

REGISTRATION FORM

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Institution:.....

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Payment Details:

Mode of payment : DD / Electronic Transfer

No: Date :

Net Banking Details (Transaction ID and

Account holders Name):

Amount can be credited through cheque, NEFT, RTGS,
DD (Cash will not be accepted).

Account Name : JSS University CDSA Grant Account

Account Number : 64172916655

IFSC code : SBIN0040547

Bank : State Bank of India

Sri Shivarathreshwara Nagara branch, Mysuru -15

For e-registration send scan copy to cdsa.jssu@gmail.com

Registration fee

On or Before 15th March

Participants from academia: INR 2000 + GST, 18% = 2360

Participants from Industry: INR 4000 + GST, 18% = 4720

After 15th March:

Participants from academia: INR 2500 + GST = 2950

Participants from Industry: INR 5000 + GST = 5900

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His Holiness

Jagadguru Sri Shivarathri Deshikendra Mahaswamiji

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Principal

JSS Medical College

Advisor

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Director Training, CDSA, Faridabad

Organizing Chairperson

Dr. Pratibha Pereira

Head,

Centre of Clinical Research Excellence
JSS AHER

Organizing Secretary

Dr. Neha Joshi

Clinical Research Investigator

Centre of Clinical Research Excellence
JSS AHER

Treasurer

Mrs. Vinaya Rani

Clinical Research Investigator

Centre of Clinical Research Excellence
JSS AHER



JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Accredited 'A' Grade by NAAC

With Blessings of His Holiness

Jagadguru Sri Shivarathri Deshikendra Mahaswamiji

**CENTRE FOR CLINICAL RESEARCH EXCELLENCE
(CCRE)**

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



Venue

Sri Rajendra Auditorium

JSS Medical College, Mysuru - 570015

INVITATION

The Centers of Excellence (CoE) is a network of institutions initiated by CDSA, Dept. of Biotechnology, Government of India; which includes clinical research sites that are geographically distributed across India and have the capacity to conduct local and global clinical studies of utmost standards. CDSA fosters partnerships and is a member of CoE. This partnership with leading clinical research and academic institutions collectively works towards enhancing the national capacity & capability to trigger innovative and breakthrough technology development and accelerate the translation of effective research in public and private sectors. The workshop is a collaborative effort of CDSA, Faridabad and COE at JSS Academy of Higher Education and Research (Center for Clinical Research Excellence, CCRE).

Learning Objective

* Introduction to clinical research methodology, research ethics, regulatory issues, and best practices in conduct of clinical trials

* Educate and train participants in various GCP guidelines such as ICH-GCP, Indian GCP, ICMR guidelines for conducting research on human subjects

* Develop the process of critical thinking among researchers, so they ask research question and conduct studies that are meaningful in a local as well as global context.

Who can participate?

- * Practicing clinicians, Faculty members, Senior Residents and PG from Medical/ Dental Institution
- * Research scholars in Biomedical Sciences, Pharmaceutical Sciences and Pharmacy Practice
- * Hospital/Health care administrators
- * Faculty from Indigenous system of Medicine Institutions
- * Clinical trial industry personnel like CRCs, Monitors, Auditors, etc.

Number of Participants: 50 (First come first serve basis, no spot registration)

Last Date of Registration : 20th March, 2018

Day - 1 23rd March, Friday, 2018

Time	Topic	Facilitators
8:00 AM	Breakfast & Registration	
9:00 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
9:30AM	Course Overview & Vote of Thanks	Dr. Sucheta Banerjee K Director, Training CDSA, Faridabad
9:45AM	Clinical Research Methodology: Overview	Dr. Pratibha Pereira Head, Center for Clinical Research Excellence, JSS AHER, Mysuru
10:30 AM	Overview of GCP: <ul style="list-style-type: none"> • What is GCP? Why GCP? • Principles of GCP • CDSCO, WHO, ICH 	Dr. Sucheta Banerjee K Director, Training CDSA, Faridabad
11:15AM	Networking Tea	
11:30AM	Current Regulations and guidelines for conducting clinical trials in India	Shri. A.B. Ramteke Former Joint Drug Controller (India) CDSCO, Consultant: CDSA
12:15PM	Ethical Considerations in clinical research <ul style="list-style-type: none"> • EC Functioning & Accreditation • Informed Consent Process • Confidentiality & Privacy • Vulnerable Population • Revised ICMR guidelines • Subject rights and duties 	Dr. Pratibha Pereira Head, Center for Clinical Research Excellence, JSS AHER, Mysuru
1:00 PM	Group Photograph	
1:15 PM	Lunch Break	
2:00 PM	Safety Considerations in clinical research <ul style="list-style-type: none"> • Risk-benefit Assessment of trial protocol • AE & SAE Reporting 	Dr. Krishna Undela Lecturer JSS College of Pharmacy Mysuru
2:45 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
3:15PM	Tea/ Coffee Break	
3:30PM	Group Activity Session-1 (Documentation)	Moderator: Dr. Neha Joshi
4:15PM	Clinical trial Data Management: Impact of digitalization	Speaker from Industry
4:45 - 5:30 PM	Quality Assurance: Roles and Responsibilities of monitor	Dr. Sucheta Banerjee K

Day - 2 24th March, Saturday, 2018

8:00 AM	Breakfast	
8:45 AM	Recap & Discussion of Group Activity 1	
9:30 AM	Roles and responsibilities of an Investigator <ul style="list-style-type: none"> • Ensuring Protocol compliance • Reporting Protocol Violation 	TBD
10:30 AM	Roles and Responsibilities of Sponsor and Institution	Speaker from Industry
11:15 AM	Tea Break	
11:30 AM	Overview of Data Analysis and Biostatistics practices in clinical trials	Dr. Smitha MC Assistant Professor, Dept. of Community Medicine JSS Medical College, Mysuru
12:15AM	Panel Discussion: Conducting the ideal trial: Expectations vs. Challenges	Moderator: Dr. Pratibha Pereira
1:00 PM	LUNCH	
1:45 PM	Critical Thinking: How to generate and execute a meaningful research idea	Dr. Praveen Kulkarni Assistant Professor Dept. of Community Medicine JSS Medical College, Mysuru
2:45PM	Group Activity Session-2 (Designing a study)	Moderator: Mrs. Vinaya Rani G Clinical Research Investigator Center for Clinical Research Excellence, JSS AHER, Mysuru
3:15PM	Tea Break	
3:30PM	Current & Future scenario of Clinical Trials in India: Scopes and Challenges	Speaker from Industry
4:15	EXIT ASSESSMENT	
4:45 PM onwards	Feedback & Valedictory Session	

Workshop Secretariat:

CDSA-CCRE Office

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