

# Ad Hoc AEs

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Record ID \_\_\_\_\_

## Participant information:

[phone\_screen\_arm\_1][fname]

[phone\_screen\_arm\_1][lname]

[phone\_screen\_arm\_1][phone\_number\_main]

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STAFF: Is there anything to report to the HCP/PI?

No

Yes

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STAFF: Is participant currently smoking?

Yes

No

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STAFF: Is participant currently taking study medication?

Yes

No

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Staff member - please describe this Ad Hoc event

(Please add your name, the date, and time once you complete this field. Save the instrument as unverified after you are done. Then email Dr. Mahoney to inform him that this participant has a SEC/SAE to be reviewed.)

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HCP/PI - Order/Instructions:

(Please provide instructions to the staff about how the treatment should proceed (e.g., continue medication, discontinue medication, decrease dosage, etc.). )

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HCP/PI - Is this an SAE?

No

Yes

(An SAE is any adverse event, without regard to causality, that is life-threatening or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity; or a congenital anomaly or birth defect. Any other medical that, in the medical judgment of the Principal Investigator/Study Physician, may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed above is also considered a SAE. A planned medical or surgical procedure is not, in itself, an SAE, even if hospitalization is necessary.)

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HCP/PI - Response

- Participant may continue in the trial
- Participant may NOT continue in the trial
- Participant opts to withdraw from study
- Study medication should be continued
- Study medication should NOT be continued
- Dose adjustments recommended \_\_\_\_\_
- Other comments \_\_\_\_\_