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Site Monitor Feedback

By Norman M. Goldfarb

Site monitors play an important role in clinical studies. In addition to verifying regulatory compliance and source data accuracy, monitors can train and advise site personnel on how to improve quality (and increase efficiency), thereby building quality in, instead of just inspecting errors out.

However, it is all too common for a site monitor to arrive at a site, inspect the documentation, chat pleasantly with site personnel, and then race off to the next site. The site might not receive the visit follow-up letter for weeks, if at all. In the meantime, the site cannot correct any errors found by the monitor or improve its processes to prevent future errors. Pressure is increasing on monitors to complete visits quickly, allowing little time for constructive discussions, but it is much more efficient to detect and remedy small problems before they can become big problems.

It is thus important for the site to extract as much feedback as possible from the site monitor before he or she leaves. The end-of-visit meeting (and any interim meetings) should consist of more than just pleasantries; it should also cover substantive issues that the site can start to address immediately. The site should ask the monitor for a copy of the deviation log that he or she will use to draft the visit follow-up letter. Ideally, most or all of the items will have been collaboratively resolved before the visit ends. When the visit follow-up letter eventually arrives, it should contain no surprises for the site.

It is also important for the site to elicit the monitor's views on a broad range of performance attributes. For example, it is important for the site to know if it made an error in test article accountability, but it might be even more valuable to obtain the site monitor's assessment of the site's test article accountability process and how it could be improved. By aggressively seeking such information, the site communicates to the site monitor that it really wants to improve its performance. It also assures the site monitor that the site will not be offended by constructive criticism. The parties can then work together to improve the site's processes.

Sites might find that some site monitors provide feedback that appears to be overly critical (or useless), but the greater challenge will be obtaining honest feedback that is critical enough. Over time, a site can demonstrate to a monitor that it sincerely wants honest feedback and not just empty reassurances. Sites should not assume that monitors would offer only criticism; there should also be an opportunity for legitimate praise, an excellent opportunity to strengthen the relationship.

As time goes by, sites can learn what normal feedback looks like so they can probe deeper when changes indicate an emerging problem or a stubborn trouble spot. At that point, because site monitors have been providing feedback, it becomes easier to enlist their help in addressing such issues.

The discussion above addresses site monitor feedback from the site's perspective, assuming the site monitor will not volunteer the information. However, the site monitor and his or her employer also benefit from the process, so they should take the initiative if the site does not.

A site monitor feedback form is available at https://www.magiworld.org/standards. It is designed for sites to use when requesting feedback but can be modified easily for site monitors to use when offering feedback.

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