



**DEPARTMENT OF BIOSTATISTICS**  
Biostatistics Resource and Training Centre  
Advanced Clinical Data Management Centre  
Christian Medical College, Vellore - 632 002, India.

**Dr. L. JEYASEELAN**, Ph.D., F.R.S.S., F.S.M.S.,  
Professor and Head  
Course Coordinator

---

October 17, 2017

Dear Friends,

I am happy to inform you that we are conducting "**Clinical Trials Course - Design, Analyses, Interpretation and Reporting**" in collaboration with the Department of Health Research Methods, Evidence and Impact, McMaster University, Ontario, Canada, in the Clinical Epidemiology Unit and the Biostatistics Resource & Training Centre, Department of Biostatistics, Christian Medical College, Vellore, India, from **December 11-15, 2017**.

Attached herewith the brochure. The brochure and application can be downloaded from our website:

[www.cmc-biostatistics.ac.in](http://www.cmc-biostatistics.ac.in)

The last date for submitting the application is **December 02, 2017**.

If you need further information, please feel free to contact us.

Sincerely,

**Dr. L. Jeyaseelan**  
Course Coordinator



Faculty:

Prof. Shrikant I Bangdiwala  
McMaster University, Canada.

# Clinical Trials Course

## “Design, Analyses, Interpretation and Reporting”

**December 11-15, 2017**



**Course offered by**

Biostatistics Resource and Training Centre,  
Clinical Epidemiology Unit,  
Christian Medical College, Vellore, India.



In collaboration with the Department of Health Research Methods, Evidence and Impact,  
McMaster University, Ontario, Canada.

## Course Description

This course provides thorough knowledge in the principles and practice of clinical trials to study the effect of an intervention on health outcomes. This will include lectures, practices, participant's presentation, and group work.

## Course Objectives

- To impart knowledge in principles and practices of controlled clinical trials, through lectures and practices
- To impart the basic concepts in Ethical issues in research, Journal critique and in Systematic reviews.
- To discuss and clarify the methodological challenges in the planning, conduct and analyses of a trial.
- To impart the basic skills necessary in monitoring the trial and to develop a quality data management system.

## Who Should Apply?

This course is tailored to researchers working in Pharmaceutical Industries, medical, allied health professionals, nonmedical faculty and researchers actively involved in trials, or teaching or in furthering their knowledge and skills in methodology.

## Benefits

Each participant will be randomly allocated to a group and the group will be assigned a research question and given background materials to develop a protocol following GCP and CONSORT guidelines. Each group's protocol development process will be facilitated by a mentor. Each group will be asked to present their protocol orally to the rest of the groups and faculty for discussion.

## Course Fee

**Rs 10,000** per person for Academic Participants and

**Rs 15,000** for Non Academic Participants

(Course kit, Lunch, snacks and tea will be provided)

**Course Fee should be paid in full by December 02, 2017.** Payment can be made by **Demand Draft (DD)** in favour of “**Christian Medical College Vellore Association Account**”, payable at Vellore.

## Accommodation

Participants will have to bear their own expenses for travel, boarding and lodging. The Organizers will provide Lunch and Snacks. However, the organizers may arrange basic accommodation with A/C facility in the college campus on request. Only limited accommodation is available on campus and priority will be given to the female participants on first come and first served basis. however, a list of hotels has been attached in the brochure for you to choose.

## Venue

Biostatistics Resource and Training Centre (BRTC),  
Department of Biostatistics,  
Christian Medical College,  
Bagayam, Vellore - 632 002.

## nMaster

The cost of the nMaster software is fixed for Rs.2500/- for Academic / Government institutions and Rs.5000/- for Commercial. However, those who would participate in this workshop from the Academic / Government institutions, a concession of Rs.1000/- will be offered to buy this nMaster software (price - Rs.1500/-).

**The number of participants:** Limited to 45 admissions & this will be purely on first come first served basis.

**Note:** After Registration if cancelled the course fee will not be refunded.

## About Faculty



**Dr. Shrikant I Bangdiwala** graduated in Mathematics and subsequently received his PhD in Biostatistics from The University of North Carolina at Chapel Hill (UNC), USA in 1980, where he worked as Research Professor of Biostatistics at Univ. of North Carolina and retired in December 2016 after 36 years of service. In January 2017, he moved to McMaster University, Canada as Statistics Director, Population Health Research Institute, and Professor, Dept. of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, Canada. In McMaster University he is currently training the Statisticians and supervising randomized controlled trials. There are about 26 statisticians are working under him. He was the chair of two Data and Safety Monitoring Boards (DSMB) and a member of nine DSMBs. He was the co-investigator for over 10 clinical trials projects. He has been the faculty for over 25 clinical trial related workshops and short courses. He has over 20 publications alone on clinical trials and over 100 publications in public health and medicine. He was one of the founding members of the Injury Prevention and Research Centre of UNC and member of the Board of Scientific Counselors of the National Centre for Injury Prevention and Control. He was teaching clinical trials for the graduate program at UNC. He was the biostatistical advisor for the International Clinical Epidemiology Network (INCLIN) and a visiting faculty for the Department of Biostatistics, Christian Medical College, Vellore, India.

