R&D Outsourcing Partner Selection: Factors Influencing Firms to Use Contract Research Organisations in Commercialising Biotechnology Innovations?

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Abstract

The principal objective of this study is to investigate the factors that influence biotechnology (biotech) firms to outsource research and development (R&D) activities to contract research organisations (CROs). Propositions are constructed from extent literature to create a framework as a basis to guide this research with potential future directions and limitations of the research then observed.

Keywords: R&D outsourcing, partner selection, biotechnology, drug innovation

Introduction

While copious scholarship has examined antecedents to firm decisions to outsource, relatively limited literature explores this from a biotech-CRO context (Bhalla & Terjesen 2013; Sen & MacPherson 2009; Molho 2013; Howells, Gagliardi & Malik 2008). This is despite extensive research confirming that biotech firms gain competitive advantages when they collaborate with external parties throughout the innovation and commercialisation lifecycle (Audretsch 2001; Gurau 2005; Terziovski & Morgan 2006; Hall & Bagchi-Sen 2007). This paper sets out a framework to examine R&D project-level outsourcing by biotech firms including factors influencing their decision to engage CROs.

For this research outsourcing is defined "as the transfer of activities and processes conducted internally to an external party" (Hätönen & Eriksson 2009, p. 142). A core firm capability often discussed in outsourcing literature relates to R&D outsourcing defined as: "concerned with the antecedence, processes, and implications of sourcing innovation from player's outside the firm's boundaries" (Hsuan and Mahnke (2011, p. 1). Grimpe and Kaiser (2010) outline that R&D outsourcing relates to a contractual agreement between the firm and supplier or vendor.

As the focal context of this paper relates to commercialisation practices within the biotechnology industry, it is important to recognise that varying definitions of biotechnology exist (AusBiotech 2011; Audretsch 2001; Ernst & Young 2001; OECD 2005; Friedrichs 2018; Friedrichs & van Beuzekom 2018).

Common to all these definitions is the recognition that biotechnology broadly relates to the development of innovative discoveries from living organisms such as bacteria, enzymes, yeast and mammalian cells, as opposed to man-made, synthetic innovations creations (Segal 2018; Ahern 2016; LaFleur 2008; van Beuzekom & Arundel 2006). The OECD developed the most recognised definition that forms the basis of this paper, defining biotech as:

> "The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services" (Friedrichs & van Beuzekom 2018, p. 8).

Central to biotechnology (biotech) commercialisation is the quick "transferring a product (technology) from the venture's R&D lab to the market" (Zahra and George (1999, p. 320). Equally important are arguably are being able to strategically exploit external networks, such as R&D outsourcing to achieving commercial advantages (Kunttu 2017; Bäck & Kohtamäki 2015). Today, contract research organisations (CROs) play a critical role in scientific R&D outsourcing. CROs captured over a third of global R&D drug development budgets in 2016, with predictions this will increase to 48% of budgets by 2020 (Wilson, Willoughby & Wallach 2016, p. 9). Since 2002, the United States (US) CRO Index reflecting the price growth of stock market listed CROs has significantly outperformed the American Standard and Poors 500 Index which captures the performance of the broader universe of stock market listed companies, capturing industry curiosity and attention (see

Figure 1) (Wilson, Willoughby & Wallach 2016; Wilson-Wright, Wallach & Tran 2017).

SUGGEST INSERT FIGURE 1 HERE

Supplier selection is a key aspect of R&D outsourcing having been discussed extensively in high technology industries like information technology (IT) (Shah & Swaminathan 2008; Edvardsson & Durst 2014; Tiwana & Bush 2007). Yet, relatively few have studied this from a biotechnology perspective, particularly in the area of drug development of human therapeutics (referred more commonly as drugs) and their relationships with CROs as suppliers of R&D outsourcing. This paper seeks to fill this gap.

