

**Adverse Event Log**

ID. No.: subjid - \_\_\_\_ Alpha Code: alpha\_code

**Instructions: Review all new or unresolved adverse events with the patient. If the Serious Event Type is anything other than Non-Serious, complete a Serious Adverse Event Initial Reporting Form and notify the Safety Officer within 24 hours. If this is an ocular adverse event involving one eye, please check the R or L boxes; if this is an ocular adverse event involving both eyes check both the R and L boxes.**

|       | Adverse Event Coding                           |             |                         | FLAME AE Coding             |   |                           |                          |                          |                          |                     |         |                          |                         |
|-------|--|-------------|-------------------------|-----------------------------|---|---------------------------|--------------------------|--------------------------|--------------------------|---------------------|---------|--------------------------|-------------------------|
|       | MedDRA Code<br>(provided by<br>Safety Officer) | MedDRA Name | Seriousness<br>of Event | Relationship<br>to Study Tx | Maximum<br>Severity<br>(Intensity)<br>Grade | aecontrt<br>Tx for<br>AE? |                          | Ocular<br>AE<br>Eye(s)   |                          | aeflametxt<br>FLAME |         | Start Date<br>(DDMMYYYY) | Stop Date<br>(DDMMYYYY) |
| AE #  |  |             |                         |                             |   | No                        | Yes                      | R                        | L                        | Tx                  | Outcome |                          |                         |
| aeseq | aecode   | aeterm      | aeaer                   | aerel                       | aesev                                       | aeeyes_                   | r                        | aeeyes_                  | l                        |                     | aeout   | aestdtc                  | aeendtc                 |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |
|       |  |             |                         |                             |   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                     |         |                          |                         |

| FLAME AE Code Table  |   |   |   |  |
|--|---|---|---|--|
| Seriousness of Event<br>(Complete an SAE form for<br>anything other than Non-<br>Serious)  | Relationship to Study<br>Treatment  | Maximum Intensity Grade   | FLAME Treatment (Tx)  | Outcome  |
| 1 = Non Serious<br>2 = Congenital Anomaly<br>3 = Hospitalization<br>4 = Disability<br>5 = Medically Significant<br>6 = Life Threatening<br>7 = Death | 1 = Unlikely or Unrelated<br>2 = Possibly Related<br>3 = Probably Related<br>4 = Definitely Related<br>5 = Unable to assess | 1 = Mild<br>2 = Moderate<br>3 = Severe<br>4 = Life Threatening/disabling<br>5 = Death | 1 = Drops continued<br>2 = Drops temporarily stopped<br>3 = Drops withdrawn<br>4 = N/A Drops no longer prescribed | 1 = Not Recovered<br>2 = Recovered<br>3 = Resolved with Sequelae<br>4 = Recovering/ Resolving<br>5 = Fatal |