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Review Article

Clinical research education: a mini-review of the available opportunities for future and current clinical trial managers

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ABSTRACT

Various for-profit as well as not-for-profit organizations offer educational opportunities for project managers. Often, these are generic (not industry-specific) as the goal is to attract a wide audience of students. Examples include Six Sigma and the Project Management Professional ® program. Although students may be granted an opportunity to research their own industry as part of the curriculum, these programs generally do not focus on clinical research project management skills in particular. Therefore, it can be difficult for Clinical study managers/clinical project managers, and others within the clinical research field, to find appropriate training opportunities. This aim of the study was to provide valuable information on some of the primary available educational opportunities that exist for those entering the clinical research management workforce, or who are otherwise interested in expanding their knowledge in this field.

Keywords: Education, Six sigma, Agile, Trials, Management, Credentials

INTRODUCTION

Academic clinical research education programs

Students who choose to advance their clinical research knowledge via academic opportunities can opt for clinical-research specific degree programs. These programs often teach students about the managerial side of clinical research, e.g., cost-effective analysis and data management, but also place a strong emphasis on biostatistics, epidemiology and translational medicine. Many top-level universities including the Harvard Medical School and the London School of Hygiene and Tropical Medicine offer clinical research degree-conferring programs.[1]

Kapoor, Wu and banks researched whether these programs are valuable in terms of initiating a successful career as a clinical investigator. They conducted a retrospective study of 25 people who had completed the Master of Clinical Research program and the Clinical Research Fellowship at Harvard School of Public Health/Brigham and Women's Hospital in Boston, Massachusetts. They measured success by exploring how many of the fellows received research funding to conduct a clinical trial within 3 years of completing the program. The authors concluded that "formal clinical research training culminating in an MPH degree during fellowship was extremely valuable in helping fellows initiate a career in clinical research".[3]

The significant limitation to their publication is that it does not speak to the success of the trials that were conducted by the former students. Instead, it only makes the case that a graduate degree in clinical research promotes the professional interests of those seeking to endeavor on a career in clinical research. Strom et al. made a similar observation concerning the Master of Science in Clinical Epidemiology program, which they described as 'a model for clinical research training' and whose past participants often obtained careers in academic medicine.[4] In the US, the Accreditation Council for Graduate Medical Education requires postgraduate medical residency programs to teach physicians about the scientific inquiry process, specifically

'how research is designed, conducted, evaluated, explained to patients, and applied to patient care'.[3,5] However, the council does not provide coursework or specific guidance for how this should be accomplished. Instead, each medical school program must make its own determination as to how much emphasis it wants to place on clinical research vs other topics.

Professional clinical research education programs

There are also a variety of non-academic clinical research-specific educational opportunities available for current and aspiring clinical researchers. In the United States clinical research industry, the best-known certificate program is the Certified Clinical Research Professional (CCRP®) program offered by the Society of Clinical Research Associates (SOCRA). The program teaches participants about GCP, ICF, Clinical Safety Data Management Definitions and standards, the principles of the Belmont Report, the DoH and other key guidelines and regulations needed to conduct clinical investigations involving humans. A lesser known but also recognized credential is the Association of Clinical Research Professionals-Certified Professional (ACRP-CP). In Europe, a similar program is offered by the European Center for Clinical Research Training. The company offers online, classroom and webinar courses on topics such as clinical operations, quality assurance, regulatory management, and other clinical research topics. Other programs include the Postgraduate Certificate in Clinical Trials offered by Parexel Academy (a branch of Paraxel International Incorporated) in Berlin, Germany and the World Medical Device Organization (WMDO) certificate program which has its European branch in Switzerland and offers online coursework with an on-site exam.

Despite the variety of academic professional programs available that teach participants about the principles of project management, and in some cases about clinical trials management in particular, there is an overall lack of knowledge concerning whether such credentials and certifications in fact lead to more effective management of clinical trials and increased success rates for clinical trials. Nonetheless, as described below, some limited available research suggests that the implementation of standardized and recognized project management principles from other industries can contribute to more effectively managed clinical research efforts.

