

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

98. Just Do It

At a recent conference, I was in a room with about 120 clinical research associates, many of them site monitors. The speaker, in a session about site monitoring, talked about the importance of training sites in FDA/ICH good clinical practice. (The FDA has adopted the ICH E6 GCP Guideline as a non-enforceable guidance.) During the Q&A, I asked the audience to raise their hands if they could name three differences between ICH guidelines and FDA (CFR) GCP regulations (which are enforceable). Five people raised their hands. How can we expect research sites to know the ICH guidelines if the site monitors watching them for compliance don't? Perhaps some training for everyone is in order. What am I missing here?

99. Who can you trust?

In March 2006, Kasyap Technologies Pvt. Ltd, a software development and training services company, organized Focus India, a conference promoting clinical research in India. As of January 2007, despite multiple promises, Kasyap has not reimbursed speakers for thousands of dollars of travel expenses. One of the speakers says "I've chalked it up to an expensive lesson about dealing with people from a culture that does not value honesty in business dealings." Ouch! I thought the conference was supposed to *promote* doing business in India. Let us hope that this incident is isolated and not representative of business ethics in the Indian clinical research industry. What am I missing here?

Do you know a better way? Is something getting under your skin?

Please send your thoughts for future columns to ngoldfarb@firstclinical.com.

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