**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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| **COMMENTS:**  | **Staff initials/log entry date:** |
| **PI review (sign/date):** |