

Good Clinical Practice Q&A: Focus on Medical Care

What guidance, if any, has the FDA provided regarding its views on the extent of medical care that a clinical investigator should provide to clinical trial subjects, for example, for conditions/illnesses unrelated to the study or outside the investigator's area of expertise?

Under a subsection entitled, "reasonable medical care necessitated by participation in a clinical trial," the FDA offered a series of recommendations through an October 2009 guidance entitled, "Investigator Responsibilities — Protecting the Rights, Safety and Welfare of Study Subjects." In fact, the final guidance provides specific language establishing, as an investigator responsibility, "providing reasonable access to needed medical care, either by the investigator or by another identified, qualified individual (e.g., when the investigator is unavailable or when specialized care is needed).

"During a subject's participation in a trial, the investigator (or designated subinvestigator) should ensure that reasonable medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial participation." The guidance states, "If the investigator does not possess the expertise necessary to provide the type of medical care needed by a subject, the investigator should make sure that the subject is able to obtain the necessary care from a qualified practitioner. For example, if the study involves placement of a carotid stent by an interventional neuroradiologist and the subject suffers a cerebral stroke, the neuroradiologist should assess the clinical status of the subject and arrange for further care of the subject by a neurologist. Subjects should receive appropriate medical evaluation and treatment until resolution of any emergent condition related to the study intervention that develops during or after the course of their participation in a study, even if the follow-up period extends beyond the end of the study at the investigative site.

"The investigator should also inform a subject when medical care is needed for conditions or illnesses unrelated to the study intervention or the disease or condition under study when such condition or illness is readily apparent or identified through the screening procedures and eligibility criteria for the study. For example, if the investigator determines that the subject has had an exacerbation of an existing condition unrelated to the investigational product or the disease or condition under study, the investigator should inform the subject. The subject should also be advised to seek appropriate care from the physician who was treating the illness prior to the study, if there is one, or assist the subject in obtaining needed medical care."¹

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2010, #2.37 p. 52-53

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2010," is available for \$45.95 at <http://www.barnettinternational.com>.