From: OC GCP Questions
To: [redacted]
Subject: Adverse Event Reporting
Date: Thursday, September 18, 2014 1:37:31 PM

Good afternoon –

t would be difficult for me to answer your specific question as I am not familiar with your study. It is best to ask the sponsor or the FDA program manager for direction if the study is under ND.

However I am providing you with additional information below. (Guidance and final rule on safety reporting requirements) You will find these links very useful.

A discussion related to this issue occurs in FDA's draft guidance "Safety Reporting Requirements for NDs and BA/BE Studies" (available at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf). This draft guidance was issued in concert with FDA's final rule, which published on September 29, 2010, "Investigational New Drug Safety Reporting Requirements for Human Drug and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

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: Thursday, September 18, 2014 2:39 AM
To: OC GCP Questions
Subject: Adverse Event Reporting

Dear Officer,

Hope this mail finds you well. I write this mail just wanted following question regarding AE reporting.

The case is subject had been experiencing thrombocytopenia and the severity varies from time to time (grade 3 in very beginning and get worse to grade 4) base on lab result. There are 2 handlings on AE reporting. Please confirm which one is correct OR preferred.

A, report 2 separate AEs due to difference in severity. One AE with severity of grade 3 and other is AE with severity of grade 4.
B, report one AE because subject is not recovered from grade 3 thrombocytopenia but getting worse. So that means this is one single continuous AE and the Max severity (grade 4) will be recorded.

Please let me know if there is any guidance for this kind of case from GCP level.
Look forward to your response.
[redacted]