

Knowledge process outsourcing firms: An exploratory study of Lambda Therapeutic Research Ltd. (India): Implications for multinational pharmaceutical companies in Australia

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A small step

History suggests that some western companies have viewed organisations in countries like Japan, Korea and, of late, China and India with contempt for their business and human resource practices. The perception has been that some firms in these countries have produced cheap products, hired cheap labour and followed poor process and management practices. However, IT firms, and, more recently, biotechnology firms in India are attracting the attention of multinational firms.

Monash University is ideally placed to investigate practices within the region, because of the multicultural nature of its academic community and its long history of collaboration with industry. Various faculties at Monash University have signed MOUs with universities in India and are undertaking collaborative research. The Marketing Department, in the Faculty of Business and Economics has taken a step toward 'engaging the world' in a new study designed to understand how knowledge process outsourcing firms (KPOs) such as Clinical Research Organisations (CROs) strategically integrate with multinational pharmaceutical companies (MPCs) and build on their respective strengths to identify opportunities. Aggarwal and Pandey (*Evalueserve – Your global knowledge partner*, July 16, 2004) refer to KPO as 'offshoring of knowledge-intensive business processes that require significant domain expertise' while Nair (2006) refers to KPO as 'processes that demand advanced information search, analytical interpretation and technical skill as well as some judgement and decision making'. For the purpose of this paper, KPO is defined as knowledge intensive, yet critical, activities that are outsourced to other entities rather than be completed in-house.

This article provides an understanding of how one KPO – Lambda Therapeutic Research based in Ahmedabad in India has evolved in recent years. In so doing, the article demonstrates a new era of world class organizations with international standards of operation, negating some of perceptions of poor business practice in developing countries. It also provides pharmaceutical organizations in developed countries both knowledge based research and development opportunities. The author observed people at work over three weeks and interviewed employees at different levels within the organization.

The problem

The *Economist* (2007) indicates that the generic drug market is worth US\$60 billion and by 2009, 35 top branded prescription drugs will lose their patent rights. As patent rights will no longer be a barrier to enter this market, MPCs will find themselves competing with generic drug companies. This increasingly competitive market place has forced vertically integrated MPCs, like Pfizer and GlaxoSmithkline, to divert scarce resources from research and clinical trials to marketing activities (*Economist*, 2007). But, MPCs must continue to research and develop new drugs in order to survive, compete and prosper. Survival is dependent on the continuous development of new drugs through clinical trials, and bringing these drugs to the market quickly and economically.

From a strategy perspective, industry analysts (Roger Longman – Windhover Information – January 27, *The Economist*) insist that MPCs ought to move away from vertical integration towards horizontal integration and outsource essential clinical trial activities to overseas CROs. "Big drug firms must move towards a disaggregated model to focus on a few areas of core competence, such as drug discovery ... many [non-core] activities can be put out to growing regions of biotechnology start-up

firms, [and] contract research organizations” (Roger Longman – Windhover Information – January 27, *The Economist*). MPCs may reduce the risk of horizontal integration when (a) products can easily be transferred, (b) knowledge is shared between partners, (c) there are good control mechanisms and (d) good governance is practised.

Scholarly contributions to network theory in marketing (Achrol, Reve, and Stern 1983; Achrol 1991; Anderson, Hakansson, and Johanson 1994; Webster 1992) and in the strategic management literature (Gulati 1995; Gulati, Nohria, and Zaheer 2000) have dominated industrial marketing management of late. As competition intensity grows in industrial markets, firms improve their chance of survival by developing networks, and seek marketing opportunities in new markets with new products in collaboration with partners (Achrol and Kotler 1999; Kotler, Adam, Brown, and Armstrong 2003). These networks have risen to prominence due to industrial restructuring, new players in the market, downsizing, and business process outsourcing in order to gain a competitive advantage over similar firms (Achrol 1997).

