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
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?