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| # | Date Reported  | Adverse Event Description | Start Date | End Date | Ongoing(Y or N) | Outcome1 | Severity/Grade2 | Serious (Y or N) | AE Treatment3 | Action Taken**4** | Attribution5 | PI Initials | Date of PI Initials |
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| **Outcome1** | **Severity/Grade2** | **AE Treatment3** | **Action Taken4 with Study Intervention** | **Attribution/ Relatedness5** |
| 0 – Fatal  | 1 – Mild | 0 – None  | 0 – None | 0 – Definite |
| 1 – Not recovered/not resolved | 2 – Moderate | 1 – Medication(s) | 1 – Interrupted | 1 – Probable |
| 2 – Recovered w/sequelae | 3 – Severe | 2 – Non-medication TX | 2 – Discontinued  | 2 – Possible |
| 3 – Recovered w/o sequelae | 4 – Life Threatening |  | 3 – Dose reduced  | 3 – Unlikely |
| 4 – Recovering/Resolving | 5 – Death (Fatal) |  | 4 – Dose increased | 4 – Unrelated |
|  |  |  | 5 – Not Applicable | ^5 – Not Applicable (did not receive intervention) |

□ Check if no AEs reported during the study.