***Non-DataFax* MTN-017 Follow-up Medical History Log**

PTID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Page #: \_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| **Medical Condition** | **Onset Date (dd-MMM-yy)** | **Severity Grade** | **Reported on**  *no*  *yes*  **AE Log CRF?**  *AE Log Page #*  \_\_\_ \_\_\_ \_\_\_ |
| **Outcome Date (dd-MMM-yy)** | **Relationship to study product**  *Not Related*  *Related* |
| **Study product administration:**  ***no change temporary hold permanent discontinuation***  ***Record on AE Log***  ***CRF***  ***Complete PH-1 Log as needed.*** | | | **Medication Taken?**  *no*  *yes*  *Report on*  *Concomitant*  *Medications Log.* |
| **Comments** | | | **Staff Initials/Log Entry Date** |

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| --- | --- | --- | --- |
| **Medical Condition** | **Onset Date (dd-MMM-yy)** | **Severity Grade** | **Reported on**  *no*  *yes*  **AE Log CRF?**  *AE Log Page #*  \_\_\_ \_\_\_ \_\_\_ |
| **Outcome Date (dd-MMM-yy)** | **Relationship to study product**  *Not Related*  *Related* |
| **Study product administration:**  ***no change temporary hold permanent discontinuation***  ***Record on AE Log***  ***CRF***  ***Complete PH-1 Log as needed.*** | | | **Medication Taken?**  *no*  *yes*  *Report on*  *Concomitant*  *Medications Log.* |
| **Comments** | | | **Staff Initials/Log Entry Date** |

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| --- | --- | --- | --- |
| **Medical Condition** | **Onset Date (dd-MMM-yy)** | **Severity Grade** | **Reported on**  *no*  *yes*  **AE Log CRF?**  *AE Log Page #*  \_\_\_ \_\_\_ \_\_\_ |
| **Outcome Date (dd-MMM-yy)** | **Relationship to study product**  *Not Related*  *Related* |
| **Study product administration:**  ***no change temporary hold permanent discontinuation***  ***Record on AE Log***  ***CRF***  ***Complete PH-1 Log as needed.*** | | | **Medication Taken?**  *no*  *yes*  *Report on*  *Concomitant*  *Medications Log.* |
| **Comments** | | | **Staff Initials/Log Entry Date** |

**Follow-up Medical History Log (non-DataFax)**

Purpose: This form is used to document and track all medical conditions observed in or reported by the study participant during follow-up. This includes all signs, symptoms, pelvic exam abnormal finding, physical exam abnormal findings, and Grade 1 or higher laboratory values.

General Information/Instructions: Once the participant is enrolled and before the participant’s first follow-up visit, transcribe all entries on the Pre-Existing Conditions CRF that are marked as ongoing at Enrollment onto this log. Review and update entries (with Outcome Date) at each required follow-up visit. Add new entries at each required follow-up visit as needed.

Item-specific Instructions:

• **Page:** For each participant, number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.

• **Medical Condition:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, record each symptom as a separate entry. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT.”

• **Onset Date:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the symptom/condition; if the condition is discovered during the study visit exam, the date of the study visit exam; if the condition is an abnormal lab result, the date on which the specimen was collected. If the “day” portion is not known, record zeros for the day (example “00-JAN-13”).

• **Outcome Date:** At minimum, month and year are required. Record one of the following, as appropriate: the date the participant reports no longer experiencing the symptom/condition, or the date of the exam/specimen collection at which the change in status/outcome is first noted. If ongoing during follow-up, leave item blank. If ongoing at study termination/study exit, record “OAT” for “ongoing at termination”.

• **Severity:** Consult the appropriate *Division of AIDS (DAIDS) Table for Grading Adult and Pediatric Adverse Events, and Addendum 3 - Rectal Grading Table for Use in Microbicide Studies.*

• **Relationship to study product:** Mark the assessment of the relationship between the condition and the study product regimen (oral, daily gel, RAI gel) the participant was on at the time of onset. If the onset date is during a washout period, assess the relationship of the condition to the most recently used study product regimen. Mark “Related” if there is a reasonable possibility that the condition may be related to the study product. Mark “Not related” if there is not a reasonable possibility that the condition is related to the study product.

• **Report on AE Log CRF?:** Mark “yes” if the condition has been reported on an AE Log case

report form.

• **Study product administration:** Mark “no change” if the condition has no effect on the participant’s use of study product (i.e., the condition does not result in a clinical product hold or permanent discontinuation). Mark “temporary hold” if the AE results in a clinical product hold. Mark “permanent discontinuation” if the AE results in permanent discontinuation of study product. Note that any conditions that result in permanent discontinuation must be reported on an AE Log CRF. Complete a Clinical Product Hold/Discontinuation (PH-1) Log CRF as applicable.