

## Ensuring Proper Training for Clinical Research Staff in Less Time



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*Note: The views expressed in this article are those of the author and do not necessarily represent those of the employer, GxP Lifeline, its editor or MasterControl Inc.*

There has never been a more exciting time to be involved in clinical research. We're seeing more advances in life-changing medical devices and pharmaceuticals than at any other time in history, creating a growing demand for qualified clinical research associates.

The U.S. Bureau of Labor Statistics estimates jobs for medical scientists will grow by [13 percent](#) [1] from 2012 – 2022.

It only makes sense then that clinical research professionals need continuing education to keep up with a rapidly evolving industry.

But here's the reality: *many clinical research associates spend as much as 75 percent of their time on the road.* They're so busy traveling from one site to the next that it's difficult to find the time to keep up on the latest regulations, which can directly impact a study's compliance. Additionally, clinical research sponsor organizations may be reluctant to invest in the training and development their staff needs due to high turnover and costs, and lack of time.

This raises two critical questions: **How much training is necessary for clinical research professionals, and how can sponsors find more cost-effective ways to provide it?**

Clinical research professionals often come from a variety of industries, ranging from nursing or pharmacy to biological sciences or health record maintenance. Their expertise is often heavily dependent upon what they learned while working at a previous employer.

Therefore, the training they receive is not always consistent across the industry or sufficient for the complex world of clinical research.



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*This article is related to the [Whitepaper: Clinical CAPA: Embedding Quality into Clinical Research](#). To get the full details, please [download your free copy](#).*

## What Type of Training Is Necessary?

The U. S. Food and Drug Administration and the International Conference on Harmonization have issued detailed regulations to ensure clinical research is conducted safely and thoroughly, but they do not require clinical research professionals to have specific accreditation. In fact, they are not detailed in specifying what type of training is required of whom, or when. The FDA regulations simply require that investigators and monitors are “qualified by training and experience” to conduct the tasks they routinely perform.

A [2014 survey](#)[2] of clinical research professionals in Arizona, a state which has experienced significant growth in the biomedical science industry in recent years, highlights some of these inconsistencies in training.

Approximately one-third of respondents stated they received the majority of their clinical research training on the job and through classes they attended on their own.

Just 22 percent said they completed a clinical research educational program.

Professional organizations such as the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SOCRA) provide voluntary accreditation through successfully passing an exam testing industry-specific knowledge. This is a good start towards demonstrating competence, but how can clinical research professionals gain the knowledge they need to be experts in their field?

**Hiring clinical research professionals who have been trained demonstrates an organization's commitment to the highest standards of quality, ethics, and professionalism.**

Consider these educational goals as a guideline for what knowledge is most critical in our industry.

- A thorough understanding of:
  - FDA Clinical Research Regulations
  - Good Clinical Practice (GCP) Standards
  - Subject Confidentiality: HIPAA and HITECH
  - Human Subjects Protection
  - The History of Clinical Research
  - Role-based training for Investigators, Research Coordinators, Monitors, Project Managers (and others) based on responsibilities

Although the Arizona Clinical Research Workforce Survey illustrates some of the challenges of requiring specific certification for clinical research professionals, it also shows a demand for continuing education in this rapidly growing field. More than half were required to obtain continuing education to maintain employment or keep their license current.

## How Can Sponsors Make Training More Affordable and Accessible?

Let's face it; hosting an in-person training session is not always practical. Clinical research sponsors often manage multiple sites and numerous associates who continually travel between them. Investigators and site staff are busy balancing patient care schedules.

The training itself must also be flexible to adapt with changing regulations. Manuals are often outdated as soon as they are published, and regulation handbooks are only helpful as references if clinical research associates know where and how to find the information they contain.

Finally, the most effective training is that which is based on real-world experience.

**For these reasons, sponsor organizations are increasingly looking to online training programs to prepare clinical research associates for the challenges of the job.**

With a variety of online training programs for clinical research professionals on the market now, it's important to choose the right one. Sponsors should select a program that provides foundational [knowledge in these basics](#) as well as continuing education in a variety of topics.

Proper training assures sponsor organizations that their research meets all of the industry's standards of compliance, and that their clinical studies will be conducted in a well-controlled, high quality manner that will withstand the rigors of regulatory inspection.

## References:

- [1] Bureau of Labor Statistics data on medical scientists, [www.bls.gov](http://www.bls.gov) (accessed April 7, 2015)
- [2] Luna, Gaye, Ed.D.; Robbins, Julie, RN, CCRP; Wells, Chris, Ed.D., MBA, CCRP, "Arizona Clinical Research Workforce Survey," Online Journal for Workforce Education and Development, Volume VII, Issue I, Spring 2014, available online via <http://opensiuc.lib.siu.edu/cgi/viewcontent.cgi?article=1153&context=ojwed>

## About the Author

*Sandra Maddock is president and CEO of [IMARC Research](http://www.imarc.com), a contract research organization that provides clinical trial support services to sponsors seeking worldwide approval of their products. With a focus on compliance, IMARC offers project management, monitoring, auditing, consulting and training, including IMARC University, a new series of online training courses for clinical research professionals.*

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