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What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

104. Worse than nothing

Site monitors are very good at finding missing and inconsistent data. Data managers clean up the rest. What neither can find, however, are data that look good on the surface, but are wrong nevertheless. There is no way to find and fix these hidden errors. They cause statisticians to overestimate statistical power, possibly leading to erroneous conclusions, or no conclusions at all. When a low-quality site records bad data, it's worse than no data at all. The only solution is to collect good data in the first place. That means working with research sites that collect good data. High-quality sites are worth their weight in gold, but we don't often see premium pricing for premium-quality data. What am I missing here?

105. We have a problem; can you guess what it is?

Busy IRBs receive thousands of IND safety reports each year. Each report potentially signals a safety hazard for clinical trial subjects. Unfortunately, for blinded studies, safety reports do not reveal whether the subject is receiving experimental drug or the control. It's like receiving customer complaint forms that do not mention whether the complaint is about your product or that of your competitor. Furthermore, they may reveal little information about the subject's medical condition. That's like receiving a customer complaint that says only "it doesn't work." According to new OHRP guidance on adverse event reporting, a "monitoring entity," such as a data and safety monitoring board, should filter IND safety reports for the IRBs. It probably makes sense to designate someone to do a rough-cut classification and quickly forward the reports to the IRBs, along with a summary of events to date. Why not give IRBs information they can actually use? 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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