

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

68. Hey! I'm Doing that Study Too

Has a sponsor ever set up an online discussion group for the investigators and study coordinators? Site monitors and study newsletters facilitate some information-sharing, but, for the most part, each site climbs the learning curve on its own. Perhaps sponsors don't want bad news getting around or sites ganging up on them. Software companies accept the same risks with user groups and they certainly have dissatisfied customers. What am I missing here?

69. Third Time the Charm?

Last week, a CRO business development executive in Asia told me he gets periodic requests from sponsors wanting to do a trial offshore because they can't do it in their home country. That's terrible. This week, a sponsor told me that they were going offshore with a trial because the FDA erroneously refused approval of their application. That's terrible. Regulator-shopping is well into the gray zone, but sometimes may be appropriate. However, as with IRB-shopping, previous non-approvals should be disclosed. My guess is that they usually aren't. If the regulators were to trade notes, non-disclosures would become obvious. What am I missing here?

70. Compared to What?

The FDA's mission is to ensure that drugs and other medical products are safe and effective...compared to a placebo. Comparing the published results of different trials for different drugs is a fruit store problem. Including positive controls, i.e., the competition, can be career-limiting for pharmaceutical scientists, but it sure would be helpful for us customers. Perhaps Congress should instruct the FDA to require the comparability information we need. What am I missing here?

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