**Adverse Event Form**

*A trained doctor is needed to collect this information.*

**General**

* An AE is defined as a new event that occurs during treatment or an existing medical condition that get worse during treatment.
* Pre-existing AEs (at the start of treatment) are medical conditions associated with previous treatment and should not be included in the AE form.
* Use one AE form per event.
* For a Serious Adverse Event (SAE), complete the SAE form instead of this AE form and submit to the PV unit within 24 hours.
* Tick the box in the right column that apply to the AE being reported.
  + Organ grouping listed on the left side of the table is assigned for study purposes.
  + The right column on the table lists abnormalities in laboratory tests, symptoms and conditions.
* AE of interest on the right column of the table are in bold.
  + AE of interest should be captured no matter the severity. Many of these may be related to the new TB drugs (bedaquiline or delamanid) or companion drugs (linezolid).
* Other AE do not need to be captured unless it results in a change in the TB treatment regimen (stopping or decreasing the dose of a TB drug) or it is considered as relevant by the doctor.

**Identifying Information**

* **AE ID #:** After filling out this form, enter the new AE into the Adverse Event Log. At this time, an AE number will have to be selected which is unique to this episode. Write this number at the top of the AE form. This will link this form to the relevant episode recorded on the AE log. The AE log appears as a summary table on the EMR once an event has been entered in the relevant forms.
* **Date of reporting the event**: this is generally the date that the form is being filled out.
* **Date of onset of event**:
  + If AE is a symptom enter the date when the symptom was first noticed.
  + If AE is an abnormal test, enter date of medical evaluation.
* **Were all anti-TB drugs suspended due to this AE?** Mark YES if the patient's TB treatment regimen had to be suspended for any length of time because of a severe AE. If only one or some drugs had to be suspended, then mark NO. For example, if the patient developed a severe drug-induced hepatitis and all drugs were suspended until liver enzymes returned to normal, mark YES.

**Adverse Events**

* Cardiovascular disorders
  + Cardiac rhythm – any abnormality in cardiac rhythm.
  + Prolonged QT interval – corrected QT interval prolonged on electrocardiogram (make sure an ECG is done and an ECG form is filled out).
* Chemistry
  + Hypokalemia – serum potassium level 3.4 mEq/L (milliequivalents per liter) or less.
  + Hypomagnesemia – serum magnesium level 1.4 mmol/L (millimoles per liter) or less.
  + Lactate (lactic acidosis) – lactate level at ULN (upper limit of normal) or higher, with or without acidosis.
* Ear disorders
  + Hearing impairment (hearing loss) is decreased hearing capacity from baseline.
  + Tinnitus is noise or ringing in the ears.
  + Vestibular disorder is characterized by dizziness, imbalance, nausea and vision problems.
* Endocrine disorders
  + Hypothyroidism — defined as any elevation in TSH above upper limit of normal plus a clinical decision to treat with levothyroxine.
* Enzymes
  + Increased liver enzymes:
    - Elevation in AST, Aspartate Aminotransferase (or Serum glutamic oxaloacetic transaminase, SGOT) 1.1 x upper limit of normal or greater; or
    - Elevation in ALT, Alanine Aminotransferase (or Serum glutamic pyruvic transaminase, SGPT) 1.1 x ULN upper limit of normal or greater.
* Eye disorders
  + Optic nerve disorder (optic neuritis) – inflammation of the optic nerve often resulting in loss of color vision or decrease in visual acuity.
* Gastrointestinal disorders
  + Diarrhea – frequent and loose bowel movements 3 or more times a day.
  + Dyspepsia – abdominal discomfort such as burning stomach, bloating, heartburn, nausea and vomiting.
  + Nausea – queasy sensation or the urge to vomit.
  + Oral discomfort/dysphagia – oral discomfort, difficulty in swallowing.
  + Pancreatitis – inflammation of the pancreas.
  + Vomiting – one or more episodes of vomiting a day.
* Hematology
  + Absolute neutrophil count low – absolute neutrophil count of 1500/mm3 (per cubic millimeter) or less
  + Anemia – hemoglobin level 10.5 g/dL (grams per deciliter) or less
  + Platelets decreased – platelet count of 75,000/mm3 (per cubic millimeter) or less
* Immune disorders
  + Allergic reaction – local or generalized hypersensitivity response, may manifest as pruritus without rash progressing to urticaria, angioedema and anaphylaxis.
* Musculoskeletal disorders
  + Arthritis – inflammation of joint
  + Arthralgia – marked discomfort in a joint
  + Myalgia – muscle tenderness
  + Tendinopathy – tendon injuries from mild inflammation, partial tear to tendon rupture
* Neurological disorders
  + Dysgeusia – abnormal sensation of taste of food; may or may not relate to decrease in sense of smell.
  + Headache – pain in the head not confined to any nerve distribution.
  + Paresthesia (peripheral neuropathy) – burning, tingling, numbness or prickling sensation on extremities.
  + Seizure – sudden involuntary skeletal muscular contractions of cerebral or brain stem origin.
* Reproductive system and breast disorders
  + Gynecomastia – breast enlargement in males.
* Psychiatric disorders
  + Anxiety – feelings of apprehension of danger and dread accompanied by restlessness, tension, tachycardia, and dyspnea unattached to a clearly identifiable stimulus.
  + Depression – melancholic feelings of grief or unhappiness.
  + Headache
  + Psychosis – personality change, impaired functioning and loss of touch with reality.
  + Suicidal ideation – Any thoughts of taking one’s own life
* Renal and urinary disorders
  + Acute kidney injury (acute renal failure) – creatinine level increase of >0.3 mg/dL (milligrams per deciliter); creatinine 1.5 – 2.0 x above baseline.
* Skin disorders
  + Mucocutaneous symptoms — any symptom from general scale, from localized itching to life-threatening conditions like Stevens Johnson syndrome.
  + Pruritus – Intense itching sensation.
  + Skin hypo- or hyper-pigmentation – Loss of skin pigment or darkening of the skin.
* Other
  + A symptom, abnormal exam finding, condition or test not listed above.

**Severity**

* Intensity of AE expressed in grades. Please refer to the endTB Guide for any AE in the list above. For all other AE, use the Severity Grading Scale (also includes all of the AE in the list above).
* Grade – Mark the grade assigned to the AE. If the AE being reported consists of more than one abnormal test, symptom or condition, choose the highest grade assigned according to the Severity Grading Scale.

**Related tests results**

* List any tests or diagnostic procedures pertaining to this AE:
  + Test – Name of laboratory or diagnostic test
  + Date – Date of test results
  + Value – Test results including units (e.g. %, mg/dL)