A review of outsourcing business models in the CRO space.

Dr Vikki Renwick, Tepnel Pharma Services, Livingston, Scotland.

It is difficult in the modern world of pharmaceutical and biopharmaceutical development not to consider outsourcing as an integral aspect of bringing a new therapeutic agent from the early stages of discovery through to regular manufacture and distribution. The relationship between "Contract Givers" and "Contract Acceptors", as defined in the rules and regulations of Good Manufacturing Practice, has evolved significantly past the envisioned interaction of a buyer and seller or transactional relationship.

Whilst the regulatory framework within which the relationship is managed from a quality perspective, the commercial mechanisms for establishing and managing the outsourcing paradigm has moved on significantly to the point that in terms of pharmaceuticals and healthcare development the sector is slowly getting ready for the evolution in how these relationships are governed and executed.

So what is this "next step change?" University of Tennessee researchers have been studying outsourcing relationships for over a decade and have created a what they have coined as the "Vested" outsourcing business model. The University of Tennessee, College of Business Administration describe Vested as being,

"...a business model, methodology, mind-set and movement for creating highly collaborative business relationships that enable true win-win relationships in which both parties are equally committed to each other's success. When applied, a Vested approach fosters an environment that sparks innovation, resulting in improved service, reduced costs and value that didn't exist before — for both parties." [1]

The Vested methodology enables organisations to expand their understanding and application of traditional outsourcing partnerships which shift buyer-suppliers relationships from a "What's in it for Me" to a "What's in it for We" mindset and economics – truly creating win-win relationships.

This article explores the evolution of outsourcing models and then looks more closely to the future of outsourcing. We consider how pharmaceutical companies and their supply chain partners can make the shift to a Vested "What's in it for We" approach for structuring outsourcing contracts.

The Evolution of Outsourcing in the Pharmaceutical Industry

Developers and manufacturers of therapeutic agents or pharmaceuticals are no longer the behemoths that they used to be. The current estimated value of the outsourced drug development market ranges from minimally $28.75bn per annum[2] to more than $90-105bn per annum[3] depending on how or rather whom you include as being a part of the landscape. Irrespective of definitions and inclusion criteria, the outsourcing marketplace has and continues to grow at a compound annual growth rate which is reflective of a continued change in the way by which pharmaceuticals are researched, developed, brought to market and then routinely manufactured throughout the products lifecycle.

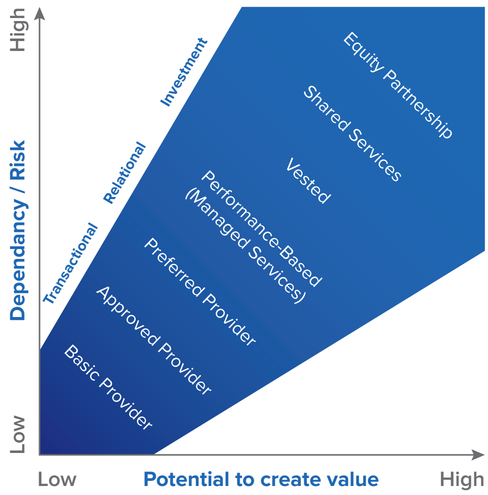
It would be nice to suggest that this evolution was a reflection of Darwin's model for "survival of the fittest" but in reality the journey from the days of pharmaceutical companies deploying an entirely integrated model to the increasing level of outsourcing is a much more complex and dynamic situation, driven by factors both internal and external to the industry. However, macroeconomics cannot be ignored and these growing and constantly changing elements are driving a shift from looking inwardly to drive innovation to looking externally to the wealth and breadth of organisations, across the healthcare spectrum, to help drive forward the next evolution of pharmaceutical development and manufacture.

Consequentially, the mechanisms through which "old school Pharma" engages with this shift change, in how they bring new therapeutics to patients, also need to be re-envisioned, with an awakening realisation that getting the best results and patient outcomes requires more than just picking and choosing suppliers to plug a gap. The models of outsourcing have changed and evolved with the ongoing changes in the pharmaceutical industry and with each progressive iteration of the model is a recognition that as Albert Einstein once said, "we cannot use yesterday's solutions to resolve tomorrows problems" and that the best partners are those who have a different mind-set.

In their research and subsequent paper Vitasek et al[4] are clear in their emphasis that each business on a case by case basis should always look to assess and select the model that is right for their outsourcing or procurement needs but they also advocate that moving to a more "sophisticated outcome-based sourcing business model for more strategic relationships that have the ability to create value and drive innovation".

