

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

106. Trust me, I've done this before

Before making new protocols and informed consent forms official, some sponsors share them with a few lead investigators. However, they probably do not share them with less-expert investigators and study coordinators that likely represent the bulk of the research sites. And they almost certainly do not share them with likely study subjects. How many companies start marketing their products without testing them first with real-world potential customers? What am I missing here?

107. Blinded by the light

Every study goes through an important milestone – verification of the study database against the case report forms (CRFs). But, of all the potential sources of error, how important is the CRF-to-database step? With paper CRFs, double-keying the data should eliminate most data entry errors. (I've heard rates as low as 1 in 10,000.) With eCRFs, there should be zero errors in this step. In contrast, manually transcribing data from source documents or worksheets to CRFs is a much bigger source of error, even with 100% source data verification by site monitors. Manually writing data onto paper source documents or transcribing it from source documents to worksheets are even higher risks. To make matters worse, many of these step-one errors are undetectable. We can polish the CRF-to-database step to a bright shine, but perhaps we should look more closely at earlier stages in the process. With well-trained site personnel and electronic source documents (eSource), we can start with good data and load it right into the study database. 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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