

CRO Management: Why Sponsors Don't Do a Better Job and What They Can Do About It

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Introduction

In today's clinical development environment, efficiency has joined quality and speed as a critical success factor. Many organizations view the use of CROs¹ as an approach to driving efficiency, so it should come as no surprise that the use of CROs is becoming more and more common. In fact, sponsors are choosing to use CROs in order to drive efficiency on many different fronts.

The use of CROs is intended to drive efficiency by increasing flexibility. By using CROs, sponsors can increase their flexibility by decreasing their need for full-time internal staff and expanding their access to a wider range of expert external resources. For example, an organization that is developing in a range of therapeutic areas can employ CRO staff members who are expert in each of those therapeutic areas by leveraging specialized CROs.

In addition to staffing efficiency, CRO use also drives cost-related efficiency gains. As for-profit businesses, CROs are highly incented to aggressively manage their staff and overhead costs—a practice that translates into more efficient utilization and trial conduct.

In the same vein, a CRO is positioned to reduce overhead costs per trial in a way that sponsors typically are not. For example, for fixed assets like a CRO's Phase I unit, more volume can be pumped through the same unit than is possible with a single sponsor, thus reducing the overhead costs to be born by each project. In the same respect, CRO CRAs are utilized more efficiently because they can support multiple sponsors' trials in the same region, reducing the need for travel and increasing overall CRA utilization.

¹ Note on the use of the term CROs: A wide array of outsourced service providers offer a diverse variety of services to clinical development organizations. For the purposes of this discussion, we'll refer to this assortment of service providers simply as contract research organizations (CROs).

Whether the efficiency gained is in sponsor flexibility or cost savings, the use of CROs appears to be a win-win for sponsors and CROs. The sponsor wins by reducing their overhead and being able use exactly the right resources at exactly (and only) the right time. The CRO wins by profiting on their engagements. On paper, it's the perfect arrangement.

Overview: S³ Approach to CRO Management

In reality, the sponsor-CRO relationship is not always a win-win. While sponsors are clearly enticed by the efficiencies that can be gained through CRO use—the CRO industry's growth rate is estimated at 11%, while the estimated overall R&D spending growth rate is at 3.5%²—there is nonetheless a downside to the relationship. That downside is the fact that a sponsor using a CRO must entrust its trial's performance to a third party, and that same performance is ultimately the measure upon which the sponsor's development organization is judged by its senior management.

At the end of the day, no matter the approach taken—insourcing or outsourcing—success will be judged by the ability of the development organization, given the resources provided, to produce high-quality clinical data that move the progress of a target forward. As use of CROs grows, that measurement of success is largely in the hands of CROs, and therefore only secondarily in the hands of the pharma and biotech companies that employ them.

This concept of entrusting performance success to CROs is not new to “virtual” pharma and biotech companies (i.e., companies that outsource all of their development work); however, it is largely a new challenge for more traditional organizations. It has only been in recent years that non-virtual pharma and biotech companies have crossed the tipping point to conducting a significant percentage of their development work through the use of third parties. Unfortunately, few of these companies' business models have changed to reflect this new reality.

For outsourced trial activities, this disconnect between business model and management approach often has disastrous results. In many cases, sponsors find themselves managing by crisis, a situation in which individual vendors are only loosely managed until a crisis arises.

