

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

243. Does anyone have a MAP?

Study sponsors love high-enrolling sites. On the other hand, there’s not much love for sites that enroll zero subjects. But the least appealing site for a sponsor is one that enrolls only one subject, unless that’s what the sponsor had in mind. A site with only one subject costs the sponsor almost as much as a site with five or 10 subjects. To save costs, the sponsor could close the site and offer to enroll the subject (if he or she is receiving the test article in a Phase 3 or maybe Phase 2 study) in a managed access program (MAP) set up for this purpose. The subject would then obtain the study medication and an appropriate level of medical monitoring. The consent form would have to explain this possibility. 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 editor@firstclinical.com.

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