

## Panel Discussion 3

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#### Making India a Clinical Trials Hub

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TR Bhoopathy, Dr Aravinda Babu, Dr Ajoy Kumar, Aluri Srinivas Rao, Utkarsh Palnitkar and Dr Malathi Lakshmi Kumaran.

How to take forward regulatory reforms and harmonization of standards for global play? How to boost clinical trials infrastructure and human resources? How about a self-regulation policy for ethical clinical trials? How to enlarge the CRO pipeline for Indian companies? Utkarsh Palnitkar, director, life sciences, Ernst & Young India, moderated this session to figure out how services opportunity needs to be tapped. Dr Aravinda Babu, head, operations, WellQuest, Dr Ajoy Kumar, COO, Neeman Asia, TR Bhoopathy, managing director, Magene Lifesciences, Dr Malathi Lakshmi Kumaran, IPR consultant and Aluri Srinivas Rao, director, ICICI Ventures were the panelists.

"There is a need for remedial mechanisms for CROs in regulatory aspects, ethics committees and patient protection."

- Utkarsh Palnitkar, director, life sciences, Ernst & Young India

"Data confidentiality is an important issue that needs attention. The sponsors from the US and some of the European countries are major sources of revenue as about 10 percent of the revenue is generated from the local sponsors. The companies can build a scaleable business by entering strategic alliances with big pharmaceutical companies. We should have presence in the US and Europe."

- Dr Aravinda Babu, head, operations, WellQuest

"About 90,000 trials are being conducted globally. There is a huge opportunity before the Indian CROs. But we only have about 500 trained and skilled people capable of doing the trial related processes. The risks and rewards in this sector are growing and there is a need for a transnational center. One should understand that CROs are concerned about the benefits to the patients and increase the level of standard of medicine."

- Dr Ajoy Kumar, COO, Neeman Asia

"Trained and skilled people are key factors. We need to take up the issue of education and training. Clinical research is a potential future for India as many reports pointed out that it would be a \$1 billion market by 2010."

- TR Bhoopathy, managing director, Magene Lifesciences

"We need a strong IP and specialized courts to take up cases related to IPR. Besides we have to look at addressing the issues such as protection for volunteers and insurance cover."

- Dr Malathi Lakshmi Kumaran, IPR consultant

"Funding is not an issue for the CRO sector. The spark should come from the industry. The companies are doing well with the first mover advantage and are also looking at couple of successful models."

- Aluri Srinivas Rao, director, ICICI Ventures

"There is need for a database of patients and diseases, which are more prevalent in India."

- Dr PK Seth, CEO, Lucknow Biotech Park