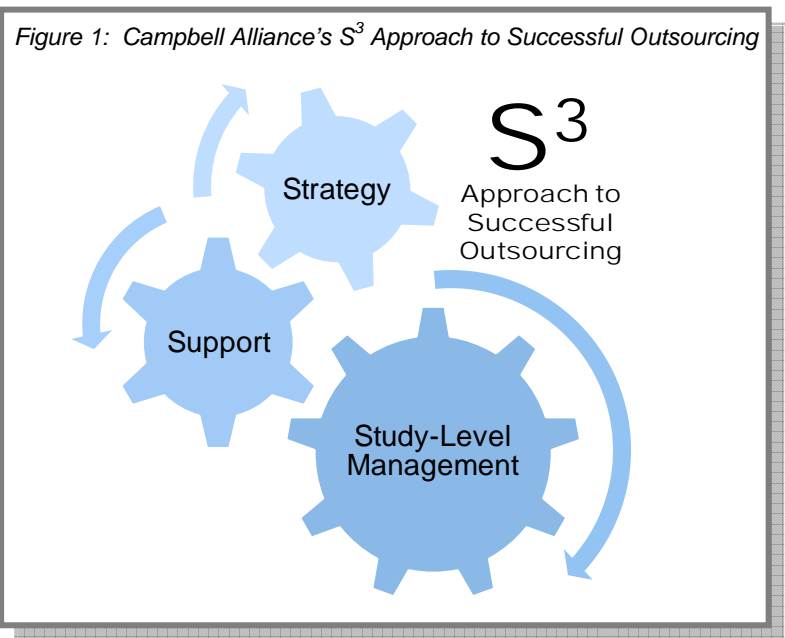
Even if there are no major incidents in the course of the trial, it doesn't mean that the sponsor is out of the woods. Seemingly smoothly running studies can have hidden data quality issues found only after submission. For example,

² Sobering Up From A Volatile Ride - Part II: Pharmaceutical Services Industry Update. Baltimore, MD: Wachovia Capital Markets, LLC, December 8, 2008:4.

ceftobiprole encountered delays because the FDA was unable to review the clinical data collected by a CRO until “issues of data integrity have been resolved.”³

To avoid such outsourcing pitfalls and gain the efficiencies that can be driven by CRO use, sponsors who outsource all or part of their development activities must adapt their approach for managing in-house trial activities to fit the unique demands of outsourcing. This is often a significant challenge because many staff members who are managing CROs grew to that level of responsibility by successfully managing internal staff and sites directly. In other words, they know how to effectively manage staff to successfully conduct trials; they do not know how to effectively manage a CRO to effectively manage its staff to successfully conduct trials. That’s not to say that experience managing internal staff and sites isn’t necessary to manage CROs; it simply means that this experience is not enough.

So what is enough? We’ve talked about lots of ways to do it wrong, but how does an organization do it right? In short, what is the formula for outsourcing success? At Campbell Alliance, we’ve boiled the formula down to three key components—strategy, support, and study-level management—Campbell’s S³ Approach to Successful Outsourcing.



Strategy

Strategy is the first step in addressing the disconnect between development’s business model (increased outsourcing) and its management approach (traditional in-house study management tactics). By creating a deliberate organization-wide outsourcing strategy, an organization can make smarter decisions and greatly increase the likelihood of achieving outsourcing’s benefits.

Smarter means outsourcing when it makes strategic sense instead of just using CROs on an “as-needed” basis. The most obvious drawback of outsourcing “as

