New, Strategic Outsourcing Models to Meet Changing Clinical Development Needs

Dr Janet Jones and Michael Minor

Abstract

The impact of increasing clinical costs and the need for more data to support higher efficacy demands and overcome regulatory hurdles for market entry means that every Company is faced with the challenge of how to do more with a smaller budget. As budgets get squeezed the pharmaceutical Industry has been looking at how to contain or reduce cost and support an increased number of projects. With the growing sophistication of outsourcing, this is an increasingly important area of focus. Some Pharmaceutical Companies have moved from tactical, case by case, outsourcing to new, more strategic relationships, which involve outsourcing functions that were historically held as core pharmaceutical functions. An increasing number of Sponsors are looking at strategic relationships which are based on more creative outsourcing approaches. As the need and sophistication of these outsourcing models and the sponsors / CROs involved in them, these approaches are becoming more transformational and need to be based on a strong partnership. Lessons learned from working with sponsors in a partnership model have been examined and two key challenges addressed in detail: the need for bilateral central control though a strong governance model and the importance of early planning and commitment.

Key words: CRO / sponsor partnerships, outsourcing, governance, feasibility

INTRODUCTION

Relentless scrutiny on the cost of new medicines and the larger body of evidence needed to clear new regulatory hurdles for market entry make the return on investment required to develop new health care products a case of diminishing returns. Pharmaceutical companies are responding with a variety of strategies to expand pipeline and improve efficiency of development.

Over the last 10 years, Pharmaceutical companies have been getting larger through peer acquisition and by augmenting their pipeline by in-licensing compounds. Recent examples including Merck-Schering Plough, Roche-Genentech and Pfizer-Wyeth show that the size of mergers has also increased. The resultant corporate mass and complexity of these mega companies adds to organizational inertia which in turn inhibits the ability to rapidly bring new compounds to market and compete effectively.

In an attempt to become more nimble and reduce both mass and fixed costs associated with large headcounts, many of these companies have already, or will soon downsize internal staff levels and turn to outsourcing to keep product development moving forward. This presents new challenges as headcount reductions lead to concurrent departure of internal experience and loss of operational surge capacity.

Outsourcing has traditionally been used as a tactical measure to relieve capacity deficits and gain access to research experience. The typical focus has been on cost and quality in single outsourced projects. Many companies have made significant investments to identify outsourcing models

Dr Janet Jones, *PhD, Senior Director Project Information & Feasibility, ICON Clinical Research, Europe*

Michael Minor, *VP Proposals & Business Intelligence, ICON Clinical Research, US*

which reproducibly provide high quality deliverables at an acceptable price.

Now, newer strategic outsourcing initiatives are being instituted to totally replace functions historically held as core corporate functions, as summarized in Figure 1. This type of transformational approach represents a major philosophical shift which yields operational models totally dependent of external resources. It also provides new challenges in relationship management because, unlike tactical outsourcing, you are "married" to your partner with little prospect for changing vendors mid-stream or for taking the programs back in-house.

The following industry and situational analysis evaluates the strengths and potential application of a variety of outsourcing tactics and strategies used to effectively augment research support. Also included are considerations for governance models to promote communication and issue resolution where the strategy is to invoke transformational change and replace internal capability with external expertise and capacity. In the end, a company strategy may be to adopt multiple tactics to reduce cost per unit delivered with the prospect of long term sustainable financial and process improvements.

Industry and situational analysis of strategic partnerships

The greatest cost effectiveness and benefits come with a predictable, integrated and complete approach to outsourcing. There are several examples of reported measurable process and/or cost improvement from the deployment of the Functional Service Provider model (see Figure 1), which include 25% reduction in contract and IRB approval cycle times, decreased rejection rates for regulatory packet approval from 42% to 5%, and Data Management cost saving of 15% per page with a concurrent 20% improvement

Figure1. Trends in clinical development outsourcing, showing the wide variety of engagement models currently deployed.

