CWWeekly
A CenterWatch Publication

Special Article Reprint • July 10, 2017

Three Questions
Jim Kremidas, ACRP

CWWeekly *presents this feature as a spotlight on issues faced by executives in clinical research. This week, writer Karyn Korieth spoke with Jim Kremidas, executive director of the Association of Clinical Research Professionals (ACRP).*

Q Why do you believe there is a need to advance the professionalism of the clinical research workforce?

A The industry is focusing on initiatives to improve the quality and efficiency of clinical research through process and technology innovation. What has been largely omitted, however, is understanding the workforce and how it drives speed and quality in today's environment.

"If we are going to improve the quality of research, we need to come together and address this issue."

Jim Kremidas, executive director, Association of Clinical Research Professionals (ACRP)

There is a lack of standardization around how people are identified to be clinical researchers, how they are hired, developed, trained and, very importantly, assessed. When we look at our study coordinator population at ACRP, for example, 17% do not have a four-year college degree. That is not necessarily good or bad, but you have people with everything from high school diplomas to Ph.Ds. doing study coordinator work. The question becomes, should they have a four-year degree? Should they have a Ph.D.? There are basic competencies, skills and attributes that an individual must have to be successful in clinical research, but there is no standard way of identifying the right requirements for clinical researchers and assessing the quality of their performance.

We need to have an industry-wide initiative, which would include sponsors, CROs, regulatory agencies and nonprofit organizations, standardize the requirements for an entry-level clinical researcher, particularly at the site level. We should also create an entry-level exam to test whether a person has the appropriate competencies, training and background. Whether it's a study coordinator, clinical research associate (CRA), principal investigator (PI), project manager or site manager, they need to understand the fundamentals of clinical research, how it is conducted, how to protect patients and how to collect data appropriately.

There are a number of initiatives underway to address this issue. The Joint Taskforce for Clinical Trial Competency, organized under the sponsorship of the Multi-Regional Clinical Trials Center at Harvard University and the Alliance for Clinical Research Excellence and Safety (ACRES), for example, brought together stakeholders and defined eight core competencies required for clinical researchers. Another workgroup, which included several sponsor companies and was led by ACRP, used the framework to map competencies for the CRA role, from entry level to advanced positions. Many organizations are now implementing those competency requirements within their companies.

Q How could establishing standards for clinical researchers help improve the workforce?

A If you look at the training programs within sponsors and CROs, there is a variance across them and no way to know who is doing a good job and who is not. At the site level, the variance is magnitudes greater. In any type of quality initiative, you find the greater the variance, the greater the probability of error. If we could set a standard methodology and competency level for clinical researchers who come into the industry, it would reduce the variance we see today and improve the quality of the workforce.

We are talking about a major paradigm shift in the clinical research space. But if you look at the problems we face with FDA inspection findings, the most common clinical investigator deficiencies cited by the FDA have remained the same, including failure to follow the investigational plan and/or regulations, protocol deviations, inadequate

Special article reprint

recordkeeping, failure to report adverse events and informed consent issues. These findings come back to a lack of standardization of training and development of our workforce.

Q Could codifying standards for clinical researchers help improve public trust in the clinical research enterprise?

A Patient safety is another key element. As we continue to spread the word to the general public about the value of clinical research, we need to know that people conducting clinical research protect patients and know what they are doing. That is not 100% the case these days. It would behoove the industry, from a perception standpoint, if patients knew that the investigator is not only a physician and the coordinator is not only a nurse, but they also have credentials to do clinical research and that they know how to make sure that participants are safe.

If you get your hair cut, the barber cutting your hair must have a license. If you join a clinical trial, the study coordinator doesn't need a license or to even be credentialed. I'm not suggesting that we need to have licenses for clinical researchers. Yet if we want to improve the quality of research, which has all kinds of benefits in terms of faster-to-market, fewer errors and better patient safety, the industry needs to come together, set something up and monitor ourselves to make sure that we have competent people conducting these activities. We do not want to have the government come in and legislate something, which could happen eventually if we are not careful.

It worries me when people say it's too big of a problem. If we are going to improve the quality of research, we need to come together and address this issue. The problem is not going to go away unless we do something about it.

CWWeekly (ISSN 1528-5731). Volume 21, Issue 27.