

**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

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:** 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]