**Reportable Adverse Event Log**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Form Completion Date:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | Participant ID:   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Couple I/P Chk* | RAE Page number:  \_\_\_\_\_\_\_ |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Instructions****: Complete and fax the* ***RAE*** *for serious adverse events (SAEs) for index or partner participants and for adverse events related to PrEP for partner participants and death or study-related events for baby participants.* | | | | | | | | | | | | | |
| **1** | Adverse event: *Record diagnosis if available.* | | | | | | | | | | | | |
| **2** | Onset date: | | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | | | | |
| **3** | Reported at visit: | | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | | | | |
| **4** | Severity: *See instructions.* | | | | *Grade 1—Mild* | | | | | | | |  |
|  | *Grade 2—Moderate* |  | *Grade 3—Severe* | |  | *Grade 4—Potentially life-threatening* | | |  | | **Death** | |  |
| **5** | Relationship to study medication: | | | | | | | | | | | | |
|  | *Definitely related* |  | *Probably related* | |  | *Possibly related* | | |  | | *Probably not related* | |  |
|  | *Pending* |  | *Not related, reason:* | |  | | | | | | | | |
| **6** | Study medication administration: |  | *Not applicable* | |  | *Temporarily withheld (* | | |  | | *Permanently discontinued* | |  |
|  |  |  | *Continued* | |  |  | | |  | |  | |  |
| **7** | Status or outcome of AE: | | | | | | | | | | | | |
|  | *Continuing* | | | |  | *Continuing at end of study participation* | | | | | | |  |
|  | *Resolved* | | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | | | | |
|  | *Death* | | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | | | | |
|  | *Severity increased* | | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | | | | |
| **8** | Treatment: | | *None / N/A* | |  | *Procedure/surgery* | | |  | | *New/prolonged hospitalization* | |  |
| *Medication* | |  | ***Report on Partner Concomitant Meds Log*** | | | | | | | |
| *Others: Specify* | |  | | | | | | | | |
|  | Type of event: | | *SAE* | |  | *AE related to PrEP* | | | |  | | **If AE, end of form** | |
| **9** | **Type of SAE event: *Mark all that apply*** | | | *Death* |  | *Hospitalization* |  | *Disability* | | | | |  |
| *Life threatening / Grade 4* |  | *Intervention to prevent above* |  | *Congenital anomaly* | | | | |  |

**Completed by:** *(initials/date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**Forms Instruction**

The **Reportable Adverse Event Log** should be completed and faxed for the following types of adverse events:

• All serious adverse events (SAEs) for both index and partner participants;

• Adverse events felt related to PrEP for partner participants; and

• Death or study-related events for baby participants.

For in-depth information about adverse event reporting and safety monitoring, consult the study protocol..

**Item-specific Instructions:**

|  |  |
| --- | --- |
| **Page #** | Number the pages sequentially throughout the study, starting with page 01. Use each page number only once.  Do not re-number a page once it has been faxed to DF/Net, unless a correction to the numbering is required.  Do not re-use page numbers if a **Reportable Adverse Event** is deleted. |
| **Item 1** | Record the most specific available event diagnosis. This may be obtained from hospital or other available records, or may be assessed by the site clinician as appropriate. The event should be recorded concisely (e.g., “malaria”), avoid writing a narrative description. If records indicate multiple diagnoses, record the one diagnosis which is assessed as the primary cause of the event. |
| **Item 2** | The onset date should be the exact date that the adverse event started, if known. This may be the date of symptom onset for an illness or date of an accident/trauma. If a laboratory event, the onset date should be the date of specimen collection. If any part of the date is unknown, a partial date may be entered, completing as much of the date as possible and lining through the unknown portion, with comment “unknown”. |
| **Item 4** | Severity is determined by referring to the DAIDS grading table. |
| **\Item 5** | Study clinicians should determine the relationship to study medication, PrEP for partners and ART for indexes.  Site Safety SOP appendix 1 offers information to assess the potential relationship between specific symptoms/diagnoses and the study drugs used in this trial. |
| **Item 6** | Indicate the study medication administration in response to the reported RAE as determined by study personnel. If study medication was already withheld or withheld at the visit for another reason, indicate “N/A”.  If a participant missed doses or declined, this does not constitute a temporary hold.  Only partner participants should have a **PSDI** completed when study drug is “Temporarily withheld” or “Permanently discontinued.” |
| **Item 7** | This should be changed as the status/outcome of the AE changes. If the event is continuing when the form is filled out, but then resolves, then the response should be amended, and the item should be initialed and dated.  If any of the items on the right are applicable to the participant (resolved, death, severity/frequency increased), the status/outcome date needs to be recorded. |
| **Item 8** | For this item, mark all that apply. If the treatment for the event included medication, complete the **Partner Concomitant Medications Log.** |
| **Item 9** | Indicate whether this event is an SAE (partner, index, or baby), or an AE related to PrEP (partner only). |
| **Item 9a** | If the event is an SAE, indicate the type of SAE. Mark the box to indicate the type of outcome which classifies  the event as an SAE using the following guidelines:  • Death: any event which causes the death of the participant  • Life-threatening/grade 4: event which is life-threatening or otherwise grade 4 in severity.  • Hospitalization: an event which causes a new hospitalization or prolongation of an existing hospitalization.  • Disability: event causing persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions  • Intervention to prevent above: An event which, based on medical judgment, immediately jeopardizes the participant and requires medical or surgical intervention to prevent any of the above outcomes  • Congenital anomaly: a congenital anomaly/birth defect identified in a participant's baby or fetus. A congenital anomaly is reported |