

## Clinical Researcher

March 2021

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PEER REVIEWED

## **Are Clinical Research Coordinators Recognized as Professionals?**

Erika Stevens, MA; Liz Wool, RN, BSN, FACRP, CCRA, CMT



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.

This article identifies the gaps in industry recognition and classification practices for CRCs.

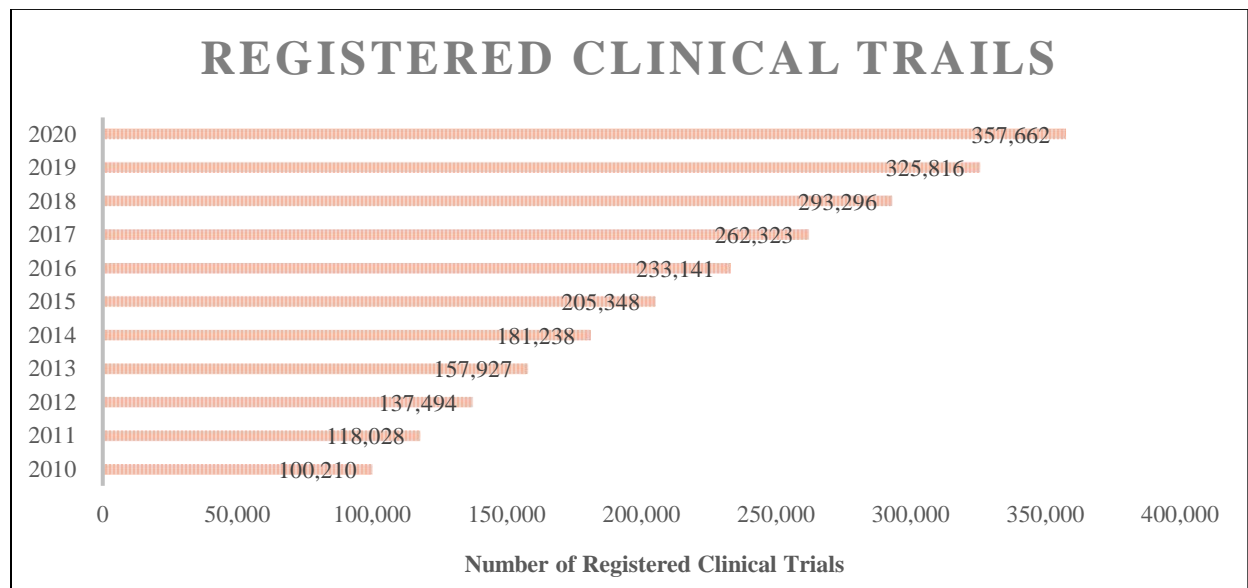
Understanding national demographic benchmark trends among CRCs and clearly defining position expectations will provide insight into the professionalization of the CRC position. The ability to establish a clearly defined career roadmap for the CRC—one based on a thorough understanding of the role's salient competencies—better enables job performance and provides opportunities for career advancement and credentials to those in the profession.

## Background

The CRC (also referred to as clinical trial administrator, research coordinator, 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. {1}

Although the field of clinical research continues to grow in the U.S., with the number of clinical trials having more than doubled in the past 10 years {2} (see Figure 1), much of the workforce supporting this growth remains unrecognized by the Bureau of Labor Statistics (BLS). {3}

**Figure 1: Registered Trials on ClinicalTrials.gov, 2010–2020 (as of November 12, 2020)**



While absent data on CRCs, BLS published an article on occupations in biotechnology referencing CRCs, describing their primary functions as recruiting and screening patients who try new treatments and monitoring and reporting on patient progress. {4} As of 2019, medical scientists and clinical laboratory technologists/technicians are recognized and tracked in the annual occupational outlook handbook from the BLS, but absent still is a CRC listing. Medical scientists are defined as those who “conduct research dealing with the understanding of human diseases and the improvement of human health; engage in clinical investigation, research and development (R&D), or other related activities.” {5} Meanwhile, research managers, research

analysts, and survey researchers make the list, but their definitions do not address the competencies required for the role of the CRC.

