

From: OC GCP Questions
To: [REDACTED]
Subject: A question about CTCAE
Date: Thursday, May 19, 2016 12:26:00 PM

Good afternoon --

I cannot specifically answer your question. It is best to seek advice from the sponsor or review the protocol for clarifications on event reporting.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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-----Original Message-----

From: [REDACTED]
Sent: Thursday, May 19, 2016 3:12 AM
To: OC GCP Questions
Subject: A question about CTCAE

Hello,

A quick question about CTCAE v4. Distinction between grade 2 and grade 3: Specifically, the meaning of the term "limiting," when CTCAE says "limiting instrumental, or self care, ADL." Is it appropriate to assign grade 3 when the patient has *any difficulty* performing a self care ADL, or should he/she be *unable* to perform it?

Thank you very much in advance for clarifying.

[REDACTED]