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The Outsourcing Balancing Act

Pre-Approval Inspection Readiness

Travelling Toward the Intersection of Drug Development and Delivery: Are we there yet?

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The Outsourcing Balancing Act

Achieving the best blend of oversight and involvement

I n recent years, more and more clients have become interested in the principle of outsourcing. Clients are moving beyond simply asking the "make versus build" or "outsource or not" questions. They are considering more specific alternatives, such as:

- What are the best models for their situation, such as "insourced" work with their internal staff, full-service outsourcing (FSO), functional service partnerships (FSP) or hybrid approaches;[1]
- Seeking preferred partnerships with a small number of vendors vs. spreading work across many vendors ("eggs in a basket");
- How to best manage communications and interactions between the client and various vendors; and
- The best approach to provide overall oversight.

Client leadership likes the idea of outsourcing to help better realize the full potential of their products and staff and to distribute risk by shifting certain tasks to vendors. The contract research organization (CRO) market is worth $29 billion and approximately 40% of clinical development currently is outsourced.[2] That number is expected to grow at a 7% CAGR to $40 billion by 2020, as pharmaceutical sponsors continue to invest in R&D and outsource a greater portion of that R&D to independent services providers.

THE OUTSOURCING CONUNDRUM

In practice, when a client is outsourcing for the first time, it is common for them to work in the manner they always have worked and use the outsourcing vendor in more of a staff augmentation capacity. This directed approach limits the value that can be gained from more established outsourcing and most notably can lead to additional cost for the client as there will likely be activities that are duplicated, such as oversight management. Sometimes, there can be a perception that the cost of managing an offshore contract is more expensive than an onshore contract.[3] This line of thinking highlights the challenge in balancing the client's regulatory requirement to "provide oversight."[4]

The following are five primary reasons why we believe some outsourcing relationships result in a duplication of effort and we offer some ideas to reduce the duplication.

1. The operational team hasn't completely bought into the bigger picture. Robust change management plans are essential when outsourcing. When drafting a change management plan for outsourcing the following are some important points to consider:

- Explain the reasons for the change;
- Define the scope and type of the change;
- List all stakeholders and define a plan for each stakeholder;
- Identify the change management team;

• Create a communication plan; and
• Execute on the agreed plan and manage any issues/roadblocks in a timely manner so as not to impact the deliverables.

Change management plans can deliver the vision of senior management e.g. such as how the CRO adds value by enabling experienced client staff to focus on more sensitive internal projects.

This was demonstrated at a recent large pharma company kickoff meeting to initiate a centralized submission model. The meeting was attended by representatives from various client functional groups, local client affiliate representatives and team members from the new outsourcing partners. As the meeting progressed it became evident the client had not fully explained its vision for outsourcing to all its internal stakeholders. As a result, those who endorsed the outsourcing approach were overshadowed by those who were concerned by the plan, which prevented their full engagement with the concept.

By ensuring that a robust change management plan is developed and activated to complement the overall project outsourcing plan, the CRO and the client senior management can ensure that initial resistance and lack of clarity on the outsourcing strategy can be reduced significantly.

2. As the "owner" of the product, the client ultimately is accountable to internal stakeholders. As a result, it may take the client team time to develop trust in an outsourcing partner and equally the CRO to trust the client. The process of building mutual trust can be accelerated by defining clear roles, responsibilities (Responsible, Accountable, Consulted and Informed - RACIs)[5] and realistic project plans that are then used to manage and monitor timely deliverables. PPD has planned and led teambuilding workshops as part of partnership kickoff meetings[1] to facilitate high engagement of cross-organizational teams. This has the benefit of creating an icebreaker opportunity outside of the main project scope, which makes it easier for team members to relate to one another.

There are numerous examples where building this mutual trust can accelerate the team's journey through the emotions of the change curve. Those emotions can be exacerbated by staff feeling threatened by outsourcing and becoming protective of their workloads, or by making the relocation of work and redistribution of tasks more arduous than may be necessary.

At times, these situations can lead to a "them vs. us" attitude. However, with collaborative discussion, robust change management plans and clear mapping of tasks with visibility of the overall project requirements, teams can overcome this period of anxiety and form more effective working relationships.

3. Reluctance to recognize the experience and expertise of the CRO team. The client team has an in-depth knowledge of its products, process and systems, while the outsourcing team initially does not have this same level of experience. In outsourcing partnerships, the learning curve of the CRO team needs to be accelerated to enable the CRO team to add the greatest value to the client team as quickly as possible. Robust implementation and training programs at the onset of a partnership and immediate access to client systems can significantly reduce this factor as the client team recognizes and acknowledges that the CRO team has undergone the same training as a new client team member. For instance, the CRO IT team needs to work closely with the client IT team to review what systems are common across the two organizations and how to connect for a partnership-level integration. This collaborative approach enables team members to work and share ideas together, which helps enhance trust and respect for each contributor. Alternatively, PPD has formed partnerships with several clients who invest in a "one-team" approach by generating new systems to share information and new processes that may be hybrids of existing processes or may be bespoke processes for specific partnerships. This approach minimizes any resistance based on experience, as both the client and the CRO teams are on the same process learning curve and are learning together.

