

## **BREAKFAST ROUND-TABLE SERIES SESSION – VII**

### **Serious Adverse Events – Responsibility of Participants in a Clinical Trial**

**April 10, 2012  
09.00 a.m. – 10.30 a.m.**

With the constant evolution in the law, the regulatory mechanism and guidelines on payment of compensation to victims of clinical trials in the event of a SAE or death, participants in a clinical trial need to understand the full ramifications. While the roles of the participants are defined, it is not an easy task to distinctly demarcate when it comes to assigning liabilities in the event of a SAE or death. Several questions usually emerge - what is the potential level of exposure for the subjects and the other participants? In the event of a SAE or death of a subject, what are the legal actions that the participants can face? In 2011, the Central Drugs Standard Control Organization proposed certain amendments to the Drugs and Cosmetics Rules, 1945 regarding compensating the victims. The draft guidelines:

- propose compensation in the event of death/injury during clinical trials;
- prescribe specific responsibilities of Sponsor(s), Investigator(s) and Ethics Committee;
- provide power to the licensing authority to suspend or cancel clinical trial or restrict the Sponsor or local representative or CRO to conduct any further clinical trial in India.

Mr. Neeraj Dubey, Principal Senior Associate and Mr. Divij Kumar, Associate will discuss the foregoing elements and recommend steps that can be taken to minimize the risks and liabilities involved in case of a SAE.

We hope you will make the time to attend and participate in a meaningful and an interactive discussion.

#### **RSVP:**

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