From:	OC GCP Questions
To:	[redacted]
Subject:	AE Data Collection When Should Both 'AESEV Severity/Intensity' and 'AETOXGR Standard Toxicity Grade' be Collected?
Date:	Friday, July 31, 2015 11:58:52 AM

Dear [redacted]

This is the 5th office at FDA that I have contacted. Please see their answer below. I am sorry that it took so long to obtain an answer and the answer might not be what you are looking for.

Kind regards,

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

ANSWER –

Hi, this should be the sponsor's choice. They can also contact the review team to get input.

Thanks,

Rui Li, MD, MS
Computer Scientist
Office of Business Informatics
CDER, FDA
(240)402-2629

From: [redacted]
Sent: Wednesday, July 29, 2015 11:30 AM
To: OC GCP Questions
Subject: Re: AE Data Collection When Should Both 'AESEV Severity/Intensity' and 'AETOXGR Standard Toxicity Grade' be Collected?

Hi Doreen,

I hope everything is okay with your family. No one else has responded to me.

For the purposes of the project we used only AETOXGR Standard Toxicity Grade. The question I have is general and not related to a specific IND. I was wondering when would both AESEV and AETOXGR be used.
[redacted]

On 29 July 2015 at 17:11, OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:
Good morning –

I was away from the office for a few weeks for a family emergency. I know your email circulated around a few offices here at FDA as my office is not the correct office to respond. Do you hear back from FDA? If not, if your study is under an IND, it is probably best to consult the regulatory project manager of the IND for guidance and 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, July 07, 2015 5:59 AM
To: OC GCP Questions
Subject: AE Data Collection When Should Both 'AESEV Severity/Intensity' and 'AETOXGR Standard Toxicity Grade' be Collected?

Dear Sir/Madam,

In relation to the collection adverse event (AE) data under what conditions would both 'AESEV Severity/Intensity' and 'AETOXGR Standard Toxicity Grade' be collected.

These are two SDTM AE variables. It is mentioned that either one or the other should be collected however on certain circumstances both should be collected. Please can you inform me when this is the case or provide me with a link to where this is described.

Thank you in advance.