It is important to explore the biotech industry because compared to other high technology R&D outsourcing situations, biotech commercialisation faces extreme complexities, cost, time restraints caused by regulatory oversight, increasing risks and uncertainties from which the firm and CRO must operate (Howells, Gagliardi & Malik 2008). Such research is important because of the critical role CROs play in aiding biotech commercialisation (Masri et al. 2012). Biotech ventures are attributed for: transferring discoveries out of universities; developing innovations through the commercialisation life cycle; and acting as innovation suppliers to larger biopharmaceuticals (Big Pharma) (Triulzi, Pyka & Scholz 2014; Buchholz & Collins 2013; Pisano 2006). Haeussler (2011) suggests "biotechnology is one of the sectors in which cooperative commercialization is regarded as an attractive means of commercialization."

While research has focused mainly on strategic alliances between universities, other biotech firms and Big Pharma particularly in regard to alliance forming and mergers and acquisitions (Oliver 2016), it has neglected CROs (Balconi & Lorenzi 2017; Masri et al. 2012; Howells, Gagliardi & Malik 2008). This is despite evidence that such relationships have fueled CRO growth to such an extent that in 2016 the global CRO market was valued at US$35.41 billion, with predictions to reach US$64.58 billion by 2021, growing at a CAGR of 12.8% (Frost & Sullivan 2017a, p. 8). Today, CROs have grown from burgeoning consultancy practices in the 1970s, to a heterogenous array of large multinational enterprises (MNEs) like Quintiles that offers turn-key full services to encompass all stages of R&D, to smaller, specialty niche

firms offering R&D outsourcing services primarily to the pharmaceutical, biotechnology and medical device industries (ENP Newswire 2017; Frost & Sullivan 2017b; Frost & Sullivan 2016).

Many firms consider outsourcing as offering access to complementary technical competencies, efficiencies in relative costs and other benefits (Xia & Gautam 2015). Yet, outsourcing incurs certain risks associated with internal firm capability dependence, knowledge loss and exposure to various opportunistic vendor behaviour (Lowman et al. 2012), making partner selection a critical first step.

The most salient issues regarding outsourcing, particularly as they relate to biotechnology firms, will now be outlined and propositions are then made. Each proposition is then subsequently aggregated into a potential framework to guide the future collection of primary data.

TECHNICAL COMPETENCIES

Resource based views (RBV) and extended theories relating to knowledge based views (KBV) often suggest that a key benefit of R&D outsourcing relates to access to having access to key tacit knowledge capabilities that underpin external firm technical competencies (Aziati, Juhana & Hazana 2014; Spithoven, Clarysse & Knockaert 2011). Howells, Gagliardi and Malik (2008) survey UK-based pharma firms where they discover that "research and technical capabilities" are the top ranked reason for CRO selection. A Tufts Clinical Trial Study found that: "on average those working at CROs were investing about 10% more frequently in all areas of study initiation (feasibility, identification, selection, and startup) and more frequently invest moderately to heavily across all areas when compared with sponsors" (Lamberti et al. 2018). CROs were found to dedicate more human capital, invest in better business processes, and had access to established relationships with investigators and site providers (Lamberti et al. 2018, p. 6).

However, technical competencies refer to more than just having access to skills and expertise, but that these are complementary or congruent with the firms internal capabilities (Shih 2015). In biotech, the ability to create complementary synergies of skills is paramount to project success (Bhalla & Terjesen 2013). This aids the firm to "focus on core competencies" as exemplified in Contract Pharma's top reason for outsourcing (Contract Pharma 2018).

Shih (2015, p. 87) suggests that: "Sponsors searching for a trustworthy CRO to conduct outsourced work look for corresponding technical competency, quality, turnaround time, and cost." Often firms will seek specific resources for broader strategic purposes like using CROs to gain access emerging markets and patient pools, or to access unique technology found in a particular country which the CRO has strong ties (Kamat 2014; Sahu 2014; Sariola et al. 2015; Joshi 2018; Xia & Gautam 2015). Bhalla and Terjesen (2013) case study of ten US-based emerging biotech firms propose that firms outsource to gain access to strategic resources. Balconi and Lorenzi (2017) interview 20 decision makers from 13 emerging biotech firms to find support for the view that emerging firms are dependent upon CROs in drug development because CROs specialise in gaining access to a greater depth and magnitude of tacit knowledge (Balconi & Lorenzi 2017, p. 489). This leads to the proposition:

Proposition 1: The higher the firm perceives their internal technical knowledge within the project's domain, the lower is the likelihood of outsourcing that project.

