LEVERAGING COMMUNITY & PEER-BASED APPROACHES TO IMPACT THE HIV TREATMENT CASCADE AMONG MSM IN SOUTH AFRICA
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Investigative Team

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  - Dr Ebrahim Hoosain
- **Study Sponsor**
  - Centers for Disease Control and Prevention, Division of Global HIV/AIDS

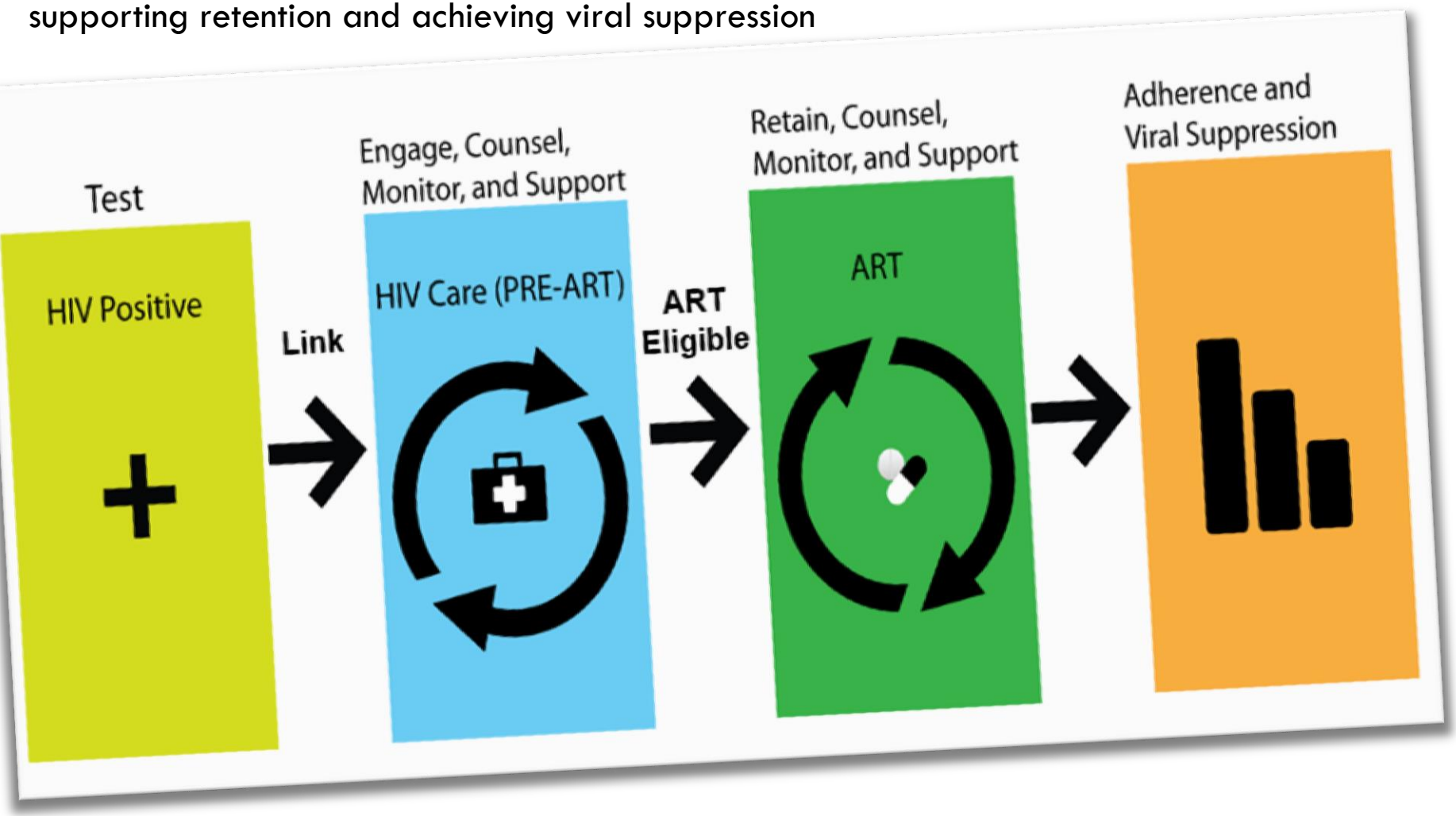
Background

- SA MSM high risk of HIV acquisition/transmission
- SA National Strategic Plan on HIV, STIs and TB 2012-2016 acknowledge MSM as key population
- disproportionate burden of HIV among MSM wherever studied
- Only 40% of ART eligible patients on treatment
- MSM face additional barriers to care, stigma, discrimination
- To reduce new HIV infections
  - **Testing**
  - **Linkage to care**
  - **Treatment**

