**From:** OC GCP Questions
**To:** [redacted]
**Date:** Friday, February 17, 2017 2:13:00 PM
**Attachments:** [redacted]

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Good afternoon --

FDA does not have any regulations applicable to clinical laboratories supporting clinical trials, nor any requirements as to how a clinical laboratory should provide information, such as normal ranges, to clinical sites.

As you reference the "Essential Documents" chapter of FDA's official guidance, the ICH E6, "Good Clinical Practice: Consolidated Guidance," states that sites and sponsors should maintain records of normal values/ranges for medical, laboratory, and technical procedures for tests included in the protocol (section 8.2.11), and certifications/accreditations to document the competence of the facility performing these tests (section 8.2.12), again, there is no specific detail as to how the clinical laboratory should provide this information to a study site.

Also there are a number of organizations, accreditation bodies, and other government agencies in the United States that have established standards for clinical laboratories. In the U.S., the principle 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 and applies to just about any clinical laboratory which 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. To learn more about CLIA, you can visit their website at www.cms.hhs.gov/clia/

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION



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**From:** [redacted]
**Sent:** Friday, February 17, 2017 1:04 PM
**To:** OC GCP Questions
**Subject:**

This question is in regards to Section 8.3.6 of ICH e6 GCP, the guideline to collect and "to document normal values and ranges that are revised during the trial." For a clinical trial that uses data from lab results from local labs, would the reference ranges listed on a given patient's lab results and entered into an Electronic Data Capture/eCRF system by a site and source data verified by a monitor satisfy this section/purpose of ICH GCP?

As it is not always apparent to a monitor or even to the site whether updates have been made to the

reference ranges being used by a site's laboratory, it can be difficult at times to ensure that the trial master file contains all reference ranges/normals used for data/labs collected from the local laboratories. As one can infer that the reference ranges listed on a given patient's lab results are the most updated/revised normal values and ranges for that lab, and per ICH e6 section 8.1, "It is acceptable to combine some of the documents, provided the individual elements are readily identifiable", would the FDA accept that reference ranges captured in the eCRF (essential document section 8.3.14) comprise or satisfy the essential document element of section 8.3.6 of ICH e6?

Thanks for your help.

Regards,
[redacted]