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Unpacking CRO Outsourcing

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Harnessing Innovation and Added Value in Pharma CRO Outsourcing

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EXECUTIVE SUMMARY

There is perhaps no industry more greatly challenged by today's volatile and fast paced economic environment than that of the Pharmaceutical industry. Money is tighter, government regulation is expanding, profits are diminishing. And yet, pharmaceutical companies are expected to produce new breakthrough medicines on faster timelines than ever before.

There was a time when the Pharmaceutical industry experienced relative ease of big profits. A 2001 Corporate Watch article claimed some Pharmaceutical companies enjoyed profit margins of 70 – 80%.[1] Reasons included lack of price elasticity (if there is only one drug that can help, a patient will buy that drug no matter the price), and limited competition (because of patent control.) In 2006, more than 90% of Pharmaceutical revenues came from medicines that had been on the market for more than five years.

But fast forward. Today the environment is much different. Pharmaceutical companies are facing the patent cliff with key patents of many important medicines drawing to their end. As the expirations occur, large pockets of revenue do as well. Competing Pharmaceutical companies can legally create generics and the monopolies cease to exist. Industry experts proclaim, "The good times with more or less guaranteed high margins are over."[2]

Pharmaceutical companies are fighting these pressures in various ways. This white paper – sponsored by Roche - provides a deep dive into CRO outsourcing key strategies. Pharmaceutical organizations have increasingly turned to outsourcing – as a way to increase speed to market and reduce costs of drug development. The goal of this white paper is to study the applicability of using a Vested Sourcing Business Model for CRO. The Vested® model – developed by University of Tennessee research - provides a methodology for organizations to create highly collaborative win-win relational contracts purposely built to drive innovation and outcome-based results.

The report is divided into the following five parts:

- **Part 1** provides a brief **introduction** and outlines the research methodology we took in developing this white paper.
- **Part 2** highlights a **structured framework for understanding Sourcing Business Models** as well as provides insights into the changing landscape of strategic outsourcing.
- **Part 3** provides insights into the **evolution of partnering models in life sciences** and highlights current trends within the CRO outsourcing environment.
- **Part 4** offers **observations about CRO practices** and opinion regarding the limitations of a transactional Sourcing Business Model.
- **Part 5** explores the **viability of using a Vested Sourcing Business Model** for CRO outsourcing.

We conclude the white paper by providing a short summary and call to action.

PART 1: INTRODUCTION AND RESEARCH METHODOLOGY

Many Pharmaceutical organizations are turning to creative approaches to create a competitive advantage. One of these is ***Contract Research Outsourcing (CRO).*** CRO is a key strategy that pharmaceutical companies use to speed innovation of new drugs is outsourcing clinical research to CROs. During the last decade, many companies found advantage in moving from a vertical and fixed operational model with in-house professionals dedicated to clinical studies to an outsourcing model that involves both internal and external services. Gradually, outsourcing became the norm and Contract Research Organizations (CROs) now perform the majority of clinical research activity.

But are pharmaceutical companies approaching CRO outsourcing optimally? A *Quintiles* Insight Brief explains, "Many sponsor/CRO interactions involve inefficiencies caused by unnecessary duplication or task sharing. In this case, the sponsor remains focused on managing studies and there is task and role ambiguity, leading to confusion, frustration and inefficiencies through redundancy. A better situation would be a more streamlined partnership, with joint responsibilities and interactions reserved for a small number of critical tasks. Here, the sponsor concentrates on managing its partners; there is task and role clarity – which fosters trust and innovation – and enhanced efficiencies and deliverables.[3]

The question becomes "Can you have both – reduced costs ***and*** innovation?" This white paper seeks to answer this question by exploring the viability of a Vested Sourcing Business Model for CRO outsourcing. This is a question Roche procurement executives had when sponsoring this white paper.

RESEARCH METHODOLOGY

The University of Tennessee research team first turned to secondary research to get grounded on pharmaceutical outsourcing. The team explored trends in CRO as well as identified publicly available information that points to how companies are approaching CRO outsourcing. The second part involved interviews with leaders involved in CRO sourcing – both from pharmaceutical suppliers and from CROs. The list of interviews presented a good mix across of various disciplines responsible for CRO outsourcing, including clinical practitioners, procurement, supplier relationship managers, and CRO service providers. The objective was to provide a glimpse of the variety of experiences found throughout the pharmaceutical world.

With an understanding of CRO in general, the research team then turned to comparing the specific CRO environments with learnings from over 14 years of ongoing research into outsourcing. The result is contained in this white paper.

The findings – outside of the quotes and cited articles - are expressed solely as opinions of the University of Tennessee researchers.

PART 2. UNDERSTANDING SOURCING BUSINESS MODELS

Part 2 of this white paper provides insights into the changing landscape of strategic outsourcing. We also introduce the University of Tennessee's research into a continuum of seven Sourcing Business Models that provides a structured framework for understanding how pharmaceutical companies can create more value with supplier relationships.

THE CATCH-22 OF CONVENTIONAL OUTSOURCING MODELS

For decades, organizations have thought of procurement as a "make vs. buy" decision when approaching outsourcing initiatives. Many falsely assume if they "buy," they should use competitive "market" forces to ensure they get the best deal. This is especially true in organizations where procurement professionals are measured and earn their bonuses for achieving year-over-year cost savings. As organizations seek to get the best price within the market, the default approach is to use a transaction-based model where the buying organization can "test the market" by easily comparing prices across transactions (e.g. price per hour, per widget, per mile, per kilogram, etc.).[*] This works well for simple transactions with abundant supply options and low complexity where the "market" self-corrects with competition. After all, if a supplier does not perform there is minimal risk and cost to rebid the work and switch out suppliers.

A Catch-22 emerges when an organization wants to drive innovation and create a unique competitive advantage - yet it decides to use the "market" to buy a particular good or service.[4] For starters, suppliers develop innovation based on generic market trends rather than unique needs that could create a competitive advantage for the buyer's organization. Likewise, organizations miss opportunities by not initiating more strategic and transparent discussions with their suppliers. The result is a lack of a common definition about how client-specific investments and innovations can create value for both the buyer's organization and the supplier's. Buyers then find that their suppliers meet contractual obligations and service levels but do not drive innovations and efficiencies at the pace the buyers desire.

The reluctance of suppliers to volunteer ideas is particularly vexing to pharmaceutical companies in regard to their clinical suppliers that work across a spectrum of buyers and situations. Logically, the supplier has experience and knowledge that could benefit the studies they are conducting for the buyer. Unfortunately, pharmaceutical companies frequently engage in both internal and external protocols that effectively "lock out" new ideas.

For example, procurement professionals are taught to use "leverage" and "exploit" techniques to help them increase their buying power. They are encouraged to have uniformly available goods and services where a buyer can easily compare "apples to apples" and avoid potential supplier protests due to subjectivity in the supplier selection process. In some cases, procurement policies are even written in such a way that buyer/supplier communication about potential innovative solutions is limited.

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[*] *It might be suggested the pharmaceutical industry uses "time" in the same way other industries use "cost" to make choices about supplier awards.*

To make matters worse, it is not uncommon that procurement professionals are measured on (and often incentivized on!) driving cost reductions through a Purchase Price Variance metric.[5] This drives short-term emphasis on "price" paid versus overall value or a focus on reducing total ownership costs. To top it off, far too many lawyers hunker down with the single-minded goal of shifting risk and emphasizing shorter term contracts to limit supplier dependency.

These practices are magnified when combined with a conventional transactional Sourcing Business Model where a supplier is paid for every activity. The more hours, the more units, the more researchers, or lines of code written—the more revenue and profit for a supplier. Frustrated buyers find their suppliers meet contractual obligations and service levels, but they do not drive innovations and efficiencies at the pace the organization wishes. Suppliers argue that investing in their customer's business is risky because buyers will simply take their ideas and competitively bid the work. Or, at an even more basic level, the contract offers no reward to the supplier offering innovative ideas. In fact, there is often a dis-incentive because finding efficiencies can lose revenue. Consider the following:

- A reduction in research hours, for example, translates to a loss in revenue. If a contract specifies and pays for 10 researchers and the supplier finds it can do the job with only 8, chances are excellent there will be the full contingent of 10 – the supplier does not share in efficiency gains.
- A CRO is inherently incentivized to continue working on a project despite signs of failure. After all, the CRO continues to be paid – there is no upside to reporting the faulty nature.

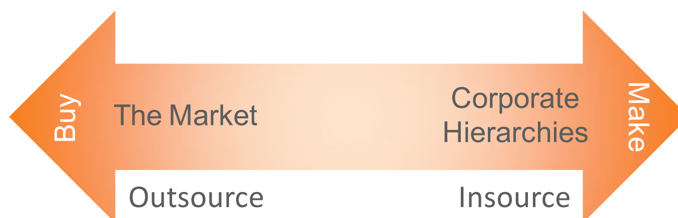
In short, a transactional model pits buyer against supplier with conflicting goals. On the one hand, organizations want suppliers to close gaps when they lack core competency. They desire suppliers to be innovative and provide solutions. Yet, on the other hand, they drive competition and commoditization, which prevents suppliers from wanting to invest in innovation. The result is that the industry is at a crossroads, with both buyers and suppliers wanting innovation — but neither wanting to make the necessary investments.

THE CHANGING LANDSCAPE OF STRATEGIC SOURCING

Dr. Oliver E. Williamson – professor of economics at the University of California, Berkeley – challenged the traditional view of sourcing with his work in Transaction Cost Economics. Williamson received the Nobel Prize for his work in 2009. One of Williamson's key lessons that organizations should view sourcing as a continuum rather than a simple market based make-or-buy decision.

Perhaps the best way to think of Williamson's work is to consider (Figure 1 below) free-market forces on one side and what Williamson refers to as "corporate hierarchies" on the other. In the middle, Williamson advocated that organizations should use a "hybrid" approach for complex contracts.

Figure 1: A Continuum of Outsourcing Solutions



Although both a market and hierarchical approach offer advantages, both have clear disadvantages as well. Williamson has shown that the market doesn't always work as efficiently as theory leads one to believe.[6]

The University of Tennessee has been researching what Dr. Williamsons' refers to as "hybrid" models for over a decade. The result of the research has led to the codification of seven Sourcing Business Models along Williamson's continuum – three of which are classified as "hybrid" models. It also resulted in developing a comprehensive methodology for one of the most progressive Sourcing Business Models – what UT researchers have coined as Vested. The research has produced six books and dozens of white papers and case studies showing the power of shifting along the continuum to more strategic relationships – especially Vested relationships.

SEVEN SOURCING BUSINESS MODELS

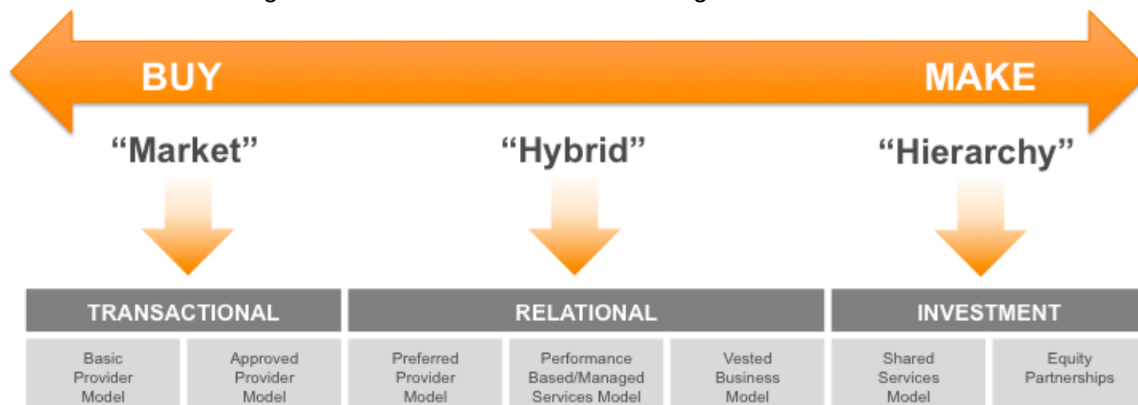
Research by the International Association for Contract and Commercial Management (IACCM) shows that most organizations operate under conventional transaction-based models that are constrained by a formal, legally oriented, risk-averse, and liability-based culture.[7] There is growing awareness that transactional-based approaches do not always give each party the intended results.[8]

We outline seven Sourcing Business Models (featured in detail in the book Strategic Sourcing in the New Economy: Harnessing the Potential of Sourcing Business Models in Modern Procurement[9]) that fall into the three categories along Oliver Williamson's sourcing continuum.

