From: OC GCP Questions
To: [redacted]
Subject: Onset time for recording of adverse events in clinical studies of an investigational prodcut
Date: Monday, September 28, 2015 8:35:56 AM

Good morning –

t depends on the nature of the adverse event (AE), the protocol, and whether the AE is nonserious or serious. A detailed discussion related to this issue occurs in FDA's draft guidance "Safety Reporting Requirements for NDs and BA/BE Studies" (available at http //www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf). This draft guidance was issued in concert with FDA's final rule, which published on September 29, 2010, "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products." Information on this final rule is available at the following link: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358 htm

Additionally, please see 21 CFR 312 64(b) states –

b) Safety reports. An investigator must immediately report to the sponsor any serious adverse event, whether or not considered drug related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the drug caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the drug and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor. The investigator must record nonserious adverse events and report them to the sponsor according to the timetable for reporting specified in the protocol

Please also see FDA's guidance on Adverse Events reporting to IRBs

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

Please note, 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.

If you have additional specific questions related to AE reporting, you may contact CDER, Office of Medical Policy directly. CDEROMP@fda hhs.gov

I hope this information is helpful. Please contact us again at gcp questions@fda hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, September 25, 2015 3:21 PM
To: OC GCP Questions
Subject: Onset time for recording of adverse events in clinical studies of an investigational prodcut

Hi,

I've received conflicted data on when there's a requirement to record and report an adverse event in the scope an interventional clinical study. Is it:

- upon intervention with IMP [per NCI presentation, 2006, Elizabeth Ness]
- from signing of informed consent form [ICF].

Your response greatly appreciated,

Cheers,

[redacted]