**Dr. Abraham Peedicayil MBBS, DGO, MPH, MD, FRCOG**, Professor



and Head, Dept of Obstetrics & Gynaecology and Head, Gynaecologic Oncology Unit, CMC Hospital, Vellore 632004, India. Trained at UNC, Chapel Hill and has been member of the Clinical Epidemiology Unit since 1992. Has been involved in teaching

epidemiology and participating in clinical and epidemiological research at CMC, Vellore. Main clinical interest is gynaecological oncology.

**Dr. Thambu David Sudarsanam**, Professor of Medicine at the



Christian Medical College Vellore and coordinator of the clinical epidemiology unit in CMC and member of the South Asian Cochrane network. Trained both MBBS and MD General Medicine in the Christian Medical College Vellore. His interests include Infectious diseases, epidemiology and systematic reviews. He is also

interested in Nutritional interventions for TB and the problems of HIV and TB co-infection. He is also the coordinator for the PG Research Methodology and Dissertation writing workshops in CMC.

**Dr. L. Jeyaseelan**, Professor of Biostatistics at the Department of



Biostatistics, Christian Medical College, Vellore. He has been teaching Epidemiology and Clinical Epidemiology for the Masters Program at this Department. He is specialized in Clinical Epidemiology, Bayesian Methods, Bootstrap, and Mixture Distributions. He is the founder of the Biostatistics and Resource and Training Centre

(BRTC). He has been organizing short courses in Biostatistics, Epidemiology, and Advanced Statistics Methods for the last 15 years. He is also the founder of the Clinical Data Management Centre (CDMC) to support data management, analyses and report writing for Vaccine and Drug trials. This is the first ever recognised data management centre in an academic institution in India. He is also member of the DSMB of Department of Biotechnology (DBT) and WHO. He has published over 135 papers in public health and medicine. He is the PI of the nMaster sample size calculation software from this Department. He is Investigator or Co-investigator of nearly 10 Epidemiological studies and about 15 capacity building projects.

**Dr. Visalakshi Jeyaseelan**, Senior Lecturer, Department of Biostatistics, Christian Medical College, Vellore,



has been working as a faculty for the past 12 years. She has also had a Masters Degree in Public Health in Biostatistics from the University of North Carolina, Chapel Hill, USA. She has been serving as a resource person in most of the

shortcourses conducted in the Department. She is a member of the IRB in this institution. Her interest mainly lies in Clinical Trials, Bootstrap techniques and Bayesian modeling. She also helps the Biostatistics Masters students in their dissertation. She is involved in teaching post graduate medical students within



the institution and in other medical colleges. Her role in updating herself mainly arises from the challenging consultations as she regularly helps the post graduate medical students and faculty in CEU for their research. She has 45 publications so far.

## Course Content

### Building the Evidence

- Introduction to Clinical Trials
- Defining the Research Question – PICO
- Evidence from various research designs
- Introduction to Phase I & Phase II Studies
- Introduction to research project
- Journal Club exercise continued
- Design considerations (Part I)
  - Phase III trials
  - Superiority vs non – inferiority hypotheses
  - Parallel, crossover and factorial designs
  - Adaptive Designs, Two stage Designs
- Examining the evidence
  - Journal critique guidelines

### Design and Conduct Issues

- Ethics in Clinical Research
  - Ethics dictates design and conduct
- Design considerations
  - Placebo vs usual care control arm
  - Masking – allocation concealment, maintenance
- GCP principles
  - Quality Assurance
- Laboratory Quality Assurance
- Intervention allocation
  - Simple, stratified, cluster randomization
  - Blocking; permuted blocks
  - Adaptive randomization schemes
  - Optimized randomization
  - Exercise with Trial Data Analyzer
- Systematic Review and Meta – Analysis

*Participants to finalize their group's study design, randomization scheme, and required sample size*

## Data Analyses and Monitoring Issues

- Statistical methods for end-of- study analyses
  - Descriptive analyses and Survival analyses
- Statistical methods for interim analysis
- Data and Safety Monitoring Boards
- Case studies of early stopping
- Journal article critique by participants

*Participants develop their protocol's analysis strategy*

## Data Analyses & Study Management

- Types of Analyses
  - Intention to treat (ITT)
  - Per protocol analysis (PP)
  - As Treated Analysis
  - Handling missing data: imputations and challenges
- Study management
- Dealing with missing outcomes
- Analysing Change
- Necessary sample size

*Participants finalize their protocols & presentations*

## Cluster randomization & Group presentations

- Cluster Randomization
- *Presentation of group's protocols*

### Course Co-ordinator/Address for communication

Dr. L. Jeyaseelan,

Professor and Head

Biostatistics Resource and Training Centre (BRTC)

