

# Clinical Trials Course

“Design, Analyses, Interpretation and Reporting”

July 7-11, 2008



Course offered by  
Biostatistics Resource and Training Centre,  
Department of Biostatistics, Christian Medical College,  
Vellore, India.

In collaboration with the Department of Biostatistics,  
University of North Carolina, Chapel Hill, USA.



## **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, practicals, participant's presentation, and group work.

## **Course Objectives:**

- To impart knowledge in principles and practices of controlled clinical trials, through lectures and practicals
- 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:**

- The participants will be provided with a copy of nMaster1.0 sample size calculation software.
- 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:**

Rs10, 000/ per person  
(Lunch, snacks and tea will be provided)

**Course Fee should be paid in full by June 25, 2008.** Payment can be made by Demand Draft in favour of "**Christian Medical College Vellore Association Account** ", payable at vellore.

**Venue:**

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

**The number of participants:** limited to 30 admissions will be purely on first come first served basis.

**Secretariat / Contact person**

Mr. C. Jayaprakash  
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**Course Co-ordinator:**

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## 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) in 1980, where he currently holds the rank of Research Professor of Biostatistics. He currently is designated as a 'Fulbright Senior Specialist' in Global Public Health. He was the chair of two Data and Safety Monitoring Boards (DSMB) and a member of nine DSMBs. He has been 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 is one of the founding members of the Injury Prevention and Research Centre of UNC, and currently is a member of the Board of Scientific Counselors of the National Centre for Injury Prevention and Control. He has been teaching clinical trials for the graduate program at UNC. He is a biostatistical advisor for the International Clinical Epidemiology Network (INCLIN) and a visiting faculty for the Department of Biostatistics, Christian Medical College, Vellore, India.

**Dr. Prathap Tharyan**, MD, MRCPsych, Professor of Psychiatry, trained for his MBBS and MD at CMC Vellore. He joined the department in 1987 and has worked here since except for three years (1992-1995), when he worked at Oxford in the UK towards the MRCPsych (1994). He was head of Psychiatry Unit II from 1996- 2007 and of the Department of Psychiatry from 2003-2007. He was additional Vice-Principal (Research) at CMC from 2006 June –January 2008. He is currently Associate Director for CMC from Feb 2008. He is the Director of the Prof. BV Moses and ICMR Advanced Centre for Research and Training in Evidence Informed Health Care at CMC Vellore and Director of the South Asian Cochrane Network ([www.cochrane-sacn.org](http://www.cochrane-sacn.org)) a part of the international *Cochrane Collaboration* ([www.cochrane.org](http://www.cochrane.org)). He is also an Editor with the Cochrane Schizophrenia Group and a systematic review author with several other Cochrane review Groups. He is an associate editor of the biomed central journal '*Trials*' and of the '*Journal of Evidence Based Medicine*'. He is also a member of the Scientific Advisory Group of the WHO-International Clinical Trials Registry Platform and the WHO Guidelines Review Committee. He is a member of the steering and technical advisory groups of the Clinical Trials Registry-India ([www.ctri.in](http://www.ctri.in)). His areas of interest are evidence-based health care, conducting pragmatic clinical trials and evidence-based ethics.

**Dr. Sujith J Chandy** is currently Professor at the Department of Pharmacology & Clinical Pharmacology, CMC Vellore. He is also heading the Dept of Pharmacy. Besides his role in teaching and problem based learning, he is involved in research mainly in the areas of rational use of medicines, pharmacoepidemiology, and applied kinetics. In addition, he is assisting the clinical data management centre and the hospital with adverse event data as well providing advice and input into various clinical trials. He is also a resource person for research ethics workshops and pharmacovigilance workshops.

**Dr. L. Jeyaseelan** is 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 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 8 years. He is also the founder of the Clinical Data Management Centre (CDMC). He is the Chair of DSMB at the Christian Medical College, Vellore. He is also member of the DSMB of Department of Biotechnology (DBT) and WHO. He has published over 80 papers in public health and medicine. He is the PI of the nMaster sample size calculation software from this Department. He is Investigator and Co-investigator of nearly 10 Epidemiological studies.