- Transactional (Williamson's "Market" category)
    1. Basic Provider Model
    2. Approved Provider Model
- Relational (Williamson's "Hybrid" category)
    3. Preferred Provider Model
    4. Performance-Based/Managed Services Model
    5. Vested Business Model
- Investment (Williamson's "Hierarchy" category)
    6. Shared Services Model
    7. Equity Partnership Model (e.g. joint ventures, subsidiaries)

The models differ from a risk/reward perspective and should be evaluated in the context of what is being procured. The characteristics and attributes for each of these approaches are reviewed in detail below. Figure 2 (following page) shows how the Sourcing Business Models fall along the sourcing continuum.

Figure 2: The Continuum of 7 Sourcing Business Models



1. TRANSATIONAL: *BASIC PROVIDER MODEL*

A basic provider model is transaction-based. It typically has a set price for individual products and services for which there are a wide range of standard market options. Typically these products or services are readily available, with little differentiation in what is offered.

A basic provider model is used to buy low-cost, standardized goods and services in a market where there are many suppliers and switching suppliers has little or no impact on the business. Buyers typically use frequent competitive bidding (often with pre-established electronic auction calendar events). Often a purchase requisition triggers transactions that signal that the buying company agrees to buy preset quantities of goods or tasks (e.g., widgets or hours). Some organizations even use purchase cards for these types of simple purchases.

The buyer–supplier relationship is based largely on a review of performance against basic criteria. For example, did the supplier work the hours claimed? Did the goods received meet the agreed to quantity, cost and delivery times?

2. TRANSACTIONAL: *APPROVED PROVIDER MODEL*

An approved provider model also uses a transaction-based approach. However, goods and services are purchased from prequalified suppliers that meet certain performance or other selection criteria. Frequently an organization has a limited number of preapproved suppliers for various spend categories from which buyers or business units can choose. Multiple suppliers mean costs are competitive, and one firm can easily be replaced with another if the supplier fails to meet performance standards.

Procurement professionals often turn to approved providers as regularly solicited sources of supply when bidding is conducted. An approved provider may or may not operate under a Master Agreement, which is an overarching contract with the buying organization. Approved providers

may or may not also have volume thresholds to be in an "approved" status. In addition, approved providers may or may not participate in supplier management reviews.

In order to create a seamless and readily accessible supply chain, many organizations develop lists of approved providers. The advantages are many. For example, a preapproved list saves time when seeking particular goods and services. The approval process ensures parity between bidding qualified suppliers. As an organization selects its approved provider list, it molds the required qualifications to its unique business objectives and strategy.

3. RELATIONAL: *PREFERRED PROVIDER MODEL*

Like the basic and approved provider models, a preferred provider model uses a transaction-based economic model. A key difference between a preferred provider and the other transaction-based models is that the buyer has made the choice to move to a supplier relationship where there is an opportunity for the supplier to add differentiated incremental value to the buyer's business to meet strategic objectives. This insertion of the supplier's contribution into the buyer's business processes creates the need for a ***relational contracting model.*** Thus contracts with specifically chosen supplier(s) by design should assume a more collaborative relationship. Repeat business and longer-term and/or renewable contracts are the norm.

Similar to an approved provider model, buyers seek to do business with preferred providers to streamline their buying processes. Buying organizations typically enter into multi-year contracts using Master Agreements that allow them to conduct repeat business efficiently. It is important to note that preferred providers are still engaged in transaction-based economic models. However, the nature and efficiencies of how the organizations work together go beyond a simple purchase order and consider how a supplier can provide value-added services.

Often preferred providers agree to put value-added solutions in place for buyers. Value added solutions can take many forms. As an example, medical clinics in the United States often use either Labcore or Quest Diagnostics to perform lab tests. Labcore provides value added services by setting up on-site resource in doctors' offices—a significant value add.

4. RELATIONAL: *PERFORMANCE-BASED/MANAGED SERVICES MODEL*

A performance-based (also sometimes referred to as a managed services model) is generally a formal, longer-term supplier agreement that combines a ***relational contracting model with an output-based economic model***. A performance-based model seeks to drive supplier accountability for output-based service-level agreements (SLAs) and/or cost reduction targets. A performance-based agreement typically creates incentives (or penalties) for hitting (or missing) performance targets.

Sourcing decisions are based not only on a supplier's ability to provide a good or service at a competitive cost, but also on its ability to drive improvements based on its core competencies. Performance-based agreements shift thinking away from activities to predefined outputs or events measured by SLAs.. Performance-based agreements require a higher level of collaboration than preferred provider contracts because there is a higher degree of integration between the supplier and the buying organization. In addition, buyers need to apply more formalized supplier relationship management efforts to review performance against objectives

and specify the incentive or service credit (also referred to as a malice payment or penalty) payments that are embedded in the contracts.

Some service industries are seeing an evolution in managed services agreements where a supplier guarantees a fixed fee with a pre-agreed price reduction target (e.g., a 3% year-over-year price decrease). The assumption is that the supplier will deliver on productivity targets. These guaranteed savings are often referred to as a “glide path” because there is an annual price reduction over time. Managed services agreements are a form of a performance-based Sourcing Business Model.

5. RELATIONAL: *VESTED SOURCING BUSINESS MODEL*

A Vested Sourcing Business Model is a hybrid relationship that combines an ***outcome-based economic model with a relational contracting model*** by incorporating the Nobel Prize–winning concept of behavioral economics and the principle of shared value where the buyer and supplier share risk and share reward.[10] Using these concepts, companies enter into highly collaborative arrangements designed to create and share value for buyers and suppliers above and beyond conventional buy-sell economics of a transaction-based agreement. In short, the parties are equally committed (Vested) to each other’s success.

The Vested business model was popularized when University of Tennessee researchers coined the term after studying highly successful buyer-supplier relationships.[11] Vested is a highly collaborative Sourcing Business Model where the organization and the supplier have an economic interest in each other’s success (e.g. win-win contract). A Vested business model is best used when an organization has transformational and/or innovation objectives that it cannot achieve by itself or by the using conventional transactional Sourcing Business Models (Basic Provider, Approved Provider, Preferred Provider) or a Performance-Based agreement.

University of Tennessee research shows typical outsourcing contracts are rife with unintended consequences because of opportunism by either (or both) the buyer or supplier. It is important to understand the dynamics of unintended consequences that can, at the very least, add cost. And, at worst, unintended consequences undermine performance and can even scuttle alliances. A Vested agreement aligns the interests of the buyer and supplier and shares risk and reward – thus eliminate most if not all misalignment found in traditional outsourcing agreements.

Transformational and Innovation objectives form the basis of a Vested relationship because the provider is rewarded for helping the buyer achieve mutually defined Desired Outcomes — even when some of the accountability is shared with the buying organization. Desired Outcomes are generally categorized as an improvement to cost, schedule, market share, revenue, customer service levels, or overall business performance.

6. INVESTMENT: *SHARED SERVICES MODEL*

Organizations that struggle to meet complex business requirements with a supplier can always invest to develop capabilities themselves (or insource). One approach is to develop an internal shared service organization (SSO) with the goal of centralizing and standardizing operations that improve operational efficiencies. A shared services model is typically an internal organization based on an arm’s-length outsourcing arrangement.[12] Using this approach, processes are often

centralized into an SSO that charges business units or users for the services they use.[13] In some instances, SSOs are formed externally to the company (such as a subsidiary).

Some organizations combine a shared service model with outsourcing. For example, Microsoft has a shared services organization that is responsible for back office finance administration. However, the SSO does not perform the majority of the work; rather the work is outsourced to Accenture using a Vested model.

7. INVESTMENT: *EQUITY PARTNERSHIPS*

An equity partnership creates a legally binding entity. They take different legal forms, from buying a supplier (an acquisition), to creating a subsidiary, to equity-sharing joint ventures or entering into cooperative (co-op) arrangements. Equity partnerships are best used when an organization does not have adequate internal capabilities and does not want to outsource.

Some organizations decide they do not have internal capabilities yet they do not want to invest in a shared services organization. In these cases, organizations may opt to develop an equity partnership such as a joint venture or other legal form in an effort to acquire mission-critical goods and services.

Equity partnerships, by definition, bring costs "in house" and create a fixed cost burden. As a result, equity partnerships often conflict with the desires of many organizations to create more variable and flexible cost structures on their balance sheet. As mentioned previously, equity partnerships have grown significantly in recent years – especially acquisitions and joint ventures.

DIFFERENT MODELS – DIFFERENT SYSTEMS

While business needs have evolved, the fundamental nature of how we procure goods and services has not. The vast majority of organizations (public and private) still use the same transaction-based approach for procuring complex goods and services as they do to buy more simple commodities and supplies.

Unfortunately, many business professionals wrongly assume that a transaction-based business model is the only way to architect a supplier contract. For simple transactions with abundant supply and low complexity, a transaction-based business model is the most efficient model. The real weakness of a transaction-based approach emerges when any level of complexity, variability, mutual dependency or customized assets or processes are part of the transaction. As Dr. Oliver Williamson's Nobel Prize winning work shows, a transactional approach cannot produce perfect market-based price equilibrium in variable or multi-dimensional business agreements. In many instances, hybrid Sourcing Business Models built with relational contracts and output or outcome-based economic models are more appropriate.

Arjan J. van Weele, NEVI professor of purchasing and supply management at Eindhoven University of Technology in the Netherlands, offers the following advice for thinking about outputs and outcomes.

> "Preferably the buyer should always strive for an output or outcome specification. The reason for this is that it allows the supplier more degrees of freedom to select the work methods that suit them best and organize the work in the best possible way.

> All of this should work out positively in terms of pricing, but also in terms of quality and flexibility. Moreover, the supplier is requested to put down a certain performance, which is relevant when the buying organizations seek a Performance-Based contract. In general, Performance-Based contracts are largely preferred over contracts in which the supplier only commits to perform certain activities.
>
> This, however, is too easy a statement. From a purchasing point of view, it is always very important to check whether a service provider is capable of delivering the required output or outcome. And more generally—the more difficult to specify the outcome and output—the more difficult to arrange Performance-Based contract."[14]

For this reason it is imperative that organizations consciously select the most appropriate Sourcing Business Model for their situation. We like to think of a Sourcing Business Model as a "system," as each is purposely built to optimize the business needs given critical operating factors. Think of a system like a Slinky toy[15] – it's designed to work all by itself once it's put in motion. The book Strategic Sourcing in the New Economy: Harnessing the Potential of Sourcing Business Models in Modern Procurement goes into great detail about each of the seven Sourcing Business Models and shares insights into how to strategically source and architect each model.

Chris Holmes, head of procurement strategy and transformation for a Fortune 200 pharmaceutical company, offers the following advice: "It is critical for procurement organizations to realize the continuum of what's available and what's appropriate for the whole situation. If you don't understand the basics of the relationship and what drives the behaviors and motivations, you can easily over-invest or under-invest in a supplier. Any mismatch leads to conflict within other contract terms, whether pricing or total cost."[16]

As you become familiar with how Sourcing Business Models work, you will see that each model is specifically built to form a system that helps buyers and suppliers work in harmony based on the nature of their circumstances.

