THE CENTERWATCH MONTHLY

Medical Writing Takes Off in India

Medical writing is the latest niche CRO service to be a focus in India. India-based company Cactus Communications has opened an office in the US, positioning itself to become a player in Western markets.

With an English-speaking, highly skilled workforce and an infrastructure that meets international standards, India can expect to see more niche CRO services outsourced there.

Pharmaceutical companies have begun considering new areas that can be contracted to outside firms and increasingly want to shift non-core activities to offshore locations to meet development goals and lower costs.

Not only have contract research organizations (CROs) expanded both their global footprint and range of services in order to meet these growing demands, but smaller specialty companies also have emerged to help drug sponsors cut time and cost in getting new drugs to market.

One of those smaller companies that has ramped up its services in recent months is Cactus Communications, an India-based medical communications firm that just opened North American operations for its Editage division. The Mumbai-based company, which also has a branch office in Tokyo, opened a satellite office in Memphis, Tenn., as part of a plan to expand its business offerings and provide medical writing and scientific editing services to both the pharmaceutical industry and academia.

The launch of the Editage brand in North America for Cactus Communications, which has become one of the first medical communications firms in the United States that has its headquarters in India, reflects a larger trend toward companies involved in India's drug development and manufacturing industry positioning themselves to become players in western markets.

Through its efforts to incorporate in the United States, Cactus Communications extended its focus beyond Asia and began looking for business in North America.

"We wanted to grow beyond our traditional markets which have been in the Far East," said Cactus Communications' CEO Anurag Goel. "The U.S. is the base for most large pharmaceutical companies. A presence here will help us gain a deeper understanding of the medical communications industry and fill any gaps in the services we offer. Further, a physical presence in the U.S. will ensure that our clients have someone to talk to in their own time zone. It will reduce any perceived barriers due to geographical distance."

India's Booming Outsourcing Market

Editage's decision to offer services to pharmaceutical companies and academia in the U.S. market follows a period of remarkable growth in drug company outsourcing to India, a trend that has been well-documented in recent years. The contract research market in India is growing at a rate of 25% a year. Trials registered with the U.S. Food and Drug Administration (FDA) in India have increased tenfold from 2002 to 2007, with India moving up substantially in the rankings from 29th in trial initiations in 2001 to 7th in 2007, according to FDA Form 1572s.

Industry studies show that the cost of clinical trials can be reduced 35% to 50% by using CROs in India, a democratic English-speaking country that has a highly skilled workforce, a large pool of potential treatment-naïve patients and an infrastructure that meets international standards. In addition to clinical trial work, some drug sponsors have shifted R&D manufacturing and IT services to outside partners in India. Today, many see a trend toward pharmaceutical companies reaching deeper into their processes and finding new areas to outsource as companies redefine their core competencies, focus internal resources on those areas, and then outsource non-core activities to providers who can do it faster, more efficiently and cheaper.

Editage's expansion into North America anticipates that pharmaceutical companies increasingly will turn to India, the only emerging market where English is the primary language, for the medical writing and editing services needed for a myriad of drug development activities, from the editing of a PowerPoint presentation to the writing of safety reports and other documents that support the drug approval process.

"The whole reason to open up North American operations is simply because that is where many of the Big Pharma headquarters are. Big Pharma is undergoing a lot of reconstruction and that reorganization involves India and China. It's the right services at the right time for the right reasons," said Donald Samulack, Ph.D., vice president of Medical Affairs and Strategic Partnerships at Cactus Communications, who is tasked with the North American launch of Editage.

Entering U.S. Market

As Samulack, who has worked both in the clinical and academic spheres, watched the

Reprinted from Volume 15, Issue 11
November 2008

far-reaching changes in pharmaceutical company outsourcing practices in recent years, he wanted to tap into the new opportunities created by globalization in the pharmaceutical industry.

"I've seen changes in pharma's movement toward India and China to outsource clinical trials, and huge increases in academic competitiveness in peer-review for the publication of manuscripts and solicitation of research funding. There is so much flux happening. That started to get my entrepreneurial spirit going," Samulack said.

