Form 1: Study Screening Form

Study site:  Study screening date: --

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| 1. **Patient Information** |

1. Sex:  Male  Female
2. Year of birth:   Estimated  Not Reported
3. Participant Initials:  DR-TB Registration Number:

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| 1. **Non-invasive Exclusion Criteria** (if any of the following is “**YES**”, complete Non-Enrollment Form) |

1. Is the patient less than 18 years of age?  YES  NO
2. Did patient ever received second-line drugs for one month or more  YES  NO
3. Does the patient have extra-pulmonary TB without pulmonary TB  YES  NO
4. Is the patient unable to take oral medication?  YES  NO
5. Is the patient taking any medications contraindicated with the medications  YES  NO

in the Study treatment regimen?

1. Is the patient pregnant or breast-feeding?  YES  NO
2. Does the patient have severe or intractable extra-pulmonary TB?  YES  NO

(e.g. tuberculous meningitis or miliary tuberculosis)

1. Does the patient have a known allergy to any medication in the Study  YES  NO

treatment regimen?

*If any question is answered “Yes” - STOP: patient does not meet eligibility criteria. Skip to Section D and complete Form 2.*

*If all answers are “No” - discuss study with patient.*

*If patient provides verbal consent for additional testing, complete Section C.*

*If patient does not want to discuss the study, or refuses additional testing, skip to Section D and complete Form 2.*

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| 1. **Invasive Exclusion Criteria** (*if any of the following is “****YES****”, complete Non-Enrollment Form 2*) |

1. Does the patient have documented resistance to a fluoroquinolones?  YES  NO

(by LPA or phenotypic DST)

1. Does the patient have documented resistance to a second-line injectable agent? (by LPA or phenotypic DST  YES  NO
2. Does the patient Have a heart rate-corrected QT (QTc) interval of  YES  NO

≥450msec on ECG at screening?

1. Does the patient have AST or ALT > 3 times the upper limit of normal?  YES  NO
2. Does the patient have a creatinine clearance below 20 mL/min per 1.73 m2  YES  NO

body surface area?

*If any question is answered* ***“YES”*** *- patient does not meet eligibility criteria. Document ineligibility in Section D and complete Form 2.*

*If all answers are* ***“NO”*** *-**patient is eligible for enrollment.*

* + *Discuss study and ask patient if they are willing to consent to study participation* 
    - *If patient is willing to consent, document enrollment in Sections D and F, complete informed consent process, and complete Form 3.*
    - *If patient is not willing to consent, document decline in Section D and complete Form 2*
    - *If site chooses not to enroll the patient, document this in Section D and complete Form 2*

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| 1. **Enrollment status** |

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| Patient will be enrolled in the study  Complete Section E. Complete Form 3. |
| Patient will **not** be enrolled in the study  Complete Form 2. |
| 1. **Comments** |

Please use the space below to describe why an investigator feels a patient is critically ill, and unlikely to survive more than 4 months.

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| 1. **Enrollment** |

If patient is enrolled in the study, please enter Participant ID:

Participant ID: -

*(Study Site) (Study Number)*

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| 1. **Form Completion** |

PRINT name of person completing form:

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Date Screening Form completed: --