MTN 009
Protocol Overview

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Purpose of Study

- Primary Objective:
  - To determine prevalence of HIV drug resistance in a population of women interested in participating in an HIV prevention study **who test HIV positive prior to screening**
- Secondary Objective:
  - Understand potential spread of HIV drug resistance
  - Examine possible relationships between HIV drug resistance and risk behaviors

Exploratory Objectives

- To identify polymorphic or subtype-specific sequence changes in HIV-1 that may impact susceptibility to ARV drugs
- To estimate the proportion of HIV-positive women who have chronic versus recent HIV-1 infection

Study Design

- Multi-site - MRC HIV CTU
  - Botha's Hill
  - Chatsworth
  - Isipingo
  - Overport
  - Tongaat
  - Umkomaas
  - Verulam
- Cross-Sectional

Study Population

Participant Accrual

- N = 350 evaluable HIV positive women
  - Approximately 1000 women will be recruited in order to reach N value
  - Over approximately 2 years

Eligibility Criteria

- Inclusion
  - Present to pre-screen or screen for an HIV prevention trial
  - Women between the ages of 18 and 40 years
  - Able and willing to provide informed consent
  - Able and willing to provide adequate locator information

Eligibility Criteria

- Exclusion
  - Any condition that, in the opinion of the investigator, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achievement of the study objectives

Study Procedures

Screening and Enrollment Defined

- For MTN-009:
  - Screening = procedures performed to determine participant eligibility
  - Enrollment = the act of assigning a MTN-009 Participant ID (PTID)

Screening and Enrollment (Visit 1)

- All study assessments (i.e. for study endpoints) are scheduled to be completed at the Screening and Enrollment visit

Screening and Enrollment (Visit 1)

- Procedures:
  - Administrative and Regulatory
    - Informed consent
    - Determine eligibility
    - Collection of locator information
    - Assign PTID
    - HIV pre/post-test counseling
    - Provision of rapid test results
    - Reimbursement

Screening and Enrollment (Visit 1)

- Procedures:
  - Clinical
    - Blood specimen collection
  - Laboratory
    - Rapid HIV testing
    - CD4, viral load and drug resistance testing for HIV positive participants
  - Data collection
    - CRFs (4)
    - ACASI (1)

Screening and Enrollment (Visit 1)

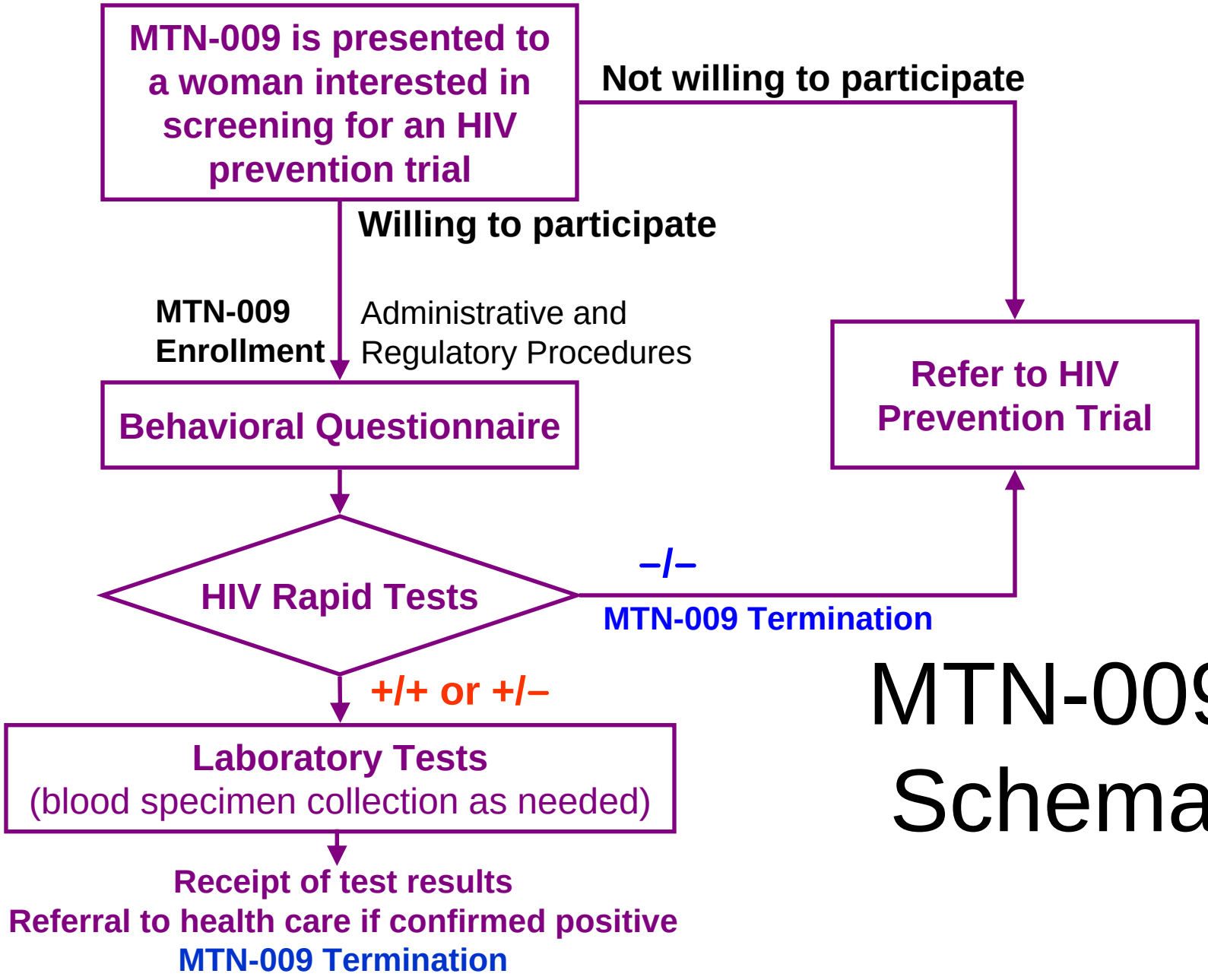
- Procedures:
  - Participants who test HIV-negative
    - Referral to HIV prevention trial (e.g. VOICE)
  - Participants who test HIV-Positive
    - Referral to health care provider
    - Schedule follow-up visit 1

Follow Up Visits

- HIV-positive participants will return to the clinic for 2 additional visits (visits 2-3) to receive CD4, viral load, and drug resistance test results

Follow Up (Visits 2-3)

- **Follow Up (Visit 2)**
  - Pre/post-test result counseling
  - Provision of CD4-positive T cell count
  - No data will be collected at this visit
- **Follow Up (Visit 3)**
  - Pre/post-test result counseling
  - Provision of plasma viral HIV-1 RNA level (viral load)
  - Provision of HIV-1 resistance test result, as needed
  - No data will be collected at this visit



MTN-009 Schema

Any Questions?

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Thank You

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