From: OC GCP Questions
To: [redacted]
Subject: Phase III Clinical Trial - Enrollment Question
Date: Thursday, January 30, 2014 1:02:52 PM

Good afternoon –

My office cannot answer your question as all studies are different. I recommend that you seek advice from the FDA Review Division that you are working with on your specific study (e.g. your assigned FDA Project Manager for the IND). You should also consult your reviewing IRB.

Sorry I could not be more helpful.

Kind regards,

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

From: [Redacted]
Sent: Thursday, January 30, 2014 12:19 PM
To: OC GCP Questions
Subject: Phase III Clinical Trial - Enrollment Question

Hello

I am working on a global trial that has study sites in the US and have a question.

The number of study subject, as written in the protocol, was "up to 440 subjects". It was changed via a protocol amendment in 2012 to "approximately 440". The currently-approved protocol in the US has the language – "approximately 440".

In looking at enrollment, the sponsor's statisticians have determined that enrollment should be raised to 700 to achieve the study's goals.

We have amended the protocol, increasing the number of subjects to "approximately 700, and are in the process of submitting that amendment for review and approval to all the country-level competent/regulatory authorities and study sites' IRBs.

My question is this:

If enrollment reaches 440 subjects before the amendment raising the number from "approximately 440" to "approximately 700", would the study have to stop enrolling in the US or would the study be

able to continue to enroll given the number of subjects being noted as “approximately 440” and the amendment in process of being reviewed?

Thank you for your guidance,
[Redacted]