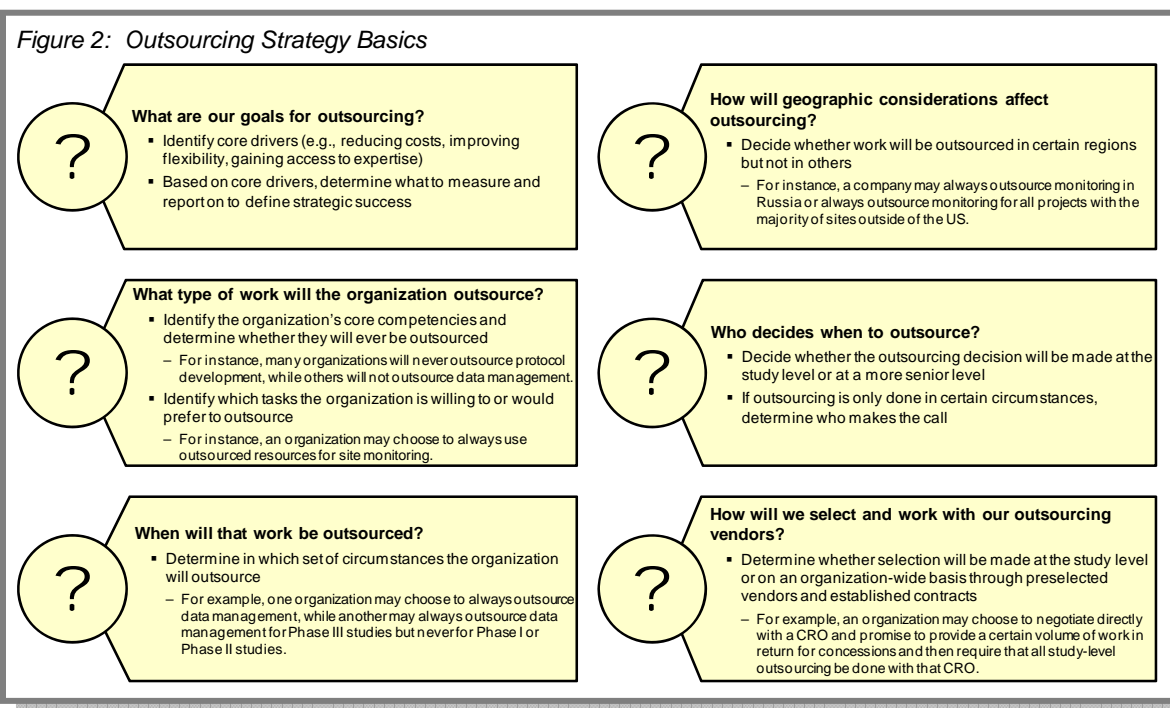
³ Source: FDAnews. After Site Audit, FDA Delays Approval of J&J’s Ceftobiprole. Available at: <http://www.fdanews.com/newsletter/article?articleId=113058&issueId=12232>. Accessed on March 6, 2009.

needed” is that companies can end up insourcing activities and trials that could be easily and successfully outsourced while outsourcing activities and trials that are better suited to internal capabilities and more direct management. Putting an outsourcing strategy in place can help organizations overcome this and other drawbacks of the “as-needed” approach.

An outsourcing strategy defines when and how an organization will outsource. Knowing when outsourcing will happen means that a company’s staff is prepared and poised for CRO management success. The inherent chaos in outsourcing “as needed” does not allow the organization to prepare its staff to effectively manage CROs because the organization does not know who will be called on to manage a CRO or when they will be called on to manage a CRO until it happens.

In addition to having a prepared staff, companies with a clear outsourcing strategy are also much more likely to have the right number of staff members at the right time. Without a plan, “as needed” outsourcers often end up with too many or too few staff members, both of which take their toll on the organization’s success. In the case of overstaffing, internal staff often end up duplicating efforts of CRO staff in an effort to “prove their value” to the company. Conversely, “as needed” outsourcers can also find themselves in a position where they do not have enough staff members available to even manage the CRO’s conduct of trial activities, much less conduct those trial activities themselves.

By putting an outsourcing strategy in place, an organization can avoid these issues and lay the groundwork for success. While every development organization is different, all organizations should address the following basic questions in their outsourcing strategy:



By answering these questions and establishing an outsourcing strategy, an organization is essentially laying the foundation on which all outsourcing management success rests; therefore, if an organization wants to control its performance by controlling the performance of its CROs, the first step is establishing an effective outsourcing strategy.

Support

The second step in Campbell's S³ Approach to Successful Outsourcing is establishing support. Support can take many forms, but for the purposes of this discussion, we will focus on the most common form of support—a purchasing or outsourcing group.

Many organizations have a purchasing or outsourcing group (support group) that focuses on the selection and negotiation of contracts with CROs and other outsourcers. While these groups can support outsourcing without an outsourcing strategy in place, in that scenario, the organization will never realize the group's full value. This is because without a strategy, support groups tend to focus almost exclusively on cost and time as their key measures for success. When an outsourcing strategy is in place, the goals of outsourcing and the approach are made explicit, and thus the support group can focus and measure its performance against the organization's strategic goals. This leads to better alignment between the study-level staff who manage the CROs and the support group assisting with their outsourcing efforts.

