From: OC GCP Questions
To: [redacted]
Subject: Requirement for the collection of normal ranges from the local labs when using a common set of normal ranges
Date: Wednesday, August 02, 2017 8:54:00 AM
Attachments: [redacted]

Good morning --

While I am aware that this is listed in the ICH-E6 GCP guidance among the documents needed at a site before the clinical study starts, neither I nor my colleague could remember or locate such a requirement in any FDA regulation pertinent to the conduct of clinical studies. While FDA does concur with ICH-E6, it is accepted as guidance and, if an area is not also specifically in regulation, it is not actually required.

If the normal ranges for a clinical laboratory are included on all its laboratory reports, it would seem that would indeed constitute documentation of these ranges. However, since a study may employ a number of different laboratories across study sites, it might be worthwhile for the sponsor to retain some documentation of the normal ranges for each of the sites. This might be useful when comparing laboratory values across the study and data for an essential value are seen that might, on first glance, appear not to agree. The fact that the laboratories used have different normal ranges for that measurement may help to explain the apparent differences.

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

Kind regards,

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

From: [redacted]
Sent: Monday, July 31, 2017 6:24 PM
To: OC GCP Questions
Subject: Requirement for the collection of normal ranges from the local labs when using a common set of normal ranges

Dear Sir/ Madame,

Per ICH E6 section 8 (ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL), regarding the item “NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL,” purpose of the document is “To document normal values and/or ranges of the tests” the guidance states that this document must reside

in the files of both investigator/ institution and the sponsor.

For a multi-site study where local labs are being used to obtain lab values (and the normal ranges from the lab are used by the investigator to assess safety), but where a common set of normal ranges (the ranges published by the American Medical Association) is being used for data analysis is there still a need for the sponsor to collect/ keep on file the lab normal ranges from the local labs?

Thank you,