From: Toth-Allen, Jean
Sent: Thursday, September 14, 2006 8:40 AM
To:[purged]
Subject: RE: Question

Dear [purged]:

Thank you for your inquiry regarding numbers of clinical trials an individual investigator takes part in. Please excuse my delay in responding.

There is nothing in FDA regulations or guidance that specifically addresses this issue. It would be difficult to guesstimate such a number as trials can have varied degrees of complexity and clinical investigators and their sites have varying capacities, some of which are dependent on the medical specialty involved. It would appear that how many clinical studies can reasonably be simultaneously conducted will depend on a number of factors, including but not limited to, the complexity of each study, the number of clinical trial staff available at the site, and the capability of site facilities to conduct required trial procedures appropriately and in a timely fashion. In addition, conflict of interest issues may arise should an investigator attempt to simultaneously conduct trials for similar products from competing companies.

Sorry if this answer does not prove particularly useful in any real life situation you may be considering.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: [purged]
Sent: Tuesday, September 05, 2006 6:04 PM
To: OC GCP Questions
Subject: Question

Hello-

What would a safe and reasonable number of studies one PI should be overseeing? This question came up the other day, and I am not sure I have ever heard anyone define this, and does the FDA have a guideline or a certain number to go by? Thank you for your time.

Regards,

[purged]