| **Visit 13 (Last Study Product Administration Visit/Early Termination Visit) Checklist** | | |
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| **Procedures:** | | **Staff Initials** |
|  | Confirm identity and PTID |  |
|  | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE. * Enrolled in another study ==> STOP. Immediately contact PSRT and Management Team for further guidance. |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Review elements of informed consent as needed. |  |
|  | Review/update locator information. |  |
|  | Provide available test results from previous visit. Provide and document treatment and/or referral as needed. |  |
|  | Complete the **MTN-026 Study Gel Request Slip**. The white original copy will be delivered to the pharmacy, and the yellow copy (bottom) stored in the participant’s file. |  |
|  | Collect urine for:   * Qualitative hCG (for female participants)   Enter results onto Pregnancy Test Result CRF.  If clinically indicated for:   * Dipstick urinalysis * Urine culture * NAAT for GC/CT   Enter results onto STI Tests CRF once available. |  |
|  | Collect blood samples for PK:   * + 0 hour (pre-dose) \_\_\_ mL [tube type] |  |
|  | Collect unused dose provided to be administered at home, if applicable. Document on Product Dispensation and Returns CRF. |  |
|  | Complete Sexual Lubricant CRF. |  |
|  | Provide product, relevant product use instructions, and lubricant |  |
|  | Observe dose application. Document date and time of dose application on Directly Observed Dosing CRF. |  |
|  | Collect blood samples for:   * PK:   + 30-60 minutes \_\_\_ mL [tube type] OR   + 120 minutes \_\_\_ mL [tube type]   Document PK blood collection on LDMS Tracking Sheet and Timed Specimen Storage Collection CRF.  If clinically indicated:   * CBC with differentials and platelets \_\_\_ mL [tube type] * AST, ALT \_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type] * Syphilis \_\_\_ mL [tube type   Enter results onto Local Laboratory Results CRF and/or Hematology CRF and/or STI Tests CRF, if indicated once available. |  |
|  | If indicated, perform and document targeted physical examination on the Physical Exam CRF and Vital Signs CRF. |  |
|  | Perform and document anorectal exam. Collect rectal samples (See Genital Exam Checklist). |  |
|  | Female participants: Perform and document pelvic exam. Collect pelvic samples (See Genital Exam Checklist). |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. Document menstrual information on Cervical Specimen Storage CRF. |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. |  |
|  | *If Early Termination Visit:* Administer appropriate Follow-up CASI Behavioral Questionnaire. Document administration on CASI Summary and CASI Tracking CRFs. |  |
|  | *If Early Termination Visit:* Have participant complete the in-depth interview with remote interviewer at the agreed upon time. Document administration on the CASI Tracking CRF. |  |
|  | Provide and document protocol counseling per Protocol Counseling Worksheet. |  |
|  | Confirm/Schedule next study visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit. |  |
|  | *If Early Termination Visit:*   * Determine participant preference for post-study contact. * If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results. * If applicable, schedule clinically indicated follow-up for all unresolved grade 2 and higher AEs and related AEs at this visit. * Inform the participant of planned methods and timeframes for dissemination of study results. * Determine and document whether participant is willing to be contacted about future studies for which s/he may be eligible. |  |
|  | Perform QC1: while participant is still present, review the following for completion:   * Follow-up Visit Summary * Anorectal Exam * Product Dispensation and Returns * Directly Observed Dosing * LDMS Specimen Tracking Sheets and Timed Specimen Storage * Pelvic Exam and Pelvic Exam Diagrams * Physical Exam and Vital Signs (if indicated) * Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated) * Concomitant Medications Log (as applicable) * Supporting chart notes, as needed * Visit Checklist |  |
|  | Provide reimbursement |  |
| **POST-VISIT PROCEDURES** | | |
|  | Ensure that data is entered into the study database (and perform QC2 review, if applicable) ensuring all data entered into the study database is accurate and complete.  Required Visit Forms:   * Follow-up Y/N * Follow-up Visit Summary * Sexual Lubricant * Anorectal Exam * Product Dispensation and Returns * Timed Specimen Storage * Treatment Discontinuation * Additional Study Procedures (for pregnancy testing) * Pregnancy Test Results (female participants only) * Pelvic Exam (female participants only) * Pelvic Exam Diagrams (female participants only) * Cervical Specimen Storage (female participants only)   *Required if Early Termination:*   * CASI Summary and CASI Tracking * Study Discontinuation   If Indicated:   * Physical Exam * Vital Signs * Missed Visit * Hematology * Local Laboratory Results * STI Tests * Participant Replacement   Log CRFs (if newly-completed or updated):   * Adverse Event Summary/Log * Concomitant Medications Summary/Log * Protocol Deviations Summary/Log * Pregnancy Outcome Summary/Log (female participants only) |  |

**Additional Notes/Comments/Referrals:**