Emerging Clinical Trial Locations

Market dynamics and the changing healthcare and regulatory environment

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Report Overview

Pharma and biotech companies are attempting to combat escalating R&D costs and lengthy clinical trial timelines by improving patient recruitment and the efficiency of clinical trial analysis/reporting. The biopharmaceutical market has recognized the opportunities and advantages that exist by conducting clinical trials in emerging markets. Although these markets offer a number of significant benefits over traditional clinical trial settings, there remain a variety of challenges and problems associated with conducting trials in emerging regions.

‘Emerging Clinical Trial Locations’ is a new report published by Business Insights that provides a comprehensive examination of the clinical trial landscape in emerging countries, with specific focus on China, India, Central and Eastern Europe and Latin America. It identifies the major drivers and barriers to conducting clinical trials in emerging regions and profiles key issues for consideration when selecting a trial site. For each featured region, this report provides an assessment of pharma market dynamics, the healthcare system and CRO-related infrastructure, leading CROs established within the region and the regulatory and legislative frameworks that govern the conduct of clinical trials.

“Use this report to review key emerging clinical trial locations based upon their healthcare market dynamics, CRO-related infrastructure and regulatory environments...”
Key Findings

- **Russia is one of the world leaders in patient enrolment** - the average patient recruitment rate in 2006 exceeded 4.7 patients per site per month. For some nosologies, this figure is 10 times higher than in Western Europe and the US.

- **The value of the Polish clinical trial market** for Phase I to Phase IV clinical trials and bioequivalence studies has been estimated to be worth €167m ($224m) in 2008, having increased in value by 10% from the previous year.

- **The number of clinical trials in Brazil has increased from 9 in 2000, to 1177 by 2008.** In Argentina the number of trials has risen from 6 to 801 over the same period, while Mexico has witnessed an increase from 63 to 2014.

- **The Chinese Clinical Trial Register (ChiCTR) and The Clinical Trials Registry in India (CTRI)** have helped to encourage all clinical trials in these regions to be registered before the enrolment of the first participant, and to disclose the mandatory 20 items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset.

- **China’s IP protections systems still have a number of serious flaws**, despite attempts to conform with international IP protection standards through amendments of the Patent Law and restriction of product approvals by the SFDA.

- **The Chinese CRO market was valued at $250m in 2008.** The market is expected to grow at a CAGR of 33% over the next four years to reach $791m in 2012. By that time, Chinese CROs will account for an estimated 2.3% of the global CRO market.

- **By the end of May 2009, 895 clinical trials were registered in India.** By comparison in 2006, 150 clinical trials had been approved by the Drug Controller of India (DCI).

- **India is able to offer significant cost savings compared with conducting clinical trials in western countries.** Phase I trials are approximately 50% cheaper than western equivalents, while Phase II and Phase III are 60% less expensive.

- **The costs of conducting clinical trials in Latin America vary from substantially less expensive than the US to slightly more expensive.** In recent trials, the cost per patient for Latin America has varied from savings of 50% to relative cost increases against US per patient costs.
Use this report to...

Assess the viability of key emerging clinical trial locations including China, India, Eastern Europe and Latin America by analyzing each region based on:

- Pharma market dynamics
- Drivers of CRO market growth
- Barriers to CRO market growth
- Healthcare systems and hospital resources
- Related regulation and legislation

Examine the phases of the clinical trial process with analysis of clinical trial protocols, related ethical issues, clinical trial study design and planning, patient identification and recruitment, and the influence of regulatory authorities and agencies.

Understand how new technology platforms are enhancing clinical trial effectiveness and identify the issues and challenges associated with these innovations.

Analyze the major market drivers and barriers for clinical trials in emerging markets with analysis of the key benefits and challenges associated with trial sites in emerging countries and the key considerations for site selection.
Sample 1

Chapter 3: India

Market drivers
There are considerable logistical and logical reasons why India is emerging as a country which is gaining favor as a preferred nation where clinical trials are and will be carried out.

Figure 3.21: Types of disease and types of hospitals in India

In addition lack of access to even the most basic healthcare amongst the marginalized and socially disadvantaged population leads to significant and growing inequalities in health and healthcare throughout the nation. This means that a person from the poorest quintile of the population, despite having more complex and severe health problems is six times less likely to access hospitalization than a person who comes from a more privileged background. Similarly patient compliance with the clinical trial protocol once recruited is generally higher amongst Indians than those recruited in western countries. These factors all contribute to the creation of a very large, diverse and treatment naïve population in India who are willing to participate in clinical trials in India because:

- It provides them with access to treatment they would not otherwise been able to have;
- It gives an opportunity for individuals to try new and improved drugs in the hope of getting benefits from new medicines;
- It offers hope for patients with incurable disease or who are in the critical stages of the disease.

These features of the potential patient population ensure that patient recruitment is significantly quicker with a corresponding reduction in the time taken to conduct clinical trials compared to trials conducted in western countries.

