| **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 the OLE |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol.  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol* |  |
|  |  | Administer Product Choice Assessment Questionnaire (Interviewer Administered) |  |
|  |  | Review/update locator information |  |
|  |  | Complete Interviewer-administered assessment (SMSQ)  *Refer to instructions in the interviewer-administered assessments as well as the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | Administer CASI (behavioral assessment)  *Refer to instructions in the CASI assessments as well as 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   *NOTE: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the site investigator.*   * LFTs (AST, ALT, total bilirubin, alkaline phosphatase)   *NOTE: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the site investigator*   * Plasma storage * Syphilis serologic testing   *NOTE: Perform testing at Day 0 if not done within the last 6 months* |  |
|  |  | Collect urine for GC/CT testing |  |
|  |  | Collect rectal swab for GC/CT testing |  |
|  |  | 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.

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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. |  |
|  |  | **If not done at Day 0**: Obtain written informed consent for Version 5.0 of the Protocol  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol* |  |
|  |  | 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   *NOTE: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the site investigator*   * LFTs (AST, ALT, total bilirubin, alkaline phosphatase)   *NOTE: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the site investigator*   * Plasma storage (Must be collected prior to injection) |  |
|  |  | 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.

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| **Step 4b: Loading Dose Cabotegravir Injection – for participants initiating**  **or restarting CAB injections**  **Day 0** | | | | |
| --- | --- | --- | --- | --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|  |  | Confirm participant identity and PTID |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol **ONLY** if not obtained at a previous study visit.  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol.* |  |
|  |  | Applicable **only** to participants who did not complete Step 4a:   * Discuss with participants the options for ongoing study participation and the Steps under OLE**)** * Administer Product Choice Assessment Questionnaire (Interviewer Administered) |  |
|  |  | Review/update locator information |  |
|  |  | Interviewer-Administered, SMSQ  *Note:* *Refer to form instructions and the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | Administer CASI  *Note:* *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   *NOTE: 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) * Syphilis serologic testing   *NOTE: Perform if not done within the last 6 months* |  |
|  |  | Collect urine for GC/CT testing  *NOTE: Perform testing at Day 0 if not done within the last 6 months* |  |
|  |  | Collect rectal swab for GC/CT testing  *NOTE: Perform testing at Day 0 if not done within the last 6 months*  *NOTE: If testing cannot be done locally, it may be done at another laboratory. Consult the LC for guidance.* |  |
|  |  | Collect unused product |  |
|  |  | Administer CAB injection |  |
|  |  | ISR Evaluation  *NOTE: Do not actively solicit this information from participants.*  *NOTE: If an ISR is reported, document on the ISR eCRF.*  *NOTE: Symptoms experienced immediately at the time of an injection are NOT considered ISRs. No ISR assessment is required at the visit at which the injection is provided*. |  |
|  |  | 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.

