

What am I Missing Here? Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

43. Investigator Meetings

Investigator meetings are expensive: They cost sponsors about \$1,500 per head (\$3,000 per site). They cost sites a similar amount in lost revenue. The primary purpose of this investment is to train site personnel. To this end, most of the time is spent covering (a) material in the protocol and investigator's brochure, and (b) the basic rules of engagement such as GCP. However, it makes no sense to fly people across the country to review material in documents that study personnel could read at their leisure in the airplane. If I were running an investigator meeting, I would give everyone a test on arrival. Anyone who fails gets a free ride back to the airport.

Training in basic GCP and the like can easily be obtained – with certification – over the Internet or through in-person training courses offered almost every week of the year. We could then use investigator meeting time for training that requires personal presence – demonstrations and exercises from the old "watch one, do one, teach one" school of medical education. No-one expects physicians to provide high-quality care the first time they perform a procedure, so why does this industry set lecture-trained study personnel loose on the first subject in each study? What am I missing here?

44. Confidentiality Agreements: The Industry's Best-kept Secret

The primary purpose of confidentiality agreements (CDAs) is to prevent the disclosure of confidential information. The secondary purpose is to define sanctions against transgressors for letting the horse out of the barn. Each sponsor creates its own CDA template, fine-tuned to keep its horses in the barn. When a sponsor gives its confidential information to a site, the people conducting the study – the investigator and study coordinator – are the people most likely to make an unauthorized disclosure. A CDA accomplishes its primary purpose only to the extent that site personnel comply with it. To comply with the specifics of that particular CDA, site personnel have to read it.

There are two types of sites:

- a. Sites where the investigator and study coordinator do not read the CDA because they don't read legal documents, and
- b. Sites where the investigator and study coordinator do not read the CDA because someone else at the site reads them.

With multiple CDAs, there is really no point reading them, because remembering their subtle distinctions is way more trouble than its worth. On the other hand, if the industry had a standard CDA, investigators and study coordinators might invest the time to read and understand it. What am I missing here?

45. No Free Lunch

A couple of years ago, the regional manager for a top-ten pharma treated our study team to lunch at a local restaurant. On the way back to the office, he offered one of our employees a job as a CRA. Leaving aside certain questions of etiquette, the episode raises a difficult contradiction for the industry: By hiring CRO and site employees, sponsors create their own problems with employee turnover at sites and CROs. Sponsors can't have it both ways. They could at least agree

to not hire their service providers' employees during a study. They could also give minimally-adequate time (perhaps a month) for the service provider to find and spin up a replacement. There are more than business operations at stake: If you've ever seen a new coordinator take over a study cold, you might wonder about the implications for subject safety and data quality. What am I missing here?

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