Comprehensive Hands-on Training Program: Clinical Trial Conduct

St. John's Medical College & Hospital, Bangalore, from 22 to 27 Nov 2025

Course Report

Background

St. John's Medical College and Research Institute, Bangalore, (Division of Clinical Research and Training, DCRT) has been conducting short-term courses on health research methods since 2009. We started with an NIH grant in 2009 for 5 years and continued thereafter. In the last 16 years, we have trained over 2900 participants from 83 institutions in 45 cities across 11 countries.

With the grant from NBM-BIRAC (National Biopharma Mission - Biotechnology Industry Research Assistance Council), we conducted two training programs:

a) Assam Medical College and Hospital, Dibrugarh, Assam, held from 26 Oct to 31 October 2025,
b) St. John's Medical College & Hospital, Bangalore, from 22 to 27 Nov 2025.

Each training program included 28 interactive lectures, hands-on sessions on data management and statistics, and case-based discussions. The programs focused exclusively on advanced RCT designs, including detailed sessions on adaptive designs, community-based trials, pragmatic trials, non-inferiority designs, and factorial designs. There were sessions on data management, investigational product management, budget, ethics and regulatory aspects.

Overall, this course provided participants with a comprehensive understanding of the design, conduct, and management of various types of RCTs. The participants were familiarised with statistical methods for these RCT designs.

Faculty

There were seven faculty members who took sessions at St. John's Medical College & Hospital, Bangalore

Sl. No.	Name	Department / Designation	Years of Research Experience	h-index
1	Dr Denis Xavier	Course Director; Professor & Head, Pharmacology, Div of Clin Research	27+	85
2	Dr Prem Pais	Professor Emeritus, Medicine, Division of Clinical Research & Training	30+	54
3	Dr Atiya Faruqui	Professor, Pharmacology	19+	10
4	Dr Deepak Kamath	Associate Professor, Pharmacology	13+	11
5	Dr Tinku Thomas	Professor & Head, Department of Biostatistics	20+	49
6	Dr Aakanksha Singh	Project Officer, Division of Clinical Research & Training	6+	2
7	Ms Freeda Xavier	Programme Manager, Division of Clinical Research & Training	24+	3

Mr Vijay Parthasarthy, Country Head, Clinical Operations, Novo Nordisk, was a guest speaker from industry for the program at St John's Research Institute, Bangalore.

Objectives of the course:

1. To enhance knowledge and skills in RCT designs, conduct, analysis and interpretation.
2. To explore collaborations for impactful trial conduct in India.

Participants:

The participants were faculty, postgraduate and PhD students from medical, dental, nursing and pharmacy colleges. We had 25 candidates from 13 cities across India.

LIST OF PARTICIPANTS:

25 participants from 17 institutes across 13 cities and 10 states and union territory.

Sl. No.	Name	Institution	City & State
1	Ameeka Shereen Lobo	Centre for Chronic Disease Control	New Delhi, Delhi
2	Ankur Sharan	Centre for Chronic Disease Control	New Delhi, Delhi
3	Ashlesha Ghormade	AIIMS Nagpur	Nagpur, Maharashtra
4	Bharath S	National Institute of Mental Health and Neurosciences (NIMHANS)	Bengaluru, Karnataka
5	Bhavya	AIIMS Bhopal	Bhopal, MP
6	Bhuvaneshwari Govindarajan	Sri Ramachandra Institute of Higher Education and Research (SRIHER)	Chennai, Tamil Nadu
7	Chandru E	The Erode College of Pharmacy	Erode, Tamil Nadu
8	Damanpreet Singh	Christian Medical College	Ludhiana, Punjab
9	Imtiyaz Ahmad Shah	Sher-i-Kashmir Institute of Medical Sciences (SKIMS)	Srinagar, Jammu & Kashmir
10	Kamalesh Kumar A	The Erode College of Pharmacy and Research Inst	Erode, Tamil Nadu
11	Kirthiha Govindaraj	AIIMS Madurai	Ramanathapuram, TN
12	Leo Francis C	AIIMS Bibinagar	Hyderabad, Telangana
13	Mahima Badhan	Centre for Chronic Disease Control (CCDC)	Delhi, Delhi
14	Mohammed Muneersha Tk	Metromed International Cardiac Centre	Kozhikode, Kerala
15	Palak Poddar	AIIMS Nagpur	Nagpur, Maharashtra
16	Poojaashree Srinivasan	Sri Ramachandra Inst of Higher Education & Research	Chennai, Tamil Nadu
17	Radhika Kannan	Jubilee Mission Medical College & Research Inst.	Thrissur, Kerala
18	Ragul R	The Erode College of Pharmacy and Research Inst	Erode, Tamil Nadu
19	S Abarna	The Erode College of Pharmacy	Erode, Tamil Nadu
20	S Edmin Christa	Centre for Chronic Diseases Control	New Delhi, Delhi
21	Sabu Augustine	AIIMS Madurai	Ramanathapuram, TN
22	Sushmitha K	ICMR – National Institute of Malaria Research	Bengaluru, Karnataka
23	Swarndeep Singh	VMMC & Safdarjung Hospital	New Delhi, Delhi
24	Victor Moirangthem	Regional Institute of Medical Sciences	Imphal West, Manipur
25	Vineeth Jaison	Christian Medical College & Hospital	Ludhiana, Punjab

Summary of the participants:

Feature	St John's Program
Total Participants	25
Age Range	23–55 yrs
Cities Represented	13
Research Experience	0.5–15 yrs
Participants with Publications	21
Publication Range	1–10
Number of Specialities	21

St John's Medical College, Bangalore

Inauguration and orientation

The inaugural session of the program at St John's Research Institute, Bengaluru, began with **Dr Atiya** welcoming the gathering. **Dr Denis Xavier**, Course Director, provided an orientation to the **Division of Clinical Research and Training (DCRT)**, outlining the training programmes conducted so far, along with the objectives, approach, and methodology of the current course.

