From: OC GCP Questions
To: [redacted]
Subject: Question about Adverse Events
Date: Tuesday, April 14, 2015 12:56:13 PM

Good afternoon ---

Based on the limited information in your email, I don't think the scenario you describe would meet the definition of an adverse event. However a detailed note to file would be beneficial to explain the situation. Additionally, I recommend that your consult the sponsor of your study to get direction from them as I don't know your investigational product or what is required to be reported per the protocol and/or the investigator's brochure.

All adverse events need to be recorded but not all need to be reported. Please see the guidance links below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf

Please see section III (A) on pages 3 -5, "How to Determine If an AE is an Unanticipated Problem that Needs to Be Reported"

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

Unexpected and serious as well as when to report a SAE is explained in the guidance in detail. If the study is under IND, you can always consult the FDA review division that is overseeing your study for more specific guidance.

If I have not adequately answered your question, you may consult the Office of Medical Policy at CDEROMP@fda.hhs.gov as they are the experts on AE reporting and developed the FDA guidances.

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: Monday, April 13, 2015 6:31 PM
To: OC GCP Questions
Subject: Question about Adverse Events

Hello,
Sorry if this question has been asked before. I tried to look through the list of questions people asked but couldn't find anything related.

We had a situation where a subject returned for a visit on a trial and reported they started taking medication for seasonal allergies. When we questioned the subject as to when the seasonal allergies started, they said they have always had it and forgot to report it as part of medical history. I understand that if a current medical condition becomes worse during a study, then an AE needs to be written, but would an AE need to be written if the subject only forgot to report it during the medical history interview and their severity of seasonal allergies remained the same as before they started?

Thanks,
[redacted]