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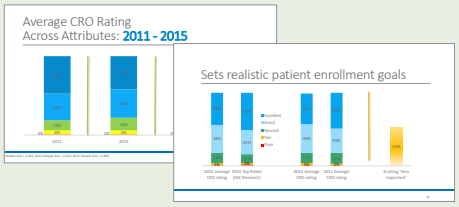

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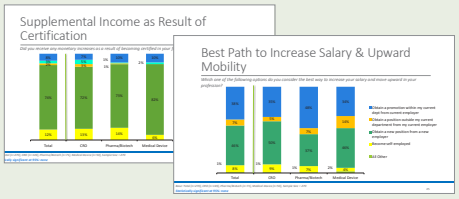

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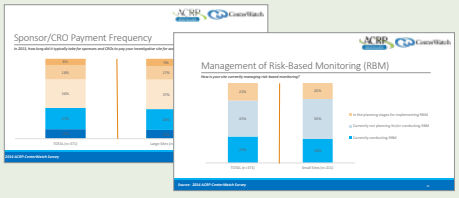

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Photographs by Steven McBride

ABOUT OUR COVER: Pictured from left to right, Natalie Stone, MS, CCRC; Dr. David Morin, Director of Clinical Research for Holston Medical Group (HMG); and Denise Brummitt, Regulatory Specialist at HMG's HQ in Kingsport, Tenn. Above, more members of Dr. Morin's team.

Columns

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GUEST EDITOR'S MESSAGE

Paula Smailes, RN, MSN, CCRC, CCRP

[DOI: 10.14524/CR-15-4097]

The Genesis and Progression of a Clinical Research Career

Clinical research careers are increasingly sought after thanks, in part, to a booming biotechnology industry. As pharmaceutical and device companies continue to bring new products to market, the vast array of positions to assist with these discoveries are in high demand.

There are well-known roles in this field, such as principal investigator, research nurse, clinical research coordinator (CRC), clinical research associate (CRA), data manager, and regulatory manager. Yet, there are also other positions—biostatistician, medical writer, quality assurance specialist, auditor, trainer and educator, logistic specialist, and more—that may not be as commonly thought of, but are crucial to the industry's success.

Finding a Clinical Research Position

As a former ACRP chapter chair, I was commonly asked by local attendees of chapter events how someone could find and land a job in clinical research. In this issue, we have two articles to address that very topic. First, in "How to Enter the Clinical Research Field," Joy L. Frestedt and her coauthors offer many suggestions for those interested in a clinical research career to get their foot in the door. This article overviews the common positions found in research, strategies for action, and how to make yourself marketable when you otherwise have no experience. We further learn that capitalizing on transferable skills, networking, internships, and volunteering are key activities to help you get the experience that can launch you into a research career.

Tammy Root takes this a step further by explaining how to navigate a job transition with her article, "Penguins to People." As a former

animal researcher, she used her transferable skills to make the jump to research in human subjects.

I see reflections of myself in these two articles. I was an operating room nurse who loved writing her thesis, and I wanted to break into the clinical research industry. I got my big break thanks to transferable skills; I applied for a pulmonary research nurse position because I had the kind of experience in bronchoscopies that was in demand at the organization that hired me. As it turns out, they had many openings, and with my consent, I was placed in adult pharmaceutical research, where I spent most of my clinical research career.

Onboarding a New Hire

As we think of the next step in the career path after getting the job, it would be onboarding. Charlotte Hurst and colleagues provide us with a nice overview using hands-on practicums for new CRAs. Having a training program with preceptors who serve as mentors for new hires can be the recipe for success for these new staff. The authors explain the philosophy behind nine clinical assignments reflecting professional standards for CRA education and practice in which core competencies were established.

Organizations take significant time and financial risk with new hires. If new staff are not welcomed into an environment that promotes a successful transition to a new role, there is a good chance that person may not stick around to see if it works out.

Growth and Development for Existing Clinical Research Professionals

So, you did it! You landed yourself that clinical research position of your dreams and you love it. Time passes and you realize you would like more, but more of what? How can you advance your career? Our edition continues down the career path, beginning with Patricia Kasper on "Five Smart Strategies to Develop Your Clinical Research Career." She offers valuable insights for making your next move once you have been in a clinical research position for some time.

Those readers who have climbed the ladder and are presently in research administration may benefit from the study conducted by Diana Naser on the "Leadership Practices of Clinical Trials Office Leaders in Academic Medical Centers." Her original research captures traits identified by leaders using a Leadership Practices Inventory for identifying where personal and professional development may be needed. Her study can be a guide to administrators for identifying areas for improvement in their style of leadership practices within clinical research.

Finally, in their article on "The Professionalization of Research Coordinators," Erika J. Stevens and Esther Daemen help to identify job requirements of the CRC and how it is a key position in this industry. The concept of core competencies for the CRC has become an increasingly hot topic, thanks in part to the Joint Task Force described in this article. As the authors explain, the role of the CRC remains undefined within the regulations or International Conference on Harmonization guideline, but is an increasingly important function in the conduct of clinical trials.

Deepening Your Research Roots

As I look back at my clinical research career, I see that my advancement has largely been rooted in several things which you will find throughout this issue. The first instrumental move was to become certified; it demonstrated my commitment to this industry and let all future employers see that I had the knowledge base to perform in the position for which I applied.

Secondly, I started to take chances. It began when I thought I had a decent idea for a poster presentation, so I submitted it to an international conference. It was accepted, and would become the first of many. The same thing happened with writing—I looked for "calls to potential authors" and found my work accepted.

Perhaps the biggest push to my career has been volunteerism. Now, I recognize that we currently live in a world with tremendous demands, especially as we balance careers with family. However, if you can spare a little bit of time to volunteer for professional organizations, the rewards will be priceless.

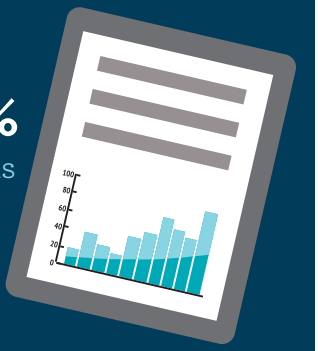
For all of you with plans to transition to clinical research or for those who want to advance, I hope you are able to find an article in the pages ahead that relates to you and your current professional situation.

The first instrumental move was to become certified; it demonstrated my commitment to this industry and let all future employers see that I had the knowledge base to perform in the position for which I applied.

Paula Smailes, RN, MSN, CCRC, CCRP, (paula.smailes@osumc.edu) is a systems analyst and clinical research trainer at the Ohio State University Wexner Medical Center and visiting professor for Chamberlain College of Nursing. She also is the 2015 vice chair of the ACRP Editorial Advisory Board and sits on the ACRP Professional Development Committee.

BY THE NUMBERS

Facts and figures affecting clinical trial conduct from the far corners of the research enterprise.



A global study of trial master file (TMF) owners found that **38%** of contract research organizations surveyed now use electronic TMF applications, versus just **21%** in 2014, with **58%** saying faster study start-up is a key driver, and **50%** citing cost savings.

Source: Veeva, www.prnewswire.com/news-releases/global-life-sciences-industry-survey-reveals-significant-jump-in-cro-use-of-electronic-trial-master-file-etmf-applications-528024001.html

Nearly **one out of every 10** U.S. for-profit healthcare company board positions is held by an individual with an academic affiliation being compensated an average of $193,000 in 2013 for board membership, and often holding significant company stock.

Source: University of Pittsburgh School of Medicine, www.eurekalert.org/pub_releases/2015-09/uops-mna092415.php

An academic research organization has reduced the timeline to complete the clinical trials endpoint adjudication process by an average of **30%** by implementing a new cloud-based solution.

Source: Harvard Clinical Research Institute, http://globenewswire.com/news-release/2015/10/12/775244/0/en/Harvard-Clinical-Research-Institute-Cuts-Event-Adjudication-Timeline-by-30.html

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A Message from ACRP's New Executive Director

Taking on a new role is always challenging, yet exciting. You never know exactly what you've gotten yourself into, but the anticipation of working with new people toward a common goal is extremely motivating.

Whenever I start with a new organization, I like to spend time listening to and learning from the folks who know it the best. As I acclimate myself to my new position with ACRP, I have been speaking with members of the Association, the staff supporting the organization, and clinical research colleagues outside the organization. The feedback has been tremendous, and we should be proud that ACRP is held in such high regard.

I was fortunate to be given a copy of a special issue of the predecessor of this publication, *The Monitor,* from 2006 which highlighted the 30th anniversary of ACRP. In the Chair's Message, Robin Newman looked to the future as she wrote:

> "This challenges the next generation of ACRP leadership to maintain a stable organization in a less stable world. To be successful, tomorrow's leaders will have to firmly hold the ACRP mission and vision in mind…."

These words held true then, and are still true today, as we sit on the cusp of our 40th anniversary.

The Speed of Change

In recent years, our industry has been constantly evolving around us. In my 30-plus-year career, I have never seen change happening so rapidly. It's been amazing to consider how things have progressed since I started at Eli Lilly as a sales and marketing person.

Half-way through my 24 years at Lilly, I was fortunate to transition into clinical development and help the firm drive operational efficiencies. Moving to contract research organizations for the past six years gave me a whole new perspective on research operations, and now being able to work with ACRP is indeed an honor. However, in all that time, nothing matches the challenges we face today.

The clinical research enterprise is experiencing exponential growth in the number of trials being conducted. As a result, there is an increase in demand for volunteer patients, site monitors, study coordinators, and investigators. However, there just are not enough people expressing interest and being developed to fill these roles.

We have a gap in the industry that needs to be rectified. Who better to provide the training and certification needed to fill that gap than ACRP?

Delivering on the Mission

We are in a business that delivers a wonderful service—improved heath to patients in need. Without clinical development, there would be no advancement in the science of health. We often forget this simple fact due to the busy day-to-day activities with which we find ourselves involved.

We are very fortunate to be members of an organization that keeps patients healthy and ensures research is performed ethically, responsibly, and professionally everywhere in the world. As members of ACRP, we must continue to work together to ensure these goals are met. We are on a noble mission.

I look forward to working with each of you to continue our quest of improving healthcare. Please feel free to reach out and send me your ideas and concerns.

A *Clinical Researcher* Round-up: Career Advice That Works

Mallory Frazier, MS, CCRC

James Michael Causey

[DOI: 10.14524/CR-15-4100]

HOW TO PUT THE "WORK" BACK INTO NETWORKING

It's easy to crank out a few letters or perfunctorily hand out a deck of business cards at trade shows. However, networking probably won't do you much good without a plan, says Mallory Frazier, MS, CCRC.

Her secrets: Identify the right people and know your specific goal.

"So many times you collect cards and are (or I was) too young and inexperienced to really follow up in a meaningful way," Frazier says. Forget that mass e-mail or snail mail campaign. Instead, send out 20 meaningful and personalized e-mails to people you've identified who have information that could help you. Don't expect to hear from them all, Frazier cautions, "but a few will want to talk to you."

Frazier's used LinkedIn to find most of her prospects. She aims for an in-person meeting, but advises being willing to settle for a phone call. "It will work fine and could lead to an in-person meeting."

Results? "Using this method during my last job search I landed three really good interviews at places I actually wanted to work. As comparison, for my last job search (as a young and not bold person), I blindly sent out almost 200 applications" and drew a weaker crop of interviews.

FIND YOUR FUTURE SELF

Natalie Pasquenza recently had a career crisis. "Where am I going from here, and do I really want to retire without having done more?" The questions hit hard for the manager of research nursing for the Pediatric Clinical Trials Unit at the University of Louisville.

Her husband made a simple suggestion. "He told me to find someone, either within my organization or outside my organization that was in a position that was similar to what I may want in the future." Then reach out and offer to take them to lunch and let them know you hope to chat about your "professional" crisis with a goal of coming up with a plan. Did it work?

"Voila! I met with two women who have done fantastic things at our university, and I now have new goals and plans to get there."

Bottom-line: Do NOT sit back and wait for someone to offer to be a mentor, or depend on a formal mentoring program, as that is much too passive. Your job future is 100% up to you, and you have to actively pursue it.

That said, if you work for Quintiles, it might be somewhat easier to identify and connect with the perfect mentor (see "Quintiles Coaching, Mentoring Programs Shore Up Weaknesses").

GIVE THE BOSS SOME PERSPECTIVE

Asking for a raise usually isn't a simple task, but some approaches work more effectively than others. A Certified Clinical Research Coordinator

Nicky Rousseau, CPA, CFP

(CCRC®) who wished to remain anonymous told *Clinical Researcher,* "I had been with my company for more than 10 years and rose (slightly) through the ranks. A few years back, I asked for my salary to be reviewed and compared nationally, and was given a $5,000 raise." While she was hoping for a bigger salary hike, she believes she might not have even gotten what she did without using her tactic.

QUINTILES COACHING, MENTORING PROGRAMS SHORE UP WEAKNESSES

Quintiles has worked hard to develop effective in-house coaching and mentoring programs, but you have to know how to use them, says Nicky Rousseau, CPA, CFP, senior director of the company's Program Management Office.

Just as Frazier stressed the importance of having a clear goal (see "How to Put the 'Work' Back Into Networking"), Rousseau encourages coachees to come to their coach with a very specific request. For example, a clinical research associate who is often out of the office might ask a coach for help finding ways to increase his or her presence in a virtual environment and feel more connected to the home office.

"Coaching should be more than just uplifting," Rousseau says. Everyone loves a good pat on the back or a cheer from the sidelines, but good coaches are there to help you identify your professional gaps and find ways to fill them.

Quintiles' robust mentoring program has boiled the process down to three focused meetings in which employees first identify an area where they wish to improve. For example, the program has helped employees who feel uncomfortable making presentations learn directly from those whose performance they admire. The "expert" can offer concrete examples of ways to improve tone, clarify information presented, and better engage the audience.

Elisa A. Hurley, PhD

[DOI: 10.14524/CR-15-4095]

Notice of Proposed Rulemaking to Change the *"Common Rule"*: A Brief Overview

On September 8, 2015, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies released a long-anticipated Notice of Proposed Rulemaking (NPRM) proposing changes to the Federal Policy for the Protection of Human Subjects, or the "Common Rule." The NPRM represents the first proposed changes to the Common Rule since it was published in 1991, and the most substantive revisions to the core regulation governing federally funded human subjects research in the United States since 1981. The proposed revisions have implications for researchers and research staff, institutions, institutional review boards (IRBs), and research sponsors.

Rationale for the Proposed Changes

The goal of the proposed changes is to "modernize" the Common Rule in three respects. The first has to do with changes in how research is conducted. The research enterprise has changed significantly since the Common Rule was published, thanks in large part to technological and scientific advances around research use of the Internet, mobile technologies, biospecimens and genomics, and so-called "big" data.

In addition, research settings have changed. More and more studies involve multiple sites, and research is increasingly conducted outside the realm of academic medical centers and universities—in clinicians' offices, outpatient clinics, community hospitals, and virtually. Furthermore, the number and types of trials—including clinical trials, observational studies, cluster randomized trials, and cohort studies—has expanded. The NPRM proposals attempt to make the human subjects research oversight system better fit today's research.

