

Emerging Clinical Sites: India and China

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Overview

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Outsourcing Trends in the Pharmaceutical Industry

- In the past, US and European pharmaceutical companies have lagged in outsourcing R&D to other countries
- Currently R&D outsourcing is steadily growing and it is expected to increase at a rate of approximately 14% annually. ⁽¹⁾



Reasons for outsourcing



1. Upcoming patent expiration

- Over \$150 billion dollars worth of products will lose patent protection over the next decade ⁽¹⁾

2. Pricing Pressure

- From 2003 to 2007 pricing strains pared ~ \$9 billion in US dollars ⁽²⁾

3. A slowing pipeline of new drugs

- FDA regulators approved only 21 drugs in 2003, compared to 56 in 1996 ⁽³⁾

4. High R&D costs

- In 2007, global pharmaceutical companies spent 58.8 billion on R&D ⁽⁴⁾
- The cost of developing a new medication has soared from 54 million in 1976 to 1.3 billion in 2005 ⁽⁵⁾

5. Better regulatory environment in developing countries

1. Global Generics Guide: Part 2."Datamonitor. June 2006.

2. Outsourcing among Pharmaceutical and Biotech Firms. A.T Kearney. 2004.

3. FDA. Center for Drug Evaluation and Research.

4. Pharmaceutical Industry Profile 2008. PHRMA.

5. Tufts Center for the Study of Drug Development

The most outsourced activity: **Clinical trials**

- By moving clinical trials offshore, pharmaceutical companies can reduce drug development cost from US\$1 billion to \$250 million ⁽²⁾
- Human resources
86% of clinical trials in US fail to recruit subjects on time ⁽³⁾

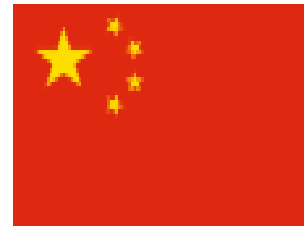
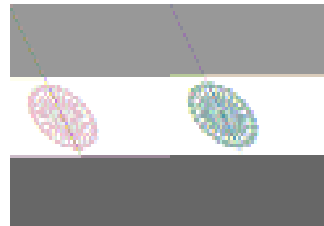
1. Kermani F, Chin JY. Entering a New Era of Clinical trial Outsourcing. Drug Development. 2006

2. Vicki Brower. Going global in R&D. Embo Reports. European Molecular Biology Organization. 2004

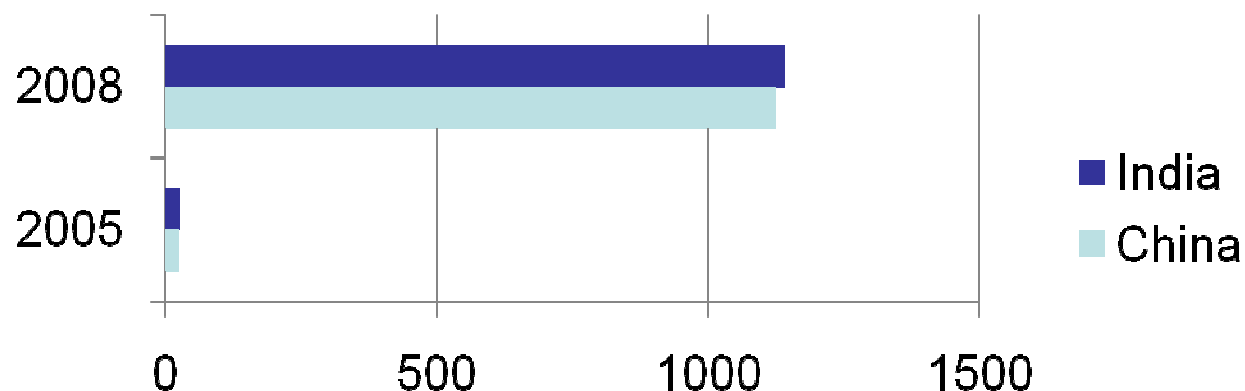
3. Clinical Trials Today. CenterWatch.

Outsourcing destinations: **India and China**

- India and China are currently the most attractive locations for clinical trial conduct outside of the US ⁽¹⁾



- The number of clinical trials conducted in India and China is accelerating. Currently there are 1138 trials in India and 1122 in China ⁽²⁾, compared to three years ago ⁽²⁾



1. Bailey W, Cruickshank C, Sharma N. Make Your Move: Taking Clinical Trials to the Best Location. A. T. Kearney.

2. International Clinical Trials Registry Platforms Search Portal. WTO.

India and China: Attractions

1. Population

- Large: 1.3 billion and 1.1 billion people in China and India respectively
- Wide spectrum of diseases (cerebrovascular disease, respiratory infections, cancer, etc.) ^(1, 2)
- Easily accessible
- Often treatment naïve



India and China: Attractions

2. Costs

- Low labor and infrastructure costs
 - Direct cost savings could run as high as 60%-80% on salaries and 60-70% in cost per patient ⁽¹⁾

3. Growing R&D capabilities and resources

- Numerous sites suitable for clinical trials
 - 70-80 sites in India ⁽²⁾, 250 sites in China ⁽³⁾

1. Looking Eastward: Tapping China and India to Reinvigorate the Global Biopharmaceutical Industry. BCG Report.

2. Lamb M, Setley S. Clinical Trials Logistics: The Trial of Emerging Markets. Clinical Trial Service. 2005.

3. Gambrill S. Chinese regulators, Pharma Industry Address Ethics Committee Challenges. Clinical Trials Today. 2008.

India and China: Attractions

4. Better regulatory environment

India-2005 legislation for the enforcement of IP , amendment of Schedule-Y of the Indian Drugs and Cosmetic Rules Act

China-1999-issues GCP, 2001 joins WTO, 2002-laws to improve IP

5. Potential commercial payoff

It is predicted that Chinese and Indian people will spend more than 50 million on pharmaceuticals by 2015 ⁽¹⁾



India and China: Challenges

1. IP Protection:

India and China have long history of not having IP laws

2. Lengthy Approval Process:

In China the approval process takes between 9-12 months and between 3 to 4 months in India ⁽¹⁾, compared to 30 days in the US ⁽²⁾

3. Language Barrier:

In China most people are not fluent nor proficient in English

4. Ethical Issues:

There are reports that some clinical trials conducted in India and China may be unethical or illegal

1. Looking Eastward: Tapping China and India to Reinvigorate the Global Biopharmaceutical Industry. BCG Report.

2. [Drug Approval Application Process](http://www.fda.gov/cder/regulatory/applications/). FDA. www.fda.gov/cder/regulatory/applications/ - 19k

Ways to mitigate challenges and speed up clinical trials: CROs

- Partnership with CROs
 1. CROs have knowledge on local regulations, testing facilities, expertise on running clinical trials, and a skilled workforce
 2. According to a study done by the Tufts Center for Drug Development, pharmaceutical companies who partnered with CROs tended to complete projects faster, while maintaining quality comparable to submissions involving minimal use of CROs. ⁽¹⁾

Outlook

- The clinical research market in India and China has a bright future as:
 1. The market value increases
 2. We become more experienced
 3. We continue to create valuable partnerships across industries