

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

61. Look, It's a Study Subject!

I recently attended the PRIM&R/ARENA annual meeting in Boston. A highlight of the program was a talk by, get ready for this, a real live study subject. The speaker was also a medical researcher, but still, it's the first time I've personally heard a study subject speak at an industry conference. We spend a lot of time talking about subjects, but not much time listening to them. Why not include at least one study subject speaker at every conference? What am I missing here?

62. Da Da Da! Super-DSMB to the Rescue!

At the same PRIM&R/ARENA meeting, there was an amazing debate about whether or not sponsor proprietary study information should be protected or disclosed. The issue arises, for example, if there is parallel research by multiple companies on multiple drugs in the same chemical family. If one drug shows alarming adverse events, the FDA is legally prohibited from disclosing that "trade secret" information to the sponsors, IRBs, DSMBs or investigators of the other drugs. The safety data may look OK for each drug, but no one can raise an alarm if the aggregate data is troubling. Why not create Super-DSMBs (Data & Safety Monitoring Boards) responsible for reviewing aggregate data and raising a red flag if necessary? What am I missing here?

63. The Study in the Closet

Now that most pharmaceutical companies are more-or-less complying with clinical trial registry requirements, it's time to turn our attention to Investigator's Brochures (IBs). IBs presumably tell the complete story of the research history of the study drug. What if one of ten past studies didn't show the results the sponsor was hoping for? What are the chances that that study will be featured in the IB? At minimum, IBs should list all previous studies with a brief synopsis of the results. If there are too many mystery studies, investigators may want to pass on the new one. What am I missing here?

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