Elisa A. Hurley, PhD

The NPRM represents the first proposed changes to the Common Rule since it was published in 1991, and the most substantive revisions to the core regulation governing federally funded human subjects research in the United States since 1981.

The second respect in which the NPRM proposes to modernize the Common Rule involves the changing relationship between the public and the research enterprise. The NPRM acknowledges the recent emergence of a more "participatory" research model, in which the public actively expresses its views about the value and acceptability of research studies, and subjects and communities are increasingly seen as active partners in research.

Furthermore, members of the public now expect to not only be informed of, but involved in, decisions about how their information or biological materials are used. Because research subjects and the public at large have become stakeholders in the research enterprise in a way they weren't 25 years ago, many agree that the research oversight system must serve the goal of increasing transparency and building public trust in research.

Third, the NPRM seeks to "strengthen the effectiveness and efficiency" of what many see as an outdated and cumbersome research oversight system in light of the changes noted above. The NPRM acknowledges that, in many cases, our current regulatory framework does not appropriately calibrate the level of review a study receives to the level of risk of harm it poses.

A stated goal of the NPRM is to institute a review system that avoids requirements which add little to subject protections, but merely impose administrative burdens, leading to inefficiencies. The proposals aim to simplify and streamline the oversight system to better protect and respect research subjects while also fostering important research.

Taking all of these considerations into account, the NPRM explicitly frames many of its proposed changes as an effort to strike the appropriate balance between the Belmont principles of autonomy (i.e., respecting persons) and beneficence (i.e., fostering socially valuable research). Furthermore, many of the 88 questions embedded in the NPRM request public input on whether the proposals achieve that balance.

With this rationale and framework in mind, let's look at some of the specific changes proposed.

Key Changes Designed to Enhance Protection of Subjects

The first change involves "tightening" the requirements for informed consent. The NPRM outlines several new requirements about how information must be organized and presented to potential subjects to facilitate their understanding of the reasons to enroll in a research study or not.

For example, the proposal says that, during the consent process, required information must be presented first, and that consent forms must include only the required elements. Any additional information should appear in appendices.

In addition, the NPRM proposes new required elements of informed consent, including, where applicable, a statement that a subject's biospecimens may be used for commercial profit and whether the subject will share in that profit, and a statement regarding whether clinically relevant research results will be disclosed to subjects and under what conditions. These changes are designed to increase transparency and make consent "more meaningful."

A second significant change with respect to informed consent is that consent would generally be required for secondary research use of stored biospecimens, whether or not those biospecimens are identifiable. Under the current rules, secondary use of biospecimens from which identifiers have been removed does not count as human subjects research, and thus is not subject to any regulatory provisions.

Under this proposal, such de-identified biospecimens would be considered human subjects, hence the consent requirements would apply. The proposed rule does allow, however, that the consent requirement could be met by means of "broad" consent (i.e., consent to future unspecified research) obtained at the time of biospecimen collection.

It is worth noting that, in the rationale for this change, the emphasis is placed on autonomy—specifically, people's interests in what happens to their biological materials—rather than on any increase in privacy risks associated with de-identified biospecimens. It is also notable that the NPRM proposes changes to the requirements for waivers of informed consent, making it extremely rare that research with biospecimens would be granted a waiver.

A third revision designed to deliver stronger and better protections is the proposal to extend the

Common Rule to cover all clinical trials conducted at an institution receiving *any* federal funding for research, regardless of the funding source of any specific clinical trial. The purpose of this "clinical trial extension" is to ensure that all clinical trials—the type of studies likeliest to pose significant risks—are covered by human subject protection measures. Clinical trials already subject to U.S. Food and Drug Administration (FDA) oversight but not the Common Rule would not be affected by this change.

Changes Designed to Increase Efficiency and Decrease Burden

The NPRM proposes the creation of a new category of "excluded" activities that are entirely outside the scope of the regulations. The NPRM identifies 11 specific exclusions, in three general categories:

1. activities deemed not to be research (e.g., oral history, journalism, and biography; public health surveillance; operational monitoring and program improvement);
2. activities considered to be "low-risk" where protections similar to those usually required by IRB review are independently mandated (e.g., collection or study of information gathered for nonresearch purposes when the sources are publicly available; data collection and analysis of private health information already subject to the Health Insurance Portability and Accountability Act); and
3. low-risk activities that do not "meaningfully diminish subject autonomy" (e.g., secondary research use of de-identified biospecimens that is designed only to generate information about an individual that is already known).

The stated rationale for creating the first exclusion category is ongoing confusion about whether some common types of activities, including program improvement activities and oral history, fit the regulatory definition of research. Importantly, that definition is not changing, nor do the six specific exclusions in this category eliminate the need to make determinations about whether some other types of activities are or are not research.

The NPRM also expands the categories of exempt research to include four new exemptions. Unlike excluded research, exempt research, as in the current rule, would be required to comply with some of the provisions of the rule.

The NPRM proposes eight exemptions, and divides them into three categories according to the level of risk involved and thus the level of protections called for:

1. low-risk interventions that do not require application of privacy safeguards to protect information and biospecimens;
2. research that may involve sensitive information and thus requires application of such privacy safeguards; and
3. secondary research involving biospecimens and identifiable private information that requires application of privacy safeguards, broad consent, and limited IRB review.

The NPRM proposes two new procedures relevant to exempt research that are specifically designed to eliminate the need for IRB review, but without providing details about either. The first is an exemption determination tool, to be created by the federal agencies at a later date, which would allow investigators or others familiar with a study to enter accurate information about the study and receive a determination of whether it is exempt, thus eliminating the need for administrative or IRB review.

The second, mentioned above, is a set of to-be-created privacy safeguards that, when in place at an institution, would eliminate the need for IRB review of research that collects or otherwise involves sensitive or private information or biospecimens. Implied here is the idea that IRB review may not be the best mechanism for ensuring data security and participant privacy.

In addition, the NPRM proposes to eliminate the continuing review requirement for most minimal-risk research, and for studies that have reached the stage of analyzing data.

The final change I'll highlight concerns cooperative (multisite) research. The NPRM proposes that, in the United States, if institutions are working together on research, then those institutions must rely on a single IRB for their research review.

To support this mandate, the NPRM proposes a change in the jurisdiction of the Common Rule. Currently, it is only institutions "engaged" in research that are held responsible for complying with the regulations, even when research review is conducted by an external IRB. The proposed rule would hold external IRBs directly accountable for compliance with the regulations; this change is designed to remove one of the barriers institutions have cited in using external IRBs for research review.

What Happens Next?

It is important to remember that the NPRM is just a proposal. It is possible that a final rule will not include all of the provisions outlined here. It would thus be premature for IRBs, researcher teams, or institutions to start implementing any of these provisions, or to make changes with respect to how

We don't know when a final rule will be published, although there is some indication that the federal agencies would like to see a final rule in place before the end of the Obama administration.

they conduct and review human subjects research in light of these proposals.

The NPRM is the second stage in the federal rulemaking process for proposed revisions to the Common Rule. You may remember that in July 2011, an Advance Notice of Proposed Rulemaking was published, followed by a 90-day public comment period. HHS received more than 1,000 comments, which were taken into consideration in the formulation of the NPRM.

Another 90-day public comment period began the day the NPRM was officially published, and ends December 7, 2015. Comments received will be taken into account in the preparation of the final rule.

We don't know when a final rule will be published, although there is some indication that the federal agencies would like to see a final rule in place before the end of the Obama administration.

For most of the provisions, the effective date would be one year from publication of the final rule, though for the provisions concerning consent for storage and secondary use of biospecimens and use of a single IRB for cooperative research, institutions would have three years before they have to be in compliance with the new rules.

It is worth noting that the FDA is not one of the federal agencies included in the NPRM, just as the agency is not a signatory to the Common Rule. Instead, FDA has its own human subject protection regulations at 21 CFR parts 50 and 56 in the *Code of Federal Regulations*. The FDA will undertake a separate rulemaking process after the publication of a final revised Common Rule, and, in an effort at harmonization, will propose changes to its rules that reflect the new Common Rule to the extent possible.

Conclusion

It is unquestionably an exciting time for all of us involved in the human subjects research enterprise, albeit an uncertain one. We know significant changes are coming, we just don't know how long we will have to wait, or just what is in store. There is still time to provide your input on the proposed changes and potentially have an impact on the final rule. I strongly encourage you to do so.

Elisa A. Hurley, PhD, has served since 2014 as executive director of Public Responsibility in Medicine and Research (PRIM&R), an organization dedicated to creating a strong and vibrant community of ethics-minded research administration and oversight personnel, and providing educational and professional development opportunities to that community. She had earlier served as PRIM&R's education director and as an assistant professor of philosophy at the University of Western Ontario.

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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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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-2015-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 11147-2015-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.

Five Smart Strategies to Develop Your Clinical Research Career

PEER REVIEWED | Patricia Kasper, MS, CCRA

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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: *Consultant with P. Kasper & Associates, LLC*

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

PEER REVIEWED | Charlotte S. Hurst, PhD, RN, CNM
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LEARNING OBJECTIVE
After reading this article, participants should be able to identify strategies for developing a successful hands-on clinical learning opportunities for BSN students studying to become clinical research associates.

DISCLOSURES
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Nothing to disclose
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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]

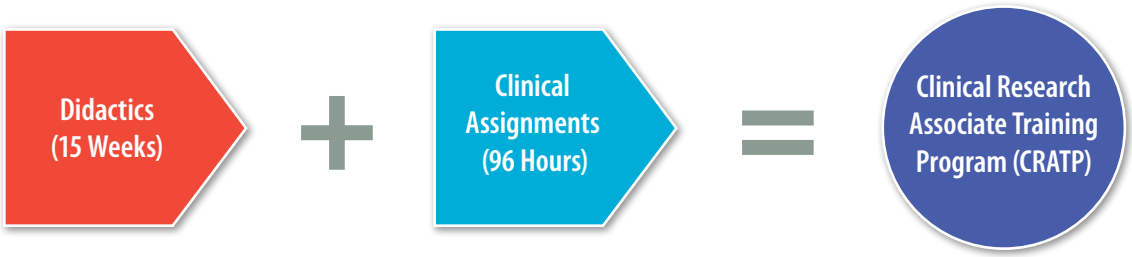
In 2010, as a recipient of the National Institute on Minority Health and Health Disparities grant award, the School of Nursing at Dillard University in New Orleans, La., established the Minority Health and Health Disparities Research Center (MHHDRC) to address low participation in clinical trials and 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

FIGURE 1: Schematic of the Clinical Research Associate Training Program Model



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

- 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 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.

Researchers suggest that practical training under the supervision of trained preceptors help learners close the gaps between didactic skills and applied skills by increasing learner exposure to real-life settings.

- **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.

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 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 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.

Acknowledgments

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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

[DOI: 10.14524/CR-15-0035]

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.

LEARNING OBJECTIVE
After reading this article, learners should be able to explain the professionalization 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 defining 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

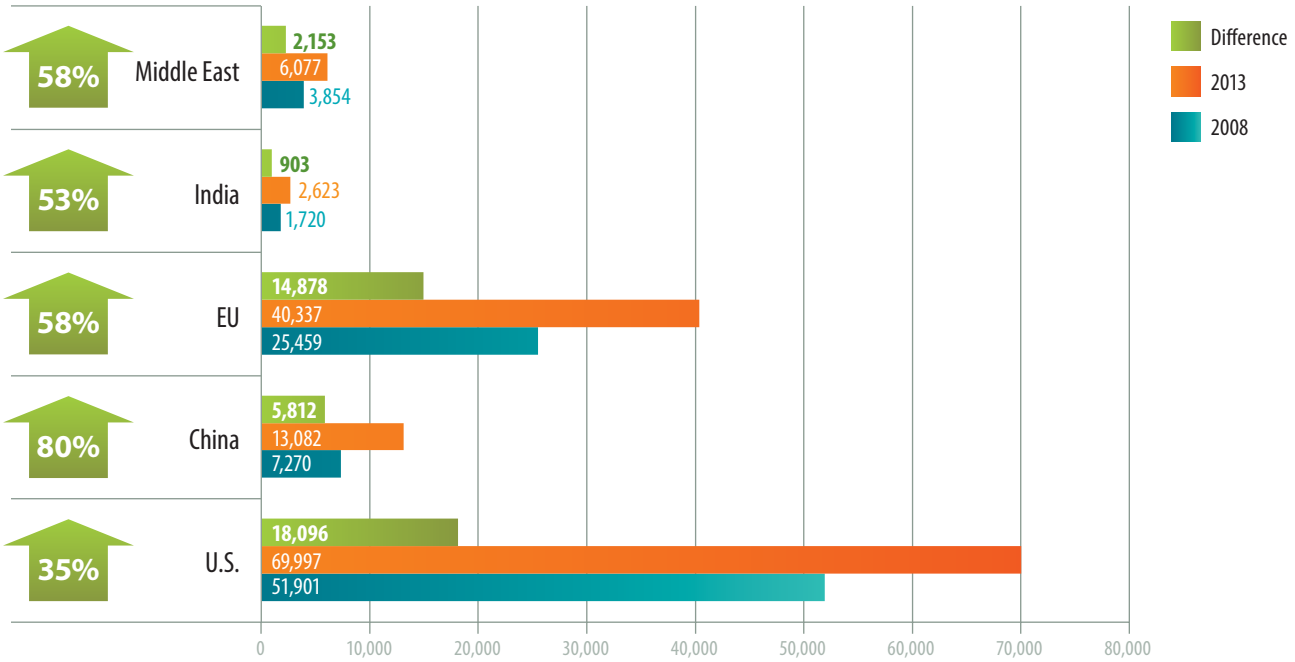
The CRC (also referred to as clinical trial administrator, clinical trial nurse, and other terms) role is not described or defined in regulations or in the Good Clinical Practice (GCP) E6 guideline of the International Conference on Harmonization. Nevertheless, the CRC role merits attention due to its 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 negotiation, 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

"The CRC is the heart and soul of the research study. . . and ultimately, it is the CRC who carries forward the research goals, thereby playing a significant role in the success of the research study."[3]

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



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]

