**Appendix 8 - Adverse Event Log**

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| **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 1o Grade 2o Grade 3o Grade 4o 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 Relatedo Unlikely Relatedo Possibly Relatedo Related |
| **What action was taken with study treatment?** | o Dose Increasedo Dose Not Changedo Dose Reducedo Drug Interruptedo Drug Withdrawno 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 Noneo Concomitant procedureo Other (specify) |
| **What is the outcome of this adverse event?** | o Fatalo Not Recovered / Not Resolvedo Recovered / Resolvedo Recovered / Resolved with Sequelaeo Recovering / Resolvingo Unknown |