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| **Step 4c: 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 |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol **ONLY** if not obtained at a previous study visit. (**Day 0)**  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol.* |  |
|  |  | Applicable **only** to participants who did not complete Step 4b (**Day 0**):   * Discuss with participants the options for ongoing study participation and the Steps under OLE**)** * Administer Product Choice Assessment Questionnaire (Interviewer Administered)   *NOTE: Do not repeat for participants who transition from Step 4b or Step 5 and completed these procedures in Steps 4a, 4b, or 5* |  |
|  |  | Review/update locator information |  |
|  |  | Interviewer-Administered, SMSQ (**Day 0, Weeks 16 and 48**)  *Refer to instructions in the interviewer-administered assessments as well as the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | Administer CASI (**Day 0,** **Weeks 16 and 48**)  *Refer to instructions in the CASI assessments as well as the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | 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   *Note: If it was performed during Step 4a or 4b, do not perform at Day 0 of Step 4c.*   * LFTs (AST, ALT, total bilirubin, alkaline phosphatase * Syphilis serology   *Note: Perform testing at Day 0 if not done within the last 6 months; perform testing at all other visits as per Table 9 of the protocol*  At Week 48 visit:   * HCV Ab Testing   *Note:* *Do not to be repeat if infection was documented at a prior visit.* |  |
|  |  | Collect urine for GC/CT testing (**Day 0,** **Weeks 24 and 48**)  *NOTE: Perform testing at Day 0 if not done within the last 6 months* |  |
|  |  | Collect rectal swab for GC/CT testing (**Day 0, Weeks 24 and 48**)  *NOTE: Perform testing at Day 0 if not done within the last 6 months*  *NOTE: If testing cannot be done locally, it may be done at another laboratory. Consult the LC for guidance.* |  |
|  |  | Administer CAB injections |  |
|  |  | Adherence counseling regarding attending CAB injection visits  *NOTE:* *At Week 48 adherence counseling should be tailored to each participant. For example:*   * *A participant who wants to continue CAB injections either in Step 6 or through local PrEP services should be reminded of the importance of receiving their next injection within 8 weeks of Week 48.* * *A participant who does not want to continue CAB injections should be told where they can go locally for other PrEP services and reminded of the importance of continuous PrEP coverage.* |  |
|  |  | ISR Evaluation and reporting  *NOTE: Do not actively solicit this information from participants.*  *NOTE: If an ISR is reported, document on the ISR eCRF.*  *NOTE: Symptoms experienced immediately at the time of an injection are NOT considered ISRs. No ISR assessment is required at the visit at which the injection is provided*. |  |
|  |  | 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 |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol **ONLY** if not obtained at a previous study visit.  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol.* |  |
|  |  | Applicable **only** to participants who did not complete Steps 4a – 4c:   * Discuss with participants the options for ongoing study participation and the Steps under OLE**)** * 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))  *Refer to instructions in the interviewer-administered assessments as well as the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | Administer CASI (**Day 0,** **Weeks 24 and 48 (**72, 96,120, 144, if required))  *Refer to instructions in the CASI assessments as well as the Schedule of Forms for whom and when these assessments should be administered* |  |
|  |  | 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   *NOTE: Defer testing at the discretion of the investigator if it was done within the last month prior to Day 0*   * LFTs (AST, ALT, total bilirubin, alkaline phosphatase)   *NOTE: If testing was performed within the last month prior to Day 0, testing may be deferred at the discretion of the site investigator.*   * Syphilis serology   *NOTE: Perform testing at Day 0 if it was not done within the last 6 months: perform testing at all other visits required.*  At Weeks 24 and 48 (72, 96, 120, 144, if required)   * HCV Ab Testing   *NOTE: Do not repeat if infection was documented at a prior visit* |  |
|  |  | Collect urine for GC/CT testing and urinalysis (**Day 0,** **Weeks 24 and 48** (72, 96, 120, 144, if required))  *NOTE: Perform STI testing at Day 0 if not done within the last 6 months: perform testing at all other visits required.* |  |
|  |  | Collect rectal swab for GC/CT testing (**Day 0,** **Weeks 24 and 48**) (72, 96, 120, 144, if required)  *NOTE: Perform testing at Day 0 if not done within the last 6 months; perform testing at all other visits as noted* |  |
|  |  | Dispense pills |  |
|  |  | Provide adherence counseling  *Adherence counseling at participant’s last Step 5 study visit:*   * *Participants ending study participation: counseling should include information about locally available PrEP services and a reminder of the importance of continuous PrEP coverage.* * *Participants moving to Step 6: these participants should receive adherence counseling as per site’s SOP.* |  |
|  |  | 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.