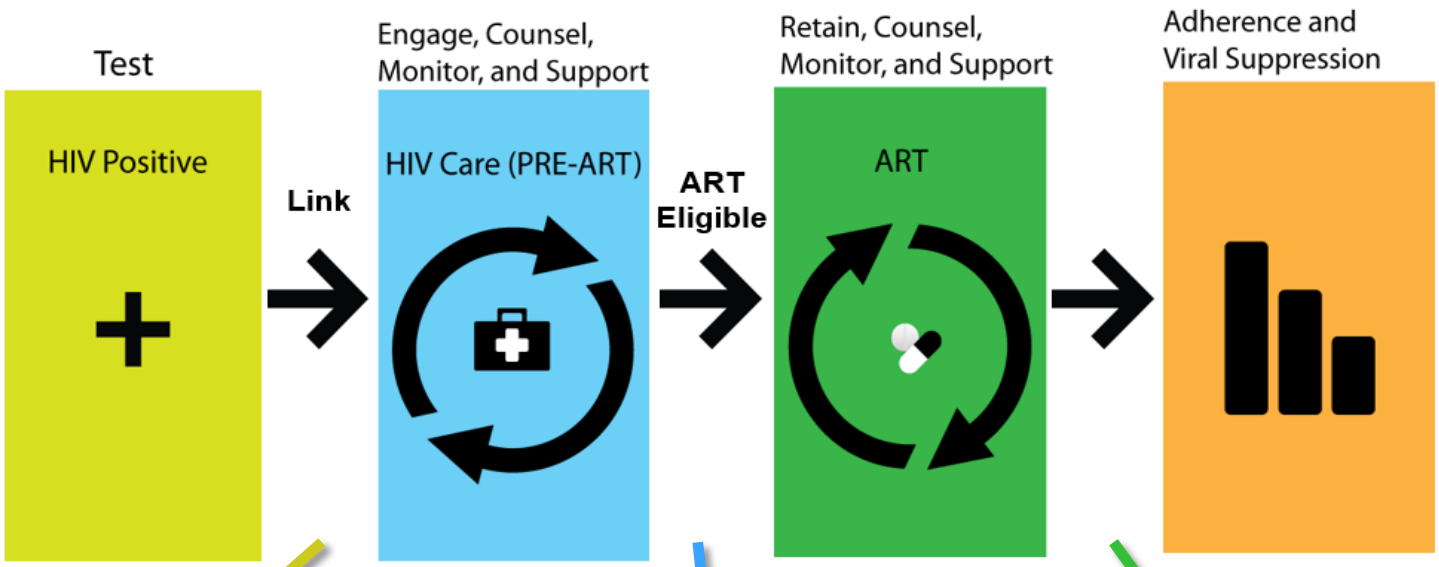
Study Purpose & Objectives

- Launch an effectiveness-implementation trial to Investigate the effectiveness (fidelity, feasibility, applicability, acceptability) of a package of innovative interventions
- To optimize continuum of care for difficult-to-reach MSM – essential for comprehensive HIV prevention, treatment, and care programs
  - Implement community-driven strategies to diagnose to find MSM who are unaware of their HIV status
  - Increase linkage to care and treatment initiation
  - Achieve viral suppression among treatment initiators through adherence support - retain MSM living with HIV in care and support adherence
  - Improve program delivery and uptake of services
- Capacity building in South African cities with little MSM services; build on existing programs in other sites
- Implementation science: test package of interventions that can be reasonably implemented and scaled up if effective
  - Measure utility (acceptability, feasibility, & uptake) of: POC CD4 vs standard clinic-based CD4 testing; peer-based adherence support for VL suppression; decentralization of ART programs and ideally establish best practices
- By implementing a package of community, individual, & peer-based interventions, we aim to improve treatment initiation, clinic retention, and medication adherence for treatment-eligible MSM, and improve monitoring of CD4 count among treatment-ineligible men.

