Optimizing Cross-Organizational Team Performance and Management

A sponsor–contractor team can prevent relationship failures by using a good team strategy to overcome organizational, cultural, and functional boundaries

You've just been selected to manage a huge, difficult, and pivotal phase 3 trial. As with most studies, this one has a tight schedule. But because of problems with another compound under development, much of your clinical operations staff is unexpectedly tied up. As a result, you'll have to outsource the work, which puts you behind schedule almost before you start. How can a cross-functional, cross-organizational team of people complete this project given its time, cost, and quality constraints?

Working across functions is difficult because each team member comes with his or her own goals, limitations, and perspectives. Getting medical monitors, contract research associates, and statisticians to work together seamlessly and effectively is a formidable challenge, especially when their time is shared among multiple studies and projects. Now add a CRO to the mix and the challenge becomes even tougher. Not only is the team working across multiple functional boundaries, but it's also working across organizational and company cultural boundaries (see Figure 1). It's no wonder, then, that sponsor–CRO teams can fail so easily.

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One way to avoid trouble is to treat the cross-organizational team as a full-fledged partnership dedicated to completing the project on time and on budget. This seems obvious, but most outsourced projects fail right from the outset because the CRO is treated as an outsider rather than as a team member. A sponsor–CRO team can avoid failure by using a good team strategy that includes the following key points.

Make It Explicit

Typically, internal teams operate with implicit norms. Team members from the sponsor's company know the standard company policies and procedures as well as who to contact when they need help. They also know the expectations of other groups such as the way the statistics group prefers to receive data or the way the medical writing group prefers to have data formatted. However, the CRO does not know any of that implicit information. For an outsourcing team to perform well, implicit norms must be communicated as explicitly as possible. Disclosure can be specified within the contract, but it can be executed more effectively through checklists and best practices. A good way to seek out essential information is to have a third party conduct quick interviews in key departments of both organizations to determine the type of information the CRO needs to produce what the sponsor wants. Some important questions to ask are highlighted in the "Information CROs Need to Know" sidebar, and decisions that must be agreed on are detailed in the "Decisions to Make" box.

Decisions to Make

Issues that should be made explicit include

- deadlines
- quality requirements
- cycle times
- meeting dates and times
- processes and procedures
- software
- site characteristics
- locations of personnel
- key contacts and decision makers.

problems and must be avoided?

Information CROs Need to Know

- What absolutely must happen to achieve success?
- What would be nice to have but is not required?
- What is unnecessary for this project?
- What situations could cause delays or problems and must be avoided?

Forecasting Potential Failures

Every project runs into trouble at some point. What distinguishes successful projects from disastrous ones is the team's ability to predict failures before they occur and to recover quickly when a failure happens. If a sponsor has done a good job of making instructions explicit, then it will have uncovered several places where things could go wrong. The next step is to figure out in

Jim Miller's Outlook

The five largest clinical CROs — **Quintiles Transnational Corp.** (www.quintiles.com); **PPD, Inc.** (www.ppdinformatics.com); **Parexel International Corp.** (www.parexel.com); **Covance, Inc.** (www.covance.com); and **Kendle International, Inc.** (www.kendle.com) — have formed the Association of Clinical Research Organizations (ACRO) to ensure that they have a seat at the table in the upcoming congressional debates about human research subject protection. Based in Washington, DC, the industry group has chosen Quintiles chairman Dennis Gillings to chair ACRO this year and PPD's CEO, Fred Eshelman, as chairman-elect for 2003.

Congressional efforts to strengthen human research subject protections provided the impetus to establish ACRO. Efforts are underway in both the House and Senate to pass new protection legislation. The proposed measures include greater regulatory oversight of clinical research and extension of the "common rule" (the regulations governing federally funded research) to all clinical research activity.

"The CRO industry didn't exist 25 years ago when the common rule was promulgated," noted Doug Peddicord, PhD, legislative director of ACRO. Today, "CROs are central to the drug development process," he said. "As regulators and legislators look at the potential for oversight of research, they are interested in understanding the role of all the players, including CROs." ACRO presented written testimony before a Senate subcommittee on 23 April 2002.

Beyond the immediate legislative activities, Peddicord expects ACRO to play a role in advancing the contract research industry. He observed that "there is great variability in the size and capabilities of CROs" and anticipates that the group will help ensure and promote the quality of CRO services. ACRO plans to issue eligibility guidelines for new members by the end of June.

