Advanced Clinical

INSIGHT BRIEF

Managing Your Clinical Project Risk: Is it Time to Change Your Current CRO?

Considerations for determining whether keeping your current partnership in place will put your company at risk

Caroline Redeker
SVP, Corporate Development at Advanced Clinical

Introduction

Long-standing relationships and strategic partnerships between CROs and pharma, biotech, and device companies are critical to long-term success and program efficiencies.

However, when your "partner" is not functioning like a partner, transitioning one or more functions may be necessary in order to mitigate risk, maintain performance, and ensure the success of your program.

Whether you are an outsourcing leader, a functional leader or a project manager, you have options to ensure that your trial meets timelines and maintains quality. The steps below will give you the ability to understand your options and make educated decisions in the process.

Considerations for Transitioning to Another CRO

Changing CROs mid-project can be a risky proposition. On the other hand, not switching CROs may present a greater risk to your project depending on a number of factors. Consider the following:

Is my CRO financially stable? It is important to watch for signs that may indicate financial instability. If the time was not taken to perform due diligence on your chosen CRO's stability at the start of a project, now would be a good time to conduct this important analysis. Some CROs are struggling financially as they manage cash flow in the highly competitive clinical research environment. As Sponsors cancel projects or delay decisions to move compounds forward, CROs rely on limited backlog, and smaller companies rely heavily on lines of credit to survive. When CROs experience cash flow problems or abrupt project cancellations, the next step is typically to reduce staff in order to maintain viability. Another sign of instability is change in billing practices and/or payment terms, especially without a change in project scope.

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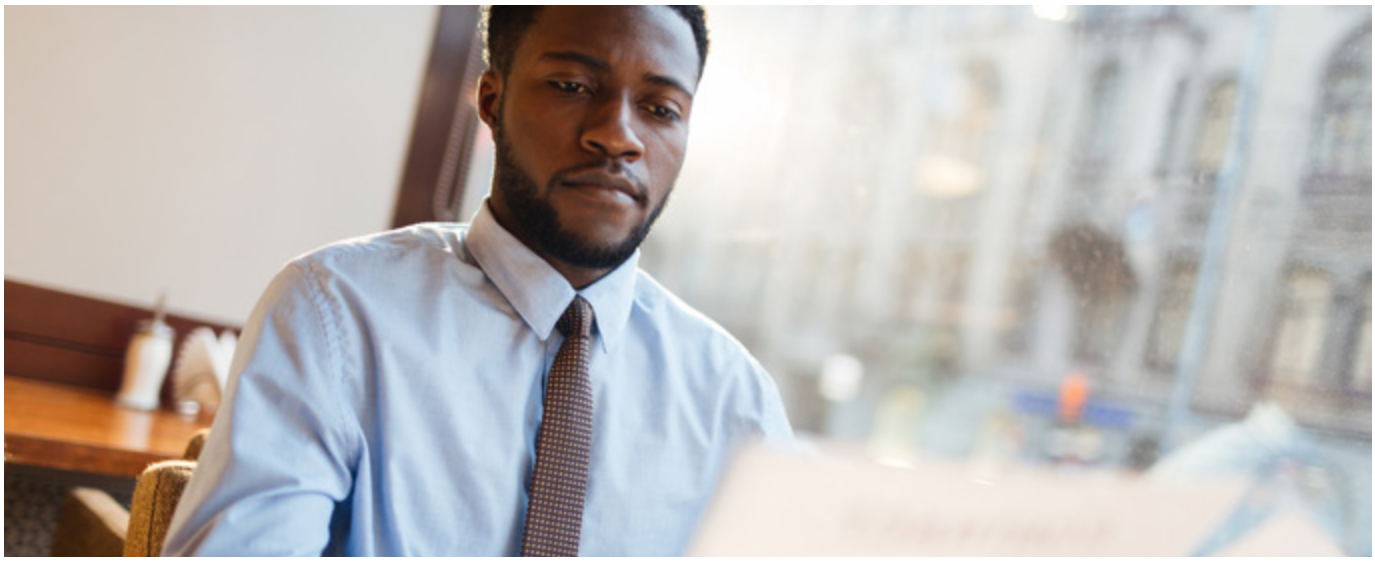
Is my CRO going through a transition/ownership changes? CROs have been consolidating for years, and ownership changes continue to be more and more common. Private equity groups have taken interest in the CRO market and are becoming highly invested in this industry. With change in ownership often comes changing of priorities in addition to significant internal disruption. Clients can get caught in the flurry of change, including competing agendas and/or redundancies within merging companies, incongruent technological platforms, prioritizing of clients, and layers of bureaucracy. Projects often take a back seat to self-preservation or various internal exercises that occur when shaping a new organization. When this happens, changing CROs may be better for your project in the long-run.



