

Good Clinical Practice Q&A: Focus on Central Labs

More and more studies include the use of a central laboratory or central reading facility to evaluate laboratory samples, ECGs, X-rays, etc. What is required to document the qualification of these facilities?

FDA's regulations do not specify what documents are required to demonstrate that a facility is qualified to perform such work. However, the 2009 guidance on "Investigator Responsibilities; Protecting the Rights, Safety and Welfare of Study Subjects" does mention these third-party organizations. In Section III.A.4.b of the Guidance, it mentions that there are often critical aspects of a study performed by parties not involved directly in patient care or contact and not under the direct control of the clinical investigator. For example, clinical chemistry testing, radiologic assessments, and electrocardiograms are commonly done by a central independent facility retained by the sponsor. Under these arrangements, the central facility usually provides the test results directly to the sponsor and to the investigator. Because the activities of these parties are critical to the outcome of the study and because the sponsor retains the services of the facility, the sponsor is responsible for ensuring that these parties are competent to fulfill and are fulfilling their responsibilities to the study.

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.