



Good Clinical Practice (GCP) Training: Current Practices and Challenges

Executive Summary of the Expert Meeting held January 31, 2014

Bethesda North Marriott Hotel & Conference Center, Bethesda, MD

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

Meeting materials, including agenda, participant list and presentations, are available on the Clinical Trials Transformation Initiative website at: <http://www.ctti-clinicaltrials.org/what-we-do/ctti-projects/gcp-training/expert-meeting>

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MEETING OBJECTIVES

The goal of this meeting was to seek consensus on the key elements of GCP training and the frequency, format, and competency of training required to conduct clinical studies in the United States.

MEETING EXECUTIVE SUMMARY

“GCP training is the floor, not the ceiling.”

On January 31, 2014, the Good Clinical Practice (GCP) Training Project Working Group convened an expert meeting involving stakeholders with expertise in this topic. Participants included representatives from academic institutions, industry (including pharmaceutical and contract research organizations), government agencies, health systems, professional societies, independent consultant companies, and the patient advocacy community. Draft recommendations developed by the Working Group for the key elements of GCP training as well as the frequency, format, and competency testing for such training were shared with participants, with the goal of seeking feedback from the experts on these draft recommendations.

Session topics were designed to elicit stakeholder discussion, beginning with an overview of the current landscape for GCP training. In the first session, speakers and participants agreed that while GCP training is essential to research competency, the frequent—and often redundant—training dissuades physicians from participating in research and distracts investigators from meaningful study oversight. Findings from a literature review suggested that heterogeneity in the content and expectations of GCP training programs may have introduced inefficiencies in initiating clinical research. Discussion focused on the need to clarify the goals for GCP training and make use of the flexibility of online delivery, thus allowing for more resources to be devoted to protocol-specific training. Salient points included (1) deficiencies at sites are recurrent issues related to the key GCP elements and (2) one way to train more efficiently would be to ensure recognition of other organizations’ training certification across the clinical research enterprise.

The second session was a moderated discussion of the key elements for GCP training recommended by the Working Group—the 13 elements in the investigator section of ICH E6 and 3 additional elements for consideration. Experts provided comments on the GCP elements focusing on the need to train more efficiently. Comments included that GCP training components should be meaningful and not just serve as documentation to fulfill requirements. Other key points included (1) GCP training is only one piece of the training and experience an investigator needs to conduct a trial, (2) if GCP training can be made more efficient, then more time can be spent on essential protocol-specific training, and (3) GCP training should highlight activities that are performed for clinical research that are in addition to activities performed for medical care (e.g., safety reporting, informed consent, and IRB review).

The third session addressed differential (i.e., role-based) GCP training and whether such training is better conducted uniformly, or made to fit to an institution's and trainee's needs. A job analysis survey conducted among individuals serving three types of clinical research functions (coordinators, monitors, and investigators) was presented. Results suggest tailoring GCP training and evaluating GCP knowledge as it pertains to each clinical function. The value of applied knowledge (i.e., giving trainees what they need to perform their job better) was stressed. The question of whether actual trial activity could suffice to demonstrate GCP competence was discussed.

The fourth session was a panel discussion of the recommended frequency and format of GCP training and demonstration of GCP competency. It was noted that the literature review found little evidence for an optimum frequency, format, or assessment of competency for GCP training. While the experts agreed that a benefit of an online format is flexibility, some felt an online format does not foster knowledge retention. The benefits of interactive learning and mentorship for new investigators were raised. Discussion brought out some additional points: (1) for frequency of GCP training, it was suggested that recertification every 3 to 5 years could be acceptable, (2) there are interesting online formats and e-learning software available in related fields (e.g., CME) that could be adopted; (3) evaluation of GCP learning could be made more rigorous by testing for the principle behind the training, (4) the content of training could be designed to focus on frequently observed noncompliance issues; and (5) although testing out of training may be an option, a researcher does not always remember what the guidelines state, making refresher training useful.

The last session focused on how to integrate GCP principles in everyday practice, and how to design training to improve actions, processes, and outcomes within the clinical research enterprise. Topics included reducing investigator burden through sponsor recognition of equivalent GCP training provided by another sponsor or organization within a specified time period, and designing training that presents a real-world picture of clinical research. Benefits of applied GCP training include allowing learners to think critically, make missteps in a safe environment, and learn strategies for reducing noncompliance. An initiative to harmonize GCP components across multiple geographical regions into a single set of core competencies was also described.

The meeting was closed by thanking the experts for their thoughts and ideas, which will be used to refine and finalize the draft recommendations on GCP training in a white paper generated by the Working Group.

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ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership to identify and promote practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options.

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