



**Using the  
Build-Operate-Transfer Model (BOT) to Outsource Life  
Science R&D to India**

**Nihar Prasanna  
Director  
Acunova Life Sciences Pvt. Ltd.**

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## **Preface**

### **Success of the IT model in outsourcing**

The Business Process Outsourcing industry is a young and nascent sector in India and has been in existence for a little more than six years. Despite its recent arrival on the Indian scene, the industry has grown phenomenally and has now become a very important part of the export-oriented IT software and services business. What initially began as an activity confined to multinational companies has today developed into a broad based business platform backed by leading Indian IT software and services organizations and other third party service providers. The BPO market expanded its base with the entry of Indian IT companies and the market today is characterized by the existence of these IT giants who are able to leverage their broad skill-sets and global clientele to offer a wide spectrum of services via this business model. Today, Indian IT companies are offering a variety of outsourced services ranging from customer care, transcription, billing services and database marketing, to Web sales/marketing, accounting, tax processing, transaction document management, telesales/telemarketing, and HR hiring. The success of this model has prompted this research study to further test its applicability in the life science sector.

### **Outsourcing life science research to India**

Acunova Life Sciences Pvt. Ltd. (ALS) And Manipal Acunova Pvt. Ltd. (MAPL) seek to understand the reasons why global companies benefit by conducting research and development in the Life Sciences in India. Specifically, are parameters such as human capital, cost competitiveness and speed, the reasons why companies want to outsource life science activities to India? Human capital and cost competitiveness have historically been the reasons to outsource Information technology (IT) related work to India but it remains unclear, if these parameters hold in the area of life sciences. This study tries to answer some of these questions by surveying a number of domestic as well as multinational companies in India.

### **Identifying Best Practices**

ALS and MAPL want to understand best practices by learning about the business challenges faced in various organizations in discovery, development and diagnostics. These best practices might be in hiring, training, risk management, cost reduction and so on. The goal is to use the knowledge gained to help us accelerate best practices within the organization while de-emphasizing and eliminating others.

### **'Build-Operate-Transfer' (BOT) Model for Life Sciences**

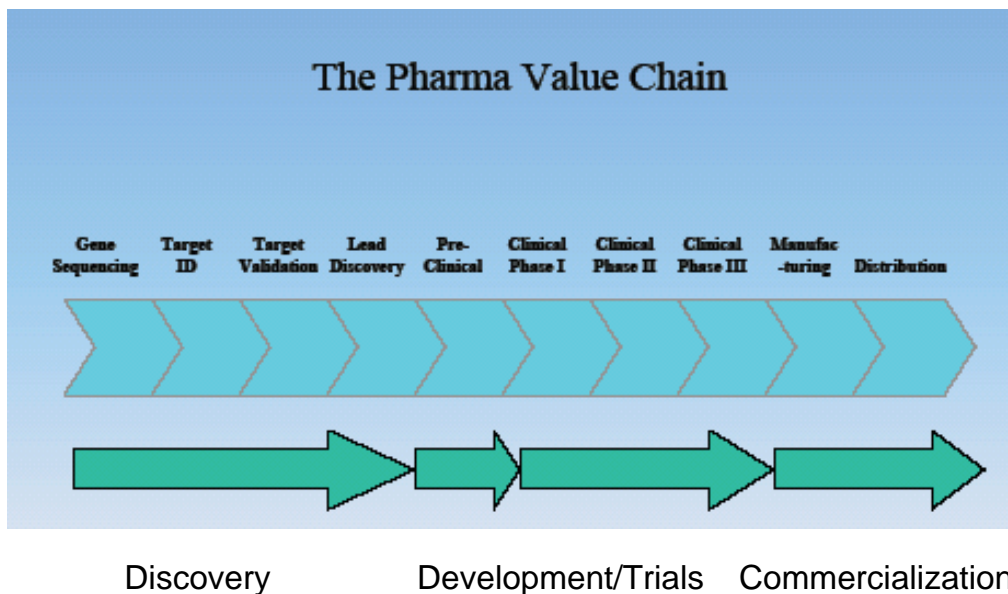
The third aim of this study is to confirm whether the BOT model is applicable in the life science space. Since there are no real world examples of this business model in India the researcher will rely on opinions of companies who do outsourcing related work. The goal here will be to use this new knowledge to construct BOT proposals to prospective clients in drug discovery and diagnostics.

Manipal Acunova and Acunova Life Sciences have sponsored this research study by providing the necessary funding and guidance, without which this study would not have been possible. This research study was conducted between July and October 2005 and report finalized in December. MAPL and ALS hold exclusive rights of ownership to this report

## I. Introduction

### **A. Current Status of Outsourcing Life Science R&D to India**

In the late 1980's and early 1990's, multinational companies (MNC's) seriously began to explore India's potential as a competitive research destination. Although this early wave consisted largely of research labs that served their own local manufacturing operations; the trend today is shifting to various models of contract research. There are three main areas in the pharma value chain where outsourcing of R&D takes place in India:



**Fig.1 Value Chain in a Pharmaceutical Company**

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### **Discovery Research**

Drug discovery is an early yet highly research intensive stage in the pharmaceutical industry. Activities in this stage include target discovery/validation, lead generation and lead optimization. India has witnessed a significant increase in the emergence of Indian divisions of MNC's providing drug discovery and development services. AstraZeneca, GSK and several leading global Contract Research Organizations (CROs) such as Quintiles, Covance and Parexel have entered the Indian market in recent years. With the early phase drug discovery and chemical synthesis global markets valued at USD 4 billion, India, currently at 0.7 % (of the total market) continues to rapidly grow at 40-50% per annum (E&Y BPV,2005).

In drug discovery, Indian Pharmaceutical companies are extremely strong in chemistry driven drug discovery activities such as organic synthesis, medicinal chemistry, process chemistry and analytical chemistry. After recognizing the capabilities of Indian companies in this area and the

attached cost advantages, several big pharma companies are evaluating to outsource their R&D processes to India.

A few examples of companies that do contract research in the drug discovery area are Syngene (Biocon), Aurigene, Avesthagen, Triesta Sciences, Nicolas Piramal, Shasun etc. Some of these companies are primarily into chemical synthesis (Syngene, Shasun) while others (Aurigene, Avesthagen) are into discovery in Biologics.

### **Drug Development (Clinical Trials)**

Drug development or clinical trials, which comprise two thirds of total development costs, has been facing escalating pressure akin to R&D activities. The clinical trial process includes many different phases (Phase I through IV) that include animal testing as well. Multinational companies like Aventis and GSK are flocking to India to launch their trials. Multinational companies are not the only ones to benefit from these trials – India does too. The consultancy firm Mckinsey estimates that US and European pharmaceutical companies will spend US\$1.5 Billion a year on clinical trials in India by 2010 (Nature, 2005).

India shows up strong on the competitive market radar due to its huge patient population, English speaking doctors and investigators (majority of who are educated in western countries) and a large pharmaceutical presence that has dominated the world markets due to low cost generics. In this space both Indian and multinational pharmaceutical companies rely on Indian CRO's to outsource their clinical trials. Weather it is a CRO specialized in Clinical Data Management or one that provides a complete solution; pharmaceutical companies make their choice based on strategic and operational objectives.