Tactical outsourcing - contracting of work on a transactional basis, usually on an as needed or case-by-case basis.

- Rapid deployment, to meet immediate outsourcing needs
- No pre-qualification of vendor pools required
- Study by study placement, not strategic or transformational
- Limited opportunity to gain efficiencies or to recover effort spent in setting up sponsor / vendor relationship

Preferred provider relationship – development of a stronger partnership with a selected set of CROs to outsource a number of studies based on competencies, therapeutic match, geographic reach, specialized services.

- Some reduction in internal vendor management time with some economies in total spend
- Improved process cycle times
- This approach is best suited where Sponsors outsource frequently and already have a large pool of pre-qualified CROs.
- These engagements typically have a defined life span
- Limited long term focus on improvement consistency in cost and overall quality of deliverables.
- Relationships take more time to develop and maintain but the return on investment for both parties is sufficient for both sides to value the continued participation.

The Functional Service Provider relationship this is a company wide approach in which a whole service area is outsourced, such as data management, clinical monitoring, investigator payments, etc.

- Readily applied to any repetitive task in which process, knowledge and expertise are required. Retraining is not required when the next project is to be outsourced
- Improved operational function and efficiencies in set up with the repeated used of the same vendor.
- Reduce process cycle time and costs with some gain in efficiency.
- Sponsor resource still required to oversee the process and to manage the interaction of multiple service streams
- Eliminating redundant internal departments and improved vendor quality, shortened process timelines will reduce unit costs.

Business Process Outsourcing involves outsourcing the operations and responsibilities for a specific business function to a service provider.

- The outsourcing partner may completely eliminate an internal process.
- Best suited for services with a defined process for the delivery of services including those services which are heavily IT dependent.
- This can lead to the elimination of a redundant internal function
- Reduces costs for non-core processes to support business functions.

Full development outsourcing. In this case the CRO becomes an extension of the Sponsor in the execution of the whole molecule or specified parts of the clinical development plan.

- Pre-selection of a limited number of partner CROs. Time and effort required to set up the relationship for both the Sponsor and Partner CRO.
- Therapeutic aligned allowing the Sponsor to selects CRO partners based on their ability to completely support global, full-service programs in relevant therapeutic areas
- Sponsor has access to the CROs cross Industry therapeutic operational experience
- Fixed price contract with shared risk and reward. Requires bilateral trust and transparency and commitment to share early planning.
- Strong governance and management support is essential to success.
- Best opportunity to improve productivity and cost effectiveness.
- Provides for capacity, flexibility and responsiveness to a growing portfolio.

in productivity per FTE (Full Time Equivalent). In some case these improvements have allowed Sponsors to move process off the critical path for study execution.

Companies are also using the Functional Service Provider relationships as transformational vehicles where functions or departmental activities are completely externalized. There are several published examples such as Wyeth / Accenture for data management, Pfizer/ ICON for start up and Investigator contracting and Lilly / ICON for monitoring services in Europe. In each of these examples the sponsor reduced fixed costs related to supporting internal headcount, improved cost basis per unit of work and secured staff trained and dedicated to the sponsor process.

Sponsors are increasingly moving towards more strategic

clinical development partnerships and are selecting therapeutically aligned partner CROs to participate in all phases of program execution for the assigned therapeutic areas, including study design. These are typically non-competitive assignments that give Sponsors access to the CRO's therapeutic and operational expertise. In this model the CRO functions as an extension of the produce development and is fully integrated with the internal client teams: providing the Sponsor with exposure to different operational modeling.

Outsourcing costs are typically evaluated solely on the vendor budget for the work to be performed. In reality, the total expense of managing a project (internal and external) should be considered. Some outsourcing tactics have much leaner footprints within the Sponsor making the models collectively much more efficient than others to deploy. Evaluating the internal matrix for support is essential to identifying which models may offer bigger returns than simply managing to lower vendor unit costs. Cost should also be considered for other business processes such as contracting and finance support in the evaluation of the total support matrix expense.