KNOWLEDGE SPECIFICITY

Both KBV and transaction cost economies (TCE) suggest that the ability for the firm to outline the precise project requirements goes to the heart of knowledge or asset specificity (Panda & Leepsa 2017; Subasingha, Sedera & Murphy 2012; Tiwana & Bush 2007; Zsidisin & Ellram 2003; Spithoven, Clarysse & Knockaert 2011). However, Howells, Gagliardi and Malik (2008) identifies that a key challenge faced

in biotech relates directly to both parties inability to predict project outcomes, requiring high degree of flexibility. Balconi and Lorenzi (2017) suggests that such situations often require firms to incorporate flexible contractual terms to prevent project failure.

Yet, a firm's inability to understand all aspects of the project often drives firms to use CROs because they have tacit industry knowledge of how to navigate regulatory approval processes and gain access to long established relationships with investigators, trial sites and patient pools (Xia & Roper 2016). This gap in tacit industry knowledge can be deduced from a Bioanalysis Zone Survey that lists "therapeutic/scientific expertise", "reputation for high quality service" and "technology capabilities as key reasons for selecting outsourcing partners (Craddock & Nadarajah 2017). Similarly, Contract Pharma Annual Reports identified "quality of service", "GMP" and "regulatory inspection history" as highly ranked considerations for selecting outsourcing partners (see

Table 1) (Contract Pharma 2017; Contract Pharma 2018). Getz (2006) outlines a Tufts Study that shows how firms typically use CROs for significantly more complex submissions to the FDA. The findings reveal that CRO submissions were submitted 30 days closer to the projected submission date with the same standards of quality (Kruse et al. 2014).

Proposition 2: Firms are more likely to choose to outsource a project to a CRO with higher knowledge specifiability.

TRANSACTION COST ADVANTAGES

Transaction costs discussed in TCE take into account not only the comparative cost savings (relative costs) of outsourcing (Bahli & Rivard 2003; Odagiri 2003), but also "direct and indirect expenses of negotiating, monitoring, and enforcing explicit and implicit contracts between firms" (Tiwana & Bush 2007, p. 263). Traditionally CROs arose at a time when Big Pharma was downsizing internal firm resources and seeking to achieve cost and scale flexibilities (Masri et al. 2012). Deteriorating sale prices coupled with elongated development costs and escalating timelines arising from the Thalidomide tragedy and subsequent enactment in 1962 of The U.S. Kefauver Harris Amendment, caused firm to seek for solutions outside the firm (Masri et al. 2012; Mirowski & Van Horn 2005).

While Big Pharma might have been the impetus to creating the CRO industry known today. Industry reports show that on average smaller firms (<$250 million annual revenue) lacking funds to acquire necessary infrastructure are responsible for outsourcing 68% of their R&D to CROs, as compared to larger pharmaceutical firms (43%) (Wilson, Willoughby & Wallach 2016). Sen and MacPherson (2009, p. 28) found that while cost savings was a "strategic driver" influencing outsourcing decisions but often failed to translate into reality with "37% of their [small to medium biopharma] respondents stated that outsourcing did not result in cost savings."

Contract Pharma Industry annual reports on pharmaceutical outsourcing suggests that costs might be a relevant selection criterion ranked it consistently below “Confidentiality”, “Quality” and “Regulatory Inspection History” (see

Table 1) (Contract Pharma 2018; Contract Pharma 2014; Contract Pharma 2015; Contract Pharma 2016; Contract Pharma 2017). Yet, Frost & Sullivan (2016, p. 3) suggests that cost-competitiveness when firms are evaluating CROs with similar quality and capabilities, cost becomes determining factor. Leading to the next proposition:

Proposition 3: The lower the perceived relative costs compared to the firm's own cost of doing the project internally, the higher likelihood the firm will outsource to that CRO.

