

Clinical Trials in India just got Cheaper

By Kirsty Barnes

28/02/2007 - **India's budget finance minister has today announced a tax exemption on all services carried out by its contract research and clinical trials industry – a saving of 12.24 per cent.**

The exemption proposal has been already approved by parliament and will come into effect at the start of [India's](#) financial year on 1 April 2007.

The decision removes a previous stumbling block that international pharmaceutical sponsors faced when considering contract research organisations (CROs) in India and is designed to give a boost to this budding market.

"This is very positive news for India's contract research industry and will definitely have an impact in the decision making process for many pharmaceutical companies," Dr Umakanta Sahoo, managing director of [Chiltern International](#) in India told Outsourcing-Pharma.com.

"This saving of 12.24 per cent is a big amount – a saving that will now be passed onto clients."

Cost-savings are a significant draw card for many pharmaceutical companies when deciding to outsource clinical research to countries in emerging markets such as India and Latin America.

In the last 10 years, skyrocketing costs of R&D have led to a growth explosion in the clinical services industry as pharma companies scramble to cut costs.

The average [cost](#) of running a US-based [clinical trial](#) per patient is \$5,404 for Phase I, \$6,538 for Phase II and \$7,635 for Phase III. According to an analysis last year by Rabo India Finance, conducting a clinical trial in a lower-cost destination such as India, for example, can cost up to 60 per cent less than in the US.

However, while quickly gaining momentum, India's much hyped clinical research industry is still yet to really take off. Since its introduction of patent protection laws in 2005, the industry has been growing three digits, however, this growth has not been as fast as many have predicted.

A report by analysts at McKinsey estimated that clinical research in India will be a \$1bn (€800,000m) industry by 2010, although many analysts expect it will be closer to half that.

It is hoped that this move by the Indian government will give the industry the kick that it needs to live up to expectations.

"To make India a preferred destination for drug testing, I propose to exempt clinical trial of new drugs from service tax," says an extract from article 157 of the Government of India's Budget for the year 2007-08.

"Also, total exemption from service tax is being provided to technical testing and analysis for testing of new drugs, vaccines and herbal remedies, on human participants by a CRO approved to conduct clinical trials by the Drugs Controller General of India."

"This exemption from Government of India will attract more clinical trial outsourcing as the pharmaceutical sponsors will heavily benefit on their cash outflows on account of their expenses on CRO fees and other variable pass through expenses," said India's budget finance minister Palaniappan Chidambaram.

The contract research industry in India is only beginning to sprout its wings and until now

there has been much domestic debate as to whether this sector should be subject to the same service tax that other industries in the country face. In the 2005-06 budget, CROs were required to pay 10 per cent service tax. In the 2006-07 budget, this tax was raised to the current level of 12.24 per cent, which is much higher than similar service taxes of around 4 per cent in other countries such as the UK.

Currently, CROs are having to ask sponsors for reimbursement of this service tax and paying it to the government. Hence today's announcement comes as a welcome surprise to the contract research industry, which has been heavily petitioning the government for the exemption in a boost international business.

"The Scientific Committee and the Ministry of Health in India have both been very supportive of this decision and this sends out very positive signals to international firms that India is taking the continued development of this industry very seriously," said Sahoo

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