From: Kezer, Doreen M
To: [redacted]
Subject: Audit in BA/BE Studies
Date: Friday, April 25, 2014 10:22:05 AM

Good morning --

As you wait for a response from CDER, please see a few guidance documents that might be helpful to you.

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf

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

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

The Center for Drugs (CDER) will have to comment on your specific question related to BA/BE studies. Their direct email address is druginfo@fda.hhs.gov

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: OC GCP Questions
Sent: Tuesday, April 22, 2014 11:59 AM
To: [Redacted]
Subject: Audit in BA/BE Studies

Good morning --

I sent your email to the Center for Drugs (CDER) last week. I am checking to see if someone responded to your question.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

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-----Original Message-----

From: [Redacted]

Sent: Monday, April 14, 2014 2:42 AM

To: OC GCP Questions

Subject: Audit in BA/BE Studies

Dear Team,

I understand that Sponsor's auditing mechanism for clinical trial studies has significant result!

Is it mandatory to audit all the BA/BE studies provided sponsor is involved in monitoring for all the study and study has been outsourced to qualified CRO!

Will appreciate your quick response!

[Redacted]