# Taking a New Approach to Monitoring

**By Mark Shapiro**

Careful monitoring is a necessary and important part of any clinical trial — so necessary and important, in fact, that it has changed very little over the history of conducting clinical trials. Required by both U.S. and international agencies, clinical trial monitoring helps ensure the integrity of the data, the consistency of the science, and of course, the safety of the patient.

Today's clinical research associate (CRA) may monitor 10 to 12 concurrent studies, with all the associated travel, management and reporting responsibilities. Burnout is a constant problem, as CRAs endure separations from their homes and families while fulfilling their professional responsibilities at multiple sites. It can be a challenge for clinical research organizations (CROs) to retain trial monitors due to the demands of the job.

However, improved technology adoption and clinical operation processes are now making it possible to redefine the role of the CRA, while at the same time reducing stress, decreasing costs and increasing clinical trial oversight. Some clinical research organizations are adopting a methodology called **Just-in-Time Monitoring** that is dramatically changing the way they interact with trial sites.

## Monitoring is Like Major Surgery

Most clinical trials receive monitoring visits about every eight to 10 weeks. The CRA usually has a detailed checklist of items to evaluate, and must then submit a report back to the sponsor regarding the site's performance in carrying out the trial and protecting patient well-being. Typical areas of interest include:

- document collection and retention
- integrity of source data
- consistency of data recording
- adherence to protocol
- rate of enrollment
- incidence of adverse effects
- compliance with safety measures

Unfortunately, a site monitor's visit to collect this information can often be disruptive and potentially inaccurate, since it only reflects a brief snapshot of the overall study. As investigators and research staff scramble to provide information needed by the CRA, clinical aspects of the study may be put on the back burner temporarily. This may slow or skew study results, or even impact patient care.

Carla Radke, a lead monitor at our company, offered this analogy, "Traditional site monitoring is like major exploratory surgery, where the patient is opened up from stem to stern to look for problems. It causes serious disruption while trying to find a faulty system or a disease process, with the possibility of missing more subtle clues to the patient's health."

## Minimally Invasive Monitoring

Much as surgeries have become less invasive with the use of remotely driven cameras and laparoscopic devices, just-in-time monitoring of clinical trials can also be far less invasive and disruptive. By adopting just-in-time monitoring methods and utilizing an integrated clinical operations and data management platform, CRAs can provide a new level of monitoring service that pinpoints problem areas and pays more attention to early warning signs. Benefits of this approach include:

***Detecting and addressing problems early***

With a site receiving monitoring visits at eight- or 10-week intervals, it is possible that problems could occur and not be noticed until the monitor arrives. Once an issue is detected, it could also take some time to implement corrective action, and may be another several weeks before the CRA can verify that the corrective action was successful.

With just-in-time monitoring, a CRA can view a variety of data elements remotely and immediately detect any outlying or troublesome data, such as an adverse effect. An improved level of visibility into the data means that small problems can be spotted early and don't have the opportunity to develop into larger problems that might slow the study or endanger a patient.

Remote monitoring that includes complete data visibility makes it possible to implement corrective actions and get near-immediate feedback on the effectiveness of those actions. Slight alterations in course early on avoid the need for gross adjustments later.

***Strengthening relationships with trial sites***

CRAs strive to maintain good working relationships with the staff and investigators at the trial sites. But dealing with problems or issues often puts the CRA in the awkward position of having to mete out corrective action or take harsh measures that can potentially damage the relationship with the site.

Using remote monitoring to detect small issues before they become big problems means the CRA can be less punitive and more collaborative. Rather than visiting only every several months, or issuing queries and directives, a CRA can use remote data analysis findings as a basis to share feedback more informally. More frequent communication builds trust, fosters partnership and strengthens the relationship with the site. CRAs can work collaboratively with site personnel to proactively seek solutions rather than dictating what must be done.

Ms. Radke commented, "As a monitor, I don't enjoy being the 'clinical police.' I prefer being there as a team member, since after all, we're all working toward the same outcome, which is clean data for the study."

***Reducing the costs of conducting trials***

Monitoring accounts for a large portion of the direct cost for any clinical trial, but that cost can be reduced by using remote data analysis to tailor the need for visits. Instead of simply visiting every two months on a schedule, just-in-time monitoring can help determine when visits are actually required, based on patient accrual.

Constant monitoring of trial data and site performance also help to make visits more efficient and purposeful. Instead of having to spend days looking at everything, a CRA is able to pinpoint exact areas that need to be addressed while on-site. This allows visits to become more strategic in nature, where the CRA and site personnel work together to solve specific problems and set future goals.

It's estimated that using just-in-time monitoring can save as much as 30% of the cost of monitoring the trial, just from deploying the CRA more efficiently and making better use of his or her time at the site.

***Focusing on ethics and regulatory compliance***

Another outcome of enhanced efficiency is that CRAs can focus on achieving higher levels of regulatory compliance and protection for patients. Instead of spending the bulk of their time on source document verification, CRAs can increase the time they spend ensuring the trial is ethically executed and appropriately documented.

Study sites get greater peace of mind knowing that the CRA is working harder on their behalf to safeguard the patient while also increasing the quality of the research.

***Avoiding CRA stress and burnout***

Clinical trials monitoring can be a grueling job that entails a punishing schedule and mounds of paperwork. Through the use of data-driven just-in-time monitoring, a CRO could potentially cut CRA travel by as much as 30% without jeopardizing trial integrity or patient safety.

Reducing the wear and tear on CRAs is an important consideration for a job that has both high turnover and a steep learning curve. Retaining experienced CRAs is far less expensive than constantly recruiting and training new ones. Making the job less stressful and less travel-oriented is very attractive to CRAs who are feeling the strain.

## Making the Change

A key aspect of realizing the benefits from just-in-time monitoring is to actually incorporate the data-driven model into clinical trials. Many study sponsors and sites are using technology to collect and store trial data, but haven't taken the next step to integrate the data from disparate systems into meaningful information.

In these cases, technology-based data collection is not much more useful than collecting it manually, and in fact adds an extra step to the process. To avoid being burdensome, data collection tools must be incorporated into the overall study framework in a way that encourages their use as part of conducting the trial. Furthermore, the data from laboratory and clinical systems must be viewed as a whole in order to glean real intelligence from the data stream.

Ultimately, data-driven solutions result in enhanced outcomes for the research sponsors and better relationships with the sites. And providing cleaner data on time and under budget can make CROs more successful.

While just-in-time monitoring is an excellent way to increase efficiencies and reduce costs, it doesn't remove the need for careful on-site monitoring to ensure adherence to protocol and attention to patient safety. However, it can elevate those on-site visits to make them more focused, more strategic and less disruptive to patient care.

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