

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

58. To Inflict Pain or Not to Inflict Pain: The 32-cent Question

The people who decide which blood collection devices to pack in study visit kits must not have been on the receiving end. Sites that want to minimize subject pain and anxiety donate the standard needles to charity and use safety "butterflies" (needles with wingettes) instead. Safety butterflies are easier to use, result in fewer sticks on average, and cause less anxiety for the subject because the pointy part is hidden. On the other hand, butterflies cost 32 cents more than "straight" needles – less in volume. (Contact the author for a low-cost source.) What am I missing here?

59. I Know Something You Don't Know

Sponsor audits require a significant time commitment by site personnel – usually without compensation from the sponsor. The auditor writes a report to the sponsor on what he/she found. He/she may give some pointers to the site but does not share the report with the site. Any findings useful to the sponsor are also probably useful to the site. Even FDA investigators share their findings and give the site an opportunity to respond. What am I missing here?

60. Who Died and Made You King?

Federal law gives IRBs oversight responsibility for clinical trials. It's a very serious responsibility that most IRBs take very seriously. That is not to say, however, that 100% of IRB decisions are correct. However, unlike almost every other institution in the United States, each IRB has final authority. There are no IRB Boards of Appeal or a Supreme IRB. (Has anyone ever sued an IRB or contacted a hospital president to reverse a decision?) IRBs thus have absolute power over their dominion, and we all know what absolute power can do to even well-meaning people. A few checks and balances would do IRBs good. What am I missing here?

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