**Adverse Event Form AE ID #: \_\_\_\_\_\_\_\_**

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| --- | --- |
| Surname: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Given name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Facility patient ID#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  EMR ID#: \_\_ \_\_ \_\_ — \_\_ \_\_ \_\_ — \_\_ \_\_ \_\_ \_\_ \_\_ | |
| Date of onset of event: \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (DD/MMM/YYYY) | |
| Date of reporting the event (today's date): \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ | |
| Were all anti-TB drugs suspended due to this AE?(place in log!) | ☐ Yes ☐ No |

#### Use one AE form per event. Tick the box in the right column that applies to the AE being reported.

|  |  |
| --- | --- |
| **Organ system** | **Common Adverse Events**  **(check ONE)** |
| *Cardiovascular disorders* | ☐ Cardiac rhythm  ☐ **Prolonged (corrected) QT interval** |
| *Chemistry* | ☐ **Hypokalemia (K ≤ 3.4 mEq/L)**  ☐ Hypomagnesemia (Mg ≤ 1.4 mmol/L)  ☐ Lactate (serum lactate greater than ULN) |
| *Ear disorders* | ☐ **Hearing impairment (hearing loss)**  ☐ Tinnitus  ☐ Vestibular disorder |
| *Endocrine disorders* | ☐ **Hypothyroidism** |
| *Enzymes* | ☐ **Increased liver enzymes (ALT increased or AST increased (≥ 1.1 x ULN))** |
| *Eye disorders* | ☐ **Optic nerve disorder (optic neuritis)** |
| *Gastrointestinal disorders* | ☐ Diarrhea  ☐ Dyspepsia  ☐ Nausea  ☐ Oral discomfort/dysphagia  ☐ Pancreatitis  ☐ Vomiting |
| *Hematology* | ☐ **Absolute neutrophil count low (ANC ≤ 1500/mm3)**  ☐ **Anemia (Hb < 10.5 g/dL)**  ☐ **Platelets decreased (< 75,000/mm3)** |
| *Immune disorders* | ☐ Allergic reaction |
| *Musculoskeletal disorders* | ☐ Arthralgia  ☐ Arthritis  ☐ Myalgia  ☐ Tendinopathy |
| *Neurological disorders* | ☐ Dysgeusia  ☐ Headache  ☐ Peripheral neuropathy (neurosensory disorder or paresthesia)  ☐ Seizure |
| *Reproductive system and breast disorders* | ☐ Gynecomastia |
| *Psychiatric disorders* | ☐ Anxiety  ☐ Depression  ☐ Psychosis  ☐ Suicidal ideation |
| *Renal and urinary disorders* | ☐ **Acute kidney injury (acute renal failure)** |
| *Skin disorders* | ☐ Mucocutaneous symptoms (includes rash)  ☐ Pruritus  ☐ Skin hypo- or hyper-pigmentation |
| ***Other adverse events*** | |
| *Other (enter one adverse event) if not listed in the most common list:* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Severity**

|  |  |
| --- | --- |
| Grade | ☐ 1 ☐ 2 ☐ 3 ☐ 4 |

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| --- |
| Form filled by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |
| Form entered by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |

**Outcome**

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| --- | --- |
| Date of AE outcome | \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (DD/MMM/YYYY) |
| Outcome of this AE | ☐ Fatal  ☐ Not resolved  ☐ Resolved  ☐ Resolved with sequelae  ☐ Resolving  ☐ Unknown |

**Severity**

|  |  |
| --- | --- |
| Maximum severity grade | ☐ 1 ☐ 2 ☐ 3 ☐ 4 |

**Causal Factors: Anti-TB drugs**

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| Is this adverse event related to any of the TB drugs in the patient’s regimen? | ☐ Yes ☐ No |

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| **Anti-TB drugs** | **Possibly Related to AE?** | **Final action taken** |
| Drug 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |
| Drug 2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |
| Drug 3: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |
| Drug 4: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |
| Drug 5: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |

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| Form filled by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |
| Form entered by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |