From: OC GCP Questions
To: [redacted]
Subject: Adverse Event Definition
Date: Tuesday, May 27, 2014 2:05:28 PM

Good afternoon --

Your question was forward to my office for a response. 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. This guidance give you definitions of adverse events and other specific AE reporting. Please see section III, A. in the guidance.

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Please find the ND safety reporting final rule and draft guidance at: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 gcpquestions@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: CDER DRUG INFO
Sent: Tuesday, May 27, 2014 12:21 PM
To: OC GCP Questions
Subject: FW: Adverse Event Definition

Hi GCP,

I am forwarding for your consideration and possible direct reply.

Thanks and have a great day!
Cherryn

Cherryn Chang, Pharm.D.
Division of Drug Information
FDA|CDER|OCOMM

From: [Redacted]
Sent: Sunday, May 25, 2014 11:25 PM
To: CDER DRUG INFO
Subject: Adverse Event Definition

Dear Officer,

Hope this mail finds you well I write this mail just wanted to seek further clarifications on AE definition

One of my clinical trial protocol says 'AE should ONLY be reported after 1st dose of investigated product' I think that is okay since we do have following statement from in ICH Topic E 6 (R1) regarding AE definition It states 'subject administered a pharmaceutical product…'

However how about abnormalities identified during screening period? (after Informed Consent date up to 1st dosing date)? What is the general practice? I'm instructed to report all abnormalities during screening as Medical History but for some acute events during screening visit, it would be weird to report them as Medical History rather than AE

1.2 Adverse Event (AE)
Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product

Please kindly advise…
Thank you for your reply in advance! [Redacted]