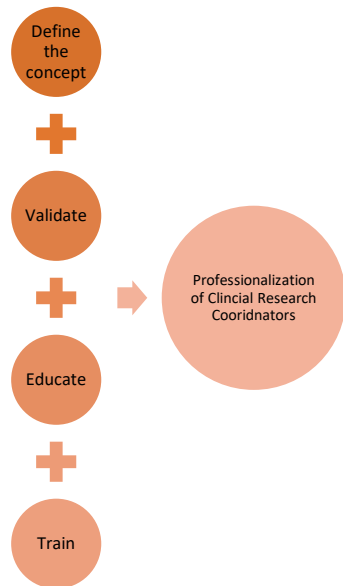
Arguably, understanding human diseases, improving health, and engaging in clinical investigation and R&D could fall under the purview of the CRC. While the BLS does not recognize CRCs, various membership-based organizations recognize clinical research personnel within the field of clinical research. For example, [the membership](#) of the Association of Clinical Research Professionals (ACRP) includes CRC as the largest specialty role represented in its ranks. Still, how does the occupation of the CRC become one that is recognized officially as a profession by regulatory authorities and other levels of government?

### **In Search of Professional Recognition**

The first of four steps (see Figure 2) is to define the concept by aligning similar organizations into a common industry. Webster defines industry as, “manufacturing activity as a whole and [an activity] that employs a large personnel and capital especially in manufacturing.”<sup>{6}</sup> Similarly, the BLS defines industry as “a group of establishments that produce similar products or provide similar services.”<sup>{7}</sup> In this case, aligned organizations participating in clinical research would be classified as functioning within the clinical research industry.

Broadly defined, those who “engage in clinical investigation and R&D, or other related activities” are part of the clinical research industry—this includes executives, staff, and vendors tied to sponsors of studies (from pharmaceutical, medical device, biotech, and biologics firms, independent principal investigators acting as sponsors, patient recruitment specialists, contract research organizations [CROs], etc.), personnel at study sites (based in private healthcare practices, academic medical centers, health systems/hospital networks, site management organizations, etc.), and relevant employees in regulatory bodies (e.g., the U.S. Food and Drug Administration, Office for Human Research Protections, Centers for Medicare and Medicaid Services, etc.).

**Figure 2: Steps for the Professionalization of CRCs**



Thus, a wide swath of what may to the uninitiated seem to be only loosely related organizational occupations fall within the clinical research industry. The BLS allows for a given industry to have employees in dozens of occupations,{7} and leverages the North American Industry Classification System coding structure to group establishments together based on their primary activity and those with similar labor into 20 industry sectors.{8}

The next step in validating an occupation is to define the responsibilities directly related to the job role. In a presentation leveraging two national CRC datasets from the Clinical and Translational Science Award (CTSA) Research Coordinator Task Force, Speicher et al. present evidence of tasks well outside the original defined scope of clinical trial management.{9} Later, Speicher et al. published results of the CTSA’s CRC survey indicating the roles and responsibilities assigned to CRCs are vast and not clearly defined.{10} Many of the tasks identified in the results align with those defined by BLS as “participating in clinical research investigation.”

The defined competencies for the clinical research professional remained unclear until the Joint Task Force for Clinical Trial Competency published its competency domains for clinical research.{11} The task force outlined the knowledge and skills required throughout the clinical

research enterprise and, in May 2018, ACRP published core competency guidelines for the CRC, identifying entry-level, mid-level, and senior-level competencies and tasks. {12} Competency models solidify required knowledge and mastery of tasks within an industry, providing detailed information about job requirements and proficiency. {13} Identifying and mapping the required skillset needed to perform the expected position enables assessment and confirmation of acceptable performance for the assigned job/role.

Many industries use education as a pathway for the levels of comprehension and ability necessary to perform job-based requirements. In the same career outlook article on jobs in biotechnology, BLS recognizes most CRC jobs require a minimum of a bachelor’s degree and in some positions a master’s degree. {14} A variety of academic programs offer industry-specific diplomas or degrees specializing in the field of work, and educational opportunities to support clinical research continue to expand. The Consortium of Academic Programs in Clinical Research (CoAPCR) lists 51 clinical research academic programs. {15} Leveraging the CRC competency model criteria, educational programs can more clearly align curricula to specified job functions.

A recent snapshot of the ACRP member database shows that 43.26% of respondents to a request about educational attainment hold a bachelor’s degree as their highest level of achievement, while 43.73% have one or more graduate degrees (see Table 1). {16}

**Table 1: Reported Highest Level of Education of Responding ACRP Members in 2020**

<b>Highest Education</b>	<b>Count</b>	<b>% of Total</b>
High School Diploma	259	2.64%
Associate/Two-Year Degree	650	6.63%
Bachelor’s Degree	4,260	43.26%
Master’s Degree	3,095	31.57%
Doctorate Degree	1,192	12.16%
Paraprofessional Diploma (LVN, medical assistant, etc.)	347	3.54%
<b>Total Respondents</b>	<b>9,803</b>	<b>100%</b>