When these goals are aligned, the support group can bring tremendous value to the outsourcing management process by prequalifying vendors, negotiating vendor contracts, and tracking the metrics needed to determine whether the organization is meeting its outsourcing goals.

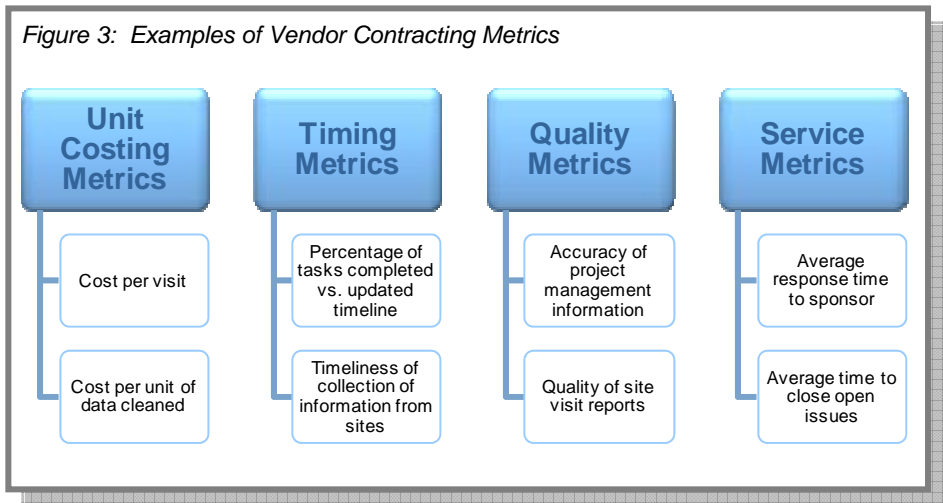
A support group's value-add starts with prequalifying vendors, which helps the study-level CRO manager by narrowing the list of potential CROs. When a CRO is prequalified, the manager knows that the vendor has the skills and personnel to meet the organization's needs, the vendor's reputation is supportive of its selection, and the vendor's terms are generally reasonable and likely to be acceptable. By eliminating organizations from the list that don't meet these basic criteria, the support group helps the study-level CRO manager focus his or her effort on the best possible options. For example, it keeps managers from taking the "I know someone" approach to vendor selection, which can often be driven by emotional considerations. It also reduces the risk that the organization will not be able to agree to terms with the vendor after investing time and resources in getting to contract negotiation.

Even in cases when vendors are not prequalified, a support group can aid in the selection of potential vendors because, unlike study-level staff who may select a vendor once or twice a year, the support group has much more marketplace experience. Furthermore, the support group members have access to the overall corporate vendor performance metrics, not just their own personal experiences. Similarly, the support group knows when others within the organization have used a particular vendor, allowing for valuable internal references.

Once a vendor is selected, the support group can help the study-level CRO manager by negotiating vendor contracts. The support group is better positioned for this task because it is familiar with industry-standard contract terms and service-level agreements around cost, timeline risk, quality, productivity, and sponsor-vendor relationship. The support group is also familiar with key metrics that must be gathered to support the organizational strategy as well as the study-level managers, as illustrated in Figure 3.

By leveraging the support group's knowledge and experience in negotiating CRO contracts, an organization can avoid the need to train all study-level managers on contract negotiation skills and avoid the potential strain

Figure 3: Examples of Vendor Contracting Metrics



on the working relationship between the study-level manager and the CRO should the contract discussions become heated.

Beyond study-level support for outsourcing, support groups should help the entire organizational outsourcing effort by tracking the organization-wide vendor performance metrics outlined in the organization's outsourcing strategy. These metrics should be centrally gathered and reported on at set intervals in order to allow the organization to track its effectiveness.

