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

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<th>Time</th>
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<td>8:00 AM- 9:00 AM</td>
<td>Breakfast &amp; Registration</td>
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| 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 |
### Day 1: 23rd March, Friday, 2018

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<th>Time</th>
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| 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

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<tr>
<td>8:30 AM- 9:00 AM</td>
<td>Breakfast</td>
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<tr>
<td>9:00 AM – 9:30 AM</td>
<td>Recap &amp; Discussion of Group Activity</td>
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| 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, |
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<th>Time</th>
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<tr>
<td>12:15AM -1:00 PM</td>
<td>Panel Discussion Conducting the ideal trial: Expectations vs. Challenges</td>
<td>Moderator: Dr. Pratibha Pereira</td>
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<td>1:00 PM- 1:45 PM</td>
<td>Lunch</td>
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<td>1:45pm-2:45 PM</td>
<td>Critical Thinking and Research Methodology: How to generate and execute a meaningful research idea</td>
<td>Dr. Praveen Kulkarni Assistant Professor, Department of Community Medicine, JSS Medical College, Mysuru</td>
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<tr>
<td>2:45PM-3:15 PM</td>
<td>Designing Clinical Trials: Overview and Group Activity</td>
<td>Moderators: Mrs. Vinaya Rani G Dr. Neha Joshi Clinical Research Investigator Center for Clinical Research Excellence, JSS AHER, Mysuru</td>
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<tr>
<td>3:15PM-3:30 PM</td>
<td>Tea Break</td>
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<tr>
<td>3:30pm-4:15 PM</td>
<td>Current &amp; Future scenario of Clinical Trials in India: Scopes and Challenges</td>
<td>Dr. Rajendra H. Jani Independent Consultant Drugs and diagnostic R&amp;D, Clinical research and medical affairs</td>
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<tr>
<td>4:15- 4:45 PM</td>
<td>EXIT ASSESSMENT</td>
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<td>4:45 PM onwards</td>
<td>Feedback &amp; Valedictory Session</td>
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