Indian Society of Clinical Research (ISCR), Western Chapter
&
South Asian Chapter of American College of Clinical Pharmacology (SAC-ACCP)

Second Clinical Research Case Discussion Meeting

"Case discussion related to Informed Consent, Safety and other issues in clinical research "

Meeting Date: 1530-1700 hrs on 24th July 2015; Friday
Venue: JMLT, Seth GS Medical College& KEM Hospital, Parel, Mumbai
[https://www.google.com/maps/search/kem+hospital+parel/data=!4m2!2m1!4b1?dg=dbrw&newdg=1]

Introduction: Issues related to Placebo controlled studies, informed consent and safety reporting are discussed and debated amongst the clinical research community and has several nuances which needs to be kept in mind by all stakeholders based on the changing regualtions in India.
In the current regulatory climate, the investigator, EC member and sponsor need to be aware of guidelines/regulations as applicable in such complex scenarios. Often the P.I and the site coordinator require hand holding by the CRA/Medical Monitor to ensure that the patient is managed as per the protocol but in compliance with changed regulations.
The case discussion will try to throw light on the different facets of recent clinical trial guidance and regulations from the perspective of clinical research/operations professional, Investigator, ethics committee, medical monitor and Sponsor/CRO.

Target Audience: Clinical Research, Medical Affairs, Regulatory Affairs professionals, Ethics committee members, and Investigators.

Faculty: To be announced soon

Organizer cum *RSVP*: Dr Sanish Davis, Medical Director, Covance. sanish.davis@covance.com
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Note: There is no entry fee. Please come and be seated on time so that you do not disturb others who are on time. Seating will be on first come basis.