CRO Consolidation

The contract clinical research segment of the pharmaceutical outsourcing industry seems to be going through a period of consolidation. Companies are being bought and sold as big players pursue corporate strategies and marginal players seek long-term survival. Here's a quick rundown of some major deals to date.

PPD, Inc. has made two major acquisitions thus far. It has acquired **Medical Research Laboratories International**, a central laboratory service with labs in Kentucky and Belgium, and **Piedmont Research Center** (www.piedmontrc.com), a preclinical CRO with facilities near Research Triangle Park, NC. Unquestionably the most profitable clinical CRO during the past three years, PPD is putting its retained earnings to work building its laboratory services business.

Celeris Corporation (www.celeriscorp.com), a small, publicly traded clinical CRO, announced a nonbinding letter of intent to sell its clinical monitoring and data management assets to privately held **StatProbe, Inc.** (www.statprobe.com). Celeris had revenues below $10 million and has been chronically unprofitable.

SFBC International (www.sfbci.com) acquired **Anapharm Inc.** (www.anapharm.com), a provider of phase 1 and 2 clinical research services. Publicly traded SFBC has been an active acquirer in the past year.

Kendle International acquired **Clinical and Pharmacologic LLC Research, Inc.** (www.clinres.com), a phase 1 facility specializing in bioequivalence studies for generic drugs.

The clinical research arena presents many opportunities for consolidation, with hundreds of companies offering monitoring, data management, patient recruitment, and laboratory services. Laboratory services, because of their capital investment requirements and operating leverage, are particularly attractive to large CROs because of more competitive barriers to entry.

Inveresk IPO

Inveresk Research Group, Inc. (www.inveresk.-com), a CRO that remade itself through a major acquisition, has announced plans for an initial public offering. The company developed a significant preclinical research business in the 1990s. It then changed its profile in April 2001 when it acquired **ClinTrials Research Inc.** (www.ctbr.com), the publicly traded clinical CRO that struggled in the late 1990s. Inveresk generated total revenues of $156 million in 2001, of which 60% was from the preclinical research business and 40% was from clinical research services. Of the total revenues, 54% was generated in Europe and 46% in North America.

Reducing a burdensome debt load is a major drive behind the proposed public offering. The current primary shareholder of Inveresk, **Candover Investments PLC** (www.candover.com), acquired the company in a management buyout in 1999 for $78.8 million. That transaction and the subsequent acquisition of ClinTrials for $115.1 million were financed through bank debt and debt securities totaling $205.8 million. Debt service is now eating up cash flow, and Iveresk plans to use the IPO proceeds to repay a large portion of the debt. The price and timing of the offering had not been announced at press time.

It has not been a good year for pharmaceutical and biopharmaceutical companies seeking to raise equity. Yet the value of CRO stocks has risen significantly, which improves Inveresk's chances.

advance what should be done when a failure occurs. For each potential failure, the team should ask these questions: What are the warning signs for this failure? What are the potential consequences of this failure? What should be done now to prevent the failure from occurring? After a warning sign has been detected, what can be done that will prevent the failure or lessen its consequences? Who should be watching for the warning signs? What should be done if the failure occurs anyway?

By answering those questions, the team will create a contingency plan for each failure. More important, it will acknowledge that failures can and will occur and tells team members that it's all right to sound the alarm if they think a failure is imminent.

Develop early-warning metrics. Once the project's potential failures are identified, the team can develop a few metrics that will help alert them when trouble is brewing. For example, if the team is concerned about keeping enrollment rates on track, then it might create metrics related to key precursor events. If it believes that academic sites are slow to enroll or cause underenrollment but

