

Booming Clinical Trials Market in India



RNCOS

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RNCOS, formed in the year 2002, aims to outsource all your business needs and serve your customers in their quest for the information. RNCOS is transforming the concept of 'Outsourcing' by adapting it into a strategic management preference to attain world-class operational excellence and competitive advantage.

RNCOS specializes in Industry intelligence and creative solutions for contemporary business segments. Our professionals study and analyze the industry and its various components, with comprehensive study of the changing market behavior. We provide corporations with an insight of the 'industry, competitive and market' necessary to compete in today's business environment. Additionally, our team focuses on the cause and effect relationship between federal and state regulations and the industries affected by regulation.

The company also works closely with small and medium sized consultancy firms, in various industry sectors. We assist in back-end research and data gathering processes. Our accuracy and data precision proves beneficial in terms of pricing and time management that assist the consultants in meeting their objectives in a cost-effective and timely manner.

About the Report

India has emerged as a strong base for clinical trials in recent times. Due to the multitude of benefits it offers, the country is fast growing as a centre for conducting clinical trials for many international companies. So RNCOS has launched its research report called “**Booming Clinical Trials Market in India**” to give first-hand information on the Indian clinical trials market. It investigates the key competitive advantages/disadvantages India has when it comes to conducting clinical trials in the country. The report also does a through study of the key factors which evaluate the country’s clinical trials, such as patient pool, patient recruitment, cost, time, government regulations, intellectual property, human resources, infrastructure and ethical issues.

India, with its huge patient base, low cost advantage, completion of clinical trials on time, improving infrastructure, and with a strong government support is witnessing a double digit growth in its clinical trials market. All major pharmaceutical companies and Clinical Research Organizations (CROs) have already started conducting their clinical trials in India, and with improving infrastructure, industry friendly regulations and trained workforce, the growth is only likely to increase in future.

However, to achieve its goal of becoming a global hub of clinical trials, the country will have to overcome challenges like unethical trials, delay in trial approval, inappropriate protection of clinical data, and lack of Good Clinical Practice (GCP) certified sites and investigators.

Key Findings

- Indian clinical trials market is expected to grow at a CAGR of nearly 36% between 2006 and 2011 to register revenues worth US\$ 546 Million in future.
- One of the biggest advantages of conducting clinical trials in India is the availability of a large patient pool that can be recruited at much shorter time then it takes to recruit patients in the west.
- India by 2011 will be conducting more than 15% of the total global clinical trials.
- India presently lacks in GCP trained investigators (which are less than 1000). Their demand is projected to reach between 3000 and 6000 by 2010.

- India does not provide “Data Exclusivity” in clinical trials unlike the US and EU members.
- The salaries of a clinical data specialist and Medical writer in India are around 15% and 9% respectively of what they get in the US.
- The clinical trials market will drive the growth of the Diagnostics and Pathology Industry in India.

Key Issues and Facts Analyzed

- Evaluation of past, current and future market trends.
- Discussion about the factors driving the clinical research market.
- An analysis of the opportunities created by the market.
- A review on the government regulations on the market.
- An analysis of the major challenges faced by the market.

Key Players Analyzed

This section provides the overview, key facts financial information of prominent players in the Indian clinical trials market like Quintiles, Ranbaxy, Dr Reddy’s Laboratories, Roche, Pfizer etc.

Research Methodology Used

Information Sources

Information has been sourced from books, newspapers, trade journals, and white papers, industry portals, government agencies, trade associations, monitoring industry news and developments, and through access to more than 3000 paid databases.

Analysis Methods

The analysis methods include ratio analysis, historical trend analysis, linear regression analysis using software tools, judgmental forecasting, and cause and effect analysis.

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2. Global Clinical Trials Market

2.3.3 Latin America

The Latin American Clinical research outsourcing market is also quite promising the market is driven by factors such as proximity to the US and improving healthcare Infrastructure in many Latin American countries particularly in Brazil and Argentina. The Clinical RESEARCH Outsourcing market in Latin America was valued at 0.57 Billion in 2005, although the market is very small it is a potentially emerging market in the future.

The hottest destinations for conducting clinical trials in Latin America are Brazil, Argentina, Mexico and perhaps surprisingly, Columbia, which is expected to undergo a period of rapid growth over the next few years, along with Peru and Chile.

