**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.

| Period 3 End/Final Clinic Visit/ Early Termination (Visit10) |
| --- |
|  **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/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. 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 SIL CRF.**  |  |  |
|  | **Administer appropriate Follow-up CASI Behavioral Questionnaire, based on most recent regimen completed. Select option for final study period.****Note:** CASI Questionnaire must be administered prior to HIV and adherence counseling. |  |  |
|  | **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:*** AST, ALT \_\_\_ mL [tube type]
* CBC with differentials and platelets \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* HIV serology \_\_\_ mL [tube type]
* Plasma for Storage \_\_\_ mL [tube type]
* Blood for PK \_\_\_ mL [tube type]

If clinically indicated: * 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.
* If [both] test[s] positive ⇒ INFECTED ⇒ STOP. Permanently discontinue study product. Refer to SSP Section 5.6.4.2 for additional procedures.
* [If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required. Advise participant that additional visits and tests may be needed to confirm or clarify his/her HIV status.] If confirmed HIV positive, refer to SSP Section 5.6.4.2 for additional procedures.
 |  |  |
|  | *[Bangkok and Pittsburgh sites only: insert the following language]***Rectal biopsy/fluid procedural counseling** |  |  |
|  | **Review/update medical history.** **Complete/update AE Log CRF(s), if applicable.** |  |  |
|  | **Review medications history. Update Concomitant Medications Log CRF, if applicable.** |  |  |
|  | **Collect urine** **(15-60 mL) for**: * NAAT for GC/CT

If clinically indicated: * Dipstick urinalysis
 |  |  |
|  | **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. |  |  |
|  | **The following AEs, identified as continuing, must be re-evaluated within 30 days from this visit:*** **All grade 2 and higher AEs**
* **All AEs related to product use**
* **Previously reported AEs found to have increased in severity**
* **All SAEs/EAEs.**

Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan in the participant’s chart notes. |  |  |
|  | **Perform physical exam. Complete Abbreviated Physical Exam CRF.**  |  |  |
|  | **Perform and document anorectal exam. Collect rectal samples (See Rectal Exam Checklist).** Complete Anorectal Exam, Specimen Storage, and Rectal Biopsy/Fluid Subset Specimens CRFs. |  |  |
|  | **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(s) (if indicated).** |  |  |
|  | **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].
 |  |  |
|  | **Complete the MTN-017 Product Request Slip, indicating participant is no longer in study, and deliver white original copy to the pharmacist, per site SOPs.**  |  |  |
|  | **Instruct participant to contact clinic to report any new or worsening AEs within 7 days of today’s visit (Final Clinic Visit).**  ***NOTE:*** *Any AE that is “continuing” 7 days after the Final Clinic Visit should be marked “continuing at end of study participation.”* |  |  |
|  | **Reinforce site contact information and:** * If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results.
* If applicable, schedule clinically indicated follow-up for all unresolved grade 2 and higher AEs and related AEs at this visit.
* Inform the participant of planned methods and timeframes for dissemination of study results.
* Determine and document whether participant is willing to be contacted about future studies for which s/he may be eligible.
* Determine participant preference for post-study contact.
 |  |  |
|  | **Perform QC1: while participant is still present, review the following for completion:*** Follow-up Visit Summary
* Data Convergence Interview
* PK Data Convergence Interview
* LDMS Specimen Tracking Sheets
* 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 interview.** |  |  |
|  | **Enter data from the PK and Data Convergence Interview(s) into web-based forms within 7 days of interview.** |  |  |
|  | **Once the PK result from visit 10 is received, complete a new PK Data Convergence Interview form (items 1-3) to document the result. Enter data from the form into the web-based form.** |  |  |
|  | **QC and then Fax all required DataFax forms to SCHARP DataFax.****Period End Visit Forms:** * Abbreviated Physical Exam
* Anorectal Exam
* End of Study Inventory
* Follow-up Visit Summary
* Follow-up CASI Tracking
* HIV Results
* Product Dispensation and Return
* Rectal Biopsy/Fluid Subset Specimens, if applicable
* Safety Laboratory Results
* Specimen Storage
* STI Test Results
* Termination

**If Indicated:*** HIV Confirmatory Results

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

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