



dian population and its low cost label are the major attractions as a clinical trial destination.

The Institute of Clinical Research (India) dean and a former professor at All India Institute of Medical Sciences, S K Gupta, puts India's current clinical trial business at \$700 million (Rs 70 crore).

According to him, introduction of phase I trials will see India's clinical trial business touch \$2 billion (about Rs 8,600 crore) by 2010.

"Clinical trial business has seen tremendous growth since India started participating in phase II and phase III clinical trials. Already there are about 400 ongoing clinical trial programmes in the country. India is now mature enough to permit phase I trials also", Gupta said.

The multinational pharmaceutical companies are eagerly awaiting the outcome of the consultations.

"When it comes to phase I trials, cost is not the main cri-

teria. Collected data, reliability and confidentiality become critical. We are confident that Indian centres can deliver ICH GCP (international standards) compliant results for phase I trials as we have a number of excellent centres with all the required technical expertise matching the best in the world," said Ranjit Shahani, vice-chairman and managing director, Novartis India.

However, representatives of the public health organisations, who were part of the recent consultation, said India is yet to have capabilities to effectively monitor phase I trials. "A wide ranging public debate is essential before government can amend the laws to allow phase I trials.

"Legal protection to the clinical trial subjects (patients or health volunteers who undergo the trials) should be in place. Liabilities of the company and its responsibilities towards the patient should be spelled out," a representative said.