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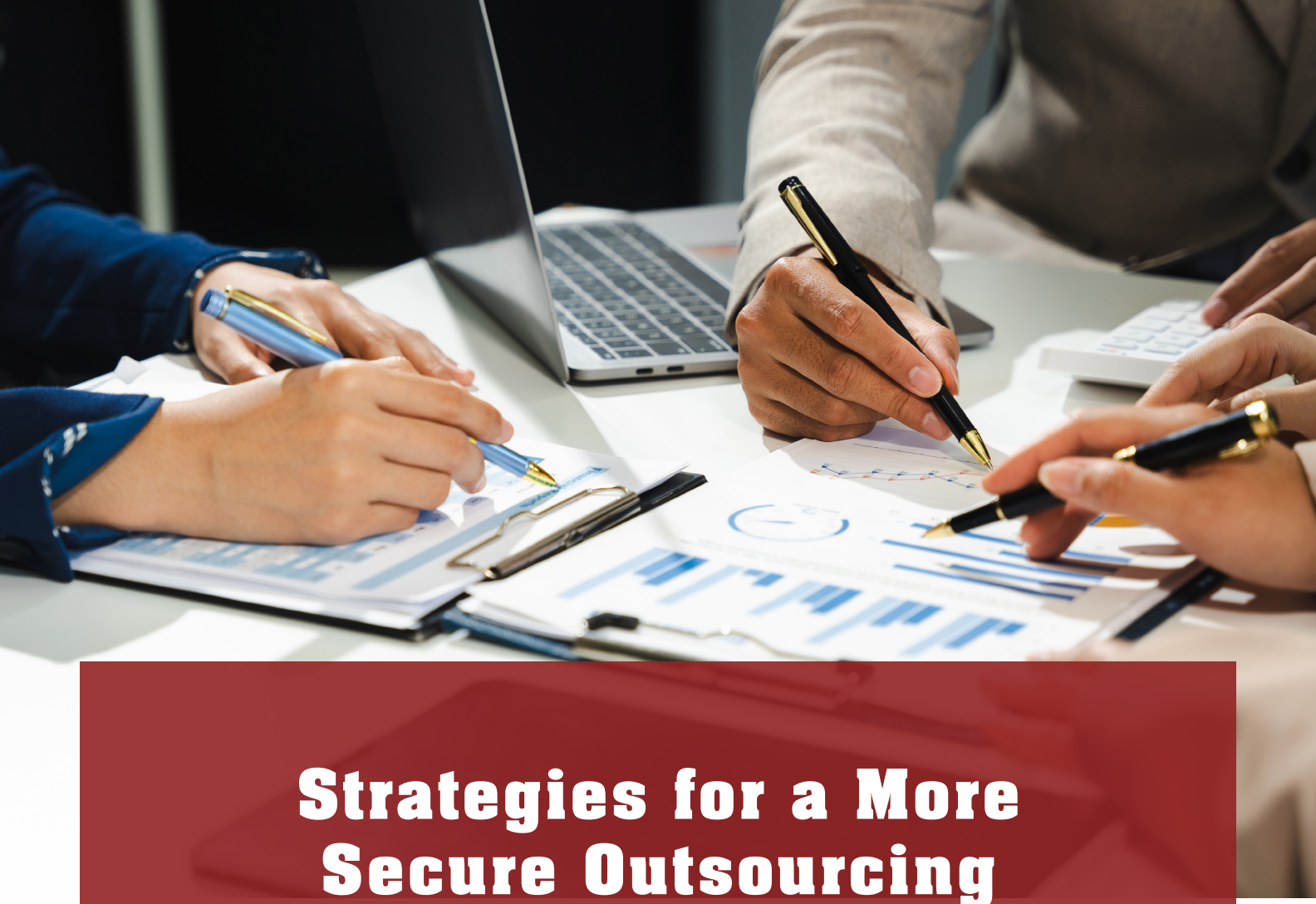
Strategies for a More Secure Outsourcing Bottom Line

We cannot “slow the burn” as the pharmaceutical industry leans more on CRO partners to complete critical tasks, but we can better understand and manage that burn.



