



St. John's Medical College & Research Institute Bangalore, India

In Collaboration with faculty from
McMaster University, Canada & Duke University, USA

Diamond Jubilee – 3rd Annual One-week Course on Randomized Controlled Trials

Sep 4th to 8th, 2023



Designed & Conducted by

Division of Clinical Research & Training
St. John's Medical College & Research Institute, Bengaluru, India

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About the RCT course

This third one-week course on 'Randomized Controlled Trials (RCTs)' is conducted in collaboration with McMaster University, Canada and Duke University, USA.

This course will cover the principles and practices of RCTs for evaluating healthcare interventions. The course will also cover the operational aspects such as data management, adjudication, monitoring, inspection, audit, budget, ethics, and regulatory aspects. The participants will also be familiar with data management including statistical analysis and its interpretation.

Objective of the course:

To provide participants a comprehensive understanding of the various aspects of designing, conducting and managing different types of RCTs.

Topics covered:

RCT Designs & Analysis <ul style="list-style-type: none">• RCT: key concepts• Cluster RCT• Factorial trials• Non-inferiority trials• Adaptive trials• Expertise based trials• Stepped wedge trials• Implementation trials• Community based trials• Real world trials• Pragmatic trials	Interventions: <ul style="list-style-type: none">• Drugs/ devices/ surgical• Complex Behavioral Statistics: <ul style="list-style-type: none">• Sample size for different RCT designs• Parametric & Non-parametric tests• Mixed linear models• Survival analysis	Techniques: <ul style="list-style-type: none">• Randomization• Blinding• Allocation concealment• Investigational Product Management Operations issues: <ul style="list-style-type: none">• Regulatory• Documentation/ manuals• Data management• Adjudication• Budgets• Insurance/Compensation
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At this course, you will gain skills and knowledge to

- Design and implement RCTs.
- Recognize a range of trial design options.
- Specify and critically evaluate the key elements of trial design.
- Understand the logistics and practicalities involved in designing trials
- Understand the regulatory and ethical frameworks that govern trials and to ensure patient safety and data integrity.

Who should attend:

- Faculty, postgraduate and PhD students from medical, dental, nursing and pharmacy.
- Ethics committee members, regulators, librarians and health policy makers.
- Anyone looking to learn about health research and evidence based medicine practices.

Eligibility:

Must have attended any basic health research methodology course.

Methods:

The course has 20 interactive lectures, 4 small group protocol discussions, 4 journal clubs and 4 project presentations. The course book will be given to the participants on the first day of the course. Other reading materials/scientific papers will be sent in advance to the registered participants.

Speakers and course faculty:

Speakers include experienced researchers from St. John's Medical College, McMaster University, Canada, Duke University, USA and Thrombosis Research Institute, London.

Dr. Bradi Granger, PhD is a Professor at the Duke University School of Nursing, the Duke-Margolis Center for Health Policy, and Director of the Heart Center Nursing Research Program. She has led a number of NIH, industry, and foundation-funded studies in the field of medication management.

Her work has been published in The Lancet, the American Heart Journal, the Journal of Advanced Nursing, Patient Education and Counseling, and the European Journal of Cardiovascular Nursing, among others. She has scopus h-index of 25.





Dr. Christopher Granger, MD is a Professor of Medicine in the Division of Cardiology at Duke University and past Director of the Cardiac Care Unit for the Duke University Medical Center. Dr. Granger is a Fellow of the American College of Cardiology, the American Heart Association, and of the European Society of Cardiology. He served for 10 years on the Board of External Experts of the National Heart, Lung and Blood Institute (NHLBI) and has co-authored more than 800 peer-reviewed manuscripts and several books including the classic Fundamentals of Clinical Trials. He has scopus h-index of 154.

Dr. Deepak Kamath, M.D is Assistant Professor at St. John's Medical College and Research Institute, Bangalore, India and an Indian Alliance (Wellcome Trust-DBT) Early Career research fellow. He has also worked on the NIH/NHLBI funded SPREAD study. As part of Indian Alliance project, he has developed and evaluated an intervention to improve self-care and clinical outcomes in heart failure patients.



He was selected as a World Heart Federation "Emerging Leader" in 2015. He has published several papers in reputed journals, has authored 3 textbook chapters and has scopus h-index of 8.



Dr. Denis Xavier MD, MSc is Professor of Pharmacology, and Head, Division of Clinical Research and Training at St. John's Medical College and Research Institute, Bangalore, India. With Prof. Prem Pais he set up the Clinical Research Division in 1999 and collaborations in about 200 Centers in India and recruited over 115,000 participants in about 45 major clinical research projects.

