

Site Monitors from Hell

By Fran Dickson and Ruth Steele

Site monitoring is a tough job. Effective site monitors travel constantly, interpret ambiguous regulations, pay meticulous attention to endless details, handle unexpected crises with equanimity, and work well with a wide variety of site personnel. Some site monitors have not mastered these skills; the worst are known to sites as the Site Monitor from Hell (SMFH).

SMFH Behaviors

How do you know if a problematic site monitor qualifies as a SMFH? Common SMFH behaviors include:

1. Asks that the case report forms be prepared for monitoring, but then spends the entire visit on the regulatory binder.
2. Arrives late, conducts personal conversations by telephone and email, disappears from time to time, and then, with no notice at the end of the day, asks the study coordinator to stay "just a few minutes more."
3. Consumes hours of the study coordinator's time "being friendly," distracting everyone else in the office as well.
4. Is unfamiliar with the study protocol.
5. Interrupts the study coordinator with every issue, even during subject visits.
6. Responds to most questions by saying "I'll check on that," but never gets back with an answer. Complains when the site then "goes around" them.
7. Finds "issues" in medical records that require medical training to interpret, without having such training.
8. Makes a federal case out of every minor thing, suggesting that a team of FDA investigators is practically on its way for a full inspection.
9. Makes no effort to resolve issues during the monitoring visit.
10. Is more interested in criticizing the study coordinator for making mistakes than in determining the cause of the problems and preventing them in the future.
11. "Critiques" the study coordinator's shortcomings in full earshot of other site personnel and monitors in the room.
12. Bypasses the study coordinator to communicate directly with the investigator. Often "raises concerns" about the study coordinator with the investigator, rather than discussing them with the study coordinator's best friend.
13. Spends his/her time talking and laughing loudly with a co-monitor, who is there, presumably, because the workload is too heavy.
14. Treats the study coordinator as an unwelcome distraction.
15. Demands changes to study records and procedures, citing non-existent regulatory requirements.

16. Disorganizes or intentionally “reorganizes” study records and test articles.
17. In the middle of the study, demands time-consuming changes, for example to concomitant medication logs, based on “sponsor requirements;” the next site monitor often demands that everything be changed back to the original method.
18. Complains constantly about the travel, the study, the sponsor, other sites, and his/her neighbor’s dog, apparently on the principle that misery loves company.
19. Can never be found between visits when really needed, for example, when an SAE occurs or the protocol needs clarification in the middle of a study visit.
20. Sends the visit follow-up letter to the site, raising issues that were not discussed during the visit.

Two Site Monitors in One

I was the study coordinator on an oncology study that was difficult from the start. After the second interim monitoring visit, our monitor moved on to greener pastures. Eight weeks later, a replacement monitor arrived. It was Marty’s (not her real name) first monitoring visit on her own; she had been a pharmacy technician previously.

I began to go through the study binders, but Marty politely preferred to look through them on her own without explanation; otherwise she would get confused. When I walked to check on her, she was carrying on a full conversation with herself. (Example: Now what do you mean you put it there? Oh yes, I guess that makes sense. Well, maybe, you should try it here. No, I don’t think that would work. Well come on Marty, what are you thinking?) I asked her if she needed any help. She said no; she was finding everything she needed, so I told her I was off to a subject visit.

In the middle of the subject visit, I received a page from Marty. After finishing, I went to see her. She was upset because I hadn’t returned her page. She wanted to know where she could get a cup of freshly brewed coffee. I asked her not to page me during subject visits unless it was an emergency. I would be back to see her after the next subject visit.

An hour later, she paged me again during a subject visit. I ignored the page, but she paged me again 10 minutes later, so I called her. She wanted to know where she could get lunch. I politely told her about the cafeteria and offered the assistance of our administrative assistant to find it.

After lunch, I hear what sounds like a heated argument coming from Marty’s office. Much to my surprise, she was arguing with her stomach over what she ate for lunch. It seems she ate something that disagreed with her and her stomach was displeased.

Marty visited our site 15 times. Once she settled in with our ground rules, the relationship was fine. We even became accustomed to her “co-monitor.”

Remedies

What should a site do with a SMFH? It is a tricky question because any corrective action could make the situation worse. The site will probably have to live with this person for the length of the study, and it may create a long-term enemy. Before taking any action, the first step is to identify the problematic behaviors and determine what is really happening. Is the site sure the SMFH is not behaving correctly? Are the behaviors serious or is it better to just tolerate them? Are site personnel contributing to the problems? Can the site address

the problems without involving the SMFH? If the behaviors are intolerable, what exactly does the site want the SMFH to do differently?

If corrective action is required, one or more people from the site should meet face-to-face with the SMFH to discuss the issues. If the study coordinator can handle the discussion, it will save face for the SMFH. If not, both the investigator and study coordinator should be in the room to show solidarity and facilitate an efficient process. The discussion may be awkward, but, if handled right, it will clear the air and enable everyone to work together productively.

Every attempt should be made to address problems in a constructive manner. Ask the SMFH if he/she has issues with your site; perhaps both parties can improve. Assume that everyone in the room wants to solve the problems. Criticize the behaviors, not the person. Provide specific examples. Ask the SMFH for his/her perspectives. If you are lucky, the SMFH will not have been aware how you perceive his/her behaviors and will be willing to change them. Explain the reason for the criticism. For example, if visit reports arrive the night before the next visit, do not criticize the SMFH for being a thoughtless procrastinator; explain that you need timely reports to prepare for the next visit. Ask the SMFH if he/she agrees that timely reports are a reasonable request. Ask the SMFH if he/she can correct the problem in the future. There may be extenuating circumstances; for example, the SMFH's supervisor may be sitting on the reports. Focus the discussion on causes and remedies. Agree on practical solutions, such as a deadline of three days prior to visits. Solutions do not need to be perfect, but they must be tolerable. Document the discussion in writing.

If the SMFH does not cooperate or meet his/her commitments, and the problems warrant further action, the next step is to talk to the SMFH's supervisor. If your issues are legitimate, the SMFH's supervisor may have heard them before from other sites or wondered why the SMFH's sites often perform poorly. Tell the SMFH that you intend to discuss the issues with his/her supervisor. Explain that you need to enlist the supervisor's help because your collective best efforts have not found a solution to the problems. Ask the SMFH for guidance. Do not blame the SMFH; just describe the situation objectively. Reasonable people can differ. It is quite possible that the SMFH has made a good faith effort and shares your frustrations. The SMFH may not want to share with you his/her problems with management. He/she may actually welcome your help in persuading a supervisor to change something. If the SMFH wants a second chance to resolve the problems, allow it, but not a third, fourth and fifth chance. It may be necessary to escalate the issues up the management chain.

If serious problems cannot be resolved with respectful, constructive and assertive discussions, more serious action is required. At this point, the SMFH may not be your biggest fan, but he/she may have bigger issues with his/her management. It may be necessary to tell the sponsor that you can no longer work with the SMFH. This action may cause the sponsor to audit your site to get a handle on the situation. As a last resort, you and the sponsor may agree that study termination is the best course of action. If the site has acted professionally, the site/sponsor relationship can survive.

If you can resolve your issues with a site monitor, he/she does not qualify as a SMFH. If you do not even try, you have no right to make judgments. Professional relationships do not require that everyone be best friends; they can tolerate imperfections. If you work at your relationships with problematic site monitors, you will be prepared when a true SMFH arrives at your site.

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