

STRATEGIC EVOLUTION OF FIRM'S CORE ACTIVITIES: CASE STUDY EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY

ABSTRACT

This research examines the strategy evolution of core activities of firms in the pharmaceutical industry. Drawing on the evolutionary perspective, we look at the dynamic changes in the strategic decision making process of firms over time. Specifically, we focus on the offshoring and outsourcing decisions of clinical trials which is a core activity in the pharmaceutical industry. Using multiple case studies, we propose five stages in the evolution process starting with in-house sourcing strategy followed by foreign affiliates, domestic outsourcing and offshore outsourcing. In the final stage of this evolution process, firms retract from outsourcing and start to re-internalize their core activities. Our research contributes to the literature by adopting a longitudinal perspective and simultaneously examining offshoring and outsourcing.

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EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY

1. INTRODUCTION

Offshoring and outsourcing of core activities is a recent phenomenon that has become increasingly important in the last decade. Prior to the 1990s most firms conducted their core activities inhouse while offshoring and outsourcing only the peripheral activities. This research studies the evolution of the firms as they move away from the traditional inhouse model to alternate sourcing strategies. Earlier studies (Tiwana and Keil, 2007; Bartelemy and Quelin, 2006) have looked at outsourcing and offshoring as a one-time decision by solely focusing on cross sectional research design. But firms are continuously changing their strategies in response to internal and environmental factors. An important question for international business and strategy researchers is how firms evolve from conducting their core activities in-house to offshoring and outsourcing them. Using a series of case studies on firms in the pharmaceutical industry we focus on the stages of evolution and the internal and external factors that drive the firms to one stage to the next.

There has been extensive literature in international business and related fields on offshoring and outsourcing activities of firms (Erramilli, 1991; Doh, 2005; Gilley and Rasheed, 2000; Mol, Tulder and Beije, 2005). These studies have focused mostly on the inputs (determinants/drivers) or outputs (performance) of this phenomenon but relatively few have looked at the transition process inspite of the growing demand for strategy process research (Malnight, 1996; Barnett and Burgelman, 1996; Van De Ven and Huber, 1990; Chakravarthy and Doz, 1992). This study develops an evolutionary perspective of the sourcing strategies of the

firm. By adopting a longitudinal perspective this study will examine the dynamic changes in the strategic decision making process of firms 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 set many objectives to achieve a certain strategy and the ability to meet these objectives in turn depends on the resources available to the firm. We 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 inhouse to external and international sourcing of core activities, we will use the multiple case analyses. 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, theory building through 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 (Yin, 2003) that has important theoretical importance as well.

We study the strategy evolution of drug development in the pharmaceutical industry. Specifically, we focus on the outsourcing and offshoring of the clinical trials which primarily involves the testing of compounds, discovered in the earlier stages, on human subjects. Clinical trials are a core activity of the pharmaceutical industry and account for approximately 42% of the total R&D expenditure.

Three important factors are used in the selection of firms: type of firm, country of origin of the firm and age of the firm. The pharmaceutical industry is made up of pharmaceutical and biotechnology firms and the firms in our study represent these two segments of the industry. The

firms in this research are from North America and Europe which increases the external validity of our 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 two sources: semi structured interviews with directors and vice presidents of clinical operations and archival documents. A survey done on clinical trials is 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 three provides an overview of the research settings and section four discusses the methodology used in this study. Section five presents the findings of this study. This section discusses the five stages of strategic evolution and the internal and external factors driving the evolution. Finally, section six concludes.

2. LITERATURE REVIEW

In this section we provide an overview of the current literature on offshoring and outsourcing. We then discuss how our research contributes to the literature by using the evolutionary perspective. Sourcing strategies relate to decisions made by firms regarding activities a firm chooses to perform internally and the activities it outsources to third party service providers. The firm also has to decide on the geographic location of the activities, whether to conduct it at home or in other host country. In this research we adopt a dynamic perspective to offshoring and outsourcing by looking at qualitative data. Most of the prior research has used empirical methodology to study this phenomenon without adding the temporal element to the strategy decisions.

Definitions

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, which is known as captive offshoring, as well as to third parties also known as offshore outsourcing. Outsourcing refers to transfer of activities to third parties but this can be to domestic vendors as well as offshore vendors. Offshoring and outsourcing have traditionally been associated with the more repetitive and specialized tasks such as manufacturing operations of a firm but there has been a shift in the last decade towards offshoring and outsourcing of services and sensitive core business processes such as R&D (Leiblein, Reuer and Dalsace, 2002). Outsourcing of services has become significant only from the late 1980s (Erramilli, 1991), because previously it was thought that attributes of services, such as intangibility, simultaneity, or perishability, would render contract work, especially across country boundaries, difficult if not impossible (Boddewyn, Halbrich and Perry, 1986). But due to the recent advances in the information and communication technologies (ICT), services can now be offshored to other distant locations as well as outside the firm boundaries.

Outsourcing refers to the split in the value chain whereby firms can concentrate on their core competences by moving some of their tasks to subcontractors. According to McCann and Mudambi (2005) “the disaggregation of the value chain is the outcome of the firms combining the comparative advantages of the geographic locations with their own resources and competences to maximize their competitive advantages”. According to this analysis the interplay of comparative advantages with competitive advantages would determine the boundaries of the firm (outsourcing decisions) as well as the optimal location of value chain components (offshoring decisions).

Prior literature has found that internationalization (offshoring) of R&D has gained significant importance since the late 1980s; although firms from smaller European countries like Switzerland, Belgium and Scandinavia had internationalized their R&D as early as the 1960s (Cantwell and Hodgson, 1991; Cantwell, 1995; Pavitt and Patel, 1991). Externalization (outsourcing) of R&D has also been prevalent since the late 1990s (Howell, 1999; Jones, 2000; Narula, 2001; Hagerdorn, 2002).

While internationalization and externalization of R&D has been widely examined (Gammeltoft, 2006; Cheng and Bolan, 1993; Narula, 2001), there has been little research on the spread of the firm's activities over all these strategies (Grossman and Helpman, 2003). What is novel in today's phenomena is the emergence of a combination of offshoring to foreign affiliates as well as outsourcing to third party vendors by multinational enterprises (MNEs) and the coincidence of externalization of R&D and its relocation. There has also been a significant increase in the nature and extent of externalization and internationalization of R&D activities in the recent years (Howells, Gagliardi and Malik, forthcoming). We also contribute to the literature on internationalization and externalization by simultaneously examining the two in the decision making process of the firm.

There has been extensive research on the typologies of outsourcing and offshoring (Chakarabarty, 2006; Mylott, 1995; De Vita and Wang, 2006). Some researchers have also looked at the drivers or determinants of offshoring and outsourcing (Lewin and Furlong, 2005; Contractor and Thakur, 2008; Alexander and Young, 1996; McFarlan and Nolan, 1995). Others have examined the impact of offshoring and outsourcing on performance (Amaral, Billington and Tsay, 2006; Aron and Singh, 2005; Mol, Tulder and Beijer, 2005; Gilley and Rasheed, 2000). 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: a firm may already be outsourcing but decide to shift from domestic to foreign supplier, it may decided to outsource and offshore to a foreign firm simultaneously, and lastly a firm may already have a foreign affiliate but decides to switch to a foreign owned supplier. The last trajectory can happen 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.

Evolutionary Perspective

In this paper we use the evolutionary perspective to construct a dynamic 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 previously 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 (Nelson and Winter, 1982; Chang, 1996). By adopting the evolutionary perspective in our study we look at the temporal changes in the strategy of the firm brought about by the various factors.

We look at the 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 we examine are host country infrastructure (Loree and Guisinger, 1995; Cheng and Kwan, 2000), intellectual property rights

regime (Maskus, 2000), and availability of local resources such as patients and physicians (Azoulay, 2003).

3. RESEARCH SETTING

This section discusses the research setting of the paper. Our research focuses on the pharmaceutical industry which has recently undergone many changes (Galambos and Sturchio, 1996). Until the 1980s, the big pharmaceutical firms were fully integrated and performed all the operations inhouse, from drug discovery to marketing (Cockburn, 2004). But from 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 (Steiner et al., 2007; John, 2006; Hall, 2000).

Increasing threat from generic drugs after patent expiration and the growth of follow on products increased the problems of firms in this industry (Malnight, 1995). The industry also faces price pressures from governments, world health authorities and 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 outsourcing and offshoring 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).

We study clinical trials in the pharmaceutical industry which were traditionally done in-house within the home country but are now increasingly outsourced and offshored to auxiliary firms such as Contract Research Organizations (CROs) and foreign affiliates (Azoulay, 2004).

CROs are specialized third party firms which conduct clinical trials for pharmaceutical and biotechnology firms. Since clinical trials are an integral part of R&D in the pharmaceutical industry they are considered as core activities which are a source of competitive advantage.

According to Glickman et al. (2009) approximately one third of all clinical trials are being conducted outside the developed countries. A significant portion of the clinical trials are being conducted in developing countries indicating that the pharmaceutical industry is moving towards globalization of clinical trials (Berndt, Cockburn and Thiers, 2006). The industry has also moved towards externalization of the clinical trials. In a recent study Mehta et.al.(2007) found that almost one fourth of all clinical trials expenditure is outsourced by the pharmaceutical industry. Azoulay (2004) also found that approximately 23% of the clinical trials are outsourced to CROs.

4. 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, we use case study research methodology. Data collection involved two sources: semi structured interviews and archival data from Fast Track. Fast Track 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 provides us with the number of clinical trials that were outsourced or offshored for the last twelve years from 1995 -2007.

This paper is part of a larger research program and we also surveyed close to 60 firms in the pharmaceutical industry. The firms were asked to rank, in order from the oldest to the newest, their sourcing strategies. The four strategies in the survey question were: inhouse,

foreign affiliates, domestic outsourcing and foreign outsourcing. This helps us improve the external validity of our study and make it applicable to the industry.

We study four firms from the pharmaceutical industry in this research. The research objective was to investigate the evolution of sourcing strategies of core activities such as clinical trials. 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. Our 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. We have two firms from North America and Western Europe each in our study and are in the process of approaching Japanese pharmaceutical firms. 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 our external validity we have firms of different ages in our study. 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 firms had to first complete an online questionnaire after which the executives were approached with a set of questions (See Table 1). Interviews lasted for about an hour and the executives approached in this study were either vice presidents or directors of clinical operations. We also interviewed few former executives of these firms to gain some historical perspective. Multiple interviews were conducted for each firm and detailed notes were taken. In some instances, the interviews were recorded after obtaining permission from the interviewee.

Data analysis was an evolving and iterative process and we first created detailed case write-ups for each firm. The case write-ups were sent to all the participants to ensure that we had

all the correct information. This was done to check if the internal validity and reliability of the data was maintained. We then triangulated the data from the primary and secondary sources. After multiple revisions, we used the case study database to analyze the commonalities between the four firms. Through pattern matching techniques (Yin, 2003) we generated a conceptual framework comprising of environmental and internal factors that influenced strategy evolution.

We now discuss the four firms in this study referred to here as firms Alpha, Beta, Charlie and Delta (See Table 2).

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 thirty three countries. The firm is also highly diversified and focuses on seven therapeutic areas. Approximately seventy percent of its total R&D budget is spent on clinical trials. The pipeline is also very strong and the firm has many drugs in different phases of development.

Firm Beta

The second firm in our study is a big 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 five 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 our study is also a European firm, but from another country, which is one of the biggest firms in the global pharmaceutical industry. This multinational firm has foreign affiliates in over 100 countries and is also very 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 our 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 six therapeutic areas. The firm has many foreign affiliates which operate under 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 spends close to sixty percent of R&D on clinical studies.

5. FINDINGS

In this section we discuss the findings from our multiple case studies. Detailed interviews with the clinical trial executives in the pharmaceutical industry revealed that the four firms in our study followed similar evolutionary pattern for their clinical development sourcing strategies. We next discuss the five stages (See Figure 1) we observed in our qualitative study along with the external and internal factors that were important at each stage.

Stage 1 – Inhouse Strategy

In the first stage the four firms in our study conducted all their clinical development inhouse. 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 on the core activities. Firms tend to emphasize on centralization of their drug development in the early stages of their life cycle. Firms also felt 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 and a ticking patent clock. In the initial stage, firms still have relatively fewer clinical trials in their pipeline and the requirement for resources is also limited. At this stage, young firms such as Alpha and Delta have limited overall experience in drug discovery and development. Firms also tend to retain their core activities inhouse at this stage because their processes are still highly tacit. Firm Beta prefers to retain its trials inhouse because it considers 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 inhouse was better and thus all aspects of the development ranging from design, conduct, monitoring and analysis were done inhouse.

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.

Stage 2 – Foreign Affiliates Strategy

As firms grew and gained more international experience, they started locating some of their clinical development activities in foreign affiliates. In this second stage, the core activity is still concentrated in the headquarters 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 becoming the preferred location for conducting clinical trials for specific therapeutic areas. This confirms some of the prior literature on subsidiary mandates (Birkinshaw, 1996; Cantwell and Mudambi, 2005).

One of the main reasons for firms to move to this second stage is internal growth. 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 feel 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 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 primary 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 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 may not be enough patients to study 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.

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

Stage 3 – Domestic Outsourcing Strategy

In the past decade almost all firms in the pharmaceutical industry have ventured into outsourcing. 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 Contract Research Organizations (CROs).

Although firms are moving towards domestic outsourcing at this stage, they still prefer conducting clinical trials internally and in many instances the important and critical studies are still done inhouse. A lot of the outsourcing decisions are based on capacity. If the firm has more clinical trials than it can manage internally due to resource constraints, then it will 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 and affiliates could not complete all the trials internally. In some instances, firms also outsource to get rid of excess capacity. Firm Delta tried to use outsourcing to reduce its head count thereby reducing its overhead costs. Firms also tend to outsource more transactional tasks such as contract negotiations with hospitals or sites and archiving of clinical trial records at this stage.

There is a difference in the type of outsourcing done by firms in this industry at this stage. All firms follow either of the 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 contrast, 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 them, 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 the more trials a firm does with a CRO the cheaper it is per patient. Beta and Delta also uses niche CROs from time to time for their specialized services.

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

Stage 4 – Offshore Outsourcing Strategy

The fourth stage in the sourcing strategy evolution is the shift to offshore outsourcing. The firms in our study, with the exception of Delta, started with domestic outsourcing and after gaining adequate experience graduated to offshore outsourcing. Delta first started with offshore outsourcing because its regional headquarter in Europe had started using local CROs in smaller European countries three to four years before the firm headquarter in North America.

The drivers for foreign outsourcing are similar to that of stage 2 for foreign affiliates. Firms want to use 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 in 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 just have to 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. They also have 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.

Stage 5 – Retraction

The last stage in this evolutionary process is retraction where firms swing back from the pendulum and move towards greater internalization. This could happen due to a few different reasons such as the firm over extends itself and is unable to manage outsourcing. In our firms, 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.

Another important reason behind Alpha's retraction was the conflict between the headquarters and the foreign affiliates. When Alpha entered stage 4 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 and worried that they were losing importance within the firm. The firm also shrank a bit during this time and had a weaker pipeline. Thus due to the conflicts with 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 inhouse usually within the headquarters country.

While the other three firms in our study have not reached this last stage they do face some internal conflict due to offshore outsourcing. Beta is considering reducing its offshore outsourcing due conflict with its affiliates. Currently the firm tries to reduce friction by involving the affiliate in the decision making process. The firm uses offshore outsourcing only if the affiliate is unable to do the clinical trials. Charlie also had some problems with its foreign affiliates but in the past couple of years the communication between the headquarters and affiliates has improved to avoid 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 incase a CRO is selected.

6. CONCLUSION

Using multiple case studies on firms in the pharmaceutical industry, we trace the evolution of sourcing strategies of core activities. Specifically, we look at the sourcing strategies of clinical trials which is a core activity for these firms.

Overall, we find evidence that firms tend to follow a similar trajectory regardless of size, age and country of origin. Firms tend to start with conducting clinical trials inhouse in the headquarters but as they grow and gain more international experience they tend to offshore some ancillary clinical trials to their foreign affiliate. The third stage of the sourcing evolution is relocation of activity to domestic service providers. This shift in sourcing strategy is primarily driven by internal resource restrictions and cost. The firm after gaining experience in domestic outsourcing moves 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 our evolution cycle is the retraction of outsourcing activities by some firms. This is a very interesting finding and contributes to the literature on outsourcing which has not researched this reversal of the trend. We 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 three of outsourcing much before it was prepared to manage its internal resources and organizational structure.

Our 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 three when the firm starts using domestic

outsourcing, they do still conduct some of their core activities internally in their headquarters and foreign affiliates. 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 we use qualitative research methodology we only have four firms in our study. This impacts the external validity of our study but we have tried to overcome this by triangulating our findings with results from a question in an online questionnaire which also addresses the evolution of sourcing strategies. We have also used secondary data to increase the reliability of our findings. This is a work in progress and we are in the process of collecting information from more firms especially of Japanese origin. We are also searching for more archival information to supplement our interview based data.

We believe our study makes important contributions to the literature on offshoring and outsourcing. Most of the prior studies have focused on outsourcing or offshoring but we look at the spread of activities across all the four sourcing strategies of the firm. We 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 retraction. It will also be interesting to examine if firms will internalize most of their core activities in the future.

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Table 1 – Sample Questions for the Structured Interviews

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| <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? |
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Table 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		1980s
Stage 1	Inhouse	Inhouse	Inhouse	Inhouse
Stage 2	Foreign Affiliate	Foreign Affiliate	Foreign Affiliate	Foreign Affiliate
Stage 3	Domestic Outsourcing	Domestic Outsourcing	Domestic Outsourcing	Offshore Outsourcing
Stage 4	Offshore Outsourcing	Offshore Outsourcing	Offshore Outsourcing	Domestic Outsourcing
Stage 5	Retraction – greater inhouse	Beginning of retraction		

Figure 1 – Strategy Evolution