PROJECT COMPLEXITY

The degree of project or task complexity is another aspect of outsourcing discussed often in TCE (Bahli & Rivard 2003; Odagiri 2003; Odagiri 2001). Outsourcing studies suggest that more complex projects benefit staying within the firm to avoid incomplete contract risks because vendor competencies may be limited, outcomes are uncertain often resulting in mounting unanticipated costs (Louviere 1988; Hardgrave, Davis & Riemenschneider 2003). In biotech, while the regulatory process of commercialising drug discoveries is typified as inherently complex, requiring extensive breadth and depth of different and idiosyncratic technological resources, such circumstances have the opposite effect, compelling them to seek multiple strategic alliances (Welter, Bosse & Alvarez 2013, p. 281). A Credit Suisse Report surveying fifty (n=50) decision makers identified that 77% of respondents indicated that increased complexity in clinical trials was driving them to use CROs, with just over a quarter (26%) seeking CRO services earlier in the project previously to avoid increasing elongated timelines (Wilson-Wright, Wallach & Tran 2017, p. 15). More complex areas like oncology and CNS was said to "represent the largest portion of revenue… consistent with industry commentary" (Wilson-Wright, Wallach & Tran 2017, p. 7). This draws to the next proposition:

Proposition 4: The higher the perceived technical complexity of the project, the higher the likelihood the firm will choose to outsource it to CROs.

OPPORTUNISTIC THREATS

Agency theory and TCE identify certain risk arising from vendor threats of opportunism (Guo, Hua & Jiang 2017; Kim & Mahoney 2005). This is defined as "lack of trust that a vendor will honestly fulfill project obligations" (Tiwana & Bush 2007, p. 266). Vendor observability is the flipside of opportunism, because it enables the firm to monitor and govern the behaviour of the supplier or CRO (Bahli & Rivard 2003; Guo, Hua & Jiang 2017; Kim & Mahoney 2005; Lamminmaki 2011). Opportunistic threats are not uncommon to biotech, having often associated with loss of IP and knowledge leakages arising from jointly created knowledge or knowledge gained by a CRO before or during the project (Howells, Gagliardi & Malik 2008). Lowman and Trott (2012) identified how dependence on CROs can produce certain "innovation risks" in outsourcing clinical trials including: information leakage; loss of core competencies; and loss of firm absorptive capacity (Lowman & Trott 2012; Lowman et al. 2012).

Yet, Kamuriwo and Baden-Fuller (2016, p. 1043) suggest firm reliance on external parties of core capabilities is not unwise or risky, but "an exemplar of pushing the envelope of boundaries to accessible R&D outsourcing." High levels of collaboration and communication are thought to aid in alleviating such concerns (Kamuriwo & Baden-Fuller 2016). Though, Hoecht and Trott (2006) find higher cooperative behaviour exposes firms to greater information leakages. Smed and Getz (2013) discovered establishing clear, transparent communication and collaboration guidelines throughout the process was paramount to success. Often establishing monitoring and governance mechanisms is offers as solution for mitigating such threats (Williamson 1979; Williamson 1981; Odagiri 2001; Spithoven, Clarysse & Knockaert 2011). Other strategies include: ongoing informal interactions (Narayandas & Rangan 2004); establishing coordinate learning between parties (Bailey, Leonardi & Chong 2010); use multiple suppliers/vendors to

minimise dependence (Slater, Mohr & Sengupta 2014); and basing relationships on reciprocal dependencies, such as requiring CROs to commit project resources as a way of ensuring project commitment (Balconi & Lorenzi 2017; Hall & Bagchi-Sen 2007).

Proposition 5: The higher the threat of opportunism perceived by the firm for a project, the lower the likelihood that the firm will choose to outsource to a CRO.

