



TATA MEMORIAL CENTRE

GOOD CLINICAL PRACTICE COURSE 2024 (Virtual GCP- 2024)

11th May, 2024
ADVANCED COURSE

Time	Topic	Faculty
09.00 am - 09.45 am	ICH GCP E6/R3 – an update	Seema Pai
9.45 am to 10.45 am	E- Consent	Kishore Kumar
10.45 am - 11.10 am	Investigator Responsibilities in Academic studies	Shiv Kumar. T.
11.10 am - 11.55 pm	Decentralized CTS	Sanish Davis
11.55 pm - 12.10 pm	Break	Break
12.10 pm - 12.55 pm	AI and Clinical Research	Arun Bhatt
12.55 pm - 01.30 pm	Protocol deviations and their impact on Clinical trials	Durga Gadgil
01.30 pm - 02.15 pm	RWE studies	Deepa Chodankar



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BASIC COURSE

Time	Topic	Faculty
09.00 am -09.45 am	Indian Regulation	Amita Bhave
09.45 am - 10.30 am	Evolution of Ethics and Basics of GCP	Durga Gadgil
10.30 am - 11.15 am	Investigator Responsibilities	Anand Pendse
11.15 am -12.00 pm	Informed Consent Document and Informed Consent Process	Saket Ghaisas
12.00 pm - 12.15 pm	Break	Break
12.15 pm - 01.00 pm	Safety Reporting in Clinical Trials	Harish Naik
01.00 pm - 01.30 pm	Investigational Product Management at Study Site	Prachi Patil
01.30 pm - 02.10 pm	Source Documents & Data	Shirsha Chakraborty
02.10 pm - 02.40 pm	Monitoring	Durga Gadgil



16th ANNUAL SHORT COURSE IN CLINICAL RESEARCH METHODOLOGY

30th September 2023 and 7th October, 2023

CLINICAL RESEARCH SECRETARIAT & DEPARTMENT OF ATOMIC ENERGY & CLINICAL TRIAL CENTRE

Dates: 30th September 2023

Course outline: Online Virtual interactive class

Date / Time	Topics likely to be covered	Faculty / Speaker
9.00 am to 11:30 pm	Day 1: Session 1	
9.00 to 9.45 am.	Generating a Research Question	Naveen Mammudi
9.45 am to 10.30 am	PubMed Search	Medha Joshi
10.30am to 11.00am	Phases of Clinical Trials	T Shiva
11.00 am to 11.30 am	Randomization	Jeffery Raj
11.30 am to 11.45 am	Break	
11.45am to 1pm	Day 1: Session 2	
11.45 am to 12.15 pm	Study Designs	Girish Chinnaswamy
12.15 pm to 1.00 pm	Protocol/Aims/Objectives/ Methods	Prachi Patil
1.00 pm to 1.15 pm	Break	
1.15pm to 2.45pm	Day 1: Session 3	
1.15 pm to 1.45pm	Making of a CRF and ICD	Sarbani Ghosh-Laskar
1.45 pm to 2.45pm	Electronic Data Base and SPS	Sadhana Kannan

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Dates: 7th October, 2023

Course outline: Online Virtual interactive class

Date / Time	Topics likely to be covered	Faculty / Speaker
9.00 am to 11:00 am	Day 2: Session 1	
9 am to 10 am	Why Statistics, p-value, Errors, Sample size and Standard Error	Bhaskar Krishnamurthy
10am to 11 am	Which Stats test where?	Bhaskar Krishnamurthy
11 am to 11.30 am	Measures Of Association – (AR,RR,OR,NNT)	Nithya Gogtay
11.30 am to 11.45am	Break	
11.45 am to 12.30 pm	Day 2: Session 2	
11.45 am to 12.30 pm	Diagnostic tests	Gita Nataraj
12.30 pm to 1.00pm	Survival analysis	Sadhana Kannan
1 pm to 1.15 pm	Break	
1.15pm to 3.30pm	Day 2: Session 3	
1.15pm to 2pm	Meta-Analysis	Priya Ranganathan
2pm to 2.45pm	Referencing styles	Prakash Nayak
2.45pm to 3.30pm	Medical Writing- Publication and posters	Sandeep Bavdekar

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