Lusaka 035 Flow Fitted to MTN 003

~1 week

Pre Screening VCT (hCG too? depending on cost)

SP1

IC Booklet given

Provide FP

≤ 2 weeks

SP2

IC Booklet reviewed

Provide FP, if not at SP1

≤ 2 weeks

SP3?

Appt for IUCD or implant Insertion off-site

SP3/4?/Enrollment
Review of Checklists/Worksheet

- SP2 Checklist
- Screening Pelvic Checklist
  - Change in order - shift down of SP2 Behavioral Eligibility Form
  - Shortened wording
- Between SP2 and Enrollment Worksheet
  - Additions of breastfeeding, adequate locator, contraception
  - Suggested reformatting re eligible and non eligible boxes
Suggestion

- Simplify U/A instructions and create a U/A Flow Sheet to use throughout each screening attempt
Ppt-Reported Baseline Medical Menstrual History - Site MO feedback

- Uncomplicated ppt took approximately 30 minutes to administer
- Need more space for description
- Consider additional notes page
- Guide
SP2/Enrollment Behavioral Eligibility Form

Issues:

Q3  Surgical sterilization of partner making ppt ineligible conflicts with Q4 and protocol page 42

Q4  24 months (2 years) versus “duration of study”

Q5  previous vaccine trial participation greater than 30 days ago

Q6  24 months (2 years) versus “duration of study”
I am now going to ask some questions about you, your sexual behaviors and your health. There are no right or wrong answers, and every answer is important, so we need you to be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. In the past six weeks (42 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? yes  no

2. Are you breastfeeding now? yes  no

3. Which method of contraception are you currently using? **Mark all that apply.**

   - Oral contraceptive pills
   - Contraceptive injections
   - Contraceptive implants
   - Contraceptive ring
   - Contraceptive patch
   - Intrauterine contraceptive device
   - Surgical sterilization of participant (as verified per site SOP)
   - Surgical sterilization of partner(s) (as verified per site SOP)
   - Other, specify: __________
   - None

   **If “surgical sterilization of participant,” go to item 5.**

   **Participant is ineligible.**
4. If you were to join this study, would you be willing to use this contraceptive method or another reliable method for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo provera), contraceptive implants (for example, norplant or jadelle), contraceptive rings, contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of your partner(s) ............... yes no

If no, participant is ineligible.

If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.

If yes at Enrollment, participant is ineligible.

5. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products? .................................................................

6. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)? ................................................................. yes no

If no at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, and only needs more time to provide adequate locator information, schedule Enrollment Visit (or another screening attempt) to occur when adequate locator information is available.

If no at Enrollment, participant is ineligible.

End of interview. Complete item 7 after the interview.

7. Was the participant willing and able to provide adequate locator information as defined in site SOPs? ................................. yes no

If no at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, and only needs more time to provide adequate locator information, schedule Enrollment Visit (or another screening attempt) to occur when adequate locator information is available.

If no at Enrollment, participant is ineligible.
Vaginal Test Results Form

Issues:
- Who initials and dates this form?
  - the person who collects the specimens
  - the person who does the test
  - or the person who transcribes the results
Issue:

- Page 3 instructions arrow placement obscures text
Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Vaginal Test Results (VTR-1)

Participant ID
Site Number - Participant Number -

Initial Collection Date

Vaginal Test Results

Alternate Collection Date

Not done/Not collected

dd MMM yy

1. VAGINAL WET PREP STUDIES

Not done

1a. Homogeneous vaginal discharge

1b. pH

1c. Whiff test

1d. Clue cells > 20%

1e. Trichomonas vaginalis

1f. Buds and/or hyphae (yeast)

Wet Prep:

Alternate Collection Date

Not done/Not collected

dd MMM yy

2. Trichomonas Rapid Test

3. BV Rapid Test

At Screening:
If participant is diagnosed with Trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, she must complete treatment and be asymptomatic to enroll.

During Follow-up:
If participant is diagnosed with Trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, complete an Adverse Experience Log. Note: asymptomatic bacterial vaginosis and asymptomatic vulvo-vaginal candidiasis are not reportable as AEs.

Who initial/dates here??
5. Please answer the following questions based on the participant's laboratory results from the Screening Part 1 and Screening Part 2 Visits.

5a. Is the participant pregnant? ................................................................. yes  no

5b. Is the participant HIV-infected per the screening algorithm in protocol Appendix II? .................................................................

5c. Is the participant's AST or ALT > 1.5× site lab upper limit of normal (ULN)? .......

5d. Is the participant's calculated creatinine clearance <60 mL/min? .................

5e. Is the participant's serum creatinine greater than the site lab ULN for women?

5f. Is the participant's hemoglobin < 10.0 g/dl? ...........................................

5g. Is the participant's platelet count < 100,000/mm³? .................................

5h. Is the participant's serum phosphate level below the site lab lower limit of normal (LLN)? .................................................................

5i. Did the participant test positive for Hepatitis B surface antigen (HBsAg)? .......

5j. Is the participant's dipstick urinalysis for protein ≥ 1+ or greater from a single visit?

5k. Does the participant have at least two dipstick urinalysis protein results of 1+ or greater at separate visits? .................................................

5l. Is the participant's dipstick urinalysis result for glucose ≥ 1+ or greater from a single visit? .................................................................

5m. Does the participant have at least two dipstick urinalysis glucose results of 1+ or greater at separate visits? .................................................

If yes to any, participant is ineligible. For all exclusionary test results, except HIV infection and dipstick urinalysis results, participant may be retested and enrolled (or being another screening attempt) if the retest result is not exclusionary per protocol.

6. Does the participant have any other condition that, in the opinion of the Itr/designee, would preclude informed consent, make participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives? ................................................................. yes  no

If yes, participant is ineligible.