Offshoring Opportunities

The outsourcing of data management to emerging countries continues to increase, and new technologies and processes are being brought to market to bridge the gap, as pharmaceutical companies look for cost-effective ways to process clinical trial data

The clinical data management (CDM) sector is one of the fastest growing segments in the industry's newly emerging markets. Large volumes of clinical data are being outsourced to countries such as India and China, resulting in more global clinical trials moving from the west to the east. Challenges such as the lead time for regulatory approvals are not obstacles to clinical data management activity, and technologies such as electronic data capture (EDC) remind us that the world is flat and geographical separation is no longer a barrier. In addition, there is a rapidly developing pool of well trained resources – skilled in data management processes and technology – and India represents a significant proportion of the Certified Clinical Data Managers of the Society for Clinical Data Management (SCDM), outside the US.

The role of the data manager is changing. In the west the role is primarily related to project management and overseeing outsourced relationships; their counterparts in the east mostly still serve as hands-on data managers – apart from those who manage sponsor relationships. The level and the quality of the work that is being outsourced is continuously improving, and typical business models, such as the full time equivalent (FTE)/functional service provider (FSP), are being used widely. Global pharmaceutical companies are investing significantly in setting up these models and finding resources for emerging countries who are now well-versed in using a vast variety of applications, including Oracle Clinical, RAVE, INFORM, as well as various other clinical trial softwares coming into the market. There is also a growing awareness of standards and guidances, such as CDISC, CSUICI and 21 CFR Part 11. In addition, a lot of medical professionals have moved into this domain, which adds the unique 'clinical' edge to data management services provided out of countries such as India. BPOs, CROs and ITES are all making a foray into this market and lean Six Sigma methodology can be applied effectively.

Global View

The international pharmaceutical market is growing at a rate of five to seven per cent and is expected to reach $880 billion this year, compared to a growth rate of four to five per cent in 2010, according to IMS Health (1). A significant component of this growth, however, will be driven by the 17 'pharmerging' countries, which are predicted to have grown to between $170 to 180 billion – a 10 per cent increase compared to last year. Among these, Japan and Australia represent mature markets, whereas India, China and Singapore are rapidly becoming preferred destinations for clinical trials. China is the world's third-largest pharmaceutical market and is predicted to grow at a rate of 25 to 27 per cent to more than $50 billion next year, whereas the US is expected to reach $320 to $330 billion (1). On the other hand, in terms of human resources and their availability, India ranks second, behind only the US, as per AT Kearney's Global Services Location Index, 2011 (2).

The common belief is that Asia is becoming a hub for clinical trials. However, the US NIH recently reported that the majority of clinical trials (52,107) are still being conducted in the US, with 7,356 in China and 1,400 in India. This is against a global figure of over 120,000 clinical trials. Only 1,745 trials are currently ongoing in south Asia, as compared to 7,356 in east Asia. For

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example, once the registration of clinical trials with the Clinical Trials Registry of India was made mandatory in June 2009, it was observed that, compared to only 11 trials being registered between July and December 2007 (when registration was still optional) the number increased to: 137 between January and December 2008; 546 between January to December 2009; and 806 between January to December 2010. Dr Surinder Singh, the Drug Controller General of India, reported that as of 28 January 2011, the number of trials registered with CTRI stood at 1,581 (3).

Thus, while it is apparent that the majority of clinical trials are still being conducted in the west, statistics show that the number of clinical trials occurring in emerging countries is increasing rapidly, and that there is increasing support for outsourcing to these countries.

Linda Talley, Global Advisor of Biopharmaceutics, Clinical Pharmacology and CDS at Eli Lilly explains: "In 2010, the Asia Pacific region is home to more than 45 per cent of the world's population. As a result, there is a major need for medications and therapies to meet the medical needs of the region. Clinical trials conducted in Asia can yield information to help prevent major illnesses, improve preventive care, predict which treatments have a higher likelihood of success, reduce mortality rates and create a healthcare environment that is based on data, outcomes and best practices employed

in other countries. As clinical data managers working in a global economy, we have a keen interest in making clinical data best practices, tools and data analyses readily available where they are not today".

With millions of dollars being invested in multinational clinical trials, and 20 to 35 per cent of this being used for data management, this segment clearly represents a rapidly growing revenue stream, and a clear reason why CROs, BPOs and ITES are increasingly investing in this sector. While a major proportion of the CDM revenue comes from Phase 3 trials, international Phase 2 trials cost between $250 and $300 million, with the CDM component only representing about five to 15 per cent of that cost (4).

In spite of an increasing convergence towards international regulatory requirements, outsourcing issues still remain a key challenge. However, strong IT capabilities support the implementation of data management; India's IT service is expected to grow to $8.1 billion in 2011, reflecting a CAGR of 18.6 per cent between 2006 and 2011 up from $4.1 billion. Infrastructure application integration would represent 21 per cent of the total IT services opportunity (5). Not only do 25 per cent of India's engineers have the basic skills for offshore IT jobs – compared to 10 per cent in China and Russia respectively – India also has a large number of qualified medical specialists who contribute to the core clinical review component of CDM and would cost less than half of those in the US (6).

