

**MTN 003 SCREENING PART 1
PRESENTATION
JOHANNESBURG
LILONGWE SITE
12 NOVEMBER 2008**

CLIENT FLOW

RECEPTION

- Welcome participant
- Confirm identity- confirm whether VOICE PTID was assigned before
- Determine screening attempt
- Check for co-enrollment
- Refer participant to the interview room

CLIENT FLOW

INTERVIEW ROOM

- Determine legal age of participant
- Obtain informed consent
- Assign PTID
- Obtain locator information
- Administer demographics form
- Administer screening part 1 eligibility form
- Refer exam room

CLIENT FLOW (cont'd)

EXAM ROOM

- Measure weight
- Collect urine and do PT
- Send urine to Lab for dipstick urinalysis and for GC and CT
- Refer participant to counseling room

CLIENT FLOW (cont'd)

COUNSELLING ROOM

- Provide HIV pre-test counseling
- Do risk reduction counseling
- Draw blood for HIV testing and remaining for CBC, Liver and renal function test, Hepatitis B surface antigen and antibody and Syphilis serology testing

CLIENT FLOW (cont'd)

COUNSELING ROOM

- Provide rapid HIV test results and post test counseling
- Transcribe rapid results onto screening and enrolment HIV test results forms
- Offer for HIV counseling and testing for partner
- Provide condom and refer to clinician

CLIENT FLOW (cont'd)

CLINICIAN

- Medical eligibility determination
- Disclosure of available results
- Treatment for STI/UTI if clinically indicated
- Refer for contraception if clinically indicated and back to reception room for review of visit and reimbursement

SPECIMENS

ADMINISTRATIVE

- Specimens requiring ASAP results will be immediately taken to Lab next door
- Tests will be run from Mondays to Friday, between 7:30am and 4:30pm and emergencies on weekends and public holidays

SPECIMENS (cont'd)

TRANSPORTATION AND TRACKING

- Transported to Lab in cooler boxes
- Specimen collection tracked through duplicate Lab request forms

SPECIMENS (cont'd)

TRANSPORTATION AND TRACKING

- In clinic pH and PT tracking logs
- Daily reconciliation of archived samples between Lab and clinic.
- Daily posting of results in the MTN 003 folder based in the Lab

SPECIMENS (cont'd)

QA/QC

- Daily monitoring of temperature in clinic
- Random selection and testing of samples by Lab staff - QA/QC monitoring
- Weekly positive and negative controls done in clinic, results documented in QC logs and reviewed monthly
- Monthly review of all in clinic logs by Lab personnel

STUDY PRODUCT

RANDOMIZATION

- Review randomization procedure with participant
- Assign next sequential envelope
- Open envelop in front of participant
- Complete prescription in front of participant

STUDY PRODUCT contd

- If Gel or tablets nurse escorts participant to pharmacy with prescription
- Duplicate remains in folder
- Product adherence counseling

PRODUCT EXCHANGE

- Continuous counseling
- Use of color coded ribbons

FORMS

- Locator
- Demographics
- Screening Part 1 Eligibility
- Safety Laboratory Results
- STI Laboratory results
- Screening and Enrollment HIV Test Results