Adverse Event (A) Worksheet

Participant ID: _____ **Namecode:** _____

DESCRIPTION OF EVENT

1. Date notified of/identified adverse event:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

2. Description of Adverse Event

2a. Provide a description of the event:

_____

_____

_____

2b. Enter the code that best describes the adverse event:

SELECT CODE WHEN ENTERING FORM ON WEBSITE

_____

2c. If ocular event, select eye *(otherwise, leave blank)*

☐ OD (Right) ☐ OS (Left)

If an event occurred in both eyes, complete an AE Form for each eye

3. Date of onset (or worsening of a pre-existing condition):

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

4. Is the adverse event a worsening of a pre-existing condition present prior to study entry?

☐ Yes ☐ No

5. Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam?

☐ Yes ☐ No

6. Maximum intensity (severity):

☐ Mild ☐ Moderate ☐ Severe

7. Is there a reasonable possibility that the event was caused by a study treatment/study device?

☐ Yes ☐ No

7a. If *Yes*, which study treatment/device?

_____

☐ Uncertain – *(Mark uncertain only when a study involves more than 1 treatment or device and you cannot determine which one caused the event.)*

8. Is there a reasonable possibility that the event was caused by a study procedure?
(i.e., a diagnostic procedure and not a study treatment)

☐ Yes ☐ No

8a. If *Yes*, which study procedure?

_____ **1**

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9. Effect on study treatment/device:

☐ No change
☐ Discontinued temporarily
☐ Discontinued permanently
☐ Reduced dose
☐ Reduced use frequency/schedule

10. Does the event meet criteria for a serious adverse event?

☐ Yes ☐ No

If Yes, complete the Additional Information for Serious Adverse Event section below

TREATMENT OF ADVERSE EVENT

1. Did patient receive treatment for the adverse event?

☐ Yes ☐ No

If *Yes*, complete the following:

1a. Surgery/procedure

☐ Yes ☐ No

If *Yes*, complete the following:

Type of surgery/procedure:

_____

Date of surgery/procedure:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

1b. Medication

☐ Yes ☐ No

If *Yes*, list medications here and complete a Concomitant Medication Form for each medication:

_____

_____

_____

1c. Other:

☐ Yes ☐ No

If *Yes*, detail:

_____

_____

_____

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OUTCOME

1. Outcome

☐ Ongoing (further improvement or worsening possible)
☐ Ongoing, medically stable (further change not expected)
☐ Complete Recovery
☐ Recovered with Sequelae
☐ Fatal

1a. If *Complete Recovery* or *Recovered with Sequelae*, complete the following:

i. Date of recovery (with or without sequelae):

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

1b. If *Fatal*, complete the following:

i. Cause of death:

_____

ii. Date of death:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

ADDITIONAL INFORMATION FOR SERIOUS ADVERSE EVENT

1. Criteria defining event as serious adverse event: *(check all that apply)*

☐ Death
☐ Congenital Anomaly
☐ Life Threatening
☐ Hospitalization – initial or prolonged
☐ Significant Disability or Incapacity
☐ Other _____

2. Weight:

_____ ☐ kgs ☐ lbs ☐ Not available

3. Relevant tests/laboratory data (including dates)?

☐ Yes ☐ No

If *Yes*, list:

_____

_____

_____

4. Other relevant history, including preexisting medical conditions *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*:

☐ Yes ☐ No

If *Yes*, list:

_____

_____

_____

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5. Concomitant medical products and therapy dates (exclude treatment of event)?

(List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. DO NOT include products used to treat the event.)

☐ Yes ☐ No

If *Yes*, please explain:

_____

_____

_____

COMMENTS

_____

_____

_____