**Baseline Assessment**

**REGISTRATION AND DEMOGRAPHICS**

* **EMR ID#** is a patient identifier number. The EMR ID# can be assigned by the project or automatically by the EMR. It is created as follows: Country ISO code (standard 3 letters) – Registration facility code (3 numbers assigned to the facility) – Consecutive patient code (5 numbers assigned to each patient, none repeating per registration facility). For example:
  + Peru - facility 1 - patient 1: PER-001-00001
  + Peru - facility 1 - patient 2: PER-001-00002
  + Peru - facility 2 - patient 1: PER-002-00001
  + Lesotho - facility 1 - patient 1: LSO-001-00001
* **Registration Number**: This is a treatment identifier. This number **MUST** be entered for all patients on treatment. It identifies the specific course of treatment for this particular patient. A patient identified by an EMR ID# could have more than one registration number, each one identifying a separate course of treatment within the EMR.
  + In some countries, it is standard practice to assign a unique number when a patient enters treatment. This number can be used here, but it must be unique to each course of treatment.
  + If it is not standard practice based on local or government regulations, a systematic numbering system should be developed internally. For example, this could be created by appending 2 digits to the EMR ID. These last two digits will represent the order of treatment, starting from 01 for all the patients. Example: PER-001-00001-01 (Peru, Site #1, Patient #1, Treatment #1).
* **Date of Birth:** Complete any information available from the patient. If day or month of birth are unknown but the year of birth is known, provide 01 for date and July for month. For example:
  + Patient birth year (1980), month and day unknown: 01/Jul/1980.
  + Patient birth year (1981) and month (Sep) known, day unknown: 01/Sep/1981.
* **Age (yrs):** Complete according to information provided for "Date of Birth" or to the information provided by the patient if the date of birth is unknown. Age or Date of Birth will be auto-calculated on the EMR depending on which field is updated on the form. If both are provided Date of Birth should be used for EMR and patient tracking.

**SOCIAL HISTORY**

* **Marital status**: Mark only one; specify the marital status if ‘other’ is marked
* **Homeless within the past year**: Mark YES if respondent reports that presently or at any time in the last 12 months he/she has lacked housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility (e.g. shelters) that provides temporary living accommodations, and an individual who is a resident in transitional housing (e.g. any unstable or non-permanent situation). A homeless person is an individual without permanent housing who may live on the streets; stay in a shelter, mission, abandoned building or vehicle; or in any other unstable or non-permanent situation. Unstable or non-permanent housing does not include prison or temporary housing provided by the government/NGO in order for the patient to receive MDR-TB treatment in a different city.
* **Employment status**: Choose one option. Mark EMPLOYED if the respondent reports that he/she has a full- or part-time job. Mark UNABLE TO WORK if the person is too sick to work or disabled. Mark UNEMPLOYED if respondent reports that he/she does not have a job, and is available to work. Individuals who were temporarily laid off from a job and are waiting to be called back to that job also meet the definition of unemployed. Mark OTHER if respondent does not fit any of the above options (e.g. respondent is currently in prison).
* **Refugee, displaced or migrant**: Mark YES if respondent reports that he/she has been forced to flee his/her home. Mark NO, otherwise.
* **In prison**: Mark YES if respondent reports that presently or at any time in his life he/she has been in prison. If YES: Mark CURRENTLY if respondent reports being imprisoned currently. Mark IN THE PAST if respondent reports that he/she has been imprisoned some time in the past (and is not imprisoned anymore)
* **Health worker**: Mark CURRENTLY if respondent reports he/she currently works (with or without pay) in the testing, treatment, or support of others receiving medical care. This includes cleaning staff in health care facilities. Mark IN THE PAST if respondent did this kind of work previously, but presently does not.
* **Does the patient drink alcohol?** Mark YES if patient reports consuming alcohol currently. Mark NO if the patient does not consume alcohol currently. Mark UNKNOWN if the alcohol consumption status is unclear.
  + **If YES: How many standard alcoholic drinks does the patient drink per week?** One alcoholic drink is defined as (NIAAA):



**TB HISTORY**

The following questions should be answered after deciding on the treatment start date, which depends on the situation of the patient. (see explanation of treatment start date in Treatment Initiation). For example, if the regimen is being changed due to adverse events (e.g. replacement of kanamycin with bedaquiline) but the patient does not fulfill the definition of failure, the treatment start date is the start date of the original regimen and not the date that the treatment was changed to include a new drug. This is not considered a new treatment, but rather a continuation of the original treatment (See explanation of treatment start date: Situation 2). In this case, the following questions should be answered from the point of the start date of the original regimen, not the start date of new TB drugs.