Think about it this way. If you don't properly build a supplier agreement, a frustrating business model mismatch can develop because your system is not working in harmony. And your system must stay in balance as the world around you changes. After all, business is dynamic. If you are not thinking in terms of creating a self-correcting system, your supplier relationship can easily get out of whack. Case in point: How many times have you seen a good deal go bad because "business happens"? Getting your sourcing system right becomes increasingly important as you shift along the sourcing continuum to Sourcing Business Models that incur more risk, uncertainty, and supplier dependency.

As buyers work to apply the Sourcing Business Model theory, they must understand the key to success is architecting buyer–supplier alignment between the overall relationship and how the commercial agreement is structured. And that architecture is different depending on which Sourcing Business Model is most appropriate for the specific situation. Appendix 1 provides a "cheat sheet" into how each of the Sourcing Business Models should be structured.

PART 3: THE EVOLUTION OF CRO OUTSOURCING

The purpose of Part 3 is to provide an overview of the history and current trends within the CRO outsourcing environment. We also share key challenges and provide insights what some pharmaceutical companies and suppliers are doing to make the shift to more strategic relationships.

EVOLUTION OF CRO OUTSOURCING

Outsourcing for CRO services became prevalent in the 1970's when government regulations demanded robust documentation; the need for data management created a new opportunity for statistical consulting. By 1998 CRO outsourcing had established a firm hold as a key strategy for pharmaceutical companies with 77% using outsourcing for collection and monitoring and 57% for statistical analysis.[17] Outsourcing evolved significantly and now includes clinical trial activities. Today CRO is the norm for pharmaceutical companies.

A key reason for using CROs is to shift fixed costs to variable costs associated with third party providers. Outsourcing effectively means there can be less investment in R&D infrastructure. Additionally, use of CROs expands geographical opportunities and access to intellectual property. Large CROs also have capacity to deliver patient pools across populous regions such as Central and Eastern Europe, Asia-Pacific, India, China, and Africa.

The 11th Annual Outsourcing Survey indicated there was an increased demand for CRO outsourcing in 2015 compared to the previous year. In the EU market alone, CRO contracting was expected to reach $13.52 billion for 2015, up from $7.10 billion (2008[18]). Companies report they are outsourcing more because they are virtual (30%), while a significant number say they lack the capabilities in-house (14%).[19]

The Nice Insight 2015 Pharmaceutical and Biotechnology Outsourcing Survey suggests the majority of companies that outsource to CROs expect they will achieve reductions in project lengths and costs through use of cloud based systems. Nearly 50% think the use of web-based life science labs will mean cost and time efficiencies. Mobile technology is seen as enabling communication and study monitoring. Nearly all respondents (96%) desire to work with CROs that employ new technologies to improve safety, traceability, quality, and efficiency.[20]

The Nice survey also indicates an interest in robotic automation for routine testing is gaining interest as well as CROs in emerging markets. Prevalent areas of interest are analytical, bio-manufacturing, blending, clinical research and monitoring, biostatistics, and chemical synthesis services.

Today, many trade publications espouse that seeking innovation from within is not sufficient to meet the demanding nature of today's climate. A Drug Discovery World article sums up what many are saying. "By offering an on-demand staff of experts and capabilities in drug discovery and development, the right CRO can be looked to for their capabilities and capacities necessary to go from concept to proof-of-principle and even beyond including bridging studies for candidate selection, safety, and post-ND studies."[21]

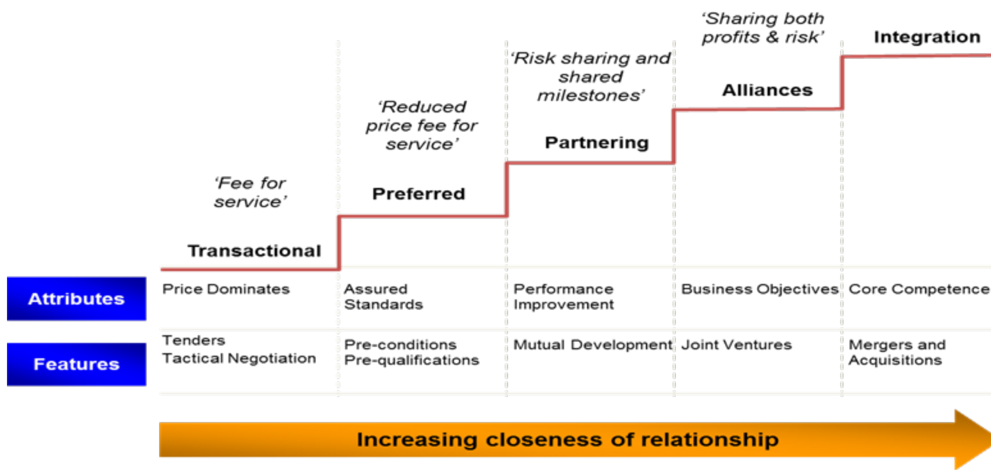
KEY TRENDS IN CRO OUTSOURCING

Secondary research points to two key trends in CRO Outsourcing: the rise of strategic relationships and risk sharing. To some extent, these are related; organizations that seek strategic partnerships surely must consider how they will share risks and rewards that are a result of the partnership. Both of these trends are addressed below.

THE RISE OF PARTNERING AND ALLIANCE RELATIONSHIPS

One significant trend in the Pharmaceutical industry is the rise of "partnering" approaches. Figure 3 below outlines how IBM segments the partnering trend.

Exhibit 3: The Trend Toward Partnering



Source: IBM Consulting

A few key themes emerged as pharmaceutical companies began exploring the more advanced models outlined in Exhibit 3.

- ***The rise of "preferred" suppliers***: Most companies worked for decades under a conservative, traditional transactional mentality with their suppliers. Now, many procurement organizations realize that working with "preferred suppliers" allows purchasing to leverage their buying power The promise of repeat business is a means to drive cost down in the drug development continuum.
- ***The emergence of strategic "partnering":*** IBM classifies "partnering" models as agreements that use risk sharing and shared milestones with suppliers. Partnering typically limits the number of suppliers to a short-list for future consideration on new R&D projects, statements of work, contingent labor programs, access to talent pools, or functional service provider (FSP) models to staff clinical development projects across all phases of the drug development continuum. The Vested Sourcing Business Model would be classified as a strategic supplier partnership.
- ***Alliances and Integration:*** IBM suggests alliances typically come in the form of a joint ventures and integration usually comes in the form of mergers and acquisitions. Roche demonstrated one of the earliest examples of this when it purchased majority interest in

Genentech in 1990. In 2009, the alliance was strengthened as Roche spent $46.8 billion to acquire full ownership and enter a full-blown company merger. Industry experts at the time were skeptical the merger could work. Laurence Lasky, a Silicon Valley venture capitalist who spent 20 years as a scientist at Genentech, said he expected top managers of Genentech to leave Roche. “They’re Swiss and Genentech is a bunch of entrepreneurial California cowboys.” Roche was fully aware of the culture differences. Rather than attempt to make Genentech conform to the traditional pharmaceutical model, the agreement left Genentech’s autonomy intact, allowing for its own Board of Directors and governance – a strategy that proved to be highly intelligent.

Although Roche expected a cost savings of $750-850 million dollars annually, the primary motivation was improved coordination of product development. “It should be very easy because practically the entire portfolio is in common,” said Viren Mehta, managing member of Mehta Partners, a consulting firm that advises drug companies and investors. “These two companies have grown up closer than any two independent companies could be expected to be.”[22] Time has proven the wisdom of the alliance, as Genentech has become the American public face of Roche in the extremely successful partnership.

As acquisition opportunities become more limited, organizations are likely to look to more strategic partnering approaches for working with existing suppliers. A Quintiles study suggests that pharmaceutical companies will seek to shift up the sourcing continuum for outsourcing relationships. “In theory, outsourcing relationships often evolve along a continuum from tactical, transactional, ‘fee-for-service’ arrangements where price dominates to strategic partnerships where both profits and risks are shared, and core competence is the dominant factor. Normally, the benefits and closeness of the partnership are lowest for the transactional relationships and highest for the strategic partnerships, thus, companies restricting themselves to less strategic options will encounter major barriers to maximizing potential benefits.”[23]

A Vantage Partners study digs even deeper, providing quantified benefits of collaboration between customers and their key suppliers. “Customers reported realizing, on average, 40% more value from their most collaborative key suppliers compared to their least collaborative key suppliers. Life Sciences companies in particular reported realizing, on average, 49% more value.”[24]

The study goes on to enumerate benefits of closer, more collaborative relationships beyond the obvious - increased patient safety, improved regulatory compliance, and enhanced quality of trial data. Additional benefits included:

- “Enabling early engagement between Sponsor and CRO in protocol design and study planning — which is very difficult, if not impossible, under a transactional model where competitive bidding precedes any engagement with a CRO or service provider.
- Reducing transaction costs associated with the need for RFP development, bid submission, and evaluation at the start of every clinical study.
- Increasing willingness to invest in joint training, improved systems, after-action analysis of clinical studies, and in general, to work together to jointly drive continuous improvement of the clinical development process
- Enabling both Sponsors and CROs to build up tacit knowledge about how to work together effectively”[25]

Anita Lavin, Life Analytics Group, also believes there is great benefit from more strategic supplier relationships. Lavin perceives change coming within an era of connectivity. "CROs have so much data; they see the whole industry. Finding ways to share data will drive the industry to greater breakthroughs. I see opportunity to blend the roles and responsibility between supply chain and business development."

RISK SHARING

Declining annual cash flows limit a pharmaceutical organization's ability to invest in internal programs. Therefore, firms look for ways to lower development costs, access external capacity, and share financial risks of development, while retaining downstream control of product rights. A McKinsey report reports, "These innovative risk-sharing models enhance early development's risk–reward profile by decoupling ownership from activity, commitment from control, involvement from information, and reward from risk."[26]

A Journal of Clinical Pathways article offers an excellent summary of current types of risk sharing agreements (RSA). The authors explain, "Recent regulatory changes have made it possible for drugs to be approved by the US Food and Drug Administration (FDA) more quickly and with less stringent data, particularly for treatments that address areas of high unmet need. A result of these changes is that health decision-makers have less data to consider when determining a drug's value and position with the current treatment setting in order to set pricing for the drug. In such situations, payers have engaged in risk-sharing agreements (RSAs), in which the risk is shared by both the payer, which agrees to pay reimbursement costs for the product despite uncertainties about its clinical or health economic value, and by the drug manufacturer, which typically agrees to make a financial- or outcomes-related concession depending on the future performance of the product."[27]

Lilly, Merck, and GlaxoSmithKline offer some examples of risk sharing deals. Each signed integrated drug discovery and -development alliances with Indian or Chinese bio pharmaceutical companies, such as Piramal Healthcare and Ranbaxy Laboratories. In these deals, the low-cost company takes on development responsibilities for specified programs through proof of concept, when the global pharmaceutical company regains rights to the compound in exchange for milestones, royalty payments, and, in some instances, co-promotion rights in certain geographies. Companies can therefore advance internal programs that would not otherwise meet investment hurdles on a risk-adjusted, full-cost basis."

Other examples include Quintiles and its alliance with Eisai. In exchange for milestone payments, Quintiles funds in part and leads the development of multiple indications for six oncology products through Phase II proof of concept. Pharmaceutical Product Development (PPD) spun off its compound-partnering business; combined with an initial capital commitment of about $100 million, the move helped the business expand without diluting PPD's core contract research earnings.

These initiatives demonstrate that sharing of project financing and risk with clinical research organizations present viable options for companies to access both the capacity and the resource needed to advance promising programs. In these models, the partially at risk CRO develops the asset with funding from the investment partner. The pharmaceutical company offers that partner a premium upon the successful outcome.