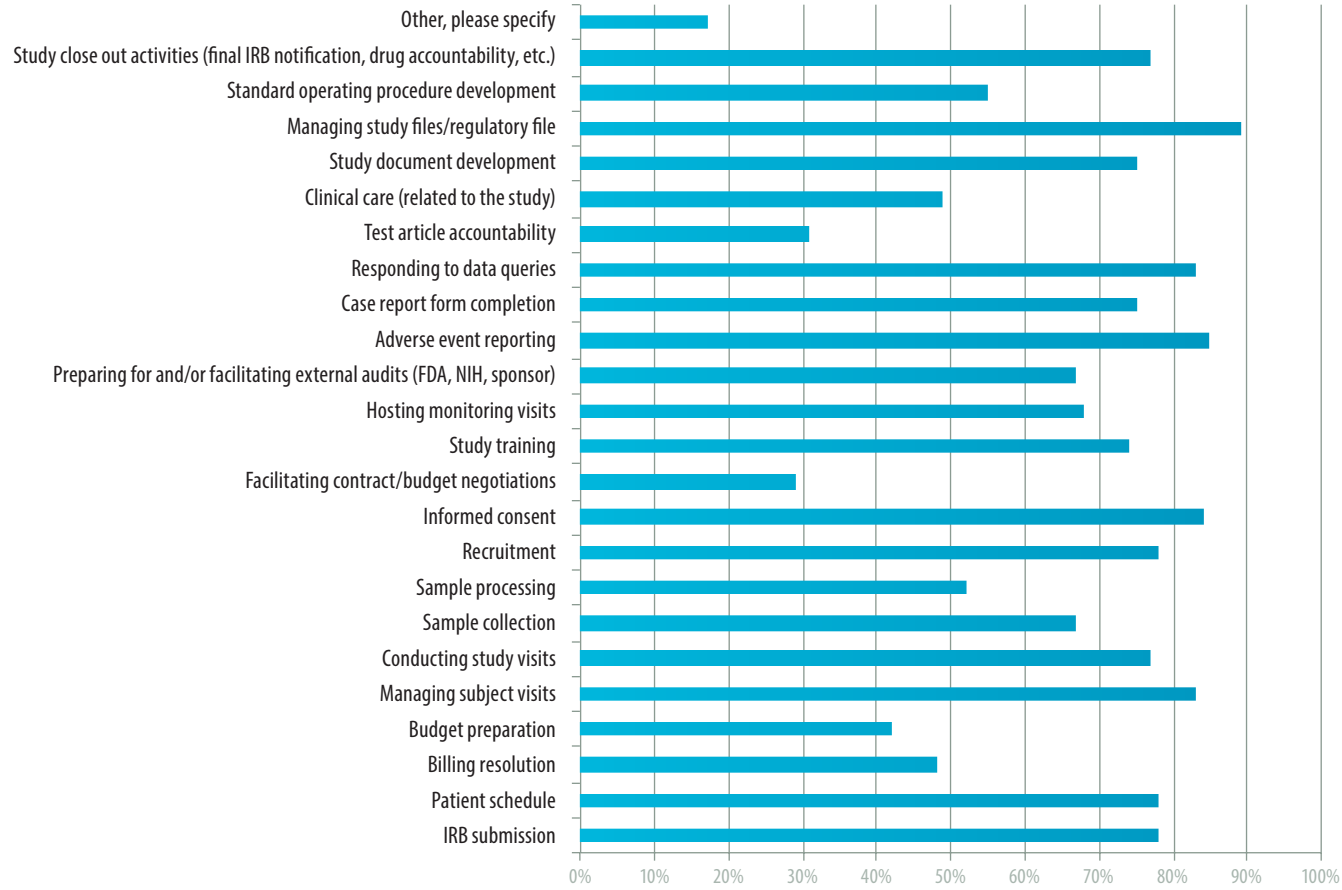
The new European Union (EU) regulation (applicable as of April 2016) will require a description of the qualification of the investigators and requires supporting documentation, such as curriculum vitae. Any previous training in the principles of GCP or experience obtained from work with clinical trials 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

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 accountabilities 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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HOME STUDY HS

Careers in Clinical Research

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

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

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 include:**

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

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

The R&D Behind Your Elevator Pitch

A few mere seconds of conversation

Talking with people who could be good connections to future positions or projects will never go out of fashion. Opportunities to engage in conversation that quickly sums up what you have to offer are becoming more frequent. No longer consigned to just the elevator, the "elevator pitch" is now the staple of networking meetings and professional conferences that bring industry professionals together. And in our ever more connected online world, the well-crafted "self" sales pitch is morphing into a form that fits today's communication channels.

A successful pitch encapsulates four phases:

PHASE I: It's memorable and establishes a common connection

PHASE II: It shows your relevance to your audience

PHASE III: It communicates your skills

PHASE IV: It engages your audience

MAKE IT MEMORABLE & ESTABLISH A COMMON CONNECTION

By making your pitch memorable, you'll achieve the first step in successfully communicating who you are and what you have to professionally offer. Take a moment to imagine the pitch scenario from the point of view of a hiring manager at the end of a long day at a job fair. What are the chances that your pitch will be successful if it's not memorable? Memorability greatly increases the chances of your pitch having the desired outcome.

It's equally important to avoid the mistake of launching into a sales pitch before an audience that's neither interested nor invested in what you're saying. If you're attending an event or conference, do your homework and make a plan of attack. Find out which professionals are participating in a panel, speaking at the event or are just likely to be there, and identify to whom you'll likely seek out and pitch.

> Your best pitch should always leave your audience with the memory of a wonderful conversation with an interesting professional.

Find a common connection to use as an icebreaker. Think about education, career and personal interest paths that share a similar direction, or mutual acquaintances.

SHOW YOUR RELEVANCE TO YOUR AUDIENCE

Your next task is to find out how you as a professional are relevant to the person you'll be meeting. Determine what you have to offer that could benefit this person. For example, is he or she about to head a research project that builds on something you've worked on? Then that's your hook; your opportunity to get beyond the niceties and suddenly become of interest.

COMMUNICATE YOUR SKILLS

Communicate your skills concisely, but clearly, so your audience recognizes you as a valuable asset. Your skills are more than what you do; they're how you solve problems that are relevant to the person you're talking to. Give examples that highlight how your skills helped you address specific challenges, but also interest your audience because they need somebody with your abilities on their team.

ENGAGE YOUR AUDIENCE

The natural ability to hold someone's attention is a gift shared by all the best live performers. Think of your favorite stand-up comics, and you've most likely felt at one time or another that each was telling you a joke in confidence. Great performers can make you forget there's anyone else in the room. Just like them, to be successful, you must use your skills of observation to deliver your pitch in a style that engages your listener. My best advice to engage your audience is to 1.) ask questions, 2.) build on your audience's responses, and 3.) maintain eye-to-eye contact.

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Are you a QUALIFIED Clinical Research Professional?

The term qualified is the guiding standard for the clinical research professional's (CRP) work assignment.[1] Webster's dictionary defines "qualified" as "being 'competent' to perform the assigned work, duty, function or task." Given our healthcare industry roots, competency-based training for the CRP is based on the model used to train healthcare professionals (e.g., doctors, nurses).

A competency-based training approach includes:

- Employee training procedures
- Robust job descriptions (experience, knowledge, skills, abilities)
- Identification of job duties, functions, topics for On-the-Job Training (OJT)
- Comprehensive training plans (includes on-the-job training[2])
- Selection of trainers per defined requirements (competencies, work performance review)
- Maintenance of employee training files
- Strategic training program design:
  - »Definition of learning outcomes
  - »Training platform considerations that are in alignment with the learning outcomes
  - »Identification of 'what's next' after training completion (e.g., OJT)

Successful implementation of competency-based training programs includes the design and delivery of training using an appropriate training platform that supports employee engagement and optimal performance.

Virtual Classrooms: Virtual classrooms are internet based, interactive, online learning environments that embody the same attributes as instructor-led classes. Live engagement between the trainer and learners (presentations, information sharing [whiteboard], discussion and Q&A, access to learning resources and group collaboration) promotes learner collaboration on course activities in groups via a designated online 'room'. This approach also allows the trainer to work with each group in their 'room' to answer questions and to support and facilitate learning. Assessment mechanisms can include knowledge checks and more robust exams. Virtual classrooms provide the platform for the trainer and globally located participants to collaborate and interact just as they would in an instructor-led class.

Core Competency Training Development and Design Considerations

Live Classrooms: Live instructor-led classroom training brings the trainer and learners into the same room, in the same location. This allows for active, intimate engagement and interaction between the trainer and learners. The trainer delivers the course, and includes discussion and Q & A time with the learners. Further, learners work in groups on course activities/exercises. Assessments can be delivered in a variety of ways including knowledge checks, robust exams and/or demonstration of learning through interactive exercises.

Web Seminars: Web Seminars are interactive, live training presentations in which the trainer and learner connect via the internet. Webinars include: live training presentations, discussion and Q & A with the trainer and learners, knowledge checks, as well as communication features via the "chat" tool and breakout groups.

Self-paced eLearning: eLearning is an internet-based, self-paced, online learning activity that delivers training to the learner but does not include live trainer interaction (discussion, Q&A, etc.). eLearning content and technology use varies, particularly as it relates to interactivity with the learner. For example, slides with audio narration do not allow learner engagement with the course materials, however, the use of eLearning software, engages the learner with exercises, activities, knowledge checks and quizzes.

Barnett International's consulting, education and training services provide thought leadership and the expertise required to achieve your training goals while utilizing all of these training platforms, resulting in the initial and on-going development of a 'qualified' work force.

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BARNETT INTERNATIONAL
Leaders in Clinical Research Training

Martin Robinson, PhD

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How to Create a Training Plan

One of the key roles of a manager is to ensure that his or her team members are competent in their respective job roles in order to achieve their goals, and to ultimately support the organization's objectives.

By demonstrating a link between the achievement of business objectives and the establishment of a learning and development plan, managers are much more likely to get the support they need to implement their strategy.

One of the ways that a manager can maintain the competence of the team is to ensure that a learning and development plan is in place, both for individuals and for the team as a whole. The plan should be linked to the team's objectives, which in turn should be in line with the organization's business needs and goals. If this is not the case, the whole exercise will be irrelevant, and time and money will be wasted on training that is ineffective and unwanted.

Link Training to Business Goals

The process should start with the manager reviewing the organization's business objectives for the forthcoming year. The team objectives should feed into these overarching goals. If the organization's business objectives are not available, then team objectives should be set as a matter of course.

By demonstrating a link between the achievement of business objectives and the establishment of a learning and development plan, managers are much more likely to get the support they need to implement their strategy.

Factors that managers need to consider include:

- whether the organization may be planning to restructure and reorganize
- any obvious gaps in team performance
- analysis of any issues of noncompliance and subsequent corrective and preventive actions (CAPAs)
- changes in the team structure
- new additions to the team
- any forthcoming changes in regulations or working practices (e.g., standard operating procedures)

The organization may be planning to recruit significant numbers of new staff during the forthcoming year. Managers need to decide what impact this will have when devising a learning and development plan. The integration of new staff will make demands on the time of the staff already in place.

Use Information from Multiple Sources Without Over-Analyzing

There is a wide variety of methods for collecting information for a learning needs analysis. The secret is to get the key data quickly and yet accurately, so that a sound basis is formed on which to analyze the results and make recommendations for implementation of the learning plan.

Using simple questionnaires is a good way of getting lots of information relatively quickly. The drawback is that it may lack the accuracy of other methods. Ideally, it should take each person no longer than about 10 minutes to complete the questionnaire. Questions should be used to uncover what training the staff feel they need to increase their confidence and do their jobs competently.

Interviewing a cross section of staff will get more in-depth information and the chance to probe more deeply into key areas. This is more time consuming, but people often enjoy being asked their opinions, so there is a greater chance of a high level of participation.

Sometimes interviewing people in small focus groups is very useful. This can give the overall perception of a team, and has the advantage of gathering the opinions of several people at once.

Get Commitment from Key Stakeholders

Trying to identify the learning needs of an organization without input and commitment from the key stakeholders will seriously weaken the project.

Martin Robinson, PhD

Trying to identify the learning needs of an organization without input and commitment from the key stakeholders will seriously weaken the project.

Martin Robinson, PhD, (mrobinson@iaocr.com) is principal director of IAOCR.

The first stage is to identify who the key stakeholders are; one obvious group is the senior management of an organization. These are the people who will need to make a commitment to the learning and development plan, in terms of resources time and budget. Other stakeholders could include clients, business partners, and suppliers.

Interviewing a cross section of the key stakeholders will provide insights on their perceptions. Agreement from the stakeholders should be sought about their desired outcomes. It is important to make sure they are realistic, and that they cover issues that learning and development can influence.

Further, it is extremely useful to identify a "sponsor" from the senior management team. This is the person who frequently holds or allocates the budget for training. The other aspect of this person's role is to act as an internal champion for the learning and development strategy.

Eventually, agreement should be reached with the senior management team about how the analysis is going to be conducted. At this stage, a budget may have been agreed upon, including resources and timelines for the delivery of the training program. This will set the limits on what learning methods can be used, such as self-directed e-learning, coaching, face-to face training, webinars, etc.

In other situations, the budget, resources, and timelines may be drawn up once the analysis has been conducted and the size and scope of the required program have become more apparent.

The objective is to deliver a cost-effective solution that will deliver a return on investment and add value to the team, and ultimately to the organization. In the next appearance of this column, we will be looking at how to determine return on investment for training.

Leadership Practices of Clinical Trials Office Leaders in Academic Medical Centers

PEER REVIEWED | Diana D. Naser, PhD, APRN, MSN, MS, CCRP

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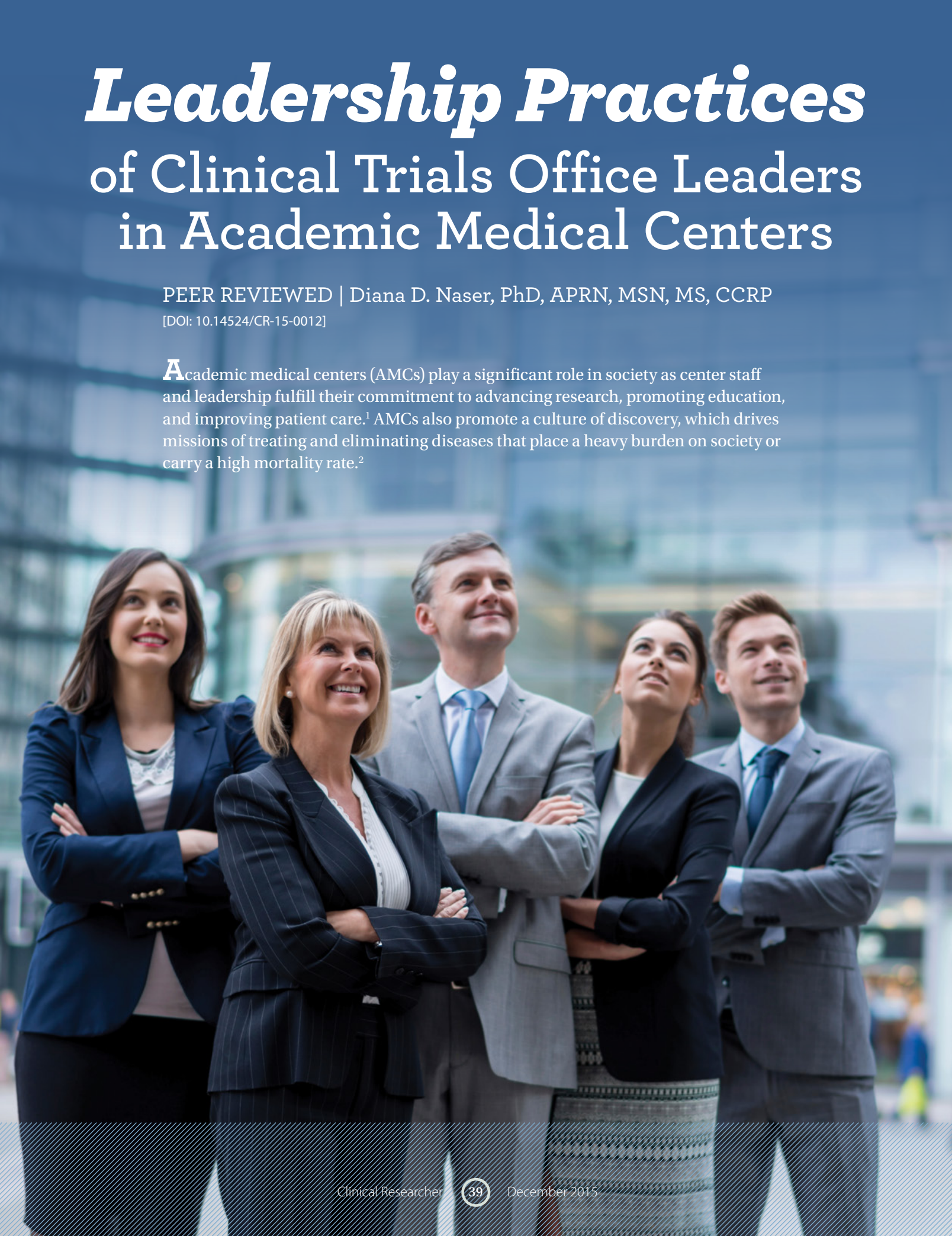
Academic medical centers (AMCs) play a significant role in society as center staff and leadership fulfill their commitment to advancing research, promoting education, and improving patient care.[1] AMCs also promote a culture of discovery, which drives missions of treating and eliminating diseases that place a heavy burden on society or carry a high mortality rate.[2]



The leadership practices exhibited by clinical trials office leaders at an AMC have the potential to favorably affect the center's image and organizational commitment to the overall research mission of the institution.

