

## eDSI: Data Selection form

This form supports your request to access data from the endTB Observational Study, endTB or endTB-Q Clinical Trials, showing the selection of databases and variables required to perform your research.

### 1. Data

Please select which investigation you would like data about

- endTB Observational Study Data
- endTB Clinical Trial Data
- endTB-Q Clinical Trial Data

### 2. endTB Observational Study Data

- I. Below is a list of datasets collected during the endTB Observational study as outlined in the data dictionary. Please select the required datasets to address your research question:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> _6_MONTH_POST_TREATMENT_OUTCOME_  | 24. <input type="checkbox"/> BASELINE_RESISTANCE              |
| 2. <input type="checkbox"/> _6M_PTO_REASONS_FOR_NO_POST_TREA  | 25. <input type="checkbox"/> BASELINE_TEMPLATE                |
| 3. <input type="checkbox"/> ADVERSE_EVENTS_TEMPLATE           | 26. <input type="checkbox"/> BIOCHEMISTRY_LABS_STD            |
| 4. <input type="checkbox"/> AE_DRUGS_STOPPED                  | 27. <input type="checkbox"/> CALCULATED_OUTCOMES              |
| 5. <input type="checkbox"/> AE_FORM_AE_SEVERITY_REVIEW        | 28. <input type="checkbox"/> DERIVED_AGE                      |
| 6. <input type="checkbox"/> AE_FORM_COMORBIDITY_OF_OTHER_CAU  | 29. <input type="checkbox"/> ELECTROCARDIOGRAM_TEMPLATE       |
| 7. <input type="checkbox"/> AE_FORM_NON_TB_DRUG_OF_OTHER_CAU  | 30. <input type="checkbox"/> ENDTB_COHORT_UNIQUE              |
| 8. <input type="checkbox"/> AE_FORM_OTHER_CAUSAL_FACTORS_REL  | 31. <input type="checkbox"/> EOT_REASONS_FOR_FAILURE_DEFINITI |
| 9. <input type="checkbox"/> AE_FORM_RELATED_TEST_RESULT       | 32. <input type="checkbox"/> EOT_REASONS_FOR_TREATMENT_INTERR |
| 10. <input type="checkbox"/> AE_FORM_TB_DRUG_TREATMENT        | 33. <input type="checkbox"/> FOLLOWUP_TEMPLATE                |
| 11. <input type="checkbox"/> AUDIOMETRY_TEMPLATE              | 34. <input type="checkbox"/> FORMATS_DATASET                  |
| 12. <input type="checkbox"/> BACTERIOLOGY_CONCEPT_SET         | 35. <input type="checkbox"/> HDS_TYPE_OF_TB_RELATED_SURGERY   |
| 13. <input type="checkbox"/> BACTERIOLOGY_CULTURE_RESULTS_DET | 36. <input type="checkbox"/> HEMATOLOGY_LABS_STD              |
| 14. <input type="checkbox"/> BACTERIOLOGY_DST_RESULT_DETAILS  | 37. <input type="checkbox"/> HEP_C_TREATMENT_INITIATION_TEMPL |
| 15. <input type="checkbox"/> BACTERIOLOGY_HAIN_TESTPCR_RESULT | 38. <input type="checkbox"/> HEP_C_TREATMENT_OUTCOME_TEMPLATE |
| 16. <input type="checkbox"/> BACTERIOLOGY_OTHER_DRUG_DETAILS  | 39. <input type="checkbox"/> HOSPITAL_ADMISSION_NOTIFICATION_ |
| 17. <input type="checkbox"/> BACTERIOLOGY_SEQUENCING          | 40. <input type="checkbox"/> HOSPITAL_DISCHARGE_SUMMARY_TEMPL |
| 18. <input type="checkbox"/> BACTERIOLOGY_SMEAR_MICROSCOPY_TE | 41. <input type="checkbox"/> HTI_REASON_THAT_DAA_WAS_NOT_GIVE |
| 19. <input type="checkbox"/> BACTERIOLOGY_XPERT_TEST_RESULTS  | 42. <input type="checkbox"/> HTI_REASON_TO_START_DAA_AT_THIS_ |
| 20. <input type="checkbox"/> BASELINE_DISEASE_SITE            | 43. <input type="checkbox"/> LAB_RESULTS_OTHER_TESTS_TEMPLATE |
| 21. <input type="checkbox"/> BASELINE_DRUGS_USED_IN_ARV_TREAT | 44. <input type="checkbox"/> LAB_RESULTS_PREGNANCY_TEMPLATE   |
| 22. <input type="checkbox"/> BASELINE_KNOWN_DRUG_ALLERGIES    | 45. <input type="checkbox"/> LAB_RESULTS_SEROLOGY_TEMPLATE    |
| 23. <input type="checkbox"/> BASELINE_METHOD_OF_MDR_TB_CONFIR | 46. <input type="checkbox"/> MONTHLY_TREATMENT_COMPLETENESS_T |