As more and more multinational clinical trials are being implemented, business models and technologies grow increasingly complex, making the management of the outsourced relationships more difficult. Common concerns include data security, the spiralling wage bill and the relatively lower experience levels of a local data manager compared to those from the US. Despite this, CDM remains an exponentially growing industry and a key function that is outsourced to emerging geographies.

The way data management is handled differs considerably across the globe and a common concern is whether data management as a profession would continue to exist (7). It would surely, but the role would need to evolve and diversify. The role of the data manager in the west is transforming into one where project management and the managing of outsourced relationships is key; as semantic interoperability sets in, they act as a data broker, with little to no hands-on data processing responsibility (8). The challenge lies, however, in trying to ensure that processes are in place for guaranteeing control without duplicating efforts, thereby ensuring data quality as well as having adequate hands-on expertise to check compliance with regulatory requirements. In emerging countries, the majority of data management companies follow the FTE/FSP outsourcing model. As a result, a large percentage of data managers specialise in a particular function. Further up in the hierarchy, project planning and customer relationship management become essential skills (9). The FSP model provides the sponsor greater flexibility to work with a vendor, which gives the desired levels of functional expertise, regional capabilities, therapeutic expertise, regulatory know-how and local agency connections. This also allows sponsors to rapidly expand their global clinical trial footprint without having to invest extensively in establishing local affiliates.

The level of understanding of global regulatory requirements, data standards and concepts such as semantic interoperability in emerging countries needs to be established further. Experience levels in data management are lower than in the west, with five to six years considered to be on the higher side, as compared to 10 to 15 years in the west. Attrition levels are higher and the spiralling wage structure is impacting labour arbitrage. On the other hand, more end-to-end activities are being outsourced to emerging countries as increasing confidence levels are being established in their capabilities. The data management community in emerging countries at large represents a young

community that is intelligent, focused on quality, dedicated and eager to learn.

There are over 70 companies offering CDM services in India, and data management has been growing rapidly; valued at about $40 million in 2006-2007, it is projected to have grown to about $150 million in 2010 (10).

More companies are investing in 21 CFR Part 11 compliant off-the-shelf software applications, such as Oracle Clinical, rather than using home grown applications. These offer more credibility in the market and assist in the seamless integration of clinical trial applications, which gives sponsors improved efficiencies. Other applications that are utilised include INFORM, RAVE and SAS Pheedit. Companies are also investing in acquiring an ISO 27001 certification, which ensures information security.

Some important perspectives that should be kept in mind while outsourcing or offshoring CDM activities include (11):

- Ensuring effective change management and communication processes in order to engage the internal team to provide the required support for this initiative
- Ensuring that the vendor's team has been effectively trained on the sponsor's systems and standard operating procedures (SOPs), and that effective 'train-the-trainer' models are in place
- Implementation of the right governance model to establish leadership and accountability on both sides, as well as to ensure that the right issues are communicated at the right level
- Ensuring that systems are in place to address timezone and cross-cultural differences (12)
- Ensuring a phased transition of activities
- Ensuring a measured reduction in oversight, and therefore costs, over a period of time, supported by well-defined SLAs that measure compliance with regulatory requirements, quality and timelines

- Making all efforts to ensure that as far as possible, all vendors perform all data management activities within one system
- Establishing that appropriate issue escalation plans and contingency plans are in place and appropriate measures of effectiveness are taken
- Measuring the added value that the vendor brings to the table, in addition to meeting defined requirements, through the implementation of process improvements and the application of lean practices

As well as guaranteeing compliance with regulatory requirements, it is also important that the vendor's data management team is trained in, and understands, the significance and implications of guidances and regulations. These include FDA guidances such as the draft guidance on 'Electronic Source Documentation in Clinical Investigations', or the earlier guidances on 'Computerized Systems Used in Clinical Investigations' and 'Part 11, Electronic Records and Electronic Signatures – Scope and Application', or the EU Data protection Directive and Data Safe Harbor principles and awareness of the fact that as of May 21, 2009, Genetic Information Nondiscrimination Act (GINA) has changed the term 'Protected Health Information' to include genetic information. It is also of value to the sponsor to invest in training the vendor's team, especially when following an FTE/FSP model, as non-compliance will have a direct impact on the sponsor. It is also advisable for vendors to invest in getting their data managers certified through the Society of Clinical Data Management's professional certification programme, which serves as a stamp of credibility for a person in this profession (13).

Conclusion

Whether it was the Wyeth-Accenture deal which brought CDM to India, or the SIRO-Pfizer, Astra Zeneca-Cognizant, TCS-GSK Pharma or i3-Eli Lilly partnerships, clinical data management will be outsourced, and emerging countries, such as India, will continue to grow as

the key destination for the offshoring of these activities (14). Clinical data management as a profession will not become extinct, but as offshoring and EDC technologies grow in parallel, the role of the data manager will evolve.

Susan Howard, Global Compound Lead of Oncology at GlaxoSmithKline explains, "The cost of clinical trials will continue to be scrutinised by regulators throughout the world as the costs of medications must remain as affordable as possible. All involved in the pharmaceutical sector must keep a watchful eye to control and/or avoid unnecessary costs. Emerging countries will continue to play a large role in the processing of clinical trial data as long as these costs are also kept under control. The work at pharmaceutical companies will be on high level oversight and coordination of many vendors in the trials".

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