

Attachment E03 – NCI/DCTD/CTEP Financial Disclosure Form

OMB #xxxx-xxxx
Expiration Date: xx/xx/xxxx

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB #xxxx-xxxx). Do not return the completed form to this address

Screenshots

Information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

**CONFIDENTIAL
FINANCIAL DISCLOSURE FORM**

The FDA requires that the following confidential financial disclosure information be collected for all investigators (see 21CFR 34.4). Any pharmaceutical company that submits a marketing application for any drug, biologic product, or device is required to submit certain information concerning the compensation to, and financial interests of, any clinical investigator participating in any clinical study submitted in the marketing application. The Cancer Therapy Evaluation Program (CTEP) is collecting this confidential information annually for all CTEP-registered investigators.

Please indicate below if you, your spouse, or dependent children have any of the following disclosable financial arrangements.

Do you currently have or have you at any time in the past year had any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study?*

Yes No

Have you had any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria?*

Yes No

Do you currently have or have you at any time in the past year had any proprietary interest in the product tested in the covered study held by the clinical investigator?*

Yes No

Do you currently have or have you at any time in the past year had any significant equity interest, as defined in 21 CFR 34.2(b), held by the clinical investigator in the sponsor of the covered study?*

Yes No

Actions	CTEP ID	Pharmaceutical Company*	Site Address*
<input checked="" type="checkbox"/> Delete	AZP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike PO Box 15437 Wilmington 19850-5437 DE US

If you answered Yes to any of the questions above, please provide the name of the pharmaceutical company or companies with whom the financial arrangement exists (add an attachment if needed).

This form must be electronically signed and submitted as per the NCI Registration requirements for your Registration Type. Completed forms will be maintained by the Pharmaceutical Management Branch, CTEP as part of your confidential investigator registration file. This information will only be provided (1) to a pharmaceutical company which has an agreement (e.g., a Clinical Trials Agreement [CTA] or a Cooperative Research and Development Agreement [CRADA]) with CTEP if CTEP is notified that a licensing application is being prepared by that company or (2) to a Cooperative Group of which you are a member if CTEP is notified that a clinical trial is being developed by that Group and a pharmaceutical company with whom you have indicated a financial arrangement. You may be contacted in the future by a pharmaceutical company representative or by your Cooperative Group administrative staff for additional information.

Figure 1: Electronic Capture of the Financial Disclosure Form

Breakdown of Elements

There are four different Yes/No questions of the Financial Disclosure Form that are electronically captured, with an option to provide additional information if the investigator answered 'Yes' to any of the questions:

1. Do you currently have or have you at any time in the past year had any financial arrangement entered into between the sponsor of the covered study and the

clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study?

2. Have you had any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria?
3. Do you currently have or have you at any time in the past year had any proprietary interest in the product tested in the covered study held by the clinical investigator?
4. Do you currently have or have you at any time in the past year had any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study?

If the investigator answered 'Yes' to any of the above questions, a field will appear where the investigator can add the following information:

1. Add New Record: Allows the investigator to add a new record of information.
2. Delete: Allows the investigator to update or delete a row of information.
3. CTEP ID: The CTEP ID of the pharmaceutical company.
4. Pharmaceutical Company: The name of the company.
5. Site Address: The address of the pharmaceutical company