



Special Report:

How to Avoid the Six “Black Holes” that Undermine CRO Assessment Initiatives

- Why rationalize your clinical research outsourcing?
- Common pitfalls to the process
- The six “Black Holes” that undermine clinical outsourcing initiatives
- The four questions to ask any alliance management or negotiation consultant before hiring them to help you with the initiative

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If you're in charge of clinical outsourcing at a pharmaceutical company, you're probably doing everything in your power to contain costs and save time as you assess, select and work with Contract Research Organizations. And you've probably been paying attention to the industry trends to reduce the pool of qualified providers and standardize the process of bidding, costing, negotiating, and communicating.

Good Reasons to Rationalize

The theoretical reasons for choosing and staying with a select group of CROs are obvious and powerful. Ultimately, they come down to three: lower costs, increased efficiencies and quality, and reduced risks. Let's examine these one at a time.

Lower Costs:

Some of the world's largest pharma companies have achieved significant discounts from their qualified CROs. How much? Anywhere from four to as high as fifteen percent is not unusual. And the CROs are glad to give these discounts in exchange for high volume and greatly reduced sales and marketing expenses. If the cost savings were the only advantage to reducing the CRO pool, you wouldn't

need any other reason to justify it to the CRO and the investors. How much does a 10% reduction in CRO rates translate to in your situation?

Increased efficiencies and quality:

When you work with a small pool of dedicated suppliers, you can negotiate a common set of processes across the board. Sharing, planning, communicating, negotiating, reporting and troubleshooting all follow the same predictable, efficient system. More importantly, you are now working with CROs who have a stake in your long-term success. Because you communicate efficiently and strategically, they are able to plan their own resourcing to meet your future needs. Imagine knowing that the right project team will be available for your critical study months before you need to deploy.

Reduced risks:

Because you become a cornerstone account for your CROs, there is a greater probability that you will be assured their highest levels of quality: the best project teams, proactive quality assurance, and stellar client service. You have eliminated 99% of the causes of failed trials, dirty data, and missed timelines. Your trials get the expertise and attention they deserve, so you have a greater chance of shortening the timeframe of the clinical development process.

Common Pitfalls

Our predictions:

Prediction #1: You've been planning for a rationalized sourcing initiative for months, maybe even a year or two.

Prediction #2: Your company has put you in charge of a task force or committee to study best practices and get the ball rolling.

Prediction #3: You and your committee are too busy with your everyday responsibilities to dedicate the time and focus the sourcing initiative requires and to implement all the required steps.

Prediction #4: You're considering hiring someone to manage the process, but you're not sure of the necessity, the specific role of that individual and the type of experience that person would need to have.

The Six “Black Holes”

If we're right on at least three out of four, realistically you may not be able to do what it takes to realize the tremendous cost, efficiency and quality benefits we just talked about. In our experience, the following is a partial list of the tasks that typically get under-resourced in the initial project plan:

1. Needs assessments and internal satisfaction surveys

This step is critical to the process. Without asking your operational teams what they value and what they don't like about working with particular CROs and then communicating to them what you've heard, you're going to end up with no buy-in and no utilization. Haven't you seen giant initiatives fall flat because the people who were supposed to benefit never got consulted and never felt listened to? Without buy-in, your project teams will attempt to find ways to get around your qualified providers and work with whomever they want, however they want, even if “mandates” are in place, thus derailing the process.

2. Executive Sponsorship

We've seen time and again that without true executive sponsorship for major initiatives, the “plug gents pulled” on funding before you've accomplished anything meaningful. If it's your project, it's your responsibility to ensure meaningful, long-term support is in place and demonstrate overwhelming, incontrovertible ROI. It's imperative to prove the value proposition to the senior executives responsible for clinical budgets and why rationalized sourcing makes sense from not only a financial but also a quality perspective. For the success of the initiative in the long-term, it is important to keep the executives engaged and ensure their support long after the contracts with your preferred CROs are finalized.

3. Continual marketing to internal teams

Not only must you get input from your internal teams, you must continually market the benefits of your initiative to them. From their perspective, they're worried about lack of choice, reduced autonomy, one-size-fits-all procedures that maximize effort and minimize efficiency, complacency among the short-lists of suppliers, and reduced quality. It's important to address these concerns head-on as well as to explain the value and benefits of the new system you're developing.

