

1st MOPI Bioequivalence Workshop

Monitoring Module Program 29 - 30 June 2009



Day 1 – 29 June 2009

Time	Topic	Description
8:30 – 9:30 am	Defining the basic requirements of GCP	<ul style="list-style-type: none"> - Overview of ICH/GCP requirements - Understanding the role of DCA/NPCB and EC - Understanding the roles and responsibilities of the clinical research teams and the sponsor - Brief review of the drug development process
9:30 – 10:00 am	Exercise 1	Defining the basic requirements of GCP
10:00 – 10:30 am	Tea Break	
10:30 – 11:30 am	Role of a SMART clinical trial monitor	<ul style="list-style-type: none"> - The GCP and GLP requirements - Before a study – site selection, pre-study visit, EC/CTIL submission, study initiation, investigator's meeting - During a study – enrolment visit, study monitoring - After a study – study close-out
11:30 – 12:15 am	Complying with informed consent requirements	<ul style="list-style-type: none"> - The 21 elements in the informed consent - Privacy of subject's information - Confidentiality of data - Ethical issues
12:15 – 12:45 pm	Exercise 2	Complying with informed consent requirements
12:45 – 1:45 pm	Lunch	
1:45 – 2:45 pm	Evaluation of a BE study protocol and Case Report Forms	<ul style="list-style-type: none"> - What are the important components in a protocol – study design, inclusion/exclusion criteria, enrolment etc. - What are the important sections in CRF and source document verification
2:45 – 3:30 pm	Putting GLP into perspective for GCP Trials	<ul style="list-style-type: none"> - Introduction to GLP - Quality assurance and audit findings of testing laboratories - Validation and QC criteria
3:30 – 5:00 pm	Exercise 3	Designing your Monitoring Checklist
5:00 – 5:30 pm	End of Day & Summary	

Day 2 – 30 June 2009

8:30 – 9:15 am	Statistical Analysis for the Non-Statistician	<ul style="list-style-type: none"> - Definitions and commonly used terminology - Beyond 90% Confidence Intervals
9:15 – 10:00 am	Managing and reporting of adverse events	<ul style="list-style-type: none"> - Definitions and commonly used terminology - Reporting requirements from the EC, Investigator and sponsor - Time frames of reporting
10:00 – 10:30 am	Tea Break	
10:30 – 11:00 am	Exercise 4	Managing and reporting of adverse events
11:00 – 12:00 pm	Preventing fraud and scientific misconduct	<ul style="list-style-type: none"> - Maintaining accurate records - Interpretation of BE report - How to detect fraud in CRF and clinical trial materials - Misleading data and results
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	Case Study 1	
2:30 – 3:00 pm	Discussion & Presentation	
3:00 – 4:30 pm	Case Study 2	
4:30 – 5:00 pm	End of Day & Summary	