







Day 1 – 26 February 2024 **Good Clinical Practice Training Programme**

	Title	Description	Facilitator
08h30 09h00	Registration Sign in for day 1		All
09h00 09h30	Welcome remarks,	Discussion	Secretariat
09h30- 11h00	Introductions, Expectations	Presentation	All
	Introduction to GCP	Presentation	Charles Makasi
	Principles of GCP	Presentation	
11h00 11h30	Tea/Coffee		
11h30- 13h30	Ethics committees/IRBs	Presentations	Godfather Kimaro
	Investigator Responsibilities	Presentation	Godfather Kimaro
		Presentation	-
13h30 14h15	Lunch		
14h15-16h30	Data management and Good Documentation Practices	Presentation	Charles Makasi
	Essential Documents	Presentation	Godfather Kimaro









Day 2 - 27 February 2024 **Good Clinical Practice Training Programme**

	Title	Description	Facilitator
08h30 0845	Sign In for Day 2		
08h45- 11h00	The Protocol/Phases of Clinical Trials	Presentation	Godfather Kimaro
	Informed Consent process	Presentation	Godfather Kimaro
	Monitoring Clinical trials (Clinical monitoring)	Presentation	Charles Makasi
11h00 11h30	Tea/Coffee		
11h30 - 13h30	Safety: Assessment and Reporting	Presentation	Charles Makasi
	Monitoring of Clinical Trials (DSMB)	Presentation	
13.30hrs- 14.15hrs	Lunch		
14.15hrs -16h15	SOPs	Presentation	Godfather Kimaro
	Quality Management Systems QA/QC/Audits/Inspections	Presentation	Godfather Kimaro









Day 3 – 28 February 2024 **Good Clinical Practice Training Programme**

	Title	Description	Facilitator
08h30 0845	Sign In for Day 3		
08h45- 11h00	Vulnerable Subjects	Presentation	Godfather Kimaro
	Quality Management Plan	Presentation	Godfather Kimaro
11h00 11h30	Tea/Coffee		
11h30 - 13h30	Investigational Products	Presentation	Charles Makasi
13.30hrs- 14.15hrs	Lunch		
14.15hrs -15h15	Discussion	Presentation	All









Day 4 – 29 February 2024 **Good Clinical Laboratory Practice (GCLP)**

	Title	Description	Facilitator
08h30 0845	Sign In for Day 3		
08h45- 11h00	Introduction to Good Clinical Laboratory Practice	Presentation	Mkunde Chachage
	Lab Organisations and Personnel	Presentation	Mkunde Chachage
11h00 11h30	Tea/Coffee		
11h30 - 13h30	Facilities and safety	Presentation	Mkunde Chachage
	Analytical plans and protocols	Presentation	Mkunde Chachage
13.30hrs- 14.15hrs	Lunch		
14.15hrs -15h15	Occurrence management	Presentation	Mkunde Chachage
	Sample management	Presentation	Mkunde Chachage
15h15 16h15	Source data record and reporting	Discussion	Godfather Kimaro









Day 5 - 01 March 2024 **Good Clinical Laboratory Practice (GCLP)**

	Title	Description	Facilitator
08h30 0845	Sign In for Day 4		
08h45- 11h00	Standard operating procedures	Presentation	Godfather Kimaro
	Laboratory Equipment Management	Presentation	Mkunde Chachage + Fatna Kivava (mentee)
	Laboratory Procurement & Inventory	Presentation	Mkunde Chachage + Fatna Kivava (mentee)
11h00 11h30	Tea/Coffee		
11h30 - 13h30	Methods validation	Presentation	Mkunde Chachage
	Introduction to Quality assurance & Quality control	Presentation/Activity	Mkunde Chachage
13.30hrs- 14.15hrs	Lunch		
14.15hrs -15h15	External quality assessment	Presentation	Mkunde Chachage
	Laboratory Information System	Presentation	Mkunde Chachage