## Course content

### Monday July 7:

#### Day 1:

#### Building the Evidence

09.00 – 10.30

Refining the research question  
– observational vs. experimental  
Review of research designs  
Confounding in research

11.00 – 13.00

Statistical considerations on design:  
Phase I, II and III trials  
- superiority vs non-inferiority

14.00 - 15.30

Systematic reviews, meta analyses  
Cochrane Collaboration in SE Asia

16.00 - 17.30

Journal critique guidelines

*Evening*

*Participants to refine their group's research question, review the evidence, and elaborate their hypothesis*

### Tuesday July 8:

#### Day 2:

#### Design and Conduct Issues

09.00 -10.30

Design alternatives for Phase I, II, III trials  
- Parallel, crossover and factorial designs  
- Ethical considerations – placebo or control arm  
- Masking and allocation concealment  
- GCP principles  
- Quality assurance

11.00 - 13.00

Intervention allocation  
- Simple, stratified, cluster randomization  
- Adaptive randomization schemes  
- Blocking; permuted blocks  
- Optimized randomization  
Exercise with RALLOC/STATA  
Case studies with challenges

14.00 - 15.30

Ethics in clinical research

16.00 - 17.30

Necessary sample size  
Exercises using nMaster1.0

*Evening*

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

## Wednesday July 9:

### Day 3: **Data Analyses and Monitoring Issues**

- 09.00 - 10.30      Statistical methods for end-of-study analyses
- Phase I, II, and III trials
  - Hypotheses of superiority vs non-inferiority
  - Analysis of crossover and factorial designs
  - Statistical tests - survival analysis, logrank, M-H
  - Use of post-randomization information (adherence)
  - ITT, per-protocol, 'completers'
- 11.00 - 13.00      Statistical methods for interim analyses
- Group-sequential boundaries
  - Stochastic curtailment
  - Conditional power
  - Statistical implications of early stopping
- 14.00 – 15.30      Data and Safety Monitoring Boards
- Role and responsibilities
  - Case studies of early stopping
- 16.00 - 17.30      Journal article critique by participants
- Evening*              *Participants develop their protocol's analysis strategy*

## Thursday July 10:

### Day 4: **Data Analyses & Study Management**

- 09.00 -10.30      Handling missing data: imputations and challenges  
Adjusting for baseline variables
- Methodological issues
- 11.00 – 13.00      Secondary analysis
- Secondary analyses of the primary outcome
  - Secondary outcomes
  - Sub-group analyses: Uses and abuses
  - Bias in Randomized Controlled Trials
- 14.00 – 15.30      Study management
- Monitoring process
  - Coordinating protocol implementation
  - Internal & external reporting

16.00 – 17.30 Multicentre vs multi-site studies  
- Study governance  
- Publication management

*Evening* *Participants finalize their protocols*

**Friday July 11:**

**Day 5: Clinical Data Management and Monitoring**

09.00 -10.30 Ethical considerations  
Adverse event coding and reporting  
Role and responsibilities of the PI, Sponsor

11.00 -13.00 Case Studies Presentation.  
14.00 – 15.30 *Presentation of participant's protocols*

15.30 – 16.00 Workshop evaluation

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## Format of Application

**Name in Capital** \_\_\_\_\_

(for Certificate purpose)

**Age** \_\_\_\_\_

**Sex** M / F

**Occupation** \_\_\_\_\_

**Activities** \_\_\_\_\_

**Address** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Phone & Mobile** \_\_\_\_\_

**Email** \_\_\_\_\_

Educational Background

**Degree** \_\_\_\_\_

**Area of Concentration** \_\_\_\_\_

**Have you ever taken Epidemiology/Biostatistics Course earlier** Y / N

**Accommodation:** may be arranged for Lady participates with in the campus

DD Amount Rs. \_\_\_\_\_ Date: \_\_\_\_\_

DD Number: \_\_\_\_\_ Bank: \_\_\_\_\_