Strategies for a More Secure Outsourcing Bottom Line

By inSeption Group

The pharmaceutical industry has evolved in the past two decades and, as a result, the process of forging a healthy, productive relationship with outsourcing partners has changed. The depth and breadth of that change will likely intensify as countless molecules enter active development and high demand for services strains research and manufacturing capacity. With increasing focus on rare diseases and narrowly defined patient populations, the industry environment favors outsourcing more than ever before.

A recent webinar asked experts from across the pharmaceutical/biopharmaceutical industry to share their experiences mitigating financial risks before partnering with a contract research organization (CRO). The presenters emphasized the critical role sponsors play in setting the team up for success, beginning with meticulous contract review during the partner selection process. In this rapidly shifting environment, “slowing the burn” must start with better understanding and management of the underlying drivers that can make or break a partnership.

Adapt to Shifting Funding Dynamics

Most sponsors are funded by venture capital (VC) and private equity, so pressure is high to manage costs and maximize the bottom line. CROs have responded by offering a variable cost approach that accommodates drug development's growing customization and complexity, as well as fragmented trials supported by a variety of executional models, countries, and site types.

Some of this is due to industry course correction: early in the 2000s, funding was readily available for most companies, even early, preclinical-stage organizations. Now, more complex indications and personalized medicine are necessitating a shift in how companies are built. Huge general and administrative (G&A) expense budgets, supporting big management teams and large infrastructures, are giving way to investor-driven initiatives that minimize overhead costs: hiring fewer people, minimizing physical footprint, and outsourcing as much as possible.

Complex protocols and more selective funding also make for a tight job market. It is a natural process, not unlike the housing market or inflation: it comes and goes, but when you are in the middle of it, it can be frustrating and difficult.

Take Ownership and Establish Expectations

It is easy to blame a CRO when a trial goes awry. But, how did the sponsor make their needs known? Did they set unreasonable or extraneous secondary/tertiary endpoints? Did the sponsor express dissatisfaction when things started going badly? Disagreements are part of any working relationship, and sponsors must be prepared to manage problematic relationships or to replace individuals who are not performing as promised. At most sponsors, the head of ClinOps takes ultimate responsibility for maintaining relationships with the CRO and its staff, as well as communicating expectations.

If you want to encourage true partnership with a CRO that is willing to wade into the deep end of projects with you, you must provide them tools to succeed, too. A recent example is a trial that was not recruiting well. Structurally, the key reason was clear: the sponsors wrote an extremely difficult protocol and hired very few support personnel before abdicating control of the study to a CRO. Before long, problems arose, change orders started piling up, and costs ballooned.

Breakdowns occurred between the sponsor's sense of what it wanted and what the CRO thought it was providing. The CRO was left managing a complex project that was not clearly mapped out, and they had to figure out how to save it. Had the sponsor taken ownership from the beginning, many issues could have been avoided. Keep in mind that failures do not always fall at the feet of the CRO; they can be pinned on the chief medical officer (CMO) or head of ClinOps. The CRO is, from a management point of view, merely a tool for those roles to accomplish their tasks, and so they must not neglect their role in setting a clear vision.

Trial Planning is the Foundation of Trial Execution

Many trial failures result from errors during the planning stage, not just from poor implementation. Sometimes the protocol is too complex, patients are asked to do too much, and/or sites are overburdened. It is important to think through how to simplify implementation and to realistically assess whether patients and sites are capable of the activities required by the trial.

In sharing a plan with a CRO, pay careful attention to questions they ask throughout the request for proposal (RFP) and bidding process. Insightful, difficult questions can indicate the CRO has thought deeply about the protocol. They understand it and they have identified risks and/or problems. CROs that ask zero or few questions, or their questions completely miss the mark, should raise red flags. Ask the CRO for its implementation strategy if need be. As a sponsor, you want to see genuine contemplation on the CRO's part regarding what it can and cannot do for a given price.

Next, work to contractually prevent the "A team" versus "B team" bait-and-switch. Often, during the business development period and the bid defense, a sponsor deals with the CRO's most impressive individuals, only to receive a trial team that does not include those people. An open and honest conversation, and even contract stipulations, can help ensure your trial gets the team it needs—and the one you were promised.

