BioSpectrum the business of Bio & Health Sciences

Increasing the chances of clinical trial success in India

10 September 2008 | News

Image not found or type unknown

Increasing the chances of clinical trial success in India

Drug development has shifted from being discovery constrained to development constrained.

Image not found or type unknown

Dr Anand Bidarkar
He is Vice President, SIRO Clinpharm Pvt Ltd and a well known clinical research expert and an international speaker on issues facing the Indian CRAMS and biotech sector.

The development of new discovery and development technologies has significantly accelerated the search for new drugs to combat disease. The rapid identification of potential leads has led to an increased demand for clinical development resources. For the first time in history, drug development has shifted from being discovery constrained to development constrained.

The recent safety issues with a number of drugs on the market has further aggravated the situation with regulators asking for greater evidence from clinical trials before approving new drugs as well as insisting on continued testing post approval. Constraints in clinical R&D are driving up the costs and time to market of potential new drugs.

Recent statistics indicate that over 80 percent of clinical trials in western countries are delayed for various reasons most prominent among them being slow patient enrollment and availability of trained resources. The pharmaceutical and the biotech industries globally are in the process of exploring new geographical options to overcome the bottlenecks in the

traditional areas.

India has emerged as an attractive new destination for conducting clinical trials as well as other related activities like data management, biostatistics and medical writing. All the top 10 pharmaceutical companies have an active clinical trials program in India and according to data released by the planning commission in April 2008, the volume of trials in India is greater than in China. The promise of faster trials at economical costs is attracting a large number of companies to India, while many of them benefit from the move, an increasing number fail to gain any advantage. This not only affects the plans and fortunes of the company and the CRO executing the project, if involved, but also brings a bad reputation to the industry as a whole in India.

The reasons for the failure in many cases can be traced back to the trial planning or award stage. The boom in the clinical research industry has led to mushrooming of a large number of clinical research organizations (CROs). Many of these startups have only a rudimentary knowledge and capabilities of project execution in clinical research. The lack of understanding coupled with the desperation to land business leads to unrealistic delivery commitments and costs a sure recipe for failure.

A number of pharmaceutical and biotech companies outsourcing their trials to India often get carried away by the hype of speedy patient enrollment. While it is well documented that India does offer these advantages, the quantum varies significantly and is based on multiple factors including the therapeutic area, site selection, and recruitment practices. These companies often fall for proposals that quote a high patient enrollment rate and do not delve in to details of suggested figures.

A structured feasibility is fundamental to drafting a project execution plan with the right enrollment estimates. Many companies, including CROs and biopharmaceuticals compromise this process. The tight deadlines for submission of a proposal mean that this process is accomplished in a tearing hurry with inputs taken in haste from the first available investigators. This is very often not a true representation of what is achievable once a trial is initiated. Poor feasibility ranks among the top reasons for project delays and failure.

The enrollment rate is a critical component of the proposal; it determines not only the total project duration but also the number of patients that can be sourced from a particular country as well as the cost. Companies should ensure that the feasibility is carried out in a transparent and well defined manner; there is no undue pressure to quote unrealistic enrollment rates and there is a meaningful discussion on the feasibility estimates before the award of the contract.

The second reason for the failure of projects is the overt emphasis on costs. Companies looking to base their clinical projects in India need to realize that due to the nascent stage of the industry in India many cost conserving measures used in the western countries like optimizing the monitoring frequency and project manager co-monitoring can prove to be counter productive in India. A majority of Indian sites require continuing guidance and frequent monitoring to carry out patient enrollment as per plan and more importantly ensure compliance to GCP guidelines.

The average experience of Indian CRAs is about 1.5 to 2 years and though they are quite competent in their basic understanding, many of them require a greater degree support from their project managers in comparison to the west. There is also a need for a greater degree of therapeutic area and protocol training and this should not be compromised in an effort to reduce cost.

In most instances, travel in India takes up greater duration of time than in the west for comparative distances; this can impact the time available to a CRA for site monitoring on outstation day trips and a stay over might be required. Sponsors and CROs that overlook these factors in an attempt to save costs suffer quality and enrollment issues. Before companies award projects they should carefully evaluate the project execution plan to ensure that sites and the CRAs are adequately supported. CROs that overlook these issues can often provide quotes that are up to 20-30 percent lower, taking this up at face value often means being penny wise and pound foolish.

Companies conducting their clinical trials in India also need to suitably adapt their standard operating procedures to suit the Indian conditions. This is helpful to ensure compliance at all levels as well as for the successful conduct of the project.

Lack of adequate site knowledge is another significant factor leading to project failure. Site knowledge influences compliance, budgets and eventually timelines and quality data.

Sites in India has very little experience of clinical trials, many of those that have the experience are saturated with multiple trials. Many companies also report delays due to administrative procedures at the site.

Companies should ensure that sites are evaluated in depth at the feasibility and the site qualification stage. All sites that are

included in the trial should undergo a Gap analysis and a strategy should be in place at the project commencement stage to deal with the gaps at the site level. This can go a long way in ensuring the success of the project.

While India's growth as a clinical research destination is backed by strong fundamentals, it is also critically dependent upon successful project execution in terms of timelines and quality. While the issues discussed above are not comprehensive and there are several other factors that can contribute to the fate of a project, a careful consideration of these can significantly enhance the successful conduct of a clinical trial in India. Companies operating in the clinical research space need to consider these factors carefully for the continued growth of the industry in India.

The views expressed herein are the personal views of the authors and do not necessarily represent the views of the company they represent or any of its member firms.