# Standard Operating Procedure for Eligibility Evaluation

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# Standard Operating Procedure for

# Eligibility Evaluation

## PURPOSE

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| This standard operating procedure (SOP) describes the process of study eligibility evaluation of potential candidates in the endTB Clinical Trials. |

## SCOPE

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| This SOP applies to activities concerning the referrals of potential patients to the study personnel in all sites involved in the endTB Clinical Trials. In addition, it describes the procedure for checking inclusion and exclusion criteria. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| **Site Principal Investigator (Site PI)** | * Accountable for patient eligibility * Supports delegated Site Co Investigator and delegated study personnel in ensuring that the study eligibility evaluation is conducted according to the study protocols * Ensures that patients who do not meet the eligibility criteria have access to appropriate treatment, free of charge, within the routine program. |
| **Site Principal Investigator (Site PI) and/or delegated Site Co Investigator (Site CI)** | * Takes a detailed medical history, performs physical examination of the patient, organizes sample collection and tests to be done during the screening, reviews the patient’s eligibility criteria, and makes a decision on the patient’s enrollment in the trials * Obtains informed consent for screening and study. |
| **Site Study Coordinator (Site SC)** | * Identifies referral site(s) where patients will be pre-screened and ensures good contact between referral clinics and the trial site. |
| **Delegated data entry personnel** | * Supports the Site Principal Investigator and Site Co Investigator with data recording and entry into the eCRF. |

## DEFINITIONS and ABBREVIATIONS

eCRF – electronic Case Report Form

## PROCEDURE

### Pre-screening eligibility evaluation

1. The referral points for pre-screening of prospective participants may vary by site. The **Site PI and/or Site SC** will introduce the trial to potential referral locations and facilitate referral of potential candidates.
2. During the pre-screening of prospective participants, facility staff[[1]](#footnote-2) should review the information listed in the study protocol, Chapter 7.1.1, if available in the medical records, and refer the patient to the endTB Clinical Trial team.

No personal data of prospective participants should be collected for study purposes prior to the signature of the screening consent.

1. The following additional criteria may be used to evaluate potential participants for referral:
   * Residents of endTB catchment area;
   * 15 years of age and older (or 18, depending on sites);
   * Non-pregnant woman;
   * Non-lactating mother.
2. The process for referring potential participants to the study personnel should be guided by the local institutional policies. The Site SC or designee should be in regular contact with referral facility staff to coordinate and ensure prompt referral of patients who meet the pre-screening criteria.

### Eligibility evaluation during screening

1. IRB-approved study information must be provided to interested potential participants and a written informed consent for screening will be obtained from the patients who agree to be screened for the study. Screening consent must be obtained prior to any trial-specific evaluation by study staff. A unique subject ID (screening) number specific to the study must be assigned to screening-consented participants before any screening visit procedures begin. Please refer to the ***endTB Clinical Trial: Manual of Procedures*** regarding the convention for assigning subject ID numbers.
2. Delegated site staff should perform the exams and tests listed in the study protocol, Chapter 7.1.2, once the patient has signed the screening informed consent form.
3. Screening data should be recorded in the source document and entered in the screening eCRF (see **Data Entry Guidelines** for data entry timelines).
4. The screening period may require several visits to assess the patient’s eligibility criteria; it should be completed as quickly as possible to minimize delay to treatment and in light of the maximum 14-day interval between screening consent and randomization. The screening process may be stopped as soon as any exclusion criterion is detected.
5. Patients found not to be eligible for the study due to laboratory abnormalities may be retested within the screening window (14 days). Any retesting will ideally be performed 3 days after the initial test; shorter intervals are also acceptable if necessary to comply with the screening window. If any ineligibility persists, the patient will be excluded from the trial.
6. All screening results should be compared against criteria for inclusion and exclusion. Refer to Appendix 1 for the list of inclusion/exclusion criteria and related clarifications.
7. All reasons for exclusion should be recorded in the source document and entered into the eCRF. The main reason for study exclusion should be identified by the **Site CI**, recorded in the source document, and entered into the eCRF.
8. If the patient is found to be ineligible for study participation at the screening visit, the **Site CI and delegated site clinician** should organize treatment of the patient according to the program’s guidelines at trial site health facility or at referral clinic.

### Eligibility evaluation during Baseline

1. Baseline visit procedures can only be completed after all screening test results are available, and eligibility has been confirmed according to screening results.
2. Full study information will be provided to patients and baseline informed consent obtained from patients who agree to participate in the study. Baseline informed consent will be obtained prior to baseline visit procedures.
3. Delegated study staff should perform the exams and tests that are listed in the study protocol, Chapter 7.2, after the patient signs the baseline Research informed consent form.
4. Data should be recorded in the source document and entered in the screening eCRF (see **Data Entry Guidelines** for data entry timelines).
5. Baseline procedures that are necessary for eligibility assessment must be completed prior to randomization. Results of these procedures should be compared against criteria for inclusion and exclusion. Refer to Appendix 1 for the list of inclusion/exclusion criteria, and related clarifications. Baseline procedures that are not necessary for eligibility assessment can be run in parallel to randomization and study regimen initiation.
6. Eligible participants should be randomized as soon as possible but no longer than 14 days after signing the screening consent. Please refer to the VennLife worksheets and manuals for randomization procedures.
7. Patients randomized to experimental regimens with linezolid will undergo an additional randomization to determine which reduced linezolid dose (300 mg daily or 600 mg thrice weekly) will be assigned. This will occur at Week 16 or after a linezolid-related adverse event requiring dose reduction, whichever is earlier.
8. All data collected from the baseline visit procedures should be recorded in the source document, and entered into the eCRF (see **Data Entry Guidelines** for data entry timelines). If an eligible patient has not been randomized within 14 days of the screening consent date, s/he may not be randomized without being re-consented and rescreened under a new screening number. This rescreening may occur once.
9. If a participant is found to be ineligible for randomization, all reason(s) for exclusion should be recorded in the source document and entered into the eCRF. The main reason for study exclusion should be identified by the **Site PI and/or Site CI**, recorded in the source document, and entered into the eCRF. The **Site PI and/or Site CI** should also ensure that all ineligible patients are referred for appropriate care.

## REFERENCES

## None

## SUPPORTING DOCUMENTS

* SOP SP-001-CT Obtaining Informed Consent (endTB Site Study Document)
* endTB Clinical Trial: Manual of Procedures (endTB Site Study Document)
* endTB\_IWRS Worksheets (endTB Site Study Document)
* endTB\_IWRS Manuals (endTB Site Study Document)
* SOP SP-018-CT Management of Specific Adverse Events (endTB Site Study Document)
* SOP SP-019-CT Concomitant Medications (endTB Site Study Document)
* OpenClinica Data Entry Guidelines (endTB Site Study Document)

## APPENDIX

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| **Number** | **Title** |
| A1 | SP-013-CT\_A1- Eligibility Criteria for Randomization |

1. Study staff should not be involved in screening activities until and unless screening consent has been signed. [↑](#footnote-ref-2)