



Cultural Dimensions

Clinical trials present a number of challenges for global pharmaceutical companies, says Gary Muddyman of Conversis, but additional issues are raised when the trials are extended to developing countries



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The global clinical trials industry is currently estimated to be worth nearly \$10 billion, and is expected to grow even further as concerns over safety and a highly competitive pharmaceutical market continue to drive demand for large clinical trials. In fact, according to a report from pharmaceutical R&D experts LeadDiscovery, global revenues from clinical trials have increased by almost 15 per cent in the last year alone (1).

Increasingly, developing countries are becoming a desirable location for much of this clinical research. To understand the reasons behind this change in policy, one simply needs to look at the complete drug development cycle. The entire process, which starts in the research labs and ends with a new drug being launched in the market, is not only time consuming but also extremely expensive.

As a result, global pharma companies based in developed countries are increasingly turning to developing countries and emerging economies around the world for their clinical trials, as reduced costs – as well as easy availability of patients with varied diseases – make developing regions a preferred destination for clinical research outsourcing.

WHAT DEVELOPING COUNTRIES DELIVER

According to the *Offshoring Times*, the cost of drug development is now estimated at \$1 billion, and clinical trials on humans – a critical phase in new drug development – can sometimes account for 40 per cent of the total cost (2). Outsourcing clinical research to developing countries can allow global pharma companies to trim costs considerably. Clinical trials in India, for instance, can often cost 50 to 60 per cent less than the average cost in the US.

Even more than cost, time is a crucial factor for pharma companies. When you consider that a patent only lasts 20 years, more than half of that time is often already gone by the time the drug is discovered, approved for clinical trials, tested and finally marketed.

The best way to speed up this process is to recruit patients for drug trials quickly, which is increasingly difficult to achieve in Western countries, since patients enrolling in clinical trials are not typically financially compensated for their participation, but simply benefit from free doctors'

consultations and treatment. As a result, developing countries – and especially those with limited medical resources of their own and/or poor social security systems – provide a good backdrop for new drug trials. Patients in these countries are often motivated to participate in these clinical trials by the prospect of gaining access to excellent physicians, as well as close medical supervision during the trial. As such, the rate of drop-outs tends to be lower than in the West and patient compliance is very good, resulting in more qualitative data.

For this reason, India is high on the list of preferred locations for new clinical trials, having emerged as a major powerhouse after a period of foreign rule and several decades during which its economy was virtually closed. As the world's largest democracy and second most populous country, India's population is predicted to overtake China by 2050.

Today, India is often referred to as one of the world's new 'tiger' economies. In GDP (purchasing power parity) terms it is the world's fourth largest economy, but in GDP per capita it is ranked only 152, reflecting both the size of the population and the relative poverty of many citizens.

CULTURAL COMPLICATIONS

Although it is popular as a location for clinical trials, India and its culture also present many challenges to the process. Companies that choose to conduct clinical trials within India and other developing countries will need to have a strong understanding of a diverse mix of languages and cultures.

Cultural differences can be difficult to detect, and may range from something as simple as the use of colour and images to something as personal as religion. Words, phrases and symbols can mean very different things in different countries, which is why a total understanding of each country and region's culture is essential in order to ensure that trials are successful in developing countries.

India, for example, has managed to preserve its own unique customs, whilst allowing traditions and ideas from other cultures to influence its development. In India, religion is a way of life. Despite the elimination of the traditional caste system, its attitudes still remain and affect all aspects of Indian

culture. The concept of fatalism stems from one of the most characteristic traits of Indian culture – that is, spirituality.

These attitudes will certainly influence – and to some extent dictate – how clinical trials are rolled out in India. For example, elders in India are revered and shown great respect: to overlook this fact could prove disastrous for foreign companies that might be more familiar with the attitudes, beliefs and behaviours of pensioners in their own country.

Likewise, in India, the head is considered the seat of the soul, and visitors are typically advised that they should never touch someone else's head, not even to pat the hair of a child. Of course, in a clinical setting, this rule may need to be relaxed or suspended, but it will still be extremely important to handle this interaction tactfully.