Historically the pharmaceutical monitoring structure requires a monitor to go to site every 4 to 6 weeks and do a source base verification for every page for every patient. It is very expensive. There is a different concept that sends monitors only when a risk is flagged through operation. For example, is there a patient classified as a male taking pregnancy tests? Or, does the same name show up in multiple places?

KEY CHALLENGES OF CRO OUTSOURCING

Despite growth in outsourcing, both sponsors and service providers point out ongoing challenges in outsourcing relationships. The top issue continues to be communication and culture. One respondent from the sponsor side of the IBM 2015 study said, “Be clear on what your process can support—lead times, documentation, communications, OTD, etc. Do not make promises that you know cannot be met.”[28]

Forty-six percent of respondents cited this as the top challenge of the sponsor-contract services relationship. Quality assistance was the next top challenge cited (40%) followed by vendor qualification and selection (37%), documentation (36%), and analytical method development (26%).

From the service providers’ perspective the top challenges cited when working with pharmaceutical companies are insufficient information (63%), unrealistic deadlines (62%) and infrequent communication (40%). One respondent said it is important “to treat us as a part of their team and share their entire strategy so that we can truly add value.”[29]

While there is a trend to more strategic relationships, most organizations fall behind in physically creating strategic contracts that truly drive innovation. Some openly criticize pharmaceutical companies as simply labeling suppliers as “strategic” without truly concluding agreements that foster the desired behaviors. The definition of “strategic” tends to be more about the size of financial commitment to any given supplier rather than a relationship to achieve true strategic goals.[30]

Most secondary research supports the fact that CRO outsourcing continues to be a tactical solution to a short-term problem, managing cost and increasing R&D capacity. After all, a chemist in India has an annual salary of $20,000 -$40,000, whereas a chemist in the United States earns $80,000 and up, per year[2]. And, tight budgets restrict the yearning to expand infrastructure. The reluctance to move across the sourcing continuum to more collaborative agreements is frustrating to suppliers. “Precedence has shown that the benefits of outsourcing increase exponentially as one progresses through the relationship continuum. It is the desire, and indeed the frustration of the CRO industry, that only a handful of companies have embraced strategic outsourcing in full and to its greatest benefit.”[31]

Ann Kilrain - Head of Alliance Management for Jazz Pharma - offers a first hand perspective on why organizations are reluctant to change. Kilrain personally tried to shift to a more collaborative Vested Sourcing Business Model with two different CROs while in a prior role at a large biopharma company – and failed. “The objective was to drive innovation through a Vested agreement. We started by approaching two different suppliers that had worked with us for many years. Philosophically we had support at the highest levels. We worked with the chief scientific

officers to get alignment and even put resources against it. However, we could not get the CRO over the finish line.

Kilrain offers three reasons why the suppliers failed to make the shift. The first is that "long held perception on both sides that if Pharma is paying the money, they should have the command. This leads to a business relationship that features a downward spiral of expecting the other party to single handedly fix all the issues." The second reason is the CRO suppliers have not typically seen themselves as innovative. And those suppliers that are innovative don't always feel that they have support from Pharma to figure out how to solve problems." Kilrain suggests the third reason is perhaps the most difficult challenge to overcome. "Companies are measured and evaluated under an existing transactional model. This means the Pharma procurement is focused on price reductions and the suppliers are focused on revenues. While there are some progressive thinkers, the majority of stakeholders are stuck in the old paradigm. In our case the CRO suppliers said a Vested model would take an investment, cut into their revenue, and add risk. Also, I consistently hear that their other clients were not clamoring for such a model. They weren't seeing that a win-win Vested model would also reward them for their success. The bottom line is that until organizations change how they measure success against outcomes, I predict the industry will be slow to change."

Kilrain is cautiously optimistic for the future state of CRO outsourcing. "While most organizations will continue to chase the desire to actually partner without really understanding the investment and change management that is required to change, most likely there will be one or two companies that will go beyond lip service and completely change the paradigm." Making the shift is one reason Ann Kilrain left a large pharmaceutical company to pursue a career with Jazz Pharma as Head of Alliance Management and focus on partnering relationships. "As a smaller Pharma company we have the ability to drive change faster than Big Pharma."

The question is, "Will the pharmaceutical industry harness the potential of Sourcing Business Models by moving along the continuum, seeking real strategic outsourcing relationships to achieve long term, truly strategic outcomes?" The following section provides insight into how pharmaceutical companies and suppliers are shifting to more strategic relationships.

PHARMA COMPANY EXAMPLES OF MORE STRATEGIC PARTNERSHPS

ROCHE

In recent years, the Business Development team at Roche has entered into committed alliances with both public and private entities, which look much different from the typical straightforward M&A. Even when Roche acquires majority interest, some partner firms retain their independent structure and hold protected relationships with pre-existing clients and initiatives. The relationships differ from traditional outsourcing because they are goals driven, expressly longer in duration, and carry large, ongoing Roche financial commitment.

A few examples:

Cote d'Ivoire:[32] - Since 2008, Roche has supported government programs that focus on awareness, prevention, early detection and therapeutic management of viral hepatitis and breast cancer in sub-Saharan Africa. In 2014, Roche doubled down, entering into a five-year agreement

with the Cote d'Ivoire Ministry of Health to provide access for low income patients to innovative treatments. The patient pays a small portion of the cost; the government and Roche pay the remainder.

Foundation Medicine Inc:[33] - Roche announced a broad collaboration agreement with Foundation Medicine Inc (FMI) in January 2015. The partnership carries the potential of $150,000,000 funding to accelerate FMI's new product development initiatives, optimize treatments for oncology patients, and better design and understand the results of clinical trials based on commercial collaboration agreements.

The collaboration advances FMI's position in molecular information and genomic analysis. It gives Roche opportunity to optimize the identification and development of unique treatment options for cancer patients. By combining forces, FMI benefits both in financial stability and advanced market position. Roche gains by getting a foothold in emerging technologies.

It is important to note that, although Roche acquired a majority interest in FMI, the company retains its independence. Michael J. Pellini M.D., President and Chief Executive Officer of Foundation Medicine, relates, "The structure of our agreement with Roche allows us to maintain the entrepreneurial spirit at Foundation Medicine and ensures that our business model, network of partnerships and objectives are not altered.

Catalent Biologics:[34] - In January 2016, Roche entered into an alliance with Redwood Bioscience, Inc a wholly owned subsidiary of Catalent, to gain access to the SMARTag platform with an option to take commercial licenses to develop molecules directed a defined number of targets. Roche agreed to pay an initial $1,000,000 as well as provide additional funding during the initial phase of the collaboration.

What's In It For Roche:

- Collaboration focuses on development of novel molecules using SMARTag technology to couple different therapeutic modalities.
- Roche will have option for commercial licenses to develop such molecules after initial phase of the collaboration.

What's In It for Catalent:

- The potential to receive up to $618 million in development and commercial milestones, plus royalties on net sales of products, if Roche pursues commercial licenses and all options are exercised.

The preceding examples show how the business development teams at Roche endeavor to reach out to organizations in creative ways to expand the potential for discovery and value. Collaborations with entities that are structured differently than itself – the world's largest biotech company - offer possibilities of speed and nimbleness that are otherwise unlikely.

NOVARTIS[35]

In 2012, Novartis began a shift in both how they approach procurement and outsourcing. Through the creation of Novartis Business Services (NBS), Novartis is taking steps to improve profitability

by generating synergies across businesses by harmonizing services across Group and divisions. The scope of NBS covers over $6 billion in expenses, and complements other ongoing productivity initiatives, including manufacturing footprint.[36] "NBS has outlined several key goals: keep managed costs flat and absorb inflation and volume/demand growth; streamline and consolidate (e.g., optimize size of the organization, rationalize IT applications); optimize geographical footprint (centralization and offshoring of certain transactional activities); leverage scale (e.g., accelerate sourcing productivity, vendor spend, and process optimization); and facilitate cross-divisional coordination (e.g. real estate and facility services spend optimization). Overall, since 2011, Novartis has generated savings of approximately $10 billion, of which half was derived from procurement that was achieved by leveraging, scale and category and demand management. "[37]

The Novartis Business Services (NBS) division operates under the mantra "Integrated Solutions That Matter." Its internal research suggested, "Without rigorous contract management, 75% of sourcing savings can disappear within eighteen months. As such, Novartis adopted the Vested Sourcing Business Model to develop collaborative supplier relationships that would create value beyond what is in contract language. Novartis has been an early proponent of Vested with its supply chain and facilities management spend categories.

At the very outset, NBS defined a Shared Vision of what they wanted – "A trusted partnership driving innovation, quality, and value to enhance patient lives and be market leaders." Also, they committed to a Statement of Intent that summarized shared values and behaviors:

1. Operate an Industry-leading innovative Supply Chain resulting in measurable value and sustainable efficiencies.
2. Deliver customer service excellence that exceeds the competition, customers, and partnership expectations.
3. Implement a standardized compliance & quality system that ensures uninterrupted supply and patient safety.

MERCK[38]

The International Association of Outsourcing Professionals (IAOP) recently honored Merck with its 2016 Global Excellence in Outsourcing award for its outsourcing success achieved by the development of a Center For Excellence (CoE). The COE contributed to the realization of 25-30% savings over the respective contractual term (typically 3-5 year contract terms). It leveraged outsourcing leading practices and innovative methodologies to transform the entire outsourcing life cycle, from portfolio assessment through steady state governance.

The CoE was established within the procurement division in order to deploy dedicated resources to assess and accelerate outsourcing opportunities throughout the organization. Leaders believed procurement to be far more than buyers of goods and services. Rather, procurement activities would be critical to the strategic objectives for innovation, efficiency, and added value.

Critical to the development of the CoE was putting the right team in place. The lead of what is called the Externalization Center of Excellence is a Certified Outsourcing Professional (COP) with extensive outsourcing experience. He recruited a group that was a mix of existing Merck employees who "knew the landscape" and new COP certified recruits that had strong, hands-on/ real-time experience within outsourcing and consulting environments.

Within the past year, the Merck Externalization CoE leveraged outsourcing leading practices that helped accelerate the setup of the CoE, and has delivered about 25-30% in savings over the respective contractual term (typically 3-5 year contract terms), through various outsourcing and optimization activities. They expect the current project pipeline will drive an additional 20% spend externally over the next 5 years. Fifteen additional projects are currently under evaluation.

The most important lesson learned according to the Externalization CoE lead - "Outsourcing done right can bring great value. But, if you don't put enough time into change management, you'll never get it to work." [39]

PFIZER

The question for Pfizer was how to grow its revenue stream despite having 9 of its blockbuster drugs lose patent protection. Add to that the following fact, - "Pfizer has 90 plants on six continents; more than 300 external suppliers / contract manufacturers; 175 market-based logistics / distribution centers; more than 35,000 SKUs; 2,109 global logistics lanes, in 808 distinct country-lane pairs; 45,454 shipments; and 17,394 freight contract line items."[40]

To meet the challenge of this mélange of activity, Pfizer looked to the clouds. That is, cloud based computing that transformed its supply chain into a virtualized information and process layer between Pfizer and its service providers and trading partners. Pfizer and its external providers no longer have their own proprietary data sets or operating systems," says Jim Cafone, president of Supply Network Services. "Instead, they all use the same platform to manage the network via activities such as performance monitoring, network analysis and management of contract rates. Thus, while the network may change over time, no new integrations are required of Pfizer. The layer insulates Pfizer from the underlying physical changes and allows network participants to be added or removed rapidly." [41]

BAXTER BIOSCIENCES

John Orloff, M.D., global head of research and development at Baxter BioSciences, offers insight into emerging trends. "The clinical trial enterprise is endangered because the model is antiquated and has not kept pace with advances in technology. Contract research organizations (CROs) of the future will rely on different business models, becoming stronger strategic partners with sponsors. They will be fully integrated into team structures and will have accountability for delivering on a program with objectives and rewards similar to sponsor team members (i.e., much less transactional and much more strategic and program-oriented)."[42]

CROs offer a great example of how outcome-based economic models differ from transactional economic models. Traditionally, life sciences companies engage a CRO as a staff augmentation resource to manage clinical research trials. Most often CRO relationships fall under a preferred provider Sourcing Business Model and use a transactional economic model.