PROJECT OUTCOME MEASURABILITY

Project outcome measurability is defined as "the extent to which the outcome of a project can be precisely evaluated using predefined criteria such as project milestones, schedules, costs, and acceptable defect levels" (Tiwana & Bush 2007, p. 268). Agency theory suggests that establishing project milestones, incentives (and penalties) at the outset of an outsourcing relationship tied to performance enhances the project outcomes (Lamminmaki 2011; Panda & Leepsa 2017). Often these are embedded within contractual agreements, where firms agree to provide certain incremental performance incentives (Guo, Hua & Jiang 2017).

Howells, Gagliardi and Malik (2008) suggest that a central aspect of biotech is that outcomes are inherently uncertain giving rise to difficulties in the parties establishing complete contracts at the outset of a project. Kloyer and Scholderer (2012) discovered that "milestone dependent payments were ineffective as incentives against opportunism… (and) statistically unrelated to the degree of supplier opportunism in market-distant R&D collaboration" (Kloyer & Scholderer 2012, p. 355). They suggest that in R&D collaboration, suppliers are less likely to act opportunistically when buyers (firms) incorporate into the contract certain ownership rights, such as sharing in royalties or licensing opportunities (Kloyer & Scholderer 2012). Shared ownership rights promotes reciprocal dependence. Hu and Hafsi (2015) found that reciprocal dependence aided in risks associated with unobservability, uncertainty and incentive

misalignment (Hu & Hafsi 2015). Similar views are shared by Balconi and Lorenzi (2017) who suggest that contract should include flexible terms to anticipate uncertainty such as funding gaps so that projects are not stalled. In drawing these ideas together, the following proposition is:

Proposition 6: The higher the measurability of a project's outcome, the higher is the likelihood that managers will choose to outsource it.

FRAMEWORK

In discussing these above propositions, a framework is proposed to guide future exploration and theory testing (See Figure 2). This framework largely reflects an earlier study assessing project-level IT outsourcing in Japan and the United States (Tiwana & Bush 2007). Given biotech's various contextual idiosyncrasies, testing this framework within the context of biotech both extends our understanding of high technology outsourcing, and acts to confirm or contrast any contextual differences between IT and biotech.

To the authors knowledge, there is no empirically tested model examining R&D outsourcing in biotech. While some initial groundwork has commence with conceptual papers identify the CRO industry evolution as phenomenon (Masri et al. 2012; Howells, Gagliardi & Malik 2008; Balconi & Lorenzi 2017) and some case study analysis' (Lowman & Trott 2012; Bhalla & Terjesen 2013; Gupta et al. 2009; Gupta & Polonsky 2014), little scholarship offers a comprehensive framework to empirically explore and test R&D outsourcing in biotech (Gupta & Polonsky 2014; Gupta et al. 2009).

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CONCLUSIONS, LIMITATIONS AND FUTURE RESEARCH

In summation, as decisions are made from multiple perspectives exploring decisions from multiple theoretical perspectives such as provided in this framework is thought to produce a more complete picture (Bäck & Kohtamäki 2015). Initial steps have been made such as Bhalla and Terjesen (2013) who combined both TCE and RBV. Gupta et al. (2009) introduces the KBV exploring R&D outsourcing in the pharmaceutical industry offering several propositions ripe for future empirical testing, providing support for a framework that incorporates TCE, agency theory and KBV (Tiwana & Bush 2007).

In developing a framework, future studies might also wish to explore the difference between firm and CRO perspectives, in light of industry studies identifying misalignment of party perspectives (Craddock & Nadarajah 2017). Research might wish to compare firm-level selection decisions between different biotech indications (oncology vs. orphan drugs to address are illnesses) or compare decision making between the "various stages of the product development process" (Rothaermel & Deeds 2006, p. 203).