Rev. Fr Jesudoss Rajamanickam, Director, St John's, addressed the participants and encouraged them to *think differently in order to make a meaningful difference*. The programme was also graced by **Dr Tony Raj, Dean, St John's Research Institute**, and **Dr George D'Souza, Dean, St John's Medical College**, who shared brief remarks and conveyed their support.

Course methods

The course had 28 interactive lectures, two small group protocol discussions, and four project presentations. There were 15 lectures on various RCT designs and methods, five on statistics, two on project management, one on introduction to GCP & regulations, one on AE & SAE reporting, one on conduct of trials, one on Introduction to QA processes: Audits, inspections and monitoring.

Topics included:

A. Trial methods
    1. Formulating Research Questions & Objectives
    2. Randomisation
    3. Allocation Concealment
    4. Blinding
    5. Informed Consent
    6. Reporting of Adverse Events (AEs) & Serious Adverse Events (SAEs)
    7. Grant Writing
    8. Research Publications

B.RCT Designs

9. Factorial Trials
10. Cluster RCT
11. Large Simple Trials
12. Non-inferiority Designs
13. Adaptive trial Designs
14. Stepped-wedge trial Designs
15. Interrupted Time Series (ITS)
16. Real-World Evidence (RWE) Trials
17. Pragmatic Trials
18. Decentralised Trials

C. Data management

19. Documentation & Essential Records
20. Essential Documents for Trial Conduct
21. Database types
22. Data Management- hands on

D. Biostatistics

23. Statistics for Clinical Trials
24. Parametric Tests
25. Non-parametric Tests
26. Sample Size Calculation with hands-on
27. Correlation & Regression
28. Survival Analysis
29. Subgroup Analysis

E. Project Management

30. Roles, Responsibilities & Trial Conduct
31. Investigator
32. Sponsor
33. Monitor
34. Inspector
35. Auditor
36. Remote Monitoring
37. Clinical Research Coordinator (CRC)
38. DSMB
39. Audits
40. Inspections
41. Monitoring
42. Good Documentation Practice (GDP)
43. Investigator's Brochure
44. Data & Safety Management
45. Trial Budgeting

F. Regulatory

46. Good Clinical Practice (GCP) & Regulations
47. Indian GCP
48. NDCT 2019

49. Clinical Trials Registry – India (CTRI)
50. ICH–E6(R3) Amendment
51. Clinical Trial Agreement (CTA)
52. Medical Management and Compensation

Project Presentations

The **group activities** included four project presentations (Cluster RCT, Factorial Design, Non-inferiority and Large Simple Trials)

The speakers for project presentations were picked up randomly by chits. After the presentations, the entire group answered questions from the audience and faculty.

Here is the summary of the presentations:

Group	Date	Study design	Study title	No. of centres	Budget
Group B	26 Nov	Factorial Design	Effect of a gamified home exercise application and structured caregiver counselling on motor function in Duchenne muscular dystrophy: a multicenter 2×2 factorial randomised controlled trial.	160, 20 centres	8.25 Cr
Group D	26 Nov	Factorial	m-Health-based Lifestyle Intervention versus Routine Care for Improving Hepatic Steatosis in Individuals with MASLD (Metabolically Associated Steatotic Liver Disease) — A Multicenter, Hospital-based, Large Simple Randomised Controlled Trial in India (m-LIVER Trial)	8416, across, 15 centres	4.50 Cr
Group A	27 Nov	cRCT	SAFE-AMMA Trial: Impact of Community-Based Psychoeducation and Telehealth Approach on Post-Partum Depression among postnatal women in Rural India.	3859, across 60 clusters	6.02 Cr
Group C	27 Nov	Non-inferiority	A Non-Inferiority Randomised Controlled Trial comparing the efficacy of transcranial Direct Current Stimulation and Oral Escitalopram in Obsessive Compulsive Disorder (NICE-OCD trial)	500, across 7 centres	2.37 Cr

Group A

Group B

Group C

Group D

Course Evaluation

All participants provided a **structured** as well as an **open evaluation** of all aspects of the course.

The following were the responses of participants in the structured evaluation:

Category	Sub-Component	Average Rating (out of 5)
Lectures	Choice of Topic	4.86
	Quality & Content	4.75
	Choice of Faculty	4.79
Group Discussion	Methodology	4.89
	Utility	4.68
Project Presentation	Methodology	4.71
	Q&A	4.82
Others (Logistics)	Food	3.93
	Reading Material	4.14
	Time Schedules	4.54
Overall Assessment	Overall Course Rating	**4.82**

Open/unstructured Feedback

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

1. "Super glad to have been selected. I was waiting for three years to do this course."
2. "It's a well-curated workshop. Thanks for the opportunity."
3. "Loved every session and all the seamless presentations."
4. "A really comprehensive and well thought-through workshop."

5. “Excellent workshop. Totally worthwhile. Value for money and value for time.”

Recommendation for improvement:

1. “Extend the duration by making it into 2 parts - two months apart (a break of 30 - 40 days for us to go through the crash course material and understand the ‘what/how/why’ of each concept, revisit the slides, and complete assignments/ research work). So that the course would be more easier to imbibe.”
2. “The content is vast, so the papers helped. It would be good having books or other structured reading material to revise the course.”
3. “The sitting area could be improved for project work. A JC discussion on one trial design each could be incorporated.”
4. “I don’t think its needed, but slightly slow on slides in some hard-to-get concepts.”
5. “Selecting participants based on the requirement of HoD deputation could be changed to selecting based on their CV, allowing all participants to get an equal chance.”

-------End of Report--------