| **Step 4a: (Daily Oral Cabotegravir – OPTIONAL for participants initiating****CAB injections)** **Day 0** |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID per site SOPs. |  |
|       | [ ]  | Discuss with participants the options for ongoing study participation and the Steps under Version 4 of the protocol |  |
|       | [ ]  | Obtain written consent for Version 4.0 of the Protocol |  |
|       | [ ]  | Administer Product Choice Assessment Questionnaire (Interviewer Administered) |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Complete Interviewer-administered assessment (SMSQ) |  |
|       | [ ]  | Administer CASI (behavioral assessment) |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Provide HIV counseling |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Collect blood for: * HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* Creatinine\*
* LFTs\* (AST, ALT, total bilirubin, alkaline phosphatase)
* Plasma storage

\*Note: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the investigator |  |
|       | [ ]  | Dispense sufficient pills to last until the next follow-up visit plus approximately one-month buffer supply) |  |
|       | [ ]  | Provide adherence counseling |  |
|  |  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next appointment, if applicable |  |
|       | [ ]  | Provide reimbursement, if applicable |  |

Notes for Step 4a: Please refer to Table 7 of the Protocol for further guidance.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Step 4a: (Daily Oral Cabotegravir – OPTIONAL for participants initiating****CAB injections)** **Week 4** |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID per site SOPs. |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Obtain self-reported pill adherence |  |
|       | [ ]  | Pill count and document in the participant chart **(optional procedure)** |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Provide HIV counseling |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Collect blood for: * HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* Creatinine
* LFTs (AST, ALT, total bilirubin, alkaline phosphatase)
* Plasma storage
 |  |
|       | [ ]  | Provide adherence counseling regarding attending first CAB injection visit |  |
|       | [ ]  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next study visit, if applicable |  |
|       | [ ]  | Provide participant reimbursement, if applicable |  |

Notes for Step 4a: Please refer to Table 7 of the Protocol for further guidance.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Step 4b: (Loading Dose Cabotegravir Injection – for participants initiating****or restarting CAB injections after hiatus\*)** **Day 0** |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID |  |
|       | [ ]  | Applicable **only** to participants who did not complete Step 4a:* Discuss with participants the options for ongoing study participation and the Steps under Version 4 of the protocol**)**
* Obtain written informed consent for Version 4.0 of the protocol
* Administer Product Choice Assessment Questionnaire (Interviewer Administered)
 |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Interviewer-Administered, SMSQ(*Refer to form instructions and the Schedule of Forms for whom and when these assessments should be administered*) |  |
|       | [ ]  | Administer CASI(*Refer to instructions in the CASI assessments and the Schedule of Forms for whom and when these assessments should be administered*) |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Provide HIV counseling |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Collect blood for: * HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* Creatinine (Do not perform if it was done during Step 4a)
* LFTs (AST, ALT, total bilirubin, alkaline phosphatase)
* Plasma Storage (must be collected prior to the loading dose)
 |  |
|       | [ ]  | Collect unused product |  |
|       | [ ]  | Administer CAB injection  |  |
|       | [ ]  | ISR Evaluation |  |
|       | [ ]  | Provide adherence counseling regarding attending CAB injection visits |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next study visit, if applicable |  |
|       | [ ]  | Provide participant reimbursement, if applicable |  |

Notes for Step 4b: Please refer to Table 8 of the Protocol for further guidance.

\* Hiatus is defined as ≥8 weeks late for previously-scheduled CAB injection

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Step 4c: (Every 8 week [Standard] Cabotegravir Injections)** **Day 0, Weeks 8, 16, 24, 32, 40, and 48***Circle applicable visit week* |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID |  |
|       | [ ]  | Applicable **only** to participants who did not complete Step 4b:* Discuss with participants the options for ongoing study participation and the Steps under Version 4 of the protocol**)**
* Obtain written informed consent for Version 4.0 of the protocol
* Administer Product Choice Assessment Questionnaire (Interviewer Administered)
 |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Interviewer-Administered, SMSQ (**Day 0, Weeks 16 and 48**) |  |
|       | [ ]  | Administer CASI (**Day 0,** **Weeks 16 and 48**) |  |
|       | [ ]  | Provide HIV counseling |  |
|  |  | Offer condoms and lubricant |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Enter weight data to applicable CRF (**Weeks 16 and 48**) |  |
|       | [ ]  | Collect blood for: At all visits:* HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* Plasma storage (Must be collected prior to injection)

