

SPEAKING OF SERVICE ...

How To Choose A CRO

SEPTEMBER 10, 2008

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

-
- [Comments](#)
 - [Tell a Friend](#)
 - [Print](#)

It's a phone call we've come to expect. It may come from a pharmaceutical, biotechnology or medical device company. A sponsor rings up and says: "When we chose a contract research organization (CRO) to monitor our trial, we thought we were getting *more* experience. But what we ended up getting was quite the opposite. The trial is now behind schedule. We'd like to cut ties with our current CRO and get the trial back on track."

Not long ago, we got a call like that from a company conducting a pivotal musculoskeletal device trial. The sponsor had initially retained another CRO to monitor its study, but called us to rescue the trial, mainly due to the inexperience of the clinical research assistants (CRAs). **ProTrials Research** was able to assign experienced monitors immediately. The trial is back on track.

Key Criteria

While the size of a company's workforce is one factor to consider when choosing a CRO, there are many others. Choosing the right CRO is important to your project. By focusing on a full spectrum of parameters, sponsors may improve the results and increase the odds of partnership that supports a successful trial.



Jodi Andrews

Let's start with experience. What you see might not necessarily be what you get. Some CROs may emphasize the experience they have. But what really makes the difference is the experience and availability of the staff actually working on *your* trial. Ask about that.

During the CRO selection process, it may also be useful for the sponsor to find out how many projects each CRA is typically supporting at once. Assignment to more projects can provide the CRAs with exposure to more therapeutic areas, but it may not provide them with the in-depth knowledge of the specific area that the sponsor needs.

Assess Experience

It's also worth inquiring about average length of industry experience of the CRAs in both the therapeutic and clinical arenas. Look for seasoned veterans. At ProTrials, our project managers average more than 17 years of experience. Our regional CRAs average more than 10 years of experience.

Some CROs can have significant employee turnover. This may help keep costs down in some cases, as those individuals will not need raises, promotions and the like. But once a project gets rolling, turnover could prove costly to a sponsor with challenging clinical projects or sites new to research.

It's worth asking how long CRO employees stick around. Turnover is indicative of the health of the work environment. Sadly, staff that is consistently asked to manage too many sites, or travel too frequently,

burn out and quit. When interviewing a potential CRO, ask to see its employee retention rate. A company that isn't proud of this information, or doesn't readily provide it, may be working its staff too hard. That could affect the quality of your data or the project's schedule.

Flexibility

Once the skills of the CRO are established, consider the speed and nimbleness of the CRO's communications. Having a responsive CRO is essential. During the selection process, see how quickly the prospective vendor answers phone calls and emails. Global projects place an even greater premium on responsiveness. The work is being distributed across geographical areas and time zones.

Flexibility is also crucial. It may seem attractive to work with a CRO that has highly detailed standard operating procedures (SOPs) in place. However, if the CRO's personnel is unable to deviate from those standards, the sponsor may pay for unneeded services. A single-site, Phase I study may not really need a project manager who submits a project status report on a monthly basis.

Another example: Perhaps the sponsor wants its proprietary visit report templates to be used, not the forms provided by the CRO. It's important to make sure a CRO can be flexible enough to meet the requirements of any project.

Cost Considerations

Appropriate oversight is equally invaluable. In some companies, the senior managers are so removed, they can't possibly know when problems are brewing. Try to find out if top executives at a CRO have a finger on the pulse of all of their projects. Even if they don't get directly involved in the day-to-day activities, it is important for them to have a broad idea of where a project stands to make sure it is on track, on time and on budget.

In a regulated industry like ours, it's essential for a CRO to have processes for quality oversight. During the selection process, ask the prospective supplier: "What's your quality control program? Can you show me the process by which you ensure the quality of a project?"

Finally, cost is always a factor in selecting a service provider. Watch out for an unusually low bid, which could mean the CRO does not understand the specifications of the trial or is underestimating the resources needed for the project. By the same token, a high cost does not always mean the sponsor will get a more experienced or higher quality team. Some CROs have large overhead and administrative costs that must be recouped one project at a time.

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

*Editor's note: This is a **January, 2008 article** on ProTrials. Authors interested in writing for ClinPage should read **our editorial guidelines**.*