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Oxygen Healthcare helps British companies break new frontiers in outsourcing drug development

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India has the potential to be the premier destination for conducting global clinical trials for a number of large drug companies. Oxygen Healthcare research suggests that patient recruitment rather than cost will be the driving force. Following the boom in IT services, India is gearing up to open up a new front in outsourcing.

At present it is estimated that 1% of the global clinical trials are conducted in India. These are mostly for bioequivalence studies to develop generic products.

Shifts in India's legal and patent policies allied with other factors such as foreign and local investment, changing perceptions on doing business in India, emerging Indian Pharmaceutical companies on the international scene and returning experienced expatriates suggest that figure may increase to 10% over the next five years.

India has a large patient pool with a population of over a billion heterogeneous people; within these there are many untreated patients (in the tens of millions) for diseases that are also prevalent in the western world such as asthma, diabetes, cardiovascular diseases, cancer and Alzheimer's disease.

One of the key factors driving Western companies to develop drugs in India is patient recruitment.

For rare diseases such as mouth cancer, it could take a company about three years to recruit the appropriate number of patients for a large trial, however in India the prevalence of these diseases is much higher due to the amount of tobacco chewed thus recruiting patients for these types of indications could be done in a third of the time. Reducing the time to develop a drug by even six months could mean a billion pounds of extra revenue if the compound being developed became a blockbuster drug.

Oxygen Healthcare believe that for larger drug companies the cost saving of developing a drug in India would be a tertiary objective, acceptability of the data by regulatory authorities such as the FDA and EMEA are primary followed by faster development time (e.g. quick patient recruitment).

However, the costs saving of developing drugs in India are significant. Overall, the cost of conducting a trial in India is estimated to cost less than half of the total cost in the UK.

India has 162 medical colleges that produce 17,000 medical graduates every year who are fluent in English. In addition

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many highly trained medical doctors that have trained and worked abroad have started to return to India. Thus they understand the international requirements and have the capacity to undertake large clinical trials.

Many multi-nationals have developed an "Indian Strategy" and the rest are unlikely to be left behind. New partnerships, alliances, investments are being developed at a dizzying pace.

For example:

- Astra Zeneca opened \$10m research facility in Bangalore and committed \$40m to a Tuberculosis treatment
- Pfizer has committed \$1.5m for an academy for clinical research and training in Mumbai
- GSK has entered a research partnership with Ranbaxy labs to develop drugs
- Novo Nordisk will outsource \$10.5m worth of clinical trials to Dr Reddys for its new diabetes drug.

Leading industrialists are investing in Life Sciences and Clinical Trials divisions (Reliance), leading Biotech's are going public (Biocon) and existing smaller players are investing heavily and taken on an international feel, NRI's are returning to India and investing in new facilities in order to specifically serve the Indian market.

Sunil Shah of Oxygen Healthcare says: "The opportunities in India for the drug development industry in the next 5 years are comparable to the impact on the technology industry over the last 5 years. Companies large and small need to be thinking now about their strategy, they can be sure that their competitors are!"

About Oxygen Healthcare Ltd

Oxygen Healthcare is a boutique strategic consulting firm based in Cambridge.

For more information contact:

Sunil Shah
+44 (0) 7887 574787

 [Email to author](#)

reference: <http://www.oxygenhealthcare.com>

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