VOICE
Screening Part 1 Visit

Operational Walkthrough
Johannesburg, South Africa
November 2008

Protocol Requirements

- Administrative, Behavioral, and Regulatory Procedures
  - Informed consent for screening
  - Demographic information
  - Behavioral eligibility information, using the Screening Part 1 Eligibility form
  - Locator information

Protocol Requirements

- Administrative, Behavioral, and Regulatory Procedures
  - HIV pre-test counseling
  - HIV/STI risk reduction counseling
  - Offer HIV counseling and testing for partners
  - Provision of condoms
  - Reimbursement
  - Schedule next visit (if applicable)

Operational Considerations

- Administrative, Behavioral, and Regulatory Procedures
  - Participant identification and checking for co-enrollment in other studies are not listed as “required procedures” in the protocol, but should be performed at each visit

Operational Considerations

- Administrative, Behavioral, and Regulatory Procedures
  - Obtain written informed consent before performing any screening procedures
  - Determine participant age as part of the screening informed consent process
  - Date of informed consent for screening begins the 56-day screening and enrollment period

Protocol Requirements

- Clinical Procedures
  - Medical eligibility information
    - Using the Screening Part 1 Eligibility form
    - May require clinician review of TB status
  - Weight
  - Urine collection (15-60 mL)
  - Blood collection (approximate volumes)
    - 15 mL in red top tubes (plain or serum separator)
    - 6 mL in lavender top tube (EDTA)

Protocol Requirements

- Clinical Procedures
  - Pelvic exams may be performed at Screening Part 1 if local standards of care require an exam to guide treatment of STI/RTI symptoms

Protocol Requirements

- Clinical Procedures
  - Disclosure of available test results
  - Treatment for UTI/STI/RTI if clinically indicated
  - Offer of STI testing and treatment for partners if indicated
  - Ascertainment of current contraceptive method (if any) and contraceptive counseling
  - Provision of contraception if indicated per site SOP

Operational Considerations

- Clinical Procedures
  - Time required to evaluate current genital symptoms
  - STI/RTI treatment regimens
    - Use single-dose observed regimens
    - No test of cure required
    - But treatment must be completed and any symptoms resolved before enrollment

Protocol Requirements

- Laboratory Procedures
  - Urine pregnancy test
  - Dipstick urinalysis for protein, glucose, nitrites, and leukocyte esterase
  - Urine SDA for gonorrhea and chlamydia

Protocol Requirements

- Laboratory Procedures
  - HIV serology
  - Syphilis serology
  - Complete blood count with differential and platelets
  - Serum chemistries: AST, ALT, creatinine, phosphate
  - Hepatitis B surface antigen test
  - Hepatitis B surface antibody test

CBC With Differential

- Required elements per protocol
  - Hemoglobin
  - Hematocrit
  - MCV
  - Platelets
  - White blood cells
  - Neutrophils – absolute count AND percentage
  - Lymphocytes – absolute count
  - Monocytes – absolute count
  - Eosinophils – absolute count
  - Basophils – absolute count

Operational Considerations

- Laboratory Procedures
  - Volume of testing for eligibility criteria
  - Coordination of clinic and lab
    - Days and hours of operation
    - Transporting and tracking specimens
    - Tracking result reports
  - Monitoring temperature and maintaining QC/QA for tests performed in clinic

Operational Considerations

- Laboratory Procedures
  - Calculating creatinine clearance

$$\frac{(140\text{-age in years}) \times (\text{weight in kg}) \times (0.85)}{72 \times \text{serum creatinine in mg/dL}}$$

Operational Considerations

- Laboratory Procedures
  - Tracking dipstick urinalysis results across screening and enrollment visits
    - If 2+ or greater for protein or glucose ⇒ INELIGIBLE
    - If 1+ for protein or glucose ⇒ repeat testing at Screening Part 2

Operational Considerations

- Scheduling next visit
  - 56-day screening and enrollment period
  - Number of Screening Part 2 visits that can be scheduled on any one day
  - Time required to receive lab test results
  - Participant's menstrual period
  - Current UTI/STI/RTI symptoms / time to resolution following treatment
  - Any other current exclusionary conditions / time to resolution
  - Continue current screening attempt?

Sequence of Procedures

- Check for co-enrollment before proceeding to screening informed consent process
- Obtain informed consent before performing any screening procedures
- Assign PTID after informed consent obtained
- Provide HIV pre-test counseling before collecting blood for HIV testing
- Order procedures for maximum screening efficiency — perform procedures with highest expected screen-out rate first — and minimum waiting time during visit
- Stop when participant found to be ineligible

MTN
microbicide trials network

What are your questions?

Questions for Site Input

- What study information materials would you provide to potentially eligible participants at the end of the Screening Part 1 visit?
- Would you spend time explaining/discussing these materials at the Screening Part 1 visit, or wait until the Screening Part 2 visit?