Currently there are more than 20 well-established clinical trial organizations in India including few leading global CROs like Quintiles, Omnicare, etc. These companies are offering Phase I to IV clinical trials services and are well equipped to comply with the global standards such as ICH-GCP guidelines (E&Y BPV, 2005).

According to another estimate by PhRMA and ING Barings LLC, outsourced clinical phase I-IV market in 1998 was about US \$4.4 billion and is projected to grow to US \$7.8 billion in 2002. Around 80,000 clinical trials are being conducted globally each year. It is estimated that 20-30% of global clinical trial activities are being conducted in developing countries. The 2002 Indian clinical trials market of \$30-35 million is projected to grow 8-10 times by 2010 to \$ 250-300 million

## **Diagnostics**

The diagnostics space includes companies conducting specialty testing and medical device companies. The diagnostics and pathology business in India presents a high margin and has low entry barriers. A conservative estimate would put gross margins at about 50 per cent and there is no licensing requirement except to obtain the license under the Shop and Establishment Act (E&Y BPV, 2005). There are about 30,000 pathology labs in India and only a few prominent ones have any international accreditation. The industry is dominated by six major players namely SRL Ranbaxy, Dr. Lal's Pathology, Metropolis, Pathnet India, Thyrocare and Nicholas Piramal's Wellspring. The industry's other players include Ezy Health, Medinova, Elbit & NM Diagnostics. International players such as Specialty Laboratories Inc. and Quest Diagnostics do not have presence in India. Moreover large international path labs have preferred Singapore over India for establishing their presence in Asian region.

Medical devices companies include medical imaging at an anatomical level and at a molecular level. Good examples would be instruments such as Computed Tomography (CT) scanners as well as research laboratory instrumentation such as DNA sequencers and immunoassays systems. In medical imaging many big players have set up large R & D centers in India: GE, Phillips, Siemens and Toshiba. In the laboratory instrumentation space players like Applied Biosystems, Beckman Coulter, and Beckton Dickinson have entered India but primarily through 3<sup>rd</sup> party distributors. Few companies (Sartorius, Waters, and Invitrogen) have come in as wholly owned subsidiaries and setup small R & D teams.

## **B. Advantage India**

Setting up a life science research facility and conducting Clinical trials in India has its inherent advantages. Primary advantages fall in three areas:

### **Intellectual Capital:**

- Access world class capabilities of Indian human capital in technology and science.
- Quality manpower
  - Large English speaking scientific talent pool
  - Over 0.7 million science & technology graduates every year
  - 3500 doctorates in science every year
  - Proven capabilities in chemistry, pharmacology, IT and statistics
  - ~ 20% of scientists in pharma/biotech R&D in US are of Indian origin. Some are returning to India.
- Knowledge generation/innovation – Innovative low cost life science/diagnostic solutions to suit local affordability in India and similar markets.

- Wealth of traditional medicinal knowledge & systems is another opportunity

**Cost:**

- Low cost of life science research – Infrastructure, labor and operating costs lower by 40 % of US cost.
- Emerging track record of developing drugs at a fraction of the cost in the west by Indian Pharma.

**Speed to Market:**

- Large patient and disease diversity – clinical trial opportunity, market
- Speed of patient recruitment in big metropolitan cities

**C. Recent Changes in Intellectual Property Regulation**

India is a signatory to intellectual rights protection under WTO framework from 2005. Product patents are protected post 2005 versus the earlier policy of protection to process patents. This removed a major obstacle to global companies to do IP related Life Science research in India. There are several implications of a strict product patent regime post 2005:

- Stimulus to higher domestic investment in basic R&D and discovery led research
  - *Higher probability of new therapeutics coming out of India in the next 5-10 years*
- Increased Confidence among MNC's to offshore/outsource R&D activities and manufacture of patented products
  - *Increased activity in Pharma and domestic Contract Research and Manufacturing (CRAMS) industry*
- Enhanced scope of collaborative research involving IP sharing
  - *There will be a shift in Indian companies from being merely fee for services providers to IPR driven organizations*
- In-licensing and marketing alliance opportunities for payers with strong domestic distribution set up
  - *Alternative revenue streams for domestic players and greater access to patients*
- Likely Exodus of a large number of Indian scientists & researchers from the west
  - *Brain gain likely to close gaps in skill sets and improve quality of research*

**D. Modes of Entry into Competitive Markets**

**Wholly Owned Subsidiary**

In a wholly owned subsidiary, the parent company owns 100 percent of the common stock. This mode of entry is considered to have high risk in the short term, since the parent needs to invest a

lot of money, time and resources to set up business in a bureaucratic country. In India, wholly owned subsidiaries are more common with companies with large market capitalization who have the resources to overcome risk of infant mortality.

### **Joint Venture**

Joint Ventures are the most common way that MNC's enter India and is less risky than the wholly owned subsidiary option. Foreign companies form joint ventures with domestic companies successful in the market and having experience in services in a therapeutic area. The foreign companies generally bring new technologies and business practices into the joint venture, while the domestic companies already have relationships and requisite regulatory permissions within the country along with a share in the domestic market. Financial risk is shared. Local familiarity of partner reduces infant mortality risk. MNC's typically exit the JV into a 100% owned company after a 5-6 year period. Disadvantage in JV is that exit costs are high.

### **Build-Operate-Transfer (BOT) Model**

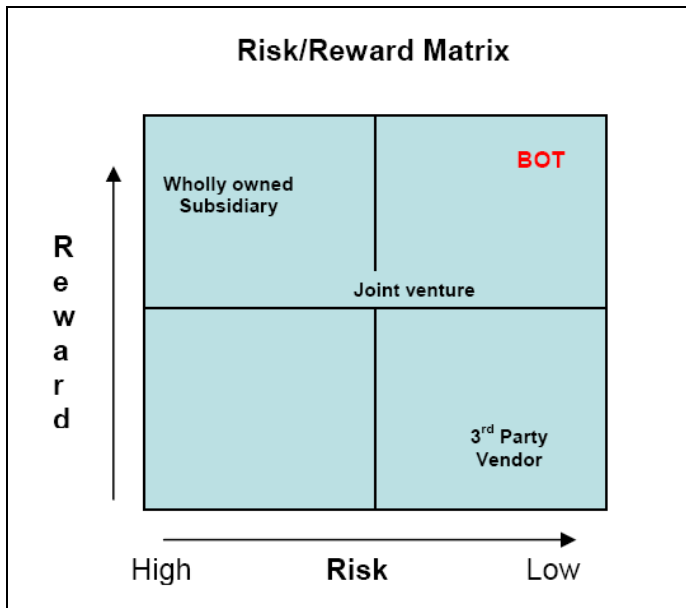
This model is commonly used in the IT sector and is known as an Onsite - Offshore Development Center (ODC). In this model, a local Company sets up an exclusive team, facility and IP protected environment for a client. At the end of 3-5 years, at pre agreed terms, the client purchases the ODC. By keeping 20-30% of the staff in the Onsite, Global IT companies have found that, this model de-risks infant mortality with no financial investment. At the end of 3-5 years, they buy into a readymade operation while leaving the learning curve behind!