While there are several significant benefits to working with a support group, the group's customer service orientation can put those benefits at risk. Given their unique skill set and knowledge base, many support groups are experts in their area; however, it is ultimately the study-level manager who will be held accountable for the performance of the CRO. Therefore, the support group needs to treat the study-level manager as a key customer and work hard to meet their needs while providing them the benefit of their expertise and knowledge.

Some support groups view themselves in a driving instead of supporting role, and lose sight of their customer service responsibilities. This can be caused by a misalignment of goals between the support group and the study-level managers, bringing their objectives into conflict. This leads to frustration on the part of the study-level managers and can result in them working around the support group.

Study-Level Management

Even without a strategy and in the absence of a support organization, outsourcing success can still be achieved at the study level. While strategy and support are important to outsourcing success, study-level management—the third S in Campbell's S³ Approach to Successful Outsourcing—is vital to outsourcing success.

While study-level management is by far the most important aspect of successful outsourcing, it is typically the most difficult because it always involves a significant number of relationships and often involves multiple CROs. Having multiple CROs adds an extra layer of complication because it requires the coordination of multiple parties to create a collective result. In multiple-CRO environments, CROs that are not performing at expected levels often point a finger at other CROs as the reason. This requires the sponsor to become involved in resolving issues among CROs, in addition to resolving issues with each individual CRO.

Given the significant challenge of study-level management, two components must be in place to for success: the right skills and the right supporting tools.

Skills

At the highest level, study-level managers for outsourced studies must have both functional knowledge and managerial skills. Functional knowledge is usually the area in which most study-level managers excel, because they typically grew to their management position by successfully executing the activity (e.g., data management) that they're now managing. For example, someone on the sponsor side managing a CRO's data management services typically understands from their own experience how to measure data quality and track performance.

While functional knowledge is typically not an issue, management can be a challenge for the typical study-level manager. In their role, they need general management skills, as well as third-party management skills, which includes

- Project management
- Communication
- Management by objective
- Conflict resolution

To ensure that those being called on to manage CRO activities have these skills, a skills assessment should be conducted. If the study-level manager lacks the appropriate skills, just-in-time training should be arranged to develop the necessary skills. To help the study-level-manager put that training into action, the study-level manager should also be given a mentor with more CRO management experience who can coach them as they encounter issues.

Supporting Tools

Another means for supporting the study-level manager's CRO management success is to provide them with a structured CRO Management Toolkit, which contains the best-practice tools and processes that the organization has found to be effective in managing CROs. The CRO Management Toolkit provides study-level managers with everything they need to manage expectations on both sides of the vendor relationship.