4. Some client teams start with a preconceived perception that the CRO will not deliver the expected high-quality compliant outputs due to the savings that can be provided by the CRO. This may be due in part due to prior outsourcing experiences or to reluctance to change behaviors. CROs, by their very nature, operate under lean models and have removed inefficient working processes (e.g., double handling of data and reduction in touch points in communication pathways). These lean processes allow for delivery in less time and usually at a lower cost compared with the clients' long-established in-house processes.

Traditionally, CROs count every 15-minute period and the teams are aware of time and productivity metrics. CROs tend to know how long tasks take and how much they cost. For various reasons, the client team is not always as aware of timing and cost and can be hesitant to comment because this level of transparency is not always appreciated.

5. The use of specialized offshore hubs often gives cause for concern. This is mostly caused by a general lack of understanding of the culture of these offshore offices. There is sometimes a perception that these offices do not follow ICH guidelines or other globally accepted standards. This is not the case. For PPD, regardless of the location, all company staff are trained to the same standards and deliver to the same global levels of quality defined.

Change is difficult. For some clients, adapting to changes in systems/process and team structure is a major hurdle. They have been doing their work in a specific way for many years and suddenly not only is the work outsourced, but the client team is asked to take a different approach. CROs are experts in setting up partnerships and are constantly working with different clients, so they are accustomed to dealing with change and can support the client through this change.

Teams that have been involved in mergers and acquisitions that see changes in headcount and structure are especially sensitive to changes in job responsibilities, which can lead to feelings of insecurity[6] and mistrust. Based on the authors' experience, the understanding and acceptance of the various emotions of the change curve are extremely important. Each of the client team members will have a different rate at which they transition through the change curve. When this is acknowledged by the project manager and included in the overall project plans, proj-

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ects tend to get to a steady state much more quickly than those that do not acknowledge the change curve emotions.

What are the implications of duplication of efforts related to oversight? The authors would like to suggest the following as the main impacts:

• Reductions in the potential for effective communication and process efficiencies;
• Increases in the client workload rather than reducing it;
• Increases in the potential for errors due to lack of transparency in roles and responsibilities (i.e., who does what and when); and
• Demotivation of team members, both with the client and the CRO.

COMMUNICATION AND PROCESS EFFICIENCIES
As mentioned previously, one of the key benefits of an FSP is the opportunity to closely evaluate the processes required for the partnership. This evaluation is carried out jointly with the client and the FSP teams and utilizes Lean Six Sigma principles with Lean Six Sigma practitioners.

Based on our experience, partnership manuals developed solely for that partnership enable the teams to develop new processes or re-engineer existing processes to ensure that roles and responsibilities are clearly defined and agreed to by all team stakeholders.[7] We have observed that one of the largest contributors to unsuccessful projects is the lack of clarity around who does what and when.

The use of process maps, in addition to SOPs, can aid in providing the level of transparency and clarity necessary to ensuring success by providing clear accountability and ownership and, at the same time, ensuring a lean process with no double handing or duplicate steps. The process maps also clearly demonstrate the sequence of tasks and those that can be carried out concurrently and those that can only be handled sequentially.

If the partnership experiences duplicate oversight, this Lean Six Sigma process becomes redundant, thereby increasing the workload rather than reducing it.

The team relationship/spirit can become compromised if the client team becomes frustrated due to its "apparent" additional workload, despite senior management saying that the outsourcing will "save them time." The CRO team members can become frustrated because they feel they are undervalued, resulting in reduced satisfaction and demotivation.

The "one-team" approach developed by using Lean Six Sigma can unite the team from the very early stages of the transition, ultimately developing a strong robust foundation for the partnership. The combined frustration of the client and CRO may lead to poor communication styles, misinterpretations and an abundance of long, unnecessary emails, which can result in a "blame" culture.

CONCLUSION
Whether you want to reduce the number of CRO partners or enable your internal resources to focus on more strategic aspects rather than less complex operational tasks, there are tools that can be put in place to ensure that your outsourcing strategy is optimized and is fit for purpose.

When deciding on an outsourcing strategy the client's procurement, operations and senior management teams all should be engaged so they have a stake in the partnership and can buy into same strategy.

The "one-team" approach—which includes implementation plans, change management plans, communication pathways, reviews/generation partnership processes and governance procedures in the request for proposal (RFP)—is one way to ensure internal client resources will have the confidence to release tasks to the vendor.

By including those recommended items in the RFP, you will be establishing a level of transparency that will reduce the potential for micromanagement while facilitating appropriate oversight, delegation and delivery, which will result in a happy, motivated and productive outsourcing partnership.

In addition, the use of a service level agreement (SLA) and agreed partnership metrics can ensure delivery in an efficient and effective manner. These metrics provide an excellent baseline for continuous improvement, which will be seen in terms of enhanced efficiency, quality and delivery. In the end, as stated at the start of this article, the goal is to reduce duplication and redundancy by the client team so they can focus more of their time and energy on internal projects and reducing their costs, two of the key reasons for outsourcing. **CP**

For a full list of references please visit the online version of this article at ContractPharma.com

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