

# T2K—Training 2000

## GCP Training for a New Era

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**T**he year 2000, the beginning of a new decade, and—many say—a new millennium. The global clinical research community has entered an era of opportunity. And it's time to reevaluate our operations and move in new directions. One critical area that needs our attention is training, particularly GCP training. So I propose that we launch T2K—Training 2000. The goal of T2K is improved ethical, regulatory, and protocol compliance. With everyone involved in developing new human medical products thoroughly trained, the research community could consistently meet essential GCP criteria.

Measured against training for comparable fields, specialty training for clinical research personnel lags behind. The essential component of specialty training for the global clinical research community is good clinical practice. Yet, although the global clinical research community agrees upon basic GCP standards, it has not settled on training standards.

At the dawn of the 21st century, GCP training can best be described as a hodgepodge of serendipitous activities of arguable quality. Until the global clinical research community identifies and harmonizes core GCP knowledge, skill, and behavioral competencies for every position in clinical research, we will all—including the patients whom we strive to help—painfully endure the consequences of GCP noncompliance. And the research community will continue to misuse the minimal funds that management allots for training clinical research personnel.

Every staff member needs training. Since the 1990s, when public training programs for clinical research personnel began to emerge, the global clinical research community has primarily focused on training people in two positions: coordinators at the clinical site and monitors for the sponsor. Training coordinators and monitors is smart. Those individuals provide invaluable services to investigators and sponsors. Furthermore, those jobs often provide a pathway to other opportunities in clinical research—in project management, regulatory affairs, quality assurance, and data management.

Unfortunately, this decade-long focus on coordinator and monitor training has lulled the global clinical research community into a stupor of overconfidence with its haphazard approach to GCP training. For the highly regulated environment we work in, our training efforts are mediocre at best. The global clinical research community has been remiss in its responsibility to ensure that all clinical research personnel—including investigators—are well trained.

Emphasis on coordinator training. The heavy emphasis on coordinator training is based on the prevalent assumption that training coordinators is a substitute for training investigators—an erroneous and perilous hypothesis. The perception that investigators do not have time for GCP training is near dogma. When surveyed about their experiences, investigators typically evaluate their meager GCP training as uninspiring, irrelevant, perfunctory, and a waste of time. Consequently, investigators often refuse to attend GCP training. When

pressed, however, they concede that someone needs to know “the regs.” And, a site's coordinator may be sent to a training program as a surrogate for the investigator, and for the entire research team.

The global clinical research community has condoned this substitution for too long. And this arrangement is increasingly unacceptable to regulatory authorities, at least to those in the United States. The Food and Drug Administration (FDA) is sending a clear message to the clinical research community that properly GCP-trained investigators and staff are the standard. In a recent warning letter to an investigator, for example, FDA stated, “We expect that clinical investigators and clinical staff fully trained in Good Clinical Practices and in FDA regulations for human clinical trials would not have made the numerous errors that were documented in the inspection.”<sup>1</sup>

Because investigators are clinically, legally, and ethically responsible for the conduct of the trial, they and their entire research teams must receive initial and ongoing GCP training. The global clinical research community needs to collaborate to identify, develop, and harmonize standards for investigator GCP training—and all members of the investigator's team need GCP training commensurate with their investigator-delegated and supervised duties.

“Experienced” does not necessarily mean “well trained.” The emphasis on monitor training is based on the common and justified perception that monitors are the eyes and ears for the sponsor in the field, where the research is conducted. They must understand the rules of good clinical

It's a good time for the global clinical research community to focus on GCP training for everyone involved in trials of new drugs.

practice to be able to report on compliance to the sponsor. Unfortunately, despite the acknowledged need for monitor training, many sponsors and, in particular,

many instances neither experienced nor well-trained monitors are overseeing and ensuring investigator GCP compliance. Yet, sponsors are obligated to

of extraordinary guidance documents, a process that continues into the new millennium. The expert working groups who contributed Herculean efforts to

num offers the global clinical research community a rare opportunity to reevaluate and refocus its training operations and plan new directives.

Let's kick off the 21st century with a global training initiative—Training 2000. It can provide the path to improved ethical, regulatory, and protocol compliance. If ever there was an ideal time for the global clinical research community to champion harmonized GCP training, it is now.

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many contract research organizations (CROs), have neither the time nor the money to train monitors. Thus the current trend is toward hiring only "experienced" monitors.

Just as we should not consider coordinator training a substitute for investigator training, we should not assume that an "experienced" monitor is automatically a "well-trained" monitor. In the United States, for example, initial monitor training is often on-the-job, fly-by-the-seat-of-your-pants training—sometimes combined with attendance at a public program. The global clinical research community has not adopted, nor even identified, standards for preparing monitors to oversee GCP or for ongoing training for those already working as monitors.

The violations cited in FDA warning letters suggest that in

provide trained monitors to vigilantly survey the conduct of the clinical trial.

Certification is not necessarily the answer. Some may propose certification as a method for establishing standards for clinical research personnel. But it is not the panacea that many would like to believe. Certification is not a substitute for training or education. The trend toward certification is worrisome if the global clinical research community accepts "certified" as a proxy for "well trained" and evades its obligation to train investigators, coordinators, monitors, and other clinical research personnel.

Global training standards needed

During the 1990s, the International Conference on Harmonisation (ICH) significantly raised standards by producing a series

this initiative have provided the global clinical research community with a blueprint for developing unified standards for training. In particular, the ICH guideline for GCP should serve as a foundation for identifying core GCP knowledge, skill, and behavior competencies for investigators, monitors, and institutional review boards.<sup>2</sup>

It is logical to continue the work begun by ICH by embracing the GCP guideline as a model for developing GCP training standards. Using the methods that worked for the ICH expert working groups—with regulatory and industry representatives from the three ICH regions, European Union, Japan, and the United States—a similar strategy can be implemented to develop and harmonize GCP training standards. The beginning of a new century and a new millen-

## References

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