

Good Clinical Practice Q&A: Focus on FDA Inspections

Is the sponsor/monitor or contract research organization (CRO) permitted to be present during an FDA inspection of a clinical trial site?

Although there is no FDA prohibition against a sponsor/monitor/CRO representative being present during an FDA site inspection, such a practice would be unconventional. Some sponsors do want to be present during inspections, however.

Sites are advised to alert a sponsor of upcoming inspections so that the company may assist with preparations.¹

Can the FDA request that a clinical trial site not contact a sponsor regarding an upcoming site inspection?

In general, if the FDA is conducting a routine inspection, it anticipates that a sponsor will be notified by site staff and that the sponsor will probably take action to assess GCP compliance prior to the FDA visit. Many FDA investigators even appreciate the work that monitors do to prepare sites for upcoming agency inspections. "Most of the time, at least 90 percent of the time, the sites are trained to contact the sponsor [regarding a pending inspection]," says FDA Bioresearch Monitoring Specialist and Field Investigator Mike Rashti in *The Global GCP Compliance Report 2006: US, EU, and Japan* (www.barnettinternational.com). "So if I show up for an inspection, and look at the monitoring log and saw that somebody such as a study monitor was there last week, I know somebody went there to ease the inspection because it makes my job easier. They put the records together, put all of the original consent forms in one binder, and make sure that everything is accessible to us. So the sponsor usually sends a monitor to pull together the records for us to ease our inspection."

If the FDA is worried that a particular sponsor may "paper over" problems, it can simply show up unannounced.²

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2008, #10.34 p. 291
2. Ibid. #10.38, p. 293-294

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2008," is available for \$45.95 at <http://www.barnettinternational.com/>