The leadership practices exhibited by clinical trials office leaders at an AMC have the potential to favorably affect the center's image and organizational commitment to the overall research mission of the institution;[3] however, it is not exactly clear what best practices are exhibited by these leaders, and this represents a gap in knowledge. When this study was conducted, there was no evidence that the leadership practices of clinical trials office leaders had formally been evaluated across AMCs.

NATURE AND PURPOSE OF THE STUDY

The purpose of this study was to determine the leadership practices of clinical trials office leaders in AMCs. The Leadership Practices Inventory Self instrument (LPI-Self)[4] served as the tool of choice for this quantitative study, and was used by permission of the developers of the instrument.

The study was approved by the institutional review board of Capella University. The target population for this study was clinical trials office leaders at AMCs in the U.S. whose titles included director, associate director, assistant director, administrative director, medical director, or manager.

RESEARCH QUESTION

The main research question for this study was: To what extent do clinical trials office leaders at AMCs exhibit the five leadership practices identified by Posner and Kouzes?[5]

INSTRUMENTATION

The LPI-Self instrument contains 30 statements related to the five leadership practices:

- Challenging the Process
- Inspiring a Shared Vision
- Enabling Others to Act
- Modeling the Way
- Encouraging the Heart

The practices are rated using a 10-point Likert scale, and each is represented by six statements. A score reflecting the degree to which an individual exhibits the particular leadership practice is assigned to each of the five practices. The lowest per-practice score is 6 and the highest score is 60.[6]

In 2000, Kouzes and Posner established internal reliability for the LPI-Self instrument to range from .80 to .87.[7] This instrument has been used in other contexts/industries, but had not been previously been used in clinical research. This was confirmed in a discussion with one of the developers, who indicated that he would like to see the instrument used in as many different industries as possible. Therefore, the instrument was deemed appropriately transferable to clinical research.

DATA COLLECTION AND ANALYSIS

AMCs were identified by reviewing the membership list available on the Association of Academic Health Centers (AAHC) website.[8] A search was then conducted on the websites of these AMCs to identify their clinical trials office leaders. The websites of National Cancer Institute (NCI)-designated cancer centers and institutions designated part of the Clinical and Translational Science Awards (CTSA) program of the National Institutes of Health were also visited.

Additional sources of study participants were those individuals listed in public membership directories and webpages of all known AMCs not listed in the membership directory of the AAHC. Some larger institutions had more than one clinical trials office and multiple clinical trials office leaders.

A cover letter with the LPI-Self instrument was sent to 237 clinical trials office leaders at various AMCs across the U.S. AMCs were targeted, as this

TABLE 1: Clinical Trials Office Leaders' Overall LPI Scores

Modeling the Way	Inspiring a Shared Vision	Challenging the Process	Enabling Others to Act	Encouraging the Heart
48.32	44.64	45.92	51.95	47.81

(The lowest possible score is 6 and the highest possible score is 60.[6])

had been the researcher's primary affiliation. Data collected from the AMCs clinical trials office leaders were kept anonymous and analyzed using SPSS software.

RESULTS OF STUDY

A total of 98 clinical trials office leaders completed the LPI-Self survey tool, for a participation rate of 41.3%. Among the respondents, 58% had a cancer research focus while 42% had a noncancer focus; 24% were physicians and 74% were nonphysicians. In terms of AMC designation, 17% of the responding leaders were from CTSA centers, 12% were from NCI-designated centers, 50% were from centers that had both CTSA and NCI designation, and 20% were from centers that had neither CTSA nor NCI center designation.

As touched on earlier, within the LPI-Self instrument, each leadership practice category is represented by six statements, with each statement rated by respondents using a 10-point Likert scale. Respondents were asked to indicate the relative frequency with which they exhibit various leadership behaviors or characteristics reflected in the statements. The Likert scale scores are defined in the LPI-Self as follows[4]:

1 = almost never
2 = rarely
3 = seldom
4 = once in a while
5 = occasionally
6 = sometimes
7 = fairly often
8 = usually
9 = very frequently
10 = almost always

Table 1 provides information about the extent to which clinical trials office leaders exhibit the five leadership practices identified by Posner and Kouzes. Of note, the leadership practice "Enabling Others to Act" yielded the highest mean score (51.95) of the five leadership practices, while the leadership practice of "Inspiring a Shared Vision" had the lowest mean score (44.64).

The mean and minimum/maximum scores for each question are presented in Tables 2 through 6.

TABLE 2: "Modeling the Way" Leadership Practice

Statement	Mean	Minimum	Maximum
I follow through on the promises and commitments that I make.	9.12	7	10
I set a personal example of what I expect of others.	8.98	6	10
I build consensus around a common set of values for running our organization.	8.11	5	10
I am clear about my philosophy of leadership.	8.02	2	10
I spend time and energy making certain that people I work with adhere to the principles and standards we have agreed on.	7.69	3	10
I ask for feedback on how my actions affect other people's performance.	6.39	1	10

These findings indicate that clinical trials office leaders, on average:

- very frequently follow through on promises and commitments made, and set a personal example of what they expect from others.
- usually build a consensus around a common set of values for running their organization, and are usually clear about their philosophy of leadership.
- fairly often/usually spend time and energy making certain that people they work with adhere to the principles and standards agreed upon.
- sometimes ask for feedback about how their actions affect other people's performances.

TABLE 3: "Inspiring a Shared Vision" Leadership Practice

Statement	Mean	Minimum	Maximum
I speak with genuine conviction about the higher meaning and purpose of our work.	8.61	4	10
I paint the "big picture" of what we aspire to accomplish.	8.04	3	10
I talk about future trends that will influence how our work gets done.	7.78	3	10
I appeal to others to share an exciting dream of the future.	6.84	2	10
I describe a compelling image of what our future could be like.	6.78	2	10
I show others how their long-term interests can be realized by enlisting in a common vision.	6.54	1	9

These findings indicate that clinical trials office leaders, on average:

- very frequently/usually speak with genuine conviction about the higher meaning and purpose of their work.
- usually paint the "big picture" of what they aspire to accomplish.
- fairly often/usually talk about future trends that will influence how work is done.
- sometimes/fairly often appeal to others to share and exciting dream of the future, describe a compelling image of what the future could look like, and show others how their long-term interests can be realized by enlisting in a common vision.

TABLE 4: "Challenging the Process" Leadership Practice

Statement	Mean	Minimum	Maximum
I ask "What can we learn?" when things don't go as expected.	8.24	5	10
I make certain that we set achievable goals, make concrete plans, and establish measurable milestones for the projects and programs that we work on.	7.85	2	10
I seek out challenging opportunities that test my own skills and abilities.	7.69	3	10
I challenge people to try out new and innovative ways to do their work.	7.53	2	10
I search outside the formal boundaries of my organization for innovative ways to improve what we do.	7.48	3	10
I experiment and take risks, even when there is a chance of failure.	7.11	3	10

These findings indicate that clinical trials office leaders, on average:

- usually ask what they can learn when things don't go as expected.
- fairly often/usually make certain they set achievable goals with measurable milestones for projects and programs they work on, seek challenging opportunities to test their own skills and abilities, and challenge people to try out new and innovative ways to do their work.
- sometimes search outside the formal boundaries of the organization for innovative ways to improve what they do, and sometimes experiment and take risks even when there is a risk of failure.

The leadership practice "Enabling Others to Act" yielded the highest mean score (51.95) of the five leadership practices, while the leadership practice of "Inspiring a Shared Vision" had the lowest mean score (44.64).

TABLE 5: "Enabling Others to Act" Leadership Practice

Statement	Mean	Minimum	Maximum
I treat others with dignity and respect.	9.49	8	10
I develop cooperative relationships among the people I work with.	8.99	7	10
I actively listen to diverse points of view.	8.49	6	10
I support the decisions that people make on their own.	8.44	5	10
I give people a great deal of freedom and choice in deciding how to do their work.	8.39	4	10
I ensure that people grow in their jobs by learning new skills and developing themselves.	8.15	4	10

These findings indicate that clinical trials office leaders, on average:

- very frequently treat others with dignity and respect, and develop cooperative relationships with people they work with.
- usually/very frequently actively listen to diverse points of view, support the decisions people make on their own, give people a great deal of freedom and choice to decide how to do their work, and ensure people grow in their jobs.

TABLE 6: "Encouraging the Heart" Leadership Practice

Statement	Mean	Minimum	Maximum
I praise people for a job well done.	8.42	4	10
I give the members of the team lots of appreciation and support for their contributions.	8.28	5	10
I publicly recognize people who exemplify commitment to shared values.	8.13	3	10
I make it a point to let people know about my confidence in their abilities.	8.07	4	10
I make sure that people are creatively rewarded for their contributions to the success of our projects.	7.47	2	10
I find ways to celebrate accomplishments.	7.44	2	10

These findings indicate that clinical trials office leaders, on average:

- usually praise people for a job well done, give members of the team lots of appreciation and support, publicly recognize people who exemplify commitment to shared values, and make it a point to let people know that their leader has confidence in their abilities.
- fairly often make sure people are creatively rewarded for their contributions to the success of the projects, and find ways to celebrate accomplishments.

CONCLUSION

In the ever-changing clinical research environment, AMCs seek leaders who are visionary and innovative. Clinical trials office leaders have the ability to positively promote the clinical research mission of AMCs, thus it was the intent of this research to build the foundation for a knowledge base about the leadership practices of these leaders.

For the "Modeling the Way" leadership practice category, the results indicated that clinical trials office leaders very frequently follow through on promises and commitments made, as well as set a personal example of what they expect from others. In the "Inspiring a Shared Vision" category, results show that these leaders very frequently/usually speak with genuine conviction about the higher meaning and purpose of their work. For the "Challenging the Process" practice, we see that the leaders usually ask what they can learn when things do not go as expected. In the "Encouraging the Hearts" category, leaders were found to usually praise people for a job well done, give members of the team lots of appreciation and support, publicly recognize people who exemplify commitment to shared values, and make it a point to let people know that their leader has confidence in their abilities. Finally, in terms of "Enabling Others to Act," the results revealed that these leaders very frequently treat others with dignity and respect, and develop cooperative relationships with people with whom they work.

Clinical trials office leaders at AMCs may find these results of this study useful for personal development and for identifying areas for improvement in their style of leadership practices. AMCs were targeted for this study, but areas for future research could involve using LPI instruments to assess leadership practices at contract research organizations and the pharmaceutical/medical device industry, which may reflect different organizational cultures.

In addition, the LPI-Other instrument could be administered to clinical trials office staff to learn more about how they perceive the leadership practices of their clinical trials office leaders. Additional research results are available to reflect LPI-Self results based on type of clinical trials office at the academic center (with or without a specific focus on cancer research), type of clinical trials office leader (physician vs. nonphysician), and type of research center designation (CTSA center, NCI-designated center, both CTSA and NCI center, neither CTSA nor NCI center) and will be submitted to this journal for future publication.

The author wishes to express her gratitude to all the clinical trials leaders who participated in this study, which is believed to be the first use of the LPI-Self instrument for clinical research leaders at AMCs.

For the "Challenging the Process" practice, we see that the leaders usually ask what they can learn when things do not go as expected.

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Business Association Agreements— *Essential Contract Terms*

A covered entity must have a written agreement with a business associate to share protected health information (PHI). A business associate agreement is not required for a covered entity to disclose PHI to a researcher, provided that the covered entity obtains documentation that the research has been approved by an institutional review board or privacy board.[1] However, clinical research professionals are frequently consulted to assist in healthcare operations activities that may require a business associate agreement—including data aggregation, accreditation, and quality assurance.

For a covered entity to disclose PHI to a business associate, it must obtain satisfactory assurances through a "written contract or other written agreement or arrangement with the business associate that meets the applicable requirements" in the *Code of Federal Regulations*.

The Health Insurance Portability and Accountability Act of 1996[2] (HIPAA) regulations defines a business associate as a person or entity that "creates, receives, maintains, or transmits [PHI]" on behalf of a covered entity.[3] The Office for Civil Rights with the U.S. Department of Health and Human Services (HHS) cautions that, "Covered entities may disclose [PHI] to an entity in its role as a business associate only to help the covered entity carry out its healthcare functions—not for the business associate's independent use or purposes."[4]

For a covered entity to disclose PHI to a business associate, it must obtain satisfactory assurances through a "written contract or other written agreement or arrangement with the business associate that meets the applicable requirements" of 45 CFR 164.504(e) in the *Code of Federal Regulations*. A business associated is allowed to further disclose PHI to another subcontracting business associate, provided that the business associate obtains assurances from the subcontractor, in accordance with 45 CFR 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information.[5]

The Office for Civil Rights with HHS publishes sample business association agreement provisions, and notes that, "a business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of [PHI] that are not authorized by its contract or required by law."[6]

Essential Contract Terms

The HIPAA regulations describe the essential contract terms for a business associate agreement **[emphasis added]** (see Table 1):

> A contract between the covered entity and a business associate must:
>
> (i) Establish the **permitted** and required **uses and disclosures** of [PHI] by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity…
>
> (ii) Provide that the business associate will:
>
> (A) **Not use or further disclose** the information other than as permitted or required by the contract or as required by law;
>
> (B) **Use appropriate safeguards** and comply, where applicable, with subpart C of this part with respect to electronic [PHI], to prevent use or disclosure of the information other than as provided for by its contract;
>
> (C) **Report** to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including **breaches of unsecured [PHI]** as required by § 164.410;
>
> (D) In accordance with § 164.502(e)(1)(ii), **ensure that any subcontractors** that create, receive, maintain, or transmit [PHI] on behalf of the business associate agree to the **same restrictions and conditions** that apply to the business associate with respect to such information;
>
> (E) Make available [PHI] in accordance with § 164.524 **[patient access to PHI];**
>
> (F) Make available [PHI] for amendment and incorporate any **amendments to [PHI]** in accordance with § 164.526;
>
> (G) Make available the information required to provide an **accounting of disclosures** in accordance with § 164.528;
>
> (H) To the extent the **business associate** is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation;
>
> (I) Make its internal practices, books, and records relating to the use and disclosure of [PHI] received from, or created or received by the business associate on behalf of, the covered entity **available to the Secretary** for purposes of determining the covered entity's compliance with this subpart; and
>
> (J) At termination of the contract, if feasible, **return or destroy all [PHI]** received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction

is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize **termination of the contract** by the covered entity, if the covered entity determines that the business associate has **violated a material term of the contract.**

Noncompliant Business Associates

A covered entity is not in compliance with the HIPAA provisions allowing disclosures to business associates "if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible."[7] This also extends to business associates who knew of a similar pattern of noncompliance of a subcontractor.