The BOT model can also appear in different variations: one of which is called BOOT (i.e. Build-Operate-Option to Transfer). In this variant, the client prefers to setup after 3-4 years a 100% operation for R & D, while continuing to have the BOOT unit operate independently under the Indian services company. In this variation, the 100% subsidiary focuses on strategic and sensitive R&D work while the BOOT unit does less strategic work. The BOT model is less risky than a joint venture and more rewarding, particularly over the first 5 years. The BOT model has not been tested in the Life Science space. In addition there are no examples of MNC's who have used BOT to enter into the life science sector in India. Therefore BOT will be the model, which we will focus on in greater detail in this report.

### **Third Party – Contract Research Organization**

A contract research organization (CRO) plays the role of the third party when companies want to outsource only a few functions or activities to a foreign country. There are numerous CRO's in India that cater to specific areas in drug discovery and drug development and there are some that cater to all aspects of R&D. There is no monetary investment required when working with a CRO

other than paying the project fee. In India, foreign direct investment tends to flow through this low risk medium mainly because MNC's are still unfamiliar with the Life Science space in India.



**Fig 2: Risk Reward Matrix in a 5 YR Time Horizon**

### **Build-Operate-Transfer Model – Characteristics**

Build-Operate-Transfer (BOT) is a Business Model, wherein an Indian Company receives a franchise from an overseas corporation to finance, design, construct, and operate a facility for a specified period, after which ownership is transferred to the sponsor. During the time that the Indian company operates the facility (i.e. program management and other day to day operations), it is allowed to charge facility user, appropriate fees, rentals, and charges stated in the contract to enable the Operator to recover investment, operating and maintenance expenses in the project/program.

### **Drivers for BOT Models**

U.S. and European corporations are moving operational components offshore to India and other competitive locations, in many cases developing their own subsidiaries to support worldwide operations. The benefits are:

- Cost savings compared to 3rd party vendor partnerships
- Direct control on hiring and retention
- Ability to retain Intellectual property rights
- Unfortunately, many 100% subsidiaries are facing delays and not realizing their business goals, with some even forced to shut down due to execution problems related to unforeseen, 'in-country' challenges. The Build-Operate-Transfer model offers an

attractive alternative that helps them evolve gradually into a wholly owned subsidiary, at substantially lower risk.

### **BOT Model Benefits**

BOT offers attractive business benefits over the traditional subsidiary/Joint venture/3rd party vendor path:

- Rapid scaling of operations – Ability to hire and retain 100 molecular biotechnologists in as little as 3 months!
- Lower infrastructure set-up costs – Lease lab space for as little as \$2 per Sq. Ft/month, with no outlay on deposits and capital investments
- Shared Infrastructure – Client can access expensive capital equipment which is less frequently used on time share basis from the Indian operator.
- Share Risk and Upside – Allows the client to gradually evolve from a low to a high volume business with financial risk taken by Indian operator
- Better IPR protection than a 3rd party vendor – Each team member works exclusively for the client while entering into a 1:1 direct NDA with them.
- Reduced time to operations through utilization of knowledgeable Indian Operator management resources responsible for:
  - Real Estate
  - Government rules and regulatory compliance
  - Legal
  - Cultural transition
  - IT infrastructure procurement
  - Security
  - BOT Model is more conducive medium in assisting a company to set up a wholly owned subsidiary in the long run.

### **BOT Model Risks**

- Close proximity of client facility to competitor's facility run by the Indian operator could pose risk to confidentiality and IPR
- Business Continuity Risk - Change of ownership of the Indian operator could cause uncertainty in the continuity of the project.

## **II. Study Objectives**

- I. **Primary Objective:** to test whether human capital, cost competitiveness and speed are the real reasons why multinational companies want to come to India to do life science related work.

a. *Primary Hypothesis: Human capital, cost competitiveness and speed are the three main reasons why multinational companies set up operations in India.*

II. **Secondary Objective:** to test the applicability of the Build-Operate-Transfer Model in the life science space.

a. *Secondary Hypothesis: BOT Model is the preferred option for a global company to conduct research to obtain advantages of human capital, cost competitiveness and speed.*

### **III. Study Methodology**

This report is based on data collected from desk research and in-depth interviews held with key members of 15 Life Science Companies<sup>1</sup> in drug discovery, drug development and Diagnostics. Companies included Indian owned and Multi National Companies.

The first step was to identify the organizations to be targeted and to build consensus for the study. Successful organizations in key bioclusters of India were chosen. Globally, the Life Science sector thrives in a few locations popularly known as bioclusters. Bio-clusters are geographic location where there is a high prevalence of biotech or pharmaceutical companies. This is often explained by the increased prevalence of major academic research institutions. Often clustering is seen because the location might have a business friendly environment, good infrastructure, one or two successful life science companies and availability of venture capital. Science thrives when there is a nucleus of scientists striving for excellence. The five main bioclusters in India are:

1. **Bangalore**
2. **Mumbai (Bombay)**
3. **Chennai (Madras)**
4. **Hyderabad**
5. New Delhi

In this research study we visited four (in **Bold**) major bio-clusters of India. The organizations were categorized based on years of operation, education profile of workforce, revenue recognition models, IPR, business challenges, etc. Various representation techniques were considered to effectively present the findings in our analysis.

The research team subsequently held in-depth interviews with them. A detailed questionnaire was administered during the course of the study. Prior to it being tested, the questionnaire was

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<sup>1</sup> Refer to Appendix for Names of Organizations and Individuals Interviewed

reviewed and validated by two expatriates based in the United States. Both individuals were affiliated with notable academic institutions. Two questionnaires were made; one specifically for pharmaceutical companies and another one that was generic.

The questions were in two categories: people and process. The first category addressed topics pertaining to:

- Human capital
- Workforce profiles
- Details of facility
- Revenues

While the second category focused on:

- Business challenges
- Technology Challenges
- IPR
- Cost/Risk Related Issues

The research team aggregated the entire data using a statistical package for all respondents. The questionnaire was developed on the popular web-based survey tool known as SurveyMonkey© (www.surveymonkey.com). Data was analyzed on quantitative as well as qualitative parameters. Key variables were analyzed using the Chi-square test with ETA corrections whenever possible. Pearson correlation coefficients were used to correlate or build relationships between two variables.

In addition to this, the concept of the BOT model was tested on a mid-cap biotechnology company based out of Europe. A proposal was made (highlighting the characteristics and benefits as mentioned in section I. D) to build a research lab to develop assay kits in the area of genomics. The result of this proposal will be discussed in the discussion section of the report.

