VOICE Enrollment Visit

Operational Walkthrough
Johannesburg, South Africa
November 2008

Before the Enrollment Visit

Before the Enrollment Visit

- Complete initial QC/QA review of Screening Part 2 visit documentation
- Receive, review, grade, and assess the clinical significance of the participant's screening Pap result (either result report from Pap collected at Screening Part 2 or documented normal Pap within the 12 months prior to enrollment)
- Receive, review, grade, and assess the clinical significance of the results of any clinically indicated lab tests performed at Screening Part 2

Before the Enrollment Visit

- Complete Screening Part 2 Medical Eligibility form
- Assess eligibility based on lab test results
- Assess clinical management and referral needs
- Transcribe lab test results onto case report forms
- Document all review and action steps
- Complete additional QC/QA and eligibility reviews

Protocol Requirements at the Enrollment Visit

Confirmation of Eligibility

- Before proceeding to enrollment, complete eligibility determination:
  - Verify visit date is within 56 days of informed consent for screening
  - Check for co-enrollment
  - Review all prior screening documentation
  - Re-confirm participant-reported eligibility information

Confirmation of Eligibility (cont)

- Actively review and update medical/menstrual history and current medications
- Urine collection and pregnancy test
- Blood collection and HIV counseling & testing
  - Includes HIV/STI risk reduction counseling, offer of counseling and testing for partners, and provision of condoms
- Provision of contraception if indicated

Confirmation of Eligibility (cont)

- If clinically indicated or if needed to confirm eligibility:
  - Dipstick urinalysis
  - Pelvic exam components
  - Any other behavioral, clinical, and/or lab assessments

Confirmation of Eligibility (cont)

- For participants determined to be eligible, confirm/verify eligibility per site SOPs
- For potential participants confirmed to be eligible, proceed to enrollment informed consent process
  - After informed consent process is completed, all eligibility criteria will have been assessed

Proceeding to Enrollment

- After obtaining informed consent, proceed with procedures to complete the enrollment process and perform “on study” procedures

Administrative, Behavioral, and Regulatory Procedures

- Informed consent for specimen storage and possible future research testing
- Behavioral risk assessment
  - Baseline Behavior Assessment form
  - Baseline ACASI Questionnaire

Clinical Procedures

- Contraceptive counseling
  - May have been done prior to informed consent for enrollment, as part of eligibility determination

Clinical Procedures

- If indicated, Hepatitis B vaccination or documentation of declination of vaccination
  - Participants who are HBV susceptible will be given information and offered the vaccine series starting at their enrollment visits
  - For enrolled participants who are susceptible but decline vaccination at enrollment, the vaccine series may be initiated any time during follow-up

Clinical Procedures

- Blood collection for plasma archive
  - May have been done prior to informed consent for enrollment, to avoid “second stick”
  - Approximately 4 mL for HIV testing, plus 10 mL for archive
  - Keep 10 mL refrigerated between collection and completion of enrollment procedures
  - After enrollment, deliver to lab, with LDMS Specimen Tracking Sheet

Laboratory Procedures

- Plasma archive
  - Plasma archive is critical for confirmation of primary study endpoints
  - Verify receipt of blood collected for plasma archive in the laboratory per site SOPs
  - Perform clinic-lab reconciliation of plasma archive specimens as least weekly

MORE Administrative, Behavioral, and Regulatory Procedures

- Randomization – will be covered in detail in SCHARP presentations

MORE Administrative, Behavioral, and Regulatory Procedures

- Provision of study product, instructions, and adherence counseling
  - Participant obtains product supplies at pharmacy
  - Then returns to clinic for instructions and counseling
  - Then completes first product use in clinic
  - Then receives further instructions (as needed) and adherence counseling
- Reimbursement
- Schedule next visit (if indicated)

Operational Considerations

- Determine and confirm/verify eligibility before proceeding to informed consent for enrollment
  - May require additional behavioral, clinical and lab procedures
  - Expected to be time and labor intensive
- Obtain informed consent for enrollment before performing any “on study” procedures
  - Expected to be time and labor intensive

Operational Considerations

- After informed consent, but before randomization:
  - Blood collection for plasma archive
  - Hepatitis B vaccination if indicated
  - Behavioral risk assessment
- After randomization:
  - Provision of study product, instructions, and adherence counseling
    - Expected to be time and labor intensive
    - DO NOT inspect or handle unwrapped gel applicators in the clinic (have receptacles available)

Questions?