

From: [OC GCP Questions](#)
To: [Redacted]
Subject: Question Clinical Meaningful Difference
Date: Tuesday, January 21, 2014 12:02:11 PM

Good afternoon –

Please contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov. They most likely will forward you email to one of the review divisions for a response.

Kind regards,

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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: Tuesday, January 21, 2014 11:09 AM
To: OC GCP Questions
Subject: Question Clinical Meaningful Difference

Hello,

I am part of a team designing a clinical study and I was wondering if the FDA can give me some insights in what a Clinically Meaningful Difference is. Also, is it possible to know what this difference should be for an Oncology drug when compared to a Standard of Care?

Thank you,
[Redacted]