Good Clinical Practice Q&A: Focus on Study Records

Are pre-study, or study initiation, monitoring visits required under GCP requirements?

Generally, the pharmaceutical industry splits pre-study monitoring visits into two distinct categories: qualification/selection visits and initiation visits. Qualification/selection visits determine that the site is able to conduct the study, and initiation visits assist the site in its preparation to enroll its first subject. Generally, qualification/selection visits are waived if a sponsor or clinical research organization has recently worked with a site and there remain no questions regarding its capabilities. Initiation visits are waived if a site does not need any assistance in preparing to enroll its first subject. When a site initiation visit is not held, it is always a good idea for the monitor to visit a site after it has enrolled its first few subjects.

Although FDA GCP regulations do not describe a pre-study visit, qualification visits are strongly recommended in the FDA’s “Guideline for the Monitoring of Clinical Investigations” (1988). According to the guideline, “a sponsor is responsible for assuring, through personal contact between the monitor and each investigator, that the investigator clearly understands and accepts the obligations incurred in undertaking a clinical investigation. Prior to the initiation of a clinical investigation, the monitor should visit the site of the clinical investigation...”

While the ICH’s GCP guideline does not mention “pre-study” or “preinvestigation” visits specifically, it states in its appendix that both a “pretrial monitoring report” and a “trial initiation monitoring report” are considered essential documents. The pretrial monitoring report, which should be maintained in the sponsor’s files, should “document that the site is suitable for the trial,” says the guideline. The trial initiation monitoring report, which the site should maintain in its files and which can be combined with the pretrial monitoring report, should document that the trial procedures were reviewed with the investigator and the site staff. The ICH guideline also lists several monitoring responsibilities that would be difficult to fulfill without the benefit of a pre-study visit—for example, the monitor is responsible “for verifying that the investigator... has resources..., including laboratories and equipment... adequate to safely and properly conduct the trial...”

Further, the ICH GCP guideline (5.18.3) states that, “in general there is a need for on-site monitoring, before, during, and after the trial; however, in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators’ training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP.”

Some companies consider “pre-initiation” investigator meetings, which are group meetings held to educate all participating clinical investigators/study coordinators/research nurses regarding a study, to be a replacement for individual site initiation visits. Such meetings, however, do not meet the criteria of a “visit” as described in the FDA’s 1988 monitoring guideline.¹

Reference

Source