| **Visit 3 (Single Dose Administration Visit) Checklist** | | |
| --- | --- | --- |
| **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 treatment and/or referral as needed. |  |
|  | If clinically indicated, perform and document targeted physical exam using Physical Exam CRF. |  |
|  | Obtain vitals (if indicated) and document on Vital Signs CRF. |  |
|  | Review/update medical, medication, and for female participants, menstrual history, as needed. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. |  |
|  | Complete the Sexual Lubricant CRF. |  |
|  | Complete the **MTN-026 Study Gel Prescription**. Send the white original copy to the pharmacy. File the yellow copy (bottom) 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] |  |
|  | Obtain study product and lubricant  Note: Staff should evaluate safety prior to administration of product. |  |
|  | Administer/apply dose application. Document date and time of dose application on Directly Observed Dosing Log CRF |  |
|  | Collect blood samples for:   * Blood for PK:   + 30-60 minutes \_\_\_ mL [tube type] OR   + 120 minutes \_\_\_ mL [tube type]   Document PK blood collection on Timed Specimen Storage CRF and LDMS Specimen Tracking Sheet  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 Hematology CRF, Local Laboratory Results CRF and/or STI Test Results CRF*,* if indicated once available. |  |
|  | Perform and document anorectal exam, per participant PK/PD assignment. Collect rectal samples (See Genital Exam Checklist). |  |
|  | If clinically indicated, for female participants, perform and document pelvic exam on the Pelvic Exam CRF and Pelvic Exam Diagrams form. |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. |  |
|  | Administer appropriate Follow-up CASI Behavioral Questionnaire. Document administration on the CASI Summary and CASI Tracking CRFs. |  |
|  | 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 Adherence Counseling worksheet |  |
|  | Confirm/Schedule Visit 4 and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling before next visit. |  |
|  | Perform QC1: while participant is still present, review the following for completion:   * Visit checklist * Follow-up Visit Summary * Sexual Lubricant * LDMS Specimen Tracking Sheets and Timed Specimen Storage CRF * Anorectal Exam * Concomitant Medications Log (as applicable) * Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated) * Physical Exam (if indicated) * Vital Signs (if indicated) * Pelvic Exam (if indicated) * Pelvic Exam Diagrams (if indicated) * Supporting chart notes, as needed |  |
|  | 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 CRFs:   * Follow-up Yes/No * Follow-up Visit Summary * CASI Summary and CASI Tracking * Sexual Lubricant * Anorectal Exam * Timed Specimen Storage * Additional Study Procedures (for pregnancy testing) * Pregnancy Test Results (female participants only) * Pharmacy Dispensation (completed by and accessible to site pharmacists only)   If Indicated CRFs:   * Physical Exam * Vital Signs * Hematology * Local Laboratory Results * STI Tests * Pelvic Exam (female participants only) * Pelvic Exam Diagrams (female participants only) * Study Discontinuation * Participant Replacement Assessment   Log CRFs (if newly-completed or updated):   * Adverse Event Summary/Log * Concomitant Medications Summary/Log * Directly Observed Dosing Log * Protocol Deviations Summary/Log * Pregnancy Outcome Summary/Log (female participants only) |  |

**Additional Notes/Comments/Referrals:**