

The Medical Scribes - Express Pharma

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With the demand for medical writing professionals increasing, and more medical writing/clinical research activities being outsourced to India, keeping down costs will become very difficult. Also, there is room for improvement and scalability of the involved professionals. Arshiya Khan writes about the medical writing trends in India

The recent move by the President of United States, Barack Obama, to come down heavily on outsourcing companies and weaning off their tax breaks does manage to create a level of ambiguity and restlessness amongst the boardrooms in our subcontinent. However, they are not discouraged to the extent that it has shattered their confidence, and that that they are being forced out of the US market. The sheer numbers do suggest that the Indian tiger cannot be tamed so easily, at least as far as the medical writing industry goes.



We have been strongly emerging as a readily available 'knowledge bank' which the US buys. The cost dynamics prove that Indians are much more cost-effective than their own technical experts in the US, despite the tax breaks. The outsourcing trend of medical writing service has been on the rise since 2002 and has taken rapid strides, especially from 2005 onwards in absolute numbers, in spite of continually increasing base.

As per Goldman Sachs, international spend on allied services forms 20 percent of total R&D spend (data management, pharmacovigilance and medical writing) and has grown by five percent between 2005 and 2007. In contrast, as per Zinnov Consulting, Compounded Annual Growth Rate (CAGR) of allied services in India has been 21 percent. Thus, the future depends on the ability of Indian companies/CROs to develop capabilities to meet the regulatory, time and quality requirements of global pharma companies.

The key components

"Medical writing is a non-core activity for pharma cos, and hence, although they do not want to bear the cost of maintaining in house medical writing teams, the work needs to get done, and is thus outsourced to countries like India"



- Anurag Goel
CEO
Cactus Communications

Last two years have seen a spike in outsourcing, especially from European and US pharma companies. "Bulk of the work is coming in from top 50 firms who have adapted a similar IT outsourcing model and applied those processes to medical writing work also," says Dr Vijay Shekhar, Senior Manager, Medical Writing, MakroCare Clinical Research.

Besides this, pharma cos are going through major restructuring initiatives resulting in job cuts and outsourcing of non-core activities. At the same time, there is an increasing pressure from regulatory authorities and the pressure to publish both positive and negative clinical trial results has resulted in an increase in the need for medical writers. "Medical writing is a non-core activity for pharma cos, and hence, although they do not want to bear the cost of maintaining in house medical writing teams, the work needs

to get done, and is thus outsourced to countries like India," says Anurag Goel, CEO, Cactus Communications. According to the 2005 CenterWatch vendor and outsourcing survey that looked at most frequently outsourced services by CROs, medical writing came in fourth with approximately 40 percent of respondents stating that they outsource their medical writing work. What these global companies look for when they outsource to India is knowledge of relevant regulations and guidelines. Example: ICH E3/E9, knowledge of drug development, organizing/planning skills, written language skills-scientific and technical English, and ability to synthesize and analyze clinical trials results to write a succinct report.

Advantage India

Medical writing is a critical and complex activity involving the creation of scientific documentation that facilitates, among other things, interpretation of clinical research results, and clarity on drug use guidelines, besides providing other medical information about the products. This task requires deep understanding of regulatory/scientific guidelines and involves liaising with many different stakeholders such as clinical research scientists, doctors, and so on. Medical writing is recognized as a task that requires special skills, such as a thorough understanding of clinical and medical data, as well as the ability to present information clearly and concisely in well structured documents as per guidelines. India has a

large number of qualified and experienced professionals who are also proficient in English language. This, along with attractive cost arbitrage opportunities, makes India a preferred destination for medical writing outsourcing.

In the clinical data lifecycle, data is first managed (clinical data management—CDM), then analyzed (statistical analysis) and subsequently, the results interpreted as well as documented as per regulatory and scientific guidelines. As the first two activities have been outsourced to India-based service providers, it was a logical progression for global pharma organizations to outsource medical and scientific writing activities as well, feels Sairamkumar.