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| **Step 6:** Cabotegravir Injections  Weeks 56, 64, 72, 80, 88, 96  *Circle applicable visit week* | | | | |
| --- | --- | --- | --- | --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|  |  | Confirm participant identity and PTID |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol **ONLY** if not obtained at a previous study visit.  *Note: Participants should be followed under the appropriate Steps contained in Appendix V of the Protocol.* |  |
|  |  | Review/update locator information |  |
|  |  | 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 72 and 96**) |  |
|  |  | Collect blood for:  At all visits:   * HIV Testing (please refer to the HIV testing algorithm found in Figure 10 of the Protocol and 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 Weeks 72 and 96 visits   * LFTs (AST, ALT, total bilirubin, alkaline phosphatase   At Weeks 56, 72, and 96 visits   * Syphilis serology   *NOTE: Perform testing at Week 56 if not done within the last 6 months; perform testing at all other visits as noted*  At Week 96 visit:   * Creatinine * HCV Testing   *NOTE: Testing does not need to be repeated if infection was documented at a prior visit. HCV Ab testing is required.* |  |
|  |  | Collect urine for GC/CT testing (**Weeks 56, 72, and 96**)  *NOTE: Perform testing at Week 56 if not done within the last 6 months; perform testing at all other visits as noted* |  |
|  |  | Collect rectal swab for GC/CT testing (**Weeks 56, 72, and 96**)  *NOTE: Perform testing at Week 56 if not done within the last 6 months; perform testing at all other visits as noted* |  |
|  |  | Administer CAB injections |  |
|  |  | Provide adherence counseling  *NOTE #1: Adherence counseling at Week 96 should be tailored to each participant and include a reminder of the importance of receiving their next CAB injection or other PrEP through local services within 8 weeks of last injection.*  *NOTE #2: A participant’s final visit in Step 6 may occur before Week 96 if CAB is approved and available locally, or if a participant does not want to or cannot continue receiving CAB injections* |  |
|  |  | ISR Evaluation and reporting  *NOTE #1: Only report on an eCRF an ISR that meets the definition of an SAE (others ISR should be documented in source documents). An ISR typically begins 24-48 hours after an injection.*  *NOTE #2: Do not actively ask participants about IRS sign and symptoms; these should be reported by the participant and documented for the visit at which that injection occurred.*  *REMINDER: symptoms experienced immediately at the time of an injection are NOT considered ISRs.* |  |
|  |  | 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 6: Please refer to Table 11 of the Protocol for further guidance.

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| **Procedures and Evaluations – For Participants Who Are Not Continuing Under the OLE** | | | |
| --- | --- | --- | --- |
| **Initial/date** | **Completed** | **Procedures** | **Comments** |
|  |  | Confirm participant identity and PTID |  |
|  |  | Discuss with participants the new information per Version 5.0 of the Protocol |  |
|  |  | Obtain written informed consent for Version 5.0 of the Protocol **ONLY** if not obtained at a previous study visit. |  |
|  |  | Review/update locator information |  |
|  |  | Provide HIV counseling |  |
|  |  | Offer condoms and lubricant |  |
|  |  | Collect blood for:   * HIV Testing (please refer to the HIV testing algorithm found in Figure 10 of the Protocol and 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 * Syphilis serology\* |  |
|  |  | Collect urine for GC/CT\* testing |  |
|  |  | Collect rectal swab for GC/CT\* testing  *NOTE: If testing cannot be performed at the local laboratory, testing at another laboratory will be considered* |  |
|  |  | Schedule next study visit, if applicable |  |
|  |  | Provide participant reimbursement, if applicable |  |

Notes: Please refer to Table 12 of the Protocol for further guidance.

*\*Perform testing only if not done within the last 6 months*

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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: The Week 48 visit should be timed as closely as possible to 52 weeks after the participant received their last injection.* |  |

Note for Reactive or Positive HIV Test Results: Please refer to Table 12 of the Protocol for further guidance.

\**HIV Confirmation Visit procedures apply to participants with a reactive or positive HIV test during Steps 4 a-c and 5, or at their final study visit (if not continuing under the OLE). Participants with a positive or reactive HIV test during the OLE or at their final study visit (if not continuing under the OLE) and have ever received an active CAB injection at any time during previous study conduct, will be followed according to Table 13 of the Protocol. Participants who have a positive or reactive HIV test during the OLE or at their final study visit (if not continuing under the OLE) and have only ever received oral TDF/FTC and/or oral CAB will be referred to local care. Procedures listed for Weeks 12, 24, 36, and 48 apply only to participants with confirmed HIV infection during Steps 4b and 4c of the study. Participants with confirmed HIV infection in Step 5 may undergo similar procedures as determined by the members of 083CMC@hptn.org. Participants with confirmed HIV infection in Step 4a will be terminated from the study and referred to local care.*

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

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