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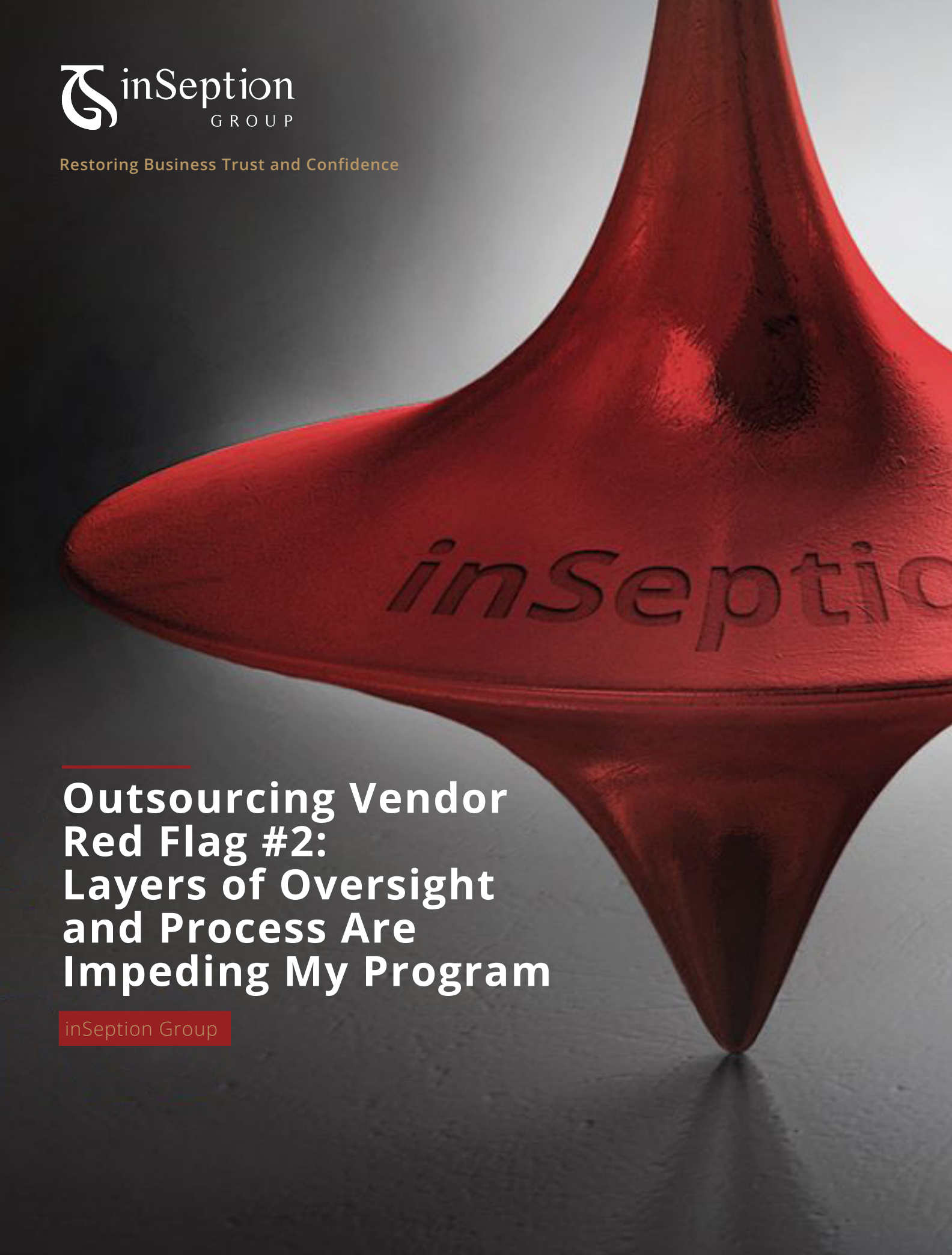

Outsourcing Vendor Red Flag #2: Layers of Oversight and Process Are Impeding My Program

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A recent webinar asked experts from across the pharmaceutical/biopharmaceutical industry to share their experiences mitigating financial risk before selecting an outsourcing vendor (e.g., a contract research organization [CRO]). Individuals in clinical operations (ClinOps) and organizational leadership from both sponsor and vendor companies discussed the challenges of safeguarding clinical programs between the lines of bids and contracts, as well as potential solutions.

The panelists examined three key red flags relevant to outsourcing vendor selection, exploring the consequences of missing those warning signals and how to overcome associated issues. This article, the second in a series of three, looks at what can happen (and what has happened) when a vendor's company composition feels onerous, with multiple layers of management that seem to benefit the vendor but do not necessarily help the client's program.

STRAIGHTEN OUT MISALIGNED EXPECTATIONS

Misaligned expectations can result from many factors, including a misreading or misunderstanding of the average CRO's business model, particularly large CROs. These companies typically are structured with layers of management and approval, which means that even the simplest decisions require multiple people. Ultimately, this approach can drag out timelines and run up costs.

This depth of management is less about ensuring your trial progresses smoothly and more about hiding the CRO's deficiencies (lack of continuity, lack of therapeutic expertise, cost overruns, change orders, etc.) or appeasing their own stakeholders (e.g., legal counsel, regulators, and investors). When selecting such a vendor, you must be aware of these dynamics to operate successfully with them.

Another factor impacting misaligned expectations can be adherence to the protocol. Often, there is dissonance between the financial contract and the CRO's incentives, which means the CRO may execute your protocol in ways that benefit it financially and may not be the best for your interests if it impedes the CRO's ability to meet its own metrics. Getting the contract to align as closely as possible to how you intend to operationalize your protocol becomes a critical art form, necessary in ensuring you can meet obligations to your own stakeholders.

To accomplish this, foster conversations within and between various organizational departments, both in your company and at the CRO. The importance of these conversations is amplified in smaller sponsor companies, which may lack the resources or experience to ask focused questions and to understand the way the CRO operates. This exercise includes not only in-house personnel, but also resources available to you (e.g., a consultant for risk assessment).

For the vendor, program success depends heavily on protocol quality. The protocol must be designed to satisfy questions the sponsor seeks to answer, to fit within the study's target population, and to accommodate sites' capabilities. Making sure the trial's goals are realistic falls on the sponsor, not on the vendor.

After effective communication, the second element of proper expectation-setting is the structure and the people at the vendor who are going to operationalize the trial. It is common for CROs to present their best personnel at the beginning of a project, only to assign different staff after the program is started. Sponsors are often not informed or involved in this decision. It may be the employee's first time working on a clinical trial or they've been pulled from another program because another company did not like working with them. Sponsors should ask directly who will execute their trial and have some contractual requirements triggered if changes are made.

Insist on meeting the individuals who will work on your project throughout its life cycle so you can start to build a relationship with them, as well as vet their experience, critical thinking skills, and ability to produce high-quality work. It is not unheard of to state within a contract (paraphrased), "We control the team assigned to us. If we don't like them, we will request new people, but you can't pull them off our study after they have been approved by us and assigned to the study." If a CRO balks at this stipulation, it should be considered a red flag.

No matter the vendor or the service, perhaps most important is to have a champion at the vendor who essentially acts as your agent and advocates for your project's needs — somebody in a senior position who can be held accountable if deliverables are not as expected. This may be a business development representative or a particularly adept lead clinical research associate (CRA). Or, your company may initially have requested X, Y, and Z, but circumstances have changed and now you need A, B, and C in a way that does not break the bank. An "inside person" can help you navigate unexpected circumstances, acting as a financial steward and program champion within the CRO.

Too many of us have encountered large CROs whose underlying message conveys, "This is how we do things. This is how our clinical trial management system (CTMS) works. This is how we record monitor visit reports. Take it or leave it." Such a scenario may be unavoidable in certain situations, and sometimes it is helpful to rely on the CRO's infrastructure and process. But identifying early their ability and willingness to be flexible is important, because you will likely need to call on it down the road.

Assess whether you are being offered a fit-for-purpose solution and ask questions to ensure the bid/contract does not contain unnecessary bloat. Discern alignment between your project,

your company needs, and the solutions being presented by the CRO. A proposal is often a sneak peek at how the vendor solves issues. If that proposal does not meticulously reflect what is in the RFP and what you've communicated, that is a red flag.

WHERE IS THE FLEXIBILITY I WAS PROMISED?!

Vendor promises of flexibility and adaptability occasionally run headlong into contrary CRO SOPs. Avoid this outcome by examining the vendor's SOPs early in the relationship. Some sponsors can use SOPs created by their own ClinOps departments. Ask specific questions up front and find out what happens if organizational and vendor SOPs do not align (e.g., How would we waive that provision?). If you know early on that you do not like some aspect of the SOPs, write your own SOP and have the CRO follow it. If they cannot, that is another red flag. They might be a great CRO, but they probably are a bad fit for you.

OUTCOMES IN THE CONTRACT: A DOUBLE-EDGED SWORD

Adding outcomes to a contract seems like a common sense way to ensure both partners' business goals are met during the collaboration. These outcomes are often recruitment goals or incentive-based language. However, real-world execution or sponsor-requested changes may prevent the CRO from reaching those outcomes.

So, outcomes clauses tend to please CEOs or boards, but they are often ineffective in practice. A contract may stipulate bonuses or incentives for certain team members at certain milestones, but there are many elements of the industry over which neither the sponsor nor the CRO has control.

For example, patient enrollment depends, among other things, on the therapeutic area and protocol feasibility/burden. Patients and sites generally do not want to be involved with a protocol that has unnecessary or excessive patient burden. Most times, the CRO has no more control over enrollment than the sponsor, and even less control of the protocol – so it is often disingenuous to ask the CRO to guarantee to enroll X patients by Y date. They may be willing, but the unpredictable nature of clinical trial work makes outcome clauses like this tricky to pull off. It is vital to structure the clauses around trial elements that can be controlled and are associated with measurable, consistent, high-quality deliverables from the CRO.

At the end of the day, CROs are expected to make their margin. If they start to see a contract negatively impacting the margin, they are likely to take the penalty if your project is not a huge revenue generator for them versus other clients. A CRO could pull resources off your project to maintain its margin and defensively state, "We're late already anyway." This disproportionately affects smaller or complex trials whose science requires flexibility; larger studies with bigger budgets and a more straightforward regulatory path have a lot more leverage because, at that point, the CRO is unlikely to walk away.

Ultimately, contract clauses that would be more conducive to the trial meeting its established timelines incentivize trial startup, shutdown, and cleanup. You also want to incentivize behaviors. This promotes flexibility by empowering teams to change direction as needed throughout the trial and seek solutions rather than clinging to pre-established (and often superfluous or futile) processes. To learn more, visit https://inseptiongroup.com.

Part 1 in this series discusses how to handle cookie-cutter bids and contracts whose stipulations have not been tailored specifically

to your needs. Part 3 explains how to follow your instincts when a bid feels inaccurate and/or is lower than expected.

WEBINAR PANELISTS

- **NOTE:** Panelists' roles and organizations are current as of this article's writing and are subject to change.
    - **Raul Lima**, Owner, Versaten Pharma Consulting, LLC
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