**Follow this guide immediately upon determining a participant’s pregnancy test is positive. Refer to the MTN-034 SSP, Protocol, and site SOPs for additional details.**

**I. Next steps when determining pregnancy (complete at same visit as the pregnancy test)**

1. Document pregnancy test outcome on **Pregnancy Test Results CRF**.
2. Counsel participant on results and refer for antenatal care (per site SOP). Explain the immediate procedures to be done.
3. Provide HIV pre-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.**
4. Collect the following blood samples and send to lab:
	1. HIV Testing- EDTA or plain tube 4 mL
	2. DBS for PK testing
	3. CBC with platelets
	4. Creatinine clearance (take height measurement for calculation)
5. Perform HIV rapid tests
6. Collect specimens for biomarkers: vaginal and cervical swabs and CVL (using Pelvic Exam checklist)
7. Collect dispensed VR or unused tablets and send to pharmacy. Complete the following:
	1. **Site-Specific Clinic Study Product Accountability Log**
	2. **Ring Insertion and Removal CRF** or **PrEP Provisions and Returns CRF**, as applicable.
	3. **Study Product Request Slip** and **Product Hold Summary/Log CRF** for product HOLD
8. Administer behavioral assessments:
	1. Administer the **Early PUEV/Discontinuers ACASI** and document on the **ACASI Summary CRF**, if not already done at visit. Administer the ACASI survey (ring, tablet, or “no product”) that corresponds to the product she was using at the time of the positive pregnancy test.
	2. Administer the **Product Preference and Acceptability CRF,** if not already done at visit.
	3. If applicable, update Qualitative Participant Log (QPL).
9. ProvideHIV post-test counselingfor potential HIV infectionusing the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet** and offer condoms.
10. Conduct modified product adherence counseling providing drug level feedback, if scheduled and participant is willing. Complete **Adherence Counseling CRF** and document on the **Adherence Counseling Worksheet**.
11. Complete the **Pregnancy Report CRF, Pregnancy History CRF,** and, *if applicable,*the **Pregnancy Outcome Log CRF.**
12. Offer participant to remain in study follow-up with a modified visit/procedure schedule (See considerations in section II below)\*
13. Document specimen storage and laboratory test results, as applicable:
	1. **LDMS Tracking Sheet** and **Specimen Storage CRF**
	2. **HIV Test Result** and **Local Laboratory Results CRFs**
14. Complete a **MTN-034/REACH Pregnancy Case Worksheet** and submit per instructions in worksheet.
15. Complete all other procedures per the applicable visit checklist except for study product provision.

\* For a participant who chooses NOT to remain in the study, request that she complete those Early Termination Visit procedures still permissible for a pregnant participant not yet completed at this visit.

**II. Further Study Visit Considerations for Pregnant Participants**

For participants who choose to remain in REACH study follow-up:

1. Use a modified visit checklist through scheduled study exit/Visit 24 (See sample **MTN-034 Pregnant Participant Visit Checklist)** in place of the regular visit checklist.
2. Protocol-specified procedures as scheduled at study visits may be performed except for:
	1. hCG urine testing
	2. Provision/retrieval/collection of study VR(s) or study tablets, and provision of product use instructions
	3. Pelvic examination as well as associated procedures after 24 weeks of pregnancy, unless the participant indicates comfort with continuing vaginal procedures post 24 weeks
	4. Collection of PK and biomarker specimens
	5. Adherence and product preference/acceptability assessments, including ACASI
	6. Provision of protocol adherence and product adherence disclosure counseling. *Note: modified contraceptive counseling should be provided.*
	7. Provision or referral for HPV vaccine. If the vaccine series was initiated prior to pregnancy, scheduled doses may resume after the pregnancy outcome, at clinician discretion. The HBV vaccine should continue to be offered during pregnancy.
3. For a participant who is pregnant and becomes HIV-infected, refer to the MTN-034/REACH HIV Confirmation and Seroconversion Guide and contact the MTN-034 Management Team.
	1. MTN LC will perform expedited HIV-1 resistance testing to provide information about possible resistance that might impact the efficacy of ART regimens to reduce mother-to-child HIV-1 transmission.
	2. Refer participant to local providers for antenatal care and prevention of mother-to-child transmission services (per site SOP).
	3. Note: HIV testing for infants is provided by the study, if not otherwise accessible by the participant.

**III. Managing Pregnancy Outcomes**

1. Pregnancy outcomes if ascertained, whether participant remains in the study or not, should be documented within chart notes and on the **Pregnancy Outcome Log CRF.**
	1. Possible methods to determine pregnancy outcomes include: medical records or other written documentation from licensed practitioner, participant self-report, or negative pregnancy test performed by study staff.
	2. For a participant still in the study, complete an **AE Log CRF** if the pregnancy outcome is a reportable AE, and complete and submit an EAE Report if also an EAE.

c. Counsel to breastfeed per current WHO guidelines, if applicable.

1. A participant who remained in the study during pregnancy may resume product use post-pregnancy outcome per the following:
	1. VR or Truvada use may be resumed no earlier than 8 weeks after birth or loss of the pregnancy.
		1. For a pregnancy loss, the product restart timeline begins upon the date of the loss (i.e. bleeding, elective termination, etc.). A negative pregnancy test date should be used if the date of pregnancy loss is completely unknown.
	2. Before resuming product, the participant must 1) confirm a negative pregnancy test performed by study staff, 2) not be breastfeeding, 3) be otherwise clinically eligible, 4) and be approved by site consultation with PSRT. *NOTE: A pelvic exam is required before resuming VR use.*
2. **III. Managing Pregnancy Outcomes**
3. The participant should resume product use based on her current position in her assigned study sequence i.e. if resuming in Month 11 (Period 2), she would start on the product assigned for Period 2 and use until Month 16 (Period 2 product end use); if resuming in Period 3, she may choose either or neither product.
4. PK and biomarker specimens, behavioral assessments, and product adherence disclosure counseling should resume at follow-up visits as scheduled (switch back to regular visit checklists).
5. Continue to follow women pregnant at study termination (scheduled or early) until the pregnancy outcomes are ascertained. Document per III.A above.
6. Make every reasonable effort to contact participants and collect infant outcomes approximately one year after delivery for those pregnancies that result in live birth. Document in chart notes.