

Workshop on Good Clinical Practice

Dec 5-6, 2009, New Delhi

Day 1- Dec 5, 2009		
Time	Activities	Speakers
9:30 – 10:00	Registration	
10.00 – 10:30	Introduction to ICH GCP <ul style="list-style-type: none"> ▪ Historical perspective ▪ Indian GCP guidelines 	Empower Faculty
10:30 – 11:00	Ethics –Indian perspective	Empower Faculty
11:00 – 11:45	Consent of Patients <ul style="list-style-type: none"> ▪ Consent forms ▪ Vulnerable patients/Mental Capacity Act ▪ Emergency Cases ▪ Examples ▪ Patient information leaflet ▪ Common Errors 	Empower Faculty
11:45 – 12:30	Regulations of Clinical Trials: India	Empower Faculty
12:30 - 13:30	Lunch	
13:30 – 14:30	<ul style="list-style-type: none"> ▪ UK GCP overview ▪ Why does an Indian Researcher need to know about foreign regulation? ▪ New Developments and Emerging Trends in GCP 	Professor R. Breckenridge
14:30– 15:30	UK Ethics process	Professor R. Breckenridge
15:30 – 15.45	Break	
15.45 – 16:45	<ul style="list-style-type: none"> ▪ Regulations of Clinical Trials: UK ▪ Recent developments /legislations in Europe 	Professor R. Breckenridge
16:45 – 17:30	Summary and Discussions	

Day II – Dec 6, 2009

10:00 – 11:30	<p>Overview of modern drug development</p> <ul style="list-style-type: none"> ▪ Target based drug delivery ▪ Model based drug delivery ▪ Biologicals –implications for development ▪ Surrogate markers of activity 	Professor R. Breckenridge
11:30 – 12:00	Clinical Trials Roles and Responsibilities	Empower Faculty
12:00 – 12:30	Adaptive clinical trials and Phase 0 trials	Professor R. Breckenridge
12:30 – 13:30	<p>Trial documents/SOPS</p> <ul style="list-style-type: none"> ▪ Protocol documents ▪ Documentation 	Professor R. Breckenridge
13:30 – 14:15	Lunch	
14:15 – 14:45	Source data verification	Empower Faculty
14:45 – 15:30	Fraud and misconduct in clinical trials	Professor R. Breckenridge
15:30 – 15:45	Break	
15:45 – 16:45	<p>Audit and inspection in clinical trials</p> <ul style="list-style-type: none"> ▪ Examples of questions ▪ Examples of problems 	Professor R. Breckenridge
16:45 – 17:15	<p>Clinical trial safety/adverse events</p> <p>Historical perspective</p> <p>Current practice</p> <p>Future Challenges</p>	Professor R. Breckenridge
17:15 – 18:00	Summary and Discussions	Professor R. Breckenridge