

Training Agenda for

“Best Practices and Standard Procedures in Clinical Study Management”

3 - 5 Aug 2022 at Pullman Bangkok King Power

Organized by BIOPHICS, Faculty of Tropical Medicine, Mahidol University

Time	Topics	Instructors
03 Aug 2022 (Day 1)		
9.00-10.30 (1 hour 30 mins.)	Clinical Trial- Basic concepts <ul style="list-style-type: none"> - Phases of Clinical trials - Quasi-experiment VS. Randomized - Blinding 	Assoc.Prof. Saranath Lawpoolsri Niyom Faculty of Tropical Medicine, Mahidol University
10.30 – 10.45	Coffee Break	
10.45-12.15 (1 hour 30 mins.)	Clinical Trial Designs-I <ul style="list-style-type: none"> - Parallel Design - Cross-over - Factorial Design 	Dr.Lokachet Tanasugarn Faculty of Tropical Medicine, Mahidol University
12.15 – 13.15	Lunch	
13.15 – 14.45 (1 hour 30 mins.)	Randomization <ul style="list-style-type: none"> - Stratified randomization - Block randomization - Practice 	Assoc.Prof. Saranath Lawpoolsri Niyom & Team Faculty of Tropical Medicine, Mahidol University
14.45 – 15.00	Coffee Break	
15.00 – 16.30 (1 hour 30 mins.)	Randomization & Blinding Procedures	Prof.Dr.Punnee Pitisuttithum & Team Faculty of Tropical Medicine, Mahidol University

Time	Topics	Instructors
04 Aug 2022 (Day 2)		
9.00-10.30 (1 hour 30 mins.)	Clinical Trial Designs-II <ul style="list-style-type: none"> - Adaptive Design - Stepped Wedge Design 	Assoc.Prof. Jaranit Kaewkungwal Faculty of Tropical Medicine, Mahidol University
10.30 – 10.45	Coffee Break	
10.45 – 12.15 (1 hour 30 mins.)	Hypothesis development <ul style="list-style-type: none"> - Non-inferiority - Superiority - Switching between non-inferiority and superiority 	Assoc.Prof. Saranath Lawpoolsri Niyom Faculty of Tropical Medicine, Mahidol University
12.15 – 13.15	Lunch	
13.15 – 14.45 (1 hour 30 mins.)	Sample Size Calculation <ul style="list-style-type: none"> - Probability to observe 1 event (Phase 2 trial) - Estimate single mean/proportion - Compare mean/proportion - Compare GMT - Non-inferiority/superiority - Clustered trial - Practice 	Assoc.Prof. Saranath Lawpoolsri Niyom & Team Faculty of Tropical Medicine, Mahidol University
14.45 – 15.00	Coffee Break	
15.00 – 16.30 (1 hour 30 mins.)	Sample Size Calculation (Cont.) <ul style="list-style-type: none"> - Probability to observe 1 event (Phase 2 trial) - Estimate single mean/proportion - Compare mean/proportion - Compare GMT - Non-inferiority/superiority - Clustered trial - Practice 	Assoc.Prof. Saranath Lawpoolsri Niyom & Team Faculty of Tropical Medicine, Mahidol University

Time	Topics	Instructors
05 Aug 2022 (Day 3)		
9.00-10.30 (1 hour 30 mins.)	Descriptive statistics <ul style="list-style-type: none"> - Descriptive statistics - Basic inferential statistics 	Asst.Prof. Thundon Ngamprasertchai Faculty of Tropical Medicine, Mahidol University
10.30 – 10.45	Coffee Break	
10.45-12.15 (1 hour 30 mins.)	Inferential statistics (Selection of appropriate statistical methods) <ul style="list-style-type: none"> - Compare means & non-parametric - Compare proportions - Compare time to event - Repeated measures - Clustered trial 	Asst.Prof. Thundon Ngamprasertchai Faculty of Tropical Medicine, Mahidol University
12.15-13.15	Lunch	
13.15-14.45 (1 hour 30 mins.)	Statistical Analysis Plan <ul style="list-style-type: none"> - Concept - Interim analysis - Components 	Assoc.Prof. Saranath Lawpoolsri Niyom & Team Faculty of Tropical Medicine, Mahidol University
14.45 – 15.00	Coffee Break	
15.00 – 16.30 (1 hour 30 mins.)	Statistical Analysis Plan <ul style="list-style-type: none"> - Practice 	Assoc.Prof. Saranath Lawpoolsri Niyom & Team Faculty of Tropical Medicine, Mahidol University