- |   |   |
|---|---|
| 47. <input type="checkbox"/> MTC_ADDITIONAL_CONTRIBUTING_MEDI | 63. <input type="checkbox"/> REGLIST_BASELINE                 |
| 48. <input type="checkbox"/> MTC_ADDITIONAL_CONTRIBUTING_PATI | 64. <input type="checkbox"/> SAE_FORM_COMORBIDITY_OF_OTHER_CA |
| 49. <input type="checkbox"/> MTC_ADDITIONAL_CONTRIBUTING_PROG | 65. <input type="checkbox"/> SAE_FORM_NON_TB_DRUG_OF_OTHER_CA |
| 50. <input type="checkbox"/> MTC_ADDITIONAL_CONTRIBUTING_REAS | 66. <input type="checkbox"/> SAE_FORM_OTHER_CAUSAL_FACTOR     |
| 51. <input type="checkbox"/> MTC_DOT_RATE_DETAILS             | 67. <input type="checkbox"/> SAE_FORM_OTHER_CAUSAL_FACTORS_RE |
| 52. <input type="checkbox"/> NONTBDRUGORDER                   | 68. <input type="checkbox"/> SAE_FORM_RELATED_TESTS           |
| 53. <input type="checkbox"/> OUTCOME_END_OF_TREATMENT_TEMPLAT | 69. <input type="checkbox"/> SAE_FORM_SAE_SEVERITY_REVIEW     |
| 54. <input type="checkbox"/> PAST_TX_DRUGS1MO                 | 70. <input type="checkbox"/> SAE_FORM_TB_DRUG_TREATMENT       |
| 55. <input type="checkbox"/> PASTTB_REGIMENS_DRUGS            | 71. <input type="checkbox"/> SERIOUS_ADVERSE_EVENTS_TEMPLATE  |
| 56. <input type="checkbox"/> PERFORMANCE_STATUS_TEMPLATE      | 72. <input type="checkbox"/> STUDY_DRUG_BASELINE_CX_RES       |
| 57. <input type="checkbox"/> POST_TREATMENT_FOLLOWUP_TEMPLATE | 73. <input type="checkbox"/> STUDY_DRUG_BASELINE_SMEAR        |
| 58. <input type="checkbox"/> PREGNANCY_REPORT_FORM_TEMPLATE   | 74. <input type="checkbox"/> TBDRUGORDER                      |
| 59. <input type="checkbox"/> PREVIOUS_TX                      | 75. <input type="checkbox"/> TREATMENT_INITIATION_TEMPLATE    |
| 60. <input type="checkbox"/> PRF_INFANT_DETAILS               | 76. <input type="checkbox"/> TREATMENTREGISTRATION            |
| 61. <input type="checkbox"/> PRF_NON_TB_DRUG_EXPOSURE         | 77. <input type="checkbox"/> TX_ALL_RESISTANCE_SETS           |
| 62. <input type="checkbox"/> PRF_TB_DRUG_EXPOSURE             | 78. <input type="checkbox"/> XRAY_TEMPLATE                    |

II. To specify data related to your research question, please select below the baseline variables which define your population. Column names below, shown in quotation marks, align with those used in the data dictionary:

