

**Good Clinical Practice and Informed Consent Workshop
December 2-3, 2010
Cape Town, South Africa**

	Start Time	Session - Presenter	
Day 1	8:30 AM	Opening Orientation to Workshop	
	8:45 AM	Introduction to Good Clinical Practice	Tab 1
	9:05 AM	ICH Guidelines	Tab 2
	9:25 AM	Group Exercise	
	10:25 AM	Break	
	10:45 AM	Protocols	Tab 3
	11:30 AM	Group Exercise	
	12:15 PM	Lunch	
	1:15 PM	Informed Consent Documentation	Tab 4
	1:45 PM	Group Exercise	
	2:45 PM	Informed Consent: The Process	Tab 5
	3:15 PM	Break	
	3:35 PM	Group Exercise	
	4:05 PM	Institutional Review Board/Independent Ethics Committees	Tab 6
	4:35 PM	Questions and Answers	
	4:50 PM	Adjourn	
Day 2			
Day 2	8:30 AM	Group Exercise	
	9:30 AM	Source Documents	Tab 7
	9:45 AM	Essential Documents	Tab 8
	10:15 AM	Group Exercise	
	10:45 AM	Break	
	11:05 AM	GCP Requirements: Data Management	Tab 9
	11:35 AM	Group Exercise	
	12:05 PM	Lunch	
	1:05 AM	Monitoring	Tab 10
	1:20 PM	Group Exercise	
	1:40 PM	QA/QC	Tab 11
	1:55 PM	Group Exercise	
	2:55 PM	Investigator's Responsibilities	Tab 12
	3:20 PM	Break	
	3:40 PM	Group Exercise	
	4:10 PM	Sponsor's Responsibility	Tab 13
	4:25 PM	Questions and Answers	
	4:45 PM	Evaluations	
	5:00 PM	Adjourn	