From: OC GCP Questions
To: [redacted]
Subject: A question on clinical trial
Date: Wednesday, April 01, 2015 12:27:12 PM

Good afternoon –

I cannot answer your question as I am unaware of the specifics of the study or the investigational product. Please contact the FDA regulatory project manager of the study under question.

Kind regards,

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

From: [redacted]
Sent: Wednesday, April 01, 2015 1:52 AM
To: OC GCP Questions
Subject: A question on clinical trial

Dear,

I am a clinical trial professional. I needed a small clarification on few things.

There is a one study ongoing which has different parts in the same study. Each part has different design and different patient pool. But all the the parts are part of one single study and one single trial.

Now the question is can patient who are enrolled into one part of the study after the completion and a gap of 3 months (an exclusion criteria) be enrolled into other part of the study subject to all the criteria.

Scientifically (safety wise, PK etc) there is no issue at all and there is a good proof. The protocol does not exclusively say that patients can be enrolled in other part of the study.

Please let me know if there are any references for this kind of situation. The study comes under FDA submission.

[redacted]