We propose to implement a package of interventions and assess uptake, feasibility, acceptability, coverage at each stage of the HIV continuum of care and treatment cascade: finding MSM unaware of their HIV status, increasing treatment initiation, supporting retention and achieving viral suppression



HIV testing and treatment cascade
(credit W El-Sadr)

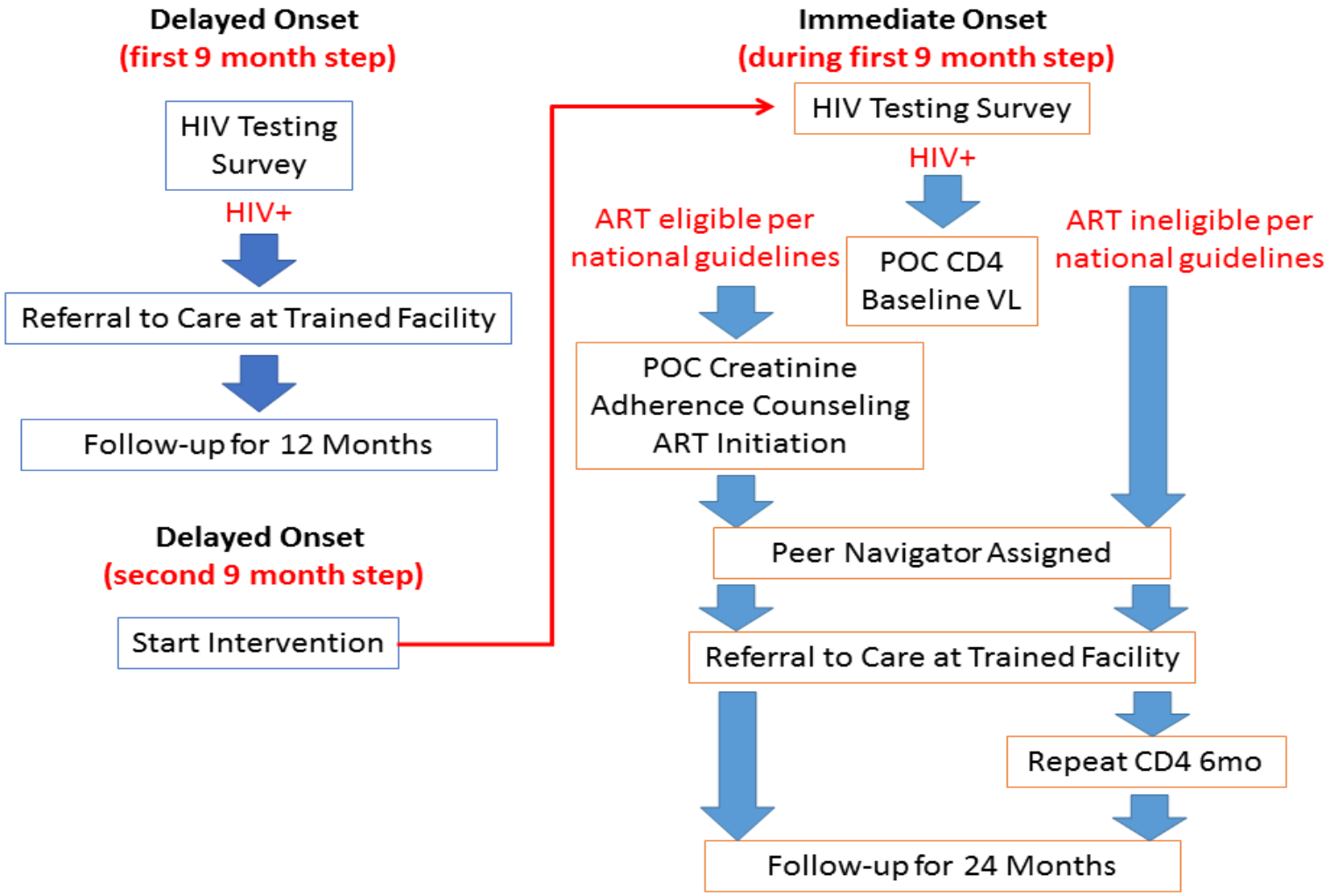


Aim 1: diagnose MSM unaware of HIV status

Aim 2: use POC CD4 testing to return results and improve determination of ART eligibility

Aim 3: assess utility of peer-based adherence support for achieving/sustaining VL suppression

Study Design



Study Design

- All groups receive the intervention
- Delayed on-set (single-step, stepped wedge)
- Determines feasibility of roll-out
- Determines time from intervention to effect
- Ability to Measure Implementation Outcomes
- Allows for comparison of effects across groups (both intervention and control time periods
  - Allows for 2 different comparison effects
    - Between immediate vs Delayed Onset
    - Delayed Onset
      - Before and After Implementation

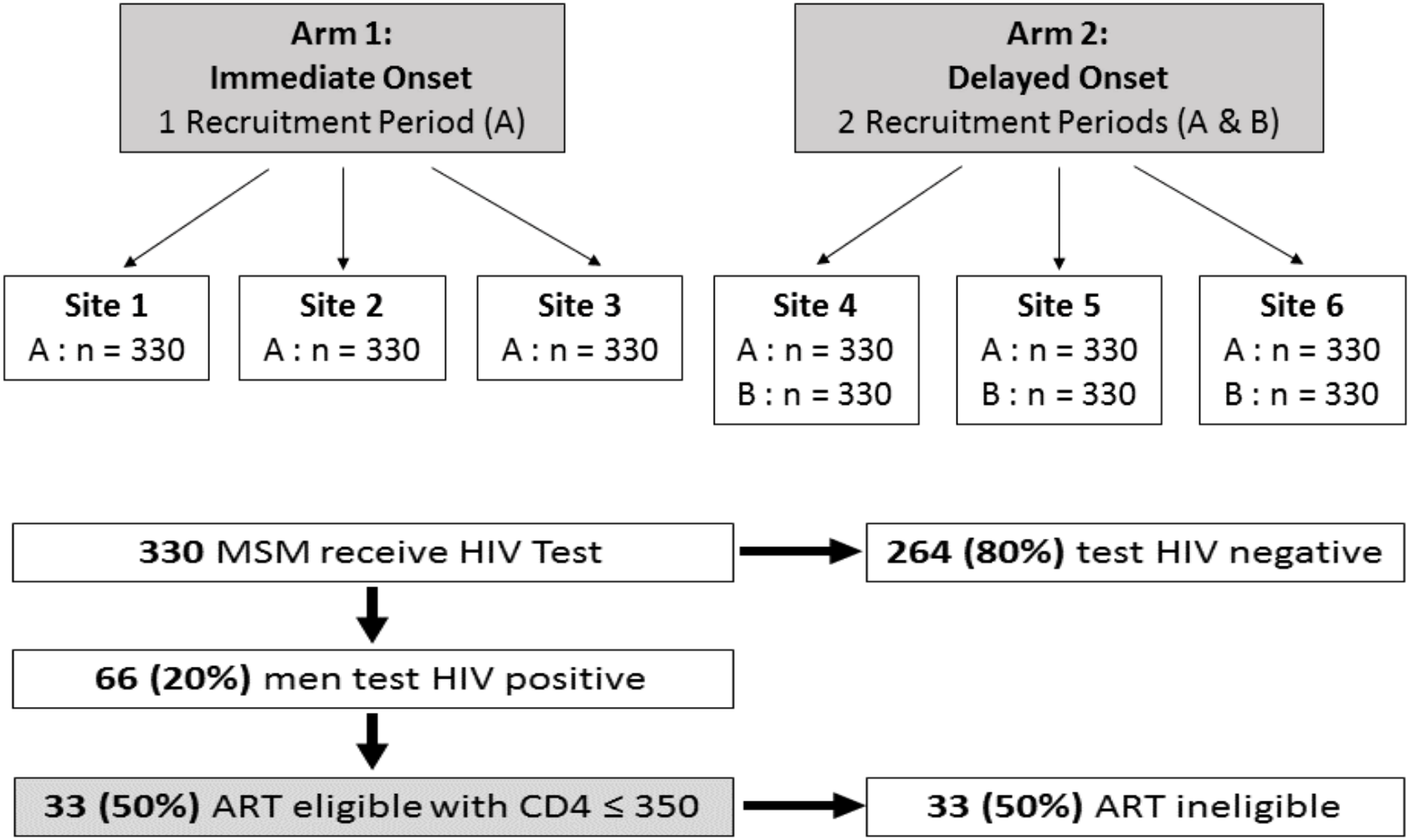
Study Population

- Inclusion Criteria
  - ≥18 years of age
  - Male sex at birth
  - Anal sex with another man in the past 12 months
    - Do not have to self-identify as gay, bisexual or transgender
  - Resident of the study site area
  - Able to complete study instruments, with or without assistance, in local languages (English, Xhosa, Tshivenda, Xitsonga, Isiswati, IsiZulu or Afrikaans)
  - Has access to private messages via a mobile phone
  - Willing to provide contact information, including mobile phone number
  - Willing to have study staff abstract clinic records and access laboratory results for up to 24 months after enrollment
  - Not currently on ART
- Exclusion Criteria for Follow Up
  - Men who test negative for HIV
  - Diagnosed with HIV and already on ART

