledge and methodology to design, implement, and assess clinical research

➔ Communicate effectively, both orally and in writing, with others in the clinical research profession

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OPEN BOOK TEST

This test expires on December 31, 2016
(original release date: 12/1/2015)

Five Smart Strategies to Develop Your Clinical Research Career

1. Keeping current with technology will ensure that clinical researchers are:
- **A.** Better, faster, and more accurate with their jobs
- **B.** Eliminating shadow charts
- **C.** Generating fewer queries
- **D.** Meeting recruitment goals

2. According to this article, when reading new regulations, you should know:
- **A.** The history behind the regulation
- **B.** The date it went into effect
- **C.** How it became a law
- **D.** Which research subjects no longer qualify

3. When networking, it is important to:
- **A.** Be an extrovert with a lot to say
- **B.** Discuss new regulations
- **C.** Maintain connections with your colleagues
- **D.** Ask for relevant job opportunities

4. A key element of networking is to develop a tracking system in order to?
1. Remember key elements
2. Sharpen your Excel skills
3. Track each person in your network
4. Share it with your peers
   - **A.** 1 and 4 only
   - **B.** 2 and 3 only
   - **C.** 1 and 3 only
   - **D.** 2 and 4 only

5. When someone has given you advice, a connection, a good idea, or a job lead, how often should you thank them?
- **A.** Once
- **B.** Twice
- **C.** Three times
- **D.** When it's convenient

6. Which of the following applies for keeping up-to-date with your clinical specialty?
1. You demonstrate professional responsibility
2. You become an expert at your job
3. You gain the respect of your research team
4. You will be a successful clinical researcher
   - **A.** 1, 2, and 3 only
   - **B.** 2, 3, and 4 only
   - **C.** 1, 3, and 4 only
   - **D.** 1, 2, and 4 only

7. This article suggested which of the following for keeping up with your clinical specialty?
- **A.** Write down a gap in your knowledge and how to fill it
- **B.** Ask patients about their disease
- **C.** Read medical journals
- **D.** Attend investigator meetings

8. Volunteering can advance your career by:
- **A.** Filling your free time
- **B.** Helping research sites that are understaffed
- **C.** Adding to your resume
- **D.** Furthering the clinical research enterprise

9. When it comes to volunteering, we learn from the article you should NOT:
- **A.** Ask to be paid after three months
- **B.** Do it just to make an impression
- **C.** Interact with research participants
- **D.** Be involved in contracts with the sponsor or CRO

10. In order to keep your resume current, how often should you add accomplishments?
- **A.** Monthly
- **B.** Quarterly
- **C.** Semi-annually
- **D.** Annually

Enhancing Skills for Clinical Research Associates Through Hands-On Clinical Practicums

11. Which of the following events most accurately describes the components of the current skill sets required for clinical research associates (CRAs) in the 21st century?
- **A.** The increase in the cost of clinical trials
- **B.** The shortage of CRAs
- **C.** The increase in diversity of clinical trial subjects
- **D.** The increase in the complexity and rigor of initiating, implementing, and evaluating clinical trials

12. In this article, students completed a two-part, year-long CRA training program. Components required for students advancing from the didactic (theory) component of the program to the clinical component of program included which of the following?
1. Achievement of 100% score on the didactic midterm and final
2. Completion of the Collaborative IRB Training Initiative (CITI) Human Subjects Training Program
3. Attendance at a two-day clinical orientation of the clinical sites conducted by professionals in clinical research
4. Receipt of a certificate indicating successful completion of NIH's module on Protecting Human Research Participants
   - **A.** 1, 2, and 3 only
   - **B.** 1, 2, and 4 only
   - **C.** 1, 3, and 4 only
   - **D.** 2, 3, and 4 only

13. What are the purposes of the Dillard University CRA hands-on clinical component training program?
1. Offer learners a hands-on clinical practicum
2. Provide skilled CRA experts to function as clinical preceptors
3. Train BSN learners to become proficient instructors in the BSN nursing program
4. Enhance learners' skills in monitoring clinical trial plans, completing source documents and case reports, and understanding standard operating requirements
   - **A.** 1, 2, and 3 only
   - **B.** 1, 2, and 4 only
   - **C.** 1, 3, and 4 only
   - **D.** 2, 3, and 4 only

14. The use of preceptored practicums to assist CRA learners closes the gap between theory and practice by:
- **A.** Learners requesting limited clinical experiences
- **B.** Increased learner exposure to real-life situations
- **C.** Meeting the need of clinical agencies for more CRAs in clinical trials
- **D.** Students teaching clinical preceptors current theory to enhance their clinical practice

15. Which of the following describe components of an effective clinical preceptorship program for CRA learners?
1. Incorporates affiliates with approved clinical research status
2. Approved guidelines developed by the CRA training program
3. Collaboration between the training program and the preceptors
4. Provides compensation for the preceptor and the clinical agency
   - **A.** 1, 2, and 3 only
   - **B.** 1, 2, and 4 only
   - **C.** 1, 3, and 4 only
   - **D.** 2, 3, and 4 only

16. Responsibilities for CRA training programs include which of the following?

1. Preceptor orientation
2. Assigning no more than three learners to one preceptor
3. Communication between the learner and the CRA faculty
4. Providing feedback to the facility at the end of the learning activity

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

17. Which of the following characteristics is required when selecting a clinical training site for CRA learners?

   A. A faculty and staff learning environment
   B. The training program develops institutional orientation guidelines
   C. The facility use a large number of outside personnel as staff
   D. The clinical site has adequate resources to meet the learning objectives

18. Which of the following activities are criteria for the learner becoming proficient in mastering a task?

   A. The more a learner performs a task, the more proficient he/she becomes
   B. The more a learner studies and memorizes the content, the better he/she executes the skill
   C. Preceptor-led discussions increase learners' knowledge and skill of the task to be performed
   D. The more events a learner observes, the more proficient he/she becomes in mastering the task

19. Which of the following responses describes the most appropriate answer for the utilization of the nursing process for baccalaureate nurses in a CRA training program? The nursing process:

   A. Serves only for implementing and evaluating the health of clinical subjects
   B. Serves as a five-component critical thinking tool for problem solving
   C. Serves as the tool to meet global regulatory guidelines for clinical subjects
   D. Serves as a tool to make medical diagnoses for inclusion/exclusion of subjects in clinical trials

20. The clinical preceptor survey results, in this article, indicated which of the following?

   A. The learner did not have enough time to adequately meet the clinical outcomes
   B. The clinical assignments activities did not correlate with student learner objectives
   C. Clinical assignments developed for CRA learners were clinical skills performed by CRAs
   D. There were too many clinical assignments to adequately meet the needs of the learners during a one-day clinical experience

The Professionalization of Research Coordinators

21. The ability to establish a clearly defined roadmap for the CRC based on the role's competencies:

1. Better enables job performance
2. Provides opportunities for career advancement and credentials for the CRCs
3. Ensures an increase in the CRC role's average wages
4. Avoids the need for CRC training

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

22. The largest growth rate globally of clinical trials from 2008 to 2013 occurred in which of the following countries/regions?

   A. China at 80%
   B. United States at 85%
   C. Europe at 90%
   D. India at 95%

23. Over the past decade, research and development employment showed a strong secular growth trend, increasing by how much, while total U.S. employment grew only 1%?

   A. 5%
   B. 15%
   C. 20%
   D. 26%

24. Measures for defining competency of a CRC include which of the following?

1. Education level
2. Clinical research certification
3. Coaching/mentorship received
4. Training level

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

25. Competencies encompass which of the following arenas necessary for particular set of tasks or objectives?

1. Coordination
2. Skills
3. Attributes
4. Behaviors

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

26. A competent professional is best described as?

   A. One who possesses the required abilities across domains, as defined by education or practice
   B. One who possesses the required abilities in one (the CRC) domain, as defined by education or practice
   C. One who possesses proof of the required level of coaching
   D. One who possesses proof of the required years of experience

27. Attempts have been made to define general research-related competencies and role-specific competencies. The Joint Task Force (JTF) for Clinical Trial Competency's work resulted in the delineation of how many competency domains for the clinical research professional?

   A. 8
   B. 10
   C. 12
   D. 15

28. Is it correct to say that since competency domains have been identified by the JTF, organizations do not have to develop competencies relevant to their area of expertise and/or roles?

   A. No, because detailed descriptions of each domain and the roles within are available to guide organizations with the development of competencies relevant to their area of expertise and/or roles they serve in clinical research.
   B. No, because local regulatory bodies need to endorse the competency domains as set by the JTF before they can be implemented, and adjustments to the competencies may be required to achieve endorsement.
   C. Yes, because the competency domains defined by the JTF can be used as presented for any organization, no matter its area of expertise and/or roles.
   D. Yes, because the competency domains have been endorsed by the ICH and can be applied as presented to any clinical research role in the U.S., EU, and Japan regions.

29. The JTF competency domains for the clinical research professional:

1. Ethical and patient safety considerations
2. Clinical trial operations
3. Leadership and professionalism
4. Budgeting and insurance compliance

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

30. A professional with a good grasp of research competencies may accomplish which of the following?

1. Very easily find a job in clinical research without having to provide proof of experience in the role
2. Ensure that ethical principles and values are upheld in human studies research
3. Be entitled to a higher wage upon hire
4. Assess and apply regulatory processes and procedures to the clinical research conduct

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