**Appendix 8 - Adverse Event Log**

|  |  |
| --- | --- |
| **AE Number** |  |
| **What is the adverse event term?** |  |
| **Start Date** | DD- MMM- YYYY |
| **Is the adverse event ongoing?** | O Yes  O No |
| **End Date** | DD- MMM- YYYY |
| **What is the MeDRA grade of the adverse event?** | o Grade 1  o Grade 2  o Grade 3  o Grade 4  o Grade 5 |
| **Is this event an adverse drug reaction (ADR)?** | O Yes  O No |
| **Was the adverse event serious?** | O Yes  O No |
| **Did the adverse event result in death?** | O Yes  O No |
| **Date of Death** | DD- MMM- YYYY |
| **Was the adverse event life threatening?** | O Yes  O No |
| **Did the adverse event result in initial or prolonged hospitalization for the participant?** | O Yes  O No |
| **Hospital admission** | DD- MMM- YYYY |
| **Hospital discharge date** | DD- MMM- YYYY |
| **Did the adverse event result in disability or permanent damage?** | O Yes  O No |
| **Was the adverse event associated with a congenital anomaly or birth defect?** | O Yes  O No |
| **Was the adverse event a medically important event not covered by other serious criteria?** | O Yes  O No |
| **Was this adverse event related to study treatment?** | o Not Related  o Unlikely Related  o Possibly Related  o Related |
| **What action was taken with study treatment?** | o Dose Increased  o Dose Not Changed  o Dose Reduced  o Drug Interrupted  o Drug Withdrawn  o Not Applicable |
| **Did the adverse event cause the participant to discontinue the study therapy?** | O Yes  O No |
| **Was a concomitant or additional treatment given due to this adverse event?** | O Yes  O No |
| **Please record any medications on the Concomitant Medication Details CRF** | |
| **Was any other action was taken?** | o None  o Concomitant procedure  o Other (specify) |
| **What is the outcome of this adverse event?** | o Fatal  o Not Recovered / Not Resolved  o Recovered / Resolved  o Recovered / Resolved with Sequelae  o Recovering / Resolving  o Unknown |