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My Experience as a Remote Site Monitor

By Susan M. Radtke

I had wanted to move to the high desert of New Mexico for several years to be closer to family. Unfortunately, job opportunities in the area are scarce, especially in clinical research. Eventually, I was able to obtain a work-from-home position as a remote site monitor (RSM) for a large contract research organization (CRO). I sold my Ohio Valley house, packed up the car, and headed west. The transition from a position at a site to the RSM role would prove to be every bit as overwhelming as the transition from 50 inches of rain per year to less than ten. This article is based on my experience during the past two and a half years as an RSM.

When I joined the project as one of the first five RSMs, I was assigned to a group of Phase 3 oncology protocols that had been under way for about a year. Enrollment had already started at some sites and other sites were still preparing for site initiation visits (SIVs).

Remote monitoring can be defined as "inspecting study data and documents from a location remote from the site."[1] With the study already underway, the addition of the RSM role created challenges both for sites and for the study team, including the following:

- The clinical trial managers had to incorporate the RSM role into their studies' monitoring plans.
- Transitioning certain study responsibilities from the traditional site monitors ("CRAs" in this article) to an RSM made some of those CRAs feel less sure of their role.
- Some of the sites were unclear about how the RSM role would work.

Because the CRAs travel extensively and RSMs do not travel, I was to be the first point of contact for sites. On these particular studies, RSMs were *not* responsible for requesting or reviewing source data. Source data verification was conducted during onsite visits by the CRA. My RSM role was basically to stay engaged with the sites (initially over 30 sites, later to decrease as additional RSMs joined the project) and be the troubleshooter when issues arose for sites. I dealt with protocol questions, supply issues (lab kits, electronic diaries, investigational product (IP), etc.), and access to vendors, as well as assisting the CRAs with any site issues that arose.

A major part of my role was to meet via telephone for roughly 30 minutes every other week with each site's study and regulatory coordinators. These conversations were to help prevent potential issues by reviewing with the site their IP supply, lab kit supply, staff changes, data capture, and other areas. Based on my previous experience at an oncology site, I wondered whether busy sites would be able to make time for these meetings. I knew how research subject visits, physician requests, lab samples, and adherence to protocols could take priority. I knew I would have to communicate with the sites in a very concise, action-focused manner and be very respectful of their time.

On the other hand, since I was familiar with complex oncology protocols and data capture, and with the vendor systems used on the studies (e.g., EDC and IVRS), I could often respond usefully to many of the questions the sites asked.

The data monitoring committee (DMC) was about to meet for the first time, meaning that all the case report forms to date had to be complete, and with all queries resolved.

Unlike the CRAs, I was "always" in my "office." I immediately found myself asking all the sites for "I need it now" data and query resolutions. These requests continued for the duration of the study, with additional DMC meetings and database locks, so urgent and multiple ad hoc requests seem to be a normal part of the RSM job.

As a "disembodied voice," I have not had the benefit of face-to-face interactions with my sites in forming personal relationships, so some of the sites seemed a bit less willing to make the extra effort to meet my needs as they would for a CRA.

Despite these challenges, I settled into the RSM role and now believe that experienced, well-trained RSMs can play an important role in clinical trials. The most important benefits, as I see them, include the following:

- Immediate availability to sites to help answer protocol and other operational questions, especially when sites are screening and enrolling their first subjects. With these interactions, I could help sites avoid costly errors while they were learning the protocol.
- Immediate availability to help follow up on the site's behalf with any outstanding issues that might be holding up randomization, such as tracking down tissue samples or lab results, or sending needed forms or manuals.
- Immediate availability to assist sites with data entry questions, queries and other vendor system issues.

The RSM role is still in its infancy, so there is a lot of adapting and learning on the job. However, now that I have seen the benefits of an "always on" communicator and troubleshooter, I do think this can be a valuable role.

I am still learning to adapt to life in the desert, too, which is beautiful in its own way.

Reference

1. "Investigative Sites Speak Out About Remote Monitoring," Norman M. Goldfarb, May 2017, Journal of Clinical Research Best Practices

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