

**OFFSHORING AND OUTSOURCING OF CORE
CORPORATE ACTIVITIES: THE GLOBAL RELOCATION
OF PHARMACEUTICAL INDUSTRY CLINICAL TRIALS**

By

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ABSTRACT OF THE DISSERTATION

The Offshoring and Outsourcing of Core Corporate Activities:

The Global Relocation of Pharmaceutical Industry

Clinical Trials

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Prof. Farok Contractor

This dissertation examines the offshoring and outsourcing of core activities in the pharmaceutical industry. Using primary and secondary data sources, the dissertation adopts a multi-level approach to examine four research questions related to the sourcing strategies of core activities such as clinical trials. Specifically, I look at operational and strategic factors that influence the decision to relocate core activities both organizationally (in-house versus external vendors) and geographically (activities conducted in home nation versus trials in foreign countries). Drawing on Dunning's framework, the dissertation next examines the role of four motives (resource, market, efficiency and strategic asset seeking) in the offshoring decisions while distinguishing between offshore outsourcing and offshoring to foreign affiliates. Using multiple case studies, the third study further investigates the evolution of firms sourcing strategies from conducting core activities in-house to increasingly outsourcing and offshoring

them. The final study in the dissertation examines the impact of offshoring and outsourcing on the performance of core activities.

Data for this dissertation comes from multiple sources: Primary data from in-depth structured interviews and online survey of vice presidents of clinical affairs of pharmaceutical and biotechnology firms, as well as secondary data from Medidata, Orbis, and World Development Indicators.

The dissertation offers evidence that firms tend to use different sourcing strategies for different motives. Specifically, offshoring to foreign affiliates is primarily driven by strategic factors and firms tend to prefer this strategy for strategic asset seeking purposes. Offshore outsourcing on the other hand is motivated by resource and efficiency seeking behavior and the important determinants for this strategy are mainly operational. The third type of sourcing strategy is domestic outsourcing and firms are driven by both strategic as well as operational determinants for this strategy. The qualitative study on strategy evolution points towards a five stage process which begins with in-house sourcing followed by domestic outsourcing, foreign affiliates, offshore outsourcing and finally backsourcing of core activities. Evidence from the dissertation suggests that outsourcing has a positive impact on performance when compared to in-house while offshoring has a negative impact compared to domestic sourcing.

DEDICATION

To my parents, Suresh and Kalpana Thakur

My lifelong teachers, friends and my conscience. You encouraged me to dream
and gave me the courage to pursue those dreams.

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CHAPTER 1

INTRODUCTION

1.1 Framing the Context

Offshoring and outsourcing of core corporate activities is a relatively new phenomenon that has become increasingly important in the past few decades (Manning, Massini and Lewin, 2008). Traditionally, firms would retain control over their core activities, such as research and development (R&D) and information technology (IT), that are sources of competitive advantage but these processes are now becoming more geographically and functionally dispersed (Gammeltoft, 2005).

Recent changes in the techno-economic paradigm, such as cross-fertilization of technologies across disciplines and growing technological diversification of firms, have led to an overall increase in offshoring and outsourcing of R&D (Bardhan and Jaffee, 2005; Narula, 2001). Improvement in the policy environments, increase in global competition, and the associated increase in costs and risks of R&D are a few factors that have influenced the externalization of R&D. According to Cheng & Bolon (1993), the factors that contributed to the increase in internationalization of R&D are improvements in information communication technologies (ICT) as well as in social and economic resources, which provided better infrastructure in host countries. Increased

uniformity in international patenting also played an important role in internationalization of R&D activities.

According to Archibugi and Michie (1997), multinational enterprises (MNE) generate innovations through R&D and globalize them using three main strategies: 1) international exploitation of technology produced at home, 2) global generation of innovations through international R&D (internationalization) and 3) global technological collaborations (externalization). Prior literature has found that internationalization of R&D has gained significant importance since the late 1980s although firms from smaller European countries like Switzerland and Belgium had internationalized their R&D as early as the 1960s (Cantwell and Hodgson, 1991; Cantwell, 1995; Patel and Pavitt, 1991). Externalization of R&D has also been prevalent since the late 1990s (Hagerdorn, 2002; Howell, 1999; Jones, 2000; Narula, 2001) but most of the inter-firm collaborations were between firms of the same country.

While internationalization and externalization of R&D have been widely examined by the two separate streams of research (Cheng and Bolan, 1993; Gammeltoft, 2006; Narula, 2001), there has been little research on the combined spread of the firm's activities over all these strategies (Grossman and Helpman, 2003). What is novel in today's phenomenon is the emergence of a combination of offshoring to foreign affiliates as well as outsourcing to third party vendors by MNEs and the coincidence of externalization of R&D and its relocation. There has also been a significant increase in the extent of externalization and internationalization of R&D activities in the recent years (Howells, Gagliardi and

Malik, 2008). MNEs now have to make strategic choices, regarding the mix of R&D activities, such as whether to conduct the R&D in-house or outsource it as well as whether to do so within the home country or in foreign countries. Firms can now spread their core corporate activities across four sourcing strategies: *domestic in-house*, *foreign affiliates*, *domestic outsourcing* and *offshore outsourcing* (Contractor et al. 2010).

Table 1.1: The Global Spread of Core R&D Activities

Ownership	Geography	
	Domestic (Within Geographic boundaries)	Offshore (Outside Geographic Boundaries)
In-house (Within Organizational Boundaries)	A) Entirely In-House Activities Within the Headquarters Country	C) Entirely In-House Activities In Fully-Owned Foreign Affiliates
Outsourcing (Outside Organizational Boundaries)	B) Outsourced Domestically in the Headquarter Country	D) Outsourced From Foreign Providers (<i>Outsourcing AND Offshoring Combined</i>)

The framework adopted in this dissertation is the spread of core activities which is measured for the four sourcing strategies adopted by MNEs (see Table 1.1). The dimensions of this two-by-two matrix are geography and ownership. Quadrants C and D in Table 1.1 cover “offshoring,” – whether retained in-house

or provided by foreign vendors. Quadrants B and D covers “outsourcing,” to either domestic or foreign vendors. Quadrant A covers in-house functions that continue to be retained in the home country operations of the MNE. Quadrants B and D involve not only arms-length R&D providers, but also include strategic partners with whom the firm undertakes joint research (Contractor and Lorange, 2002) – something becoming common in many areas.

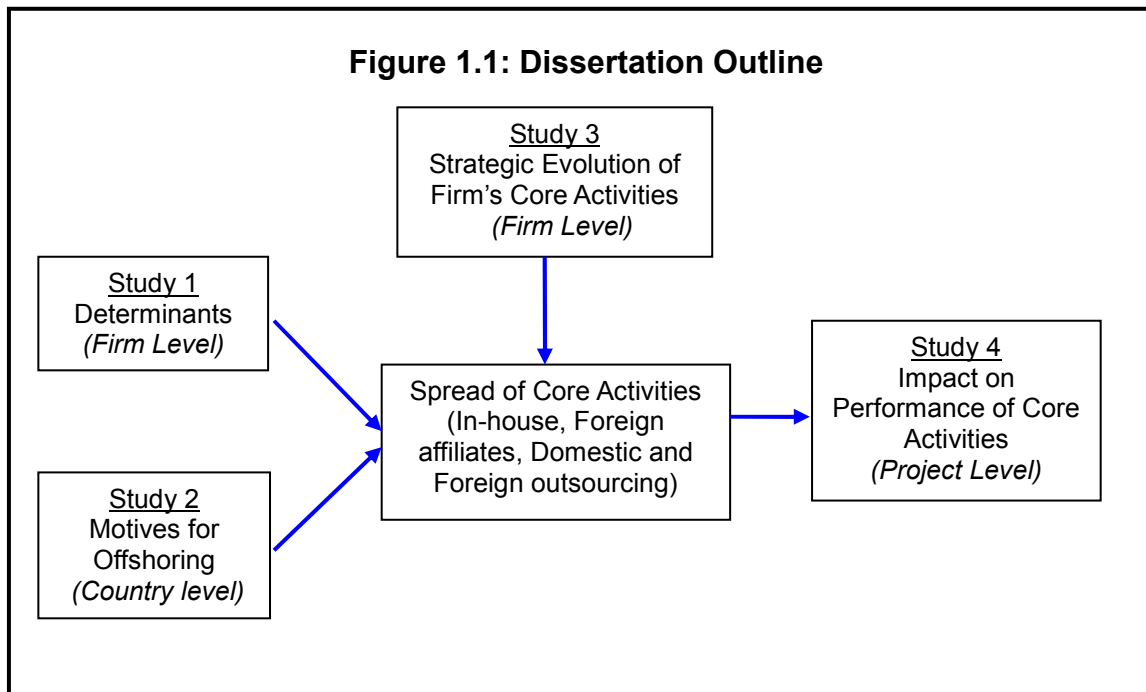
1.2 Research Question

This dissertation examines four research questions related to the spread of core activities of the pharmaceutical industry (See Figure 1.1). In the first study, I look at strategic and operational factors that influence the decision to locate core activities both organizationally (in-house versus external vendors) and geographically (activities conducted in home nation versus activities in foreign countries). The second study examines the role of four motives (resource, market, efficiency and strategic asset seeking) in the offshoring decisions of core activities while distinguishing between offshoring to foreign affiliates and offshore outsourcing (Quadrants C and D in Table 1.1).

Using multiple case study analysis, the dissertation next studies how firms evolve from conducting core activities in-house to offshoring and outsourcing them. Finally, the dissertation examines the impact of offshoring and outsourcing on project level performance of these core activities.

A recurring theme in all four studies is the change in the firm’s sourcing strategy, for core activities, over the past few years. The first two studies look at the antecedents of this phenomenon at the firm and country level. The third looks

at the process of this change while the final of the four studies looks at performance implications of this phenomenon.



1.3 Theoretical Background

This dissertation draws on various international business and strategy theories to study offshoring and outsourcing. The first study on firm specific determinants uses neo-institutional theory (DiMaggio and Powell, 1983; Levitt and March, 1988) to look at mimetic adoption of firms. The literature on corporate image (Fomburn and Shanley, 1990) is also used to develop hypotheses regarding the importance of maintaining corporate image of the firm in the sourcing decisions. The second study on offshoring motives adopts the Dunning's framework on FDI (Dunning, 1993) by looking at resources, efficiency, market and strategic asset seeking behavior of the firm.

The qualitative research on strategy evolution examines the different stages of sourcing strategy using the evolutionary perspective (Barnett and Burgelman, 1996). The final study on the relationship between offshoring-outsourcing and performance uses Transaction cost economics (Williamson, 1979) and Resource Based View (Barney, 1991) as theoretical lenses to examine outsourcing. This study also draws on the literature on internationalization-performance (Contractor et, al. 2003) and liability of foreignness (Zaheer, 1995) to look at the relationship between offshoring and performance.

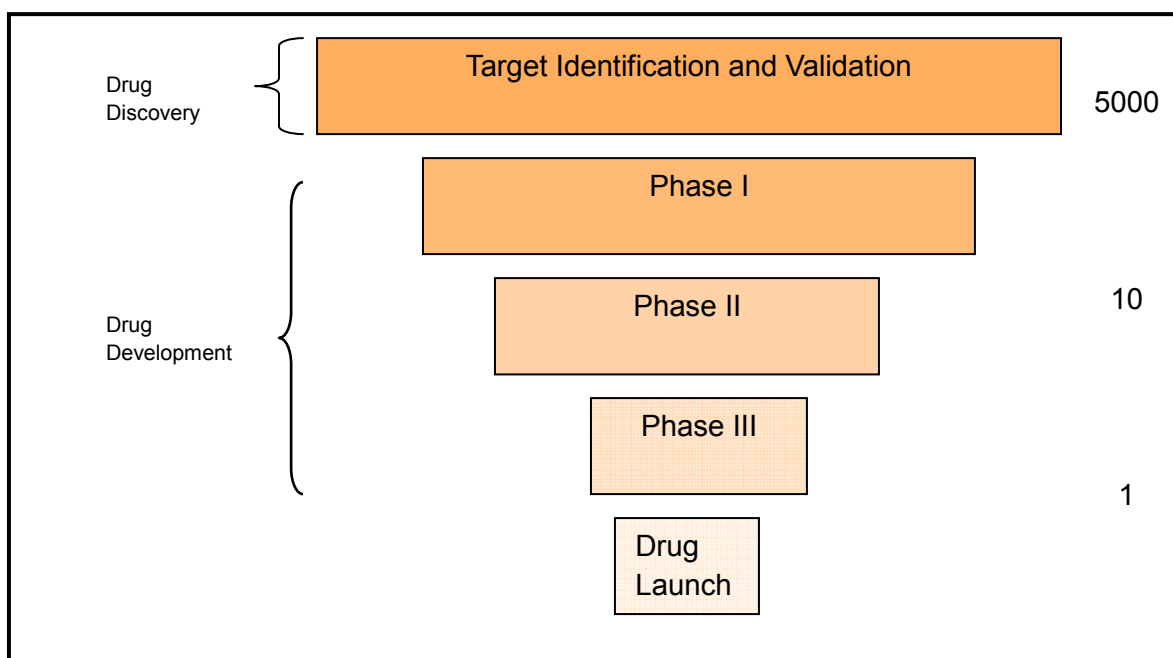
1.4 Research Setting

This dissertation examines offshoring and outsourcing of core activities in the pharmaceutical industry. The industry has heavy investment in R&D and traditionally the firms in this industry had developed full-scale capability to carry out a plethora of R&D functions (Piachaud, 2004). The pharmaceutical R&D includes many scientific and clinical activities which can be broadly divided into drug discovery and drug development. This dissertation focuses on the offshoring and outsourcing of the drug development process which primarily involves the testing of compounds, discovered in the earlier stages, on human subjects (Rettig, 2000). All new drugs have to go through clinical testing before they are submitted to the regulatory agency for approval (See Figure 1.2).

Drug development is a core activity in the pharmaceutical industry due to the high costs involved as well as the long duration of the clinical trials. The clinical trials account for approximately 42% of the total expenditure on R&D (PhRMA, 2007) and are important to overall cost structure of drug development

(DiMasi et al., 2003). During clinical trials, pharmaceutical firms are required to follow standards of good clinical practices and failure to do so can lead to rejection of the drug by the regulatory agencies. Since clinical trials are a bridge between drug discovery and marketing of the drug, they are considered a core activity by executives in the pharmaceutical industry. Efficient management of clinical trials is a source of competitive advantage as firms can improve profitability by reducing time to market.

Figure 1.2: Pharmaceutical R&D



The R&D expenditure has been increasing more than proportionally to the new drug approvals, thus it has become very crucial for pharmaceutical and biotechnology sponsors of research to constantly seek ways to leverage their constrained resources. Firms are trying to increase productivity while reducing costs by outsourcing to domestic and foreign third party service providers and offshoring to foreign affiliates. Political, economic, social and technological

factors have also forced the industry to move away from the traditional model of in-house R&D to a more dynamic and flexible model (John, 2006; Hall, 2000; Steiner et al., 2007).

Clinical trials have not been widely studied in the management literature although the other stages of the pharmaceutical R&D process have received significant attention (Henderson and Cockburn, 1994; Dierickx and Cool, 1989). According to Azoulay (2002) “the economic analysis of clinical trials process still remains in its infancy”. Thus by looking at clinical trials in this dissertation I contribute to the sparse literature on this important economic activity.

1.5 Overall Methodology

This dissertation contains four studies: three quantitative and one qualitative research study. The four studies look at the offshoring and outsourcing phenomenon from different levels of analysis using primary and secondary data. The first study focuses on determinants at the firm level. The determinants are divided into strategic and operational factors and the study also examines the structure of decision making process for sourcing strategies using nested tree structures.

Primary data is gathered from pharmaceutical and biotechnology firms using internet based questionnaire. The questionnaire was developed after preliminary in-depth interviews with Vice Presidents of Clinical Research of four large pharmaceutical firms and two smaller biotechnology firms. The survey contains questions regarding the firm and country level determinants for offshoring and outsourcing. The respondents were either Vice Presidents or

Directors of clinical trials who have knowledge of the overall spread of clinical trials.

Secondary data on clinical trials at the project level is obtained from Medidata Inc. (formerly known as Fast Track Systems), which provides panel data on clinical trials from 1997 to 2005 and covers both pharmaceutical and biotechnology sponsored trials. The empirical model is estimated using nested logit regressions.

The second study in the dissertation looks at four offshoring motives: resource, market, strategic asset and efficiency seeking motives. The study examines offshore outsourcing and captive offshoring (foreign affiliates) and compares which of the four motives is significantly important for each of the two offshore sourcing strategies. In addition to the data on clinical trials from Medidata, this study also includes country level data from World Development Indicators (WDI) and other country level indexes such as POLCON (Henisz, 2000). A negative binomial regression model is estimated to test the hypotheses in this study.

The dissertation also include multiple case studies of pharmaceutical firms and biotechnology firms to examine the path taken by firms from Quadrant A to Quadrant D in Table 1.1 and this contributes to the literature on strategy evolution. The firms selected for the case studies include US pharmaceutical firms and non US pharmaceutical firms. I also have larger pharmaceutical firms as well as smaller biotechnology firms in the study. The firms are selected to

maximize within case variation and to facilitate more in-depth analysis. Semi structured interviews and archival data was used for the case study analysis.

The dissertation also examines the impact of offshoring and outsourcing on the performance of the core activities. The relationship between offshoring, outsourcing and performance has not received much attention in the literature. The relatively limited prior research has found mixed or insignificant results on this relationship since performance was measured at the firm level (Bhalla et al., 2006; Gilley and Rasheed, 2000). The unit of analysis for this study is at the project level and data from Medidata is used to empirically test the relationship. Firm level economic data, obtained from Orbis, published by Bureau Van Dijk, is used to control for firm heterogeneity. Containing many years of detailed financial and operating data on global MNE parents, the ORBIS dataset is an excellent source of available data on the operations of MNEs. Heckman's two stage model is estimated to control for self selection by firms.

1.6 Summary

This dissertation explores four research questions related to the offshoring and outsourcing of core activities. My results suggest that firms tend to use different sourcing strategies for different motives. Specifically, offshoring to foreign affiliates is primarily driven by strategic factors and firms tend to prefer this strategy for strategic asset seeking purposes. Offshore outsourcing on the other hand is motivated by resource and efficiency seeking behavior and the important determinants for this sourcing strategy are mainly operational. The third type of sourcing strategy is domestic outsourcing and firms are driven by both

strategic as well as operational determinants for this strategy. There is a great deal of heterogeneity within the industries in terms of the percentage of offshoring and outsourcing of core activities. The results of this dissertation suggest that the variation across firms can be explained by the difference in firm's focus towards strategic and operational goals.

The qualitative study on strategy evolution points towards a five stage process which begins with in-house sourcing followed by domestic outsourcing, foreign affiliates, offshore outsourcing and finally back sourcing of core activities. Evidence from the research also suggests that outsourcing has a positive impact on performance when compared to in-house while offshoring has a negative impact compared to domestic sourcing.

The research contributes to the literature on offshoring and outsourcing which has mostly focused on the different typologies (De Vita and Wang, 2006; Erber and Ahmed, 2005; Gilley and Rasheed, 2000) or on entry decisions and location choices (Graf and Mudambi, 2005; Doh, Jones, Mudambi and Teegen, 2005). The bulk of R&D continues today to be performed within the parent firm of multinational companies. However, a transition is underway to devolve this function to (a) foreign locations and (b) to external service providers and/or alliance partners. By focusing on this transition, the dissertation addresses the gap in the literature on corporate R&D, which has traditionally focused solely on either internationalization or externalization strategies.

Most of the studies on the scope of the firm have either used survey data which has problems of endogeneity, or secondary data which may not correctly

measure the constructs. By using a combination of both methodologies, the dissertation overcomes these drawbacks and provides a better picture of offshoring and outsourcing phenomenon.

The next chapter offers a detailed literature review of offshoring and outsourcing as well as further examines the narrower stream of literature on internationalization and externalization of corporate R&D. The third chapter provides a macro view of this phenomenon as well as discusses the research setting in greater detail. This is followed by the fourth chapter which examines the determinants of the spread of core activities at the firm level (Study 1). The fifth chapter presents the findings on the motives for offshore outsourcing and captive offshoring (Study 2). The sixth chapter addresses the question of how firms evolve in their sourcing strategies (Study 3) and the seventh chapter discusses the relationship between offshoring, outsourcing and performance (Study 4). The final chapter integrates the findings from the four studies and offers some implications of this research.

CHAPTER 2

REVIEW OF LITERATURE

2.1 Introduction

In the last two decades, the study of offshoring and outsourcing has gained considerable attention by both mainstream media as well as the academic community. Recent discussions suggest that firms are now increasingly moving activities across geographical (domestic versus offshoring) and organizational (in-house versus external vendors) boundaries. When making sourcing decisions, firms choose from four strategies: domestic in-house, foreign affiliates, domestic outsourcing and offshore. Offshoring and outsourcing is no longer limited to peripheral and low-value-added activities as firms are now relocating their core activities that were traditionally retained in-house. Core is defined as critical or fundamental skills and activities that are required to create unique value for the customers (Quinn and Himler, 1994). According to Contractor et. al. (2010), some of the characteristics of core activities are: high strategic value to the firm, source of competitiveness, difficult to separate from the value chain and high transaction costs.

This chapter provides a systematic review of the prior literature on offshoring and outsourcing of core activities. The literature serves as the basis for the arguments and hypotheses developed in later chapters. The first objective of this chapter is to provide a review of significant theoretical and empirical research

on offshoring and outsourcing. Since this dissertation examines the offshoring and outsourcing of core activities, specifically R&D, the second objective of this chapter is to review studies that focus on internationalization and externalization of R&D. The third objective is to identify gaps in the literature reviewed in the earlier sections. I also discuss how this dissertation addresses some of these important questions and then conclude the chapter by summarizing some important contributions to the literature.

2.2 Review of Offshoring and Outsourcing Literature

Research on offshoring and outsourcing can be found in three literature streams: international business literature which predominantly emphasizes locational issues, strategic management literature which focuses on the boundaries of the firm and the supply chain management literature which examines the distributional aspects (Maskell et al., 2007). Drawing on studies from these three streams of research, the first subsection looks at the definition and typologies of offshoring and outsourcing. This is followed by a discussion of the theories commonly used to examine offshoring and outsourcing. The last sub-section reviews major areas of research in this literature.

2.2.1 Definitions and Typology

According to UNCTAD (2007) offshoring is defined as the relocation or transfer of activities abroad and this includes transfer of activities within the MNC network of foreign affiliates, (sometimes known as captive offshoring) – Cell (C) in Table 1.1, as well as to third parties (also known as offshore outsourcing) –

Cell (D) in Table 1.1. Outsourcing refers to transfer of activities to external third parties but this can be to domestic vendors – Cell (B) in Table 1.1, as well as to offshore vendors – Cell (D) in Table 1.1. Outsourcing is different from buying products from a separate entity in the market as it involves a two way exchange of information, coordination and trust (Erber & Ahmed, 2005). It refers to the ‘integration/disintegration’ decisions made by the firm (Gilley and Rasheed, 2000; Perry, 1992).

Both offshoring as well as outsourcing are based on the firm’s “...disaggregation of the value chain (and) combining the comparative advantages of the geographic locations with their own resources and competences to maximize their competitive advantages” (McCann and Mudambi, 2005). Pyndt and Pedersen (2006) also define offshoring as synonymous with productive activity taking place outside the home country (internationalization) and outsourcing with the productive activity taking place outside the firm (externalization).

Prior literature has classified offshoring into two broad categories based on the distance between the home and host countries. According to Erber and Ahmed (2005) and Chakarabarty (2006), nearshoring refers to the relocation of activities to destinations that are in close geographic proximity to the country of origin. Farshoring refers to relocation to countries which are geographically distant from the headquarters and the activities that remain in the country of origin are known as onshore processes. Mol, Tulder and Beije (2005) have proposed another typology for offshoring by distinguishing between international

outsourcing and regional outsourcing. According to them, free trade regions, such as the EU and NAFTA, reduce the transaction costs for sourcing and make it easier to offshore within the trading block. However, the distinction between nearshoring and offshoring, and regional and global outsourcing has not become popular in the recent research and thus in this dissertation the term offshore is used to denote all activities done outside of the home country.

There has been also been extensive research on the typologies of outsourcing. For instance, outsourcing can occur either through substitution or through absenteeism (Chakarabarty, 2006). Outsourcing through substitution is to the relocation of activities from inside the firm boundaries to outside vendors whereas absenteeism based outsourcing refers to the outsourcing of activities that had never been done in-house in the past. According to Mylott (1995), outsourcing can also be classified as: full outsourcing, where the vendor is fully in charge of all the activities and processes, and selective outsourcing where the vendor is in charge of one or a few activities.

Other studies have further classified outsourcing based on the type of relationship with the vendor (Mol et. al. 2005; Quelin and Duhamel, 2003; Sacristan, 1999). For instance, strategic outsourcing involves stable and long term collaboration with the vendor while arms length outsourcing is based on a purely short term exchange relationship between the two parties. Hunter (2006) has further extended this classification to include transformational outsourcing in addition to tactical and strategic outsourcing. Tactical outsourcing is used to achieve operational efficiencies and strategic outsourcing is done to achieve

better return on investment. On the other hand, transformational outsourcing is used to take advantage of new innovation and business models and also to reposition the firm in its markets.

De Vita and Wang (2006) proposed a more extensive taxonomy of outsourcing that traces the shift in the nature of outsourcing. According to them, there are three generations of outsourcing; the first generation outsourcing refers to contractual arrangements confined to the procurement of non-core competences such as payroll processing and security. This type of outsourcing became popular in the 1980s and was driven by the need to cut costs. The second generation of outsourcing became common in the mid 1990s when firms started outsourcing their near-core activities which had strategic importance such as software design and data processing. This generation also saw a movement towards outsourcing of services which was driven by the developments in ICT. The drivers for this type of outsourcing were primarily access to complementary resource and capabilities in addition to cost savings. The third generation of outsourcing that has become dominant in the past few years is the outsourcing of most if not all the value chain activities. This includes outsourcing of core competences such as R&D and is driven by efficiency, innovativeness and adaptation. In this current generation outsourcing is itself a core competence. By looking at core activities this dissertation focuses on the third generation of outsourcing.

2.2.2 Theories for Offshoring and Outsourcing

Two of the most widely used theories in the offshoring and outsourcing literature are the transactions cost economics (TCE) theory and Resource Based View (RBV). The transaction costs theory, developed by Coase (1937) has been used to study outsourcing and near versus farshoring of firm activities. This theory has received attention by the outsourcing literature since it explains why some activities are retained inside firm boundaries while others are outsourced. According to Williamson (1979), activities should be retained within organizational boundaries under conditions of uncertainty, asset specificity and continual recontracting.

There are two types of costs: production and transaction costs. While outsourcing reduces production costs, it also has the potential to increase transaction costs of an activity. Transaction costs are composed of many different costs such as searching and negotiating with partners and cost of monitoring and enforcing the contract (Agarwal and Ramaswami, 1992; Erramilli and Rao, 1993; Makino and Neupert, 2000). This theory suggests that only when transaction costs of market exchange are greater than the benefits of externalization then internalized operations are preferred (Brouthers, 2002; Hennart, 1991). This same line of reasoning can also be applied to offshoring of activities. According to Rugman and Verbeke (2007) firms are more likely to locate activities closer to their home country (near shoring) due to transaction costs associated with internationalization. Even if a firm locates its activities with foreign affiliates it incurs additional costs related to monitoring and coordination.

The second theory, RBV is popular in the strategic management literature. It focuses on the internal characteristics of the firm and views the firm as a collection of resources (Barney, 1991). When applied to offshoring and outsourcing, the RBV suggests that the internal resources and capabilities are strengths that should guide the firm's strategies (Grant, 1991). This theory has been used to analyze the relationship between the sourcing strategy and the external environment which in turn defines the boundaries of the firm (Rodriguez and Robaina, 2006). Researchers have used this theory to argue that firms can exploit resources by outsourcing and offshoring without extending the corporate boundaries. Some of the research questions examined with the help of the theory include the reasons for firms to turn to outsourcing (Gilley and Rasheed, 2000; Teng et. al., 1995) and its impact on organizational performance (Murray et.al. 1995; Poppo and Zenger, 1998). This theory suggests that firms do not necessarily have to depend on internal resources but can also acquire complementary resources from outside geographic and organizational boundaries (Argyres, 1996).

TCE and RBV have often been used to make opposing suggestion regarding offshoring and outsourcing. But on closer examination of offshoring and outsourcing using these two theories, it appears that whether an activity should be offshored or outsourced depends on the idiosyncratic resources required. Both RBV and TCE suggest that only resources and activities which are costly and firm specific need to be internalized.

The third theory that has been used to explain outsourcing is Agency theory. This theory has been used to examine the relationship between the firm and its outsourcing vendor. The theory was formulated to examine the survival of firms when there is separation of ownership and control (Fama and Jensen, 1983). Agency costs involved due to this separation include costs of monitoring, structuring and bonding which are quite similar to transaction costs. The most important focus of agency theory is on developing the most efficient contract governing the principal-agent relationship. The theory is applicable to outsourcing since the relationship between the firm and vendor is that of principal and agent. One of the important drawbacks of outsourcing is the losses incurred by the firm due to failed relationships with the vendor. Using the agency theory, Logan (2000) proposes a solution to design contracts and relationships that provide an environment of trust and reduce failure rates. The agency theory has also been used to study risk scenarios and associated risk factors of outsourcing (Bahli and Rivard, 2003).

Lastly, theories of internationalization (Johanson and Vahlne, 1990) and FDI (Dunning, 1979) have also been used to examine the offshoring of activities (Doh and Pearce, 2003). The OLI paradigm by Dunning (1979) suggests that firms internationalize their activities to combine firm specific ownership advantages (O) with location specific advantages of the home country (L). According to him most of these activities were internalized (I) and therefore the OLI paradigm is more applicable for captive offshoring to foreign affiliates. Recent discussions on the use of OLI paradigm in the context of offshoring

suggest that ownership and internalization are no longer relevant while location is the most important for this area of study (Doh, 2005). The literature on liability of foreignness (Zaheer, 1995) has also been used to examine factors that deter firms from entering certain host countries. Firms face liability of foreignness due to lack of familiarity with foreign cultures, environments and markets (Zaheer and Mosakowski, 1997). These theories have been used to develop theoretical frameworks to examine firm location decisions for offshoring (Bunyaratavej, Hahn and Doh, 2007; Graf and Mudambi, 2005).

