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

**Patient Information**

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

**Event Information**

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| 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 |

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| 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**

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| 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**

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