



Screening ID No.: S \_\_\_\_ - \_\_\_\_ screening\_id

EF (001.2)

10/14/21

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## Eligibility Form

**Instructions:** If the subject is determined to be ineligible (a STOP is reached), suspend the visit and complete questions #18 and #19.

1. Visit Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Day Month Year

### INCLUSION CRITERIA

**Subject is ineligible for the study** if either question is answered **No**:

		Yes	No
2.	Did the subject sign the consent form? <span>elconsent</span>	<input type="checkbox"/> _1	<input type="checkbox"/> _0 STOP
3.	Is the subject aged 15 years or older? <span>elage15</span>	<input type="checkbox"/> _1	<input type="checkbox"/> _0 STOP

**Eye is ineligible for the study** if any of the following criteria are answered **No**:

		Right Eye (OD)		Left Eye (OS)	
		Yes	No	Yes	No
4.	Diagnosis of upper eyelid trichomatous trichiasis (TT)?	<input type="checkbox"/> _1 <span>eltt_ru</span>	<input type="checkbox"/> _0 OD not eligible	<input type="checkbox"/> _1 <span>eltt_lu</span>	<input type="checkbox"/> _0 OS not eligible
5.	Is lid rotation surgery planned on an upper eyelid with TT?	<input type="checkbox"/> _1 <span>ellidsurg_ru</span>	<input type="checkbox"/> _0 OD not eligible	<input type="checkbox"/> _1 <span>ellidsurg_lu</span>	<input type="checkbox"/> _0 OS not eligible

### EXCLUSION CRITERIA

**Subject is ineligible for the study** if any of the following criteria are answered **Yes**:

		Yes	No
6.	Contraindication(s) to the use of the test articles, including a known allergy or sensitivity to the study medication (fluorometholone) or its components. <span>eltestart</span>	<input type="checkbox"/> _1 STOP	<input type="checkbox"/> _0
7.	Contraindications to the use of Azithromycin (including known pregnancy). <span>elazithro</span>	<input type="checkbox"/> _1 STOP	<input type="checkbox"/> _0
8.	Any significant illness or condition that could, in the study clinician/coordinator's opinion, be expected to interfere with the study parameters or study conduct; or put the subject at significant risk? <span>elillness</span>	<input type="checkbox"/> _1 STOP	<input type="checkbox"/> _0



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**Subject is ineligible for the study if any of the following criteria are answered Yes:**

		Yes	No
9.	Any severe / serious ocular pathology or medical condition which may preclude study completion or increase the risk of harm in the study (e.g., suspicion of non-trachomatous active ocular infection or suspicion of glaucoma where an intraocular pressure spike would be vision threatening? <span style="color: red;">elsevere</span>	<input type="checkbox"/> <b>1 STOP</b>	<input type="checkbox"/> <b>0</b>
10.	Any condition present at baseline for which it is anticipated ocular or systemic corticosteroid therapy would be required. <span style="color: red;">elbaseline</span>	<input type="checkbox"/> <b>1 STOP</b>	<input type="checkbox"/> <b>0</b>

### EXCLUSION CRITERIA-Eyes

**Eye is ineligible for the study if any of the following criteria are answered Yes:**

		Right Eye (OD)		Left Eye (OS)	
		Yes	No	Yes	No
11.	Previous upper lid eyelid surgery for trachomatous trichiasis?	<input type="checkbox"/> <span style="color: red;">elprevsurg_ru</span> <b>OD not eligible</b>	<input type="checkbox"/> <b>0</b>	<input type="checkbox"/> <span style="color: red;">elprevsurg_lu</span> <b>OS not eligible</b>	<input type="checkbox"/> <b>0</b>
12.	Currently using ocular anti-hypertensive medication? (prior intraocular pressure (IOP) lowering surgery is acceptable)	<input type="checkbox"/> <span style="color: red;">elantihyp_r</span> <b>OD not eligible</b>	<input type="checkbox"/> <b>0</b>	<input type="checkbox"/> <span style="color: red;">elantihyp_l</span> <b>OS not eligible</b>	<input type="checkbox"/> <b>0</b>
13.	Glaucoma sufficiently advanced that an intraocular pressure spike potentially would put the patient at substantial risk of vision loss, per study clinician/coordinator's judgment.	<input type="checkbox"/> <span style="color: red;">elglaucoma_r</span> <b>OD not eligible</b>	<input type="checkbox"/> <b>0</b>	<input type="checkbox"/> <span style="color: red;">elglaucoma_l</span> <b>OS not eligible</b>	<input type="checkbox"/> <b>0</b>
14.	Other than trachoma, any active ocular infections (bacterial, viral, or fungal), or any active ocular inflammation (e.g., scleritis, iritis).	<input type="checkbox"/> <span style="color: red;">elinfections_r</span> <b>OD not eligible</b>	<input type="checkbox"/> <b>0</b>	<input type="checkbox"/> <span style="color: red;">elinfections_l</span> <b>OS not eligible</b>	<input type="checkbox"/> <b>0</b>
15.	Is there Phthisis bulbi in either eye?	<input type="checkbox"/> <span style="color: red;">elphthisis_r</span> <b>OD not eligible</b>	<input type="checkbox"/> <b>0</b>	<input type="checkbox"/> <span style="color: red;">elphthisis_l</span> <b>OS not eligible</b>	<input type="checkbox"/> <b>0</b>
16.	Intraocular Pressure (IOP) Measurements at screening: <ul style="list-style-type: none"><li>Measure IOP 3 times in each eye.</li><li>Enter results and the median of the 3 readings</li></ul>	<b>Right Eye (OD)</b> a) <input type="checkbox"/> Not measurable (skip to question #17) <span style="color: red;">eliopsc1nm_r</span> b) ____ mmHg <span style="color: red;">eliopsc1_r</span> c) ____ mm Hg <span style="color: red;">eliopsc2_r</span> d) ____ mmHg <span style="color: red;">eliopsc3_r</span> e) Median of 3 IOP readings: ____mmHg <span style="color: red;">eliopmedian_r</span>		<b>Left Eye (OS)</b> a) <input type="checkbox"/> Not measurable (skip to question #17) <span style="color: red;">eliopsc1nm_l</span> b) ____ mmHg <span style="color: red;">eliopsc1_l</span> c) ____ mm Hg <span style="color: red;">eliopsc2_l</span> d) ____ mmHg <span style="color: red;">eliopsc3_l</span> e) Median of 3 IOP readings: ____mmHg <span style="color: red;">eliopmedian_l</span>	



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		Yes	No	Yes	No
17.	Is the median IOP $\geq 22$ mmHg or Not Measurable?	<input type="checkbox"/> <sub>1</sub> <b>eliop22_r</b> <input type="checkbox"/> <sub>0</sub> OD not eligible	<input type="checkbox"/> <sub>1</sub> <b>eliop22_l</b> <input type="checkbox"/> <sub>0</sub> OS not eligible	<input type="checkbox"/> <sub>1</sub> <b>eliop22_r</b> <input type="checkbox"/> <sub>0</sub> OD not eligible	<input type="checkbox"/> <sub>1</sub> <b>eliop22_l</b> <input type="checkbox"/> <sub>0</sub> OS not eligible

18. Is the **subject** eligible for the study? Yes ☐<sub>1</sub> **eleligible** No ☐<sub>0</sub>

18A. Which **eyes** are **eligible** for the study?

a. **Right eye** eligible? **elelig\_r**  
Yes ☐<sub>1</sub> No ☐<sub>0</sub>

b. **Left eye** eligible? **elelig\_l**  
Yes ☐<sub>1</sub> No ☐<sub>0</sub>

19. Name & certification number of study nurse assessing eligibility:

a. Print Name: \_\_\_\_\_

b. Certification #: \_\_\_\_\_

18B. Enter the FLAME Subject ID Number and Alpha Code assigned to this subject:

ID # \_\_\_\_: \_\_\_\_ **subjectid**

Alpha Code: \_\_\_\_ **alphacode**

Data entry complete date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Data entered by initials: \_\_\_\_