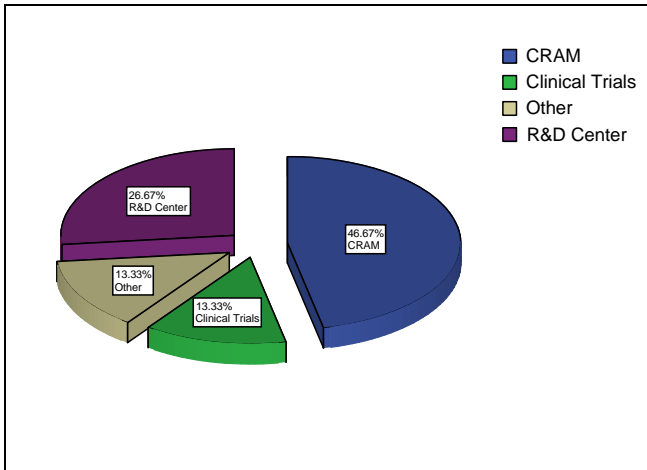
#### **IV. Findings**

Respondents who did not answer a question and questions that were deemed not applicable to the particular company were excluded from the analysis.

##### **A. Classification of Organizations**

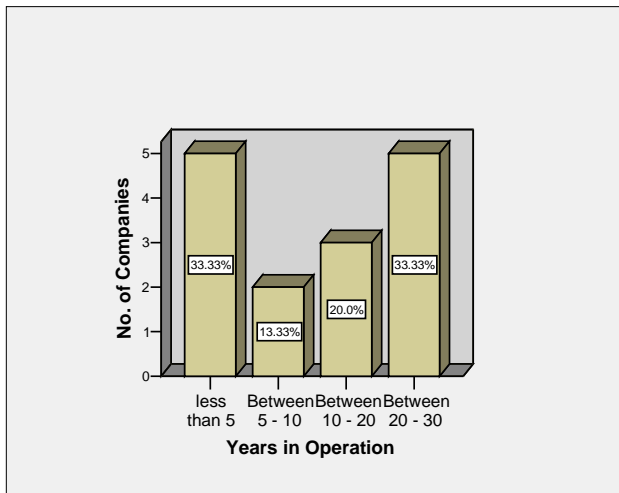
The sample set can also be categorized by departments as follows (fig3). Contract Research and Manufacturing (CRAM) constitute close to 50 percent of the sample mix and include both drug discovery and development organizations. 'Clinical Trials' refers to pharmaceutical companies

that are outsourcing clinical trials. 'Others' refers to organizations that do not fall in any of these categories.



**Fig 3: Distribution of Organizations**

We have classified our organizations based on a broad understanding as given below.



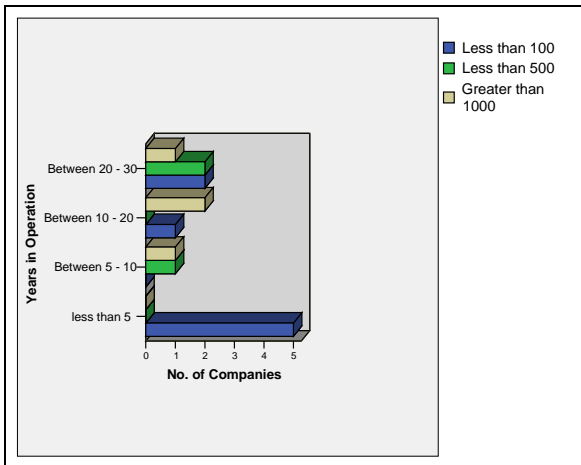
**Fig 4: Classification by Years in Operation**

Stage 1: Less than 5 years (5 companies are in the first stage. i.e. 33.33%)

Stage 2: Between 5 – 10 years (2 companies are in the second stage, i.e. 13.33%)

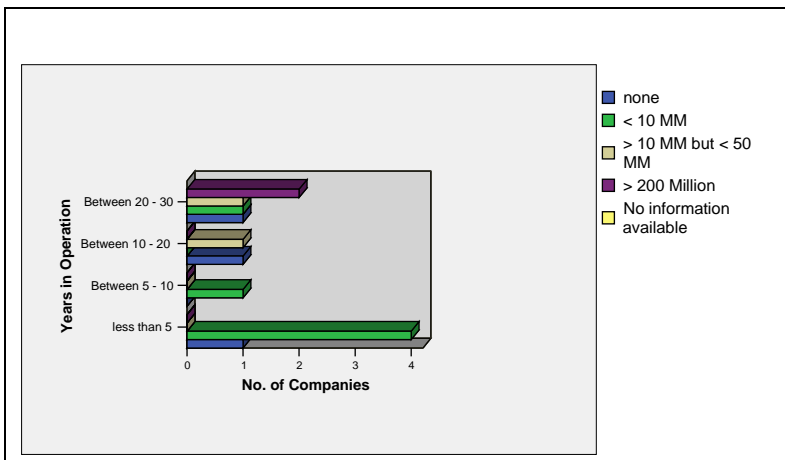
Stage 3: Between 10 – 20 years (3 companies are in the third stage, i.e. 20.00%)

Stage 4: Between 20 – 30 years (5 companies are in the fourth stage, i.e. 33.33%)



**Fig. 5 Classification by Workforce size and Staging**

Here we observe the staging of organizations with respect to number of employees. The data shows that over 50 percent of our sample consists of companies that have less than 100 people. Usually in most industries, organizations start small and grow over a period of time but it is a very different scenario here. Even though we observe a general trend of industries growing larger over time we also see that almost 50 percent of the companies that have less than 100 people have been in operation for over 10 years. This tells us that in life science research outsourcing; organizations have a smaller critical mass when compared to those in other industries.

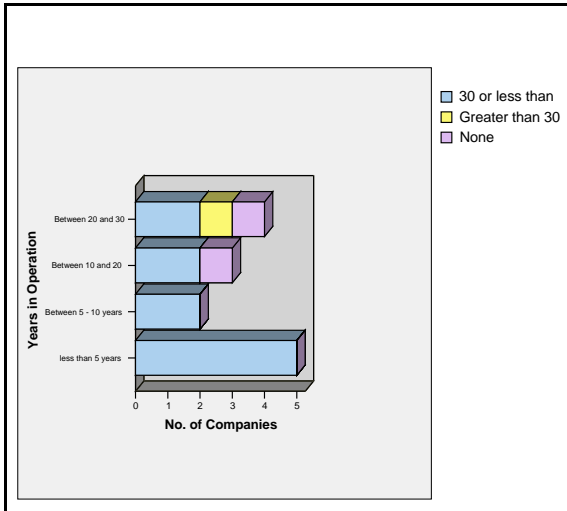


**Fig 6: 2004 Revenues**

Almost 50 percent of the organizations had revenues of less than 100 million dollars in 2004. A good number of startups also fell into this category. We expected to see established companies, especially those in contract manufacturing make revenues greater than 10 million dollars. There were a few examples of well established companies that made no revenues but this was because they were cost center's (i.e. GE R&D). The average organization in India made less than 100 million dollars whether it fell in drug discovery or development classification.

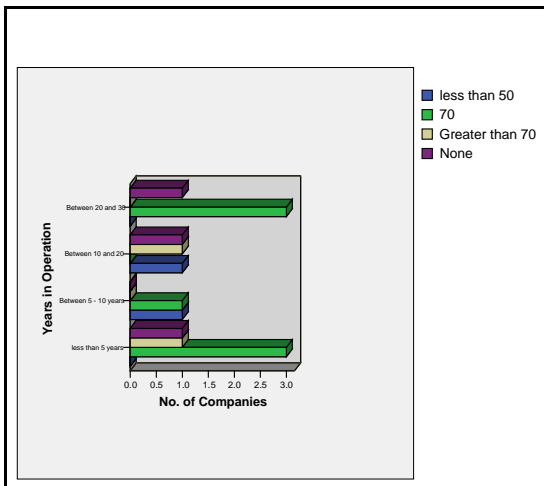
## B. Human Capital

Human Capital has been a parameter that has been in discussion for a long time in India. It encompasses but is not limited to academic backgrounds, domestic and international work experience and Intellectual property generation and retention.



