

**ADVERSE EVENTS AND SPECIAL SITUATIONS**IRB Approved at the
Protocol Level
Nov 08, 2023

Participant ID:

Has this patient experienced an adverse event? ☐ Yes ☐ No

Adverse Event/Special Situation: _____

Start Date: month _____ day _____ year _____ ☐ Unknown ☐ Not ApplicableStart Time: _____ ☐ Unknown ☐ Not ApplicableEnd Date: month _____ day _____ year _____ ☐ Unknown ☐ Not ApplicableEnd Time: _____ ☐ Unknown ☐ Not Applicable Ongoing ☐Severity: ☐ Mild ☐ Moderate ☐ SevereWas event serious? ☐ Yes ☐ No

Serious Adverse Event Due To:

☐ Death of Patient☐ Life-threatening☐ Hospitalization☐ Prolongation of Hospitalization☐ Congenital Anomaly/Birth Defect☐ Persistent or Significant Disability/Incapacity☐ Important Medical Event (Medically Serious)☐ Not ApplicableDeath of Patient: ☐ Yes ☐ NoDeath date: month _____ day _____ year _____ ☐ UnknownAutopsy performed? ☐ Yes ☐ No ☐ Unknown ☐ Not ApplicableCause of death: _____ ☐ UnknownAdmission date: month _____ day _____ year _____ ☐ Unknown ☐ Not ApplicableDischarge date: month _____ day _____ year _____ ☐ Unknown ☐ Not Applicable

Protocol Defined Adverse Event of Special Interest

☐ Yes☐ No☐ Not Applicable

Specify:

☐ Severe Hypersensitivity Reaction☐ Moderate/Severe Ophthalmic Adverse Event☐ Anaphylaxis Related To Adverse Event

Relationship to Study Drug:

☐ Yes☐ No☐ Not Applicable☐ Reasonable Possibility☐ No Reasonable Possibility



Additional Contributing Factors:

- ☐ Decreased access due to medications/health care provider and/or avoidance of seeking medical care
☐ Other reasons or due to pre-existing medical condition
☐ None
☐ Not Applicable

Action Taken Regarding Study Medication:

- ☐ Dose Not Changed ☐ Drug Withdrawn
☐ Dose Reduced ☐ Unknown
☐ Dose Increased ☐ Not Applicable
☐ Drug Interrupted

If Suspect Drug Was Stopped, Was the Event Recovered?

- ☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

If Suspect Drug was Stopped and Restarted, Did the Event Reappear?

- ☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

Specify Product Name: _____

Batch Number (all medications): _____ ☐ Unknown ☐ Not Applicable

Outcome:

- ☐ Fatal ☐ Recovered/Resolved
☐ Recovering/Resolving ☐ Not Recovered/Not Resolved
☐ Recovered/Resolved With Sequelae ☐ Unknown

Treatment of Adverse Event:

- ☐ None ☐ Other
☐ Concomitant Medication ☐ Not Applicable

Other Treatment of Adverse Event, Specify: _____

Did this Adverse Event result in discontinuation of the patient from the study?

- ☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

Relevant Lab/Diagnostic Test

- ☐ Yes ☐ None ☐ Unknown ☐ N/A

Lab Tests: _____

Results (specify units and normal range): _____

Date (dd/mm/yyyy): month _____ day _____ year _____

Normal ☐ Yes ☐ No

Clinically Significant ☐ Yes ☐ No

Case Narrative (Please provide full details of the event): _____