| **MTN-033: Visit 3 (Period 1) & Visit 5 (Period 2) Dosing Visits 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. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), *if indicated*). Document in chart notes. | |  |
|  | | Administer Follow up CASI Questionnaire. Document administration on the **CASI Summary** and **CASI Tracking CRFs**.   * Visit 3 Behavioral Assessment * Visit 5 Behavioral Assessment | |  |
|  | | Have participant complete the in-depth interview (IDI) with remote interviewer at the agreed upon time. Document administration on the **CASI Tracking CRF**. | |  |
|  | | Review/update participant’s medical/medications history to verify and update all information recorded at previous visit. Document all updates as needed on relevant source documents, **Baseline Medical History Log CRF** and **Concomitant Medications Log CRF**. | |  |
|  | | As needed, assess AEs and document on **Adverse Event Summary** and **Adverse Event Log** CRFs. | |  |
|  | | *If indicated*, perform a targeted physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF**. | |  |
|  | | *If indicated*, administer pharyngeal swab for GC/CT. Complete **STI Test Results CRF** upon receipt of lab results. | |  |
|  | | Complete the **MTN-033 Study Gel Prescription**. Send the white original copy to the pharmacy. File the yellow copy (bottom) in the participant’s file.  *Note: If there are any issues with the study applicator or dispensed study product and a new supply is needed, staff should complete an MTN-033 Study Gel Request Slip. Send the white original copy to the pharmacy. File the yellow copy (bottom) in the participant’s file.* | |  |
|  | | *If indicated*, collect urine (15-60 mL) and perform tests:   * Dipstick urinalysis/culture * NAAT for GC/CT   Complete **STI Test Results CRF** upon receipt of lab results. | |  |
|  | | Collect blood samples for PK:   * 0 hour (baseline) \_\_\_ mL [tube type] | |  |
|  | | For participants assigned to insert gel from a single pre-filled applicator   * N/A (if inserting gel with a coital simulation device) * Provide study product and study lubricant * Review gel insertion instructions and important information * Have participant insert into the rectum the entire contents of one pre-filled applicator * Complete the **Dose Administration** CRF | |  |
|  | | For participants assigned to insert gel with a coital simulation device   * N/A (if inserting gel from a single pre-filled applicator) * Complete all required fields on the ‘Clinic Instructions & Record for Measuring Coital Simulation Device Gel Dose’ form. * Provide coital simulation device, weighing dish containing study product, and bag containing ancillary supplies to participant * Review participant instructions for use of coital simulation device and study product * Have participant, using gloved hands/fingers, apply gel to the coital simulation device and/or their anus the way they would during sex and insert the coital simulation device for approximately five (5) minutes. * Complete the **Dose Administration CRF** | |  |
|  | |  | |  |
|  | | Collect blood samples:  *If clinically indicated*:   * CBC with differentials and platelets \_\_\_ mL [tube type] * AST, ALT \_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type] * Syphilis \_\_\_ mL [tube type]   Required:   * Plasma for PK [10] mL [tube type] at the following timepoints after dose administration: * 0.5 hours * 1 hours * 1.5 hours * 2 hours * 2.5 hours * 3 hours * 4 hours   Document collection on **LDMS Tracking Sheet** and **Specimen Storage CRF**.  Document collection on [add site-specific laboratory testing source document], **LDMS Tracking Sheet** and **Specimen Storage CRF**. When results are ready, document on the **Hematology**, **STI Test Results**, and **Local Laboratory Results CRFs**, as applicable. | |  |
|  | | Based on participant’s PK/PD assignment, perform and document rectal exam using the **Genital Exam Checklist** and complete the **Anorectal Exam CRF**, **Timed Anorectal Specimen Storage CRF** and **Anorectal Specimen Storage CRF**. | |  |
|  | | *If indicated*, perform and document genital exam using the **Genital Exam Checklist** and complete the **Genital Exam CRF**. | |  |
|  | | Provide and explain all available findings and results. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), *if indicated*). | |  |
|  | | Conduct protocol counseling and document on **Protocol Counseling Worksheet**. | |  |
|  | | Complete the **Follow-up Visit Summary and Follow-up Visit Summary CRFs**. | |  |
|  | | Offer condoms. | |  |
|  | | Perform QC1 review while participant is still present, reviewing the following:   * Visit checklist, to ensure all required procedures were completed * **LDMS Tracking Sheet**, **Anorectal Exam CRF**, **Timed Anorectal Specimen Storage CRF** and **Anorectal Specimen Storage CRF** for completeness, accuracy and consistencybetween forms * **AE Log**, **Baseline Medical History Log** and **Concomitant Medications Log CRF** to ensure all conditions, medications, AEs are captured consistently and updated * **Chart notes** to ensure completeness and accuracy | |  |
|  | | Confirm/schedule next study visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or to request information and/or counseling before next visit. | |  |
|  | | Provide reimbursement | |  |
| **POST-VISIT PROCEDURES** | | | | |
| 27. | Ensure that data is entered into Medidata Rave (and perform QC2 review, if applicable) ensuring all data entered is accurate and complete.  Required CRFs:   * Anorectal Exam * CASI Summary * CASI Tracking * Follow-up Visit Y/N * Follow-up Visit Summary * Dose Administration (*for applicator regimen only*) * Hematology * Specimen Storage * Timed Anorectal Specimen Storage | |  | |
|  | | If Indicated CRFs:   * Local Laboratory Results * STI Tests Results * Additional Study Procedures * Genital Exam * Missed Visit * Participant Replacement Assessment * Physical Exam * Product Discontinuation * Study Discontinuation * Vital Signs   Log CRFs (if newly-completed or updated):   * Adverse Event Summary/Log * Baseline Medical History Log * Concomitant Medications Summary/Log * Protocol Deviations Summary/Log   Paper Forms:   * Genital Exam Checklist * LDMS Specimen Tracking Sheet * Supporting chart notes, as needed * MTN-033 Study Gel Prescription * Protocol Counseling Worksheet * *Study Gel Request Slip (if indicated, in the event previously dispensed applicator is unusable)* | |  |

**Additional Notes/Comments/Referrals:**