The list of cultural sensitivities is many and varied: beckoning for instance can be construed as an insult, whilst standing with your hands on your hips will be interpreted as an angry, aggressive posture. It would be impracticable to list all of the various rules and nuances here, yet any company that underestimates the importance of these gestures and behaviours is likely to struggle when it comes to conducting clinical trials abroad.

LOCALISATION

Any activity associated with clinical trials – from initial marketing to post-trial reporting – must be tailored to meet the needs of the host country. A basic, literal translation of key documents and fact sheets is not sufficient; it is essential that cultural differences and local sensitivities are captured as well. Without a doubt, clinicians will be accepted more successfully if the cultural, political, economic and social nuances of any given market are acknowledged.

This attention to detail is known as localisation, a term which describes the overall task of adapting products, services, websites and all other marketing materials in accordance with linguistic, cultural, technical and other locale-specific requirements of the target market.

To be truly localised, all communications must be presented to the participants in a way that demonstrates an understanding of the market in which it is being introduced. Flyers, brochures and signage must take account of local customs and preferences; they must be mindful of the cultural and social norms within the target country, and of course any translations must be accurate and comply with the legal and regulatory requirements of each market.

For example, even though the country of Moldova speaks Romanian, there are certain spelling differences and other localisation issues that make Moldova quite distinct from Romania; to overlook these differences when planning an extended drug trial could cause both legal and ethical problems.

Clinical trials in Nigeria – the most populous country in Africa and one of the world's largest oil producers – will bring similar challenges. For a start, it is worth noting that Nigerians appreciate spending time to speak on a personal level, and so any communications need to respect this preference from the outset.

Clinicians should also note that Nigeria is a hierarchical society, which means that people are respected due to their

age and position. Therefore, when meeting elders or other high-status individuals, it is common to lower the eyes or make a slight bow. Likewise, it is important to always use people's titles and to never use first names until explicitly invited to do so.

Also, due to cultural differences between Nigeria's diverse populations, various communication styles exist. For example, people from the southwest may enrich their conversation with proverbs and other sayings, while southern Nigerians will tend to be more frank and direct.

The first and most obvious factor to consider when attempting to address any of these cultural differences – whether in Nigeria or another foreign country – is language. Bulgarian and Romanian, for example, are widely perceived as difficult languages for native English speakers; Bulgarian for instance is based on the Cyrillic alphabet and contains 30 letters and has several verb tenses that don't exist in English.

When it comes to patient recruitment, linguistic and cultural issues are extremely important; when dealing with issues such as 'informed consent', there is no room for misunderstanding. In some countries, patients may be unwilling to participate in a clinical trial unless it has some perceived benefit for them. Studies have shown, for example, that reasons for non-participation in drug trials can often be traced back to negative feelings about the purpose and intent of clinical trials, as well as the language used and other cultural barriers.

CONCLUSION

Despite these challenges, the trend for conducting drug trials in developing countries is set to expand even further. South America, for example, has emerged as a location that provides particular advantages for clinical trials, as it: offers highly qualified medical personnel, many of whom have had training in the US or Europe; holds a tradition of Western medicine; and has, in many countries, well-established regulations for clinical trials and regulatory agencies that provide efficient review and approval processes.

However, as pharma companies continue to extend their global reach, some will face tough challenges in the market. Differing clinical trial demands in differing locales; differing sales and distribution channels across the globe; the coordination of multiple, simultaneous launches to market; and drug cloning and counterfeiting. The pharma industry needs to insist on accuracy of information at all times.

In order to meet these challenges, pharma companies will not only need to have a truly globalised operation in every facet of their business, but will also need to pay strict attention to the linguistic, cultural, technical and other locale-specific requirements of the countries that have agreed to host their clinical trials. ♦

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References

1. http://www.leaddiscovery.co.uk/reports/The_Clinical_Trials_Market_2006.html
2. http://www.offshoringtimes.com/Pages/2006/BPO_news926.html