

## What Am I Missing Here?

### Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

#### 167. What? Who me?

Investigators who conduct investigator-initiated clinical trials (IITs) assume all the responsibilities of the sponsor. One of the sponsor's most important roles is to monitor site performance. Because of the cost and hassle, many IITs are not (self-)monitored, potentially leading to severe FDA and OHRP sanctions. Monitoring does not have to be elaborate, but it has to be. If investigators want to talk the sponsor talk, they have to walk the sponsor walk. What am I missing here?

**Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).**

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