In this dissertation, offshoring and outsourcing will be examined primarily through the TCE, RBV and internationalization theory lenses. Separate chapters will however draw on other theories such as internationalization-performance theory, Dunning's framework on FDI motives and the neo-institutional theory to explain this phenomenon.

2.2.3 Research Streams in Offshoring and Outsourcing

In this section I attempt to identify some of the existing and emerging themes of research on offshoring and outsourcing. This burgeoning literature on can broadly be divided into three streams of research. The first set of studies on offshoring and outsourcing examine the drivers and determinants of this phenomenon (Argyres, 1996; Gassmen et.al., 2004; Quinn and Hilmer, 1994). The second related research stream focuses on the location choice and entry decisions made by firms (Contractor and Mudambi, 2008; Doh et al., 2008; Mudambi and Tallman, 2008). The last group of studies look at the impact of offshoring and outsourcing on firm performance (Gilley and Rasheed, 2000; Mol,

Tulder and Beije, 2005). In the following subsection I look at these three broad research streams and discuss recent research.

Drivers and Determinants of offshoring and outsourcing

A spate of research studies on offshoring and outsourcing has examined the factors and drivers of this phenomenon at the country level (Aubert et. al., 2004; Klass et. al., 2001; Leiblein and Miller, 2003). There has also been some research on the determinants at the firm level but most of these studies have primarily examined the role of operational factors in sourcing decisions.

At the firm level, researchers have found that factors such as product diversity (Ono and Stango, 2005), prior experience in offshoring and outsourcing (Maskell et al., 2007) and financial leverage (Loh and Venkatraman, 1992) are positively associated to offshoring and outsourcing. On the other hand, determinants such as high degree of asset specificity and transaction frequency (Murray and Kotabe, 1999) are negatively related. Recent studies (Lewin et. al., 2009; Lewin and Peeters, 2006) have proposed other firm level determinants such as access to qualified personnel, growth, speed in market entry and the need to become global players.

Some other extensively examined firm specific factors are firm size (Borzekowski, 2004), R&D intensity (Mol, 2005), degree of internationally performed R&D (Hankson and Nobel, 1993) and prior firm performance (Loh and Venkatraman, 1992). Although widely examined, the findings for these factors were either inconclusive or contradictory. For instance, Ono and Stango (2005) find that larger firms have greater economies of scale which makes it more

difficult for them to outsource slices of their value chain but on the other hand these large firms also have greater bargaining power with outside vendors which make it more beneficial to outsource (Veugelers and Cassiman, 1999).

R&D intensity of the firm has also been examined as a driver for offshoring and outsourcing. Few of the studies suggest that R&D intensive firms may be discouraged from offshoring and outsourcing since it is usually more difficult to appropriate innovative activities that are not performed in-house (Mol, 2005; Teece, 1986) and the risk from opportunism is also higher (Williamson, 1985). But recent studies find that R&D intensive firms are outsourcing more in the recent years to remain competitive and access complementary resources and competences (Das and Teng, 2000; Santoro and Chakrabarti, 2002). Prior experience of the firm in international R&D is also an important determinant because of learning effects. According to Hewitt (1980), it takes some time for a firm to appreciate the advantages of international R&D and hence the more experience a firm has in conducting R&D abroad the more likely it is to internationalize further and experiment with offshore outsourcing.

Cost is also an important determinant of spatial and organizational fragmentation (Bettis, 1992; Bryce and Useem, 1998; Deavers, 1997; Jensen and Pedersen, 2007; Quelin and Duhamel, 2003). But cost cutting becomes even more important if the performance of the firm is poor. Poor performing firms are forced to streamline their activities (Loh and Venkatraman, 1992) and thus outsource to third party vendors. Outsourcing can not only reduce costs, due to economies of scale and scope of the vendor (Harrigan, 1980), but also improve

flexibility and efficiency (Dess et al., 1995; Quinn, 1992). According to a recent study by Huang, Chung and Lin (2009), the main reasons for outsourcing and offshoring R&D are costs reduction, minimizing business risks and hastening product market entry.

Prior firm experience in offshoring and outsourcing is a driver of this phenomenon since firms are path dependent (Lewin et.al. 2009; Pedersen and Jensen, 2007; Pisano, 1990). Firms with greater experience will offshore and outsource more complex and advanced activities as compared to firms with little to no experience. This is because the range of options considered by the firm are limited to internal sourcing in the absence of prior experience with offshoring or outsourcing (Hutzschenreuter et al., 2007).

This section discussed a few widely examined firm level determinants. In the next subsection I look at some country level factors which influence location choice.

Location Choices

Early studies on offshoring have looked at the location choices for firms and the factors that improve the attractiveness of host countries (Doh, 2005; Kotabe and Murray, 2004; Mudambi, 1995; Mudambi and Navarra, 2003). Much of the research on location choices has looked at the country level factors that increase the propensity of a firm to offshore outsource or use foreign affiliate to conduct certain value creating activities. For instance, Contractor and Mudambi (2008) examine human capital and information technology related factors that determine the attractiveness of a location for offshoring. They find that higher

human capital in the country has a positive impact on offshoring and the effect was especially greater for developing countries in Asia. Other researchers have also found that human capital is an important factor in location choice especially for business process outsourcing (Graf and Mudambi, 2005; Doh, Jones, Teegen and Mudambi, 2005).

Some other country level factors examined are telecommunication infrastructure and legal environment of the host country (Luce and Merchant, 2004). Overall infrastructure and institutions of the country are also key drivers for offshoring (Caldwell et. al., 2004; Kshetri, 2007; Mudambi, 1995).

Cost advantages offered by emerging markets such as India and China is an important factor that influence the location choices of firms especially from more developed countries (Carmel, 1999; Deavers, 1997; Flores and Aguilera, 2007; Girma and Gorg, 2004; Hunter, 2006; Lewin and Peeters, 2006). Greater cost savings from offshoring can be realized if there are significant differences between the home and the host country, particularly in terms of labor costs and wages (Cheng and Kwan, 2000; Dossani and Kenney, 2004; Woodward and Rolfe, 1993). But contrary to these findings, some newer studies have also found that a country is more likely to be attractive for offshoring of services if the wages levels are higher (Bunyaratavej, Hahn and Doh, 2007). According to this research, cost reductions in low wage countries are offset by poor quality especially for the service oriented industries.

Researchers have found that cultural differences between the home and host country increases the costs of offshoring and thus decrease the

attractiveness of the location (Bunyaratavej et. al., 2007; Gupta and Raval, 1999). In a recent study, Doh et. al. (2009) find that common language between the home and host country plays a role in predicting where firms offshore. Love and Roper (2001) examined the agglomeration and clustering of offshoring and outsourcing activities by looking at other locational factors such as population density, government R&D, and regional R&D intensity, GDP per capita, financial and regulatory barriers of host country. Agglomeration and clustering is also found to be an important factor in the recent years (Lewin and Peeters, 2006; Manning and Lewin, 2007). Another factor that influences the location choice is the size of home country (Mol et.al, 2005; Wyckoff, 1993; Ruigrok and Van Tulder, 1995) which is reflective of the local market. Many of the studies discussed in this subsection find that the preferred location for offshoring in the recent years is India (Hunter, 2006; Lewin and Peeters, 2006).

While most of these studies examine host country environmental factors that improve the attractiveness of the firm, recent study by Lewin et. al. (2009) looks at home country factors that drive the need for offshoring. According to them, shortage of skilled workers in developed countries such as US and decline in earnings of firms in these countries are the focal drivers of offshoring.

Impact on Performance

The third research theme looks at performance implications of offshoring and outsourcing. While much of the research on offshoring and outsourcing focuses on the drivers and determinants (Aubert et. al., 2004; Leiblein and Miller, 2003), relatively little has been done on its impact on performance. The limited

research on this relationship has focused primarily on the performance at the firm level (see exceptions Bhalla et al., 2008; Gilley and Rasheed, 2000; Leiblein and Miller, 2003). The studies that do explore this relationship still remain inconclusive on whether offshoring and outsourcing enhances or hinders firm performance. On one hand, there is some empirical evidence on the positive impact on performance (Bryce and Useem, 1998; Fixler and Siegel, 1999; Jiang et. al., 2006) but on the other hand, researchers have also found a negative impact on firm performance (Amaral, Billington and Tsay, 2006). However, most of the studies have not found any empirically significant results (Aron and Singh, 2005; Bhalla, Sodhi and Son, 2006; Ehie, 2001; Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005).

Some of the advantages associated with offshoring and outsourcing that can lead to positive impact on performance are cost improvements (Bettis, Bradley and Hamel, 1992; Fill and Visser, 2000), greater focus on core competences (Kotabe and Murray, 1990), flexibility (De Vita and Wang, 2006; Harrigan, 1985) and reduction in risk (Quinn, 1992). Factors that can have a negative impact on performance are decline in innovation (Kotabe, 1992), greater coordination requirements, reduction in control (Gilley, Greer and Rasheed, 2004) and excessive dependence on vendors (Alexander and Young, 1996).

The impact of offshoring and outsourcing on firm performance were measured using different performance indicators. Kotabe et.al. (1998) proposed three measures of performance to study this relationship and they are strategic, financial and quality measures. Some studies have used financial measures of

firm performance such as return on assets, return on sales and return per employees (Gilley and Rasheed, 2000; Gorzig and Andreas, 2002). Non financial measures used by this stream of literature include R&D outlay, innovation output (Gilley et.al., 2004) and market performance measures such as market share and sales growth (Mol. et.al., 2005).

2.3 Offshoring and Outsourcing of Core Activities

As the types of offshored and outsourced activities evolved from basic and codified, such as call centers, to more complex activities such as R&D, the literature has also gradually shifted focus. In this section I review research on internationalization (offshoring) and externalization (outsourcing) of core activities, specifically R&D.

Internalization of R&D is a recent phenomenon (Granstrand and Sjolander, 1990; Pearce and Singh, 1992) that has gained significant importance since the late 1980s although firms from smaller countries internationalized much earlier (Cantwell and Hodgson, 1991; Cantwell, 1995; Pavitt and Patel, 1999). This literature on internationalization of R&D has found that historically European multinationals had more foreign R&D locations than US firms (De Meyers and Mizushima, 1989). This is especially true for pharmaceutical firms from small countries as these firms can reduce high R&D costs by moving to other low cost countries. According to Gassman et al. (2004) high tech MNCs, operating in small markets with little R&D resources at home, carried out around 50% of their R&D resources outside home country by 1980s.

Externalization of R&D has also been examined by scholars from the late 1990s onwards (Howell, 1999; Jones, 2000; Narula; 2001) although most of this research has focused on inter firm partnerships, alliances and university firm linkages. Most of the externalization activity until recently was between firms of the same country. Due to the lack of international R&D collaborations there are limited studies which combine the internationalization and externalization of R&D. But this is changing as there has been a recent trend where firms are simultaneously engaging in a combination of captive offshoring as well as offshore outsourcing.

MNEs tend to follow three successive stages for generating innovations through R&D (Archibugi and Michie, 1997). In the first stage of this taxonomy, firms conducted most of their R&D at home and then exploited the innovations in foreign market. This was the strategy adopted by many firms prior to the 1980s. In the second stage, firms move towards generation of innovation through global R&D and this became popular in the 1980s. In the third stage, firms enter global technological collaborations and this stage signifies the externalization of R&D.

The MNEs have gradually evolved to the second stage as evinced by the recent increase in the total global R&D spending from \$438 billion in 1991 to \$576 in 1996. Firms no longer internationalize their R&D only to exploit their home based competences abroad with minor adaptations to the products. They now use offshore R&D facilities as 'listening posts' to track new technological developments and to generate new innovations abroad using foreign location specific advantages (Cantwell 1995; Chesnais 1992; Dunning and Narula 1995;

Pearce and Singh, 1992). Evidence of recent internationalization of R&D can be found in the distribution of R&D performed by foreign firms. The distribution indicates that in the 1990s most of the R&D was still being done at home while this has changed dramatically in the past few years (Archigugi and Iammarino, 2002). Thus with increasing internationalization of R&D, the nature of offshore R&D has evolved from competence exploitation to that of competence creation.

According to Gammeltoft (2005) there are six motives behind internationalization of R&D and they can be classified as: market driven (exploitation of home based assets), production driven (supporting host country production activities), technology driven (tapping into foreign S&T & monitoring other rival firms), innovation driven (generating new assets), cost driven (exploiting factor cost differentials) and policy driven (exploitation of local regulations and monitoring systems). Robinson (1988) also found an additional motive which is to take advantage of incentives provided by foreign governments such as R&D grants, tax write offs and direct loans.

The third stage in Archibugi and Michie' taxonomy (1997) is the externalization of R&D which, in some cases may occur between the first and the second stage. MNEs move their R&D activities outside the organizational boundaries although these collaborations were until recently limited to other domestic firms. Externalization of R&D is a complicated process which includes a range of inter-firm collaborations such as licensing, joint ventures, R&D contracts and outsourcing as well as quasi external activities such as strategic alliances (Narula 2001). Most of the prior literature in this stream focuses on inter-firm

partnerships and collaborations (Hagerdorn, 2002; Love and Roper, 2002; Ouchi and Bolton, 1988) but there is limited research on outsourcing as a mode of externalization of R&D. The overall literature indicates that there is a growth in inter-firm R&D collaborations since the late 1980s and early 1990s (Arora and Gambardella, 1994; Chesnais, 1988).

2.3.1 Recent Growth in R&D Offshoring

The recent increase in the internationalization of R&D can be attributed to several factors. These factors can be broadly classified into two groups: demand oriented factors to better serve the market and supply oriented factors to access location specific resources (Grandstrand et.al., 1993).

Cheng and Bolan (1993) also identified other factors that contributed to the increase in multinational R&D, such as improved information and communication technologies (ICT) that facilitated greater coordination; improved social, technological and economic resources that provided the necessary infrastructure as well as overall improvement in international patent protection which made it easier to protect foreign inventions. Other factors that have resulted in an increase in international R&D are: imitative behavior (Aharoni, 1966), shortage of scientists in developed countries (Hankanson and Zander, 1988) and pressure by host governments to establish R&D facilities (Behrman and Fischer, 1980). Firms are also moving their R&D to foreign locations to speed up the technology development process and to reduce R&D costs (UNCTAD WIR, 2005).

Gassmenn et al. (2004) suggest that the drivers of international R&D can be divided into science - technology related issues and sales - output efficiency factors. Science and technology factors are R&D personnel, know how sourcing and regional infrastructure while sales and output factors are proximity to customers and markets, improvements of image, and compliance with local regulatory requirements.

However in spite recent increases, R&D is still among the least internationalized functions of the MNEs (UNCTAD, 2005). Internalization of R&D is a highly complicated process as it introduces problems of geographic distance, market variations, language and cultural differences. These problems, while present in the internationalization of other activities, are significantly more complex for the R&D process (Fischer and Behrman, 1979). Since R&D is a risky activity other problems such as balance between coordination and autonomy also arise. Some other barriers to internationalization of R&D are political risks, immobility of top class personnel, leakage of knowledge and lack of trust (Grassmann et al., 2004).

2.3.2 Recent Growth in R&D Outsourcing

Externalization of R&D, more specifically externalization through outsourcing, has also increased in the recent years. According to Narula (2001), there are several factors that determine the choice between internal and external R&D activities and they can be divided into firm specific competences, evolution of technologies and the strategic environment. According to him, as technology becomes more mature and codified it becomes easier to outsource it to third

parties. Externalization of R&D is driven by push and pull factors and the combination of these two types of factors have made the firms aware of their lack of resources to conduct all their R&D in-house (Piachaud, 2004). Push factors are constantly changing technology, rising costs and high risks associated with R&D and the pull factors include the attractiveness of external sources of R&D (Sen and Rubenstein, 1990).

Outsourcing of R&D has received relatively little attention in the literature with a few exceptions (Howell, 1999). According to Howell, Galiardi and Malik (2008) outsourcing of R&D is different from other types of outsourcing because of issues relating to exchange, learning and trust. Specifically, the issue of prior disclosure and information asymmetry become important for knowledge intensive industries with high degree of uncertainty (Mowery, 1984).

The propensity to internationalize and externalize R&D varies across industries with consumer goods industries and resource based industries having higher degree of internationalization (Pavitt and Patel, 1999). Industries, such as aeronautics and motor vehicles, which have higher technological opportunities tend to have greater home country based R&D while the pharmaceutical industry has above average globalization and externalization of R&D.

2.4 Gaps in the Literature

Based on the above literature review, I now identify few gaps in the literature on offshoring and offshoring. I also provide a brief overview of how I plan to address these gaps in this dissertation.

The extensive literature on determinants of offshoring and outsourcing has primarily focused on operational factors such as financial leverage, access to qualified personnel, firm performance and prior experience. There is lack of research which has simultaneously looked at strategic and operational factors that influence the sourcing decisions of the firm. While studying operational factors would suffice for offshoring and outsourcing of basic and peripheral activities, there is a need to look at more strategic factors that are considered during the decision making process for core and complex activities. I contribute to the literature by examining strategic determinants such as the mimetic imitation and maintaining of corporate image along with operational determinants such as cost, quality and speed. Most of this research on determinants examines non-core activities and I address the gap in the literature by studying the drivers of offshoring and outsourcing of core and complex activities.

Prior research on location choice of offshoring activities has examined different country specific factors that improve the attractiveness of the host country. However the attractiveness of the location depends to a large extent on the motive of the investment and this has not received attention by prior studies. Most studies do not distinguishing between captive offshoring and offshore outsourcing and this is a gap in the literature since the motives for offshoring would also decide the choice between the two offshoring strategies. In this dissertation, using Dunning's framework (1993) for foreign investment, I look at the role of four motives (resource, market, efficiency and asset seeking) in the

location choice of R&D as well as the influence this has on the choice between foreign affiliates and offshore vendors.

The relationship between offshoring outsourcing and performance has also received scant attention by prior studies. Most of the existing research has been conducted at the firm level which could be a reason behind the inconsistent and inconclusive findings on this relationship. Firm performance is a function of many different strategies and it is may be statistically difficult to find impact from a single sourcing strategies. Mol et.al. (2005) recommended the use of more project level performance measures to better examine this relationship. In this dissertation, I use project level performance measures such as duration and cost of the project to examine the relationship between offshoring outsourcing and performance.

As also evinced by the review in this chapter, most of the research has looked at inputs (determinants) or output (performance) of this phenomenon without looking at the process in spite of the growing need for strategy process research (Malright,1995). In this dissertation, using multiple case studies I look at how firms evolve from conducting core activities in-house to offshoring and outsourcing them. Using the evolutionary perspective, I examine the strategy evolution of firms thus addressing the gap in process research.

2.5 Conclusion

This research contributes to the literature on offshoring and outsourcing which has mostly focused on the typologies of offshoring and outsourcing, location choices and entry decisions made by the firm. By examining the input,

process as well as the output implications of offshoring and outsourcing of core activities such as clinical trials, this research will improve the general understanding of offshoring and outsourcing.

This dissertation also addresses the gap in the literature on corporate R&D. Prior research has addressed either the internationalization process or the externalization process of R&D. There is a growing need to integrate these two streams of research. By simultaneously examining the spread of activities across the four quadrants of Table 1.1, this research provides a richer analysis of the process.

CHAPTER 3

CONTEXTUAL POSITIONING OF THE DISSERTATION

The previous chapter provided a review of the academic literature on offshoring and outsourcing. In this chapter I first discuss the macro-level trends of this phenomenon drawing on academic and non academic research. Since this dissertation focuses on the pharmaceutical industry, the second section narrows down to examine this phenomenon at the industry level and discusses some industry specific characteristics of offshoring and outsourcing. The third section provides a micro-level overview of offshoring and outsourcing of clinical trials which is a core activity of the firms in the pharmaceutical industry.

3.1 A Macro View of the Phenomenon

Offshoring of business processes has become increasingly popular since the early 1990s due to the technological advances made during the dot-com boom. These advances in ICT enabled codification of activities as well as better telecommunication systems. The near simultaneous liberalization and globalization of many developing economies such as India and China further fueled the growth in offshoring of activities from the industrialized countries of North America and Europe.

Initially, firms offshored primarily low value activities such as routine business office processes, call centers and basic software maintenance. But with greater competitive pressures and lower trade barriers, firms are now offshoring

activities which are higher up in the value chain. High value activities such as R&D, tax processing, market research and knowledge processes are now offshored to the developing countries to access skilled workers at a fraction of the cost.

Most of the offshoring is done by firms from developed country such as US and UK along with other countries of Western Europe. India continues to be one of the top ten exporters of services to these industrialized countries. According to A.T. Kearney Report (2009), on location attractiveness index, India is the most attractive location followed by China and Malaysia. There is however a minor shift in geography of offshoring with countries in North Africa and Middle East fast emerging as new locations for offshoring due to proximity to Europe (A.T. Kearney, 2009). Eastern European countries like Czech Republic were preferred locations for nearshoring by Western European firms but they have now lost some of their appeal due to rising wage costs. Many firms prefer to offshore activities close to home to avoid liability of inter-regional foreignness (Osegowitsch and Sammartino, 2008). Nearshoring is preferred especially by European firms who find intra-regional relocation cheaper due to similar institutional, legal, political and educational environments (Rugman and Verbeke, 2005).

Farshoring to India, while still very popular, has also been affected due to challenges arising from increasing wages and stronger currency which has reduced its competitiveness in the recent years. Many MNEs are now

considering alternatives to India and China and the importance of second tier locations such as Philippines, Vietnam and Jordan is increasing.

Two recent and interesting trends have been observed in the past couple of years stemming from the global economic downturn. First, while a few years back most of the offshoring was done by firms from developed country, now firms from emerging country have also started offshoring their activities. For instance, Indian firms such as Infosys and Wipro are offshoring to China and Eastern European countries. Second, many firms are bring back their previously offshored activities. Caterpillar is the latest firm to join in this trend to bring back its operations back home (Wall Street Journal, March 2010). General Electric is also planning to move its activities back from China to the US. This swing back to the home country is known as reshoring or onshoring and is primarily driven by weaker US dollar and Euro as well as initiatives from the home country governments to encourage growth of domestic industry to increase employment. Thus while due to globalization there has been an increase in offshoring of business processes this has also been accompanied by some recent reversal in trends.

Firms have also backsources some of their activities in the last few years as discussed in Chapter 6 on strategy evolution. Backsourcing is the internalizing of previously outsourced activities. Onshoring and backshoring trends suggest an optimal level of offshoring and outsourcing and firms tend to bring back their activities once they pass this optimal level because of higher costs. As evinced by the research on strategy evolution, firms that outsource extensively may face

problems in coordinating the various vendors especially if they are foreign. The study on performance in Chapter 7 also provides evidence that the performance of core activities decreases with offshoring. Since offshoring involves higher transaction costs, the obvious benefits of locating in low cost countries are often eroded leaving offshoring to be a more expensive option. Thus the recent trends of reversal can be explained by the crossing of the optimal level of offshoring and outsourcing by firms.

Firms usually offshore activities through their foreign affiliates as well as through offshore vendors. According to the Bureau of Economic Analysis (BEA), offshoring by US firms to their foreign affiliates has increased from \$183 billion in 1999 to \$364 billion in 2008. During this ten year period the average growth rate of offshoring to foreign affiliates was 8.3 percent although there was a dramatic decline in 2001-2002. This decline suggests that while offshoring to foreign affiliates is increasing, high political and economic risks can lead to a downturn. More recent years since 2005 saw a sudden increase in offshoring at the annual rate of close to 16 percent. The American firms prefer to use foreign affiliates especially for computer and information services as well as R&D. As of 2008 these two functional areas accounted for approximately 25 and 21 percent, respectively, of total services offshored by US firms.

Outsourcing is one of the fastest growing industries worth approximately \$500 billion in 2009 (Plunkett Research, 2008). This industry has seen rapid increase both in domestic and offshore outsourcing. According to Plunkett Research the three main functional areas that are outsourced are: 1. Logistics

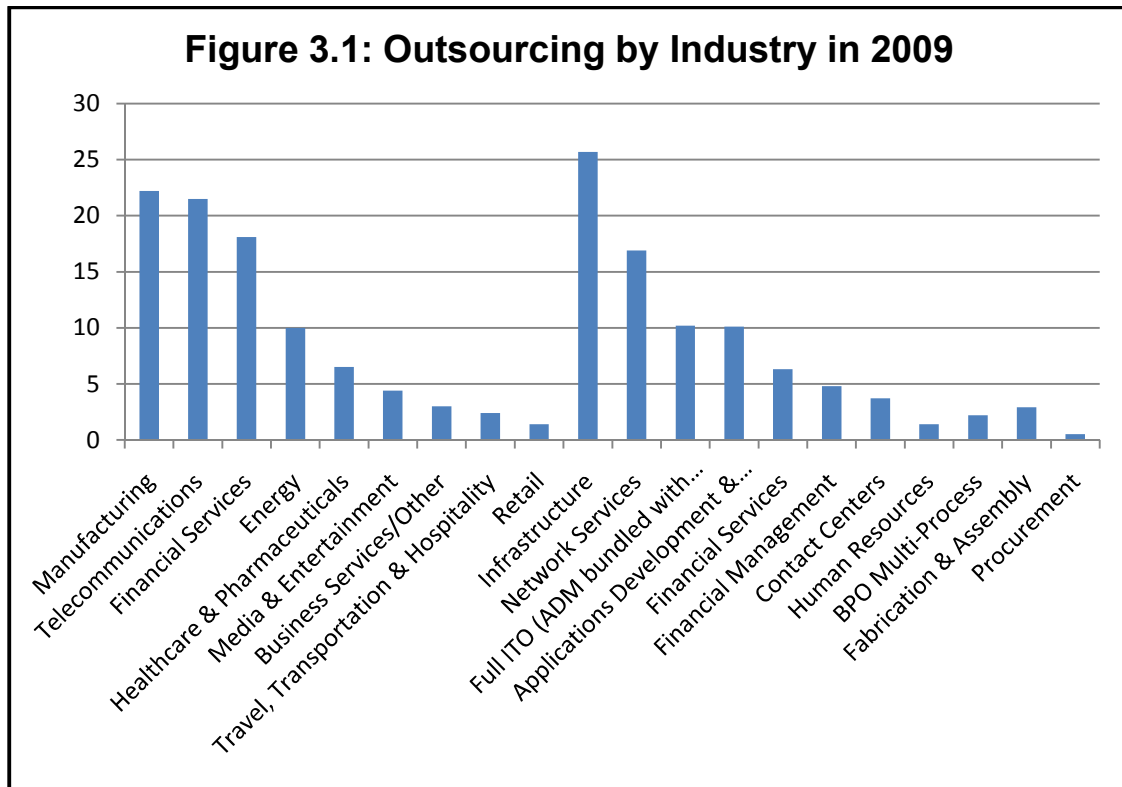
and distribution, 2. Information technology services and 3. Business processes such as call centers. Outsourcing logistics and distribution to third party logistics (3PL) firms is often used by MNEs to ensure efficient flow and storage of raw materials and goods. IT services is also one of the largest functional areas outsourced with global spending close to \$1.5 trillion in 2009 and India accounting for 51 percent of the market share for IT outsourcing (NASSCOM, 2009). Worldwide business processes outsourcing saw a growth of 12.3 percent in 2008 and India continues to be a key player in the offshore outsourcing with annual growth rates of 18-20 in business process exports (NASSCOM, 2009). Other functional areas that are outsourced include R&D and manufacturing.

An important change in the trend in offshore outsourcing is the weakening of the US firm's dominance as the source of outsourcing contracts. According to the study by Plunkett Research (2009), \$89 billion were spent on global outsourcing contracts in 2008 of which \$27 billion came from the Americas while Europe had higher expenditure with around \$50 billion in a single year. This shows that while North American firms are outsourcing, they lag behind European firms. North America has been the highest outsourcing region until recently but that is changing in part because of a trend towards back sourcing and onshoring by American firms as well as higher spending by European firms.

Figure 3.1 shows that industries also vary in terms of outsourcing their activities. Infrastructure is the most outsourced industry followed closely by manufacturing and telecommunications. The first wave of outsourcing was driven by the manufacturing sector which still continues to be one of the industries with

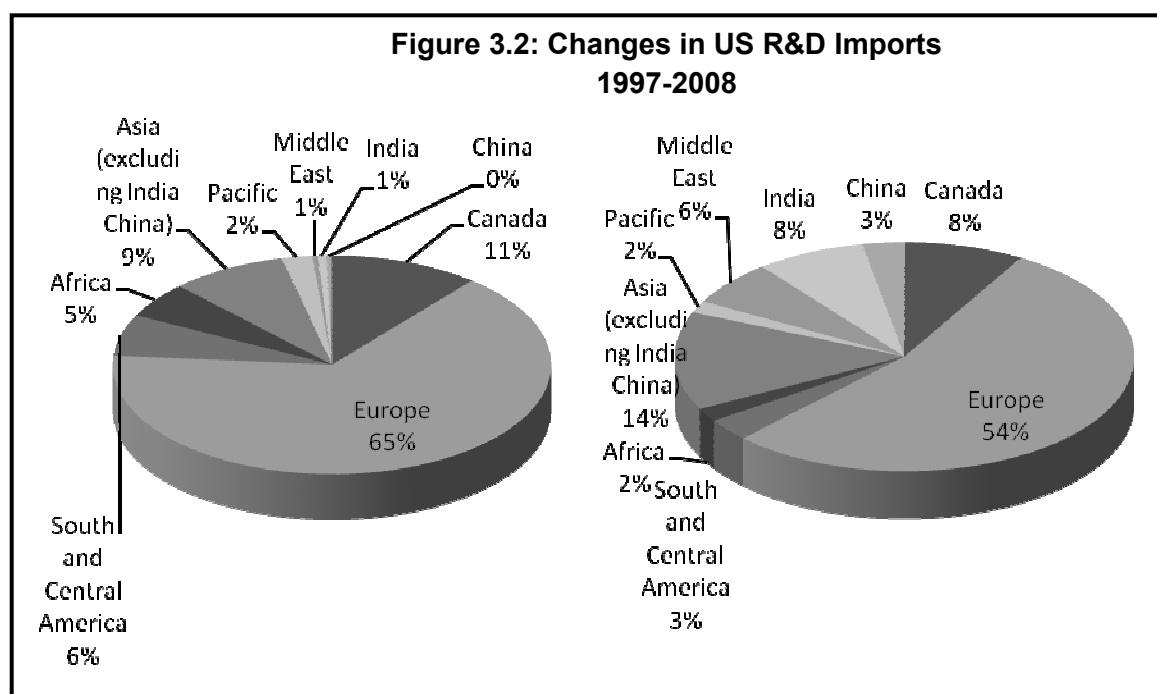
the highest outsourcing expenditure (Bardhan and Kroll, 2003). The second wave of outsourcing saw an increase in externalization of more high value activities and services from industries such as IT, financial services and telecommunications. Thus the second highest industries with outsourcing expenditures are telecommunication and finance. There are significant differences in the first and second wave of outsourcing with first wave focusing mostly on low value while the later on high value activities. The first wave had the greatest impact on blue-collar jobs while the second wave of service outsourcing impacted white-collar jobs. More high tech industries such as healthcare and pharmaceuticals have relatively low outsourcing expenditure at 6.5 billion. The low outsourcing rate in high tech industries could be due to concerns of leakage and privacy. The industries with the lowest outsourcing expenditure are primarily consumer service industries such as retail, travel, and hospitality. These industries have low levels of outsourcing because of quality concerns since the customer receives the service directly from the firm.