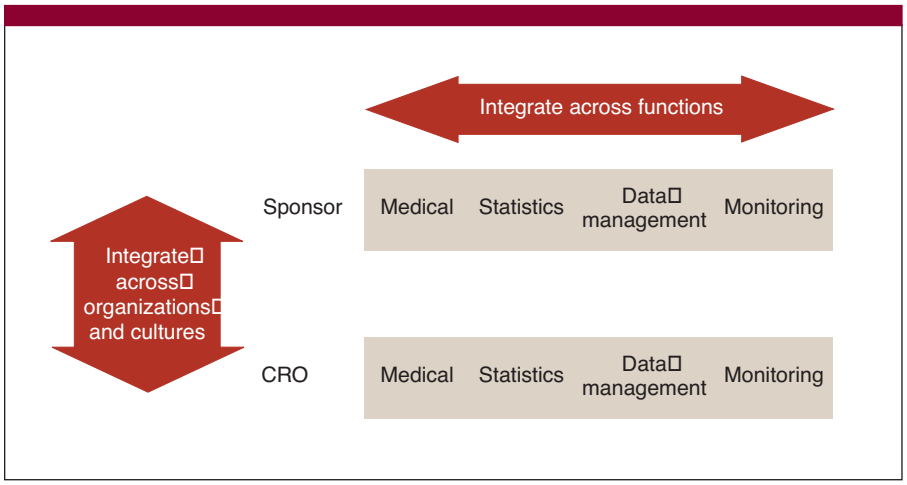

Figure 1. Sponsor–CRO teams must work across organizational, cultural, and functional boundaries.

that nonacademic sites will be the backbone of enrollment, then the team could track the site initiation rate for nonacademic sites. If the initiation rate is low, then the team has an early warning that enrollment problems are looming. Early warning indicators can be developed for every project, and metrics can be invaluable for alerting the team to trouble before it occurs.

Communication is Essential

Once the team has developed metrics, it should use them. Reviewing metrics at each team meeting and at critical points in the project helps the team prevent trouble. The project manager might even want to offer team rewards for achieving metric goals.

Hold weekly meetings. Every project manager has probably heard this statement too many times: "If only we had communicated better, this wouldn't have happened." Despite hearing it so often, sponsor–CRO teams still have problems communicating. A simple method to ensure better communication is to hold weekly teleconferences, or even better, weekly face-to-face meetings. The key is to have the meetings weekly. By meeting regularly, people will get to know one another better and become more comfortable with each other.

Weekly meetings should follow guidelines. Attendance should be mandatory, even if a team member has nothing specific to talk about at a particular meeting. The goal is to share information and to search for potential trouble areas, so various perspectives are needed.

The meetings should focus on problem avoidance and risk reduction, not problem solving. The team should keep an action-item list with real deadlines and then make sure that the action items are completed by those deadlines.

If someone identifies a problem, the team should appoint a few people to develop solutions, put an action item on the list, and move on. (The solution group should have an appropriate balance of sponsor and CRO representatives.) That way, the team will avoid getting bogged down with issues that are the responsibility of only a few members.

The team must review the early warning metrics at each meeting to ensure that everything is on track. Many groups use metrics as the central focus of the meeting to guide discussion about the most critical aspects of the project.

The meetings should be short (about 30–60 minutes), and time limits should be enforced.

Establish communication points at critical junctures. After identifying potential failures and warning signs, the team can establish special communication points at critical junctures. For example, if a team is worried about enrollment, then it can set up a meeting after the first patient is enrolled. The goal of the meeting could be to determine whether upcoming patient enrollments are on schedule and what should be done if they're not. The team also could meet after the first case report forms are entered or after the CRO submits the first set of statistics. Although one could expect ongoing communication between the CRO and sponsor for monitoring or statistics purposes, these special communication points aim to involve the entire team in problem-avoidance and problem-solving activities.

Provide time for feedback from the CRO. At each meeting, the CRO and sponsor should each have an opportunity to identify challenges, problems, and potential failures. As a result, team members will begin airing concerns instead of trying to bury them.

Provide regular opportunities for team development. For a project to meet its deadline, the sponsor–CRO team will have to function with incredible efficiency. Some project managers may think efficiency means they don't have time for team development, but just the opposite is true. Hundreds of teams have started out at full tilt only to be slowed to a crawl by squabbling and finger-pointing. Time spent on activities such as developing roles and responsibilities, holding effective meetings, making group decisions, giving and receiving feedback, and learning problem-solving techniques can pay back handsomely later in saved time and increased cooperation. Budgeting some time every month for improving team functioning is important. This practice can be thought of as periodically lubricating the mechanism that makes the team run.

The best team development strategies use "just-in-time" techniques in which a little theory is coupled with immediate application to the team's current challenges. These techniques are unlike immersion techniques in which the team goes off-site for a day or two to focus strictly on team development. The immersion approach feels good, but the effects tend to dissipate quickly, and the team returns to its original behaviors. In contrast, the just-in-time approach typically has a lasting effect on the team's performance. ***BP***

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