Is my CRO underperforming? Underperformance can mean different things to different people. Whether it is timeline issues, quality of the work, high staff turnover, or unanticipated additional costs, your project can be at risk very quickly. If the underperformance is due to a root problem within the CRO, it may be time to make a change. Sometimes changing a function will fix the problem, and other times you may need to change providers completely. From the beginning of a project and throughout, it is smart to define how you will measure your CRO performance relative to expectations.

Am I concerned about the quality and security of my data? The integrity and security of data is one of the most critical components of your trial. Understanding how the data is managed and protected should be considered going into the trial. Does your CRO understand the regulations around the data, use of login IDs, and other critical security steps in place? Do I have a qualified team on my project in clinical monitoring, document management, medical monitoring, safety and data management? Does a defined quality plan exist with appropriate backups and escalations?

Is my CRO transparent and communicating like a partner? Visibility into your trial and the status of your site relationships, study data and overall study management practices is important to knowing your risk. With today's innovation and communication vehicles, companies should be able to have an overall understanding of their trial status, how the integrity of the data is tracked, and whether their CRO is actually performing as promised. If your CRO is not openly creating this type of environment, you may need to consider why!

Risks of a Transition

Contract Consequences – It is critical that you read and understand your entire contract to understand any consequences and financial implications. Often you will find termination clauses that will result in additional fees in the form of a percentage plus any additional fees to close out the project. In addition, database ownership can be difficult. "Who owns the data" may be different than "who owns the database" that has been built. Make sure you know how your contract reads to fully understand the cost to switch providers.

Understanding the Budget Changes and Comparing new RFPs with Current CRO Contract - Every CRO builds budgets differently. In addition to any penalties you may need to pay for terminating early, there may be additional fees from the new CRO. Truly understanding what is in the budget is necessary to avoid change orders in the future. There will likely be duplicate items, such as Kick off Meeting fees, CRA and Team training, and other important start up activities. These items are usually minimal and will pay for themselves when the project is well-managed and on-track to complete within the timeline.

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Time Loss – How do I keep my project moving forward during the middle of the transition? This is a risk that needs to be strategically addressed in a transition plan. When choosing the new CRO, it is important to understand how they have specifically managed this in the past without disrupting project timelines or quality. If they have not successfully transitioned before, you may consider a different CRO. Projects can easily transition without losing time, which is addressed below in Critical Steps for a Seamless Transition.

Risks of "Not Transitioning" Your Project

Delays to project – More than likely if a CRO is underperforming in some way, there will be a delay to the project completion. Whether it is not meeting study start up timelines, lack of subject enrollment, or a fundamental issue with monitoring or cleaning data, extra time needed in a major functional area will cause an overall project delay—thereby creating a delay in a Sponsor's ability to complete a filing or related milestone.

Integrity of the Study – Key to the integrity of the study is the data. The data can be compromised in many ways, and ensuring your CRO is functioning in a way that protects the data is critical. If your CRO is falling short in monitoring practices, data management, medical/safety monitoring, or other relative functions, your project is at great risk.

Financial Implications - Study delays mean added costs whether it is more sites, more time, more resources or other additional fees. One of the biggest sponsor complaints about CROs is the infamous "change order" when there is no change of project scope. Even worse, if the integrity of your protocol or study data is compromised, the financial implications can be huge, including having to change the design, repeat the study, or other significant costly initiatives.

Critical Steps for a Seamless Transition

1. **Creating a Safe Environment** – It is incumbent on the Sponsor to set the tone for the transition; mutual respect between the transitioning parties, setting expectations and desired outcomes is effective in ensuring a successful outcome.
2. **Planning is Critical** – If a transition strategy is decided, the plan is as important as the decision. Each activity and function, as well as supporting technologies, all need to be evaluated. Decisions will need to be made as to the extent of the transition (all or specific functions), the players, the timeline and details about how each and every step of the transition affects the overall program transition.
3. **Informing the Current CRO** – It is critical that the new CRO has a signed contract (or Letter of Authorization) before the current CRO is informed. Leading up to the contract, the new CRO should define how they plan on leading this transition and the timeline and costs for the roll out.

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4. **Project Leadership** - As the Sponsor, clearly communicating your expectations will make for a smoother transition. The important pieces of information you have recognized during this process will need to be considered in the new plan (visibility, leading indicators, data integrity and communication). The new CRO will manage to that defined and agreed upon strategy and measure/communicate to meet the sponsor expectations.
5. **Meetings and Knowledge Transfer** – A defined kickoff meeting between the CRO and Sponsor is an important step in determining the project's operational strategy, roles and responsibilities, communication, and transition strategy. Any knowledge within the sponsor will be transferred to the new CRO so all planning can be finalized and holes identified for discussions with the old CRO.
6. **Continued Professionalism and Sensitivity of Remaining Work with the old CRO** - In making the best choice for your new CRO, ensure that they have led transitions such as this before with successful outcomes. Having the new CRO working with the old CRO to transition information and communicate can be tricky if you do not select the right partner. Understanding how to function in an awkward situation is a developed skill set. Any holes in the knowledge for the new CRO will need to be filled by the old CRO, so this relationship is critical to the success of the transition.
7. **Integration of Study Vendors** – Communication with other study team members (lab, ECG, diary) is also critical. All interactions with vendors will need to be assumed in a similar or redefined manner as to not lose time or quality on the project.
8. **Timelines** – Measuring the current status of meeting milestones, and projecting the new timeline encompassing the transition, together are one of the most important components of the transition plan. Understanding where the timeline may be missed and where there is an opportunity to make up time will keep the project on goal for meeting milestones.
9. **Transfer of Obligations** – Once all information is shared between CROs, the transfer of obligations can be assumed by the new CRO. Often you can include that date within the contract ahead of time to be assumed according to the plan.

