From: OC GCP Questions
To: [redacted]
Subject: Attempts to collect information from Discontinued subjects
Date: Friday, July 31, 2015 6 55:34 AM

Good morning –

Below are previous questions that were submitted regarding AE collection that were answered by FDA's Office of Medical Policy (OMP). These questions and answers might be helpful to you.

Can or should a "sponsor" collect data on an individual, who is no longer considered a study subject, after their 24-month visit?

Response- A sponsor should continue to collect data on a subject experiencing an ongoing adverse event beyond the 24 month visit (and record the data in the CRF) if the information that would be obtained is pertinent to the investigation (e g., could contribute useful information about the safety profile of a drug). Factors to consider include whether the event is serious and the extent to which the event is already characterized. If the event is serious, the investigator should generally continue to follow the patient, and should always follow if the event is also unexpected. For nonserious events there may be less reason to continue to follow, particularly for events already listed in the Investigator Brochure.

If FDA expects the sponsor to collect data beyond the 24-month visit, how long after does this expectation extend (3 months, 6 months, indefinitely)?

Response- Generally, the protocol should provide for follow-up of some types of adverse events until they are resolved (or clinically stable if not expected to resolve). The investigator should seek clarification from the sponsor if necessary. If the sponsor has specific concerns, they should discuss them with the review division.

Similarly regarding data collection after a subject has exited from the study, an individual returns two weeks later to their primary care physician (who happens to be the PI in the study the individual just participated in) with a new AE , SAE, or request to remove the implant. Although the study is ongoing, this individual has already completed the study and ended their participation. Can or should a "sponsor" collect the additional data learned about this individual since the individual is no longer in the study?

Response- It is not usually necessary to collect information on an adverse event that occurs after study completion. The follow-up period provided for in the protocol is generally considered adequate to capture adverse events that may be related to the test article. However, if an investigator believes an event occurring after the patient has completed the trial may be related to the test article, the investigator should inform the sponsor. The sponsor should evaluate as it would any other event reported by the investigator.

The investigational product should have been collected at the time the subject terminated the study. You should consult the sponsor as to how you can obtain P after the study has ended or after the subject terminated the study. FDA regulations state –

PART 312 -- NVESTIGATIONAL NEW DRUG APPLICATION

Subpart D--Responsibilities of Sponsors and Investigators Sec. 312.59 Disposition of unused supply of investigational drug.
The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with 312.57.

Please see some helpful guidance links below –

http //www fda gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm227351 pdf

FDA has a guidance document titled, "Guidance for Clinical Investigators, Sponsors, and RBs Adverse Event Reporting to IRBs - Improving Human Subject Protection" that can be found at http //www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079753 pdf.

Please find the ND safety reporting final rule and draft guidance at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358 htm

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda hhs.gov.

Kind regards,

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From: [redacted]
Sent: Thursday, July 30, 2015 5:08 PM
To: OC GCP Questions
Subject: Attempts to collect information from Discontinued subjects

What is the industry standard for attempts to contact discontinued subjects about information needed for the clinical trials(AE follow up, product return, etc.)?

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