From: OC GCP Questions
To: [redacted]
Subject: PI Conflict in Dual Role as Health Authority Employee
Date: Monday, July 28, 2014 2:09:38 PM

Good afternoon –

I cannot specifically answer your question. You will have to determine whether there is a conflict of interest in the scenario you describe. However, I can offer the following information.

A conflict of interest in a clinical trial related to a clinical investigator may be considered a conflict between the private interests and official responsibilities of the clinical investigator and the objective design, conduct and reporting of the clinical trial. A risk of such interests is that they may lead to intentional or unintentional bias or errors in the clinical trial and may compromise the well-being of the human research subjects.

You may be interested in the U.S. Department of Health and Human Services (HHS) guidance document, "Financial Relationships and Interests in Research Involving Human Subjects" (available at http://www.hhs.gov/ohrp/policy/fguid.pdf), which raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and, if so, what actions could be considered to protect those subjects.

You should check with your local and national laws and policies to see if there are any requirements related to conflict of interest and clinical trials. The U.S. has regulations related to federally funded studies and ensuring objectivity ("Responsibility of Applicants for Promoting Objectivity in Research for which Funding is Sought" and "Responsible Prospective Contractors" available at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

For studies that will be submitted to FDA to support marketing applications, there are requirements that clinical investigators report their financial interests and arrangements to the study sponsor (see 21 CFR part 54, Financial Disclosure by Clinical Investigators, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1). The clinical investigator financial disclosure information, along with the steps taken to minimize bias in the study, is submitted to FDA in a marketing application supported by the clinical trial and is used in the evaluation of the conduct of the study and the integrity of the study data. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, July 28, 2014 1:32 PM
To: OC GCP Questions
Subject: PI Conflict in Dual Role as Health Authority Employee

Dear Office of GCP Compliance,

We are the sponsor of a Phase 2 and Phase 3 clinical study, and seek your guidance on a potential conflict of interest with a PI on our studies.

Background: The PI started participation in these clinical studies in 2010. There were no conflicts of interest or financial interest noted at that time. Then in 2011, the PI became employed by the health authority in his country. His primary role with the health authority is to provide Periodic Safety Update Reports for products that are approved by the European Medicines Agency (EMA). He has stated that he only evaluates those drugs that are already approved or registered by the EMA, and that he does not have any influence on the registration process or drug approval.

Position: From our perspective, there is no conflict of interest between his employment at the health authority and his official responsibilities as a clinical investigator and the objective conduct and reporting of the clinical studies. Further, we don't believe that his role with the health authority would lead to bias or errors in the clinical studies, nor do we feel that his participation compromises the well-being of the patients in our studies. Therefore, we can allow the PI to continue in his role on our studies in parallel with his employment at the health authority as long as we can assure and appropriately document through a signed certification from the PI that:

1) the PI continues to comply with the protocols and local regulations;
2) the PI has no financial or other interest; and
3) the PI will not be a reviewer of any clinical data associated with this drug.

Question: Do you agree that there is no conflict of interest with his role in the health authority, and the PI can continue to participate in the studies?

We want to understand your perspectives on this topic, and look forward to your response. Thank you in advance.

Kind regards,
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