Case Study 1:

Biopharmaceutical Company – Phase III Global Program

A biopharmaceutical company (Sponsor) hired a mid-sized CRO as a partner to manage its Phase III global program. Relationships between the Sponsor and the senior management team at the CRO were strong, and all understood the success of the program was critical to the Sponsor company financial health. During the project startup, the CRO partner acquired 2 additional CROs becoming a large CRO, which changed the senior management structure and functional leadership, thus the trusted senior management team left and the relationship was significantly different. The new ownership/management increased the fees, and there were other delays and distractions affecting the project. The Sponsor felt as though their program was no longer a priority and was behind in startup timelines; therefore, the Sponsor selected Advanced Clinical as the new CRO Partner.

Important Factors Considered:

- Sponsor was behind in getting the program started due to FDA hold/review
- In addition to the existing CRO, multiple ex-US CROs were also selected to assist with global patient enrollment and would need to be managed
- Timelines had been previously communicated to the investors and public, which meant speed, accuracy and quality were imperative as there would be no room for unexpected delays
- Due to the study criteria of the program, all sites needed standardized diagnostic equipment, and patient retention and engagement was critical to success of study. Patients only had one treatment visit and needed to remain in the study for one year following the treatment.

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Results:

- Advanced Clinical recruited and activated 60 North American-based sites in 16 weeks
- Study startup was expedited in order for Sponsor to achieve first patient in (FPI) goal; kickoff meeting to FPI including startup & EDC new build was achieved in ~ 6 weeks (30 business days)
- A risk mitigation plan was implemented and kept the program on time through dedicated enrollment focus; cost/benefit analyses were frequently run to assist in decision-making
- High retention rate (only 12 patients lost) through continual engagement from sites/team
- Dedicated, enrollment-focused Project Manager allocated to study to develop site-by-site enrollment plans, as well as coaching to sites on patient communication
- Sites provided with packages of patient-facing tools as well as internal reference tools (e.g., site-facing reference phone application “app”)
- The program enrolled all patients and database lock was achieved on time despite the challenges of starting behind schedule and transitioning to a new CRO

Case Study 2:

Biotechnology Company – Phase I Dose Escalation Program

A biotechnology company (Sponsor) was working with a CRO that changed ownership once the project was initiated. The concerns with the CRO were multiple: 1) financial billing approach and pricing change requests asking for earlier payments 2) CRO staff was not anticipating needs, but rather causing the Sponsor more work and the need to direct the team and 3) the Sponsor could not get data in the correct format in order to make quick dosing decisions due to the CROs SOPs/silos and lack of experience. The Sponsor transitioned to Advanced Clinical after communication and requests were unable to be met by original CRO.

Important Factors Considered:

- A new EDC platform that the new CRO had not utilized in the past
- Well-known thought leaders as Investigators
- Costs needed to be relatively comparable to current program with understanding that some items would be duplicated
- The Sponsor needed a project team to manage the project without much direction
- The transition and timing would be critical to the success of the program

Results:

- CRO’s Data Management team trained within EDC system prior to starting on the project (certified as builders for future work)
- Transition was professional and organized to ease the burden on the original CRO
- Data given to the Sponsor correctly for quick decisions from the onset
- Project remained on time throughout the process

CAROLINE REDEKER

SENIOR VICE PRESIDENT, CORPORATE DEVELOPMENT

Caroline is a results-oriented professional with 28 years of clinical research experience. She is currently responsible for driving innovation and brand expansion, creating new service offerings, and building corporate efficiencies for Advanced Clinical. She has worked within multiple contract research organizations, led and grown business development and marketing teams, budget and contract teams, and patient recruitment teams. She has also worked directly with customers on hundreds of clinical programs and developed many long-term, strategic, customer relationships. Caroline is consistently driven by the perspective of the customer and is passionate about delivering exceptional service and an overall better clinical experience for every program. Caroline received her Bachelor's degree in Finance and Management from Central Michigan University experience for every program. Caroline received her Bachelor's degree in Finance and Management from Central Michigan University.

ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research—approaching each opportunity with foresight, character, resilience and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions.

Visit our website to learn more: www.advancedclinical.com