Advanced Clinical Data Management Centre (ACDMC)

Department of Biostatistics, Christian Medical College,

Bagayam, Vellore 632 002. India

### Secretariat / Contact person

Mr. C. Jayaprakash / Mr. Sankar

Email: [biostats@cmcvellore.ac.in](mailto:biostats@cmcvellore.ac.in)

Phone: (0416) 2262703, 2284205

**Clinical Trials Course - Design, Analyses, Interpretation and Reporting**  
(DECEMBER 11-15, 2017)

**REGISTRATION FORM**

**NAME IN CAPITAL (FOR CERTIFICATE PURPOSE)** : DR / MR / MS / MRS \_\_\_\_\_

**AGE** : \_\_\_\_\_ **SEX: M / F**

**EDUCATIONAL BACKGROUND** : \_\_\_\_\_

**DESIGNATION** : \_\_\_\_\_

**DEPARTMENT** : \_\_\_\_\_

**INSTITUTION** : \_\_\_\_\_

**ADDRESS** : \_\_\_\_\_

: \_\_\_\_\_

**STATE** : \_\_\_\_\_

**PHONE & MOBILE** : \_\_\_\_\_

**PERSONAL EMAIL** : \_\_\_\_\_

**OFFICIAL EMAIL** : \_\_\_\_\_

**ACCOMMODATION** : **REQUIRED / NOT REQUIRED**  
• ONLY LIMITED ACCOMMODATION AVAILABLE  
• PRIORITY WILL BE GIVEN TO THE FEMALE PARTICIPANTS

**IF REQUIRED, TENTATIVE DATE & TIME: ARRIVAL** \_\_\_\_\_

**DEPARTURE** \_\_\_\_\_

**DD AMOUNT : Rs.** \_\_\_\_\_ **DATE** : \_\_\_\_\_

**DD NUMBER** : \_\_\_\_\_ **BANK** : \_\_\_\_\_

**NOTE: AFTER REGISTRATION IF CANCELLED THE COURSE FEE WILL NOT BE REFUNDED**

**SIGNATURE**

# List of Hotels available in Vellore

Vellore city STD code is +91- 416

Hotel name	Single non AC	Double non AC	Single AC	Double AC	Phone Nos	Distance from Venue (approx)
<i>Darling Residency</i> <a href="http://www.darlingresidency.com">http://www.darlingresidency.com</a>			2424/-	2788/-	2213001 4202006 4202007	3.5 kms
<i>Grand Krishna</i> <a href="http://hotelgrandkrishna.com">http://hotelgrandkrishna.com</a>			2350/-	3528/-	2258189 2258289 2258389 2258489	15 kms
<i>Hotel Surabhi International</i> <a href="http://www.hotelsurabi.com">http://www.hotelsurabi.com</a>			2424/-	2788/-	2216399 2216499 2216599	3.5 kms
<i>Baby Residency</i> <a href="http://www.babyresidency.com">http://www.babyresidency.com</a>			1814/-	2055/-	2226484 2213285 2227584	3 kms
<i>Aavanaa Inn</i> <a href="http://www.hotelaavanaainn.com">http://www.hotelaavanaainn.com</a>	1697/-	2060/-	2424/-	2788/-	2215073 2215074 2228935	6 kms
<i>River View</i> <a href="http://www.hotelriverview.org">http://www.hotelriverview.org</a>			2182/-	2666/-	2225251 2222349 2225218 2225108	7 kms
<i>Mount Paradise</i> <a href="http://hotelmountparadise.net">http://hotelmountparadise.net</a>	1000/-	1350/-	1500/-	1700/-	222831 2235531 2212631	10 kms
<i>Sri Srinivasar Residency</i> <a href="http://www.srinivasaresidency.com">http://www.srinivasaresidency.com</a>		1455/-		1940/-	2232725 2232726 2232727	7 kms
<i>Sri Annamalaiyar Residency</i> <a href="http://annamalaiyarresidency.com">http://annamalaiyarresidency.com</a>		1500/-		1814/-	2229999	7 kms
<i>Kumaran's Millennium Residency</i> <a href="http://www.mmresidency.in">http://www.mmresidency.in</a>	950/-	1200/-	1200/-	1600/-	2245500	10 kms.
<i>Lingam Residency</i>	650/-	650/-	950/-	950/-	2220971	6 kms.
<i>Koona Residency</i>		525/-		825/-	2211298	6 kms.
<i>Arunachalam Lodge</i>		700/-		1400/-	2210979	6 kms.
<i>AMP Lodge</i>	300/-	400/-			3292652	1 Km.
<i>Ananda Bhavan</i> <a href="mailto:vimdes@rediffmail.com">vimdes@rediffmail.com</a>		500/-			2266770	1 Km.

**Note: Rates may be subject to revision**