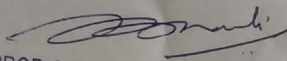


Name of the value added courses (with 30 or more contact hours) offered	Course Code (if any)	Year of offering	No. of times offered during the same year	Duration of course	Number of students enrolled in the year	Number of Students completing the course in the year
Value added courses for Post Graduate Medical Students : Good Clinical Practices (Basic Courses) + Good Clinical Practices (Advanced Courses) + CRM (Clinical Research Methodology)		2014	1	4 days	141	141
Value added courses for Post Graduate Medical Students : Good Clinical Practices (Basic Courses) + Good Clinical Practices (Advanced Courses) + CRM (Clinical Research		2015	1	4 days	147	147
Value added courses for Post Graduate Medical Students (Good Clinical Practices (Basic Courses) + Good Clinical Practices (Advanced Courses) + CRM (Clinical Research		2016	1	4 days	138	138
Value added courses for Post Graduate Medical Students : Good Clinical Practices (Basic Courses) + Good Clinical Practices (Advanced Courses) + CRM (Clinical Research		2017	1	4 days	139	139
Value added courses for Post Graduate Medical Students: Good Clinical Practices (Basic Courses) + Good Clinical Practices (Advanced Courses) + CRM (Clinical Research Methodology)		2018	1	4 days	138	138


 PROF. S. D. BANAVALI, MD
 DEAN (ACADEMICS)
 TATA MEMORIAL CENTRE
 MUMBAI - 400 012.

GOOD CLINICAL PRACTICE 2016

(Advanced Course)

TATA MEMORIAL CENTRE, MUMBAI

6 Feb 2016

10.30 am to 11.15 am	Introduction, Changing Regulatory Scenario- Sch. Y of the Drug and Cosmetic Act Of India Dr. CS Pramesh
11.15 am to 12.15PM	Investigator Accreditation Dr. Arun Bhatt
12.15 pm to 12.45 PM	BREAK - <u>Lunch</u>
12.45Pm to 1.30 PM	Informed Consent Process and Recording. Dr. Saket Ghaisas
1.30 am to 2.30 PM	Clinical Data - Importance of Clean Data. Dr. Nimita Limaye

2.30 pm to 3.15 PM	Safety reporting and its relevance to causality assessments –Ms.Snehal Chalke
3.15 pm to 3.45 pm	Audits & Inspections- How prepared are we?Dr. Karan Thakkar
03.45 pm	Acknowledgement & Vote of thanks Dr. Manju Sengar, <u>followed by tea.</u>

GOOD CLINICAL PRACTICE 2016

(Basic Course)

TATA MEMORIAL CENTRE, MUMBAI

6 Feb 2016

9.30 am to 10.30 am	Introduction to Clinical Research, Regulatory Scenario in India	Dr. CS Pramesh
10.30 am to 11 30 am	Investigator Responsibilities	Dr. Durga Gadgil
11.30 am to 11.45 am	Tea Break	
11.45 am to 12 45 pm	Informed consent process	Dr. Saket Ghaisas
12.45 pm to 1.30 pm	Lunch Break	
1.30 pm to 2.30 pm	Source and Essential Documents	Ms. Snehal Chalke
2.30 pm to 3.15 pm	Safety Reporting – AEs and SAEs	Dr. Viraj Suvarna
3.15 pm to 3.30 pm	Tea Break	
3.30 pm to 4.30 pm	Investigational Product management	Ms. Shabina/Ms. Nazia
4.30 pm to 5.15 pm	Audits and Inspections	Dr. Karan Thakkar
5.15 pm	Vote of thanks	Dr. Manju Sengar

10th Annual Short Course in Clinical Research Methodology 2016

Saturday/Sunday 28 and 29 May 2016

Venue: Prof. R. D. Choksi Auditorium,

2nd Floor, Golden Jubilee Block,

Tata Memorial Hospital, Mumbai

Saturday 28 th May 2016 – DAY 1		
8:15- 8:30	Registration and Breakfast	
8:30- 8:45	Introduction / Welcome	
8:45-9:15	Generating a Research Question	C.S. Pramesh
9:15- 10:45	PubMed Search	Vasumathi Sriganesh
10.45-11.00	Tea Break	
11.00 -11:30	Study Design	Manju Sengar
11:30 -12:15	Phases of Clinical Trials	Hari Menon
12:15– 13:00	Writing Aims, Objectives and End points	C.S. Pramesh
13:00-13:45	Lunch Break	
13.45-14.15	Writing Protocol Methods	Girish Chinnaswamy
14:15-15:15	Why Statistics, data type, summary data, distribution of data	Nithya Gogtay
15:15-15:30	Tea Break	
15:30-16:15	Which tests to choose	Nithya Gogtay
16:15 -17:00	Standard Error, Confidence Intervals	Vikram Gota
	End of Day 1	

