|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AE Recorder’s Initials & date** | **Adverse Event** | **Date of Onset** | **Intensity** | **Attribution to Study Treatment** | **Action take with study treatment** | **Is AE a result of a con med?**  | **Other action taken for AE?** | **SAE or AESI?****If SAE, report required** | **Is event ongoing** | **Outcome** | **Outcome Date** | **PI Signature** |
|  |  |  | **1=mild****2= moderate****3= severe** |  | **1 = dose not changed****2 = drug interrupted****3 = drug withdrawn****4 = NA** |  | **1=none****2= hospitalization (new or prolonged)****3=Con med****4=Procedure** |  |  | **1 = Fatal****2 = Not recovered/resolved****3 = Recovered/Resolved****4 = Recovered/resolved w/Sequelae****5 = Recovering/Resolving****6 = Unknown** |  |  |
|  |  |  |  | Related [ ] Not [ ] Related |  | Yes [ ]  CM name: \_\_\_\_\_\_\_\_\_No [ ]  |  | AESI [ ] SAE [ ]  | [ ]  Ongoing□ Ongoing EOS  |  |  |  |
|  |  |  |  | Related [ ] Not [ ] Related |  | Yes [ ]  CM name: \_\_\_\_\_\_\_\_\_No [ ]  |  | AESI [ ] SAE [ ]  | [ ]  Ongoing□ Ongoing EOS  |  |  |  |
|  |  |  |  | Related [ ] Not [ ] Related |  | Yes [ ]  CM name: \_\_\_\_\_\_\_\_\_No [ ]  |  | AESI [ ] SAE [ ]  | [ ]  Ongoing□ Ongoing EOS  |  |  |  |
|  |  |  |  | Related [ ] Not [ ] Related |  | Yes [ ]  CM name: \_\_\_\_\_\_\_\_\_No [ ]  |  | **AESI [ ]** **SAE [ ]**  | [ ]  Ongoing □ Ongoing EOS  |  |  |  |

□ Check if no AEs reported during the study.