IMPACT OF OFFSHORING AND OUTSOURCING OF CORE ACTIVITIES ON PERFORMANCE: AN EXAMINATION OF CLINICAL TRIALS

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Abstract

This paper examines the impact of offshoring and outsourcing of core activities on the overall performance of the firm and project level performance of these core activities. Specifically, we look at whether offshoring and outsourcing of clinical trials has a negative impact on performance and also whether conducting clinical trials inhouse is a better option for the firms. The research setting for this study is the pharmaceutical industry and we focus on clinical trials which is an important part of the R&D process. Our empirical data come from the CROCAS dataset compiled by FastTrack Systems. The study focuses on the period 1997-2005 and analyzes data on 14,305 clinical trials from 98 firms in the pharmaceutical industry. Controlling for unobserved firm characteristics, our results show that conducting trials inhouse and in foreign affiliates has a positive impact on the overall performance of the firm.

Key Words: Outsourcing, Offshoring, Pharmaceutical, Clinical Trials.

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1. INTRODUCTION

Offshoring and outsourcing of research and development (R&D) is a relatively new phenomenon that has become increasingly important in the past few decades. Traditionally, firms would retain control over their core activities, such as R&D and IT, that are sources of competitive advantage but these processes are now becoming more geographically and functionally dispersed (Gammeltoft, 2006). 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 (Narula, 2001; Bardhan and Jaffee, 2005). Other factors that have influenced the externalization of R&D are improvements in the policy environments, increase in global competition, and the associated increase in costs and risks of R&D. According to Cheng & Bolon (1993) the three factors that contributed to the increase in international R&D are improved information and communication technologies (ICT), improved social and economic resources which provide better infrastructure in host countries, and increased uniformity in international patenting.

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, Belgium and Scandinavia had internationalized their R&D as early as the 1960s (Cantwell and Hodson,1991; Cantwell, 1995; Pavitt and Patel, 1991).

Externalization of R&D has also been prevalent since the late 1990s (Howell, 1999; Jones, 2000; Narula; 2001; Hagerdorn, 2002) although it was mostly in the form of inter firm alliances and contracts. According to Archibugi and Michie (1997), firms usually generate innovations through R&D and globalize them using three main categories: 1) international exploitation of technology produced at home, 2) global generation of innovations through international R&D (internationalization of R&D) and 3) global technological collaborations (externalization of R&D).

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). This is especially important in the world economy as what is novel in today's phenomena is the emergence of a combination of offshoring to foreign affiliates as well as outsourcing to domestic and foreign 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). Firms today have an option to choose from four sourcing strategies: *inhouse, foreign affiliates, captive offshoring* and *offshore outsourcing* (See Table 1). These four strategies represent the decisions made by the firm to locate core activities both organizationally (in house versus external vendors) and geographically (trials conducted in home nation versus trials in foreign countries).

One of the important issues raised by this phenomenon of simultaneous externalization and internationalization of R&D is the impact of these important strategic

decisions made by the firm on the performance. According to recent anecdotal evidence, offshoring and outsourcing can have both positive and negative impact on performance. Some drawbacks proposed by earlier literature, such as loss of control, conflicts in organizational culture, instability and lack of organizational learning can lead to a decline in firm performance.

Using panel data from Fast Track Systems, this paper examines the impact of offshoring and outsourcing of core activities on the overall performance of the firm as well as project level performances of trials. Specifically, we look at whether offshoring and outsourcing of clinical trials has a negative impact on performance and whether conducting core activities inhouse is a better option. The research setting for this study is the pharmaceutical industry and we focus on clinical trials which is an important part of the R&D process. The study focuses on the period 1997-2005 and analyzes data on 14,307 clinical trials from 82 firms in the pharmaceutical industry.

In the next section we give a brief literature review and develop hypotheses relating to offshoring, outsourcing and performance. Section 3 provides an overview of the research settings and discusses the different phases of clinical trials. In sections 4 and 5, we describe the methodology and results, and the final section concludes.

2. LITERATURE REVIEW AND THEORETICAL BACKGROUND

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 (foreign affiliates), 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 standardized tasks such as manufacturing operations of a firm but there has been a recent 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 became 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).

