

# HIP-CY Implementation Science Protocol Summary

Stakeholders' Meeting

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# CRPSs



# Study Title

Using Implementation Science To Understand And Design Stakeholder Informed Innovative Interventions To Improve Youth HIV Prevention And Care Continuums In Rural And Urban Uganda.

## Short title

HIV Prevention and Care interventions for Youth in Uganda (HIP-CY).

# Background

1

Adolescents and young adults (AYA) have a **high HIV incidence and poor treatment outcomes** along the entire HIV prevention and care cascade, compared to adults.

2

Despite the high HIV burden, both uptake of oral **PrEP** (HIV negatives) and achieving **viral suppression** (HIV positives) are **sub-optimal among youth** in sub-Saharan Africa.

3

**Cabotegravir, a new long-acting antiretroviral (CAB-LA)** is highly efficacious PrEP choice, compared to oral PrEP  
**SEARCH intervention** increases viral suppression in AYA

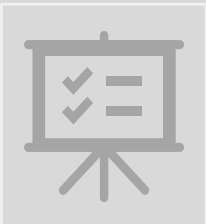
# Study Aims



1. To conduct formative research to enhance understanding of the barriers and facilitators for implementation of the proposed HIV prevention and care interventions in Aim 2 as well as capacity building and translation plans in Aim 3.



2. To assess the rollout of culturally acceptable, feasible HIV prevention and care interventions among AYA at high risk, on uptake and persistence to CAB-LA or SEARCH-YOUTH treatment support intervention.



3. To strengthen the capacity of Implementation Science and to translate findings into policy and guidelines through clearly defined and established channels.

# Study Aim 2

- **Aim 2a:** To assess delivery models (community pharmacy/drop-in center and health facility) to increase uptake & persistence on CAB-LA with a hybrid effectiveness implementation type II design
- **Aim 2b:** To evaluate scale up of the real-world implementation of the SY multilevel intervention in routine HIV clinics in Uganda
- **Aim 2c:** To estimate the direct and indirect costs of delivering long-acting PrEP (CAB-LA), the implementation of the SEARCH-YOUTH intervention, and evaluate cost-effectiveness



## Primary Endpoints

**AIM 1:** Understanding of implementation outcomes using CFIR

- Scale-up feasibility (different from trial feasibility)
- Mechanisms of action of the intervention that results in success or failure (CAB-LA)
- Sustainability
- Key factors that impact the effectiveness of individual components of each intervention
- Implementation barriers and facilitators from the delivery side



# End points

## Aim 2:

- **2a:**
  - Effectiveness of two delivery models (community vs health facility) on increasing uptake and persistence of CAB-LA
  - Implementation Science indicators of the intervention feasibility, acceptability, adoption and maintenance using the RE-AIM framework
- **2b:**
  - Implementation science indicators of intervention feasibility, adoption, fidelity, and sustainment using the RE-AIM framework
  - Effectiveness of Search Youth intervention on viral suppression
- **2c:**
  - Cost and cost-effectiveness of the implementation of two evidence-based interventions for HIV prevention and HIV care among AYAs in Uganda

