From: OC GCP Questions
To: [redacted]
Subject: Clinical Trials and Human Subject Protection
Date: Friday, January 10, 2014 10:29:45 AM

Good morning –

From an FDA standpoint, we would expect the laboratories used to analyze clinical specimens for clinical trials to be qualified. If the sponsor is using a central laboratory, it would be sufficient for them to retain documentation of the laboratory's qualifications, which usually includes background information on the director. It would, however, seem important to know the reference ranges for the laboratory. Since these can vary from laboratory to laboratory, that information is necessary for the CI to interpret specific laboratory results, particularly when values may be near the upper or lower parts of typical ranges.

In the United States (US) oversight of the conduct of clinical laboratories is under the Centers for Medicare and Medicaid (CMS) as specified by the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Amendments (CLIA), which is under the purview of the Centers for Medicare and Medicaid (CMS) not FDA. Information about CLIA can be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/ and the current CLIA regulations can be accessed at http://wwwn.cdc.gov/clia/regs/toc.aspx. Therefore, FDA has not issued any regulation or guidance regarding clinical laboratories equivalent to ISO and JCI, as we do not have authority to do so. Most US study sites use a CLIA-certified laboratory for testing required as part of clinical studies. When a study requires a specialized test that is only available at laboratories that may not fall under CLIA (e.g., an academic site), FDA expects to see certification that the laboratory is capable of performing the particular test accurately and reproducibly. For non-US study sites, FDA would expect to see certification/accreditation as required by the country/state in which the study is conducted. If the laboratory in question for some reason lacks such an accreditation, we would need to see evidence that the laboratory is capable of performing the particular testing accurately and reproducibly.
If a site is officially under the company's Investigational New Drug approval (IND) for the study or a non-IND non-US site, FDA would have concerns about accepting data from the site in support of an application or submission if the laboratory used could not be shown to be competent to analyze the samples. For studies that are conducted under an IND, the regulations require the clinical investigator (CI) at the study site to complete and sign a Form FDA 1572. It spells out the obligations of the CI under 21 CFR 312 and, once signed, becomes a contract to abide by the protocol and applicable regulations. The front of that form has a place to enter the name and location of the clinical laboratories that will be analyzing study samples. This is so the sponsor can determine if those laboratories are appropriate for the given study. Therefore, we hold the sponsor primarily responsible for ensuring that the laboratories used are capable of performing the necessary study testing both accurately and reproducibly. However, FDA regulations and international GCP guidelines and laws consider the conduct of a clinical study to be a system of checks and balances, where the sponsor, CI, and independent ethics committee (IEC) have overlapping responsibilities. Therefore, even if the sponsor is remiss in ensuring the quality of the clinical laboratory used, that would not remove the responsibility from the CI/study site to ensure appropriate conduct of the study, which includes analysis of study samples by a laboratory that is capable of producing accurate and reproducible results.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov if you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice

Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Thursday, January 09, 2014 11:40 PM
To: OC GCP Questions
Subject: Clinical Trials and Human Subject Protection

Dear Sir/Madam

I would like to know the FDA requirements for Clinical Labs authorised to conduct human lab test for clinical trials submitted to FDA
Kindly advise

[Redacted] is an integrated healthcare company in [redacted] and our lab is ISO and JCI accredited. You can read more about us on [Redacted]

Hope to hear soon.

Thank you

Regards
[Redacted]