



**Workshop on Randomized Controlled Trials and Principles of GCP
Trivandrum, India
December 2-5, 2010**

	Start Time	Session - Presenter	Tab
Thursday, December 2	8:30 AM	Registration	
	8:45 AM	Opening – Rakesh Aggarwal	
	8:50 AM	Welcome – Paolo Miotti	
	8:55 AM	Introductions – Rakesh Aggarwal	
	9:10 AM	Objectives and Overview of Clinical Research – David Grimes	1
	9:20 AM	Read Generating Allocation Sequences (Chapter 10)	
	9:45 AM	Generating Allocation Sequences in Randomized Controlled Trials – Kenneth Schulz	2
	10:45 AM	Break	
	11:15 AM	Individual Exercise: Generating Sequences for Randomized Controlled Trials – Kenneth Schulz	
	11:45 PM	Ethical Issues and Randomized Controlled Trials - David Grimes	3
	12:15 PM	Read Allocation Concealment (Chapter 11)	
	12:45 PM	Lunch	
	1:30 PM	Allocation Concealment - Kenneth Schulz	4
	2:15 PM	Recruitment Strategies – David Grimes	5
	2:45 PM	Emergence and Principles of ICH E6- Good Clinical Practices (GCP)- Presentation and Exercise - Sam Griffith	6
	3:45 PM	Break	
	4:00 PM	The Protocol- presentation and exercise- Sam Griffith	7
	5:00 PM	Questions and Answers - Faculty	
	5:30 PM	Adjourn	



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	Start Time	Session - Presenter	Tab
Friday, December 3	9:00 AM	Read Blinding (Chapter 14)	
	9:30 AM	Blinding – Kenneth Schulz	8
	10:00 AM	Blinding Strategies (e.g. placebo, double-dummy – David Grimes	9
	10:30 AM	Individual exercises and discussion of randomization and blinding strategies – Rakesh Aggarwal/Amita Aggarwal	
	11:30 AM	Break	
	12:00 AM	Read Exclusions (Chapter 13)	
	12:30 PM	Exclusions in Randomized Controlled Trials - Kenneth Schulz	10
	1:00 PM	Lunch	
	2:00 PM	Responsibilities of the Investigator, presentations and exercises- Sam Griffith	11
	3:15 PM	Break	
	3:30 PM	Informed Consent, presentations and exercises- Sam Griffith	12
	5:00 PM	Outcomes in Randomized Controlled Trials (including Surrogate and Composite) - David Grimes	13
	5:30 PM	Adjourn	
Saturday, Dec 4	9:00 AM	Retention Strategies – Kenneth Schulz	14
	9:30 AM	Basic analysis presentation in Randomized Controlled Trials (baseline comparisons, primary outcomes, person-time analyses, confidence intervals, p-values – David Grimes	15
	10:00 AM	Small Group Exercise: Design a Randomized Controlled Trial	
	11:00 AM	Break	
Continued on page 3	11:30 AM	Discussion of Randomized Trial Designs – David Grimes	



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	Start Time	Session - Presenter	Tab
Saturday, December 4 (cont'd)	12:15 PM	Lunch	
	1:15 PM	Reporting of Randomized Trials – CONSORT - Kenneth Schulz	16
	1:45 PM	Institutional Review Boards/Ethics Committees, presentation and exercise - Sam Griffith	17
	2:45 PM	Break	
	3:15 PM	Essential Documents- presentation and exercises - Sam Griffith	18
	4:15 PM	Sponsor Responsibilities (including quality management, monitoring, auditing, and source documentation) - Sam Griffith	19
	4:45 PM	Analysis exercise – Rakesh Aggarwal/Amita Aggarwal	20
	5:30 PM	Questions and Answers - Faculty	
	6:00 PM	Adjourn	
Sunday, December 5	8:30 AM	GCP Review - Sam Griffith	21
	8:40 AM	Analysis in Randomized Controlled Trials (subgroups, interim analyses) – Kenneth Schulz	22
	9:10 AM	Special Issues Related to Randomized Controlled Trials in India – Rakesh Aggarwal	23
	9:40 AM	Sample Size and Power in Randomized Controlled Trials - Kenneth Schulz	24
	10:30 AM	Evaluations	
	10:45 AM	Final thoughts from OAR, NIH – Paolo Miotti	
	10:50 AM	Closing Comments – Rakesh Aggarwal	
	11:00 AM	Workshop Concludes	