**Fig 7: Prevalence (percent) of PhD's in a company**

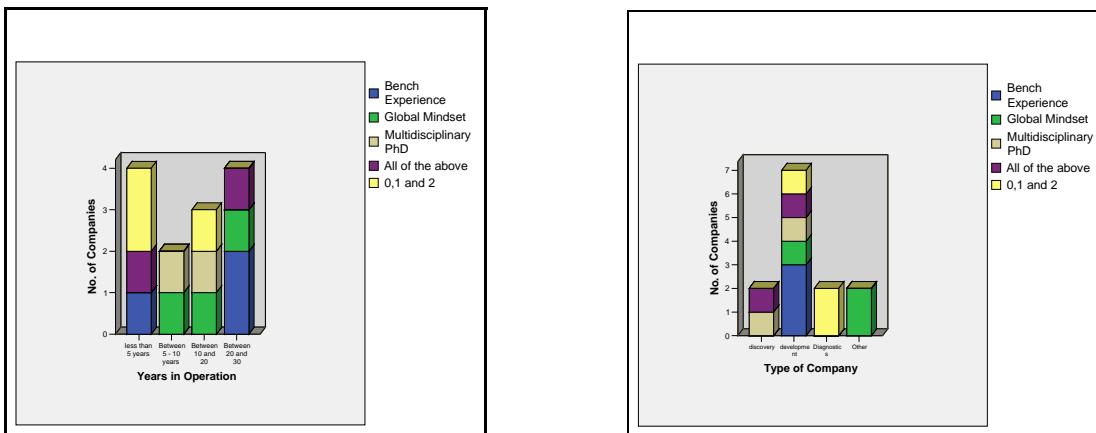
In general, PhD's comprise less than 30 percent of the employees in an organization in our sample. This is opposite of what is generally observed in the west where more than 50 percent of the employees hold PhD's. This contrast can be explained by the type of work being undertaken in the west and the type of outsourcing work that Indian companies undertake.



**Fig 8: Prevalence (percent) of post-graduates in a company**

Over 50 percent of the companies have a workforce with 70 percent or more that hold a Master of Science (MSc.) or a Master of Pharmacy (M.Pharm) degree. In our study the well established

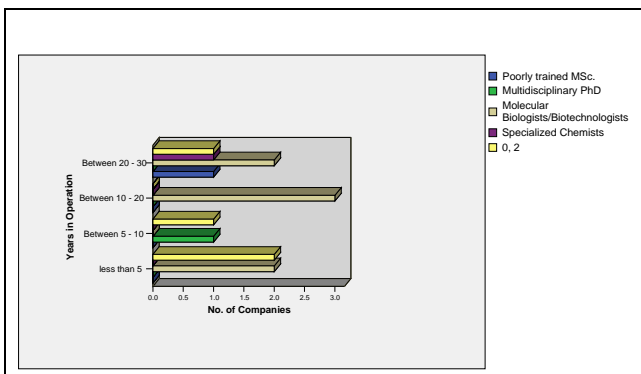
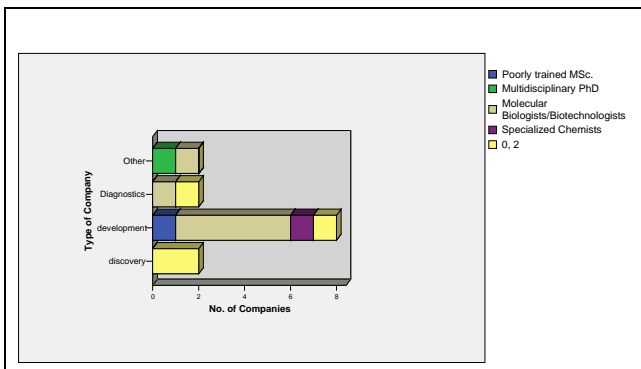
(stage 4) pharmaceutical organizations had more MPharm's than MSc. Highly skilled MSc's and MPharm's are large in supply in India. Most of them tend to be recruited by companies that conduct contract research and manufacturing. Another interesting supply driven factor in talent is a relatively higher number of registered medical practitioners working in Life Science research in India. A multi disciplinary team of Pharmacists, Scientists and Doctors is more feasible to compose in India than in western countries. However the percentage of PhD's is relatively lower in India when compared to the west.



**Fig 9, 10: Critical Attributes of a Researcher**

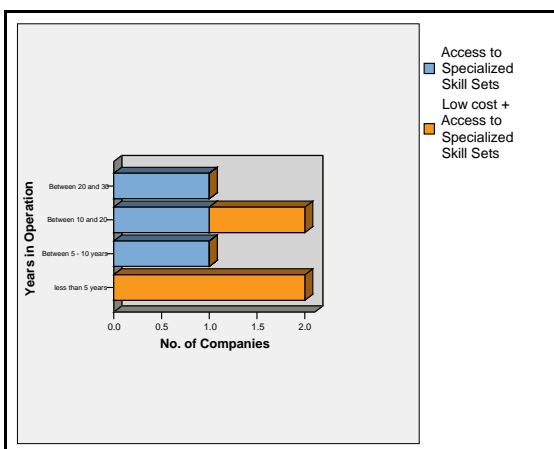
Each respondent was asked to list what he or she thinks are the critical attributes of a researcher. We wanted to see if there was any consensus across the industry and whether or not attributes that were critical early on remained so as the organization grew larger. Fig 7 shows that start-up organizations look for several attributes (i.e. bench experience, global mindset, multidisciplinary PhD's) but as the organization grows certain attributes become more important than others. Organizations that were between 5 and 20 years old were more interested in recruiting people with multidisciplinary PhD's and those who had worked internationally.

Fig 8 shows that bench experience is the single critical attribute that firms in drug development seek when they hire researchers. Bench experience has become a pre-requisite to getting hired by a CRAM organization.



