## Good Clinical Practice Q&A: Focus on FDA Investigations

**In the past, FDA compliance officials have noted that some industry sponsors have failed to secure compliance after routine monitoring discovered problems at study sites. Do they still perceive this to be a problem?**

Agency officials continue to emphasize their concerns in this area. "In the last few years, the FDA has observed data reliability questions with several NDAs and BLAs such that we may now be reaching a point where we can evaluate our experience across the applications and the sponsors to look at trends," said Leslie Ball, M.D., in a February 2010 interview. "So [in terms of) early observations…, one is that when significant noncompliance is observed at multiple clinical investigator sites, inspections of the sponsor and/or monitor may reveal inadequate quality systems, such that root cause analyses are not done to evaluate patterns and correct problems while the studies are ongoing. And surprisingly, we've even observed that monitors have sometimes detected errors or problems but provided inadequate follow-up to ensure that the corrective actions were implemented. So that's part of the reason why we're emphasizing the idea of quality systems. The sponsor should be looking to have a system in place such that they can detect and correct the problems in real time."

CDER is also conducting a pilot program that could further spotlight sponsor efforts and successes in this area. Under the program, CDER will be undertaking follow-up inspections within six months to a year after a clinical investigator receives a warning letter to ensure that the site implemented corrective actions promised in response to the warning letter.

In addition, CDER's December 2008 update to Compliance Program Guide 7348.811 instructs FDA field staff, during clinical investigator inspections, to assess "follow-up activities performed by the clinical investigator when the monitor(s) found deficiencies or recommended changes, for example, in the conduct of the study or records associated with the study."[1]

### Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2010, #4.7 p. 111

### Source

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