Sale of Protected Health Information

Without a HIPAA authorization,[8] a covered entity may not sell PHI where "the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the [PHI] in exchange for the [PHI]."[9] This does not include PHI disclosed for research (pursuant to 45 CFR 164.512(i) or 164.514(e)) "where the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the [PHI] for such purposes."[10]

Conclusion

There are three different flavors of written agreements between a covered entity and a recipient of PHI:

- **Clinical trial agreements** are typically used for drug and device trials and should describe any obligations of the covered entity related to PHI that may require assistance of the recipient(s) of research-related PHI (e.g., breach notification, accounting of disclosures, minimum necessary, restrictions and protections of PHI, etc.).
- **Business associate agreements** are typically utilized when a covered entity contracts with an external entity with the intent to share PHI (for a variety of reasons, including data assistance and quality).
- **Data use agreements** are utilized when a covered entity intends to share a limited data set with an external entity.[11]

TABLE 1: Essential Contract Terms of a Business Associate Agreement

Essential Contract Term	Citation
Permitted uses and disclosures	45 CFR 164.504(e)(2)(i)
Prohibited uses and disclosures	45 CFR 164.504(e)(2)(ii)(A)
Appropriate safeguards (including electronic)	45 CFR 164.504(e)(2)(ii)(B)
Reporting breaches and noncontracted uses or disclosures	45 CFR 164.504(e)(2)(ii)(C)
Subcontractor obligations	45 CFR 164.504(e)(2)(ii)(D)
Patient access to PHI	45 CFR 164.504(e)(2)(ii)(E)
Right to amend PHI	45 CFR 164.504(e)(2)(ii)(F)
Accounting of disclosures of PHI	45 CFR 164.504(e)(2)(ii)(G)
Extension of covered entities obligations to business associate	45 CFR 164.504(e)(2)(ii)(H)
HHS audit access	45 CFR 164.504(e)(2)(ii)(I)
Return or destroy PHI at termination of contract	45 CFR 164.504(e)(2)(ii)(J)
Termination of contract upon material violation	45 CFR 164.504(e)(2)(iii)

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2. *Pub. L.* No. 104-191, 110 Stat. 1936.
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4. Office for Civil Rights—U.S. Department of Health and Human Services, Business Associates (December 3, 2002, rev. April 3, 2003). www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/businessassociates.pdf
5. 45 CFR 164.502(e).
6. Office for Civil Rights, U.S. Department of Health and Human Services, Sample Business Associate Agreement Provisions. www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html
7. 45 CFR 164.504(e)(1)(ii).
8. 45 CFR 164.508(a)(4).
9. 45 CFR 164.502(a)(5)(ii).
10. 45 CFR 164.502(a)(5)(ii)(B)(2).
11. Ibata B. (2015) Research Compliance—Data Use Agreements and Limited Data Sets. *Clin Res* 29(1), 68-69.

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Penguins to People: *Lessons Learned in Transferring Skills Between Dissimilar Jobs*

PEER REVIEWED | Tammy Root, MS

[DOI: 10.14524/CR-15-0021]

It was my dream growing up to work with animals. When I was 16, I was fortunate to be hired as a zookeeper. It was a lifelong goal for me to work in the zoo field and be able to teach visitors of all ages about animals from around the world.

To reach my goal, I pursued an undergraduate degree in wildlife science at Purdue University. Later, having worked for several years with every class of animal and in middle management, I became the principal investigator for what was known at the zoo as Project Penguin (more about this later).

As I took on my new role, I sharpened my management skills by earning a master of science in management at Indiana Tech. Moving up the career ladder, I finally felt as though as I was nearing the top when I became an administrator.

Unfortunately, in an administrative role, I found I was no longer working with animals as directly as had earlier been the case. Eventually, as my hunger for research grew, I felt it might be time for a change.

After 23 years in the zoo field, I made the move from conducting research with penguins to concentrating on studies with people. Changing careers by transitioning from animal research to clinical research was somewhat difficult for me; however, I learned that the fundamental methodologies and techniques are the same in any type of research.

Transferable Skills

One of the biggest strengths I had to build upon during the transition came from transferable skills, as described in the sections ahead.

With my research in animals, I had been a principal investigator in rockhopper penguins (*Eudyptes crestatus*), which meant I wrote and executed protocols and protocol amendments for studies with these birds. Amendments were necessary due to changes in training techniques that had to be implemented in order to gather the kinds of information needed to answer the zoological field's research questions about rockhoppers.

Even though the research was carried out in animals, these research protocols were constructed in the same manner as found in clinical research protocols.

COMMUNICATION FOR RESEARCH QUESTIONS

Project Penguin began because the zoo had 10 to 15 rockhopper penguin eggs laid yearly, but only produced one or two chicks. At this rate, captive rockhopper penguin populations would soon be struggling.

Due to the trend we were seeing with our collection, we sent out very lengthy surveys to communicate with all of the institutions worldwide that exhibited these birds. By doing this, we could provide background on the captive species population and relay to management the importance of Project Penguin.

The survey questions focused on breeding successes and failures, diet, vitamin regimen, lighting, water chemistry, number of eggs each pair laid, number of eggs produced, and incubation methods.

After the data were reviewed, Project Penguin officially began and a mission statement was formed. It stated:

"Project Penguin aims to increase the reproduction of Rockhopper Penguins in captivity through behavioral, physiological, and reproductive research, and organize a nationwide reproduction research effort in order to develop a self-sustaining captive population."

Just as many clinical trials are multisite and conducted internationally, I had already been communicating with sites internationally to gather evidence in support for the need to conduct our study.

DATA COLLECTION

Another transferable skill I had was data collection. The penguin team looked at the sperm quality and quantity of our male population. The big question was how do you collect sperm on an animal that doesn't like to be handled as an adult?

This was a new challenge for me. I didn't know where to begin, since this had not been previously done in any zoo. I looked at semen collection techniques in poultry and practiced them on chickens at Purdue University. We used the same techniques for the rockhoppers and succeeded.

PROJECT MANAGEMENT

Just like in clinical research, animal research involves a great deal of project management skills; one aspect of this is meeting project timelines. "Screening" for Project Penguin studies took a few days to a few months, and "baseline" was the first day of collection.

Changing careers by transitioning from animal research to clinical research was somewhat difficult for me; however, I learned that the fundamental methodologies and techniques are the same in any type of research.

For the application process, I made sure my resume showed all of my research skills, my team orientation, and my willingness to learn new processes.

The rest of the schedule was set for which days to collect and which days to continue training and reinforce training. "End of study" differed for each bird. The guideline for our end of study was simple: If a bird didn't produce semen two weeks in a row, he was considered as having completed the study. Of note, penguins will stop producing sperm at different stages of the breeding season.

DOCUMENTATION AND MONITORING

In animal research, documentation and monitoring are key steps the same as in clinical research. Prior to a clinical research study, documentation is presented to the institutional review board to show site and staff qualifications. In animal research, documentation is presented to the project lead to ensure that each team member is qualified to participate.

Throughout the entire process, documentation or other evidence was gathered as to what each sample showed us; how the birds behaved each collection period; what eggs were produced; and incubation methods. Meanwhile, just like in clinical research, it is important to document any adverse events or unusual behaviors the birds may experience.

Finally, although animal research in a zoo community doesn't have a "monitor" to make sure our documentation is well organized and thorough, a team of curators will review the project periodically for completeness and before any publication of the results.

Marketing Myself and the Interview Process

In 2012, I pursued new job opportunities in research. At first, I only looked at animal research positions, but over time I also looked at clinical research positions. To be honest, I didn't think I had the skills to perform in a research coordinator role, but applied for some openings of this sort anyway.

For the application process, I made sure my resume showed all of my research skills, my team orientation, and my willingness to learn new processes. I also highlighted those skills in my cover letter by telling a story of how each skill helped me in zoo research.

When I was contacted for an interview, I was very excited, and following the meeting, I immediately sent an e-mail with a thank-you letter attached. When I was invited to a second interview, I went with more questions about the company, the expected job duties, and how I would be trained. The interview went well, and I was ultimately offered the position.

Challenges of Transitioning to Clinical Research

When I started in clinical research, I had no medical background; I had a biology and research background, with a special interest in animal behavior. While I had transferable research skills, it was an adjustment for me.

Although some of the research concepts were the same, the terminology was unique. For example, "consent" in Project Penguin meant getting consent from another zoo to allow its animals to participate in the study.

There were also techniques I needed to learn for clinical research. I had hands-on training for EKGs and blood draws (I already knew how to draw blood on animals, but not people). Another challenge was that the clinical research protocols often seemed fragmented—with similar information found in multiple places, such as the schedule of events and appendices. In animal research, the protocol is organized into sections with all relevant information included within sensible, respective areas.

These were a few of the areas I struggled with, but in time, I acquired new skills and developed a better understanding of clinical research workflows.

Animal Subjects vs. Human Subjects

The main difference between animal and clinical research comes in terms of educating the subject.

When training an animal, you can be creative in your methods. Sometimes, you will have to "capture a behavior" and then put that behavior on cue. Other times, you can take one simple behavior and "shape" it into something more difficult.

With clinical research, when you train a person to fill out an electronic diary or use an injector, they learn from the coordinator explaining or demonstrating the items to them.

Another difference is how frustrations are expressed within studies. When an animal doesn't understand what the trainer is trying to

do or doesn't like it, the animal normally uses the defense of biting. Penguins don't just bite—they like to pinch the skin of a human and twist it.

If a person is frustrated with the instruction or the protocol, he or she will vocalize this frustration to a study coordinator. Some patients may even refuse to come in for their next scheduled visit and contact the coordinator by phone or e-mail stating that they are done with the study.

People skills are definitely needed for study recruitment and retention in clinical trials.

Career Transition Success

When making a career change, one of the most important strategies for success is to look at your experience and skills and focus on how they can apply to the position of your dreams.

Clinical research can be a great second career for detail-oriented people with customer service skills. As you apply for a clinical research position, your resume must show off your key strengths and career highlights. You may want to describe how you turned a project that was failing into a success.

Research sites need staff members who are team players, who adapt to change easily, and who are eager to learning new skills and processes. Knowing your strengths and weaknesses will open up many doors. The key to all of this is to be persistent and keep an open mind.

I have never regretted my career change. True, there are days I miss the animals, but I feel that I've grown as a researcher in my new position.

In the animal world, we reference the acronym SPIDER. This stands for Setting goals, Planning, Implementing, Documenting, Evaluating, and Readjusting. This concept can be applied to the everyday life of any person.

My career in SPIDER would be:

S: become a zoo keeper

P: planned on a lifetime career in the zoo world

I: developed training and enrichment programs for optimum animal care in captivity

D: published my protocols and findings in animal keeper journals and a college textbook

E: felt I had moved up the zoo ladder as far as I wanted to and needed a career change

R: pursued a different avenue in the research field that called for acquisition of new skills and refinement of old ones

The concept is the same in both major phases of my career so far: "Research is research." Yourdictionary.com[1] defines research as a "careful and organized study or gathering of information about a specific topic." With any research project, you define the problem, implement the project, document your successes and failures, amend any changes, and calculate your results. It doesn't matter if you are working with penguins, elephants, rodents, or people.

I'm in the research field because I enjoy taking a problem at hand and participating in trying to solve the problem. While the transition wasn't easy, I largely credit transferable skills and an open mind for making the career change from research in penguins to people a success.

Transferable Skills and Experience: Going from Animal to Clinical Research

- Communication
- Data Collection
- Protocol Development
- Goal Setting
- Documentation
- Persistence
- Project Management

Reference

1. Yourdictionary.com. Accessed February 25, 2015.

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How to Enter the CLINICAL RESEARCH FIELD

PEER REVIEWED | Joy L. Frestedt, PhD, RAC, CPI, FRAPS | Anita Kablinger, MD, CPI | Paula Smailes, RN, MSN, CCRC, CCRP

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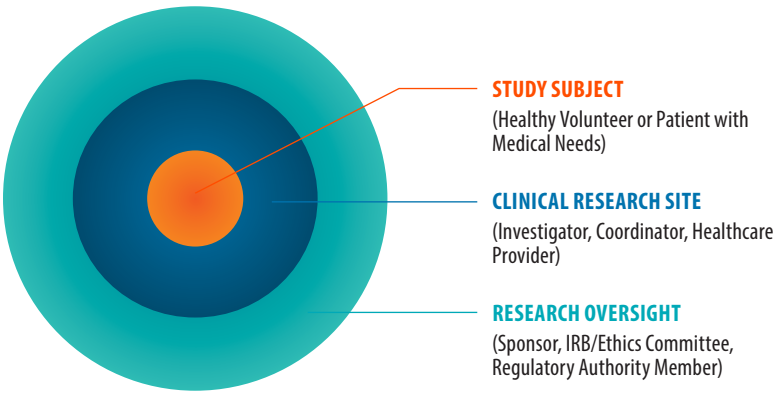
This article was written in response to the large numbers of people attending free "How to Enter the Clinical Research Field" webinars offered by the Association of Clinical Research Professionals (ACRP) in 2012[1] and more recently on September 5, 2014. The vast interest in this program caused potential audience members to be turned away due to the cap placed on enrollment.

FIGURE 1: Key Stakeholders in Clinical Research



The numbers and types of questions received from participants in these programs suggested many individuals would like to know more about the processes used to enter the clinical research field. This article was written to describe several processes to consider and to answer some of the common questions, including "What is the clinical research field?" and "How do I get my first job in this field?"

As discussed in the sections to come, one way to start getting answers might be to begin networking with the people involved with clinical research.

Who are the Stakeholders in the Clinical Research Landscape?

A "stakeholder" is a person or group "without whose support the organization would cease to exist."[2] The main stakeholders in clinical research are:

- sponsors of studies (e.g., drug, device, and food companies)
- regulatory authorities (e.g., the U.S. Food and Drug Administration [FDA], Health Canada)
- study sites (with site-based investigators, study staff members, study subjects, and members of ethics committees and institutional review boards [IRBs])

- professional organizations of researchers (ACRP, etc.)
- research advocacy groups (Center for Information and Study on Clinical Research Participation, the Research Advocacy Network, etc.)
- public health departments (National Institutes of Health, state departments of health, international ministries of health, etc.)
- vendors who contribute to the clinical research enterprise (e.g., contract research organizations [CROs], independent contractors, service providers, etc.) (see Figure 1).

