ACRP advances CRC competency-based standards

By Karyn Korieth

The **Association of Clinical Research Professionals** (ACRP) has launched a new initiative to develop competency standards for clinical research coordinators (CRCs) as part of a larger effort to advance the professionalism of the clinical research workforce.

The project will establish minimum standards regarding the knowledge and skill required for entry-level study coordinators and create a hierarchy of competencies focused on performance rather than longevity. Pathways needed for CRCs to advance their careers will be clearly defined and ACRP will develop tools to assess job proficiency, identify gaps and provide training.

Beth Harper, ACRP workforce innovation officer, said since the industry lacks standard competency-based job descriptions and training requirements or assessments for study coordinators, the quality of the workforce varies greatly. An experienced nurse might become a study coordinator at a site or, alternatively, the office receptionist might inherit the role. For ACRP, the fact that the most common **FDA** inspection findings, which include protocol deviations and informed consent issues, haven't changed for several years at investigative sites indicates a need for clearly defined and enforced core competencies.

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Implementing competency-based job descriptions could allow unexperienced study coordinators to enter the workforce by demonstrating knowledge through the completion of training courses, which could help boost the availability of a qualified talent pool, and would bolster opportunities for professional advancement. Historically, the industry has prioritized a two-year experience requirement over validated competency for CRCs and a recent study in the *Journal of Law, Medicine & Ethics* found that most open CRC positions take an average of three to six months to fill. Another report published in *Clinical and Translational Science Journal* found 41% of CRCs said they don't feel they have an opportunity for career advancement or development, which contributes to high turnover rates.

"We want to help people see that if you focus on your competencies and understand where your competence gaps are, regardless of your experience, you may be able to accelerate to a higher level much more quickly by demonstrating that you are competent," said Harper. "People could see there is an opportunity to make a career and not just leave because they were disappointed or had a bad experience."

The announcement of the CRC initiative is part of the ACRP's aim of leading the standardization of the clinical trial workforce and to support its ongoing development through competency-based education and training. In April, the organization introduced its Core Competency Framework for Clinical Study Monitors.

"We look forward to this initiative having a lasting impact on the quality and professionalism of the clinical research workforce," said Jim Kremidas, executive director of ACRP. "We hope to collaboratively equip industry with standardized measures of competence that will help reduce variance in workflow competence and assist in growing the clinical research workforce of tomorrow."

The new CRC initiative, which will be driven by the ACRP Workforce Innovation Steering Committee (WISC), will build on a set of high-level standards established by the Joint Task Force (JTF) for Clinical Trial Competency, which were developed by a multi-stakeholder group to serve as a framework for defining professional competency

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throughout the clinical research enterprise. WISC will map how competencies in the eight core domains outlined by the JTF apply to the study coordinator role at different levels. The committee plans to publish a first draft of its CRC competency framework by early next year. As organizations begin to test and implement the standards, and as technologies and processes change, the competencies are expected to continue evolving.

Membership of the WISC includes representation from a broad group of private and public stakeholders, including the **Association of Clinical Research Organizations** (ACRO), **Amgen**, **Bioclinica**, **Greater Gift Initiative**, **Medix**, **Medtronic**, **NIH**, **Pfizer**, **PPD**, **Roche** and the **U.S. Department of Veterans Affairs Office of Research and Development**.

Recognition of the need to advance the professionalization of the clinical trial workforce has grown in recent years as the industry faces difficulties filling clinical research jobs and as many in the workforce express frustration with the lack of career advancement opportunities. In addition, a recent study conducted by a recruitment agency for the clinical research industry reported that a review of CRA resumes in its database showed 17% contained false information.

Other organizations have taken steps to standardized clinical research workforce competencies in recent years. **INC Research**, which has merged with **inVentiv Health**, for example, developed a competency-based training program for entry-level CRAs that integrated training and the development of skills. **George Washington University**, where Harper is an adjunct professor, recently revamped its curriculum to align with the JTF competency framework. In another example, PPD began a CRA training program for veterans based on competency standards, which was designed to bypass standard work experience requirements.

In one of the most far-reaching initiatives, the **Duke University School of Medicine** built competency-based job descriptions for research professionals institution wide and adapted JTF core competencies into its assessments and training opportunities. Revising its job classifications—consolidating the number from 80 different classifications to 12—and building a three-tiered ladder into core classifications, allowed Duke to standardize roles and encourage professional development.

"We went about the job classification with competencies because, in my mind, that is where the industry of clinical research is going. Whether you are an academic medical center or industry, we have to get to competency-based training. We have to get to a place where people can show us they are competent in their role and it's a good fit for them. We have to stop flying by the seat of our pants and saying, 'Hopefully this person will work out.' We need to put some concrete things in place that actually demonstrate something is true, or not true, in terms of job performance," said Denise Snyder, associate dean for clinical research, Office of Clinical Research, Duke University School of Medicine. "It builds more fairness and expectations into what the job really is and what they need to be able to do."

Going forward, Harper said the industry needs to be proactive in defining competencies and adopting standards before the government creates mandates or licensure requirements for clinical research professionals.

"We want to say, as an industry, we believe in the need for standards, they will enhance the quality of the workforce and translate into improved quality in the conduct of clinical trials," said Harper. "If we don't have adequately trained and competent people, the quality issues will prevail, no matter how much technology we have."