Our review is focussing on the evolution of the business model from transactional, through performance and onto outcome based approaches as the most innovate and mutually beneficial approach. Figure 1 provides a graphically representation of how each of the models relates to both the dependency of the supplier relationship and the ability for the supplier to create shared value.

Figure 1: Sourcing Continuum Business Model Framework.



Source: Strategic Sourcing in the New Economy

As Figure 1 conceptually depicts, suppliers are able to create more value as relationships shift along the sourcing continuum towards business outcomes. However, this requires the buyer and supplier to work in a more strategic nature with higher levels of dependency. We are cognisant that other models are also being deployed within the sector, such as asset transfer/divestment from the contract giver to the contract acceptor or the insourcing model of the contract giver maintaining a facility or capability but "outsourcing" the recruitment and staffing to the contract acceptor. Neither of these models provides the landscape that drives the innovation, which delivers the desired outcomes or big payoffs for the company.

Transactional Outsourcing

At its most base level outsourcing is conducted using a pure transactional model. Through the adoption of this model, buying organisations purchase and pay for task level activities. Transactional business models have been in existence for centuries, the idea of paying someone to do something is not new. However difficulties start to arise when the complexity, variability and the mutual dependency also starts to increase as a part of the transaction.

Transactional outsourcing is by its very nature an at arm's length arrangement. Contract givers who adopt this model do not normally wish to engage in a dialogue or contribute any resource, time or effort in achieving the required output. There are a number of reasons behind this route as presented in Table 1 below but in essence it all comes down to a decision as to whether a company wants to spend the time/effort to "make" themselves or buy it in.

Table 1: Primary drivers for transactional outsourcing.

Reasons to Outsource	Why?
Non-core	Know what you do and do it well, use the talents and skills of others
Adds competitive advantage	Present a wider package of capabilities than the opposition
Creates arm's length relationship	Pick and choose at will, no relationship, loyalty no shared outcomes

Economically, for transactional suppliers nothing changes.

Transactional outsourcing works under three guises none of which deviate in principle from the recognised model but in terms of the outsourcing supplier can make a significant difference in terms of the value of the Contract Giver to the Contract Acceptor (Table 2).

Table 2: Types of Transactional Relationships.

Supplier Type	Characteristics of Relationship
Transactional Supplier	1. One of many suppliers 2. Typically low price services 3. Typically volume requirement 4. PO trigger or web shop
Approved Supplier	1. Unique differential from other suppliers 2. Cost or efficiency advantage from above 3. There is a clear differentiator which is Contract Giver specific, a. Geographical location b. Cost c. Quality 4. One of many/few pre-qualified suppliers in a pool of transactional based business
Preferred Supplier	1. Pre-qualified supplier who has demonstrated a measured level of performance 2. Demonstrable ability qualified around a. Experience b. Supplier rating system c. Compliance performance d. External certification

As a Contract Giver the journey from being a transactional supplier to a preferred supplier brings with it increased levels of expectation in terms of demonstrated capability, quality and experience (Table 3). However, preferred supplier does not equate to true win-win partnership and neither does it provide loyalty or commitment.

Within such a journey there are a number of stages that must be acknowledged, discussed and finally superseded.

Table 3: Attributes of Transaction Based Business Models[5.]

Relationship	Focus	Interaction	Co-operation	Level of Trust	Market Availability
Transactional	Cost efficiency	Standard T&C's, Fixed price	Low Automated purchasing process	Minimal Transaction by transaction basis	Abundant Easy to source No relationship required
Approved Supplier	Economy of scale	Blanket pricing agreements	Medium Based on pricing or specification	Medium Agreed terms Agreed pricing	Managed locally Cross functional
Preferred Supplier	Capability Capacity Technology	Statement of Works, Contract, Pricing agreement	Long Term Master service agreement	High defined contract agreed spend levels	Added Value and capability Less abundant

Transactional outsourcing at its most base level is both the simplest and most common method of engaging external support. It is however primarily driven by economics such that increasing pressure is placed on the contract acceptor to reduce price such that the contract giver can retain margins in highly competitive markets. Within transactional business there is no opportunity for relationship building and unfortunately most transactional relationships at either the approved supplier or preferred supplier status are still operated under a command and control structure, primarily dictated through the desired outcomes of procurement at the detriment of the other stakeholders.