The heterogeneity in the outsourcing strategy of firms across industries is due to the differences in modularity of the technology, availability of specialized third party vendors, minimum efficiency scale required and the level of competition in the industry. Few industries such as infrastructure and manufacturing have higher minimum efficiency scale due to which it is more economical to outsource to vendors who have economies of scale.



Offshoring and outsourcing of core activities is also a new trend which has become prominent across industries in spite of the above mentioned industry level differences. R&D has traditionally been retained within the home country and also within firm boundaries. But firms from developed countries are now fine slicing and decentralizing this activity by relocating it across geographic and organizational boundaries (Contractor et.al. 2010). The United States has many highly R&D intensive firms and examining the level of imports of R&D services by US firms shows a dramatic increase in offshoring of this activity. According to the BEA data, US firm imported \$887 million worth of R&D services but this has grown to \$14061 million in 2008. Most other developed countries have also seen similar increases in imports of R&D services.

There have been also been changes in R&D location of offshoring although Europe is still the most preferred location for US firms. Imports from Europe have increased at a decreasing rate although it still continues to be the most preferred location for offshoring R&D. The changes observed in Figure 1.2 show that imports from India and China, which are one of the upcoming locations for offshoring of core activities, have more than tripled even though India has seen a faster growth than China in R&D. The rest of Asia has only seen a marginal growth in this functional area. One interesting trend was that Latin America saw a drastic decrease in its percentage of the R&D exports and this could be because of unstable environment in many of the South American countries.



Source: BEA data

3.2 Overview of the Pharmaceutical Industry

The research setting of this dissertation is the pharmaceutical industry which is one of the most R&D intensive industries. According to Jones (2000),

the international R&D intensity of pharmaceuticals is 13.5% which is the highest along with the software industry. R&D is a core activity in this industry and is one of its important sources of competitive advantage (Dierickx and Cool 1989; Henderson and Cockburn, 1994; Piachaud, 2004). Until the 1980s the big pharmaceutical firms were fully integrated and performed all the operations in-house, from drug discovery to marketing (Cockburn, 2004). During this time the industry had a period of high growth due to numerous scientific breakthroughs resulting in many blockbuster drugs.

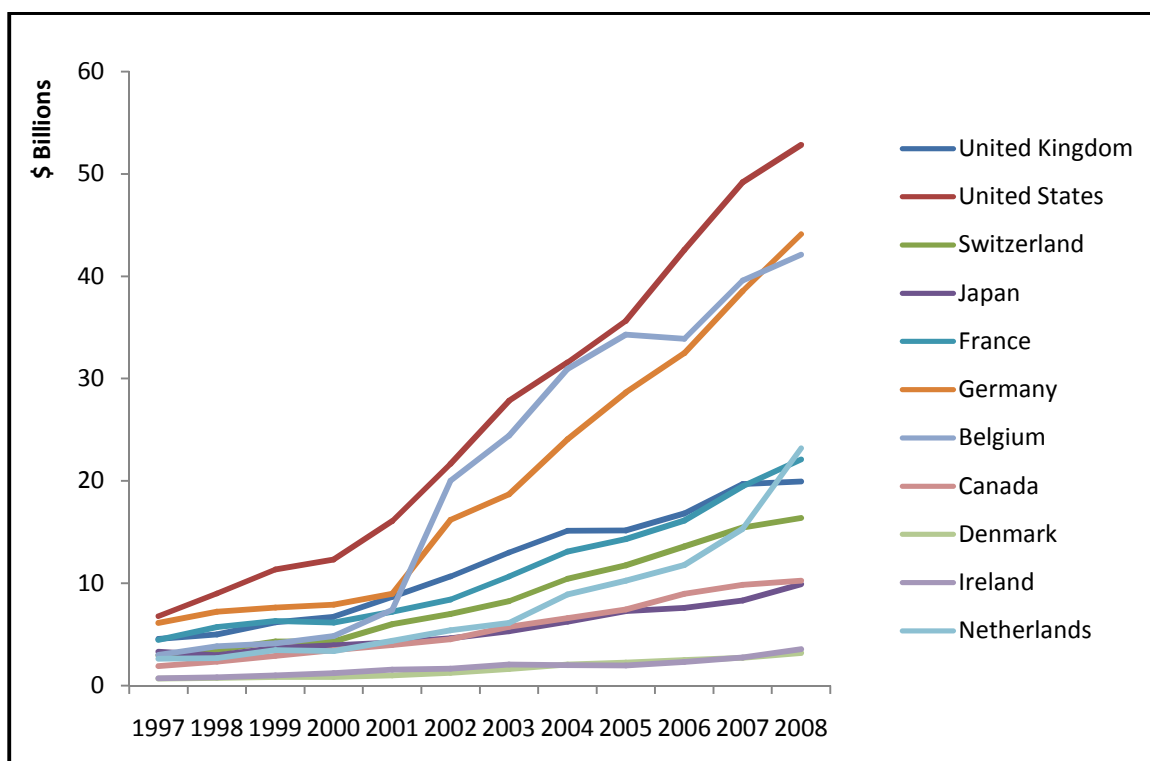
But since the last couple of decades, the industry is facing a lot of challenges due to rising costs accompanied by longer development time, oncoming patent expirations of many blockbuster drugs, fewer replacement drugs, changing technology and higher litigation costs (John, 2006; Hall, 2000; Steiner et al., 2007). Increasing threat from generic drugs after patent expiration and the growth of follow-on drugs, that treat the same medical condition, worsened the problems of firms in this industry (Malnight, 1995). The industry also faces price pressures from governments, world health authorities, insurance entities (King, 2004; Scherer, 2004) and increasing global competition (Sen, 2006).

To overcome these challenges the industry is increasingly developing new drugs offshore, and outsourcing its core activities. R&D offshoring and outsourcing in the pharmaceutical industry includes a gamut of activities such as preclinical testing, clinical trials, laboratory services, bio-statistical analysis, drug

discovery services, clinical packaging, regulatory affairs and bio-manufacturing (Findlay, 2007).

Figure 3.3 shows a steep increase in importing of services in the pharmaceutical industry. The graph includes imports from foreign third party vendors as well as foreign affiliates. The OECD countries in this graph are included in the sample used for this dissertation and the figure suggests increased internationalization of this industry.

Figure 3.3: Pharmaceutical Industry Service Imports 1997-2008



Source: OECD data

The firms in the industry are also including outsourcing as a part of their corporate strategy to overcome the rising costs of R&D, threats from generic firms as well as to improve speed to market for their drugs. According to an industry study done by Frost and Sullivan (2008) the global R&D outsourced by

the pharmaceutical industry was approximately worth \$11 million in 2001 but in less than a decade the outsourcing expenditure has more than doubled to \$24 million in 2008. R&D outsourcing accounts for more than 50 percent of total expenditure on outsourcing by this industry. Another important functional activity outsourced by the pharmaceutical industry is manufacturing and the market for its outsourcing grows 10 -12 percent annually (Piachaud, 2001). I next discuss the drug development in this industry which is the research setting for the dissertation.

3.3 Offshoring and Outsourcing of Clinical Trials

Clinical trials are an important part of the R&D conducted by the pharmaceutical industry and account for approximately 42% of the total R&D expenditure (See Figure 1.2). The clinical trial studies are very expensive and take a long time (Cockburn, 2006). The trials which were traditionally done in-house within the home country but the pharmaceutical firms are now increasingly outsourcing and offshoring drug development to auxiliary firms such as Contract Research Organizations (CROs) and foreign affiliates (Azoulay, 2004).

Table 3.1 outlines the four distinct phases of clinical development. Phase I recruits around thirty to hundred normal human subjects and lasts up to a year. The primary purpose of this phase is to determine the safety of the compound and includes the evaluation of drug absorption, distribution, excretion and structure-activity relationship. The phase II of clinical trials is larger than phase I studies and recruits up to a few hundred diseased human subjects. The primary purpose of this phase is to test the efficacy of the drug as well as to test for

safety. The third phase is the largest and recruits anywhere from a few hundred to several thousand human patients and lasts from two to four years. This phase tests for the efficacy and costs and benefits associated with the drug.

When a drug successfully completes the three phases it is submitted to the FDA for approval. Once approved the pharmaceutical firms may sponsor phase IV studies, which are post marketing clinical trials, to monitor the long term drug efficacy, safety and costs and benefits of the drug. In this dissertation, I do not look at phase IV studies as they are not part of the drug development process.

Table 3.1: Phases of Clinical Trials

Trial	Number of Patients	Purpose
Phase I	30 - 100	Drug Safety
Phase II	50-300	Drug Efficacy
Phase III	300-3000 <	Costs and benefits
Phase IV	1000<	Long term risks and benefits

Offshoring and outsourcing decisions pertaining to clinical trials are unique compared to other functions in terms of the frequency of decision making. While outsourcing of other business activities such as HR and IT are a onetime decision, sourcing strategy decisions for clinical trials have to be made more frequently and the factors may vary from trial to trial. Thus offshoring and

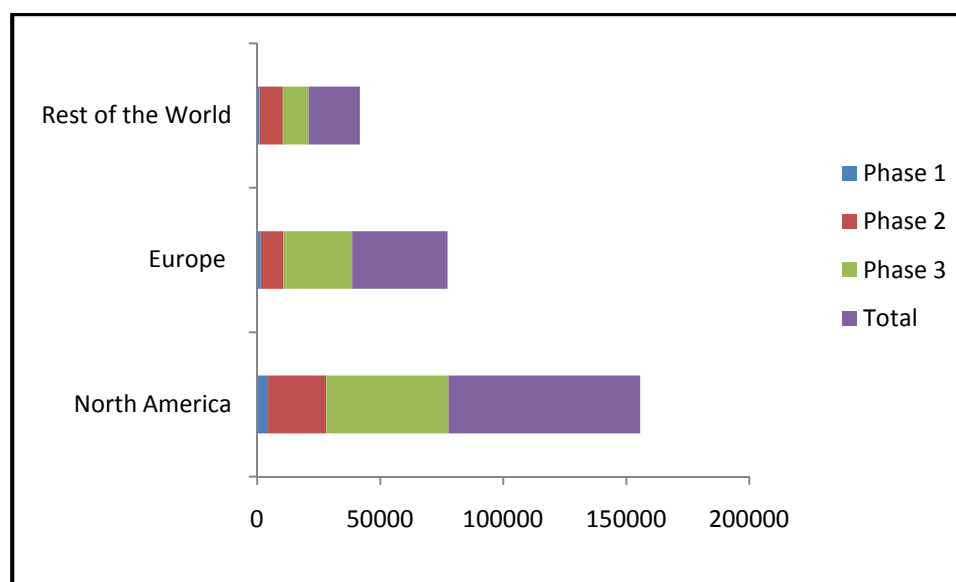
outsourcing of clinical trials is unique because the boundaries (geographic and organizational) of the firm can shift on project by project basis (Azoulay, 2004).

Offshoring of clinical trials is becomingly important in this last decade largely due to the adoption of the Good Clinical Practices (GCP) by different countries. GCP is an international quality standard established by the International Conference on Harmonization (ICH) and is crucial for offshoring of clinical trials as it allows firms to collect trial data from other parts of the world. While the US adopted GCP in the 1980s, European countries followed in the 1990s but developing countries such as China, Indonesia and India adopted it in 2001. Offshoring of clinical trials to these countries picked up only after adoption of these guidelines.

But while offshoring of clinical trials is on the rise it is still concentrated in the developed countries. Approximately 20% of clinical trials are located in emerging countries (Berndt, Cockburn and Thiers, 2006). Figure 3.4 shows the total clinical trials conducted by US firms between 2006 and 2008. Since the clinical trials reported here are only from US firms there is a higher concentration of trials in the US in this figure but the graph reflects the general pattern of geographic location of the clinical studies. For trials conducted by European firms, North America accounted for 50 percent of all trials while Europe was only 27 percent. Figure 5.1 shows the total offshored clinical trials by US, European and Japanese firms between 1997 and 2005 that were examined in this dissertation. This figure reflects the same pattern with the highest concentration in North America followed by Europe. However, in the last few years North

America and Europe have lost approximately 3 percent of their share of clinical trial sites while Eastern European, Asian and Latin American countries have seen an increase of 1-2 percent (Karlberg, 2009). Western European firms are also now looking to Eastern European countries to locate their clinical trials.

Figure 3.4: Clinical Trials Sponsored By US Firms 2006-2008



Source: ClinicalTrials.gov

Outsourcing of clinical trials to third party vendors known as Contract Research Organizations (CRO) has also increased. The services offered by CROs are: quality assurance and control, pre-clinical pharmacokinetic, pharmacology and toxicology studies, design, conduct and analyze phase I and phase II studies, management of multi-center studies, manufacture and database management, and statistical analysis and reporting (Cockburn, McClurg and Cichoracki, 1997). In a recent study, Mehta et.al. (2007) found that almost one fourth of total clinical trials expenditure is outsourced by the pharmaceutical

industry. Azoulay (2004) also found that approximately 23% of the clinical trials are outsourced to CROs.

Thus an overview of the trends in the offshoring and outsourcing suggest an increase in this phenomenon in the recent years although there are some instances of reversal in this trend. Outsourcing and offshoring in the pharmaceutical industry is a more recent phenomenon and while firms are seeking these sourcing strategies most of the core activity is still located in the developed countries of North America and Europe. In the following four chapters, I empirically examine this phenomenon at a more micro level.

CHAPTER 4

STRATEGIC VERSUS OPERATIONAL DETERMINANTS OF OFFSHORING AND OUTSOURCING

4.1 Introduction

A review of prior research on determinants of offshoring and outsourcing revealed a one sided focus on operational determinants. Most of these studies have examined firm specific factors such as size, prior experience, R&D intensity and prior performance. Existing literature has not distinguished between strategic and operational factors that influence the decision to offshore and outsource. This is extremely important in today's economy where firms no longer offshore and outsource only peripheral, low value activities. With the recent internal and environmental changes, firms are now moving their core activities outside geographic and organizational boundaries. Due to this shift in the structure of the firm, there is a greater need to examine the determinants of internationalization and externalization of core activities. While offshoring and outsourcing of peripheral or non core activities can be associated with operational drivers such as cost and flexibility (De Vita and Wang, 2006), the sourcing decisions for core activities involve consideration of strategic factors as well.

Since this current generation of sourcing strategies is driven by both operational and strategic factors, in this chapter I look at five firm level factors

that influence the decision to locate core activities both organizationally (in-house versus external vendors) and geographically (home nation versus foreign countries). The determinants of the spread of core activities are examined for the four sourcing strategies adopted by MNEs which are: domestic in-house, domestic outsourcing, offshore outsourcing, and foreign affiliates (refer to Table 1.1). The firm level operational factors are cost, quality and speed. The strategic factors that influence firm decision are the need to maintain corporate image and mimetic adoption. This study contributes to the literature by focusing on core activities and simultaneously examining offshoring and outsourcing. The chapter also contributes to the literature by looking at the decision making structure for the sourcing strategies using the nested logit model. The empirical results from this model suggest a two stage decision process in which, firms first choose between in-house sourcing and domestic outsourcing, and second between domestic and offshore sourcing.

The quantitative dataset used for this research is the CROCAS dataset published by MediData. This unique database contains detailed project level data on clinical trials and identifies the trials that were outsourced and offshored. The sample in this research has data on approximately 10,628 clinical trials from 53 firms, in the pharmaceutical industry, originating from 10 countries. The secondary data from an online survey of firms in the pharmaceutical industry is matched with the primary data to examine the five determinants.

In the next section I review research on offshoring and outsourcing of R&D activities and then develop hypotheses relating to the firm level determinants for

the sourcing strategies. In sections 4.3 and 4.4, I describe the methodology and results, and the final section concludes.

4.2 Literature Review and Theoretical Background

Offshoring and outsourcing are important strategic decisions made by firms in today's and these decisions are driven by strategic considerations and are part of the overall strategy of the firm (Rasheed & Gilley, 2005). In their recent work, Pyndt and Pederson (2006) examine the sourcing strategies of firms and according to them, offshoring is synonymous with productive activity taking place outside the home country (internationalization) and outsourcing with the productive activity is taking place outside the firm boundaries (externalization).

The literature on the determinants of offshoring and outsourcing has looked at many firm level factors such as firm size (Bardhan and Jaffee, 2005; Borzekowski, 2004), R&D intensity (Mol, 2005) prior firm experience (Lewin et.al. 2009; Pedersen and Jensen, 2007; Pisano, 1990) and prior firm performance (Loh and Venkatraman, 1992). Most of these earlier studies had focused on firm drivers that influenced the decision to outsource and offshore non-core activities. Offshoring and outsourcing of core activities such as R&D is far more complex and goes beyond short term operational drivers that were examined previously.

In this study I look at five firm level determinants of core activities. Specifically, I look at operational determinants such as cost, quality, speed as well as strategic determinants such as imitation and corporate image. In the following subsections I discuss existing literature on each determinant and develop hypotheses.

4.2.1 Cost Savings

Cost has been an important operational determinant for offshoring and outsourcing of non core activities (Bettis et.al., 1992; Bryce and Useem, 1998; Deavers, 1997; Jensen and Pedersen, 2007; Lewin and Couto, 2007; Quelin and Duhamel, 2003;). Literature on FDI has found that cost differences between home and host country is an important driver for locational choices made by MNEs. Differences in cost can arise mainly due to difference in labor costs (Cheng and Kwan, 2000; Farrell et.al., 2005; Woodward and Rolfe, 1993) which is an important factor of production especially for the service industry.

While cost savings from offshoring and outsourcing has been an important factor for peripheral activities, such as call centers, its importance for core activities has not been examined previously. It is necessary to test the importance of cost savings in the context of R&D because while managers consider cost savings from offshoring, there are also numerous risks involved which render cost saving as an insignificant factor for R&D. But cost minimization can still be an important driver for offshoring R&D activities since R&D constitutes a significant part of the firm's budget (Huang, Chung and Lin, 2009). According to Grandtrand et.al. (1993), cost differentials stemming from lower wages and set up costs, is an important motive for internationalization of R&D. Offshoring decisions are often made because of the notion that low cost countries considerably reduce costs due to wage differences for skilled workers.

Outsourcing, both domestic and offshore, also have the potential to reduce costs as firms can convert fixed costs into variable costs (Alexander and

Young, 1996), and reduce capital invested by accessing external competencies and resources (McFarlan and Nolan, 1995). Since third party vendors specialize in a narrow range of activities and often serve multiple firms, they benefit from economies of concentrated scale which reduces their operating costs. According to Embleton and Wright (1998) small companies benefit from outsourcing due to these economies of scale while larger companies benefit by shedding ill managed activities. Thus, it is often perceived by decision makers that outsourcing leads to lower costs for the firm.

Accordingly, I propose that the greater the emphasis on cost savings in the sourcing decisions of core activities, the greater the propensity to offshore and outsource.

Hypothesis 1a: Other things equal, there is a positive relationship between cost savings and offshoring to foreign affiliate.

Hypothesis 1b: Other things equal, there is a positive relationship between cost savings and offshoring to third party vendor.

Hypothesis 1c: Other things equal, there is a positive relationship between cost savings and domestic outsourcing.

4.2.2 Quality

Offshoring and outsourcing is not just a cost saving exercise since it also important to maintain quality of the R&D process. There is often a tradeoff associated between cost and quality especially when offshoring and outsourcing in the service sector and to emerging markets. According to Bunyaratavej, Han and Doh (2007), firms often tend to give greater importance to quality when

forced with intense competition at home. While some researchers have found quality to be an important driver for offshoring, they have also found that poor quality service is one of the highest perceived risks of offshoring. (Lewin and Peeters, 2006). As evinced by other researchers (Levy, 2005; Moules, 2004), quality of offshored processes is often a concern due to lack of face to face communication. According to Dossani and Kenney, (2003), there are two types of capabilities, formal education and firm specific capabilities. Since there are differences across countries in these two types of capabilities, quality of offshored activities may vary from home to host country. Quality is also a concern due to the complexities of coordinating work performed in different geographic locations (Doh, 2005).

Some quality related challenges from offshore outsourcing are the failure of the foreign vendor to perform according to the requirements, and lack of competence (Perry and Devinney, 1997). Quality can also be lower in outsourcing since the vendor may have an incentive to save money by offering poor quality services and products (Embleton and Wright, 1998). While these drawbacks are possible in both domestic and offshore outsourcing, geographic as well as cultural and institutional distance between home and host country makes quality a greater concern in offshore outsourcing.

Firms are less likely to have quality concerns for domestic outsourcing since geographic proximity facilitates better monitoring of the activities. One of the main drivers of domestic outsourcing of R&D is the potential to improve the quality of the R&D (Beulen et.al., 1994). Outsourcing enables the firm to access

expertise that it does not own and is especially useful during the transition periods of the firm (Fill and Visser, 2000; Bunyaratavej et.al. 2008). Firms gain from outsourcing as they can choose suppliers whose products and services are considered among the best (Cassidy, 1994; Dess et al., 1995; Laabs, 1996; Quinn, 1992) and meet the firm's requirements. While the above arguments in favor of outsourcing are also applicable to offshore outsourcing, disadvantages stemming from geographic distance will outweigh the benefits.

Thus I propose that when quality is of high importance for a particular project then firms are more likely to retain them within home country. I also hypothesize, that firms have greater propensity to domestically outsource activities if they see a potential to improve or sustain the quality of their products or services.

Hypothesis 2a: Other things equal, there is a negative relationship between quality and offshoring to foreign affiliate.

Hypothesis 2b: Other things equal, there is a negative relationship between quality and offshoring to third party vendor.

Hypothesis 2c: Other things equal, there is a positive relationship between quality and domestic outsourcing.

4.2.3 Speed

Another aspect of operational efficiency is the speed in completion of the task, which can impact the firm's responsive to the market. Offshoring improves the speed of completing the project by giving the firm access to large labor supply (Carmel and Schumacher, 2005). Speed from offshoring is also achieved

due to round the clock work hours across continents (Gupta et.al., 2007; Lewin et. al, 2009).

External sourcing through domestic and foreign vendors also improves speed of the R&D process in a firm (Kessler et. al., 2000). According to Quinn (2000), outsourcing speeds up the innovation process especially in high technology industries such as pharmaceuticals and semiconductor since suppliers have greater knowledge depth and innovate at a faster rate. Outsourcing organizations can be faster due to their large dedicated team of workers and also because they focus on a narrow range of activities (Holcombs and Hitt, 2007). According to Azoulay (2004), speed of project completion is especially important for the clinical trials since there are time costs involved. Time costs are the costs incurred from lost sales opportunities due to the delay in development of a drug whose patent clock is ticking. Since drug development is extremely lengthy process the time costs involved are very important to the firm. Speed can be increased from offshoring due to the access to the “drug naïve” population of which there is a more plentiful supply abroad (Kapler and Puhala, 2008). The duration of clinical trials also can decrease due to abundant supply of qualified physicians in offshore locations. Thus I hypothesize, that the speed of project completion is an important factor in the decision to offshore and outsource.

Hypothesis 3a: Other things equal, there is a positive relationship between speed and offshoring to foreign affiliate.

Hypothesis 3b: Other things equal, there is a positive relationship between speed and offshoring to third party vendor.

Hypothesis 3c: Other things equal, there is a positive relationship between speed and domestic outsourcing.

4.2.4 Mimetic adoption

The first strategic determinant examined in this chapter is mimetic adoption. According to the neo-institutional theory, firms imitate other firms in the pursuit of legitimacy or for the widespread use of taken for granted practices (DiMaggio and Powell, 1983; Guillen, 2002; Levitt and March, 1988; Martin et al., 1998). Imitation occurs when a firm's use of a practice or strategy increases the likelihood of adoption of the same by other firms (Hausnschild and Miner, 1997). Imitation happens because of mimetic forces and normative pressures from a firm's relationship with others which forces the firm to adopt new practices (Burns and Wholey, 1993). Firms also often economize on search cost through imitation of other firms within their own population (Cybert and March, 1963).

Firms imitate to gain legitimacy, as a practice becomes more prevalent, it becomes more legitimate and permissible in the eyes of the firm's stakeholders (Abrahamson & Rosenkopf, 1993; Scott, 1995). Mimetic imitation is especially important for MNEs who have to overcome problems of legitimacy (Kostova and Zaheer, 1999) arising from liability of foreignness in foreign markets (Zaheer, 1995). Isomorphism is also important to gain legitimacy in host country markets (Kostova and Roth, 2002).

Mimetic adoption has been observed for many firm strategies such as diversification (Haverman, 1993), international market entry (Guillen, 2002), and mergers and acquisitions (Yang and Hyland, 2006). Mimetic adoption is more common in industries that have high levels of competition and the pharmaceutical industry is one such case. According to Piachaud (2004) the pharmaceutical industry is semi-oligopolistic in nature and the top one hundred firms account for 80% of total pharmaceutical sales. Thus the pharmaceutical firms are more likely to imitate their competitors due to the high level of rivalry in the industry.

Due to uncertainty and cognitive limitations, firms may mimic the actions of their competitors especially for offshoring and outsourcing their R&D. Since R&D is a risky and uncertain process, firms may follow their competitors in terms of the location of activities to reduce search costs. Clinical trial is also a highly sensitive process involving many ethical issues and firms may use imitation to gain legitimacy among their stakeholders. Mimetic isomorphism is aided by the fact that all firms in an industry face the same changing conditions in the business environment– in this case, the establishment of independent offshore third party service providers (CRO), greater technical skill in foreign personnel, and improvements in IP protection and enforcement.

Thus I hypothesize, that firms are more likely to relocate their core activities across geographic and organizational boundaries if their competitors have done so previously.

Hypothesis 4a: Other things equal, there is a positive relationship between mimetic adoption and offshoring to foreign affiliate.

Hypothesis 4b: Other things equal, there is a positive relationship between mimetic adoption and offshoring to third party vendor.

Hypothesis 4c: Other things equal, there is a positive relationship between mimetic adoption and domestic outsourcing.

4.2.5 Maintaining Corporate Image

The second and last strategic determinant is importance of maintaining corporate image. There is extensive research on corporate image (Belt and Paolillo, 1982; Fomburn and Shanley, 1990; Gatewood, Gowan and Lautenschlager, 1993) which found that decision makers pay attention of the impact of the decision on the firm's reputation when considering different strategy options. The firm's reputation is an intangible asset which can be a source of future revenues (Wilson, 1985). When a firm is undertaking some strategic decisions it should consider the impact on the reputation and image of the firm. Research has shown that reputation has a positive impact on the strategies adopted by the firm (Weigelt and Camerer, 1988).

Offshoring and outsourcing of core activities are important strategic yet controversial decision which can have negative consequences on the firm's reputation. Offshoring has often been blamed for job losses in the home country while outsourcing has been questioned for quality purposes. However the threat to corporate image is greater in domestic and offshoring outsourcing than offshoring to foreign affiliates. Foreign affiliates are considered part of the MNC

network and concerns such as job losses and transfer of resources are less applicable to this sourcing strategy. While job losses are not a concern in domestic outsourcing, stakeholders are often concerned regarding outsourcing of core and sensitive activities. Thus I propose that firms are less likely to engage in domestic and offshore outsource to maintain impressions with the stakeholders such as customers, employees, suppliers and also the shareholders.

Hypothesis 5a: Other things equal, there is a positive relationship between the need to maintain corporate image and offshoring to foreign affiliate.

Hypothesis 5b: Other things equal, there is a negative relationship between the need to maintain corporate image and offshoring to third party vendor.

Hypothesis 5c: Other things equal, there is a negative relationship between the need to maintain corporate image and domestic outsourcing.

Table 4.1 presents a summary of all the five sets of hypotheses. The next subsection will outline the methodology employed to these hypotheses.

Table 4.1: Summary of Hypotheses

	Foreign Affiliates	Offshore Outsourcing	Domestic Outsourcing
Cost Savings	+	+	+
Quality	-	-	+
Speed	+	+	+
Mimetic Adoption	+	+	+
Corporate Image	+	-	-

4.3 Methodology

This section provides an overview of the methodology adopted to examine the firm level determinants of offshoring and outsourcing of core activities. The following section outlines the data and the sample. This will be followed by a discussion on the operationalization of constructs and the empirical model.

4.3.1 Data

This research focuses on the pharmaceutical industry and the firms included in this sample are pharmaceutical manufacturing companies (prescription and over-the-counter) as well as biotechnology firms that undertake pharmaceutical research. There are no generic firms in the sample.

The quantitative dataset used for this research is CROCAS published by MediData. This unique database contains detailed project level data on clinical trials and identifies the trials that were outsourced to CROs and/or offshored. The sample in this study has data on approximately 10,628 clinical trials from 53 firms, originating from 10 countries.

The primary data for this study is from an internet based survey. The survey contains questions regarding the firm level determinants of offshoring and outsourcing. The questionnaire was sent to Vice Presidents and Directors of clinical trials in the pharmaceutical industry. Based on preliminary interviews with executives in the industry it was decided that the type of questions asked were best suited for VPs and Directors who have knowledge of the overall spread of clinical trials. A pilot study involving four pharmaceutical and two biotechnology firms was conducted to test the validity and reliability of the survey instruments.

