

# GCP Training for Clinical Investigators: The Top Priority for a New Era

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**T**HE GLOBAL CLINICAL RESEARCH COMMUNITY *may be entering the 21st century scientifically and technologically, but our current standards for clinical investigator Good Clinical Practice (GCP) training are more characteristic of the Dark Ages. It is time for us to move forward and identify clinical investigator GCP training as our number one priority for T2K — Training 2000 — the beginning of a new era in training initiatives for the global clinical research community. Our common goal is to enhance ethical, regulatory and protocol compliance by everyone involved in bringing new medical products to market—including clinical investigators.*

Regrettably, clinical investigators, who are ethically, legally and clinically responsible for the conduct of the study, have been ignored, excused, or at best, offered a watered-down briefing of their obligations according to global GCP standards.

A common approach to investigator GCP training is to send the investigator's research coordinator to a training course on how to coordinate clinical trials. While coordinator training is a smart investment, it is not a surrogate for investigator GCP training. Clinical investigators, who primarily are physicians, and routinely claim to be too busy to attend training, should not be allowed to conduct clinical trials until they satisfactorily complete documented initial and ongoing GCP training.

## A SHARED RESPONSIBILITY

The importance of GCP training

for clinical investigators can be linked to the 1996 International Conference

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on Harmonisation Guideline for Good Clinical Practice (ICH GCP). In the introduction, GCP is defined as "an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects."<sup>1</sup>

The ICH GCP guideline identifies three parties responsible for GCP compliance: institutional review boards/independent ethics committees (IRBs/IECs), investigators and sponsors. Each party is accountable for ensuring GCP compliance by everyone under its authority. The responsibility for GCP compliance also includes the obligation to provide initial and ongoing GCP training for all personnel involved.

This shared responsibility for GCP training and compliance places IRBs/IECs, clinical investigators and

sponsors in a unique collaborative partnership that relies on mutual trust and cooperation. While these three ICH parties ultimately are accountable to regulatory authorities and the public, they are also responsible to each other for ensuring GCP training and compliance.

Sponsors and IRBs/IECs hold clinical investigators responsible for GCP compliance, yet they often allow investigators to duck their responsibilities for GCP training. This position is reckless because investigator GCP noncompliance can frequently be linked to inadequate training. We want to prevent and minimize investigator GCP noncompliance because it is the right way to conduct clinical trials.

Sponsors and IRBs/IECs each have the authority to mandate that investigators complete initial and ongoing GCP training as a prerequisite for conducting clinical trials. In the United States, the Department of Health and Human Services (HHS) holds IRBs accountable for the dismal state of investigator GCP training; sponsors should also share this culpability. Sponsors and IRBs/IECs need to work together to implement changes in investigator GCP training.

" GCP training for every clinical investigator must be our top priority for T2K—Training 2000."

### SETTING STANDARDS

At the dawn of the third millennium, the global clinical research community has no standards for investigator GCP training, or for any GCP training. Our universal GCP training standards should emanate from IRBs/IECs, sponsors and clinical investigators — not the regulatory authorities — and they should be based on ICH GCP guidelines. Collectively, these three responsible ICH parties know "the ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects."<sup>2</sup>

The global clinical research community can no longer condone the

meager level of investigator GCP training as the modus operandi for the 21st century. In partnership with IRBs/IECs, sponsors and clinical investigators, we must be proactive and implement changes voluntarily before we are forced to scramble in response to initiatives by regulatory authorities.

GCP training for every clinical investigator must be our top priority for T2K — Training 2000 — the beginning of a new era in training initiatives for the global clinical research community. Our common goal is to enhance ethical, regulatory and protocol compliance by everyone involved in bringing new medical products to the global market — including clinical investigators.

<sup>1</sup> International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Good Clinical Practice: Consolidated Guideline. May 1, 1996.

<sup>2</sup> Ibid.

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