|  |  |
| --- | --- |
| Name of Responsible Investigator: | |
| Institution: | |
| Report completed by: | |
| Date of Report: | Type of Report: ❒ Initial ❒ Follow-up # \_\_\_\_ ❒ Final |

**Patient Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Patient RZ #: | Age: | Sex:  ❒Male ❒Female | Date patient started study intervention: |

**Event Information**

|  |  |
| --- | --- |
| Event Onset Date/time: | Name of Event: |
| Date Became Aware of Event: |
| Description of Event: | |
| Seriousness Criteria (check all that apply):  ❒ Death  ❒ Life-threatening  ❒ Requires or prolongs hospitalization  ❒ Results in persistant or significant disability/incapacity  ❒ May require medical or surgical intervention to prevent on of the other outcomes  ❒ Congenital anomaly or birth defect  ❒ Other serious medical event | |
| Outcome:  ❒ SAE persisting at time of report  ❒ Complete recovery/return to baseline  ❒ Resolved (no sequelae)  ❒ Resolved with sequelae, specify  ❒ Death, specify date/time  ❒ Unknown/Lost to follow-up | |
| Is the event unexpected? ❒ Yes ❒ No | |
| Relationship of study intervention to event:  ❒ Not related  ❒ Unlikely related  ❒ Possibly related  ❒ Probably related | |

|  |
| --- |
| Action Taken with Study Intervention:  ❒ Study intervention completed at time of event onset  ❒ Study intervention ongoing  ❒ Study intervention interrupted (temporarily), specify date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❒ Study intervention permanently stopped, specify date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Action Taken to Treat the Event:  ❒ None  ❒ Uncertain  ❒ Surgery  ❒ Other procedures (non-surgical)  ❒ Blood or blood products  ❒ Drug therapy  ❒ Other |
| Treatment Details: |

**Other Report Information**

|  |  |
| --- | --- |
| Past medical history/comorbidities: | ❒ Separate page attached  ❒ Demographic CRF completed |
| Laboratory tests and investigations related to event: | ❒ Separate page attached  ❒ None |
| Other relevant information: | ❒ Separate page attached  ❒ None |
| Other event information the investigator wishes to report: | |

**Signatures**

|  |  |  |
| --- | --- | --- |
| Report Completed by: | Signature: | Date: |
| Site Investigator: | Signature: | Date: |