The pilot study was also used to identify industry specific determinants of the spread of activities. Ninety eight pharmaceutical and biotechnology firms were approached to match the firms in the secondary dataset. Of these fifty three firms responded to the survey. In spite of the small number of firms in the study the sample is very representative of the industry as I have both large and small pharmaceutical and biotechnology firms. The firms in the study are also well spread across the triad region of North America, Europe and Japan which is where the industry is concentrated.

4.3.2 Variables

The dependent variable in this chapter is the choice of sourcing strategy which is measured as a set of four discrete strategy choices that cannot be ordered. The four strategy alternatives are: domestic in-house, foreign affiliates, offshore outsourcing and domestic outsourcing. The unit of analysis is at the individual project level (clinical trials) and for each project there are four observations with alternative specific variables. The dependent variable is 1 if the strategy was chosen for that clinical trial, zero otherwise.

To test for robustness, I also used the proportion of clinical trials for each firm as the dependent variable. But since the results are not significantly different, I do not include them in the chapter but discuss this robustness test in Appendix C.

All the five firm level determinants are from the survey. Respondents were asked to indicate the importance of the determinant for each of the four sourcing strategies. Participants were provided with a five-point Likert scale ranging from

'highly important' to 'not important' in addition to a 'not applicable' category. *Mimetic adoption* was measured using two items: 1. Imitating rival firms to remain competitive and 2. Imitating competitors to remain gain legitimacy. *Cost* was measured as the cost savings in operating and running the clinical trials for the different strategies. *Speed* was measured as the speed of the drug development process. *Quality* was a two item measure which included sustaining of quality of the trials and improvements in quality from sourcing strategies. The last independent variable is *Corporate image* and respondents were asked to rate the choice of sourcing strategies to maintain corporate image.

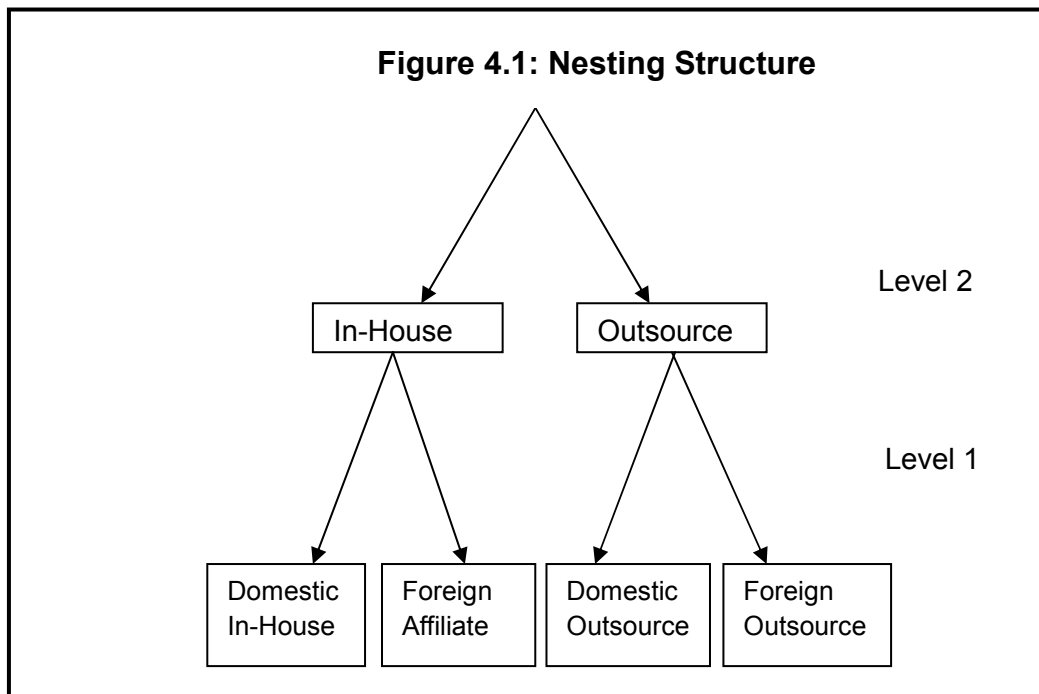
In addition to the variables of interest, I include controls for project level factors such as phase of clinical trial and the therapeutic areas using dummy variables. A language dummy variable is included since firms are more likely to offshore their core activities to countries which have the same language as the home country. I also control for firm size measured as the total number of employees as well as firm fixed effects. In separate models I include controls for firm age, R&D intensity and firm performance but the results for the five determinants do not change in significance and hence are not reported in this chapter.

4.3.3 Econometric Model

To empirically test the model I estimate a nested logit regression. The nested logit model relaxes the Independence of Irrelevant Alternatives (IIA) property and also allows me to test for the structure of the sourcing decision making process. I have alternative specific as well as individual specific variables

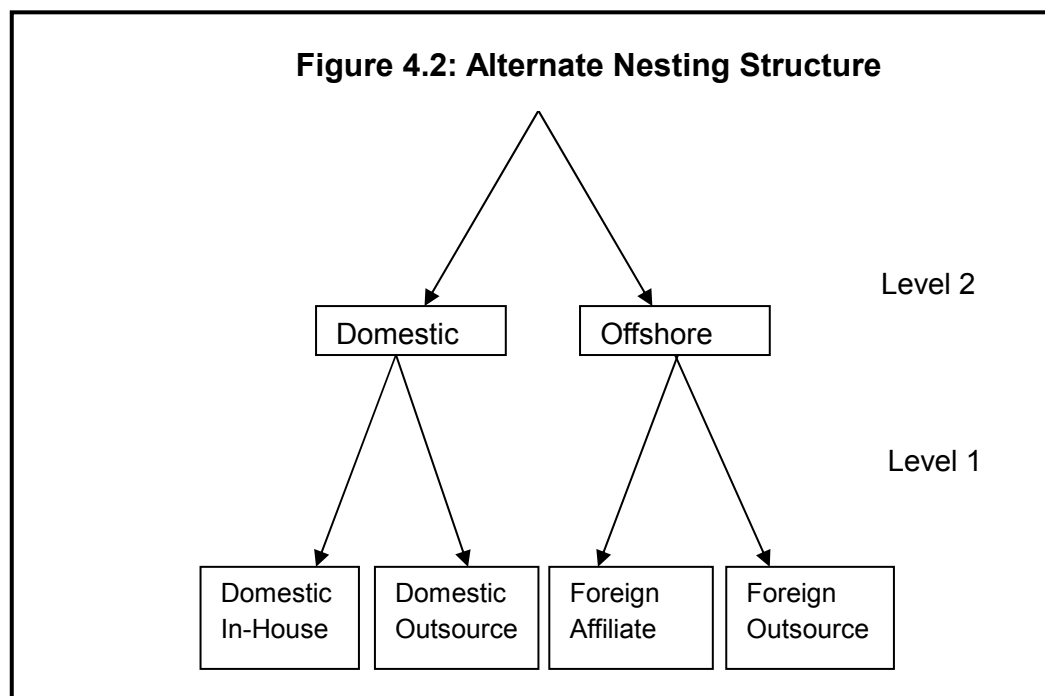
in this model. Alternative specific variables vary for each of the four sourcing strategies while individual specific variables vary by firm and project (clinical trial).

I test a two stage decision process using two levels with two nests each. In the upper level of the decision tree (See Figure 4.1), the firm has to choose between in-house and outsourcing and in the lower level the two branches have two choices each. The four alternatives in the lower level of the nests are domestic in-house, foreign affiliates (below the in-house branch) and domestic and offshore outsourcing (below the outsourcing branch). The inclusive value coefficients for the two nests were less than one indicating a goodness of fit.



An alternate nested model was also estimated to test whether the firm first chooses between domestic and offshore strategies and then between in-house and outsourcing (See Figure 4.2). The inclusive value coefficient estimates for the two nests, in this alternate decision tree, exceeded one. This suggests that

the two sourcing options are independent within these nests with no potential tradeoffs and hence do not belong in the nesting structure (Gangrade, Pendyala and McCullough, 2002). Because the alternate model did not offer acceptable inclusive value parameter coefficients, it was not adopted, and therefore detailed model estimation results and parameter estimates are not included in this chapter. The one tailed chi squared likelihood ratio test was also used to choose between the alternate nesting structures and based on this test the first nesting structure is more accurate and hence the alternate structure was rejected.



4.4. Results

4.4.1 Descriptive Statistics

The firms in the pharmaceutical industry in general, and also in the sample, are highly concentrated in the Triad countries: USA, Western European countries and Japan. There are a total of 10,628 clinical trials in this study. Of these, 2,949 trials were conducted in-house in home country and 6,282 were

conducted in foreign affiliates. 411 clinical trials were domestically outsourced while 986 were offshore outsourced. This suggests that most of the core activity continues to be retained inside firm boundaries although more trials are conducted outside the home country.

Table 4.2 presents the correlation matrix for all the variables in the study. Most variables have very low correlation except for cost and speed which were marginally correlated (0.51). Alternate variations of the model were run to examine whether removing one of the two variables of concern influenced the results. The results did not change when these two variables were individually removed.

Table 4.2: Correlation Matrix

	Quality	Speed	Cost	Imitation	Corporate Image	Employees
Quality	1.00					
Speed	0.41	1.00				
Cost	0.16	0.51	1.00			
Imitation	0.22	0.15	0.31	1.00		
Corporate Image	0.16	0.29	0.46	0.12	1.00	
Employees	0.19	0.15	0.10	0.25	-0.38	1.00

4.4.2 Regression Results

Table 4.2 presents the results from nested logit model. The results are reported in three columns. The first and second columns report results for foreign affiliates and offshore outsourcing respectively. The last column shows

the results for domestic outsourcing. As mentioned in the previous section, in-house is the base category.

Table 4.3: Nested Logit Regression

Variables	Individual Specific	Foreign Affiliates	Offshore Outsourcing	Domestic Outsourcing
Cost		0.905**	0.373***	-0.032
Speed		-1.396***	0.497***	0.153*
Quality		-0.081***	-0.314**	0.336**
Corporate Image		1.028***	-0.863**	-0.049
Imitation		0.32***	-0.0085	0.238***
Employees	-0.000346			
Language	1.062**			
Phase 2	0.241*			
Phase 3	0.436***			
Inclusive Value	-0.133			
In-house				
Inclusive Value	0.901			
Outsourcing				
Log Likelihood		-8018.26***		

In hypotheses 1a and 1b, I proposed that there is a positive relationship between cost savings and offshoring to foreign affiliates and offshore vendors respectively. The results from nested logit regression suggest that firms are more

likely to choose offshoring, to foreign affiliates and foreign vendors, over domestic in-house sourcing when cost savings is important in the decision making process. In hypothesis 1c, I had also proposed a positive relationship between cost savings and domestic outsourcing. The coefficient for this variable was negative but not significant and thus this hypothesis 1c was not supported in the model

The second set of hypotheses focuses on the relationship between quality and sourcing strategy choice. I had hypothesized a negative relationship between quality and the three offshoring and outsourcing strategies suggesting that firms are more likely to retain their core activities in-house in domestic country if quality is highly important. Quality was negative and significant for foreign affiliates and offshore outsourcing supporting the hypotheses that the probability of choosing offshoring decreases over in-house sourcing when quality is important. Domestic outsourcing is positive and highly significant in the model suggesting that firms tend to use domestic outsourcing to improve quality. This could be because domestic vendors have better quality due to economies of scale. These local vendors do not have communication and coordination problems as is the case with offshore vendors which could be the reason why they are viewed favorably by firms for quality purposes.

The third determinant is speed of completion and I predict that all the sourcing strategies have a positive relationship with speed. While hypotheses 3b and 3c are supported in the model, hypothesis 3a is highly significant but the sign of the coefficient is opposite of what was predicted. This suggests that the firms

have lower probability to choose foreign affiliates when speed is required. This result appears consistent with the third empirical study (Chapter 6) in this dissertation which finds that actual duration of clinical trials is longest when they are managed by foreign affiliates.

Mimetic adoption is a strategic determinant and in hypotheses 4 a,b and c, I propose a positive relationship with all the three sourcing strategies. The relationship between foreign affiliates and mimetic adoption is highly significant and positive thus supporting hypothesis 4a. This finding suggests that firms are likely to follow competition by locating clinical trials in their foreign affiliates. Hypothesis 4c is also supported as domestic outsourcing coefficient is also positive and significant. Surprisingly, the coefficient for offshore outsourcing is negative and insignificant, thus hypothesis 4b is not supported.

Finally, the last set of hypotheses deal with corporate image and I propose a positive relationship for sourcing to foreign affiliates and negative relationship for offshore and domestic outsourcing. This determinant was supported for foreign affiliates and offshore outsourcing but not for domestic outsourcing suggesting that maintaining corporate image is more important for offshoring. The control for firm size is negative but insignificant.

4. 5 Conclusion

In this chapter, I examined five firm level determinants of offshoring and outsourcing of core activities. The prior literature on offshoring and outsourcing has mostly focused on the different typologies (De Vita and Wang, 2006; Erber and Ahmed, 2005; Gilley and Rasheed, 2000) or on entry decisions and location

choices (Doh et al.,2008). While there has been limited research on operational determinants, relatively few studies have examined strategic determinants of this phenomenon. I contribute to the literature on offshoring and outsourcing of core activities by simultaneously looking at both types of determinants.

In this chapter, I also examine the structure of decision making for the sourcing strategies of the firm. While it is likely that most firms simultaneously consider the strategic alternatives of outsourcing and offshoring, inclusive value coefficient estimates and post estimation tests of likelihood ratios for the two alternate decision trees show that the first model is a better fit, compared to the second. In the first model, the upper level of decision making focuses on in-house versus outsourcing, while the lower level looks at domestic versus offshore sourcing. This suggests that firms' decision-making may have gone further down the outsourcing path than the offshoring path – a tentative conclusion consistent with aggregate industry patterns. This structure has not been examined by previous researchers and contributes to the literature on sourcing decisions.

The results from nested logit estimation show that firms tend to prefer offshoring to foreign affiliates when factors such as cost savings, maintaining corporate image and imitating competitors are important. Firms are less likely to use foreign affiliates when speed of completion and quality of the clinical trials are important. The findings suggest that internationalization leads to difficulties with coordination and the quality of the core activities, conducted outside home country, is questionable due to differences between countries in terms of infrastructure, regulatory environment and availability of skilled workforce. The

greater coordination costs, liability of foreignness, and cultural distance reduce speed of execution in foreign affiliates. Some of these problems stemming from distance also apply to offshore outsourcing but the positive relationship between speed and offshore outsourcing suggest that foreign third party providers have already built up experience that (relatively new) foreign affiliates have not yet achieved and hence do not face delays in completion due to liability of foreignness. Cultural distance while important for foreign affiliates is not a factor especially if the offshore vendor is regional as is often the case. The offshore vendors do not face liability of foreignness like the foreign affiliates which could also be the reason why speed is expected to be faster in offshore outsourcing. Overall findings for the foreign affiliates suggest that firms use foreign affiliates for clinical trials primarily for strategic purposes rather than for operational reasons such as quality and speed.

The empirical results also show that offshoring to third party vendors is expected to reduce costs as well as faster speed. Similar to foreign affiliates, offshore outsourcing is negatively related to quality. Firms in the pharmaceutical industry are more likely to retain their core activities in-house due to negative corporate image. Offshore outsourcing has received bad publicity in developed home countries due to the associated job losses. Firms in these countries may refrain from using this sourcing strategy if maintaining corporate image is of greater importance. Overall findings suggest that operational factors are more important for offshore outsourcing.

Domestic outsourcing is associated with greater quality and faster speed and firms are more likely to use domestic outsourcing to imitate their competitors. Quality is positively associated with domestic outsourcing suggesting that domestic outsource vendors can have the highest quality controls and standards – perhaps even more than the focal firms themselves. Because of repeated experiences for a number of clients, they build up a level of experience and standards that is unsurpassed. These specialized providers also benefit from economies of concentrated scale (Holcomb and Hitt, 2007) which explains the positive relationship between domestic outsourcing and quality and speed. Surprisingly, cost is not an important driver for domestic outsourcing and this could be due because firms do not see cost savings in relocating activity within the same home country. Similar wage structure and cost of patient recruitment could lead firms to pay less attention to cost savings from domestic outsourcing. Firms are also more likely to use domestic outsourcing to follow their competitors and to maintain their competitive advantage. Reputation of the firms is not an issue for domestic outsourcing probably because it is less controversial than offshore outsourcing.

This research shows that both strategic and operational factors influence the decision of locate core activities both geographically and organizationally. By only focusing on one type of determinants, previous studies were only looking at the partial picture. My results suggest that strategic determinants are more important for foreign affiliates while operational

determinants are more so for outsourcing. A combination of operational and strategic factors is important for domestic outsourcing.

This research has a few limitations especially due to the small number of firms that responded to the online survey. But since I look at multiple clinical trials within these firms, I overcome the problem of small sample size. The study also focuses on a narrow slice of the value chain in the pharmaceutical industry and it would be interesting to see if the determinants are equally important for other core activities such as basic research and drug discovery.

Nevertheless, I feel the results of this research contribute significantly to the literature on internationalization and externalization of core activities such as R&D. The bulk of R&D continues today to be performed within the parent firm of multinational companies. However, a transition is underway to devolve this function to (a) foreign locations and (b) to external service providers and/or alliance partners. An important question, for the International Business, Strategy, as well as the Technology Management fields, is the determinants of this transition, across firms.

CHAPTER 5

MOTIVES FOR OFFSHORING: OFFSHORE OUTSOURCING AND CAPTIVE OFFSHORING

5.1 Introduction

In the previous chapter I looked at firm specific operational and strategic determinants of offshoring and outsourcing. In this chapter, I focus exclusively on offshoring and evaluate the role of internationalization motives in the choice of offshore sourcing strategies. As firms evolve and become more geographically dispersed (Gammeltoft, 2005), it is becoming increasingly important to examine the motives behind offshoring. Firms that offshore have to decide on whether to locate the activities within their foreign affiliate or outside the firm boundaries with foreign vendors.

According to Kohler (2002), there are significant differences between these two offshore sourcing strategies but there very few studies that differentiate between the two while looking at location choices of international activity. These two offshore strategies involve different dynamics especially in terms of the advantages to the firm. For instance, on one hand foreign affiliates can be associated with internalization advantages such as lower coordination and monitoring costs. On the other hand, outsourcing can eliminate bureaucracy costs and the higher fixed costs of establishing a foreign affiliate (Alyson, 2006; Grossman and Helpman, 2002).

As firms are increasingly locating their core activities in foreign locations, decisions such as the choice between the two offshore strategies and the choice of location could depend on the motives behind internationalization. Different countries attract different types of foreign investments based on the location specific advantages. In this chapter, I examine the choice of sourcing strategy based on the investment motives in a country.

There has been extensive research that has focused only on the choice of location for FDI (Cantwell, 1989; Florida, 1997; Hankson and Nobel, 1993; Kogut and Chang, 1991) but there are no prior studies that have compared location choices for foreign affiliates and offshore vendors. Dunning (1980), in his seminal work, stressed on the importance of location in the internationalization process of the firm. Firms are now locating many of their core activities such as R&D in foreign locations (Cantwell and Harding, 1997) and there is a need to look at the motives behind internationalization of such core activities. While prior literature has examined R&D location decisions (Nachum and Zaheer, 2005), it has not looked at Dunning's framework of four motives (Dunning, 1993) in this decision making process.

According to Dunning (1993), there are four motives for foreign investment and they are *resource seeking*, *market seeking*, *efficiency seeking* and *strategic asset seeking*. Previous research has mostly assumed that internationalization of core activities such as R&D is primarily driven by strategic asset seeking behavior of the firms (Deng, 2007; Dunning & Narula, 1995; Kogut and Chang, 1991). However, not all R&D in different host countries is driven by strategic

asset seeking motive. For instance, pharmaceutical firms often conduct their R&D in developing countries to create market awareness and thus gain market entry. This is a type of market seeking investment decision made by the firms. On the other hand, many firms also conduct R&D abroad to gain access to resources such as patients which is a type of resource seeking behavior. Finally firms also locate R&D abroad, especially in developing countries, to access cheaper skilled workers and scientists and this is an efficiency seeking type of offshoring activity.

In this chapter I assess the role of the four motives in offshoring decisions while distinguishing between offshore outsourcing and captive offshoring. Specifically, I examine the choice of sourcing strategy based on the motive for offshoring to different countries.

Dunning in his original work proposed this typology for decisions made by the firm regarding the expansion of foreign production but in this paper I extend this framework to look at decisions related to core activities such as R&D. While this typology has been used to examine the location of activity in foreign affiliates, I contribute to the literature by using it to study offshore outsourcing as well. Firms can internationalize their core activities using other means such as licensing and joint ventures. But I only look at offshore outsourcing and foreign affiliates as the means of internationalization since licensing and joint ventures are not common in internationalization of clinical trials in this industry.

Furthermore, I suggest that due to their complementarity with the basic research, the R&D activities under study have a dual character, i.e. they show

characteristics of competence exploiting (CE) and competence creating (CC) activities. They are integral part and a core activity of the pharmaceutical product creation process and are therefore a CC activity. But their complementarity to research with focus on large-scale tests rather than IPR also gives them some traits more related to CE due to efficiency concerns.

The empirical data on clinical trials comes from CROCAS database, compiled by Medidata. The country level data comes from World Development Indicators (WDI) as well as separate indexes that measure political risk and intellectual property rights regime of the host countries. I focus on the period 1997-2005 and analyze data on thirty seven countries.

In the next section I give a brief literature review and theoretical background. I also develop hypotheses relating to the four motives for offshoring and the choice between foreign affiliates and offshore outsourcing. In sections 5.3 and 5.4 I describe the methodology and results, and the final section concludes.

5.2 Literature Review and Theoretical Background

In this section, I look at the choice of sourcing strategy for each of the four motivations for internationalization of R&D activity. Prior research has used the term internationalization primarily to denote FDI, but in this paper I use it to signify any international activity made by the firm outside of its home country using foreign affiliates or external vendors. I use the term offshoring to mean the same as internationalization since according to UNCTAD (2007) offshoring is

defined as the location or transfer of activities abroad and this includes transfer of activities within the MNC network as well as to third parties.

In the international business literature the motives for internationalization of firm activities are examined quite extensively. According to Dunning (1993) there are four motives for internationalization: resource seeking, market seeking, efficiency seeking and strategic asset seeking. These four motives will be discussed in greater detail in the following subsections. There is also a narrower stream of research on the motivations behind offshoring of R&D activities of the firm. Researchers have proposed two broad motives which are: home base exploiting (Abernathy and Utterback, 1978; Hakanson, 1990; Hymer, 1976; Vernon, 1966) and home base augmenting (Cantwell, 1991; Dunning, 1998; Florida, 1997; Kuemmerle, 1996; Wesson, 1993). Home base exploiting is aimed at using existing firm resources to increase firm value while home base augmenting is directed towards increasing the stock of a firm's assets through offshore investments (Dunning, 2000). Home base augmenting motive is similar to the Dunning's strategic asset seeking motive (Kuemmerle, 1999).

March (1991) used a similar classification of R&D activities and distinguished between exploration and exploitation. According to him, exploration involves gaining new information and is similar to home based augmenting while exploitation involves using current information available to the firm and is similar to home based exploitation. Some other motives have also been proposed such as technology seeking motive (Shan and Song, 1997) and capability augmenting motive (Kuemmerle, 1999) but these are not very different from previously

examined motives. Most of these R&D specific motives are equivalent to the four motives in Dunning's typologies and so I only examine these four motives in this study.

The focus of analysis in this study is the relationship between these four motives and the two offshore sourcing strategies: foreign affiliates and offshore outsourcing. I next develop hypotheses for each of the four motives.

5.2.1 Resource Seeking Motive

Resource seeking is the oldest motive for internationalization of firm activities. Firms especially from developed countries offshore to less developed countries to access resources not easily available at home. However in the recent years, firms from emerging markets also engage in resource seeking behavior to acquire resources such as raw materials and energy sources that are in short supply at home (Buckley et. al., 2007). These resources included both natural as well as created resources of a location. Firms often seek more specific created resources such as brand names and design facilities in host countries and have to offshore as these resources are often immobile (Behrman, 1974).

While resource seeking motive is usually associated with foreign production, it is also important for offshoring of core activities. Firms locate their production facilities close to the resources in the host country and often times co-locate their R&D activities close to these production locations (Ambos, 2005; Hankson and Nobel, 1993; Pearce, 1989). In many instances, firms enter new countries to access resources that are directly required for their R&D activities.

Few studies have shown that resource seeking R&D is becoming very common and foreign investments in R&D are shifting away from market seeking towards more resource seeking investments (Chiesa, 1996; Kuemmerle, 1999; Le Bas and Sierra, 2002; Patel and Vega, 1999).

Offshoring of R&D in the pharmaceutical industry is often driven by resource seeking behavior. Drug development is a complex process where the firm has to recruit numerous patients for clinical trials. Firms from developed countries often offshore clinical trials to emerging countries or to other developed countries with larger populations to access patients. The population of a country is an important resource for clinical trials since larger a patient base fastens the patient recruitment process. Resource seeking is different from efficiency seeking which is primarily driven by cost savings. For instance, Japanese firms conducting clinical trials in the North America to access patients is different from the same firm conducting trials in Eastern Europe to take advantage of lower costs.

For offshoring to access resources of a country, firms have to choose between foreign affiliates and offshore vendors. Since offshore vendors are deeply embedded in the network of hospitals and do not face liability of foreignness (Zaheer, 1995), they are more likely to have faster patient recruitment compared to foreign affiliates. Foreign affiliates may be at a disadvantage for resource seeking purposes (Bunyaratvej et. al, 2007) since they are considered as outsiders in the host country.

Thus since third party offshore vendors, such as local CROs, have the necessary experience and networks for recruiting local patients in a country, firms will tend to use offshore outsourcing for resource seeking investments.

Hypothesis 6: Other things equal, offshore outsourcing is positively associated with resource seeking motive.

5.2.2 Market Seeking Motive

Market seeking investments is the most common motive for internationalization where firms often use 'follow the customer' logic. Typically this type of investment is undertaken to serve particular markets by local production and distribution rather than exporting from home country (Nachum and Zaheer, 2005). Some of the drivers of this type of investment are high tariffs rates, tax incentives offered by host countries and transaction costs arising from transportation.

Firms use market seeking offshoring of R&D to access new markets in the host country (Dunning, 1998; Kumar, 2001; Patel and Vega, 1999). Since tastes and preferences differ across countries, firms want to locate their innovative and developmental activities close to the final consumer in order to better serve their needs. Firms often conduct R&D in foreign markets to generate new innovations which are more applicable to the host country. As local demand grows, local R&D facilities are helpful in adapting existing products to local needs (Hakanson, 1990; Vernon, 1966). According to Kumar (2001), the market size of the host country has a positive effect on the volume of R&D expenditures by multinational

firms. Firms also use market seeking investments to create a physical presence in the market in order to discourage potential competitors.

By conducting R&D in host countries, firms create awareness of their products in these markets. In context of the pharmaceutical firms, conducting clinical trials in the countries, where the firm plan to sell drugs after regulatory approval helps improve market visibility for the drug. Since clinical trials involve recruitment of patients, firms can create a market for the drug even before it is officially launched. By conducting their developmental activities in their future markets, the firm also creates awareness among the physicians and generates legitimacy among the users and the government.

Conducting clinical trials creates awareness of the drug among the end users and physicians regardless of the sourcing strategy. Thus, I propose that market seeking motive is important for locating clinical trials with foreign affiliates as well as with offshore vendors.

Hypothesis 7a: Other things equal, offshoring to foreign affiliates is positively associated to market seeking motive.

Hypothesis 7b: Other things equal, offshore outsourcing is positively associated to market seeking motive.

5.2.3 Strategic Asset Seeking Motive

The third motive is strategic asset seeking which is similar to home base augmenting motive proposed by Kuemmerle (1999). This type of internationalization activity is driven by the need to acquire new technological base rather than exploit existing assets. Literature suggests that firms not only

exploit their firm specific assets in foreign countries but also develop and acquire new assets in host countries (Almeida, 1996; Chang, 1995). There are two broad streams of research in the literature on strategic asset seeking investments: analysis of location of international R&D (Cantwell, 1995; Cantwell and Janne, 1991; Cantwell and Mudambi, 2005) and absorption of new technology (Fosfuri and Motta, 1999; Siotis, 1999).

According to prior research, knowledge and technology is highly localized and to access clusters which are centers of innovation (Zucker, Darby and Armstrong, 1998), firms often have to locate core activities such as R&D in these clusters. Firms offshore to benefit from localized knowledge spillovers and to access strategic assets. Spillovers from research universities, publically funded research institutes and competitors usually enhance the attractiveness of the location for asset seeking FDI (Kuemmerle, 1999). Researchers have found that augmenting knowledge base is an important driver of FDI especially in R&D (Cantwell, 1989; Florida, 1997; Wesson, 1993).

Pharmaceutical firms not only locate their basic research in offshore clusters but also conduct their developmental activities in such locations. Firms conducting clinical trials in a particular therapeutic area can benefit from locating close to other clinical sites that are also conducting trials in the same therapeutic area. Doing so will enable them to access physicians who are already specialized in certain areas and have experience in dealing with patients with specific ailments. In the case of this industry, physicians and the universities that they are affiliated with are important strategic assets. In many instances, firms

offshore their trials to recruit well known physicians, who are thought leaders, for their trials since it adds to the credibility of the drug.

Even when offshore investments are driven by strategic asset seeking motives, firms have to choose between captive and offshore outsourcing. Since the rationale behind this motive is to access strategic resources, firms will prefer to use foreign affiliates who can directly tap into the local knowledge clusters. Foreign affiliates serve as antennae for local knowledge and information (Zaheer and Manrakhan, 2001) and are listening posts for the firms. Firms need to internally develop the absorptive capacity so that their foreign affiliates can benefit from localized spillovers. But if a firm offshore outsources then it will not be able to access the strategic assets in a location as it will still remain an outsider. Thus, when offshoring for strategic assets, firms will have greater propensity to use their foreign affiliates.

Hypothesis 8: Other things equal, offshoring to foreign affiliates is positively associated to strategic asset seeking motive.

5.2.4 Efficiency Seeking Motive

The final motive for offshoring is efficiency seeking. This type of investment is primarily driven by the need to geographically spread value creating activities to take advantage of cost differentials. The aim of the firm for this type of investment is to align the activities of the firm with the comparative advantage of each country to reduce costs (Nachum and Zaheer, 2005; Zaheer and Manrakhan, 2001). Firms use efficiency seeking investments to take advantage of economies of scale and scope in host countries (Bevan and Estrin,

2000; Campos and Kinoshita, 2003; Dunning, 1993, Kinoshita and Campos, 2004).

Offshoring for efficiency is especially important for certain R&D activities such as clinical trials. These operations occur on large scale and are relatively routinized activities making it attractive for MNEs to take advantage of cost differentials between countries.

When choosing a sourcing strategy for this type of investment, firms are more likely to use offshore outsourcing. This is because there are greater savings with outsourcing as compared to foreign affiliates. Third party suppliers benefit from economies of concentrated scale in one piece of the value chain because they focus on a narrow range of activities (sometimes for multiple clients). By outsourcing to such suppliers, even diversified firms as well as smaller firms can take advantage of these economies of scale in the outsourced vendor organizations (Holcomb and Hitt, 2007) and obtain resources at a cheaper cost due to better bargaining power enjoyed by these vendors.

Thus I propose that there is a higher propensity for firms to use offshore outsourcing for efficiency seeking purposes.

Hypothesis 9a: Other things equal, offshore outsourcing is positively associated to efficiency seeking motive.

Table 5.1 outlines the summary of the four hypotheses that will be empirically tested in the following sections.

Table 5.1: Summary of Hypotheses

	Foreign Affiliates	Offshore Outsourcing
Resource Seeking		+
Market Seeking	+	+
Strategic Asset Seeking	+	
Efficiency Seeking		+

5.3 Methodology

This section provides an overview of the methodology adopted to examine the offshoring of core activities such as R&D. Offshoring refers to the sourcing of activities across geographic boundaries and includes sourcing through foreign affiliates and offshore vendors that are outside of the organizational boundaries (Lewin et al., 2009). I look at the four motives behind internationalization via offshore outsourcing and captive offshoring. The following section outlines the data and the sample. This will be followed by a discussion on the operationalization of constructs and the empirical model.

5.3.1 Data

The quantitative dataset on clinical trials, used in this research is CROCAS published by MediData. This unique database contains detailed project level data on clinical trials and identifies the trials that were offshored to foreign CROs (third party vendors) and foreign affiliates. The dataset focuses on the period 1997-2005 and contains data on approximately 123,000 clinical sites corresponding to 14,305 clinical trials from 98 firms, in the pharmaceutical industry, originating from 12 countries.

Country level data is from World Development Indicators (WDI) and to a large degree the data quality varies systematically by national source resulting in an unbalanced panel dataset. I was able to obtain useable data, which I defined as having non-missing observations for at least one year for a given country. In this research, the sample contains data on 37 host countries. I excluded countries that had less than 20 trials over the total time period. After eliminating country-year observations with missing data, I have a final sample size of 317 country-year observations.

5.3.2 Variables

Dependent Variables -The dependent variables for this study are FOREIGN and OFF.OUT. FOREIGN is measured as the count of all clinical sites managed by foreign affiliates in a given country in a given year. OFF.OUT is the count of all clinical sites that are offshore outsourced to third party vendors. Since the count data in the model was over dispersed, negative binomial was more appropriate compared to poisson (Greene, 2008).

Independent Variables – The study has four independent variables to measure the four offshoring motives. The first independent variable is POPULATION which is a measure of the resources available in a host country. This is the proxy for the resource seeking motive and it captures the number of potential patients available for the drug trial before regulatory approval. I assume that the larger the population of a country the larger the patient base thus availability of patients is the largest resource for a clinical trial.

The second motive is market seeking and this is measured by HEALTH which is the total health expenditure of the country in constant US dollars. Health expenditure is a good measure of the spending on health related products and greater the expenditure the more attractive the host country market for pharmaceutical drugs.

The third motive is strategic asset seeking and this is measured by the number of physicians (PHYS) in the country. Physicians are an important strategic asset for the pharmaceutical industry since the physicians are the point of contact with the patients (Azoulay, 2003). The physicians, also known as clinical investigators conduct the experimental human studies and their quality of work is important for getting credible results from the experiments. Access to local physicians especially the “thought leaders” in a host country increases the credibility of the drug and also improves the chances of identifying flaws in the drug or trial design.

The last motive is efficiency seeking and I use GDP per capita adjusted for purchasing power (GDPPPT) as a proxy for the cost of conducting clinical trials in the host country since GDP per capita reflects the salaries and wages in the country. Lower the GDP per capita of the country the lower the wages in the host country. Thus in order for the hypothesis 9 to be supported the coefficient for GDP per capita has to be negative and significant.

Controls – In addition to these key variables, I added controls for each country’s regulatory and institutional environment. GCP is a dichotomous variable which is 1 once the country adopts Good Clinical Practices. The pharmaceutical

industry is a highly regulated industry and I control for the institutions in the country with the GCP variable. I also include a control for the intellectual property rights protection regime of the country with the IPR variable (Ginarte and Park, 1997) as well as the prior total offshoring activity in a country. POLCON is an index to measure the political risk in the host country (Henisz, 1999) and is used as a control. Firm's offshore location choices are influenced by prior experience and I use a one year lag variable for total offshoring. I also use fixed effects to control for country and time.

5.3.3 Econometric Model

I estimate a panel negative binomial model with country fixed effects and year controls. Negative binomial regression model was used because the count data was over dispersed in the sample rendering poisson estimation unsuitable. Panel negative binomial with country fixed effects provides several important advantages in eliminating alternative explanations. For instance it helps eliminate alternative explanations driven by country level differences. Controlling for country and year fixed effects is also useful in correcting for possible omitted variable bias.

The panel negative binomial regression model (Benner and Tushman, 2002) used are:

$$\log \lambda_{it} = X_{i,t} \beta + \sigma \varepsilon_i + \mu_i$$

Where $\Pr(y = r) = (\lambda^r \varepsilon^\lambda) / r!$

y is observed count of the dependent variables and r is an integer. X is the vector of explanatory variables of country l at time t . σ is correction for over dispersion and μ_i is time invariant country i fixed effect.

5.4 Results

5.4.1 Descriptive Statistics

The clinical trial sites in the study are primarily concentrated in developed countries of Europe and North America (See Figure 5.1). Even though Japan has a strong pharmaceutical industry, the study does not have any clinical trials that were conducted in this country. This could be due to the conservative medical society, high costs and long duration associated with conducting clinical trials in Japan (Gross and Hirose, 2007).

There are also very few clinical trials in developing countries such as India and China and this could be because the sample is from 1997-2005. It is possible that there are a greater proportion of clinical trials in the more recent years. However data from clinicaltrials.gov, a US government run website, suggests that less than 20% of clinical trials were conducted in developing countries during 2006-2008 (Karlberg, 2009). Eastern European, Brazil and Russia are among the popular low cost destinations for clinical trials in the sample.

The home countries are from developed countries in the triad regions of North America, Europe and Japan. The pharmaceutical industry is concentrated in these regions and so the sample in the study is representative of the industry in general.

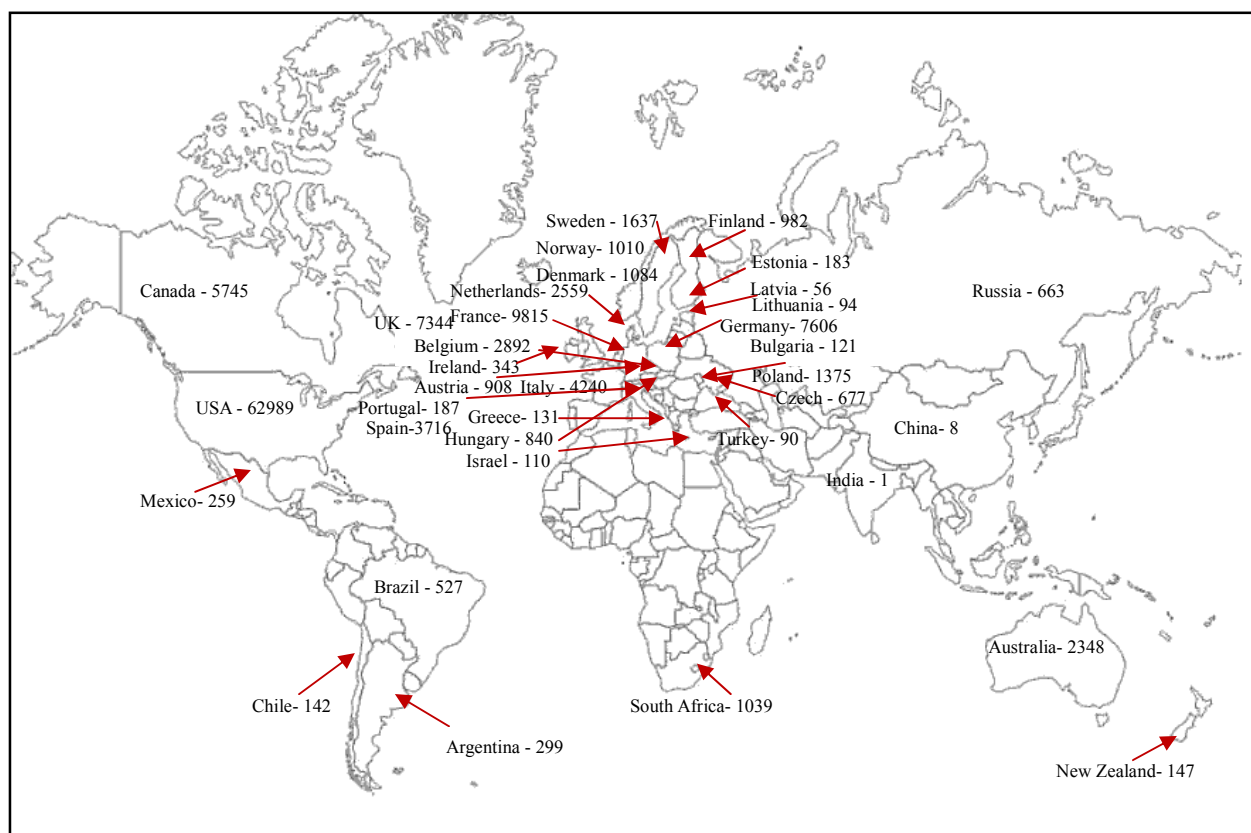
Figure 5.1: Location of Clinical Sites (1997-2005)

Table 5.2 gives the mean and standard deviation of the variables in the model. I report the raw values of the variables, rather than the logs or other transformations, to facilitate examination and all dollar values for GDP per capita and healthcare expenditure are expressed in constant US dollars. The average number of foreign affiliate managed clinical sites is 208.49 while offshore outsourced sites are much fewer at 45.2. PHYS is the number of physicians per 1000 people and the mean is 2.75. POLCON ranges from 0 to 1 with the mean as 0.42

Table 5.2 also reports sample medians, since, for some variables the means are significantly biased up by large country data. Note, for example, that

the mean healthcare expenditure is approximately \$724056.9, while the median health expenditure is only \$174216.

Table 5.2: Descriptive Statistics

Variables	Mean	SD	Median
FOREIGN	208.49	452.68	59
OFF.OUT	45.2	138.20	6
POPULATION	101.16	103.94	81
HEALTH	724056.9	2445974	174216
PHYS	2.75	0.89	3
GDPPPT	22206.88	12099.26	23320
GCP	0.63	0.48	1
IPR	4.05	0.73	4
POLCON	0.42	0.49	0
PRIOR ACTIVITY	253.69	571.74	68

Table 5.3 presents the correlation matrix for the independent variables. As expected, there is high correlation between healthcare expenditure and GDP per capita.

Table 5.3: Correlation Matrix

	POPULATION	HEALTH	PHYS	GDPPC	GCP	IPR	POLCON
POPULATION	1.00						
HEALTH	0.36	1.00					
PHYS	-0.28	0.10	1.00				
GDPPC	0.02	0.72	0.16	1.00			
GCP	-0.02	0.38	-0.05	0.52	1.00		
IPR	0.06	0.44	0.05	0.06	0.52	1.00	
POLCON	-0.17	-0.04	-0.03	0.19	-0.06	-0.04	1.00

5.4.2 Regression Results

Table 5.4 shows the results from negative binomial regression for offshore outsourcing. As there were a few highly significant correlations between few of the study variables, several alternate variations of the models were run to examine whether removing specific variables of concern influenced the results. I report the regression results in two columns. The first column contains results from Model 1 with only the control variables while the second column contains the results for the full model.

Table 5.5 presents the results for the second dependent variable: FOREIGN. Model 3 contains only control variables while Model 4 has the complete model for foreign affiliates.

Table 5.4: Negative Binomial – Offshore Outsourcing

Explanatory Variables	Model 1	Model 2
POPULATION		0.00746***
HEALTH		-0.0018***
PHYS		0.00311
GDPPPT		-0.00427**
GCP	0.2809*	0.2420
IPR	0.6543***	0.5812***
POLCON	-0.2068	-0.0775
PRIOR ACTIVITY	0.00101	0.00718
YEAR	0.4755***	0.5273***

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.10

In hypothesis 6, I proposed that offshore outsourcing of core activities is positively associated with resource seeking activity. As can be seen from the results in the Model 2, the coefficient for POPULATION is positive and highly significant thus supporting the first hypothesis. I also find that POPULATION coefficient is marginally significant in Model 4 for foreign affiliates suggesting that firms also use this sourcing strategy for resource seeking.

Table 5.5: Negative Binomial – Foreign Affiliates

Explanatory Variables	Model 3	Model 4
POPULATION		0.00709**
HEALTH		-0.00293***
PHYS		0.00428**
GDPPC		-0.0065
GCP	0.4076*	0.3116
IPR	0.2717*	0.1013
POLCON	-0.5537**	-0.3907*
PRIOR ACTIVITY	0.0013	0.0003**
YEAR	0.4271***	0.5233***

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.10

I next hypothesized that offshoring of core activities, to foreign affiliates and offshore vendors, is positively associated to market seeking motive. Results from Model 2 and 4 shows that the proxy variable for market seeking motive, health expenditure, is highly significant but the sign was opposite to the expectations. To test for robustness, I estimated several different models but the

sign and level of significance did not change for this motive. Thus I do not find support for hypotheses 7a and 7b.

In hypothesis 8, I predict a positive relationship between foreign affiliates and strategic asset seeking motive. This hypothesis was supported in the model 4. The non significant coefficient in Model 2 indicates that firms do not choose offshore outsourcing when offshoring for strategic assets.

In the final hypothesis I propose that offshore outsourcing is positively associated with efficiency seeking motive. The hypothesis is supported as the negative sign of the coefficient indicates a decrease of sites with increasing costs. GDPPPT was not significant for foreign affiliates suggesting that this sourcing is not driven by cost savings.

Turning to the controls, the regulatory variable GCP was only marginally significant in Models 1 and 3 while insignificant in the full models. This is surprising since prior research suggests that the regulatory environment of the country is important for offshoring of R&D. One possible explanation is that firms do not offshore their core activities to countries that have not adopted GCP. According to Ramamurti (2004), a minimum level of regulation and standards is required to attract foreign investment. IPR is positive and highly significant for offshore outsourcing suggesting that firms are more concerned about protection of intellectual property only when offshoring to foreign vendors. IPR is not an important factor for foreign affiliates and this is due to internalization of the activity which mitigates the risk of leakage. POLCON, the control for political risk in the host country, was significant only for foreign affiliates. This result suggests

that firms are more concerned about political risks for sourcing with foreign affiliates due to the higher investments required in this strategy. The last control for prior offshoring activity in the host country was not significant except in model 4 where it was marginally significant. This suggests that only when offshoring to foreign affiliates, firms consider past investments and this could be because of path dependence.

5.5 Conclusion

In this research, I focus on the importance of four motives for offshoring of core activities such as R&D. Specifically, I examine the relationship between resource, market, strategic asset and efficiency seeking motives and the two offshore sourcing strategies.

Controlling for unobserved country characteristics, the results from this study suggest that firms are more likely to use offshore outsourcing for resource and efficiency seeking purposes. Offshore outsourcing allows firms to access local networks within a country as well as benefit from lower costs due to economies of scale and scope offered by the foreign vendor. Firms are more likely to use foreign affiliates for strategic asset seeking purposes. Foreign affiliates are within the organizational boundaries and firms will prefer this strategy if they want to tap into host country knowledge networks. I also find weak support for the use of foreign affiliates for resource seeking purposes.

The results suggest that firms are less likely to offshore for market seeking purposes which is counter intuitive and interesting. This negative relationship could be because I measure market seeking as the expenditure of a country in

healthcare. While healthcare expenditure is a measure of the existing market in the host country it could also indicate the presence of a local pharmaceutical industry. As suggested by the literature on crowding out (Shaver and Flyer, 2000) existence of foreign and local firms in an industry leads to greater pressure on markets. It is possible that the results are driven by the presence of a strong local industry which discourages foreign firms entering such markets.

Prior research on internationalization has not looked at the difference between offshore outsourcing and foreign affiliates in terms of the four motives but this chapter suggests that there is a difference in the motives for the two sourcing strategies. Firms tend to prefer one sourcing strategy over another based on the motive for entering a particular host country.

This study has a few limitations, truncation of the WDI data is one such significant limitation. Some of that is overcome by using country fixed effects, but clearly, country fixed effects cannot make up for the many country-year with no available data. I also do not have much variance in the independent variables within a country which could be a cause of weak results. For instance number of physicians does not vary from one year to another. Similarly, I recognize that the independent variables of interest are only proxies for the phenomenon I am interested in studying.

Nevertheless, I feel the results from this study contribute to the literature on offshoring and outsourcing. The research suggests that resource seeking and efficiency seeking continue to be important motives even for core activities. One reason for this finding can be the dual character of clinical trials, which show

traits of CC and CE activities. While the literature sees these two as mutually exclusive, I posit that some core R&D activity can be both. In this paper, I look at two types of offshoring: to foreign affiliates and to third party vendors. Future research should explicitly look at the differences between these two offshoring strategies and the impact on location choices as a result of these differences. I also contribute to the literature on R&D by looking at clinical trials which in spite of being a significant economic activity of the pharmaceutical industry has not received significant attention by the international business and strategy field.

CHAPTER 6

STRATEGIC EVOLUTION OF FIRM'S CORE ACTIVITIES

6.1. Introduction

Recent years have seen dramatic changes in the organizational structure and sourcing strategies as firms redefine their geographic and organizational boundaries. This chapter studies the evolution of the firms as they move away from the traditional in-house model to alternate sourcing strategies. Earlier studies (Bartelemy and Quelin, 2006; Tiwana and Keil, 2007) have looked at outsourcing and offshoring as a one-time decision by primarily focusing on cross sectional research design. But firms are continuously changing their strategies in response to internal and external environmental factors and the strategic decision making process is not static.

An important question for international business and strategy researchers is how firms evolve. More specifically, how sourcing strategy has evolved from almost complete dependence on in-house sourcing to increasing use of offshoring and outsourcing for core activities. Using a series of case studies on firms in the pharmaceutical industry I focus on the stages of evolution of sourcing strategy and the internal and external factors that drive firms from one stage to the next.

There has been extensive literature in international business and related fields on offshoring and outsourcing activities of firms (Doh, 2005; Erramilli, 1991;

Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005). These studies have focused mostly on the inputs (determinants/drivers) or outputs (performance implications) of this phenomenon. Relatively few have looked at the transition process inspite of the growing demand for strategy process research (Barnett and Burgelman, 1996; Chakravarthy and Doz, 1992; Malnight, 1996; Van De Ven and Huber, 1990). This research develops an evolutionary perspective of the sourcing strategies of the firm by examining the dynamic changes in the strategic decision making process over time.

According to the evolutionary perspective, the strategies of firms evolve over time in response to internal and external threats and opportunities (Chang, 1996; Malnight, 1996). Firms adopt strategies to meet certain objectives and the ability to meet these objectives depends on the resources available to the firm. I examine the various internal and external factors that influence the changes in a firm's strategy.

To answer this "How" research question on the evolution of firm strategy from domestic in-house to external and international sourcing of core activities, I use multiple case studies. This method is especially useful for a relatively unexplored topic (Eisenhardt, 1989). Since there hasn't been much research on the evolution of firm's sourcing strategy, case study research provides greater insights to the process of outsourcing and offshoring. Explanatory case study based research is also appropriate for this study as it is complex practitioner driven and contemporary phenomenon that has theoretical importance (Yin, 2003).

I study this evolution of sourcing strategy in the pharmaceutical industry, focusing on the outsourcing and offshoring of the clinical trials. This chapter presents case studies of four firms from this industry.

Three important factors are used in the selection of firms: type of firm, country of origin and age of the firm. The pharmaceutical industry is made up of pharmaceutical and biotechnology firms and firms in this study represent these two segments of the industry. The firms are from North America and Europe which increases the external validity of the study. Age of the firm is also taken into consideration because of an *a priori* assumption that older firms have different sourcing strategy than younger firms.

Data collection involves multiple sources: semi structured interviews with directors and vice presidents of clinical operations and archival documents. Responses from a survey done on clinical trials are also used to enhance the external validity of the study.

The next section presents literature on offshoring and outsourcing of core activities and discusses prior strategy research that adopts an evolutionary perspective. Section 6.3 discusses the methodology used in this study and Section 6.4 presents the findings of this study. This section discusses the five stages of strategic evolution and the internal and external factors driving the transition to the next stage of this evolution. Finally, section 6.5 concludes.

6.2 Literature Review

In this section I provide a brief overview of the current literature on offshoring and outsourcing. I then discuss how this research contributes to the

literature by drawing on the evolutionary perspective. Sourcing strategies relate to decisions made by firms regarding the geographical and organizational boundaries of the firm. Similar to the other studies in this dissertation, I look at four sourcing strategies: domestic in-house, foreign affiliates, domestic outsourcing and offshore outsourcing. In this research I adopt a dynamic perspective to offshoring and outsourcing, by looking at qualitative data since most of the prior research has used quantitative data to study this phenomenon.

6.2.1 Offshoring and Outsourcing

There has been extensive research on the typologies of outsourcing and offshoring (Chakarabarty, 2006; De Vita and Wang, 2006; Mylott, 1995). Some researchers have also looked at the drivers or determinants of offshoring and outsourcing (Alexander and Young, 1996; Lewin and Furlong, 2005; McFarlan and Nolan, 1995). Others have examined the impact of offshoring and outsourcing on performance (Amaral, Billington and Tsay, 2006; Aron and Singh, 2005; Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005). But there has been no longitudinal study tracing the offshoring and outsourcing decision making process of firms (except for Sako, 2005). Sako (2005) suggests three different trajectories towards offshoring: 1. A firm may already be outsourcing but decide to shift from domestic to foreign supplier, 2. It may decided to outsource and offshore to a foreign firm simultaneously, and 3. A firm may already have a foreign affiliate but decides to switch to a foreign owned supplier. The last trajectory happens when the foreign affiliate is sold to local firms and this leads to

knowledge spillovers in the host country. However this was a conceptual paper without any empirical evidence.

6.2.2 Evolutionary Perspective

In this chapter I use the evolutionary perspective to construct a temporal model of sourcing decisions. According to Barnett and Burgelman (1996, page 7), “taking an evolutionary perspective on strategy means developing dynamic, path-dependent models that allow for possible random variations and selection within and among organizations”. The evolutionary perspective has been used to study many different strategic decision making processes such as diversification (Hoskisson, Hitt and Hill, 1991), restructuring (Chang, 1996), distribution systems (Geoffrion and Powers, 1995), strategic alliances (Doz, 1996) and strategic business exits (Burgelman, 1996). According to the evolutionary theory of the firm, the decision making process depends on the various external and internal factors (Chang, 1996; Nelson and Winter, 1982) and adopting this evolutionary perspective I look at the temporal changes in the strategy of the firm brought about by the various factors.

I examine internal factors that impact strategy such as internal resources (Grover and Cheon, 1996), prior experience (Levitt & March, 1988; Nelson & Winter, 1982) and costs (Bettis et al. 1992; Bryce and Useem, 1998). Some external factors that I study are host country infrastructure (Cheng and Kwan, 2000), intellectual property rights regime (Maskus, 2000), and availability of local resources such as patients and physicians (Azoulay, 2003).

6.3 Methodology

This section provides an overview of the methodology adopted to examine the evolution of the sourcing strategy of firms in the pharmaceutical industry. Since this research focuses on the decision making process, I use case study research methodology. Data collection involved two main sources: semi structured interviews (See Table 6.1 for sample interview questions) and archival data from Medidata. Medidata is a confidential database that contains detailed project level data on clinical trials and identifies the clinical trials that were outsourced to CROs. This database contains data on over 14,000 clinical trials from ninety eight firms that were outsourced or offshored in the last nine years from 1997-2005.

Table 6.1: Sample Questions for the Structured Interviews

- | |
|---|
| <ol style="list-style-type: none"> 1. How has your firm evolved in the location and conduct (organizationally and geographically) of clinical trials? Were there any changes in strategic direction? 2. How long did each strategy last (number of years)? 3. What factors (external and internal) led to the changes in your sourcing strategies? 4. How did these changes affect: management, employees, relation with CROs? 5. Which strategy was the best for the successful completion of clinical trials? 6. Which direction is the firm planning to follow in the future? 7. How has the relationship (FSP/ contractual/strategic) between the sponsor firm and CROs evolved? 8. How has the relationship between the headquarters and affiliates changed? |
|---|

I also use data from an online survey to supplement my findings from the qualitative study. As part of the dissertation I surveyed close to 60 firms in the

pharmaceutical industry. Respondents were asked to rank, in order from the oldest to the newest, their sourcing strategies. The four strategies in the survey question were: in-house, foreign affiliates, domestic outsourcing and foreign outsourcing. The survey data is used to improve the external validity of the study.

Three important factors were used in selecting the firms. The first criterion was the type of firm since the pharmaceutical industry is made up of pharmaceutical and biotechnology firms. The study has two firms from each category. The second criterion was to select firms based on the country of origin. The firms in the pharmaceutical industry are mostly from developed countries and are concentrated in the Triad region: North America, Western Europe and Japan. I have two firms from North America and Western Europe each in this study. The last criterion was the age of the firm since the pharmaceutical industry has some very old firms dating back to the nineteenth century as well as some young firms. In order to improve external validity I have firms of different ages. Two of the firms in the study are more than a hundred years old while the other two are approximately thirty years old.

All the four firms had to first complete the online survey questionnaire after which the respondents were approached for interviews. Preliminary interviews lasted for about an hour and the executives approached in this study were vice presidents of clinical operations who are involved in the decision making process. Subsequent interviews with other key informants such as directors of clinical operations and clinical trial managers were longer and lasted for approximately two hours. These interviews enabled me to inquire about how firms evolved over

time. I also conducted follow up interviews with few former executives of these firms to gain some historical perspective. A total of sixteen pharmaceutical executives were interviewed. The interviews were based on a semi structured interview guideline. The questions were reviewed by an industry expert before they were used for the interview. The interview questions are included in Table 6.1. Detailed notes were taken for all the interviews and in some instances the interviews were recorded after obtaining permission from the interviewee. All interviews were face-to-face except for two which took place over the phone.

Data analysis was an evolving and iterative process and I first created detailed case write-ups for each firm based on the interview transcripts and other information from company websites. The case write-ups were sent to all the participants to ensure that I had all the correct information. This was done to check if the internal validity and reliability of the data was maintained. I then triangulated the data from the primary and secondary sources. Data from Medidata is used to check for trends and patterns in sourcing strategy. An inconsistency in the findings prompted a second round of interviews to gather further data. After multiple revisions, I used the case study database to analyze the commonalities between the four firms. Building on individual case findings a cross case analysis was conducted (Stake, 2006). Through pattern matching techniques (Yin, 2003) I generated a conceptual framework comprising of environmental and internal factors that influenced strategy evolution and the different stages.

I now discuss the four firms in this study referred to here as firms Alpha, Beta, Charlie and Delta. The names of all the firms have been changed to protect the identity of the firms.

Firm Alpha

The first case in this research is a large North American biotechnology firm that is involved in the discovery, development, manufacturing and marketing of human therapeutic drugs. Firm Alpha was founded in the early 1980s which coincides with the start of evolution of the biotechnology industry. The firm is highly internationalized and has operations in over thirty countries. The firm is also highly diversified and focuses on several therapeutic areas. Approximately seventy percent of its total R&D budget is spent on clinical trials. The drug pipeline is very strong and the firm has many drugs in different phases of development.

Firm Beta

The second firm in the study is a European pharmaceutical firm with operations in multiple countries. This firm will be referred to as firm Beta in this research. This is a relatively old firm with roots going back to the eighteenth century but the firm has seen a recent wave of mergers and acquisitions in the last decade. Firm Beta focuses on multiple broad therapeutic areas and has a very large clinical pipeline. This firm has operations in over hundred countries and spends approximately fifty percent of its R&D expenditure on clinical trials.

Firm Charlie

The third firm in the study is also a European firm, but from another country. This multinational firm is very international with foreign affiliates in well over hundred countries and also diversified with portfolio spanning over eight therapeutic areas. Like most firms in the industry, this firm was created by a merger of two pharmaceutical firms in the early 2000s. Of the two firms that merged, one was a medium sized firm while the second was a relatively large firm. This firm spends approximately sixty percent of its R&D budget on clinical trials.

Firm Delta

The fourth firm in the study is a biotech firm which was also started in the early 1980s in the North America. This firm is quite large with approximately 100-110 clinical trials in a year spread across several therapeutic areas. The firm has many foreign affiliates which operate under multiple regional headquarters. This firm has three regional headquarters beside its North American global headquarter. Its operations are spread in over hundred countries and this firm also spends close to sixty percent of R&D on clinical studies.

6.4 Findings

In this section I discuss the findings from the four case studies. Detailed interviews with the clinical trial executives in the pharmaceutical industry revealed that the four firms in the study followed similar evolutionary pattern for their clinical development sourcing strategies. I next discuss the five stages (See Table 6.2), I observed in this qualitative study, along with the external and internal

factors that were important at each stage. Table 6.2 also shows the evolution of the four firms in the study.

