From: OC GCP Questions
To: [redacted]
Subject: Response is in-progress: Clinical Database AE Cut-off Dates
Date: Monday, March 10, 2014 12:30:50 PM

Dear [Redacted] –

The Office of Medical Policy asked me to respond to your additional questions and suggested that your also send your questions to CDRH. Since you and I have sent the questions to CDRH with responses that weren't very helpful, I would not recommend doing that again.

As state previously, generally once a subject withdraws from a study, the clinical investigator would not have access to data after the time of withdraw. I have included a few past questions that might be helpful to you. Please see the attached PDF files above.

I think the best course of action at this point is to have the sponsor contact the FDA review division that is overseeing their study to receive a clear understand of AE collection after the subject withdraws from the study. If the protocol is not specific regarding AE collection, perhaps the protocol needs to be revised. As a consultant to the sponsor, I see no reason why you could not participate in the call.

I apologize that you have not received clear answers to your specific questions.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [Redacted]
Sent: Wednesday, February 26, 2014 9:06 PM
To: CDER OMP
Subject: FW: Response is in-progress: Clinical Database AE Cut-off Dates

Dear CDER Representative,

Your office provided responses [in blue] to my questions below. I have some additional questions below [in red] that I hope you will address. I believe this is an important topic that we should have a general, consistent response to ensure all sponsors are collecting and reporting the data the same way. I would imagine it is possible that the study results might look very different depending on which way the sponsor believed was the correct and compliant approach.

Kind Regards,

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From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Wednesday, February 26, 2014 6:41 AM
To: [redacted]
Subject: Response is in-progress: Clinical Database AE Cut-off Dates

Dear [redacted] –

You are correct in your statement below that generally information is not collected when a subject completes or withdraws from a trial. However, it must be different for collecting adverse events. I would have to defer to CDER OMP as they wrote the guidance on adverse events and are considered the experts. I would contact them directly for answers to your additional questions.

CDEROMP@fda.hhs.gov

Or as suggested in their email, have the sponsor contact the appropriate FDA review division for clarification and guidance.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]

Sent: Monday, February 24, 2014 3:59 PM
To: OC GCP Questions
Subject: RE: Response is in-progress: Clinical Database AE Cut-off Dates

Doreen,

First, thank you for continuing to follow up in obtaining a response to the questions below. As the specific request was from a device sponsor, they are still interested in obtaining a response from CDRH.

With regard to the responses in 1.a. and 2, how can a sponsor collect data after the subject has exited the study since the protocol and consent form did not stipulate this? Would it not violate the subject's rights for the *sponsor* to monitor and collect data on a subject who is no longer in the study?

With respect to the response in 1.c., the protocol did not provide for this [as stipulated in the scenario below]. This is the reason for the question. I agree the investigator should ask the sponsor; however, it is the sponsor who is requesting clarification from the FDA on how to respond to the investigator. Again, this is an ongoing study with no provision in the protocol or consent form for continued follow up after the subject has completed their last study visit and been exited from the study. Again, this ties back to question 1.a with respect to the sponsor's (not the investigator) obligation and rights to monitor and collect data on a subject who is no longer enrolled in the study. If I were a study subject, I would not expect that a pharmaceutical or medical device company could have the right to continue looking at my medical chart and collecting data about me after I completed the study. Am I incorrect? And I get it that we all would like that data (e.g., sponsors and FDA), but I question whether we have the right to collect it. Clearly, these are not easy questions; however, I have come across them enough at this point to ask for guidance. I want to ensure that any advice takes all parties and considerations into account (e.g., subject, sponsor, IRB, FDA). Can I please request a response to my additional questions?

Kind Regards,

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