



**WORKSHOP ON
CLINICAL TRIALS:
DESIGN AND
ANALYSIS
PROCEDURES**

July 20th – 22nd, 2017

*Sponsored by
Medical Council of India
(MCI)*

**Organized by
DEPARTMENT OF PHARMACOLOGY,
GITAM Institute of Medical Sciences
and Research**

6 credit Hours by APMC

Venue:
Medical Education Unit, II Floor, GIMSR

INVITATION

India's strong value proposition has attracted many multinational pharmaceutical companies to enter into or significantly expand existing operations in India in the fields of drug discovery, contract manufacturing and clinical research. Due to high costs involved, drug companies are constantly exploring ways to outsource clinical trials to countries that provide services at lower costs and more efficient timelines.

India, due to its large patient population and genetic pool, can provide both cost-savings and speedier trials. However, India accounts for 20% of the world's disease burden and 16% of the world's population, but less than 1.4% of global clinical trials are being carried out in India. Medical Colleges and Research Organizations paid little attention towards clinical trials. There is a dire need of trained professionals who can undertake robust clinical trials efficiently in India.

Clinical trials form an indispensable tool for progression of health care. Evidence gathered through well designed and appropriately analyzed clinical trial data is mandatory for the regulatory approval for commercializing new drugs. Even though there is an increasing trend to undertake

clinical trials in India in recent years, its awareness among health care professionals remain far less from satisfactory. Lack of clear understanding about scientific, logistic and procedural methods involved in clinical trials is the draconian reason put forth.

Topics for Discussion:

- Clinical trial Designs
- Ethics involved in conducting a clinical trial
- Trial Methodology (how to plan for a trial, various procedures involved)
- Writing a clinical Trial protocol
- Preparation of CRF
- Randomization and blinding
- Management of clinical trial data
- Types of analysis
- Critical analysis of published clinical trial data
- Sample size estimation
- Various statistical methods in analysis of trial data

Contact Persons

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Resource Persons:

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10. **Dr. S. P. Rao, M.D.**, MBA (Hosp. Admin), Principal, GIMSR
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GITAM UNIVERSITY

GITAM University, named after Mahatma Gandhi, established u/s 3 of the UGC Act, 1956, has made a mark of its own in teaching and research of global standards.

The University is located in three picturesque campuses at Bengaluru, Hyderabad and Visakhapatnam. With a multidisciplinary approach, the University offers 128 programs at UG, PG and Doctoral levels in diverse disciplines

GITAM Institute of Medical Sciences and Research (GIMSR)

GITAM Institute of Medical Sciences and Research permitted with an annual intake capacity of 150 MBBS students is offering International standard futuristic and evidence based education through eminent faculty and e-class facilities. The GITAM Hospital is strategically located and is surrounded by urban, rural and tribal areas. GIMSR apart from teaching is involved in trying to find solutions to various healthcare problems by bringing eminent clinicians/researchers onto one common platform.



Registration Form
LAST DATE TO RECEIVE FILLED
APPLICATIONS 15TH JULY 2017
(Please fill in Block Letters)

Title: Mr/ Mrs/ Dr. Name: _____

Age: __ Gender: __ Designation: _____

Department: _____

Address: _____

MCI Reg No: _____

E mail: _____

Mobile No: _____

DD/ NEFT Transfer No:

Reasons to attend Workshop: _____

Signature:

Seats limited to 40 participants only. The participant fee is Rs. 2000 payable by DD (A/C No: 761302010000808 in favour of Seminar & workshops GIMSR, IFSC code: UBIN0576131. This fee covers teaching and training material, DVD, 3 days breakfast, lunch, snacks and tea.

Accommodation for outside participants:

Limited free accommodation is available at the GIMSR Campus.