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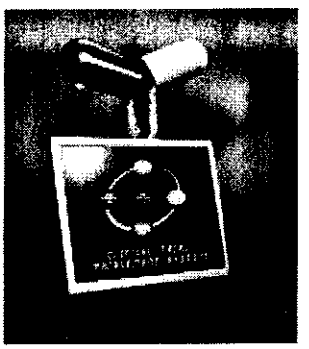
Betting big on CDM

With a strong IT base and a booming clinical research industry India is proving to be a good destination for Clinical Data Management (CDM) outsourcing. ***Arshiya Khan*** *analyses the trends and the outsourcing models*



The Clinical Data Management (CDM) industry is the fastest growing and possibly the most profitable segment of the bio services industry. During 2006-07, it grew to $40 million, a growth of 53 percent over the previous year. The outsourcing of MNC clinical trials to India is a prime growth driver for this market, though they are a few large dedicated CDM companies of Indian origin as well. The Indian clinical trials market in 2006 was $140 million and has been growing at a Compounded Annual Growth Rate (CAGR) of 40 percent for the last three years. At this rate, it is likely to scale up to $600 million by 2010. Correspondingly, CDM market is expected to ramp up to $150 million by the same time, as per an October 2007 report by Cygnus Business Consulting and Research.

Trends, evolution and the outsourcing boom

Earlier, CDM was considered an integral part of clinical development and was typically an activity performed by in-house teams in global pharma companies. With the maturing of the IT and Business Process Outsourcing (BPO) process management, and the volume of CDM work increasing, as well as with the introduction of customised software for CDM, a number of companies started outsourcing this to Clinical Research Organisations (CROs) and more recently to IT companies based in India.

India's entry into the CDM space began with Accenture being chosen as Wyeth's partner for all its data management requirements. Later there were companies like Eli Lilly and Pfizer who brought their CDM work to India, with both working with a CRO and an IT partner. They probably saw greater value in outsourcing more transactional work to IT companies and work that required a high degree of scientific insight to CROs. Prior to this, India was only doing medical transcription for the West which was not value added work. "But this has changed as most MNCs now regularly outsource CDM related work to India and have even developed India centres for CDM, pharmacovigilance and medical writing," avers Dr Ramananda S Nadig, President and Deputy Dean, Clinical Research Education and Management Academy (CREMA).

The spending of pharma companies in CDM runs into millions of dollars. Typically, data management costs account for 20-35 percent of the total cost of a clinical trial. Similarly, according to various reports about CDM and biostatistics, there have been over $8-10 million deals per year from Big Pharma companies. Major work for CDM comes usually in phase III trails. For international trials, phase II cost usually ranges from $200 to $350 million and CDM would get budgeted between five to 15 percent of this total.

Why India?

"Most MNCs now regularly outsource CDM related work to India and have even developed India

CDM is highly technology-driven and needs the use of IT systems, hence pharma companies outsource it to BPOs and IT companies. "And India, with its huge clinical and medical talent, is increasingly being looked at as 'the' strategic offshoring

centres for CDM, pharmacovigilance and medical writing"

- Dr Ramananda S Nadig
President and Deputy Dean
Clinical Research Education and Management Academy (CREMA)

"In future, only those players who can overcome the challenges of understanding and managing regulatory compliance needs, cost pressures and ensure high service quality will survive and thrive in this space"

- J Sairamkumar
Practice Leader
Life Sciences, Cognizant

destination for services related to clinical research," avers J Sairamkumar, Practice Leader, Life Sciences, Cognizant. This is borne out by the fact that today almost 82 percent of US companies rank India as their first choice for IT outsourcing destination

Another contributing factor for outsourcing is that to India it gives clients a cost benefit of 65 percent, so they are likely to outsource more to India. Chetan Tamhankar, CEO, SiroClinpharm, highlights yet another reason. Drug development process is highly uncertain and there are cycles of peak and troughs. In this scenario, it makes sense for pharma/biotech companies to keep only a minimal staff on their rolls and use outsourced help during periods of peak workload. The best example of this is Accenture's tie up with Wyeth and Eisai, Cognizant with Astra Zeneca and Pfizer, TCS with GSK Pharma and Eli Lilly, Pfizer's tie-up with SiroClinpharm for all its data management services, TCS provides data management support for Asian Clinical Trials and Neeman's JV with Sinetesi, INC.

Besides following GCP and information security policies, there are no major regulatory requirements for CDM in India. And this is an added advantage according to Koteshwar Govind, Deputy Manager, Max Neeman International. He remarks, "The (US) Food and Drug Administration (FDA) is accepting data from Indian clinical trials and data management. Secondly, the MNCs are more than willing to outsource their needs to India because of it's technological innovation, creditable quality, operational flexibility, cost effectiveness, time-to-market and competitive advantage."

Even beyond the talent pool, service providers such as Cognizant have added significant business value to sponsors in terms of enhanced quality of work, innovation and standardised global processes. These factors will help fuel the growth of CDM and related services in India, adds Sairamkumar.

Getting back to Cygnus' report for CDM, there are over 70 companies in India offering services in this niche area. Most of them find it a logical extension of their other bio-services business. These include CROs, clinical trial organisations, IT services companies and hospitals. There is a mix of players who are involved in CDM. For mid sized and smaller clients, companies like SiroClinpharm, Reliance, MakroCare, Acunova have good software infrastructure and process management in place. CROs like Quintiles, Kendle, Neeman, and Asian Clinical Trials are also involved in CDM.

