

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

94. Just tell them

The National Quality Forum has published a report – "To Err is Human" – endorsing 30 safe practices to reduce the frequency of medical mistakes in hospitals. The report estimates that these mistakes cause as many as 100,000 patient deaths and countless injuries per year. The report requires hospitals to disclose medical errors to affected patients and their families. Because medical treatment in clinical trials is protocol-based and involves close attention to subjects, our error rates are probably relatively low, but not zero. If there is no observable injury to the subject, do we always disclose the error? Let's get ahead of the curve on this one and add disclosure of medical errors to informed consent forms. What am I missing here?

95. I can't wait to get started

Most investigator meetings include a 45-minute session on GCP. Forty-five minutes is better than nothing, but not if it gives investigators the impression they now know how to conduct a clinical trial. The first slide for these sessions should read: "WARNING! IN 45 MINUTES YOU WILL KNOW ENOUGH ABOUT GCP TO GET INTO REAL TROUBLE." 45 minutes? Who are we kidding? How about requiring additional training; free online courses are available. Why not teach qualified attendees about an advanced topic in a separate room? 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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