

# VOICE

## Month 1 and Month 2 Visits

Operational Walkthrough  
Johannesburg, South Africa  
November 2008

# Protocol Requirements

- Visit Scheduling
  - Target visits every 28 days following the study enrollment date (Day 0)
  - Visit window opens: target date -14 days
  - Visit window closes: target date +13 days
  - SCHARP will provide a tool to generate visit calendars for each participant

# Visit Scheduling Question

Given that follow-up visits are scheduled to take place every 28 days, how many “monthly” visits will each participant be scheduled to complete during one calendar year?

# Protocol Requirements

Administrative, Behavioral, and Regulatory Procedures



	M1	M2
Participant identification	✓	✓
Check for co-enrollment	✓	✓
Locator information	✓	✓
Behavioral and study product adherence assessments	✓	✓

# Protocol Requirements

## Administrative, Behavioral, and Regulatory Procedures

	M1	M2
HIV pre- and post-test counseling	✓	✓
HIV/STI risk reduction counseling	✓	✓
Offer HIV counseling and testing for partners	✓	✓
Provision of condoms	✓	✓

# Protocol Requirements

## Administrative, Behavioral, and Regulatory Procedures

	M1	M2
Provision of product supplies, instructions, adherence counseling	✓	✓
Reimbursement	✓	✓
Schedule next visit	✓	✓

# Operational Considerations

- Behavioral and study product adherence assessments
  - Participant return of unused product supplies to pharmacy: when?
  - Coordination and communication between clinic and pharmacy: pharmacy will need to provide clinic with amount of product returned, re-issued, and newly dispensed
  - Behavioral interviews should take place before study product adherence counseling

# Protocol Requirements

## Clinical Procedures



	M1	M2
Interval medical & menstrual history	✓	✓
Current medications	✓	✓
Contraceptive counseling	✓	✓
Provision of contraception	*	*
Weight	✓	*
Physical exam	✓	*
Pelvic exam	*	*

\* = If clinically indicated



# Protocol Requirements

## Clinical Procedures

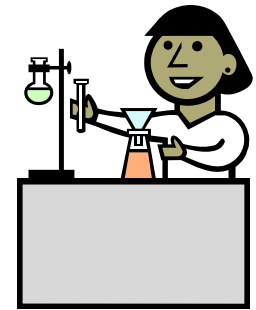
	M1	M2
Urine collection	✓	✓
Blood collection	✓	✓
Disclosure of available test results	✓	✓
Treatment for UTI/STI/RTI	*	*
Offer of STI testing and treatment for partners	*	*
Hepatitis B vaccination	*	*

\* = If clinically indicated

# Blood Collection

(approximate volumes)

- Month 1
  - 1 x 5 mL lavender top (EDTA)
  - 1 x 5 mL red top (no additive)
- Month 2
  - 1 x 5 mL lavender top (EDTA)
  - Or fingerstick if validated



# Protocol Requirements

## Laboratory Procedures

	M1	M2
Urine pregnancy test	✓	✓
Dipstick urinalysis		
-Protein	✓	*
-Glucose	✓	*
-Nitrites	*	*
-Leukocyte esterase	*	*
HIV serology	✓	✓
Serum chemistries		
AST, ALT, phosphate, creatinine	✓	*

\* = If clinically indicated

# Protocol Requirements

## Laboratory Procedures

- Other lab procedures that may be done if clinically indicated
  - Tests and specimen archive associated with pelvic exams
  - Urine SDA for gonorrhea and chlamydia
  - Syphilis serology
  - Complete blood count with differential and platelets
  - Hepatitis B tests (surface antigen, surface antibody)

# Study Product Supplies and Adherence Counseling

- After completing all evaluations at each visit, determine eligibility to continue product use
- Complete Study Product Request Slip
  - Re-Supply
  - Hold
  - Permanently Discontinue
- If product use is continued, provide adherence counseling

What are  
your questions?