Comprehensive Hands-on Training Program: Clinical Trial Conduct

Assam Medical College and Hospital, Dibrugarh, Assam, held from 26 Oct to 31 October 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 Assam Medical College and Hospital, Dibrugarh, Assam

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

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 10 cities across India. 25 candidates from 10 cities across India attended the course.

LIST OF PARTICIPANTS:

25 participants from 9 institutes across 10 cities and 7 states.

Sl. No.	Name	Institution	City & State
1	Abhimanyu Behera	MKCG Medical College and Hospital	Berhampur, Odisha
2	Ajanta Deuri	Diphu Medical College	Diphu, Assam
3	Bhupendra N Mahanta	Lakhimpur Medical College	Lakhimpur, Assam
4	Dhruba J Saikia	Assam Medical College	Dibrugarh, Assam
5	Farhat Rafique	Integral Inst. of Medical Sciences & Research	Lucknow, Uttar Pradesh
6	Gamlen Murmu	Silchar Medical College and Hospital	Silchar, Assam
7	Jishnu Pr. Baruah	Assam Medical College and Hospital	Dibrugarh, Assam
8	Julee Rajkhowa	Assam Medical College and Hospital	Dibrugarh, Assam
9	Kankana Gogoi	Assam Medical College and Hospital	Dibrugarh, Assam
10	MGowshik Siddharthan	Assam Medical College and Hospital	Dibrugarh, Assam
11	Madhumita Bhakta	MKCG Medical College and Hospital	Berhampur, Odisha
12	Mallicka	Integral Institute of Medical Sciences	Lucknow, Uttar Pradesh
13	Meghali Chaliha	Assam Medical College	Dibrugarh, Assam
14	Mittal Rathod	P.D.U. Government Medical College	Rajkot, Gujarat
15	Nabanita Nirmolia	Assam Medical College	Dibrugarh, Assam
16	Pallavi Boro	Tomo Riba Inst. of Health & Medical Sciences	Naharlagun, Arunachal Prads
17	Pechimayum D Devi	Jawaharlal Nehru Institute of Medical Sciences	Imphal, Manipur
18	Progyashree Borthakur	Assam Medical College and Hospital	Dibrugarh, Assam
19	Rituparna Bora	Assam Medical College	Dibrugarh, Assam
20	Samrat S Bhandari	Sikkim Manipal Institute of Medical Sciences	Gangtok, Sikkim
21	Snehasmita Ghosh	Assam Medical College and Hospital	Dibrugarh, Assam
22	Swarnali D Baruah	Assam Medical College	Dibrugarh, Assam
23	Tazkira Begum	Assam Medical College	Dibrugarh, Assam
24	Vaishali Majumdar	Jawaharlal Nehru Institute of Medical Sciences	Imphal, Manipur
25	Velu Sougaijam	Jawaharlal Nehru Institute of Medical Sciences	Imphal, Manipur

Summary of the participants:

Feature	AMC Dibrugarh Program
Total Participants	25
Age Range	24–60 yrs
Cities Represented	10
Research Experience	1–20 yrs
Participants with Publications	17
Publication Range	1–10
Number of Specialities	7

Assam Medical College, Dibrugarh, Assam

Inauguration and orientation

The inauguration session at Assam Medical College, Dibrugarh, was attended by **Dr Sanjeeb Kakati,** Principal cum chief superintendent of Assam Medical College and **Dr Reema Nath,** Vice Principal of Assam Medical College.

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	Sample Size and No. of centers	Budget
Group A	30th Oct	Non-inferiority	Functional Outcomes of Non-Operative versus Surgical Management in Elderly Patients with Proximal Humerus Fractures – A Non-Inferiority Randomised Controlled Trial	560, one centre	52.3 L
Group B	30th Oct	Large Simple Trials	Impact of 12 months BCC (Behavioural Change Communication) intervention in enhancing adherence to long-lasting insecticidal net use and annual diethylcarbamazine & Albendazole intake among adults in Dibrugarh district, Assam, India: A large simple randomised controlled trial	1320, one centre	4.36 L

Group C	31st Oct	Factorial	Effect of oral multiple-micronutrient and Vitamin C add-on to standard Iron and Folic acid therapy on Haemoglobin concentration amongst women of reproductive age with anaemia attending a tertiary care hospital in Assam: A 2×2 factorial randomised controlled trial	436, one centre	1.03 Cr
Group D	31st Oct	cRCT	Effectiveness of Short Messaging Services (SMS) alert and social and behavioural change communication (SBCC) to improve adherence to Iron Folic Acid (IFA) supplementation among pregnant women (18-45 years): A cluster Randomised Controlled Trial	573, 23 clusters	Not presented

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	4.92
	Quality & Content	4.88
	Choice of Faculty	4.92
Group Discussion	Methodology	4.80
	Utility	4.69
Project Presentation	Methodology	4.84
	Q&A	4.79
Others (Logistics)	Food	4.80
	Reading Material	4.69
	Time Schedules	4.76
Overall Assessment	Overall Course Rating	**4.80**

Open/unstructured Feedback

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

1. "Statistical test clarity. Understanding difficult study designs & rationale. Ethics & important guidelines (NDCT, ICH). Protocol preparation & budget planning, ideas about prepared. Hands on experience in overall development."
2. At the end of the day you know how much you don't know. Start on time, learn more. A research is done by 'US'. Not I/Me/You. Learnt importance of note taking. How to involve every participants in the training.
3. The 3 R's, Rule, Regulation & Responsibility. Motivation to something meaningful to community. Learning and do little what with best efforts and intention.
4. Team building, team management, mentorship.
5. How to keep the participants engaged. How to be humble & strict at the same time. How to keep/ maintain attention span in a long session.

Recommendation for improvement:

1. Better process of randomisation for team work (other process than chit picking). Request to be a part of course on implementation research * adaptive trials.
2. More content related to parametric & non-parametric.
3. Giving example of research papers that includes psychological aspects.
4. If possible any further workshops on data analysis using software.
5. More detailed workshop on each aspects of the training.
6. Slides can be more attractive. Smaller breaks within lectures & between lectures.

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