

Table S1: Treatment outcomes as shown in the ShORRT Master protocol

| EVENT | DEFINITION |
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| Favourable outcome | Composite outcome corresponding to the combination of “cured” + “treatment completed” (= treatment success) without recurrence over the 12-month follow-up period. Note: this outcome can also be defined as “recurrence-free cure” |
| Cured | A patient with bacteriologically confirmed MDR/RR-TB who has completed 9-12 months of treatment by 9/12-month regimen protocol without evidence of failure AND at least two consecutive cultures taken at least 30 days apart are negative at the end of the treatment and at least one month earlier. |
| Treatment Completed | A patient who completes 9-12 months of treatment by 9/12-month regimen protocol without evidence of failure BUT without bacteriological evidence (negative culture at the end of the treatment phase and at least one month earlier). |
| Treatment Failed | Treatment terminated or need for permanent change of the regimen protocol of at least two anti-TB drugs because of: <ul style="list-style-type: none"> • lack of sputum culture conversion after 4 months of treatment, or • bacteriological reversion of sputum culture after 5 months of treatment in a patient with previous culture conversion to negative, or • evidence of additional acquired resistance to drugs in the study, or • adverse drug reactions (ADRs) (leading to the change of at least two anti-TB drugs in the regimen) |
| Died | A patient who dies for any reason during the course of treatment. |
| Lost to follow-up | A patient whose treatment was interrupted for 2 consecutive months or more. |
| Not evaluated | A patient for whom no treatment outcome is assigned (this includes cases “transferred out” to another treatment unit and whose treatment outcome is unknown/can’t be assessed) |
| Withdrawn | A patient is taken off the 9/12-month regimen for any reason other than treatment failure (for example, baseline second-line drug resistance, withdrawn patient informed consent or other reasons) and referred to the PMDT program for routine care. |
| Treatment Success | The sum of <i>cured</i> and <i>treatment completed</i> . |
| Recurrence | Cure or treatment completion followed by two consecutive positive cultures during post-treatment follow-up (without genotyping information on baseline and recurrent strain), or one positive culture with clinical signs and symptoms or radiographic deterioration. |
| Relapse | Recurrence in which isolates of the recurrent episode share the same genotype pattern with isolates of the first episode of MDR-TB. |

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| Reinfection | Recurrence in which isolates of the recurrent episode and isolates of the first episode of MDR-TB have different genotype patterns. |
| Conversion (to negative) | <p>Culture is considered to have converted to negative when two consecutive cultures taken at least 30 days apart are found to be negative. In such case, the specimen collection date of the first negative culture is used as the date of conversion.</p> <p>In case patients were culture negative at baseline, a negative culture result at month 4 may be considered as “initial conversion”.</p> |
| Reversion (to positive) | <p>Culture is considered to have reverted to positive when after an initial conversion, two consecutive cultures taken at least 30 days apart are found to be positive.</p> <p>In case of patients who are culture negative at baseline, a positive culture result at month 4 may be considered as “initial conversion”.</p> |
| Treatment adherence | 90% of the treatment doses were taken based on information in the treatment cards, measured over the entire treatment period. |
| Permanent disability | <p>A combined outcome, using the modified Medical Research Council Dyspnoea scale (mMRC), based on which patients with a score above 2 are considered permanently disabled in terms of their pneumological function.</p> <p>In addition, all serious adverse events by system organ class that are not resolved at the end of treatment, should be summarised by treatment regimen.</p> <p>This is a measure of a programme’s ability to start treatment promptly and treat patients effectively.</p> |
| Serious Adverse Event (SAE) | <p>Any untoward medical occurrence that may present in a TB patient during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment, which either leads to:</p> <ul style="list-style-type: none"> ▪ death; ▪ a life-threatening experience; ▪ hospitalization or prolongation of hospitalization; ▪ persistent or significant disability; ▪ a congenital anomaly. |