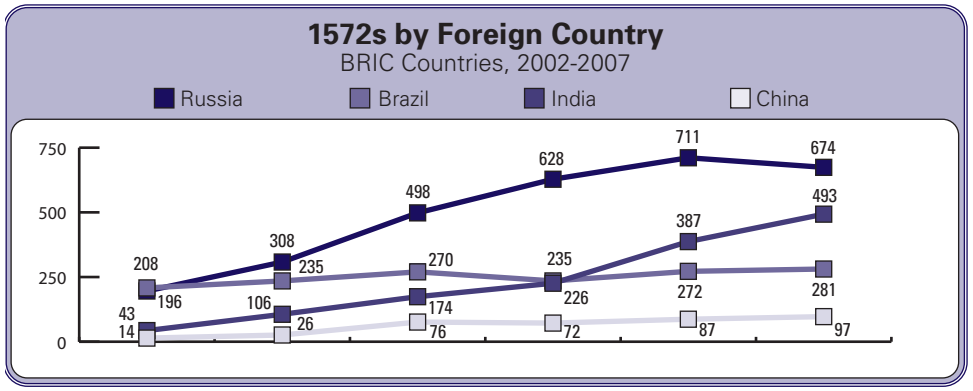
With these thoughts in mind, last year Samulack attended the American Medical Writers Association meeting in Atlanta, Ga., where he met the heads of the medical writing and editing teams from Cactus Communications. Most of the client base for Cactus Communications at the time was from Asian countries, including China, Japan and South Korea. Samulack and Goel discussed expanding the India-based company into North America. "Even though it's not starting their business from scratch, it's really opening up the North American side of their business from scratch," Samulack said.

The North American office not only expands the company's geographical footprint, but also its business model. Since the parent company was established in 2002, its mainstay has been scientific and English-language editing on an academic level; the company has edited more than 32,000 manuscripts, with about half of that number from the fields of medicine and life sciences. The company's medical writing experience includes clinical manuscripts, clinical study reports, and safety reports to scientific manuscripts, grant applications and scientific poster presentations. In all, Editage has more than 9,500 clients from 30 countries, a group that includes drug sponsors, CROs, medical communications companies, academic researchers, clinicians and doctoral students.

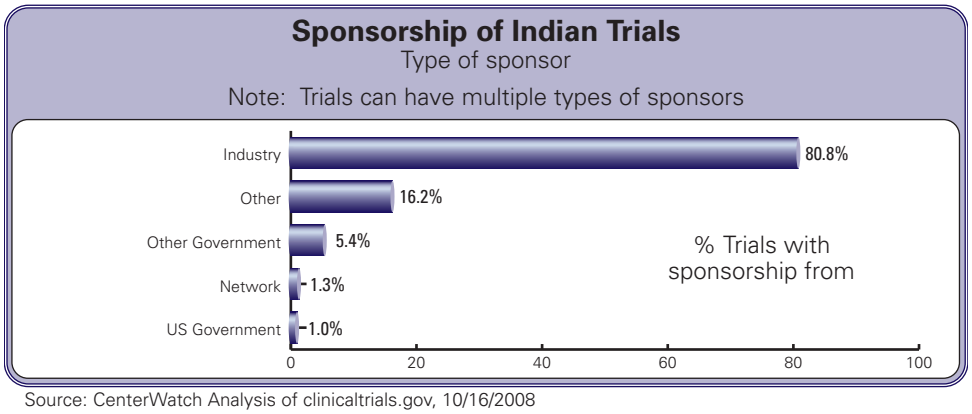
In recent years, as clinical trial work has surged in India and China, Cactus Communications also has ramped up the medical writing and English language services needed to support the pharmaceutical industry. In India, the company has assisted writing teams from both domestic and global pharmaceutical companies, while in China work has included training professionals who not only need to learn English, but also to learn medical terminology in English in order to support clinical trial work in their country. "We already are on the ground doing grass-roots training in order to serve the greater pharmaceutical good," Samulack said.

