

## 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.<sup>1</sup>

### **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. If the FDA is worried that a particular sponsor may "paper over" problems, it can simply show up unannounced. Unannounced "for cause" FDA site inspections rarely occur, however, and all routine inspections are announced.<sup>2</sup>

### **Does the FDA perform routine inspections of sites conducting trials under INDs for which the investigator is the sponsor (i.e., sponsor-investigator)?**

Typically, no. Generally, what triggers a routine inspection of a site is the submission of clinical or other data in an NDA and the need for the FDA to base important regulatory decision-making on those data. Since the limited data (a few patients per site) collected by a sponsor-investigator are not typically collected for, or submitted in, a marketing application on which the FDA must make a regulatory decision, these sites are not typically inspected. The exception would be the case in which a possible problem comes to light, a situation that would likely trigger a "for cause" inspection.

Events that might trigger a "for cause" inspection include a "whistleblower" (informant) report to the FDA, reports of possible fraud or of serious adverse reactions, or a complaint from the drug's manufacturer that an investigator is inappropriately studying the drug for an off-label purpose, among others.<sup>3</sup>

### **Reference**

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pg. 183
2. Ibid, pg. 186
3. Ibid, pg. 190

### **Source**

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>