He was Principal Investigator of NIH Center of Excellence to counter chronic diseases (2009-14). He runs courses in Research Methods, Biostatistics and EBM. He has over 170 papers in leading journals such as the Lancet, NEJM, JAMA, Circulation, European Heart Journal, Heart, AHJ, Nature Cardiovascular, IHJ etc. He has four book chapters and is Section Editor of a cardiology textbook. He is listed in the top 2% of global scientists in the Stanford Ranking-2021 and has h-index of 86 (Google Scholar); 71 (Scopus) and over 68,217 citations.



Dr. Gordon Guyatt MD, OC, FRSC is a Distinguished Professor in the Departments of Medicine and Health Research Methods, Evidence and Impact at McMaster University, Hamilton, Ontario, Canada. In 1990, Dr. Guyatt coined the term '**evidence-based medicine**' and since then he has provided leadership in developing the methods for evidence-based clinical decision making and evidence-based practice guidelines worldwide.

He has published over 1600 papers in peer-reviewed journals; his scopus h-index is 230 and over 160,000 citations.

Dr. PJ Devereaux, MD is a cardiologist, perioperative care physician, and clinical epidemiologist. He is the Director of the Division of Perioperative Care at McMaster University. He is a Senior Scientist and the Scientific Leader of the Anesthesiology, Perioperative Medicine and Surgical Research Group at the Population Health Research Institute.



He has published >370 peer reviewed papers and >80 book chapters, editorials, and commentaries and has an h-index of 105 and 132,754 citations.



Dr. Prem Pais, MD is the former Dean and Head of Department of Medicine at St John's Medical College, Bangalore India. He is the Chief Mentor of the Division of Clinical Research and Training at St. John's Research Institute. He was instrumental in setting up the St. John's Research Institute within the medical college campus and later set up the Division of Clinical Research and Training.

He is currently Chair of Scientific Advisory Group of division of NCD of the ICMR New Delhi as well as a member of the ICMR Scientific Advisory Board. He is also Chairperson of the CVD Research Group and member of the Scientific Advisory Group of the National Centre for Disease Informatics and Research (ICMR), Bengaluru. He has scopus h-index of 62.

Mr. Saverio Virdone is a Biostatistician graduated from the University of Padua (Italy). His primary research interests are the application of statistical methods for observational studies and register-based research for patients with cancer and cardiovascular diseases. He is currently working at the Thrombosis Research Institute (UK), where he is involved in different studies that assess medications' effectiveness and safety and evaluate public health interventions in patients with atrial fibrillation. He has collaborations with the Duke Clinical Research Institute (US) for the development and validation of prediction models and clinical risk scores. He is also a PhD scholar at the London School of Hygiene and Tropical Medicine (UK). His PhD research is aimed to provide reliable and up-to-date global estimates of cancer cure indicators which are often missing from current survival statistics. He has scopus h-index of 18.



Dr. Shrikant Bangdiwala, PhD is a professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Hamilton, Ontario. He is the Director of Statistics and Senior Scientist at the Population Health Research Institute, and a former Fulbright Senior Specialist in Global Public Health, and holds faculty positions in universities in Chile, South Africa and India.

He is a member of the USA NIH National Institute of Allergy and Infectious Diseases (NIAID) "COVID-19 Preventive mAb Data and Safety Monitoring Board" (DSMB). He has scopus h-index of 71.

Dr. Tinku Thomas, PhD is Prof and head of Biostatistics at St. John's Medical College. She is actively involved in the design and conduct of several longitudinal and experimental studies. She has been teaching biostatistics to postgraduate students, medical and nursing students for the past 16 years. She also taught in NIH sponsored research methodology courses held by the Division of Clinical Research & Training, St. John's Research Institute. She has scopus h-index of 31.



Note: Most speakers have been on the last year's course and are subject to change based on their availability. Since some faculty members are from abroad, they will give their talk via videoconference.