Following education, the pathway to professionalization often requires certification, licensing, or credentialing. Certification supports the mastery of a specific skillset that is aligned to the job. “A certification is a credential that you earn to show that you have specific skills or knowledge. They are usually tied to an occupation, technology, or industry. Certifications are usually offered by a professional organization or a company that specializes in a particular field or technology.”{17}

Professions requiring certifications/licensing are arrayed across many industries. In 2018, more than 48 million people reported that they hold an occupational license or certification.{ 18} While some employers require certification for clinical research positions, certification is not mandated throughout the industry. Still, data support increased trial performance with certification.{ 19}

Haeusler’s analysis of four retrospective multicentered trials combined ACRP’s principal investigator certification (CPI) and CRC certification (CCRC) as evidence of Good Clinical Practice training and reported significantly fewer protocol deviations among those certified.{20} Nearly 10 years later, Hodges and Akroyd’s study reported fewer protocol deviations among CPIs and suggested a requirement for principal investigator certification may improve data quality in clinical research.{21} Further, in a 2018 Drug Information Association meeting, Tufts, ACRP, and the WIRB-Copernicus Group presented data analyzing 7,000 active CRCs, finding those with ACRP certification have fewer protocol deviations compared to their non-certified peers.{22}

While the evidence supports improved clinical research performance with certification, we reiterate that neither the clinical research industry nor its regulators currently require certification. At any rate, ACRP’s exam-based CCRC program is accredited and has produced more than 20,500 certificants in its 28-year history.

Arguably, certification supports the pathway to professionalization for CRCs by virtue of being a data-validated measurement of CRC capability. An Association for Clinical and Translational Science assessment of training for CRCs identifies a gap in certification and recommends a

formal assessment.{23} In a recent review of the literature, Bocchino et al. suggest that a blending of competency and performance outcomes may be required for assessing job performance.{24}

The roadmap to attain a BLS ranking for the CRC is well defined, and the research industry has collaborative work to do to achieve the goal of having the CRC recognized as a profession. Detailed in Table 2 are the requirements to be recognized as a profession by BLS.

**Table 2: BLS Requirements and Clinical Trials Industry Status**

<b>BLS Requirement</b>	<b>Status in Industry</b>	<b>Explanation</b>
Pay	Not uniform in the industry.  Data available from ACRP.	Median data for wage and salary workers. Includes the top 10% and bottom 10% of the workers in the occupation.
Typical Entry-Level Education	Not uniform in the industry.	What is required to enter the workforce for occupation.
Work Experience in Related Occupation	Not uniform in the industry.	Transferrable knowledge and skills. Common substitutes for formal types of training or education.
Other Experience	Not uniform in the industry.	Experience in volunteering or while in school that can aid in attaining the job.
Important Qualities	Not uniform in the industry.	Skills, aptitudes, and personal characteristics.
Certification, Licenses, Registrations	Not required to get a job as a CRC.	Are any of these needed for the occupation. If it is needed, how does the worker attain?
Work Environment and Workforce Schedules	Not uniform in the industry.	Working conditions, typical workplace, level of physical activity, working hours.
Work Performed	Detailed job descriptions are not uniform in the industry publication by Speicher et al.{10}	Responsibilities, duties, and tasks; who the CRC interacts with; and frequent technology used.



BLS Requirement	Status in Industry	Explanation
Training and On-the-Job Training Needed to Attain Competency	Not uniform in the industry.	<p>Post-employment classroom and on-the-job training needed for the occupation.</p> <p>Internships and apprenticeships are addressed in this section for job training.</p> <p>Competencies published by ACRP, Society of Clinical Research Associates (SoCRA), and Multi-Regional Clinical Trials Center of Harvard.</p>
Advancement	Not uniform in the industry.	What is required for advancement in the occupation (e.g., certification, formal education). Also, opportunities for advancement can come from within an organization (becoming a manager or supervisor, for example).
Number of Jobs	Needs to be compiled from various sources.	Employment, or size, of the occupation in the based year of the employment projections.
Job Outlook	Needs to be compiled from various sources.	<p>Projected percentage change over a decade.</p> <p>Job prospects for people to enter the occupation with information about how easy or hard it is to enter the occupation.</p>
Employment Change	Needs to be compiled from various sources.	Projected numeric change in employment over a decade.
State and Area Data	Needs to be compiled from various sources.	Sources for employment, wages, and projections data by state and area.

BLS Requirement	Status in Industry	Explanation
Similar Occupations	Needs to be compiled from various sources.	Does another occupation have similar job duties or similar required skills?
More Information	Needs to be compiled from various sources.	Provides links to associations, organizations, and other institutions that provides readers with additional information.

