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

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

Clinic #: __ __ Site #: __

*NOTE: Complete this form to report a **new** **serious** adverse event. 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. Is this an initial report or a follow-up report?

☐1 Initial
☐2 Follow-up → **STOP!** Complete a Serious Adverse Event Follow-Up Form

2. AE # (from AE Log): _____

3. MedDRA Code: _____

4. MedDRA Short Name: _____

5. Gender

☐F Female
☐M Male

6. Birth Date

__ __ - __ __ - 19 __ __
Month Day Year

7. Race

☐1 White
☐1 Asian
☐1 Black/African-American
☐1 American Indian/Alaskan Native
☐1 Native Hawaiian/Pacific Islander
☐1 Unable to answer

8. Patient's estimated height:

___ feet ___ ___ inches

9. Patient's estimated weight:

___ ___ ___ pounds

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10. Was study masking broken?

☐0 No
☐1 Yes

11. Date of Onset:

__ __ - __ __ - 20 __ __
Month Day Year

12. Date Clinical Center Staff Notified:

__ __ - __ __ - 20 __ __
Month Day Year

13. Description of Event/Outcome (Use additional pages if necessary):

14. Follow-Up Plan (Use additional pages if necessary):

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15. Severity (intensity) of Event

- ☐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.

16. Seriousness of Event

- ☐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

→ 16A. Does your local IRB require reports of SAEs with this type of attribution?

- ❑0 No, skip to question 17
- ❑1 Yes, answer 16B.

16B. Date report sent to IRB:

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

17. Was this an expected event?

- ☐1 Yes
- ☐0 No

18. Ophthalmologist's Attribution of Causality

- ☐1 Unrelated to study drug →
- ☐2 Unlikely related to study drug →
- ☐3 Possibly related to study drug
- ☐4 Probably related to study drug
- ☐5 Definitely related to study drug
- ☐6 Related to Injection Procedure
- ☐7 Not assessable

→ 18A. If attribution is unrelated or unlikely is there another more likely explanation?

- ❑0 No
- ❑1 Yes, specify: _____

_____

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19. Was the study drug discontinued?

☐0 No, skip to question 22
☐1 Yes

20. Did the event abate after discontinuation of the study drug?

☐1 Yes
☐0 No

21. Was the study drug reintroduced?

☐1 Yes → 21A. Did the event reappear after reintroduction of the study drug?
❑0 No
❑1 Yes

☐0 No → Complete a Medication Supply Stop Form

22. Were concomitant medications taken at time of event?

☐0 No/None
☐1 Yes → Attach Concomitant Medication Log

23. Comments on relevant medical history
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

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24. Comments/reports on laboratory data

☐0 None ☐1 Copy of reports attached

25. Outcome of event

☐1 Not Recovered
☐2 Recovered →
☐3 Resolved with Sequelae →
☐4 Recovering/Resolving
☐5 Fatal →

25A. Resolution Date:

__ __ - __ __ - 20 __ __
Month Day Year

☐1 Check if date unknown

25B. Date of Death:

__ __ - __ __ - 20 __ __
Month Day Year

26. Initial Reporter (person informing clinic staff of event)

☐1 Patient
☐2 Family Member
☐3 Friend
☐4 Health Care professional (specify) _____
☐5 Other (specify) _____

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Clinic #: __ __ Site #: __

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

    a. Initials: ___ ___ ___

    b. Certification #: ___ ___ ___ ___

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

    _____ _____
    Date Signed

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

    a. Initials: ___ ___ ___

    b. Certification #: ___ ___ ___ ___

30. Signature of person who completed this form:

    _____ _____
    Date Signed

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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:**