For readers who are not familiar with the term, a CRO is an organization providing support for clinical research on a contract basis (e.g., a team of study monitors may work for a CRO and be assigned to monitor multiple studies, or a CRO may provide laboratory services or regulatory services, etc.).

TABLE 1: Typical Research Roles and Responsibilities at a Clinical Trial Site

Tasks	MD/DO PI	Non-MD PI	CRC	Other*
Feasibility assessment	x	x	x	x
Contract and budget	x	x		x
Protocol knowledge	x	x	x	x
IRB and regulatory filings	Delegate to others	Delegate to others	x	x
Recruiting/screening	Delegate to others	Delegate to others	x	x
Informed consent	x	x	x	As appropriate
Physical exam	x	As appropriate		
Medical care	x	Delegate to MD/DO		
Adverse event/serious adverse event/unexpected adverse event assessment	x	As appropriate	As appropriate	As appropriate
Administration of test article	x	As appropriate	As appropriate	As appropriate
Product accountability	Delegate to others	Delegate to others	x	x
Vital signs and assessments	x	x	x	x
Data collection and entry	Delegate to others	Delegate to others	x	As appropriate
Data review	x	x	x	As appropriate

**Research nurse, recruiter, research manager, research pharmacist, data entry specialist, statistician*

What Types of Positions Are Common in Clinical Research?

The Institute of Medicine defined cross-disciplinary clinical research to include "…a continuum of research spanning a wide range of activities…" and stated "Clinical investigation, …includes all studies intended to produce knowledge valuable to understanding the prevention, diagnosis, prognosis, treatment, or cure of human disease."[3]

To meet the needs of this varied clinical research industry, many positions exist, including the traditional roles of principal investigator (PI), clinical research coordinator (CRC), clinical research associate (CRA), medical monitors, regulatory specialists, and administrative professionals.

The PI is usually a medical doctor (MD) or doctor of osteopathy (DO), but may also be someone with a terminal degree such as a PhD or PharmD or others qualified by training and experience. The PI may delegate tasks, but not responsibility, to the other members of the team (see Table 1). The PI oversees the clinical trial at the site, and can provide medical care when the PI is an MD (see Figure 2).[4,5]

CRC responsibilities (see Figure 3) include ensuring the protocol is followed, recruiting subjects, conducting study visits, accounting for drugs and/or devices, documenting activities in source documents and case report forms, working with monitors, and attending investigator meetings. CRCs may be assigned to one or more studies in various phases, and they communicate concerns or clarifications to the PI and study sponsor as needed.

To meet the needs of this varied clinical research industry, many positions exist, including the traditional roles of principal investigator (PI), clinical research coordinator (CRC), and clinical research associate (CRA), as well as the more recent roles of medical monitors, regulatory specialists, and administrative professionals.

The CRA evaluates (or monitors) the protection of human subjects, verifies study data, liaises between the study sponsor and the site, and ensures compliance with the clinical research protocol (see Figure 4). The CRA may be self-employed (e.g., home based) or employed by a pharmaceutical firm, device manufacturer, or a CRO.

These positions often involve extensive travel, but may also be "in-house" at a sponsor location with minimal travel. Although many CRA positions exist, experience is usually required. One publication states that the CRA "…is in high demand. However, most pharmaceutical, medical device, biotechnology companies, and [CROs] are looking for CRAs with a minimum of one or two years of experience."[6]

Other clinical research positions aside from the PI, CRC, and CRA include:

- The medical monitor, who is usually an MD responsible for study oversight at the sponsor level, and supports the PI by responding to questions about the protocol and patient safety, including any history of serious adverse events.

FIGURE 2: PI Duties

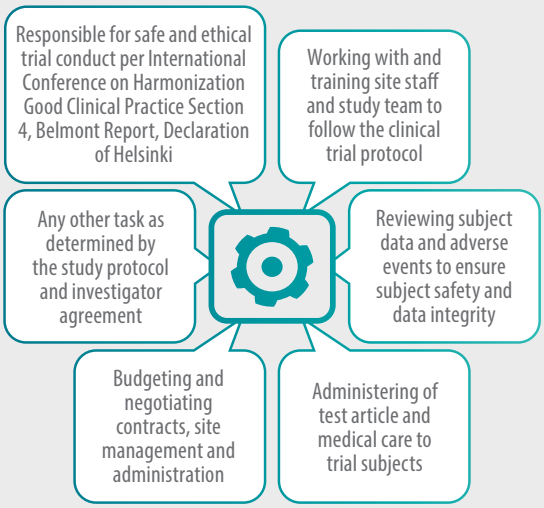
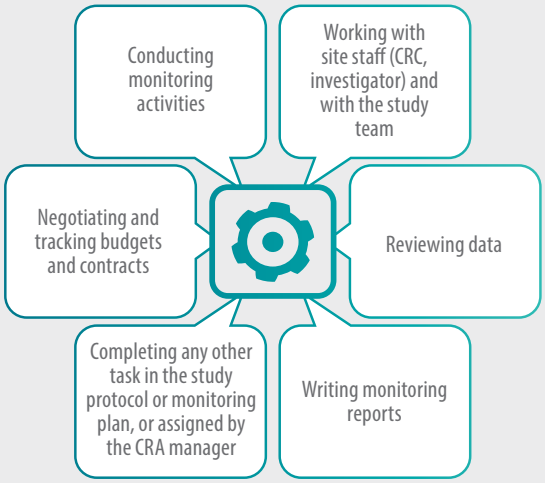


FIGURE 3: CRC Duties

FIGURE 4: CRA Duties



Sponsor companies, CROs, and sites often have other clinical research positions (e.g., project managers, trainers/educators, billing coordinators, information technology specialists, safety reviewers, lobbyists, marketing specialists, etc.), and they may engage third-party vendors to provide equipment and supplies needed to conduct research.

- The regulatory specialist or manager, who usually has experience working in the regulatory arena, and may be found at both the site and sponsor levels. He or she is responsible for ensuring regulatory files are complete and IRB approval is obtained prior to the start of the trial, drafting and filing safety letters, updating regulatory binders by ensuring certifications and licenses are current for the life of the trial (at the site level), and creating and organizing documents for the regulatory authority (at the sponsor level).
- Administrative professionals, who may work at sites to maintain files (e.g., at the ethics committee, data review committee, data safety monitoring board, or the IRB).
- Subject recruiters, who may develop advertisements and schedule study subjects for study visits.
- Data coordinators or managers, who are responsible for organizing and ensuring accurate analyses of the clinical data collected at investigative sites.
- Technical writers, who are needed to create brochures and recruitment ads, as well as investigator brochures[7] and technical documents.
- Biostatisticians, who usually have advanced training in math and statistics, and are typically responsible for designing the statistical analysis plan for the protocol, setting adequate enrollment numbers to reach statistical significance, analyzing the data, and ensuring the accuracy of the conclusions drawn from the data by limiting all forms of bias and making the data relatable to the public.

Sponsor companies, CROs, and sites often have other clinical research positions available (e.g., project managers, trainers/educators, billing coordinators, information technology specialists, safety reviewers, lobbyists, marketing specialists, etc.), and they may engage third-party vendors to provide equipment and supplies needed to conduct research. These vendors may also have still other clinical research positions (inspectors, auditors, quality affairs staff, advisors, reviewers, diagnostic or clinical laboratory staff, consultants, etc.).

Advice on Entering the Field

Many options and paths are available for individuals to achieve professional goals and enter clinical research; however, many people ask "How do I get experience in clinical research, when clinical research experience is required for a clinical research job?" Several suggestions may help, including the advice to be prepared to start at an entry-level (or lateral) position if you have no (or little) experience (see Table 2).

Clinical research uses both hard and soft skills,[8] so consider maintaining an inventory of all transferable skills and experiences to identify your capabilities and areas where you are in need of improvement. A good practice is to keep a training file with a list of transferable skills and including all transcripts of classes taken along with degrees and certifications (especially any clinical research training and experience documentation). This list may help to identify a direction or place to start (see Table 3).

In addition, these skills should be carefully included in your resume to help land an interview once you begin applying for openings. However, you may do well to remember that not all persons are cut out to be clinical researchers.

One indirect way to learn if you will enjoy clinical research work is to consider being a clinical research volunteer or study subject, in order to see how the clinical research enterprise works from the inside. Clinical trials needing volunteers are listed online at www.clinicaltrials.gov or www.researchmatch.com. Other volunteer opportunities may exist within the clinical research industry at a study site, within a sponsor company, or at a CRO.

Consider how you might practice talking about your experience and education in clinical research before any interview. For example, network with clinical research professionals and ask if any would be willing to conduct a mock interview with you for a specific clinical research job. During this practice interview, take criticism and feedback as ideas for improvement.

Another idea is to record your responses to typical interview questions and have a friend or colleague listen to the results and provide feedback.

When employers interview potential candidates for roles in clinical research, they look for passion, relevant skills, culture fit, personality fit, and excitement for the role.[9] Be prepared to discuss each of these areas when the interview opportunity finally arrives.

TABLE 2: Strategies for Action

Actions	Steps
Look for opportunities	Ask around, discuss with others
Apply to entry-level/lateral positions	Offer to start anywhere
Network to find a project to work on	Volunteer to help out
Learn the clinical research landscape	Do the homework (read, discuss, learn)
Participate in meetings/shadow professionals	Seek experiences, ask for work
Join a professional organization	Network at an ACRP and/or Society of Clinical Research Associates conference
Keep an open mind	Act on new ideas

TABLE 3: Transferable Skills and Experiences Inventory

Skill	Experience (be sure to name the project, topic, operation)
Analyzing data	Tabulated data from a project
Serving customers	Answered phones for clinic operations
Managing projects	Cared for an ill/disabled patient
Editing	Edited a newsletter
Using technology	Computers, software: MS Word, Excel, Powerpoint, social media, etc.

Networking and Internships

Although networking is a common feature of career building for most people, in the clinical research field, networking remains a priority for securing new and improved positions. Targeting local and regional groups involved in experimental, clinical, or education projects is the easiest way to begin.

Professional organizations offer networking opportunities, and many clinical research and professional publications advertise lectures, seminars, and jobs. Joining online groups and blogs about clinical research can also be a way for an individual to meet people in clinical research positions.

Volunteer roles may not allow direct patient care, but will often allow unique opportunities to see clinical research operations and behind-the-scenes workflow, which offers valuable knowledge and experience.

If you have not been active in networking before, ask others how they network and remember, the art of networking involves doing something memorable with the people you meet. The goal is not only to help you secure a new work position in clinical research, but also to expand your list of contacts and put together names and faces of the people you should remember.

Ask lots of questions and consider asking individuals about internships. People may not have thought about having an intern, but they might create an internship opportunity at their workplace that could be a great way for an individual to gain experience while learning the ropes.

Volunteering

Volunteering to do clinical research work is often a good way to network and get an introductory understanding of clinical research. The quality and type of experience matters, because expertise with research processes and regulatory requirements is required for most clinical research jobs.

Volunteer roles may not allow direct patient care, but will often allow unique opportunities to see clinical research operations and behind-the-scenes workflow, which offers valuable knowledge and experience. PIs are often happy to have volunteer help if a volunteer offers their skills, qualifications, and time to help do needed work at the site.

IRBs must have at least one member on the IRB from the community. The community volunteer

reviews studies and participates in the work of the IRB, which is an excellent way to gain clinical research exposure while learning how human subjects are protected.

Several professional organizations also have volunteer opportunities, including for example, the structured mentorship program with the Public Responsibility in Medicine and Research organization and within special interest groups of the Drug Information Association.

Other professional organizations also provide volunteer opportunities at the local, national, and international levels. As ACRP[10] declares, "Donating your time...not only opens doors to advocacy and strategic roadmaps, but it also allows you to cultivate your leadership skills."

Access to programs in professional associations may be restricted to members, so consider the value of professional organization membership as you explore a clinical research career. Further, remember to ask about all laws related to your volunteer work since the Fair Labor Standards Act in the U.S. may be interpreted to not allow volunteers to do the same work as a paid employee.

Developing Your Action Plan

The first step in entering the clinical research field is to become knowledgeable about the positions, opportunities, language, and regulations of research.

Next, update your resume and/or curriculum vitae after reviewing examples of professional resumes from people sharing your clinical research interests. List your relevant skills, experience (including volunteering), and education, whether the coursework is completed or in progress. If you haven't yet acquired specific research training, focus on your transferable skills for the research position you seek.

A formal resume clear of grammatical errors, typos, or use of multiple fonts/styles is required.[11] Remember, your resume is a direct reflection of you and must be accurate, honest, and verifiable. Potential employers will likely fact-check degree dates, publications, drug testing, felony, arrest, driving records, tax records, credit reports, and social media, so be sure your information is correct.

Also, the start of your resume must convince the reader to further explore your work history with you in an interview, so learn how to create a "10-second pitch" describing yourself and your goals so you can get to the interview stage.[12]

When employers interview potential candidates for roles in clinical research, they look for passion, relevant skills, culture fit, personality fit, and excitement for the role.

The interview process itself may lead to a request for references, so identify people in advance who will accurately confirm your skills/experience in a positive light, and discuss this with each person in advance, so they are ready for the call if/when it comes.

Scrutinize the research environment and apply to specific entry-level positions, supportive functions, or lateral moves appropriate to your education, training, and experience.

Consider how to partner with recruiters who may help provide information and consultation on the clinical research market or a specific organization where you might want to work. Review professional organization websites to see if they list job openings (e.g., ACRP Career Center at www.acrpnet.org/careers/index.html).

Beyond the types of volunteering mentioned earlier, you may also want to try shadowing a research professional in your local institution or hospital, or asking to "sit in" on research meetings, IRB reviews, or community programs. Offer to help with study-related administrative tasks, initiate informational interviews and get-togethers with people involved in clinical research, and assist with article finding, summation, or data assessment according to your unique abilities and the needs uncovered in your network.

Do your best to learn about the training and the needs uncovered in your network and education you may need. For example, the Joint Task Force for Clinical Trial Competency[13] (including representatives from ACRP among many others) defined eight competency domains for the education and training requirements of clinical research professionals:

1. Scientific Concepts and Research Design
2. Ethical Considerations, Patient Care, and Safety
3. Medicines Development and Regulation
4. Clinical Trial Operations
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communication and Teamwork

An action plan for entering the clinical research field has many customizable parts, including specific goals for networking, education (e.g., classwork and on-the-job training in clinical topics like research design, clinical trial operations, ethical principles, data management, etc.), and experience (e.g., volunteer positions, internships, etc.).

Conclusion

For those who are interested in a career in clinical research, many opportunities exist in today's market. Having education and experience in science, business, and research practices can improve prospects for success in entering the clinical research field.[14] Getting started can be challenging, but knowing the field and some potential steps to take can keep the job search moving in the right direction.

Keep in mind that understanding the clinical research field means knowing the language. Clinical research uses many processes and lots of medical terminology, abbreviations, and acronyms. Learning the language might be one place to start, although no single formula exists to find a great clinical research position, and the exact entry point has many variations.[15]

Interested individuals can use the tips and tools provided in this article to develop an action plan for entering the clinical research field.