In order to define each of these areas in a uniform manner to be recognized as a profession by the BLS, the research industry needs to form a CRC Professionalization Workforce Alliance comprised of various professional associations (e.g., ACRP, SoCRA, Society for Clinical Research Sites) and sites (e.g., government, non-government, networks, etc.). This alliance would agree upon, promote, and implement the BLS requirements in order to demonstrate standardization of the CRC role in the research industry. This requires our industry to break down the “silos”—each stakeholder’s niche in the industry—for the greater good of having our CRCs recognized as professionals. This alliance would also provide the future framework and approach for the industry to collaborate on the professionalization of other roles, such as the site monitor/clinical research associate.

**Summary**

The clinical research industry is well positioned to align sites, sponsors, CROs, and other organizations supporting clinical research to clearly develop the roadmap for the professionalization of the CRC role. Leveraging the work of the Joint Task Force for Clinical Trial Competency and ACRP’s CRC core competencies defines the occupation. Industry-specific education and training provide the foundation for meeting the tasks assigned to the CRC role. Quantifying competency and confirming comprehension are garnered through assessment. The professionalization of CRCs relies on the culmination of these steps as referenced in Figure 2. As an industry, we are well positioned to implement the necessary training and to confirm the comprehension of defined competencies that will be the catalyst for eventual BLS classification and recognition of CRCs as professionals.

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PEER REVIEWED

## **When the Phases are Exhausted**

Preethi Sriram, DHSc, MSN, BSN



The approval process for new drugs in the United States is designed to be rigorous, and the U.S. Food and Drug Administration (FDA) provides oversight and monitoring of the overall process through regulations and guidelines in order to ensure that new products are both safe and effective once made available to the general public. In order to accomplish this, the FDA requires those developing new drug products to conduct safety and efficacy studies in an exact manner. { 1 }

After preclinical studies are conducted, the different phases of clinical trials in human subjects are Phase I, II, and III before any approval and marketing of a new drug product, followed by the possibility of Phase IV postmarketing studies.

Portney and Watkins {2} describe the preclinical phase as happening in laboratory settings, often in animal models, before a drug is tested in humans. Phase I is described as when researchers start experimentations in humans to collect data on the dosage, timing, and side effects of the drug, and is usually conducted on a sample set of subjects that range from 20 to 80 participants who may be healthy or, as is often the case for oncology drugs, may have the indication of interest. Phase II comes next in a larger set of participants who are always patients if the therapy has been shown to be safe in Phase I, and this is when the drug is studied to demonstrate its efficacy. Phase III studies are randomized, double-blinded experiments that compare the new drug with the standard of care or placebo, and these trials usually involve the largest subject populations, ranging from hundreds to even thousands of participants. Phase IV studies are

described as taking place after the drug has been approved, when the researchers may continue to investigate its effects in cases of other therapeutic indications or in different populations than those involved in the original trials.

## **Considering the Options**

When a patient with a difficult-to-treat condition is not enrolled in a clinical trial due to not meeting the criteria of the study, or when there is no trial available for his or her specific disease, it may seem that there are few options left regarding cutting-edge treatment. The remainder of this article discusses lesser-known avenues to enrollment in clinical trials, the possibilities for using repurposed drugs that are already on the market for some other condition in off-label circumstances, and details of how compassionate use or expanded access studies are managed.

### *Access to Clinical Trials*

In situations of rare diseases/terminal illnesses, it is important to know what treatment options are available for individuals apart from current standard of care, including the options within clinical trials.

Unger et al.<sup>{3}</sup> notes there are four barriers with regard to clinical trials—structural, clinical, physician, and patient barriers—expanded upon here with more detail:

- **Structural barriers** occur when a patient who would otherwise be willing to participate in a clinical trial finds that none are available for his or her condition at a particular treating institution.
- If a trial is available and the patient is assessed for eligibility but excluded due to not meeting the inclusion criteria, this is a **clinical barrier**.
- A **physician barrier** occurs if the patient would be eligible for a study but his or her physician never mentions the study, essentially taking the choice away from them.
- **Patient barriers** may include factors related to treatment preferences, transportation- and work-related challenges, income and insurance levels, family and peer pressures, religious beliefs, and other considerations.

A study by Carey et al.{4} found that the major barrier to trial participation is that potential participants are not invited to be screened for studies. Meanwhile, Duma et al.{5} conducted a review on cancer clinical trials conducted from 2003 to 2016 and found that, from the 1,012 trials reviewed, only 310 (31%) documented the ethnicities of the 55,689 total participants in those studies. It was noted by the authors that, when ethnicities were recorded, participation varied by ethnic groups and that non-Hispanic whites were more likely to be enrolled than African Americans and Hispanics. Another finding from the review was that subjects younger than 65 years of age had a higher likelihood of being enrolled than the elderly. Low recruitment was also noted amongst females compared to males. The authors note that most of the trials included in the analysis were completed between 2013 and 2017, and that the ratio of participation of minorities decreased following 2011.

