From: OC GCP Questions
To: [redacted]
Subject: Question about Adverse event
Date: Tuesday, March 25, 2014 9:17:05 AM

Good morning

All adverse events need to be recorded but not all need to be reported. The investigator is required to report serious adverse events to the sponsor and must include an assessment of whether there is a reasonable possibility that the drug caused the event (21 CFR 312.64). The sponsor is required to report serious and unexpected suspected adverse reactions to FDA and all participating investigators (21 CFR 312 32(c)(1).

The investigator should follow the protocol regarding the format for reporting the investigator's assessment to the sponsor. Additionally please see FDA's guidance documents below related to adverse event reporting.

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

As stated above, the investigator should report adverse events to the sponsor in accordance with the protocol, ensuring that at a minimum the investigator is complying with 21 CFR 312.64(b) (e.g., immediately report serious adverse events to the sponsor, report non-serious adverse events in accordance with the protocol): http://edocket.access.gpo.gov/cfr_2004/aprqtr/21cfr312.64.htm.

Please find the ND safety reporting final rule and draft guidance at: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. 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, March 24, 2014 5:18 AM
To: OC GCP Questions
Subject: Question about Adverse event

Dear FDA,

Running a study on a diagnostic procedure we came across the following question/point of discussion.
In case of you discover a pathology (eg. Cancer) that is obviously there long before the PICD signature, is this to be considered as AE or Medical History?

Thanks a lot for your advice
[Redacted]