Sample Size Assumptions

- Intra-cluster correlation of 0.05
- Coefficient of variation of cluster size is 0.25
- Power of 80%
- Statistical significance of 0.05
- All calculations were conducted with a starting proportion of 0.50. We used this conservative proportion to ensure we account for a large enough sample size.
- Magnitude of effect of intervention between 20 and 40% over standard of care
- 20% HIV Prevalence
- 50% ART Eligibility
- 10% Annual LTFU

Sample Size Calculation



Interventions

- All sites prior to enrollment
  - LGBT sensitization in clinics - clinical training on lesbian, gay, bisexual and transgender (LGBT) - Complete at clinics MSM attend - ANOVA, MSMGF/JHU, or Fenway Health
  - Decentralized HIV testing and counseling - Bring testing to CBOs (non-clinic spaces) to increase HIV testing among MSM in all sites
  - HCT is the "entry-point" for continuum of prevention, treatment, care, support and wellness
- Experimental condition
  - POC CD4 testing - Assess treatment eligibility at time of diagnosis to encourage treatment initiation
  - POC treatment initiation (if feasible) - NIMART nurse to initiate treatment if eligible
  - POC creatinine - for eligible men: for men with low CD4 and creatinine clearance rate ≥60 mL/min
  - Peer Health Navigators -HIV-infected men linked to study participants to encourage adherence and retention in care (1 navigator per 10 men)
- Control Arm
  - Standard care

Primary Outcomes

- Viral suppression is the ultimate outcome the package of interventions intends to impact
  - undetectable HIV viral load within 6 months of initiating treatment.
  - We will measure the proportion of ART eligible men enrolled in the study who achieve viral suppression within 6 months of initiating ART at the end of the 12-month follow-up period.

Secondary & Implementation Outcomes

Secondary Outcomes
Proportion of HIV-positive men who enter care
Proportion of men who receive CD4 results
Proportion of ART-eligible men who initiate ART
Time to ART initiation for ART-eligible men
Proportion of ART-eligible men who initiate ART and are retained in care
Proportion of treatment ineligible HIV-infected men who receive a CD4 test within 6 months following their study visit CD4

Implementation Outcomes
Acceptability of outreach/CBO-based testing intervention
Relative advantages of non-clinic-based ART initiation & retention package compared to standard of care
Perceived credibility of CBOs to initiate ART as compared to standard ART clinics
Utility of decentralized NIMART-trained nurse initiated ART and peer navigator based support
Implementation costs associated with experimental condition
Maintenance and routinization of using clinic-based approaches and peer-navigators for retention as indicators to describe potential sustainability of the interventions

Study Sites

- Nelson Mandela Bay Metro in EC Province
- Pietermaritzburg District in KZN Province
- Mopani District in Limpopo Province
- Alexandria in Gauteng Province
- Gert Sibande District in Mpumalanga Province
- Cape Town Metro in Western Cape Province

Staffing and Staff training

- Consistent within each site – Appoint 9 staff:
  - 1 coordinator, 1 NIMART trained nurse, 3 Peer Health Navigators, 2 Community Mobilizers, 2 counsellors; recruitment during site visits, appointment of local people, adverts being finalized
- Organizational structure – Project Director, HSRC Co-Ordinator, Site Co-ordinator
- Training on study procedures, research principles, data collection, chart abstraction and SMS system
- Training done in centralized location, followed by site specific training
- SOP/training materials to be developed
- Collaborators complementary roles – next slides

Implementation Progress to date

- Study Approvals
- Site selection
- Staffing and staff training
- Training plan
- Lab issues
- Immediate next steps
- Timelines

Study Approvals

- Protocol development
- Protocol revisions
- CDC Review
  - Approved
- HSRC Ethical Review
  - Approved
- Provincial clearance
  - Approved

Proposed District

- Woodstock, Cape Town CBD
- HSRC Office is based in Plein Street, Cape Town

MSM-Competent Facilities Identified

- Woodstock CHC
- Chapel Street Clinic
- Spencer Road Clinic
- Green Point CHC
- Claremont Clinic
- Silvertown Clinic
- Gugulethu Clinic

