BioSpectrum the business of Bio & Health Sciences ASIA EDITION

India's CRO industry raises concerns at workshop

July 16, 2012 | News | By BioSpectrum Bureau

India's CRO industry raises concerns at workshop



New Delhi: At a media workshop on the clinical research industry (CRO) held at Delhi on July 13, 2012, industry experts urged the media to report in a balanced way. The workshop attended by the journalists from mainstream media, were briefed by the industry on its functioning and related issues. Organized by the Indian Society for Clinical Research (ISCR), an association of clinical research professionals, and Quintiles India, it included the sessions focused on patient safety, patient rights and the importance and need for clinical research for drug development in India.Ã?Â

Putting forth their views on behalf of the industry were Dr Krathish Bopanna, president, Indian Society for Clinical Research; Dr Arun D Bhatt, executive committee member, Indian Society for Clinical Research, Dr Shoibal Mukherjee, chief medical officer, Quintiles and Dr Shamsher Divedi, VIMHANS.

Dr Shoibal Mukherjee highlighted various misconceptions about the overall trial deaths. Dr Mukherjee explained, "The negative event monitoring includes the non-serious event as well. That is apart from serious events where data is sent to Drug Controller General of India (DGCI) in 14 days.

Parliamentary committee has confirmed that the drug related death cannot be necessarily confirmed at the end of the trials." He also pointed towards the fact that there are five times more recruitment by the non-pharma sponsors as compared to pharmaceutical companies. These include NGOs and global funding agencies involved in huge trials.

Dr Mukherjee found the use of term "illegal trials" as misleading. He said, "It is not right to call a trial illegal technically. The reason is that most of the times only a site or two in one particular location might have issues, but that in no way can be that clinical trial conducted a global scale can be termed illegal."

Dr Arun Bhatt put the Indian clinical research market at an estimated $300 million. He cited evolved healthcare system, manpower skills and the 20 percent of global disease burden in India as the reasons why India is considered for trials by clients. Calling the reports mentioning India as a hub of clinical research wrong, Dr Bhat added further that India holds only two percent share in the globally held clinical trials. However, he also talked about the decreasing Indian share. "India has to solve its regulatory issues and Drug Controller General of India (DCGI) has to be strengthened," added Dr Bhat.

Dr Shamsher Divedi said the gap between the industry and the people needs to be bridged. Talking about the need for harsher laws, Dr Divedi opined, "The deliberate acts of mismanagement on part of doctors need to be severely punished. There must be deterrents for the people who wrongly mould undesired people for trials as per their convenience. However it is to be noted that only 10 percent of doctors are involved in clinical trials."

Explaining the process of clinical trials, Dr Krathish Bopanna highlighted the importance of clinical trials to achieve the drug development. He said, "The drug development generally takes 800 million to 1.7 billion. Out of 5,000 to 10,000 targets, only 250-300 generally pass through screening into preclinical trials. After that the clinical trilas hardly have five left and finally it is one molecule that is either rejected or accepted by FDA. So, the trials process can hardly be considered simple."

The deliberations at the workshop concluded that the checks and balance need to be strengthened. Experts believed that while it is necessary to delist the doctors, institutes and organizations if they are found guilty of any wrong doings, it is also not fair to demonize the whole industry.