

Perceptions of Investigator GCP Training

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HY IS IT THAT INVESTIGATORS, *who according to Good Clinical Practice (GCP) are responsible and accountable for the conduct of a clinical trial at the research site, receive little or no GCP training? Trainers receive different answers to this question depending on whom they ask — coordinators, monitors or investigators themselves.*

Coordinators and monitors readily acknowledge that investigators desperately need GCP training. Yet coordinators, and to some degree monitors, overwhelmingly perceive that investigators are “too busy” for GCP training. Because we, as trainers, perceive that investigators are “too busy,” we typically neglect, excuse, or at best, offer investigators a watered-down briefing of their GCP responsibilities. In addition, we have come to accept that coordinator GCP training is a surrogate for investigator GCP training when it is not. While investigators often *are* busy people, they still need good investigator training.

Investigators will generally agree that they need GCP training—training that is interesting and targeted to their needs. When investigators are given the opportunity to attend investigator-targeted GCP training that is well-designed and delivered, they will invariably evaluate the training as

beneficial because it increased their knowledge and understanding of their investigator responsibilities. Unfortunately, many investigators report that

their GCP training was boring, irrelevant, perfunctory, and a waste of time. What can we do to improve investigator GCP training?

STEPS FOR INVESTIGATOR GCP TRAINING

Effective investigator-targeted GCP training requires skillful development and delivery. The process starts with a description of the target audience, which should include the current level of investigator GCP knowledge and experience.

The second step, content development, begins with a needs assessment to identify GCP problems and issues. Coordinators, monitors, and auditors are a prime source for input, as are investigators themselves. Content should also include new and updated GCP information; for example, changes in regulations or new guidance documents.

Since GCP content is often

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perceived as “dry stuff,” the third step is often the most challenging—designing and delivering investigator GCP training that is unforgettable. This requires the trainer to demonstrate out-of-the-box thinking. My personal goal is for the investigators to say at the end of a GCP workshop, “Thanks. I had no idea I was responsible for all of that.”

Let’s look back at our original question: Why is it that investigators — who according to Good Clinical Practice (GCP) are responsible and

accountable for the conduct of a clinical trial at the research site — receive little or no GCP training?

It’s a good question. Take a few moments to think about it. Talk to your co-workers. Talk to an investigator about it.

If we can uncover the reasons for the current inadequate state of investigator GCP training, we’ll have a better chance of implementing effective programs in the future and meeting our goal of GCP compliance.

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