

OHTS Adverse Event: AE

Patient ID:

□ □ □ □ □ □ □ □

Today's Date:

□ □ / □ □ / □ □
mm dd yy

Complete Adverse Event form for adverse events occurring from consent date of OHTS Phase 3 to last visit in OHTS Phase 3.

1. Describe the adverse event: _____

2. Diagnosis, if known: _____

3. Date of onset:

□ □ / □ □ / □ □
mm dd yy

Check here if estimated date:

4. Severity: Check only one.

- Patient not aware of condition
- Awareness of system cluster symptom-but easily tolerated
- Discomfort causing interference of usual activity
- Incapacitating with inability to work or do usual activity
- Patient death (Complete "Confirmation of Death: DT" Form)

5. Check organ system(s) affected by sign/symptom (cluster): Check all that apply.

- | | |
|--|--|
| <input type="checkbox"/> Ocular | <input type="checkbox"/> Cardiovascular |
| <input type="checkbox"/> General constitutional symptoms | <input type="checkbox"/> Blood & Immune system |
| <input type="checkbox"/> Skin, Hair & Nails | <input type="checkbox"/> Gastro-Intestinal |
| <input type="checkbox"/> Musculo-Skeletal | <input type="checkbox"/> Genito-Urinary |
| <input type="checkbox"/> Head & Neck | <input type="checkbox"/> Neurologic |
| <input type="checkbox"/> Endocrine | <input type="checkbox"/> Psychiatric |
| <input type="checkbox"/> Respiratory | <input type="checkbox"/> Other _____ |

6. Description: Check all that apply.

- Condition requiring medical attention
- Ocular surgery
- Surgery excluding ocular surgery
- Substantial or permanent disability
- Outpatient hospitalization (≤ 23 hour stay)
- Inpatient hospitalization (>23 hour stay)
- Prolongation of existing hospitalization
- Life threatening (patient in immediate risk of dying from event as it occurred)
- Cancer
- Overdose
- Other _____
- None of the above

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7. Outcome of event (Leave blank if patient is deceased): Check only one.

- No longer present/no residual effects
- No longer present/residual effects
- Ongoing
- Undetermined

8. Relation to Participation in OHTS Phase 3: Check only one.

- Not related
- Possibly related
- Probably related
- Definitely related

Investigator Signature (required)

Date

Form Completed by (CC or PI):