From: OC GCP Questions
To: [redacted]
Subject: Subject monitoring timeframe for AEs/SAEs
Date: Wednesday, April 29, 2015 12:45:12 PM

Good afternoon --

How long an AE should be monitored depends on the protocol, the investigational product, and the AE. Please see the information below.

Some serious adverse events can be anticipated to occur in the study population at some frequency independent of investigational drug exposure (e.g., from a background regimen). At the time of protocol development, the sponsor should identify in the protocol serious adverse events that it does not plan to report individually in an expedited manner because they are anticipated, along with a plan for monitoring the events (see pages 11-12 of the Safety Reporting Requirements for NDs and BA/BE Studies guidance for additional discussion of anticipated events).

Link to guidance:
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Please find the ND safety reporting final rule and draft guidance at: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

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.

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

From: [redacted]
Sent: Tuesday, April 28, 2015 1:05 PM
To: OC GCP Questions
Subject: Subject monitoring timeframe for AEs/SAEs

Hello,
I'm trying to find in the regulations where it states how long a study subject must be monitored for the occurrences of AEs/SAEs. I had thought it was 30 days after the last study drug/ study intervention or 5 half-lives. But I can't find it anywhere. I'm not asking about reporting to the FDA, I'm specifically asking how long we must monitor the subject for them.
Can you please send me the reference to answer this question?
Thanks so much!!
[redacted]