



Clinical Trials Market - India

July 2009

Executive Summary

Market

- Revenues from clinical trials were USD XX mn in 20--; Expected to reach USD YY mn by 20--
- Total A clinical trials were conducted in India in 20--
- India's share in global clinical trial market in 20 -- was a% and is likely to reach b% in 20--
- c% of clinical trials conducted in India in 20 -- were Phase III trials

Drivers & Challenges

Drivers:

- Cost competitiveness
- Disease prevalence in India
- Sound medical infrastructure
- International quality standards

Challenges:

- Shortage of research professionals
- Lack of data exclusivity
- Delays in trial approval
- Challenges of unethical trials

Government Regulations

- Clinical trial can be initiated only after approval from Drugs Controller General of India (DCGI)
- Clinical trials are governed by Scheduled Y of Drugs and Cosmetics act and Indian Council of Medical Research (ICMR) guidelines
- Registration of trials involving humans has been made mandatory starting in June 2009 on the Clinical Trials Registry-India (CTRI) website

Competition

- International pharmaceuticals companies are the major sponsors of clinical trials
- Many Indian and foreign pharmaceutical companies have tied up with other specialist clinical research companies for development of new drugs
- Internationally certified central laboratories and research institutes also conduct clinical trials in India
- Some of the leading CROs in India include Company 1, Company 2, Company 3



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- Introduction
 - Overview
 - Drivers & Challenges
 - Government Regulations
 - Competition
 - PE Investments
 - Key Developments

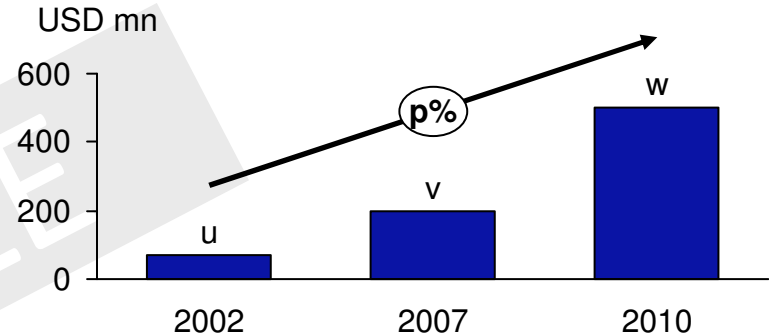


India is fast emerging as the most preferred destination for clinical trials

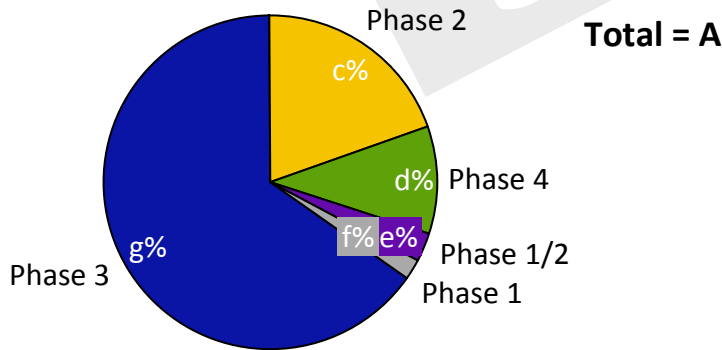
Overview

- Clinical trial research constitutes 2/3rd of R&D spending
- Low cost and speedy trials have made India a preferred destination for clinical trials
- India's share in global clinical trials market is expected to increase from a% in 20-- to b% in 20--