Now that Cactus Communications has incorporated in the U.S., Samulack will market the medical writing and editing resources from India to pharmaceutical companies and academia in the west.

While Editage will promote its scientific editing services to academia in the U.S., including editing for both peer-review and non-peer-review journals, Cactus Communications also wants to leverage its academic expertise to gain work from pharmaceutical companies. "Because of my pharmaceutical experience, it started opening up their eyes (at Cactus Communications) as to the opportunities that were on their own doorstep in India, as well as China and North America. They already are networking with the Indian pharmaceutical and CRO community with respect to medical writing, scientific editing and the training of medical writing teams in these companies. On a global basis, we are not only serving the needs of the pharmaceutical community, we are working together to conduct the training required to unleash the international resources at hand," said Samulack.



Source: CenterWatch Analysis, 2008; FDA, 2008

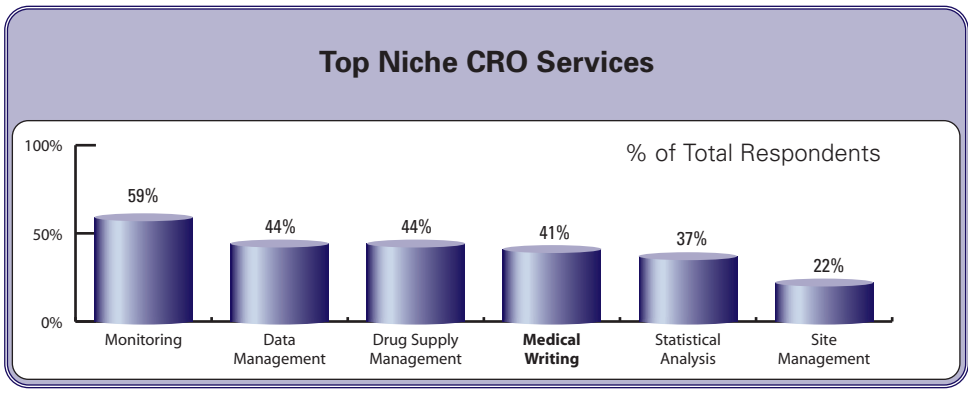


Source: CenterWatch Analysis of clinicaltrials.gov, 10/16/2008

Breaking the Triangle

While pharmaceutical companies already outsource a portion of their medical writing work to CROs, medical communications firms and freelancers, Samulack maintains Editage has the advantage of allowing drug sponsors to "smartsource," a term that has gained popularity recently in the global business community.

Smartsourcing combines the strategy of outsourcing select non-core activities with using multiple sourcing providers that can offer shorter and more flexible contracts. "The classic model for project management is the triangle, where you have cost, scope and time as intricately tied parameters of a project. In this model, you can't shorten the time without increasing the cost. You can't increase the scope without increasing either the time or the cost. It is traditionally taught as an unbreakable paradigm," Samulack said. "My argument is that if you smartsource to India, you break that triangle. If you want to talk about cost, we can help. If you want to talk about scope, we have an extensive pool of highly trained writers and editors to help. If you want to talk about time, you can lock a document at 5 p.m. in the evening, go home, and we can work through the night to advance the project while you sleep. We can help any company break project management paradigm constraints just by smartsourcing with us."