It is important for both patients and providers to be aware of how to find clinical trials. One online resource on this topic{6} notes that a starting place is the website [www.clinicaltrials.gov](http://www.clinicaltrials.gov), a registry of trials maintained by the United States National Library of Medicine at the National Institutes of Health (NIH) and holding registrations from more than 329,000 trials from 209 countries. Another resource{7} providing information for where to search for cancer indications notes that the National Cancer Institute's Cancer Information Service can provide a tailored search for clinical trials, and that many of the advocacy groups that exist for specific types of cancer maintain lists of relevant clinical trials or can refer individuals to organizations or websites that match patients to trials.

A resource for patients with rare diseases{8} notes that disease advocacy organizations have medical boards and services for physician locators and/or networks for patients, all of which can help in finding healthcare professionals who are familiar with specific conditions. Further, the Genetic and Rare Diseases Information Center helps patients find advocacy groups related to their specific conditions, and the Patient Recruitment and Public Liaison Office at the NIH provides information about participating in research at NIH hospitals.

It is important for healthcare providers to be aware of such resources as these as they seek to help patients find trials for which they may be eligible. Table 1 summarizes various resources that both providers and patients can utilize.

**Table 1: Resources for Patient and Providers Who Are in Search of Trials**

Source	Website/Contact	Summary
ClinicalTrials.gov	<a href="https://www.clinicaltrials.gov/">https://www.clinicaltrials.gov/</a>	A database of privately and publicly funded studies conducted around the world.
National Cancer Institute (NCI) Cancer Information Service	<a href="https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cancer-information-service">https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cancer-information-service</a> 1-800-4-CANCER (1-800-422-6237)	This is NCI’s link to the public for interpreting and explaining research findings in a clear and understandable manner, and for providing personalized responses to specific questions about cancer.
National Organization for Rare Disorders (NORD)	<a href="https://rarediseases.org/for-patients-and-families/connect-others/find-patient-organization/">https://rarediseases.org/for-patients-and-families/connect-others/find-patient-organization/</a>	Lists free resources for patients and families affected by rare diseases. Organizations interested in being listed should contact <a href="mailto:membership@rarediseases.org">membership@rarediseases.org</a> .
RareConnect	<a href="https://www.rareconnect.org/en/communities">https://www.rareconnect.org/en/communities</a>	RareConnect responds to rare disease patients’ need for information and connection by creating international online communities and discussion groups for specific diseases.
FDA.gov For Physicians: How to Request Single Patient Expanded Access (Compassionate Use)	<a href="https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use">https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use</a>	When a physician wants to submit a Single Patient Expanded Access request to obtain an unapproved investigational drug for an individual patient, he or she must first ensure that the manufacturer is willing to provide the investigational drug for expanded access use. If the manufacturer agrees to provide the drug, the physician should follow



		the steps given to submit an Investigational New Drug application to the FDA.
Genetic and Rare Diseases (GARD) Information Center	<a href="https://rarediseases.info.nih.gov/diseases">https://rarediseases.info.nih.gov/diseases</a>	GARD maintains a list of rare diseases and related terms to help people find reliable information.
National Institutes of Health (NIH) Patient Recruitment and Public Liaison Office	<a href="https://clinicalcenter.nih.gov/participate1.html">https://clinicalcenter.nih.gov/participate1.html</a> 1-800-411-1222	Professional nurses answer questions and provide information regarding the NIH Clinical Center's clinical trials and associated topics. Both the general public and practicing physicians may ask for details on specific research studies and the criteria for patient referral.
Expanded Access for Medical Devices	<a href="https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices">https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices</a>	This page is intended to help healthcare providers and device manufacturers learn about expanded access options for medical devices and associated criteria and requirements for each.

### *Repurposing of Drugs for Off-Label Use in Clinical Settings*

Fajgenbaum and Rader{9} note that repurposing drugs is faster and far more economical than starting development of a new drug from inception, as many targets for drugs are shared across different diseases. The authors also note that historically, there have been many notable success cases for drug repurposing, for instance sirolimus for lymphangiomyomatosis.

In another publication, Fajgenbaum et al.{10} note that the COVID-19 pandemic is the largest pandemic that has been seen in decades, yet in its early days there were no specific, FDA-

approved drugs for use in COVID-19 patients. The authors provide a systematic review of numerous off-label treatments for possible use against COVID-19.