* **Has the patient ever been treated for TB in the past?** If the patient or the patient's medical records confirm a history of previous TB treatment, then mark YES. TB treatment means that a patient was diagnosed with active TB and received more than one month of anti-TB drugs. Isoniazid preventive treatment is not considered TB treatment. If the patient has never received TB treatment before, mark NO. If it cannot be confirmed, mark UNKNOWN.
  + **If YES, year of the start of patient's first TB treatment?** Write the YEAR when the patient started TB treatment for the first time. If the patient has a history of multiple TB treatments, then write the year of the first TB treatment only. If the year can not be confirmed, mark UNKNOWN.
* **Has the patient ever had more than 1 month of treatment for DS-TB in the past?** Mark YES if the patient was diagnosed with a susceptible strain and subsequently received TB treatment with first line drugs. In the case of presumptive TB treatment (prescribed in the absence of DST), any treatment regimen consisting only of first-line TB drugs (isoniazid, rifampicin, ethambutol, pyrazinamide or streptomycin) may be considered treatment for presumptive DS-TB. For example, any empiric Category I or II regimen can be considered treatment for DS-TB, if DST was not done before treatment.
* **Has the patient ever had more than 1 month of treatment for DR-TB in the past?** Mark YES if the patient was diagnosed with a drug-resistant strain and subsequently received TB treatment with second-line drugs. In the case of presumptive TB treatment (prescribed in the absence of DST), any treatment regimen including second-line injectables (kanamycin, amikacin, capreomycin) or oral second-line TB drugs may be considered treatment for presumptive DR-TB.
* What is the outcome of the most recent **DR-TB** treatment? (check one only)
  + **Cured**. Treatment completed as recommended by the national policy without evidence of failure AND 3 three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.
  + **Completed**. Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.
  + **Failure**. Treatment terminated or need for permanent regimen change of at least two anti-TB drugs. Multiple reasons for treatment failure may be marked.
  + **Lost to follow-up**. Treatment was interrupted for 2 consecutive months or more. Multiple reasons for lost to follow-up may be marked.
  + **Not evaluated:** Includes cases whose treatment outcome is unknown and cases whose treatment outcome is transferred out. This includes patients who are transferred back to DS-TB treatment.
  + **Treatment adapted:** An empirical treatment that was ended due to DST results showing resistance to second line drugs and therefore rendering the current treatment sub-optimal or ineffective. In such a case the outcome of the empirical treatment would be given as *treatment adapted* and a new regimen will be started which will include new TB drugs
* **Drugs taken for greater than one month (check all that apply):** Mark ALL drugs taken for more than 1 month *before the treatment start date*—see Treatment Initiation section for an explanation of the treatment start date. For example, in the case that new TB drugs are being started to reinforce an empiric regimen after second-line DST results show pre-XDR or XDR, then mark all drugs taken during the empiric treatment by the patient before the new regimen including new TB drugs is started.

**PAST MEDICAL HISTORY (CO-MORBIDITIES)**

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

Generally this information will be collected by asking the patient, but in some cases, prior medical records may be available for review. Only current co-morbidities should be indicated in this section. For example, if the patient had breast cancer 10 years ago but was cured, mark NO under "Cancer".

* **HIV serostatus:** 
  + If the patient has been diagnosed with HIV, mark POSITIVE and write the date that the patient was diagnosed. If the patient presents the results of a negative test done within the preceding 3 months, mark NEGATIVE.If there is no written documentation or the latest negative test was done more than 3 months prior the date of the interview, ask for a new HIV test, and mark UNKNOWN on the baseline form. Once results are available, put them in the Laboratory Results form.
* **Diabetes**: Mark YES if the patient has been diagnosed with diabetes. If there is a documented HbA1c, then also record it here.
* **Chronic renal insufficiency**: defined as a reduction in kidney function for over 3 months.
* **Cirrhosis**: defined as end-stage liver disease that is often caused by alcohol, hepatitis B or C.
* **Chronic obstructive pulmonary disease**: defined as obstructive lung disease marked by progressive shortness of breath and loss of lung function.
* **Cancer**: Includes a current diagnosis of cancer of any type. Mark NO, if the patient has a distant history of cancer that was cured.
* **Heart disease or atherosclerotic disease**: This includes a history of heart attack or angina; a history of stroke or peripheral vascular disease (e.g. claudication), and a diagnosis of other types of heart disease, such as congestive heart failure, that are not related to atherosclerotic disease.
* **Confirmed Hepatitis B**: Written documentation or test results should be reviewed to confirm diagnosis. A positive hepatitis B surface antigen (HBsAg) test is sufficient for a diagnosis of chronic hepatitis B infection.
* **Confirmed Hepatitis C:** Written documentation or test results should be reviewed to confirm diagnosis. A positive hepatitis C antibody test is sufficient for a diagnosis of hepatitis C infection.
* **Depression**: Mark YES only if the patient has received this diagnosis from a psychiatrist, psychologist, or other doctor.
* **Other psychiatric illness**: This includes any mental illness that was diagnosed by a psychiatrist, psychologist or other doctor. For example, bipolar disorder, psychosis, anxiety disorder, etc.
* **Seizure disorder (chronic):** Mark YES only if the patient is currently receiving treatment for chronic seizures.
* **Other pre-existing diseases**: Write any other pre-existing diseases in free text in the box provided.

