From: Hommel, Carolyn - OC
Sent: Wednesday, October 25, 2006 1:23 PM
To: [purged]
Subject: RE: CSR appendix question - investigator listing

Dear [purged],

If it's just a list of names/sites that were recruited by the sponsor but didn't actually enroll/accrue subjects, I don't see why it's a problem to include this information. It's my impression that this information has generally been routinely submitted to the agency.

There's no specific regulatory requirement (that I'm aware of) about listing or not listing non-enrolling investigators in the clinical study report, so you're free to do what you like. However, if you were to be audited and found to have "omitted" something, it may raise questions as to what else may have been "omitted." Thus, in my opinion, it's always better to be as inclusive and up front as possible.

Carolyn

From: [purged]
Sent: Tuesday, October 24, 2006 1:23 PM
To: OC GCP Questions
Subject: RE: CSR appendix question - investigator listing

Hi Carolyn,

Thanks for your prompt response.

CSR is a common acronym for the clinical study report. I work for a CRO and we are working with a sponsor to assemble a CSR.

In my opinion, the appendix of the CSR that we are submitting should clarify that non-enrolling investigator's were omitted from the listing and I would also like to see some kind of documentation of the sponsor's acknowledgement that the non-enrolling sites will be omitted from the appendix listing (see ICHGCP guidance E3 sec.16.1.4).

If this particular clinical study report were to be audited by a regulatory authority, would the omission of non-enrolling investigative sites raise a flag with an inspector?

Please advise.

Thank you,
[purged]

OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:
Dear [purged]:

While FDA's regulations require sponsors to "...submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol..." [See 21 CFR 312.30(c)], such amendments would be submitted while the study is ongoing. I'm not familiar with the term "CSR" (it doesn't appear in FDA's regulations), but I'm guessing that it's a summary record of some sort that is being submitted after a study has been completed.

My advice would be to list all investigators in the appendix, and annotate the list to show how many subjects were screened and enrolled at each site, including those who may have screened some but did not enroll any subjects. By including all investigators/sites, you would be less likely to omit a site that did, in fact, enroll subjects.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 14-B17
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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: Tuesday, October 24, 2006 10:18 AM
To: OC GCP Questions
Subject: CSR appendix question - investigator listing

Hello,

I have a question regarding investigator/affiliation listings in a CSR appendix (16.1.4). What is the regulatory authorities view on only listing the investigators in a study who enrolled subjects and leaving off the listing investigator's who were active on the study but did not enroll any subjects. How would this be viewed by the regulatory authority? Would further clarification be required?

Thank you for your time,

[purged]