Certainly, given the emergence of CROs into developing countries like India and China (Kamat 2014; Sahu 2014; Sariola et al. 2015; Joshi 2018) it might be interesting to investigate different perspectives between an emerging country and more established biotech country like USA or UK. Likewise, proximity or geographic distance might impact on CRO selection. Mohiuddin (2011, p. 70) suggests that future outsourcing scholarship might wish to explore more global offshore aspects relating to the "underlying process leading to outsourcing decision… [or] the differences between the decision-making processes at small & medium sizes (SMEs) and large organizations…"

Recent evidence shows that virtual companies from locations like US and Australia are beginning to use Chinese CROs to serve as cost-effective partners to provide discovery and preclinical activities until the candidate reaches clinical stages, where they are able to sell or license discoveries (Xia & Gautam 2015).

All such suggestions are some of the many avenues that are underexplored when considering biotech R&D outsourcing.

Tables and Figures

Figure 1. CRO Index October 2002 to April 2016. Source, Wilson, Willoughby and Wallach (2016)

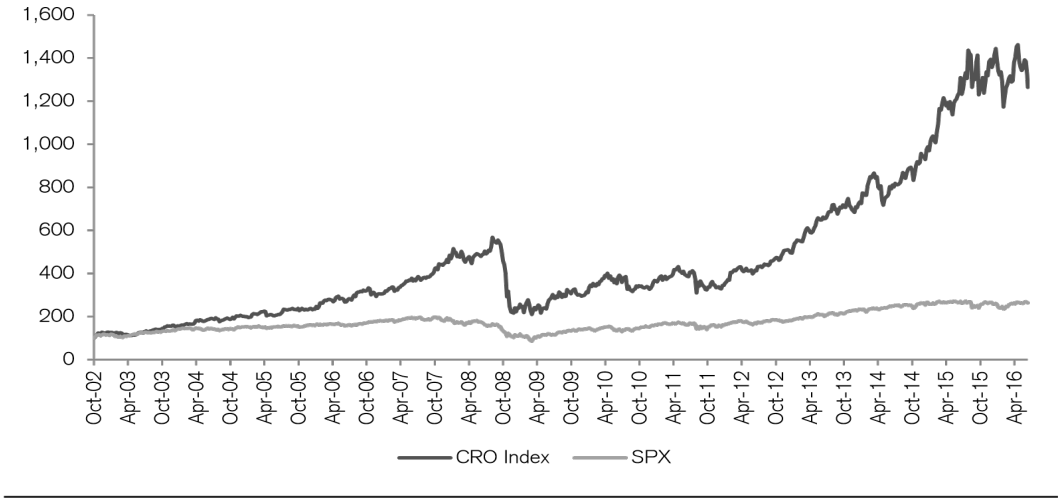
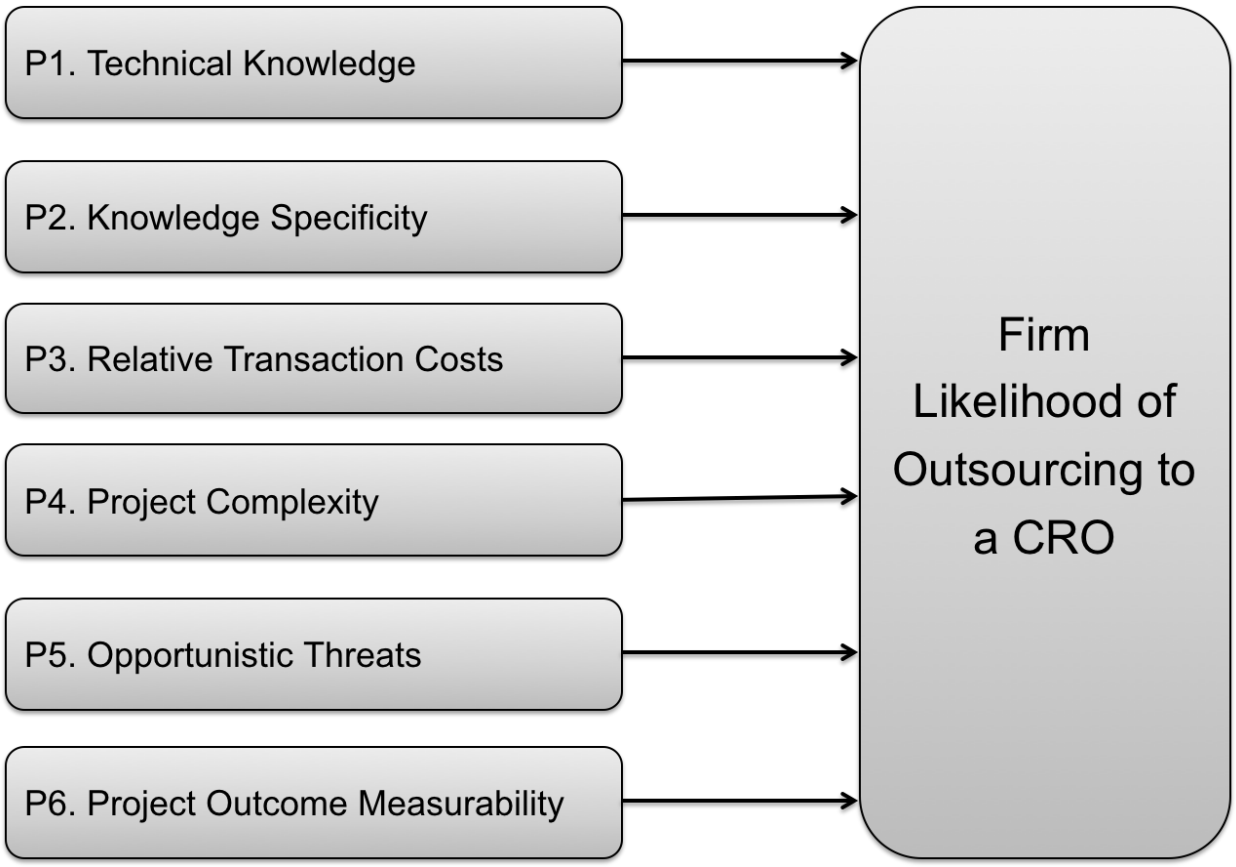