Previous Participants' Feedback:

What previous participants liked about the course (quoted verbatim):

1. The depth in which topics were discussed, journal clubs, interactive sessions.
2. Experienced faculty, motivated cooperative staff and the group work.
3. Compact schedule, uninterrupted technical service delivery, friendliness.
4. Covered most important topics of RCTs, faculty who taught had enormous experience.
5. Brilliantly structured course, well planned and executed.
6. Ensuring 100% participation by all using "chit" system for presentation as well as Q& A.
7. Course director and faculty's method of teaching and answering all queries of all participants. Teaching by course director on how to make slides, how to present journal club and project, group discussions and hard work and dedication of all my group members.
8. The best of national and international experts in the field as faculty members who shared their experience and knowledge without reservations.
9. Commendable organizing team, time management in strict deadline, team work, networking and collaborative work.
10. Hands on training in protocol writing and project presentation.
11. Comprehensive learning, a different experience altogether with constant adrenaline rush, especially the Zen Protocols, working in groups for JC and Project Presentations.

About Division of Clinical Research & Training at St. John's

The Division of Clinical Research & Training (DCRT) is led by Dr. Prem Pais MD, Professor of Medicine and former Dean, St. John's Medical College (SJMC) and Dr. Denis Xavier MD, MSc, Professor of Pharmacology, SJMC.

We design and conduct several large National and International clinical trials and observational studies mainly in non-communicable diseases. Since 1999 we have recruited about 115,000 participants in over 60 research projects.

Some of the landmark studies are:

INTERHEART, INTERSTROKE, PREMISE, CREATE-ACS, INSPIRE, MACE, RELY-AF HOPE-3, CREATE, OASIS 5 & 6, POISE, CURRENT, FUTURA, RELY, PRoFESS, VITATOPS, ASPIRE, VISION, APOLLO, MANAGE, AUGUSTUS, ARISTOTLE, POISE-2, POISE-3, TIPS, TIPS-K, TIPS-3, ACHIEVE, ENRICH-AF.

Our studies have been published in leading journals, such as, the Lancet, JAMA, NEJM, Nature Cardiovascular, American Heart Journal, Heart, Circulation, European Heart Journal, Indian Heart Journal, JAPI etc.

We were selected as a Centre of Excellence (CoE) to counter chronic diseases in developing countries (2009-2014) by the National Institutes of Health (NIH, USA). Over 5 years, we conducted 3 large multi-center knowledge translation studies. This included primary (PREPARE) and secondary (SPREAD) prevention of ischemic heart disease and an observational studies in stroke (INSPIRE).

One of our key goals is to train the next generation of health professionals and researchers in India and other countries. We started training in health research methods with a NIH grant in 2009 for 5 years and continued thereafter.

In the last 14 years we have trained over 2000 health professionals from 83 institutions in 45 cities across 12 countries.

In the year 2021, we started this short course exclusively on RCTs. This course will provide the participants a comprehensive understanding of the various aspects of designing, conducting management, analysis and interpretation of different types of RCTs.



Individual Award



Group Award

Application Process


Interested and eligible candidates must register for the course. For spot registration, please do write to us and get your eligibility verified before making your travel arrangements.

Once registered, applications will be screened. Eligible participants will receive payment details and enrollment will be confirmed once the payment is done.

[Click here for registration](#)

Contact rct_training@sjri.res.in for further details.

Registration fee including GST:

	Academics/Regulators/EC	Industry	For Registration:
Early bird (till 20 th Aug)	Rs 12,500	Rs 15,000	 SCAN ME
From 21 st Aug to 3 rd Sep	Rs 13,500	Rs 17,000	
Spot registration	Rs 15,000	Rs 20,000	

Registration fee includes course material, breakfast, coffee/ tea, snacks & lunch.

Concession Criteria

25% discount in the registration fees:

- For 3 or more candidates from the same academic institution
- For students/ trainees, candidates from our network institutions

To avail of the discount, a letter from your Departmental / Institutional Head should be sent to rct_training@sjri.res.in & addressed to:

Dr. Denis Xavier MD, MSc (Clin Epi), Course Director.

Note: Scholarships and Travel bursaries are available for select candidates (T&C apply).

Venue

St. John's Medical College and Research Institute, Bangalore

Travel and Accommodation:

On-campus accommodation available on request.

Non-AC: Twin Sharing: Rs.560/- per day; Single: Rs.840/- per day

AC: Twin Sharing: Rs.1120/- per day; Single: Rs.1680/- per day

For more details visit

https://sjri.res.in/clinicalresearch/activity_details/647



SCAN ME

Course director:

Dr. Denis Xavier, MD, MSc (Clin Epi)
Professor and Head, Dept. of Pharmacology,
Head, Division of Clinical Research and Training,
St. John's Medical College and Research Institute.
Bangalore



Pope Paul Auditorium



Session in progress



St. John's Medical College

Brochure Designed by

Division of Clinical Research & Training
St. John's Medical College & Research Institute, Bengaluru, India