**MATRIX-001 Protocol Deviation Log**

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| **Name of Site:** |  | | |
| **Protocol Title:** | MATRIX-001: A Phase I Randomized, Placebo-Controlled, Double-Blind Study to Assess Safety, Pharmacokinetics, and Modeled Pharmacodynamics of a Vaginal Insert Containing Tenofovir Alafenamide and Elvitegravir | | |
| **Site Investigator:** |  | **Site Number:** |  |

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| **PTID** | **Deviation Type\*** | **Deviation Details** | **Deviation Start Date (DD/MMM/YY)** | **Deviation Stop Date (DD/MMM/YY)** | **Is deviation required to be reported to IRB/EC?** |
|  |  |  |  |  | No  Yes  If yes, date reported: |
|  |  |  |  |  | No  Yes  If yes, date reported: |
|  |  |  |  |  | No  Yes  If yes, date reported: |
|  |  |  |  |  | No  Yes  If yes, date reported: |
|  |  |  |  |  | No  Yes  If yes, date reported: |

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| **Protocol Deviation Log** |
| **Purpose:** This form documents and reports protocol deviations identified for study participants. |
| **General Information/Instructions:** Complete this form each time a protocol deviation is identified. Consult the MATRIX Prime-Clinical Trials Hub (matrixcthub@matrix4prevention.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation. |
| |  |  | | --- | --- | | **Code** | **Description** | | **01** | **Inappropriate enrollment:** The participant enrolled and not all eligibility requirements were met. | | **02** | **Failure to follow trial randomization or blinding procedures:** Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff. | | **03** | **Study product management deviation:** Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements. | | **04** | **Study product dispensing error:** The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. **Do not include any information related to study product assignment (product codes) on this form.** Pharmacy staff must follow up with the Study Pharmacist separately. | | **05** | **Study product use/non-use deviation:** Participant did not use the study product (including product refusals) or used it incorrectly (i.e., not in accordance with protocol requirements). | | **06** | **Study product sharing:** Participant has shared study product with another person or study participant. | | **07** | **Study product not returned:** Study product was not returned by the participant per protocol requirements. | | **08** | **Conduct of non-protocol procedure:** A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice. | | **09** | **Improper AE/EAE follow-up:** Use when an AE or EAE is not followed-upper protocol. For example, a clinical finding/ lab result that is not re-assessed as outlined in the protocol. | | **10** | **Unreported AE:** Site staff become aware of an AE, but not report it per protocol requirements. | | **11** | **Unreported EAE:** Site staff become aware of an EAE, but not report it per protocol and DAIDS EAE Manual requirements. | | **12** | **Breach of confidentiality:** Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant’s name on a case report form. | | **13** | **Physical assessment deviation:** Include missed or incomplete physical/pelvic/rectal exam assessments. | | **14** | **Lab assessment deviation:** Include missed, or incomplete lab specimen collection. | | **15** | **Mishandled lab specimen:** Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens. | | **16** | **Staff performing duties that they are not qualified to perform:** Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure. | | **17** | **Questionnaire administration deviation:** A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed. | | **18** | **Counseling deviation:** Protocol-required counseling was not done and/or not documented correctly. | | **19** | **Use of non-IRB/EC-approved materials:** Include use of ANY study-related material that requires IRB or EC approval for use per site requirements. | | **20** | **Use of excluded concomitant medications, devices, or non-study products** | | **21** | **Informed consent process deviation:** Examples include failure to accurately execute and/or document any part of the informed consent process. | | **22** | **Visit completed outside of window:** Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window. | |