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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **#** | **Adverse Event** | **Onset Date**  (mm/dd/yy) | **End Date**  (mm/dd/yy) | **AE Intensity** | **Relationship to Study Drug** | **Expected** | **Action Taken** | **SAE** | **Treatment** | **DLTa** | **Outcome** | **Investigator**  **Review** |
|  |  |  | Ongoing | 1 2 3  4 5 | 1 2 3 4 | Yes  No | 1 2 3 4 | Yes  No  (if Yes, report SAE) | 1 2 3 4 | Yes  No | 1 2 3  4 5 6 | Date: |
| Signature: |
|  |  |  | Ongoing | 1 2 3  4 5 | 1 2 3 4 | Yes  No | 1 2 3 4 | Yes  No  (if Yes, report SAE) | 1 2 3 4 | Yes  No | 1 2 3  4 5 6 | Date: |
| Signature: |
|  |  |  | Ongoing | 1 2 3  4 5 | 1 2 3 4 | Yes  No | 1 2 3 4 | Yes  No  (if Yes, report SAE) | 1 2 3 4 | Yes  No | 1 2 3  4 5 6 | Date: |
| Signature: |

**aDLT: Dose Limiting Toxicities describe side effects of a drug/treatment considered serious enough to prevent an increase in the dose/level of that treatment. DLTs are defined by the study protocol.**

**AE Intensity** **Relationship to Study Drug** **Action Taken**  **Treatment for Event**  **Outcome**

1= Mild 1= Not Related 1= Not Applicable 1= None 1= Resolved

2= Moderate 2= Probably Not Related 2= Dose Not Changed 2= Medicine Taken 2= Resolved w/ Sequelae

3= Severe 3= Possibly Related 3= Drug Interrupted 3= Non-drug Therapy 3= Ongoing

4= Life threatening 4= Probably Related 4= Drug Withdrawn 4= Other Medication Dose 4= Death

5= Death Modified 5= Ongoing at Death

6= Unknown

PI Signature at conclusion of study participation:

|  |  |  |  |
| --- | --- | --- | --- |
| PI Signature: |  | Date: |  |