CRO relationships are often plagued with poor communications and misalignment of economic interests. Life sciences organizations want high-quality data in order to get a new drug approved. CROs are economically incented to spend more time and perform more tasks under transactional economic models.

When a life sciences firm and its CRO move to an outcome-based economic model, they agree to work collaboratively and share risks and rewards associated with the ultimate desired outcome: gaining government approval for a new drug and successfully launching a new drug. As such, the parties enter into a contractual agreement that shifts thinking away from price per hour or activity to a pricing model with incentives for the supplier to drive success toward ultimate outcomes. When making this transition from transactional to outcome-based, it is important to recognize that suppliers have purposefully taken on more risk. Buyers must purposefully create mechanisms that reward suppliers for this added risk when and if outputs and outcomes are achieved.

Orloff concludes, "Communication issues underlie many challenges that arise in an outsourced model. Lack of timely communication or failure to listen to legitimate requests from either party can seriously undermine the relationship and introduce unnecessary delays or even compromise the outcome of the trial. Integration of the outsourced personnel into a cohesive team model, along with good up-front strategic planning, will help to mitigate many of these issues. Leadership on both sides can help by fostering a collaborative team environment."

SERVICE PROVIDERS RISE TO THE CHALLENGE AS WELL

As pharmaceutical buyers seek multiple point solutions, service providers seek ways to meet their customers' needs in more flexible and customized ways. Pricing mechanisms will change as suppliers take on more risk and commit to lessen customers' headaches. The nature of master/servant, parent/child relationships will evolve as buyers move along the Sourcing Business Model continuum. As Ann Kilrain cautioned earlier, many – maybe most – CROs are not currently equipped to successfully enter highly collaborative partnerships. Bonnie Keith, President of the Forefront Group and a former member of the White House Advisory Council for the Pharmaceutical Industry, explains, "Pharmaceutical companies believe they are spending too much money and getting less than desirable benefits. Relationships aren't that great and, because of that there is duplicative expense due to a perceived need for oversight. Companies will find the innovation they seek when they create agreements with clear requirements for their strategic goals. CROs will be happy to share when there is compensation for keying up possible value data and finding efficiencies."

There are organizations that are striving to bring new mindsets to the marketplace. Here are a couple examples.

KELLY OCG®

Kelly Services's® OCG (Outsourcing and Consulting Group) is one supplier that is making the shift to more strategic outsourcing models. According to Chris Jock, vice president of KellyOCG's Global Managed Solutions, "Kelly Services is much more than a staffing organization. We have made significant strides in shifting from a transactional staff augmentation approach to also providing a comprehensive array of talent supply chain management solutions and services such as Global Managed Solutions,"

One example is a European-based MNC pharmaceutical company that needed to retain key talent and scale-up its Global Clinical Data Management function in support of clinical study submissions for regulatory approval. Kelly created a talent sourcing alliance named

ADAPTIEVE. The result was an improvement in the TCO in more cost-effective headcount by approximately 10% or nearly €180K per headcount in the first year of operations. This approach was deemed so successful that it was expanded from the initial target headcount of 25 to 50 over the last 12 months with the added innovation of providing off-site delivery capabilities due to facility constraints at the customer's main campus. In addition, the customer is evaluating the result with thoughts of expanding the approach globally (e.g. US, EMEA and Asia-Pacific) and adding more business and types of roles to the Kelly portfolio.

Chris Jock explains how Kelly is adjusting its sourcing approaches within the life science market's changing product life cycle. "Standardization creates levels of improvement and reduces head count which lays the foundation for optimization. After that, comes innovation, and finally, transformation. To operate effectively, we, as leaders, need to embrace change management and build GRC (governance, risk, and compliance processes) into our solutions. By moving through the different stages, we generate value measured by more effective organizations (e.g. improved resource utilization), products delivered to patients faster, time saved, and achievement of other business and patient goals."

TEPNEL PHARMA SERVICES, A BRAND WITHIN HOLOGIC LTD.

Tepnel Pharma Services is actively transforming its own workplace to meet the challenges of pharmaceutical outsourcing. For the past couple of years, Tepnel had been engaged in cultural changes starting with the leadership team, the objective was to find ways to work together, strengthen and revitalize supplier/customer relationships.

During this process General Manager Vikki Renwick attended the Biotech Outsourcing conference where she was introduced to the Vested business model by the UT and one of Tepnel's' customers. Renwick brought the idea back to the leadership team's Senior Director, David Scott. After learning more, the leadership team embraced the changes needed to support moving from a transactional model to Vested. "We were immediately attracted to the Vested approach, which builds relationships on collaboration, trust, transparency and mutual benefit. It made sense to us because this was a good fit with the Tepnel culture."

But making the strategic shift was not easy. "While management liked the idea of Vested, the concept was not an instant success with everyone. The sales staff viewed success as getting the highest possible rate. One of the principles underlying Vested is 'leaving something on the table' and that was foreign for sales reps. With time and more education, Vested is now accepted as an exciting new way to approach business partnerships."

Adopting the Vested mind-set turned Tepnel approach to relationship management on its head. David Scott explains, "We are not going in saying, 'This is what we sell. How much will you pay?' We approach companies asking them what they wish to achieve and learn if there elements of Vested. For example, Tepnel may share information regarding the ten ailments – contract provisions that carry unintended consequences – or the Five Rules that guide a Vested agreement. "We speak from a different mindset and way of working. We think of outsourcing from someone else's perspective and have more valuable conversations as a result."

The Tepnel team actively promotes the concept of Vested as an innovative way to meet outsourcing challenges. Knowing the pressure to perform well for customers requires finding

skilled people and expertise that fit within the available budget, Tepnel is determined to bring innovative solutions by incorporating the Vested mindset and architecture. “Pharma wants to bring a product to market. Tepnel bring our skills and knowledge to the table. Ultimately, we want to help effectively provide important medicines and research for the ultimate outcome the patient.”

At this point, Tepnel has not entered into an official Vested agreement with a pharmaceutical company. However, optimism is not without basis. Tepnel are in conversation with organizations in the United States. In one instance, after an initial meeting, Tepnel were invited back and presented on the Vested model with excellent response. “Change comes slowly to Pharma companies; I predict another twelve months will pass before we enter into a contractual agreement,” relates Scott.

It is not just companies that stand to benefit from Tepnel’s new approach. David Scott sits on Scotland’s Life Sciences Scotland Industry Leadership Group (LSSILG) as well as its subset Pharma Services Steering Group where he is industry co-chair. This governmental leadership initiative is designed to develop and grow Scotland’s pharmaceutical services through collaborative working practices and is now talking Vested philosophy. That is, if they can grow the pie instead of worrying about how to divide the pie – everyone will gain. Scott smiles, “The members don’t have any idea about Vested itself, but you hear the Vested phrase ‘What’s In It For We’ all the time.”

PART 4. OBSERVATIONS ABOUT PHARMACUETICAL CRO OUTSOURCING PRACTICES

Part 4 summarizes six key observations from the in depth interviews with leaders across multiple organizations in multiple disciplines.

1. MOST CRO OUTSOURCING IS FUNDAMENTALLY TRANSACTIONAL

Most interviewees expressed the bulk of CRO outsourcing is transactional in nature – meaning they pay CRO service providers a fee for services (e.g. agree on a rate card and pay for number of hours). Although there is often talk of having "strategic partners", more often than not, being "strategic" refers to the size of business granted and money spent rather than the achievement of critical goals and objectives. While some interviewers stated they were consciously trying to build more collaboration relationships with CROs, they reported contracts remain styled in transactional mode.

Through the years, contracts have also become more and more complicated. They can easily be an inch thick of paper. Interviewees shared complex legally written contracts make it difficult for people to understand the content. One interviewee reported "It almost becomes a stalemate where both parties are trying to interpret the contract in different ways." This pits the sponsor of the study against the supplier in an adversarial relationship.

Anita Lavin, Life Analytics Group, suggests more effective approaches create a positive sum game by using data to inform the most sound decisions. Important questions must be answered. Where are the points of pain? Where is the process out of control? Are we using the right measures? Or, are we measuring things that were important ten years ago? What exactly are you really looking to achieve? Lavin reveals, "Once we know these things, the sponsor can incentivize the CRO to deliver results that are consistent with what they want. If the CRO is paid by hours, it will strive to build up more hours. The agreement must be built to strategic objectives."

Conclusion: Simply put, large, overly legalistic and transactional contracts impede the ability to move flexibly within the marketplace and can stop innovative ideas in their tracks.

2. SILOS ARE AN IMPEDIMENT TO EFFECTIVE CRO OUTSOURCING

Most large Pharmaceutical companies operate in a "functionally focused" environment. While this can bring autonomy, many interviewees felt functional silos were an impediment to effective CRO outsourcing. Certainly this was a lessons learned by Merck when they embarked on its award winning initiative to create a Center For Excellence (CoE).

Merck operational environment was like many of today's industries. Work tended to be contained by specific activity – what are frequently referred to as silos. Working within what are independent and self-supportive departments frequently meant duplication of efforts, excess FTEs, and bureaucracies. As the CoE was tasked to bring improvements to divisions across the Merck spectrum, it enjoyed a view from a much broader perspective. This created a huge advantage as myriad opportunities for cost savings and efficiencies became clearly evident.

The holistic view mentioned earlier was critical to negotiation of better prices. When the entire scope of Merck relationships with a supplier are known, there is increased leverage at the bargaining table. For example, one supplier held three contracts for three different sections of Merck. Because the Merck departments operated independently, none of them knew about the others. When the CoE shared the total amount of Merck spend with the supplier, the managers were able to leverage the total spend, not just their portion. Prices were reduced 15% across the board.

Merck reports the most important lesson learned according to the Externalization CoE lead - "Outsourcing done right can bring great value. But, if you don't put enough time into change management, you'll never get it to work." [43]

Conclusion: Bottom line, there is need for cross-functional teams that work together proactively to create synergies and ensure that each division's priorities are considered within the outsourcing process. A team approach would provide a more holistic view of the process and eliminate much of the inefficiency and expensive re-negotiation now present within the system. Better understanding between divisions may also decrease suspicion and blaming that occurs because of lack of knowledge and understanding of each other's needs and priorities.

3. THE RFP STANDARDIZATION CATCH 22

There is a Catch 22 when it comes to RFP and other procurement process standardization. Although the standardization offers an efficient and common operations platform, it also causes angst for non-procurement "users" of the process and for suppliers. It may be surprising that, internally, non-procurement pharmaceutical leaders don't standardized RFP processes much better than suppliers do.

Most view standardized RFP processes and tools as cumbersome and arbitrary. There are boxes to be filled in that don't necessarily pertain to the study practitioners seek. But, getting authorization to edit or omit the information can be difficult to impossible. Sometimes, people run into departmental politics and tunnel vision; one division certain aspects are unnecessary, but another department feels they are mandatory. "It is a headache to resolve, so it's easier to just go along," is a sentiment we heard repeatedly. Another issue arises if the standard forms are not regularly reviewed and updated as they become unresponsive to present need.

From the supplier side, we hear "You can't force ideas into boxes. The forms are built so reviewers can compare similar responses. There is no opportunity for innovation in the boxes…reviewers are not interested in innovation. The reviewers are interested in, 'are you going to do it on time?' " It may be inaccurate that reviewers have little interest in innovation. However, the template approach creates dynamics that convey that perception.