<b>"Variable_label"</b>	<b>Response Options "VALUE LABEL"</b>	<b>"Variable_name"</b>	<b>Csv file "Dataset"</b>
Gender	<input type="checkbox"/> [1] Male <input type="checkbox"/> [2] Female	sex	TREATMENTREGISTRATION
5-year age group at start of study drug	<input type="checkbox"/> [1] < 15 years <input type="checkbox"/> [4] 15-19 years <input type="checkbox"/> [5] 20-24 years <input type="checkbox"/> [6] 25-29 years <input type="checkbox"/> [7] 30-34 years <input type="checkbox"/> [8] 35-39 years <input type="checkbox"/> [9] 40-44 years <input type="checkbox"/> [10] 45-49 years <input type="checkbox"/> [11] 50-54 years <input type="checkbox"/> [12] 55-59 years <input type="checkbox"/> [13] 60-64 years <input type="checkbox"/> [14] ≥65 years	age_grp_study_drug	DERIVED_AGE
Disease site	<input type="checkbox"/> [1] Pulmonary <input type="checkbox"/> [2] Extrapulmonary	pulm_dis	BASELINE_DISEASE_SITE
Pregnancy at Treatment Start	<input type="checkbox"/> [0] FALSE <input type="checkbox"/> [1] TRUE <input type="checkbox"/> [99] Unknown	preg_base	TREATMENT_INITIATION_TEMPLATE

HIV Serostatus	<input type="checkbox"/> [0] Negative <input type="checkbox"/> [1] Positive <input type="checkbox"/> [99] Unknown	hiv_base	BASELINE_TEMPLATE
Diabetes (type I or II)	<input type="checkbox"/> [0] FALSE <input type="checkbox"/> [1] TRUE <input type="checkbox"/> [99] Unknown	diab_base	
Confirmed Hepatitis B	<input type="checkbox"/> [0] FALSE <input type="checkbox"/> [1] TRUE <input type="checkbox"/> [99] Unknown	hepb_base	
Confirmed Hepatitis C	<input type="checkbox"/> [0] FALSE <input type="checkbox"/> [1] TRUE <input type="checkbox"/> [99] Unknown	hepc_base	
All TB Drugs	<input type="checkbox"/> [10] Isoniazid <input type="checkbox"/> [11] Rifampicin <input type="checkbox"/> [12] Ethambutol <input type="checkbox"/> [13] Pyrazinamide <input type="checkbox"/> [14] Streptomycin <input type="checkbox"/> [20] Amikacin <input type="checkbox"/> [21] Kanamycin <input type="checkbox"/> [22] Capreomycin <input type="checkbox"/> [30] Levofloxacin <input type="checkbox"/> [31] Moxifloxacin <input type="checkbox"/> [40] Prothionamide <input type="checkbox"/> [41] Ethionamide <input type="checkbox"/> [42] Cycloserine <input type="checkbox"/> [43] Terizidone <input type="checkbox"/> [44] P-Aminosalicylic Acid <input type="checkbox"/> [45] P-Aminosalicylic Acid Monosodium Salt <input type="checkbox"/> [50] Bedaquiline <input type="checkbox"/> [51] Delamanid <input type="checkbox"/> [52] Linezolid <input type="checkbox"/> [53] Clofazimine <input type="checkbox"/> [54] Cilastatin / Imipenem <input type="checkbox"/> [55] Amoxicillin And Clavulanic Acid <input type="checkbox"/> [56] Meropenem <input type="checkbox"/> [57] Clarithromycin <input type="checkbox"/> [1000] Thioridazine	tbdrug	TBDRUGORDER

### 3. EndTB Clinical Trial Data

I. Below is a list of datasets collected during the endTB study as outlined in the data dictionary. Please select the required to address your research question:

- |  |  |
|--|--|
| 1. <input type="checkbox"/> AE                                 | 18. <input type="checkbox"/> MentalHealthAssessment          |
| 2. <input type="checkbox"/> AudiometryNeurologicOphthalmologic | 19. <input type="checkbox"/> MissedIncompleteVisit           |
| 3. <input type="checkbox"/> BASELINE                           | 20. <input type="checkbox"/> PregnancyFU                     |
| 4. <input type="checkbox"/> ChestXray                          | 21. <input type="checkbox"/> PreviousTBMedication            |
| 5. <input type="checkbox"/> ConcomitantMedication              | 22. <input type="checkbox"/> Randomization                   |
| 6. <input type="checkbox"/> Derived_pop                        | 23. <input type="checkbox"/> RIFResistance                   |
| 7. <input type="checkbox"/> DST                                | 24. <input type="checkbox"/> ScreeningPreScreening           |
| 8. <input type="checkbox"/> ECG                                | 25. <input type="checkbox"/> SputumSmearMicroscopyMTBCulture |
| 9. <input type="checkbox"/> ECOG                               | 26. <input type="checkbox"/> TreatmentAdherence              |
| 10. <input type="checkbox"/> EndStudyTreatment                 | 27. <input type="checkbox"/> TreatmentChange                 |
| 11. <input type="checkbox"/> FQResistance                      | 28. <input type="checkbox"/> TreatmentInitiation             |
| 12. <input type="checkbox"/> HbA1cGlucose                      | 29. <input type="checkbox"/> TreatmentOutcomeEVG             |
| 13. <input type="checkbox"/> HCVFU                             | 30. <input type="checkbox"/> TSHViralLoadCD4                 |
| 14. <input type="checkbox"/> HematologyBiochemistry            | 31. <input type="checkbox"/> VitalSignsPhysicalExam          |
| 15. <input type="checkbox"/> HIVFU                             | 32. <input type="checkbox"/> UnscheduledVisitNumber          |
| 16. <input type="checkbox"/> Hospitalization                   | 33. <input type="checkbox"/> VisitDate                       |
| 17. <input type="checkbox"/> LinezolidRand                     |  |

II. To specify data related to your research question, please select below the baseline variables which define your population. Column names below, shown in quotation marks, align with those used in the data dictionary.

Baseline variables	Options "RESPONSE_OPTIONS"	CSV file name "Dataset"	Variable named in the CSV "ITEM_NAME"
<input type="checkbox"/> Sex	<input type="checkbox"/> [1] Male <input type="checkbox"/> [2] Female	ScreeningPreScreening	SCSEX
<input type="checkbox"/> Age group	<input type="checkbox"/> [1] <18 <input type="checkbox"/> [2] 18-45 <input type="checkbox"/> [3] ≥45	Derived_pop	AGE_CAT
<input type="checkbox"/> Hepatitis B	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		HBSAGRES_BL
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		HCVRES_BL
<input type="checkbox"/> HIV	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		HIVRES_BL
<input type="checkbox"/> Diabetes	<input type="checkbox"/> [1] Positive		DIABETES

	<input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		
<input type="checkbox"/> Medication name	<input type="checkbox"/> [1] Amikacin <input type="checkbox"/> [2] Bedaquiline <input type="checkbox"/> [3] Capreomycin <input type="checkbox"/> [4] Clofazimine <input type="checkbox"/> [5] Cycloserine <input type="checkbox"/> [6] Delamanid <input type="checkbox"/> [7] Ethambutol <input type="checkbox"/> [8] Ethionamide <input type="checkbox"/> [9] Isoniazid <input type="checkbox"/> [10] Kanamycin <input type="checkbox"/> [11] Levofloxacin <input type="checkbox"/> [12] Linezolid <input type="checkbox"/> [13] Moxifloxacin <input type="checkbox"/> [14] PAS <input type="checkbox"/> [15] Prothionamide <input type="checkbox"/> [16] Pyrazinamide <input type="checkbox"/> [17] Terizidone	TreatmentInitiation	BLTTINAM