Population ethnicity and genetic diversity
With a booming population of over 1.15bn, India not only has a genetically diverse population compared with western countries but it also has a population with a very large pool of different acute and chronic disease conditions. Figure 3.21 illustrates the 3 different major disease types found in India, the variations of disease types depending on social status within the country as well as illustrating the hospital structure within India.
Chapter 4: China

Major cost savings
An additional major consideration is the substantial cost savings which can be made by conducting clinical trials in China. Although the costs associated with conducting a clinical trial in China are rising it is known that the costs associated with conducting clinical trials in China are significantly lower than the equivalent trial in a Western country. Current estimates show that preclinical chemistry ranges between 30-60% of the cost of similar analytical work carried out in western countries. Similarly toxicological and animal testing have been determined to be approximately 30% of the cost of western countries. More specific domestic estimates suggest that Phase I clinical trials in China are 15% of the price in the West, while Phase II/III trials cost 20% of the price in the West.

Increasing importance of the pharmaceutical market in China
China has emerged as one of the world’s largest and fastest growing pharmaceutical market in the world. According to IMS forecasts, China will become the seventh largest pharmaceutical market in the world in 2009 and the second largest in 2020, with a market capacity of US$220bn. This growth is attributed to the country’s rapid economic growth and the increased healthcare spending by the Chinese Government to reform the healthcare system. This has helped improve the accessibility to and desire for medical care amongst the entire population. Important additional factors include: the aging of the population and the consequent increase in age-related disorders; the urban migration of the population; and improved awareness of self-healthcare. In recognition of the importance of the Chinese pharmaceutical market multinational companies are using clinical trials as a marketing tool to help drive access to and early adoption of new treatments.

US government opens FDA offices in China
On 18th July 2007, President Bush issued an executive order creating an Interagency Working Group on Import Safety, chaired by the Health and Human Services Secretary, Michael Leavitt. This led to a strategic framework for continual improvement in import safety. A key element of this was a shift in focus towards a risk-based, prevention-focused approach designed to ensure that safety is built into products before they are exported to the US.
**Chapter 5: Latin America**

**Clinical trial regulation - Brazil**

The steps taken during the application and approval of clinical trials in Brazil are outlined below. The initial step is to translate the appropriate documents such as the clinical trial protocols into Portuguese. Up until the introduction of changes to the regulatory process introduced by ANVISA in July 2008 the initial stages in obtaining approval to conduct a clinical trial in Brazil required the sponsor or CRO to:

- Approach and get approval from local ethics committee(s) that have jurisdiction over each investigator site you plan to use;
- Approach and get approval from Brazil’s national central ethics committee;
- Approach and get approval from ANVISA;
- Go through the importation process that is necessary for any drug coming into the country.

After these new regulations take effect the sponsor or CRO will be required to:

- Approach and get approval from the local ethics committee of the “coordinator site,” which is usually the biggest, most robust site being used for the study;
- Approach the national central ethics committee and ANVISA, in parallel, followed by the importation authorities.

**Updates on clinical trial authorization (CTA) processes**

On 5th June 2008, ANVISA announced under Resolution 39 that it had approved the Regulation for Obtaining the Comunicado Especial Único for conduction of clinical trials in Brazil. These new regulations have restructured the regulatory process. Instead of having to seek and get approval from various bodies sequentially, a sponsor or CRO can now have reviews by the national Research Ethics Committees (RECs) within CONEP and approval of the proposed clinical trial sites by ANVISA conducted at the same time.
Chapter 4: Central and Eastern Europe

Russia - Concerns and issues obtained from regulatory inspections by the FDA

The FDA has been carrying out inspections of study centers in Russia since 1995. In total the FDA have carried out 49 audits on the activities of Russian clinical study centers since 1995. According to the FDA data, as of 7th January 2009, 13 FDA inspections were conducted in the Russian investigative sites during 2008, - the maximum annual number since 1995 when the first FDA inspection was conducted in Russia. Three inspections were conducted in Moscow, six – in St. Petersburg, two – in Saratov, one – in Novosibirsk, and one in Yaroslav. No inadequacies were found in a total of 25 of these FDA inspections (no action indicated (NAI)). 23 inspections resulted in VAI (Voluntary Action Indicated), i.e. objectionable conditions were found but the problems did not justify further regulatory action, and any corrective action was left to the investigator to take voluntarily. From the total of 49 inspections one case was a negative grade obtained (official action indicated (OAI)) where regulatory and/or administrative sanctions by FDA were indicated. For comparison, in the US the indices are 19%, 75% and 6%, respectively.

The classification of inspection deficiencies found by the FDA in Russia is provided in Figure 6.54. This illustrates that keeping inadequate records accounted for 44% of the total deficiencies. This corroborated the finding in regulatory inspections and independent audits of trials conducted across the CEE countries. The other deficiencies were attributed to the reluctance of the patients to give the unused medication back, missing source data as investigators enter data directly into the Code of Federal Regulations (CFRs), patients entering prior to giving their informed consent or violating a selection criteria, serious adverse events not reported in time and transcription errors.

Lack of clinical trial experience amongst hospital staff and hospital services

While the recruitment and quality in clinical trials meet very high standards in Eastern European countries there are a number of issues concerning translation problems (particularly Russian) of the study related documents and the shortage of trained and experienced local staff to manage trials in some parts of individual countries. In time these issues should resolve themselves as hospital staff gain experience and the logistics of preparing the documentation in the local language becomes easier.
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