From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, February 22, 2006 8:06 AM
To: [Redacted]
Subject: RE: adaptive trial design

Dear [Redacted]:

The Food and Drug Administration (FDA) regulations on adequate and well-controlled studies (see 21 CFR 314.126) do not specifically address "adaptive trial design," nor do we have any guidance on this issue.

I have shared your e-mail with the Office of Medical Policy in the Center for Drug Evaluation and Research, as that office may be interested in developing guidance on this topic in the future.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, February 21, 2006 10:13 AM
To: OC GCP Questions
Subject: adaptive trial design

Hello,

I received this address from someone in the FDA documentation section.

There is a rumor around that "adaptive trial design" is being discussed at the FDA, and that there might be some information available, although there is no guidance. Is there anything at all on the website? Maybe a presentation or other types of information?

A small company with which I am working would like to start with a phase II trial, and, after choosing the dose, continue the phase II patients (at the chosen dose) to be analysed with the phase III patients for long term

outcome.

Thanks for any help you can give.

[Redacted]