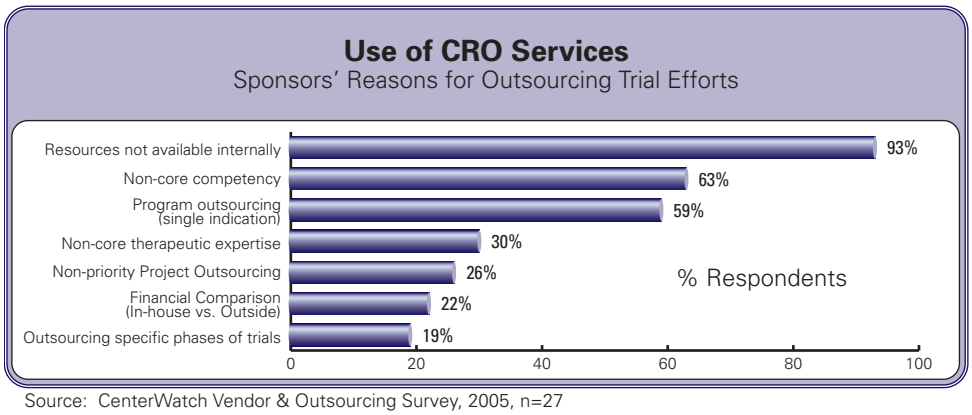
Source: CenterWatch Vendor & Outsourcing Survey, 2005, n=27

Some past experiments with pharmaceutical companies trying to offshore medical writing to India have been unsuccessful. Previous problems include complaints that only the simplest of documents could be prepared in India, deadlines were missed and documents were finished only after handholding and rewriting from experienced writers. As a result, there was some pull-back from contracting medical writing work to India and many drug sponsors turned to traditional medical writing and editing providers, such as freelancers, with their contract work.

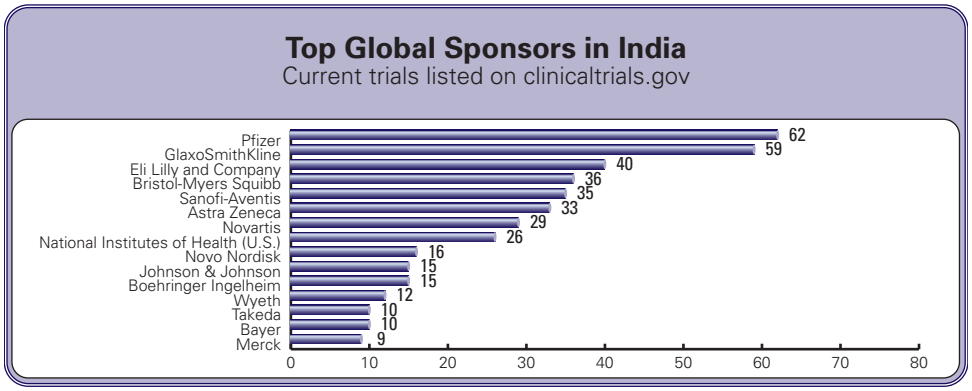
But in more recent years, there has been a strong interest in medical writing in India, more training for those in the field, and the workforce has gained significant regulatory experience. "Pharma has said they have had some pain in having to work with India because there has been a learning curve," Samulack said. "From my point of view, we've gone through phase one of that learning curve. It may have been painful, but now we are in phase two. And phase two is where you really see the benefit. You now have a large, energized, intelligent, entrepreneurial and trained workforce. I think that pharma will once again have to revisit the cost benefit, but, more so, the time benefit and the scope benefit, of using large writing teams that are coordinated in India."

Cactus Communications, which has 160 employees, has a culturally diverse team of editors and writers from Canada, the United States, Europe, China, Japan and India in its Editage division. The company employs a three-step screening process when hiring new staff; the process eliminates about 95% of job candidates. In addition, all employees must complete in-house training sessions on various writing and ethical guidelines relating to the pharmaceutical industry, including Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) guidelines, Consolidated Standards of Reporting Trials (CONSORT) and International Committee of Journal Medical Editors (ICJME) guidelines, as well as English language training. Employees complete external training programs in areas such as medical writing and statistics.