The relationship between offshoring, outsourcing and performance has not received much attention from prior researchers. According to Mankiw and Swagel (2006) there has been little analysis of the impact of offshoring and outsourcing since

researchers view it as a new form of international trade which inspite of creating winners and losers also leads to an overall increase in productivity and income. Most of the existing research on offshoring and outsourcing focuses on typologies and taxonomies (DeVita and Wang, 2006; Sako, 2005) or the initial entry decision of the firm and locational factors (Doh et al. forthcoming; Mudambi and Tallman, forthcoming) but there is relatively little research on the impact of these offshoring and outsourcing decisions on the subsequent performance of the firm or even performance of the offshored activities. Most of the prior research refers to anecdotal evidence on the impact of offshoring and outsourcing on performance (see exceptions Bhalla et al., forthcoming; Gilley & Rasheed, 2000; Leiblein and Miller, 2003).

The relatively limited theoretical and conceptual research has suggested mixed effects on the relation between outsourcing, offshoring and performance. For instance, one hand offshoring and outsourcing could improve performance due to lower costs, greater flexibility to cope with dynamic environments, specialized skills and access to newer resources which improves competitive advantage of firms (Bryce and Useem, 1998). According to Quinn and Hilmer (1994) offshore outsourcing allows firms to access a larger pool of suppliers and pick the most suitable supplier thus ensuring higher efficiency.

On the other hand, researchers who are not in favor of offshoring and outsourcing suggest that externalization and internationalization leads to inefficiency due to differences in management styles, host country risks and increased coordination requirements (Fischer & Behrman, 1979; Amaral, Billington, & Tsay, 2006). According to some authors offshore outsourcing can lead to a decline in the innovative capacity of

the firm (Kotabe, 1990; Teece, 1987) and also increases the threat of competition from the third party suppliers of the outsourced activity (Bettis et al., 1992; Prahalad & Hamel, 1990; Quinn, 1992). Other negative possible outcomes from outsourcing are excessive dependence on suppliers (Alexander and Young, 1996), hidden costs (Quinn and Hilmer, 1994), loss of know how (Earl, 1996) and the service provider's lack of necessary capabilities (Aubert et al., 1998). Doh (2005) suggests that outsourcing and offshoring could also challenge the development and deployment of firm specific capabilities and thus negatively impact the firm's competitive advantage.

There have been a few studies that have empirically tested the relationship between offshoring, outsourcing and performance (Bhalla et al., 2006; Gilley and Rasheed, 2000; Ehie, 2001). These studies have found no significant relationship between performance and outsourcing and offshoring at the firm level (Gilley and Rasheed, 2000, Bhalla, Sodhi and Son, 2006; Mol, Tulder and Beije, 2005). In an exploratory study, Bhalla et al. (2006) examined the relation between performance and offshoring of IT services, without distinguishing between captive offshoring and offshore outsourcing, and found no significant link between the two constructs. Gilley and Rasheed (2000) examined the impact of outsourcing on the firm performance and the moderating role of firm level strategy and environmental dynamism. They examined the overall outsourcing intensity of the firm and distinguished between outsourcing of peripheral and core activities. 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. Firms following cost based strategies benefited more from outsourcing than firms following differentiation strategies. According to the authors there may be a

relationship between outsourcing and performance at the individual functional areas which their data didn't capture at the firm level. Aron and Singh (2005) also found that many firms had mixed outcomes from offshoring. In a recent study, Hezewijk (working paper) examined the relationship between manufacturing outsourcing and performance and found that operation strategy of the firm had a significant influence on this relationship.

The relation between offshoring and performance is also important for the corporate sector. According to A. T. Kearney report when asked the question if company's offshored business' performance met their expectation, nearly a quarter of the respondents were unsure while about 51% said that the performance met the expectation.

Offshoring of core activities such as R&D especially in high technology fields such as the pharmaceutical industry is counter intuitive when looked through the lens of the resource based view (RBV) and the competence based view. Both these views argue that firms focus on internally developing their core competences while outsourcing their peripheral activities (Prahalad & Hamel, 1990). According to Barney (1991), firms develop those resources and capabilities that are valuable, rare, imperfectly imitable and non substitutable within the firm boundaries. But the pharmaceutical firms that outsource their R&D are in effect moving the activities outside the firm which could have lead to sustained competitive advantage in the long run. According to Rasheed and Gilley (2005) firms must retain their core technologies inhouse and outsource their peripheral activities. According to them the firms should constantly upgrade their core competences to avoid opportunistic behavior by their suppliers.

