From: OC GCP Questions
To: [redacted]
Subject: Question about Adverse event
Date: Wednesday, March 26, 2014 8:19:38 AM

Good morning –

As stated below, the protocol should dictate what should be recorded as an AE. If you are not he sponsor, please also consult the sponsor of your study. However, if you can clearly document that the condition existed prior to enrollment in the study than it would seem that documenting it in the clinical history might seem appropriate. If your study is under an ND with FDA you can always consult the review division that is overseeing your study for more specific advice.

Kind regards,

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

From: [Redacted]
Sent: Tuesday, March 25, 2014 11:31 AM
To: OC GCP Questions
Subject: RE: Question about Adverse event

Hi,

Thanks for your answer, however the question was more focused on how to classify those pathology that are discovered during the study but are clearly there from long before the study.
Should we report as AE or clinical History?
[Redacted]