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

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

|  |  |
| --- | --- |
| Did this AE become an SAE?  If yes, SAE Case ID # | ☐ Yes ☐ No  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date of AE outcome | \_\_ \_\_ /\_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (DD/MMM/YYYY) |
| Outcome of this AE | ☐ Fatal (fill out an SAE form)  ☐ 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| ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |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| ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |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| ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |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| ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |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| ☐ Yes  ☐ No | ☐ Dose maintained (no changes)  ☐ Dose reduced  ☐ Drug permanently withdrawn  ☐ Unknown |

**Other Causal Factors**

|  |  |
| --- | --- |
| Are there any other causal factors, such co-morbidities, procedures, other non-TB drugs, etc.? (check ALL that apply) | ☐ Non TB drugs  ☐ Comorbidity  ☐ Other |

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| **Related other non-TB drugs (ART, diabetes drugs, etc.)** |
| 1. |
| 2. |
| 3. |

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| **Related co-morbidities (chronic kidney problem, diabetes, etc.)** |
| 1. |
| 2. |
| 3. |

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| **Other related or causal factors (procedure, etc.)** |
| 1. |
| 2. |

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