Thus, we hypothesize that outsourcing, both domestically and to foreign providers, has a negative impact on the overall performance of the firm while inhouse activities improve performance. Offshoring to foreign affiliates has a positive relationship with performance because there are lower coordination costs compared to outsourcing. Internal relocation of clinical trials to foreign affiliates also improves performance because many of the resources necessary for sustained competitive advantage are intangible and deeply embedded in an organization (Teece, 1992). Accordingly we hypothesize:

H1a: Other things equal, clinical trials conducted inhouse has a positive impact on the overall performance of the firm.

H1b: Other things equal, offshoring of clinical trials to foreign affiliates has a positive impact on the overall performance of the firm.

H1c: Other things equal, domestic outsourcing of clinical trials has a negative impact on the overall performance of the firm.

H1d: Other things equal, offshore outsourcing of clinical trials has a negative impact on the overall performance of the firm.

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; Gorzig and Andreas, 2002; Gilley and Rasheed, 2000). For instance, Mol et al. (2005) distinguished between global and regional outsourcing and measured the performance effects at the firm level but did not find any significant relationship. The authors recommend the use of better measures of outsourcing

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.

The effects of offshoring and outsourcing on the overall firm performance are difficult to discern as its influence is relatively small compared to other influences on performance. According to Jiang and Qureshi (2006), the measurement of outsourcing effects on a particular department or activity may be diluted if the unit of analysis is the firm. It is also widely known in the economics and finance literature (Shaver, 1998; Kruse, 1992; Mumford and Dorwick, 1994; Hitt et al. 2004) that profits are endogenous and self selection on hard to measure or unobservable characteristics can cause bias strategy performance estimates. It may be possible that firms self select offshoring and outsourcing strategies based on their past performances.

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

On the other hand, Cavalla (1997) point out to some of the drawbacks with outsourcing of clinical trials such as loss of control, conflicts in organizational culture, instability and lack of organizational learning. Some studies also find that the delays in clinical trials were often caused by contract budget negotiations and approvals (Paraxel,

2007). Cockburn (2006) also suggest that increase in costs and delays in drug approval can be partially explained by the vertical disintegration of the industry. Outsourcing creates new risks due to the pharmaceutical firm's incomplete control over CRO's processes and personnel (Kapler and Puhala, 2008) and these risks are usually addressed with greater monitoring.

Thus, due to these drawbacks associated with outsourcing and offshoring of clinical trials, we argue that clinical trials performed inhouse, within the parent country and in foreign affiliates, will have better performance compared to trials conducted by external CROs.

H2a: Other things equal, clinical trials conducted inhouse has a positive impact on the overall performance of the trial.

H2b: Other things equal, offshoring of clinical trials to foreign affiliates has a positive impact on the overall performance of the firm.

H2c: Other things equal, domestic outsourcing of clinical trials has a negative impact on the overall performance of the trial.

H2d: Other things equal, offshore outsourcing of clinical trials has a negative impact on the overall performance of the trial.

Thus due to the conflict in the literature regarding the impact of outsourcing and offshoring on the actual performance, it is important to examine this relationship. According to Howell et al. (working paper) getting R&D outsourcing wrong can have significant impact on the short and long term future of the firm.

In this study we measure the impact of outsourcing and offshoring on the performance of the firm as well as on the performance of the clinical trials. At the firm

level we measure performance as return on assets and net profits. For the project level performance we use one financial and two non financial measures and they are: duration of study, size of the study (number of patients recruited) and the cost of the conducting the study. These three measures of performance are used because some of the important drivers of outsourcing and offshoring are cost savings (Jiang and Qureshi, 2006), speed of completion (Maromonte, 1998) and the quality of the study (Bryce and Useem, 1998). Maromonte (1998) identified four criteria to evaluate performance and they are quality performance, delivery performance, cost performance and product advancement performance.

Recent research (Lewin, Manning and Schurch, working paper; Hezewijk, working paper) on the relationship between outsourcing and performance have examined performance in terms of quality, innovation, cost, delivery, renewal rates of contracts, duration, and longevity of client relationships. But these studies have either examined manufacturing outsourcing (Hezewijk, working paper) or used qualitative data from the service providers (Levin et al., working paper).

3. RESEARCH SETTING

The research setting of this paper 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 software and IT. R&D is a core activity in the pharmaceutical industry and is one of its important sources of competitive advantage (Henderson and Cockburn, 1994**;** Piachaud, 2004; Dierickx and Cool 1989). Until the 1980s the big pharmaceutical firms were fully integrated and

performed all the operations inhouse, 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 dozens of blockbuster drugs. But for 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). 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).

The pharmaceutical R&D includes many scientific and clinical activities such as synthesis, extraction, biological screening, dosage formulation, and clinical trials. These activities can be broadly divided into drug discovery and drug development. This research will focus on the outsourcing and offshoring of the clinical trials (drug development) which primarily involves the testing of compounds, discovered in the earlier stages, on human subjects.

"Clinical trials is central to translating the promise of biomedical research into improved clinical practice – the neck of the scientific bottle" – Rettig (2000).

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. The clinical trial studies are very expensive and take a long time. The time to bring a new chemical entity (NCE) from pre clinical and clinical phase to regulatory review is estimated to range from 6.8 to 18 years (Cockburn, 2006). The clinical trials which were traditionally done in-house within the home country but the pharmaceutical firms are increasingly outsourcing and offshoring drug development to auxiliary firms such as contract research organizations (CROs) and foreign affiliates (Azoulay, 2004).

*****INSERT FIGURE 1*****

Outsourcing and offshoring 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 one time decision, decisions related to clinical trials have to be made for each project and the factors may vary from trial to trial. Outsourcing and offshoring of clinical trials are also unique because the boundaries of the firm can shift on project by project basis (Azoulay, 2004).

The clinical development studies are divided into four distinct phases: Phase I recruits around thirty to hundred normal human subjects and lasts up to a year. The primary purpose of this stage is to determine the safety of the compound and includes the evaluation of drug absorption, distribution, excretion and structure-activity relationship (Lee et al., 2006). The success rate is around 70% for this stage. 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. This type of study lasts up to two years and has a 50% success rate. The third phase is the largest and recruits anywhere from a few hundreds 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, and has success rate close to 80%. The third phase tests the drug using randomization of patients and controls with placebos or other standard medical care drugs (Randomized control trials). 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.

*****INSERT TABLE 2*****

4. METHODOLOGY

This section provides an overview of the methodology adopted to examine the spread of clinical trials and its impact on performance. The impact on performance will be measured for the four technological strategies adopted by MNEs which are: inhouse clinical trials, domestic outsourcing, captive offshoring, and offshore outsourcing. The following subsection will outline the data collection procedures and the sample. This will be followed by a discussion on the operationalization of constructs and the variables used.

Data

This research focuses on the pharmaceutical industry and the firms included in this sample are pharmaceutical manufacturing companies (prescription, over-the-counter, and generic products) as well as biotechnology firms that undertake pharmaceutical

research. A significant portion of prior research used either pharmaceutical or biotech firms but we include both these two types of firms as they represent the two important layers of the pharmaceutical industry (Howell et al., 2008).

The quantitative data for this research will come from datasets published by Fast Track Systems Inc, Bureau Van Dijk and Standard & Poor's. The first confidential dataset used in this research is CROCAS made available by Fast Track Systems Inc. This database has detailed project level data on clinical trials and identifies the trials that were outsourced to CROs. 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. The firms in this sample are mostly from developed countries and are concentrated in the Triad region: North America, Western Europe and Japan. There are 53 large pharmaceutical firms, 21 medium/small sized firms and 24 biotechnology firms in our sample. CROCAS has data on nearly all large pharmaceutical and biotechnology firms and the sample is representative of the industry as a whole. Data from clinicaltrials.gov is also used to complement the data from Fast Track. These two dataset are used to empirically examine the impact of offshoring and outsourcing on project performance.

Firm level data is from Compustat, compiled by Standard & 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. Compustat also has financial data on firms including ones which have exited the industry either due to mergers and acquisitions or through dissolution.

Variables

The first dependent variable for this study is the overall firm performance which is measured as the net income. The data for this measure is from Orbis and Compustat. The dependent variable was deflated to take out inflation, logged and forward lagged by one year. We also used net revenue and gross income as measures of performance but since the results were similar we only report net income in this paper.

The main independent variable, for the firm level analysis, is the spread of clinical trial activities which is measured for the four technological strategies adopted by MNEs (see Table 2). Quadrants B and D in Table 1 cover "offshoring," – whether retained in-house or provided by foreign vendors. Quadrants C 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 multinational company. Quadrants C and D involve not only arms-length R&D providers, but may also include alliance partners with whom the firm undertakes joint research – something becoming common in many areas especially clinical research, (Contractor and Lorange, 2002). These variables are operationalized as number of clinical sites in a particular quadrant as a percentage of total number of clinical sites (see Table 2).

*****INSERT TABLE 1*****

We include controls for firm specific factors such as size which is measured as the number of employees. We also control for each country's effective tax rates by using data from the U.S. Department of Commerce, Bureau of Economic Analysis. We use year fixed effects to control for time. We also include a dummy variable to control for the type of firm with 0 for biotechnology firms and 1 for pharmaceutical firms.

For the project level performance we use one financial and two non financial measures and they are: duration of study, size of the study and the cost of the conducting the study. Duration of the study is measured as the number of days for clinical trials; size of the study is operationalized as the number of patients recruited and the cost of the study is the total payment paid for the study. All the three measures of performance are from the Fast Track database and are transformed into their natural logs.

The independent variables for the project level study are the spread of clinical trials, across inhouse, foreign affiliates, domestic and foreign CROs, which is similar to the variables used in the firm level study. The difference between the firm level estimation and project level estimation is that the trials are aggregated at the project level in the later. We also include project level controls, such as therapeutic area, phase of the trial, as well as firm level controls such as firm type and country of origin.

Model

To measure the impact of offshoring and outsourcing on firm performance, we use Random Effects (RE) model as we have panel dataset.

$$Y_{i(t+1)} = \beta_o + \beta X_{it} + a_i + u_{it}$$

The $Y_{i(t+1)}$ is the dependent variable where i is the firm and t+1 denotes the time period with a 1 year forward lag. X is the vector of independent variables and a_i is the unobserved time (invariant factors) and u_{it} is the idiosyncratic error term.

We do not estimate a Fixed Effects (FE) model because it requires at least two observations per firm and some of the firms in our firm have data only for one year.

To measure the impact of offshoring and outsourcing on project level performance, we use multivariate regression analysis as we have three dependent

variables. We used factor analysis to identify any underlying factors but did not find any significant factors.

$$Y_j = \beta_o + \beta_r X_{jr} + \varepsilon_j$$

The Y_j is the dependent variable where j is the number of dependent variables. X is the vector of independent variables for each of the dependent variables and ε_j is the error term.

5. RESULTS

Descriptive Statistics

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

*****INSERT TABLE 3*****

Table 3 gives the sample mean, median, and standard deviation of the variables in our model. We report the raw values of the variables, rather than the logs, to facilitate examination. All dollar values are expressed in 1996 $US. Table 3 also reports sample medians, since, for all the variables in dollar values, the means are significantly biased up by large firms data.

Table 4 gives the distribution of the clinical trials across the therapeutic areas. There are totally 15 areas with the highest number of trials in oncology, pharmacokinetics, central nervous system and cardiovascular. This is representative of the industry as a whole. Table 5 looks at the distribution of clinical trials across the four

main phases. Most of the trials in our sample are for phase three which is expected as this is the most frequently conducted trial in the pharmaceutical industry.

Table 6 gives a break down of trials by year and by strategy and according to this table there were more clinical trials done between 1997 and 2002 in our data. On closer examination (See Table 7) it appears that this may be because there are fewer firms in the last couple of years in our sample which can be explained by the mergers and acquisitions in the industry.

Regression Results

Table 8 shows our random effects results. We report our regression results in two columns. The first column contains only the main effects model and the second column contains the full model with firm level control for employees, home country level control of effective tax rates and the dummy variable to control for the type of firm.

*****INSERT TABLE 8*****

In hypothesis 1a, we proposed that firm performance is positively associated with the clinical trials conducted inhouse. As can be seen in both the regressions, inhouse clinical trials are highly significant.

In hypothesis 1b, we proposed that there is a positive relationship between clinical trials conducted by foreign affiliate and firm performance. This variable is significant in both the models although it is marginally significant in the full model.

Hypothesis 1c proposes that there is a negative relation between domestic outsourcing and firm performance. This variable was not significant in both the regressions but the signs were in the expected directions. Hypothesis 1d focuses on the relationship between foreign outsourcing and performance and this is not supported in the

full model regression. This variable was marginally significant in the main effects model suggesting that a negative relationship exists between foreign outsourcing and performance.

Turning to the control variables, the number of employees, which controls for the size of the firm, was positive and highly significant. This indicates that larger firms had better performance which is not very surprising. Also not surprisingly, firm performance was strongly negatively related to host-country effective tax rates. The dummy variable for the type of firm is also positive and significant.

*****INSERT TABLE 9*****

Table 9 shows the project level results obtained from multivariate analysis. At the project level hypothesis, we found some mixed results for the four sourcing strategies. We had measured performance using the three variables: the duration of trials, cost of conducting the trial and finally the number of patients used which is a measure of the size of the trial. In hypothesis 2a, we had proposed that there is a positive relation between inhouse trials and performance and we found that there is a significant and negative relation between cost and inhouse trials indicating that as more trials are done inhouse the cost of conducting trials decreases. We also found that the relation with duration was significant and negative while size was also negative and significant. This indicates that as more trials are done inhouse, fewer patients are recruited which is contrary to our hypothesis. Thus two of the three measures of performance supported our first hypothesis at the project level.

In hypothesis 2b, we had hypothesized that there is a positive relationship between clinical trials conducted by foreign affiliates and performance. We found that

there is a significant and negative relationship between foreign affiliates and cost while as significant and positive relation with duration. We also found a negative and significant relationship with size of trials.

Hypothesis 2c proposes that there is a negative relationship between domestic outsourcing and performance. We found that the relationship with cost is negative but insignificant while with duration the coefficients are positive and significant. Domestic outsourcing is negative and highly significant for size of the trial. This suggests that hypothesis 2c is partially supported in two of the three measures of performance.

In the final hypothesis 2d, we argue that there is a negative relationship between offshore outsourcing and project performance. We found that there is a positive and significant relationship with cost which supports our last hypothesis. We found there is a positive and significant relationship with duration and negative and significant relationship with size. This shows that our final hypothesis was fully supported.

The control variables for this study were phase of trial, therapeutic area, parent type and trend to control for time. Most of these variables were highly significant with the exception of parent type for cost measure.

6. CONCLUSION

In this research, we examined the impact of outsourcing and offshoring on the performance of the firm. Specifically, we looked at whether outsourcing and offshoring has a negative impact on firm performance. There is relatively little literature on this research but the question asked is extremely important for the long run performance of the firm. Controlling for unobserved firm characteristics, our results show that

conducting trials inhouse and in foreign affiliates has a positive impact on the overall performance of the firm. We did not find support to our hypothesis on outsourcing, although we found marginal support for foreign outsourcing. However the signs of the coefficients suggest that there is a negative relationship.

Measuring the impact of offshoring and outsourcing at the firm level has many limitations. The effects of offshoring and outsourcing on the overall firm performance are difficult to discern as its influence is relatively small compared to other influences on performance. To overcome this limitation, we analyzed data at the project level to examine the relationship between offshoring and outsourcing on the performance of the clinical trials. For the project level performance we used one financial and two non financial measures and they are: duration of study, size of the study (number of patients recruited) and the cost of the conducting the study. By measuring performance at the firm as well as the project level we hope to provide a richer analysis of this phenomenon.

We found partial support for all three measures. Our results indicate that clinical trials conducted inhouse and in foreign affiliates decreases the cost of conducting trials. Inhouse trials led to a decrease in the length of conducting trials however we found that they actually increased the length of conducting trials with foreign affiliates. This was contrary to our hypotheses and we suggest that this may occur because of the greater distance between the parent and foreign affiliates which can increase coordination requirements and thus delay the completion of the trials. We also found that as more trials were conducted in inhouse and foreign affiliate's trials the number of patients recruited actually decreased and this is also contrary to our hypothesis and demands a more detailed investigation.

Our domestic and foreign outsourcing results suggest that the duration of conducting trials increases with these two sourcing strategies. There are also fewer patients recruited for these external trials. The cost of conducting clinical trials also increases for offshore outsourcing but we did not find significant findings for the domestic outsourcing. Thus we found complete support for our last project level analysis which suggests that offshore outsourcing has a negative impact on project performance.

We feel that our results contribute significantly 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 technological strategies of the firm. This is still a working paper and our present results of firm level performance and project level performance tell a rich story about the micro and macro level impact of offshoring and outsourcing of core activities. In the future versions of this research we plan to use data on drug approvals, from NDA pipeline published by FDC reports, as a measure of project performance. We also plan to include more controls at the firm and project level.

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Figure 1. Pharmaceutical R&D

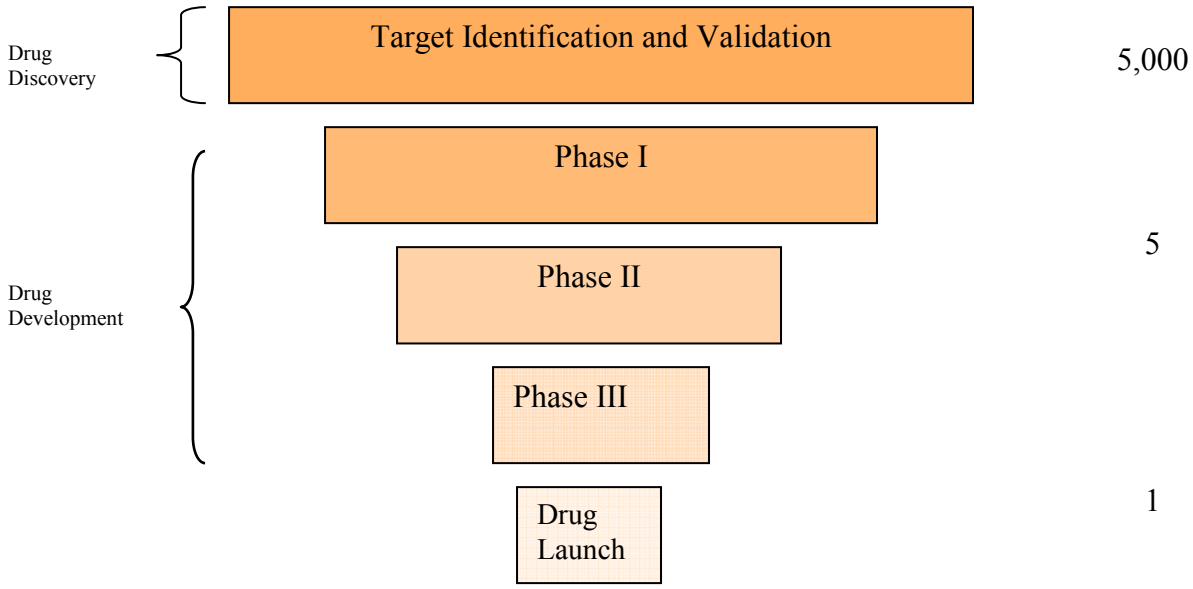

Figure 2

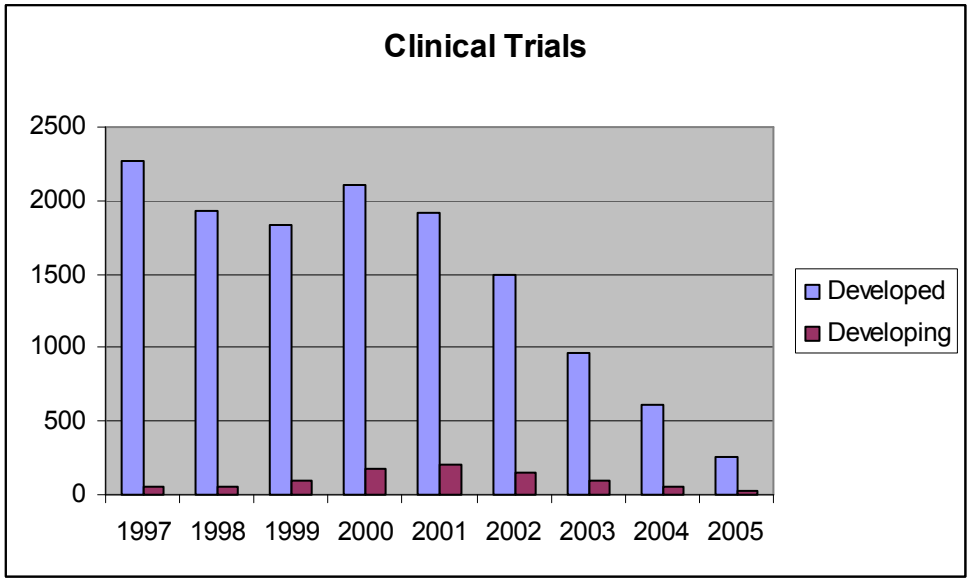
Clinical Trials
2500
2000
1500
1000
500
0
1997
1998
1999
2000
2001
2002
2003
2004
2005
Developed
Developing

