| **MTN-033: Visit 3 (Period 1) & Visit 5 (Period 2) Dosing Visits 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. 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:**