

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

108. It's just a stack of paper

Counting site fees, site monitoring, investigator meetings, study drug, data management, and other costs involved in producing a clean CRF, it costs a study sponsor about the same \$20,000 to buy a CRF as to buy an automobile. Most cars leave the dealer's lot with problems in one to five of roughly 15,000 parts, a defect rate averaging about 0.02%. As measured by data queries, a typical 80-page case report form (CRF) contains 12 errors in about 1,000 data fields, a defect rate of 1.2%. Counting hidden errors that are never detected, the error rate is easily 2%, or 100 times the rate in automobiles. An automobile has thousands of intricate moving parts. A CRF is just a stack of paper. If automobile companies can manufacture cars that are almost defect-free, why can't we do the same for CRFs? Perhaps automobile companies have the right idea when they build quality in rather than try to inspect defects out. What am I missing here?

109. I'm not here to sell you anything

There are two types of sales: The first type is transactional sales, where the focus is on making the sale with minimal interest in the buyer's best interests. (Think used cars.) The second type is consultative sales, where the focus is on helping the buyer make the right decision for him or her. In transactional sales, the seller doesn't have to believe in the product because the best interests of the buyer are not a factor. In consultative sales, the buyer has to trust the seller. To establish this trust, the seller has to believe in the product, or he/she will seldom make a sale. Recruiting a subject for a clinical trial is a form of selling. If we have the potential subject's best interests in mind, consultative selling is a highly honorable activity. But if we don't believe that the study is good for at least some people, we are just doing sleazy transactional selling. Have you ever been forced by management to recruit subjects for a study you don't believe in? Next time, just say no and explain why you don't want to do transactional sales. 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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