The total population in the Latin American region was estimated at 555 Million and the main therapeutic areas in research were diabetes, oncology, respiratory, pain and inflammation, infectious diseases and pediatrics

Table 2-4: Latin America - Characteristics of Clinical Research Outsourcing Market, 2005

Market Characteristics	
Total Market Size (in Billion US\$)	0.57
Population (in Million)	555
Main Therapeutic Areas	Diabetes, Oncology, Respiratory, Pain and Inflammation, Infectious diseases, Pediatrics

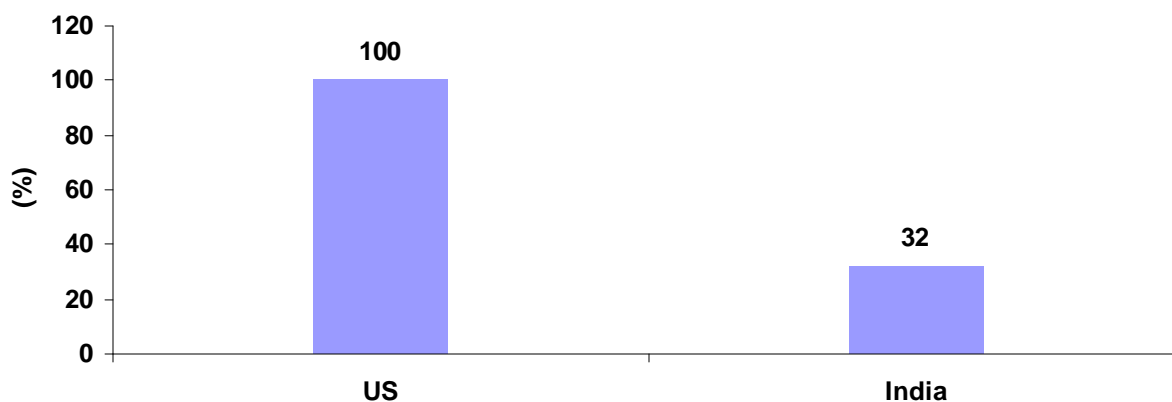
Source: [REDACTED]

Note: [REDACTED]

3.2.2.3 Patient Availability & Recruitment

Availability of eligible patients and their recruitment is a major bottleneck in the timely completion of clinical trials. Statistics indicate that only 6% of eligible patients in the US actually participate in clinical trials. As a result, 87% of trials in the US are behind in their recruitment and enrollment. In Contrast the recruitment times in India are much faster, it is estimated that patient recruitment for clinical trials in India is more then 3 folds faster with companies saving 68% of the time to recruit patients in India as compared to the US.

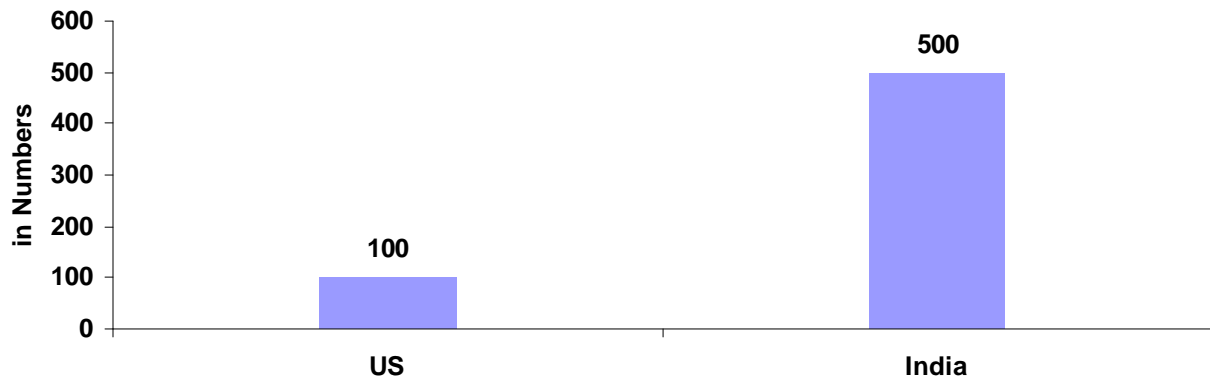
Figure 3-20: India & US - Recruitment Time for Patients Participating in Clinical Trials (%)



Source: [REDACTED]

The Number of patients per site remains high in India as compared to the US and Western European countries. This can be attributed to a faster and easier patient recruitment in India; take for example the case where, Germany's Mucos Pharma asked Siro Clinpharm in Mumbai to help with a clinical trial for a drug to treat head and neck cancer. To find 650 out of 750 volunteers for the trial, Siro Clinpharm had to go to only five hospitals in India and found the volunteers within 18 months. To find the remaining 100 volunteers in Europe, Mucos Pharma spent nearly twice as much time and recruited patients from 22 hospitals.

Figure 3-21: India & US - Patient Concentration per Site (in Numbers)



Source: [REDACTED]

One of the major reasons, why sites can enroll a large number of patients in a short time is the fact that India has a large number of patients with unmet medical needs and by enrolling in clinical trials these patients are able to access free medical care, tests and drugs, which they otherwise are unable to afford.