**CLINICAL EXAMINATION**

*A trained clinician (doctor or nurse) is needed to collect this information.*

See the SOPs for detailed instructions on how to measure:

* Vital signs
* Brief peripheral neuropathy screen
* Visual acuity (Snellen test)
* Colorblindness screen (Ishihara test)
  + N.B. for the Ishihara test, enter the number of CORRECT plates. If the number of correct plates is at least 10/11 then the color vision is normal. If not, it is abnormal.

**CASE DEFINITION**

*Any trained clinician (doctor or nurse) can collect this information.*

The following questions refer to the case definition at the time of the treatment start date (see explanation of treatment start date in Treatment Initiation)

* **WHO registration group:** Patients are assigned to a registration group based on the treatment history at the treatment start date (see Treatment Initiation section for an explanation of the treatment start date). Mark the appropriate group according to definitions below:
  + **New:** A patient who has received no or less than one month of anti-TB treatment (patients are considered New if DST was performed within one month of the start of treatment, even if they had received more than one month of first-line drug treatment for TB by the time that the DST results returned and they were registered for second-line TB treatment.)
  + **Relapse:** A patient who was previously treated for TB and whose most recent treatment outcome was Cured or Treatment completed, and who is subsequently diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
  + **Treatment after loss to follow-up:** A patient who had previously been treated for TB and was declared Lost to follow-up at the end of the most recent course of treatment.
  + **Treatment after failure:** A patient who has received first-line or second-line treatment for TB and in whom treatment has failed.
  + **Other previously treated patients:** A previously treated TB patient whose outcome after the most recent course of treatment is unknown or undocumented. This option should also be marked when closing a treatment course as "treatment adapted".
* **History of past anti-TB drug use:** Provide the most suitable option based on the anti-TB regimen/s received in the past for one month or more. "In the past" means before the treatment start date of this MDR-TB treatment—see Treatment Initiation section below for how to find the treatment start date. For example, in the case that new TB drugs are being started to reinforce an empiric regimen after second-line DST results show pre-XDR or XDR, then "in the past" refers to before the empiric regimen was started, not when the new TB drugs are started. If the patient has never been treated for TB in the past, then do not tick any box. The EMR will automatically skip this question if NEW is ticked in the previous question.
* **Disease site:** Mark the appropriate type of TB. Extrapulmonary TB includes lymphatic, pleural, abdominal, etc. If extrapulmonary TB is marked, then specify the exact site of disease. If the patient has both, pulmonary and extrapulmonary TB, then mark both.
* **Detection of *M. tuberculosis*?**
  + BACTERIOLOGICALLY CONFIRMED means that there was a laboratory test positive for *M. tuberculosis*. Acceptable laboratory tests are listed in the following question.
  + NOT CONFIRMED, CLINICALLY DIAGNOSED means that there has never been a laboratory test positive for *M. tuberculosis*.
* **What was the method of confirmation?** All of the listed methods are common and acceptable methods of detection of *M. tuberculosis*. Mark all the options that apply. If ‘OTHER TEST’ is marked, then specify the method.
* **Drug resistance and subclassification of drug-resistance:** If there are several DST results, use one that reflects the pattern of resistance on the treatment start date listed in the Treatment Initiation section.
* **Subclassification of drug resistance profile:** If there are several DST results, use the pattern of resistance on the treatment start date listed in the Treatment Initiation section. Important subclassification definitions:
  + **Confirmed MDR:** resistance to at least both isoniazid and rifampicin.
  + **Confirmed pre-XDR (FQ):** resistance to any fluoroquinolone, in addition to multidrug resistance.
  + **Confirmed pre-XDR (Inj):** resistance to any of the three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.
  + **Confirmed XDR:** resistance to any fluoroquinolone, and at least one of the three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.
* **MDR-TB diagnosis date:** 
  + This is first date that the patient was diagnosed with MDR-TB.
  + For patients that have a confirmed diagnosis of rifampicin resistance, write the date of the first such DST result.
    - If the patient has multiple DST results showing MDR, pre-XDR or XDR, write the date of the first such test.
    - Since an Xpert MTB/RIF positive for rifampicin resistance is often considered presumptive evidence of MDR, if an Xpert MTB/RIF positive rifampicin resistance was followed by one more more full DST showing MDR, write the date of the Xpert MTB/RIF test.
  + For patients who were treated with an MDR regimen without bacteriological confirmation, then write the first date that the patient received the MDR regimen.
    - For example, if a patient was started empirically on an MDR regimen after failure of first-line treatment, but DST was not done, write the date that the MDR regimen was started.
    - This includes patients treated because they were household contacts of MDR-TB patients, and patients who could not tolerate any first-line TB drugs due to severe allergic reaction.