EDCTP Good Clinical Practice and Good Clinical Laboratory Practice
***Trainer-of-trainers'* competency workshop**
Johannesburg, South Africa, 12-14 June 2018

AGENDA

Southern Sun OR Tambo airport hotel **12 June 2018 (Day 1)**		
Session	**Approximate time**	**Content**
Registration	07h30-08h30	
Day 1 session 1	08h30-10h30	• Welcome, official opening and overview of EDCTP (*Dr Thomas Nyirenda, South-South Networking & Capacity Building Manager, EDCTP*) • Introductions and background (All) • The drug development pathway & phases of clinical trials (*Dr Hennie Geldenhuys, Director, CREDE*)
Tea	10h30-10h45	
Day 1 session 2	10h45-12h45	• Roles and responsibilities of stakeholders in clinical research • Important guidelines, key historical incidents, background & current status of important regulations governing the conduct of clinical trials
Lunch	12h45-13h30	
Day 1 session 3	13h30-15h30	• Principles of GCP, GLP, GCLP and how they relate to each other • Ethical principles and their application in the field • Important concepts & terminology in clinical research
Tea	15h30-15h45	
Day 1 session 4	15h45-17h00	• Measures for participant protection including safety reporting and data and safety monitoring

Southern Sun OR Tambo airport hotel 13 June 2018 (Day 2)		
Session	**Approximate time**	**Content**
Day 2 session 1	08h30-10h30	• Trends and developments in clinical trial regulation and implementation • Investigator delegation and supervision • Responsibilities of the Investigator and the study team
Tea	10h30-10h45	
Day 2 session 2	10h45-12h45	• Group Photo (All) • Informed Consent • Good documentation practice
Lunch	12h45-13h30	
Day 2 session 3	13h30-15h30	• Good documentation Practice (*continued*) • Best practice for designing source documentation
Tea	15h30-15h45	
Day 2 session 4	15h45-17h00	• Designing and applying a Quality Management System and Plan

Southern Sun OR Tambo airport hotel 14 June 2018 (Day 3)		
Session	**Approximate time**	**Content**
Day 3 session 1	08h30-10h30	• Implementing Corrective Preventative Actions (CAPA) • Recruitment and Retention strategies
Tea	10h30-10h45	
Day 3 session 2	10h45-12h30	• Operational metrics in clinical trials • Good Data Management (GDM) Principles • Preparing for monitoring, audits and maintenance of site files

Lunch	12h45-13h30	
Day 3 session 3	13h15-15h15	• Best training practice, the 4MAT training system and implementation of training to study teams
Tea	15h30-15h45	
Day 3 session 4	15h30-16h30	• TRUST ethics project: (*Dr Michelle Singh, Project Officer, EDCTP*) • Conclusion & Discussion • Feedback & Evaluation
End of workshop		