Further, in his book, *Chasing My Cure: A Doctor's Race to Turn Hope Into Action*,<sup>{11}</sup> Fajgenbaum describes how an uncle of his was diagnosed with metastatic angiosarcoma. When asked if a sample of the tumor could undergo genetic testing, the healthcare provider declined, saying that such testing, in the opinion of the doctor, would only impact treatment selection in 10% of the population. The author delved deeper and requested that a PDL-1 test be performed, and if the test was positive, that the doctor consider treating his uncle with an FDA-approved PD-L1 inhibitor or its receptor. The provider's response was that, even if the test was positive, the drug most likely would not work and would be expensive. In the uncle's course of getting a second opinion, an oncologist performed a genetic test that found the cancer cells were positive for PD-L1. The author's uncle was prescribed one of two already FDA-approved drugs for lung cancer and melanoma. After starting the drug, the uncle showed dramatic improvement in his symptoms, laboratory abnormalities, and tumors. Faigenbaum notes the particular case of his uncle receiving the drug has led to other off-label use of it, as well as to new clinical trials for the drug and drugs similar to it.

In many life-or-death situations, patient advocacy can benefit patients who do not have medical or healthcare backgrounds by helping them to conduct self-study on their therapeutic indications. It can also help them to seek guidance from trusted healthcare workers, or someone who is knowledgeable about their disease state, who can advocate for them regarding off-label use of a drug that is already on the market.

#### *Compassionate Use/Expanded Access*

In a memoir, *The Perfect Predator: A Scientist's Race to Save Her Husband from a Deadly Superbug*,<sup>{12}</sup> an American husband-wife couple writes about how the husband had become sick when vacationing in Egypt and was taken to a local hospital for potential treatment. From there, he was flown to a hospital in Germany, where a pseudocyst was discovered growing on his pancreas which had a bacterial strain of *A. baumannii* that is resistant to antibiotic treatment. He was flown back to America for further treatment and care, and his wife learned from her research

on the condition that certain viruses known as phages could be of use in such conditions. In an interview conducted by Corbyn,{ 13} the authors describe how phages were first discovered in 1917 by Felix d'Herelle, but he unfortunately had an arduous time getting the work accepted because he lacked formal medical training and was considered a “vagabond scholar.”

The authors also describe in the interview with Corbyn that, after penicillin came to the market in the 1940s, phage therapy largely fell out of sight in the West during the Cold War but continued in Russia. While conducting this research, the wife, who is a colleague and friend of the chief of infectious diseases at UCSD School of Medicine, shared her findings with him, and he agreed that if she were able to find phages that matched the bacterial infection for her husband, he would contact the FDA and get approval for compassionate use of the experimental therapy. With help from a researcher from Texas A&M University, a phage was found that could be used against *A. baumannii*. The wife was also able to access another phage cocktail from the U.S. Navy, which was the treatment that ultimately worked in her husband’s case.

While this example is heartening and shows a successful pathway taken in an extreme situation, it is important to realize that not everyone may actually get the off-label drug required for their condition in the same manner. For example, Rangarajan{ 14} describes having a daughter with a lysosomal storage disorder and how her physician followed the protocol of the pharmaceutical firm Shire for applying for compassionate use of one of its products in her case. The drug was already being tested in clinical trials, but the daughter was not eligible for them, and the company denied the request. The author notes that while there is, in theory, a “right to try” policy allowing those who are critically ill to go directly to the company and bypass the FDA, there is nothing forcing the company to take positive action in any particular case.

For the case of the patient or family advocating for expanded use, it is important to work with experts in the field and doctors who are willing to help in seeking FDA approval for trials or help in managing a pharmaceutical company’s appeals process (see Table 1).

### *Devices vs. Investigational New Drugs*

While the examples referenced so far have related to clinical trials of drugs and their off-label uses, similar concepts can be applied with regard to medical devices. Information from the

FDA.gov website{15} notes that expanded access is a potential option for patients with serious or life-threatening indications to gain access to medical devices that have not been approved for treatment outside research studies—assuming there are no comparable or reliable alternative therapy options available. The three options noted by the FDA outside clinical trials include emergency use, compassionate use, and treatment Investigational Device Exemption (IDE). It is noted that, while emergency use of an investigational device does not require FDA approval, compassionate use and treatment IDE do; all three require follow-up reports as well to the FDA (see Table 1).

### *Seeking Second Opinions*

Katella{16} notes that Yale Medicine doctors often see patients who would like to obtain second opinions on their conditions but worry about insulting their primary doctors. Noting that truly professional doctors are not offended by such desires and that second opinions may be important in some cases—for example, in complex disease situations or when the treatment plan is unclear—Katella adds that the process can include getting a referral from the current doctor and determining if insurance will cover the cost. Further it is important to gather documentation on the patient’s relevant medical history and the original doctor’s reports to be shared with any secondary healthcare providers being consulted.

