MTN 003
Screening Part 2 Visit

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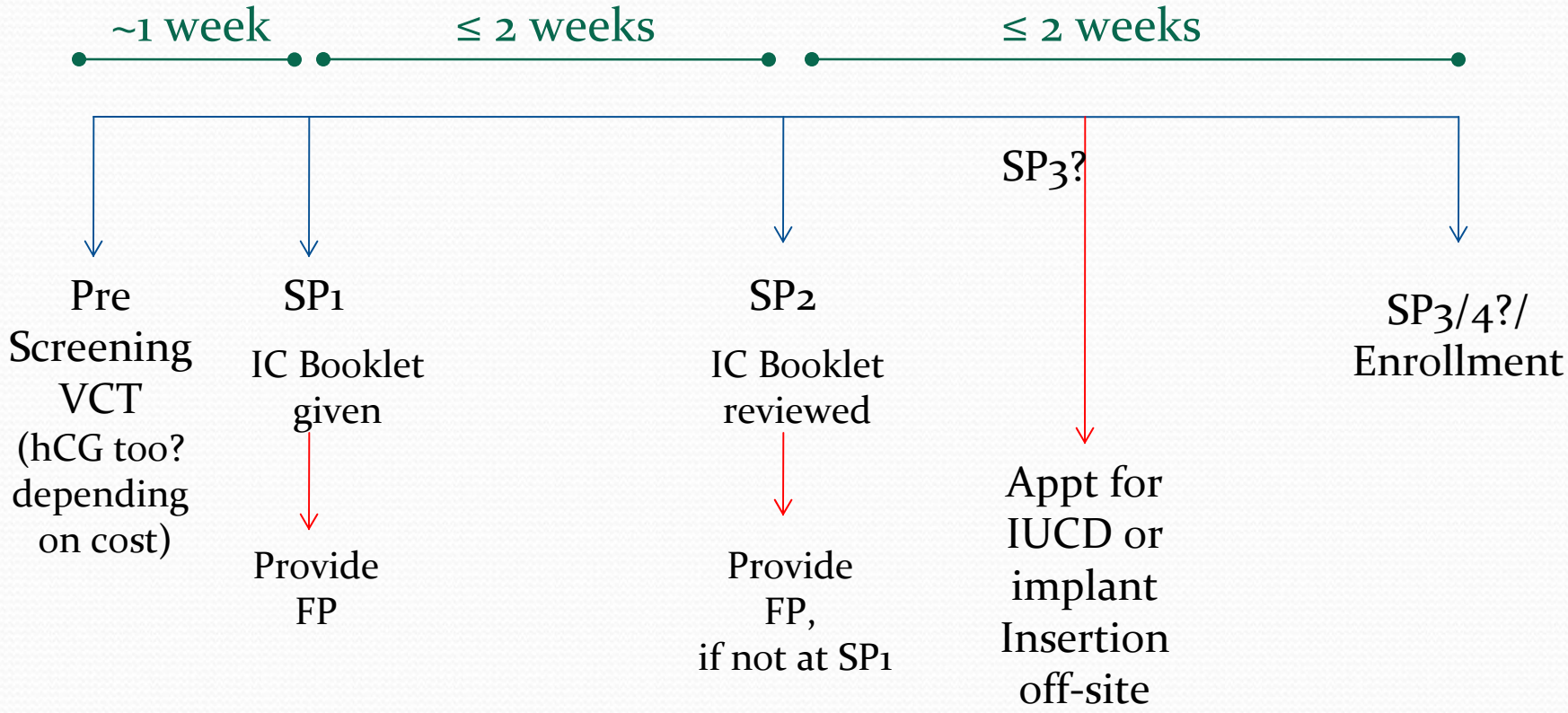
Lusaka 035 Flow Fitted to MTN 003



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:

Q 3 Surgical sterilization of partner making ppt ineligible conflicts with Q4 and protocol page 42 ➡

None ppt is ineligible

Q4 24 months (2 years) versus "duration of study"

Surgical sterilization of partner making ppt ineligible

Q5 previous vaccine trial participation greater than 30 days ago

Q6 24 months (2 years) versus "duration of study"

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MTN003 VOICE (160)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]

Site Number Participant Number Chk

Screening Part 2/Enrollment Behavioral Eligibility

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

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* ☐ → ***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 43 days after last pregnancy outcome.***

2. Are you breastfeeding now? ..... ☐ ☐ → ***If yes, participant is ineligible.***

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) → ***If "surgical sterilization of participant," go to item 5.***
- ☐ Surgical sterilization of partner(s) (as verified per site SOP) → ***Participant is ineligible.***
- ☐ Other, specify: _____
- ☐ None → ***Participant is ineligible.***

[ ][ ][ ][x] 15-OCT-08

[0][1] Language

_____ Staff Initials / Date

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Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Screening Part 2/Enrollment Behavioral Eligibility

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.***

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

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, 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

SP2 Medical Eligibility – Page 3

Issue:

- Page 3 instructions arrow placement obscures text

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Vaginal Test Results (VTR-1)

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MTN003 VOICE (160)

VTR-1 (143)

Visit Code ____.__ 1

Participant ID ___-_____-__ (Site Number – Participant Number – Chk)

Vaginal Test Results

Initial Collection Date: dd MMM yy

Alternate Collection Date: Not done/Not collected; dd MMM yy

1. VAGINAL WET PREP STUDIES

		negative	positive
Not done			
1a.	Homogeneous vaginal discharge		
1b.	pH ____.____ → *If > 4.5 mark as positive.*		
1c.	Whiff test		
1d.	Clue cells > 20%		
1e.	*Trichomonas vaginalis*		
1f.	Buds and/or hyphae (yeast)		

Wet Prep: _____ Staff Initials/Date

Alternate Collection Date: Not done/Not collected; dd MMM yy

		negative	positive
2.	Trichomonas Rapid Test		
3.	BV Rapid Test		

Trichomonas and BV Rapid Test: _____ Staff Initials/Date

Who initial/dates here??

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.

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MTN003 VOICE (160)

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number – Participant Number – Chk)

Screening Part 2 Medical Eligibility

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

5. Please answer the following questions based on the participant's laboratory results from the Screening Part 1 and Screening Part 2 Visits.

		yes	no
5a.	Is the participant pregnant?	☐	☐
5b.	Is the participant HIV-infected per the screening algorithm in protocol Appendix II?	☐	☐
5c.	Is the participant's AST or ALT > 1.5x 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 < 10.0g/dl?	☐	☐
5g.	Is the participant's platelet count < 100,000/mm^3?	☐	☐
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 2+ 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 2+ 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 IoR/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.