It would be naïve to suggest that there is no room for transactional based business models as we move forward, simplicity of the relationship coupled with cost/price dynamics will ultimately ensure its survival but it is proposed that the manner in which transactional business is conducted will also have to change, as the virtualisation of Pharma.

Performance based business models

Where traditional transactional outsourcing, in its various guises, details a straight forward cash for *something* approach, the quality, consistency or reliability of the product or service purchased can remain variable. As with any transaction, there will be a set of "rules" or expectations which seeks to protect both parties but inevitably these extend to little more than each single transaction, do not look to the bigger picture and ultimately seek to protect only one party, depending on which side you sit on!

The development and manufacture of therapeutics and pharmaceuticals is both a highly regulated and expensive undertaking. Latest estimates on the total cost required to bring a new or novel pharmaceutical to market is $2.6bn[6] but even when the estimated costs of ca 10 years ago sat around the $1bn mark, something different had to be developed to ensure that those dollars invested in delivering new and innovative pharmaceuticals were not wasted. In essence a different form of governance was required to ensure that whatever was being purchased was effectively fit for its intended purpose or use.

Quality, consistency and reliability require that a different set of perspectives come into play. Performance based outsourcing brought with it the advent or perhaps rather the re-emphasis on service level agreements. A requirement for the contract giver and contract acceptor to transcend their relationship beyond the exchange of money for the goods or services to a situation in which the parties were required to agree, in advance, a set of parameters which would govern payment. These triggers are in principle based on delivery of a pre-determined set of outcomes that action a transactional payment.

Performance-based outsourcing is more about results and relationships than it is about the price of services or the financial resources of the contract giver. By this measure, it moves away from the basic fundamentals of transactional outsourcing but ultimately, performance based outsourcing is still a buying strategy that specifies the results needed by the contract giver, sometimes in agreement with the contract acceptors to create a competitive value, not to focus on the processes or the commitment of all the stakeholders to achieve those results.

Within a performance based outsourcing model, the key element is the aforementioned service level agreement. It is effectively the scope of works, the criteria which defines the expected results. It is acknowledged that the agreement provides value to the contract giver but often ignores or compresses the desired outcomes of the contract acceptor.

It maximises the mission of the contract giver to both gain competitive advantage through primarily cost saving measures against pre-determined levels of service or product functionality but also in achieving a position of maximum value for the contract giver against a promise of a term of commitment. For any service provider moving from any of the aforementioned transactional models onto one of promised stability and forecasted revenue. This is not an undesirable outcome.

Performance based business models also introduce an additional element of risk and reward, more commonly characterised by penalties for failing to deliver the agreed performance measures. The contract giver is rewarded on meeting the agreed performance measures but also penalised, through contractual clauses, for failure. Incentives to innovate or deliver in excess of the agreed measures are equally possible but less likely to be incorporated.

Performance based business models are an evolutionary step up from the transactional relationships earlier discussed. They move to a more structured form of relationship but not necessarily a partnership. As previously noted the service level agreement and performance measures are a procurement tool to maximise contract givers outcomes but they also provide a platform for the next evolution of outsourcing interaction which still, from a regulatory perspective sees a contract giver and acceptor but which allows for more dialogue and actual partner shipping to commence. Performance measures and key performance indicators are useful but they do not always add value or provide scope for innovation and in terms of outsourcing in the pursuit of value added healthcare, the best solutions are found through partnerships.

Outcome based business models

In 1960 Rolls Royce, the premium British motor car manufacturer of the time, adopted an outsourcing model across all of its businesses. It was centred around the concept of performance based logistics and was specifically designed to facilitate outcomes over transactions and performance measures.

"Performance Based Logistics (also commonly referred to as Performance Based Life Cycle Product Support and PBL) is an outcome-based product support strategy for the development and implementation of an integrated, affordable, product support package designed to optimise system readiness and meet the purchasers requirements in terms of performance outcomes through long-term product support arrangements with clear lines of authority and responsibility." [7]

