|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject ID | Adverse Event | Start Date/  Stop Date | Severity | SAE\* | Relationship to Study | Action Taken | Outcome\*\* | Reported to IRB (Yes/ No), Date reported if applicable |
|  |  |  | Mild  Moderate  Severe | Yes  No | Not Related  Unlikely Related  Possibly Related  Related | None  Outpatient Treatment  Hospitalization  Other:  \_\_\_\_\_\_\_\_\_\_\_\_ | Recovered  Improved  Ongoing  Death  Unknown |  |
|  |  |  | Mild  Moderate  Severe | Yes  No | Not Related  Unlikely Related  Possibly Related  Related | None  Outpatient Treatment  Hospitalization  Other:  \_\_\_\_\_\_\_\_\_\_\_\_ | Recovered  Improved  Ongoing  Death  Unknown |  |
|  |  |  | Mild  Moderate  Severe | Yes  No | Not Related  Unlikely Related  Possibly Related  Related | None  Outpatient Treatment  Hospitalization  Other:  \_\_\_\_\_\_\_\_\_\_\_\_ | Recovered  Improved  Ongoing  Death  Unknown |  |
|  |  |  | Mild  Moderate  Severe | Yes  No | Not Related  Unlikely Related  Possibly Related  Related | None  Outpatient Treatment  Hospitalization  Other:  \_\_\_\_\_\_\_\_\_\_\_\_ | Recovered  Improved  Ongoing  Death  Unknown |  |
|  |  |  | Mild  Moderate  Severe | Yes  No | Not Related  Unlikely Related  Possibly Related  Related | None  Outpatient Treatment  Hospitalization  Other:  \_\_\_\_\_\_\_\_\_\_\_\_ | Recovered  Improved  Ongoing  Death  Unknown |  |

\*All AEs that are fatal, life-threatening, requires inpatient hospitalization or prolongation of an existing hospitalization, and results in persistent or significant disability or incapacity are considered serious adverse events and require reporting to the IRB within 24 hours via phone or by email from the time of awareness to the situation.