Serious Adverse Event Initial Reporting Form

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

*NOTE: Complete this form to report a **new serious** adverse event. Notify the FLAME Safety Officer via phone or email within 24 hours, and follow-up with submission of this report within 3 working days. Data enter this completed form in the REDCap database and submit any de-identified supporting documentation to the FLAME Safety Officer.*

Questions #1-30 to be completed by the Study Team:

1. Is this an initial report or a follow-up report? sastatus
   - Initial ☐1
   - Follow-up ☐2 → STOP! Complete a Serious Adverse Event Follow-up Form

2. Adverse event #: _____ (from adverse event log) saseq

3. Gender: sagender
   - Female ☐F
   - Male ☐M

4. Birth Date: sabrthdtc __ __ / __ __ / __ __ (Day Month Year) ☐ Check if date of birth is unknown sabrthdtcunk and enter estimated age: saestage _____ years

5. Race: sarace
   - African ☐1
   - Other ☐2 Specify other race: saraceothsp _____

6. Patient's estimated height: height
   __ __ __ cm

7. Patient's estimated weight: weight
   __ __ __ kilograms

8. MedDRA code for this SAE: sacode _____

9. SAE Onset date: __ __ / __ __ / __ __ (Day Month Year) sastdtc

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10. Description of SAE: saterm

11. Comments on relevant medical history (e.g., Diagnoses, allergies, previous drug reaction, smoking history, etc.) samedhx

12. Comments/reports on laboratory/other investigation data (if applicable) salabdata

13. Seriousness of Event saser

- Congenital Anomaly ☐1
- Hospitalization ☐2
- Disability ☐3
- Medically significant ☐4
- Life threatening ☐5
- Death ☐6

14. Severity (Intensity) of Event: sasev

- Mild ☐1
- Moderate ☐2
- Severe ☐3
- Life threatening/disabling ☐4
- Death ☐5

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15. Was the event expected (from a Regulatory perspective)?

A. In terms of severity? saexpsev

Expected ☐1

Unexpected ☐2

B. In terms of type of event? saexptype

Expected ☐1

Unexpected ☐2

16. Was this an ocular event? saocular

No ☐0

Yes ☐1 →

16 A. Check affected eye(s): saeyes

Right only ☐0

Left only ☐1

Both eyes ☐2

17. Did the patient receive treatment for the event? satx

No ☐0

Yes ☐1 →

17A. Specify treatment: saocularstx

Update the Concomitant Medication Log if new medication was given

18. Were concomitant medications taken at time of event? sacontrt

No ☐0

Yes ☐1 →

Update the Concomitant Medication Log

19. Was study masking broken? samask

No ☐0

Yes ☐1

20. Were the study drops discontinued? sadrops

No ☐0 →

If No, Skip to question 23.

Yes ☐1 →

20A. If Yes, enter date study drops were discontinued: __ __ / __ __ / __ __ sadropsdtc
Day Month Year

N/A (no longer using study drops) ☐2 →

20B. If N/A, enter date study drops completed: __ __ / __ __ / __ __ sadropscompdtc
Day Month Year

And skip to question 23.

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21. Did the event abate after discontinuation of the study drops? sadisc

- No ☐0
- Yes ☐1

22. Were the study drops reintroduced? sareintro

- No ☐0
- Yes ☐1 →

22A. Date study drops were reintroduced: __ __ / __ __ / __ __ sareintrodtc
Day Month Year

22B. Did the event reappear after reintroduction of the study drops?
No ❑0 sareintroreappear
Yes ❑1

23. What was the outcome of the event? saout

- Recovering/Resolving ☐1
- Resolved ☐2 →
- Resolved with sequelae ☐3 →
- Not Resolved ☐4
- Fatal ☐5 →

23A. Date resolved: __ __ / __ __ / __ __ saendtc
Day Month Year

23B. Date of death: __ __ / __ __ / __ __ sadsdtc
Day Month Year

Complete a Patient Death form

24. Follow-Up Plan (if applicable): safup

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25. Date Clinical Staff Notified about SAE: __ __ / __ __ / __ __ sanotified
Day Month Year

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

- Patient ☐1
- Family Member ☐2
- Friend ☐3
- Health Care professional ☐4 →
- Other ☐5 →

26A. Specify sareportsp

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27. Check if any of the following **de-identified** documents are being submitted to the Safety Officer (check all that apply)

No documents	☐1	sadocuments___0
Discharge summary	☐1	sadocuments___1
Autopsy report	☐1	sadocuments___2
Death certificate	☐1	sadocuments___3
Laboratory reports sadocuments___4	☐1	
Other reports sadocuments___98	☐1	→ 27A. Specify ___sadocothsp___

28. Name and certification number of person who completed this form:

a. Print name:_____

b. Certification #: ___ ___ ___ ___

29. Signature of person who completed this form:

_____

30. Date form completed __ __ / __ __ / __ __
Day Month Year

Questions #31-33: To be completed by the Safety Officer:

31. Is there a reasonable possibility that the study drops caused the adverse event? sacaused

Definitely	☐0
Probably	☐1
Possibly	☐2
Unlikely	☐3
Unable to assess	☐4

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32. Attribution of adverse event (check all that apply):

Concomitant Medication	☐1	saattrib___1
Study Product	☐1	saattrib___2
Surgery/intervention	☐1	saattrib___3
Underlying disease	☐1	saattrib___4
Route of Administration	☐1	saattrib___5
Other cause, Specify: saatribsp	☐1	saattrib___6

33. Date the report(s) were sent by the Safety Officer to the IRBs/other gov't agencies:

__ __ / __ __ / __ __ **OR** ☐1 Check if NOT yet Sent
Day Month Year

Data entry complete date: __ __ /__ __/__ __

Data entry initials: _____