From: OC GCP Questions
To: [redacted]
Subject: Inquiry about Remote Inspection
Date: Monday, December 22, 2014 11:55:08 AM

Good morning --

I am not familiar with FDA conducting "remote" inspections at this time. For more information on inspections of all parties, please see the links below.

Clinical Trials and Human Subject Protection > Bioresearch Monitoring Program (BIMO)

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126555.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf

FDA's Office of Regulatory Affairs (ORA) is responsible for conducting FDA inspections. You may wish to contact someone from this office. Please see the link below.

Investigations Operations Manual > ORA Directory

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.

-----Original Message-----
From: [redacted]
Sent: Monday, December 22, 2014 2:26 AM
To: OC GCP Questions
Subject: Inquiry about Remote Inspection

Dear Sir/Madam

My name is [redacted] working for clinical quality assurance department of [redacted]
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I have heard that FDA conducted a remote inspection of a certain sponsor's clinical research this year.

I also found the information that FDA conducted a remote inspection of a Clinical Investigator (CI) site in the year 2008.

This type of inspection is very unfamiliar to me. I am very interested in it.

I hope I could have more information about it so that I can learn and also share it with my colleges and

[redacted] members.

It would be appreciated if you could answer the questions below:

1. What will trigger you to conduct a remote inspection? In other words, how do you determine organizations for remote inspections? What factors (e.g. risk, conditions/requirements, site location) will be considered in decision making of entities/research/data to be inspected?

2. How do you conduct remote inspections (for example, using online document sharing system or making a request for documents to be provided by e-mail)?

3. How many times have you conducted remote inspections since 2008 or what is the percent of such inspections every year since 2008?

4. Which type of organizations was included in the scope of remote inspections? (Sponsor, CRO, CI site, IRB, or Other; if there is any other type included in the scope please give me the detail.)

5. Which area is the scope of remote inspections (limited in the US or all countries of the world covered)?

I greatly appreciate your cooperation in advance.

Best regards,

[redacted]