The local media in India is apprehensive about managing the growing market for drug trials in India. *Times of India* (“India a hotbed for clinical trials” March 18, 2007) claims that although the Government of India has removed financial disincentives by eliminating the service tax on clinical trials, the regulatory body Drug Controller General, India (DCGI) is not yet ready to deal with the influx of new clinical trials and doubts that it is technically equipped to handle this strategic challenge. Moreover, governance issues contribute to an environment that is fraught with risks for the both the companies and the broader community. Soft regulatory regimes, and inconsistent rules and regulations, all impact on the difficulty of operating a MPC in India. Although conducting clinical trials in India provides MPCs with access to a large pool of treatment-naïve subjects, the vulnerability of trial participants, who may be financially needy and ignorant of their rights, and unscrupulous recruiters, all contribute to a difficult environment for MPCs.

Strategic significance conducting clinical trials in Indian CROs

Global consulting firms like McKinsey and the Boston Consulting Group (BCG) have reported the benefits of outsourcing non-core, yet critical, activities to recognized and established CROs in India. For example, it is estimated that 20 – 30% of global clinical trials activities are being conducted in developing countries (Lambert, MJ. et al. – *Application Clinical Trials*, 2004). The 2002 Indian clinical trial market of \$30 -35 million is projected to grow 8-10 times by 2010 to \$250 -300 million (Borfitz, D. – *Center Watch* 2003). However, these projections are based on MPCs following world’s best practice and being operated by English speaking, Western-trained, professionals.

Recent research completed by BCG (May 2006, “*Harnessing the Power of India: Rising to the Productivity Challenge in Biopharma R&D*”) suggests that multinationals must evaluate the following factors such as (1) previous experience with multinationals (2) security and control, (3) aversion to risk and (4) budget. However, the most critical determinant of a multinational is the nature and scope of its planned activities. For example, clinical trials, data management or less complex chemistry activities may be outsourced, however, complex chemistry work or preclinical trials in contrast might require a local collaborator with proven track end-to-end capabilities or facility tooled with state-of-the-art equipment and qualified staff. The models therefore are activity based business model or ‘cherry picking’ defined as the process of selecting individual activities, typically routine in nature or a project based business model that deconstructs the value chain in order to deliver the total package back to the multinational as defined and agreed protocol.

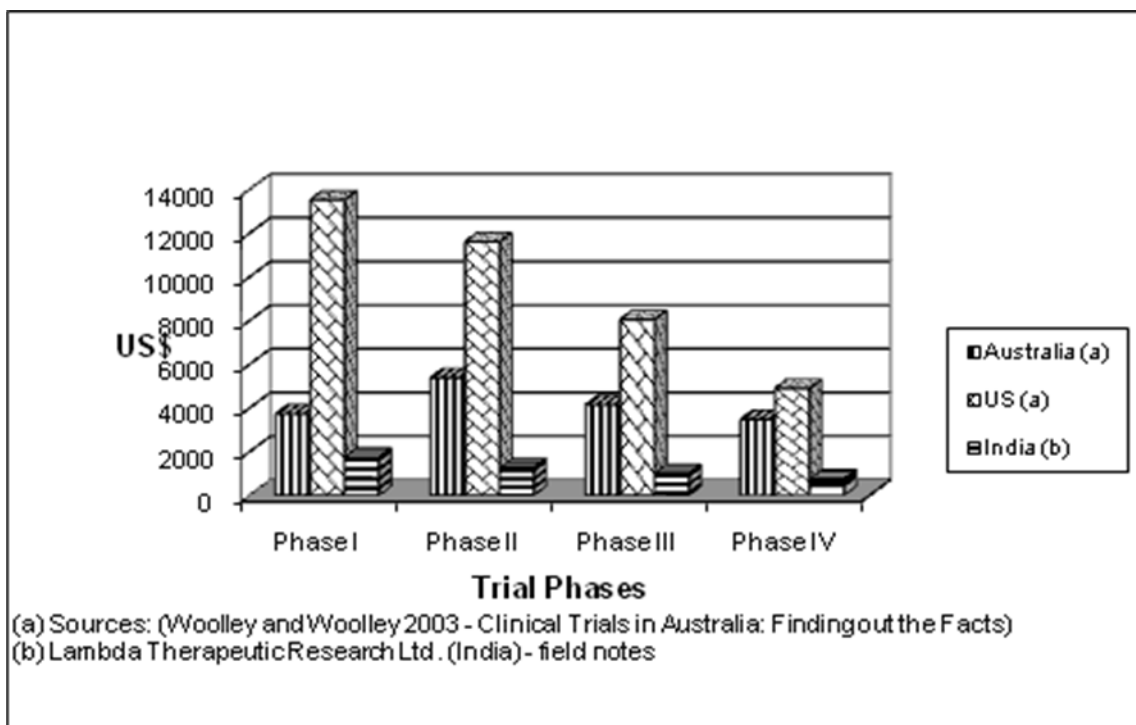
Australian pharmaceutical research institutions will need to consider an appropriate business model when engaging a CRO. Tertiary institutions have been at the forefront of new drug trials for the treatment of cancer. For example, Professor Tom Kay (St. Vincent’s Institute) states that “... with the cancer affecting bones, drugs based on the institute’s research are in advance clinical trials overseas” (*Australian Broadcasting Corporation*, “Funding boost expected to benefit obesity and cancer research, April 2, 2004).