Conclusion: We believe Pharmaceutical companies should reconsider their approach to highly competitive bidding for CRO work. We believe that sponsors would be better served by shifting to a more collaborative bidding approach – either a Request for Solution or a Request for Partner for the most strategic relationships.[†] *At the very least, the standardized tools should have a*

[†] *The University of Tennessee has a white paper that shared the various competitive bidding methods – including a Request for Solution and Request for Partner. Download the white paper for free in our research library at vestedway.com/library*

regular cycle for review and update. In additions, standardized templates should be modified to allow for more flexibility (not every field is required and providing the option for "additional" questions.

4. SPONSORS ARE NOT GETTING THE DESIRED INNOVATION WITH SUPPLIERS

Although 96% of major pharmaceutical firms now have at least one integrated alliance (compared to 63% in 2008), a recent study showed the impact on performance is lacking. Kenneth Getz, Director of the Sponsored Research Program at Tufts Center for the study of Drug Development, reported, "Poor utilization and lack of trust is making these types of relationships no more effective than traditional CRO use. We looked at a collection of Phase I and Phase II studies…What we found was that in no case was the CRO partner being used in the way it was intended." Getz continues, "Instead we saw organizations were mixing and matching approaches depending on the preferences of the clinical team [resulting] in widely inconsistent behavior within companies in terms of when and how they would use an integrated partner."[44]

Interviews confirmed this.

Suppliers also reported common themes. "Working with a pharmaceutical company with multiple divisions is really like working with different companies, each with differing procedures and protocols." Suppliers also believe the pressure to meet timelines is a greater determinant to contract award than a thirst for innovation. "The process has no time allocated for us to enter into the kind of dialogue that could develop innovative approaches."

There are pockets within the industry that are approaching working with CROs differently. When a supplier knows it is a preferred supplier with a guaranteed scope of work ahead, there is more 'What's in it for We. (WIIFWe) The CRO has visibility of what's coming up. Because there is a portfolio, staff essentially goes from one study to another. This means the CRO can offer better price and staffing. The long-term approach provides time for PPD experts to put ideas on the table. When the CROs have months to get a study off the ground, they can offer better quality and get the work done more efficiently. The CRO gets the benefits of predictable business and staff that enjoys working within the environment. The buyer receives value from fresh ideas and improved results.

However, we note most of this type of initiative is limited to select areas and retains the traditional dynamic of parent/child – master/servant relationships that are predominant within most outsourcing environments. The power ratio is clearly tipped to pharmaceutical companies – not to suppliers. Even in the largest relationships in which resources on both sides are allocated to joint governance, too often "They talk the talk more than they actually walk the walk."

Interviewees believed that "win-win" relationships with suppliers were definitely more of a buzzword than a practice. Transactionally focused contracts are a key contributor to the lack of supplier innovation. Sponsors pay the supplier for activities – a fee for service most often defined by a rate card - rather than for achieving outcomes.

In addition, contracts tend to be highly prescriptive – telling the CRO exactly how to do the work rather than encouraging the CRO to be the experts. The contracts do not allow the time and

space for suppliers to "play" with ideas and offer alternative approaches. Nor do contracts reward CROs for bringing efficiencies and/or new ideas to the table. One interviewee liked CRO contracts to "a overly legal temporary staffing" arrangement.

Conclusion: While pharmaceutical companies are looking for – and not getting - innovation from suppliers, we sense the answer to this conundrum may be as simple as "You are getting exactly what you are asking and paying for."

5. CONVENTIONAL COST SAVINGS APPROACHES HAVE A LIMITED LIFE

In response to a changed economic environment, pharmaceutical companies endeavor to contain their outsourcing budgets. After years of diligent budget trimming, prices have been reduced through volume consolidation, competitive pricing and process efficiency. We heard repeatedly that "the low hanging fruit is has been picked." Simply put, more creative approaches are required.

More than one pharmaceutical company shared they are using volume as a way to get price concessions. For example, augmenting vendor opportunities with a fuller scope or even choosing to award additional business to a supplier without a bid process. The general sentiment is "the more business a supplier has …the better prices they offer." While this may yield to lower prices, it does not provide longer-term advantages such as enabling access to newer, innovative CROs that may not be as large as some of the mainstream CROs. It also does not promote supplier diversity goals.

CRO service providers report they are able to offer reduced prices for more volume because they save money by not having to invest in business development.

Virtually all interviewees – from both pharmaceutical companies and CROs - believed ability to get further cost cutting would not be feasible. In fact, some clinical practitioners feared further cost cutting might actually lead to pressures to cut quality.

One interviewee summed up the majority of sentiments nicely. "We have now entered into the mode of cost stabilization. We will have to be more proactive regarding productivity and look for the overall value– not just costs."

Conclusion: Getting significant added value is hampered by transactional contracts. Better results come from moving along the sourcing continuum.

6. RESISTANCE TO CHANGE IS A REAL OBSTACLE

Albert Einstein perhaps said it best. "*The significant problems we face cannot be solved at the same level of thinking we were at when we created them."* Yet, person after person, company after company, line up reflexively in actions that protect the status quo. Resistance to change is a most common obstacle to progress and cause of stagnation. It is a normal, human response that must be anticipated whenever considering taking a different path.

Perhaps an alternative phrase for would be 'fear of failure.' Our research showed many pharmaceutical professionals are philosophically receptive to change that could have positive impact on their jobs and relationships. Yet, many observe that other units or individuals exhibit behaviors that reflect barriers to change and/or implementation of new ideas. Additionally, there is prevailing feeling that change must come "from the top" – that, as individuals, there are significant limitations to their own authority to introduce change to the process.

Sometimes, change is discouraged by conventional mindsets operating within siloed areas. Some folks simply like the established and controlled experience, feeling it brings stability, fairness, and consistency to the process. Advocates for standardization argue greater adherence to common practice yields efficiencies and builds confidence in the system. The more ardent supporters may query, "If it ain't broke, why fix it?"

Company and division goals can also be a deterrent to trying new things. A manager may worry that a new initiative that flounders may negatively impact the incentives and bonuses tied to objectives defined by past practice and anticipated growth. Failure to achieve a new initiative may deflate personal ambition and impact the opportunity to rise up through the ranks. For these reasons, it may seem safer to stick with the status quo.

And, finally, sometimes it is neither resistance to change nor fear of failure that stands in the way of doing things differently. It is plain old practicality. There is always more than enough work to get done. There is never enough time. Going through a lengthy bureaucratic process to obtain permission to deviate from standard protocol or forms can be "more effort than it's worth". It's easier to simply go along with the established expectation.

Individual leadership seems to be the common denominator for an approach to transformation and receptivity to new ideas. Without exception, those individuals who are currently involved with more collaborative and long-term CRO relationships reported they felt the freedom to operate. The prevailing sentiment was, if they should experience failure in any way, the team around them – especially their managers – has their backs. That unequivocal support carries huge impact on both attitudes and behaviors.

Conclusion: Fear of change/Fear of failure lurks silently, and can be a serious impediment to transformation. The good news is that leaders generally indicate they will embrace positive change when it brings improvement. An environment that provides unwavering support for the process as well as anticipation that, when trying something new, mis-steps may occur is critical. Leaders at the highest level possible must send this clear message.

PART 5: THE VIABILITY OF VESTED FOR CRO OUTSOURCING

Part 5 explores the viability of a using a Vested Sourcing Business Model for CRO outsourcing.

To help you understand if a Vested business model is appropriate, we turned to the University of Tennessee research outlining the business attributes that are conducive for a Vested model. The University of Tennessee provides an open source Business Model Mapping toolkit to help companies identify which Sourcing Business Model is most appropriate for their situation. The toolkit helps companies think through 25 business attributes. By working through the toolkit, companies such as Roche can best determine which Sourcing Business Model is most appropriate. The 25 attributes span across the following dimensions:

- What level of dependency exists between the buyer and supplier organizations?
- What is the overall availability of the service/product in the marketplace?
- To what extent is what you are outsourcing a "core competency"?
- To what extent is there business risk in what you are outsourcing?
- How much potential is there to create mutual advantage?
- What is the nature of the workscope?
- What is the criticality of the work?
- What are your risk tolerance preferences?

We have taken the knowledge from our secondary research and interviews and completed a hypothetical business model map for the CRO outsourcing spend category. We explore each of the dimensions and 25 attributes below, providing a physical "map" of each attribute on the sourcing continuum. Based on our observations, we highlight each attribute in orange color to indicate where we believe CRO falls on the sourcing continuum ranging from transactional contracting to relational contracting to an investment based model.

As the Business Model Map indicates, the nature of CRO demands professional workers and the highest quality, safety, and operational attributes. Our conclusion is ***the nature of the work and overall business environment is fraught with risk – making it a good candidate for a Vested model that shares risk and reward.***

Supplier Dependency. The Business Model Map indicated pharmaceutical companies would be best served with a relational contracting model. The industry scores high in the area of supplier dependency because interviews revealed that CRO suppliers needed a relatively high level of skilled personnel and the cost to switch suppliers can be steep. In addition, it was important that buyer and supplier relationships be integrated with a high degree of collaboration would be the most successful.

Attributes to Determine Best Relationship Model	Transactional Contract		Relational Contract			Investment
	A	B	C	D	E	F
Dependency						
Overall cost to switch suppliers	Low	Low	Medium	Medium to High	Medium to High	High
Physical asset specificity (location, machinery, processes)	Low	Low	Medium	Medium to High	Medium to High	High
Skill level needed for predominant personnel	Unskilled	Semiskilled	Skilled	Professional	Professional	Expert
Level of supplier Integration/interface required (systems, support processes)	None	Low	Medium	High	Very High	Critical

Availability of Service/Product in the Marketplace. The Business Model Map also suggests a relational contract for CRO efforts. Specifically, we believe that while there is a wide-to-moderate availability of CRO suppliers, the market needs more sophisticated suppliers than simple transactional models yield.

Attributes to Determine Best Relationship Model	Transactional Contract		Relational Contract			Investment
	A	B	C	D	E	F
Overall availability of service/ product in marketplace	Widely Available	Widely Available	Wide to Moderate Availability	Limited number of capable suppliers	Limited number of capable suppliers	Scarcely Available
Availability of human resources	High	High	Medium	Low	Low	Low
Availability of required technology	Universal	Limited	Restricted	Restricted to Scarce	Scarce	Unique
Access to buyer's critical systems and processes	None	Low	Medium	High	Very High	Critical

Extent that Service is a "Core Competency". Based on interviews, we scored the pharmaceutical's CRO spend sector as having some or a critical level of strategic impact. Innovation is key to the success with CRO suppliers playing a critical role in the ability to bring new products to market. While companies could insource CRO work (move to an investment based model), it is likely they will continue using suppliers to support them. For this reason, we believe a relational contract is most appropriate.

Attributes to Determine Best Relationship Model	Transactional Contract		Relational Contract			Investment
	A	B	C	D	E	F
Strategic Impact/Core Competency for Buyer	No	No	No	Maybe	Maybe	Yes

Extent of Business Risk. A successful CRO supplier can have positive (or negatively) impact the bottom line. The need for regulatory compliance and variability in demand also scored on the higher end of the continuum indicating a relational contract would be most appropriate.

Attributes to Determine Best Relationship Model	Transactional Contract		Relational Contract			Investment
	A	B	C	D	E	F
Degree of Business Risk						
Profit Impact (volume purchased, % of total purchased costs, impact on business growth)	None	Low	Medium	High	Very High	Critical
Service failure impact on end customer/brand experience	None	Low	Medium	High	Very High	Critical
Service failure impact on internal customer experience	None	Low	Medium	High	Very High	Critical
Regulatory compliance policy	Meet Standard	Meet Standard	Meet Standard or Higher	Meet Standard or Higher	Meet Standard or Higher	Meet Standard or Higher
Uncertainty of demand	N/A	Manage unanticipated demand spikes with multiple sources	Provider response to unanticipated volume spikes limited	Contractual ability for supplier to respond to spikes	Contractual flexibility for supplier and client to respond to spikes to optimize the business	Capacity is set based on captive assets plus using market if not asset specific

Potential to Create Value. We believe that CRO services have a significant potential to create value. CROs have a high potential to increase a pharmaceutical company's revenue and drive innovation. For this reason we believe that an outcome-based economic model is best suited for CRO outsourcing.