On the IT front, BPO divisions of Accenture and Cognizant, Tata Consultancy Services' (TCS) BPO, Satyam BPO, Wipro and IBM are the top level players that are handling some mega deals in this sector, and are betting big on CDM. They have been working with top global pharma companies for over four to five years now and have gained a fair degree of maturity to handle large scale and complex data management projects. Few other companies are also making inroads into this sector. Besides, there are also medical transcription players who are getting a major chunk of work.

Outsourcing business models

India is emerging as an IT superpower and a clinical research hub. This has resulted in a higher-than-expected growth of clinical research-related services in India, including CDM. The Indian IT industry is rapidly moving away from cost as its differentiator and is building

competencies to tackle client requirements much higher up in the value chain. This, coupled with the high speed and quality of service, has catalysed a spurt in outsourcing in domain intensive areas like CDM. Quality and fast response are the new buzzwords to dominate business processes which ensure accurate, reliable services to the customers and an efficient business model will certainly help.

There are three main models—the individual project outsourcing model, the Full Time Equivalent (FTE) model and the functional service provider model. Companies like SIRO that have an operational base in data management in India and Europe are able to work on hybrid models that provide the advantage of the best expertise from Europe coupled with scale from India to provide high quality, optimal cost solutions.

Big CROs offer their Indian counterparts to use their global server, software and other infrastructure with addition of user licenses to extend their data management business. Hence, they can save costs on some hardware and software to start the data management business.

In the FTE model, pharma companies outsource the job of developing the facility, offices and human resources (FTEs) to a service provider, who could be a CRO or an IT company with the understanding of the clinical trial data management and biostatistics business. The human resources in this case could be statistical programmers, statisticians, data viewers, DB designers and medical writers.

In the functional service provider model, pharma companies provide the hardware, software and arrange for their installation and training. This model is essentially an extension of the contract staffing model as the service-provider provides both the office and manpower. The vendor will act as a Functional Service Provider (FSP) on project/protocol basis after certain pre-decided years.

Developments

Some great advancements in CDM in India include quality of results in limited time as well as reduction in use of paper. Until now, India has witnessed different types of players venture into the CDM area. Some of them are full- fledged CROs starting to hive off data management units into independent offshore CDM hubs, while some of them are IT/ITES companies that leverage mature software processes, technology expertise, the ability to scale and domain knowledge to provide data management solutions, and yet others are pharma companies setting up captive biometrics and data management operations solely on their own or through partnerships.

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Max Neeman International

"In the future, only those players who can overcome the challenges of understanding and managing regulatory compliance needs, cost pressures and ensure high service quality will survive and thrive in this increasingly competitive space," predicts Sairamkumar.

In the current scenario, it makes sense for pharma/biotech companies to keep only a minimal staff on their rolls and use outsourced help during periods of peak workload

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CEO
SiroClinpharm

And as far as the Indian pharma industry is concerned, it has made great strides in novel drug discovery in the past three to four years. In fact, the industry is at a stage where it can finally throw off the 'generics-only' tag that it has traditionally carried. There is a concerted focus now on developing data management and analytics capabilities that are required to support drug development. On the development

front, the industry has adopted leading products in the areas of EDC, CDM, CTMS as well as Adverse Event Reporting (AERS).

Similarly, CROs, large and small, are creating facilities and infrastructure, and spending millions of dollars for procurement, installation and training for the highly publicised 21 CFR Part 11 compliant software (like Clin Trial, Oracle Clinical and PheedIt), to become 'Full/Complete Service Provider'. Some CROs are getting ISO 27001 certification, which ensures information security. The bigger global players are scaling up their operations to hire more people and moving their business from elsewhere to India and are catering to the growing demand for cost effective and good quality data management. Besides having access to the best of CDM softwares and systems available globally, the talent base has also matured. Global pharma companies have trained many members of the staff of their India based vendors hence there is greater parity with global capabilities than a few years back. India does more than 60 percent of all outsourced CDM work now; though Australia and to some extent China have started work in this area. Also many global CROs have been increasingly off shoring a lot of their business process and data management functions to low-cost locations such as Asia-Pacific, Africa and Eastern Europe. "However India still lacks the depth of expertise available in the West," remarks Tamhankar.

Going ahead

CDM market in India will expand rapidly in the years to come as long as Indian companies are able to offer large scale data management services at very optimal costs. The concept of gaining advantages through outsourcing data management work to India has now been proven beyond doubt. Also, as major biopharma companies have outsourced their work to India and have gained tremendous advantage in terms of cost savings and speed, the next tier of companies is now increasingly looking to outsource and are exploring possibilities. This will boost the flow of work to India.

EDC is an emerging trend and a majority of the trials in the coming years will shift to this mode of data transfer from the traditional paper based data capture. This will further facilitate outsourcing of CDM.

So undoubtedly, CDM market in India is poised for a steady growth. A hint of who will dominate the market is given by Mahesh Malneedi, President, MakroCare, who says that as more and more trials become paperless and move towards EDC, companies that have thorough EDC capabilities will be best positioned to capture market share, feels.

While there will be competition for work between CROs and IT companies, most companies will choose IT companies for work of a more transactional nature and prefer CROs for work requiring deep clinical research domain expertise. A few companies are already working on this model. What would matter most in the long run, in both cases, are consistent, flawless execution capabilities.

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