Good Clinical Practice Q&A

In cases in which an investigator submits an IND (i.e., an “investigator IND”) to initiate a study with an approved drug, or in which the investigator determines that the study is exempt from IND submission requirements, what are the regulatory responsibilities of the drug company that manufacturers the drug?

In the simplest terms, the investigator is the study sponsor, also called the “sponsor-investigator,” in such cases, and he or she would bear all the burdens of the study sponsor. Therefore, the drug firm would not have regulatory responsibilities associated with such studies.

FDA regulations (21 CFR 312.3(b)) emphasize this in defining the term “sponsor-investigator” as “an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.”

The ICH guideline’s definition of sponsor-investigator (1.54) is equally clear on the regulatory responsibilities of this individual: “An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of sponsor-investigator include both those of a sponsor and those of an investigator.”

It is worth noting that, in the past, FDA field investigators have noted compliance issues with sponsor-investigators. In some cases, they noted, sponsor-investigators are fulfilling their investigator-related requirements but are failing to become aware of or fulfill their sponsor-related requirements, such as monitoring the study. In fact, in its latest Compliance Policy Guide 7348.811 for clinical investigator inspections (December 2008), the FDA instructs agency field staff to “determine if any monitoring was done and, if so, describe [and] obtain a copy of the monitoring SOP, if available.”

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