

Turning It Around

Managing A Rescue Trial

February 05, 2009

By Jodi Andrews, co-founder and CEO, [ProTrials](#)

Nothing was off schedule. The trial had been going for just a month. The contract research organization (CRO) had done nothing wrong. But the sponsor had identified the need for a change, partly because of a perception that its project may not have been a sufficiently high priority for the CRO. And so another “rescue” trial was born.

It’s one of the most challenging requests a CRO can receive. The sponsor of an ongoing pharmaceutical, biotechnology or medical device trial asks a second CRO to pick up the management and monitoring of a trial mid-stream—and see it through to completion. It may be that the cost is trending in an ominous direction, that the original CRO was not able to accommodate the demands of the trial, or that other parameters have changed unexpectedly.

My firm, [ProTrials Research](#), receives rescue trial requests on a regular basis. It’s gratifying for a new or existing client to trust that our experienced project managers and monitors can get the trial back on track and keep it there. It’s up to us to make sure that happens. The first thing we do is to assess and plan.

Assess and Plan

While it’s tempting to jump in and throw resources at a challenging situation, the best first step is to conduct a detailed conversation with the sponsor to understand the circumstances of the trial and the expectations of the sponsor, including the details of what worked and what didn’t.

It’s important that the sponsor and the CRO be “on the same page” regarding goals and what is feasible in terms of process and deadlines. Focusing on the critical path activities to bring the trial back on track is essential. Identifying critical risk areas, e.g., does certain data need to be re-monitored, is also essential.

It is important to be flexible to meet the sponsor’s objectives and build trust between the sponsor and CRO right from the onset. In addition, if the original CRO is open to discussion, it is important to collect their feedback and input. There are typically two sides to every story. To do the best job possible, you need to collect feedback from all sides. The source of the problem may be easily identified or surprisingly elusive.

During the planning process, it is important for the new CRO to provide a realistic budget to the sponsor for completion of the trial. Changing to a new CRO mid-trial may or may not add significant expenses to the budget depending on what is driving the change. It is

imperative that the CRO provide an accurate and realistic budget to the sponsor, so all parties have the same expectations.

No Rushing

The next step is to make a comprehensive assessment of the current state of the project. Asking the right questions at the right time is essential.

How many subjects have been enrolled compared to target? What percent of monitoring has already been completed? What is the status of regulatory document collection? What is the status of data entry and the query process? As part of the assessment, the subject recruitment plan and monitoring plan must be reviewed, and revised if necessary. Additionally, time lines agreed on by the sponsor and the previous monitoring group must be reviewed and assessed, and may need to be re-determined.



Jodi Andrews

Finally, the plan for training of the monitors must be designed and agreed on by the sponsor and CRO. It is very important that the new monitoring group have access to completed visit reports and pertinent site communication documents. This will help in training the new monitors and will assist in a smoother transition. The new monitors need to be well trained and knowledgeable about all aspects of the study, prior to taking over the study sites.

Create Trust

One of the most important factors in implementing the successful change of a monitoring team is to make sure all communication within the team and with the study sites is clear and transparent.

As soon as the determination to bring on a new team has been made, communication must be sent from the sponsor to the study sites regarding the change, introducing the new monitoring group. The new monitors then call each site to introduce themselves, assess the sites' current situations, and schedule monitoring visits immediately, if warranted. A major priority for these phone introductions and the first monitoring visit is to quickly develop a trusting relationship and assure the sites that they have 100 percent support from the new monitors.

Equally important is the communication between the sponsor and the new monitoring team. When monitoring begins, it is quite possible that the new monitoring team may come across processes or requirements from the sponsor that need to be adjusted. The monitoring team and sponsor must have open communication channels so that the new monitoring team can be successful.

Regular communication between the sponsor and study project manager should be scheduled, at least weekly at the start. Regular updates for both groups on a frequent basis are essential, especially at the beginning, to make sure expectations are being met, and challenges are being addressed.

Initial Visits

This first visit is crucial in building the relationship with the study center. The clinical research associate will need to leave time in their schedule to speak with the study coordinator(s) and find out what they would like to see done differently in the remaining time of the study. In addition to creating a working relationship which establishes that “we are all on the same team,” monitors do a spot-check of key variables.

They may also re-monitor some of the already-collected safety and efficacy data, to ensure consistency. The monitors assess the sites’ performance, identifying any issues, and communicate with the data management group regarding trends in queries and other parameters.

After several of the first visits have been completed, the new monitoring team will need to evaluate the overall status of the study sites and make recommendations to the sponsor on action items and time lines. Depending on the evaluation, adjustments may be made to the monitoring plan, overall time lines, and budget.

Ongoing Oversight

As the trial continues moving forward, timely monitoring and data collection is a priority, as well as cleaning up any backlog on these tasks. Monitors continually approach the sites in a supportive manner, being mindful of the challenges the sites may previously have had with the trial, and the disruption of changing monitors mid-stream, to ensure their cooperation in fulfilling all required tasks.

Monitors also contribute to global trackers developed by the project manager to make sure all aspects of the trial are being managed with good oversight. Ongoing and proactive communication between the new monitoring team and the sponsor is an essential piece to keep the project moving in the right direction. It is important for the monitoring team to give frequent updates to the sponsor on the progress being made.

We take seriously the trust placed in us to assume responsibility for a rescue trial. The way we manage communication, collaboration, and collection of information is vital to a successful transition from one monitoring group to another, and to the ability to see such a trial through to successful completion.

Jodi Andrews is co-founder and CEO of [ProTrials Research](#), a women-owned CRO that provides professional clinical operations services to pharmaceutical, biotechnology and medical device companies.

