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Good Clinical Practice Q&A: Focus on Clinical Labs

Does the FDA have any regulations and/or guidances applicable to clinical laboratories or services (e.g., ECGs) that are used to generate data for a clinical trial?

In an informal response to this question, the FDA stated that the agency "does not have any specific guidances or regulations applicable to clinical laboratories supporting clinical trials. There are, on the other hand, a number of organizations, accreditation bodies, and other government agencies that do have various standards for clinical laboratories. As you may know, the principal government standard, enforced now by the Centers for Medicare and Medicaid Services (CMS), is CLIA certification. This is carried out under the Clinical Laboratory Improvement Act (CLIA) and applies to just about any clinical laboratory that carries out clinical testing (except for research) in interstate commerce. Although CLIA certification is not required for a clinical lab to participate in an IND study, it does represent a standard that is acceptable to FDA for the purposes of clinical diagnostic testing... It is considered good clinical practice to maintain documentation of a laboratory's CLIA certification as part of study records."

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.