



St. John's Medical College & Research Institute

Bangalore, India

In Collaboration with faculty from

McMaster University, Canada and Duke University, USA

One Week Course on
Randomized Controlled Trials
Oct 17th to 21st, 2022



St. John's Research Institute



St. John's Medical College



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About the RCT course

This 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 on the operational aspects such as data management, budget, ethics, and regulatory aspects. The participants will also be familiar with data management including statistical analysis and its interpretation. Overall, this course will provide a comprehensive understanding of the various scientific, technical and operational aspects of conducting a RCT.

Objective of the course:

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

Topics covered:

RCT Designs & Analysis <ul style="list-style-type: none">• RCT key concepts• Cluster RCT• Factorial• Non-inferiority• Adaptive trial• Expertise based trials• Stepped wedge• Implementation trials• Community based trials• Real world/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• Survival analysis• Mixed linear models	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:

The course has been designed for faculty, postgraduate and PhD students from medical, dental, nursing and pharmacy colleges, ethics committee members, regulators, librarians and health policy makers. It may also be of interest to anyone looking to learn more about randomized controlled trials.

Eligibility:

Must have attended any basic health research methodology course.

Methods:

The course has 23 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 via email 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.





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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.

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 and has authored 3 textbook chapters.



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 Scopus h-index of 65.



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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 work has been cited over 160,000 times.

Dr. John Eikelboom, MBBS, MSc, FRCPC is a Professor in the Department of Medicine at McMaster University in Hamilton, Ontario and holds the Jack Hirsh / PHRI Chair in Thrombosis and Atherosclerosis. His research focuses on the prevention and treatment of thromboembolism in venous, cardiac, and arterial thromboembolism. He has co-authored more than 700 articles in peer-reviewed journals and since 2014 has been listed annually among the top 1% of cited researchers worldwide.



Ms. Karen Pieper, is currently the Director of statistical Sciences at Thrombosis Research Institute, London. She has been working as a statistician in the field of cardiovascular research for around 35 years. Karen Pieper is a recognized leader in teaching.

The Duke Clinical Research Institute (DCRI) created the "**Karen Pieper Award**" for mentorship and support to recognize her work in teaching clinical fellows. She has presented at numerous conferences and has been a speaker at workshops and training sessions across several countries.



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Dr. PJ Devereaux, 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 102 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.

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).





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Dr. Tinku Thomas, PhD, is Prof 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.

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

Participants Feedback:

What they liked about the course?

- The depth in which topics were discussed, journal clubs, interactive sessions.
- Experienced faculty, motivated cooperative staff and the group work.
- Covered most important topics of RCTs. Faculty who taught had enormous experience.
- Emphasis on team work and equal participation by all, supportive and encouraging faculty.
- 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.
- Very interactive nature, broad exposure to different types of RCTs, world-class reading material and lectures.
- The best of national and international experts in the field as faculty members who shared their experience and knowledge without reservations.
- Very well planned and delivered with the best possible utilization of time and online resources, despite the pandemic.
- Each class was on time. Excellent speakers/researchers from all over the world. Revision of fact that people and relations are very important part of life.
- Hands on training in protocol writing and project presentation, expertise in conducting a trial.
- Comprehensive learning. A different experience altogether with constant adrenaline rush, especially the Zen Protocols, working in groups for JC and Project Presentations.



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About DIVISION OF CLINICAL RESEARCH & TRAINING at St. John's Research Institute, Bangalore

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.

We have been conducting large observational studies (INTERHEART, INTERSTROKE, PREMISE, CREATE-ACS, INSPIRE, MACE, RELY-AF) and large multi-centre clinical trials (HOPE-3, CREATE, OASIS 5 & 6, POISE, CURRENT, FUTURA, RELY, PRoFESS, VITATOPS, ASPIRE, VISION, PEGASUS, APOLLO, MANAGE, AUGUSTUS, ARISTOTLE, POISE-2, POISE-3, TIPS, TIPS-K, TIPS-3, ACHIEVE, ENRICH-AF, COP-AF- involving anticoagulants, lipid lowering agents, anti-hypertensives and antiplatelet agents). Most of these studies are Investigator initiated studies funded by peer-reviewed grants and some are supported by Industry.

Our clinical research activities started with observational studies to identify risk factors in ischemic heart disease (Pais, Lancet- 1996, Pais, Lancet – 2004). Then we moved on to large clinical trials in acute coronary syndromes, strokes, diabetes, DVT, peri-operative ischemia etc. The first large study was the CREATE trial (Pais, Xavier, AHJ 2004, JAMA 2005) in which we recruited 8,060 acute MI patients from 60 centers. Alongside we conducted a registry in acute coronary syndromes of 20,468 patients from 89 hospitals in India (Xavier, Pais, Lancet, 2008). Thereafter we progressed to several other large clinical trials in related conditions.

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.

Having gained reasonable knowledge on risk factors and evaluated different drugs for the management of acute coronary syndromes and strokes, we moved on to comprehensive programs in the prevention of these conditions. Our focus is dual in nature: knowledge translational research and training in health research methods.

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 centre knowledge translation studies. This included primary (PREPARE) and secondary (SPREAD) prevention of ischemic heart disease and an observational studies in stroke (INSPIRE).



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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 13 years we have trained over 1900 health professionals from India and abroad.



Pope Paul Auditorium



Session in progress



Small group discussions



Zen Protocol Discussions



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Individual Award



Group Award

Application Process

Interested and eligible candidates must register for the course. For spot registration, in case you are coming from outside Bangalore, please do write to us and get your eligibility verified before making your travel arrangements.

Once registered, applications will be screened and participants will be communicated regarding their acceptance into the course. Eligible participants will receive payment details and enrollment will be confirmed once the payment is done by the participant.

[Click here for registration](#)

contact at rct_training@sjri.res.in for further details.

Registration fee including GST:

	Academics/ Regulators/ Ethics committee members	Industry
Early bird (till 20th Sep)	Rs. 7,500/-	Rs. 10,000/-
From 21st Sep to 16th Oct	Rs. 8,500/-	Rs. 12,000/-
Spot registration	Rs. 9,500/-	Rs. 15,000/-

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

Concession Criteria

25% discount in the registration fees:

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

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, Course Director.



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Venue

St. John's Medical College and Research Institute,
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Travel and Accommodation:

On-campus accommodation is available on request.

Non-AC:

Twin Sharing: Rs.560/- per day; Single: Rs.750/- per day

AC:

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

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

Course director:

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



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