

# Investigator GCP Training: A Rare Sight

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**G**OOD CLINICAL PRACTICE (GCP) TRAINING FOR INVESTIGATORS *conducting drug, biologic, or device clinical trials is a rare occurrence. Regrettably, clinical investigators, who are legally and ethically responsible for the conduct of the study at the clinical site, are ignored, excused, or at best, offered a watered-down briefing of their responsibilities according to global GCP standards. Instead, the majority of training is directed at preparing the investigator's clinical research coordinator to implement and manage a trial. Yet most coordinators, monitors, and auditors — the individuals who have a unique vantage point from which to observe an investigator's compliance with global GCP standards — will quickly report that investigators desperately need GCP training.*

Planning and implementing investigator-targeted GCP training may seem more challenging than training coordinators or monitors. Here are two challenges to investigator-targeted GCP training and some ways to overcome them.

## **CHALLENGE #1:** *The Busy Investigator*

When I ask GCP-trained coordinators if their investigators would attend comparable GCP training, the overwhelming response is, “Oh no, they’re too busy.” The perception that investigators do not have time for GCP training has become near dogma, and a primary challenge for investigator-targeted GCP training. Whether deliberate or unintentional, many investigators encourage this perception, which unfortunately undermines

our efforts to help investigators understand their GCP responsibilities.

Because we keep hearing that investigators are “too busy,” we have

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come to accept that coordinator GCP training is a surrogate for investigator GCP training when it is not.

When investigators say they’re “too busy” for GCP training, they’re really saying they don’t understand why it’s important for them; the proverbial, “What’s in it for me?” Investigators may be reflecting on past GCP training events, formal and informal, which may have been poorly designed, developed, or delivered, and consequently are remembered as being irrelevant and a waste of time. In that case, we can understand why they would continue saying they’re too busy for GCP training.

While investigators often *are* busy people, they still need good investigator training.

## CHALLENGE #2:

### *The Experienced Investigator*

Monitors frequently report that when they ask investigators about their understanding of GCP, investigators will say, "Oh, I know all about that."

This illustrates the second challenge to investigator-targeted GCP training: The assumption that investigators are experienced and know their GCP responsibilities often leads to the incorrect conclusion that investigators do not need additional GCP training.

We perceive that investigators acquire GCP knowledge in their academic clinical curriculum, in their role as a subinvestigator or as an investigator for a clinical trial, or in their accumulation of years of clinical practice. Unfortunately, for most investigators, these assumptions are inaccurate.

When I ask investigators about their clinical trial experience and GCP training, they invariably relate a tale that I call "The Accidental Investigator." For many investigators, their experience and training in

clinical research was uninspiring, fragmentary, and perfunctory. Training primarily focused on the clinical and scientific aspects of the trial rather than the regulatory requirements of GCP compliance. Yet when investigators are given the opportunity to attend an investigator-targeted GCP training program that was well-designed and delivered, they invariably evaluate the training as beneficial because it increased their

knowledge and understanding of their responsibilities as an investigator.

## OVERCOMING CHALLENGES

Effective investigator-targeted GCP training requires skillful development and delivery. Content development begins with a needs assessment to identify problems and issues. Coordinators, monitors, and auditors are a prime source for input, as are investigators themselves. Other content resources for investigator GCP training include applicable regulatory requirements and the International Conference on Harmonization (ICH) Tripartite Guideline for GCP.

Investigators appreciate well-designed and meaningful training. If we can help investigators understand their GCP responsibilities, we can better meet our goal of GCP compliance much more successfully.

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