A CRO is unlikely to lock down their entire leadership team for your trial, but they should be able to commit leaders in key positions (e.g., lead project manager) for a consistent length of time. Ask that the bid process include introductions to the team that will work on your project. This allows you to understand from those team members what else they are working on, as well as how they will dedicate the necessary time to your project. This also opens communication pathways with those individuals early in the relationship.

The bid is not just a list of tasks assigned to a dollar amount; it is a plan that your organization must understand and embrace. Everything in drug development adheres to shared tenets — regulatory compliance, patient safety, efficient processes — but the path to achieving those goals must remain flexible and adaptable as the environment changes. Both sponsors and CROs have to be more agile in handling moving parts. On the CRO side, that starts with a capable head of ClinOps who can identify what the project needs and how to structure it, based on an understanding of the sponsor's protocol, operations, and delivery.

Make Common Challenges Less Common

Despite receiving ample attention, common issues continue to plague many sponsor/CRO relationships, including:

- **Unexpected change orders and budget mismanagement** — Sponsor companies often opt for the lowest initial cost or drive the price down to a fixed amount based on the company's financial situation, versus budgeting based on the real-world costs of services they seek. Even after a protocol is set, as a trial advances toward its early phases, amendments and change orders begin to spring up. You have to expect at least a few amendments, like additional monitoring or increased data outputs. Proactively integrating them into the contract and asking for financial transparency allows you to create a smoother spending curve. This approach will also help to minimize delays and work stoppages.

- **Competing CRO/sponsor processes** — Do you, as a sponsor, have avenues to challenge competing CRO-sponsored processes? Ask more subjective questions around how the CRO's SOPs and processes work. How flexible can they be? For many sponsors, a CRO that insists you fit into their system is a non-starter. Modern execution models are so complex that the ability of each site to adapt and perform well is essential to the success of these incredibly demanding programs.

- **Being caught in CRO team members' competing priorities** — A CRO may have a highly capable individual assigned to you, but what happens when that person is supposed to spend 40% of their time on your project, 40% on someone else's project, and 40% on a third client's project? When personnel are spread too thin, it will impact the quality of their work or even drive them into burnout, prompting them to leave the CRO.

- **Lack of adequate communication** — When team members are overworked, communication is among the first things to suffer. Communication issues are a symptom of deeper rot (e.g., they can be a product of these individuals' frustration with long, seemingly thankless workdays and weeks). The more people involved in a project, the more difficult communication becomes, but what is the root cause? Are the departments siloed? Are they understaffed, so personnel are overutilized? These all turn into communication issues — or what feel like communication issues — but if your solution is more meetings and emails, you are doing it wrong.

One easy way to head off many of these issues is to create a positive environment, where team members' concerns are genuinely heard, considered where appropriate, and elevated when necessary. Personnel who feel appreciated and supported are less likely to leave the CRO, and they will not want to leave your project — taking with them legacy knowledge and stalling the project as new team members are caught up.

A sponsor that creates a receptive and engaging environment will better retain high-caliber ClinOps personnel. This same approach applies to site management. Sites should have an open dialogue with the sponsor and feel they are being listened to, rather than simply working under the shadow of an onerous protocol. "Slowing the burn" starts with understanding the shifting pharmaceutical landscape, prioritizing healthy and productive relationships with partners, and carefully considering the ways we can make clinical programs a good experience for all involved.

Learn More

The Clinical Leader-hosted webinar upon which this article is based consulted the following experts:[1]

- Raul P. Lima, Executive Vice President, Clinical Operations, inSeption Group
- Audrey Rossow, Senior Director of Clinical Operations, Alzheon
- Patricia Leuchten, Founder and CEO, Diligent Pharma
- Steven Zelenkofske, D.O., M.S., FACC, FCCP, FACOI, Principal Consultant/Board Director/CSO, SLZ Consulting LLC/DiNAQOR AG and Cadrenal Therapeutics/DiNAQOR AG

View the full webinar here.

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References

1. Panelists' roles and organizations are current as of this article's publication and may be subject to change.

About inSeption Group

inSeption Group is a full-service, global outsourcing organization built on a foundational culture of exceptional service and quality. This culture attracts a subset of people who take a personal responsibility to deliver on what has been promised. inSeption Group's ability to custom-build teams with these experts, while providing valuable continuity, distinguishes our approach from traditional outsourcing options.

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