

The Site Monitor Reborn as Consultant, Trainer and Manager

By Michael Rosenberg

Historically, the primary role of the clinical research site monitor has been to verify that study data and regulatory documents are correct at the site. Much of the site monitor's activities are thus tedious routine – essentially checking boxes according to standard operating procedures. For most site monitors, the rest of the job is a craft. As with other crafts such as carpentry and blacksmithing, the site monitor learns much of his/her trade through apprenticeship and on-the-job training. As a result, each site monitor has his/her own way of doing things. When a site monitor leaves a study, his/her replacement often has different ways of doing things, creating a period of confusion and inefficiency while the site adjusts to the new rules. This non-interchangeability of personnel (and materials) is typical of crafts.

Clinical Research data collection and validation is evolving through three stages:

Table 1. Evolution of Data Collection and Verification

Activity	Stage 1	Stage 2	Stage 3
Source document data entry	Paper	Paper	Computer
Source document data validation	Manual	Manual	Computer
Case report form data entry	Paper	Computer	n.a.
CRF data validation	Manual	Computer	n.a.

In stage 1, the entire process is manual and based on paper. The data does not enter the computer until it has been verified. In stage 2, case report forms (CRFs) and their verification are automated (eCRF). In stage 3, source documents and verification are automated (eSource), and there is no need for the intermediate CRF steps.

Stage 2 is well-underway and we are seeing the beginnings of Stage 3. A variety of products are now available to capture source data without a paper intermediary.^{1,2}

In Stage 3, the primary task of site monitors – CRF and source document verification – largely disappears. Much of any remaining manual review processes can be performed in the study sponsor's offices.

Evolution of the Site Monitor's Role

Nevertheless, there are still important functions for site monitors to perform at the site. To start with, the sponsor has a regulatory obligation and business imperative to ensure that the site is conducting the trial properly. The site monitor can continue to review the regulatory binder and other essential documents, but perhaps Stage 4 will see many of these documents standardize and move online with electronic signatures.³

With the time freed up from data verification, the site monitor can look at the bigger picture: What is going well and what isn't? What are the root causes of any problems? Are they random or systemic, short- or long-term? Provided the site monitor knows how to recruit subjects, obtain informed consent, conduct study activities, enter data, complete regulatory forms, etc., he/she can then provide advice and train site personnel.

For example, sponsors typically train investigators and study coordinators at investigator meetings and then repeat the material at site initiation visits. Sponsor personnel talk, site personnel listen, and there is some Q&A interchange. If the site monitor knows how to conduct a study visit, the site initiation meeting could instead focus on practicing (simulating) study visits, so the initial few subjects do not suffer from the site's lack of hands-on experience.

These diagnostic, training and consulting activities occur now to a limited extent. Today, they are performed as a craft, not a highly-organized industrial procedure. However in Stage 5, they can be systematized with proven diagnostic tools, knowledgebases and training materials, including online eLearning modules. Operational modeling and metrics will enable site monitors to identify problem areas and measure progress in a systematic manner.

Two important concepts become important in Stage 5:

- **Risk-adjusted monitoring.** With the availability of operational modeling, site monitors will know which operational data potentially reflect important problems, and which are random noise that will have minimal impact on the study's outcome. Site monitors can then focus their energy where it matters the most.
- **Adaptive monitoring.** As site performance changes over time, e.g., a nurse joins a study team or a competitive study completes enrollment, site monitors can shift their attention to the current problems and opportunities. Sponsors can also move site monitors to sites where their presence has the biggest impact.

As routine training and consulting become more standardized and automated, the role of the site monitor evolves further, in Stage 6, into site management. There are, of course, site managers today that work for sites. This new type of site manager will resemble today's outsourcing managers – the people who manage a sponsor's relationships with, for example, contract research organizations (CROs).

Implications for Careers

Only a small minority of today's site monitors have experience as study coordinators. Because of the different content of the jobs, it can be difficult for a study coordinator to make a successful transition to site monitoring, (even assuming the job interests them). As the role of the site monitor evolves to consultant, trainer and manager, study-coordinator experience will become important; the skills are a better fit and it is much easier to diagnose problems and provide useful advice if you have personal hands-on experience. This evolution will create problems for research sites that lose experienced personnel. On the other hand, study coordinators will be more motivated to develop their expertise so they can move into a rewarding new career path. Study coordinator losses will create more need for training and consulting at the sites. However, the drain on study sites will be limited because site monitor job satisfaction will increase, turn-over will decrease, and the number of site monitors will diminish.

Implications for Efficiency and Cost

As data collection and verification moves from Stage 1 to Stage 6, clinical trial efficiency increases and costs decline:

- Technology and lower-cost labor replaces expensive site monitor labor.
- Site monitors decline in numbers and their time is employed on high-value activities at high-impact sites.
- Errors are corrected at inception, minimizing rework.

- More accurate data means that study power increases, reducing sample sizes and statistical gymnastics.
- Research sites become more competent and therefore more efficient.
- Lessons from one site, e.g., with respect to subject recruiting, can be quickly propagated to other sites.

Implications for Data Quality

Automating data collection and verification not only reduces costs. It also improves quality:

- If a study coordinator makes an error on a paper CRF, it may be months before the error is identified. By that time, nobody may remember the circumstances and the same error may have been made numerous times. By catching the error immediately with eCRF, or better yet, eSource, the circumstances are fresh and corrective measures can prevent recurrence.
- With the noise of all these errors out of the system, study personnel and the site monitor can identify systemic quality trends more accurately and keep the site on course.

Resolving errors at point-of-entry means they do not linger until study closeout and database lock. Higher-quality data facilitates adaptive trials because the information for decisions is more accurate and available more quickly.

Costs are certain to be higher because extra steps are required to move data from paper to electronic form. Every extra step is another opportunity to introduce errors. Finally, sites that perform well using paper methods are certain to perform even better with the aid of powerful electronic tools.

Conclusion

This discussion is not just theoretical. Studies that have applied the methods described above have reduced costs of site monitoring by as much as 80% and total study costs by as much as 32%.⁴

By focusing site monitors on higher-value tasks, they make more significant contributions to the success of studies and become more valuable to their employers. By working with research sites as consultants, trainers and managers, they improve site performance and strengthen the relationship between sponsor and site. It is time to move away from utilizing site monitors like Medieval guild workers and leveraging their talents in a manner suitable for the 21st century.

References

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