Attributes to Determine Best Economic Model	Transaction-Based Economic Model			Output--Based Economic Model	Outcome-Based Economic Model	
	A	B	C	D	E	F
Potential to Create Value/Mutual Advantage						
Potential efficiency gains	None	Low	Medium	High	Very High	Significant
Potential for revenue increase	None	Low	Medium	High	Very High	Constant
Potential for innovation	None	Low	Medium	High	Very High	Critical
Size of investments needed in to achieve outcomes (buyer or supplier)	Low	Medium	High	High to Invest	Invest	Invest

Nature of the Workscope. The nature of CRO workscope aligns best for an output and outcome-based economic model. Based on the type of work that a CRO is performing, most have a degree of control over the outcome – even though there is considerable shared risk. We also believe that due to the strategic nature of the CRO services, companies should be looking to more strategic KPIs or business outcome metrics versus the transactional metrics they tend to rely on now. Lastly, we looked at the ease with which a CROs task/workscope can be specified. The ease can vary based on the type of workscope and spans across all areas. Most believe that CRO services have a significant potential to create value in virtually all of the categories.

Attributes to Determine Best Economic Model	Transaction-Based Economic Model			Output--Based Economic Model	Outcome-Based Economic Model	
	A	B	C	D	E	F
Nature of Workscope/Tasks						
Degree of supplier control over outcome	Low	Low	Low	High	Medium–High	N/A
Type of success measure desired/Required	Transac-tional Activity Metrics	Transac-tional Activity Metrics	Transac-tional Activity Metrics	Output SLA Metrics	Strategic KPI † or Business Outcomes	Strategic KPI or Business Outcomes
Ease with which task/workscope can be specified	High	High	Medium	Medium	Can Vary	Very Difficult or Impossible

Criticality of the Work. Next, we looked at the criticality of the work. We scored the risk related to operational safety to be critical because patient safety protocols are the highest priority. We also scored the risk related to operational reliability as high because we felt the performing the workscope to government regulations was essential to the safe and reliable nature of the products being delivered.

Attributes to Determine Best Economic Model	Transaction-Based Economic Model			Output--Based Economic Model	Outcome-Based Economic Model	
	A	B	C	D	E	F
Criticality of Work						
Risk related to operational safety	Minimal	Low	Medium	High	High	Critical
Risk related to operational reliability	Minimal	Low	Medium	High	High	Critical

Risk Tolerance Preferences. Lastly, we considered risk tolerances preferences for both the buyer and it's suppliers. We used our best guess based on our working knowledge from interviews and secondary research. We scored risk tolerance for pharmaceutical companies as wanting shared risk. We scored CROs supplier's risk tolerance to span all of the categories because we have seen suppliers that fall into all of these categories. In discussions with CRO suppliers, we know some of the suppliers are exploring outcome-based shared risk/reward economic models. For this reason, we believe that an outcome-based economic model (e.g. Vested) model is suitable– at least with some suppliers.

Attributes to Determine Best Economic Model	Transaction-Based Economic Model			Output--Based Economic Model	Outcome-Based Economic Model	
	A	B	C	D	E	F
Commercial Preferences						
Financial risk Tolerance for buyer	High Risk	High Risk	Medium Risk	Medium-Low Risk	Shared Risk	N/A
Financial risk Tolerance for supplier	Low Risk	Low Risk	Low Risk	Medium Risk	Shared Risk	N/A

OPINION

This white paper set out to answer "Is the Vested Sourcing Business Model appropriate for CRO outsourcing?" We believe the answer is a resounded yes. Secondary research and interviewees confirm that the pharmaceutical industry is not sufficiently served by transactional Sourcing Business Models and that it could benefit from shifting along the sourcing continuum to a Vested model. Pharmaceutical leaders, from the very top to middle managers, seek better results and are receptive to new ideas and approaches. While most interviewees had never heard of Vested before – most are clamoring for what Vested stands for; highly collaborative win-win relationships that promote achieve of outcomes – not just activities.

The Business Model Mapping exercise further validates our opinion. A completed Business Model Map of typical CRO initiative points to the need to have a relational contract with outcome based economics – thus a Vested Sourcing Business Model.

Emmanuel Cambresy, former procurement leader for Novartis's Supplier Performance and Innovation, group shares the following insight and advice about Vested.

> "If your executives have recently raised the need to **"closely partner with the business", "generate value beyond cost savings"** or **"drive innovation with strategic suppliers"** as some of their top priorities over the coming years, it looks like your procurement organization has started to fully embrace business goals by shifting its core purpose towards greater ambitions, rather than pushing for the delivery of short-term transactional sourcing objectives that are too often disconnected from the business agenda.
>
> "Regardless of the time and complexity of your journey, it will have to start with the early identification of your final destination, which should mirror the **"raison d'être"** of your procurement strategy. Ultimately, your **Desired Outcomes** should not only clearly state what you wish to accomplish for / with your internal customers in the future, but also be inclusive enough to form the base of a "friendly merger" with their own **Desired Outcomes** into **"One Shared Vision of Success".**
>
> "Just to clarify… All of this has nothing to do with the aggregation of their tactical performance targets with yours into another "joint performance scorecard", since the addition of short-term & selfish interests has always proven too weak and erratic to benefit all parties in place. Gathering competing ideas that look good on the surface might be tempting, but does not produce many results in reality as this kind of compromise remains strongly tied to politically-driven / win-lose tactics.
>
> "Instead, start to think of **"Everyone's"** understanding of **"Everyone's"** interests, powered by **"Everyone's"** willingness to partner and fuelled by **"Everyone's"** desire to drive the corporate strategy, as what ultimately triggers **"Value from / for Everyone"** (including your company, its end-customers and incidentally… you). In short, this is what **"The Sum of the Parts"** is about, and its highly consensual and holistic nature is precisely what makes it look difficult to reach. You might also remember this as **"What's In It For We" (WIIFWe)**, a mindset introduced by **Kate Vitasek** and recognized as the cornerstone of any successful partnership."[45]

A Vested Sourcing Business Model would enable pharmaceutical companies and their strategic CROs to purpose-build a contract designed to drive trust, innovation and accountability. We believe that those who apply the Vested model to strategic relationships should benefit much the way Procter & Gamble, Microsoft and McDonald's have benefited from Vested (see the book Vested: How P&G, McDonald's and Microsoft are Redefining Winning in Business Relationships for examples of Vested in practice).[46]

Today, only one company has explored Vested – Novartis - in the areas of supply chain management in Canada and facilities management in North America. However, no pharmaceutical company has yet used Vested with CRO suppliers. Our research revealed progressive suppliers such as Tepnal and Kelly OCG are willing and ready to explore Vested.

While we strongly believe Vested is a viable approach for CRO outsourcing, it is prudent to point out that shifting to a Vested business model would mean significant change for most pharmaceutical companies and CRO service providers. It would mean starting with a change of mindset. No longer would "strategic supplier" be judged on the size of spend. Rather it would mean reviewing CRO opportunities through the Business Model Mapping exercise that evaluated key areas such as the potential to create value, degree of risk, and nature of the workscope, and commercial preferences of both the buyer and potential supplier(s) involved. Having a pharmaceutical company and their supplier see the world through the same lens – is after all – a key first step in alignment of interests under a win-win Vested agreement. Likely harder will be changing from a "master-servant" mindset to a "What's in it for We" mindset where the CRO become as true partner with a mutual interests in driving innovation.

In addition, it would mean challenging some conventional procurement and contracting practices. For example, shifting to a more collaborative Request for Partner process versus the tried, true and heavily templated standardized RFP processes. And it would be challenging conventional contract structures as a Vested approach is based on a relational contract that acts a flexible framework to guide the partnership throughout the life of the project or relationship.

CONCLUSION

Research by BusinessWire forecasts that the global clinical trial service market will likely reach more than $64 Billion and the average clinical trial outsourcing penetration will likely reach around 72%. In other words, by then close to three fourths of clinical trials will likely be performed by professional CROs.[47]

With CRO outsourcing is here to stay, it becomes increasingly important that pharmaceutical companies get outsourcing right. Today's pharmaceutical professionals must learn to maneuver in an evolving environment that is more dynamic than ever. More and more this means balancing what seems to be insurmountable, conflicting goals of reducing cost structures, while, at the same time, driving innovation and mitigating risks.

These shifts point to a clear message: winning on the business battlefields of this century will be based on harnessing the power of your suppliers. Tomorrow's winners will no longer play yesterday's competitive win-at-all costs game with key suppliers. The playing field is no longer one of lowest cost or even best value, but one of highly collaborative relationships with suppliers that drive transformation and innovation for your organization. If firms are going to compete supply chain to supply chain, shouldn't all the links in the supply chain work together?

Simply put, to be successful, pharmaceutical leaders need to challenge the status quo as they think about how to move to more strategic, value creation models with its CRO suppliers.

The benefits of making the shift to a Vested business model are many.[‡] Most importantly, Vested partnerships can bring strategic and innovative results. Vested has the potential to lift an organization from the pack that desires strategic alliances, but has not as yet been able to accomplish them. Another immeasurable outcome of working closely with a reliable and trusted partner is peace of mind. It is immensely beneficial to know that a partner has your own organization's interests at heart, and will come through in any situation with value-added solutions.

The University of Tennessee research team would like to thank Roche's GPPG group for sponsoring the initial white paper exploring the viability of a Vested Sourcing Business Model in CRO outsourcing.

[‡] A detailed account of "How To Get Started" is provided in Appendix 2 of this paper.

APPENDIX 1:

Sourcing Business Model Architecture "Cheat Sheet"

	TRANSACTIONAL (MARKET)		RELATIONAL (HYBRID)			INVESTMENT (HIERARCHY)
	BASIC PROVIDER	**APPROVED PROVIDER**	**PREFERRED PROVIDER**	**PERFORMANCE-BASED/MANAGED SERVICES**	**VESTED**	**INVESTMENT (EQUITY PARTNER/ SHARED SERVICES)**
BUSINESS MODEL						
Business Model: Economic Model	Transaction Based (per Transaction, Hour or Unit)	Transaction Based (per Transaction, Hour or Unit)	Transaction Based (per activity, hour or unit)	Output Based	Outcome Based	Transactional, Output or Outcome Based
Business Model: Relationship Model	Transactional/ no relationship	Transactional/ Supplier Vetted on "Approved" List	Relational Contract— Emerging Collaboration	Relational Contract— Collaborative	Relational Contract— Highly Collaborative	Investment Based
Vision & Intent	Supply at Lowest Cost	Recurring Commodities at Fair or Lowest Costs	Value Added Capabilities at Best Value	Performance to SLA— Process Efficiencies	Shared Vision, Desired Outcomes & Value Creation	Sustainable Value
SCOPE OF WORK						
Statement of Work & Objectives	"Who" and/or "How"	"Who" and/or "How"	"Who" and/or "How" with Jointly Defined "How"	"What" Limited Emphasis on "How"	"What"	"What if", "What for" and "When"
PERFORMANCE MANAGEMENT						
Performance Focus	Simple Three Way Accounting Match	PO Requirements	Activity Based Service Level Agreements	Output Based Service Level Agreements	Strategic Desired Outcomes	P&L Based Measures
Performance Measures	Right Quantity, Right Price, Damage Free	Basic Provider Metrics + Increased Quality Emphasis	Operational + Customer Satisfaction	Operational + Relational (Values & Behaviors)	Operational + Transformational + Relational System Wide KPIs	Joint Measures of Success
PRICING						
Pricing Model & Incentives	Fixed Price/Typically No Incentives/Volume Rebates	Fixed Price/Low No Incentives/Volume Rebates	Fixed Price/Low Incentives/Volume Rebates	Price with Incentives and/or Penalties	Pricing Model with Value Based Incentives	P&L Based Equity Sharing
GOVERNANCE						
Relationship Management	Delivery & Pricing Validation (Three Way PO Match)	Some Performance & Pricing Oversight	Limited Supplier Relationship Management	Oversight Emphasis: Supplier Relationship Management	Insight Emphasis: Strategic Relationship Management	Shared Control and Management
Improve, Transform, & Innovate	None/Market Driven	Limited/Market Driven	Beginning to Focus on Incremental Improvement	Supplier Driven to Meet SLAs/Price Glide Path	Joint & Proactive Transformation Management	Core Innovation Capabilities
Exit Management	One Way/Limited Commitment to Buy	One Way/Termination for Cause & Convenience	One Way/Termination for Cause & Convenience	Perf Based Termination for Cause w/Safeguards	Joint Exit Management Plan	Divestiture
Compliance & Special Concerns	Compliance Driven/ Survey Based	Typically Compliance Driven/ Survey Based	Typically Market Based/Minimum Audit Requirements	Corporate Based Audit Requirements	Outcome Based Joint Requirements	Investment Based Joint Requirements

APPENDIX 2: Making The Strategic Shift

Having answered the question "Is Vested a viable model for the CRO outsourcing?" we believe the next question to ask is "how can the industry get started." We suggest an organization start small by piloting one supplier relationship first. Development of a Vested pilot project will grow its outsourcing capabilities within a controlled and limited environment.

