



South Asian College an Affiliate of American College of Clinical Pharmacology (SAC-ACCP)- Indian Society for Clinical Research (ISCR) Joint Workshop

on

Changing Regulatory Environment for conducting Clinical Research: Workshop for Applicants and Reviewers

16th April 2019

Venue: MCA Recreation centre, Bandra East, Mumbai

RG- 2, G - Block, Bandra - Kurla Complex, Bandra (E), Mumbai - 400 051

The regulatory changes in Drugs and Cosmetics Act, 1945, applicable to the clinical research processes released by the Ministry of Health and Family Welfare, Govt. of India over the course of the last few years have a huge impact on how clinical research is conducted in India. A key part of the change in process is the Subject Expert Committees (SEC) and the Investigational New Drug (IND) committees which have been tasked with review and approval of clinical trial proposals submitted by Pharmaceutical industry as well as academia. There has also been a change in the profile of applicants (e.g. industry) where Indian pharma industry has changed from traders to investors who are involved in applying for new drug/innovative generics applications. Multinational have changed too in their approach to the Indian market. There are also other stakeholders such as DNDi in drug development and clinical trials. This workshop is designed with purpose of sensitizing, imbibing and internalizing these changes and their impact, through talks by eminent speakers from government, academia and industry and discussion of case studies for better understanding of changed scenario.

Who Should Attend?

All the stakeholders in clinical research industry including

- Academic Investigators / Site Study Team / Ethics Committee Members,
- Pharmaceutical Industry, Sponsors, CRO and SMO Representatives,
- Pharmacovigilance Team Members,
- Clinical Research Associates, Clinical Research Trainers,
- Insurance Company Representatives,
- Regulatory Consultants
- UG and PG students and Research Scholars of Clinical Research and Pharmacy.

Why should you attend?

Opportunity to understand and interact with national and international regulatory experts

This pre conference workshop is being organized to meet the following Objectives:

- To orient stakeholders w.r.t Indian (new regulations 2019) and International review process,
- To discuss and deal with the challenges faced by all involved stakeholders and provide suggestions for improving the process further.

Workshop Agenda (updated as of 3rd April 2019)

| 08:00 – 09:00 | Registration | |
|---------------|--|--|
| Time | Topic | Faculty |
| 09:00 – 09:30 | Welcome, Objectives | Dr Nilima Kshirsagar (ICMR chair, Clinical Pharmacology) Dr Sanish Davis (Covance) |
| 09:30 – 11:00 | Session title: Overview of Review Process | |
| | <ul style="list-style-type: none"> • New Clinical trial rules 2019 – highlights for reviewers and Applicants • MHRA review process • USFDA review process <p>Discussion</p> | Dr Eswara Reddy (CDSCO, TBC) Dr Jamie Coleman (MHRA) Dr C. Sahajwala (Maryland, USA) |
| 11:00 – 11:30 | Tea | |
| 11:30 – 13:00 | Session title: Conduct and Challenges of the SEC review process | |
| | <ul style="list-style-type: none"> • CDSCO – ICMR Handbook for applicants & reviewer • Challenges with the approval of new drugs • Challenges with approval of clinical trials • Academic Institution Applicant • Perspective of SEC reviewer • Panel Discussion | Dr Nilima Kshirsagar Dr Suresh Menon (Novartis); Ms. Suneela Thatte (IQVIA) Dr Shripad Banavali (TMH, Mumbai) Dr Shobna Bhatia (SEC Member, KEM, Mumbai) Moderated by Dr Sanish Davis |
| 13:00 – 14:00 | Lunch | |
| 14:00 – 15:15 | Session title: case studies | |
| | <p>Case Scenarios based on</p> <ul style="list-style-type: none"> • IND- global/India clinical trial application; • Biosimilar application; • FDC application; • NDA application | Facilitators |
| 15:15 – 15:45 | Tea Break | |
| 15:45 – 17:00 | Presentation cum Discussion of case studies | All |
| 17:00 – 17:15 | Summary, Closing, award of certificates | Dr C. Sahajwala & Dr Sanish Davis |

Log on to <http://www.sacaccp.nirrh.res.in> for registration

| Delegates | Pre-conference Workshop |
|--------------------------------------|-------------------------|
| | Indian Rs |
| Student/Research Fellow [#] | 1000 |
| SAC-ACCP student associate member | 500 |
| Faculty/Scientist/Academia | 1500 |
| SAC-ACCP faculty associate member | 1000 |
| Industry | 3000 |