#### 4. EndTB-Q Clinical Trial Data

I. Below is a list of datasets collected during the endTB-Q study as outlined in the data dictionary. Please select the required to address your research question:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> QAE                                 | 18. <input type="checkbox"/> LinezolidRand                   |
| 2. <input type="checkbox"/> QAudiometryNeurologicOphthalmologic | 19. <input type="checkbox"/> MentalHealthAssessment          |
| 3. <input type="checkbox"/> QBASELINE                           | 20. <input type="checkbox"/> MissedIncompleteVisit           |
| 4. <input type="checkbox"/> QChestXray                          | 21. <input type="checkbox"/> PregnancyFU                     |
| 5. <input type="checkbox"/> QConcomitantMedication              | 22. <input type="checkbox"/> PreviousTBMedication            |
| 6. <input type="checkbox"/> QDerived_pop                        | 23. <input type="checkbox"/> Randomization                   |
| 7. <input type="checkbox"/> QDST                                | 24. <input type="checkbox"/> RIFResistance                   |
| 8. <input type="checkbox"/> QECG                                | 25. <input type="checkbox"/> ScreeningPreScreening           |
| 9. <input type="checkbox"/> QECOG                               | 26. <input type="checkbox"/> SputumSmearMicroscopyMTBCulture |
| 10. <input type="checkbox"/> QEndStudyTreatment                 | 27. <input type="checkbox"/> TreatmentAdherence              |
| 11. <input type="checkbox"/> QExclusion24W                      | 28. <input type="checkbox"/> TreatmentChange                 |
| 12. <input type="checkbox"/> QFQResistance                      | 29. <input type="checkbox"/> TreatmentInitiation             |
| 13. <input type="checkbox"/> QHbA1cGlucose                      | 30. <input type="checkbox"/> TreatmentOutcomeEVG             |
| 14. <input type="checkbox"/> HCVFU                              | 31. <input type="checkbox"/> TSHViralLoadCD4                 |
| 15. <input type="checkbox"/> HematologyBiochemistry             | 32. <input type="checkbox"/> VitalSignsPhysicalExam          |
| 16. <input type="checkbox"/> HIVFU                              | 33. <input type="checkbox"/> UnscheduledVisitNumber          |
| 17. <input type="checkbox"/> Hospitalization                    | 34. <input type="checkbox"/> VisitDate                       |

- II. To specify data related to your research question, please select below the baseline variables which define your population. Column names below, shown in quotation marks, align with those used in the data dictionary:

Baseline variables	Options "RESPONSE_OPTIONS"	CSV file name "Dataset"	Variable named in the CSV "ITEM_NAME"
<input type="checkbox"/> Sex	<input type="checkbox"/> [1] Male <input type="checkbox"/> [2] Female	QScreeningPreScreening	QSCSEX
<input type="checkbox"/> Age group	<input type="checkbox"/> [1] <18 <input type="checkbox"/> [2] 18-45 <input type="checkbox"/> [3] ≥45	QDerived_pop	QAGE_CAT
<input type="checkbox"/> Hepatitis B	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		QHBSAGRES_BL
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		QHCVRES_BL
<input type="checkbox"/> HIV	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		QHIVRES_BL
<input type="checkbox"/> Diabetes	<input type="checkbox"/> [1] Positive <input type="checkbox"/> [2] Negative <input type="checkbox"/> [3] Unknown		QDIABETES
<input type="checkbox"/> Extent of TB disease	<input type="checkbox"/> [0] Not extensive <input type="checkbox"/> [1] Extensive		EXTENT_DISEASE_BL
<input type="checkbox"/> Medication name	<input type="checkbox"/> [1] Amikacin <input type="checkbox"/> [2] Bedaquiline <input type="checkbox"/> [4] Clofazimine <input type="checkbox"/> [5] Cycloserine <input type="checkbox"/> [6] Delamanid <input type="checkbox"/> [7] Ethambutol <input type="checkbox"/> [8] Ethionamide <input type="checkbox"/> [12] Linezolid <input type="checkbox"/> [15] Prothionamide <input type="checkbox"/> [16] Pyrazinamide	QTreatmentInitiation	BLTTINAM

Thank you for completing the questionnaire. A team member may contact you shortly if there are any questions about your submission.

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