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Vol. 5, No. 1, January 2009 "Can You Handle the Truth?"

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

130. Audit follow-up

When sponsors audit CROs, research sites, and their own clinical operations, what do they do with their findings? In theory, they develop CAPA (Corrective Action Preventive Action) programs to ensure that problems are remedied and do not reoccur in future studies. In practice, however, it often happens that the study ends and everyone moves on to the next study with no follow-up audit, or any follow-up at all. The sponsor then sees the same problems in the next study. Maybe there is a role for management. What am I missing here?

Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to ngoldfarb@firstclinical.com.

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