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The Art of Assessment: Performance Evaluation Co-monitoring Visits

By Elizabeth Weeks

Pharmaceutical companies and contract research organizations (CROs) employ clinical research associates (CRAs) to monitor clinical study sites. Because most site monitoring is done in the field, it is challenging for study managers to know that site monitors conduct their duties. Study managers have even less contact with home-based, regional CRAs.

Study managers can measure CRA performance by the volume of case report form (CRF) pages reviewed, data query rates, visit reports, and feedback from site and project staff. However, these measures provide only indirect data on how CRAs actually conduct study visits. Many study sponsors therefore employ co-monitoring visits to directly evaluate CRA performance and facilitate training. Co-monitoring visits may also be conducted to train CRAs and confirm that they are ready to monitor independently.

The following four-step process is based on my experience and that of colleagues who have collectively completed hundreds of successful evaluation co-monitoring visits:

1. Identify the co-monitor(s)

Co-monitoring visits can be conducted by CRA managers, trainers or dedicated co-monitors. Effective co-monitors must be expert site monitors. They must also be intimately familiar with the protocol and other study documents. Without that knowledge, they will be unable to assess the CRA's knowledge. Further, they will be oblivious to much of what happens during the site visit.

2. Prepare for the visit

The co-monitor consults with the study manager about which sites are suitable for co-monitoring visits. He/she discusses any areas of special concern relating to the CRAs, sites and the study in general. He/she ensures that the study manager understands the process, expectations and objectives for the visit.

The co-monitor informs the CRA of the upcoming co-monitoring visits. They discuss suitable dates. They discuss any areas of special concern to the CRAs. The co-monitor ensures that the CRA understands the process, expectations and objectives for the visit.

3. Conduct the visit

The key to a successful co-monitoring visit is a professional, structured, methodical and consistent approach. Although practices vary slightly across companies, the fundamentals remain the same. Preparation, organization and communication are crucial.

As one might expect, the co-monitor accompanies the CRA on a site visit. Prior to or during the visit, the CRA explains to the co-monitor any open issues and presents his/her plan to investigate, document and resolve them. The co-monitor records this information for post-visit follow-up. The co-monitor observes, evaluates and documents typical site monitoring activities, such as reviewing CRFs, source documents, drug accountability records, and the regulatory binder. He/she assesses the CRA's interaction with site personnel in activities like training, issue resolution, and goal setting. These documentation and interpersonal skills are

the essential requirements for successful site monitoring visits. An effective co-monitor also serves as the CRA's mentor, providing guidance and validation through the entire process.

During the course of the visit, the co-monitor asks the CRA a variety of questions, preferably relevant to the task at hand. The CRA's answers demonstrate his/her level of knowledge about the protocol and other aspects of the study. The co-monitor should not expect the CRA to know every detail of the study, but the CRA should offer to find the answers in the protocol, regulations or elsewhere. The CRA's responses to the co-monitor indicate how he/she responds to questions from site personnel.

The co-monitor should be as unobtrusive as possible and let the CRA lead the visit. However, the co-monitor's role is not just to observe and evaluate. He/she should also help clarify and resolve issues during the visit. If possible, any interventions should be limited and conducted through the CRA. Otherwise, the interventions will distort the co-monitor's observations and evaluations.

4. Follow-up after the visit

As soon as possible after the visit, the co-monitor writes a report on his/her findings. What are the CRA's strengths and areas for improvement? This report not only identifies what went right or wrong during the visit; it also evaluates causation: Are problems due to the CRA's lack of training or experience? Are they due to environmental factors such as fatigue or stress? Are personalities playing a role? Is there a problem with the protocol or CRF?

At the conclusion of the visit, the co-monitor elicits the CRA's perspectives. (It may also be useful to obtain input from site personnel.) They discuss the visit's successes and problems. This discussion is conducted in a professional, supportive, courteous and non-judgmental manner to promote learning. The co-monitor welcomes the CRA's questions, concerns and explanations. The CRA is more likely to accept the co-monitor's recommendations if the approach is mentoring rather than blaming. The co-monitor communicates to the CRA that they are working together to accomplish the same goals. To identify a mistake does not a lesson make; to truly teach requires the insight to identify an issue, the emotional intelligence to deliver constructive criticism in a positive manner, and the patience and creativity to create and conduct a training plan that inspires the CRA to achieve his/her best performance.

Co-monitors are often responsible for managing the resolution of problems identified in the report. Their report includes a corrective action plan. The plan may include training, follow-up by the CRA, assignment of issues to other personnel, and another co-monitoring visit. The co-monitor then follows-up on the results. Some problems are easily addressed with a bit of training for the CRA. It may be necessary to adjust the CRA's monitoring schedule or switch the CRA to a site that might make a better personality fit. Follow-up activities are opportunities to make the study more successful, not to chastise the CRA or generate more frustration. The co-monitor may need to address site concerns without undercutting the CRA. Fortunately, site monitoring is good experience for handling difficult situations professionally and non-judgmentally.

An effective co-monitoring program advances the knowledge and skills of CRAs. It identifies and remedies CRA, site and general study problems, while also building the morale of both CRAs and site personnel. It gives study managers visibility into the field, so they can make more informed decisions. Not only is the current study more successful, but the CRAs start their next study at a higher level.

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