**Was the participant randomized to complete the In-Depth Interview? 🞎 YES 🞎 NO**

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| **12-Week/ Final Clinic Visit (Visit 6.0) /Early Termination Visit Checklist** |

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
| 1 | Confirm identity and PTID |  |  |
| 2 | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE. * Enrolled in another study ==> STOP. NOT ELIGIBLE. |  |  |
| 3 | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
| 4 | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
| 5 | Review/update locator information using site-specific form. |  |  |
| 6 | Administer Ring Adherence CRF |  |  |
| 7 | Administer Vaginal Practices CRF |  |  |
| 8 | Administer Exit CASI Questionnaire |  |  |
| 9 | Collect follow-up medical/medications history: review/update Follow-up Medical History Log, AE Log CRF, and Concomitant Medications Log CRF |  |  |
| 10 | If indicated, collect (15-60mL) urine for:   * NAAT for GC/CT * Dipstick urinalysis and/or urine culture |  |  |
| 11 | Provide and document the following on appropriate counseling worksheets or [site-specific source document]. Provide male condoms if needed.   * HIV pre and post-test counseling * HIV/STI risk reduction counseling   If indicated:   * Male Condom counseling |  |  |
| 12 | Collect blood for :  Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.   * CBC with platelets * Serum Chemistries * HIV serology * PK [10 mL]   Document on Pharmacokinetics, Safety Laboratory Results CRF and HIV Results CRF. |  |  |
| 13 | Perform targeted physical exam. Complete Physical Exam CRF. |  |  |
| 14 | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
| 15 | If STI/RTI/UTI is diagnosed, provide treatment. |  |  |
| 16 | Document collection of the vaginal ring using the Clinic Study Product Accountability Log and Ring Collection and Insertion CRF. |  |  |
| 17 | Complete Vaginal Ring Request Slip, indicating participant product use period is complete. Deliver white original copy to the pharmacist, per site SOPs. |  |  |
| 18 | Provide and explain all available findings and results. Refer for findings as indicated. |  |  |
| 19 | Assess/document any adverse events. Complete/update AE Log CRF as needed. |  |  |
| 20 | Remind the participant that she will be contacted via phone in one week to follow up on any problems or concerns |  |  |
| 21 | **If randomized, have participant complete the In-Depth Interview.** |  |  |
| 22 | Perform QC1 while participant is still present to ensure information is complete and accurate.  Follow-Up Visit Summary, Physical Exam, HIV Results, Pelvic Exam and Pelvic Exam Diagram (non-DataFax), Pharmacokinetics, Ring Collection and Insertion, Ring Adherence, Safety Laboratory Results, Specimen Storage, and Vaginal Practices. |  |  |
| 23 | Provide reimbursement |  |  |
| 24 | Review and fax all required DataFax forms to SCHARP DataFax.  Follow-Up Visit Summary, Physical Exam, HIV Results, Pelvic Exam and Pelvic Exam Diagram (non-DataFax), Pharmacokinetics, Ring Collection and Insertion, Ring Adherence, Safety Laboratory Results, Specimen Storage, Vaginal Practices, Follow-up CASI Tracking.  **Log CRFs (if newly-completed or updated):**  Adverse Experience Log, Concomitant Medications Log, Product Hold/Discontinuation Log, Protocol Deviations Log |  |  |