# FLuorometholone as Adjunctive MEdical Therapy for TT Surgery (FLAME) Trial

## FOLLOW UP HEALTH REVIEW FORM

ID. No.: subjid __ __ __ __ __ Alpha Code: alpha_code  Visit #: frvisit

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*NOTE: To be completed by the study team at the Week 4, Month 6, and Month 12 visits by questioning the subject and reviewing any available Health Center records.*

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1. Date of Visit: _ __ / __ __ / __ __      frvisitdtc
   Day   Month   Year

2. Has the subject had surgery on the **right eye** since the last study visit?   frsurg_r

   □₁ Yes ⟶

   □₀ No

   | |
   |---|
   | Check type of surgery performed on the **right eye**:   frsurgtype_r |
   | 2A.  □₁ Upper lid TT surgery (answer question below): |
   |     2A.1. Is there an eyelid skin incision present?  Yes □₁  No □₀  frsurgtt_rul |
   |     2A.2. How many months ago (0-12) was upper lid TT surgery: __ __  frsurgttmos_rul |
   |     □ Check if unknown  frsurgttunk_rul |
   | 2B.  □₂ Lower lid TT surgery |
   |     2B.1. How many months ago (0-12) was lower lid TT surgery: __ __  frsurgttmos_rll |
   |     □ Check if unknown  frsurgttunk_rll |
   | 2C.  □₃ Cataract surgery |
   |     2C.1. How many month ago (0-12) was cataract surgery: frsurgcatamos_r |
   |     □ Check if unknown frsurgcataunk_r |
   | 2D.  □₄ Glaucoma surgery |
   |     2D.1. How many month ago (0-12) was glaucoma surgery: __ __  frsurgglaucmos_r |
   |     □ Check if unknown  frsurgglaucunk_r |
   | 2E.  □₅ Other right eye surgery:  Specify: __frsurgothsp_r__ |
   |     2E.1. How many month ago (0-12) other right eye surgery: frsurgothmos_r |
   |     □ Check if unknown  frsurgothunk_r |

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3. Has the subject had surgery on the **left eye** <u>since the last study visit</u>? frsurg_l

$\square_1$ Yes ⟶

$\square_0$ No

> Check type of surgery performed on the **left eye**: frsurgtype_l
>
> 3A. $\square_1$ Upper lid TT surgery (answer question below):
>
> > 3A.1. Is there an eyelid skin incision present? Yes $\square_1$ No $\square_0$
> > frsurgtt_lul
> > 3A.2. How many months ago (0-12) was upper lid TT surgery: __ __
> > frsurgttmos_lul
> > $\square$ Check if unknown frsurgttunk_lul
>
> 3B. $\square_2$ Lower lid TT surgery
>
> > 3B.1. How many months ago (0-12) was lower lid TT surgery: __ __
> > frsurgttmos_lll
> > $\square$ Check if unknown frsurgttunk_lll
>
> 3C. $\square_3$ Cataract surgery
>
> > 3C.1. How many month ago (0-12) was cataract surgery: __ __
> > frsurgcatamos_l
> > $\square$ Check if unknown frsurgcataunk_l
>
> 3D. $\square_4$ Glaucoma surgery
>
> > 3D.1. How many month ago (0-12) was glaucoma surgery: __ __
> > frsurgglaucmos_l
> > $\square$ Check if unknown frsurgglaucunk_l
>
> 3E. $\square_5$ Other left eye surgery: Specify: ____frsurgothsp_l____
>
> > 3E.1. How many month ago (0-12) other left eye surgery: __ __
> > frsurgothmos_l
> > $\square$ Check if unknown frsurgothunk_l

4. Is cataract surgery recommended for either eye? frcata

$\square_1$ Yes ⟶

$\square_0$ No

> 4A. Enter eye(s) recommended for cataract surgery (check all that apply):
>
> $\square_0$ Right Eye frcataeye___0
>
> $\square_1$ Left Eye frcataeye___1

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5. Has the subject started any new medications or had changes to existing medications since the last study visit?   frnewmed

   ☐$_1$ Yes  ⟶  Enter medication changes on the Concomitant Medication log

   ☐$_0$ No

6. Has the subject had any new adverse events since the last study visit?   frnewae

   ☐$_1$ Yes  ⟶  Record on the Adverse Event Log

   ☐$_0$ No

7. Has the subject had any health event which required major medical intervention or hospitalization since the last visit?   frnewsae

   ☐$_1$ Yes  ⟶  Record on the Adverse Event Log and SAE form (if applicable)

   ☐$_0$ No

8. Are there any events listed on the adverse event log that were unresolved as of the previous study visit?   frunresolvedae

   ☐$_1$ Yes  ⟶  Ask the patient about any unresolved AEs on the Adverse Event Log and update accordingly.

   ☐$_0$ No

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9. Has the subject utilized health care beyond the usual care for TT surgery since the last study visit?   frhcu

   ☐$_1$ Yes ⟶

   ☐$_0$ No

   > 9A. Describe nature of health care utilization:
   > ___frhcudesc_____
   >
   > 9B. Was health care utilization related to TT or treatment? ☐$_1$ Yes ☐$_0$ No   frhcutx
   >
   > 9C. Outcome of health care utilization:   frhcuoutcome
   >
   > ☐$_1$ Issue on-going/still under care
   >
   > ☐$_1$ Issue resolved
   >
   > ☐$_1$ Issue resolved with sequelae

10. Are you pregnant or breastfeeding?   fu_breastfeeding

    ☐$_1$ Yes ⟶

    ☐$_0$ No

    ☐$_0$ N/A-patient male

    > 10A. Check all that apply:
    >
    > ☐$_1$ Pregnant   pregnant_breastfeeding___1
    >
    > ☐$_2$ Breastfeeding   pregnant_breastfeeding___2

11. Name & certification number of person completing form

    a.   Print Name:_____

    b.   Certification #: ___ ___ ___ ___

12. Date form completed:

    __ __ / __ __ / __ __
    Day    Month    Year

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

**Data entered by initials:** __ __