**Adverse Event Outcome**

This form should be filled out when an AE is closed, meaning that the AE is resolved or stable. This form corresponds to an AE form which originally was used to report the AE.

***This form should not be filled out for SAE. In the case of an AE that becomes an SAE, fill the first part of the form (through "Did this AE become an SAE? If YES, SAE Case ID#:") and give the SAE ID number and leave blank the outcome and causal factors of the AE.*** The outcome and causal factors should be reported in the SAE form and send to the PV Unit.

* **AE ID #:** Write the number of the AE being closed at the top right of this form. This should be the same number as on the top right of the Adverse Event Form. If this is the outcome of an SAE, then this number can be found on the Adverse Event Log.
* **Did this AE become an SAE?** If the AE fulfils the criteria of being an SAE, then mark YES and fill an SAE form.
  + **If YES, SAE Case ID#:** Write the SAE Case ID # provided by the PV unit in response to the submitted SAE form. This ID will be recorded retrospectively, after the PV Unit has responded.
* **Date of AE outcome** is the date that the AE is closed and this section is filled out.
* **Outcome of this AE**: choose the one best outcome.
  + Fatal: the event is the cause of patient's death or one of the causes of patient's death.
  + Not resolved: the event is ongoing, no improvement is observed. NOT RESOLVED should generally not be selected because it means that the AE should not be closed.
  + Resolved: the event is fully resolved or stabilized; return to baseline condition for chronic disorders.
  + Resolved with sequelae: the event is resolved, but patient has some permanent condition as a consequence of the event (e.g. mild paraesthesia following transient ischaemic attack).
  + Resolving: the event is improving, lab results returned improved results, patient’s general condition is better but not fully resolved/stabilized or returned to baseline condition.
  + Unknown: the reporter has no information on the event’s outcome.

**Causal Factors: Anti-TB drugs**

* **Is this adverse event related to any of the TB drugs in the patient’s regimen?:** Mark YES if the AE is possibly related to any of the drugs in the regimen. If YES is marked list drug name, relation to AE and final action taken in following questions.
* **Anti-TB drugs**: "Related" means that there is a reasonable possibility that the AE may be related to the drug. Elements in favour of a reasonable causal relationship include (but are not limited to):
  + A favourable temporal relationship,
  + A positive dechallenge, meaning symptoms are receding when the drug(s) is withdrawn or the dose is reduced,
  + A positive rechallenge, meaning symptoms are reappearing when the drug(s) is reintroduced or the full dose is re-administered,
  + A plausible pharmacological/biological mechanism of action (whether proven or potential),
  + Previous knowledge of similar reaction with the drug(s), or
  + No other evident cause (e.g. previous disease, other drugs).
* For each related drug, choose only one **final action taken**. These are final actions, not the actions taken immediately after the AE. For example:
  + If the related drug was stopped for 2 weeks but eventually the patient was able to tolerate the original dose, mark DOSE MAINTAINED (NO CHANGES).
  + If the related drugs was stopped for 2 weeks but eventually the patient was able to tolerate a reduced dose, mark DOSE REDUCED.
  + Mark DRUG PERMANENTLY WITHDRAWN if the drug was stopped and never restarted, or if the patient was never able to tolerate the full or reduced dose of the drug.
  + Mark UNKNOWN if the reporter does not know the final action

**Other Causal Factors**

* **Related other non-TB drugs**: These can be drugs used for treatment of AE or co-morbidities such as HIV or diabetes. In some sites, these drugs will be recorded on the Concomitant Medication Log.
* **Related co-morbidities**: If there are any co-morbidities that were related to this AE, write them here.
* **Other related or causal factors**: If there are any other factors that were related to this AE, write them here.