| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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