| **Visits 4-6 (PK Visits) Checklist** |
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| **Procedures:** | **Staff Initials** |
|  | 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.
 |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Review elements of informed consent as needed.  |  |
|  | Review/update locator information. |  |
|  | Provide available test results from previous visit. Provide and document treatment and/or referral as needed.  |  |
|  | If clinically indicated, perform and document targeted physical examination on the Physical Exam CRF.  |  |
|  | Obtain vitals (if indicated) and document on Vital Signs CRF. |  |
|  | Review/update medical, medication, and for female participants, menstrual history. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. Document menstrual information on Cervical Specimen Storage CRF at participant’s assigned PK/PD sampling visit.  |  |
|  | Collect urine (if clinically indicated) for: * Dipstick urinalysis
* Urine culture
* NAAT for GC/CT

Enter results onto STI Tests CRF once available. |  |
|  | Collect blood samples for:* Blood for PK\_\_\_ mL [tube type]

Document PK blood collection on Specimen Storage CRF and LDMS Tracking Sheet If clinically indicated: * CBC with differentials and platelets \_\_\_ mL [tube type]
* AST, ALT \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* Syphilis \_\_\_ mL [tube type]

Enter results onto Hematology and/or Local Laboratory Results CRF and/or STI Tests CRF once available. |  |
|  | Based on participant’s PK/PD assignment, perform and document anorectal exam. Collect rectal samples (See Genital Exam Checklist).  |  |
|  | For female participants, based on PK/PD assignment: Perform and document pelvic exam. Collect pelvic samples (See Genital Exam Checklist).  |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document in chart notes. |  |
|  | Provide and document protocol counseling per Protocol Counseling worksheet |  |
|  | Confirm/Schedule next visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling before next visit.***Please note:*** *At Visit 6, when scheduling next visit (Visit 7), the washout period is a minimum of 14 days and a maximum of 28 days. For female participants, the washout period should be timed to coincide with menses.*  |  |
|  | At Visit 6: Provide study condoms |  |
|  | Perform QC1: while participant is still present, review the following for completion if completed:* Visit checklist
* Follow-up Visit Summary
* Anorectal Exam
* Pelvic Exam
* Pelvic Exam Diagrams
* Cervical Specimen Storage (LMP items)
* LDMS Specimen Tracking Sheets and Specimen Storage CRF
* Concomitant Medications Log (as applicable)
* Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated)
* Supporting chart notes, as needed
 |  |
|  | Provide reimbursement |  |
| **POST-VISIT PROCEDURES** |
|  | Perform QC2 review for all applicable forms, ensuring all data entered into the study database is accurate and complete.Required Visit Forms: * Follow-up Y/N
* Follow-up Visit Summary
* Specimen Storage
* Required at participant’s assigned PK/PD sampling visit (Visit 4, 5, or 6):
	+ Anorectal Exam
	+ Pelvic Exam and Pelvic Exam Diagram (female participants only)
	+ Cervical Specimen Storage (female participants only)

If Indicated:* Physical Exam
* Vital Signs
* Local Laboratory Results
* Hematology
* STI Tests
* Study Discontinuation
* Treatment Discontinuation
* Participant Replacement Assessment
* Additional Study Procedures
* Missed Visit
 |  |
| Log CRFs (if newly-completed or updated):* Adverse Event Summary/Log
* Concomitant Medications Summary/Log
* Protocol Deviations Summary/Log
* Pregnancy Outcome Summary/Log (female participants only)
 |  |

**Additional Notes/Comments/Referrals:**