From: OC GCP Questions
To: [redacted]
Subject: Documents that the FDA Inspector is allowed to inspect
Date: Tuesday, April 07, 2015 11:30:19 AM

Good afternoon –

Generally during a FDA inspection internal audit reports are not reviewed.

I can point you to some very helpful links on FDA website.

FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities. They are located on the following web page:

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm160670.htm

Please see the guidance document below on monitoring. Occasionally sponsors and or CROs are present during the real time inspection as they can offer some added guidance and information.

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM269919.pdf

Additionally, please see the guidance document that explains FDA clinical investigator inspections. (See link below)

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

FDA Basics > What does FDA inspect?

Additionally, FDA bioresearch monitoring (BIMO) inspections at clinical sites are most often the result of assignments that are issued when a marketing application/submission is being reviewed. At that time, FDA will have the data listing (referred to as line listings) supplied by the applicant/sponsor in the application/submission. These would be the data the sponsor analyzed to provide the results presented in support of marketing, so would be data from the finalized database. These line listings will be compared with the source data at the site to determine if they are an accurate copy of the data collected. If an inspection occurs during an on-going clinical study, such line listings will not be available from the sponsor, so for the data audit portion of such inspections the FDA investigator will compare the source data with the information on the site's completed case report forms.

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

does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Saturday, April 04, 2015 11:56 AM
To: OC GCP Questions
Subject: Documents that the FDA Inspector is allowed to inspect

Hello -

I have a question re: FDA inspections. What documents are the FDA Inspector allowed to request for and inspect?

Specifically, should the Inspector be granted access to Audit Reports by Sponsor companies, or Audit Reports by internal audit teams (i.e. from same institution)?

More power to you and this very helpful site.

Best,

[redacted]