CTO SAE SUMMARY Form

## **study number:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Initial Report** | **Date Reported:**  Click here to enter a date. | **Date Site Became Aware:**  Click here to enter a date. | **Site #:** |
| **Follow-Up #1** | Click here to enter a date. |  | |
| **Follow-Up #2** | Click here to enter a date. |
| **Follow-Up #3** | Click here to enter a date. |
| **Demographics** | **Patient ID:** | **Patient DOB:** | **Patient Age:** |
| **Height:** | **Weight:** | **Gender:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization**  **(if applicable)** | **Outcome** |
|  | **Start Date:**  Click here to enter a date. | **Date of Admission:**  Click here to enter a date. | Choose an item. |
| **CTCAE Grade:** | **End Date:**  Click here to enter a date. | **Date of Discharge:**  Click here to enter a date. |

|  |  |  |  |
| --- | --- | --- | --- |
| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization**  **(if applicable)** | **Outcome** |
|  | **Start Date:**  Click here to enter a date. | **Date of Admission:**  Click here to enter a date. | Choose an item. |
| **CTCAE Grade:** | **End Date:**  Click here to enter a date. | **Date of Discharge:**  Click here to enter a date. |

*Please add events as necessary on Page 2.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CTCAE Event Term** | **Agent** | **Relationship to Study Agent(s)**  Enter *ONE* of the following: Unrelated, Unlikely Related, Possibly Related, Probably Related, Definitely Related, for **EACH study agent** | **Is this an unexpected event for the population being studied and/or the investigational agent?** | **Does the event constitute greater risk to the patient than currently outlined in the consent?** |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |

*Please add event attributions as necessary on Page 2.*

|  |  |  |  |
| --- | --- | --- | --- |
| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization**  **(if applicable)** | **Outcome** |
|  | **Start Date:**  Click here to enter a date. | **Date of Admission:**  Click here to enter a date. | Choose an item. |
| **CTCAE Grade:** | **End Date:**  Click here to enter a date. | **Date of Discharge:**  Click here to enter a date. |

|  |  |  |  |
| --- | --- | --- | --- |
| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization**  **(if applicable)** | **Outcome** |
|  | **Start Date:**  Click here to enter a date. | **Date of Admission:**  Click here to enter a date. | Choose an item. |
| **CTCAE Grade:** | **End Date:**  Click here to enter a date. | **Date of Discharge:**  Click here to enter a date. |

|  |  |  |  |
| --- | --- | --- | --- |
| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization**  **(if applicable)** | **Outcome** |
|  | **Start Date:**  Click here to enter a date. | **Date of Admission:**  Click here to enter a date. | Choose an item. |
| **CTCAE Grade:** | **End Date:**  Click here to enter a date. | **Date of Discharge:**  Click here to enter a date. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CTCAE Event Term** | **Agent** | **Relationship to Study Agent(s)**  Enter *ONE* of the following: Unrelated, Unlikely Related, Possibly Related, Probably Related, Definitely Related, for **EACH study agent** | **Is this an unexpected event for the population being studied and/or the investigational agent?** | **Does the event constitute greater risk to the patient than currently outlined in the consent?** |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |
|  |  | Choose an item. | Choose an item. | Choose an item. |

|  |
| --- |
| **If unrelated to study treatment, please clarify relationship (i.e. disease progression, concomitant medication, comorbidity):** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Death?** | **Date of Death** | **Primary Cause of Death** | **Autopsy?** |
| Choose an item. | Click here to enter a date. |  | Choose an item. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study Agent** | **Start Date** | **Date of  Last Tx** | **Cycle** | **Dose/**  **Route** | **Frequency** | **Action Taken** |
|  | Click here to enter a date. | Click here to enter a date. |  |  |  | Choose an item. |
|  | Click here to enter a date. | Click here to enter a date. |  |  |  | Choose an item. |
|  | Click here to enter a date. | Click here to enter a date. |  |  |  | Choose an item. |
|  | Click here to enter a date. | Click here to enter a date. |  |  |  | Choose an item. |

|  |
| --- |
| **Narrative of Event:** |
| **Relevant Diagnostic Procedures (Date, Result):** |
| **Relevant Co-morbidities/Risk Factors:** |
| **Relevant Concomitant Medications:** |

*Please add supplemental documentation as necessary on Page 6.*

**Seriousness Criteria:** Choose an item.

**Does this event(s) meet criteria for expedited reporting to NU IRB?**

No  Yes, UPIRSO\*

*\* A UPIRSO is an event determined to be unexpected, related or possibly related to study participation, and suggests a greater risk of harm than was previously recognized.*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | Click here to enter a date. |
| Reporter (print) | **Reporter Signature** | **Contact Information** | **Date** |
|  |  |  | Click here to enter a date. |
| Treating Investigator (print) | **Treating Investigator Signature** | **Contact Information** | **Date** |

For NU IITs: Please report to your Northwestern University Quality Assurance Monitor at [croqualityassurance@northwestern.edu](mailto:croqualityassurance@northwestern.edu) , in addition to any other protocol reporting requirements.

Please send a copy of discharge summary, when available.

|  |
| --- |
| **Supplemental Documentation:** |