Table 6.2: Description of the Firms

	Alpha	Beta	Charlie	Delta
Type of Firm	Large Biotechnology Firm	Big Pharmaceutical Firm	Big Pharmaceutical Firm	Large Biotechnology Firm
Origin	North American	European	European	North American
Firm Age	1980s	18 th Century	19 th Century	1980s
Stage 1	In-house	In-house	In-house	In-house
Stage 2	Domestic Outsourcing	Domestic Outsourcing	Domestic Outsourcing	Offshore Outsourcing
Stage 3	Foreign Affiliate	Foreign Affiliate	Foreign Affiliate	Foreign Affiliate
Stage 4	Offshore Outsourcing	Offshore Outsourcing	Offshore Outsourcing	Domestic Outsourcing
Stage 5	Backsourcing – greater in-house	Beginning of backsourcing		

6.4.1 Stage 1 – In-house Strategy

In the first stage of the strategy evolution all the four firms in the study conducted their clinical development in-house. Both the old and new firms started with internal drug development at the headquarters. The main rationale for using internal sourcing strategy was to exercise control over the core activities (Harrigan, 1984). Firms tend to emphasize centralization of their drug

development in the early stages of their life cycle. Firms also feel the need to maintain the quality of their trials and improve the speed of drug development during this stage. According to an executive at Alpha, drug development involves time costs as longer time from drug discovery to drug approval leads to loss in sales revenues due to a ticking patent clock. In this initial stage, firms still have relatively fewer clinical trials in their pipeline and the requirement for resources is also limited. At this stage, younger firms such as Alpha and Delta have limited overall experience in drug discovery and development. Firms also tend to retain their core activities in-house at this stage because their processes are still highly tacit. During this stage, firm Beta preferred to retain its trials in-house because it considered its internal employees to be more efficient in setting up external networks with their medical sites who conduct the study. Prior to its merger, Firm Charlie had a strong philosophy that clinical development conducted in-house was better and thus all aspects of the development ranging from design, conduct, monitoring and analysis were done in-house.

In the questionnaire that was sent to pharmaceutical and biotechnology firms, approximately 70 percent of the firms had started out with conducting drug development internally in the headquarters. The firms that did not conduct in-house clinical trials during the first stage of the life cycle were mainly very small biotechnology firms with limited internal resources. These small firms had conducted their clinical trials with domestic vendors from the very beginning.

6.4.2 Stage 2 – Domestic Outsourcing Strategy

In the past decade almost all firms in the pharmaceutical industry have

ventured into outsourcing. Most of the clinical development is outsourced to Contract Research Organizations (CRO) which are specialized firms offering narrowly targeted outsourcing services to pharmaceutical clients (Mirowski and Horn, 2005). Although the degree of outsourcing varies from firm to firm, most firms outsource part of their core activities to domestic service providers to gain access to external expertise. Firms such as Beta moved to outsourcing because of shrinking drug pipelines and loss of continuous innovation. Beta is also focusing on niche/orphan drugs, which requires specialized CROs.

Although firms are moving towards domestic outsourcing at this second stage, they still prefer conducting clinical trials internally and in many instances the important and critical studies are still done in-house. A lot of the outsourcing decisions are based on internal capacity. The firms are still relatively small in this second stage and if the firm has more clinical trials than it can manage internally due to resource constraints, then will it outsource to a domestic CRO. For instance, as firm Charlie and Firm Alpha grew, they started developing multiple compounds in different therapeutic areas which put a strain on the firm's internal resources. The firms had to seek external help because the headquarters could not complete all the trials internally. In some cases, firms also outsource to get rid of excess capacity. Firm Delta first used offshore outsourcing (See discussions in Section 6.4.4) but when it finally started using domestic vendors it was driven by the need to reduce its head count thereby reducing its overhead costs. Firms outsource more transactional tasks such as contract negotiations with hospitals or sites and archiving of clinical trial records in this stage.

There is a difference in the type of outsourcing done by firms in this industry at this stage. All firms follow one of the following two models: Preferred Provider model and Functional Service provider model (FSP) (Winter and Baguley, 2006). In the preferred provider model, the firm has three to four different CROs that are selected based on their prior experience and capabilities. When the firm needs to plan a new study it approaches these preferred CROs who then bid for the contract. Selection is made based on the most competitive bid. This is similar to the arms length contracting. In the Functional Service provider model, the firm has only one CRO who does all the trials without the competitive bidding process. This is a type of strategic relationship while the previous model is more of a cost based relationship.

Firms Alpha and Charlie follow the Functional service provider model while firms Beta and Delta follow the preferred provider model. Beta does not use the functional service provider model because according to the firm, the pharmaceutical industry is dynamic and this model does not adequately capture the changes in pricing of the clinical trials. But on the other hand using the functional service provider works out to be cheaper for the firm because CROs tend to have pricing based on tier system. This means that as a firm outsources more trials to one CRO, the cost per patient decreases. Beta and Delta also uses niche CROs from time to time to access specialized services.

Results from the online questionnaire show that approximately 64 percent of firms in the industry progress to this second stage of sourcing strategies.

6.4.3 Stage 3 – Foreign Affiliates Strategy

As firms grow and gain more international experience, they started locating some of their clinical development activities in foreign affiliates. In this third stage, the core activity is still concentrated in the home country but peripheral clinical trials are sent to the affiliates. Many of the firms such as firm Delta set up regional headquarters and the decision making process often became independent at the subsidiary level. Regional headquarters often design and run their clinical trials independent of their global headquarters. Such firms see intra firm specialization as some foreign affiliates become the preferred location for conducting clinical trials for specific therapeutic areas. This is similar to some of the findings by prior literature on subsidiary mandates (Birkinshaw, 1996; Cantwell and Mudambi, 2005).

One of the main reasons for firms to move to this third stage is internal growth and cost pressures. As firms start conducting more clinical trials in different therapeutic areas they need to use all the resources available outside of their headquarters. According to Firm Charlie, they started relocating their core activities to their foreign affiliates to gain access to foreign markets. They felt that conducting trials in their foreign affiliates creates more awareness about their firm in the foreign market and also lends credibility to the firm's operations.

All four firms internationalized their core activities to gain access to host country resources such as large and diverse patient base and qualified physicians. According to prior researchers (Gammeltoft, 2006; Robinson, 1988) one of the reasons for internationalization of R&D is to exploit host country

resources. North American and European firms often face difficulties in recruiting patients for their clinical studies and by moving activities abroad they are able to access countries with large populations. This is especially the case when the firm conducts clinical studies for orphan drugs as there are not enough patients to recruit in a single country. Orphan drug is a term used by the pharmaceutical industry for drugs that treat rare diseases and do not have high economic returns. Firms also internationalize their drug development to gain knowledge of foreign regulatory environments as well as to involve thought leaders in their clinical trials. Thought leaders are well known international physicians whose endorsement of the drug improves the probability of drug approval and market success.

Results from the online questionnaire show that approximately 60 percent of firms in the industry progress to this third stage of sourcing strategies.

6.4.4 Stage 4 – Offshore Outsourcing Strategy

The fourth stage in the sourcing strategy evolution is the shift to offshore outsourcing. The firms in the study, with the exception of Delta, started with domestic outsourcing and captive offshoring and after gaining adequate experience in offshoring and outsourcing graduated to offshore outsourcing. Delta first started with offshore outsourcing even before domestic outsourcing because its regional headquarter in Europe had begun using local CROs in smaller European countries. Thus Delta offshore outsourced its clinical trials three to four years before domestic outsourcing.

The drivers for foreign outsourcing are similar to that of stage three for foreign affiliates. Firms offshore to access the resources of different host countries. However the firms also take into consideration the intellectual property regime, infrastructure and competition in the host country. Since externalization of core activities involves sharing of sensitive information with external service providers, firms usually venture in to this stage only once they are confident of their ability to protect their intellectual property.

When using this strategy, the firms can choose between a global CRO and a regional or local CRO. Global CROs are large service providers who are located in many different countries and have good resources. Many firms prefer to use Global CROs for their offshore outsourcing because they have to only select one CRO who can then conduct trials in multiple countries. Firms such as Delta prefer to use regional CROs especially in Europe because these CROs have localized knowledge which is especially useful in diverse European countries. However Delta faces many challenges arising from the complexity of having multiple service providers. The firm also has problem getting standardized data and results from the different CROs.

Results from the online questionnaire show that approximately 72 percent of firms in the industry progress to this fourth stage of sourcing strategies.

6.4.5 Stage 5 – Backsourcing

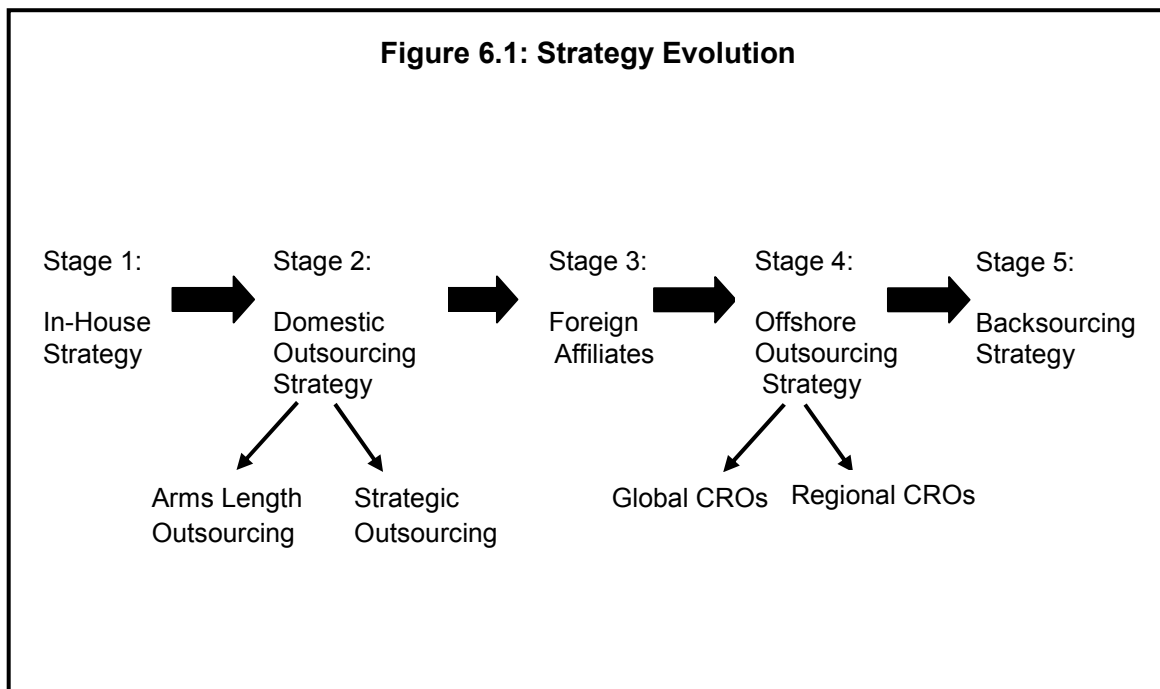
The last stage in this evolutionary process is backsourcing where some firms swing back from the pendulum and move towards greater internalization. Prior literature has called this bringing back of activities as backsourcing (Chalos

and Sung, 1998; Lacity and Willcocks, 2000). During this stage, firms internalize a sizable portion of their previously outsourced core activity. This happens due to a few different reasons such as the firm over extends and is unable to manage multiple outsourcing contracts. Among the firms in this study, Alpha has reached this stage because there was greater conflict between the firm and the CROs. The CROs felt that Alpha was not giving them adequate resources and flexibility to meet the goals, while Alpha found the employees of the CRO to be less responsive than its own. Alpha also had problems with the CROs because they were continuously missing deadlines which reduced speed of the trial.

Another important reason behind Alpha's back sourcing from outsourcing was the conflict between the headquarters and the foreign affiliates. When Alpha entered stage four and started using offshore outsourcing as a sourcing strategy, its foreign affiliates felt neglected. In this firm, foreign affiliates are considered as the buffer between the headquarters and the host country markets. When Alpha started offshoring its trials to foreign CROs, the foreign affiliates felt threatened by the possibility of losing importance within the firm. The firm also shrank a bit during this time and had a weaker pipeline. Thus due to the conflicts between the CROs and the foreign affiliates and the decrease in the firm's requirements, Alpha reduced the number of trials conducted by external parties. The work outsourced is currently restricted to more repetitive tasks such as data management in clinical trials. Anything novel is done in-house usually within the headquarters country.

While the other three firms in the study have not reached this last stage they do face some internal conflict due to offshore outsourcing. Beta is also considering reducing its offshore outsourcing due conflict with its affiliates. Currently the firm tries to reduce friction by involving the affiliates in the decision making process. The firm uses offshore vendors only if the affiliate is unable to do the clinical trials and the affiliate is actively involved in the selection of the third party vendors. Charlie also had some problems with its foreign affiliates but in the past couple of years the communication between the headquarters and affiliates has been improved to avoid internal friction. Delta is also aware of this potential for conflict with the foreign affiliates and tries to be sensitive to this issue by informing and involving the foreign affiliates in case a CRO is selected to manage the trial.

Figure 6.1 shows the five stages in this evolution cycle.



6.5 Conclusion

Using multiple case studies on firms in the pharmaceutical industry, I trace the evolution of sourcing strategies of clinical trials which is a core activity for these pharmaceutical and biotechnology firms.

Overall, I find evidence that firms tend to follow a similar trajectory regardless of size, age and country of origin. Firms tend to start with in-house clinical trials but as they grow they start using domestic outsourcing. This shift in sourcing strategy is primarily driven by internal resource restrictions and cost. The findings in this qualitative study support the results from the nested logit decision tree structure in Chapter 4 which suggests that firms are more likely to choose between in-house and domestic outsourcing before considering location related decisions.

International expansion leads firms to offshore some ancillary clinical trials to their foreign affiliate. The firm after gaining experience in domestic outsourcing and captive offshoring shift to offshore outsourcing in the fourth stage. Some of the factors that the firm take into consideration when choosing host countries is the quality of intellectual property rights regime, local competition and infrastructure of the country.

The final stage in the evolution cycle is the backsourcing of outsourcing activities by some firms. This is a very interesting finding and contributes to the literature on outsourcing which has not yet researched this reversal of the trend. I find that firms tend to face internal conflict with their foreign affiliates due to offshore outsourcing which forces them to rethink their outsourcing strategy. It is

interesting to note that Firm Alpha which is a younger firm has reached this last stage before the other older firms. This could be because Alpha started moved to stage two of outsourcing much before it was prepared to manage its internal resources and organizational structure. As discussed in Chapter 3, there appears to be an optimal level of offshoring and outsourcing.

The findings indicate that the primary driver behind the sourcing decisions is the resource capacity of the firms. Most firms today use a mixture of all four strategies although their focus changes with the different stages. For instance, in stage two when the firms start using domestic outsourcing, they continue to conduct some of their core activities internally in their headquarters. But in this stage a large portion of the core activity is done by domestic service providers and this distinguishes it from other stages.

As with most research, this study has some limitations. Since I use qualitative research methodology I only have four firms in the study. This impacts the external validity of the study but I have tried to overcome this by triangulating the findings with results from a question in an online questionnaire which also addresses the evolution of sourcing strategies. I have also used secondary data to increase the reliability of the findings. Another limitation of this study is that all the four firms are large firms with foreign affiliates and this could lead to large firm bias. It is possible that smaller firms especially boutique biotechnology firms may skip stages of in-house and foreign affiliates and only use domestic and offshore vendors due to lack of internal resources.

I believe this chapter makes important contributions to the literature on offshoring and outsourcing. Most of the prior studies have focused on outsourcing or offshoring but I look at the spread of activities across all the four sourcing strategies of the firm. I also use a dynamic approach to strategic decision making process and look at the changes in the firm's strategy over a period of time. Further research should explicitly look at the various measures taken by firms to overcome the internal conflict between headquarters and foreign affiliates due to offshore outsourcing. An important question that warrants further study is what happens after stage 5 of back sourcing. It will also be interesting to study if firms will internalize most of their core activities in the future.

CHAPTER 7

IMPACT OF OFFSHORING AND OUTSOURCING ON PERFORMANCE

7.1 Introduction

In this chapter, I examine the impact of offshoring and outsourcing on the performance of core activities. Drawing on transaction cost economics, the resource based view and literature on the internationalization – performance, I develop hypotheses regarding the relationship between four sourcing strategies (domestic in-house, foreign affiliates, domestic outsourcing and foreign outsourcing) and project level performance.

I focus on this relationship between offshoring, outsourcing and performance due to the inconclusive findings by prior research. While some researchers have found a positive relationship (Bryce and Useem, 1998), others have found negative relationship with performance (Amaral, Billington and Tsay, 2006). Many other studies have found no significant relationship between offshoring, outsourcing and performance (Aron and Singh, 2005; Ehie, 2001; Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005). Similarly, recent anecdotal evidence from the industry implies that decision makers are not sure if the performance of their offshored and outsourced projects are up to par with those retained in-house (A.T. Kearney, 2007).

By examining performance of clinical trials at the project level, I contribute to the literature which has mostly focused on firm level performance implications of offshoring and outsourcing. I also account for firms' self selection of their sourcing strategy and thus provide a more accurate measure of this relationship. Self selection becomes a problem when performance is observed only for restricted set of non random strategy choices.

I focus on the period 1997-2005 and analyze data on 14,305 clinical trials undertaken by 98 firms in the pharmaceutical industry spread across 12 countries.

In the next section I give a brief literature review and theoretical background. I also develop hypotheses relating to offshoring, outsourcing and performance. In sections 7.3 and 7.4, I describe the methodology and results, and the final section concludes.

7.2 Literature Review and Theoretical Background

The Effect of Outsourcing and Offshoring on Firm Performance

Despite the growing interest in offshoring and outsourcing, many studies have looked at the causes (Aubert et. al., 2004; Klass et. al., 2001; Leiblein and Miller, 2003) in a fine grained way, but do not provide an adequate analysis of the effects. The relationship between offshoring, outsourcing and performance has not received much attention from prior researchers (Mankiw and Swagel, 2006). Most of the prior research refers to anecdotal evidence on the impact of offshoring and outsourcing on performance at the firm level (see exceptions Bhalla et al., 2008; Gilley and Rasheed, 2000; Leiblein and Miller, 2003).

The relatively limited research at the firm level has not reached any consensus on the relationship between outsourcing, offshoring and performance (Leiblein, Reuer and Dalsace, 2002). On the one hand studies have found that offshoring and outsourcing improve performance (Bryce and Useem, 1998) but on the other hand researchers have found that these sourcing strategies have a negative impact on firm performance (Amaral, Billington and Tsay, 2006).

There have been yet another set of studies that have empirically tested the relationship between offshoring, outsourcing and performance and have found no significant relationship at the firm level (Aron and Singh, 2005; Bhalla, Sodhi and Son, 2008; Ehie, 2001; Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005).

Gilley and Rasheed (2000) examined the impact of outsourcing on the firm performance and the moderating role of firm level strategy and environmental dynamism. Their results indicate that there is no significant direct relationship between outsourcing and performance but there is a difference in the impact depending on the firm strategies. According to the authors there may be a relationship between outsourcing and performance at the individual functional areas which their data did not capture at the firm level. Aron and Singh (2005) also found that many firms had mixed outcomes from offshoring.

Firm vs. Project Level Unit of Analysis

The inconsistent findings in the literature on the offshoring outsourcing-performance relationship could be because most of the prior studies were done only with the firm as the unit of analysis and performance was measured as total

sales or profits of the firm (Bhala et al. 2006; Gilley and Rasheed, 2000; Gorzig and Andreas, 2002). Firm performance is a function of many different internal and external factors and it is difficult to find statistically significant effects of a single strategy on performance. For instance, when Mol et al. (2005) measured the performance effects at the firm level and did not find any significant relationship, the authors recommend the use of better measures of project level performance such as reliability, quality and innovation. These studies show that further research is required to examine this relationship between performance and offshoring and outsourcing at the project level (Gilley and Rasheed, 2000; Mol et al., 2005).

The performance of individual core activities is of importance to the firm and this research contributes to the overall literature by examining performance at a more micro level.

Self Selection of Strategy

Another reason for the lack inconsistent and inconclusive findings on this relationship could be due to lack of control for self selection (Leiblein et al. 2002). Decision makers make strategy choices based on their expectation of future performances. For instance, a firm which outsources its activity does so expecting the highest returns for this strategy compared to others.

These decisions are not random and there are many observable and unobservable factors that influence the strategic decision making process. By simply regressing performance on strategy without controlling for self selection, researchers are assuming that strategic decisions are random and that they are

including all the factors that influence performance in the regression (Shaver, 1998). Lack of control for self selection introduces biases in the estimation due to endogeneity of ownership and location decisions.

Despite of the widespread use of self selection technique, as proposed by Heckman (1979), in the economics literature, the management field has not adopted it for studying strategy and performance relationship (Hamilton and Nickerson, 2003). In this chapter, I study the impact on project performance while accounting for self selection. Using this technique I am also able to predict the performance had the firm selected an alternate sourcing strategy.

The following subsections will develop hypotheses at the project level relating to outsourcing and offshoring.

7.2.1 The Effect of Organizational Relocation on Performance

Transaction Cost Economics

Transaction costs economics (TCE) suggests that activities should be retained inside firm boundaries under conditions of uncertainty, asset specificity and continual recontracting (Williamson, 1979). According to Williamson (1979) there are two types of cost: production costs and transaction costs. When transaction costs of market exchange are greater than the benefits of externalization then internalized operations are preferred (Brouthers, 2002; Hennart, 1991). However since market exchange has potential to lower production costs, firms should externalize their activities if transaction costs are not high.

Transaction costs are composed of many different costs such as searching for and negotiating with partners and cost of monitoring and enforcing the contract (Agarwal and Ramaswami, 1992; Erramilli and Rao, 1993; Makino and Neupert, 2000). The transaction costs are higher for idiosyncratic transactions that occur under conditions of uncertainty (Williamson, 1979). Activities which require highly specialized assets also need to be internalized in order to avoid opportunism by the outside firm. According to this theory, there are three types of assets: site specific assets, physical assets such as machinery and human assets which require specialized training and learning by doing. In core activities such as R&D, asset specificity stems mostly from human capital investments. There is also a high degree of uncertainty involved in core activities and this gives rise to problems due to bounded rationality and information asymmetry. Thus TCE would suggest internalization of core activities such as clinical trials.

Resource based View

According to the resource based view, the firm is a collection of resources (Barney, 1991) and the competitive advantage of the firm lies in how inimitable its resources are (Penrose, 1959). These resources include tangible assets, such as capital and machinery, as well as intangible assets such as brand name and technology, which are semi permanently attached to the firm (Wernerfelt, 1984).

To fully exploit the firm's own resources and capabilities to sustain competitive advantage, firms depend on the external acquisition of

complementary capabilities (Grover and Cheon, 1996). RBV suggests that firms do not necessarily have to internalize their core activities as firm resources can also be exploited by means of contracts (Barney, 1991; Gainey and Klaas, 2003). Firms base their sourcing strategy on internally available resources but they can decide to source from outside firm boundaries even if the same activity can be done internally (Grant, 1991). Teng, Cheon and Grover (1995) find that firms are not limited to exploiting their own internal resources only but also able use other strategies to acquire complementary capabilities.

Using these two theories, I next discuss factors that can have positive and negative impact on performance due to outsourcing.

Factors that decrease performance due to outsourcing (Using TCE and RBV)

TCE implies that outsourcing has a negative impact on performance, when increases in transaction costs negate any decreases in production costs due to outsourcing. Increases in transaction costs result from numerous reasons such as: searching and negotiating with vendors, higher monitoring and coordination costs, delays in completion of project, and threat of technology leakage.

One of the important transaction costs is the cost of searching for competent vendors and the cost of negotiating contracts. Firms also face significant set up costs due to development of knowledge sharing routines with the vendor (Dyer and Singh 1998). The transaction costs are thus higher in activities which require continual recontracting with vendors.

Managing relationships with external firms also involves greater coordination and monitoring costs (Azoulay, 2004). Firms have to maintain greater control over the operations of their vendors especially for core activities such as R&D, and often have to set up separate departments to manage and supervise different vendors (Takeishi 2001). Outsourcing can also lead to loss of control over the activities performed by the vendor. This concern often leads to a higher level of monitoring which increases costs.

Firms can face delays in the completion of the projects due to higher employee turnover in the vendor firm. Outsource vendor firms often do not have dedicated teams of employees for each sponsor firm and the changes in employees working on a project could delay the completion. Delays can also occur if the quality of output is inferior and the firm has to reassign some of the activities to another vendor.

Threat of technology leakage to vendors is also a type of transaction cost especially for R&D activities (Bettis et al., 1992; Prahalad and Hamel, 1990; Quinn, 1992). Research has shown that third party vendors could become future competitors by forward integration (Cox, 1999). Some other factors that according to TCE could lead to higher transaction costs are hold-up costs (Klien, 1996), asset specificity and contract incompleteness.

Thus transaction cost theory suggests that core activities such as R&D should be internalized. Unified governance avoids transaction costs and improves performance of core activities conducted within the firm boundaries.

RBV also suggests that outsourcing can lead to decline in performance due to excessive dependence on suppliers (Alexander and Young, 1996). Firms that outsource core activities can see a decline in the innovative capacity of the firm (Kotabe, 1990) since these core activities are sources of competitive advantage. Outsourcing of core activities can lead to decline in competitiveness over long term due to loss of absorptive capacity (Cohen and Levinthal, 1990).

Accordingly I first hypothesize that domestic outsourcing decreases the performance of the core activity compared to in house sourcing.

H10a: Other things being equal, when compared to in-house, domestic outsourcing of core activities has a negative impact on the overall performance of the activity.

Factors that improve performance due to outsourcing (Using TCE and RBV)

Although arguments against outsourcing can be made using TCE and RBV, these theories can also be made to suggest factors that improve performance – when the additional costs of externalization of functions are more than offset by the benefits of outsourcing.

With rapid technological progress and automation, some portions of core activities are becoming more modularized and codified. This enables firms to outsource even complex tasks with minimal transaction costs. Codification and modularization of formerly core activities leads to a two- fold effect which has a positive impact on performance. First, transaction costs at the focal firm decrease due to lower monitoring and coordination costs and reduced training

requirements when knowledge and requirements are codified. Second, production cost in the outsourced vendor company also decrease since, as suggested by RBV, vendor firms gain easier and clearer access to specialized resources, and improve their absorptive capacity when knowledge is codified and explicit.

Third party suppliers benefit from economies of concentrated scale in one piece of the value chain because they focus on a narrow range of activities (often for multiple clients). Quinn and Himler (1994) also found that activities may be outsourced to access more specialized technological resources of the service provider. Thus according to RBV, firms can access newer resources through outsourcing which improve its competitive advantage (Bryce and Useem, 1998).

Firms also outsource their core activities for other reasons such as flexibility (Ellram, et al., 2008). Complementary external resources make the focal firm more flexible by enabling it to reduce its own fixed costs (Alexander and Young, 1996) thus streamlining its operations. In this way, with lower fixed costs, outsourcing improves performance by providing the firm greater flexibility to cope with dynamic environments (De Vita and Wang, 2006).

Outsourcing can lead to greater efficiency by increasing the speed of completion of a task, which can impact the firm's responsive to the market. This becomes even more important when the speed of completion by internal resources is slow. According to Kessler et. al. (2000), their study on technology sourcing found that external sourcing improved the innovation speed of the firm. Efficiency is also higher in outsourcing as firms can choose suppliers whose

products and services are considered among the best (Dess et al., 1995; Quinn, 1992) and fit the firm's specific requirements.

The literature on clinical trials suggests that CROs are able to conduct clinical trials up to 30% faster than average pharmaceutical firms (Lehman and Brothers, 1999). In an industry white paper, Tapon and Thong (1999) suggest that domestic outsourcing increases the efficiency and flexibility of the firm by allowing smaller investments in multiple clinical sites rather than one single investment in a large clinical study. According to them, outsourcing clinical trials improves the speed of drug development and also minimizes risks associated with clinical failure.

To conclude, recent changes in technology and more efficient governance methods have decreased transaction costs associated with outsourcing. According to the resource based view, outsourcing reduces production costs to a great extent and allows firms to access complementary resources. Recent research has found that even after taking transaction costs into account, outsourcing still leads to cost savings for the firm (Fill and Visser, 2000). This enables the firm to perform its core activities more efficiently and profitably. Thus simultaneous reduction in transactional and production costs lead us to develop competing hypothesis that outsourcing has a positive impact on performance.

H10b: Other things being equal, when compared to in-house, domestic outsourcing of core activities has a positive impact on the overall performance of the activity.

Outsourcing can be broadly broken down into two categories: domestic outsourcing and offshore outsourcing (Grossman and Helpman, 2005). Although the underlying process of these two types of sourcing strategies is similar, offshore outsourcing is more complicated and can entail higher costs than domestic outsourcing due to differences in geographical location. I will develop hypotheses on offshore outsourcing and performance after discussing internationalization in general in the following sub-section.

7.2.2 The Effect of Geographical Relocation on Performance

Thus far, I have developed hypothesis as to the effects of internalization (in-house activity) versus externalization of the activity to contract providers. In short, I have discussed organizational restructuring, with no regard to the geographical location. Next, I develop hypotheses relating to geographical relocation or offshoring of activities that were formerly performed in the headquarters country of the company. This geographical relocation of a function can be under either the company's own foreign affiliate, or contracted to a foreign vendor.

Internationalization – Performance Theory

Offshoring of core activities to countries outside the firm's home country is increasingly becoming common today due to factors such as improved ICT that facilitate greater coordination, improved social, technological and economic resources that provided the necessary infrastructure, and overall improvement in international patent protection which has made it easier to protect inventions.

The theory of internationalization – performance (I-P) suggests that there are advantages and disadvantages of internationalization (Contractor et, al. 2003). Due to these advantages and disadvantages associated with internationalization, prior literature has mixed findings on its impact on performance. Some researchers have found a negative relationship with performance due to internationalization costs (Morck and Yeung, 1991) while others have found positive impact due to advantages from international expansion (Han et.al, 1998). Drawing on the internationalization-performance literature I next make arguments in favor of and against offshoring.

Factors that improve performance due to offshoring (Using I-P)

Some of the important drivers of offshoring are lower wages and salaries, access to foreign talent, and knowledge acquisition from foreign clusters and markets. Firms often go outside their home country to access skilled workers at lower wages and salaries (Dossani and Kenney, 2004; Flores and Aguilera, 2007). Cost savings from offshoring can be realized especially if there are significant differences between the home and the host country, particularly in labor costs (Cheng and Kwan, 2000; Woodward and Rolfe, 1993). Firms from developed countries often offshore core activities to developing countries that have lower wage levels.

Firms also offshore to tap into foreign knowledge clusters (Alcacer and Chung, 2007; Cantwell and Mudambi, 2005) to generate new innovations and for technology spillovers. Since knowledge clusters are localized many firms co-locate to benefit from economies of agglomeration. Knowledge clusters provide a

pooled market for workers, specialized suppliers, better access to institutions and public goods, and opportunity for knowledge spillovers. These benefits attract foreign firms (Driffield and Munday, 2000) which can lead to higher performance of the firms.

Offshoring to gain access to foreign markets is also an important factor to improve performance of the firm. With the shift in balance of power in favor of emerging countries such as China and India, firms now offshore to gain access to these markets. As well, feedback from foreign markets constitutes an increasingly necessary input into the design process for new products and services. Offshoring also leads to greater visibility in the host country (Flores and Aguilera, 2007) and many firms now conduct their core activities abroad to create market awareness.

Factors that decrease performance due to offshoring (Using I-P)

In spite of these recent increases in offshoring, internationalization barriers and costs still exist (Hitt et al. 1997; Hymer, 1976; Sullivan, 1994). These costs are incurred due to liability of foreignness (Zaheer, 1995). By offshoring their core activities, firms face liability of foreignness due to lack of familiarity with foreign cultures, environment and markets. Zaheer and Mosakowski (1997) grouped internationalization costs as follows: spatial costs, unfamiliarity costs, host country environment costs and home country environment costs.

Offshoring may also lead to inefficiency due to differences in management styles, which leads to increased coordination requirements (Amaral, Billington, and Tsay, 2006; Fischer and Behrman, 1979). Firms have to

find a balance between coordination and autonomy especially while offshoring R&D related activities. Coordination costs also increase due to differences in culture between the home and host countries which make management of foreign teams more difficult.

While firms often seek foreign locations to reduce the cost of salaries and wages, there are significant differences in the quality of services available in the host country. Firms may benefit from lower costs in the short run, but this nominal difference in wages and salaries can be offset by lower productivity in the foreign location. Moreover, in the long run, wages in a country rise with future increases in productivity (Contractor and Mudambi, 2008).

Firms also face problems associated with differences in institutions between the home and host countries. The regulatory environment is very country specific (for example different nations have different requirements for clinical trials, test subjects and the compilation of data) and every time a firm enters a new market it has to learn and manage new foreign regulatory requirements such as patents and certifications. In many emerging countries the intellectual property protection laws are weak and this increases the risk of leakage of technology and knowledge.

Core activities such as R&D often involve a high degree of tacit knowledge which cannot be articulated and is more difficult to transfer. Although firms internalize their knowledge transfer due to the tacitness of knowledge (Kogut and Zander, 1993) this problem still exists with foreign affiliates who may be quite different from the headquarters. According to Contractor et. al. (2009) transfer of

tacit knowledge across geographic boundaries can be difficult and expensive thus adding to the cost of internationalization.

Even though there are advantages from internationalization, costs associated with the liability of foreignness can be even larger, thus leading overall to a decrease in performance. Thus I propose that offshoring of core activities leads to a decline in performance.

Firms that offshore their activities have to decide whether to locate the activities within their own foreign affiliate (i.e., within their own company boundary), or outside the firm's boundary using foreign vendors. According to Kohler (2002), there are significant differences between foreign affiliates and foreign vendors.

Locating core activities within foreign affiliates may have a positive impact due to ease in transfer of tacit knowledge, lower monitoring and coordination costs and similar organizational cultures. However, relocation of activity to foreign affiliates may also have a negative impact on performance due to lack of integration between the parent and the affiliates. Prior research (Kostova and Roth, 2002) has shown that tension can exist between the parent and the affiliate especially when the affiliate is deeply embedded in the host country. Setting up a foreign affiliate also involves additional higher fixed costs. The firm has to seek a balance between coordination and autonomy in the foreign affiliate thus increasing governance costs.

Thus I propose two competing hypotheses regarding offshoring to foreign affiliates.

H11a: Other things equal, when compared to in-house sourcing, offshoring of core activities to foreign affiliates, has a positive impact on the overall performance of the activity.

H11b: Other things equal, when compared to in-house sourcing, offshoring of core activities to foreign affiliates, has a negative impact on the overall performance of the activity.

The last type of sourcing strategy is offshore outsourcing which is more complex compared to domestic outsourcing and captive offshoring (affiliates). In the prior subsections I hypothesized that domestic outsourcing improves overall performance due to benefits from externalization such as access to specialized resources.

Offshore outsourcing *combines* elements of outsourcing (hypothesized in H1a and H1b) as well as offshoring (hypothesized in H2a and H2b). The impact of a combined *outsourcing and offshore sourcing* strategy on performance will depend on the strength of these two opposing forces. When the benefits of outsourcing outweigh the costs of keeping operations or functions internal, then offshore outsourcing can have a positive impact on performance. But if internationalization or geographical relocation costs are greater than the net benefits resulting from externalization, then this sourcing strategy will have a net negative impact on performance. In the absence of a priori research I propose two competing hypotheses:

H12a: Other things equal, when compared to in-house sourcing, offshore outsourcing of core activities has a positive impact on the overall performance of the activity.

H12b: Other things equal, when compared to in-house sourcing, offshore outsourcing of core activities has a negative impact on the overall performance of the activity.

7.3 Methodology

This section provides an overview of the methodology adopted to examine the spread of clinical trials and its impact on performance. Project performance will be examined for the four sourcing strategies adopted by MNEs which are: in-house clinical trials, domestic outsourcing, captive offshoring (foreign affiliates) and offshore outsourcing. The following section outlines the data and the sample. This will be followed by a discussion on the operationalization of constructs and the empirical model.

7.3.1 Data

The quantitative dataset used for this research is the CROCAS dataset published by MediData. The dataset focuses on the period 1997-2005 and contains data on approximately 123,000 clinical sites corresponding to 14,305 clinical trials from 98 firms, in the pharmaceutical industry, originating from 12 countries. There are 53 large pharmaceutical firms, 21 medium/small sized firms and 24 biotechnology firms in the sample. CROCAS has data on nearly all large pharmaceutical and biotechnology firms and the sample is representative of the industry as a whole.

Firm level data is from Compustat, compiled by Standard and Poor's. Compustat compiles panel data on global parents obtained from a large variety of international sources. The database has detailed current and historical financial data on the pharmaceutical industry.

7.3.2 Variables

Performance – Project level performance is measured by two variables. I use one financial and one non - financial measure and they are: the cost of conducting the study (COST), duration of the study (DURATION). These two performance measures are used because some of the important drivers of outsourcing and offshoring are cost savings (Jiang and Qureshi, 2006), and speed of completion (Maromonte, 1998). COST is measured as the total payment paid for the study, and DURATION of the study is measured as the number of weeks for clinical trials. The two performance measures are from the CROCAS database and are transformed into their natural logs.

Sourcing Strategy – The sourcing strategy is measured as a set of discrete strategies that cannot be ordered. The variable is 0 if the firm selects domestic in-house sourcing, 1 for domestic outsourcing, 2 for foreign affiliates, and 3 for offshore outsourcing. The base category for this variable is domestic in-house sourcing. In the OLS regressions I use three dichotomous variables for the strategies and in-house is the base group.

Firm Level Determinants - In the first stage of the selection model, as discussed in the next subsection, I include some firm level factors which influence the decision to offshore and outsource. The first factor is *firm size* measured as the

log of total employees. The second firm level factor is *firm age* measured as the number of years since incorporation. I also include *country of origin* and *parent type* (pharmaceutical versus biotechnology firms) as a factor. The final firm level factor is *firm performance* which is operationalized as the log of net income. I have used a three year lag for this variable.

Project Level Determinants - I also include project level factors in the first stage of the selection model. *Phase of the clinical trial* is the first project level factor. There are three different phases of clinical trials and each differs in the level of complexity. *Therapeutic area* is also a factor in the decisions related to sourcing strategies. I have clinical trials from 13 therapeutic areas in the sample. The last factor in the model is the *size of the clinical trial* measured by the number of patients recruited for the clinical trial.

7.3.3 Econometric Model

I first estimate an Ordinary Least Squares Regression model to examine the impact of sourcing strategies on project performance. The dependent variable is performance and the independent variables are three dichotomous variables: domestic outsourcing, foreign affiliates and offshore outsourcing. I also include firm and project level controls in this model.

I next use the two stage self selection model as proposed by Heckman (1979) with one modification. Heckman (1979) and others (Leiblein et.al. 2002; Shaver, 1998) used probit in their selection equation because of dichotomous choice model. But since I have multiple discrete strategies that cannot be

ordered, I use multinomial logit in the first stage (Bourguignon, Fournier, and Gurgand, 2007).

Selection Equation:

$$Y^*_j = z\beta + \eta_j$$

Where:

Y^*_j is the dependent variable and j is the choice among four sourcing strategies. Vector z represents the set of explanatory variables discussed in the previous subsection and η is the error term. The estimated coefficients from the first stage multinomial logit model is used calculate λ which is the Inverse Mills Ratio (IMR). λ is the control variable for self selection which enters the second stage performance model. IMR controls for the differences in firms selecting different sourcing strategies and helps to estimate what the performance would have been had the firm chosen another strategy (Hamilton and Nickerson, 2003).

In the second stage of the selection model I compute the outcome equations using ordinary least squares (OLS) as proposed by Heckman (1979) for each sourcing strategy while accounting for self selection.

Outcome Equation:

$$Performance_{In-House} = \beta'x + \beta_\lambda\lambda_1 + \eta$$

$$Performance_{Foreign\ Affiliate} = \beta'x + \beta_\lambda\lambda_2 + \eta$$

$$Performance_{Domestic\ Outsourcing} = \beta'x + \beta_\lambda\lambda_3 + \eta$$

$$Performance_{offshore\ Outsourcing} = \beta'x + \beta_\lambda\lambda_4 + \eta$$

Where,

Performance is measured as cost and duration in separate equations. Vector x includes intercept constant plus firm and project level factors described previously. λ is the self selection correction term for each subsample. I exclude country of origin from the vector x as I need at least one variable which influences strategy choice but does not influence performance due to identification.

7.4 Results

7.4.1 Descriptive Statistics

The firms in the pharmaceutical industry in general, and in the sample, are highly concentrated in the Triad countries: USA, Western European countries and Japan.

Table 7.1 gives the sample mean, median, and standard deviation of the variables in the model. I report the raw values of the variables, rather than the logs, to facilitate examination. All dollar values are expressed in 2005 \$US. Table 7.1 also reports sample medians, since, for some variables the means are significantly biased up by large firm and project data.

Table 7.2 presents the correlation matrix for all the variables in the study. Most variables have low correlation. Only firm size and net income are highly correlated at 0.764. In general, it is reasonable to expect larger firms to have greater net income. However, to further rule out the possible effects of correlation identified here, I ran separate models (not reported here) with only one variable at a time but the results did not differ significantly.

Table 7.1: Descriptive Statistics

Variables	Mean	SD	Median
Age	122.84	59.54	122
Net Income	3083.486	2611.87	1106
Firm Size	647,581	326,648	41,496
Project Size	1718	3635	1251
Project Duration	18.96	11.55	16
Project Cost	100,645	145,000	88,000
TA	6.47	3.64	6
Parent Type	1.96	0.355	2
Phase	2.63	1.16	3
Country of Origin	57.55011	16.54231	66

Table 7.2: Correlation Matrix

	Age	Net Income	Firm Size	Project Size	Project Duration	Project Cost	TA	Parent Type	Phase	Country Of Origin
Age	1.000									
Net Income	0.404	1.000								
Firm Size	0.372	0.764	1.000							
Project Size	0.025	-0.101	-0.085	1.000						
Project Duration	0.029	0.067	0.038	-0.236	1.000					
Project Cost	0.028	-0.003	-0.005	0.037	0.081	1.000				
TA	-0.03	-0.049	-0.039	0.159	-0.257	-0.036	1.000			
Parent Type	-	0.073	-0.124	-0.036	0.132	-0.005	0.019	1.000		
Phase	0.208	0.164	0.191	-0.172	0.342	0.032	-0.056	0.029	1.000	
Country of Origin	0.125	0.179	-0.027	0.004	-0.007	0.008	-0.083	0.146	-0.06	1.000

7.4.2 Ordinary Least Squares Model Results

The results from the OLS model are shown in Table 7.3. Model 1 measures performance as the Cost of the clinical trial and in-house strategy is the base group for this model. The first independent variable is domestic outsourcing and the coefficient is negative but not significant. The negative coefficient indicates that costs are lower for domestic outsourcing compared to in-house but since it is insignificant I do not find support for the first hypothesis in this OLS model. The coefficients for foreign affiliates and offshore outsourcing are positive and significant. This suggests that costs are higher for these two strategies when compared to in-house strategy.

Turning to control variables, only one of the firm level controls was marginally significant. The control for parent type was positive and marginally significant suggesting that pharmaceutical firms, on an average, have higher costs than biotechnology firms. Since the firm size variable is not significant this could mean that the cost of the drugs being tested is different for these two types of firms. At the clinical trial level, phase and size of the clinical trial were significant and positive. This indicates that more complex phases and larger studies cost more and this result is not surprising.

In Model 2, I measure performance as the duration of clinical trial. The findings in this model are similar to the first model. I find that coefficient for domestic outsourcing is negative but not significant while foreign affiliates and offshore outsourcing is positive and significant. Thus I find support for hypotheses 2 and 3b only in the OLS model estimates. The controls for phase,

therapeutic area and size of clinical trials are significant. The control for time is also marginally significant in this model.

Table 7.3: Ordinary Least Squares Model

Explanatory Variables	Model 1 (Cost)	Model 2 (Duration)
Domestic Outsourcing	-0.05	-0.12
Foreign Affiliates	0.82***	0.16***
Offshore Outsourcing	0.67***	0.44***
Size	0.03	0.02
Age	0.02	-0.05
Performance	0.03	0.02
Phase	0.17***	0.31***
Therapeutic Area (TA)	0.03	0.74**
Size of Trial	0.89**	0.14***
Parent Type	0.22*	0.52
Trend	-0.65	0.03*
R ²	0.28	0.24

I next estimate the two stage self selection model to control for selection bias.

7.4.3 Strategy Selection Model Results

Results from the multinomial logit regression are shown in Table 7.4. I report the regression results in three columns for three strategies: foreign

affiliates, domestic outsourcing and offshore outsourcing. In-house sourcing is the base group.

For sourcing from foreign affiliates, the coefficients indicate that bigger and older firms increase the likelihood of firms using foreign affiliates rather than in-house sourcing. Poor performance also increases the likelihood of offshoring to foreign affiliates as was proposed in the previous section. For project level factors, the results suggest that larger clinical trials are more likely to be conducted in the foreign affiliates than in-house. Other factors such as phase, country of origin and parent type were not significant for foreign affiliates.

Table 7.4: Multinomial Logit Model Estimates

Strategy	Foreign Affiliates	Domestic Outsourcing	Offshore Outsourcing
Intercept	3.21***	-0.105	4.69***
Size	0.003**	-0.0072***	-0.005**
Age	0.015***	-0.019	-0.011
Performance	-0.309***	-0.023	-0.371***
Phase	-0.359	0.045***	0.245***
TA	-0.03	0.056	-0.002
Size of Trial	0.372***	-0.063	0.084**
Parent Type	0.234	-0.602	-0.932
Country of Origin	-0.031	-0.012	-0.034
Log Likelihood	0.622*	0.131	0.128
χ^2	-8568.561		

For domestic outsourcing I find a significant and negative relationship for firm size indicating that smaller firms tend to prefer domestic outsourcing to in-house sourcing. I also find that phase of the clinical trial is positive and significant indicating that later phases which are more codified tend to be outsourced to domestic service providers. All the other factors were not significant although their signs were in the expected direction.

In the last column I observe that smaller and poor performing firms are more likely to offshore outsource. As was the case with domestic outsourcing, firms also tend to offshore outsource later phase clinical trials. The size of the clinical trial was also marginally significant and positive indicating that larger trials tend to be offshore outsourced rather than being retained in-house. All the other factors and controls were not significant.

7.4.4 Performance Outcome Model Results

Results from the second stage model, with cost as the dependent variable, are shown in Table 7.5. In Model 3 I separately estimate the performance model for each sourcing strategy and account for self selection. λ is significant and negative only for domestic outsourcing indicating that firms are self selecting only for domestic outsourcing. It appears that unobservable factors influence the decision to domestically outsource core activities. Domestic outsourcing was the only strategy choice which was not significant in the OLS model and the findings support the hypothesis that domestic outsourcing has higher performance compared to in-house. Controls for size, phase, therapeutic

area and size of clinical trials are positive and significant. These findings are similar to the OLS estimates.

Table 7.5: Performance Outcome Model (Cost)

DV - Cost	Model 3			
	In-house	Foreign Affiliate	Domestic Outsourcing	Offshore Outsourcing
Intercept	9.312***	9.745***	2.255**	8.739***
Size	0.0052***	0.014***	-0.013	-0.002
Age	-0.003	0.044	0.012	0.013
Performance	-0.086	0.075	0.392	-0.032
Phase	0.224***	0.0149*	0.511***	0.136***
TA	0.162***	0.0632***	0.066*	0.017
Size of Trial	0.853***	1.212***	1.3296	0.8417***
Parent Type	0.162	0.074	-0.989	-0.038
λ	-0.13			
λ		-0.14		
λ			-3.66**	
λ				-0.81

Self selection models allow me to predict the average performance of core activities for alternative strategies. For instance, I can predict the performance of firms, which conducted trials in-house, had they outsourced or offshored instead. Multiplying the coefficient estimates for the subsample regressions with the vector of firm attributes for each subsample (Leiblein et al. 2002; Shaver, 1998) I can predict the differences in performance for each strategy. Table 6.6 provides the performance predictions for the four strategies. The second column gives the expected performance for in-house sourcing. Firms that actually conducted core

activities in-house spent on an average \$71,976,000. Based on the self selection performance models I estimate that had this same group of firms conducted the same trials in their foreign affiliate they would have spent \$158,355,000. They would have spent \$55,783,000 and \$130,985,000 on domestic outsourcing and offshore outsourcing respectively.

The next three columns provide the expected performance, in terms of cost, for foreign affiliates, domestic and offshore outsourcing. Overall the general trend seems to suggest that performance is best for domestic outsourcing as the cost of conducting clinical trials is the lowest for this sourcing strategy. This is followed by in-house sourcing, offshore outsourcing and foreign affiliates.

Table 7.6: Predicted Performance Values from Performance Model (Cost)

	In-house	Foreign Affiliate	Domestic Outsource	Offshore Outsource
In-house Model	71,976,000	85,305 ,000	114,704,000	142,707,000
Foreign Affiliates Model	158,355,000	108,770,000	185,853,000	166,874,000
Domestic Outsourcing Model	55,783,000	61,203,000	67,258,000	55,195,000
Offshore Outsourcing Model	130,985,000	102,002,000	183,678,000	156,110,000

Table 7.7 provides the results from estimates on the second dependent variable. In Model 4, when the sample is divided into four sub strategy groups I

find that self selection is present only for domestic outsourcing. λ is marginally significant and negative for domestic outsourcing indicating that when performance is measured by duration of the project, firms self select only for domestic outsourcing based on unobservable factors. Controls for phase and size of clinical trials are positive and significant suggesting that late stage and larger trials take longer to complete.

Table 7.7: Performance Outcome Model (Duration)

DV - Duration	Model 4			
	In-house	Foreign Affiliate	Domestic Outsourcing	Offshore Outsourcing
Intercept	1.539***	1.622***	2.384	1.905***
Size	-0.124	-0.0029	-0.0027	-0.0026
Age	-0.012	-0.0019	0.0013	-0.0457
Performance	0.018	0.103	-0.023	0.049
Phase	0.238***	0.2465**	0.2468**	0.349**
TA	-0.557	-0.094	-0.197	-0.182
Size of Trial	0.284***	0.078***	0.249*	0.113***
Parent Type	0.894	0.377	0.712	0.477
Trend	0.032*	0.543	0.022	0.05*
λ	-0.047			
λ		-0.591		
λ			-0.421**	
λ				-0.0821

Table 7.8 provides the estimations similar to Table 7.6 and I again find that domestic outsourcing takes the least amount of time to complete followed by in-house, offshore outsourcing and foreign affiliates. This is with the exception for

the subsample of firms which actually conducted clinical trials in their foreign affiliates (Column 3). For this sub group I find that conducting trials in foreign affiliates is shorter compared to conducting it at an offshore vendor.

Table 7.8: Predicted Performance Values from Performance Model (Duration)

	In-house	Foreign Affiliate	Domestic Outsource	Offshore Outsource
In-house Model	10.15	10.89	6.64	8.63
Foreign Affiliates Model	15.24	17.25	18.89	14.23
Domestic Outsourcing Model	8.71	9.89	6.23	6.76
Offshore Outsourcing Model	14	17.36	12.43	12.42

The results from the two sets of models support all three competitive hypotheses. In hypothesis 10b, I propose that domestic outsourcing leads to better performance compared to in-house. This hypothesis was strongly supported as domestic outsourcing has lower costs and shorter duration compared to in-house trials. In hypothesis 11b, I predict that foreign affiliates have lower performance in conducting of core activities compared to in-house due to higher cost and longer duration and I find complete support for these hypotheses. Finally, in hypothesis 12b I predict that core activities that are offshore outsourced have higher costs and take longer to complete. I find support

for the hypothesis in the estimated performances. The competing hypothesis 12a did not receive support indicating that offshore outsourcing does not have a positive impact on performance.

7.5 Conclusion

In this chapter, I examined the impact of offshoring and outsourcing on project level performance. There has been relatively little research integrating outsourcing and offshoring into a combined strategic framework or choice as shown in Table 1.1. But the questions asked, and the organizational and geographical choices, are extremely important and impact the overall performance of the firm. Getting R&D outsourcing and outsourcing wrong can have significant impact on the short and long term future of the firm (Howell et al., working paper).

Drawing on Transaction Cost Economics, Resource Based View and the Internationalization–Performance literature, I proposed that domestic outsourcing has a positive impact on performance while offshoring to foreign affiliates has a negative impact on performance compared to in-house. I also develop competing hypotheses regarding offshore outsourcing as this sourcing strategy is a combination of outsourcing and offshoring. Using micro level data at the project level and controlling for self-selection by firms, I find that performance in terms of cost and duration is better for firms that outsource their core activities to domestic vendors. Domestic outsourcing is beneficial as it offers greater flexibility to the firm. Third party vendors are specialized firms which offer services at lower cost due to their economies of scale. While some researchers have found that cost is lower in domestic outsourcing (Filler and Visser, 2000) I find that the duration of

clinical trials is shorter as well. This is an interesting finding since domestic outsourcing entails greater coordination requirements (Quinn and Himler, 1994) which could have lead to longer duration. According to Azoulay (2004), speed of project completion is especially important for clinical trials since the remaining patent life of a future drug is continuously dwindling.

Performance is second best for core activities conducted in-house and in the home nation of the firm. Firms have traditionally retained their core activities within their firm boundaries which provide competitive advantages. The findings confirm that this strategy still retains considerable merit and remains a viable option for most companies -- although its average costs are higher than in domestic outsourcing. Field interviews with executives from the pharmaceutical industry reveal that some firms still continue to prefer in-house sourcing to outsourcing even if the costs and duration is marginally higher (See Chapter 6).

Contrary to the popular belief that internationalization is often driven by a search for lower costs, the findings here indicate the opposite. Foreign clinical trials, even within a firm's own foreign subsidiary, cost more than in the home nation of the firm and imply that country differences increase costs. I also find that offshored projects take longer to complete which suggests that differences between the home and host country increases the coordination requirements leading to a longer completion time. I find that locating core activities with foreign affiliates has a negative impact on performance due to these problems.

I also find that offshore outsourcing has a net negative impact on performance. This indicates that while there are significant benefits from

outsourcing in general, an increase in internationalization costs overwhelm, and negate, any improvements in performance resulting from outsourcing. However, controlling for country or geography – that is to say within the same foreign country or region -- offshore outsourcing produces better results and performance than work done in foreign affiliates because of the intrinsic advantages of outsourcing.

I feel that the results from this study contribute significantly to the literature on offshoring and outsourcing. Most of the prior studies have focused on outsourcing or offshoring but I look at the spread of activities across all the four technological strategies of the firm. This literature has also used firm as the unit of analysis but there are many problems in examining the impact of sourcing strategies on firm performance. I contribute to the literature by looking at performance at the project level thus providing a more micro level analysis of the phenomenon. I also control for self selection by decision makers in these firms, which has been neglected by the strategy and international business literature.

CHAPTER 8

DISCUSSION AND IMPLICATIONS

8.1 Discussion – Overview of Dissertation

Ongoing changes in the sourcing strategies of core activities have created a need for academic research to refocus on organizational and geographic boundaries of the firm. The traditional notion that core competences should be retained in-house has been challenged with firms from many high tech industries outsourcing and offshoring their complex activities. Firms are redefining boundaries by simultaneously making decisions regarding the offshoring and outsourcing of core activities such as R&D. The research streams on externalization and internationalization of R&D have remained separate until recently and due to this a gap exists in the current academic literature. By jointly examining externalization and internationalization, I am contributing to the overall literature on corporate R&D.

This dissertation seeks to answer questions regarding this current paradigm shift towards more open organizations. The first question explored in this research looks at the determinants of externalization and internationalization of clinical trials. While firms are increasingly moving towards this new paradigm there is still a great deal of heterogeneity across industries and also within an industry. These differences in the rate and degree of externalization and internationalization cannot be explained by factors such as country of origin or

firm size. For instance, firms in the same strategic groups often have different levels of offshoring and outsourcing in spite of facing similar markets and competition. The first study in Chapter 4 looks at both operational and strategic factors that could contribute to this heterogeneity in sourcing strategies.

Firms also differ in the level of offshoring to their foreign affiliates and offshore vendors. While some depend exclusively on offshore vendors, others strike a balance between the two offshore sourcing strategies. Another reason for this industry wide heterogeneity could be the difference in motive for offshoring. While prior research suggests that most of the R&D offshoring is driven by strategic asset seeking behavior, I posit that other motives, such as resource and efficiency seeking are equally important. A firm's focus on a particular type of motive could contribute to the difference in the spread of the core activities across the quadrants C and D in Table 1.1. This difference in offshoring motives is explored in second study.

This dissertation also traces the evolution of firms as the paradigm shifts and explores in greater details the internal and external environmental drivers of this change using in depth case study analysis. During this qualitative study some interesting observations are made which also help explain why firms select certain sourcing strategies over others.

Finally the dissertation looks at performance implications of this phenomenon. New strategies are often adopted without the management having concrete data on the outcome of the strategy choice. For instance, recent anecdotal evidence from the industry show that decision makers are not sure if

the performance of their offshored and outsourced projects are up to par with those retained in-house (A. T. Kearney). Even prior academic research has not reached a consensus on the impact of offshoring and outsourcing on performance. The final study in the dissertation examines this relationship at a more micro level, thus offering a finer grained analysis.

8.2 Summary of Results

Table 8.1 outlines the results from the three empirical studies in this dissertation. Since I look at three sourcing strategies with domestic in-house as the base strategy, the table, as well as this subsection, is divided into three parts: foreign affiliates, offshore outsourcing and domestic outsourcing. I next discuss the findings for each of the three strategies.

8.2.1 Foreign Affiliates

One of the most commonly used offshoring strategies is to locate core activities within the foreign affiliates. When using this strategy, the firm is relocating its activities outside geographic boundaries but within the organizational boundaries. In Study 1, executives from the industry were asked to rate the importance of each determinant when locating clinical activities in the different quadrants of Table 1.1. I find that decision makers expect cost savings by sourcing from foreign affiliates. However, results from Study 4 suggest that the costs are higher in foreign affiliates compared to the two domestic sourcing options. The study on determinants also find that the quality of the project is negatively associated with foreign affiliates and this could be because firms expect to face higher coordination and monitoring costs due to geographic

distance. Overall findings from Study 1 suggest that firms tend to locate clinical trials with foreign affiliates mainly for strategic rather than for operational reasons. Even though there is an expectation that quality is lower, firms often use this sourcing strategy to “soften the blow” from offshoring and to maintain corporate image.

Offshoring to foreign affiliates is viewed relatively favorably as compared to offshore outsourcing and firms often use this option to follow their competitors to new markets. This offshore sourcing choice is also mainly driven by strategic asset seeking motive as can be seen from the results in Study 2. Firms use foreign affiliates for resource seeking purposes although I found only marginal support for this motive. The results in Study 2 collaborate the finding in Study 1 regarding the use of affiliates for strategic purposes. The qualitative study in Chapter 6 also provides another explanation for why foreign affiliates are used. The firms in the study faced internal conflict with foreign affiliates when offshore vendors were selected for the clinical trial. One firm had to backsource its core activities due to this conflict while others had to implement additional measures to reduce friction between the headquarters and the affiliate. The results from Study 4 in Chapter 7 suggest that the speed of clinical trials was faster in offshore vendors compared to foreign affiliates. Performance of core activities was lower in foreign affiliates compared to domestically conducted activities.

Table 8.1: Summary of Results

Study	Hypotheses	Sourcing Strategy	Result
FOREIGN AFFILIATES			
Study 1 (Ch. 4)	H1a	Positive relationship with cost savings	Supported
	H2a	Negative relationship with quality	Supported
	H3a	Positive relationship with speed	Not Supported
	H4a	Positive relationship with mimetic adoption	Supported
	H5a	Positive relationship with corporate image	Supported
Study 2 (Ch. 5)	H7a	Positive relationship with market seeking motive	Not Supported
	H8	Positive relationship with strategic asset seeking motive	Supported
Study 4 (Ch. 7)	H11a	Positive relationship with overall performance	Not Supported
	H11b	Negative relationship with overall performance	Supported
OFFSHORE OUTSOURCING			
Study 1 (Ch. 4)	H1b	Positive relationship with cost savings	Supported
	H2b	Negative relationship with quality	Supported
	H3b	Positive relationship with speed	Supported
	H4b	Positive relationship with mimetic adoption	Not Supported
	H5b	Negative relationship with corporate image	Supported
Study 2 (Ch. 5)	H6	Positive relationship with resource seeking motive	Supported
	H7b	Positive relationship with market seeking motive	Not Supported
	H9	Positive relationship with efficiency seeking motive	Supported
Study 4 (Ch. 7)	H12a	Positive relationship with overall performance	Not Supported
	H12b	Negative relationship with overall performance	Supported
DOMESTIC OUTSOURCING			
Study 1 (Ch. 4)	H1c	Positive relationship with cost savings	Not Supported
	H2c	Positive relationship with quality	Supported
	H3c	Positive relationship with speed	Supported
	H4c	Positive relationship with mimetic adoption	Supported
	H5c	Negative relationship with corporate image	Not Supported
Study 4 (Ch. 7)	H10a	Positive relationship with overall performance	Supported
	H10b	Negative relationship with overall performance	Not Supported

Gray shaded portions of the table denote competing hypotheses.

