



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.

Future possibilities for Tata Memorial Centre (TMC)

All phase III trials conducted at TMC will have appropriate study monitoring plans that will lead to being seen as internally valid, trustworthy, and their results credible and defensible.

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

Registration Link: <https://tinyurl.com/usts2cf2>



RRU Seminar Room, ACTREC,
Kharghar, Navi Mumbai

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Ensuring the Integrity and Credibility of Randomized Controlled Trials



06th - 07th July, 2026

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 – 10:15 am | Introduction to Interim Monitoring: Ethical rationale and purpose for oversight of the conduct of trials | Prof. Shrikant Bangdiwala |
| | Example Trials | Mrs. Sadhana Kannan |
| 10:15 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 | |



Ensuring the Integrity and Credibility of Randomized Controlled Trials



06th - 07th July, 2026

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 | Dr. Supriya Chopra |
| 11:30 am – 12:15 pm | Practicalities of Monitoring: <ul style="list-style-type: none">• The SHEP trial• The PHRI Boundary and the COMPASS trial | Prof. Shrikant Bangdiwala Mr. Kumar Balasubramanian |
| 12:15 pm – 1:00 pm | Panel Discussion | Faculty |
| 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 | |