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What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

128. Out of sight

U.S. regulations do not require clinical labs to meet Good Clinical Practice (GCP) standards. However, ICH GCP Guidelines (E6 5.18.4), adopted as a Guidance by FDA, require monitors to verify that investigators have laboratories "adequate to safely and properly conduct the trial." Site monitors normally check for laboratory certification by The College of American Pathologists (CAP) and the Centers for Medicare & Medicaid Services (CLIA).

The Centers for Medicare & Medicaid Services (CMS) inspects and certifies clinical labs under Clinical Laboratory Improvement Amendments (CLIA). The College of American Pathologists (CAP) inspects and certifies clinical labs under CAP and also CLIA. These inspections do not cover GCP. Study sponsors ask research sites if their labs are CAP- and CLIA-certified, and sometimes send auditors for inspections. Most CAP and CLIA inspectors tour the lab, but spend most of their time in a conference room asking checklist questions and reviewing documentation. They do not verify that the systems actually work in practice. For example, they might review the data backup SOP, but would not notice that the backup server is located in the basement next to the water pipes. They would not verify that the data is actually being backed up and can be restored. Sponsor inspections are generally limited to central labs. Only a few sponsor auditors get their hands dirty on the practical aspects of sample handling, equipment maintenance, training, security, disaster recoverability, etc.

As a result, most local clinical laboratories do not follow GCP, or even know of its existence. Central labs generally know about GCP, but that does not mean they comply with it. Most clinical labs do not give special treatment to study samples and results, or even know they are for a study. They are not aware that GCP requires, for example, documentation of the storage location and transport of study samples, along with temperature and security protections. Further, they are not aware that FDA's "Guidance for Industry: Computerized Systems Used in Clinical Investigations" states that 21 CFR 11 applies to "records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained, or submitted to the FDA." We all know what can happen when nobody is watching, especially if the rules are not clear. What am I missing here?

Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to ngoldfarb@firstclinical.com.

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