**Fig 11, 12: Lacking skill sets and Talent in India**

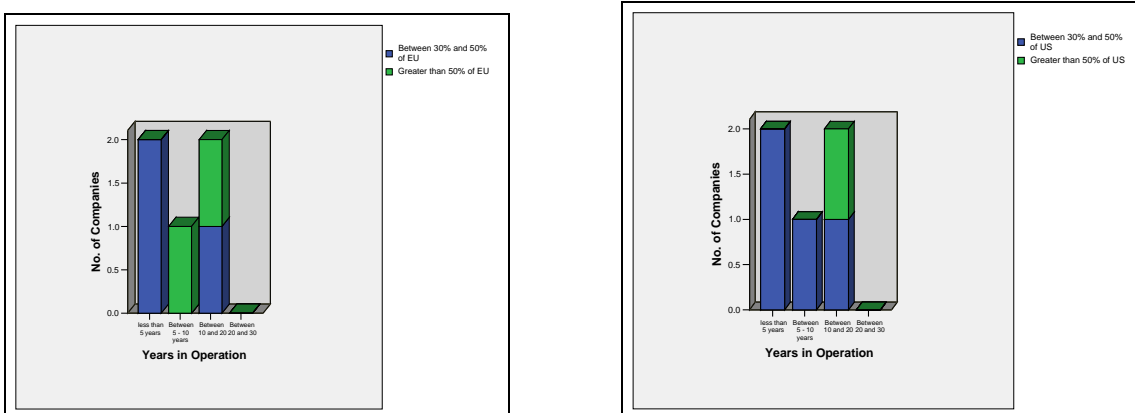
The analysis here was split to explore where industries feel they are lacking skill sets and whether or not this view changes over time. Usually, in the early years we expect contract research and manufacturing companies to value highly trained MSc's over anything else but our data paints a different picture. Although highly trained MSc's are valued at CRO's doing discovery work; molecular biologists are in higher demand and are in short supply. There is a general consensus that India has strong expertise in chemistry but is lacking in number of good molecular biologists and biotechnologists who can do lead novel drug discovery projects.



**Fig 13: Rationale for coming to India**

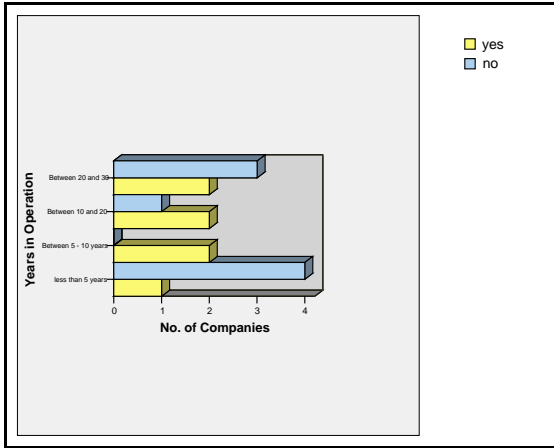
We asked each respondent what their rationale was when they decided to enter India. Surprising it was not for cost reasons. Even though cost was a contributing factor; it was the access to specialized skills sets. In clinical trial organizations; the decision was based on the availability of English speaking, US/European educated principal investigators. For pharmaceutical companies it was access to our large pool of process and combinatorial chemists. The contract research organizations in the discovery realm leveraged the large pool of post graduates with master's degrees who could perform the more routine protocol oriented tasks that the clients gave them. This was a very important question as it validated the fact that most companies were coming into India not to outsource their back-office activities and functions but rather to establish an exclusive presence and to develop product that they could market globally.

### C. Cost Competitiveness



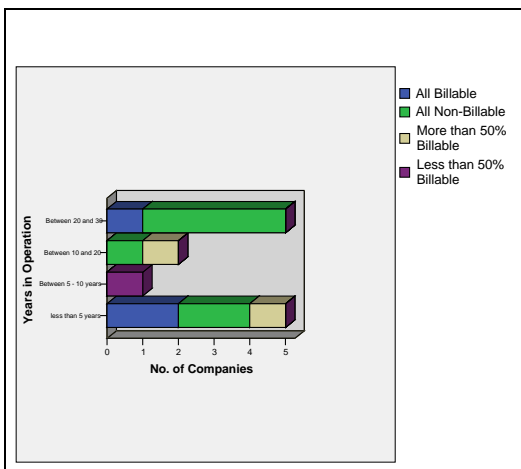
**Fig 14, 15: Cost of doing research in India (as a percent of US/EU cost)**

India is very cost competitive in conducting life science research. Only a few respondents answered specific questions about costing versus US and Europe but the data shows that generally cost savings are between 30 and 50 percent of cost when compared to US and Europe. The key finding here was that companies were de-focusing on cost and focusing more on value. With an increasing number of CRO sprouting; organizations are shifting away from pure cost arbitrage business models. It is for this very reason that many respondents chose not to answer this question. The general consensus was that India is still considered a very competitive market to carry out outsourcing projects in the life sciences however it will not be as competitive as it is in the Information Technology sector.



**Fig 16: IPR Recognized in 2004**

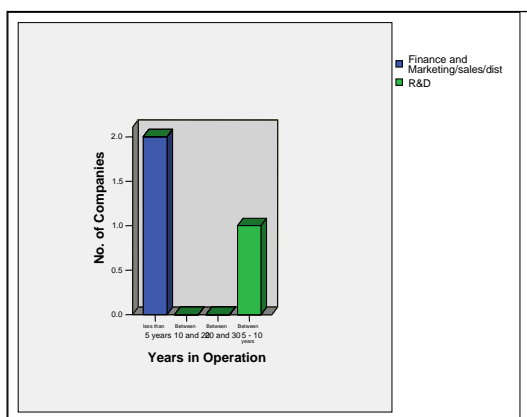
Intellectual property rights (IPR) is a major component of life science research outsourcing. It is also the primary reason why companies have been wary of competitive markets like India since they fear that intellectual property will be at risk. Fig 16 presents a very encouraging picture. More than 50 percent of our respondents stated that they recognize IPR in one way or another which shows that clients are more confident in Indian companies protecting IPR. The fact that International clients are willingly sharing IPR with Indian CRO's and drug development companies' indicates that they are encouraging their CRO partners to put down a sizeable investment and share the risks of entering into a new market.



**Fig 17: Trends in Billability of Full Time Equivalents (FTE)**

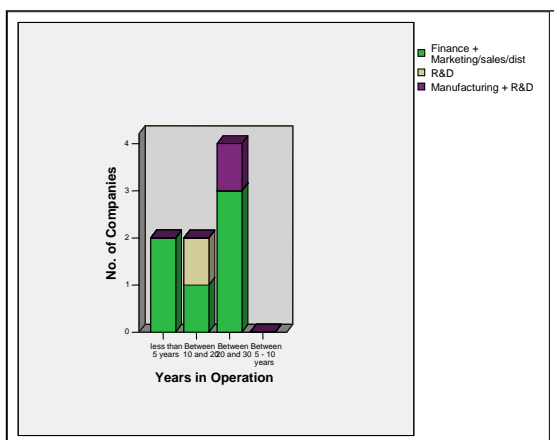
Billability trends the maturity of an outsourcing organization. Ideally, a mature outsourcing company will have close to 100 percent of their employees billed to the client. We found that 40 percent of our respondents were billing some percentage of their FTE's to their client. Interestingly we observe that a number of well established companies in the drug development sector are not billing their FTE's to the client.