Many of the global top-10 pharma organizations already outsource medical writing work to India. A recent market analysis estimates the global medical writing market size to be approximately \$700-800 million, and the India-based service providers, who compete with providers from China, Ireland, Philippines, and others, are poised to gain significant market share in this area.

Career Wise

The American medical writers' association (AMWA) and the European Medical Writers Association offer continuing education programs on various aspects of medical communications. In India, there are several courses that claim to offer training in medical writing; however, most of these are focused only on the regulatory aspects of medical communications and are not very comprehensive in their course content.

There are many small and medium sized private and government aided institutes undertaking training which together churn out more than 500 professionals in these fields. Career growth prospects are very high. This field requires highly specialized skills and good, experienced writers are much sought after the world over. Although there are a few institutes who claim to provide training in medical writing, most of the learning happens on the job. Qualified medicos (MBBS, MD professionals), PhDs are highly sought after. M Pharm and MSc post graduates with rich experience in related field are also in demand. Medical writing shows a bright future especially for a country like India where clinical research outsourcing is a fast growing business. There is and will be a huge requirement for trained professionals leading to increasing demand.

The key drivers

"The main challenge here is that Indian professionals lack experience of writing documents as per regulatory expectations, therefore, that needs an improvement"



- Dr Arun Bhatt
President
ClinInvent Research

"The major criteria for most sponsors to outsource medical writing to India is the need to obtain high quality work as per standards laid down by their own policies /SOPs by CONSORT/ICMJE by global agencies and local competitors. Also, trained writers with prior exposure are in demand"



- KV Subramaniam
President and CEO
Reliance Life Sciences

So what is really pushing the steady growth? Apart from the cost advantage, which is too obvious to get unnoticed, there are many other factors contributing to the increasing outsourcing of business processes by Western countries to India in fields like IT, R&D manufacturing, clinical trials etc. Initially, it began with quality checking work where Western clients retained core medical writing with them and asked Indian resources only conduct quality checks using the metrics provided by them. "Over time, we are getting more work that is increasing in its complexity. We, now at SIRO have done final ICH E3 reports, safety narratives, protocols, publications that were published in peer reviewed international journals in 2009 and hope to evolve the complexity of work even further," shares Chetan Tamhankar, Chief Executive Officer, SIRO Clinpharm.

The major criteria for most sponsors to outsource medical writing to India is the need to obtain high quality work as per standards laid down by their own policies/SOPs by Consolidated Standards for Reporting Trials/International Committee of Medical Journal Editors (CONSORT/ICMJE) by global agencies and local competitors. Also, trained writers with prior exposure are in demand, informs KV Subramaniam, President and CEO, Reliance Life Sciences. Besides these, the fuelling components for this growth engine are a large pool of experienced English speaking medical professionals, increasing numbers of GCP trained medical professionals, professionals with industry experience with good writing skills that translates into know how to put together reports and analyze safety data.

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Chief Executive Officer
SIRO Clinpharm

writers in developed countries like UK and the US also tend to do brisk work. Elaborates Tamhankar, "Since they work as home based individuals they do not carry any overheads like a structured company, hence, they can offer competitive hourly rates for the work they do. Limitations are in the form of lack of scalability and all their work depends upon word of mouth publicity. Amount of medical writing that comes to India can hence be placed between one and three percent of total outsourcing globally." Lack of prior experience and skilled manpower are the main reasons for the less amount of work being outsourced to India, feels Suhasini Sharma, MD, Director, Medical Writing & Medical Review, Sciformix Technologies.

In India, there are different types of people/organizations involved in providing medical writing services. There are service providers with medical writing as the only domain expertise like medical communications firms. The service is also provided by individual professionals with requisite qualification and interest; CROs offering end-to-end clinical trial services also provide medical writing as part of their service portfolio. The main players as of now in India are TCS, Siro Clinpharm, ClinInvent, Sciformix, Cognizant, Accenture, MakroCare, Quintiles, Indegene, Cactus Communications and several small and medium organizations.

