**Form 8: Serious Adverse Event (SAE) Form**

Study site:  Participant ID**:** -

**Instructions**: **THAT THIS FORM MUST BE SUBMITTED TO LCP WITHIN 48 HOURS OF THE TREATMENT SITE AWARENESS OF SAE. Attach to SAE form copies of forms 3,4,5,6 and 7.**

SAE form must be completed by the clinician when a participant has a serious adverse event (SAE) that occurs at any time during the study treatment or up to 12 months after the final study dose. **Only one (1) diagnosis or symptom should be reported per SAE Form**. If the participant died, complete and submit a Notification of Death Form. Otherwise, fill in SAE Final Conclusion section (Section E) within **45 days of the onset date**, whether or not the SAE has resolved. If the SAE has not resolved, continue to update this Form until the SAE has resolved or the study has ended. In the event of pregnancy, fill in SAE Final Conclusion section when the outcome of pregnancy is known.

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| 1. **Adverse Event Description** |

* 1. Report date: --
  2. Onset date: --

*(If* ***pregnancy****, report estimated conception date = last menstrual period date + 14 days)*

* 1. Was a diagnosis assigned? Yes No
     1. If “yes”, specify diagnosis:

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* + 1. If “no”, specify symptom:

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* 1. Was this event a worsening of pre-existing symptoms or medical condition to a grade 3 or higher?

Yes No

* 1. What type of a serious adverse event (SAE) **(select all that apply)**:

Death *(complete Form 16: Notification of Death Form)*

Any life-threatening experience

Any inpatient hospitalization **(>24 hours, including time in emergency room)** or prolongation of any hospitalization

Persistently or significantly disabling event **(as determined by the principal investigator)**

Congenital anomaly or birth defect

Other medically important event **(an event that may jeopardize the participant’s health or may require medical or surgical intervention (treatment) to prevent one of the other SAEs listed above)**

* 1. After how many post-enrollment study drugs doses did the AE occur?
  2. Clinician action taken with regard to study treatment **(check only one)**:

Dose not changed

Dose reduced

Drug interrupted **(i.e., drug held)**

Drug withdrawn **(i.e., permanently discontinued)**

Not applicable **(I.e., not taking study treatment)**

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| 1. **Comments** |

Answer the questions listed below and provide a summary of the SAE:

* How long after the dose immediately before the SAE did the signs and symptoms start?

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* Was participant seen by an MD, urgent care or ER staff **(including study staff)**?

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* Was alcohol associated with the SAE?

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* If applicable, list the medications that were prescribed to treat the SAE:

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* If applicable, describe any changes shown in the current chest x-ray in comparison to the most recent previously reported chest x-ray:

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* If applicable, describe any additional action **(not reported previously)** taken in response to the SAE

**(e.g., repeat test, follow-up)**:

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* If applicable, list other factors related to the SAE:

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* If applicable, specify how long after the onset date the SAE resolved **(hours, days, weeks)**:

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* If applicable, specify whether the participant permanently discontinued study treatment because of medical advice or participant decision:

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| 1. **Summary of SAE** |

Use the SOAP **(Subjective, Objective, Analysis, and Plan)** sequence for a clinical note.

If more than one SAE occurred on the same day, note here and report event on a separate SAE form.

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| 1. **Drug Re-challenge** |

1. Was all or any part of study treatment held for any period of time?  Yes  No **(Skip to Section E)**
2. Was participant re-challenged with the intention of restarting study treatment?

**(Re-starting treatment with a full per-protocol study drug dose is not considered a re-challenge)**

Yes  No

**(If “Yes”, complete the Drug Re-challenge table on the Concomitant Medication Form)**

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| 1. **Final Conclusion** |

1. Date of final conclusion about this AE: --
2. In the opinion of the investigator, what is the attribution to study treatment in causing this SAE?

**(Refer to attribution scale in the Manual of Procedures. Check only one.)**

Definite

Probable

Possible

Unlikely

Not related

Unclassifiable

1. In the opinion of the investigator, is this an anticipated or unanticipated AE?

**(Refer to the Manual of Procedures for definitions. Check only one.)**

Anticipated

Unanticipated

1. Indicate the maximum toxicity grade of event by the time of this report.

**(Refer to the Common Toxicity Criteria version #4.0 in the Manual of Procedures. Check only one.)**

Grade 1

Grade 2

Grade 3

Grade 4

Grade 5

4. Status of the AE **(check only one)**:

Resolved

Resolved with sequelae

Fatal **(Complete Notification of Death Form)**

If resolved, provide resolution date: --

Resolving **(I.e., improving)**

Not resolved **(I.e., ongoing or worsening)**

Unknown

* 1. Pregnancy outcome:

Not applicable

Spontaneous abortion

Elective abortion

Live birth

Fetal death

Unknown

**(If “live birth” or “fetal death”, continue to E4b, otherwise, skip to E5)**

* 1. If “live birth” or “fetal death”, were any congenital anomalies present?  Yes  No

1. Was the AE attributed to one or more study drugs?  Yes  No **(Skip to E6)**
   1. If “yes”, select the study drug(s) that the SAE is attributed to **(select all that apply)**:

Isoniazid  Ethambutol  Pyrazinamide

Kanamycin  Moxifloxacin  Clofazimine

Prothionamide  Other, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Is the **FINAL** diagnosis different from what was originally reported on the description of SAE?

Yes No

* 1. If “yes”, specify diagnosis:

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| 1. **Form Completion** |

PRINT name of person completing form:

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Date Serious Adverse Event Form completed: --