### **Conclusion**

Clinical trials should be accessible by all people, regardless of racial/ethnic background, age, or gender; however, we can see from literature this is not always the case, especially for those who are racial/ethnic minorities, elderly, and females. In cases when patients are faced with rare diseases/terminal illness, it is important that the healthcare provider help the patient and his or her family seek potential options for appropriate clinical trials. If the patient is not eligible for a trial, or in situations when there is no trial that is available, the patient and family could conduct research into the therapeutic indication and seek expert consultation for potentially using drugs that are already available on the market for off-label use.

Table 1 summarizes resources that can be utilized in searching for trials and seeking further guidance for individual patients and their healthcare providers. In certain scenarios, the patient

can also look into potential options for trying to enroll in compassionate use studies of experimental drugs or devices through FDA approval or allowance by the company testing the product.

There are benefits and limitations to each of the options described in this article, and it is important for the patient and family to work alongside their healthcare provider in order to determine the next best steps for patient treatment and care.

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**CLINICAL RESEARCHER**  
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**HOME STUDY**

**Article 1: Are Clinical Research Coordinators Recognized as Professionals?**

<https://acrpnet.org/2021/03/17/are-clinical-research-coordinators-recognized-as-professionals/>

DISCLOSURE

Erika Stevens, MA; Liz Wool, RN, BSN, FACRP, CCRA, CMT: *Nothing to disclose*

LEARNING OBJECTIVE

After reading this article, the participant should be able to summarize the status of and challenges to the clinical research coordinator role in terms of its perceived professionalism, and to describe a path forward for improving upon the situation.

**1. Clearly defining the role of a clinical research coordinator (CRC) in terms of competencies does which of the following?**

- a. Ensures a fixed salary, mandates a path toward professional licensure, and guarantees regular promotions within the organization.
- b. Provides opportunities for career advancement, bolsters efforts to obtain professional credentials, and better enables job performance.
- c. Helps principal investigators eliminate redundant staff positions, increases patient recruitment rates, and convinces sponsors to raise study budgets.
- d. Prevents job seekers from becoming study monitors too quickly, helps regulatory inspectors focus on training issues, and decreases insurance risks.

**2. How is the CRC role defined in the ICH Good Clinical Practice E6 guideline?**

- a. As primarily functioning to recruit subjects.
- b. The role is not described in the guideline.
- c. As pending definition in the forthcoming ICH E6(R3).
- d. The role is described at length in an addendum.

**3. As of 2019, which roles are noted in the article as being tracked in the annual occupational handbook from the Bureau of Labor Statistics?**

- a. Medical scientist and clinical laboratory technologist/technician.
- b. Clinical research coordinator and ethics compliance officer.
- c. Quality assurance and quality control professionals.
- d. Trial master file keeper and informed consent conductor.

**4. Which specialty role does ACRP describe as being the largest in its membership ranks?**

- a. Principal investigator
- b. Project manager
- c. Clinical research coordinator
- d. Clinical research associate

**5. According to the authors, what are the four steps required for the professionalization of CRCs?**

- a. 4-year College Degree, Entry-Level Training, Certification, Maintenance
- b. Data Collection, Petitioning the BLS, Federal Review, Full Recognition
- c. Outreach, Collaboration, Unionization, Licensure
- d. Define the Concept, Validate, Educate, Train

**6. Validation of an occupation serves which purpose?**

- a. Ensures that there is a certification process for the job role.
- b. Defines the responsibilities directly related to the job role.
- c. Defines who qualifies for a particular job role based on education.
- d. Signals to regulatory authorities that the role holder is competent.

**7. In 2018, ACRP published core competency guidelines for CRCs. Which of the following is noted as a benefit of having such guidelines?**

- a. Clears path for expected recognition of CRCs as professionals by 2030.
- b. Mandates performance expectations for CRCs at research sites/institutions.
- c. Enables assessment and confirmation of salary levels for the assigned role.
- d. Identifies and maps the required skillset needed to perform the role.

**8. For what reason does certification support the pathway to professionalization for CRCs?**

- a. Allows CRCs to demand higher wages and compensation packages.
- b. Levels the competitive field for CRCs seeking to move to other countries.
- c. Demonstrates a data-validated measurement of a CRC's capability.
- d. Guarantees adequate job knowledge for working at any research site.