- Do the research
- Network
- Volunteer
- Look for opportunities
- Apply
- Initiate and shadow
- Develop skills
- Keep an open mind

Remember the key to success is to cultivate the clinical research passion within. Be motivated, patient, optimistic, and self-confident. Take chances and don't be afraid to try something new. Keep an open mind, especially about new or unusual clinical research roles.

These suggestions can be helpful to those looking to enter clinical research, or even for those looking to switch career paths within the field. Good luck!

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CDM IS DEAD!

Long Live CDM!

Few areas of clinical development have undergone as much change in the last 10 years as clinical data management (CDM). Its demise has been predicted and assumed for decades, aided and abetted by large consultancies and investors/analysts pressuring pharma for cost-cutting. These stakeholders saw (and still see) CDM as a mere commodity to be auctioned off to the lowest bidder anywhere in the world.

Since rumors of CDM's death have been greatly exaggerated, let's look at the journey that CDM has taken toward its recent resurgence for the lessons that might be learned by other functional areas in the industry facing similar challenges.

The King is Dead

The change within CDM began with what I call the "spreadsheet argument." Those large consultancies/investors, possessing a heavy financial focus, but little operational experience in clinical development, approached senior executives with two-column spreadsheets. The left column displayed their current CDM costs; the right side was the amount it could cost if the executive would only do "X" with CDM (outsource it, offshore it, etc.).

The savings predicted were often 50% or more. This too-good-to-refuse offer had a large number of senior executives jumping at the chance to offload an entire operational unit, and CDM began its migration out of sponsor organizations and over to other providers, since the necessity for managing the clinical data didn't disappear just because the staff who used to do it did.

Governance, process, and personnel issues for how to make decentralized CDM work were addressed only after the fact, by mid-level managers who were often completely unaware of how the deal had been reached. Any chance for incorporating control over these crucial issues into the original deal as contractual obligations was long gone.

That impact of that unprepared-for new working model has taken years to dissipate: The time has been consumed with sorting out roles, developing governance models, modifying contracts for the missing pieces, and building the infrastructure required to support today's approach to CDM. The progress made in this endeavor has been unequal, to say the least, across the research sponsors and their providers, with the efforts yielding both pain and fruit.

That fruit is now setting the stage for a resurgence of CDM within the industry. Let's look at four of the developments in more detail.

The Fruits of Change

Cleaner Data. The increasing, now almost ubiquitous, use of electronic data capture tools, with their sophisticated edits and directive end-user guidance, have made clinical trial data cleaner than ever at the original point of entry. Over the past several years, we have measured, and watched our sponsor-clients measure, their data to determine how many data points are ever changed from their original values. The consistent result has been between 3% and 6%, meaning that 94–97% of the data are never touched after initial data entry. Indeed, we have seen results as high as 99%.

CDM has taken this phenomenon to heart, and is using this knowledge to direct resources away from superfluous data checking and to lower the resource allocations needed by CDM in each clinical trial. This is reshaping the arguments made for the original outsourcing/offshoring deals, as the headcount needed for a given trial is reduced. It has also opened the way for shifting resources toward new, higher value activities, such as our next fruit.

Data Analytics. The "Big Data" phenomenon that is sweeping across many industries has attracted the attention of CDM. In reconsidering its value proposition, CDM is now creating data analytics roles that apply Big Data principles to the specific characteristics of clinical research.

Moving its focus beyond just clinical trial data (electronic case report forms, etc.), CDM is applying these principles to operational data and to metadata about studies. Data-driven approaches to evaluating operational decisions, such as the frequency of onsite monitoring visits, are offering new opportunities for CDM to provide value.

Mature Providers/Mature Relationships. After many years of outsourcing, offshoring, and downsizing, CDM has now reached an equilibrium of sorts. The pros and cons of these approaches

Governance, process, and personnel issues for how to make decentralized CDM work were addressed only after the fact, by mid-level managers who were often completely unaware of how the deal had been reached.

The role of CDM on the development study team, and the skills that (new) data managers bring, have never had more potential to be essential contributors to drug development.

are better understood by all parties, and their defensiveness toward critique and revision of the approaches has decreased.

The governance so sorely missing at the start of the journey is being reconsidered and implemented, with sponsors and providers now engaging more efficiently in a client/service or payer/payee relationship, where the interests of each group are legitimately different, but capable of alignment. This has allowed a more mature approach to conflict resolution between the parties.

One important example of this is the contractual capability to move/remove underperforming provider personnel from a project. This process safeguards the execution of the sponsor's project, while recognizing and supporting the need to provide developmental feedback for the provider's underperforming personnel.

Growing Collaboration. The decentralization of CDM has, over the years, spawned a set of entities that specialize in particular aspects of the CDM enterprise. This part of the journey has also produced the unforeseen fruit of collaboration.

For example, the Society for Clinical Data Management (SCDM), the largest CDM professional organization in the industry, has set new attendance records at its annual conferences in recent years. The former one-sided predominance of sponsor-based CDM in the SCDM conference programs has been replaced by a mix of four separate, actively engaged constituencies: sponsors, academic institutions, service providers, and software vendors.

Still led by the sponsor CDM as client and payer, the collaboration is now much more like an exchange of equals, with each entity providing years of its own clinical trial experience to new approaches and new solutions.

Long Live the King

These four benefits of the painful journey have positioned CDM to flourish in the coming years within our industry. Every clinical development executive is demanding more data, more dashboards, and more decision-support, and expecting all of this to be delivered in a professional context of data accuracy, intuitive software interfaces, appropriate technical resources, and, of course, at the lowest possible cost. CDM stands ready to provide that, in ways that would have been unthinkable 10 years ago.

Meanwhile, what are the "other" roles mentioned at the beginning, those in clinical development who may experience similar change?

One of them is certainly the field or site monitor. The growing acceptance by regulatory authorities of risk-based strategies for monitoring, the advances in operational analytics described above, and the capability of remotely reviewing site documents in an electronic trial master file are likely to bring about a similar wave of change to that role. Coming along next will be the pharmacovigilance case handlers. For these and others, creative re-thinking, as illustrated by CDM's journey, offers the same chance to increase their value to clinical research and establish their own renewed value propositions.

We can't say CDM has been resurrected, because it never died. The role of CDM on the development study team, and the skills that (new) data managers bring, have never had more potential to be essential contributors to drug development. With such importance comes the critical need for CDM professionals of some new description to remain firmly entrenched inside the biopharma enterprise.

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Tips to Retain Top Talent: *How to Keep the Stars in Your Orbit*

James Michael Causey

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If you depend on the diligence of talented study monitors from your own staff or from contract research organizations (CROs) to keep your business running, here are a couple of things you should already know:

1. The number of clinical trials is on the rise.
2. The number of clinical research associates (CRAs) isn't keeping pace.
3. Trials are becoming more complex.
4. Trials increasingly require CRAs with the aptitude and willingness to learn new skill sets.

Here are two more realities you also need to face:

1. It's getting harder to find those high-caliber employees.
2. It can be even harder to keep them.

"The market is highly competitive for experienced CRAs," notes Michael Jimmink, inVentiv's vice president for strategic resourcing—a trend he and others agree isn't about to change any time soon.

Managers are challenged from both sides: Too many trials, not enough high-quality personnel. "The talent pool is not keeping up with demand" says Joe Mills, senior director at inVentiv. While the problem is most acute in the Northeast, California, and the Midwest (especially around Chicago), he says it's getting harder to find CRA talent anywhere in the U.S.

Let's take a closer look at that group of CRAs eyeing the door (see "Is Your Star Getting Restless?"). More than half of respondents to a 2015 CenterWatch/ACRP survey said work/life issues are a big factor in their mind-set. "Work/life balance is a huge piece of the puzzle," says Kristin Rocco, a former nurse now with Kelly Staffing Services in its Strategic Accounts and Operations/Americas division.

Paradoxically perhaps, the same survey found that overall job security levels among CRAs were relatively low: 57% at a CRO reported feeling "very secure" in their jobs, compared to 27% at pharmaceutical/biotech firms. While many of those CRAs might not be stars, some certainly are, and the survey suggests managers aren't doing a very good job when it comes to letting stars know their importance to the site.

Good communication is critical. However, it won't be as effective if you don't know your audience, says Lisa Palladino Kim, MS, an adjunct professor at Rutgers: "I think the first thing [managers] need [is] to find out what is important for that specific" CRA. Vague or misdirected praise is one thing; however, zeroing in on what means most to your star CRAs vastly enhances the effectiveness of the accolades you send them.

"One person I worked with just wanted to be recognized for their hard work, verbally in front of peers," Kim says. "Another just wanted the flexibility to set their own schedule so no matter what the work was or changes in climate at the office, as long as they could have flexibility, it was OK."

LEADERS LEAD

Good managers are proactive. For example, Rocco advises keeping abreast of life changes faced by your star performers. For example, if one of your star CRAs is pregnant, or has a sick parent, reach

IS YOUR STAR GETTING RESTLESS?

If you are a CRA manager, about one-third of your team is probably considering a job change in the next 12 months, according to a Centerwatch/ACRP career and salary survey released in 2015. About another 20% aren't sure one way or the other. Bottom-line: more than half of your team is in flux on any given day.

PROVEN RETENTION TIPS AND TACTICS

Kristin Rocco at Kelly Staffing Services shares some ideas she's seen work in her years of CRA recruitment:

- Personalized communications: Don't underestimate the impact of a handwritten "attaboy" note, she says. If a sponsor says something good about your CRA, drop them a note—not an e-mail, but a true, old-school card.
- Regular check-ins over the phone: Ask about workload issues. Ask about something unique to that employee (e.g., how's the new baby?) Warning: employees can sense if you're just "checking a box" with your call.
- Small tokens of appreciation: You might want to include a Starbucks or other card with that note. Even a $25 gift can have a surprisingly powerful impact.
- Send out a company newsletter: Highlight star performers. Include interesting trends you or others on your team have observed elsewhere (e.g., a new way to strengthen informed consent procedures or reach out to underserved subject populations). It can help bring together your widespread workforce, Rocco says.

out and discuss ways to help him or her adjust the workload. Don't wait for them to come to you.

While work/life balance is extremely important, it's not the only driver: Professional environment and salary round out the top three issues cited in the survey. Don't forget, though, that about a third of your team mulling a move is likely to feel that the job environment and its intellectual challenge (or lack thereof) are also big ticket items.

Many monitors are on the road 80% of the time, Rocco notes. She suggests finding ways to limit your star CRAs travel to a single region. "If you can knock their travel demands down to even 60%," you've just taken an important step toward having them stick around.

"The best way to keep star performers is to ensure that they have a worthy challenge," says Bonnie Hagermann, CEO of Executive Development Associates. A specialist in executive coaching and understanding how to work with the millennials entering the workforce, she advocates putting stars in a "stretch" situation and backing them with coaching and a mentor or two who's proven to be inspiring to others in the position.

Challenge can become an important retention catalyst, adds Linda Henman, a personnel consultant and author of several books on how to help your most important talent thrive. "Only 20% of employees feel their strengths are utilized," she says. "When they don't feel they are challenged and appreciated for their talents, they leave."

HELP THEM SEE STARS

Good managers also help their stars visualize what they want. In some cases, your stars haven't articulated—even to themselves—exactly why they might be itching to leave. Ask a star to talk to you about their dream job, says leadership consultant Lawrence Polsky. Working with Pfizer, among other clients, he's helped stars express what they are looking for, and what will get them to stay.

Some star CRAs "need a specific career ladder advancement plan, while others just like what they are doing and [can remain] happy with that," Kim echoes.

Coaching programs can help, says Mills: Such a program is "a valuable tool to retain top talent. Mentors and coaches can help people see a career path at their existing location."

While the problem is most acute in the Northeast, California, and the Midwest (especially around Chicago), it's getting harder to find CRA talent anywhere in the U.S.

IS SHE A SUPERSTAR?

It's not a science, of course, but identifying the irreplaceable stars on your team isn't as hard as it might sound. In fact, it can be kind of easy, says Kristin Rocco with Kelly Staffing Services. "You can see it right away if you know how to look." Her secret: Get feedback from immediate supervisors about what qualities they are looking for in top talent. "Stars know the industry, are always offering to help, and are glad to co-monitor with others," she adds.

An Overview of Clinical Research in Indonesia

PEER REVIEWED | Umakanta Sahoo, PhD | Diana Wibowo

[DOI: 10.14524/CR-15-0001]

About **20** of Indonesia's **76** medical schools are actively involved in clinical research.

Indonesia, the fourth most populous nation in the world, is an archipelago with more than 17,000 islands and a coastline stretching 54,720 kilometers. Indonesia's 2013 population was estimated at more than 249 million, and its gross domestic product per capita at US $4,700. The official and major language in Indonesia is Bahasa Indonesia, though English, Dutch, Javanese, and other dialects are also prominent languages, and the country is predominantly Muslim (86% of the population).

About 20 of Indonesia's 76 medical schools are actively involved in clinical research. The major cities that perform clinical trial–related activities are Jakarta, Bandung, Yogyakarta, Surabaya, and Medan, due to the concentration of resources and facilities in these locations.

The selection of trial sites within Indonesia to participate in global clinical trials is one factor that boosts drug development activities in the nation. Furthermore, the availability of research subjects due to the prevalence of a wide variety of diseases has also increased the number of clinical trials in Indonesia. Among the major causes of death in Indonesia are stroke, tuberculosis, cancer, ischemic heart disease, and diabetes (see Table 1).[1]

TABLE 1: Top 10 Causes of Death in Indonesia

1	Stroke	8%
2	Tuberculosis	7%
3	Cancer	6%
4	Road Injuries	5%
5	Diarrheal Diseases	4%
6	Ischemic Heart Disease	4%
7	Diabetes	3%
8	Major Depressive Disorder	3%
9	Lower Back Pain	3%
10	Lower Respiratory Infections	3%

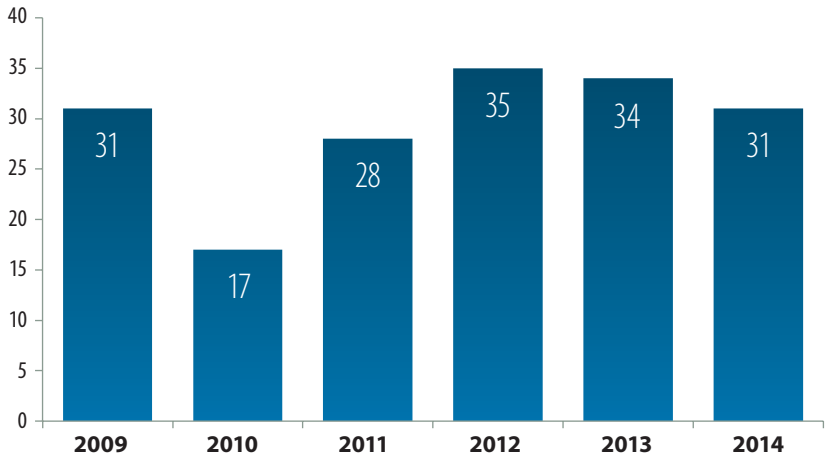
Source: GBD Compare (2010), via the Centers for Disease Control and Prevention

Prior to 2000, mostly small-scale marketing trials were undertaken in Indonesia, and there were no guidelines to control the quality of these trials.

Trends in Trial-Related Activity

Indonesian sites participate in approximately 30 to 35 new industry-sponsored trials every year. There are 268 trials already listed for Indonesia in the ClinicalTrials.gov clinical trial registry, out of which, 180 trials are industry-sponsored and the rest are sponsored by individual investigators, local institutions, or hospitals, universities, and other organizations (see Figure 1).

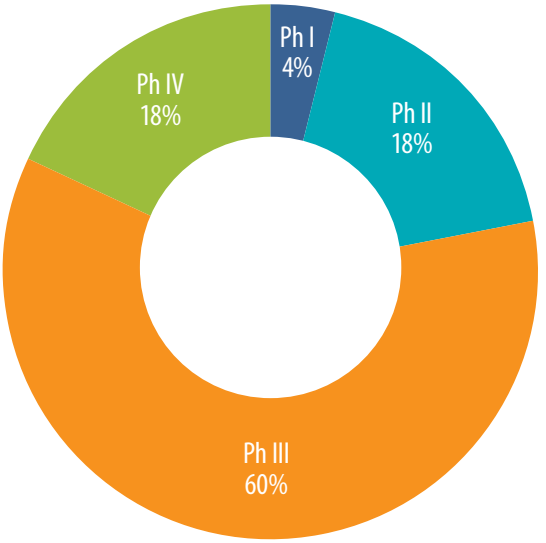
FIGURE 1: Growth of Clinical Trials in Indonesia



Source: www.clinicaltrials.gov, accessed in December 2014

Further analysis suggests these studies are undertaken in diverse therapeutic areas and almost 60% are in Phase III, 18% in Phase II, 18% in Phase IV, and just 4% in Phase I.

FIGURE 2. Trials in Indonesia by Phases



Source: www.clinicaltrials.gov, accessed in December 2014

The figures demonstrate that this country is not ready to participate significantly in Phase I studies, though a few local contract research organizations (CROs) have Phase I facilities and have conducted such studies.

Besides the sponsors of the aforementioned industry-sponsored clinical trials, some of the institutions active in clinical research in Indonesia are Indonesia University, Menzies School of Health Research, Wellcome Trust, the National Health and Medical Research Council of Australia, the National Institute of Health Research and Development of Indonesia, Showa University, and the National Institute of Allergy and Infectious Diseases of the United States.

The Regulatory Environment and Evolution of Good Clinical Practice Guideline

The National Agency of Drug and Food Control (NADFC) regulates pharmaceutical products and drugs in Indonesia. The primary functions of NADFC include premarket evaluation of medical products, legislation, regulation, standardization, and good manufacturing practice certification.[2]

The criteria and guidelines to apply to conduct clinical trials and to register products in Indonesia have been periodically updated and well laid down; they are based on assessment of a drug's risk, quality, safety and efficacy, and overall need by patients.

Though it is not a standard practice, an investigator can apply directly to the regulatory authority for clinical trial permission on behalf of the sponsor, and the license can be issued in the name of the investigator.

A committee that plays a key role in the regulatory processes in Indonesia is the National Committee on Drug Evaluation, appointed by NADFC. It comprises experts in clinical pharmacology, pharmacy, biology, and qualified clinicians recruited from universities and other relevant institutions.

Health research in Indonesia is governed by article 69 of the Indonesian Health Act No.23/1992, and research and development in the healthcare segment is covered under regulation No. 39/1995 of the same act. Furthermore, as awareness of global clinical research grew in the country, Indonesia implemented guidelines on good clinical practice (GCP) in 2001.

Evolution of GCP

Prior to 2000, mostly small-scale marketing trials were undertaken in Indonesia, and there were no guidelines to control the quality of these trials. Furthermore, ethics committees (ECs) did not exist in most institutions, most investigators did not understand what GCP was, and informed consents were often neglected.

In the year 2000, the Clinical Trial Working Group (CTWG) was established with a mission to improve the quality of clinical trials in Indonesia. The CTWG comprised people from academia, the pharmaceutical industry, clinical labs, and the nation's regulatory authority. In 2001, Indonesia adopted the International Conference on Harmonization's (ICH's) guideline on GCP and the regulatory authority issued regulations related to the implementation of GCP.

Since 2001, the CTWG carries out trainings in GCP and research methodology in various medical faculties and research centers. Other organizations also have participated in giving the GCP trainings. Today, approximately 200 clinical researchers throughout the country hold the GCP certificate, which typically can be obtained after the investigators and study staff have attended a two-day course and passed an examination. GCP training is also provided by study sponsors to investigators and their study staff prior to commencement of a clinical trial.

Clinical Trial Applications and Import Permissions

Currently in Indonesia, all premarketing clinical trials (Phases I, II, and III) are mandated to follow the GCP standard. These trials require the regulatory authority's approval prior to implementation. The sponsor must submit a clinical trial application (CTA) using form UK-1, along with the documents listed in Table 2.

There is no separate submission for an import license. If the investigational drug is to be imported to Indonesia, the import license will be needed and the sponsor must complete the drug importation information that is requested on the same UK-1 form.[3]

TABLE 2: Documents Submitted to Regulatory Authority for CTA/Import Permission

- Research protocol and written information for the research subjects
- Approvals from the EC and Scientific Committee
- Investigator's brochure
- Amount of drug needed for the trial
- Cover letter
- Summary of chemistry, manufacturing, and controls
- Summary batch protocol (for biological products and vaccines)

The sponsor and any delegates such as CRO study team members and investigators can submit a CTA for regulatory approval and importation of drugs. It is not mandatory to have a local CRO/sponsor registered in Indonesia to apply for clinical trial permission.

Furthermore, though it is not a standard practice, an investigator can apply directly to the regulatory authority for clinical trial permission on behalf of the sponsor, and the license can be issued in the name of the investigator. However, a drug registration application for a product to be used in Indonesia can only be made by pharmaceutical companies located in Indonesia through a preregistration process, which takes about 40 working days. This registration involves consultation on completeness of the registration dossier and documentation and registration fees.

CTA Review Process and Timeline

In Indonesia, EC review and regulatory submissions are done sequentially. Submission of a CTA to the regulatory authority can be done upon receipt of the EC's approval, and this is still performed via a manual hardcopy submission. The review timeline is 10 working days upon confirmation of the submission of the completed document and payment of a review fee of IDR 5,000,000 (approximately US $400). The process of ethics and regulatory submissions and approvals is shown in the flow chart on page 67.[4]

If a CTA is approved by the regulatory authority, both the letter of approval and license for drug importation will be sent to the investigator in 10

working days. The same policy is also applied to studies of drugs that are already on the market but seeking approval for new indications (pivotal studies), and to bioanalytical/bioequivalence studies.

In the case of postmarketing (Phase IV) studies, sponsors and investigators should notify the regulatory authority prior to study implementation, and if there is no response from the authority within 10 working days, a trial may be started. GCPs should be followed in sponsored studies; however, in Indonesia, postmarketing surveillance is not classified as a clinical trial. Postmarketing studies conducted only for educational purposes (i.e., for medical students, residents, etc.) have to follow the Declaration of Helsinki, but not the GCP standard.

In case of clinical trials in vaccines and rDNA products, the application process for regulatory approval remains the same, except that an additional summary of batch protocol documents must be submitted with the application for biological products and vaccines.

Ethics Committees

The first EC in Indonesia was established in 1982. Today, ECs exist in the majority of schools and hospitals conducting clinical research. The Minister of Health established the National Committee on Ethics of Health Research with the goal of improving the capabilities of the ECs, and hence rolled out the National Guidelines on Ethics in Health Research in 2003.

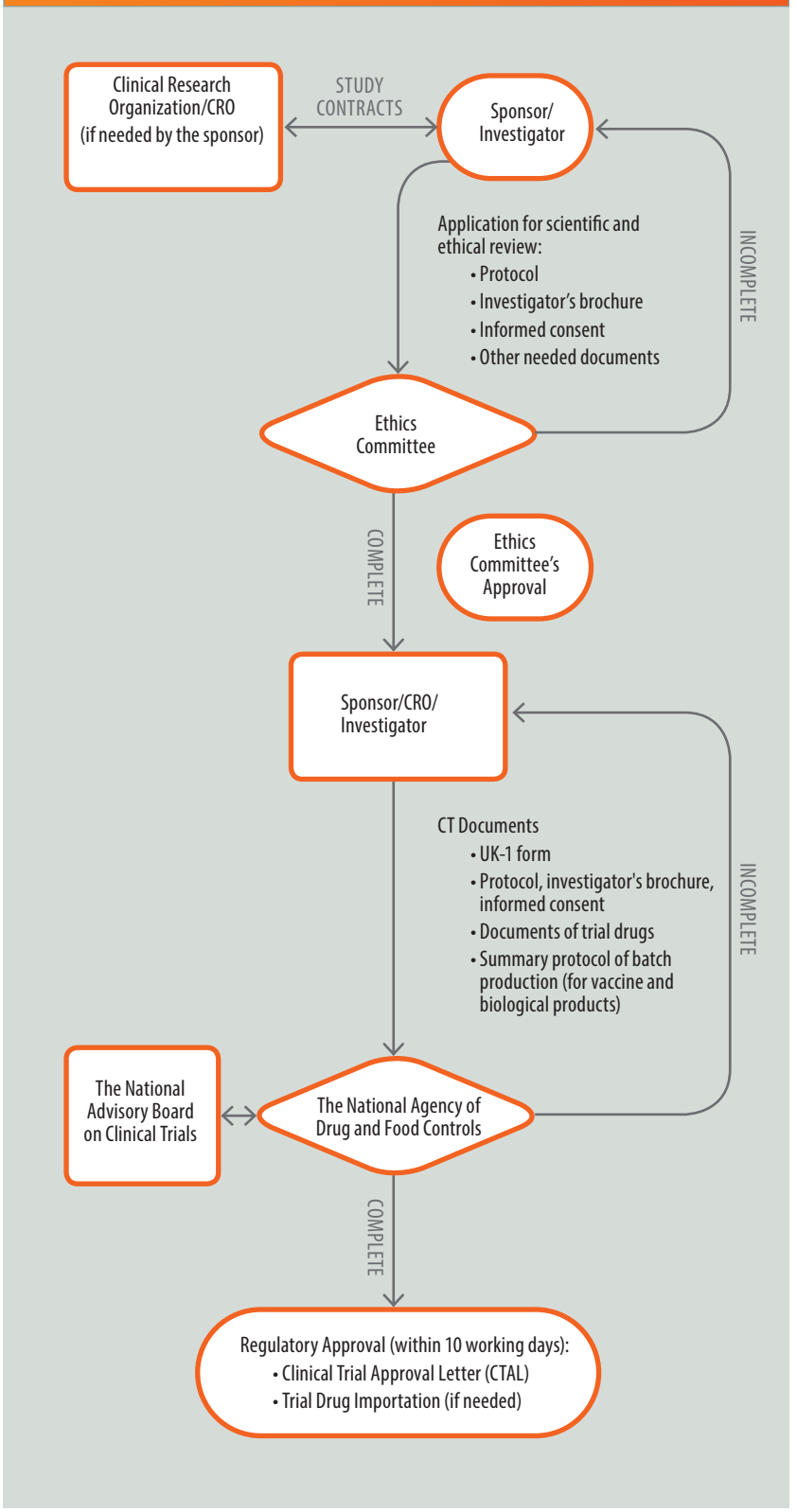
In Indonesia, there is no central EC; most ECs are attached to individual teaching hospitals. ECs follow ICH guidelines and have at least five members. If a hospital does not have its own EC, it may use the nearest available EC for clinical trial purposes.

However, there will be slightly different requirement between ECs; for example, some ECs may require the principal investigator to be present during the meeting, but others do not. The review timeline and fees may vary between ECs, some ECs may not have regular meetings, and some ECs' review fees are based on a percentage of the study budgets.

Local GCP expectations call for research protocols to be reviewed not only by an institution's EC, but also by its Scientific Committee. If an institution has no Scientific Committee, then the study's scientific aspects should be reviewed by the EC.

Not all ECs have a predetermined regular meeting schedules; some meet monthly, but others meet only when they receive submission packages. The list of documents required for EC submission varies from institution to institution; as an example, the documents required by the EC of the Faculty of

FLOW CHART: Pre-Marketing Trial (Inseparate Scientific and Ethics Committee)



Medicine at the University of Indonesia are listed in Table 3. In addition to these documents, some ECs may ask for a study budget to be submitted.

TABLE 3. Example of Documents Required for EC Submission

Document	Language	# of copies
Cover Letter	Bahasa Indonesia	1
Protocol	Bahasa Indonesia/ English	15
Case Report Form	Bahasa Indonesia/ English	15
Patient Information Sheet	Bahasa Indonesia	15
Informed Consent Form	Bahasa Indonesia	15
Investigator's Brochure	Bahasa Indonesia/ English	15
Advertisements (if any)	Bahasa Indonesia	15
Patient Diary (if applicable)	Bahasa Indonesia	15
Related Publications (if any)	Bahasa Indonesia/ English	15

Exports of Biological Challenges—Material Transfer Agreements

Biological samples exportation is strictly prohibited in Indonesia, unless the test to be performed cannot be performed in any laboratory or facility within Indonesia. For global trials requiring the shipping of biological samples to a central laboratory outside Indonesia, Materials Transfer Agreements (MTAs) must undergo Health Research and Development, Ministry of Health review and approval. Samples exportation is regulated under Decree of Minister of Health No. 657/MENKES/PER/VII/2009. For this purpose, MTA approval must be obtained prior to exportation of the samples.[5]

Challenges and Future Outlook

The conditions required to conduct trials in compliance with the tenets of GCP are much improved in Indonesia. Today, Indonesian sites can carry out high-quality clinical trials that contribute significantly to global drug development.

However, the process for MTA approval for the exportation of biological samples is a cause of concern, and an additional step that could cause delay in trial conduct. Even after obtaining MTA approval, exports of biological samples offer logistical challenges for sites participating in clinical trials.

Furthermore, there are challenges of insurance and indemnifications; few local players offer clinical trial insurance (liability coverage) for global clinical trials.

Also, there is a significant shortfall of trial monitors and experienced investigators. Since concentrations of experienced investigators are limited to just a few cities, there is always a lack of well-trained investigators in Indonesia. However, recently, support has come from the government and private institutions to train site staff and investigators.

Among other local issues, Indonesian investigators require more clinical research associate (CRA) support, compared to other countries. Culturally, face-to-face meetings are usually preferred between investigators and CRAs. Strict confidentiality and data protection guidelines do not prevail, though awareness of their importance is improving. Publication of study results is not a priority, and hence, good publishing practices must be implemented in Indonesia.

All stakeholders understand the benefits of undertaking clinical trials in Indonesia, and should strive to uphold their key roles in the conduct of ethical research.

The conditions required to conduct trials in compliance with the tenets of GCP are much improved in Indonesia. Today, Indonesian sites can carry out high-quality clinical trials that contribute significantly to global drug development.

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