From: OC GCP Questions
To: [redacted]
Subject: EIR
Date: Friday, August 14, 2015 10:37:13 AM

Good morning –

I cannot comment on the specific inspection for that clinical investigator (CI). If there is confusion as to what the CI was told, he/she should contact the FDA field investigator that conducted the inspection. Additionally your email is confusing because the CI was removed from the study for non-compliance but was told the inspection was classified as VAI and no 483 was issued. Please see #5 below.

I can offer you the following information.

Generally a redacted copy of the actual inspection report that lead to that classification is given to the CI. It is also possible to request copies of both the 483 and the inspection report as a Freedom of Information Act (FOIA) request. Information as to how to file such a request is found at http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm.

FDA's Clinical investigator Compliance Manual states –

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

4. Field investigators who observe or suspect deviations from the regulations that affect data integrity or endanger subject rights, safety, or welfare should immediately discuss their observations with their supervisor, District Compliance Officer, and the assigning Center contact and continue the inspection. The assigning Center will promptly determine if the inspection should be expanded or modified and provide direction on how to proceed in order to obtain appropriate documentation for the noted observations.

5. The field investigator issues a 483 at the conclusion of the inspection when deviations from regulations are observed. Approaches that differ from those described in FDA's guidance documents should not be listed on the 483 unless they constitute deviations from the regulations. Such deviations may be discussed with the clinical investigator or sponsor-investigator during the exit interview, however, and reported in the EIR.

The field investigator encourages the firm to submit a prompt written response to the District Office and Center regarding any inspection observations listed on the 483.

A VAI definition is also described in this document.

b. VAI - Voluntary Action Indicated. Objectionable conditions or practices were found, but the agency is not prepared to take or recommend any administrative or regulatory action –

Some VAI classifications do not generate a 483 issuance.

I t might be helpful to review the below FDA document – FDA Inspections of Clinical Investigators

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf Please see page 7.

Lastly, please see the links below that takes you to the CI inspection list.

Clinical Investigator Inspection Search
Compliance Actions (Biologics) > Clinical Investigator Status (Biologics)

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: Friday, August 14, 2015 8:56 AM
To: OC GCP Questions
Subject: EIR

We have had a partner site that had a PI who was immediately removed m their employment when they were notified by the PI that he had conducted NON Compliant activity. This site notified the pharma sponsor and the IRB as appropriate and the Sponsor notified the FDA. The partner site also performed a CAPA and put action items into effect and set up long term training programs to prevent such non compliant activities.

The site just finished with an FDA audit and indicated the PI was going to be handed the 483. They also indicated that the site would NOT be getting the EIR or any written follow up since there was only one VAI indicated verbally. I am not familiar with this since all sites I have been involved with got written follow up later and we would like full disclosure with future sponsors regarding the PI who is no longer associated with that site but was an employee when the non compliant incident took place.