## Aim 3:

- Research and non-research team members trained in implementation science

# Study Sites

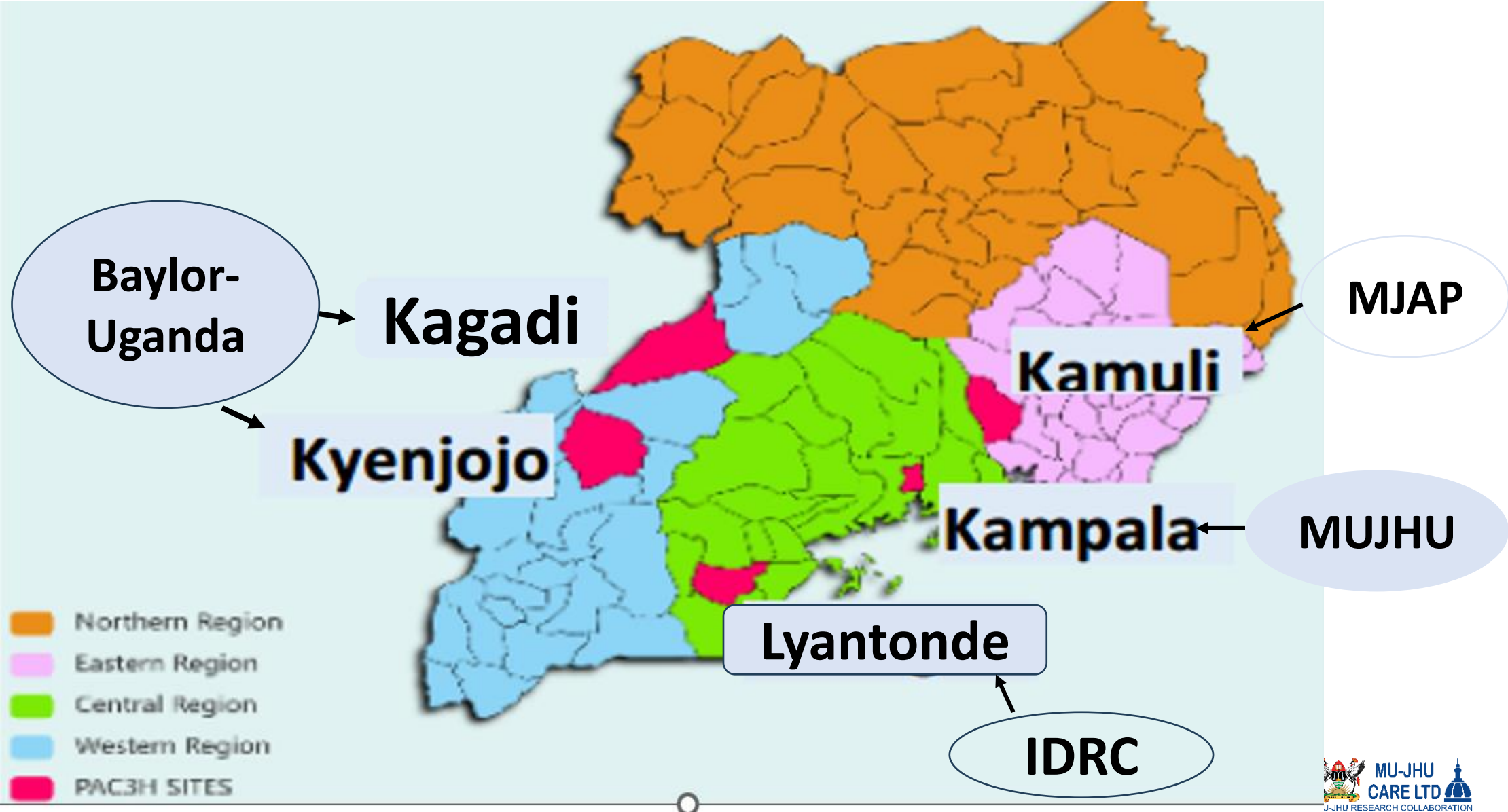


This study will be implemented by 4 consortium members (Baylor-Uganda, IDRC, MJAP and MU-JHU), operating at 5 Clinical Research Performance Sites (CRPS) in rural, semi-rural and urban Uganda.



The 5 CRPS are health center IVs (Lyantonde, Kamuli) and hospitals (Kampala, Kyenjojo, Kagadi).

# Clinical Research Performance Sites



# Study population and sample size

## AIM 1

Up to 80 participants will be selected for the focus group discussions (15 each CRPS; 2 FGD/ CRPS).

Up to 24 key stakeholders will take part in the in-depth interviews.

## AIM 2a

400 HIV negative AYA 15-24 years at high risk of HIV acquisition.

## AIM 2b

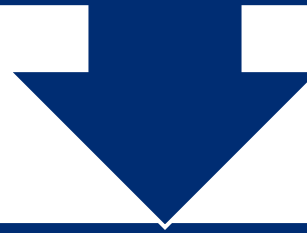
200 AYA 15-24 years living with HIV on ART but are at high risk of virologic failure.

## AIM 3

Consortium members and other key stakeholders.

# Implementation frameworks

The Consolidated Framework for Implementation Research (CFIR) framework will be used identify barriers and facilitators of potential implementation success of two innovations: CAB-LA uptake and persistence and SEARCH-YOUTH (SY) implementation