#### D. Other Areas of Interest



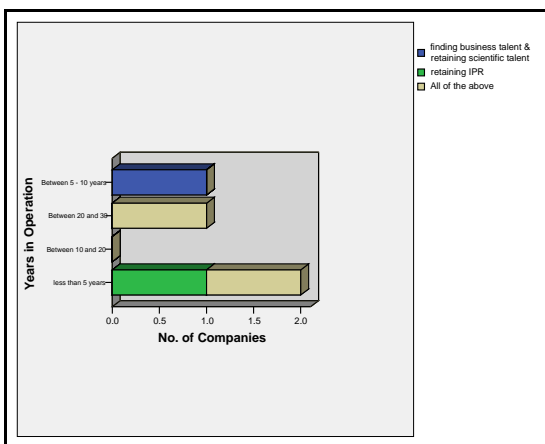
**Fig 18: Business Critical Areas in Discovery Organizations**

Business critical areas were defined as functions within an organization that were vulnerable at different stages during the lifespan of the organizations. These functions include Finance, Sales, Marketing, Distribution, Research and Development, Quality and Manufacturing. In our sample we had a limited number of discovery organizations. With this said, the majority of them were start-ups who identified Finance, Marketing, Sales and Distribution as business critical areas. Client acquisition continues to be a hurdle for startups that are forced to set up client acquisition centers in the US and in Europe.



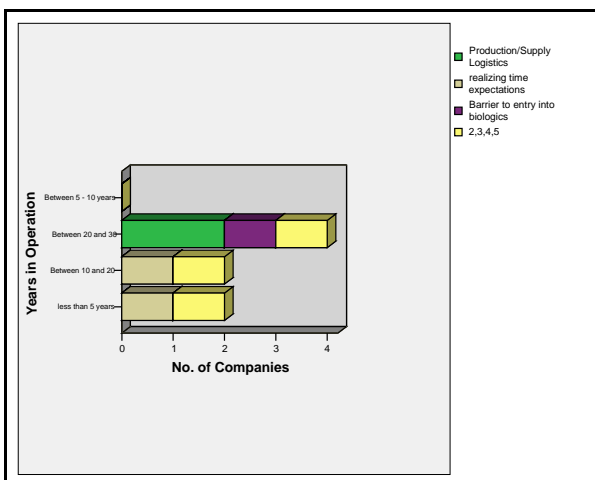
**Fig 19: Business Critical Areas for Pharmaceutical Companies**

In pharmaceuticals, the story is similar. Regardless of which stage the company is in, finance and marketing tend to remain critical areas. CRAM organizations are realizing that they need to go beyond manufacturing generic drugs. With a risky financial position at hand, companies are setting up novel drug discovery functions where they hope to identify a target or a lead molecule that they can out-license to a pharmaceutical company in the US or in Europe.



**Fig 20: Business Challenges in Discovery Organizations**

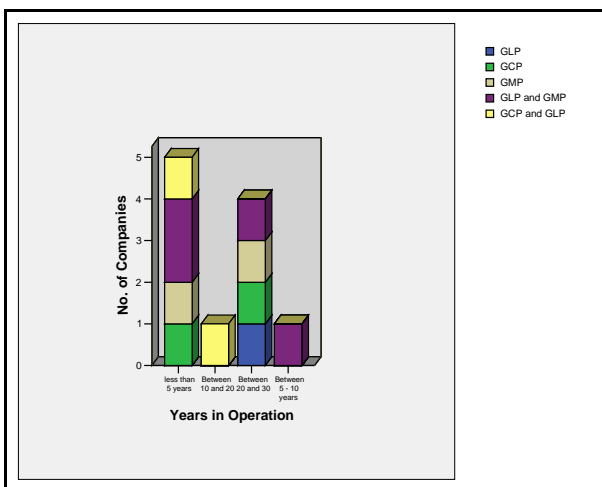
Companies at different stages responded very differently to this question. Start-up discovery organizations were facing many business challenges. These challenges included weak business development, retaining IPR and hiring and retaining good scientific and business talent. As mentioned earlier discovery organizations are finding it difficult to earn business without a strong client acquisition center overseas. This is inextricably linked to finding good business leaders. They also find it challenging to grow their business purely on a fee for service type work. International clients are not willing to share intellectual property unless the Indian company put down a sizeable investment. Finally, these discovery based CRO's are experiencing difficulty in talent retention and high attrition rates with respect to their bench level scientists. The CRO fails to foster an environment where their scientists feel like they are doing novel research while the international client fears that their IPR might be at risk when scientists leave after short periods.



**Fig 21: Business Challenges at Pharmaceutical Companies**

In the drug development space startups and well established companies sited factors such as “realizing time expectations,” “fostering value added relationships,” “body shopping,” and “barrier to entry into Biologics” (2,3,4,5) as business challenges. Venture capital is often invested in to

startups with high expectations that are often not realized. With increasing pressure to realize returns quickly organizations in India are forced to steer away from riskier areas like research in biologics and vaccines. “Body Shopping” refers to routine, repetitive work where no intellectual property is shared from the client’s side. Outsourcing of this nature is done purely for cost arbitrage.



**Fig 22: Quality Practices**

Quality is a critical parameter when it comes to outsourcing research. Good Laboratory Practice (GLP) accreditation appears to be increasing in importance among organizations. The purpose of these principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of test data among countries. If clients can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby introducing economics in test costs and time. Our study validates that accreditations such as GLP, GCP and GMP have helped put India on the map as a country that generates high quality data. Several organizations had some sort of OECD accreditation while all clinical development CRO’s conducted trials at sites trained in GCP producing data filed with US and European regulatory agencies.

#### **IV. Discussion and Analysis**

We will begin our discussion by accepting or rejecting our stated hypotheses. We accept our first hypothesis that the main reasons a multinational company would come to India would be because of the high quality of human capital, lower cost and speedy execution. Our findings put greater emphasis on human capital when compared to the other two parameters as its importance became increasingly evident through the course of our study. Our findings show that there is a strong knowledge base in chemistry with an adequate number available for hire. Similarly there is a strong knowledge base in disease management in medicine and an adequate number of doctors available for hire. However, a rather weak area is in biology. While Biologists

with a strong knowledge base are available in Bangalore & Hyderabad, the number available for hire are less than the demand for them. India's premier institutions also place more importance on theory than on practice. Our findings show that the biggest lacking skill set was poorly trained post graduates. Inder Varma, Professor of Molecular Biology at the Salk Institute, San Diego states that "India will not succeed unless it encourages innovation and rewards excellence. Indian scientific expertise frowns on questioning authority and rewards obedience." (Nature, July 2005) The future looks promising as the country continues to grant nearly 300,000 degrees and diplomas in biotechnology and biological sciences each year. The challenge is to keep these individuals from leaving to 'greener pastures.' Up to 90 percent of those who finish their PhDs at the Indian Institutes of Science go abroad (Nature, July 2005). Life Science companies need to choose projects for India where they can leverage the India advantage of knowledge base in medicinal chemistry and disease management while Biopharma companies need to select projects where the number of biologists required is not high but where a multi-disciplinary team of biologists, pharmacists and doctors can make a difference to the project.

With respect to cost competitiveness and speed; India provides a number of advantages. The cost advantages are apparent in all areas of drug discovery, drug development and Diagnostics. But as CROs increase in number in India, it becomes very difficult and challenging to differentiate solely on cost. In addition to this CROs are realizing that they need to expand beyond a "fee-for-service" model if they intend to survive. Most CROs are creating risk mitigation plans that will help them transition from a purely fee-for-service model to a speed and IPR driven organization. Speed comes from ability to bring a disease management perspective to research; that is, the ability to validate diagnostic kits faster, process a large number of samples in a shorter amount of time and enrolling patients in clinical trials faster. Access to patients and reputed principal investigators in areas of high disease prevalence like diabetes and cardiovascular disorder make India a preferred site for research in these therapeutic areas.

In our second hypothesis we discussed a business model called Build-Operate-Option to transfer, BOT for short. We tested its applicability in the life science space and found that there was very little awareness of it in Life Science companies. Most people argued that the BOT model was strictly for IT related services. Our respondents felt that a BOT environment was not conducive to protecting intellectual property as they feared that the model would experience the same attrition rates as it does in the information technology space. One organization stated that the way around this was to associate oneself with an academic institution. By doing so, one could staff the lab partly with PhD students who wished to attain industry experience while earning degree credit on the job. This will prove to be an innovative and effective way of attracting and retaining top talent in the future.

In our study methodology, we had mentioned that we tested the BOT model in the real world on a European Biotechnology company (referred to as “The Company” from here on). The findings were extremely interesting. The company stated that BOT model would be an interesting option for them as long as certain issues were addressed at an early stage. The company was looking for an Indian partner that could bring value to their research (in the case of Manipal Acunova, it was access to patient pool and customer environment). Hence projects would be selected and driven by disease prevalence, knowledge of disease management in researchers and the ability to validate this in the customer environment. The company would look into patentability and patent defensibility in India as key considerations.

The company’s key requirement is that projects should have a ‘fail quickly’ mechanism. This meant that Manipal Acunova would have to agree to terminate projects at the company’s demand if the company saw no merit to continue. The Company would contract the team for a period (say 3 years) rather than a project, so that termination would be feasible for the Indian operator.

The company requested transparency in cost. Hence the pricing would be on a cost plus model with a target for it to be at least 25% lower than Europe. The Company wanted the Indian Operator to be sufficiently motivated for high performance. Hence in addition to cost liquidation, it agreed to reward innovation and risk sharing with joint ownership of IPR and a pre-agreed royalty sharing and licensing agreement.

Most importantly the Company wanted to have an ‘Option to transfer’ which meant that they wanted to have a choice to run the laboratory independent of any subsidiary that they planned to set up in India. In this case, Manipal Acunova would build the lab and operate it for the company for the length of the contract. The company would run this BOOT (Build-Operate-Option to Transfer) facility in conjunction with their formal operations in India. This proved that the BOT model and its variant were feasible options as a mode of entry in the life science sector.

## **V. Conclusion**

Indian biotechnology companies have been remarkably successful but they have made most of their money copying branded drugs to Generics. To sustain growth they will have to become innovation engines. There is a high awareness in this area and Indian companies are trying to develop drugs and Bio-Pharmaceuticals at a fraction of global cost.

Our study showed that multinational companies come to India for life science research to leverage its human capital, cost competitiveness and speed. We found that fortune 100

companies like General Electric, Astrazeneca and Sanofi-Aventis tend to go the wholly owned subsidiary route, as the 'Indian' market presence is of high importance to them. They also tend to have higher risk bearing capacity. Whereas the smaller companies (Fortune 100- 500) tend to look into other options. One such option is the Build-Operate-Transfer model which we successfully tested to evaluate its applicability in the life science sector.

The nature of work involved plays a big factor as well; if the task to be outsourced is non-strategic, then a third party CRO can efficiently do the job. If the client is outsourcing work that is strategic in nature and is seeking for a partner to add value, then a BOT environment warrants a serious evaluation by the sponsoring company.

Although we cannot conclusively claim that the BOT Model is ideal for the life science sector (we only tested this on one real client), we conclude that it has tremendous potential to be an option for Fortune 100-500 companies that are looking at a five year time horizon and who are not willing to take the monetary risk involved in setting up a wholly owned subsidiary.

At the end of the day; for both the Client MNC and the Indian Operator, project selection will be the key to success. For speed and innovation the driving forces are:

- Ability to compose teams with Pharma, Medicine, Chemistry/Biology knowledge base and retain them.
- Projects where disease prevalence is high and significant treatment experience exists.
- Parties share risk by working on cost plus but share upside with shared IPR. An upside plus exists if project is relevant to Indian market, is patentable and the patent is defensible in India.

Finally, it is beneficial to choose an Indian partner located in the Bioclusters of Hyderabad and Bangalore as they have a science and business friendly environment with a pool of talent.

## VI. Appendix A

### Category of Company & Profile of leaders interviewed for this study

#### *Drug Discovery Organizations*

Name	Location	Contact	Title	Website
Avesthagen	Bangalore	Viloo Patel	Founder/CEO	www.avesthagen.com
Triesta Sciences	Bangalore	S. Subramaniam	Director	www.triesta-sciences.com

#### *Drug Development Organizations*

Name	Location	Contact	Title	Website
Biocon	Bangalore	Gautam Das	CEO, Syngene	www.biocon.com
Wockhardt	Mumbai	R.J Jha	Senior VP, Clinical Research	www.wockhardt.com
Nicholas Piramal	Mumbai	Ashutosh Damle	General Manager, BD	www.nicholaspiramal.com
Sanofi Aventis	Mumbai	Dhananjay Bakhle	Senior Director, Medical & Regulatory Affairs	www.sanofi-aventis.com
Asia Cryo-Cell	Chennai	Abhay Kumar	Founder/CEO	www.cryocell.com
Astrazeneca	Bangalore	Kumud Sampath	President	www.astrazeneca.com
Dabur Research Foundation	Bangalore	Rama Mukherjee	President R&D	www.dabur.com
Karnataka Antibiotic	Bangalore	M.V Pathak	Managing Director	www.kapl.com
Shasun Chemicals & Drugs	Chennai	R. Govindarajan	CEO	www.shasun.com

#### *Diagnostic Organizations*

Name	Location	Contact	Title	Website
Reamatrix	Bangalore	Balamanian	Founder/CEO	www.reamatrix.com

GE R&D	Bangalore	Guillermo Wille	Managing Director	www.ge.com
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*Others*

<b>Name</b>	<b>Location</b>	<b>Contact</b>	<b>Title</b>	
Phillips R&D	Bangalore	Bob Hoekstra	CEO	www.phillips.com
Vatsalaya Healthcare	Bangalore	Ashwin Naik	Founder/CEO	N/A

## **VII. References**

- (1) Verma Inder, "Then and Now," Nature, Vol. 436, 28 July. 2005, pp. 478-479
- (2) Jayaraman, K.S, "Biotech Boom," Nature, Vol. 436, 28 July. 2005, pp. 480-483
- (3) Padma, T.V, "India's Drug Tests," Nature, Vol. 436, 28 July. 2005, pp. 485-486
- (4) Kermani Faiz, Bonacossa Pietro, "Outsourcing Clinical Trials in the Pharmaceutical Industry," Pharmatech, 2003, pp 104-108
- (5) Ernst & Young Assurance and Advisory Business Services, "Indian Pharmaceutical Industry: Vision 2010," 24 August, 2005
- (6) Ernst & Young Assurance and Advisory Business Services, "Manipal Acunova – Business Plan Validation," 24 August, 2005