



PINION:

The Role of Certification in Developing a Quality Clinical Workforce

“Quality” is a term that is thrown around at will when speaking about clinical research—we speak of quality by design, quality systems, quality endpoints, quality management plans, quality data, quality outcomes, etc. We have been talking about quality for as long as I have been involved in clinical research, and that has been for more than 20 years.

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One thing I’ve noticed in the clinical research enterprise is that we spend a lot of time focusing on quality goals, quality outcomes, and quality processes, yet we spend very little time focusing on “quality resources” and—in particular—“quality human resources.” I would like to focus our attention in this article on the importance of the “quality clinical workforce.”

As used in various situations, the word quality may convey the standard of something as measured against other things of a similar kind; the general degree of excellence of something; or a distinctive attribute or characteristic possessed by someone or something. As nebulous as these uses may be, how do we measure quality when we are speaking about the “workforce” or human resources? That is where certification comes in, as certification is a formal recognition of professionals who have demonstrated the knowledge, skills, and abilities to perform their duties by passing a certification exam based on international standards.

Further, certification is a voluntary process to recognize individuals for meeting standards in terms of their professional experience, and for achieving educational requirements before taking the exam. Certification assures the public that an individual demonstrates specific knowledge required of a practitioner at a certain level. The goal of certification is not to educate, but to provide a means by which proficiency and knowledge can be measured, hence measuring “quality.”

Why Certification?

There are some obvious benefits to an individual from becoming certified (see Figure 1). Achieving certification demonstrates that you have met or exceeded the quality standards required in the industry and have validated your competence. It furthermore demonstrates a level of professionalism and indicates a commitment to quality standards.

In essence, certification defines you as a “quality resource” in your industry. As specifically considered within the clinical research enterprise, there are many pros to certification, including how it improves the conduct and public perception of research by establishing and continually raising the levels of quality to which we are held. More pointedly, sponsor companies and study sites are able to use certification as a yardstick by which they can have their quality resources assessed and measured.

Sources of Certification

Currently, there are several organizations that offer clinical research certification. To date, the Association of Clinical Research Professionals (ACRP) is the only organization that offers role-specific certification programs (through its affiliated Academy of Clinical Research Professionals) for the clinical research coordinator (CCRC[®]), clinical research associate (CCRA[®]), and principal investigator (CPI[®])

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roles, as well as a general certified professional (ACRP-CP®) program since 2017 for anyone who does not neatly fall into the other roles.

Other organizations, such as the Society of Clinical Research Associates, offer more generic certifications covering multiple roles and functions. Many other organizations offer various types of role-specific certifications such as the Society for Clinical Data Management, the Society of Quality Assurance, the Clinical Research Society, and the Regulatory Affairs Professionals Society, to name a few.

Any respectable organization that offers certification will take the steps necessary to ensure that certain levels of quality have been achieved through their programs. Although ACRP may have led the way in the certification of clinical research professionals, there have been other organizations that have followed—not because any higher authority mandated it, but because their members asked them to.

In time, perhaps regulatory stakeholders around the world will also embrace certification as a quality measurement, and will deem that certification of anyone performing clinical research activities be required. This may be “pie in the sky” thinking, but it would go a long way toward making our study volunteers feel confident that they are being protected and are in “good hands.”

Maintenance of Certification

For those of us who have achieved certification, equally as important is the subsequent maintenance of the designation. Throughout our careers, we want to continue to demonstrate that we are meeting or exceeding the quality standards set by the industry. Maintenance can be achieved through continuing education in both research- and healthcare-related subjects, as well as through continuing involvement in clinical research activities.

Since most individuals would prefer not to have to take a certification exam over again following a lapse in their certification status, the option for continuing education and continuing involvement is the more popular one, and the benefit to the industry is the assurance that certificants are staying abreast of the latest and greatest trends and topics in clinical research. In short, maintenance of certification validates that certificants continue to demonstrate their knowledge and skills as their careers progress (see Figure 2).

