**Form 7: Adverse Events Form**

Study site:  Participant ID**:** -

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **List all adverse events. All adverse events must be followed until resolution or until a stable clinical endpoint is reached. \*All serious adverse events, regardless of relationship to study regimen, must be reported via fax/email within 48 hours of site awareness.** | | | | | | | | | |
| **AE type** | **Onset date** | **Maximum severity grade of event by the time of this report** | **Was this a serious adverse event (SAE)?** | **If SAE, indicate type (*select all that apply*):** | **Clinician action taken with regard to study treatment:** | **Outcome (Status of the AE):** | **Was the AE attributed to one or more anti-tuberculosis drugs?** | **Record likely drug(s) that the AE may be attributed to**  **(enter drug abbreviation from the Field Manual)** | **If resolved, resolution date** |
|  | -- | Grade 1  Grade 2  Grade 3  Grade 4  Grade 5 | **Yes (Complete SAE Form)**  No | Death ***(Complete Notification of Death Form)***  Any life-threatening experience  Any hospitalization or prolongation of hospitalization  Persistently or significantly disabling event  Congenital anomaly or birth defect  Other medically important event\* | Dose not changed  Dose reduced  Drug interrupted  Drug withdrawn  Not applicable | Resolved  Resolved with sequelae  Fatal ***(Complete Notification of Death Form)***  Resolving  Not resolved **(i.e., ongoing or worsening)**  Unknown | Yes  No  Unknown | 1.\_\_\_\_\_\_  2.\_\_\_\_\_\_  3.\_\_\_\_\_\_ | -- |
|  | -- | Grade 1  Grade 2  Grade 3  Grade 4  Grade 5 | **Yes (Complete SAE Form)**  No | Death ***(Complete Notification of Death Form)***  Any life-threatening experience  Any hospitalization or prolongation of hospitalization  Persistently or significantly disabling event  Congenital anomaly or birth defect  Other medically important event\* | Dose not changed  Dose reduced  Drug interrupted  Drug withdrawn  Not applicable | Resolved  Resolved with sequelae  Fatal ***(Complete Notification of Death Form)***  Resolving  Not resolved **(i.e., ongoing or worsening)**  Unknown | Yes  No  Unknown | 1.\_\_\_\_\_\_  2.\_\_\_\_\_\_  3.\_\_\_\_\_\_ | -- |
|  | -- | Grade 1  Grade 2  Grade 3  Grade 4  Grade 5 | **Yes (Complete SAE Form)**  No | Death ***(Complete Notification of Death Form)***  Any life-threatening experience  Any hospitalization or prolongation of hospitalization  Persistently or significantly disabling event  Congenital anomaly or birth defect  Other medically important event\* | Dose not changed  Dose reduced  Drug interrupted  Drug withdrawn  Not applicable | Resolved  Resolved with sequelae  Fatal ***(Complete Notification of Death Form)***  Resolving  Not resolved **(i.e., ongoing or worsening)**  Unknown | Yes  No  Unknown | 1.\_\_\_\_\_\_  2.\_\_\_\_\_\_  3.\_\_\_\_\_\_ | -- |

\*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.