From: OC GCP Questions
To: [redacted]
Subject: RE: Query related to Sponsor communication with CRO
Date: Thursday, March 02, 2017 10:45:00 AM
Attachments: [redacted]

[redacted]

If I understand your question, you are asking if the sponsor needs to inform the PI (via letter or email) prior to a monitoring visit, by either the sponsor or CRO.

The regulations at 21 CFR 312.50 and 312.53 (for drugs) and 812.46 (for devices) say that sponsors are responsible for ensuring proper monitoring of investigations and for selecting monitors, qualified by training and experience to monitor the progress of the investigation. FDA regulations do not specifically discuss when or how a sponsor should inform a PI about the specifics of when (for example, the date and time) a monitoring visit will take place. When the regulations are silent, sponsors, investigators and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

I recommend the following documents that provide additional information related to this topic:

- FDA has draft guidance titled, "Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators" that can be found at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm446695.pdf. Section VII B addresses sponsor-investigator responsibilities with regard to monitoring ongoing investigations. The guidance says that sponsor-investigators are responsible for ensuring proper monitoring of the investigation.
- Guidance on IDE Policies and Procedures that can be found at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080203.pdf . Information related to Monitoring of Clinical Investigations begins on page 4.
- Guidance for Industry Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring that can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf
- FDA conducts BIMO inspections using our Compliance Program Guidance Manuals (CPGMs) which can be found at www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm. The CPGMS were developed to provide uniform guidance and specific instructions for inspections of Clinical Investigators and Sponsor-Investigators (CP 7348.811), Sponsors, Contract Research Organizations and Monitors (CP 7348.810), In-Vivo Bioequivalence facilities (CP 7348.001), Institutional Review Boards (CP 7348.809), and Nonclinical Laboratories (CP 7348.808). You can take a look at the CPGMs to get an idea of what FDA looks at during inspections.

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

Nicole L. Wolanski, CAPT, USPHS
Senior Health Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, FDA, WO32-5108
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

From: [redacted]
Sent: Tuesday, February 28, 2017 10:42 PM
To: OC GCP Questions
Subject: Query related to Sponsor communication with CRO

Dear FDA Representative,

Thank you in advance for acquiring your little time. This is [redacted], working as Research Scientist in clinical research.

This is regarding to the general requirements for the communication with respect to the study monitoring from Sponsor end to Clinical research organization.

As per the our thinking, Sponsor written communication (email) to visit CRO for the monitoring of the clinical study prior to start of the clinical study should be made if Sponsor may plan and documented record should be available to TMF.

My question is "Does the Sponsor should need to submit any official letter to Principle Investigator (PI) about visiting clinical facility for monitoring of the study? or email communication from Sponsor notifying the CRO for monitoring visit is enough to consider the communication? Does the official letter of monitoring request to CRO is requirement of any CFR or FDA, Please help us if it is to understand ourselves?

I appreciate your time for my question.

Thank you

[redacted]

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