**9. Haeusler's analysis of four retrospective multicenter trials showed what outcome when principal investigators and clinical research coordinators were certified?**

- a. There were significantly less protocol deviations.
- b. There were significantly more protocol deviations.
- c. The same number of deviations occurred across all investigators.
- d. Protocol deviations were confined to non-certified staff.



**10. In ACRP's history, how many CRCs have been certified?**

- a. Less than 15,000.
- b. More than 20,500.
- c. About 25,000.
- d. More than 30,500.

**Article 2: When the Phases are Exhausted**

<https://acrpnnet.org/2021/03/17/when-the-phases-are-exhausted/>

DISCLOSURE

Preethi Sriram, DHSc, MSN, BSN: *Nothing to disclose*

LEARNING OBJECTIVE

After reading this article, the participant should be able to outline potential options for gaining access to experimental treatments when normal enrollment in a clinical trial is not feasible, and to differentiate between different types of barriers to involvement in trials.

**11. What types of clinical trials need to be completed before a new drug product can be approved and marketed?**

- a. Phase I and II only.
- b. Phase II and III only.
- c. Phase I, II, and III.
- d. Phase I, II, III, and IV.

**12. What is one reason for conducting Phase I studies?**

- a. To collect data on dosing patients currently taking other medications.
- b. To look for side effects of the drug when dealing with cardiac patients.
- c. To evaluate the study drug versus standard of care for a specific condition.
- d. To collect data from healthy participants on dosage, timing, and side effects.

**13. Which of the following is a structural barrier with regard to clinical trials?**

- a. When a clinical trial is not being conducted at the patient's hospital or doctor of choice.
- b. When a patient is unwilling to work with the doctor running the clinical trial.
- c. When the patient insists on receiving active treatment instead of a possible placebo.
- d. When a clinical trial has finished enrollment before the patient can be screened.

**14. A patient who would like to participate in a clinical trial but does not or cannot because of their work hours as well as the fact that their last A1C value was above the study's allowable range would be experiencing which of the following barriers?**

- a. Structural and Clinical
- b. Clinical and Physician
- c. Clinical and Patient
- d. Structural and Patient

**15. Which of the following findings was noted in the cited article of cancer clinical trials conducted from 2003 to 2016 by Duma et al.?**

- a. More than half of the studies reported the ethnicity of their participants and most studies recruited predominantly female participants.
- b. The number of participants younger and older than 65 years of age was roughly the same as the number of female vs. male participants.
- c. Cancer clinical trials recruited primary African Americans and Hispanics who were more than 65 years of age.
- d. Less than a third of the studies reported on the ethnicities of their participants and the ratio of participation of minorities decreased in more recent years.

**16. The article notes which of the following as a resource for patients and providers in search of clinical trials?**

- a. Public Responsibility in Medicine and Research
- b. National Organization for Rare Disorders
- c. Office for Human Research Protections
- d. European Medicines Agency

**17. Why are drugs sometimes repurposed?**

- a. It can be faster and more economical than starting over with a new drug in the development stage.
- b. Regulatory agencies may prefer that fewer treatments be in development at one time for less common conditions.
- c. Some primary care doctors aren't knowledgeable about all the uses some newer drugs have so they "repurpose" older ones.
- d. Repurposing drugs is the only ethical way to discover treatments for most forms of rare diseases.

**18. "Compassionate use" refers to which of the following?**

- a. A law that compels a company to bypass the U.S. Food and Drug Administration (FDA) if a qualified doctor petitions the company to allow a critically ill patient to use its drug.
- b. Approval gained through the FDA for use of an experimental drug, typically with the help of an expert in the field and/or doctors willing help work with the pharmaceutical company's appeals process.
- c. Giving experimental treatments to sick animals that have not gone through all the necessary clinical testing for the drugs to gain approval for use in humans yet.
- d. A situation in which patients are allowed to use an investigational drug even though the condition they have is not the same as what the drug is being developed for.

**19. What are the differences between medical devices and investigational drugs in regard to off-label use?**

- a. Drugs are regulated by the FDA while medical devices are not when used off-label.
- b. Off-label use of a medical device cannot be done in a life-threatening situation/indication.
- c. Emergency use of an investigational medical device does not require FDA approval, but compassionate and treatment Investigational Device Exemptions do.
- d. Off-label medical devices must be used in conjunction with an on-label investigational drug under the supervision of representatives from the sponsors involved.

**20. The author notes which of the following about patients seeking second opinions?**

- a. They should only ever seek second opinions from someone their physician approves.
- b. They should find experts online who can diagnose them and prescribe lower cost treatments.
- c. They should always trust that the only opinion they need is their primary physician's.
- d. They should not worry that a professional doctor will be offended by this desire.