From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, June 12, 2006 1:24 PM
To: [purged]
Subject: RE: clinical trials

Dear [purged],

I know that posting information about clinical trials for serious diseases and conditions is encouraged. You can go to the web at: http://www.clinicaltrials.gov/ which does this.
ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. We advise that the information provided on ClinicalTrials.gov should be used in conjunction with advice from health care professionals.
There is a registration site that provides more information. In part, it states: "Clinical trials are registered with ClinicalTrials.gov via a web based data entry system called the Protocol Registration System (PRS).
ClinicalTrials.gov allows the registration of trials that:
are approved by a human subject review board (or equivalent) and
conform to the regulations of the appropriate national health authorities.
ClinicalTrials.gov facilitates registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative requiring prior entry of clinical trials in a public registry as a condition for publication.
Multi-site trials and multi-sponsor trials are susceptible to duplicate registration, thus care must be taken in how the trials are registered. For multi-sponsor trials it is the lead sponsor who should take responsibility for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered once and only once."
I'm not aware of any regulation that would require the posting of this information; however, I will admit that I'm not necessarily in the best position to know. You might want to keep an eye on the Unified Agenda which is published (I think) semi-annually and which lists proposed and final regulations.
I hope this information is helpful to you.
Sincerely,
Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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: Monday, June 12, 2006 9:31 AM
To: OC GCP Questions
Subject: clinical trials

I am trying to find out if the FDA is going to start requiring Pharma companies to start posting information on ongoing clinical trials. I have not found any proposed regulations on this topic, but have heard this from colleagues numerous times and am trying to find out some information. Anything you can provide me on this topic would be greatly appreciated.

Thank you,

[purged]