To surmise, offshoring to foreign affiliates is used for strategic purposes rather than operational reasons. Firms chose this strategy even when the costs are higher compared to domestic sourcing and the duration is longer compared to offshore outsourcing.

8.2.2 Offshore Outsourcing

The next sourcing strategy examined is offshore outsourcing and I find that firms tend to use this strategy to achieve cost savings and faster speed (Chapter 4). However findings from the performance study (Chapter 7) suggests that costs are higher for this strategy while the speed is only marginally faster compared to foreign affiliates. Similar to foreign affiliates, decision makers associate offshore outsourcing with decreased quality.

Firms use this offshore strategy for resource and efficiency seeking purposes as evinced by results in Chapter 5. This along with the findings on determinants suggests that firms will choose offshore outsourcing primarily for operational rather than strategic reasons. Since most of the core activities are offshored to foreign affiliates for strategic purposes, firms often backsource their offshore outsourced activities due to internal conflict in the firm. This confirms prior findings by researchers that strategic goals of the firm take precedence over operational goals. The performance is also lower for this strategy when compared to domestic in-house and domestic outsourcing.

One of the interesting findings in this dissertation is that offshoring, both to foreign affiliates and offshore vendors, in general has higher costs and longer duration which goes against common perception regarding offshoring. I posit that

perhaps cost savings and faster speed are realized from offshoring peripheral or simpler activities only which do not require greater coordination with headquarters. I also find that there are significant differences between the two offshore sourcing strategies in terms of drivers and motives as well as performance.

8.2.3 Domestic Outsourcing

The third sourcing strategy is domestic outsourcing. The results from this dissertation indicate that cost is not an important determinant for domestic outsourcing (Study 1) even though the study on performance shows that the costs are the lowest for this strategy. Domestic outsourcing is associated with faster speed and better quality. The findings from the performance study confirm that duration is indeed the shortest for domestic outsourcing. Domestic outsourcing is also driven by the need to follow competitors and the results from the first study show that this sourcing strategy is influenced by a combination of operational and strategic factors.

The case studies show that firms tend to use domestic outsourcing after in-house sourcing in the strategy evolution and this is often driven by the lack of internal resource. Firms however tend to retain more tacit or complex projects in-house and outsource relatively easier projects to outside vendors. However this changes as the firm gains more experience with outsourcing.

The case studies in Chapter 6 and the findings from nested logit (Chapter 4) suggest that outsourcing is usually done at an earlier stage compared to offshoring. The nested logit modeling results support the tree structure where the

firm first chooses between in-house and outsourcing and then between domestic and foreign. The alternate tree structure where firm first chooses between domestic and foreign and then between in-house and outsourcing was not supported. Thus domestic outsourcing is one of the earliest sourcing strategies adopted by the firm and it has a positive impact on the performance of core activities.

8.2.4 Overall Findings

This dissertation examined the offshoring and outsourcing of core activities. One of the motivations for this research is the heterogeneity within an industry in terms of sourcing strategies. For instance, one firm in the pharmaceutical industry conducts close to 65 percent of its core activities in-house while its close competitor conducts only 15 percent of the same activity in-house. These firm level differences in sourcing strategies cannot be explained by more obvious factors such as firm size, age or country of origin. In this dissertation, I find that some of the differences in the sourcing strategies can be explained by the overall orientation of the firm. Offshoring and outsourcing of core activities, unlike that of other peripheral activities, is driven by strategic and operational factors. While some firms place greater emphasis on strategic factors and hence make greater use of their foreign affiliates, others focus on operational factors and depend on external vendors. Thus the differences in the focus of the firm help to explain this intra-industry heterogeneity.

The dissertation also finds that offshoring and outsourcing of core activities is a very complex phenomenon. Findings from Study 4 suggest that

operational performance of the firm decreases as it offshores to foreign vendors and foreign affiliates. Yet the increasing use of these alternate sourcing strategies suggests that offshoring and outsourcing of core activities are to a great extent driven by strategic factors. In the following subsections I further discuss the findings of this dissertation and its contributions to the academic field, managers and governments.

8.3 Academic Contributions

The academic contributions of this dissertation are discussed under two subsections. The first subsection discusses the contributions made by this dissertation, to the literature as well as to the theory development in this stream of research. The following subsection outlines the methodological contributions made by the dissertation.

8.3.1 Gaps in the Literature and Theoretical Contributions

The dissertation contributes to the literature on internationalization and externalization of corporate R&D by simultaneously examining both of these related phenomenon. Most of the prior literature has focused on internationalization or externalization primarily because firms until recently only collaborated with other firms in the same geographic regions. But as this paradigm is changing, it is becoming important to look at the decision making process of firms especially related to sourcing strategies of core activities. This dissertation shows that the sourcing strategy choices are different and firms select a strategy based on their motives and strategic needs. I find that firms often select not so optimal sourcing strategies which could lead to weaker

operational performance in order to benefit from long term strategic gains. The dissertation also contributes to the recent literature on offshoring and outsourcing which has mostly focused on low value and peripheral activities.

The dissertation's theoretical contributions lie in its use of multiple theories to study the phenomenon. Previous studies have used transaction cost economics or resource based view to study outsourcing or offshoring without integrating the two theories. These theories have often been viewed as having opposing propositions especially regarding outsourcing. I develop my hypotheses by jointly looking at them and thus show that these two theories are not conflicting. I also use other theories such as eclectic paradigm's FDI motives to study offshoring strategies as well as neo-institutional theory and literature on corporate status to examine the research questions related to the determinants of this phenomenon.

The dissertation also adopts the evolutionary perspective to look at the stages of evolution in a firm's sourcing strategy. This theoretical lens has not been used previously by studies in this research stream in spite of the need for more process research. Using qualitative research, I show how firms move from one stage to another while paying attention to the external and internal factors.

8.3.2 Empirical Contributions

Methodologically, this dissertation makes a number of contributions to the international business and strategy field. Most of the studies in this field have either used survey data which has problems of endogeneity or secondary data

which may not correctly measure the constructs. By using a combination of both these methodology, this dissertation provide a better picture of offshoring and outsourcing. This dissertation also introduces the international business and strategy field to a unique dataset on clinical trials. This dataset from Medidata has only been used once before by Azoulay (2004) in the economics field. The dataset contains detailed data on clinical trials at site level for over 123,000 sites. In addition to using quantitative data, the dissertation also contains qualitative data from multiple case studies to provide a richer analysis of this phenomenon.

This dissertation also attempts to combine macro and micro level research by studying the phenomenon at multiple levels. The research questions have been examined at the following levels of analysis: country, firm and project level. Conducting multi-level research is relatively uncommon in the field but what makes it desirable is that results from one level of analysis can be used to confirm the findings from another level. For instance, counter intuitive results from the study on project level performance can be explained by the difference in motives at the country level as well as the different determinants at firm level of analysis.

The empirical studies in this dissertation also use sophisticated econometric techniques to address the questions raised by the gaps in the literature. In spite of the wide spread use of Heckman selection model in the economics literature, the management literature has yet to adopt this technique. Firm strategy choices are not random and not controlling for self selection by firms could lead to biased results. I also use the nested logit technique to

examine the structure of decision making for the sourcing strategy and this has not been previously used either. Nested logit models are useful when examining a hierarchical decision process such as the sourcing strategy decision.

Lastly, even though drug development through clinical trials is a significant economic activity for the pharmaceutical industry it has not received adequate attention by the field. With the exception of Azoulay (2004) most studies on pharmaceutical firms have looked at R&D as a whole or only focused on basic research. But with clinical trials accounting for close to half the R&D expenditure, a separate study to examine its dynamics is needed. By using multiple sources of data and multiple level of analysis, this dissertation looks at the recent shift in industry towards a model of greater offshoring and outsourcing of clinical trials.

8.4 Managerial Implications

Offshoring and outsourcing of core activities such as clinical trials is a new phenomenon that is still vastly unexplored. While strategic decisions are made after due considerations, it appears that there is a gap between the decision maker's expectations and the actual performance implications of offshoring and outsourcing. This research has important managerial implications as the findings suggest that performance does not necessarily improve with offshoring. However when compared to in-house activities, outsourcing is a much better sourcing strategy. For instance, conducting clinical trials with domestic vendors is cheaper than domestic in-house. Performance measured in terms of duration is also better when outsourcing both domestically and offshore. Offshoring increases the duration of the trial which is contrary to the popular belief. Firms need to

understand that offshoring and outsourcing must not be done purely for operational purposes but also for strategic purposes. When operational factors are more important for the firm then outsourcing is the better sourcing strategy but when strategic factors are important it is better for the firm to maintain all activities in-house or offshore to foreign affiliates.

The results from the case study also shed some interesting light on the internal dynamics of the firm. Offshore outsourcing could lead to tension between the headquarters and the foreign affiliates who feel threatened by the external competition for resources. While back sourcing would be the final option for the firm, this research shows that decision makers can be more proactive and engage the foreign affiliate in the decision making process to avoid conflict. Some of the firms in the study consult their foreign affiliates while selecting foreign vendors and also outsource only when the trials cannot be managed internally. As also evinced by the qualitative study, firms can over extend themselves with makes it difficult to manage the various trials going on outside the firm. Recent trends discussed in Chapter 3 suggest an emergence of onshoring of activities where the firms bring back their previously offshored activities. Reversal of this phenomenon in some instances, suggests an optimal level of offshoring and outsourcing. Externalization and internationalization involves extensive coordination and monitoring costs which may be overlooked by decision makers and firms need to maintain optimal level in order to benefit from this phenomenon.

Offshoring of core activities such as R&D is not done solely for strategic asset seeking purposes. Firms, also offshore their core activities for resource and efficiency seeking purposes. The decision makers must consider offshoring for market seeking purposes as this is an effective way to create awareness in future markets. Offshore outsourcing must be considered for resource and efficiency seeking while foreign affiliates are a better option for strategic asset and market seeking motives.

8.5 Government Policy Implications

I next discuss policy for host and home country governments. The recent global recession has turned out to be a boon as well as a bane for the offshoring and outsourcing phenomenon. On one hand, many MNEs from developed countries are looking at these alternate sourcing strategies to reduce costs, improve efficiency and profits in this sluggish economy. But on the other hand, weakening Euro and Dollar accompanied by rising wage costs in developing countries has led to a slowdown of this phenomenon. Findings from this dissertation suggest that firms do not offshore only for efficiency seeking purposes. Host country governments that are seeing a decrease in their offshoring and outsourcing industry must try to attract investments driven by strategic asset and market seeking motives as these are less sensitive to changes in wage costs.

Host country governments can try to create a more conducive environment for these types of activities by encouraging higher education, better infrastructure and regulations, lower political risks as well as better intellectual

property rights protection. Establishing a certain threshold for regulation is essential for attracting foreign investment. For instance, I find that adoption of Good Clinical Practices (GCP) is only marginally significant for offshoring. This result can be explained by the lack of investment in the countries before the adoption of this standard. Since firms, especially in highly regulated industries such as pharmaceuticals face tough regulations at home, they do not consider countries without basic standards and regulations when offshoring their core activities.

Current trends, discussed in Chapter 3, suggest that offshoring of core activities, such as clinical trials, to developing countries is still in the nascent stages. Host country governments can play an important role in increasing their country's share of this budding new market. For instance, many developing countries like India are highly dependent on offshore outsourcing. To progress from being a provider of basic activities to more high value activities, the government must develop local industry and encourage growth of specialized third party vendors to attract such investments.

Firms that offshore and outsource their core activities are mostly from developed countries. The governments in these countries are often concerned because of offshoring and the related job losses. Figure 5.1 in Chapter 5 shows that while firms from these countries are the source of offshoring of clinical trials, these countries are also the primary recipient of offshored activities. For instance, while US pharmaceutical firms offshore clinical trials to the other countries, the country has also received close to 63,000 clinical trials from other countries. Prior

clinical trials conducted in a country are important for attracting new projects which explains why developed countries with strong local pharmaceutical industry attract more projects. Results from Study 1 suggest that firms tend to offshore to their foreign affiliates to follow their competitors. This finding has important implications for countries which have a strong local industry. Developed country governments need to continue to build a stronger local industry as well as supporting industries to attract investments from other developed countries.

However, my findings also suggest that firms often offshore to obtain resources. Clustering of too many pharmaceutical firms could deter new clinical trials as firms will have to compete for scarce country specific resources such as patient base and qualified physicians. Crowding out effects is one of the reasons for firms seeking newer countries to locate their clinical trials and home country governments need to consider how many offshore investments to allow into the country to prevent overcrowding. Oversaturation of clinical trials, besides deterring new foreign investments, may also drive local firms to search for less crowded countries to locate their trials.

8.6 Limitations

As is the case with most research, this dissertation has a few limitations. First, this is a single industry study and the findings from this dissertation may not be applicable to firms in other industries. One could argue, for instance, that the frequency of conducting clinical trials is much higher than other core activities and so the decision making process for each clinical study may not be of strategic importance. However limiting the study of core activities to a single

industry ensures a detailed analysis. There is usually a tradeoff between internal and external validity of a study and in this dissertation greater emphasis was given to internal validity. In spite of the limitations of a single industry study, the findings of this dissertation could be applied to other highly research intensive industries such as the semiconductor industry.

The second limitation of this dissertation is the small number of firms that participated in the online survey. The goal was to match the firms in the secondary data, from Medidata, with firms in the primary data. So while the population for the study was 98 firms, I was able to get complete responses from only 53 firms. The marginally low response rate is due to high privacy concerns by the firms in the pharmaceutical industry and the unwillingness to share firm specific data. But even though the sample is small, it is very representative of firms in the global pharmaceutical industry.

The final limitation of this study is that data is available only till 2005 due to which I do not have many clinical trials in developing countries. Most of the clinical trials in the sample are located in the triad region of North America, Europe and Japan. Since offshoring to developing countries is very recent, this data does not fully capture the recent upswing. But even today only a small percentage of all R&D activities are offshored to developing countries due to infrastructure problems and other regulation related problems (A.T. Kearney, 2004). Secondary data from Clinicaltrials.gov show that even in 2006-2008 less than 20 percent of all clinical trials were conducted in developing countries. Thus the data is still representative of the current state in the global pharmaceutical

industry. The data starts from 1997 which is approximately when firms started offshoring and outsourcing clinical trials.

8.7 Future Research

This dissertation focuses on offshoring and outsourcing of core activities in the pharmaceutical industry. Few avenues for future research are suggested in this section. Evidence from case study research suggests that firms have to choose between arms length and strategic outsourcing. Additional work is needed to expand the two-by-two matrix in the Table 1.1 to include the two types of outsourcing hence making it a two-by-three matrix.

The second topic for future research is the strategies adopted by vendor firms. The current research focuses only on the outsourcer firms but further research is warranted to examine strategies adopted by the vendor firms. Many of these third party vendors are multinational firms and have their own offshore affiliates. An in-depth analysis of the structure of these vendor firms and their relationship with the outsourcing firms is essential.

Backsourcing and onshoring is also a new trend that is emerging and it is important to examine why firms choose to bring back their offshored and/or outsourced activities. In Chapter 6, I find that one of the firms in the case study had to backsource due to conflict with foreign affiliates and over extension of the firm boundaries. Future research looking at the conditions under which firms' backsource or onshore and the impact on corporate image would add to this stream of literature.

This dissertation also found that the performance of the foreign affiliates is weaker than the domestic vendors as well as domestic in-house and one explanation for this finding could be that firms do not have enough experience with offshoring to foreign affiliates. Another avenue for future research is to explore the role of learning, which is achieved through international experience of the firm, on the performance of activities by foreign affiliates.

Since this is a single industry study future research can also look at offshoring and outsourcing of core activities in other industries with varying R&D intensities and compare the findings with this dissertation. This dissertation also focuses on the development part of the pharmaceutical R&D and a natural extension to this study is to look at the research part of the R&D.

8.8 Summary

This dissertation address important strategy and international business related questions. Using, primary and secondary data sources the dissertation adopts a multi level approach to examine four questions related to the offshoring and outsourcing of core activities. Chapter 4 examines the strategic and operational determinants of the sourcing strategies while Chapter 5 focuses on the four main motives for offshoring. Chapter 6 is a longitudinal study which looks at strategy evolution and Chapter 7 examines performance implications at the project level.

Even though the dissertation has a few limitations that were identified in the earlier subsection, this research makes significant contributions to the academic literature.

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Appendix A

Macro-Level Data on Offshoring and Outsourcing

Table 1: Imports from the Pharmaceutical Industry

	United Kingdom	United States	Switzerland	Japan	France	Germany	Belgium	Canada	Denmark	Ireland	Netherlands
1997	4567000000	6763000000	2964000000	3319000000	4459000000	6111000000	2992000000	1905000000	685519652	721740512	2620000000
1998	4995000000	8991000000	3457000000	2958000000	5703000000	7216000000	3834000000	2332000000	750906480	791244685	2676000000
1999	6170000000	11330000000	4308000000	3677000000	6308000000	7606000000	4114000000	2894000000	820731915	993681483	3472000000
2000	6724000000	12310000000	4293000000	3917000000	6160000000	7902000000	4821000000	3449000000	834756419	1220000000	3373000000
2001	8664000000	16050000000	5992000000	4212000000	7216000000	8966000000	7411000000	3961000000	998787278	1547000000	4358000000
2002	10640000000	21650000000	6996000000	4614000000	8394000000	16190000000	20000000000	4517000000	1249000000	1655000000	5392000000
2003	12990000000	27820000000	8242000000	5297000000	10650000000	18670000000	24410000000	5735000000	1619000000	2062000000	6124000000
2004	15120000000	31550000000	10430000000	6254000000	13090000000	24080000000	30960000000	6596000000	2043000000	1981000000	8902000000
2005	15160000000	35640000000	11750000000	7279000000	14310000000	28620000000	34290000000	7439000000	2237000000	1966000000	10240000000
2006	16810000000	42580000000	13580000000	7590000000	16140000000	32480000000	33870000000	8960000000	2491000000	2312000000	11790000000
2007	19680000000	49160000000	15440000000	8296000000	19470000000	38530000000	39580000000	9843000000	2702000000	2740000000	15320000000
2008	19930000000	52840000000	16370000000	9913000000	22100000000	44100000000	42100000000	10230000000	3167000000	3548000000	23190000000

OECD Data 1997-2005

Table 2: Outsourcing by Industry in 2008

Industry	Outsourcing In Billion. US \$
Manufacturing	22.2
Telecommunications	21.5
Financial Services	18.1
Energy	10
Healthcare & Pharmaceuticals	6.5
Media & Entertainment	4.4
Business Services/Other	3
Travel, Transportation & Hospitality	2.4
Retail	1.4
Infrastructure	25.7
Network Services	16.9
Full ITO (ADM bundled with Infrastructure)	10.2
Applications Development & Maintenance (ADM)	10.1
Financial Services	6.3
Financial Management	4.8
Contact Centers	3.7
Human Resources	1.4
BPO Multi-Process	2.2
Fabrication & Assembly	2.9
Procurement	0.5

Plunkett Research 2009

Table 3: Import of R&D Services by US Firms

	Canada	Europe	South & Central America	Africa	Asia (excluding India China)	Pacific	Middle East	India	China
1997	54	320	30	26	42	11	2	3	2
1998	62	427	29	24	54	20	3	3	3
1999	117	473	26	22	38	14	29	5	23
2000	72	451	40	19	118	20	27	10	25
2001	91	419	25	60	55	11	28	16	9
2002	141	640	27	48	123	15	9	15	5
2003	188	798	90	57	107	28	16	18	6
2004	184	1350	99	81	128	38	14	50	19
2005	230	1544	100	118	146	41	23	48	22
2006	837	5782	231	195	937	158	588	427	92
2007	974	6957	337	218	1317	227	751	678	246
2008	1252	8022	470	284	2064	250	944	1142	440

BEA Data in Millions of \$

Appendix B

Survey Cover Letter and Instrument

Date:

Dr.
Director/ Vice President, Clinical Operations
 Company name
 Address

Subject: **Research Study on Offshoring and Outsourcing of Clinical Trials (Phase 1, 2, & 3)**

Dear Dr.

Purpose:

Rutgers University, NJ is conducting a global study on the offshoring and outsourcing (see definitions below*) of clinical trials. Specifically, we look at what factors influence the decision to locate clinical trials in different organizational forms (in house versus external vendors) and geographically (trials conducted in home nation versus trials in foreign countries). We also examine the impact of offshoring and outsourcing on the performance of clinical trials.

Your participation in this online survey will help academic research answer important strategic questions. The approximate time to complete this questionnaire is 15 - 20 minutes. Please consider the following survey questions for your firm or division as a whole and provide us with approximate percentages. A very rough estimate will do. Focus on clinical trials done for registration purposes only.

Confidentiality:

We assure you that your responses are confidential and will not be shared with others except in aggregated and blind statistical form.

Participants will receive a final report and will be invited to a seminar covering the survey findings:

Respondents will get a free copy of the research summary and be invited to participate in a seminar, sponsored by *Blanche & Irwin Lerner Center for Pharmaceutical Management Studies* at Rutgers University, where the research results will be presented. This seminar will also provide an excellent opportunity for you to interact with Directors and Vice Presidents of Clinical Operations/Research from other pharmaceutical and biotechnology firms as well as the academic community.

If you have any questions, please feel free to contact us directly at: 724-840-1643, fax: (973) 353-5691, or e-mail: thakur@andromeda.rutgers.edu.

Your assistance with this research project is greatly appreciated.

Sincerely,

Professor Farok Contractor
 PhD Dissertation Supervisor
 Rutgers Business School
 Rutgers Business School
 Rutgers University
 Rutgers University

Pooja Thakur,
 Doctoral Candidate

Definitions:

* **Outsourcing** – Clinical trials (monitoring, medical writing, data management) conducted by external CROs, at home or abroad.

Offshoring – Any Clinical trials done outside of the headquarter country (whether done by your firm or CRO)

In-house – Trials conducted by your firm in the headquarters (regional and global) country.

Foreign affiliate – A company in which your firm has a shareholding (including 100% owned subsidiaries)

Domestic CROs – CROs located in home country including global CROs

Foreign CROs – CROs located in foreign country (regional or country based)

1. Are you answering the following questions on behalf of your **affiliate/ division** ☐ or **firm as a whole** ☐ ?
2. Number of employees in your affiliate/division or firm: _____

3. What is the **overall spread** of your clinical trials in terms of geographic locations?

United States of America & Canada:	_____ (% of number of trials)
Western Europe:	_____ (% of number of trials)
Central and Eastern Europe (Including Russia):	_____ (% of number of trials)
Latin and Central America:	_____ (% of number of trials)
Asia (Including India and South East Asian Countries):	_____ (% of number of trials)
Japan:	_____ (% of number of trials)
Rest of the World (Turkey, Australia, New Zealand, South Africa):	_____ (% of number of trials)
Total:	100%

4. How many broad therapeutic areas (TA), for instance oncology, does your firm focus on? _____

5. What is the current **global spread of the total expenditure** on all clinical trials? Please provide us an approximate percentage (A very rough estimate will do).

a) Value of Entirely In-House Clinical Trials Within the headquarters' country	_____ (% of spending)
b) Value of Entirely In-House Clinical Trials In your Foreign Affiliates	_____ (% of spending)
c) Value of Clinical Trials Outsourced to Foreign External CROs	_____ (% of spending)
d) Value of Clinical Trials Outsourced Domestically to External CROs in the home country*	_____ (% of spending)
Total:	100%

6. Of the category 4d* (see above), what percentage of the value of clinical trials do domestic CROs, in turn conduct outside of the domestic country? _____%.

7. What is the impact of **domestic outsourcing (external CROs in the headquarter country)** of clinical trials on:

- a) The performance of the clinical study?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|
- b) The overall performance of the sponsor firm?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|

8. What is the impact of **offshore outsourcing (foreign CROs)** of clinical trials on:

- a) The performance of the clinical study?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|
- b) The overall performance of the sponsor firm?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|

9. What is the impact of **offshoring** clinical trials to your own **foreign affiliates** on:

- a) The performance of the clinical study?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|
- b) The overall performance of the sponsor firm?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|

10. What is the impact of conducting **in-house** clinical trials in your headquarters on:

- a) The performance of the clinical study?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|
- b) The overall performance of the sponsor firm?
- | | | | | |
|---------------------|--------------|---------|----------------|-----------------------|
| Highly Satisfactory | Satisfactory | Neutral | Unsatisfactory | Highly Unsatisfactory |
|---------------------|--------------|---------|----------------|-----------------------|

11. Which factors do you consider in deciding to locate clinical trials both **organizationally (in-house versus outsource)** and **geographically (in home nation versus in foreign countries)** and how important are these factors?
 In choosing the location of clinical trials from among the four columns (1 – 4), how important is each factor?
 For instance, consider how important maintaining positive corporate image is when choosing between in-house, domestic outsource, foreign outsource and foreign affiliates.

Use the following scale to indicate the extent to which you agree with each statement.

Not Important Factors 1.....2.....3.....4.....5 Highly Important Factors	<i>Please answer one column at a time below</i> In each box below write 5 to 1 or N/A			
How important are the following factors? Use a 5 point scale (5 indicating highly important) , (1 indicating not important) and (N/A = not applicable)	1. Trials conducted by Your Firm in Headquarters country (Regional & Global)	2. Trials done by CROs in Headquarters (Regional & Global) Country	3. Trials done by independent Foreign CROs in foreign countries	4. Trials done by your own Foreign Affiliates abroad
Flexibility of Resources				
Access to Diverse and Unique Group of Patients				
Access to Expertise of External CROs				
Your Firm's Prior Outsourcing Experience				
Sustaining Quality of the Trials				
Speed of the Drug Development Process				
Imitating Competitors to gain Legitimacy				
Complexity of the tacit and un-codified knowledge				
Cost of Operating and Running the Trials				
Imitating rival firms to remain Competitive				
Maintaining Corporate Image				
Possibility of Leakage to Generic Companies				
Improving Quality by alternate sourcing strategy				
Availability and Expertise of Physicians/ Investigators				
Creating Awareness in Target Markets (Entry Point)				
Political Stability of the Country				
Regulatory Environment of the Country				
Infrastructure in the Country				
Cultural Differences between Home and Host Country				
Intellectual Property Rights Regime of the Country				
Your Firm's Prior experience in Clinical Trials outside the Headquarter country				

12. What is the spread of outsourced clinical trials? (A very rough estimate will do).

CROs with whom you have a distant contractual relationship :	
(i) Domestic CRO _____%	(ii) Foreign CRO _____%
CROs with whom you have a cooperative or strategic relationship :	
(iii) Domestic CRO _____%	(iv) Foreign CRO _____%

13. When choosing between a **distant contractual relationship** with a CRO or a **strategic partnership** with a CRO, please indicate whether you agree or disagree with the following statements:

	Disagree		Neutral	Strongly Agree	
	1	2	3	4	5
The firm prefers a strategic partnership to a distant contractual relationship when:					
Potential partner is also involved in drug discovery					
Potential partner has dedicated teams					
Potential partner Adheres to Good Clinical Practices (GCP)					
Higher Initial Investment is Required from the partner					
Scope of therapeutic expertise is broader					
Your firm has considerable tacit knowledge					

14. What is the current spread of the clinical trials, in terms of number of studies, across the different phases? Please give us a rough estimate of the current spread.

	Phase I	Phase II	Phase III
Total Trials done by your firm			
Done by your firm in headquarter country			
Outsourced to CROs in home nation			
Outsourced to CROs abroad			
Done by Foreign Affiliates			
Total	100%	100%	100%

15. How has your firm evolved in the location and conduct (organizationally and geographically) of clinical trials?

Please write number 1 for the oldest, and 4 for the most recent.

In-house trials _____ Foreign Affiliates _____ Domestic CROs _____ Foreign CROs _____

16. How much do you spend on contracted clinical trials? _____

17. Approximately what percentage of total R&D budget is spent on Clinical Trials? _____

Appendix C

Robustness Test for Study 1 on Determinants

Since the dependent variable in Study 1 (Chapter 4) was at the project level, I ran a separate model at the firm level to check for robustness. Aggregating clinical trials by firm and year, I have four dependent variables for this model which are proportions and add up to 1. For instance, firm A has the following values for the four dependent variables for a given year: 0.2 – In-house; 0.3 –Foreign affiliates; 0.4- Domestic outsourcing; 0.1 – Foreign Vendors.

Using compositional data analysis (Aitchison, 1986), I transformed the three dependent variables ($yy1 = \log(y1/y4)$) with in-house as the base group ($y4$). Next, I ran the multivariate regression analysis and the results from this model are presented in the table below. The results are similar to the project level model and hence confirm robustness of the empirical estimation in Chapter 4.

Variable	Foreign Affiliate	Offshore Outsourcing	Domestic Outsourcing
Cost	0.043**	0.045***	0.403
Speed	-0.088***	0.153**	0.522*
Quality	-0.077***	-0.567***	0.574**
Corporate Image	0.301***	-0.38*	-0.122
Imitation	0.231**	-0.156	-0.086**
Employees	-0.004	-0.251	-0.009
Language	0.192*	0.093***	0.381
Adj. R ²	0.565	0.366	0.425

CURRICULAM VITAE

POOJA THAKUR

1980	Born 1 st October in Hyderabad, India
1996	Graduated from Rishi Valley School, India
1998	Graduated from Nasr High School, Hyderabad, India
2001	Bachelors of Commerce (Hons) from Osmania University, Hyderabad, India
2003	MBA from Indiana University of Pennsylvania,
2004	E-Center Manager, Pennsylvania State Employees Credit Union
2010	PhD in Management from Rutgers University

Awards

2008	Best Doctoral Thesis Proposal Award, European International Business Academy (EIBA)
2008	Promising Dissertation Proposal Award, International Management Division, Academy of Management (AOM)
2008	Dissertation Research Award, Technology Management Research Center, Rutgers University
2007	Best Proposal Runner Up, TAMIU Doctoral Consortium

Publications

2010	Newburry, W. and Thakur, P. "Multi-Level Impacts on Perceived Career Opportunity from Global Integration", <i>International Journal of Human Resource Management</i> , forthcoming.
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