In another indication that not only Editage employees, but also the broader



Source: CenterWatch Vendor & Outsourcing Survey, 2005, n=27



Source: CenterWatch Analysis of clinicaltrials.gov, 10/16/2008

workforce in India, has entered the mainstream medical editing and writing community, the Board of Editors in the Life Sciences (BELS), which now has members in North America and Europe, will travel to India this month to give 41 Editage editors the Editor in the Life Sciences (ELS) certification exam. This is the first time that the standardized exam has been held in Asia. "We recognize the growing community of scientific editors in India and believe that the ELS credential benefits both editors and employers, allowing editors to demonstrate proficiency and employers to hire editors with that demonstrated proficiency. Expanding BELS to India is a logical extension of our presence in North America, Europe and Australia," said Leslie Neistadt, registrar of BELS. "We are excited about the opportunity to interact with our colleagues in India. Increasing awareness of the ELS credential in India will benefit both editors and employers in a highly competitive market."

Quality Control

One element that differentiates Cactus Communications from many other medical communications firms is its internal processes, according to Samulack. Last year, the company earned ISO 9001:2000 certification, which certifies that Editage's in-house document and editing processes meets quality management criteria set by the International Organization for Standardizations (ISO). Before granting the certification, ISO evaluated the consistency and the confidentiality of the company's quality management processes and the control of document records, along with its infrastructure and workflow. "The automated management process for document flow in the company is very streamlined, as are our client-management systems and processes. This allows us to be able to service 9,500 clients worldwide on an individual basis," Samulack said.

These strong processes will benefit the company, Samulack believes, as pharmaceutical companies increasingly want their medical writing partner to provide an audit trail, particularly after the scrutiny Merck has undergone in recent months regarding the development, guest authorship and publication of medical research studies about its pain drug Vioxx.

"Pharma, from my perception, is downsizing and outsourcing whether it be domestic or international, not only for financial reasons, but to some degree to mitigate their risk. In the future, pharma is really going to be looking for partnerships with companies that can withstand an audit. The average freelancer cannot withstand an audit. Many medical communications firms, except for the big ones, cannot withstand an audit," Samulack said. "Now, the trend in the industry is toward being able to withstand an audit in medical writing. We are well positioned for this. Because of our in-house systems, I can tell you exactly who has touched what document at what time of day, and then what they did to it. All of that is monitored and recorded. From a pharmaceutical perspective, that is going to turn out to be one of our major strengths."

Looking Ahead

As pharmaceutical companies increasingly look to contract clinical trial work in emerging countries, companies have begun to align themselves as global players in order to support these activities by centralizing their services in India.

Even though pharmaceutical companies have outsourced drug development work to India since the early 2000s, Samulack said other medical communications firms failed to consider the possibility of Indian companies competing for medical writing and scientific editing work globally. "We definitely consider our entry into the North American market a disruptive force, even though Big Pharma has been looking at India for a long time," Samulack said. "Rest assured, as in any other market economy, India is a disruptor, China is a disruptor and even Korea is going to be a disruptor. Shift happens. Now is gone."

According to industry reports, the Indian pharmaceutical offshoring industry is expected to become a $2.5 billion industry by 2012 as the pharmaceutical industry looks for more cost-effective ways to bring new drugs to market. In addition to outsourcing manufacturing, clinical trials, clinical data management, biostatistics and even some drug discovery work, Cactus Communication's Goel believes the outsourcing of medical communications services to India will continue to increase.

"India offers several advantages for the outsourcing of medical writing and scientific

editing work. We have a talent pool of nearly 13 million science graduates. English is the business language of India making communications with sponsors simpler and faster. The difference in time zones also is proving to be an advantage as deadlines are generally short and work sent during the evening in the U.S. can be completed in India during the day. This being said, companies in India offering these services need to work toward establishing quality standards for these services to ensure consistency in quality as positioning based on cost advantage alone is not sustainable in the long term," Goel said.

Other India-based companies involved in the pharmaceutical industry have adopted similar strategies. Ranbaxy, for example, has begun to move its skill beyond producing generic drugs and increased its R&D spending to compete with western drug companies.

In addition, many CROs in India are looking to enter the U.S. market. For instance, the Ahmedabad-based Veeda Clinical Research has set up an office in the United States and its subsidiary, Veeda Oncology, acquired U.S.-based CRO International Oncology Network earlier this year.

—Karyn Korieth