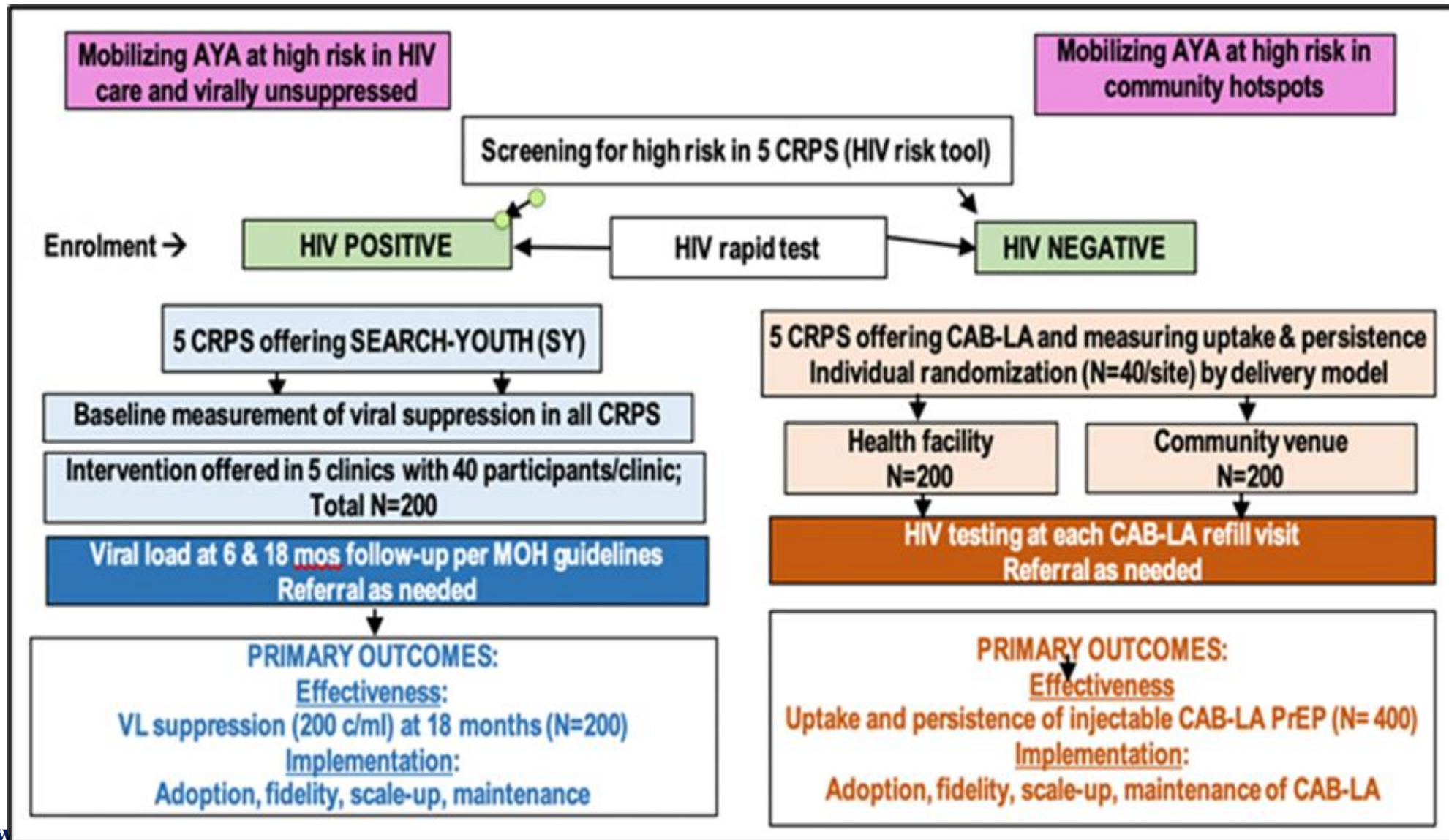


The RE-AIM Framework will be used to:

Assess the effectiveness of two delivery models on increasing uptake and persistence of CAB-LA

Feasibility, adoption, fidelity, and sustainment and effectiveness of SY on viral suppression

# Aim 2: Study schema



# Aim 2

Aim 2 will be informed by Aim 1 with regards to specific implementation

- **Aim 2a:** will individually randomize AYA to assess delivery models (community pharmacy/drop-in center and health facility)
  - increase uptake & persistence on CAB-LA with a **hybrid effectiveness type II design**
- **Aim 2b:** will evaluate scale up of the real-world implementation of the SY multilevel intervention in routine HIV clinics in Uganda using a **hybrid effectiveness type III design**
- **Aim 2c:** To estimate the direct and indirect costs of delivering long-acting PrEP (CAB-LA), the implementation of the SEARCH-YOUTH intervention, and evaluate cost-effectiveness

# Aim 2a intervention

- **Acceptability:** Enrolled AYA, health care providers and stakeholders will complete individual semi-structured questionnaires at end of study.
  - Assess acceptability of the intervention as well as delivery model.
- **Feasibility:** During and at end of study, staff at delivery locations will undergo interviews to provide insight into barriers faced during implementation.
  - Check records at both facility and community delivery models and compare with records for oral PrEP using national data.



# Aim 2b intervention

- The **SY multilevel intervention** is an efficacious strategy for improving virologic suppression in AYA aged 15-24 years living with HIV in East Africa (Ruel T, Mwangwa F, et al. A multilevel health system intervention for virological suppression in adolescents and young adults living with HIV in rural Kenya and Uganda (SEARCH-Youth): a cluster randomised trial).
- Providers and clinic in-charges will be trained (standardized 5-day training) on all aspects of the intervention.
- AYA living with HIV will receive the standard HIV care package of the MOH plus the SY package.

# Components of the SEARCH-YOUTH intervention

Life Stage  
Assessment  
Tool

Alternative Clinic  
Access  
(Before or after  
hours, off site, or  
by telephone)

Provider E-  
collaborative  
discussion of  
difficult cases  
as needed

Rapid Viral Load  
Feedback ASAP  
(<72hrs)

# Aim 3: Capacity building

Level 1  
Consortium research team

Level 2  
Non-research stakeholders



# Aim 3: Capacity building

We propose a two-level approach to build capacity in ImS for this research consortium

- **The first level will target consortium investigators** and staff leveraging on the existing structures of the Fogarty-funded D43 grant “*Building Implementation Science Capacity at Makerere University to Strengthen the Response to the HIV/AIDS Epidemic in Uganda*” (PIs Kamyá & Semitala)
- **The second level will target other stakeholders** and will use the experience gained through the U-AHISA’s participation in a grant “*Building implementation science capacity at Regional Referral Hospitals and their catchment communities to improve adolescent HIV care in Uganda*” (PIs Kamyá, Semitala & Namusoke-Magongo)

