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Contract Research: Risk and Reward

Risk management considerations for conducting clinical trials outside ICH regions by Gadi Saarony, VP, General Manager, Parexel Consulting.

by Contributed Editorial

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With the rising costs of conducting clinical trials and the competition for trial subjects in North America and Western Europe, many pharmaceutical companies are studying the possibility of moving some of their trials to emerging markets such as India and China to reduce costs and gain access to a largely untapped pool of patients.

Although these countries offer the potential to significantly reduce costs for labor and patient recruiting, they also present a number of logistical, regulatory, and cultural challenges. Trial sponsors must carefully weigh the benefits, risks, and return on investment before committing substantial resources to conduct trials in these areas.

Clinical trials becoming an increasingly global enterprise is certainly not news, but the speed and the degree to which this transformation is occurring is stunning.

Take the United States, for example. America is increasingly the pharmaceutical industry's key profit center and what even European pharmaceutical leaders have conceded is the locus of innovation for biopharmaceutical R&D.

The Tufts Center for the Study of Drug Development reports that non-U.S. clinical trial sites comprised about 35% of sites participating in FDA-regulated research in 2005, up

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from an estimated 15% in 1997. An April 2007 study from Parexel International study, documented in Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook, found that 41% of the clinical sites signing up to conduct new FDA-regulated clinical trials in 2006 were non-U.S. trial sites. According to this study, 23,089 clinical investigators signing on to conduct such FDA-regulated studies last year were from at least 92 different countries around the world.

As the pharmaceutical industry is increasingly looking to the West for its profits, it is at the same time looking to the East and South for clinical trial participants. The Parexel study also found that among the top 10 countries supplying clinical investigators for FDA-regulated trials initiated in 2006 were Russia, Argentina, and India.

The most obvious prospective benefit of conducting trials in such countries as India or China is lower labor costs. One recent report estimated that the costs in India for scientists, physicians, and laboratory analysts are about one-fifth to one-eighth of those in the United States.

The other significant potential advantage is the availability of millions of new patients to participate in trials. Patient recruiting difficulties in North America and Western Europe are adding to the already steep cost of drug development and delaying trial initiations. For pharmaceutical companies seeking to address patient recruitment issues, the population concentrations in China and India hold tremendous promise. In addition, almost all of this population would consist of treatment-naïve subjects, who are increasingly difficult to find and recruit elsewhere.

Tempering these possible advantages are some significant drawbacks that complicate the risk/reward calculation:

Additional costs

Although labor and recruiting costs will be lower, there can be significant start-up costs to begin clinical trial operations in a new country, such as investment in facilities and infrastructure, that may be lacking. Delays because of government red tape must also be anticipated. Other factors that could increase costs include possible shortages of trained investigators, a lack of sites with clinical trial experience, and higher transportation costs to these more distant areas for trial monitoring and drug supplies.

Rough regulatory landscape

The absence of ICH standards and lack of widespread compliance with good clinical practices in these countries create questions about the acceptability of trial data by North American and European regulatory agencies. There may be bureaucratic obstacles and delays in obtaining approval for trials and permits for importing drug supplies.

Weak patent protection

Neither India nor China has a strong record of patent protection for foreign products, which may pose a significant risk to companies testing pharmaceuticals in those countries.

Cultural differences

Cultural and language barriers, especially in China, could slow down the trial process or lead to costly errors caused by miscommunication. The widespread use of traditional herbal remedies in these countries that might not be reported by trial participants or physicians could also affect trial results.

Population differences

Given that the market for ethical pharmaceuticals in China and India is relatively small,

sponsors must determine if these are the right populations for testing products that will be mostly sold to patients in North America and Europe. There may be ethnic or other differences in these populations that make trials results less than ideal for other groups of patients.

Where does that leave pharmaceutical companies looking for alternative clinical trials sites? First, India and China should not be ruled out just because there are challenges to overcome in conducting trials there. Both countries are making significant efforts to ease existing regulatory restrictions and remove other barriers that will make it more practical for foreign companies to conduct clinical trials.

Today, India seems to be ahead in recruiting clinical trials from countries based in the West, even though one recent study characterized China as possessing Asia's dominant clinical trials market. In 2006, 306 Indian clinical investigators signed FDA Form 1572s to participate in FDA-regulated clinical trials, compared with just 81 Chinese investigators, according to a new study based on data in the FDA's Bioresearch Monitoring Information System.

With Latin America already well established as an alternative location for clinical trials, those looking for new trial locations may want to consider Central and Eastern European countries such as Russia, Poland, Hungary, Romania, and the Ukraine as alternatives to India or China at the present time. Clearly, some companies are pursuing this option already — in 2006, almost as many Russian clinical investigators, 443, signed on to participate in FDA-regulated clinical trials as did UK-based investigators, 462. Investigators from Poland, Hungary, Romania, and the Ukraine were also well represented. Although the costs would be somewhat higher than emerging Asian countries, Central European and Eastern European nations have similar populations to the rest of Europe, better infrastructure, a higher availability of skilled investigators, and medical standards approaching those of Western Europe as they move toward joining the European Union. They are also much closer geographically.

Given the competitive pressures of the pharmaceutical marketplace, it makes sense for the industry to explore new ways to conduct cost-effective clinical trials. But whether the location is Asia or Eastern Europe, the key for the industry when looking at new trial locations is to test the "proof of concept" before making a major commitment to move forward. That means taking time to understand the true costs and risks of conducting trials in these new markets, developing plans to manage the risks, and then making a start-up investment to assess the concept. This approach will provide the knowledge needed to support an expansion when conditions are favorable. It is also important to line up partners with resources and experience in the target market that will help reduce start-up costs and speed up the process of beginning trials in a new country.

The bottom line for the industry is that there is tremendous potential for moving a portion of clinical trials to lower cost markets, but there are also numerous risks and challenges that must be balanced with the possible cost savings. Sponsors should move forward with caution as they explore new markets to ensure they understand all the costs before they invest.

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