CTO SAE SUMMARY Form

## **study number:**

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| **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:**      |

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| **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. |

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*Please add events as necessary on Page 2.*

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| **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.*

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| **CTCAE Event Term** | **Dates of SAE** | **Dates of Hospitalization** **(if applicable)** | **Outcome** |
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|       |       | 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. |

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

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

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| **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. |

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| **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.*

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|       |       |       | 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 , in addition to any other protocol reporting requirements.

Please send a copy of discharge summary, when available.

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| **Supplemental Documentation:**       |