**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.

| **Mid-Period 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.
 |  |  |
|  | **Collect unused study product and complete Unused Product Returns Slip. Complete item 1 on Product Dispensation and Return CRF (PDR). Complete p.1 of Data Convergence Interview form as follows:*** Transcribe regimen-specific information from item 1 on PDR to DCI.
* Transcribe participant regimen-specific SMS data from spreadsheet provided by BRWG (on Atlas web site) to DCI.
* Deliver DCI to Counselor.
 |  |  |
|  | **Complete items 1-2 on PK Data Convergence Interview form prior to interview, when applicable** |  |  |
|  | **Review elements of informed consent as needed.**  |  |  |
|  | **Explain procedures to be performed at today’s visit.** |  |  |
|  | **Review/update locator information.** |  |  |
|  | **Provide available test results from previous visit. Provide treatment and/or referral as needed.**  |  |  |
|  | **Assess if participant has experienced a social harm as a result of study participation.** If participant reports social harm occurrence, complete Social Impact Log (SIL) CRF. |  |  |
|  | **Provide HIV pre-test counseling, per site HIV testing/counseling/ support/referral SOP and HIV and Risk Reduction Counseling Worksheet, if applicable.**  |  |  |
|  | **Collect blood samples for:*** HIV serology \_\_\_ mL [tube type]
* Plasma for PK \_\_\_ mL [tube type]

If clinically indicated: * AST, ALT \_\_\_ mL [tube type]
* CBC with differentials and platelets \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* Syphilis RPR \_\_\_ mL [tube type]

Transcribe results onto Safety Laboratory Results CRF once available. |  |  |
|  | **Provide test results and post-test counseling, including HIV/STI risk reduction counseling and provision of condoms. Provide referrals if needed/requested.**Transcribe results onto HIV Results CRF**.*** If [both] test[s] negative ⇒ UNINFECTED ⇒ ⇒ CONTINUE PRODUC T USE.
* If [both] test[s] positive ⇒ INFECTED ⇒ STOP. Permanently discontinue study product. Complete Clinical Product Hold/Discontinuation (PH) Log CRF. Refer to SSP Section 5.6.4.2 for additional procedures.
* [If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ Immediately hold study product until HIV status is determined. Complete PH Log CRF. If confirmed HIV positive, refer to SSP Section 5.6.4.2 for additional procedures.
 |  |  |
|  | **Review/update medical history.** Complete/update AE Log CRF(s), if applicable. |  |  |
|  | **Review medications history.** Update Concomitant Medications Log CRF, if applicable. |  |  |
|  | **Collect urine** **(if clinically 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 CRF. |  |  |
|  | **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.**  |  |  |
|  | **Complete/update Adverse Experience Log CRF(s) (if indicated).** |  |  |
|  | **Verify participant is eligible to continue product use.**  |  |  |
|  | **Complete the MTN-017 Study Product Request Slip and deliver white original to the pharmacist, per site SOPs.**  |  |  |
|  | **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 provided 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 provided participant-centered product adherence counseling. |  |  |
|  | **Conduct the following behavioral procedures:*** **Data Convergence Interview**
* **PK Data Convergence Interview, when applicable**
* Document on Data Convergence Interview and PK Data Convergence Interview forms.
* **Participant-Centered Product Adherence Counseling.** Document in chart notes [or site-specific source document].

**Note:** The staff person providing participant-centered product adherence counseling should NOT be the same staff person who provides product use instructions and protocol adherence counseling. |  |  |
|  | **Confirm/Schedule relevant Period End Visit and advise him/her of potential length of the visit.** * If next visit is visit 4, advise participant that s/he may be need to allot an extra 30 minutes at visit 4 if chosen and consented to participate in IDPI. Advise participant that staff will contact him/her prior to the visit to schedule the IDPI, if chosen.
* 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
* Data Convergence Interview
* PK Data Convergence Interview, when applicable
* LDMS Specimen Tracking Sheet
* Adverse Experience Log (if indicated)
* Supporting chart notes, as needed
 |  |  |
|  | **Provide reimbursement** |  |  |
| ***POST-VISIT PROCEDURES*** |
|  | **Upload audio file from the PK and Data Convergence Interview(s) and Adherence Counseling Session to Atlas website within 7 days of the interview.**  |  |  |
|  | **Enter data from PK and Data Convergence Interview(s) into the web-based forms within 7 days of the interview.**  |  |  |
|  | **QC and then Fax all required DataFax forms to SCHARP DataFax.****Mid-Period Visit Forms:** * Anorectal Exam
* Follow-up Visit Summary
* HIV Results
* Product Dispensation and Return
* Specimen Storage

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

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

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