# Adverse Event Form

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| **STUDY NAME** |
| **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Pt\_ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **This form is cumulative and captures adverse events of a single participant throughout the study.**  |

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| **Severity** | Study Intervention Relationship | **Action TakenRegarding Study Intervention** | Outcome of AE | **Expected** | **Serious AdverseEvent (SAE)** |
| 1 = Mild2 = Moderate3 = Severe4 = Life-Threatening | 0 = Not related1 = Unlikely related2 = Possibly related3 = Probably related4 = Definitely related | 0 = None1 = Dose modification2 = Medical Intervention3 = Hospitalization4 = Intervention discontinued5 = Other | 1 = Resolved2 = Recovered with minor sequelae3 = Recovered with major sequelae4 = Ongoing/Continuing treatment5 = Condition worsening6 = Death7 = Unknown | 1 = Yes2 = No | 1 = Yes2 = No (if yes, complete SAE form) |

**At end of study only: Check this box if participant had no adverse events  None**

| **Adverse Event** | **Start Date** | **Stop Date** | **Severity** | **Relationship** | **Action Taken** | **Outcome of AE** | **Expected?** | **SAE?** |
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