Business models

Several Big Pharmas initially maintained huge in-house medical writing teams. Due to cost pressures, some are developing and maintaining teams in India, as this allows them to have complete control over the processes and have a dedicated team of writers who understand the company's products while controlling costs. Some are also moving to a model of using a combination of in-house and external resources to meet their medical writing needs. External agencies are generally used during peak periods when it is not possible for in-house staff to manage the workload. In case of some of the smaller pharmas, it is not feasible for them to maintain in-house writers and hence they work with one or more agencies, outsourcing certain types of work to particular agencies having expertise in that particular kind of writing or therapeutic area. Goel elucidates a few examples; some pharma companies may outsource their regulatory writing work to agency A and publication work to agency B. Novartis has a huge in-house writing team in Hyderabad. International CROs such as Quintiles also have writing teams in India. Then there are pure play med com companies such as Cactus which provide a range of publication services to pharma and CROs.

Companies that outsource are also increasingly looking for service providers who can provide them with a dedicated team of writers who they can work with, as this saves them the trouble of having to train new writers on their products and processes and allows them to manage the outsourcing process more effectively. And India has responded to these global needs in a favorable manner by developing in-house dedicated medical writing groups in pharma companies, setting up CROs and KPOs and encouraging freelancers.

Thorns in the way

Medical writing has emerged as a career option with a large number of clinical research professionals and even fresh doctors/PhDs are showing interest. However, the major challenge that the industry faces is the dearth of skilled manpower with expertise in all therapeutic areas, points out Subramaniam. Goel highlights one of the biggest complaints that they have heard companies mention is their issues with the language used by medical writers in India. Extensive reviews are required by reviewers within the company which often results in them having to rework documents.

Therefore, Goel feels that medical writing industry in India has some work to do in terms of putting in place initiatives to ensure that we are able to meet client requirements. Our efforts need to be focused on convincing drug sponsors that along with being cost effective service providers, we are also able to meet their quality requirements (quality-based positioning rather than just low-cost service provider

There is an added time zone advantage too.

Market Share

Various reports estimate the Indian drug development outsourced market size at little over Rs 1,500-1800 crore. Medical writing contributes to only about three-four percent of this with an estimated growth rate of 15-20 percent. There are more than 40 companies providing medical writing services in India, out of which more than 20 are Indian CROs. India is a major hub apart from Brazil, Philippines and Russia in terms of outsourced medical writing. In addition to country competition, local freelance medical

positioning).

In sync with this, one of the first steps that Cactus has taken is getting the Board of Editors in the Life Sciences (BELS) to conduct their certification examination in India. BELS recently conducted their second examination in India and they now have approximately 37 BELS certified editors in India of which 28 are part of the Cactus team. Having certifications like ISO also go a long way in convincing clients of its process capabilities. At Cactus, there is a three-week long language training course that all its writers and editors have to go through to ensure that they are able to meet the standards of its international clients.

What also needs improvement is service maturity, talent availability and retention. Medical writing has been outsourced only recently. While the Indian service providers understand the regulatory and documentation requirements involved, they are still in the process of developing maturity and scale in delivering this service. With the expected increase in volume of outsourcing, the experience and service maturity of Indian service providers would reach global standards. Now, due to greater awareness about opportunities in this area, there is an upswing in the proportion of trained talent entering the industry. One natural fall out of the increasing attractiveness of this outsourced service is the rapid employee turnover rate observed due to the demand supply gap which needs to be addressed at organisational and macro level.

High attrition rate is something that this industry has been grappling with for a long time. Shekhar remarks, "A major challenge currently is lack of experienced medical writers and that has led to high attrition rates." As a suggestion to deal with this burgeoning problem he says, "Increased interaction with client's internal teams and constant trainings to existing and employees is one way to minimize the challenge. Making life sciences students aware of this field as an alternate career is also important, so that there is constant intake of new people into this industry." Functional Service Providers (FSPs) such as Cognizant, have the ability to recruit and train thousands of qualified resources every month. "For instance, Cognizant has 'Certified Consultants in Regulatory Affairs' who help train the larger delivery team on regulatory requirements and guidelines. This helps reduce dependency on individuals while increasing the ability of the teams to provide high quality of service to the customers," says J Sairamkumar, VP and Practice Leader, Life Sciences, Cognizant.

"Medical writing—protocol and clinical study report are most important documents from regulatory submission view point. The main challenge here is that Indian professionals lack experience of writing documents as per regulatory expectations, therefore, that needs an improvement," says Dr Arun Bhatt, President, ClinInvent Research.

The Key Factors

J Sairamkumar, VP and Practice Leader, Life Sciences, Cognizant, gives an insight on the factors propelling medical writing industry in our country:

- Increased regulatory focus: There has been a net increase in both the number of documents as well as the quality of documents submitted to the global regulatory authorities. This has led to an increase in the cost of medical writing activities, and has added to the cost pressures the pharmaceutical industry is already facing.
- India's increased maturity, as a clinical outsourcing destination: India has been the preferred destination for clinical research related outsourcing for global pharma organizations. In the past four to five years, FSPs such as Cognizant have partnered with global pharma organizations to deliver CDM and analytics solutions leveraging a global delivery model. In the light of proven success with CDM and analytics outsourcing, global pharma organizations are looking at medical writing as the logical next choice for outsourcing to India-based service providers.
- Large, trained talent pool: India has always had a big base of medical and clinical professionals who are proficient in English. This has led to India becoming a preferred destination for clinical research related activities. The Indian service providers are keenly aware of the opportunities in this area and have increased their focus on training their experienced associates to perform more complex tasks, such as medical writing.

Cheaper, no more?

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Leaving apart the manpower tribulations, relying on cost arbitrage can become a disadvantage in the long run. As Tamhankar feels, "Medical writers work very closely to the drug molecule in determining its trends, analysis and probable outcome in the market; subsequently data confidentiality is an area of concern." Therefore, proper training and mentoring methods need to be imparted at initial stages so that thorough knowledge of the subject is passed on. After all, communication is the backbone of this industry. Thus, overemphasis on cost as a key driver needs to be reduced and focus should be shifted to quality of training at both the academic and on the job level.

Though large numbers of global pharma companies are outsourcing their medical writing to India, they seem to have had a mixed bag of experience. The primary concern is the actual higher cost compared to expected lower cost after factoring in costs involved in upfront training needs and often time and effort involved in rework in initial days. Compared to some of the other services, medical writing involves more communication on regular basis with client teams at all levels. This poses some communications problems due to culture difference and to some extent time zone differences. As the industry is just evolving, medical writers who understand project management, strict adherence to timelines and quality are very few in the market. This is quite likely to have happened due to the fact that medical writing market is much more fragmented compared to clinical monitoring leading to de-centralised control. Concerns about quality of writing have also been raised probably due to varying writing styles and interpretability at service provider's end.

Companies mainly seek quality and experience. As there are not many certifications available for medical writing, there's less priority from this perspective. That is why India tops when compared to other countries for medical writing outsourcing and the key differentiation for this advantage is English speaking qualified writers. Many international/global companies have their internal standards and processes set up with respect to style and formatting of content. Other salient and important feature is being transparent in communication. India scores high on all the above parameters. The concern is the gap in demand and supply. The demand is exceeding the supply due partly to the increasing medical writing work being outsourced to India and partly due to the education system which needs to factor in the soft skills training in addition to the pure academics.

Future seems bright

Medical writing has seen rapid growth in last two-three years of around 16 percent per annum, and this trend will continue going forward. With developed economies coming out of the recessionary trend, the market is bound to continue the positive trend. Industry stalwarts are extremely hopeful of the upcoming market trend and are hoping that the wave just catches on. "Market should easily see 100 percent growth at the minimum in next five years and will reach the same levels of current CDM outsourcing levels," says Shekhar. While the scale of outsourcing in India has not yet touched the extent of other outsourced processes such as clinical data management, it is expected that this area would mature and gain further outsourcing momentum in 2010-11.

Also the conventional US and European markets are and will be the main markets for India. US and Europe are home to world's largest pharma and biotech companies with a rich drug development pipeline. Japan is also a big market however they may lean towards China in the long run, feels Tamhankar.

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