Comparison of Age-related Macular Degeneration Treatments Trials
Serious Adverse Event Follow-Up Reporting Form

ID. No.: __ __ - __ __ __ Alpha Code: __ __ __ __

Clinic #: __ __ Site #: __

*NOTE: Complete this form to report new additional information about a previously reported serious adverse event (SAE). Fax completed form to the Coordinating Center at **215-615-3630**. If additional pages are attached, please make sure the Patient's ID No. and Alpha Code are on each page.*

1. AE # (from AE Log): _____

2. MedDRA Code: _____

3. MedDRA Short Name: _____

4. Was study masking broken since the last report?

☐0 No
☐1 Yes

5. Severity (intensity) of Event

☐0 No change since last report
☐1 Mild, little clinical significance (grade 1)
☐2 Moderate, causing some limitation; minimal/no intervention required (Grade 2)
☐3 Severe (Grade 3)
☐4 Life Threatening or Disabling (Grade 4)
☐5 Death (Grade 5) → Complete a patient death form.

6. Seriousness of Event

☐0 No change since last report
☐1 Non Serious → **STOP!** Use this form only for Serious AEs. Report all events on the Adverse Event Log.
☐2 Congenital Anomaly
☐3 Hospitalization
☐4 Disability
☐5 Medically Significant
☐6 Life threatening
☐7 Death

6.A. Does your local IRB require reports of SAEs with this type of attribution?

❑0 No, skip to question 7
❑1 Yes, answer 6B.

6B. Date report sent to IRB:

__ __ - __ __ - 20 __ __ **OR** ❑1 Check if NOT yet Sent
Month Day Year

ID. No.: __ __ - __ __ __ Alpha Code: __ __ __ __

Clinic #: __ __ Site #: __

7. Was this an expected event?
   - ☐1 Yes
   - ☐0 No

8. Ophthalmologist's Attribution of Causality
   - ☐0 No change since last report
   - ☐1 Unrelated to study drug →
   - ☐2 Unlikely related to study drug →
   - ☐3 Possibly related to study drug
   - ☐4 Probably related to study drug
   - ☐5 Definite
   - ☐6 Related to Injection Procedure
   - ☐7 Not assessable

8A. If attribution is unrelated or unlikely is there another more likely explanation?

- ❑0 No
- ❑1 Yes, specify: _____

_____

9. Was there a change in the study drug since the last report?
   - ☐0 No
   - ☐1 Yes, the study drug was discontinued →
   - ☐2 Yes, the study drug was reintroduced →

9A. Did the event abate after discontinuation of the study drug?

- ❑0 No
- ❑1 Yes

9B. Did the event reappear after reintroduction of the study drug?

- ❑0 No
- ❑1 Yes

10. Has there been a change in concomitant medications since the last report?
    - ☐0 No/None
    - ☐1 Yes →

Attach Concomitant Medication Log

ID. No.: __ __ - __ __ __ Alpha Code: __ __ __ __

Clinic #: __ __ Site #: __

11. New Relevant Medical Information
e.g., Diagnoses, allergies, previous drug reaction, smoking history, etc
☐1 Discharge Summary Attached ☐1 Autopsy Report Attached
☐1 Death Certificate Attached ☐1 Additional Pages Attached

12. New Laboratory data
☐0 None ☐1 Copy of reports attached

Comparison of Age-related Macular Degeneration Treatments Trials
Serious Adverse Event Follow-Up Reporting Form

ID. No.: __ __ - __ __ __ Alpha Code: __ __ __ __

Clinic #: __ __ Site #: __

13. Outcome of event
- ☐0 No change since the last report
- ☐1 Not Recovered
- ☐2 Recovered → 13A. Resolution Date: __ __ - __ __ - 20 __ __ (Month Day Year)
- ☐3 Resolved with Sequelae → 13A. Resolution Date: __ __ - __ __ - 20 __ __ (Month Day Year)
- ☐4 Recovering/Resolving
- ☐5 Fatal → 13B. Date of Death: __ __ - __ __ - 20 __ __ (Month Day Year)

❑1 Check if date unknown

14. Initials and certification number of ophthalmologist who reviewed this form and determined attribution of causality:

a. Initials: ___ ___ ___

b. Certification #: ___ ___ ___ ___

15. Signature of ophthalmologist who reviewed this form and determined attribution of causality:

_____ _____
Date Signed

16. Initials and certification number of person who completed this form:

a. Initials: ___ ___ ___

b. Certification #: ___ ___ ___ ___

17. Signature of person who completed this form:

_____ _____
Date Signed

Comparison of Age-related Macular Degeneration Treatments Trials
Serious Adverse Event Follow-Up Reporting Form

ID. No.: __ __ - __ __ __ Alpha Code: __ __ __ __

Clinic #: __ __ Site #: __

Coordinating Center Use Only:

Date Received:___ ___ - ___ ___ - 20 ___ ___ Reviewed by: ___ ___ ___

IRB Notification: ❑$_1$ Yes, date/time of notification: _____
❑$_0$ No, comments _____

IND Safety Report to FDA: ❑$_1$ Yes, date/time of notification: _____
❑$_0$ No, comments _____

Comment Log (attach additional pages if needed):

Date:	Initials:	Comments: