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Clinical Research Careers

A Global Perspective

All clinical researchers share a common purpose in helping to develop safe and effective therapies supported by high-integrity data and generated in environments where the rights, welfare, and safety of the clinical research subjects have been protected with diligence.

The clinical research enterprise is staffed around the world by individuals from different educational, professional, and cultural backgrounds, who hold positions across a wide range of therapeutic areas and medical product types. They work at diverse businesses, represent a variety of interests, and serve in different capacities or functional areas. Regardless of role or employer, all clinical researchers share a common purpose in helping to develop safe and effective therapies supported by high-integrity data and generated in environments where the rights, welfare, and safety of the clinical research subjects have been protected with diligence.

This article addresses some of the factors that influence career choices within the profession, and provides perspective based on the experience and opinions of the authors, each of whom has functioned as an "in the trenches" researcher in varying roles over the past 20 years, including global clinical trial management efforts. Both authors are certified clinical research associates (CCRAs®) through the Association of Clinical Research Professionals (ACRP), and have volunteered within the organization on committees and as trainers in addition to collaborating in the private sector.

Where the Work is Done

Globally speaking, geography is a major factor with regard to clinical research careers. Research rules and roles may vary based on local regulation and the culture, language, and other legal considerations, such as the underlying healthcare system, that drive the way medical products are developed and determine how the work must be done in that respective locale.

Interestingly, concerns about location are based on more than just the region in question, as the type of company or organization where the individuals work also comes into play. Whether we are speaking of a large or small business, private or public entity, clinical practice or academic center, the work environment can be highly variable, and the location may even be office-based or remote. Some clinical researchers work from home offices with virtual connections, commute locally, or travel internationally to go where the work needs to be done.

Nevertheless, there are distinct similarities that exist with regard to characteristics of clinical research professionals and the factors that influence success. These similarities, when identified, can help individuals choose a career path, or perhaps help hiring managers to select job applicants that are the best fit for a given position. The generalities and conclusions drawn may be described as stereotypical, but the reality is that, around the world, it is the

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What's in a Job

Much has been written about qualities of a good (or great) research coordinator or study nurse, clinical research associate (CRA), or auditor. These well-described attributes can be used for the development of ideal profiles for the specific positions. Individuals, however, can also benefit from this body of knowledge if they can assess their own personality and preferred style and use the assessment to help direct their career choice. The following observations should prove helpful for those looking to gain perspective on generalities that influence career choices (as well as career success), while keeping in mind that, of course, it is difficult to draw absolute conclusions.

Site Roles

Physicians who serve as the principal investigators (PIs) for clinical trials must not only have therapeutic expertise, but they must understand and be committed to good clinical practice (GCP). That means they must be willing to learn new research methodologies and comply with defined requirements, including strict adherence to clinical protocols and applicable regulations. Physicians who like to call all the shots and do things only their own way might have difficulty complying with research-related standard operating procedures and sponsor or institutional review board requirements; worse, they may have difficulty with following the approved clinical protocol to the letter. PIs must be willing to invest additional time to work with the sponsor's monitor, participate in meetings and calls, and review trial documents and records. In addition to having the right medical knowledge, a good clinical investigator can be characterized as having logical and analytical, fact-based thinking.

Study coordinators, study nurses, and other research site personnel often function independently as they perform duties that have been delegated by the PI. As long as they have the knowledge, skills, and ability to do the job, their success will be dependent on their being able to work individually or on teams, depending on the organizational structure of their research site and the oversight from the PI. They must be organized, detail-oriented, and able to keep pace with active and aggressive study timelines. Good communication and relationship management skills—building trust and confidence—are pluses that can help them to succeed in their jobs and contribute to strong site performance.

Sponsor Roles

On the sponsor side, there are many research-related positions within various functional areas and departments staffed by professionals who are trained and qualified to perform their respective duties. That being said, the following observations serve to highlight differences with regard to the various functional areas.

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Based within the clinical operations units of companies sponsoring studies (or outsourced by these sponsors from contract research organizations), CRAs—also referred to as clinical monitors—are charged with the responsibility to oversee GCP and compliance "in the field" at the clinical sites. This role demands excellent communication and organizational skills and the willingness to spend a lot of time traveling. Most successful CRAs are extroverts and are able to jump in to help coach, mentor, and direct others as needed. They typically appreciate and manage the "human factor" in an excellent way, making friends wherever they go. Good interpersonal skills are a prerequisite; however, besides a great deal of flexibility, field CRAs need to be very logical and detail-oriented thinkers in order to manage their responsibilities effectively.

Whereas CRAs usually represent the field force of the sponsor, data managers and programmers generally work in-house. They are typically very organized, and work well with details and in strict accord within a defined plan. These are data-intensive jobs that require concentration and focus, as these individuals must be able to think three-dimensionally, work independently, and interface online/remotely with others far more than on a face-to-face basis.

Those who work in safety/vigilance units typically love clear rules and are driven by timelines. Safety managers are good team players; they usually are dedicated to specific tasks within a complex workflow and have to comply with various legal, medical, and business requirements. Clear instructions, tough timelines, and a high work volume are not a problem for them. They know all the underlying rules, requirements, and responsibilities, and adhere to them with pleasure.

Regulatory affairs professionals must know the law and the applicable standards. Fortunately, they usually enjoy fact finding and continual learning. This is important, because the regulations are a moving target in the medical product development industry; knowing the laws and using creativity to adhere to them is essential in this area. These professionals never stop learning, as there's always something new going on in the regulatory arena. Unfortunately, regulatory affairs professionals are often viewed by management as an obstacle when they

mandate actions that must be taken. Although some regulatory affairs professionals might prefer to work in a silo, they have to play with many other team members outside their department, as well as interface with regulators. Diplomatic skills and polite, but assertive, advocacy are critical success factors for these individuals.

Quality assurance (QA) auditors are charged with the responsibility of assessing compliance. They must be process-oriented with a keen eye for detecting nonconformities. They must be able to assimilate data quickly and work under pressure, as deadlines are tight and assignments may be made on short notice. It's not an easy job to point out deficiencies related to the work of others, so QA auditors cannot be adverse to conflict. The best QA auditors know how to apply standards and are able to promote compliance in a positive manner. This is not an entry-level job; it requires significant levels of professional experience (most commonly as CRAs or project managers), a stable character, and the ability to detect systematic errors and provide advice for improvements.

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Project managers, of course, are charged with the responsibility of delivering projects on time and within scope and budget. Project managers are typically "big picture" people who need to focus on the overall program. Depending on the type of organization, some project managers are involved in managing the day-to-day activities and others rely on functional area managers and lead staff to focus on the details. They must be able to put their experience to work with competence and creativity, especially when working with virtual or remote teams, which calls for a healthy blend of leadership and communication skills. A good project manager requires exceptional organization skills, a holistic approach, and the ability to integrate information quickly and synthesize new ideas into project course corrections and performance improvements.

Collaboration is Key

The clinical research industry is global in its reach. The majority of clinical trials are conducted on an international scale, because the diseases and conditions the investigational products aim to treat occur globally. As such, managing people and dealing with different personalities and cultural backgrounds are important when working in international teams that are usually comprised of members from different countries, cultures, and ethnic backgrounds. Misunderstandings or neglect of diversity and differences will most likely lead to conflicts and suboptimal performance.

People from different regions of the world express themselves in different ways. For example, Southern Europeans and Asians usually communicate with a lot of words; they tend to send information in a more implicit way and try to avoid addressing topics directly. Saying simply "Yes" or "No" is regarded as impolite, because they wish to express their opinions and create understanding for them. Northern Europeans, such as Germans, are known for being direct communicators, as they prefer to express themselves in a very simple, fast, and efficient way; this is often perceived by members of other cultures as being rude. In some cultures, you will never hear "No," and hearing "Yes" does not automatically translate into agreement; it often just means "I hear you, but I do not agree with you." Other cultures like to have the same discussion repeatedly, even after a decision has been made (e.g., business negotiations in India). Of course, this not a complete list of cultural peculiarities, and these are, admittedly, generalizations intended to increase awareness.

Advice to Job Seekers

Finding the right job is not an easy task. Besides location, salary, and one's own personality and characteristics, many aspects inherent to the potential employer are important influencing factors. Smaller companies often offer jobs with a broader range of responsibilities, as they prefer employees who can multitask, work well under pressure, and switch roles quickly in order to contribute wherever needed. In such settings, "DIY" (do it yourself) must be a key capability, and you will need to learn and train yourself continuously.

Do you want to be part of building a business process? Are you willing to take risks and not be disheartened by failure; rather, you're able to jump back in and start over? Then working in the biotech environment might be right for you.

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If you want to see a product progress from the earliest stages of clinical development through to commercialization, consider working in the medical device field. Product development timelines are typically shorter than with pharmaceuticals, and you might be able to grow an entire product pipeline, market, and sell it during your professional career. Furthermore, if you see increasing regulatory requirements and shifting expectations as an opportunity, then the medical device arena may be an ideal fit.

Meanwhile, the pharmaceutical industry has faced many changes in recent years, and there is a broad range from small to large companies with varying

levels of infrastructure and bureaucracy. There are a variety of potential jobs, and having a "pharma" background is often seen as a good and solid brick in one's professional career pathway. As most of these companies develop global products, international business activities can be viewed as a further benefit.

All researchers share the responsibility of protecting human subjects. Everyone must be committed to compliance with GCP and openly embrace opportunities for process improvement.

Conclusion: Global Similarities Outweigh the Differences

No matter where the work is done or what the job is, there are commonalities in the clinical research enterprise that outweigh any and all differences that may exist within its various roles. Most importantly, all researchers share the responsibility of protecting human subjects. Everyone must be committed to compliance with GCP and openly embrace opportunities for process improvement. All must work with integrity and in accord with high ethical standards, and that is why calling someone in this profession "compulsive" is a compliment.

Clinical research is a people business; therefore, good working relationships are essential in delivering quality service and meeting organizational objectives. It's a data-driven business, which translates to the necessity for accuracy in all work products. This is an exciting industry with many career pathways, and whether one works at a clinical investigative site, for a sponsor or contract research organization, or in any other field related to the clinical development of medical products, all clinical researchers must be dedicated to excellence with regard to every aspect of their work. **ACRP**

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