

Event Name: \_\_\_\_\_

Start Date: \_\_\_\_\_ Start Time: \_\_\_\_\_ End Date: \_\_\_\_\_ End Time: \_\_\_\_\_

**Action Taken with Study Drug:**

- None
- Temporarily Discontinued
- Permanently Discontinued
- Dose Reduced

**SAE:**  No  Yes, complete below:

- Death  Life-Threatening
- Hospitalization (initial or prolonged)
- Congenital Anomaly/Birth Defect
- Persistent or Significant Incapacity
- Other Important Medical Event

**Toxicity Grade:**

- Mild  Moderate  Severe
- Life-threatening or Disabling  Death

**Causality Assessment:**

- NO (Unrelated, not related, no relation)  Yes (Definitely related, possibly related, probably related)

PI / Sub-I (MD/DO) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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**Severity:**

- Mild
- Moderate
- Severe

**Action Taken for This Event:**

- None
- Medication(s)
- Other Therapy
- Hospitalization
- Other: \_\_\_\_\_

**Is this an Injection site reaction?  
(check all that apply)**

- Redness
- Swelling
- Pain
- Induration
- Infection
- Urticaria
- Pruritus
- Angioedema

**Outcome:**

- Not Recovered/Not Resolved  Recovered/Resolved
- Recovered/ Resolved with Sequelae  Ongoing
- Recovering/Resolving  Stable