A sponsor–CRO team can avoid failure by using a good team strategy to help overcome organizational, cultural, and functional boundaries.

You’ve just been selected to manage a huge, difficult, and pivotal Phase III 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.

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 everything as explicit as possible.** 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 this implicit information. For an outsourcing team to perform well, these implicit norms must be communicated as explicitly as possible. This 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 both organizations’ key departments to determine the type of information the CRO needs to produce a good product. Some important questions to ask are

- 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?

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.

**Forecast 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 does occur. 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 advance what should be done when a failure does occur. For each potential failure, the team should ask the following:

- 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 will have told all team members that it’s all right to sound the alarm if they think a failure is imminent.

**Develop early-warning metrics.** Once the team has identified the project’s potential failures, it can identify a few metrics that will help alert it when trouble is brewing. For example, if the team is concerned about keeping enrollment rates on track after the first patient, then it might want to create metrics related to key precursor events. If it believes that academic sites will be slow to enroll or cause under-enrollment but 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 these metrics can be invaluable to alert the team of trouble before it occurs.

Once the team has developed the metrics, it should use them. Reviewing these metrics at each team meeting and at critical points in the project will help the team avoid 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 a thousand 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. A few guidelines for weekly meetings are

- Attendance should be mandatory, even if a team member has nothing specific to talk about at a particular meeting. The goal should be 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

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**Figure 1:** Sponsor–CRO teams must work across organizational, cultural, and functional boundaries.
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 only a few members are responsible for.

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

- The meetings should be short (i.e., 30–60 min), 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 few 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 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 on 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.