

Comprehensive training on the Fundamentals of Clinical Trial Protocol Assessment

Movenpick hotel, Windhoek, Namibia, 15 -19 July 2024

AGENDA

Start	End	Subject	Responsible
Day 1 Monday 15 July 2024			
Opening session			
09:00	10:00	Welcoming, Introduction of the Participants and Facilitators	All
10:00	10:30	Opening remarks <ul style="list-style-type: none"> • WHO/AFRO (5 mins) • EDCTP(5 mins) • EAC(5 mins) • SADC(5 mins) • AUDA NEPAD (5 mins) • NRA (Host) (5 mins) 	<ul style="list-style-type: none"> • Kwasi Nyarko • Thomas Nyirenda • Julius S. Otim • Sakhile Dube • Charles Sandy • Fransina Nambahu
10:30	11:00	Coffee break and Group photo	All
11:00	11:15	<ul style="list-style-type: none"> • Workshop Objectives and Programme 	Kwasi Nyarko
11:15	11	<ul style="list-style-type: none"> • Pre-test 	
Session 1: Introduction to Clinical Trial & tools			
11:15	11:35	Conducting Clinical Trials in Africa: A Primer with AVAREF	Kwasi Nyarko
11:35	12:30	Introduction to study designs, clinical trials and clinical trial authorization	Heidi Meyer
12:30	13:30	Lunch Break	
13:30	14:30	Overview Good Clinical Practice and Clinical trials oversight	<ul style="list-style-type: none"> • Alambo Mssusa • Priscilla Nyambayo
14:30	15:00	Overview of Quality Management Systems	Rhanda Adechina
15:00	15:30	Clinical Trials in Vulnerable Populations (TRUST code, fair research contracting)	Jacintha Toohey
15:30	15:45	Coffee break	
15:45	17:00	AVAREF Tools Introduction	Alambo Mssusa
End of Day 1			

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Day 2 Tuesday 16 July 2024			
Session 2: Clinical Trials Assessment – Non-Clinical Data			
08:30	10:00	Non-Clinical/ Pre-Clinical Assessments	Eric Karikari-Boateng
10:00	10:30	Hands on Practice (Pre-Clinical Assessment) (AVAREF non-clinical Review tool)	All participants assisted by facilitators
10:30	10:45	Coffee Break	All
10:45	12:30	Hands on Practice (Pre-Clinical Assessment) (AVAREF non-clinical Review tool)	All participants assisted by facilitators
12:30	13:30	Lunch Break	All
Session 3 : Clinical Trials Assessment – Clinical Data			
13:30	14:30	Pandemic Ethics	Lillian Omutoko
14:30	15:30	Clinical Evaluation (Clinical data and protocol)	<ul style="list-style-type: none"> Olga Rassokhina Priscilla Nyambayo
15:30	15:45	Coffee break	All
15:45	17:00	Hands on Practice (Clinical Assessment) (AVAREF Clinical Review tool)	All participants assisted by facilitators
End of day 2			
Day 3 Wednesday 17 July 2024			
Session 4: IMP & Quality assessment			
09:00	10:30	Investigational Medicinal Product Quality Assessment	Eric Karikari-Boateng
10:30	10:45	Coffee Break	All
10h45	12h30	Hands on Practice (Quality Assessment) (AVAREF Quality Review tool)	All participants assisted by facilitators
12:30	13:30	Lunch Break	All
Session 5: Biostatistics & Insights into Ethics Reviews for NRA reviewers			
13:30	14:30	Review by IRB, NECS for Regulatory Reviewers	Winfred Nazziwa
14:30	15:30	Biostatistics data evaluation (virtual)	Catherine Njue
15:30	15:45	Coffee break	All
15:45	17:00	Hands on Practice (Biostatistics data evaluation)	All participants assisted by facilitators
End of day 3			

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Day 4 Thursday 18 July 2024			
Session 5 Participants safety			
09:00	10:00	Clinical trials safety data assessment	PEI/Priscilla Nyambayo
10:00	10:30	Introduction to CT Inspection	Alambo Mssusa
10:30	11:00	Coffee Break	All
11:00	11:30	AVAREF Platform – Joint review	Rhanda Adechina
11:30	12:00	Regulatory Science Policy Development	Kwasi Nyarko
12:30	13:30	Lunch Break	All
13:30	17:00	Finalization of CTA assessment report	
End of Day 4			
Day 5 Friday 19 July 19 2024			
Session 6: Assessment report presentation			
09:00	10:00	Group1 presentation <ul style="list-style-type: none"> • Report presentation (30min) • Discussion (30 min) 	
10:00	11:00	Group2 presentation <ul style="list-style-type: none"> • Report presentation (30min) • Discussion (30 min) 	
11:00	11:30	Coffee Break	All
11:30	12:30	Group3 presentation <ul style="list-style-type: none"> • Report presentation (30min) • Discussion (30 min) 	
12:30	13:30	Group4 presentation <ul style="list-style-type: none"> • Report presentation (30min) • Discussion (30 min) 	
13:30	14:30	Lunch Break	All
14:30	16:30	Networking	All
End of Workshop			