From: Toth-Allen, Jean
Sent: Friday, December 15, 2006 9:14 AM
To: [purged]
Subject: RE: question from Harvard student

Dear [purged]:

Thank you for your inquiry regarding patient-reported outcomes in cancer clinical trials.

While most investigational studies are considered proprietary by their very nature, there is a database at which information about on-going trials regarding diseases and conditions that are life-threatening are discussed to assist the general public. That information is accessible through ClinicalTrials.gov accessible at http://clinicaltrials.gov/ct/gui/action/SearchAction?term=Clinical+Trials.

For general information regarding FDA's present thinking on the use of patient-reported outcomes in FDA-regulated trials, you can access a draft guidance document, issued in January 2006, at http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0044-gdl0001.pdf.

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcp.questions@fda.hhs.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice 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.

-----Original Message-----
From: [purged]
Sent: Monday, December 11, 2006 2:04 PM
To: OC GCP Questions
Subject: question from Harvard student

Hello,

I'm writing to inquire about Patient-Reported Outcomes. I am wondering where I can obtain information/documents about PRO pertaining to Cancer Clinical Trials. Thank you .
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