

## **What am I Missing Here?**

### **Thought-Provoking Questions for the Clinical Research Industry**

**By Norman M. Goldfarb**

#### **77. Until death – or whatever – do us part**

It's no secret that Clinical Research Associates (CRAs) frequently change jobs. The average CRA at many contract research organizations (CROs) camps out for only two years before moving on to another employer (often the CRO's client) that offers better compensation and benefits. Retention at many sponsors isn't much better. During a one-year study, half or more of the CRAs may leave. The replacements must undergo time-consuming training by the sponsor and/or the CRO and the site. Nevertheless, sponsors, CROs and sites do not build the resulting costs and disruptions into study budgets and plans, apparently based on the theory that admitting the existence of turnover will encourage it. That may or may not be the case, but pretending it doesn't exist is sure to foul-up a study. What am I missing here?

#### **78. Would it be OK if I bet on the winner?**

Imagine you are playing blackjack at a casino and that you know in advance at which tables you will win and at which tables you will lose. Unless you savor the challenge of defying fate, you will play at the winning tables. Now imagine that you are a CRA. You can spend your time at good research sites that enroll lots of subjects and generate high-quality data, or you can spend your time at bad sites that enroll few subjects and generate crummy data. Chances are that you will spend a significant percentage of your time at the bad sites, attempting to reform them or mitigate their errors. Your time is probably spent more effectively closing the bad sites and helping the good sites become even better. Winning gamblers learn how to bet on winning hands. Watch and learn. What am I missing here?

#### **79. Calling Dr. Hobbes**

Sites are sometimes faced with a Hobbesian choice: "Do we take the study and lose money, or do we not take the study, and lose money?" Skilled budget negotiators can boost site revenues, but only marginally. They usually can't fix a site that has to accept unprofitable studies to stay in business. (Now there's a business model!) There are four ways to fix this problem: (1) Reduce costs by increasing efficiency; (2) spread fixed costs over more subjects; (3) find studies that pay higher prices; or (4) go out of business. Budget negotiation begins in the site's "sales" department. A budget negotiator who can walk away from potential studies because the economics are unfavorable is a successful negotiator. Of course, a site that doesn't deliver the goods won't have customers lining up at the door, so the budget negotiation really begins with the last study, and the studies before that. The budget negotiator may just be the bearer of bad tidings. What am I missing here?

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