LAUNCH OF THE EAPoC VL STUDY

WORK PACKAGE 1: EFFECTIVENESS OF POINT OF CARE-VIRAL LOAD TESTING ON VIRAL LOAD SUPPRESSION

Joseph Lutaakome on behalf of WP 1 Team

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WP1 LEADERSHIP

- MRC/UVRI & LSHTM Uganda Research Unit (Lead)
- KEMRI (Co Lead)
- UNHRO/UVRI

BACKGROUND

- UNAIDS adopted the 90:90:90 strategy to end the HIV epidemic by 2020
- Challenges exist in achieving this target especially in children and adolescents
- In EA, VL suppression in this population ranges between 65%-75%
- A key strategy to achieving VL suppression is 6 monthly VL monitoring, but this has not been achieved
- A major barrier to routine VL monitoring is the centralized VL monitoring
- This is associated with delays in receiving results, transport challenges, mislabeling of samples and misplacing of results

WP1 SPECIFIC OBJECTIVES

i. To compare the rates of VL suppression between the POC VL monitoring arm and those in the centralized VL monitoring arm

ii. To compare time to VL suppression between the two study groups

iii. To estimate the cost of implementing the point of care viral load testing.

iv. Compare the proportion of participants that experience a virological rebound after initial suppression between the two arms

v. Compare the proportion of patients retained on a regimen throughout the study versus those who change regimens

vi. Document the time to initiation of intensive adherence counselling following virological failure

ELIGIBILITY CRITERIA

Inclusion criteria

- Age 0-19 years
- Documented evidence of HIV infection
- Receiving ART
- Detectable VL as per standard of care

Exclusion criteria

- Any medical conditions that require pausing of ART for >3 months

STUDY SITES/CLUSTERS

- 20 sites (10 intervention; 10 control)
  - Tanzania (3 partners): 6 sites
  - Uganda (2 partners): 6 sites
  - Kenya (1 partner): 4 sites
  - Rwanda (1 partner): 4 sites
- Cluster size: 60 participants
- Total sample size: 1200 participants

WP1 DELIVERABLES (1)

	DELIVERABLE NAME	TIMELINE (Months)	Status
1.1	Trial registration (clinicaltrials.gov)	**3** (31_May_2021)	Ongoing
1.2	Final study protocol	**6** (31_Aug_2021)	Ongoing
1.3	Clinical Trial insurance	**6** (31_Aug_2021)	Waiver to be requested
1.4	First study subject approvals package (Required for enrolment of 1st subject)	**9** (30_Nov_2021)	Ongoing
1.5	Incidental findings policy	**9** (30_Nov_2021)	Under development

WP1 DELIVERABLES (2)

	DELIVERABLE NAME	TIMELINE (Months)	Status
1.6	Clinical trial progress plan with projected dates (months)	**9** (30_Nov_2021)	Ongoing
1.7	All approvals package (Required for enrolment at all sites)	**15** (31_May_2022)	Ongoing
1.8	Midterm recruitment report	**18** (31_Aug-2022)	Ongoing
1.9	Report on status of posting results	48	

RECRUITMENT STRATEGIES OF CLUSTERS

- Increase clusters to more than 20
- Lower the VL cut off threshold to 500 copies/mL
- Change age eligibility to 0-24 years and possibly include pregnant women
- Cluster definition e.g. ≥2 sites to form one cluster (Increase m-PIMA)
- Adopt other molecular diagnostic PoC platforms (e.g. **Cepheid's GeneXpert®**) to combine clusters.

Questions

THANK YOU