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Good Clinical Practice Q&A: Focus on FDA vs. ICH GCP

Given that the FDA now has its long-standing GCP standards and then, in 1997, adopted the ICH GCP guideline as representing "the agency's current thinking on good clinical practices," what standards should a clinical trial sponsor, its monitors, and clinical trial sites follow in conducting a clinical study—the U.S. GCP regulations/guidances or the ICH GCP guideline? Or does it matter?

Since the ICH GCP guideline is more specific than—some would say goes further than—the FDA GCP regulations/guidances in selected areas (see Q1.7), conventional wisdom suggests that a company should use the ICH GCP standards for clinical studies that it intends to use in regulatory submissions globally. Adherence to this guideline, as well as additional regulatory standards of the other ICH regulatory parties, can only be expected to promote the acceptance of the clinical studies in the other ICH regions as well as other countries that subscribe to ICH standards despite not being ICH parties (e.g., Canada).

For studies to be submitted exclusively in the United States, either standard should suffice. It is important to note that FDA officials have stated that the agency will "consider clinical studies conducted under ICH GCP as meeting GCP standards acceptable to FDA." In an August 2005 article in SoCRA Source, for example, CDER Division of Scientific Investigations Deputy Director Joseph Salewski wrote that "Staff at the Division of Scientific Investigations participated in the development of the ICH E6 guideline, which is the official FDA guidance on GCP. Compliance with ICH GCP ensures compliance with FDA regulations."

Agency officials emphasize, however, that studies conducted under an IND must always, at a minimum, meet FDA regulatory requirements. It is also worth noting that, under the FDA's Bioresearch Monitoring Program, agency inspectors continue to assess sponsors, monitors, and investigators against FDA GCP standards exclusively (see Q10.18). Since the ICH GCP provisions are generally seen as being consistent with—and in some cases being more specific than—the FDA GCP regulations/guidelines, FDA inspectors, in theory, should not discover compliance problems when the ICH GCP standards are employed.

FDA officials emphasize that agency inspectors will inspect sponsors, monitors, or investigators exclusively for compliance with FDA GCP standards, regardless of the GCP standard implemented in a trial. According to CDER's Division of Scientific Investigations (DSI), the center's Bioresearch Monitoring Program (BIMO) is focused primarily on finding deviations from FDA GCP regulations, and not deviations from either FDA or ICH GCP guidelines. Following an FDA inspection of a clinical investigator, sponsor/monitor, or CRO, the Form 483-Inspectional Observations that an inspector may leave with the sponsor/monitor, investigator, or CRO should, according to CDER policy, identify ONLY observed deviations from FDA GCP regulations. [Editor's Note: an FDA inspector leaves a Form 483 only if deviations are discovered.] Although deviations from FDA guidelines should be identified and discussed in the later-developed establishment inspection report (EIR) and may be discussed in a subsequent inspection-related FDA letter (e.g., untitled letter, warning letter) to the firm or investigator, these deviations will be identified separately from the deviations from FDA regulations. DSI staffers do not recall having seen any EIR or inspection-related CDER letter that identified or discussed any deviation specifically from the ICH GCP guideline.

Over time, the differences in emphasis and specificity between the FDA standards and ICH GCP guideline should become less evident. FDA officials have stated that the agency will

"take into account the ICH GCPs" in developing new or revising existing regulations and guidance as part of routine GCP program maintenance activities.[1]

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2007 pp.8-9

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2007," is available for $39.95 at http://www.barnettinternational.com/