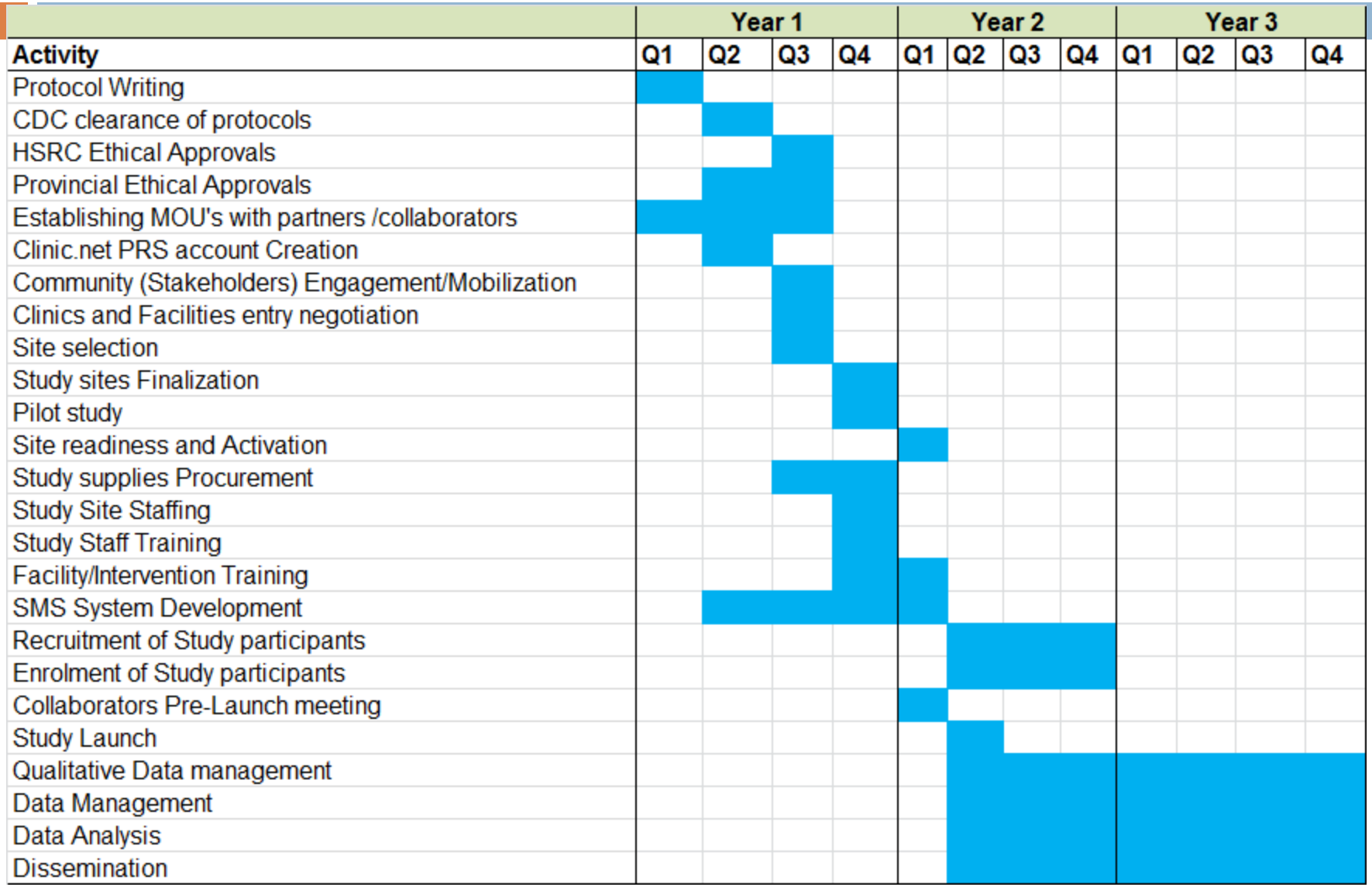
Stakeholders Identified

- **ANOVA – Health 4 Men;**
- **Desmond Tutu HIV Foundation (DTHF)**
- **The Networking HIV/AIDS Community of South Africa (NACOSA) ;**
- **The Inner Circle**
- **TB/HIV Care Association**
- **PASSOP**
- **Triangle Project**
- **SWEAT**

Stakeholders Identified (cont)

- **I AM**
- **SONKE GENDER JUSTICE**
- **Free Gender**
- **City of Cape Town (CoCT)**
- **Western Cape Government, Department of Health (PAWC)**
- **Realistic**
- **Imbumba**

KPIS Activities & Timelines

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