LEAN SIX SIGMA IN CLINICAL TRIALS

Schweikhart and Dembe explored the applicability of Lean and Six Sigma techniques to clinical and translational research projects. As described by the authors, "Lean and Six Sigma are business management strategies commonly used in production industries to improve process efficiency and quality".[11] They argue that Six Sigma's transition from the production industry to, for example, health care and software development, makes the case for its implementation in the clinical research industry as well. Six Sigma can do so in the context of clinical trials by improving the quality of the various deliverables that constitute a clinical trial, avoiding costly delays and errors, and consequently speeding up the time it takes for company with a novel therapeutic to conclude the clinical testing phase and for that therapeutic to become a recognized treatment. In their study, Schweikhart and Dembe et al found that the principles of Six Sigma, which promote a constant review of errors at their core level (and the implementation of steps to mitigate the errors), are key to developing more efficient clinical trials that adhere to the US National Institute of Health's goal to 're-engineer the clinical research enterprise'.[1,11]

They observed various specific instances where the implementation of Six Sigma resulted in clinical trial efficiencies. Examples included a 70% reduction in the time it took for clinical data to be entered into CRFs in a phase 3 trial, without significant increases in data transcription error rates, an overall reduction in the time needed to conduct a phase 1 trial and better workflows when laboratory equipment was repositioned to be physically closer to its eventual point of use. They also noted that Six Sigma principles may be appropriate in various other tasks such as clinical trial agreement (CTA) negotiations between sites and sponsors/CROs. It is widely recognized in the industry that negotiation process is a major hurdle for the timely initiation of clinical trials; the ethics submission and approval process; and the invoice and budgeting process for study activities. Schmidt, Cummings and Richards from the University of Maryland also found that using Six Sigma resulted in more expeditious activation of clinical trials.[7] Specifically, they were able to improve the 'speed, quality and cost of study start-up', while also improving transparency.[12] Six Sigma programs are offered both online and in-person by dozens of vendors.

AGILE METHODOLOGY

Agile project management can be learned by participating in programs such as the Project Management Institute's Agile Certification. Agile project management is defined as 'an iterative and incremental approach to delivering requirements throughout the project life cycle. At the core, agile projects should exhibit central values and behaviors of trust, flexibility, empowerment and collaboration'. It was originally implemented in the software industry but has since expanded to a variety of other sectors including: healthcare, telecommunications and manufacturing. As described by Pavlović et al, the application of agile methodologies to clinical trials can help reduce costs of trials and increase the quality of the trials.[11]

Further, they argue that an agile clinical trial will more accurately foresee future study needs, cut costs, lower documentation requirements (through proper use of electronic solutions), boost creativity and lead to overall better solutions and innovations. They found that only

10% of CROs utilize agile project management methodologies when managing clinical trials.

They concluded that CROs should move away from the 'in-house best practices' approach and instead strive for agile transformations of their organizations. This is also supported by Di Fiore, West, and Segnalini. They argue that all science-driven companies involved in research and development should embrace agile methodologies. Based on their study of a US pharmaceutical company that implemented agile project management, they found that the company may be able to manage twice as many programs as before 'while also increasing the success rate of the projects'.[17] It should be noted that not all aspects of agile methodology apply to clinical research. For example, agile tends to 'value individuals and interactions over processes and tools'. As clinical research is strictly regulated by guidelines, local and national laws, CPMs must ensure that the desire to conduct trials in a flexible and agile manner does not surpass the need to place regulatory compliance at the highest level of priority.

CONCLUSION

Those interested in expanding their clinical research knowledge as it relates to project management and study execution can choose to do so via traditional academic programs, industry group-affiliated programs or via programs run by companies specializing in professional education. Academic programs offer comprehensive solutions that result in a thorough understanding of the subject matter, but they take longer to complete and tuition costs may be too high for some students. These programs are particularly valuable to those who wish to become clinical trial investigators. Industry programs such as those administered by SOCRA and ACRP are widely recognized within the clinical research field as offering a strong foundation on key clinical research topics such as quality, regulations and regulatory management. Students interested in learning how to best manage trial costs and resource allocations may be best served by training in Six Sigma and Agile methodology- both of which have been proven to increase the quality and efficiency of clinical trials.

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