GETTING STARTED

We recommend the organization start by completing a Business Model Map for various CRO relationships that have potential for partnership. This will validate if potential supplier relationships are a good fit for Vested. A Business Model Mapping exercise can be completed in a one-day workshop with key stakeholders coming together to use the University of Tennessee's Business Model Mapping toolkit.[§]

From there we recommend asking for business groups and suppliers to step forward as volunteers, treating your first implementation of a Vested agreement as a "pilot". We have found that referring to something new as a pilot helps foster a mindset that the team is ready to learn and try new things. We recommend setting this tone due to the 'fear of failure', which we noted previously. In addition, we have found volunteers who raise their hands are most receptive to change and more inclined to something new and different.

To help garner interest, the organization could leverage one or more of the readily available Vested awareness resources. For example, sharing articles, white papers, books, or even doing a workshop or webinar to introduce Vested to the various business units that are a good fit.

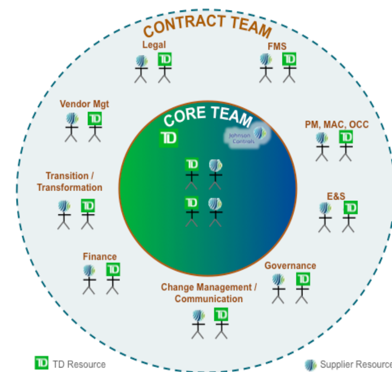
Once you have decided on a pilot, the project will need to fully follow all of the Five Rules / 10 contractual elements of a Vested Sourcing Business Model. We suggest the following steps once you have picked a pilot.

Create a Core Team.

All Vested projects start by developing a Core Team. Buyer and supplier team members are paired "two in a box" based on their roles. (Procurement/Sales, Finance/Finance, Legal/Legal, Operations/Operations) Core Teams usually consist of a minimum of 4 people (two from the buyer and 2 from the supplier) and typically no more than 12 people. Core Teams are often augmented with an "extended" team of various subject matter experts.

Figure 3 illustrates the TD Bank's Core Team and Extended Team, showing how the bank and its supplier teamed to create their Vested agreement.

Figure 3



§ *We recommend working with a Vested Center of Excellence to lead a professionally facilitated one-day workshop.*

Typically, at least one person from each company is 75% to 100% dedicated as a “Core Team Leader” with the remaining Core Team members spending 35% - 60% of their time on the restructuring effort. Extended team time commitment ranges from typically 10% to 50% based on their roles and phase in the contract. For example, finance team members will likely find themselves spending a significant amount of effort as they create a new pricing model that follows Vested Rule #4 – Pricing Model with Incentives that Optimize the Business.

Consider a Kickstarter

While many organizations jump right into completing a Vested agreement once a pilot and team are identified, many organizations choose some kind of kickstarter to build the confidence of the team – especially the Core Team. One option organizations find helpful is sending a small Core Team to the University of Tennessee’s Vested Outsourcing three-day Executive Education course in Knoxville. The course provides an emersion of Vested and gives team members a good roadmap of where they are going.

Others schedule formal kickoff workshops that are designed to bring the entire Core Team and Extended team together where they jointly get immersed into the *why* and *what* of Vested – which are essential primers before the team jumps into the *how.* The larger group also completes the first key deliverables – the shared vision, statement of intent, and high level desired outcomes – as a larger group. This gains significant buyin as all team members have a voice and opportunity to set the overall direction for the relationship.

Register for Creating a Vested Agreement online course

Once the Core and Extended Team is assembled, restructuring a relationship to a Vested business model typically takes between 4 ½ to 6 months.

Core Team members need to register for the Creating a Vested Agreement online course. The online course includes 17 modules (Modules 1-4 are part of the Vested Outsourcing Orientation). Typically Core Teams complete one module per week, ***which equates to roughly a four-month time frame to develop your deal***. However, the Core Team will develop a project plan using a template provided in the course to create a timeline that works for their unique schedule requirements.

Each module has assignments that – when completed – create the overall business agreement between the buyer and supplier. Upon completion of all assignments the parties will have created the 10 essential

Part 1: Laying the Foundation	
Introduction	How To Use This Course & Toolkit
Module 1	Getting Ready
Module 2	Contracting By The Rules
Part 2: Contracting by the Elements	
Module 3	Business Model
Module 4	Shared Vision & Intent
Module 5	Statement Of Objectives
Module 6	Performance Metrics
Module 7	Performance Management
Module 8	Pricing Model - Part 1
Module 9	Pricing Model - Part 2
Module 10	Pricing Model - Part 3
Module 11	Pricing Model - Part 4
Module 12	Pricing Model - Part 5
Module 13	Relationship Management
Module 14	Transformation Management
Module 15	Exit Plan /Special Concerns
Part 3: Staying Vested	
Module 16	Finalizing Your Agreement
Module 17	Transitioning To Your New Agreement

elements (refer to table) of a Vested Agreement.

The agreement should be vetted "in flight" by the companies' management as part of the process through a series of five Gate Reviews – one corresponding to each of the Vested Five Rules. The legal department should also be included early in the process to gain understanding of the Vested mindset.

The Vested implementation process stresses a ***"learning by doing"*** approach where team members learn – and then act. This is accomplished in a three-step cycle for each of the 17 modules that follows the contract development cycle. First, team members complete a module of the online course to "learn". Next, team members apply their learnings by collaborating to create the tools/templates and make decisions outlined in the course. The third step is for the team to come together in a workshop setting that is professionally facilitated by a Vested Center of Excellence (professionals licensed and trained to coach buyer-supplier teams to successfully create a Vested agreement). The coach reviews the team's work and facilitates the team through finalizing their deliverables.

This learning by doing approach ensures the teams fully understand the why, what and how of a Vested agreement. It also allows them to pace the execution to a formal project plan that works for their situation. By the end of the process, there is not only buy-in, the team has developed a complete contract ready for execution. Our methodology DRIVES the change – the team CO-CREATES the ultimate agreement. This is important because extreme buy-in is required. The process differs from conventional "consulting" approaches – where work is "done" but not "embedded" – because the team becomes knowledgeable content experts. The process develops strong, collaborative leaders who are committed to educate people so that knowledge and skills reside in house and relationships become sustainable. For example – P&G is in its 14th year, Microsoft is in its 8th year.

Pilot Post-Mortem – Determine Next Steps and Broader Application of Vested.

With a pilot under your belt, the organization can then determine the next steps for application of Vested in a broader context. Many organizations simply use a Business Model Mapping exercise to pick a second pilot project and repeat the process – taking lessons learned and becoming more efficient the second time around.

Because creating a Vested agreement involves a steep learning curve, we highly recommend nominating 1-3 team members from the pilot to continue their Vested education by becoming Certified Deal Architects (CDAs). The University of Tennessee CDA program is modeled after the Six Sigma black belt program where individuals learn to not just "do" – but lead and teach their organization in future projects. The CDA program consists of six courses (2 offered onsite at the University of Tennessee in Knoxville and 4 online/remote courses). Figure 4 (following page) provides an overview of the CDA program.

Figure 4: Overview of Certified Deal Architect Program

RESOURCES

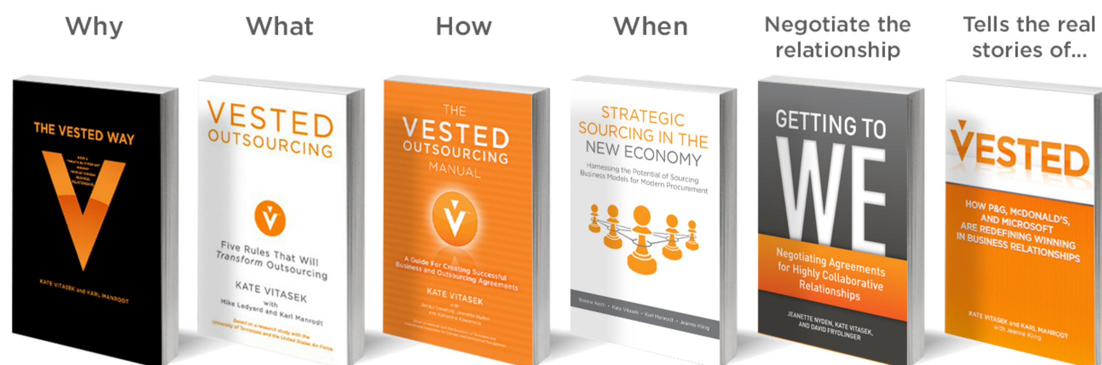
The University of Tennessee offers a tremendous amount of open source materials to help you learn more about Vested. Roche can explore more resources such as our onsite and online course or licensed materials that can help you through your Vested journey. See http://www.vestedway/library.

ACKNOWLEDGEMENTS

The University of Tennessee and the authors would like to thank the Sourcing Industry Group, the International Association for Contract and Commercial Management and the American Society for Public Administration for collaborating on this white paper. By joining forces the organizations hope to educate practitioners that it is important that procurement, contracting and business groups work together to determine the right Sourcing Business Model is matched to the right business environment and needs.

FOR MORE INFORMATION ABOUT….

The University of Tennessee is highly regarded for its Graduate and Executive Education programs. Ranked #1 in the world in supply chain management research, researchers have authored six books on the Vested business model and it's application in strategic sourcing.



For additional information visit the University of Tennessee's website dedicated to the Vested business model at http://www.vestedway.com/ where you can download white papers, watch videos, read articles and subscribe to the Vested blog. You can also learn more about our Executive Education courses in the Certified Deal Architect program as well as download the many resources and tools to help you understand and begin the Vested journey.
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[4] A Catch-22, based on the title of Joseph Heller's novel, generally is regarded as a no-win situation that uses contradictory circular logic. For instance, you may need a pass to enter a particular building, but in order to get a pass you have to visit an office in the same building.

[5] Purchase Price Variance (PPV) is a procurement metric that measures a procurement organization's (or an individual procurement professional's) effectiveness at meeting cost savings targets. The thinking about PPV is simple: If you spend $1.10 on a widget, then try to get the exact same widget next year for $1.00. The better the price that's obtained, the better the PPV.

[6] Nobel laureate John Nash's research into Game Theory showed that when individuals and organizations work together to solve a problem, the results are always better than if they had worked separately or played against each other. Similarly, the political science professor Robert Axelrod delved into the nature of competitive relationships, through his research into the Prisoner's Dilemma game. His book, *The Evolution of Cooperation*, showed that playing "nice"—or cooperating—led to the best results while maximizing mutual gains for all players.

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