**ADVERSE EVENT LOG**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **ADVERSE EVENT:** | | | | | | | | | | | | |
| **OUTCOME:**   * Recovered/resolved * Not recovered/not resolved * Recovered w sequelae * Recovering/resolving * Severity/frequency increased * Death * Unknown | **ONSET Date:**  (dd-MMM-yyyy) | **START TIME:** | | **OUTCOME Date:**  (dd-MMM-yyyy) | | | | **END TIME:** | | **ONGOING?**   * Ongoing * Ongoing EOS * Not ongoing | | |
| **DATE AE REPORTED** (dd-MMM-yyyy)**:** | | | **VISIT AE REPORTED:** | | | | **RELATIONSHIP / ATTRIBUTION:** | | | | |
| * Not Related | | | | * Related |
| **CON MED / OTHER THERAPY:**   * None * Medication * Procedure/surgery * Hospitalization (new/prolonged) * Other | **ACTION TAKEN W/ TREATMENT:**   * No change * Held * Discontinued * NA | | **SEVERITY GRADE:** | | | | | | | | | |
| * 1 (mild) * 2 (moderate) | | | * 3 (severe) * 4 (potentially life-threatening) | | | | | * 5 (fatal) | |
| **TYPE(S):**   * AE * AESI | | * SAE | | **If not recovered, is event STABILIZED?**   * No * Yes 🡪 date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| **COMMENTS:** | | | | | | | | | **Staff initials/log entry date:** | | | |
| **PI review (sign/date):** | | | |

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| **DATE AE REPORTED** (dd-MMM-yyyy)**:** | | | **VISIT AE REPORTED:** | | | | **RELATIONSHIP / ATTRIBUTION:** | | | | |
| * Not Related | | | | * Related |
| **CON MED / OTHER THERAPY:**   * None * Medication * Procedure/surgery * Hospitalization (new/prolonged) * Other | **ACTION TAKEN W/ TREATMENT:**   * No change * Held * Discontinued * NA | | **SEVERITY GRADE:** | | | | | | | | | |
| * 1 (mild) * 2 (moderate) | | | * 3 (severe) * 4 (potentially life-threatening) | | | | | * 5 (fatal) | |
| **TYPE(S):**   * AE * AESI | | * SAE | | **If not recovered, is event STABILIZED?**   * No * Yes 🡪 date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| **COMMENTS:** | | | | | | | | | **Staff initials/log entry date:** | | | |
| **PI review (sign/date):** | | | |