

From: OC GCP Questions
Sent: Wednesday, May 13, 2015 3:21 PM
To: [REDACTED]
Cc: CDER DRUG INFO
Subject: RE: Regulatory document collection for umbrella/basket trials

Dear [REDACTED],

For your second question, a sponsor is defined under the financial disclosure regulations as follows:

Sponsor of the covered clinical study – For purposes of part 54, “sponsor of the covered clinical study” means “a party supporting a particular study at the time it was carried out.” (See 21 CFR § 54.2(h).) A covered clinical study may have more than one sponsor for whom financial information will need to be collected. For example, if one party designed and conducted the covered clinical study, a second party provided funding, and a third party provided the test product, there would be three sponsors of the covered clinical study. However, if the third party in this example was reimbursed for the test product, it would not be considered a sponsor of the covered clinical study and the study would be considered to have two sponsors. Note also that the definition of “sponsor” for purposes of part 54 is different than the definition of “sponsor” for purposes of investigational new drug applications (INDs) and investigational device exemptions applications (IDEs) (see 21 CFR §§ 312.3(b) and 812.3(n)).

Additional information regarding the sponsor’s responsibilities related to financial disclosure is available in the guidance document “Financial Disclosure by Clinical Investigators” (see: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>). Note that the study can have more than one sponsor according to the financial disclosure regulations.

Regarding your first question concerning oncology basket/umbrella clinical trials, I am copying the Center for Drug Evaluation and Research’s (CDER) Division of Drug Information. Someone from CDER is better suited to address this question.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm> .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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: [REDACTED]
Sent: Wednesday, May 13, 2015 8:34 AM
To: OC GCP Questions
Subject: Regulatory document collection for umbrella/basket trials

Good morning,

Can you please address two questions regarding investigator-sponsored basket/umbrella trials?

- 1) Is there someone we can contact directly regarding regulatory document collection for these trials? We are beginning to have investigator-sponsored protocols in discussion, and we want to be certain that we are meeting our obligations appropriately. I found the very nicely done presentation by Dr. Julia Beaver, but it does not really address the question we have regarding regulatory documentation for these studies.
<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM423361.pdf>
- 2) Financial disclosure: We assume that each of the pharmaceutical companies providing drug for the study will be considered sponsors (and thus a financial disclosure form will be required for each). Can you please confirm or deny.

Thank you for your time,

[REDACTED]