In a seminar titled ‘Scope of Clinical Research and Elements of Outsourcing’ (Dec. 19, 2006) it was revealed that India has over 15,000 hospitals of which 85% are in urban areas. Modern infrastructure in information technology and transportation ensures speedy flow of clinical information and medical samples in appropriate refrigerated containers between hospitals and clinical trial centres. The climatic, socio-economic and cultural diversity of India’s population means that, pharmaceutical firms

can use India as a “hot bed” to conduct non-core clinical trial activities to facilitate a broad spectrum of drugs (Varma, S. “India a hotbed for clinical trials” *Times of India*, 2007)

In early 2005, with pressure from the international community mounting and the World Trade Organisation threatening sanctions, India finally instituted a new regime of product patents. According to BCG, these changes afforded MPCs the same intellectual property rights in India that they enjoy elsewhere by extending patent protection beyond manufacturing processes to the drug molecules. Government regulations in India have kept abreast with the latest developments in this industry and much red tape has been eliminated for efficient and timely ethics approval and patent laws. The Government has announced the Good Clinical Practices framework administered by DCGI. Currently, over 200 FDA approved clinical trials are in progress (March, 2007). Many of which are sponsored by Pfizer, BristolMyers, Squibb, and GlaxoSmithKline. Of these 10% are in Phase I trials 20% in Phase II trials, and about 70% in Phase III and IV trials. Phase I trials are conducted on healthy individuals to determine a drug’s safety profile over a set of dose range, and Phase II-III trials are performed on actual patients to test the drug’s efficacy (for more details on the on each of the Phases see Appendix). Figure 1 provides a comparison of costs for clinical trials in Australia, USA and India.

Figure 1: Comparative Clinical Trial Costs



Lambda comes of age

Lambda Therapeutic Research opened its doors in 1999 in Ahmedabad, India. This relatively new organisation has made giant strides in its short history. After its initial venture into clinical trial activities in India, the company established itself as one of the major research firms for Indian MPCs like Ranbaxy. In the following years it added to its infrastructure (opening branches in Mumbai and Chennai) and began to expand into Phase II, Phase III and Phase IV clinical trials. Additional services include clinical data management, biostatistics, pharmacovigilance and advising clients on regulatory affairs in conducting clinical trials.