10th Annual Short Course in Clinical Research Methodology 2016

Saturday/Sunday 28 and 29 May 2016

Venue: Prof. R. D. Choksi Auditorium,

2nd Floor, Golden Jubilee Block,

Tata Memorial Hospital, Mumbai

Sunday 29 th May 2016– DAY 2		
8:30-9:00	Registration and Breakfast	
9:00-9:45	Measures of Association - Odds Ratio And Relative Risk	Rakesh Aggarwal
9:45-10:30	Survival analysis	Rakesh Aggarwal
10:30-11:15	Informed consent form	Durga Gadgil
11.15–11.30	Tea Break	
11:30-12.15	Diagnostic tests	Rakesh Aggarwal
12:15-13.15	Sample size calculation - Why and How?	Rakesh Aggarwal
13:15- 14:00	Lunch Break	
14:00-14:30	Case record forms	Sarbani Ghosh Laskar
14:30- 15:30	SPSS/ Electronic Data Base with examples of data entry	Rohini Hawaldar
15.30- 16.30	Reference management	Vasumathi Sriganesh
16.30-16.35	Vote of thanks	Manju Sengar

GOOD CLINICAL PRACTICE 2017

(Basic Course)

Venue – Main Choksi Auditorium, Golden Jubilee Block,

TATA MEMORIAL CENTRE, MUMBAI

Saturday 18 Mar 2017

9.30 am to 10.15 am	Introduction to Clinical Research, Regulatory Scenario in India – An Update, including academic studies	Dr. Partha Gokhale
10.15 am to 11 am	Updates to Revised ICG GCP Guidelines	Dr. Karan Thakkar
11. am to 11.15 am	Tea Break	
11.15 am to 12 noon	Investigator Responsibilities as per Indian GCP	Dr. Manjunath TA
12. noon to 12.30 pm	Source and Essential Documents	Dr. Sanjay Kabra
12. 30 pm to 1.30 pm	Lunch Break	
1.30 pm to 2 pm	ICD and IC Process	Dr. Saket Ghaisas
2. pm to 2.45 pm	Investigational Product management	Ms. Nazia
2.45 pm to 3.30 pm	Safety Reporting – AEs and SAEs	Dr. Anand Pendse
3.30 pm to 3.45 pm	TEA BREAK	
3.45 pm to 4.15 pm	Audits and Inspection	Dr. Durga Gadgil
4.15 pm	Vote of thanks	Dr. Durga Gadgil

GOOD CLINICAL PRACTICE 2017

(Advanced Course)

Venue – Lecture Hall, Choksi Auditorium Complex, Golden Jubilee Block,

TATA MEMORIAL CENTRE, MUMBAI

Saturday 18 Mar 2017

9.30 am to 10.15 am	Introduction to Clinical Research, Regulatory Scenario in India – An Update, including academic studies	Dr. Partha Gokhale
10.15 am to 11 am	Updates to Revised ICG GCP Guidelines	Dr. Karan Thakkar
11. am to 11.15 am	Tea Break	
11.15 am to 12 noon	Elements of a good protocol	Dr. Saket Ghaisas
12. noon to 12.30 pm	Investigator Accreditation	Dr. Durga Gadgil
12. 30 pm to 1.30 pm	Lunch Break	
1.30 pm to 2 pm	EC Accreditation	Dr. Sanjay Kabra
2. pm to 2.45 pm	Safety Reporting – AEs and SAEs	Dr. Anand Pendse
2.45 pm to 3.30 pm	Risk Based Monitoring	Dr. Rajesh Jain
3.30 pm to 3.45 pm	TEA BREAK & Vote of Thanks	
	PLEASE NOTE THAT THE FIRST 2 LECTURES WILL BE HELD IN THE MAIN CHOKSI AUDITORIUM.	

11th Annual Short Course in Clinical Research Methodology 2017

Saturday/Sunday 9th and 10th September 2017

Venue: Prof. R. D. Choksi Auditorium,
2nd Floor, Golden Jubilee Block,
Tata Memorial Hospital, Mumbai

Saturday 9 th September 2017– DAY 1		
8:30- 9:00AM	Registration and Breakfast	
9:00- 9:15 AM	Introduction / Welcome	CS Pramesh
9:15-9:45 AM	Generating a Research Question	CS Pramesh
9:45-10:45AM	Literature Search	Medha Joshi
10:45- 11:15 AM	Study Designs	Priya Ranganathan
11:15-11:30AM	Tea	
11:30 -12:15PM	Phases of Clinical Trials and RCT	CS Pramesh
12:15-12:45PM	Writing Aims, Objectives and End points	Manju Sengar
12:45-1:15PM	Writing Protocol Methods	Girish Chinnaswamy
1:15-2:00PM	Lunch	
2:00-2:45PM	Why Statistics, data type, summary data, distribution of data	Nithya Gogtay
2:45-3:15PM	Which test to choose	Nithya Gogtay
3:15-3:55 PM	Measures Of Association - Odds Ratio And Relative Risk	Avijit Hazra
3:55-4:10PM	Tea	
4:10-4:40PM	How to read a paper	Gouri Pantvaidya
4:40-5:20PM	Standard Error, Confidence Intervals	Avijit Hazra