4. A strategy for determining the criteria, the number and the mix of CROs for your outsourcing initiative

This is an important step that requires thorough analysis. Some considerations:

- Corporate strategy for clinical development: therapeutic and geographical focus
- Short-term and long-term needs
- Total outsourcing spend
- Capacity of suppliers
- Need for niche providers in specialty areas
- Operational preferences
- Existing relationships

In this step, it is important to balance individual team preferences and perspectives with objective financial analyzes while taking into consideration your company's corporate strategy for clinical outsourcing.

5. A thorough, comprehensive assessment process that is and appears to be fair, objective, and scientific

Your team will be making decisions with huge financial implications for your company and your clinical outsourcing partners. This can't be seen as a subjective process. It is critical to create, publicize, and strictly abide by standardized, objective, and validated Internal Operating Processes.

The intuitive way to evaluate CROs is to interview your project teams and find out who they like. "This level of subjectivity, arguably based on personality and chance, unfortunately leaves you and your company vulnerable to charges of favoritism.

6. A framework, strategy, and process for negotiation

Once you've chosen your select group, the conduct of separate, sensitive, and confidential negotiations with each CRO is the next step. Are you an expert at negotiation theory and practice? Do you have one on your team? Does your company have a history of "hardball" negotiating tactics that elicit defensive or aggressive responses from your negotiation partners? Do you have someone who can be perceived as a mediator by the CROs, someone they trust to keep the process fair and objective?

Do you have experience with CRO costing models? Do you have an understanding of the acceptable ranges of CRO hourly rates by categories of employees? Have you ever developed a CRO bid? Do you have an advisor who understands CRO costing models and practices? If not, how will you get this intelligence to help you negotiate effectively?

These six tasks are above and beyond the actual process of rationalized sourcing. It's important to prepare for them, mentally and in the budget. Otherwise, the project could lag and your committee may lose momentum. The issue is not only a less than optimum working experience, you run the risk of losing valuable time and importantly, credibility with senior executives and your internal teams.

We have helped companies achieve their desired goals, which have resulted in mutually beneficial arrangements with their CRO partners. So we know it can be done, and done well, with tremendous results. We have also seen some initiatives that had the best of intentions fail because of lack of preparedness and consideration of important critical success factors.

Here are four questions you must ask any consulting firm before hiring them to help you with your project.

1. Have you lived in the CRO world? Do you understand their culture, their cost structures, their individual strengths and weaknesses?

There are many consulting firms who specialize in “alliance management” and strategic outsourcing. They have interesting models, elaborate flowcharts, case studies from a dozen different industries, and a roster of prestigious clients. It's hard to resist them – they just make you feel so confident that they know what they're doing.

In our experience, unless these firms are run by consultants with deep experience in CRO business development and operations, they are applying the wrong models to the industry. Clinical trials are not seatbelt webbing or sheet rock. The “Just in Time” supply chain model is completely irrelevant to clinical research.

Also, they may not know the actual costing structures of CROs. They'll guess and analyze and interpolate, but they can't guarantee the accuracy or usefulness of their numbers. At the negotiation table, knowledge is power.

2. Do you currently work with large global CROs?

CROs are not commodities. Each has its own distinct advantages and disadvantages in a given situation. Your consultants must be up to date on the

industry, and ideally are currently working with several of your potential select CROs. It's important for a consulting firm that you partner with to have complete credibility in the eyes of your negotiating partners.

3. Have you led a successful clinical outsourcing initiative like this in the past?

This one is obvious, but it's so important we decided to include it. Despite what the mutual fund ads say, the only reasonable guarantee of future performance is past performance. If your consultants haven't gone through this very process successfully in the past, they are simply not prepared for all the twists and turns in the process. They will be reacting to events instead of driving them.

4. Will you make me look like a hero every step of the way?

Your consulting firm must be willing to, indeed must insist on sitting in the back seat when anyone is looking, even if they are actually driving the whole process. This means being willing to be totally silent during negotiation sessions. Being available when you need them for support, guidance, and troubleshooting.

Our Vision

The Avoca Group is committed to increasing the quality of partnerships in the pharmaceutical outsourcing space. We work extensively with pharma and CROs. We help companies to establish mutually beneficial, long-term, healthy relationships with CROs and we operate exclusively in the win-win space.

Next Steps

If this report makes sense to you, and you think you would benefit from a consultation with one of the principals of The Avoca Group, please contact us at (609) 252-9020 or on the web at www.theavocagroup.com. Through discussions about your specific needs, we'll help you create your project plan, prioritize and cost out the elements, and establish target measures of success. At the end of that consultation, we will each decide if it makes sense to continue to work together. You'll have a taste of who we are, how we work, and what value we bring. And we'll have a sense of your outlook on strategic partnering and your company's commitment to the project.