

Good Clinical Practice Q&A: Focus on Study Drug

What should be done if, after examining a bottle of study medication, a study coordinator observes that several of the normally white tablets have turned gray?

Any time a medication does not look, smell or feel "normal," it should not be administered. That is the first step — and a simple one.

It is critical, however, that the study coordinator immediately takes additional steps to ensure the safety of the subjects at his or her site as well as all study sites. Most importantly, the study coordinator must immediately notify the principal investigator and the sponsor. Even if other tablets appear normal, the dispensation and administration of study tablets should be suspended from the point at which the "tainted" tablets were noted.

The sponsor must then notify other clinical sites as well as the manufacturer (i.e., if different from the sponsor) and supplier. The tainted tablets, along with other samples, must be analyzed as a first step in determining the cause of the problem. Possible problems could range from product component and/or manufacturing process issues to improper shipment, handling and maintenance of the tablets.

All shipments of study tablets should be halted until the manufacturer provides a written report of the analysis and findings to the sponsor (i.e., if the sponsor is not the manufacturer) and site. The sponsor must ensure that all elements of the manufacturing and shipping process met good manufacturing practice standards. The study sponsor also must ensure that the affected site and all other study sites followed proper storage and handling procedures. Before any additional study drugs are administered to study subjects, the sponsor must be certain that the problem has been addressed and that the integrity of the study product is no longer compromised. In addition, site staff must follow up carefully with subjects who may have received tainted product.

Site staff must make appropriate notations regarding such situations in the subjects' source documents, in regulatory notes to the file, and in drug accountability records.¹

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2008, #15.6 p. 393-394

Source

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