At Day 0, Weeks 24 and 48 visits* Creatinine
* LFTs (AST, ALT, total bilirubin, alkaline phosphatase

At Weeks 24 and 48 * Syphilis serology

At Week 48 visit:* HCV Testing
 |  |
|       | [ ]  | Collect urine for GC/CT testing (**Weeks 24 and 48**) |  |
|       | [ ]  | Collect rectal swab for GC/CT testing (**Weeks 24 and 48**) |  |
|       | [ ]  | Administer CAB injections  |  |
|       | [ ]  | Adherence counseling regarding attending CAB injection visits (**Weeks 8, 16, 24, 32, and 40)** |  |
|       | [ ]  | ISR Evaluation |  |
|       | [ ]  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next study visit, if applicable |  |
|       | [ ]  | Provide participant reimbursement, if applicable |  |

Note for Step 4c: Please refer to Table 9 of the Protocol for further guidance.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Step 5: (Open Label Daily Oral TDF/FTC)** **Day 0, Week 12, 24, 36, 48 (Weeks 60, 72, 84, 96, 108, 120, 132, 144 if required)***Circle applicable visit week* |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID |  |
|       | [ ]  | Applicable **only** to participants who did not complete Steps 4a – 4c:* Discuss with participants the options for ongoing study participation and the Steps under Version 4 of the protocol**)**
* Obtain written informed consent for Version 4.0 of the protocol
* Administer Product Choice Assessment Questionnaire (Interviewer Administered)
 |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Interviewer-Administered, SMSQ (**Day 0,** **Weeks 24 and 48** (72, 96,120, 144, if required)) |  |
|       | [ ]  | Administer CASI (**Day 0,** **Weeks 24 and 48 (**72, 96,120, 144, if required)) |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Enter weight data to applicable CRF  |  |
|       | [ ]  | Provide HIV counseling |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Collect blood for: At all visits:* HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* Plasma storage
* DBS storage

At Day 0, Weeks 24 and 48 visits (72, 96, 120, 144, if required)* Creatinine\*
* LFTs\* (AST, ALT, total bilirubin, alkaline phosphatase)
* Syphilis serology\*

At Weeks 24 and 48 (72, 96, 120, 144, if required)* HCV Testing (if infection was not documented at a prior visit)
 |  |
|       | [ ]  | Collect urine for GC/CT\* testing (**Day 0,** **Weeks 24 and 48** (72, 96, 120, 144, if required)) |  |
|       | [ ]  | Collect rectal swab for GC/CT\* testing (**Weeks 24 and 48**) (72, 96, 120, 144, if required) |  |
|       | [ ]  | Dispense pills |  |
|       | [ ]  | Provide adherence counseling **(Week 12, 24, and 36)** |  |
|       | [ ]  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next study visit, if applicable |  |
|       | [ ]  | Provide participant reimbursement, if applicable |  |

Notes for Step 5: Please refer to Table 10 of the Protocol for further guidance.

\*If done within last month prior to Day 0, testing may be deferred at the discretion of the investigator.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Procedures for Enrolled Participants who have a Reactive or Positive HIV Test Result** **(HIV confirmation visit, Week 12, 24, 36, 48)***Circle applicable visit week* |
| --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|       | [ ]  | Confirm participant identity and PTID |  |
|       | [ ]  | Review/update locator information |  |
|       | [ ]  | Collect directed medical history (including concomitant medications) |  |
|       | [ ]  | Perform directed physical exam  |  |
|       | [ ]  | Provide HIV counseling (**HIV confirmation visit only**) |  |
|       | [ ]  | Collect blood for: At all visits:* Plasma storage

At HIV Confirmation visit* HIV Testing (please refer to the HIV testing algorithm found in Figure 11-4 of Appendix VIII of the SSP for detailed information)
	+ HIV Rapid test
	+ Laboratory-based HIV immunoassay
	+ HIV viral load (<50 copies/mL)
* HIV resistance testing
* DBS storage

At Confirmation Visit, Weeks 24 and 48 visits * CD4 cell count
* HIV viral load

At Weeks 24 and visits* Creatinine
* LFTs (AST, ALT, total bilirubin, alkaline phosphatase)
 |  |
|       | [ ]  | Offer condoms and lubricant |  |
|       | [ ]  | Provide site contact information and instructions to report symptoms and/or clarify any questions |  |
|       | [ ]  | Schedule next study visit, if applicable |  |
|       | [ ]  | Provide participant reimbursement, if applicable |  |

Note for Reactive or Positive HIV Test Results: Please refer to Table 11 of the protocol for further guidance.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_