Moving towards full development outsourcing

The extent to which sponsor project teams are engaged and the details of how the full development outsourcing model is set up will from sponsor to sponsor. However, the core of the full development model is to create a strong and fully integrated partnership, with collective decision making to ensure that the strategies, tools, and resources deployed are the best match for the specific program. Full development outsourcing has demonstrated some of the best reported returns in improving the productivity of outsourcing. Some of the characteristics that drive efficiency are:

- Outsourcing becomes more predictable. Projects are awarded in a non-competitive manner using pre-negotiated rates, costing algorithms and contracts giving transparency in the costing process with agreement on the design and costing modifications to ensure that end value is cost effective and acceptable to both partners
- Therapeutically aligned CROs bring experience and a full complement of resources and apply cross industry knowledge to create efficient operational models and study design and the Sponsor benefits from the capabilities and integrated reporting and systems in the CRO that are already designed to be as efficient as possible.
- The CRO is actively engaged in the study design process and takes full responsibility for delivery. The commitment to delivery is and, it is well suited to a fixed price approach
- More cost effective operational practice as established by developing new, shared, more efficient processes based on creating best in class processes.
- The relationship is based on the principles of shared risk / reward. It is performance based, with clearly visible indicators of performance to give long term savings to the sponsor and profit and growth for the CRO.
- Costs for repeated CRO selection and contracting are greatly reduced and familiarity with operational processes

and interfaces involved in creating deliverable improves quality and cycle times

AstraZeneca has reported (European Pharmaceutical Contractor (EPC), "Powering Up for the Challenge", Autumn 2008) positive effects of this model, created by the ability to reduce management and oversight of the CRO. They report one-year productivity gains, as measured by outsourced study per FTE, has improved 98% with even better news observed at the 1.5-year mark of 180%. These exceed the target of 50% at one year and the stretched target of 100% at 1.5 years

To be successful the CRO needs to be a true extension of the Sponsor, to be engaged in the clinical development plan and operational delivery with a clear delineation of responsibilities that uses the skills of both parties to greatest effect. This requires a change in mindset within both organizations because the premise is that best-in-class development strategies leading to material efficiency gains must be developed

Strategic partnership lessons learned

There are always challenges to deploying new models and some may become evident before deployment while others may emerge as the combined teams learn to work together building a collaborative team dynamic. Advanced planning, at both the partnership and program level, is critical to the success of the program and to avoiding some of the challenges

- Partnership brings more responsibility and accountability to the CRO, which needs to be embraced by the CRO. It is essential to set clear expectations on these responsibilities.
- Experienced management in both the Sponsor and CRO is essential, with a well established communication path and mechanism to ensure that knowledge management is transferred
- Open and frequent communication and new communication pathways, with a constructive feedback loop and progressive lessons learned.
- Centralized control and communication is essential to ensure that different teams are aware of the strategies, results and lessons learned across the spectrum of activities.
- People will have uncertainties about function and role in the new setting and must be expected to demonstrate inertia in accepting a new model.
- This model requires advance planning and discipline to be effective. If discipline is lacking it will result in reversion to past practices as an expedient means to an end.
- There will be new ways of working, which all parties must embrace with a flexible approach
- Visibility to both parties of shared key performance indicators and open communication about performance.
- Change in mindset - Collaborative decision making is not the typical sponsor mindset and CRO staff may also have difficulty in moving up to a partner level status. It is important to co-promote leadership roles

A strong governance model and advanced planning and

are critical to the success of the program and to avoiding some of the challenges. A robust approach to feasibility and early planning is a critical step in defining the program in fixed price / outcome based contracts. In these models, the CRO accepts accountability to deliver to the agreed timelines and budget. The feasibility and planning process must include be a very robust assessment of the protocol, development environment and projected site performance using historic performance metrics as well as a detailed study assessment to define the study deliverables. It is important that this process starts early in protocol development and that the CRO is committed to the objectives of the protocol and clinical development plan.

Governance model

A deeper interdependency between Sponsor and CRO results from repeated outsourcing engagements - to the point where the investment in operational and business process improvement and resultant improved financial performance for both parties should be protected. This has driven more companies to institute Governance Boards in recognition that long-lasting business relationships require multiple cornerstones on which to build a foundation of mutual trust and respect. These are typically multi-tiered, bilateral structures that include key representation from both companies.

The Governance Board is usually headed by an Executive Oversight Committee (EOC). This requires dedicated senior delegates from both partners serving as co-chairs to be effective. It must be active and meet at regular intervals to establish open dialog and trust. The frequency of the EOC will be dependent upon the maturity of the relationship, but regularity and consistency in attendance is essential. Building trust is important if frank talk is necessary due to a material change in company direction or performance by either party. This is also the level where companies commit to each other and is essential for sharing forward-looking planning on pipeline and clinical development strategies. This level of participation is absolutely essential if transformational change is to be effected in the Sponsor Company.

The next level is an Operational Management Team (OMT) which is also a senior-level interface involving representatives of all services at the CRO supporting the client. The OMT level is where definition of the relationship takes its functional form. The CRO participants at this level are typically Operations Director or VP level and are usually line managers for Project Manager or Project Director who is responsible for the delivery of program deliverables within the CRO. They are usually also subject matter experts so that discussions about technical alignment can take place here.

This committee is essential to program development, deployment and management. It establishes program operational strategies for the execution of clinical development plans, ensures the provision of quality and consistency, assigns ownership and accountability to project goals and tasks, resolves challenges quickly and oversees the establishment of realistic goals to meet study timelines, as well as reviews study progress. Discussions also occur here for overarching progress reporting, deployment of transparent reporting tools such as project portals, status reports and measurement of KPIs as well as other mechanisms to ensure both parties are cognizant and informed of operational level challenges, both upwardly to the EOC and downwardly into the projects.

The last level down is a project level interface where the day-to-day project planning and reporting takes place. This becomes the functional level where planning documents and deliverables are completed and exchanged. This is also the level at which program efficiencies are identified and actioned. Constituents at this level are typically Project Managers or Directors and they meet as defined in communication planning or as required by the changing dynamics of the projects they are running.

A business-to-business level is sometimes included where representatives from Outsourcing, Account Management, Contracts and Finance can meet. This group ensures that the business obligations of the partnership keep pace with the changing dynamics of the clinical development plans with regard to Master Service Agreement maintenance, work order preparation, invoicing and payments.

Overall, this model fosters upward and downward channels for communication, lateral alignment checks within organizations for multifaceted support services, visibility across CRO Divisions, and offers multiple portals for issue escalation which is important in maintaining a stable long-term relationship. Collectively, the governance body structure makes for a robust platform to conduct outsourced clinical programs.

Conclusions

There is a development continuum of outsourcing models that transcend from tactical outsourcing through to a fully integrated partnership. The details of the partnership model will differ dependent on the specific sponsor / CRO alignment and needs. These models offer a new way of working that streamline intercompany management, produced a centralized transparent approach to development and align resources to produce a harmonized partnership working to give best in class drug development. In all cases the intention is to improve the efficiency of outsourcing so that internal headcount may be used to presume more value added activity, using the operational cross industry experience and effectiveness of the CRO to support the intellectual and brand management experience of the sponsor.

The intent of outsourcing work is to improve efficiency of product development so that internal headcount may be used to pursue more value added activity. So long as the CRO industry can continue to deliver dependable, quality service at a competitive cost we can expect to see increased reliance on CROs to support clinical development. Strategic outsourcing engagements may be expected to overtake tactical engagements in Sponsor companies looking to make transformational change.

References

1. European Pharmaceutical Contractor (EPC), "Powering Up for the Challenge", Autumn 2008.