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

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4= Life threatening 4= Probably Related 4= Drug Withdrawn 4= Other Medication Dose 4= Death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