| **Day 7 Visit Checklist (Visit 6)** | | | |
| --- | --- | --- | --- |
| **Procedures** | | **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. Consult the PSRT regarding on-going product use and safety considerations. |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Assess if participant has experienced a social harm as a result of study participation. If participant reports social harm occurrence, document on the Social Impact Log CRF. |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | 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). |  |  |
|  | Complete SMS items on the Ring Outage SMS and Bleeding SMS CRFs prior to the data convergence interview. |  |  |
|  | Complete the Ring Adherence CRF. |  |  |
|  | Complete the Vaginal Bleeding Assessment CRF. |  |  |
|  | Conduct Data Convergence Interview and document on the Ring Outage Data Convergence Interview and Bleeding Data Convergence Interview CRFs.   * Have Vaginal Bleeding Assessment CRF and Ring Adherence CRF data available for reference. |  |  |
|  | If indicated, collect urine pregnancy test. Complete [add site-specific laboratory testing source document, or Pregnancy Test CRF if source] upon receipt of lab test result. |  |  |
|  | Collect 10mL blood for DPV and LNG levels.  If clinically indicated, collect blood for HIV-1 serology (providing appropriate pre-test counseling prior to collection), serum creatinine, CBC with platelets and differential, and syphilis serology |  |  |
|  | Perform pelvic exam, per pelvic exam checklist. |  |  |
|  | Complete the Pharmacokinetics CRF and LDMS Specimen Tracking Sheet. |  |  |
|  | Collect follow-up medical/menstrual/medications history: review/update ongoing conditions as documented on the Baseline Medical History Log. Complete/update the AE Log and/or the Concomitant Medications Log CRF(s) as needed. |  |  |
|  | If indicated, perform targeted physical exam and obtain vital signs– complete [add site-specific physical exam and vital signs source document, or Physical Exam and/or Vital Signs CRFs if source] |  |  |
|  | Provide and document protocol adherence counseling on the appropriate counseling worksheet or [site-specific source document].  If indicated, provide appropriate HIV posttest counseling (if HIV testing was done) and HIV/STI risk reduction. |  |  |
|  | Provide product use counseling and review SMS instructions for reporting product use information and bleeding events, as needed. |  |  |
|  | If STI/RTI/UTI is diagnosed, provide treatment. |  |  |
|  | Provide and explain all available findings and results. |  |  |
|  | Assess/document any adverse events. Complete/update AE Log CRF(s) as needed. |  |  |
|  | Complete the Ring Insertion and Removal CRF. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion:   * Chart notes * Pharmacokinetics CRF and LDMS Specimen Tracking Sheet * Concomitant Medications Log * [Site-specific pelvic exam source documents (e.g., Pelvic Exam CRF and/or Pelvic Exam Diagrams] * Vaginal Bleeding Assessment CRF * Ring Adherence CRF (QC1 should be done prior to completion of product use adherence counseling) * Ring Insertion and Removal CRF [or site-specific source document if the form is not source for this data] * Ring Outage Data Convergence Interview CRF * Bleeding Data Convergence Interview CRF * AE Log CRF (if, at this visit, new AEs are reported or previously reported AEs are updated) |  |  |
|  | Schedule next visit. Provide contact information and instructions to report symptoms or problems with SMS and/or request information, counseling, a new ring, before next visit. |  |  |
|  | Provide reimbursement. |  |  |
|  | **Ensure that data is entered into the study database (and perform QC2 review, if applicable) for the following required CRFs:**   * Follow-up Visit Summary * Vaginal Bleeding Assessment * Ring Adherence * Ring Insertion and Removal * Pharmacokinetics * Pelvic Exam * Pelvic Exam Diagrams (non-Medidata, optional) * Ring Outage SMS * Bleeding SMS * Ring Outage Data Convergence Interview * Bleeding Data Convergence Interview   **Log CRFs (complete/update as applicable):**   * Adverse Events Summary * Adverse Event Log * Concomitant Medications Summary * Concomitant Medications Log * Protocol Deviations Summary * Protocol Deviation Log * Pregnancy Outcome Summary * Pregnancy Outcome Log   **If Indicated CRFs:**   * Physical Exam * Vital Signs * STI Tests * Local Laboratory Results * Pregnancy Test * Pregnancy Report and History * HIV Tests * Hematology * Specimen Storage * Treatment Discontinuation * Study Discontinuation * Participant Replacement Assessment |  |  |