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Restoring Business Trust and Confidence

Outsourcing Vendor Red Flag #1: Copy-And-Paste Bids & Cookie-Cutter Contracts

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Misaligned expectations can result from many factors, including a misreading or misunderstanding of the average CRO's business model, particularly large CROs.

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

The panelists examined three key red flags relevant to outsourcing vendor selection, explored the consequences of missing those warning signals, and discussed how to overcome associated issues. This article, the first in a series of three, turns a critical eye toward uninspired, cookie-cutter contracts.

No two clinical programs are alike, and the unique attributes of your program deserve a thoughtful, tailored approach. Yet anyone who has been in the industry long enough has noticed that CRO contracts seem to all look the same. A generic contract that is not set up to handle the nuances and challenges of your specific program can result in a barrage of unexpected upcharges or delays. Customizing the contract can help protect the trial's budget and will mitigate the risk of burning through program funds on unnecessary expenses.

DO YOU SEE DETAILS AND EFFORT BEHIND THE PROPOSAL?

Upon receiving a lusterless contract, many people initially wonder whether there was a miscommunication. What did I convey? What did the vendor internalize? Ideally, the request for proposal (RFP) sent to the vendor was clear, and (more importantly) time was set aside for outstanding questions or concerns. That includes

robust discussion on the state of the protocol, which is typically not finalized at the RFP stage.

In fact, part of the bidding exercise may include evaluating input from the vendor that could help fill in gaps or shape the final protocol. This is why effective CRO/sponsor communication is paramount from the start: it doesn't just indicate the vendor's ability to deliver a thoughtful bid; it also demonstrates their ability to analyze, operationalize, and optimize a plan. If the sponsor provided sufficient time to talk through the RFP and receives a proposal back that does not look well thought-out, or unique to their study and therapeutic area, disappointment is to be expected.

It's true that sponsors cannot rely on a CRO to "own" the process. They must be well-versed and well-grounded enough to provide consistent and reliable direction on standard operating procedures (SOPs), strategy, equipment, and other ClinOps elements. That said, it must be acknowledged that many smaller or startup organizations are not fortunate enough to have a strong ClinOps leader capable of taking ownership and oversight. They may have to rely heavily on the CRO to be an extension of their company.

In either scenario, avoiding or overcoming copy-and-paste contracts begins with the bidding process. Many CROs, particularly early in a relationship with a sponsor, leverage presentation content templates when they bid, then fail to make that presentation more specific when they perform a bid defense.

This assembly-line process should warn you right away that they are not paying close attention to your needs, or they are incapable of meeting those needs. This is particularly damaging for smaller biotechs that all but require a close relationship with someone at the CRO who will champion the biotech's needs. Arm's length will not suffice.

These early conversations and presentations are typically indicative of how the rest of the process will unfold. Again, while the sponsor has a responsibility to project complete clarity around expectations, the CRO is accountable for asking questions and "understanding the need behind the need," so to speak. These are fundamentals of operationalizing a trial: detailed conversations around expectation, backed by strong documentation.

Those elements can be missed in the rush to complete a contract because of the industry's ever-present timeline pressures. Slow down! Prompt a detailed discussion around quality expectations, identify risks in the clinical trial process, and document both. This will lead to a more precise, accurate, and meaningful contract.

> **It just comes back to fundamentals of operationalizing: detailed conversations around expectation, backed by strong documentation. That piece is sometimes missed in the rush to get to contract because we're all under such timeline pressure.**
>
> ***Patty Leuchten***
> *Founder and CEO, Diligent Pharma*

DO YOU KNOW *EXACTLY* WHAT YOU WANT?

It seems obvious: when you are preparing an RFP, you need to know what you're asking for — and the protocol itself does not hold all the answers. The protocol is a strategy, while the on-the-ground activities are "deeper in the weeds" than a protocol typically defines or describes. Look at it this way: you would not walk into a car dealership and ask them what features you need in a vehicle, or how much you should pay. You want to walk in being able to clearly describe exactly what you want and what you're willing to pay to get it — with your greatest leverage being the ability, and the shrewdness, to walk away if the deal seems sour.

Regardless of the pharma/biopharma company's size or experience, the standard remains the same: know what you need, what you expect from your CRO partner, and what, specifically, you are asking them to accomplish. If you clearly explain what you want and the CRO states it cannot deliver (or you believe it cannot deliver), you will not reach the contracting process anyway.