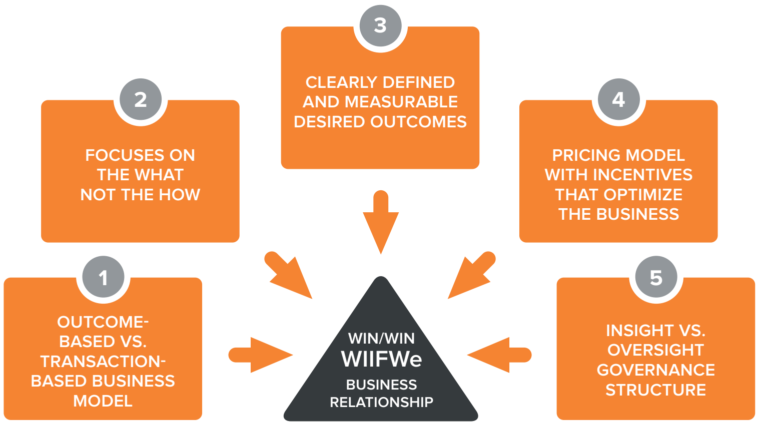
The basic premise of the model is simple, contract givers pay for or buy the results/ outcomes from the service they procure or use e.g., the value that is created. The partners, in the case of traditional pharmaceutical outsourcing the contract giver and the contract acceptor, agree a defined set of business or desired outcomes. The business transaction is in the achieving of the end result and not the myriad of transactions or performance indicators that are involved in the achievement of that result. Achievement of the result leads to reward, the parties agree their desired outcomes and then work together, in partnership and through innovation to achieve those outcomes.

Outcome based business models are not new and one example of this, the Vested business model is the research undertaken by the University of Tennessee. They did not "invent" Vested; rather researchers studied some of the most progressive outsourcing relationships and codified their findings into a set of five simple "rules".

These rules as can be seen in Figure 2, which, when applied and adhered to, have the ability to transform how outsourcing both works and is managed. Some of these outsourcing relationships have been in place for over 50 years and have consistently driven value for both the buyer and service provider over the decades. Others involved organisations consciously choosing to shift to highly strategic and collaborative relationships with a purpose to unlock innovation.

In conclusion, the way in which pharmaceuticals and therapeutic agents are being researched, developed and delivered to patients has changed significantly in the last 10 years. New models of working with partner organisations to achieve the vision and outcomes of precision medicines and value added healthcare have necessitated this change. In conjunction, the models by which contract givers and contract acceptors also require change.

Figure 2: Five-rules that will transform outsourcing



Benefits from adopting a Vested approach

- An increased focus on innovation towards achieving the intended results, not just the activities that are required to deliver them.
- Both parties are Vested in each other's success; with the associated risk and reward shared to align interests.
- Better competition: the partnership is not just about activities provided by suppliers, but solutions that co-create value.
- Consequential benefits whereby the shared focus increases the likelihood of meeting corporate goals and objectives.
- A working relationship that is mutually beneficial, sharing incentives which drive innovation and cost effectiveness.
- The adoption of mutually agreed Desired Outcomes which in turn creates ownership and a focus from all stakeholders to deliver.
- With an emphasis on Total Cost Ownership and Return on Investment, the Vested approach delivers sustainable results beyond simple "price" reductions.

The days of command and control do not meet with the expectations of 21st century collaborative working and a shift from a mind-set of "what's in it for me" to "what's in it for we" has the power to build alliances and partnerships which not only recognise but deliver on meeting the needs of all the stakeholders, building a mutually agreed set of objectives and deliverables that look to the long term rather than the here and now, unlocking innovation and ultimately improving patient outcomes.

References

1. Source: Used with permission. Vested®. www.vestedway.com. Vested Outsourcing, Inc.
2. Source: Global CRO Market, Transformation, Developments, Opportunities and Future of CRO Market, Frost and Sullivan, 2015.
3. Source: Resizing the Global Contract R&D Services Market, Tufts Center for the Study of Drug Development (Tufts CSDD), 2012
4. Strategic Sourcing in the New Economy: Harnessing the Potential of Sourcing Business Models for Modern Procurement, Bonnie Keith; Kate Vitasek; Karl Manrodt; Jeanne Kling
5. Source: Adapted from, Unpacking Sourcing Business Models: 21st Century Solutions for Sourcing Services, A White Paper by: Kate Vitasek, Bonnie Keith, Jim Eckler and Dawn Evans. In collaboration with: Jacqui Crawford, Karl Manrodt, Katherine Kawamoto and Srinivas Krishna, University of Tennessee.
6. Tufts Center for the Study of Drug Development (CSDD), 2014.
7. https://dap.dau.mil/acquipedia/Pages/ArticleDetails.aspx?aid=68d85f91-3fbf-4182-b55a-f2dbc5a33943