From: OC GCP Questions
To: [redacted]
Subject: Good Clinical Practice
Date: Thursday, November 06, 2014 1:58:12 PM

Good afternoon –

Not necessarily. Clinical studies might have double-blind trial with an active drug and placebo or(even an open – label trial with multiple doses of an active drug). These types of trials often include the word treatment in the informed consent document.

Kind regards,

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

From: [redacted]
Sent: Thursday, November 06, 2014 10:37 AM
To: OC GCP Questions
Subject: Good Clinical Practice

Dear Madam/Sir,
I am a student, enrolled in a Principle of Clinical Research -1 course. I have a question about GCP guidelines, where a word' treatment' has been used.
1.2 Adverse event (AE): An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
What I understand for the investigational product a word treatment cannot be used. I will be thankful for the clarification.
Sincerely,
[redacted]