Ensuring the Integrity and Credibility of Randomized Controlled Trials

06th - 07th July, 2026

Aim of the Workshop:

This workshop, led by experienced statisticians expert clinical trialists, Is designed to enhance the design, conduct and analyses of randomized controlled trials. Through a combination of theoretical foundational lectures, case studies, real-world examples, and hands-on work, participants will:

- Understand the ethical and theoretical principles for establishing a data management plan (DMP) that includes study monitoring to assure study integrity and credibility of the results
- Learn the roles and responsibilities of trial oversight groups, from the internal study sponsor, team investigators, study statistician and medical safety monitor, to the external independent data and safety monitoring board (DSMB), institutional review boards and government agencies
- Understand the theoretical foundations for statistical interim analysis monitoring for safety, efficacy and futility using group sequential and Bayesian methodologies
- Learn the principles of adaptive and multi-stage study designs

Expectations from the workshop

By the end of the workshop, participants will have the skills to develop the monitoring plan for a trial, including the data management plan (DMP), a study monitoring plan, a safety monitoring plan and a data and safety monitoring board (DSMB) Charter.

Registration Fee (in INR): Rs. 4000/-

Registration Link:

https://tinyurl.com/usts2cf2

RRU Seminar Room, ACTREC, Kharghar, Navi Mumbai

Ensuring the Integrity and Credibility of Randomized Controlled Trials

Patrons

Dr Sudeep Gupta
Director, TMC

Dr Pankaj Chaturvedi
Director, ACTREC

Dr Navin Khattry
Dy. Director, CRC-ACTREC

Faculty

Prof. Shrikant I. Bangdiwala, PhD
Director of Statistics
Population Health Research Institute
McMaster University, Canada

Kumar Balasuramanian
Senior Principal Biostatistician and Manager at Statistics department, PHRI
McMaster University, Canada

Mrs. Sadhana kannan
OIC, Department of Clinical Biostatistics, ACTREC

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Program Schedule		
Day 1 | 06th July, 2026		
TIME	**TOPIC**	**SPEAKER**
9:00 am – 9:15 am	**Inauguration**	
9:15 am – 9:30 am	Director's Message	Dr. Sudeep Gupta Dr. Pankaj Chaturvedi
9:30 am – 10:00 am	Introduction to Interim Monitoring: Ethical rationale and purpose for oversight of the conduct of trials	Prof. Shrikant Bangdiwala
10:00 am – 11:00 am	Interim monitoring for ensuring study integrity – Elements of a Data Management Plan (DMP)	Mr. Kumar Balasubramanian
11:00 am – 11:15 am	**Tea Break**	
11:15 am – 12:15 pm	Interim monitoring for early trial stopping due to safety, efficacy or futility - Group sequential designs and Bayesian adaptive stopping designs	Prof. Shrikant Bangdiwala
12:15 pm – 1:15 pm	Interim monitoring logistics – the independent DSMB and the DSMB Charter	Mr. Kumar Balasubramanian
1:15 pm – 2:15 pm	**Lunch Break**	
2:15 pm – 3:00 pm	Critical Appraisal: Case Study	Mrs. Sadhana Kannan
3:00 pm – 4:30 pm	Hands On – Developing a trial's oversight processes – Study monitoring, Data management plan, Safety monitoring, the independent DSMB Charter	Participants with Faculty oversight
4:30 pm onwards	**High Tea**	

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Program Schedule		
Day 2 | 07th July, 2026		
TIME	**TOPIC**	**SPEAKER**
9:00 am – 9:45 am	Adaptive multi-stage trial study design features	Prof. Shrikant Bangdiwala
9:45 am – 10:30 am	Sample size re-estimation using the Promising zone methodology	Mr. Kumar Balasubramanian
10:30 am – 10:45 am	**Tea Break**	
10:45 am – 11:30 am	Ethical and logistical concerns for adaptive designs	Mrs. Sadhana Kannan
11:30 am – 12:15 pm	Practicalities of Monitoring: • The SHEP trial • The PHRI Boundary and the COMPASS trial	Prof. Shrikant Bangdiwala Mr. Kumar Balasubramanian
12:15 pm – 1:00 pm	Critical Appraisal: Case Study	Mrs. Sadhana Kannan
1:00 pm – 2:00 pm	**Lunch Break**	
2:00 pm – 4:30 pm	Hands On – Presentation of oversight plans	Participants with feedback by Faculty
4:30 pm onwards	**High Tea**	

Special Note:

Please contact The Department of Clinical Biostatistics, ACTRC on Email: clinicalbiostatisticstmc@gmail.com for further details.