**Instructions:** Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, add a note on the checklist documenting who completed the procedure initial, date this entry, e.g., “done by {staff initials}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

| **Initiate Period 2 & 3 - Visit Checklist** |
| --- |
|  **Procedure** | **Staff Initials** | **Comments:** |
|  | **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.
 |  |  |
|  | **Refer to SSP Section 5.6.2.4 for a list of study procedures required to be completed in the event the participant missed a previous Period End visit.**  |  |  |
|  | **If participant returns unused study product, complete Unused Product Returns Slip. Update appropriate Product Dispensation and Return CRF(s) from previous visit(s).**  |  |  |
|  | **Review/update locator information.** |  |  |
|  | **Review elements of informed consent as needed.**  |  |  |
|  | **Explain procedures to be performed at today’s visit.** |  |  |
|  | **Provide available test results from previous visit, if indicated, provide treatment and/or referrals.** |  |  |
|  | **Assess if participant has experienced a social harm as a result of study participation. If participant reports social harm occurrence, complete SIL CRF.**  |  |  |
|  | **Review/update medical history. Complete/update AE Log CRF(s), if applicable.** **Note:** Ensure all related grade 2 or higher AEs have resolved or stabilized prior to product initiation. If unresolved, consult the PSRT. |  |  |
|  | **Review medications history. Update Concomitant Medications Log CRF, if applicable.**  |  |  |
|  | **Collect urine** **(if indicated) for**: * Dipstick urinalysis
* NAAT for GC/CT
 |  |  |
|  | **Administer or refer for Hepatitis B vaccine if indicated and participant consents.** Document vaccination (or participant refusal) per site SOPs, if indicated.If given, record the vaccination as a separate entry on the Concomitant Medications Log. |  |  |
|  | **Perform physical exam (if clinically indicated).** If done, complete Abbreviated Physical Exam CRF. |  |  |
|  | **Perform and document anorectal exam. Collect rectal samples (See Rectal Exam Checklist).** Complete Anorectal Exam CRF and 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.** |  |  |
|  | **Collect blood samples** **(if indicated):** * AST, ALT \_\_\_ mL [tube type]
* CBC with differentials and platelets \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* HIV serology (provide and document Pre-/Post-Test counseling) \_\_\_ mL [tube type]
* Syphilis RPR \_\_\_ mL [tube type]
 |  |  |
|  | **Complete/update Adverse Experience Log CRF(s) (if indicated).** |  |  |
|  | **Verify participant eligible to begin next product regimen:** * ELIGIBLE ==> CONTINUE
* NOT ELIGIBLE ==> STOP. Provide clinical management as needed and consult the PSRT. Complete Clinical Product Hold/Discontinuation Log CRF.
 |  |  |
|  | **Complete the MTN-017 prescription that corresponds to the participant’s [second or third] study period (Oral, Daily Rectal, or RAI Rectal) per study randomization. Deliver white original prescription to pharmacy according to site SOP.**  |  |  |
|  | **Provide product, relevant product use instructions, and lubricant, if indicated.** Document in chart notes [or site-specific source document].**Note:** The staff person providing product use instructions should NOT be the same person who provides participant-centered product adherence counseling. |  |  |
|  | **Provide protocol adherence counseling. Remind participant to record date/time of last dose prior to next visit.** Document in chart notes or [site-specific source document].**Note:** The staff person providing protocol adherence counseling should NOT be the same person who provides participant-centered product adherence counseling. |  |  |
|  | **Observe participants first dose or simulation of first does.** * Participant initiating daily rectal gel, first insertion or simulation of insertion should be performed in a private space, with staff standing by in case participant needs assistance.
* Participant initiating RAI rectal gel, first simulation of insertion should be performed in a private space, with staff standing by in case participant needs assistance.
* Participant initiating daily tablet, the first dose should be directly observed by study staff.
 |  |  |
|  | **Conduct the following behavioral procedures *if indicated*:** * **PK Data Convergence Interview**
* Document PK Data Convergence Interview on the PK Data Convergence Interview (non-DataFax) CRF and the counseling in chart notes [or site-specific source document].
* **Participant-Centered Product Adherence Counseling.**

**Note:** The staff person providing participant-centered product adherence counseling should NOT be the same person who provides product use instructions and protocol adherence counseling.  |  |  |
|  | **Review use of SMS system for adherence reporting. Give participant SMS Instruction Card to take home with relevant information filled in, if needed.** |  |  |
|  | **Confirm/Schedule next Mid-Period Visit and advise him/her 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. |  |  |
|  | **Perform QC1: while participant is still present, review the following for completion:*** Follow-up Visit Summary
* LDMS Specimen Tracking Sheet
* Adverse Experience Log, if indicated
* PK Data Convergence Interview, when applicable
* Supporting chart notes, as needed
 |  |  |
|  | **Remind the participant that s/he will be contacted via phone at the following times:** * 48-72 hours (2-3 days) from the expected date of study product initiation , and:
* 2 weeks after the expected date of study product initiation.
* If no SMS messages have been received by the system in a 48 hour period
 |  |  |
|  | **Provide reimbursement** |  |  |
| ***POST-VISIT PROCEDURES*** |
|  | **Upload audio file from PK Data Convergence Interview, when applicable, and Adherence Counseling Session to Atlas website.** |  |  |
|  | **When applicable, enter data from the PK Data Convergence Interview (non-DataFax) CRF into the applicable web-based form within 7 days of interview.**  |  |  |
|  | **QC and then Fax all required DataFax forms to SCHARP DataFax.****Initiate Period 1/2 Visit Forms:** * Anorectal Exam
* Follow-up Visit Summary
* Product Dispensation and Return
* Specimen Storage

 **If Indicated:*** Abbreviated Physical Exam
* HIV Results
* HIV Confirmatory Results
* Safety Laboratory Results
* STI Test Results

**Log CRFs (if newly-completed or updated):*** Adverse Experience Log
* Concomitant Medications Log
* Protocol Deviations Log
* Clinical Product Hold/Discontinuation Log
* Social Impact Log
 |  |  |

|  |
| --- |
| **Additional Notes/Comments/Referrals:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |