India Pharma Summit 2010

November 30, 2010, Mumbai, India

Session II: Clinical Research

Moderator: Tapan Ray

Opening remarks:

According to the Associated Chambers of Commerce and Industry (ASSOCHAM), India is poised to grab clinical trials business valued at approximately US$ 1 billion by the end of the year, up from US$ 200 million last year, making India one of the world's most preferred destinations for clinical trials.

Drug companies are drawn to India for several reasons:

1. A technically competent workforce,
2. Patient availability and huge pool of naïve patients
3. Low costs and a friendly drug-control system.

However, some serious concerns are being raised because of a lack of regulation for private trials and the uninform application of requirements for informed patients' consent and improper ethics review.

Quite a number of criteria, as stated above, favor India to establish itself as a global hub for clinical research. Besides, availability of a number of government-funded medical and pharmaceutical institutions with state-of-the-art facilities could be very useful for multi-centered clinical trials in the country. Ready availability of English speaking and well-trained and qualified manpower is yet another important factor.

Moreover, the cost to conduct a trial in India is lower by almost 50% - 75% than in the United States or in the EU. In addition, a good communication link favors quick recruitment of patients and faster regulatory approvals. Thus, clinical studies in India could be concluded faster, offering a sharp cutting for effective competition.

Due to all these reasons, India is gradually attracting collaborative contract proposals for conducting clinical trials in the country and many global Clinical Research Organizations (CRO) have already started establishing their set up in India.

With this I will start today's panel discussion

Some of the issues discussed are as follows:

1. Does India have adequate infrastructure and human capital for a global scale clinical trial in India?
2. What are the Operational Issues for Conducting Clinical Trials in India?
3. Are there any Ethical issues in clinical research?
4. What are the key regulatory issues in conducting Clinical Trials in India?
5. Should Phase I and II trials be allowed in India for all?
6. How does India compare with China in attracting Clinical Trials in India?
7. Will the absence of RDP play any significant role in making India a hub for global clinical trials?
8. How can India be more competitive in the area of CR?