



Faculty

**Stephen Walter**

Professor Emeritus

McMaster University, Canada

# Workshop on Clinical Trials: Basics and Specialised Topics

October 16-18, 2019



**Course offered by**  
**Clinical Epidemiology Unit,**  
**Biostatistics Resource and Training Centre,**  
**Christian Medical College, Vellore, India.**



**In collaboration with the Department of Health Research Methods, Evidence, and Impact  
(previously Clinical Epidemiology and Biostatistics) at McMaster University, Ontario, Canada.**

## **Background:**

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This course provides thorough knowledge in the principles and practice of clinical trials to study the effect of an intervention on health outcomes with the special focus to incorporating patient and physicians preferences in the treatment allocation. This will include lectures, practical, participant's presentation, and group work.

## **Workshop Objectives:**

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To impart knowledge in principles and practices of controlled clinical trials with the special focus on Sequential Trials for benefit and utility, Adaptive Designs, Step wedge design Real time studies will be presented.

## **Who should apply?**

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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 (to update their skills in recent developments in design and analyses).

## **Benefits:**

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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:**

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**Rs 10,000/** (Inclusive of 18% GST)

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

**Workshop Fee should be paid in full by October 09, 2019.** Payment can be made by **Demand Draft (DD)** in favour of **“Christian Medical College Vellore Association Account “**, payable at Vellore.

## **Accommodation:**

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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.

## **nMaster** (Sample Size calculation software):

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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/-).

## Venue:

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New Examination Hall (Bagayam Campus),  
Christian Medical College,  
Bagayam, Vellore - 632 002.

**The number of participants:** Limited to 40 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:

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**Stephen Walter** received his Ph.D. from the University of Edinburgh.



After faculty appointments at the University of Ottawa and Yale University, he joined the Department of Clinical Epidemiology and Biostatistics at McMaster University, where he is now a Professor Emeritus. Dr Walter has collaborated in research on internal medicine, evidence-based medicine, developmental pediatrics, environmental health, cancer etiology and medical screening. He is interested in several areas of biostatistical methodology, including: the design and analysis of medical research studies; risk assessment; evaluation of diagnostic and screening data; and regional and temporal variation in health. He has published widely on these topics (with over 450 refereed papers) in the biomedical and statistical literature.

Dr Walter is a past Editor of the American Journal of Epidemiology, and Section Editor for the Wiley Encyclopedia of Biostatistics. He served as Chair of Biostatistics in the International Clinical Epidemiology Network (INCLIN), and has been involved with research capacity development in Asia, Latin America and Africa. Dr Walter is a regular Visiting Professor in Australia and Finland, and he has been involved in research activities in several other countries. He is a past coordinator of the Health Research Methods program at McMaster, and has worked with about 100 Masters and Ph.D. students.

### **Honours and Awards:**

- Elected Fellow of the Royal Society (Canada)
- Inaugural Greenberg Award for Excellence in Methods Development and Application, North American Congress of Epidemiology.
- Winner, International People's Epidemiology Library Award (from American College of Epidemiology and Netherlands Royal Academy of Arts and Sciences); World Congress of Epidemiology.
- Co-author on "Best Paper of the Year", selected by The Lancet from the world literature.
- CIHR-CMAJ Top Achievement in Health Research Award (co-recipient); and related awards from the Orthopaedic Trauma Association, American Association of Orthopaedic Surgeons, and Orthopaedic Research and Educational Foundation.
- Inaugural Statistical Society of Canada Award for Impact of Applied and Collaborative Work.

- Elected Member, International Statistical Institute.
- Elected Fellow, American Statistical Association.
- Fellow, Royal Statistical Society.
- Honourary Life Member, Indian Clinical Epidemiology Network.
- International Society for Fracture Repair, Best Paper Award (co-recipient)
- Canadian National Health Scientist Award; CIHR Senior Investigator and Partnership Awards
- Inaugural Tait McKenzie Medal for Research, Canadian Academy for Sport Medicine.
- Distinguished Visitors Award, University of Western Australia.
- Taiwan Science Council, Distinguished Scholar Award.

**Dr. Mahesh Iyer**, is a co-founder of Sineflex Solutions LLP, a consulting



firm focused on enabling and accelerating innovation in the healthcare space. He is also the head of the BIRAC funded med-tech accelerator located at the Centre for Innovation and Entrepreneurship, IIT Hyderabad. In this role, Mahesh is responsible for mentoring

startups in the medtech space, and helping them scale their products and solutions. Mahesh Iyer has over 20 years of experience in research and development in healthcare. He has been responsible for guiding many products through the development life-cycle. Before co-founding Sineflex Solutions, Mahesh was at Novartis in various roles, including Site Head, Biostatistics at Hyderabad, and Global head for Exploratory Safety and Statistical Analytics. Prior to

Novartis, Mahesh worked with Bristol Myers Squibb and Boehringer Ingelheim.

Mahesh brings a strong analytical mind-set, deep insights into healthcare development and a proven record of implementing innovative solutions in the healthcare domain. Mahesh is passionate about enhancing industry academia collaboration; he set up one of the first part-time Ph.D. program in Statistics for Novartis associates, teaches at a number of Indian universities and has chaired multiple conferences over the years. He is currently Secretary of the Indian Association for Statistics in Clinical Trials and President of the International Indian Statistical Association, India Chapter.

Apart from his functional activities, Mahesh has led various organizational developmental activities and trainings. He is a certified coach in the areas of emotional intelligence, assessment centers, and psychometric evaluations. Mahesh has completed his Ph.D. in Statistics from Temple University, Philadelphia.

**Dr. Abraham Peedicayil MBBS, DGO, MPH, MD, FRCOG** is 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 short courses 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

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- Designs in Clinical Trials
- Cluster RCT
  - Subgroup analyses
- Randomization: Simple, Block, Stratified and Co-variate Adaptive
- Sequential Trials: Stopping Rules
- Stopping for benefits
- Stepped Wedge Design
  - CMC BIG Study
- Journal Article Critique/ Review by a Faculty ?????
- Adaptive Designs:
  - Explorative and Confirmative Trials
  - Adaptive Sample Size
  - Adaptive Randomization
- Dose Finding Designs
  - Seamless PhII/PhIII Trials
- Sequential Trials: Stopping Rules for Futility
- Practical session for stopping early
- Journal Article Critique/ Review by a Faculty
- Patient and Physician Preferences in Clinical Trials
- Presentation and Discussion of snake venom study

### Address for communication

Mr. M. Madhankumar / Mr. Sasikumar  
Clinical Epidemiology Unit,  
Christian Medical College,  
Vellore 632 004. India.  
Email: [ceu@cmcvellore.ac.in](mailto:ceu@cmcvellore.ac.in)  
Phone: (0416) 2282329, 2282759

### Course Co-ordinator

Dr. L. Jeyaseelan,  
Professor

**WORKSHOP ON CLINICAL TRIALS: BASICS AND SPECIALISED TOPICS  
OCTOBER 16-18, 2019**

**REGISTRATION FORM**

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

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

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

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

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

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

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

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

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

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

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

**ACCOMMODATION : REQUIRED / NOT REQUIRED  
(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**