In 2003-04, Lambda was approved by regulatory bodies including WHO, ANVISA (Brazil), and AFSSaPS (France) to conduct clinical trials. In 2005, Lambda obtained Federal Drug Administration (FDA) accreditation and initiated scientific data management services (SDMS) for bio-analytical laboratories with state-of-the-art technology such as automated (Liquid Chromatographic with Mass Spectrometry (LC-MS-MS) and High Performance Liquid Chromatography (HPLC), refrigerated centrifuges, deep freezers. These labs cover over 150 validated bioanalytical methods which can be

used to quantify drugs and their metabolites in nanogram or picogram levels. Lambda has also obtained Level I certification from the National Glycosylation Standardisation Program (NGSP) in the USA for HbA1C testing, the most crucial test in diabetes monitoring. This certification is a necessity for undertaking any trial on diabetes.

With a total facility area of 400,000 sq. ft. the company data suggests that while 56% of Lambda's current clients are local (India), 44% (and growing) are from the USA and Europe. For example, the list of overseas clients (in the last two years) includes, Apotex, Novartis, TEVA, Watson, Johnson and Johnson, Sandoz. This growth is mainly in Europe and USA where Lambda has established office in Germany and USA. Lambda not only provides services to MPCs but collaborates with other CROs to open up new business opportunities. In May 2007, Lambda acquired two CROs in Europe (Poland) leading to expanded bed and laboratory facilities in which to conduct clinical trials.

In January, 2008, Lambda will inject funds into better equipped laboratories (all laboratories are GLP compliant) and infrastructure such as larger in-house (260) bed facilities (see new dedicated building in Figure 2 below). The firm employs over 420 scientists and medical practitioners and has laboratories in other locations, such as Mumbai, for Phase I trials. Senior candidates are 'head hunted' and are then required to make presentation to a panel in line with the selection criteria. Initial selection of technical candidates is from special job portals followed by interviews, while freshmen are recruited from final year masters or undergraduate chemistry based programs from recognized universities. Lambda visits universities twice a year during. Senior (Lambda) staff conducts seminars and interested candidates are given recruitment packs. Selected candidates are required to sit for a test and further culling is done before they are recruited.

Figure 2: Artist impression of Lambda's new building in Ahmedabad, March 2008



In a study of governance of exchange relationships in networks, scholars have identified many factors including reciprocity, personal relationships, control mechanisms, reputation and trust as important in explaining the duration and stability of the exchange relationship. Lambda's personal relationship with its clients is highlighted through its capacity to retain its customers, and its reputation in knowledge sharing when it participates with other CROs and MPCs in the market. The formal and process control mechanisms implemented by Lambda suggest that the firm is intent on enhancing its reputation and building long term relationships based on trust. This will provide a strategic framework for an effective (doing the right things), efficient (doing things right), and adaptable (ability to adapt to 21st century market demands) organisation.

Observation of the practices in Lambda confirms that it adheres to strict practices according to protocols developed in collaboration with MPCs and local and international regulations. There is a single point of contact during the protocol development phase and a dedicated team leader coordinates all activities and reports to the client. A team of internal auditors regularly checks process activities and compliance to the protocols and external auditors are encouraged to participate. The organization also has a rigorous training and recruitment policy.

The author visited the air-conditioned dormitories (which housed volunteers) and were found to be of a very high standard equivalent to western hospitals. Sterile conditions were maintained 24/7. The organization has a database of volunteers. The selection process involves matching volunteers with the study protocol. If matched, they are invited for an interview (qualified interpreters were used when required). The selection process is captured by the following comment “the main feature of the consent process is the free will to participate ... patients [are explained] the likelihood of harm and benefits expected from the treatment ... [medical practitioners] ensure that the patients are in the condition to exercise his or her own will.”

How does this benefit us in Australia?

