

**Do You Have a Great Site Monitor?  
Ask These 10 Questions to Find Out**

**By Mindy A. Ditch**

Site monitors have a very demanding job. They are responsible for ensuring that study data and essential documents are correct and that any safety incidents are properly reported.

Proficient field site monitors are experts in good clinical practice (GCP), related regulatory requirements, and the study protocol. They have a firm understanding of the procedures, processes and systems that the sponsor, contract research organization (CRO), and sites employ in conducting the study. Proficient monitors are also skilled at monitoring processes such as source data verification, product accountability, and review of essential documents. They possess the interpersonal skills needed to effectively interact with a wide variety of site personnel, all the while juggling on-site activities, travel and administrative responsibilities. It is a very demanding job.

While remote site monitors do not travel or work physically at sites, they have the added challenges of accessing and reviewing documentation and interacting with site personnel without the benefit of being present where the research is being conducted, often with inadequate technology. Remote monitoring is also a very demanding job.

Unfortunately, due to lack of experience, training, support, aptitude or attitude, not every site monitor is proficient. When this is the case, site mistakes may be overlooked, errors may not be prevented, the monitor's instruction may not be clear, time may get wasted, and everybody may get frustrated.

A site monitor may appear to be less than proficient through no fault of his or her own. For example, the site monitor may have just been assigned to the study and is, therefore, still becoming familiar with the protocol. The monitor may have received an inadequate handoff from a previous monitor, may be overburdened with too many sites or studies, may be dealing with recent process changes, may have technical challenges with computers and software, or may have a personality or approach that do not naturally meld well with those of the study coordinator. The possibilities are endless.

When welcoming a new site monitor, try to optimize the relationship and come to a mutual understanding on how study visits and communications will proceed. Communicate to monitors that you appreciate the importance of their work. Show that you value open lines of communication. Don't be afraid to raise any issues so they can be addressed while they are still minor. A proficient site monitor will reciprocate.

As the study progresses, how will you know if you have a great site monitor? The following 10 questions can help you decide:

1. Does the site monitor act and respond in a consistent manner?
2. Does the site monitor detect things you already knew were problematic and problems of which you were not aware?
3. Does the site monitor demonstrate deep knowledge of the protocol and regulations?
4. Does the site monitor follow up on your questions and open issues from the previous visit in a timely manner?

5. Does the site monitor create good relationships and engage well with the study coordinator, investigator and other site personnel?
6. Does the site monitor escalate issues appropriately?
7. Does the site monitor correctly handle adverse events, protocol deviations, and other issues without redundancy or repetition?
8. Does the site monitor refrain from asking the same questions or requesting the same documents multiple times?
9. Is the site monitor respectful of your time?
10. Does the site monitor give the impression you are all on the same team?

If none of these questions uncover important issues, you have the good fortune of working with a great site monitor. If that is not the case, be prepared to accommodate his or her monitoring approach and personality to the extent that they do not put the quality of the study and the safety of the participants at risk. Make every reasonable effort to resolve issues with mutual understanding, tolerance and accommodation. If any important issues cannot be resolved despite your efforts, it's time to involve the study manager in a constructive manner. Study managers need to know when problems exist because it's their job to help fix them.

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