**Adverse Event Form**

Adverse Event Terms

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| **Organ System** | **Common Adverse Events**  **(choose one)** | **Organ System** | **Common Adverse Events**  **(choose one)** |
| *Cardiovascular disorders* | * Cardiac rhythm * Prolonged (corrected) QT interval | *Immune disorders* | * Allergic reaction |
| *Chemistry* | * Hypokalemia (K ≤ 3.4 mEq/L) * Hypomagnesemia (Mg ≤ 1.4 mmol/L) * Lactate (serum lactate greater than ULN) | *Musculoskeletal disorders* | * Arthralgia * Arthritis * Myalgia * Tendinopathy |
| *Ear disorders* | * Hearing impairment (hearing loss) * Tinnitus * Vestibular disorder | *Neurological disorders* | * Dysgeusia * Headache * Peripheral neuropathy (neurosensory disorder or paresthesia) * Seizure |
| *Endocrine disorders* | * Hypothyroidism | *Reproductive system and breast disorders* | * Gynecomastia |
| *Enzymes* | * Increased liver enzymes (ALT increased or AST increased (≥ 1.1 x ULN)) | *Psychiatric disorders* | * Anxiety * Depression * Psychosis * Suicidal ideation |
| *Eye disorders* | * Optic nerve disorder (optic neuritis) | *Renal and urinary disorders* | * Acute kidney injury (acute renal failure) |
| *Gastrointestinal disorders* | * Diarrhea * Dyspepsia * Nausea * Oral discomfort/dysphagia * Pancreatitis * Vomiting | *Skin disorders* | * Mucocutaneous symptoms (includes rash) * Pruritus * Skin hypo- or hyper-pigmentation |
| *Other* | Enter one adverse event if not listed in the most common list above |

**Adverse Event Form**

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| Surname: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Given name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Facility patient ID#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | EMR ID#: \_\_ \_\_ \_\_ — \_\_ \_\_ \_\_— \_\_ \_\_ \_\_ \_\_ \_\_ |

|  |  |
| --- | --- |
| **SAE #:** Write the SAE case number if the AE met the definition of an SAE and an SAE Form was submitted to the PV Unit at any time, write the SAE case number (from the top right of the SAE form). Write "NA" if the AE never met the definition of an SAE and an SAE Form was never submitted to the PV Unit. | **Outcome date:** Write the date that the AE was closed and the outcome is filled out on the original AE form. |

AE ID #\_\_\_\_ AE Term \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Date should always be written: DD/MMM/YYYY*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date |  |  |  |  |  |  |  |  | Date of AE outcome | AE Outcome |
| Severity Grade  (1 – 4) |  |  |  |  |  |  |  |  |  | ☐ Fatal ☐ Not resolved ☐ Resolved ☐ Resolved with sequelae ☐ Resolving ☐ Unknown |

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| --- | --- | --- | --- | --- | --- | --- |
| Is this adverse event related to any of the TB drugs in the patient’s regimen? | Anti-TB drugs | | | | | |
| Drug 1:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug 2:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug 3:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug 4:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug 5:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug 6:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Possibly related to AE?  ☐ Yes ☐ No | Possibly related to AE?  ☐ Yes ☐ No | Possibly related to AE?  ☐ Yes ☐ No | Possibly related to AE?  ☐ Yes ☐ No | Possibly related to AE?  ☐ Yes ☐ No | Possibly related to AE?  ☐ Yes ☐ No |
| ☐ Yes ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |
| Were all anti-TB drugs suspended due to this AE? | | | ☐ Yes ☐ No |