11th Annual Short Course in Clinical Research Methodology 2017

Saturday/Sunday 9th and 10th September 2017

Venue: Prof. R. D. Choksi Auditorium,

**2nd Floor, Golden Jubilee Block,
Tata Memorial Hospital, Mumbai**

Sunday 10th September 2017– DAY 2		
8:30-9:15AM	Registration and Breakfast	
9:15-9:45AM	Diagnostic tests	Nithya Gogaty
9:45-10:30 AM	Survival analysis	Avijit Hazra
10:30-11:00AM	Informed consent form	Durga Gadgil
11:00-11:15AM	Tea Break	
11:15-12:00Noon	Sample size calculation - Why and How?	Avijit Hazra
12:00-12:45PM	Systematic reviews and meta-analysis	Tejpal Gupta
12:45-1:30PM	Case record form	Nimita Limaye
13:30PM	Lunch Break	

GOOD CLINICAL PRACTICE 2018**(Basic Course)****TATA MEMORIAL CENTRE, MUMBAI****17 Nov 2018**

9.30 am to 10.15 am	Regulatory Scenario in India – An Update	Arun Bhat
10.15 am to 11.00 am	Revised ICH GCP Guidelines	Karan Thakkar
11.00 am to 11.15 am	Tea Break	
11.15 am to 12 noon	Investigator Responsibilities	Durga Gadgil
12 noon to 12.30 PM	Source Documents and Essential Documents	Aishwarya Iyer/Shirsha Chakraborty
12.30 pm to 1.30 pm	lunch break	
1.30 to 2.00 pm	Informed Consent and IC process	Saket Ghaisas
2.00 to 2.45 pm	Investigational Product management	Shabina/ Nazia
2.45 to 3.30 pm	Safety Reporting in Clinical trials – AE/SAE	Sachin Sadekar
3.30 pm to 3.45 pm	Tea Break	
3.45 to 4.15 pm	Audits and Inspection	Durga Gadgil
4.15 pm	Vote of Thanks	Aliasgar Moyadi

GOOD CLINICAL PRACTICE 2016

(Advanced Course)

TATA MEMORIAL CENTRE, MUMBAI

17 Nov 2018

9.30 am to 10.15 am	Regulatory Scenario in India – An Update Arun Bhatt
10 15am to 11 am	Revised ICH GCP Guidelines – Karan Thakkar
11.am to 11.15 am	Tea. BREAK
11.15 am to 12 noon	Elements of a Good Protocol - Saket Ghaisas
12 noon to 12.30 pm	Investigator Accreditation – Durga Gadgil
12.30 pm to 1.30pm	Lunch Break
1.30 pm to 2 pm	Audits & Inspections- Durga Gadgil
2 pm to 2.45 pm	Safety Reporting – AEs/SAEs – Snehal Chalke
2.45 pm to 3.30 pm	Risk Based Monitoring (RBM) – Rajesh Jain
3.30 pm onwards	Vote of Thanks and Tea – Aliasgar Moyadi

Annual Short Course in Clinical Research Methodology 2019

Saturday/Sunday 27 and 28 July 2019

Venue: Prof. R. D. Choksi Auditorium,

2nd Floor, Golden Jubilee Block,

Tata Memorial Hospital

Saturday 27 July 2019 – DAY 1		
08:15 - 08:45	Registration and Breakfast	
08:45 - 09:15	Generating a Research Questions	CS Pramesh
09:15 - 10:45	PubMed Search	Medha Joshi
10:45 -11:00	Tea Break	
11:00 -11:45	Study Designs	Manju Sengar
11:45 -12:30	Phases of Clinical Trials and Randomization	Shiva Kumar
12:30 - 13:15	Protocol Aims & Objectives & Methods	Vikram Gota
13:15 - 14:00	Lunch Break	
14:00 -15:00	Why Statistics, Statistical errors, p Value, Sample size calculations, CI, Standard error.	Raakhi Tripathi
15:00 -15:30	Which Test Where?	Nithya Gogtay
15:30 - 16:15	ICD and IC Process	Durga Gadgil
16:15 - 16:30	Tea and End of Day 1	

Annual Short Course in Clinical Research Methodology 2019

Saturday/Sunday 27 and 28 July 2019

**Venue: Prof. R. D. Choksi Auditorium,
2nd Floor, Golden Jubilee Block,
Tata Memorial Hospital, Mumbai**

Sunday 28 July 2019 – DAY 2		
08:45 – 09:00	Registration and Breakfast	
09:00 - 09:45	Measures Of Association - Odds Ratio And Relative Risk	Priya Ranganathan
09:45 - 10:15	Diagnostic tests	Priya Ranganathan
10:15 -11:00	Survival Analysis	Sadhana Kannan
11:00 – 11:15	Tea Break	
11:15 -12:00	Meta-Analysis	Shiva Kumar
12:00 -13:00	Electronic Data Base and SPSS	Vikram Gota
13:00- 13:45	Lunch Break	
13:45 - 14:30	Making a CRF	Sarbani Laskar
14:30 - 15:15	Referencing styles	Prakash Nayak
15:15 - 15:30	End of session. Take home messages.	Aliasgar Moiyadi
15:30 onwards	Tea / Coffee	