FIGURE 1: REASONS BEHIND CERTIFICATION

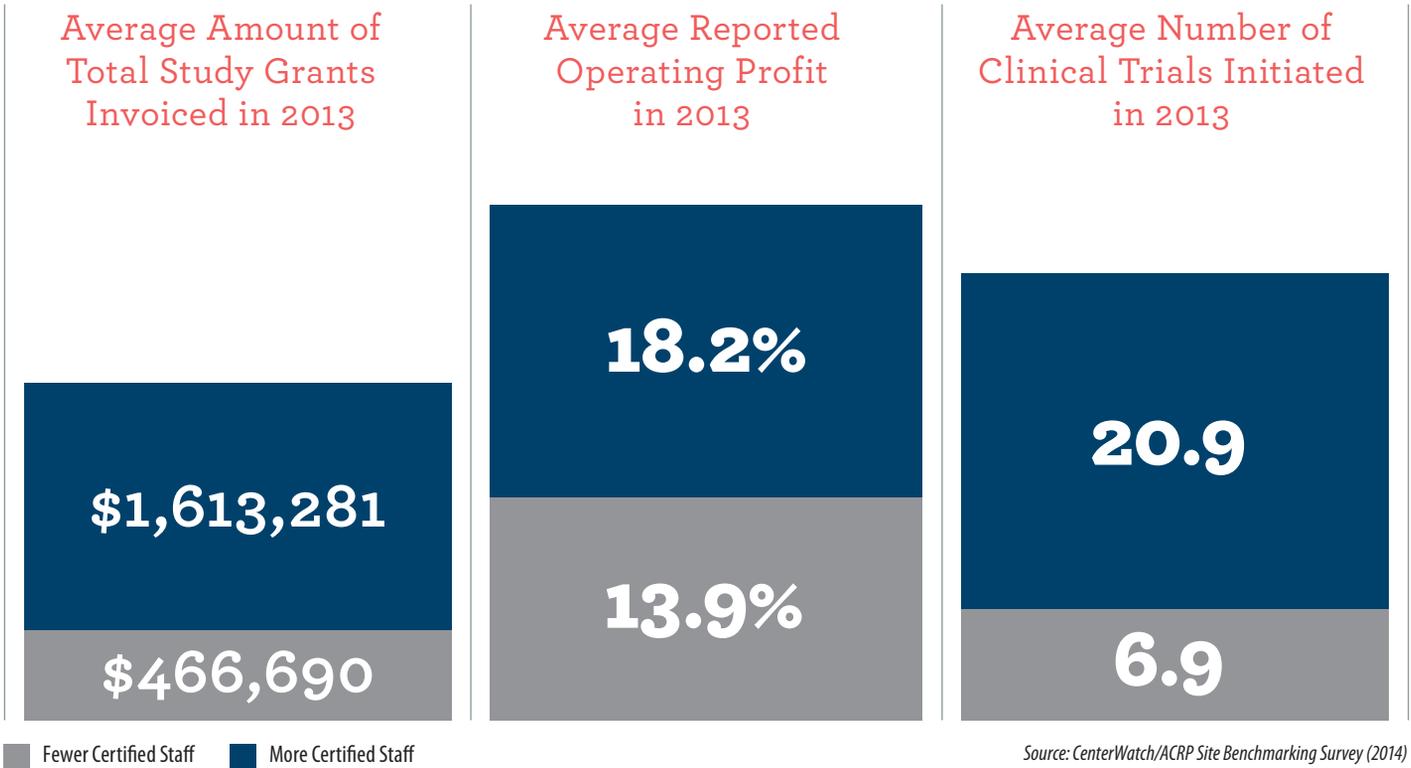


Source: Survey of ACRP Certificants (January 2013 - April 2014)

FIGURE 2: MAINTENANCE OF CERTIFICATION



FIGURE 3: INDICATORS OF CERTIFICATION'S CONTRIBUTIONS TO SITE PERFORMANCE



Source: CenterWatch/ACRP Site Benchmarking Survey (2014)

Linked to Fewer Protocol Deviations

CCRC® and CPI® certification have the potential to increase protocol adherence and improve clinical trial quality through links to fewer protocol deviations (Clinical Research and Regulatory Affairs, 2009).

Linked to More Favorable Outcomes from Regulatory Audits

A positive correlation exists between the CPI® designation and favorable outcomes (No Action Indicated) for FDA audits according to the article "CPI® Certification as Predictor of Clinical Investigators' Regulatory Compliance" (Drug Information Journal, 2012).