Table 1. Important selection criteria (#top 5 shaded). Contract Pharma Reports 2014-2018

Survey question: How important are the following factors in your selection of a Contract Service Provider (CSP) ranking 1 to 5?	Contract Pharma Annual Outsourcing Report (year)				
	2014 (Contract Pharma 2014)	2015 (Contract Pharma 2015)	2016 (Contract Pharma 2016)	2017 (Contract Pharma 2017)	2018* (Contract Pharma 2018)
Confidentiality	**4.68**	**4.78**	**4.67**	**4.65**	**4.65**
Consistency of performance	**4.77**	**4.79**	**4.80**	**4.78**	Not collected*
Cost	4.38	4.18	4.17	4.28	**4.45**
CSP Financial Security	4.44	4.19	4.23	4.28	3.51
Geography/Proximity	3.31	3.13	3.07	3.19	3.28
GMP	**4.62**	**4.57**	**4.59**	**4.72**	4.28
Innovation	3.82	3.33	3.52	3.72	Not collected*
"One-Stop" Set-up	3.54	3.27	3.41	3.51	3.72
Process optimization	4.07	3.75	3.99	3.79	3.72
Quality	**4.81**	**4.84**	**4.80**	**4.79**	**4.79**
Rapid availability	3.96	4.04	4.15	4.21	4.29
References	3.79	3.61	3.89	3.75	3.81
Regulatory Inspection History	**4.65**	4.54	4.49	**4.62**	**4.62**
Relationships	4.21	4.11	4.23	4.37	4.37
Size of CSP	3.40	3.30	3.24	3.26	3.36
Specific Technology	4.04	3.86	3.86	3.91	3.91
Timeliness	4.51	**4.63**	**4.48**	4.56	**4.56**
Value-added Services	4.11	3.83	3.89	3.95	3.95

Notes: #Top responses for each year are shaded. *2018 Report did not collect or identify these queries.

Figure 2. Decision-making framework



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