Table 1

The Global Spread of R&D Activities

Ownership	**Domestic** (within the Headquarter Country)	**"Offshore"** (outside the Headquarter Country)
IN HOUSE DOMESTIC OR FOREIGN	**A) Value of Entirely In-House Activities Within the Headquarter Country)**	**C) Value of Entirely In-House Activities In Fully-Owned Foreign Subsidiaries**
OUTSOURCING DOMESTIC OR FOREIGN	**B) Value Outsourced Domestically in the Headquarter Country**	**D) Value Outsourced From Foreign Providers**

Table 2

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**

Table 3

Descriptive Statistics

Variables	**Mean**	**SD**	**Median**
Net Income	2672.47	3443.55	1578.95
Inhouse	81.09	223.08	67
Domestic Outsource	20.24	65.05	6.5
Offshore Outsource	30.02	68.59	25
Foreign Affiliate	151.46	344.47	135
Employees	50.06	42.47	49.03
Tax	1.89	.51	1.59

Table 4

Clinical Trials by Therapeutic Areas

No.	Therapeutic Areas	Number of Clinical Trials
1	Cardiovascular	1,161
2	Gastrointestinal	379
3	Central Nervous System	1,722
4	Anti-Infective	1,058
5	Oncology	1,929
6	Immunomodulation	1,098
7	Dermatology	357
8	Endocrine	1,062
9	Pharmacokinetics	1,880
10	Hematology	263
11	Ophthalmology	157
12	Genitourinary System	701
13	Respiratory System	829
14	Pain and Anesthesia	298
15	Devices and Diagnostics	37

Table 5

Clinical Trials by Phase

Phase	Number of Clinical Trials
Phase 1	2,845
Phase 2	3,377
Phase 3 A	5,428
Phase 3 B	1,408
Phase 4	1,247

Table 6

Trials Level Data – Number of Trials By Year

Year	Total Trials	Inhouse	Foreign Affiliate	Domestic CRO	Foreign CRO
1997	2331	584	1432	123	243
1998	1986	402	1227	124	277
1999	1926	405	1141	162	298
2000	2289	427	1494	128	302
2001	2126	393	1499	60	217
2002	1634	305	1204	40	135
2003	1062	147	788	37	113
2004	656	142	453	28	42
2005	297	83	201	5	15
Total	14307	2888	9439	707	1642

Table 7

Trials Level Data – Developed and Developing Countries

	Total Number of Firms	Trials Conducted in Developed Countries	Trials Conducted in Developing Countries
1997	64	2274	57
1998	62	1936	50
1999	63	1833	93
2000	61	2112	177
2001	54	1918	208
2002	52	1489	145
2003	43	961	101
2004	42	606	50
2005	26	264	33

Table 8

Regression Results – Firm Performance

Variables	**Main Effects RE**	**Full Model RE**
Inhouse	0.0003961*** (0.0001877)	0.0003587*** (0.0001877)
Domestic Outsource	-0.0005972 (0.0006229)	-0.0005972 (0.0006229)
Foreign Outsource	-0.0264969* (0.055727)	-0.0012023 (.0007691)
Foreign Affiliates	0.0941773** (0.0558218)	0.0001765* (0.0001381)
Employees		0.010429*** (.0022126)
Tax_t		-1.288*** (0.297)
Type		1.328542*** (0.2332524)

*** = significant at 1% level; **=significant at 5% level; *=significant at 10% level

All regressions were estimated with country and year fixed effects.

Table 9

Multivariate Regression Results – Trial Level Performance

	Cost	**Duration**	**Size (Patients)**
Inhouse Trials	-31939.38***	-0.006083	-0.0036981***
Foreign Affiliates	-28718.69**	0.006212***	-0.0097575***
Domestic CROs	-40093*	0.002552	-0.0087859***
Foreign CROs	10829.38 **	-0.0030976**	-0.0078337***
Trial Phase	466405***	0.3461644***	-0.124838***
Therapeutic Area	-152163.7***	-0.0826077***	0.0417954***
Parent Type	393999.4	0.3947886***	-0.1865458***
Trend	-354808.4***	1.395322***	-0.0668737***

*** = significant at 1% level; **=significant at 5% level; *=significant at 10% level