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# How CROs Can Earn the Sponsor's Respect and Trust

**By Julie Stein**

Kforce Clinical Research has embarked on a multi-year program with one of the nation's leading pharmaceutical companies to accelerate and improve execution of clinical trials. The first three initiatives are:

- Selecting sites
- Assigning monitors and scheduling site visits
- Changing the CRO's role

## Selecting Sites

The manager for a new study typically calls on site monitors to help select sites. The study manager generally relies on the judgment of these monitors because they have the most direct contact with sites and will be responsible for those sites during the study. However, there are five potential drawbacks with using site monitors in this way:

- They are focused on a different priority: monitoring sites for current studies.
- They do not have experience with all the sites they are asked to evaluate.
- They have not yet developed expertise in the new protocol.
- Their accountability is diluted because they share the responsibility.
- They may not even end up monitoring the sites they recommend for the new study.

We have implemented a new process that improves site selection, as measured by speed, accuracy and efficiency/cost:

1. A lead site selection monitor is named. This person works with the sponsor to determine the criteria and plan for selecting sites. He or she then manages all site selection activities and serves as the primary point of communication with the sponsor about site selection matters.
2. A site selection team is formed to support the lead site selection monitor. These experienced site monitors are dedicated full-time during the site selection process to identifying and assessing sites for the study. They have appropriate therapeutic expertise and specialized training in site assessment and selection. Team members develop experience and relationships with site and sponsor personnel in their therapeutic areas. The lead site selection monitor and team are held accountable for delivering qualified sites to the team that conducts the study. Success is measured by speed, efficiency/cost, and whether the sites meet the selection criteria, enroll subjects, and deliver high-quality data
3. The study manager and/or therapeutic area leader develop the site questionnaire in consultation with the site selection team.
4. The site selection team identifies potential sites from a database and obtains site recommendations from field monitors. The sponsor may also recommend sites. The site database includes data and metrics on previous site performance.
5. The site selection team assesses these recommendations to ensure that the sites are appropriate, qualified and meet all study requirements prior to approaching them. The site selection team contacts sites, assessing level of interest and

capabilities. If on-site assessment visits are required, they are conducted by local site monitors trained by the site selection team in protocol requirements and characteristics of sites that are likely to be successful. Although the site selection team does not personally conduct on-site assessment visits, it is still accountable for site performance.

Prior to implementing this new process, our site selection results were typical of the industry. With the new process, we complete site selection an average of six days (14%) faster. The speed of the new process continues to improve with experience.

### Assigning monitors and scheduling site visits

The conventional practices of distributing sites evenly among monitors and scheduling site visits at regular time intervals creates unbalanced workloads, which damages monitor morale and fosters a culture that accepts inefficient use of time. For instance, monitors may schedule a full day at a site that ends up requiring only four hours worth of work and at another site that ends up requiring 10 hours. These unpredictable workloads lead to padded schedules and frustration all around.

To address this problem, we provide monitors with tools to accurately estimate the number of hours of work required for each site visit. We use this information in two ways: First, line managers can assign monitors to the correct number of sites; and second, monitors can schedule their site visits more accurately.

Monitor workload for a given site is driven by characteristics of the study and the site, the number of subjects enrolled, and the efficiency of the monitor. We feed metrics like subject screening numbers and actual time spent at the site into a model that predicts future workload. As the study progresses, the predictions become more accurate. The manager balances the workload across monitors, also considering therapeutic expertise, skill levels, geographic location, and prior investigator relationships.

This new system has improved monitoring productivity by 15-25%, made the manager's job much easier, and improved service to both sponsors and sites.

### Changing the CRO's Role

Since sponsors hire CROs for their expertise, it seems obvious that they will demand extensive advice from their CROs during the study planning phase, and then trust their CROs to conduct the study. Many small, inexperienced sponsors certainly rely on CROs in these ways, but large, experienced sponsors with in-house development resources often assume they know as much or more than their CROs about how to conduct studies. This is a fair assumption for CROs that conduct studies in conventional ways. CROs must earn their client's respect by developing methods and systems that are superior to conventional approaches.

CROs that employ subjective, qualitative management systems to generate unpredictable results do not inspire trust in sponsors. CROs must earn their client's trust by developing methods and systems that produce predictable and consistent results.

By developing improved and systematic site selection, visit scheduling, and other systems, we are finding that even our most sophisticated clients are relying more on our judgment and are more comfortable delegating study execution to us. Continuing improvement and expansion of such systems are as important to our success as drug development is to the success of pharmaceutical companies.

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