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Outsourcing Vendor Red Flag #3: A Bid is Inaccurate or Suspiciously Low

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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 third in a series of three, explores courses of action when a CRO's bid feels inaccurate — perhaps the services outlined are not what you expected — or the stated price feels suspiciously low.

MAKE AN INFORMED BID DECISION

If your gut is telling you something is not right, that's a great place to start. However, strategies exist to substantiate a bid's value based on more than the "sniff test." Ideally, you have protected yourself against just such an occurrence by providing potential vendors with a detailed request for proposal (RFP), including accurate, trial-specific information and ample time for communication with the vendor. These steps help mitigate the return of cookie-cutter proposals.

One advantage of sending RFPs to multiple vendors is that it allows you to evaluate bids by both similar and dissimilar organizations. Not all CROs are huge entities, and not all companies that provide clinical services characterize themselves as CROs. If you provide consistent information in your RFP to a broad set of companies, you will get a chance to see the differences in the output from company to company and you can directly compare how they react and respond. Though it may initially sound counterintuitive, you want people thinking about your program differently than you think about it.

IS THIS BID TOO GOOD TO BE TRUE?

Some factors should raise a red flag immediately. A pertinent example is a low bid reflecting — or hiding — a company that leans heavily on the change order process. Their initial bid comes in low to secure the contract, but their fee could be bolstered by numerous change orders, seemingly over every small detail or deviation. Avoid such situations by cross-checking their assumptions against your needs and expectations. Again, seek multiple bids from different types of vendors and ask specific questions about the line items in each bid or contract you receive.

Another potential red flag is a bid containing bundled line items without clarity about what each line item contains or how those costs are derived. Sometimes bundling makes it difficult to interpret the bid's base services. For example, you may see a substantial project management fee, but you don't see fees for "vendor management." Are those fees missing or part of a bundled line item?

Asking about rates is crucial. It allows you to conceptualize the plan in terms of something other than dollars and to close in on "effort." It is one thing if a bid is lower because the vendor will complete the same amount of work for 75% of a competing company's rate. But if the vendor's rates are higher and the bid still is much lower, you should be wondering just how much work they actually propose to perform. Asking about rates also gives you an idea of whether the activities the vendor proposes are calculated appropriately.

CROs that engage in these practices — counting on change orders and bundling services in a convoluted way — tend to bid low with the expectation they will execute numerous change orders. If you ask for references, those vendors will only provide people with whom they have good relationships. Thus, it is vital to leverage your personal/professional network to ask about their experiences with a given vendor.

One option for sorting through bids exists in the form of companies using an AI-powered, cloud-based platform — into which sponsors can enter information from their bids. The platforms then provide some analytics, comparing the bids across similar attributes. Regardless of how you go through bids, multiple offers will allow you to gut check what makes sense (i.e., what is abnormally high or low?). This, in turn, can give you confidence to return to vendors with pointed questions (e.g., "Your pass-through costs feel outlandish. Is there something we didn't understand or is your fee truly that much higher?").

CHANGE ORDER MANAGEMENT AND MITIGATION

Misaligned expectations, overlooked needs, or deliberately omitted services typically result in a change order. Some of the fault is in the hands of sponsors; you must expect the unexpected and allow room for a certain amount of financial flexibility. This is particularly relevant when the science is still emerging, and you must plan for the "expected unexpected" issues.

The more complex or new the program is, the more flexibility needs to be pre-built. Change order costs should be assumed in the project budget even though they are not part of the original plan. Sponsors should seek clarity from vendors up front about potential rates for change orders, providing you a more complete, forward-looking perspective of the trial's total cost.

Most protocols end up with a few change orders, but the volume should never be excessive unless the protocol was redefined. That is just the nature of the work, particularly in early-phase development, when the sponsor does not (in some cases, cannot) yet know some relevant details. The sponsor may still be working through the science, and that requires flexibility in the protocol (you almost always need more data outputs than you expect).

So, as a rule of thumb, plan for at least three change orders (one or two extra a year). Consider not only the protocol language and operationalization plan, but other factors, such as the demands of funding rounds or requests for additional data from the board of directors.

Vendors may be less likely to raise the subject proactively because they don't want to (at best) imply they cannot stick to the protocol or (at worst) tip their hand on their long-term financial strategy. Change orders are an inherent part of the process, and a strong vendor knows the best path forward is to embrace the topic, not avoid it.

Still, change order management and mitigation begins with the sponsor initiating the conversation around change orders and setting a clear, articulated point of view early in the relationship. But beware that establishing clear change order language in the contract — "this is what a change order does and does not constitute" — is no replacement for a direct and open conversation. Vendors often push back and try to implement a change order anyway. A buttoned-up contract (i.e., defining change orders and their management) is a robust defense.

A competent vendor will submit an accurate bid, accounting for all requested services, outcomes, and potential disruptions. If the trial experiences a material change prompting a change order — such as an unexpected, leadership-mandated milestone report — that is valid. But absent a material change (e.g., the vendor just didn't bid accurately) a vendor cannot simply state it needs more money. An example might be when a CRO has promised 50 percent of someone's time but then assigns that person to an additional account, then pursues a change order because they need to add a second person to complete a given task.

Indeed, the first solution vendors often proffer when something goes awry is "pay more." But nine times out of 10, all you accomplish by throwing money at the problem is losing money. You're not actually underpaying; something structural is wrong with the partnership. Until you address the underlying problem — which may sometimes require you to consider a different course or action or a different outsourcing partner — you may continue to burn through your trial's budget and put your clinical program at further risk.

But such problems can be resolved. In any clinical program, contracts and financial considerations loom large and can introduce heavy pressure on sponsors and vendors. But the basic principles of sound outsourcing partnerships are relatively simple: When you strip away protocols and processes, all day-to-day functions succeed or fail based on the quality of the people working on your program, as well as the quality of their interactions.

ClinOps and clinical trials are full of helpers, people who want to succeed by engaging their colleagues, people who want to do good by doing right. Look past the institutional layers that can impede your ability to find effective and efficient solutions. Find ways to surround yourself with the individuals who will do what it takes to safeguard the integrity and cost of your trial. To learn more, visit https://inseptiongroup.com.

Part 1 of this series looks at how to handle cookie-cutter bids and contracts whose stipulations have not been tailored specifically to your needs. Part 2 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.

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
  - **Audrey Rossow**, Director of Clinical Operations, Precirix
  - **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

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