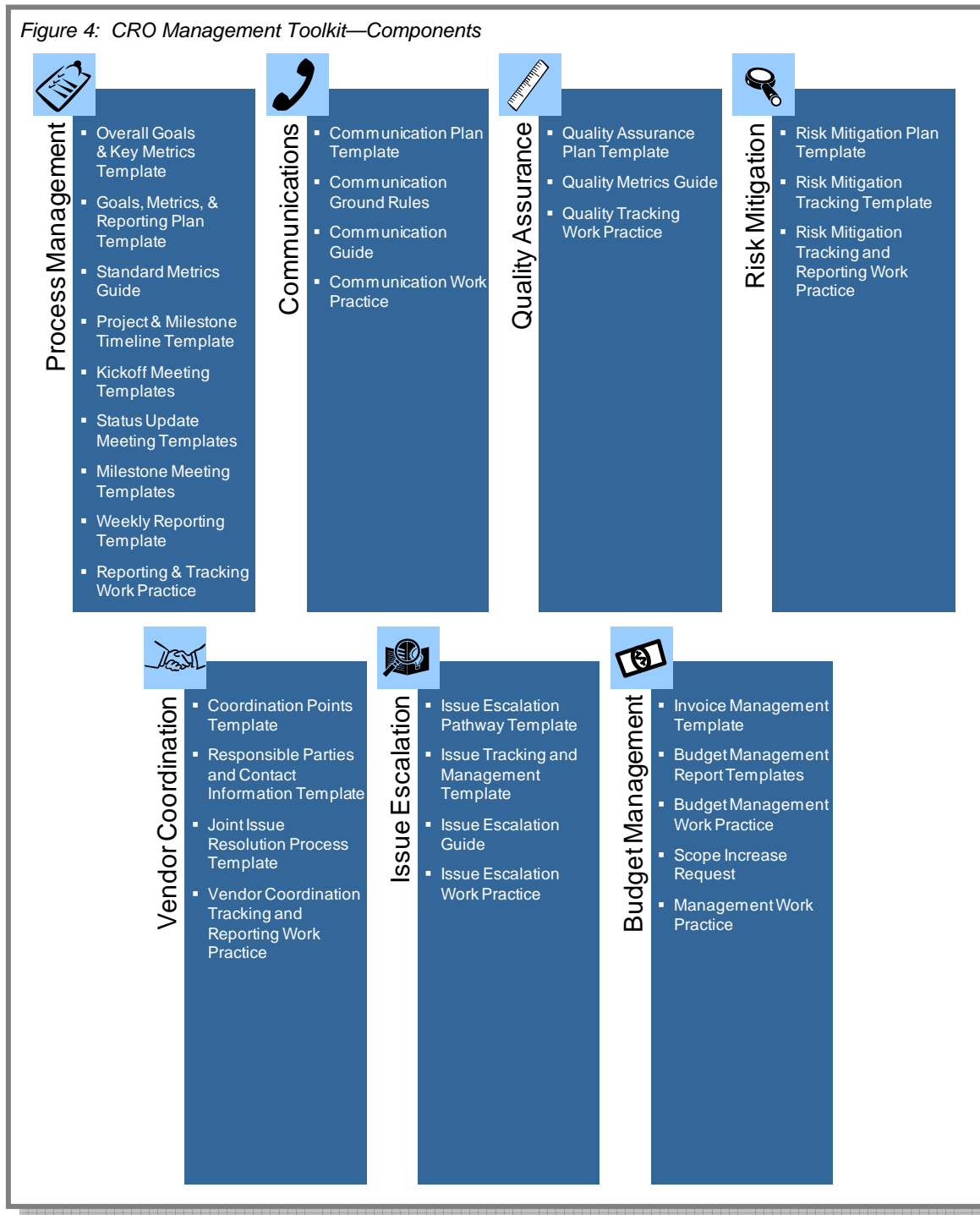
At the top level, the toolkit enables the study-level manager to define what excellence should look like from each CRO in terms of timeliness, quality, productivity, coordination with other vendors, and relationship with the sponsor. To support those definitions, the toolkit should enable the study-level manager and each CRO to agree on the following:

- Performance definitions and measures
- Reporting and tracking processes to be followed to track performance
- Communication approach to be used by the study-level manager and the CRO to ensure that progress and issues can be effectively communicated
- Risk mitigation approach to be applied by the study-level manager and the CRO to avoid common or likely risks
- Approach the various vendors will take to coordinate with each other, including an issue resolution process and assignment of responsibilities
- A sponsor-CRO issue tracking and resolution approach that outlines how study issues and CRO performance issues will be addressed
- Budget management process, including the invoicing process, the budgeting issue resolution process, and the scope extension process

To make all of these activities possible, the CRO Management Toolkit is broken into seven sections (see figure 4, next page). Each section of the Toolkit contains an explanation of how to use the tools and work practices where appropriate, as well as templates for the documents used to support the effort.

Having a CRO Toolkit in place benefits study-level managers, and in turn the organization, in many ways. In terms of efficiency, the toolkit is a huge timesaver

because it avoids the need to “reinvent the wheel” for every outsourced study in terms of tools and processes. The toolkit also sets clear and consistent expectations for both the study-level manager and senior management.



Because expectations and outputs are standardized by toolkit use, the toolkit also allows for coaching of newer study-level managers by those who are more