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| **STUDY NAME** |
| **Site Number:****Pt\_ID:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |   |

**Has the participant had any Adverse Events during this study? [ ] Yes [ ]  No *(If yes, please list all Adverse Events below)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Severity** | **Study Intervention Relationship** | **Action Taken Regarding Study Intervention** | **Outcome of AE** | **Expected** | **Serious** |
| 1 = Mild2 = Moderate3 = Severe | 1 = Definitely related2 = Possibly related 3 = Not related | 1 = None2 = Discontinued permanently3 = Discontinued temporarily4 = Reduced Dose5 = Increased Dose6 = Delayed Dose | 1 = Resolved, No Sequel2 = AE still present- no treatment3 = AE still present-being treated4 = Residual effects present-not treated5 = Residual effects present- treated6 = Death7 = Unknown | 1 = Yes2 = No | 1 = Yes2 = No(If yes, complete SAE form) |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adverse Event | Start Date | Stop Date | Severity | Relationship to Study Treatment | Action Taken | Outcomeof AE | Expected? | Serious Adverse Event? | Initials |
| **1.** |  |  |  |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |  |  |  |