CENTRE FOR CLINICAL RESEARCH EXCELLENCE (CCRE)

JSS Academy for Higher Education & Research, Mysuru

(Deemed to be University), Accredited 'A' Grade by NAAC

In collaboration with

CLINICAL DEVELOPMENT SERVICES AGENCY (CDSA)

An extramural unit of

Translational Health Science & Technology Institute, Faridabad

Presents

CME cum Workshop on

"Critical Thinking and Good Clinical Practice"

23rd -24th March, 2018

Time	Topic	Facilitators
Day 1- 23rd March, Friday, 2018		
8 :00 AM- 9:00 AM	**Breakfast & Registration**	
9:00AM -9:30 AM	Inauguration & Welcome Address	**Dr. B. Suresh** Vice Chancellor JSS AHER **Dr. Manjunath B** Registrar JSS AHER **Dr. P A Kushalappa** Director Academics JSS AHER **Dr. Basavanagowdappa H.** Principal, JSS Medical College **Dr. M.D. Ravi** Director Research, JSS Hospital
9:30AM – 9:45 AM	Course Overview & Vote of Thanks	**Dr. Sucheta Banerjee K,** Director, Training CDSA, Faridabad
9:45AM– 10:30 AM	Overview of GCP: • What is GCP? Why GCP? • Principles of GCP • CDSCO, WHO, ICH	**Dr. Sucheta Banerjee K,** Director, Training CDSA, Faridabad
10:45 AM-11:30 AM	Current Regulations and guidelines for conducting clinical trials in India	**Shri. A.B. Ramteke** Former Joint Drug Controller (India) CDSCO, Consultant CDSA
11:30AM – 11:45 AM	**Networking Tea**	
11:45AM – 12:30 PM	Requirements of Clinical Trial Documentation: Protocol, IB, ICF, CRF, CSR, Protocol Amendments	**Dr. NEHA JOSHI** Clinical Research Investigator Center for Clinical Research Excellence, JSS AHER, Mysuru

12:30PM – 1:15PM	Safety Considerations in clinical research • Risk-benefit Assessment of trial protocol • AE & SAE Reporting	**Mr. Krishna Undela** Lecturer JSS College of Pharmacy
1:15 PM – 2:00 PM	**Group Photograph & Lunch Break**	
2:00 PM- 2:45 PM	Clinical trial Data Management: Impact of digitalization	**Archana Bhattacharya** Consultant, PHFI
2:45 PM – 3:00 PM	Use of Cloud Computing technology in Patient Recruitment System for Clinical Trials	**Dr. Ramesh S Ve** Associate Professor & Head Department of Optometry School of Allied Health Sciences Manipal Academy of Higher Education
3:00PM – 3:45PM	Overview of Data Analysis and Biostatistics practices in clinical trials	**Dr. Smitha MC** Assistant Professor, Department of Community Medicine, JSS Medical College, Mysuru
3:45 PM- 4:00 PM	**Tea/ Coffee Break**	
4:00PM – 4:45 PM	Quality Assurance	**Dr. Sucheta Banerjee K,** Director, Training CDSA, Faridabad
4:45PM-5:00 PM	Group Activity	**Moderator: Dr. Neha Joshi**

Day 2- 24th March, Saturday, 2018		
8:30 AM- 9:00 AM	**Breakfast**	
9:00 AM – 9:30 AM	Recap & Discussion of Group Activity	
9:30 AM – 10:15 AM	Roles and responsibilities of an Investigator • Ensuring Protocol compliance • Reporting Protocol Violation	**Dr. Pratibha Pereira** Head, Center for Clinical Research Excellence,
10:15 AM – 11:00 AM	Roles and Responsibilities of Sponsor, Institution and Monitor	**Mr. Anirban Roy Chowdhury** Senior Director, Global Clinical Trial Operations, Merck Mysuru
11:00 AM – 11:15 PM	**Tea Break**	
11:15 AM -12:00 Noon	Ethical Considerations in clinical research	**Dr. Pratibha Pereira,** Head,

	• EC Functioning & Accreditation • Informed Consent Process • Confidentiality & Privacy • Vulnerable Population • Revised ICMR guidelines • Subject rights and duties	Center for Clinical Research Excellence, JSS AHER, Mysuru
12:15AM -1:00 PM	Panel Discussion Conducting the ideal trial: Expectations vs. Challenges	Moderator: **Dr. Pratibha Pereira**
1:00 PM- 1:45 PM	**Lunch**	
1:45pm-2:45 PM	Critical Thinking and Research Methodology: How to generate and execute a meaningful research idea	**Dr. Praveen Kulkarni** Assistant Professor, Department of Community Medicine, JSS Medical College, Mysuru
2:45PM-3:15 PM	Designing Clinical Trials: Overview and Group Activity	Moderators: **Mrs. Vinaya Rani G** **Dr. Neha Joshi** Clinical Research Investigator Center for Clinical Research Excellence, JSS AHER, Mysuru
3:15PM-3:30 PM	**Tea Break**	
3:30pm-4:15 PM	Current & Future scenario of Clinical Trials in India: Scopes and Challenges	**Dr. Rajendra H. Jani** Independent Consultant Drugs and diagnostic R&D, Clinical research and medical affairs
4:15- 4:45 PM	**EXIT ASSESSMENT**	
4:45 PM onwards	**Feedback & Valedictory Session**	