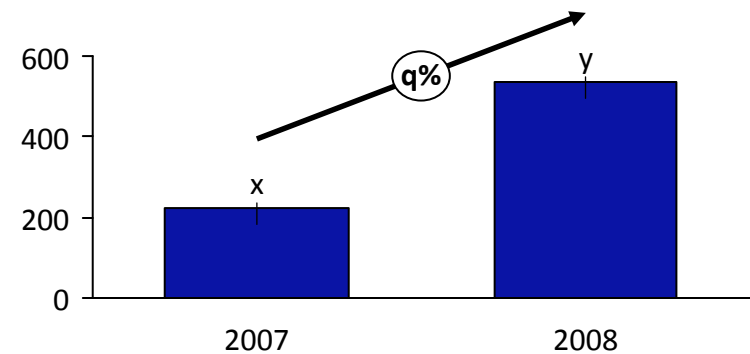
Revenues from Clinical Trials



Clinical trials phase wise India -2008







Number of Clinical Trials







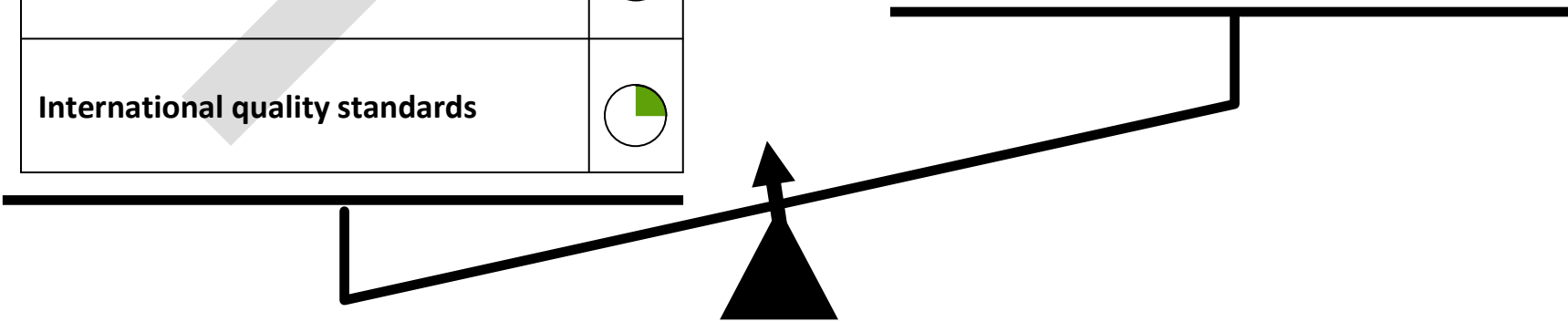
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Drivers & Challenges

Drivers	
Cost competitiveness	
Vast patient population with diverse number of diseases	
Sound medical infrastructure	
International quality standards	

Challenges	
Shortage of research professionals	
Lack of data exclusivity	
Delays in trial approval	
Challenges of unethical trials	



Trials can be initiated only after approval from Drugs Controller General of India (DCGI)

For Approval purpose clinical trials are classified into two types

Category A

- Includes clinical trials whose protocols have been approved by countries like AA, BB and CC
- Regulatory (DCGI) approval time is within x-y weeks

Category B

- Includes clinical trials whose protocols have been approved in other countries which are not listed in category A
- Regulatory (DCGI) turnaround time will be u-v weeks

- India has well-defined guidelines for carrying out various phases of clinical trials
- These guidelines are in line with the global guidelines on clinical research (ICH-GCP)
- First time exposure of new drugs (of other countries) in Indian healthy volunteers is not allowed as per the regulations in India
- Clinical research organizations (CROs) have to obtain 'no objection' letter from Drugs Controller General of India (DCGI) and import license to import the research drug
- In case samples are exported outside the country an export license is required from Directorate General of Foreign Trade (DGFT)
- Registration of trials involving humans has been made mandatory starting in June 2009 on the Clinical Trials Registry-India (CTRI) website



Clinical Research Organizations (1/7)

Company	Locations	Business Description
Company 1	Bangalore, Manipal and Mangalore	<ul style="list-style-type: none"> • Provides end-to-end services for Phase I - IV clinical research, including Clinical Trial Management, Clinical Data Management, PK/PD services and Central Lab
Company 2	Pune and Bangalore	<ul style="list-style-type: none"> • Offers services in drug discovery, medicinal chemistry, toxicology studies • It entered into Joint venture with A subsidiary, B in September 2008 • It has alliances for neglected diseases with Geneva based Drugs for Neglected Diseases initiative (DNDi), for tropical disease kala azar and anti-malarial drugs with Genzyme Corp and Medicines
Company 3	Bangalore	<ul style="list-style-type: none"> • Offers lead generation and optimization and early computational chemistry aided and design, mining and screening of novel chemical entities. • Has worked on collaborative discovery programmes with Novo Nordisk on Diabetes and discovery services with Rheosciences, Denmark • Has a pipeline of X discovery programs at various stages
Company 4	Hyderabad	<ul style="list-style-type: none"> • Works in product chemistry, organic synthesis, chiral synthesis technology • Company is focusing on high-end contract research, custom synthesis of complex chemicals and difficult to manufacture intermediates and APIs

SAMPLE

Source:



Thank you for the attention

The Clinical Trials market report is a part of Research on Healthcare Industry Series. For more detailed information or customized research requirements please contact:

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