

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question on pre-existing condition diagnosed during AE reporting period
Date: Thursday, September 11, 2014 8:17:13 AM

Good morning –

From the limited information in your email, it appears that the inherited condition should be documented in the medical history with an explanation as to how it was found as it was not directly related to the investigational product. Also, please consult the protocol to see if this type of situation is specifically addressed.

Please find the ND safety reporting final rule and draft guidance at: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.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, September 10, 2014 11:30 AM
To: OC GCP Questions
Subject: Question on pre-existing condition diagnosed during AE reporting period

To whom it may concern

I work with clinical research performing medical review of clinical trial data, and I would like to understand how the investigational site should record a pre-existing condition (i.e. an inherited syndrome) that was only diagnosed during the study drug administration period, and diagnosed only due to study-related procedures. Per my understanding, an inherited condition cannot be considered associated with the drug, and therefore, would not be considered an AE, even if diagnosed in the AE reporting period. Would this - in your opinion - be recorded as an adverse event or as medical history?
Thank you very much for any clarification you can provide.

Warm regards
[redacted]