SERIOUS ADVERSE EVENT / UP REPORTING FORM COMPLETION INSTRUCTIONS

1. TRIAL INFORMATION
   a. Trial Type – indicate if this is a Single Center or Multicenter IST
      i. All affiliate site personnel must mark Multicenter
   b. Site & Site Number – Full name of treating site & Site Number
      i. Site number is indicated on formal Site Activation Letter
   c. Overall Sponsor Investigator – CUIMC Sponsor Investigator listed on protocol face sheet
   d. Local Principal Investigator – Affiliate site PI
      i. CUIMC Sponsor Investigator and Principal Investigator will be the same
   e. CUIMC IRB Number – CUIMC IRB number is listed on study protocol (AAAXXXX)
      i. Affiliate sites may enter local IRB number in parentheses in addition to CUIMC IRB number
   f. Study Title – Enter full study title as listed on protocol
   g. Study Team Member reporting event – Name of person completing form

2. EVENT TYPE
   a. Are you reporting an Unanticipated Problem?
      i. Check each UP criteria event meets
      ii. Check yes if event being reported meets all 3 criteria listed (unanticipated, at least possibly related to participation in study, places subject/others at greater risk than previously known)
   b. Are you reporting a Serious Adverse Event?
      i. Check applicable seriousness criteria event meets
      ii. Check yes if event meets at least one of the seriousness criteria listed

3. REPORT UPDATE
   a. Select whether you are submitting an initial notification of an event or submitting a follow up to an initial report.
      i. Mark Initial if this is first notification of event to CUIMC Sponsor Investigator
      ii. Mark Follow up and include follow up report number in chronological order when reporting any updates after initial notification

4. TIMELINE OF THE EVENT
   a. Event Start Date/Time – Enter date/time event was determined to meet UP/SAE criteria
   b. Event End Date – If applicable, enter date event was determined to be resolved. If event has not yet resolved, enter “Ongoing”
   c. Date/Time Study Team Informed – the date/time the PI was made aware of event
   d. Date of Report – Enter the date the report was completed

5. SUBJECT INFORMATION
   a. Subject Study ID – Enter full subject study ID number assigned at time of enrollment
      i. **DO NOT include any identifiable personal information**
   b. Age – Enter age at time of event
   c. Gender – Indicate if patient is male or female
6. DESCRIPTION OF EVENT
   a. CTCAE term for Primary Event – Enter term as listed in CTCAE
   b. Grade – Please enter event grade using CTCAE guidelines.
   c. CTCAE Version – Enter as listed in the protocol
   d. Event Causality – indicate root cause of event
      i. If checking Study Procedure, Medical History, or Other: provide details
   e. Event Expectedness – Indicate if event is expected / not expected in relation to study agent
      under investigation according to the study protocol, ICF, and/or Investigator Brochure
   f. Attribution – Indicate if cause of event can be attributed to study drug and/or patient
      participation in study
   g. Date of Hospital Admission/Discharge – Enter dates of patient hospital admission. If patient
      was not admitted, enter “N/a”
   h. Study Treatment Information –
      i. Enter name, dose/frequency, route, and dates of each study agent subject is receiving
      ii. Indicate each study drug attribution/expectedness per Principal Investigator
          determination following review of risks indicated in protocol, ICF and Investigator
          Brochure
      iii. Check action taken with study agent following start of event
   i. Related Adverse Events – List relevant adverse events occurring simultaneously to primary
      event
   j. Brief description and treatment of events – Enter brief summary of event and any additional
      relevant clinical information
   k. Outcome - Check the applicable box
      i. If event has recovered (or recovered with sequelae) selected, enter date of recovery.
      ii. If the event is ongoing, no dates should be entered.
      iii. If the event was fatal, please enter date of death.
   l. Did patient resume study treatment following event recovery?
      i. Indicate either date treatment resumed or date of last treatment

7. RELEVANT ASSESSMENTS
   a. Enter a list of clinically significant assessments performed to diagnose and/or follow recovery
      of event
   b. Enter date each assessment was performed
   c. Attach redacted results of each assessment listed or mark assessment as Results Pending

8. RELEVANT CONCOMITANT MEDICATIONS
   a. List all concomitant medication names being administered to patient,
   b. Enter start/stop dates and dose/frequency of each medication

9. RELEVANT MEDICATION TO TREAT EVENT
   a. List all medications administered to patient to treat event
   b. If no medications were administered, mark “Not Applicable”

10. REPORTING TIME LINE (CUIMC CPDM ONLY)
    a. Section 10 will be completed by CUIMC CPDM personnel only. Affiliate Site personnel are not
       required to complete this section

11. SIGNATURES
    a. Both e-signature and wet-ink signatures are permissible
    b. Affiliate Site PI or designee must sign report prior to submitting report to MCT Core