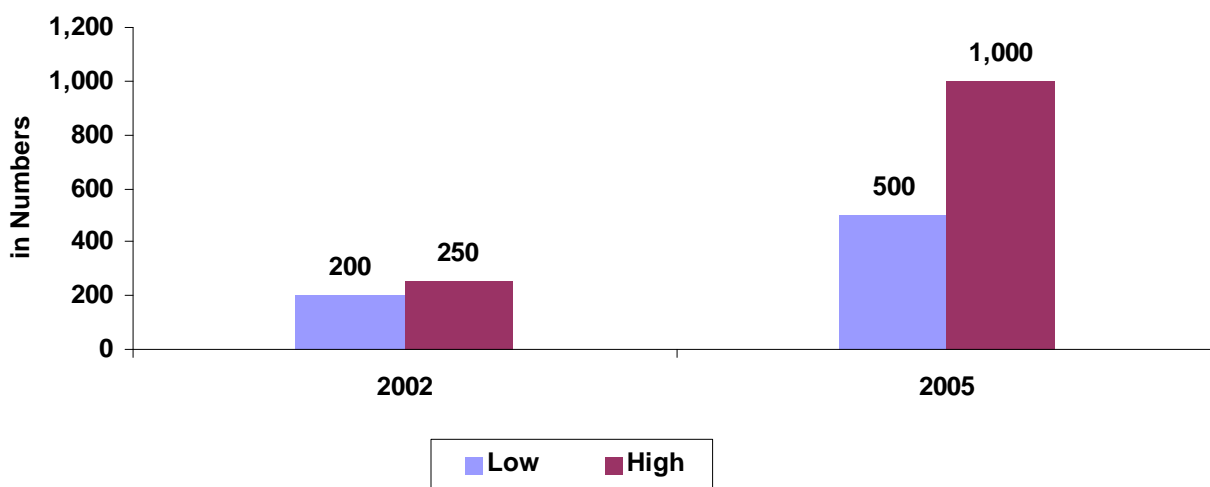
3.2.5 Infrastructure & Expertise

3.2.5.1 Trained Investigators

An investigator is a medical professional, usually a physician, under whose direction an investigational drug is administered to a human volunteer. A principal investigator is responsible for the overall conduct of the clinical trial at his/her site.

The number of GCP trained investigators is below the requirement. In 2002, India had around 200-250 GCP trained investigators, which increased to around 500-1000 in 2005. These small numbers imply that many potential clinical investigators do not have the experience of conducting GCP trials. Thus, adequate training has to be provided by the industry if it wants to increase the number of trained investigators, so that more GCP studies can be conducted in India.

Figure 3-46: India - Number of GCP Trained Investigators (2002 & 2005)



Source: [REDACTED]

With expansion of clinical trials market in India, It is expected that there would arise a need of around 3000 to 6000 investigators to conduct global clinical trials by 2010. The US market, in comparison to India, had 50,000 GCP trained investigators in 2005. This shows that there is still a lot to be done in India to take the clinical trials market to new heights.

3.2.6 Opportunities

3.2.6.3 Demand for Clinical Training Institutes

Despite the availability of infrastructure and manpower, clinical research is still in its infancy in India. This is calling for the development of capacities and capabilities in terms of infrastructure, regulatory structure, and formulation of specialized pool of research investigators.

As said above, there would be a demand for around 50,000 trained clinical research professionals. Thus, there is a very bright future for institutes which can provide professional clinical research training in order to meet the growing demands of skilled manpower by the industry.

As a result of the increasing demand, various institutions providing clinical research have already opened up in India providing both full-time and part-time courses in clinical research. An example is Institute of Clinical Research in India (ICRI) which, through its collaboration with Cranfield University, provides both M.Sc and management courses in clinical research. Many foreign companies are making inroads into India to tap this market. For example, ClinfoSource, a provider of e-training for clinical trials, is scouting for pharma companies and universities for partnerships. According to the company, the course content addresses FDA regulations, ICH GCP guidelines, ethical considerations and practical applications.

3.2.7 Challenges

3.2.7.3 Intellectual Property Protection

Indian clinical trials market has a poor history of intellectual property protection. Although India's IPR regime has improved immensely in recent times (like with the adoption of the product patents act in 2005) however, a large proportion of the US and European drug firms are hesitant to do business in India due to perceived threats to their intellectual property.

There remains a risk of counterfeit drugs through the use of a foreign drug company's clinical data by local companies. An innovator must provide confidential details (such as chemistry, manufacturing and analysis) to the regulatory authorities of the country to which it wishes to

bring its product. And as India is full of generic manufacturers who can make identical copies of a branded drug through reverse engineering, international firms will be hesitant to do business in India for quite some time.

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<http://www.rncos.com/Report/IM0102.htm>

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[Opportunities in Medical Tourism in India \(2007\)](#)

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