**TREATMENT INITIATION FORM**

This section is relevant for sites where there is a delay between the baseline assessment and the initiation of treatment. During this time period, it is possible for patients to die or be lost to follow-up. For example, in some countries, a patient could be approved by a national MDR-TB committee and then later evaluated by a responsible doctor.

**NEW DRUGS TREATMENT ELIGIBILITY**

New drug eligibility is the eligibility indications at the time of starting the NEW drugs.

* **Is the patient eligible for treatment with new drugs (according to WHO indication)?** Select YES if the patient was declared eligible for treatment with the new drugs. The rest of the form only needs to be filled if YES is selected for this question.
* **If YES, date that patient was determined to be eligible for new drugs:** Write down the date in which the patient was determined eligible. In sites where there is a "consilium" or "expert panel", this is the date of the committee meeting. In other sites, this date is when the responsible doctor starts treatment.
* **If YES, what is the indication for new TB drugs (check all that apply):**
  + **Patients for whom the construction of a regimen with four likely effective second-line drugs is not possible (check all that apply):** Select the options based on patient's DST pattern, MDR contact history, and previous TB history.
    - The first four options refer to the resistance pattern of the patient's isolates. They are mutually exclusive.
    - "Contact with a patient infected with a strain with one of the above resistance patterns" should be marked if the patient is starting treatment with new TB drugs due to being a close contact of a patient infected with a highly resistant strain.
    - "Unable to tolerate MDR drugs necessary for construction of the regimen" should be marked if the patient is being started on new TB drugs due to toxicity to one or more drugs in an MDR regimen. For example, when substituting Bdq for Km due to ototoxicity.
    - "Previously "failed" an MDR regimen" should be marked if the patient received a course of MDR-TB treatment and met the WHO criteria for failure.
  + **Other patients who have high risk of unfavorable outcome but who do not fit the above categories (check all that apply):** If the patient does not fit in any of the above categories, select the options provided here, based on patient's clinical condition and sociodemographic information.
    - "Extensive or advanced disease" is based on clinician’s assessment and judgement, but may include patients with bilateral disease, cavities greater than 5cm in size, disseminated or extrapulmonary disease, or a poor clinical condition indicated by severely low BMI or low functional status.
    - "Co-morbidities or other conditions such as drug contraindications, patients with low body mass index (BMI), HIV, diabetes" includes conditions are are associated with poor MDR-TB treatment outcome
      * HIV and diabetes (particularly uncontrolled diabetes) may be associated with poor MDR-TB treatment outcome.
      * "Drug contraindications" refer to situations in which a conventional TB drug is contraindicated. For example, the physician may decide that an injectable is too risky in a patient with chronic renal insufficiency, and prescribe Bdq instead. This option should not be marked in the case of documented previous toxicity to an MDR regimen; in such cases "Unable to tolerate MDR drugs necessary for construction of the regimen" should be marked.
    - "Patients from catchment areas that have poor MDR-TB treatment outcomes despite good programmatic conditions" should be marked in rare situations when the physician decides to empirically include a new TB drug because the patient is highly likely to be infected with a strain that is resistant to multiple second-line drugs. For example, a migrant from a country that routinely uses Bdq for all MDR-TB patients due to high rates of pre-XDR and XDR.

**CONSENT**

* **Has the Treatment with New Drugs Consent Form been explained and signed?** Mark YES if the patient signed the treatment consent form. Mark NO if consent was not obtained for any reason, including that the patient refused to sign the consent form. Mark UNKNOWN if you do not know.
* **Has the endTB Observational Study Consent Form been explained and signed?** Mark YES if the patient signed the study consent form. Mark NO if consent was not obtained for any reason, including that the patient refused to sign the consent form. Mark UNKNOWN if you do not know.

**TREATMENT START**

* Is the patient or partner pregnant at the time of starting treatment? If the patient is a female and currently pregnant OR if the patient is a male and his partner is currently pregnant then Mark YES. Mark NO if not pregnant, UNKNOWN if status is not known and NOT APPLICABLE if the female is not of childbearing age or if patient is single or if the question is not applicable to the patient.
  + **If YES, what is the estimated date of delivery?** If the patient/partner is pregnant, then write the estimated date of delivery. If a day cannot be estimated, then write the estimated month and year, and write the date as 15.
* **Did the patient start treatment?** If the patient received at least one dose of a regimen including Bdq or Dlm, then mark YES. If the patient never started treatment, then mark NO.
* **Treatment start date**:
  + **Situation 1:** The patient is starting a new regimen that contains new drugs. In this situation, when the patient starts the new regimen, the previous treatment should be closed and the appropriate outcome should be recorded. In this situation, the **treatment start date** is the date that the new treatment regimen is started.
    - For example:
      * The patient relapsed after receiving a full course of standard MDR regimen and is not currently taking any treatment. A new regimen including new TB drugs is planned.
      * The patient's prior regimen was stopped because of multiple positive sputum cultures, and has not taken any anti-TB treatment for three months. A new regimen including new TB drugs is planned.
      * The patient is persistently sputum culture positive while receiving a standard MDR regimen and the decision has been made to change to a new regimen that includes new TB drugs.
  + **Situation 2:** If an empiric regimen for a duration longer than a month is being changed due to the results of a baseline DST (i.e. the treatment is "adapted" to the baseline DST results), the previous treatment should be closed and the outcome should be recorded as "Treatment adapted". In this situation, the **treatment start date** is the date that new drugs are included as a part of the new regimen.
    - For example:
      * The patient was originally started on an empiric MDR regimen, and DST was sent at the same time. Several months later, the result of the baseline DST shows pre-XDR or XDR-TB, requiring strengthening of the empiric regimen with new TB drugs. This strengthening of the regimen should be considered a new treatment regimen.
  + **Situation 3:** If the regimen is being changed due to adverse events (e.g. replacement of kanamycin with bedaquiline) but the patient is culture negative and does not fulfill the definition of failure, this is not considered a new treatment, but rather a continuation of the original treatment. In this situation, **treatment start date** is the start date of the original regimen and NOT the date that the regimen was changed by the substitution of a new TB drugs.
    - N.B. If the patient fulfills the definition of failure (e.g. is smear- or culture-positive), then the previous treatment course should be given an outcome of "failure". This is described in Situation 1.
* **If YES, in which facility did they start their treatment?** This is the facility in which the patient starts treatment. NOTE: this can differ from the registration facility which is the facility where the patient is registered, and not necessarily the facility where the patient receives treatment. Each country will have specific designated registration and treatment facilities. These facilities will have a code in the EMR.
* **Facility Patient ID #:** This ID number is a patient specific number given by some facilities (usually hospitals) where the patient is being evaluated. For example, if the patient is being evaluated in the hospital, write the number of the hospital chart. If there is no facility patient ID#, leave it blank. This is not the registration number that is unique throughout the treatment irrespective of the treating facility.
* **If NO, reason for not starting treatment:** If the patient did not start treatment, mark the reason that the patient did not start treatment. If the reason is patient's death, mention the date of death.