Additionally, especially for organizations fielding multiple bids, it is critical to ensure the bids contain "apples-to-apples" comparisons so your organization can make a balanced and informed decision. Templates and checklists are available to help ensure bids contain all necessary elements. Several collaboratives/consortiums also serve companies sorting through bids, facilitating their decisions while not expecting them to reinvent the wheel.

I KNOW *WHAT* TO DO, BUT *WHO* WILL DO IT?

Some companies are still building the infrastructure to support a thorough RFP process. Lean teams must piece together and rely on cross-organizational or third-party expertise. It can be a messy, rushed, and time-consuming process — but it is a necessary one that serves many purposes beyond simply finding a CRO. The RFP process can not only refine details for contracting, it also can advance internal understanding of a trial protocol. Some organizations find an RFP template to be a useful tool in this respect, ensuring accurate, trial-specific information can be considered by the vendor and mitigating the risk of cookie-cutter proposals.

Consider that the sponsor likely has lived and breathed its protocol for 18 months to two years — the data, the design, notable milestones, funding, and time to market. However, even with all this awareness, the sponsor sometimes does not dig down into how the protocol will be operationalized. For example, how will the site experience be shaped, how will data and the trial master file (TMF) be documented, and how might monitoring visits be handled?

The RFP is an apt vehicle to chase down those answers. Even if your organization lacks the necessary expertise internally, you can consult with colleagues and partners who possess that knowledge. The more questions you ask, the more time, thought, and effort you invest in that process, the more you can get out of it — and the more you can set your CRO partnership up for success.

SAME KIND OF PARTNERS = SAME KIND OF RESULTS

Taking into consideration all the above, it also must be acknowledged that, if you keep encountering CROs offering bids with similar approaches and cookie-cutter contracts, you probably are (deliberately or inadvertently)

> **If you tell [a CRO] what you want and you're clear about it, and then they don't give you what you want, you probably shouldn't even get to the contracting process.**
>
> ***Steven Zelenkofske, D.O., M.S.,*** *FACC, FCCP, FACOI, Principal Consultant/ Board Director/CSO, SLZ Consulting LLC/ DiNAQOR AG and Cadrenal Therapeutics/ DiNAQOR AG*

approaching similar types of CROs. Speaking with other people and organizations can reveal unique perspectives that provide a more prismatic understanding of your protocol.

Not all groups that provide clinical research services are CROs. Often, the phrase "CRO" conjures up ideas of a model that is inefficient, expensive, and inflexible. Even the smallest, nimblest CROs can still suffer some of those constraints. In short, look outside your expectation of what a CRO can be: find different sized companies, research functional service provider collectives, etc. See what they do similarly and where they differ and use that information to enhance your understanding and execution of your trial.

Functional service providers and/or consultants also can be hired to oversee a single element or several aspects of a CRO's work (e.g., TMF management, site management, and/or medical writing). Still, it can be difficult to convince management to secure such services; do they know the exact purpose of the TMF, its value, or the importance of it being inspection-ready at all times? Or, in some instances, an initiative may be pushed by management as seemingly cheaper, but costs associated with the subsequent internal investment in oversight and making sure all those individual contractors come together synergistically adds up quickly.

Many traditional CROs propose one or two offerings. They have a playbook for those processes and a general group to carry them out; injecting flexibility into those processes typically adds cost. A better fit for most sponsors is a partner, or partners, able to "hybrid out" the assigned work, empowering the sponsor to pick and choose how it wants to engage with the CRO, manage full-time equivalent (FTE) personnel, and contract.

This flexibility allows the sponsor to shape its organization to fit the work ahead. This model is also particularly helpful to small companies who want to stay in control of their studies and have options regarding how they do so. To learn more, visit https://inseptiongroup.com.

Part 2 of this series discusses what happens (and what has happened) when a vendor's company composition feels onerous, with multiple layers of oversight and processes that seem to benefit the vendor but do not necessarily help the client's program. 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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  - **Steven Zelenkofske**, D.O., M.S., FACC, FCCP, FACOI, Principal Consultant/Board Director/CSO, SLZ Consulting LLC/DiNAQOR AG and Cadrenal Therapeutics/DiNAQOR AG

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