Other Considerations for Certification

As the clinical research industry has become more competitive, the need for its professionals to differentiate themselves from one another has become a more cogent reality. The use of credentials to demonstrate certification has become increasingly important when trying to promote one's curriculum vitae to the top of the pile.

Unfortunately, there has been some rather negative press regarding resume fraud, and one recent, controversial article cited that, out of more than 40,000 CRAs being captured by one recruitment firm, approximately 17% had falsified all or part of their resumes. As a hiring manager in the industry, I too have witnessed my share of "creative writing" when it comes to prospective applicants. This is where certification can play a role in ensuring that those applicants presenting with the credential of "certified" can be held accountable to a higher level, and employers can be assured of a standardized level of quality.

ACRP takes the use of its credentials very seriously, and has strict policies pertaining to the continued use of the "certification credential." Anyone who fails to maintain their certification must immediately stop using the credential to promote

himself or herself. In fact, misrepresentation of one's certification status through ACRP is grounds for disciplinary action through the aforementioned Academy of Clinical Research Professionals, according to its "Code of Ethics and Professional Conduct" policy.

This, once again, points to the fact that certification is formal recognition of professionals in the industry who perform at or above a certain quality standard. Prospective employers and regulatory inspectors can search a registry to ensure that anyone using the ACRP credential is actually currently certified. Falsifying credentials is a serious blemish when it comes to tarnishing one's quality reputation, and no one wants that.

Getting back to the issue of "quality," it has been demonstrated that certification through ACRP has a positive impact on clinical trial quality surrogates, such as stated at left. From the sponsor's perspective when looking at potential sites, quality plays a role. Studies have shown that having certified staff at a site leads to fewer protocol deviations and potentially increases trial adherence, and that a positive relationship can be seen between a certified PI and more favorable audit outcomes with the U.S. Food and Drug Administration (FDA).



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From a site's perspective, we can see a positive relationship between the number of certified staff and the number of study grants received, the operating profit achieved, and the number of clinical trials initiated (see Figure 3). These site performance metrics are all very important when trying to attract studies to your site; certification can therefore be seen as an investment in the professional development of a site's research personnel and the site's commitment to quality in the conduct of clinical trials. The return on investment for a site from having certified staff can be easily demonstrated.

Furthermore, certification can be used as a proxy for improved outcomes, which can be demonstrated through adherence to the protocol, compliance with the regulations, ethical practice, trial subject safety, and ultimately end-consumer safety. With respect to our quality clinical workforce, certification can be used as an acceptable method to validate that study coordinators, monitors, investigators, and other clinical research professionals have the knowledge, skills, and abilities fundamental to accomplishing their job roles.

As the arena of certification products offered through various organizations expands, there is a recognized need for more formal study of the impact on quality from the perspective of the site, the sponsor, and ultimately the patient. For now, the ship is moving in the right direction.

Conclusion

Now that we know what a quality resource is, we can measure that quality through certification. We also can demonstrate continued commitment to quality through maintenance of certification, and we are now moving to a more data-driven place whereby we can demonstrate improvements in quality through the use of "quality human resources."

Certification can be a valuable resource for a variety of stakeholders to validate that the clinical research professionals with whom they are engaging—in whatever relationship that may be (i.e., site-sponsor, sponsor-employee, site-employee, etc.)—have the knowledge, skills, and abilities fundamental to their role, and that they truly are a quality human resource and part of the "quality clinical workforce."

In a recent CenterWatch publication, ACRP Executive Director Jim Kremidas stated, "If you get your hair cut, the barber cutting your hair must have a license. In many parts of the world, if you

join a clinical trial, the study coordinator doesn't need a license or to even be credentialed." He has a very good point; does it seem right that we place so little value on quality when it comes to clinical research?

To be sure, there are certain jurisdictions around the globe where qualifications for clinical research are taken more seriously. In some countries, for example, study coordinators must hold at least a bachelor's degree, but this is not universal. Unfortunately, we have a long way to go to standardize these requirements on a global scale.

Ultimately, if we want to improve the quality of research, then industry needs to come together to make sure we have competent "quality resources" and a "quality workforce" conducting our clinical trials. There is an ever-increasing wealth of evidence as to why we need these quality human resources—among it, the fact that the equivalent of a bad haircut in clinical research can be deadly.

Resources

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