By developing a first hand knowledge of a CRO in India, research institutions can save scarce financial resources by outsourcing critical activities to local Indian institutions such as Lambda. Although Monash University's link to this organisation was from a marketing perspective, it provided an insight into an organisation in an industry that has had negative media reports. The Boston Consulting Group reports that MPCs that once denounced pharmaceutical firms in India are now partnering and entrusting Indian CROs with vital research and development, because the difficulties of operating within India can be managed more effectively with a local partner. Managers in Australian research and pharmaceutical industries will benefit by engaging with recognized and established CROs in India. Outsourcing activities generally indicate cost savings, for example, in conducting clinical trials in Phases I to IV. However, participating in the innovation process will bring about closer relationships with organizations in developing countries.

Innovation is the engine behind international competitiveness (Styles, and Harcourt (*Innovation Australia* 2005 pp 23-25). The authors suggest that being exposed to world markets in general and firms in particular will enhance innovation and create export markets for both nations. By understanding CROs like Lambda, organizations involved in Australia's international trade – like Austrade can identify and develop relationships with potential partners, sharing knowledge based opportunities in the biotechnology industry (*Biotechnology Overview* – July 12, 2007).

Discussion and conclusion

This Monash University research provides an insight into how a CRO can provide critical services to MPCs. By understanding this complex market MPC practitioners can develop networked strategies for developing and testing products and diverting scarce resources to research new drugs. The strategic significance of testing new drugs in a developing country like India is controversial. However, this study suggests that not all CROs are the same. Based on this study, MPCs need to select those CROs that are knowledge oriented, operate in controlled environments, and follow strict governance as a business model, *ceteris paribus*.

From a CRO perspective, short-run repeated contracts from MPCs or other CROs may translate to long-run repeated contracts in networks while maintaining control of process activities, sharing of knowledge, and maintenance and enhancement of a culture of knowledge building and good governance practices. Strategic outsourcing involves fundamental changes in the way CROs and MPCs synergise their respective goals in order to identify opportunities where MPCs reduce their research and development costs, while CROs get continuous access to the MPC market. From an Australian perspective conducting clinical trials in developing nations and sharing knowledge will enhance research into the pharmaceutical industry which may benefit MPCs, CROs and trade relations between developed and developing countries. Furthermore, sharing knowledge between partners may also be beneficial in bringing pharmaceutical products within the reach of people in developing countries, keep research costs down, and keep refilling the discovery pipeline. From a clinical trial perspective, Australian companies will have access to a large pool of treatment-naïve patients and skilled workforce.

Appendix

Explaining the various phases of clinical trials

There are different sorts of clinical trials depending what stage the drug (or treatment, device or test) is at. These stages are called phases.

- **Phase 1:** This is the first trial of the drug on humans (up to this point, research will usually have been conducted on animals). Healthy volunteers are given the drug and observed by the trial team over the period of the trial. The aim is to find out whether it's safe (and at what dose), whether there are side effects, and how it's best taken (as tablets, liquid, or injection for instance).
- **Phase 2:** If the drug passes muster in phase 1, it's next given to people who actually have the condition for which the drug was developed. The aim of a phase 2 trial is to see what effect the drug has – whether it improves the condition and by how much, and again, whether there are any side effects.
- **Phase 3:** Phase 3 trials are similar to a phase 2 trial except the number of people given the drug is much larger. Again, researchers are looking at safety and effectiveness. Phase 3 is the last stage before the drug is then licensed for use by the general public.
- **Phase 4:** In this phase, the drug is compared to other, existing, drugs. The idea of a phase 4 trial is to get more qualitative information – determining where exactly the drug is mostly useful, in what sort of patient. The participants in a phase 4 trial are people in the community who have the condition. How useful a phase 4 trial is can vary a lot. Those that are the most useful are those that are well designed. The design of a trial refers to the way that is structured so as to make the conclusion of the trial valid. For example, well-designed trials have a large sample size (meaning there are lots of people in the trial) and have a 'control group' (a group of people who don't receive the drug so that a comparison can be made).

Source: Lavelle P. (2005) Australian Broadcasting Corporation, Health & Wellbeing Consumer Guides on Clinical Trials. 20/02/08

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