From: OC GCP Questions
To: [redacted]
Subject: Question regarding Non Interventional Studies and Investigator (PI) Financial Disclosures
Date: Wednesday, January 08, 2014 12:40:00 PM
Attachments: FDA guidance FD by Clinical Investigators.pdf

Good afternoon –

Whether a clinical investigator needs to provide financial information to the sponsor depends on whether or not the clinical study is a "covered clinical study" as defined by the financial disclosure by clinical investigators regulations. The definition is in 21 CFR 54.2(e) and states:

Covered clinical study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase I tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute ''covered clinical studies'' for purposes of complying with financial disclosure requirements.

Further discussion of what would be considered a "covered clinical study" is available in FDA's guidance document titled, "Financial Disclosure by Clinical Investigators" (available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf). In particular, see section IV.G. Covered Clinical Study.

You will note that neither the definition nor the guidance discuss the type of study (i.e., non interventional). The determining factor is whether the study will be submitted in a marketing application or reclassification petition and relied upon to establish that the product is effective or any study in which a single investigator makes a significant contribution to the demonstration of safety. See question IV.G.1 in the guidance.

If you do not know whether the study will be submitted to FDA in the future, it may be easier to collect the information at the time the study is conducted. Otherwise, if the study is later used as a covered clinical study, you would need to act with due diligence to assemble the information at that time. Since an application may be submitted to FDA several years after a study is completed, it may be more difficult to contact clinical investigators and gather the information. Note that the regulations in 21 CFR 54.4 state, "Where the applicant acts with due diligence to obtain the information required in this section but is unable to do so..." The guidance discusses what FDA means by the term "due diligence" in question IV.B.7.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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: [Redacted]
Sent: Wednesday, January 08, 2014 9:38 AM
To: OC GCP Questions
Subject: Question regarding Non Interventional Studies and Investigator (PI) Financial Disclosures

Dear FDA Representative,

I am reaching out to you today to ask a question about Non Interventional Studies and whether it is required that Investigator Site personnel complete a Financial Disclosure Form for this study type.

We have referenced the attached ***FDA Guidance*** as well as ***Part 54 – Financial Disclosure by Clinical Investigators*** but could not ascertain if [Redacted] would need to collect Financial Disclosure Forms from Investigators Site personnel on a Non-Interventional Trial.

Your guidance would be greatly appreciated.

Thank you.
[Redacted]